



Health research priority setting assists researchers and policy-makers in conduct of research that has the greatest public health benefits and maximizes health equity.

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Health research prioritization: global and regional perspectives

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The Eastern Mediterranean Region (EMR) is confronting unprecedented health challenges, exacerbated by demographic and epidemiologic changes, large burden of communicable and noncommunicable diseases, increasing health care costs, as well as the effects of contracted emergencies, social conflicts and massive population movements (1-3). These challenges have significantly impacted the delivery of health care services, but they have also affected the capacity of the Region to conduct health research. In order to improve the health status in the EMR, evidence-based policies are critical. In October 2019, the Eastern Mediterranean Regional Committee endorsed a resolution supporting the improvement of national institutional capacity for evidence-informed policy-making for health in all Member States (4-5). Research that focuses on the regional and national health priorities is essential to develop the evidence needed for region- and country-specific solutions (6-7).

The World Health Organization (WHO) has identified four pillars as part of a comprehensive strategy that addresses research for health: 1) capacity building; 2) standards and governance; 3) translation of research to policy and practice; and 4) research priority setting (8). Priority setting helps to identify the resources needed for research, in particular as available resources are limited and waste cannot be afforded (9). Setting priorities for research can be a complex and tedious process. While different approaches to research prioritization exist, there is no clear consensus on what constitutes best practice (10-12).

Regardless of the approach followed, there are minimum criteria to be considered and followed in setting research priorities. When setting research priorities, countries and large institutions (including academic and research institutions) should follow approaches that take into consideration their needs and context (10). Furthermore, countries need to be aware of potential barriers to priority setting (e.g., linkage to identified national health priorities, involvement of stakeholders in the process, time and resources required for priority setting, and selection of appropriate priority setting approaches including reaching consensus among stakeholders). This includes barriers to implementing

the identified priorities (e.g., proper dissemination of priorities to researchers and academic institutions, availability of human, logistic, and financial resources for research) (13).

There are different examples of research priority setting in the EMR (14-20). Despite these examples, a study of 10 Arab countries reflected various levels of development and resources in their national health research systems, while only three countries reported setting national health research priorities (21). While there may be a need for further national level action on identification of research priorities (21-22), there are questions on whether previous priority settings have resulted in affirmative action on guiding health research.

A systematic review of health research priority settings in the Islamic Republic of Iran identified 36 studies, of which only one in four included an implementation plan (23). A recent study involving over 200 institutions in the EMR indicated that only half reported conducting research priority-setting exercises, of which only 40% followed a standardized approach and involved policy-makers and stakeholders in setting such priorities. In addition, only a quarter of institutions reported that they examine the extent to which health policy-makers utilize research results, and a similar number reported measuring the impact of their health research (22,24). Hence, there is still a misalignment between national health research priorities and actual research production and use (5). Examples of good practice, however, are abundant, including in emergency situations. While the world is coming to term on how to address the current COVID-19 pandemic (25), WHO has already rolled-out a global solidarity randomized controlled trial to find effective treatments for the disease. Similarly, a collective approach toward research priorities related to MERS-CoV was helpful in addressing some of the challenges caused by this regional and global concern (26-27).

Since 2016, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) conducts in-house health research prioritization exercises every two years, following a two-round priority identification exercise, and uses the Nominal Group Technique for consensus development. Outcomes of such workshops are used to develop the Calls for Proposals for Research in Priority

Areas of Public Health (RPPH) small grants and the Tropical Disease Research - Small Grant Scheme (TDR-SGS). The current calls for proposals are now available on the WHO/EMRO website (<http://www.emro.who.int/index.html>).

From WHO standpoint, research priority setting is a key action for enhancing research for health in the EMR in order to cover the gaps observed through research mapping activities (22,28-30). For example, while the region is disproportionately affected by emergencies, a bibliometric analysis of health research production in the EMR showed scarcity of published research on emergencies (30). WHO is keen to assist countries in

strengthening their health research capacity and priority setting (8). In conclusion, health research priority setting assists researchers and policy-makers in conduct of research that has the greatest potential public health benefit and maximizes health equity. Priority setting should involve different stakeholders, including policy-makers, which would increase the likelihood of the utilization of research evidence by different partners. Research priorities could also inform efforts beyond the health sector to better align research activities and funding with the evidence needs of decision-makers to achieve universal health coverage and health-related Sustainable Development Goals.

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Interaction between opium replacement therapies and HIV treatment coverage

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People who use and inject drugs are among the groups at highest risk of exposure to HIV but remain marginalized and out of reach of health and social services. People who inject drugs are around 28 times more likely to be living with HIV than the general population (1). New infections among people who inject drugs rose by 33% from 2011 to 2015, and nearly one-third of global HIV infections outside sub-Saharan Africa are caused by injecting drug use, and more than 150 000 people who inject drugs became newly infected with HIV in 2015 (1).

HIV prevalence among people who inject drugs has remained essentially unchanged since 2008, while seemingly increased in the Middle East and North Africa (MENA) region (2,3). According to the Global Burden of Disease 2013 study, injecting drug use caused 4.0% of DALYs due to HIV, with injecting drug use-attributable HIV burden highest in low- to middle-income countries (4). In the MENA region, the burden of HIV disease attributable to injecting drug use increased from a mean 4000 (1000–15 000) DALYs in 1990 to a mean 91 000 (45 000–164 000) DALYs in 2013 (4).

Coverage of opioid substitution therapy interventions remains poor at the global level, not to mention in the MENA region, and is insufficient to prevent, halt, or reverse HIV and HCV epidemics among people who inject drugs (5). However, in contexts where opioid substitution therapy and adherence to antiretroviral therapy support programs are widely accessible, comparable levels of survival are observed among HIV-positive people who inject drugs and people living with HIV (PLHIV) who do not inject drugs (6).

Any single intervention, even with high coverage, is likely to have a minor effect on HIV transmission unless implemented concurrently with other strategies. The benefit and cost-effectiveness of combined approaches to HIV prevention have been repeatedly shown through empirical evidence and model-based projection studies. Many novel interventions, such as mobile needle and syringe programmes and pre-exposure prophylaxis (PrEP), especially as part of a comprehensive package (7), and peer-run supervised injection facilities also have

promise for HIV prevention, as have modifications to existing strategies, such as facilitating assisted injection (8–11). The cost-effectiveness ratios for people who inject drugs regardless of HIV status are highly favourable for all regions, with costs per HIV infection averted ranging from US\$ 100 to \$1000 (11).

Opioid substitution therapy, needle-syringe programmes, and antiretroviral therapy together have established effectiveness in reducing drug dependency, reduced needle-sharing, improve quality of life and averting HIV infections (11). The effects are more than additive since opioid agonist therapy itself positively reduces HIV transmission (12) and is associated with antiretroviral therapy initiation, coverage, adherence, retention and viral load suppression among HIV-positive people who inject drugs (12–15). Scaling up opioid agonist therapy duration and coverage, including in prisons, would decrease all-cause mortality and avert 25.3–56.2% of HIV-related deaths over 20 years, although the lowest risk of death is seen when opioid substitution therapy and antiretroviral therapy are used jointly (16–18). Among prisoners and detainees, combining opioid agonist therapy with post-release antiretroviral therapy retention would achieve a further reduction in HIV incidence, ranging from 0.3% to 4.2% depending on HIV prevalence and programme coverage (19).

In one of the first prospective, longitudinal studies on the cascade of HIV care among key populations in low- and middle-income countries, Januraga et al. reported strikingly poor rates of retention in treatment and viral suppression, and note that attrition at each step of the care cascade needs to be well defined and understood, so that future interventions can be suitably tailored and targeted to meet the needs of the most affected key populations in each country (20).

In conclusion, countries where injecting drug use remains an important driver of the HIV epidemic need to begin and maintain large-scale comprehensive harm reduction programmes (9), in an effort to reach the most underserved populations, be they incarcerated or in the community, and to react rapidly to potential threats (21).

However, the re-emergence of epidemics among people who inject drugs underlines how vulnerable this population is to changes in the economic, social, and drug-market scene and how fragile the success of interventions can be in preventing HIV outbreaks (21). The Johns Hopkins–Lancet Commission on Drug Policy and Health not only makes a clear recommendation to invest in treatment for HIV, HCV infection, tuberculosis, and drug dependence, it also emphasizes the need to make harm reduction measures a central pillar of health systems and drug policy, to formulate policies that do not harm women, and to include health, human rights, and development in

metrics to judge success of drug policy (22).

Prevention of HIV infection needs high coverage and combined approaches. Governments, policy-makers, and public-health officials must be engaged and convinced of the importance of scaling up. We know enough about what can be effective in prevention of HIV infection. The challenge is to deliver these programmes well, and to scale (10). This comprehensive, sustained approach offers the most effective path to improve treatment coverage, achieve the 90-90-90 goals (23) and end AIDS among people who inject drugs, by 2030.

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Vitamin D deficiency in healthy children in Bahrain: do gender and age matter?

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Abstract

Background: Vitamin D deficiency is a global health problem in children. The vitamin D status of children and adolescents has not been evaluated in Bahrain.

Aims: This cross-sectional study aimed to determine the prevalence of vitamin D deficiency in healthy children in Bahrain and to investigate the relationship between vitamin D level and age and sex.

Methods: Medical records of children aged 1 month to 16 years who attended a vitamin D screening campaign at Al Kindi Specialized Hospital, Bahrain between September and October 2016 were reviewed. Data on sex and age were recorded and vitamin D level was measured as serum 25-hydroxyvitamin D [25(OH)D]. Children were grouped as: vitamin D sufficient [25(OH)D \geq 75 nmol/L], vitamin D insufficient (51–74 nmol/L) and vitamin D deficient (\leq 50 nmol/L).

Results: A total of 531 children were included in the study, 50.8% of whom were boys. Most of the children (93.4%) had low vitamin D levels; 78.3% were vitamin D deficient and 15.1% vitamin D insufficient. Only 6.6% were vitamin D sufficient. A significantly greater proportion of girls were vitamin D deficient than boys ($P < 0.001$). More primary-school children and adolescents were vitamin D deficient than preschool children ($P < 0.001$). A negative correlation was found between vitamin D level and age ($r = -0.467$; $P < 0.001$). Regression analysis showed that vitamin D level decreased by -2.164 nmol/L for each year of age.

Conclusion: Vitamin D deficiency is a problem among healthy children in Bahrain. Public health policies or interventions are suggested to improve vitamin D status in Bahrain, especially for school-aged children.

Keywords: vitamin D deficiency, child, adolescent, prevalence, Bahrain

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Introduction

Vitamin D is a vital steroid hormone (1). It is mainly produced in the skin after exposure to sunlight (1–3). If sun exposure is inadequate, vitamin D level can be maintained by taking supplements or foods that contain vitamin D (2). However, food sources of vitamin D are few (1,3).

Vitamin D has a crucial role in improving physiological function in both skeletal and extraskeletal tissues (1,2). It is essential for intestinal calcium absorption, homeostasis and bone mineralization, especially during infancy, childhood and puberty (1,2,4). Only 10–15% of dietary calcium is absorbed without vitamin D (1). Serum 25-hydroxyvitamin D [25(OH)D] levels less than 50 nmol/L can lead to a marked decrease in intestinal calcium absorption (1). This is associated with increased parathyroid hormone secretion and decreased insulin-like growth factor 1 (1). Serum 25(OH)D level is directly connected to bone mineral density with a maximum density attained when the 25(OH)D level is \geq 100 nmol/L (1). Severe vitamin D deficiency impairs bone mineralization leading to osteomalacia and rickets (2). Recent evidence shows that the role of vitamin D goes beyond calcium and phosphorous metabolism (3). Many extra skeletal illnesses

have been associated with vitamin D deficiency, such as those related to fuel metabolism, the cardiovascular system, cancer and the immune system (1,3).

Despite several preventive approaches, vitamin D deficiency has remained a global health problem in children (2,3,5). Vitamin D status in children has been evaluated in many countries (1–11). In Bahrain, two published studies on vitamin D status looked at neonatal and adult age groups (12,13). To our knowledge, the vitamin D status of children and adolescents has not been evaluated in Bahrain.

This study aimed to determine the prevalence of vitamin D deficiency in a large sample of healthy children and adolescents in Bahrain, evaluate any sex and age differences between children with low vitamin D levels and those with adequate vitamin D, and correlate vitamin D levels with children's age.

Methods

Study design and sample

This was a cross-sectional study in which the medical records of 593 healthy children who attended the vitamin

D screening campaign at Al-Kindi Specialized Hospital, Bahrain between 27 September and 1 October 2016 were reviewed. The vitamin D screening campaign is a free campaign organized by Al-Kindi Specialized Hospital, a private hospital in Manama, the capital of Bahrain, as part of their social commitments to the community. This campaign is considered a national campaign as all healthy children in Bahrain were invited. The campaign was conducted in the clinics of the paediatrics department. Children were triaged by nursing staff before enrolment for blood collection. Children with any illness were excluded in this campaign. Children were also excluded from the study if they were under one month of age or more than 16 years, and if data were missing on their health condition or serum 25(OH)D levels.

Data collection

Data on sex, age at attending the campaign and serum 25(OH)D level were collected. Age was divided into three groups: 1 month to 5 years (preschool), 6 to 10 years (school age) and 11 to 16 years (adolescent). Two millilitres of venous blood were collected from each child by trained nurses and kept in a plain tube as vitamin D test is dependent on the serum level so this type of tube should be used and not an ethylenediaminetetraacetic acid (EDTA) tube. The serum was separated from the whole blood and vitamin D levels were measured using an Elecsys vitamin D total assay (Roche Cobas E 411 analyser apparatus, Switzerland). Vitamin D status was based on serum 25(OH)D level and categorized into three groups: vitamin D deficient [serum 25(OH)D \leq 50 nmol/L], vitamin D insufficient (51–74 nmol/L) and vitamin D sufficient \geq 75 nmol/L (14,15).

Statistical analysis

Data were analysed using SPSS, version 21. Frequencies and percentages for sex, age group and vitamin D group were calculated. Fisher exact and Pearson chi-squared tests were used to compare categorical variables (sex, age groups and vitamin D groups). Continuous variables (children's age and vitamin D levels) were checked for normal distribution using the Kolmogorov–Smirnov test. Group data are presented as a mean and standard deviation (SD) or median and range. Vitamin D groups were compared using the Mann–Whitney U and Kruskal–Wallis tests. Spearman's correlation coefficient (r_s) was used to examine correlations between vitamin D level and the children's age. Coefficient of determination (r^2) and the simple regression equation were calculated. A P -value < 0.05 was considered statically significant.

Ethical considerations

Informed consent was obtained from the parents before the blood test. Patients with vitamin D deficiency were offered a free consultation with a paediatrician to discuss the result of the test and they were advised to be treated with the appropriate doses of vitamin D therapy. This study was approved by the secondary care medical research subcommittee of Al-Kindi Specialised Hospital, Bahrain, and was conducted in accordance with the principles of Helsinki Declaration.

Results

A total of 593 healthy children were tested for serum 25(OH)D level. The children came only for vitamin D screening and they were not seeking any medical consultation. Sixty-two (10.4%) children were excluded because they had no laboratory results because their blood samples were inadequate. No sick patient came for the screening; therefore no children were excluded based on the health condition. Clinical characteristics and laboratory results of the remaining 531 children are shown in Table 1. Of the 531 children, 270 (50.8%) were boys. Most of the children (93.4%) had low vitamin D levels; only 6.6% had an adequate vitamin D level. Mean serum 25(OH)D level was significantly lower in girls [37.4 (SD 19.9) nmol/L] than boys [43.4 (SD 22.4) nmol/L] ($P < 0.001$). Mean vitamin D levels for preschool children, primary-school children and adolescents were 47.4 (SD 22.4) nmol/L, 37.4 (SD 17.47) nmol/L and 27.45 (SD 17.47) nmol/L respectively ($P < 0.001$).

Table 2 shows the demographic characteristics of the children categorized according to vitamin D level (sufficient and low). A greater proportion of girls (94.3%) had low vitamin D compared with boys (92.6%), but this was not statistically significant ($P = 0.487$). The mean and median ages of the children with low vitamin D were significantly higher than those of children with adequate vitamin D levels ($P < 0.001$). A significantly greater proportion of primary-school children and adolescents had low vitamin D compared to preschool children ($P = 0.015$). Only two infants were under one year (six months and eight months); one had vitamin D deficiency (40.7 nmol/L) and the other had insufficient vitamin D (64.4 nmol/L).

The association between vitamin D group (vitamin D sufficient, vitamin D insufficient and vitamin D deficient)

Table 1 Demographic characteristics and vitamin D levels of the children (n = 531)

Variable	Value
Sex [no. (%)]	
Male	270 (50.8)
Female	261 (49.2)
Age in years [median (range)]	6 (0.53–16)
Age group [no. (%)]	
1 month–5 years	257 (48.4)
6–10 years	185 (34.8)
11–16 years	89 (16.8)
Vitamin D level (nmol/L)	
Median (range)	36.4 (7.5–175)
Mean (SD)	39.8 (21.5)
Vitamin D level (nmol/L) [no. (%)]	
≥ 75 (sufficient)	35 (6.6)
51–74 (insufficient)	80 (15.1)
≤ 50 (deficient)	416 (78.3)

SD: standard deviation.

Table 2 Demographic characteristics of the children categorized by vitamin D level

Characteristic	Vitamin D level		Total (n = 531)	P-value ^c
	Sufficient ^a (n = 35)	Low ^b (n = 496)		
Sex [no. (%)]				
Male	20 (7.4)	250 (92.6)	270	0.487
Female	15 (5.7)	246 (94.3)	261	
Age (years)				
Mean (SD)	4.04 (3.5)	6.44 (3.7)	–	< 0.001
Median (range)	2.0 (1.3–15)	6.0 (0.5–16)	–	< 0.001
Age group [no. (%)]				
1 month–5 years	25 (9.7)	232 (90.3)	257	0.015
6–10 years	8.0 (4.3)	177 (95.7)	185	
11–16 years	2.0 (2.2)	87 (97.8)	89	

SD: standard deviation.

and sex and age is shown in Table 3. Significantly more girls were vitamin D deficient than boys ($P < 0.001$). In addition, significantly greater proportions of primary-school children and adolescents were vitamin D deficient compared with preschool children ($P < 0.001$).

The Spearman correlation coefficient test showed a moderate but statistically significant negative correlation between vitamin D level and children's age ($r = -0.467$; $P < 0.001$). The coefficient of determination (r^2) was -0.934 meaning that 93.4% of the variance in vitamin D level was explained by children's age. A simple linear regression was calculated to predict children's vitamin D levels as an outcome variable based on their age as the predictor variable (Figure 1). A significant regression equation was found: $F(1,529) = 96.660$; $P < 0.001$; $R^2 = 0.154$. Children's predicted vitamin D level is equal to $-2.164(\text{Age}) \text{ nmol/L} + 21.592$, when age is measured in years. Children's average vitamin D level decreased by -2.164 nmol/L for each year of age.

Discussion

Our study showed a very high prevalence (93.4%) of low vitamin D levels in healthy children in Bahrain. Prevalence of vitamin D deficiency in neighbouring countries and worldwide is shown in Table 4 (1,3–10,12,13,16–21). The available evidence suggests that vitamin D deficiency is an important child health problem worldwide (1–13,16–21). Studies on vitamin D deficiency in child and adult populations across Europe show an overall prevalence of 13% (7260/55 844) (22). In a large, population-based Dutch cohort, 30% (1250/4167) of the children were deficient in vitamin D ($< 50 \text{ nmol/L}$) and 66% (2750/4167) had insufficient vitamin D ($< 75 \text{ nmol/L}$) (9). A study in the United States of America (USA) showed a higher prevalence of vitamin D deficiency of 40% (146/365) in healthy infants and toddlers (21). The first national estimate of rickets caused by vitamin D deficiency in Australia gave an incidence of 4.9/100 000 population a year in children ≤ 15 years (5).

Table 3 Association between vitamin D group (sufficient, insufficient and deficient) and children's sex and age

Variable	Vitamin D group			Total	P-value ^d
	Sufficient ^a (n = 35)	Insufficient ^b (n = 80)	Deficient ^c (n = 416)		
Sex [no. (%)]					
Male	20 (7.4)	45 (16.7)	205 (75.9)	270	< 0.001
Female	15 (5.7)	35 (13.4)	211 (80.8)	261	
Age (years)					
Mean (SD)	4.04 (3.5)	4.47 (3.26)	6.82 (3.7)	–	< 0.001
Median (range)	2.0 (1.3–15.0)	3.0 (0.65–15)	6.0 (0.53–16)	–	< 0.001
Age group [no. (%)]					
1 month–5 years	25 (9.7)	59 (23)	173 (67.3)	257	< 0.001
6–10 years	8 (4.3)	15 (8.1)	162 (87.6)	185	
11–16 years	2.0 (2.2)	6.0 (6.7)	81 (91.0)	89	

SD: standard deviation.

^aSerum 25(OH)D $\geq 75 \text{ nmol/L}$.^bSerum 25(OH)D = $\text{mL}51\text{--}74 \text{ nmol/L}$.^cSerum 25(OH)D $\leq 50 \text{ nmol/L}$.^dKruskal–Wallis test was used to compare differences for continuous variables and the Pearson chi-squared was used for categorical variables.

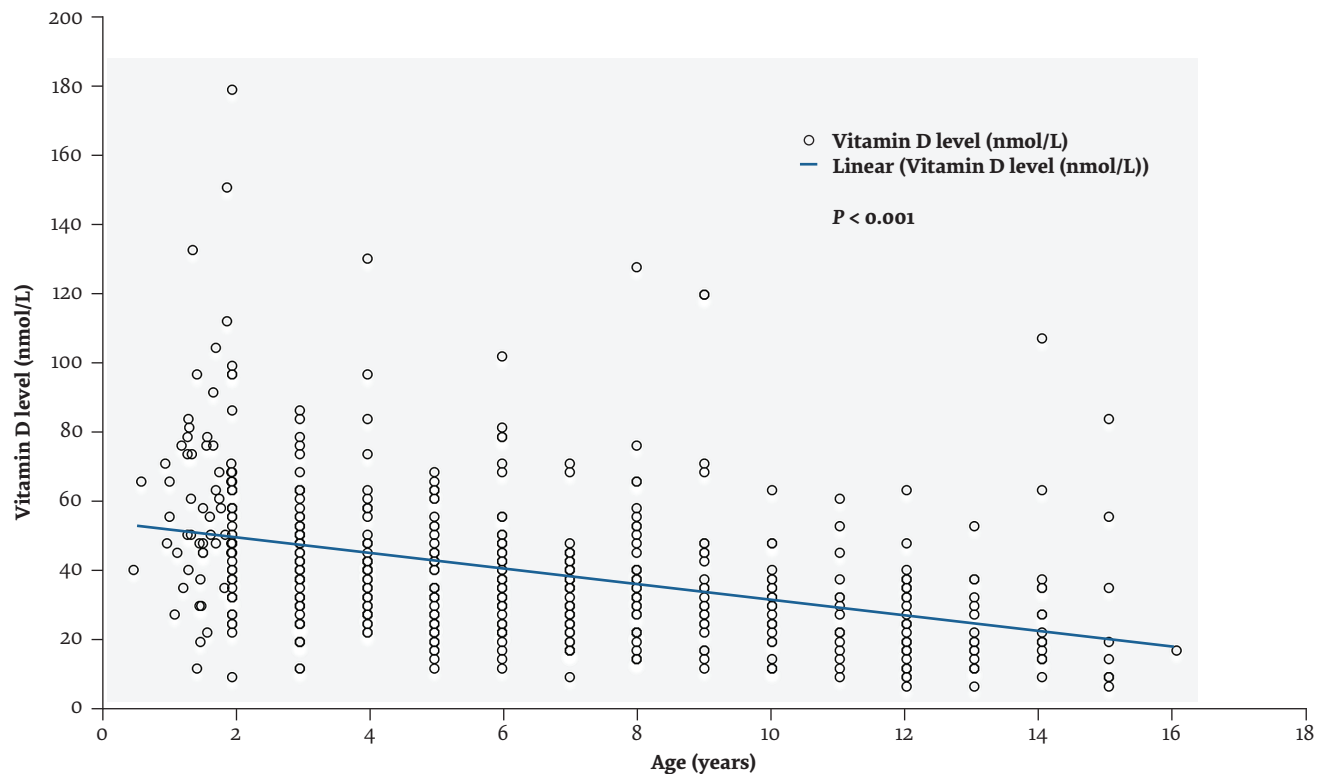


Figure 1 Relationship between vitamin D level and age in healthy children in Bahrain (n = 531)

Rickets caused by vitamin D deficiency has almost been eradicated in Western Europe and North America (1,23). However, the prevalence of vitamin D deficiency and rickets remains unacceptably high in Asia, Africa and the Middle East (1). Compared with neighbouring countries, our study showed an almost similar prevalence of vitamin D deficiency in children (78.3%) as that reported in Oman (69.1%) (217/314), Kuwait (77%) (158/204) and Qatar (68.8%) (315/458) (16–18). However, the prevalence of vitamin D deficiency in our study was higher than that reported in Saudi Arabia (45.5%, 960/2110) (1). Similar to our study, a study from Fars Province, southern Islamic Republic of Iran, reported a very high prevalence of vitamin D deficiency of 81% (388/477) in children aged 9 to 18 years (7). A Korean study of children aged 6 to 12 years found that 59% (195/330) had vitamin D deficiency (6) and a study in Turkey found a prevalence of 40% (176/440) of poor vitamin D status among Turkish children aged 0–16 years (8).

As well as high prevalence of vitamin D deficiency, 15.1% of the children and adolescents in our study had insufficient vitamin D (serum 25(OH)D = 52.4–72.4 nmol/L). Similarly, vitamin D deficiency ranged between 23% (49/209) at the end of summer and 80% (225/280) at the end of winter and vitamin D insufficiency between 12% (33/280) at the end of winter and 28% (58/209) at the end of summer in children in Ankara, Turkey (4). In a large cross-sectional study in Wuxi (southern China) among 5571 young children aged 1 to 3 years, vitamin D deficiency (serum 25(OH)D < 50 nmol/L) was found in

only 897 (16%) (19). However, the number increased to 3058 (55%) when a higher cut-off for sufficient vitamin D level was considered (≥ 75 nmol/L) (19). Another study in China on 6008 children aged 1 month to 16 years showed a lower prevalence of vitamin D deficiency compared with vitamin D insufficiency (20). In Saudi Arabia, vitamin D deficiency and insufficiency were almost equal in children and adolescents between 6 and 15 years of age, 45.5% (960/2110) and 49.9% (1053/2110) respectively (1).

In our study, we focused on the role of sex and age of healthy children on the development of vitamin D deficiency. However, other factors can play a role in the increase of vitamin D deficiency, such as low vitamin D intake and low sunshine exposure (2,4,7,8,11). Moreover, breastfeeding, skin pigmentation, covering the skin, ethnicity, season, low physical activity and high fat mass index can lead to low vitamin D levels (2,7–9,16). Although Bahrain is not affected by long winters, factors such as indoor lifestyle, avoidance of exposure to sunlight, environmental pollution and the scarce dietary sources of vitamin D should be considered in relation to the high levels of vitamin D deficiency we found (3). However, an American study in 2008 found that skin pigmentation, sun exposure, time spent outdoors and sunscreen use were not predictors of 25(OH)D concentration or vitamin D deficiency, as was hypothesized (21). However, a recent study published in 2015 from the Islamic Republic of Iran showed that vitamin D concentration was associated with sun exposure, physical activity, age and pubertal status (7). Moreover, darker skin, limited sun exposure,

Table 4 Prevalence of vitamin D deficiency in Bahrain, neighbouring countries and worldwide

Country (reference)	Total no. of healthy subjects	Age ^a	Low vitamin D (%)	Vitamin D insufficiency (%)	Vitamin D deficiency (%)	Sex difference	Age differences
Bahrain (12)	403	Newborns	90.3	37.5	52.9	–	–
Bahrain ^b	531	1 month–16 years	93.4	15.1	78.3	NS	Negative correlation
Bahrain (13)	500	Adults	86.4	37	49.4	F > M	Positive correlation
Kuwait (16)	204	9 (SD 2.7)	92	14	77	–	–
Oman (17)	314	9–10	96.5	27.4	69.1	F > M	–
Qatar (18)	458	< 16	68.8	–	–	F > M	More older children had vitamin D deficiency than younger children
Saudi Arabia (1)	2110	6–15	95.3	49.9	45.5	F > M	More older children had vitamin D deficiency than younger children
Iran (IR) (7)	477	9–18	96	15	81	NS	More older children had vitamin D deficiency than younger children
Turkey (4)	280	3–17	12–80	12–28	23–80	NS	Negative correlation
Turkey (8)	440	0–16	40	15	25	F > M	Negative correlation
China (19)	5571	1–3	16.1	–	16.1	NS	More in older age
China (20)	6008	1 month–16 years	32–94	32–94	5–57	NS	More in older age
Korea (6)	330	6–12	59.1	–	–	NS	NS
Netherlands (9)	4167	5.7–8	29.8	–	29.8	NS	More older children had vitamin D deficiency than younger children
Canada (10)	5306	6–79	5.4	–	5.4	M > F	–
Mexico (3)	1025	2–12	28–55	18–30	10–25	NS	Preschool > school age
USA (21)	380	8 months–2 years	54	40	14	NS	–
Australia (5)	851	≤ 15	47.7	91	9.0	M > F	More older children had vitamin D deficiency than younger children

UAE: United Arab Emirates; IR: Islamic Republic of; USA: United States of America; F: female; M: male; NS: no significant difference.

^aAge in years unless otherwise indicated.

^bPresent study.

– indicates no available data.

less time spent outdoors, low physical activity and low dietary sources of vitamin D were also shown to reduce vitamin D concentration in other studies (2,9,18).

In our study, no significant differences were found between boys and girls in the overall occurrence of low vitamin D. However, a significantly greater proportion of girls were in the vitamin D deficiency group, and the mean serum vitamin D level was significantly lower in girls than boys. In China, no significant difference was found between males and females in vitamin D levels even though females had lower mean levels (47.92, SD 16.47 nmol/L) compared with males (53.4, SD 16.97 nmol/L) (20). In contrast, the Saudi Arabian study reported a significantly higher prevalence of vitamin D deficiency in 97.8% (1073/1097) of females compared with 92.8% (940/101) of males ($P < 0.001$) (1). This finding may be due to less sun exposure of females because of limited outdoor activities, conservative clothing and the use of sunscreen products for cosmetic reasons (1). Similarly, the study in Turkey found that vitamin D deficiency was higher in females at the end of summer (4). However, no significant relationship was found between sex and vitamin D level at the end of winter (4).

Our work showed a negative correlation between vitamin D level and children's age. Similarly, the Iranian study showed that children's age was inversely associated with vitamin D concentration even after adjustment for physical activity, puberty stage, sun exposure and fat mass index (7). The Turkish study also reported a negative correlation between age and vitamin D levels (4); the frequency of vitamin D deficiency increased with age and was highest in adolescents and older age groups (4). We found that a significantly greater proportion of primary-school children and adolescents were in the overall low vitamin D group and vitamin D deficiency group than preschool children. This finding is similar to studies in China, the Netherlands and Turkey (8,9,20). In Europe, vitamin D levels varied considerably depending on age group (22). On the other hand, studies in Korea, United Arab Emirates and the USA found no significant difference in age between children with vitamin D deficiency and those with vitamin D insufficiency (6,11,21). Further work is still needed to clarify if the vitamin D levels are really affected by children's age. If this is the case, more studies are required to investigate the reasons for the decline in vitamin D levels in older children.

All the participants in our study were apparently healthy children. Children's vitamin D status is not typically assessed as part of routine care (21). In fact, most people with vitamin D deficiency are asymptomatic or may present with vague and non-specific symptoms (1,21). These symptoms include muscle cramps, pain in weight-bearing joints, difficulty in walking, facial twitches and carpedal spasms and may go unobserved for a long time (1,4). During childhood, clinical symptoms of vitamin D deficiency include hypocalcaemic seizures, lower-limb deformities, fractures, abnormal dentition and delayed developmental milestones (2). If vitamin D deficiency is severe and/or prolonged, linear growth impairment and many skeletal disorders may develop (1). However, obvious rickets and osteomalacia are

only the tip of the iceberg in patients with severe vitamin D deficiency (1). Vitamin D deficiency has been shown to be associated with diseases related to: insulin production such as diabetes mellitus, hypertension, cancer and the immune system (3,15,16). Even active rickets may not be identified on physical examination (4).

Most of the studies we reviewed used serum 25(OH)D level as a measure of vitamin D status in children (1,3-13,16-22) as we did. However, the cut-off points to decide vitamin D insufficiency and vitamin D deficiency are variable. Unlike our study where vitamin D levels of 50-74 nmol/L and ≤ 50 nmol/L were considered as vitamin D insufficiency and vitamin D deficiency respectively, the American Pediatric Endocrine Association recommends levels of 37.4-50 nmol/L as vitamin D insufficiency and < 37.4 nmol/L as vitamin D deficiency (24). It is important to use standardized serum 25(OH)D data in the assessment of the prevalence of vitamin D deficiency (20). In the Chinese study in Hangzhou, if the vitamin D deficiency threshold was changed to < 75 nmol/L, almost all children had low vitamin D levels (20). It is generally agreed that no individuals in the population should have a 25(OH)D concentration $< 25-30$ nmol/L (22). In Europe, after standardization of serum 25(OH)D data, the prevalence vitamin D deficiency was revised upwards and downwards in some studies (22). However, standardization has very little effect on 25(OH)D data if the population samples are small (22).

Our study has some limitations. The prevalence of vitamin D deficiency was determined using a sample of children presenting to one hospital so the results may not be representative of the whole population of Bahrain. A nationwide study would give a more accurate reflection of the true prevalence. Another limitation is that other factors affecting vitamin D levels were not reviewed, such as sun exposure, indoor life style, clothing, dietary intake of vitamin D, seasonal variation and environmental pollution.

Despite the limitations, our study is the first attempt to investigate vitamin D status among children aged 1 month to 16 years in Bahrain. The key strength was the inclusion of large number of healthy children with a wide range of ages. Our results suggest that paediatricians should have a higher degree of clinical suspicion for vitamin D deficiency and should screen all children with non-specific musculoskeletal pain. Moreover, the study provides further evidence to support public health policies or interventions to improve vitamin D status in Bahrain, especially for school-aged children as a targeted population.

Conclusion

Vitamin D deficiency is a very common problem among healthy children aged 1 to 16 years in Bahrain. Girls were more affected than boys and age was negatively correlated with vitamin D level. Further studies are needed: to calculate the prevalence of vitamin D deficiency in children sampled on a population basis; to evaluate the relationship between vitamin D level and other risk factors;

to determine whether vitamin D deficiency during childhood affects later health; and to recommend preventive and therapeutic practices to avoid the long-term complications of such a hidden medical problem.

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Competing interests: None declared.

Carence en vitamine D chez les enfants en bonne santé à Bahreïn : le sexe et l'âge ont-ils une importance ?

Résumé

Contexte : La carence en vitamine D est un problème de santé mondial chez l'enfant. Le bilan vitaminique D des enfants et des adolescents n'a pas été évalué à Bahreïn.

Objectifs : La présente étude transversale visait à déterminer la prévalence de la carence en vitamine D chez les enfants en bonne santé à Bahreïn afin d'examiner le rapport entre le taux de vitamine D et l'âge et le sexe.

Méthodes : Les dossiers médicaux d'enfants âgés d'un mois à 16 ans ayant participé à une campagne de dépistage de la carence en vitamine D à l'Hôpital spécialisé d'Al-Kindi (Bahreïn) entre septembre et octobre 2016 ont été passés en revue. Les données sur l'âge et le sexe ont été consignées et le taux de vitamine D a été évalué en mesurant la concentration de 25-hydroxyvitamine D sérique [25(OH)D]. Les enfants ont été répartis en trois groupes : taux de vitamine D suffisant [25(OH)D \geq 75 nmol/l], taux de vitamine D insuffisant (51-74 nmol/l) et carence en vitamine D (\leq 50 nmol/l).

Résultats : Au total, 531 enfants ont été inclus dans l'étude, dont 50,8 % de garçons. La plupart des enfants (93,4 %) présentaient un faible taux de vitamine D : 78,3 % présentaient une carence en vitamine D et 15,1 % un taux de vitamine D insuffisant ; seuls 6,6 % avaient un taux de vitamine D suffisant. Les filles étaient considérablement plus nombreuses que les garçons à présenter une carence en vitamine D ($p < 0,001$). Les écoliers du cycle primaire et les adolescents étaient aussi plus nombreux que les enfants d'âge préscolaire à présenter une telle carence ($p < 0,001$). Une corrélation négative a été établie entre le taux de vitamine D et l'âge ($r = -0,467$; $p < 0,001$). L'analyse de régression a montré que le taux de vitamine D diminuait de $-2,164$ nmol/l pour chaque année d'âge.

Conclusion : La carence en vitamine D est un problème touchant les enfants en bonne santé à Bahreïn. Les politiques et les interventions de santé publique pourraient améliorer le bilan vitaminique D à Bahreïn, en particulier pour les enfants d'âge scolaire.

نقص فيتامين د في الأطفال الأصحاء في البحرين: هل يهم نوع الجنس والعمر؟

حسن عيسى، محمد المالكي، عائشة السبع، عفاف محمد

الخلاصة

الخلفية: يُعتبر نقص فيتامين د إحدى المشاكل الصحية في الأطفال على مستوى العالم. ولم يُجرَ من قبل في البحرين تقييم لحالة فيتامين د في الأطفال والمراهقين. **الأهداف:** هدفت الدراسة التي شملت عدة قطاعات إلى تحديد انتشار نقص فيتامين د في الأطفال الأصحاء في البحرين والتحقيق في العلاقة بين مستوى فيتامين د والعمر ونوع الجنس.

طرق البحث: استُعرضت السجلات الطبية للأطفال الذين تتراوح أعمارهم بين شهر واحد و ١٦ عاماً من شاركوا في حملة للتجريب عن فيتامين د بمستشفى الكندي التخصصي، البحرين في الفترة بين سبتمبر/ أيلول إلى أكتوبر/ تشرين الأول ٢٠١٦. وسُجلت بيانات حول نوع الجنس والعمر وقيس مستوى فيتامين د مثل مصل ٢٥-هيدروكسيل الفيتامين د. وصُنّف الأطفال إلى مجموعات كالتالي: مستوى كاف من فيتامين د [٢٥-هيدروكسيل الفيتامين د \leq ٧٥ نانومول/ لتر]، ومستوى غير كافٍ من فيتامين د (٧٤-٥١ نانومول/ لتر)، ونقص فيتامين د (\leq ٥٠ نانومول/ لتر).

النتائج: شملت الدراسة ما مجموعه ٥٣١ طفلاً، ٨، ٥٠٪ منهم من الفتيان. ووجد أن غالبية الأطفال (٩٣، ٤٪) لديهم مستويات منخفضة من فيتامين د؛ و ٣، ٧٨٪ لديهم نقص في فيتامين د؛ و ١، ١٥٪ لديهم مستوى غير كافٍ من فيتامين د. ولم تتجاوز نسبة من لديهم مستوى كافٍ من فيتامين د أكثر من ٦، ٦٪. وكانت نسبة الفتيات اللاتي لديهن نقص في فيتامين د أكبر كثيراً من نسبة الفتيان (القيمة الاحتمالية $> ٠,٠٠١$). كذلك كانت نسبة نقص فيتامين د في صفوف طلاب المدارس الابتدائية والمراهقين أعلى منها في صفوف الأطفال الذين هم دون سن المدرسة (القيمة الاحتمالية $> ٠,٠٠١$). ووجد ترابط سلبي بين مستوى فيتامين د والعمر (الانحدار = $٤٦٧, -٠$ ؛ القيمة الاحتمالية $> ٠,٠٠١$). وأظهر تحليل الانحدار انخفاض مستوى فيتامين د بحوالي ١٦٤، ٢- نانومول/ لتر عن كل عام من العمر.

الاستنتاجات: يُعد نقص فيتامين د من المشكلات الشائعة بين الأطفال الأصحاء في البحرين. وقد اقترحت سياسات أو تدخلات صحية لتحسين حالة فيتامين د في البحرين، خاصة للأطفال في سن المدرسة.

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Prevalence of hypertension and associated risk factors in older adults in Kurdistan, Iraq

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Abstract

Background: Hypertension is an important public health problem and one of the leading risk factors for morbidity and mortality from cardiovascular diseases.

Aims: To determine the prevalence of hypertension in a population of older adults in Erbil, Kurdistan, Iraq and identify the risk factors associated with hypertension.

Methods: A community-based cross-sectional survey based on household visits was carried out from April to June 2017. The study involved 1480 adults selected through a multistage sampling method. We used a specially designed questionnaire to collect sociodemographic and clinical data from the participants through direct interview and measurement of blood pressure.

Results: Of the 1480 study participants, 809 (54.7%) had hypertension. Of these 809 hypertensive patients, 375 (46.4%) were known cases of hypertension and 434 (53.6%) were diagnosed during the survey. The multivariate analysis identified age [odds ratio (OR) = 1.1, 95% confidence interval (CI) = 1.08–1.11], male sex (OR = 2.72, 95% CI = 1.91–3.87), unemployment (OR = 1.85, 95% CI = 1.33–2.56), and obesity (OR = 2.20, 95% CI = 1.51–3.21) as significant factors associated with hypertension.

Conclusion: The prevalence of hypertension in Erbil City is high, with a high prevalence of undiagnosed hypertension. Treatment compliance was high but access to drugs was primarily from private pharmacies. This high prevalence of hypertension in Erbil City necessitates effective preventive and control measures, including comprehensive health education and screening programmes.

Keywords: elderly, household survey, hypertension, prevalence, risk factors

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Introduction

Hypertension is the most common cause of primary care visits, and it is an independent and a reversible risk factor for cardiovascular diseases (CVDs) such as myocardial infarction, stroke and renal failure. It can even lead to death if not diagnosed early and treated appropriately (1). Hypertension is considered to be a major public health problem worldwide (2). It is believed to be one of the leading causes of death and a frequent cause of outpatient visits (3). Regarding its contribution to the growing global pandemic of CVD, recently confirmed by the update of the Global Burden of Disease Study (2000), hypertension is estimated to be responsible for around 50% of CVDs worldwide (4). It is also considered to be one of the main risk factors for cardiovascular mortality, accounting for 20–50% of all deaths (5).

Hypertension among the adult population is increasing, and its complications account for 9.4 million annual deaths worldwide. Low-income countries have the highest prevalence of hypertension. The prevalence of hypertension is highest in the African Region at 46% of adults aged ≥ 25 years, and this proportion is increasing (6). About three-quarters of people with hypertension are from low- and middle-income countries, as access

to healthcare, as well as awareness of the disease, are inadequate. In general, Middle Eastern countries have a high prevalence of hypertension. A study conducted in the Islamic Republic of Iran revealed that $> 57\%$ of people aged ≥ 60 years have hypertension, compared to 3.6% of people aged < 30 years (7). Moreover, it is reported that, in 2001, the number of deaths resulting from hypertensive cardiac diseases in the Middle East and North Africa was 115 per 100 000, and the number of disability-adjusted life years resulting from hypertensive cardiac diseases was 1389 per 100 000 (8).

In 2006, a survey conducted in Iraq on chronic noncommunicable disease risk factors revealed that the prevalence of hypertension was 40.4% (9). The World Health Organization (WHO) Eastern Mediterranean Region health statistics published in 2008 revealed that the prevalence of hypertension in Iraq for both sexes was 29.4% (20.4–38.9%) (10). A household survey conducted in Thi-Qar Governorate in 2014 revealed that the overall prevalence of hypertension was 26.5% (11).

In low- and middle-income countries, many people with hypertension are not aware of their disease and the necessity for regular blood pressure checks. They may also not have access to drugs to control their hypertension

and reduce mortality and morbidity from complications such as heart disease and stroke. People may simply be unaware of the health consequences or indifferent to the risks of untreated hypertension (12). Therefore, this study aimed to determine the prevalence of hypertension in a sample of older adults in Erbil City, Kurdistan, Iraq and identify the risk factors associated with hypertension.

Methods

This community-based cross-sectional survey based on household visits was conducted in Erbil City, Kurdistan, Iraq from April to June 2017. A multistage sampling method was used to collect the study subjects. In the first stage, Erbil was divided into 20 quarters based on the administrative map of the city, and a systematic random sampling method was used to select 30 households in each quarter. For each quarter, we determined a sampling interval k as the ratio of the estimated quarter size to the sample size of 30. The first household in each quarter was selected randomly, and the next households were selected by selecting every k th household.

The study population included all the adult inhabitants of these households aged ≥ 18 years. Data were collected through direct interview using a special questionnaire designed for this purpose. The questionnaire included personal and sociodemographic information such as age, sex, marital status, educational level, employment status and type of occupation. It also included questions on smoking, alcohol consumption, diet, salt intake and physical exercise. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured for each subject on 2 occasions: after ≥ 5 minutes' rest, and then 5 minutes after the first reading. Subjects' weight and height were measured and body mass index was calculated. The surveyors were trained to administer the questionnaire and measure BP. A pilot study was conducted to test the validity and applicability of the questionnaire, and modifications were made accordingly. The pilot study revealed that the internal consistency (Cronbach's α) estimation of the questionnaire was 0.79 and the reliability coefficient was 0.82.

We used Epi-info to calculate the sample size, assuming that the prevalence of hypertension in Erbil City was similar to the previously reported 40% for Iraqi adults (13). We found that a sample size of 1473 was sufficient to achieve a 95% confidence interval (CI) for a prevalence ($\pm 2.5\%$) in this population. The sample size was increased to 1500 to accommodate for nonresponse. We assumed that each household would have 2 or 3 adults aged ≥ 18 years and visiting 600 households would produce a sample of around 1500 participants. Therefore, we selected 30 households in each of the 20 quarters.

Ethical approval was obtained from the Research Ethics Committee at our institution. Approval was also obtained from Erbil Governor and Erbil Mayor Offices. Informed consent was obtained from the participants who were assured about the anonymity of the study. The participants were informed about their BP status,

and those with elevated BP, especially patients with newly diagnosed hypertension, were advised to seek appropriate health care.

SPSS version 19 was used for data entry and analysis. The second BP measurement was used to determine hypertension. We used the 2017 American College of Cardiology/American Heart Association new guidelines for the prevention, detection, evaluation and management of high BP in adults that set a cutoff of 130/80 mmHg for hypertension (14). People with SBP ≥ 130 mmHg and/or DBP ≥ 80 mmHg during the second reading were considered to have hypertension. Student's t test was used to compare 2 independent sample means. The χ^2 test was used for comparing proportions. $P < 0.05$ was considered statistically significant. Multivariate analysis was based on binary logistic regression to adjust for and examine the independent effects of possible covariates. Odds ratios (ORs) and 95% CIs were calculated. ORs were estimated to measure the strength of the associations while 95% CIs and P values were estimated for significance testing.

Results

The survey identified 1480 adult participants in the 600 visited households. The mean (standard deviation) age of the participants was 46.4 (16.3) years with no significant difference between the mean age of men [46.7 (16.6) years] and women [46.2 (16.2) years] ($P = 0.612$). A total of 375 (25.3%) participants were in the age group ≥ 60 years, while 336 (22.7%) were in the 30–39 years age group and 307 (20.7%) in the 40–49 years age group (Table 1). A total of 1117 (75.5%) participants were female, 926 (62.6%) were housewives, 667 (45.1%) were illiterate, 1334 (90.1%) were married, and 1391 (94%) were of medium economic status. A total of 340 (23%) participants were employed with 298 (20.1%) being in the government office-based jobs.

Of 1480 study participants, 375 (25.3%) were previously diagnosed with hypertension (Table 2). Among these, 330 (88%) were regularly taking antihypertensive treatment, 22 (5.9%) were taking the treatment irregularly, while 23 (6.1%) were not taking their treatment. Two hundred and ninety-two (77.9%) obtained their antihypertensive medication from private pharmacies and only 47 (12.5%) from public hospitals without charge. Among the 1480 study participants, 809 (54.9%) had hypertension, which included both the previously and newly diagnosed cases of hypertension, based on BP readings. Of these 809 hypertensive patients, 249 (30.8%) were known cases of hypertension with uncontrolled BP, 126 (15.6%) were known cases of hypertension with controlled BP, and 434 (53.6%) did not know that they had hypertension but had a high BP reading on examination. Of the 434 newly diagnosed hypertension cases, 142 (32.5%) had isolated systolic hypertension, 38 (8.5%) had isolated diastolic hypertension, and the remaining 256 (59%) had combined systolic and diastolic hypertension.

The participants with hypertension had a significantly higher mean age [54.3 (15.1) years] than those without

Table 1 Sociodemographic characteristics of the studied sample

Variable	Frequency	Percentage
Age, yr		
20–29	251	17.0
30–39	336	22.7
40–49	307	20.7
50–59	211	14.3
> 60	375	25.3
Sex		
Male	363	24.5
Female	1117	75.5
Occupation		
Government, office-based	298	20.1
Government, labour-based	3	0.2
Private, office-based	37	2.5
Private, labour-based	2	0.1
Housewife	926	62.6
Student	35	2.4
None	179	12.1
Education		
Illiterate	667	45.1
Primary	339	22.9
Secondary	170	11.5
Tertiary	304	20.6
Marital status		
Single	142	9.6
Married	1334	90.1
Divorced	2	0.1
Widow	2	0.1
Religion		
Muslim	1421	96.0
Christian	59	4.0
Ethnicity		
Kurd	1388	93.8
Arab	8	0.5
Turkman	26	1.8
Chaldean/Assyrian	58	3.9
Socioeconomic status		
Poor	55	3.7
Medium	1391	94.0
Well	34	2.3

hypertension [36.8 (11.8) years] ($P < 0.001$). There was a significant association between hypertension and increasing age, male sex, being married, low educational level, unemployment, poor economic situation, sedentary lifestyle, lack of regular physical exercise, and increasing body mass index (Table 3). A nonsignificant association was found with smoking, alcohol consumption, table salt intake, and positive family history of hypertension 3.

Table 2 Clinical characteristics of the study participants

Characteristic	Frequency	Percentage
Previously diagnosed cases of hypertension		
Yes	375	25.3
No	1105	74.7
Compliance with antihypertensive treatment (n = 375)		
Regularly take treatment	330	88.0
Irregularly take treatment	22	5.9
Do not take treatment	23	6.1
Access to antihypertensive drugs (n = 375)		
Public hospital	47	12.5
Private pharmacy	292	77.9
Missing data	36	9.6
Prevalence of hypertension (n = 1480)^a		
Hypertensive	809	54.7
Not hypertensive	671	45.3
Prevalence of stage 2 hypertension (n = 1480)^b		
Hypertensive	593	40.1
Not hypertensive	887	59.9
Classification of hypertensive patients (n = 809)		
Uncontrolled, known cases of hypertension	249	30.8
Well controlled, known cases of hypertension	126	15.6
Newly diagnosed cases of hypertension based on examination	434	53.6
Type of hypertension among newly diagnosed cases (n = 434)		
Systolic	142	32.5
Diastolic	38	8.5
Combined systolic and diastolic	256	59.0

^aUsing 130/80 mm Hg cutoff according to the new guidelines.

^bUsing 140/90 mm Hg cutoff.

The multivariate analysis identified age (OR = 1.1, 95% CI = 1.08–1.11), male sex (OR = 2.72, 95% CI = 1.91–3.87), unemployment (OR = 1.85, 95% CI = 1.33–2.56), and obesity (OR = 2.20, 95% CI = 1.51–3.21) as significant factors associated with hypertension (Table 4).

Discussion

Our study revealed that the prevalence of hypertension in our study population in Erbil City was 54.7%. This prevalence is higher than that reported in a study in Nasiriyah City, Iraq in 2014 (26.5%) (11) and that reported across Iraq in 2006 (40.4%) (15) and by the WHO in 2013 (40%) (13). Studies conducted in neighbouring countries have also shown a high prevalence of hypertension ranging from 32.3% in Jordan to 44% in Turkey (16–18). However, a lower prevalence of 26.1% was reported in Saudi Arabia (19). The high prevalence in our study was partially attributed to using a cutoff of 130/80 mmHg according to the new guidelines (14), compared with a cutoff of 140/90 mmHg in other studies. However, even the prevalence of stage 2

Table 3 Association between hypertension prevalence and other variables

Variables	Hypertension			P
	Yes No. (%)	No No. (%)	Total No. (%)	
Age groups, yr				
20–29	44 (17.5)	207 (82.5)	251 (100)	
30–39	96 (28.6)	240 (71.4)	336 (100)	
40–49	172 (56.0)	135 (44.0)	307 (100)	< 0.001
50–59	164 (77.7)	47 (22.3)	211 (100)	
> 60	333 (88.8)	42 (11.2)	375 (100)	
Sex				
Male	230 (63.4)	133 (36.6)	363 (100)	
Female	579 (51.8)	538 (48.2)	1117 (100)	< 0.001
Marital status				
Single	42 (29.6)	100 (70.4)	142 (100)	
Ever married	767 (57.3)	571 (42.7)	1338 (100)	< 0.001
Education level				
Illiterate	460 (69.0)	207 (31.0)	667 (100)	
Primary	153 (45.1)	186 (54.9)	339 (100)	
Secondary	54 (31.8)	116 (68.2)	170 (100)	< 0.001
Tertiary	142 (46.7)	162 (53.3)	304 (100)	
Employment				
Employed	151 (44.4)	189 (55.6)	340 (100)	
Unemployed	658 (57.7)	482 (42.3)	1140 (100)	< 0.001
Economic status				
Poor	37 (67.3)	18 (32.7)	55 (100)	
Medium	758 (54.5)	633 (45.5)	1391 (100)	0.049
Well	14 (41.2)	20 (58.8)	34 (100)	
Smoking				
No	743 (54.3)	626 (45.7)	1369 (100)	
Yes	66 (59.5)	45 (40.5)	111 (100)	0.291
Alcohol consumption				
No	797 (54.9)	654 (45.1)	1451 (100)	
Yes	12 (41.4)	17 (58.6)	29 (100)	0.147
Table salt intake				
No	588 (54.4)	661 (45.6)	1449 (100)	
Yes	21 (67.2)	10 (32.3)	31 (100)	0.139
Lifestyle				
Sedentary	81 (78.6)	22 (21.4)	103 (100)	
Active	728 (52.9)	649 (47.1)	1377 (100)	<0.001
Physical exercise				
No	772 (55.3)	624 (44.7)	1396 (100)	
Yes	37 (44.0)	47 (56.0)	84 (100)	0.044
Body mass index				
Normal weight	108 (37.1)	183 (62.9)	291 (100)	
Overweight	255 (51.3)	242 (48.7)	497 (100)	
Obesity	444 (64.8)	241 (35.2)	685 (100)	<0.001
Family history of hypertension				
No	420 (53.9)	359 (46.1)	779 (100)	
Yes	389 (55.5)	312 (44.5)	701 (100)	0.543

hypertension, which is based on a 140/90 mmHg cutoff, was still considerably high (40.1%) in our study.

The prevalence of hypertension is always underestimated, especially in low- and middle-income countries (20), and the detection of high BP is made through routine examination or after the development of complications (21). Our study showed that 53.6% of the cases of hypertension were previously undetected, which comprised 29.3% of the study population. This percentage is higher compared to the 7.4% reported in the Nasiriyah study (11).

The present study showed a significant association between the prevalence of hypertension and sex (63.4% for men and 51.8% for women). However, other studies from Nasiriyah (11), Turkey (18) and the Islamic Republic of Iran (22) showed a higher prevalence of hypertension among women compared to men. In general, some risk factors for developing hypertension such as increased body weight and sedentary lifestyle might be more common in women (23).

The significant association between hypertension and increasing age might be attributed to the increased arterial stiffness in older people. An epidemiological study conducted in 2004 showed that the prevalence of hypertension was increased more than 2-fold in the aged compared to younger population (24). Our results in this regard are also consistent with those of other studies from Nasiriyah City (11) and Central India (25). According to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure in 2003, more than two thirds of the population aged > 65 years experienced hypertension (26).

We found a significant association between hypertension and marital status, with a prevalence of 57.3% among ever-married people compared to only 29.6% among the unmarried population. Married people are usually older than unmarried people, and this might explain the difference in prevalence of hypertension among these 2 groups. These results are also consistent with the studies from Nasiriyah City (11) and Central India (25). However, research has shown that married women have a lower risk of developing hypertension where marital happiness or satisfaction might play a role in attaining better health. However, experiencing change in marital status is likely to lead to some adverse effects, including hypertension (27).

The prevalence of hypertension was inversely related to the educational level in the present study. A significant association was found between hypertension and low educational level; 69% among the illiterate population, compared to 45.1% and 31.8% among participants with primary and secondary levels of education, respectively. These results are consistent with some other studies from Iraq and elsewhere (11, 28). Such an association could be primarily attributed to the low level of awareness among poorly educated people following a healthy lifestyle.

The prevalence of hypertension was significantly higher in unemployed people and those with lower

Table 4 Multivariate analysis of factors associated with hypertension

Variable	B	SE	OR	95% CI		P
				Lower	Upper	
Age	0.090	0.006	1.09	1.08	1.11	< 0.001
Female			Ref			
Male	1.000	0.181	2.72	1.91	3.87	< 0.001
Single			Ref			
Ever married	-0.463	0.248	0.63	0.39	1.02	0.062
Employed			Ref			
Unemployed	0.613	0.168	1.85	1.33	2.56	< 0.001
Well socioeconomic status			Ref			
Medium socioeconomic status	0.335	0.431	1.40	0.60	3.25	0.437
Poor socioeconomic status	0.918	0.546	2.51	0.86	7.31	0.093
Regular exercise			Ref			
No exercise	-0.003	0.284	1.0	0.57	1.74	0.992
Mild/moderate lifestyle			Ref			
Sedentary lifestyle	-0.135	0.323	0.87	0.46	1.64	0.676
Normal weight			Ref			
Overweight	0.325	0.193	1.38	0.95	2.02	0.093
Obesity	0.789	0.192	2.20	1.51	3.21	< 0.001

CI = confidence interval; OR = odds ratio; SE = standard error.

socioeconomic status. A meta-analysis showed an increased risk of hypertension among people with the lowest socioeconomic status, particularly for the indicators of income, occupation and education. The risk was particularly most evident for women (29).

Our study revealed a significant association between hypertension and increasing body mass index, with a prevalence of 64.8% among obese people compared to 51.3% and 37.1% among overweight and normal weight people, respectively. Our results were consistent with a study conducted in Central India (25). This association supports the fact that increased body weight is a primary risk factor for hypertension. The dietary patterns in Kurdistan might play a role in obesity and hypertension. The Iraqi diet is rich and varied as it reflects a rich inheritance as well as complex influences from the culinary traditions of Turkey, the Islamic Republic of Iran and the Syrian Arab Republic. The food involves large consumption of meat, especially lamb and chicken. It is also increasingly dependent on carbohydrates, primarily bread and rice, as any meal is rarely served without rice. The Iraqi diet is also characterized by high consumption of vegetables and fruit and moderate amounts of eggs, yogurt and cheese. However, it also has reduced consumption of fish or seafood (30,31). The region has witnessed an unprecedented increase in the consumption of fast food. Therefore, the dietary pattern is rapidly changing to an unhealthy diet, which might even increase obesity and its complications such as CVDs (32).

It is well known that hypertension runs in the family, but unlike other studies, this study showed an insignificant association between hypertension and

positive family history. It is possible that the participants lacked knowledge about the actual health status of their family members. Moreover, the environmental and lifestyle factors might have had more effect on developing hypertension than family history had. Several studies from Iraq and other countries have revealed a significant association between hypertension and positive family history (11,25,33).

Sedentary lifestyle and lack of regular physical exercise were also significantly associated with high prevalence of hypertension in our study. Being physically inactive also leads to increased body weight, which in turn leads to increased BP. Several other studies have shown that sedentary lifestyle and lack of physical exercise are important risk factors for developing hypertension (25,34).

The present study had several limitations. First, the study sample consisted mainly of female participants. The household visits were conducted during daylight hours when most male members of the household might have been out. We could not make follow-up visits to the households to interview the absent male adults due to logistic difficulties, such as lack of adequate funding and time available. Visiting the households for the survey purpose in the evening hours was also not culturally preferable in this locality. Second, there was the potential effect of white coat and masked hypertension on real prevalence. This problem is related to the variability of a patient's BP measurement between the physician's office and the patient's home environment. To limit the effect of these factors, we measured BP in the homes of the participants on 2 occasions and only after administering the questionnaire in a friendly manner. Third, we did not

include important risk factors for CVDs, such as lipid profile. We did not include data that required taking blood samples and laboratory investigations because of financial constraints and the possibility that participants would refuse to provide consent for invasive procedures.

Conclusions

In Erbil City there was a high prevalence of hypertension and undiagnosed hypertension. Compliance with treatment was high, but access to drugs was mainly from

private pharmacies. Hypertension was significantly associated with increasing age, male sex, unemployment and obesity. The high prevalence of hypertension in Erbil City necessitates effective preventive and control measures, including comprehensive health education activities, screening programmes, encouraging optimal and healthy lifestyles, and facilitating access to free or subsidized antihypertensive treatment.

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Prévalence de l'hypertension et facteurs de risque associés parmi la population âgée du Kurdistan (Iraq)

Résumé

Contexte : L'hypertension est un problème de santé publique majeur et l'un des principaux facteurs de risque de morbidité et de mortalité dues aux maladies cardio-vasculaires.

Objectifs : Déterminer la prévalence de l'hypertension dans une population de personnes âgées à Erbil, Kurdistan (Iraq), et identifier les facteurs de risque associés.

Méthodes : Une enquête transversale en communauté basée sur des visites dans les ménages a été menée entre avril et juin 2017. Elle incluait 1 480 adultes sélectionnés selon une méthode d'échantillonnage à plusieurs degrés. Nous avons utilisé un questionnaire conçu spécialement pour recueillir des données sociodémographiques et cliniques auprès des participants, grâce à des entretiens directs et à la mesure de leur tension artérielle.

Résultats : Sur les 1 480 participants, 809 (54,7 %) avaient une hypertension artérielle. Sur ces 809 patients hypertendus, 375 (46,4 %) avaient une hypertension connue et 434 (53,6 %) ont été diagnostiqués au cours de l'enquête. L'analyse multivariée a identifié l'âge [odds ratio (OR) = 1,1, intervalle de confiance à 95 % (IC) = 1,08-1,11], le sexe masculin (OR = 2,72, IC à 95 % = 1,91-3,87), le chômage (OR = 1,85, IC à 95 % = 1,33-2,56) et l'obésité (OR = 2,20, IC à 95 % = 1,51-3,21) comme facteurs significatifs associés à l'hypertension.

Conclusions : La prévalence de l'hypertension à Erbil est forte, avec une prévalence élevée d'hypertension non diagnostiquée. L'observance thérapeutique était bonne, mais l'accès aux médicaments dépendait principalement des pharmacies privées. Cette forte prévalence de l'hypertension à Erbil nécessite des mesures de prévention et de lutte efficaces, notamment des programmes complets d'éducation sanitaire et de dépistage.

ارتفاع ضغط الدم والعوامل المرتبطة به في صفوف البالغين الأكبر سنًا في كردستان، العراق

مريوان ساكا، شيرزاد شابو، نزار شابيلا

الخلاصة

الخلفية: يُعتبر ارتفاع ضغط الدم من المشكلات الصحية العامة وأحد عوامل الخطر الرئيسية التي تؤدي إلى الوفاة والمراضة بسبب أمراض القلب والأوعية الدموية.

الأهداف: هدفت الدراسة إلى تحديد مدى انتشار ارتفاع ضغط الدم بين السكان من البالغين الأكبر سنًا في أربيل، كردستان، العراق، وتحديد عوامل الخطر المرتبطة به.

طرق البحث: أُجري مسح مجتمعي شامل لعدة قطاعات قائم على زيارات منزلية من أبريل/ نيسان إلى يونيو/ حزيران ٢٠١٧. وشملت الدراسة ١٤٨٠ بالغًا، اختيروا باستخدام أسلوب «اختيار العينة المتعدد المراحل». وقد استخدمنا استبيانًا مُصممًا خصيصًا لجمع البيانات الاجتماعية السكانية والسريية من المشاركين من خلال عقد مقابلة مباشرة معهم وقياس ضغط الدم.

النتائج: من بين المشاركين في الدراسة البالغ عددهم ١٤٨٠ شخصًا، كان ٨٠٩ أشخاص (٥٤,٧%) مصابين بارتفاع ضغط الدم. ومن بين المرضى المصابين بارتفاع ضغط الدم (٨٠٩)، كان هناك ٣٧٥ مريضًا (٤٦,٤%) معروف أنهم مصابين بارتفاع ضغط الدم، بينما شُخص ٤٣٤ شخصًا (٥٣,٦%) منهم أثناء إجراء المسح. وحدد تحليل عديد المتغيرات العوامل الآتية بوصفها أهم العوامل التي ترتبط بارتفاع ضغط الدم: العمر [نسبة الأرجحية = ١,١، فاصل الثقة ٩٥% = ١,٠٨ - ١,١١]؛ والذكور [نسبة الأرجحية = ٢,٧٢، فاصل الثقة ٩٥% = ١,٩١ - ٣,٨٧]؛ والبطالة [نسبة الأرجحية = ٢,٢٠، فاصل الثقة ٩٥% = ١,٥٦ - ٣,٣٣]؛ والبدانة [نسبة الأرجحية = ٢,٢٠، فاصل الثقة ٩٥% = ١,٥١ - ٣,٢١].

الاستنتاجات: تبين ارتفاع معدل انتشار ارتفاع ضغط الدم في مدينة أربيل، علاوة على ارتفاع معدل انتشار ارتفاع ضغط الدم غير المُشخص. وكانت نسبة الالتزام بالعلاج مرتفعة، لكن الحصول على الأدوية كان من الصعوبات الخاصة بشكل أساسي. ونظرا لارتفاع معدل انتشار ارتفاع ضغط الدم في مدينة أربيل، يلزم اتخاذ تدابير فعالة للوقاية من المرض ومكافحته، وتشمل على سبيل المثال توفير برامج للتثقيف الصحي وتحريّ المرض.

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Prevalence and mortality of cancer among people living with HIV and AIDS patients: a large cohort study in Turkey

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Abstract

Background: Cancer is responsible for elevated human immunodeficiency virus (HIV)-related mortality but there are insufficient data about cancer in HIV-positive patients in Turkey.

Aims: We aimed to investigate the prevalence and mortality of cancer among people living with HIV and AIDS patients in Istanbul, Turkey.

Methods: Between January 1998 and December 2016, people living with HIV and AIDS patients were enrolled in this study by the ACTHIV-IST Study Group, which consists of 5 centres to follow-up HIV-positive patients in Istanbul. The cancer diagnoses included AIDS-defining cancers (ADCs) and non AIDS-defining cancers (NADCs).

Results: Among 1872 patients, 37 (1.9%) were diagnosed with concurrent cancer. Eleven patients were diagnosed during follow-up; the prevalence of cancer among people living with HIV and AIDS patients was 2.6%. Among 48 cancer patients, 35 patients had ADCs, and 32 of them were diagnosed at their first hospital admission. There were 1007 late presenters and 39 of them had cancer (29 were ADCs). The most prevalent NADCs were gastrointestinal, genitourinary, and pulmonary cancers. NADCs were mostly diagnosed during follow-up of patients. The mortality of this group was significantly higher than that of patients with ADCs (53.9% vs 22.9%).

Conclusions: These results indicate the importance of cancer screening at diagnosis and during follow-up of HIV infection. A detailed physical examination contributes to diagnosis of the most prevalent ADCs (Kaposi's sarcoma and non-Hodgkin's lymphoma), especially in late presenters. For NADCs, individual risk factors should be considered.

Keywords: human immunodeficiency virus, AIDS, cancer, prevalence, mortality

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Introduction

Patients with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) are at increased risk of developing cancer (1). This link was observed first when Kaposi's sarcoma (KS) was reported in young, homosexual men with severe immunosuppression, which was thereafter referred to as AIDS. The higher risk is mainly attributed to the impaired immune system. HIV-induced immunosuppression is responsible for the higher rates of KS and non-Hodgkin's lymphoma (NHL) and the risk increases steadily as CD4+ cell count decreases. Antiretroviral therapy reduces the increased risk of these cancers (2,3). However, non-AIDS-defining cancers (NADCs) do increase and cancer remains a significant cause of mortality in HIV/AIDS patients. Although long lifespan provides time for cancer to develop, the increased cancer risk compared to that in the matched general population demonstrates the role of other factors (4). Coinfection with other viruses, alcohol consumption,

tobacco smoking and advanced age in HIV/AIDS patients also increase the risk of cancer (5). People with HIV/AIDS have higher rates of tobacco smoking, hepatitis B and C coinfection, and human papillomavirus infection (6,7).

The increase in the number of NADCs is a challenge to the management of HIV/AIDS patients. The tumours are generally more aggressive and diagnosed at a younger age. HIV-infected patients with Hodgkin's lymphoma are more likely to present with unfavourable histological type and with higher rate of bone marrow involvement (8). The antineoplastic agents have a high likelihood of interaction with antivirals since protease inhibitors, non-nucleoside reverse transcriptase inhibitors and many antineoplastic drugs are metabolized by the cytochrome P450 system. Coadministration of these antivirals and antineoplastic agents could result in greater adverse effects and decreased efficacy (9,10). Additionally, the risk of death in cancer patients with AIDS is significantly higher than in cancer patients without AIDS for almost all cancer types (10).

After nearly 2 decades of the availability of highly active antiretroviral therapy (HAART), the size of the HIV/AIDS population is growing. As well as late presenting cases, patients receiving HAART regimens have a prolonged, mild immunosuppressive state. Especially in the setting of known risk factors for cancer, the increased incidence of cancer in HIV/AIDS patients represents a significant cause of mortality. There are insufficient data in the current literature about cancer in Turkish HIV-infected patients. In the present study, we aimed to investigate the prevalence and mortality of cancer among HIV/AIDS patients in Istanbul, Turkey.

Methods

Between January 1998 and December 2016, 1872 HIV-infected patients were enrolled by the ACTHIV-IST (Action Against HIV in Istanbul) Study Group, which consists of 5 centres, to follow-up HIV-positive patients in Istanbul. All newly diagnosed HIV/AIDS patients had a confirmatory diagnosis using a western blotting verification test (HIV BLOT 2.2; MP Biomedicals Asia Pacific, Singapore). The CD4+ cell counts were obtained by standard flow cytometry (FACScalibur; Becton Dickinson, Franklin Lakes, NJ, USA), and HIV viral load was measured by polymerase chain reaction (COBAS Ampliprep/COBAS TaqMan HIV-1 Test; Roche Molecular Systems, Pleasanton, CA, USA). Demographic data including age, sex, transmission routes, education level, marital status, history of imprisonment, CD4+ cell counts, and HIV RNA were collected from medical records and transferred to an HIV database system.

All the patients at all 5 sites received standardized care and diagnosis services. Diagnosis of cancer was established by clinical (detailed history taking and thorough physical examination), radiological and pathological/histological characteristics. Each cancer was reviewed using a standardized protocol to confirm the diagnosis and collect detailed information regarding cancer type, histology, grade, stage, and treatment from the medical records. Each site in the study used the same protocol for cancer evaluation and data collection. Cancer types were classified according to location (i.e., mucocutaneous, oral, breast, cervix, anus and lung) and/or histopathological reports (i.e., lymphoma and leukaemia). Details of histology, grade, and tumour node metastasis (TNM) staging were obtained from pathology reports and imaging studies. The cancer diagnoses included ADCs (KS, NHL, and cervical cancer) and NADCs.

Survival probability was calculated as the proportion of patients that survived beyond a specified time, and mean survival was the average length of time passed from the date of HIV/AIDS diagnosis. Categorical variables were compared by χ^2 (or Fisher's exact) test and continuous variables (age) were compared by Mann-Whitney U test. $P < 0.05$ was accepted as significant. This study was accepted by the Ethical Committee of Cerrahpasa Medical Faculty (83045809-604.01.02), Istanbul, Turkey.

Results

Among 1907 patients with HIV infection, 35 (1.8%) were lost to follow-up (The remaining 1872 (98.2%) patients were followed up for a total of 146 922 patient-months. Thirty-seven (2.0%) patients were diagnosed with cancer. Additionally, 11 (0.6%) patients were diagnosed during follow-up. The prevalence of cancer among our HIV/AIDS patients was 2.6%. Among the 48 cancer patients, 4 were female and mean age was 41.3 years. Thirty-five (72.9%) patients had ADCs, and 32 (91.4%) were diagnosed at their first hospital admission. Eight (22.8%) of 35 ADC patients and 7 (53.8%) of 13 NADC patients died during the study period. The mortality was 1.75% (32 of 1824) in non-cancer patients.

The 35 ADCs comprised 23 Kaposi's sarcomas and 12 NHLs. Among the 13 patients with NADCs, 5 had gastrointestinal cancer (3 colon, 1 esophageal and 1 liver), 3 urogenital cancer (1 kidney, 1 prostate and 1 testicular), 3 lung cancer, and 1 each laryngeal and spinal cord cancer.

The patients with NADCs were older than those with ADCs (mean age 53 vs 45 years) (Table 1). The patients with NADCs had a higher rate of HBV infection (15.4% vs 5.7%). Most importantly, the mortality rate was higher among patients with NADCs than ADCs, 53.8% vs 22.8% respectively. Moreover, while 91.4% of ADCs were diagnosed with HIV concurrently, this ratio among NADCs was 38.4%.

The survival probability of HIV-infected cancer patients was significantly lower than that of HIV-infected cancer-free patients (31.3% vs 1.7%) (Table 2). Low CD4 count was more frequent in cancer patients; cancer patients (both those diagnosed on admission and those who developed cancer during follow-up) were more likely late presenters, whose CD4 count was below 350 cells/mm³ at the moment of presentation at a healthcare facility or presenting with an AIDS-defining condition. Considering all cancer patients (diagnosed at any time), CD4 count < 350/mm³ was 38/48 (79%) compared with 968/1824 (53%) among patients without cancer ($P < 0.001$) (Table 2).

The survival rate between patients diagnosed with cancer on admission and those diagnosed during follow-up were comparable: 18.9 and 12.2 months, respectively ($P > 0.48$) (Table 3). Similarly, mortality did not differ significantly between the 2 groups. The cancers were more frequently ADCs in patients diagnosed on admission compared to those diagnosed during follow-up (87% vs 27%, $P = 0.0004$).

Thirty-five patients did not come to follow-up visits. Admission from one HIV/AIDS centre to another is frequent among patients in Turkey. However, this was not confirmed since the patients were not reached.

Causes of death other than cancer were: infection (tuberculosis, toxoplasmosis, cryptococcosis, *Pneumocystis jirovecii* pneumonia and sepsis; $n = 12$), wasting ($n = 7$), myocardial infarction ($n = 2$), suicide, cerebrovascular accident, progressive multifocal leukoencephalopathy, gastrointestinal bleeding, illicit drug use/intoxication,

Table 1 Characteristics of HIV-infected patients with cancer

Characteristic	Patients with cancer	
	ADCs n = 35 (%)	NADCs n = 13 (%)
Sex		
Female	3 (8.6)	1 (7.7)
Male	32 (91.4)	12 (92.3)
Mean age (years)	45 ± 11	53 ± 13
Age groups, n (%)		
20–30 years	7 (20)	0 (0)
31–40 years	16 (45.7)	3 (23.1)
41–50 years	5 (14.3)	3 (23.1)
51–60 years	5 (14.3)	4 (30.7)
> 61 years	2 (5.7)	3 (23.1)
CD4 count on diagnosis, n (%)		
0–200/mm ³	27 (77.1)	4 (30.7)
201–350/mm ³	2 (5.7)	5 (38.5)
351–500/mm ³	4 (11.4)	1 (7.7)
> 500/mm ³	2 (5.7)	3 (23.1)
Transmission route n (%)		
Heterosexual	15 (42.9)	11 (84.6)
MSM	20 (57.1)	2 (15.4)
IVDU	0	0
Blood transfusion	0	0
HBV coinfection, n (%)	2 (5.7)	2 (15.4)
HCV coinfection, n (%)	0	0
Patients died, n (%)	8 (22.9)	7 (53.8)
Cancer on HIV diagnosis, n (%)	32 (91.4)	5 (38.4)
Cancer during follow-up, n (%)	3 (8.6)	8 (61.5)

ADC = AIDS-defining cancer; IVDU = intravenous drug use; MSM = men who have sex with men; NADC = non-AIDS-defining cancer.

renal failure, HIV encephalopathy, alcohol intoxication, traffic accident, liver failure and undetermined (all n = 1).

Discussion

In this study, there were 32 ADCs and 5 NADCs on admission; however, on follow-up, 3 ADCs and 8 NADCs developed additionally. In other words, most of the HIV-infected patients with concurrent cancer had ADCs. NADCs were mostly diagnosed during follow-up of patients. The mortality of patients with NADCs was significantly higher than that in patients with ADCs. These findings highlight the importance of promoting cancer screening during initial diagnosis of HIV infection as well as during follow-up.

Before HAART, cancer was responsible for a minority (around 10%) of deaths in HIV-infected individuals (11). Despite the substantial decrease in ADCs in patients with HAART, cancer is responsible for approximately one third of deaths in this population (10,12). This increased role of cancer may be explained by the longer survival expectancy afforded by HAART (13), probable

Table 2 Characteristics of HIV-infected patients with or without cancer

Characteristic	No cancer n = 1824	All cancers n = 48	P
Sex			
Female	248	4	> 0.05
Male	1576	44	
Mean age (years)	37 ± 9	42 ± 13	0.02
Age groups, n (%)			
20–30 years	639 (35)	7 (14.5)	0.03
31–40 years	581 (31.9)	19 (39.6)	> 0.05
41–50 years	371 (20.3)	8 (16.7)	> 0.05
51–60 years	167 (9.2)	9 (18.8)	0.049
> 61 years	66 (3.6)	5 (10.4)	0.03
CD4 count on diagnosis, n (%)			
0–200/mm ³	445 (24.4)	31 (64.6)	< 0.001
201–350/mm ³	523 (28.7)	8 (16.7)	> 0.05
351–500/mm ³	386 (21.1)	4 (8.3)	0.03
> 500/mm ³	470 (25.8)	5 (10.4)	0.017
Transmission route, n (%)			
Heterosexual	987 (54.1)	26 (54.2)	> 0.05
MSM	821 (45)	22 (45.8)	> 0.05
IVDU	3 (0.2)	0	> 0.05
Blood transfusion	13 (0.7)	0	> 0.05
HBV coinfection, n (%)	104 (5.7)	4 (8.3)	> 0.05
HCV coinfection, n (%)	16 (0.9)	0 (0)	> 0.05
Patients died, n(%)	32 (1.7)	15 (31.3)	<0.001
Cancer on HIV diagnosis, n(%)		37 (77)	–
Cancer during follow-up, n(%)		11 (22.9)	–

ADC = AIDS-defining cancer; IVDU = intravenous drug use; MSM = men who have sex with men; NADC = non-AIDS-defining cancer.

oncogenic role of HIV (12), effect of other viruses (mainly hepatitis B, hepatitis C, human herpesvirus and human papillomavirus), advancing age, and higher prevalence of risky behaviours (e.g., alcohol consumption and tobacco smoking) (5). In the United States of America, from 1991 to 2005, the estimated number of ADCs decreased by >3-fold whereas NADCs increased by ~3-fold (anal, liver, prostate and lung cancers, and Hodgkin’s lymphoma). The increase in NADC was mainly attributed to growth and ageing of the AIDS population (14). The risk of cancer mortality is higher in patients with than without AIDS for many cancer types (10).

Late presentation with AIDS-defining disorders, including cancer, severely affects HIV management and is associated with high morbidity and mortality (15,16). Late presentation means missed opportunities for prevention and early diagnosis in most cases (17). A multicentre European study in 2013 including 30 454 patients from 34 countries reported that 48.7% were late presenters (18). This figure is even higher in Asian (19) and African (20) cohorts, reaching up to 72% and 85.6%,

Table 3 Time of cancer diagnosis and survival among HIV-infected cancer patients

Characteristic	Patients with cancer on HIV diagnosis (n = 37)	Patients with cancer on follow-up (n = 11)	P
Time from HIV diagnosis to cancer diagnosis (months)	–	35.8	
Time from cancer diagnosis to death (months)	18.9	12.2	0.48
ADC/NADC	32/5	3/8	0.0004
Mortality	9/37 (24.3%)	6/11 (54.5%)	0.07

ADC = AIDS-defining cancer; NADC = non-AIDS-defining cancer.

respectively. In Turkey, 50–70% of patients are admitted to clinical care with a CD4 count < 350 cell/mm³ (21–26). In the present study, late presenters were 53% and 81.2% of all cancers and 82.8% of ADCs were detected in this group. The fact that the majority of patients with cancers were detected on admission with a low CD4 count emphasizes the importance of early detection of the disease, thus preventing further decrease in CD4 count and allowing screening for other comorbidities including ADCs and NADCs.

In our study, ADCs comprised KS and NHL. The most common NADCs were gastrointestinal, urogenital and lung cancers followed by laryngeal and spinal cord cancers. In 2014, the registry of the Turkish Health Ministry reported that the most prevalent cancers in men were, in decreasing order, lung, prostate, colon, urinary bladder and stomach cancer, NHL, and kidney, laryngeal, thyroid and central nervous system cancer (27). In women, breast, thyroid, colon, uterine, lung, stomach and ovarian cancer, NHL, and central nervous system and cervical cancer were the most prevalent. When compared to the general population, urogenital cancer appears to have a higher prevalence among HIV-infected patients in Turkey.

Compared to the general population, HIV-infected patients have a 3640-fold increased risk of KS. This figure is 77-fold for NHL and 6-fold for cervical cancer (28). These cancers are associated with human herpesvirus 8, Epstein-Barr virus and oncogenic subtypes of human papillomavirus, respectively. The increased risk of

NADCs can be explained by the coinfection theory: anal and oropharyngeal cancer with human papillomavirus, liver cancer with hepatitis B and C viruses, and Hodgkin's lymphoma with Epstein-Barr virus (2, 29,30). In our study, nearly two thirds of ADCs were KS and the remainder were NHL. The availability of HAART has improved the immune function and decreased the risk of AIDS and ADCs (31,32). Although the incidence of KS decreased significantly after the use of HAART, it is one of the most frequently diagnosed cancers among HIV-infected individuals (10). In existing KS, HAART has been shown to induce regression in the size and number of the lesions (33). NHL is the most common ADC worldwide and was the second most common in our study. Although its incidence is decreasing in the post-HAART era, its risk is high in HIV-infected individuals (2).

Our study had some limitations. First, the sample size was small, which made clear conclusions difficult to draw. Second, the time of onset of HIV infection was not known in most cases and nearly half of the HIV-infected patients presented for clinical care at a late stage. Therefore, the effect of HIV infection on cancer development could not be easily assessed. Third, 35 patients did not attend follow-up visits and they were not reached. This potentially affected the outcomes since it is not known whether the non-attendance was due to any cancer-related morbidity or mortality.

Conclusion

Almost half of the patients with HIV infection are admitted to clinical care or are diagnosed late with AIDS-defining disorders including cancer. Late presentation is highly associated with ADCs. A detailed physical examination contributes to the diagnosis of the most prevalent ADCs (KS and NHL) especially in late presenters. Those diagnosed early still carry a higher risk of cancer. As the HIV/AIDS population survives and gets older, NADCs represent a new challenge in the care of these patients. For NADCs, individual risk factors should be considered. Additionally, the behaviour and relative frequency of NADCs may change in the setting of AIDS. Preventive strategies, screening and management should be clearly determined.

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Prévalence et mortalité du cancer chez les personnes vivant avec le VIH et les patients atteints de sida : étude de cohorte à grande échelle en Turquie

Résumé

Contexte : Le cancer est responsable d'une mortalité élevée liée au virus de l'immunodéficience humaine (VIH), mais les données relatives au cancer chez les personnes séropositives en Turquie sont insuffisantes.

Objectifs : Étudier la prévalence et la mortalité du cancer chez les personnes vivant avec le VIH et les patients atteints de sida à Istanbul (Turquie).

Méthodes : Entre janvier 1998 et décembre 2016, des personnes séropositives ont été recrutées comme sujets pour la présente étude par le groupe d'étude ACTHIV-IST, qui se compose de cinq centres de suivi des personnes séropositives pour le VIH à Istanbul. Les diagnostics de cancer incluaient les cancers classant sida et les cancers non classant sida.

Résultats : Sur 1 872 malades, 37 (1,9 %) ont reçu un diagnostic de cancer concomitant. Onze patients ont été diagnostiqués en phase de suivi post-thérapeutique. La prévalence du cancer chez les personnes vivant avec le VIH et les patients atteints de sida était de 2,6 %. Sur 48 patients cancéreux, 35 avaient un cancer classant sida, parmi lesquels 32 avaient été diagnostiqués lors de leur première hospitalisation ; 1 007 personnes se présentaient à un stade avancé de l'infection, et 39 d'entre elles avaient un cancer (29 avaient un cancer classant sida). Les cancers non classant sida les plus prévalents étaient les cancers gastro-intestinal, uro-génital et pulmonaire. Ces cancers avaient principalement été diagnostiqués chez les patients en phase de suivi post-thérapeutique. Dans ce groupe, la mortalité était considérablement plus élevée que celle des patients de cancers classant sida (53,9 % contre 22,9 %).

Conclusions : Ces résultats soulignent l'importance du dépistage du cancer lors du diagnostic et du suivi post-thérapeutique des infections à VIH. Un examen clinique détaillé contribue au diagnostic des cancers classant sida les plus prévalents (sarcome de Kaposi et lymphome non hodgkinien), en particulier chez les patients se présentant à un stade avancé. Concernant les cancers non classant sida, les facteurs de risque individuels devraient être pris en compte.

انتشار السرطان بين مرضى فيروس العوز المناعي البشري/ الإيدز والوفيات الناجمة عنه: دراسة أترابية في تركيا

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الخلاصة

الخلفية: يُعد السرطان مسؤولاً عن ارتفاع نسبة الوفيات المقترنة بفيروس العوز المناعي البشري، ولكن لا تتوفر معلومات كافية بشأن السرطان في صفوف المرضى المصابين بفيروس العوز المناعي البشري في تركيا.

الأهداف: هدفت الدراسة إلى الاستقصاء بشأن انتشار السرطان بين مرضى فيروس العوز المناعي البشري/ الإيدز والوفيات الناجمة عنه في إسطنبول، تركيا.

طرق البحث: في الفترة بين يناير/ كانون الثاني ١٩٩٨ وديسمبر/ كانون الأول ٢٠١٦، سجلت مجموعة دراسة ACTHIV-IST (العمل من أجل مكافحة فيروس العوز المناعي البشري في إسطنبول) المرضى المصابين بفيروس العوز المناعي البشري في هذه الدراسة، التي تشمل ٥ مراكز لمتابعة المرضى المصابين بفيروس العوز المناعي البشري في إسطنبول. وتضمن التشخيص أنواع السرطان التي تحدد مرض الإيدز، وأنواع السرطان التي لا تحدد مرض الإيدز.

النتائج: من بين ١٨٧٢ مريضاً، شُخص ٣٧ مريضاً منهم (٩, ١٪) بالسرطان المصاحب لفيروس العوز المناعي البشري. وشُخص أحد عشر مريضاً خلال المتابعة؛ وبلغت نسبة انتشار السرطان بين مرضى فيروس العوز المناعي البشري/ الإيدز ٦, ٢٪. ومن بين ٤٨ مريضاً بالسرطان، كان لدى ٣٥ مريضاً أنواع السرطان التي تحدد مرض الإيدز، وشُخص ٣٢ مريضاً منهم عند دخولهم المستشفى لأول مرة. وتأخر ١٠٠٧ من مقدمي البيانات، منهم ٣٩ شخصاً مصاباً بالسرطان (وكان لدى ٢٩ منهم أنواع السرطان التي تحدد مرض الإيدز). ومن بين أنواع السرطان التي لا تحدد مرض الإيدز الأكثر انتشاراً: سرطان المعدة والأمعاء، وسرطان الجهاز البولي التناسلي، وسرطان الرئة. وكانت أنواع السرطان التي لا تحدد مرض الإيدز تُشخص أثناء متابعة المرضى. ومعدل الوفيات في هذه الفئة أعلى بكثير عنه في المرضى المصابين بأنواع السرطان التي تحدد مرض الإيدز (٩, ٥٣٪ مقابل ٩, ٢٢٪).

الاستنتاجات: توضح هذه النتائج أهمية تحري الإصابة بالسرطان عند التشخيص بعدوى فيروس العوز المناعي البشري وأثناء متابعة المرضى المصابين به. ويساعد إجراء فحص بدني مفصل في تشخيص أكثر الأمراض انتشاراً من أنواع السرطان التي تحدد مرض الإيدز (ساركومة كابوزي والمفومة هودجكين)، خاصة في صفوف مقدمي البيانات المتأخرين. أما أنواع السرطان التي لا تحدد مرض الإيدز، فينبغي أن تؤخذ بعين الاعتبار عوامل الخطر الفردية.

(العمل من أجل مكافحة فيروس العوز المناعي البشري في إسطنبول).¹

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Reuse of syringes for therapeutic injections in Pakistan: rethinking determinants

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Abstract

Background: Frequent reuse of syringes during medical injections is fuelling epidemics of human immunodeficiency virus and hepatitis C virus infections in many low- and middle-income countries including Pakistan.

Aims: To explore specific factors related to syringe reuse during therapeutic injections.

Methods: We randomly surveyed 319 healthcare providers from 2 socioeconomically diverse districts in Pakistan, along with 625 of their patients.

Results: Providers see 12–25 patients per day, and provide 7–14 therapeutic injections or intravenous drips. Comparing daily stocks with injections provided, we estimated that 38% of providers (Rawalpindi: 14%, Tando Allah Yar: 44%) likely reuse syringes 2 or 3 times. Rural location and longer duration of practice predict a higher likelihood of reuse. Physicians and non-physicians were equally likely to reuse. Most patients were unaware when a syringe had been reused.

Conclusions: High rate of syringe reuse is driven by high injection demand by patients, to which providers comply. Patients are generally unaware of the harm of injections with syringe reuse or that reuse happens. Our findings suggest that patient focused approaches may help reduce syringe reuse.

Keywords: injection demand, injection safety, syringe reuse, therapeutic injections, unsafe injections

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Introduction

Syringe reuse during therapeutic injections has contributed to the global epidemics of hepatitis C virus (1,2) and human immunodeficiency virus (HIV) (3–6) infection, and is well documented in high-income (7,8) and low- and middle-income countries (9–11). In Pakistan, high reuse of syringes during therapeutic injections (13) has led to a national prevalence of hepatitis C of 4.8% (12), with some districts as high as 12%, and has contributed to at least one community outbreak of HIV infection (14). Therapeutic injections in Pakistan range from 4.2–4.6 injections per person annually (13), with 17–50% of these injections being given with reused syringes (12,13,15,16). Currently, conventional disposable syringes are used in Pakistan. The Punjab Government introduced reuse-prevention (RUP) syringes in its health facilities in 2017 (17). The World Health Organization's injection safety guidelines recommend RUP for all injections and sharp-injury protection syringes, wherever feasible (18).

We have previously demonstrated that the total national supply of syringes in Pakistan is sufficient to meet the demand for the ~1.1 billion syringes used annually for immunization, diabetes, laboratory testing and drug administration in clinics or hospitals (13). Therefore reuse of syringes cannot be attributed merely to a national shortfall of syringes as had been previously thought. However, such national aggregates hide reuse

by individual practitioners. The present study explored the extent and pattern of syringe reuse in Pakistan. We also explored a novel method to identify reuse to avoid providers' self-promotion and patients' recall biases, as well as paradigms behind injection demand and supply in communities.

Methods

Rawalpindi and Tando Allah Yar were identified in collaboration with the Pakistani Ministry of Health as districts exemplifying high and low human development indices (19), to understand injection reuse practices across the extremes of human development. Rawalpindi is a large metropolis with a large number of public and private, and primary, secondary and tertiary medical care centres and specialists. Although around half of the population of Rawalpindi District is rural, the villages are close to the city. Tando Allah Yar is completely rural and poor. Data were collected between February and April 2009.

In the first phase, all healthcare providers from all 19 Union Councils of Tando Allah Yar and 38 (1: 5) randomly selected Union Councils from Rawalpindi were listed. Thus, 6053 providers were identified as any individuals who see patients in communities, irrespective of their training or licensure. This list was used to construct a simple randomization–sampling frame to recruit healthcare providers. The study was powered for type I

error (α): 0.05 and type II error (β): 0.2; giving a total of 320 providers to be divided between districts (Epi Info). The relative number of the providers between districts was weighted for the providers per Union Councils included in the listing, giving 174 providers from Rawalpindi and 145 from Tando Allah Yar. At each healthcare provider's facility, 2 patients were approached to participate in a brief survey, from among those present at the time of study team visit and based on who was encountered first.

Provider and patient questionnaires were pretested to ensure validity and appropriateness. The providers' questionnaire asked about their training and practice pattern. The patients' questionnaire asked about their demographics and healthcare-seeking behaviour. Both were asked about knowledge about syringe reuse and its harm.

Reuse of injections was identified by 3 measures: (1) the study teams observed providers while managing patients, including while giving injections; (2) recognizing that such observations may be subject to a Hawthorne effect (20,21), where providers' behaviour may change when they recognize that they are being observed, we also asked patients if they felt that the injection they received was given with a new or reused syringe; and (3) since many patients may not have known whether a syringe was reused, we also used a proxy measure. We asked providers how many syringes they stocked for the previous day and compared these against the number of injections they said they had provided yesterday. This difference identified providers that were sure to reuse syringes since they would have insufficient syringes for all the injections they gave. This established a minimum level of reuse since providers can potentially reuse even when they have insufficient syringes. Recall bias was limited by asking only about the previous day. Variables were compared using SPSS+ version 20. Proportions of those that gave injections, and reusers were compared using χ^2 tests. Predictors of reuse of syringes were explored using linear regression with predictors described in Table 5. These factors included all that were considered relevant to syringe reuse.

The study was reviewed and approved by the Ethical Review Committee of Bridge Consultants Foundation, Karachi, Pakistan. Informed consent was obtained from all participants.

Results

We interviewed 319 providers (145 from Tando Allah Yar and 174 from Rawalpindi). Their mean (standard deviation) age was 44.5 (11.8) years in Rawalpindi and 39.6 (10.2) years in Tando Allah Yar, and there were 265 (83%) men. Around half (57%) of all providers from Rawalpindi and 26% from Tando Allah Yar were physicians, with more urban than rural providers being physicians (Table 1). Urban providers from Rawalpindi saw a mean 27.5 patients a day and their rural counterparts saw a mean 16.7. Rural and urban providers from Tando Allah Yar saw a mean 19.9 and 21.8 patients a day respectively.

We interviewed 625 patients (273 from Tando Allah

Table 1 Demographics and practices of providers

	Total	Rawalpindi	Tando Allah Yar	P
Age of patients, yr, mean (SD)				
All	42.3 (11.4)	44.5 (11.8)	39.6 (10.2)	< 0.001
Rural	39.5 (10.7)	42.9 (11.5)	37.2 (9.5)	0.002
Urban	44.7 (11.4)	45.4 (11.9)	43.4 (10.4)	0.271
Male sex, n (%)				
All	265 (83%)	133 (77%)	132 (91%)	0.001
Rural	133 (88%)	52 (83%)	81 (91%)	0.029
Urban	132 (80%)	81 (74%)	51 (91%)	< 0.001
Physician (vs. non-physician), n (%)				
All	135 (43%)	98 (57%)	37 (26%)	0.003
Rural	33 (22%)	18 (29%)	15 (17%)	0.015
Urban	102 (61%)	80 (73%)	22 (39%)	0.003
Patients seen daily, mean (SD)				
All	22.4 (18.6)	23.8 (20.5)	20.6 (15.9)	< 0.001
Rural	18.6 (16.8)	16.7 (17.7)	19.9 (16.0)	< 0.001
Urban	25.7 (19.6)	27.5 (20.9)	21.8 (15.7)	0.002

Yar and 352 from Rawalpindi). Their mean age was 34.4 (18.7) years in Rawalpindi and 32.2 (12.1) years in Tando Allah Yar; 603 (56%) were men (Table 2). Twenty percent of patients from Rawalpindi had no schooling, compared with 56% from Tando Allah Yar. Patients from Tando Allah Yar were more likely to be farmers, labourers or housewives, while those from Rawalpindi were mostly skilled labourers, housewives, office workers or students

Commonest reasons for medical visits were fever, influenza-like symptoms or body aches (51% of all patient visits) or abdominal symptoms such as pain, vomiting or diarrhoea (11% of visits). An injection was provided during 53% of patient visits in Rawalpindi and 92% in Tando Allah Yar (Table 2). Patients from Rawalpindi reported having received a mean of 5.4 injections during the previous year compared to 13.2 injections by patients from Tando Allah Yar.

Patients from Tando Allah Yar reported a mean 3.8 visits to a healthcare provider by a member of their household during the previous month, compared to 2.5 by those from Rawalpindi (Table 2). During all such visits, an injection was given. Overall, 56% patients felt that an injection was necessary. Such perceptions were higher in Tando Allah Yar than in Rawalpindi (79% vs. 39%) (Table 2). Providers reciprocated such perceptions in that 44–56% of providers felt that an injection was required for common ailments such as fever, influenza, body aches or diarrhoea (Table 4). In practice, it was highly likely that an injection would be given for fever (OR: 7.9, $P = 0.022$) but not for abdominal pain/ diarrhoea (OR 5.4, $P = 0.187$).

Providers from Rawalpindi charged a mean US\$ 1.44 for a visit when no injection was given and US\$ 1.51 if an injection was given; there were no rural/urban differences. Providers from Tando Allah Yar charged a mean US\$ 0.59

Table 2 Sociodemographic characteristics of patients

Characteristics	Total	Rawalpindi	Tando Allah Yar	P
	Mean (SD)	Mean (SD)	Mean (SD)	
Age	33.5 (16.2)	34.4 (18.7)	32.2 (12.1)	0.047
Male sex, n (%)	340 (54%)	178 (50%)	162 (59%)	0.588
Education				
No schooling, n (%)	224 (36%)	72 (20%)	152 (56%)	< 0.001
Years of education, mean (SD)	4.7 (4.830)	6.4 (4.663)	2.0 (3.756)	< 0.001
Was an injection prescribed during this visit, n (%)	614 (70%)	347 (53%)	267 (92%)	< 0.001
Injections received last year, mean (SD)				
All	8.2 (13.5)	5.4 (9.7)	13.2 (17.4)	< 0.001
Rural	10.7 (17.0)	6.4 (10.2)	15.8 (21.4)	< 0.001
Urban	6.4 (9.9)	4.9 (9.4)	10.1 (10.3)	< 0.001
Healthcare visits last month by a family member, mean (SD)				
All	3.1 (4.6)	2.5 (5.7)	3.8 (2.5)	< 0.001
Rural	3.2 (2.5)	2.6 (7.6)	3.6 (2.5)	0.003
Urban	3.1 (4.6)	2.5 (4.5)	4.0 (2.4)	< 0.001
Median injections received in these visits (SD)				
All	2 (5.09)	1.8 (5.1)	5.0 (6.5)	< 0.001
Rural	3 (6.65)	2.7 (7.8)	6.2 (7.8)	< 0.001
Urban	1 (2.80)	1.3 (2.6)	3.4 (2.7)	< 0.001
Felt an injection was necessary, n (%)				
Yes	351 (56%)	136 (39%)	215 (79%)	< 0.001
No, but the provider insisted	18 (3%)	17 (5%)	1 (0.4%)	0.840
Median provider fee for this visit (in USD), n (SD)				
All	1.10 (1.36)	1.48 (1.65)	0.61 (0.49)	< 0.001
Rural	0.95 (1.27)	1.46 (1.69)	0.56 (0.57)	< 0.001
Urban	1.24 (1.41)	1.49 (1.64)	0.69 (0.30)	< 0.001
Injection prescribed	1.42 (1.81)	1.51 (1.87)	0.59 (0.62)	< 0.001
Injection not prescribed	0.97 (1.08)	1.44 (1.42)	0.62 (0.48)	< 0.001

when an injection was provided and US\$ 0.62 when not provided. Providers charged a mean US\$ 0.56 in rural and US\$ 0.69 in urban locations. Providers from Rawalpindi reported giving a mean of 8.8 intramuscular injections, 3.5 intravenous injections and 2.3 intravenous drip daily (Table 3). Providers from Tando Allah Yar gave a mean 10.0 intramuscular injections, 3.9 intravenous injections and 1.4 intravenous drip daily. We asked providers how many syringes they had stocked for the day: 140 (48%) providers from Rawalpindi and 122 (46%) from Tando Allah Yar gave more injections than their daily stock of syringes. Therefore, they would have been likely to reuse syringes regularly. For analysis, these were labelled as likely reusers. No urban provider from Rawalpindi fell into this category, while urban and rural providers in Tando Allah Yar were similar (Table 3). Around 38% of all providers were likely to reuse consistently (Table 4). These likely reusers gave a mean 14.4 injections daily compared to 12.3 by those who were less likely to reuse syringes. Since reusers stocked around 5 syringes a day, they would likely have reused syringes for 9 injections in any given day.

Of the variables used in the linear regression model (Table 5), only practicing in Tando Allah Yar (AOR 1.92, range 1.9–7.69) and a longer duration of practice (AOR 0.6% for each year in practice, range 0.1–1%) increased the likelihood for reuse. Physicians were just as likely to reuse as non-physicians. Our teams observed patient encounters for any injection reuse and we also asked patients if they had observed syringe reuse. Both of these modes of inquiry identified reuse during < 5% of observations/visits. Nearly all providers, but few patients, were aware of the possibility of acquiring injection site injuries or infections such as hepatitis or HIV infection from reused syringes.

Discussion

We found that around half of the patients had received an injection during their current visit and that at least 38% of the providers were likely to reuse syringes during injections. Reuse happens just as often by physicians or non-physicians and is irrespective of sex of providers or the fee charged. Both providers and patients felt that

Table 3 Injection provision

Injection provision	Total Mean (SD)	Rawalpindi Mean (SD)	Tando Allah Yar Mean (SD)	P
Intramuscular injections provided daily				
All	9.4 (9.6)	8.8 (9.6)	10.0 (9.6)	0.134
Rural	9.8 (9.3)	8.2 (7.6)	10.8 (10.0)	0.020
Urban	9.1 (9.8)	9.2 (10.4)	8.9 (8.7)	0.819
Intravenous injections provided daily				
All	3.7 (4.5)	3.5 (3.7)	3.9 (4.9)	0.298
Rural	3.6 (4.2)	2.8 (3.4)	3.9 (4.4)	0.057
Urban	3.7 (4.7)	3.8 (3.8)	3.9 (5.6)	0.938
Intravenous drips provided daily				
All	1.7 (3.8)	2.3 (3.9)	1.4 (3.8)	0.037
Rural	1.6 (3.3)		1.0 (1.6)	0.003
Urban	1.9 (4.4)	1.6 (1.5)	2.1 (5.7)	0.370
Injections of any kind daily				
All	15.7 (13.4)	17.6 (15.6)	14.8 (12.6)	0.083
Rural	15.4 (11.9)	17.1 (14.5)	14.8 (10.9)	0.302
Urban	16.0 (15.1)	18.1 (15.6)	14.8 (14.9)	0.193
Providers that are most likely to reuse syringes daily				
	n (%)	n (%)	n (%)	n (%)
All	262 (47%)	140 (48%)	122 (46%)	0.637
Rural	127 (49%)	49 (52%)	78 (48%)	0.538
Urban	135 (45%)	91 (46%)	44 (44%)	0.744

Table 4 Likely reusers of syringes

	Likely non-reusers	Likely reusers	P
Likely reusers	62%	38%	
Age, yr, mean (SD)	38 (10.5)	40 (10.9)	0.385
Physician or other, n (%)			
MB BS	196 (62%)	120 (38%)	<0.001
Non-MB BS	98 (41%)	142 (59%)	0.009
Sex of provider, n (%)			
Male	232 (50%)	228 (50%)	1.000
Female	52 (64%)	29 (36%)	0.019
Years since last completed degree (SD)	21 (10.8)	24 (8.8)	0.807
Years in practice (SD)	10 (18.0)	10 (9.5)	0.204
District			
Tando Allah Yar, n (%)	143 (54%)	122 (46%)	0.196
Rawalpindi, n (%)	151 (52%)	140 (48%)	0.489
Location			
Urban, n (%)	163 (55%)	135 (45%)	0.088
Rural, n (%)	131 (51%)	127 (49%)	0.749
No. of patient examined yesterday, mean (SD)	19.4 (16.7)	28.4 (20.1)	<0.001
No. of injections given daily, mean (SD)	12.3 (9.8)	14.4 (8.9)	0.055
Fee per visit, US\$ (SD)	0.60 (0.79)	0.60 (0.69)	0.171
Do you think injection is necessary for, n (%)			
Fever	107 (54%)	91 (46%)	0.264
Influenza-like symptoms	72 (56%)	56 (44%)	0.182
Body aches	136 (53%)	122 (47%)	0.338
Diarrhoea	160 (54%)	136 (46%)	0.172

Table 5 Regression results of provider being a reuser

	Unstandardized coefficients		Standardized coefficients	95% CI for B		Sig	Exp(B) (AOR)	95% CI for AOR	
	B	SE	β	Lower Bound	Upper Bound			Lower bound of AOR	Upper bound of AOR
(Constant)	0.405	0.752		-1.110	1.919	0.593	1.499	0.330	6.816
Urban/rural	0.086	0.188	0.075	-0.292	0.464	0.649	1.090	0.747	1.591
District	-0.522	0.194	-0.434	-0.914	-0.130	0.010	0.593	0.401	0.878
Age of doctor	0.009	0.017	0.183	-0.025	0.044	0.581	1.009	0.976	1.045
Sex of doctor	0.035	0.059	0.078	-0.085	0.155	0.558	1.036	0.919	1.168
Year since last degree was completed	-0.008	0.016	-0.172	-0.040	0.023	0.592	0.992	0.961	1.023
How long you have been practicing at this clinic	-0.006	0.003	-0.255	-0.011	0.000	0.043	0.994	0.989	1.000
No. of patients examined yesterday	-0.011	0.006	-0.363	-0.022	0.001	0.079	0.989	0.978	1.001
No. of injections prescribed	0.089	0.056	1.621	-0.025	0.203	0.123	1.093	0.975	1.224
No. of intramuscular injections given yesterday	-0.061	0.053	-0.882	-0.167	0.046	0.257	0.941	0.846	1.047
No. of intravenous injection given yesterday	-0.064	0.055	-0.471	-0.174	0.047	0.252	0.938	0.840	1.048
No. of intravenous drips given yesterday	0.012	0.042	0.038	-0.073	0.097	0.776	1.012	0.930	1.102
Reuse of injections observed	-0.027	0.219	-0.015	-0.470	0.415	0.902	0.973	0.625	1.514
Reuse reported by the patient	-0.087	0.273	-0.044	-0.638	0.464	0.751	0.917	0.528	1.590
Physician/prescriber fee	-0.001	0.001	-0.058	-0.003	0.002	0.663	0.999	0.997	1.002

Values in bold are significant. AOR = adjusted odds ratio; CI = confidence interval; SE = standard error; Sig = significance.

injections were necessary for common ailments.

The high injection demand and provision seen in our study were consistent with prior experience from Pakistan (22) or the surrounding region (13,23–27). Patients expect to receive injections for minor ailments such as fever or influenza-like symptoms and willingly pay for these, on the mistaken belief in the efficacy of injections to overcome common symptoms that eventually abate with time (10). Healthcare providers comply with such wishes and are convinced of the necessity of injections. This belief is common among providers irrespective of whether they are likely or not to reuse syringes.

Syringe reuse happens against a backdrop of frequent injections. Around 38% of injection providers procure too few syringes for the injections that they provide and will likely reuse consistently. They also see more patients and give more injections. They charge slightly less per visit than providers that do not reuse syringes; however, their fees remain largely the same whether or not they give an injection. These providers stock a median of 5 syringes and give 14 injections daily; meaning that each syringe is reused 2 or 3 times. Providers' knowledge of the potential harm of syringe reuse and their incentives to reuse also mean that approaches such as information provision or availability of autodisposable syringes will not work, unless these are the only type of syringes available. Additionally, simply demanding or making laws against reuse are not likely to succeed. However, since providers' savings from syringe reuse are hidden from the patients, there may be a potential role for a patient-focused approach by which patients are made more aware of syringe reuse and its harm (18).

Community approaches that reduce information asymmetry between providers and patients have been promising (28). One intervention in Tando Allah Yar improved patient awareness from 15% to 29% within 6 months (29). Other complementary approaches may be to brand as safe providers those that visibly do not reuse syringes. Another option would be to use positive deviance inquiry in communities to reduce injection demand and syringe reuse (30–32).

One limitation of our study was that because we compared the supply of syringes versus injections given, we could only estimate the minimum reuse by providers. In reality, a provider may reuse more often, although perhaps not by much, because they would then adjust their syringe procurement accordingly in the long run.

Conclusion

Our study highlights the high prevalence of syringe reuse during therapeutic injections in communities in Pakistan and suggests that patient-centred approaches (demand reduction and increased awareness of the harm of syringe reuse), but probably not provider-centred approaches, may help reduce syringe reuse. New research should explore why patients seek such unnecessary care and test behavioural approaches such as cognitive behavioural therapy, expectation management, or whether patients will pay for safe injections, to make medical practice and injections safer in poor communities.

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Réutilisation des seringues pour injections thérapeutiques au Pakistan : réflexion sur ses déterminants

Résumé

Contexte : La réutilisation fréquente des seringues lors des injections thérapeutiques alimente des épidémies d'infections par les virus de l'immunodéficience humaine et de l'hépatite C dans de nombreux pays à revenu faible et intermédiaire, y compris le Pakistan.

Objectifs : Étudier les facteurs spécifiques liés à la réutilisation des seringues lors des injections thérapeutiques.

Méthodes : Nous avons interrogé 319 prestataires de soins, de façon aléatoire, dans deux districts du Pakistan présentant une diversité socio-économique, ainsi que 625 de leurs patients.

Résultats : Les prestataires voient de 12 à 25 patients et effectuent de 7 à 14 injections thérapeutiques ou perfusions intraveineuses goutte-à-goutte par jour. En comparant les stocks journaliers avec les injections réalisées, nous avons estimé que 38 % des prestataires (Rawalpindi : 14 %, Tando Allah Yar : 44 %) réutilisent vraisemblablement les seringues deux ou trois fois. L'implantation rurale et l'ancienneté d'exercice laissent anticiper une plus grande probabilité de réutilisation. Les médecins et les autres membres du personnel soignant étaient aussi susceptibles de réutiliser les seringues. Lorsqu'une seringue était réutilisée, la plupart des patients n'en avaient pas conscience.

Conclusions : Le taux élevé de réutilisation des seringues est induit par une forte demande d'injections par les patients, à laquelle répondent les prestataires de soins. En général, les patients n'ont pas conscience de la dangerosité des injections effectuées avec des seringues réutilisées, ni même de la pratique de réutilisation. Les résultats de notre enquête indiquent que des approches centrées sur le patient pourraient aider à réduire la réutilisation des seringues.

إعادة استعمال المحاقن للحقن العلاجي في باكستان: إعادة النظر في استعمال المحاقن ومحدداته

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الخلاصة

الخلفية: إن إعادة استعمال المحاقن تكرر من شأنه أن يوجب الأوبئة المرتبطة بفيروس العوز المناعي البشري والعدوى بفيروس التهاب الكبد C في كثير من البلدان المنخفضة الدخل والمتوسطة الدخل، ومنها باكستان.

الأهداف: هدفت الدراسة إلى استكشاف العوامل المحددة المرتبطة بإعادة استعمال المحاقن للحقن العلاجي

طرق البحث: أجرينا مسحاً عشوائياً شمل 319 مرفقاً من مرافق تقديم خدمات الرعاية الصحية من منطقتين بينهما تبأين من الناحية الاجتماعية والاقتصادية في باكستان، بالإضافة إلى 625 مريضاً من يرتادون هذه المرافق.

النتائج: يفحص مقدمو الخدمة ما يتراوح بين 12-25 مريضاً يومياً، ويعطون الحقن العلاجي أو التقطير داخل الوريد لما يتراوح ما بين 7-14 مريضاً. وبمقارنة المخزون اليومي بعمليات الحقن التي تحدث، قدرنا أنه في 38٪ من مقدمي خدمات الرعاية الصحية (روالبندي: 14٪، تاندو الله يار: 44٪) يُرجح إعادة استعمال المحاقن بمقدار مرتين أو 3 مرات. ويُرجح بنسبة أعلى إعادة استعمال المحاقن في المناطق الريفية وأثناء الممارسات الطبية التي تستغرق وقتاً أطول. ويتساوى الأطباء وغير الأطباء في احتمال إعادة استعمال المحاقن. وأفاد معظم المرضى بأنهم لا يكونون على دراية بأن المحقنة المستعملة في الحقن مُعاد استعمالها.

الاستنتاجات: يرجع ارتفاع معدل إعادة استعمال المحاقن إلى ارتفاع الطلب على المحاقن من جانب المرضى، وتلبية مقدمي خدمات الرعاية الصحية لهذا الطلب. وعامة، لا يكون المرضى مُدركين لضرر الحقن عن طريق إعادة استعمال المحقنة، أو ربما لا يكونون مدركين في الأساس أن المحاقن يُعاد استعمالها. ووفقاً للنتائج التي توصلنا إليها، نرى أن النهج التي تركز على المرضى قد تساعد في الحد من إعادة استعمال المحاقن.

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Estimating population cause-specific mortality fractions in the Islamic Republic of Iran: validation of Murray's method

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Abstract

Background: Vital civil information is recorded in only 25% of middle-income countries.

Aims: To estimate the number and causes of deaths expected in the population, using hospital mortality data and comparing them with data from the Ministry of Health and Medical Education, Tehran, Islamic Republic of Iran.

Methods: Hospital mortality data for 2011–2015 were extracted and were corrected qualitatively through reference to medical records. Using Murray's proposed method, an estimate of the expected deaths was obtained according to cause of death.

Results: During 2011–2015, 12 704 deaths were recorded in the hospital and Murray's method estimated 28 768 deaths for the entire population. The most frequent cause of death was ischemic heart disease. The results were compared with data from the Ministry of Health and Medical Education, which had a relative error of 6.9% and –13.5% respectively. The mortality rates registered by the Civil Registration Office were higher than those estimated in the present study. The mortality rates registered by the Ministry of Health and Medical Education were lower than those in the present study.

Conclusions: Considering the importance of registering deaths, alternative methods, with efficiency and low cost, are needed to estimate the number and causes of death in a population.

Keywords: cause-specific mortality rate, estimated mortality, hospital mortality, Islamic Republic of Iran, Murray's method

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Introduction

Frequency and causes of mortality are important components in the health planning of communities (1). Timely registration of deaths and correct record keeping form the basis of demographic analysis (2). In order to monitor epidemiological changes in disease, the health sector relies heavily on the proper functioning of such vital records and statistics (3). Changes in trends of the causes of mortality over time determine the direction of a country's health policies. Mortality among different age and sex groups indicates the status of health services and the health status of different groups in society (4). Despite the importance of information about the causes of mortality, data availability and accuracy are limited in many countries (5). Vital information is recorded in only 25% of middle-income countries and 5–10% of low-income countries (6,7).

In the Islamic Republic of Iran, various institutions are responsible for registering vital events such as the Civil Registration Office and the Ministry of Health and Medical Education. In addition to these institutions, regarding death registration, the forensic organization has taken some measures and collected useful information on specific causes of death (8). The Civil Registration Office and the Ministry of Health and Medical Education have always had a percentage of errors in collecting mortality data for several reasons. The vast majority of

information collected by demographic experts in the Islamic Republic of Iran, in relation to mortality rates and disagreements in this regard, confirms the failure in accurate registration of death (9).

Studies of the extent and causes of mortality in the Islamic Republic of Iran and many other countries have indicated their direct relation with the level of health and development in the countries. Therefore, such research has a major effect on programmes aimed at promoting community health and livelihood (10).

A similar study by Murray et al. was conducted based on data available in Mexico, in which hospital deaths registered were used to estimate the cause-specific mortality rate in the whole population with the minimum rate of error (11). This highlighted certain novel approaches to estimating cause-specific mortality fractions with data on cause of death collected from different institutions. The Islamic Republic of Iran is also one of the countries that Murray et al. mentioned that has potential for applying the method. In addition, the results of studies by Khosravi et al. (12) and Komijani et al. (13) point out the low registration of deaths in countries that use various statistical methods.

Using the Murray method, and considering that data available in hospitals are the most suitable and accessible source for determining the cause of death, the

distribution of the expected mortality was determined based on the international coding of diseases in the whole population of Ardebil (Northwest Islamic Republic of Iran) by sex, age and cause of death. Ardebil Province covers 17 953 km² and its population is 1 270 420 based on the 2016 census (<https://www.amar.org.ir>).

In a review of the Human Development Index, Ardebil Province scored 0.692 (middle ranking); for the whole country the Index was 0.742. The effective factors in this index include life expectancy, literacy rate, and per capita income. These data, including distribution of mortality in Ardebil Province by age, sex and cause of mortality, can be used in regional health decision-making as well as for intervention measures and improvements in mortality registration and reporting systems in the province.

Methods

Data collection

This was a descriptive–analytical study. Mortality data for 2011–2015 were extracted from the Civil Registration Office and the Death Registration System of the Ministry of Health and Medical Education, Tehran, Islamic Republic of Iran, hospitals in Ardebil Province, and Ardebil University of Medical Sciences. The hospital mortality data were collected in accordance with the regulatory checklist. Data were subsequently investigated quantitatively and qualitatively and in terms of the cause of death. In cases where the required information was not correctly registered, the quality of the data was improved by using the medical records of the deceased. The mortality rate was calculated based on the proposed Murray method. We compared this information with the data registered in the Ardebil Province Civil Registration Office and Ministry of Health and Medical Education and obtained the percentage of relative error by year, which was compared with the actual information recorded.

Information analysis

The results were calculated using Excel and the proposed Murray method using the following formula (11):

$$D_{asj} = \frac{H_{asj}}{P_{asj}}$$

D_{asj} is the total death rate for the age group a , sex s , and

the cause of death j . H_{asj} is the mortality rate in the hospital for the age group a , sex s , and the cause of death j . P_{asj} is the ratio of death in the hospital for age group a , sex s , and cause of death j . The relative error percentage was calculated based on the following formula:

$$\text{Relative error percentage} = \frac{\text{Actual amount} - \text{Test result}}{\text{Actual amount}} \times 100$$

It should be noted that due to the lack of any similar study in the Islamic Republic of Iran and the lack of access to mortality ratios in hospitals, Murray’s study ratios were used in this research.

Ethical considerations

Ethical clearance for this study was received from the School of Public Health, Shahid Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran (reference IR.SBMU.PHNS.REC.2016.141).

Results

There were 12 704 deaths in the hospitals in Ardebil Province from 2011 to 2015, covering all age groups; of which, 7341 cases were male (57.8%) and 5363 female (42.2%), with a male to female ratio of 1.36 (Table 1). The mean (SD) age of death in men was 55.19 (28.72) years compared with 57.29 (29.42) years in women. In the 1–28 days and 15–64 years age groups, the mean age at death was significantly higher in women than in men ($P < 0.05$). There were no significant sex differences in the main age at death in the other age groups.

Table 2 shows the specific estimates of the cause of death obtained using the proposed Murray method. From 2011 to 2015, the rate of expected deaths for the population was 5747.2, 5861.8, 5739.2, 5574.1 and 5845.7. The leading cause of mortality in all years of the study was ischemic heart disease. Other causes of death according to Murray’s estimation included: other cardiovascular diseases, hypertension, cerebrovascular disease, other unintentional events, stomach cancer, other malignant neoplasms, other respiratory diseases, lung cancer, low birth weight, birth asphyxia, and birth trauma.

Table 3 shows the relative error percent of the data registered in the Ardebil Province Civil Registration Office in relation to the information based on the proposed

Table 1 Age and sex distribution of deaths in hospitals

Age groups	Number (%)		Average age (SD)		P
	Men	Women	Men	Women	
28 days	842 (55.1)	685 (44.9)	2.79 (5.08)	3.41 (5.99)	0.029
< 1 year	962 (55.4)	773 (44.6)	0.46 (1.62)	0.44 (1.58)	0.712
< 5 years	1045 (55.4)	840 (44.6)	2.79 (8.85)	2.89 (9.5)	0.821
< 15 years	1116 (56.6)	891 (44.4)	0.75 (2.42)	0.73 (2.44)	0.893
15–64 years	2384 (62.3)	1441 (37.7)	46.74 (13.75)	48.99 (13.1)	<0.001
≥ 65 years	3841 (55.9)	3031 (44.1)	77.63 (7.04)	77.85 (7.30)	0.213
Total	7341 (57.8)	5363 (42.2)	55.91 (28.72)	57.28 (29.42)	0.009

Table 2 Estimated cause-specific mortality fractions based on Murray's Method, 2011–2015

Cause of death	2011	2012	2013	2014	2015
Diabetes mellitus	145.7	121.4	108.3	147.6	138.2
Ischemic heart disease	1141.6	1477.3	911.7	1284.4	1300.2
Cerebrovascular disease	408.6	454.8	399.3	445.6	589.8
Liver diseases	22.6	32.1	5.7	15.1	15.1
Other unintentional injuries	310.0	281.2	151.4	194.7	165.8
Other cardiovascular diseases	606.1	385.5	764.3	465.7	603.8
Chronic obstructive pulmonary disease	70.0	45.2	31.6	24.8	56.4
Lower respiratory infections	36.3	74.7	23.5	25.6	25.6
Other malignant neoplasms	228.3	279.9	220.4	301.8	331.5
Other digestive diseases	38.2	32.7	25.9	42.3	31.4
Intentional injuries	68.9	85.1	93.2	93.2	93.2
Nutritional deficiencies	10.3	0.0	3.4	3.4	3.4
Hypertensive diseases	461.2	633.6	675.5	398.3	510.1
Road traffic accidents	110.5	153.6	97.0	110.5	64.7
Nephritis and Nephrosis	96.8	100.5	56.6	62.1	67.6
Perinatal respiratory disorders	26.0	18.1	29.4	30.5	79.1
Ill-defined malignant neoplasms	87.8	112.9	150.5	112.9	117.9
Breast and cervical cancer	33.5	44.7	41.9	25.1	25.1
Other respiratory diseases	152.4	169.6	122.3	124.5	182.1
Ill-defined causes	529.5	162.3	503.8	42.7	0.0
Other neuropsychiatric conditions	83.0	78.1	92.8	136.7	102.5
Other noncommunicable disease	53.8	3.8	51.9	53.8	21.1
Lung cancer	151.3	159.3	98.2	127.4	169.9
Endocrine disorders	15.5	22.4	46.4	41.3	27.5
Stomach cancer	286.2	347.5	255.5	374.8	357.8
Other congenital anomalies	26.6	46.8	27.8	86.0	50.6
Diarrhoea-related diseases	1.9	11.7	7.8	1.9	1.9
HIV	1.6	0.0	1.6	3.2	1.6
Liver cancer	92.8	72.9	96.1	62.9	69.6
Congenital heart anomalies	29	25.2	58.0	61.8	17.7
Prostate cancer	36.7	91.8	73.4	51.4	51.4
Alcohol use	0.0	3.0	3.0	0.0	0.0
Other infectious and parasitic diseases	30.3	17.9	23.4	93.7	62.0
Septicaemia	26.8	4.9	20.7	3.7	0.0
Tuberculosis	8.7	3.5	12.2	7.0	1.7
Low birth weight, birth asphyxia, and birth trauma	150.5	160.7	161.9	240.5	237.1
Perinatal infections	2.1	1.1	2.1	2.1	4.2
Other neoplasms	9.4	1.6	47.1	56.5	11.0
Pancreas cancer	19.5	25.1	16.7	33.4	27.9
Colon/rectum cancer	69.4	61.3	82.7	80.0	82.7
Cirrhosis of the liver	8.0	12.0	15.9	8.0	8.0
Other perinatal conditions	40.2	24.1	63.2	72.4	73.6
Haematemesis, melaena and gastrointestinal haemorrhage	7.1	6.5	6.5	0.0	5.6
Ill-defined injuries	8.1	10.9	19.0	19.0	51.6
Other communicable and maternal conditions	4.3	5.7	40.1	5.7	11.5

Table 3 Comparison of the estimated deaths based on Murray’s method with Civil Registration Office data by sex, 2011–2015

	2011			2012			2013			2014			2015		
	Murray’s estimate	Civil registration	Relative error percentage	Murray’s estimate	Civil registration	Relative error percentage	Murray’s estimate	Civil registration	Relative error percentage	Murray’s estimate	Civil registration	Relative error percentage	Murray’s estimate	Civil registration	Relative error percentage
Male	3423.3	3524	2.9	3457.7	3453	-0.1	3259.5	3513	7.2	3237.4	3410	5.1	3396.2	3508	3.2
Female	2323.9	2715	14.4	2404.1	2697	10.9	2479.7	2763	10.3	2336.7	2754	15.2	2449.5	2558	4.2
Total	5747.2	6239	7.9	5861.8	6150	4.7	5739.2	6276	8.6	5574.1	6164	9.6	5845.7	6066	3.6

Table 4 Comparison of the estimated deaths based on Murray’s method with Ministry of Health and Medical Education data by sex, 2011–2015

	2011			2012			2013			2014			2015		
	Murray’s estimate	Ministry of Health and Medical Education	Relative error percentage	Murray’s estimate	Ministry of Health and Medical Education	Relative error percentage	Murray’s estimate	Ministry of Health and Medical Education	Relative error percentage	Murray’s estimate	Ministry of Health and Medical Education	Relative error percentage	Murray’s estimate	Ministry of Health and Medical Education	Relative error percentage
Male	3423.3	2782	-23.0	3457.7	2825	-22.4	3259.5	2856	-14.1	3237.4	3003	-7.8	3396.2	3223	-5.4
Female	2323.9	1964	-18.3	2404.1	2003	-20.0	2479.7	2112	-17.4	2336.7	2226	-5.0	2449.5	2350	-4.2
Total	5747.2	4746	-21.1	5861.8	4828	-21.4	5739.2	4968	-15.5	5574.1	5229	-6.6	5845.7	5573	-4.9

Murray method by sex and age. The relative error percent for 2011–2015 was 7.9, 4.7, 8.6, 9.6 and 3.6%, respectively. Among men the smallest difference was observed in 2012 with -0.1%, and the largest difference was in 2013 with 7.2%. Among women, the smallest difference of 4.2% was in 2015, and the largest difference of 15.2% was in 2014. The mortality rates registered by the Civil Registration Office were higher than those estimated in the present study.

Table 4 shows the difference between the data registered in Ardebil Ministry of Health and Medical Education and the information based on the proposed Murray method categorized by sex and age. The smallest difference was -4.9% in 2015 and the highest difference was -21.4% in 2012. Among men, the smallest difference was -5.4% in 2015 and the largest difference was -23% in 2011. Among women, the smallest difference was -4.2% in 2015 and the largest difference was -20% in 2012. In all years of the study, the mortality rates registered by Ardebil Ministry of Health and Medical Education were lower than those in the present study.

Figure 1 shows the obtained relative error percentage from a comparison of the Murray method results with the information from the Civil Registration Office and Ministry of Health and Medical Education over 5 years, which indicates the improvement in information registration. During this period the number of registered deaths in the Civil Registration Office was 6.9% higher compared to the Murray method estimation, while Ardebil Ministry of Health and Medical Education has -13.5% fewer registrations.

Discussion

Registering vital events, especially mortality, is essential in order to research the causes of premature death and plan effectively for health promotion programmes. The mortality rate in hospitals in Ardebil from 2011 to 2015 showed a male to female ratio of 1.36. Among all hospital deaths, 57.8% were male and 42.2% female. Studies by Foruzanfar et al. (14), Tariq et al. (15) and Pattaraarchachai et al. (16) showed similar results in terms of the sex ratio of the deceased. Khosravi et al. (2015) (17) also reported a male/female sex ratio of 1.37 among the deceased and 57.9% of deaths were in men and 42.1% in women. Moore and Wilson (18) suggested that men are more likely to die from parasitic and infectious diseases than women are, which may be due to differences in male and female immunity to these infections.

In the United States of America, United Kingdom of Great Britain and Northern Ireland, and Japan, men are twice as likely as women to die from parasitic diseases (19). Men also demonstrate more high-risk behaviours such as violence, accidents and suicide (20). Other studies also showed that the average age of death due to accidents, events and cardiovascular disease in men was lower than in women, which explains the difference in age between the sexes, which is consistent with the results of the present study (21–23).

In the present study, we found that the estimated mortality rate in all study years was higher than that registered by the Ministry of Health and Medical Education, which was consistent with previous studies

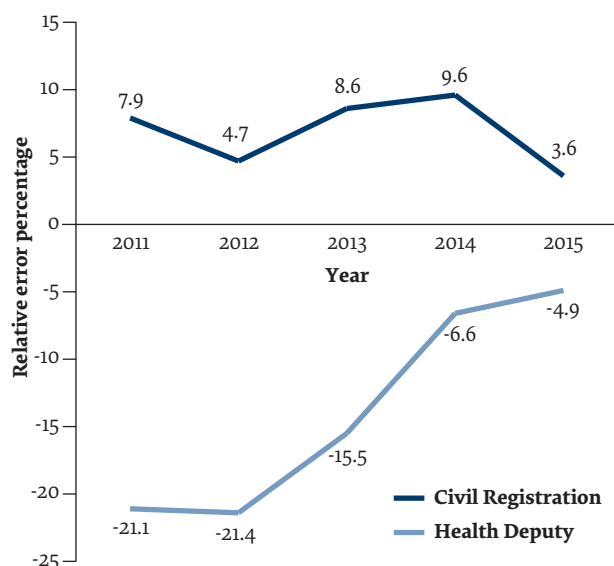


Figure 1 Relative error percentage in the Murray's estimate compared with the Ministry of Health and Medical Education and Civil Registration, 2011–2015

(9,11,13,24,25). However, the estimated mortality rate in our study was lower than that registered by the Civil Registration Office. Given that the causes of mortality in a large number of hospital deaths, especially in the early years, were unclear, these cases were placed in the other causes group and were probably related to the

most common causes of death (such as cardiovascular diseases). Clearly, by improving the hospital registration system, it can be expected that the ratio of other causes will be reduced and added to the main groups. Therefore, this study demonstrated that the population mortality estimation was more accurate than that derived from the hospital data and the relative error rate relative to mortality compiled by the Civil Registration Office decreased.

One of the major obstacles to an effective death registration system in the Islamic Republic of Iran is that the responsible authorities act individually and in isolation. Based on the experiences of the electronic system for registration of mortality in high-income countries, which have a central database, we recommend creation of a centralized meta-electronic registration system in the country.

Given the low level of registration of deaths between 2011 and 2015 indicated in this study, and the importance of information registration in health decision-making and policy-making, the current registration system seems unable to provide adequate information for the development of health programmes in the Islamic Republic of Iran. Therefore, alternative, low-cost and timeous methods are needed to enable descriptive epidemiological estimation of the population. The method used in this study has the advantage of comparing the expected rate of mortality in the form of cause-specific mortality groups, which play a significant role in decision-making and formulating health policies.

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Estimation des écarts en matière de mortalité par cause spécifique dans la population de la République islamique d'Iran : validation de la méthode de Murray

Résumé

Contexte : Les faits d'état civil sont enregistrés dans seulement 25 % des pays à revenu intermédiaire.

Objectifs : Estimer le nombre de décès prévus dans la population et leurs causes, en exploitant les données des hôpitaux sur la mortalité et en les comparant avec celles du ministère de la Santé et de l'Éducation médicale et du Bureau d'état civil de Téhéran (République islamique d'Iran).

Méthodes : Les données relatives à la mortalité hospitalière pour la période 2011-2015 ont été extraites, puis corrigées d'un point de vue qualitatif par rapport aux dossiers médicaux. En utilisant la méthode proposée par Murray, une estimation de la mortalité prévue a été obtenue selon la cause du décès.

Résultats : Entre 2011 et 2015, 12 704 décès ont été enregistrés à l'hôpital, et la méthode de Murray a permis d'estimer 28 768 décès pour la population complète. La cause de décès la plus fréquente était la cardiopathie ischémique. Les résultats ont été comparés aux données du ministère de la Santé et de l'Éducation médicale et du Bureau d'état civil, qui montraient des taux d'erreur relative respectifs de 6,9 % et -13,5 %. Les taux de mortalité enregistrés par le Bureau d'état civil étaient supérieurs à ceux estimés par la présente étude. Les taux de mortalité enregistrés par le ministère de la Santé et de l'Éducation médicale étaient inférieurs à ceux de la présente étude.

Conclusions : Compte tenu de l'importance de l'enregistrement des décès, des méthodes alternatives, efficaces et économiques, sont requises pour estimer le nombre de décès et leurs causes au sein d'une population.

تقدير الأرقام الكسرية للوفيات التي تُعزى لأسباب محددة في جمهورية إيران الإسلامية: التحقق باستخدام طريقة موراي

عباس عليبور، سهيلة خودا كريمة، آردشير خسروي، أمين عطائي

الخلاصة

الخلفية: تُسجّل المعلومات الحيوية في ٢٥٪ من البلدان المتوسطة الدخل.

الأهداف: هدفت الدراسة إلى تقدير عدد الوفيات المتوقعة بين السكان وأسبابها، باستخدام بيانات الوفيات الواردة من المستشفيات ومقارنتها ببيانات وزارة الصحة ومكتب تسجيل الأحوال المدنية في طهران، جمهورية إيران الإسلامية.

طرق البحث: استُخرجت بيانات الوفيات الخاصة بالمستشفيات للفترة بين عامي ٢٠١١-٢٠١٥، وصُحّحت من الناحية النوعية بالرجوع إلى السجلات الطبية. وقدر عدد الوفيات المتوقع، استناداً إلى أسباب الوفاة، باستخدام طريقة موراي.

النتائج: في الفترة بين عامي ٢٠١١-٢٠١٥، سُجّلت ١٢٧٠٤ وفيات في المستشفى، وقدرت طريقة موراي الوفيات بحوالي ٢٨٧٦٨ حالة وفاة على مستوى السكان جميعاً. وكان أكثر الأسباب الشائعة للوفاة هي الإصابة بداء القلب الإقفاري. وقورنت النتائج بالبيانات الخاصة بوزارة الصحة ومكتب تسجيل الأحوال المدنية، بخطأ نسبي بمقدار ٩، ٦٪، و ١٣، ٥٪ على التوالي. وكانت معدلات الوفيات المسجلة لدى مكتب التسجيلات المدنية أعلى من تلك المقدرة في هذه الدراسة. بينما كانت معدلات الوفيات المسجلة لدى وزارة الصحة أقل من تلك المقدرة في هذه الدراسة.

الاستنتاجات: بالنظر إلى أهمية تسجيل الوفيات، يلزم استخدام طرق بديلة فعالة ومنخفضة التكلفة لتقدير عدد الوفيات في صفوف السكان وأسبابها.

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Struggling with long-time low uptake of modern contraceptives in Pakistan

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Abstract

Background: Efforts to expand access to reproductive health care in Pakistan date as far back as the early 1950s. Despite such efforts, the fertility rate has declined at a slower pace compared to that in neighbouring countries.

Aims: To explore the underlying reasons and challenges for long-time low contraceptive use among female clients and key service providers of community-based family planning programmes in Pakistan.

Methods: A qualitative study was carried out with a total of 10 focus group discussions and 7 in-depth interviews with female clients and key service providers. The data were analysed using qualitative content analysis.

Results: The intra-family dynamics, that is, influence of husbands and mothers-in-law, were significant in shaping the decision-making and choice of family planning methods. In addition, inadequate counselling skills, insufficient training for service providers, weak supportive supervision, interrupted supply of contraceptives, and delays in salary disbursement were among the key family planning programme challenges.

Conclusion: Despite a well-designed community-based FP programme, providers' counselling skills need to be enhanced. However, this has to be combined with sufficient training, supportive supervision and contraceptive availability.

Keywords: lady health worker programme, family planning, contraceptives, sexual health, reproductive health

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Introduction

On average, women in low- and middle-income countries have more pregnancies than women in high-income countries have, therefore increasing their lifetime risk of death due to pregnancy-related complications (1). An estimated 303 000 women lost their lives during and following pregnancy and childbirth in 2015 and one third of these deaths were reported in South Asia (2). This statistic reflects disparities in access to reproductive health care (RHC) – considered an essential human right – among low- and middle-income countries and is possibly due to inadequate RHC provision or underutilization (3).

In order to reduce this rate of maternal mortality, the Safe Motherhood Initiative (a primary component of RHC) has identified family planning (FP) as 1 of the 4 pillars of the initiative, along with antenatal care, postnatal care and safe delivery (4). Family planning is a substantive and effective primary prevention strategy for reducing maternal mortality by decreasing chances of unwanted pregnancies, lowering fertility (5–8) and lowering exposure to pregnancy-associated complications, thereby improving overall RHC (4). As part of FP, the use of contraceptives is considered a cost-effective developmental intervention to accelerate progress across 5 Sustainable Development Goals (SDGs) (9). Despite an increasingly well-recognized and far-reaching impact of FP, the use of modern

contraceptives remains low in many low- and middle-income countries, including Pakistan (10).

The current population of Pakistan is 184.5 million and has an annual growth rate of 2%; it is projected that by 2050, Pakistan will become the fifth most populous country in the world (11). Despite 6 decades of government and private sector RHC initiatives, Pakistan has one of the highest fertility rates and lowest contraceptive use rates among all of its neighbours (12). The average contraceptive prevalence rate (CPR) in South Asian countries is 53% (2013), and Pakistan has the lowest rate at 35% (Table 1) (13).

The provision of family planning services and counselling to clients is a major task assigned to lady health workers (LHWs) of the National Programme for Family Planning and Primary Health Care commonly known as the Lady Health Worker Programme (LHWP), and is the largest community-based public sector RHC initiative serving 60–70% of women in remote and rural populations (14). The recent fourth external evaluation (Oxford Policy Management 2009) of the programme has, however, identified only marginal improvement (33–34%) in CPR across the country, having increased only by 1% (15). Figures from the current Pakistan Demographic Health Survey 2012–2013 indicate that knowledge about FP among women of reproductive age remains universal, that is, 99%, with a slight increase of CPR from 30 to 35%. The overall demand for FP is 70% with persistent unmet need. Although the Pakistani Government remains the

major provider of contraceptive methods, only 10% of users obtain their contraception from LHWs (11).

Progress towards accomplishing Millennium Development Goals (MDGs) to increase CPR to 55% by 2015 remained unachievable for Pakistan. Given this context of modest increase in CPR and high fertility rate in Pakistan, this study explored the reasons for low utilization of modern contraceptives among both end users and service providers [LHWs and lady health supervisors (LHSs)] of the LHWP, and suggested feasible strategies to overcome the issues identified.

Methods

Study design and setting

This qualitative study was carried out from July to September 2013 in urban settings of Korangi District in Karachi. With ~20 million inhabitants, Karachi is the largest and most populous metropolitan city in Pakistan (16). The study participants were selected through purposive sampling from Korangi and Shah Faisal Towns, which are covered by the LHWP.

Study participants and data collection

The study participants were divided into 2 groups: (1) registered married women of reproductive age (15–45 years) residing in the study area for > 1 year and seeking FP services from the LHWP; and (2) LHSs and LHWs who have been working under the LHWP for > 1 year and providing FP services in the study area. The data were collected mainly through 3 Focus Group Discussions (FGDs) with registered women, 7 FGDs with LHWs and 7 in-depth interviews (IDIs) with LHSs. The interviews lasted for 45–60 minutes and each FGD comprised 6–8 participants.

Data analysis

The discussions were audio recorded, then transcribed verbatim for qualitative content analysis. The codes were grouped into categories and similar categories were finally merged leading to main themes.

Ethical considerations

Ethical approval for the study was granted by the Ethical Review Committee of the Aga Khan University, Karachi, and provincial and district programme implementation units of the LHWP.

Results

The results of our qualitative study fell under two major themes: (1) low uptake of modern contraceptives from the female perspective; and (2) understanding the reasons for low uptake of modern contraceptives from the service providers' point of view.

Low uptake of modern contraceptives from the female perspective

Most FP clients reported a positive impression about the use of temporary methods of contraception. They are

Table 1 Fertility rate, CPR and MMR comparison among South Asian countries

Countries	Fertility rate	CPR %	MMR/100 000
Pakistan	3.2	35	260
Maldives	2.3	35	60
Nepal	2.3	50	170
Bangladesh	2.2	62	240
India	2.5	55	200
Sri Lanka	2.3	68	35
Islamic Republic of Iran	1.9	77	21

Source: World Health Indicators 2015. World Bank, Washington DC. CPR = contraceptive prevalence rate; MMR = maternal mortality ratio.

more inclined towards use of condoms as the preferred choice, mainly because they describe them as easy to use, readily available, having fewer side effects, and satisfying their partner. The use of other temporary methods reported by the clients include injections, pills and intra-uterine contraceptive devices.

“We use condoms. There are many benefits with them and no side effects. There is nothing bad. My health is good and my husband’s health is also good.”

Fear of side effects of contraceptives is reported as a challenge by female clients and may cause them to discontinue their use or switch to other methods with fewer side effects. The main side effects as mentioned by the clients included menstrual irregularities, palpitations, headaches, and weight gain.

“Initially I was taking pills, and then I developed problems like palpitations, headache, nausea and stomach upset. I did not find pills comfortable to use and therefore stopped. Since then, I have used condoms and I feel satisfied, and my husband is also happy.”

Spousal approval was reported as significant in determining the use of contraceptives, as emphasized by female clients. It was mainly due to lack of approval or willingness of husbands that women faced difficulty, despite their need. Besides spousal agreement and willingness, the influence of mothers-in-law was described as another social barrier affecting the family planning decision-making process. This influence was reported more in families where the husband was the only child and where more female children were born.

“My sister-in-law is not using family planning because her husband is not willing to use it. At present she has 5 children including 1 male child. The husband has a desire for more sons. To fulfil his desire, she already gave birth to 4 daughters.”

“I am a mother of 6, every child born with a gap of 1.5 years. My husband is the only son and my mother-in-law forces me not to take any tablets or anything related to FP. She keeps a close watch.”

Understanding reasons for low uptake of modern contraceptives from the perspective of service providers

Community level

Similar to the accounts of female clients, those of service providers (LHWs and LHSs) also revealed a high uptake of condoms (despite high failure rates) followed by pills and injections. They described condoms as safe, easy to use and with the added advantage of providing protection from sexually transmitted diseases. Also, at the household level, as explained by female clients, the influence of the husband and mother-in-law was considered significant in shaping family planning decision-making by couples. In most instances it was the wife who was struggling hard for FP, while the husband seemed less motivated. It was because of the lack of agreement and involvement of the husband that some of the women even used contraceptives without the knowledge of their husband and mother-in-law. Furthermore, in certain tribes the mother-in-law still believed in large families and wished her son to follow in the same manner.

“The cooperation and willingness of husbands is important for successful practice of family planning. The husband is rigid and difficult to deal with at times, and in that situation women face problems. If the husband is cooperative then it becomes easier for wives to practice family planning.”

“I visit 2 of my clients when the mothers-in-law are away from home. Because the mothers-in-law do not want them [daughters-in-law] to use contraception.”

The service providers emphasized counselling to family planning clients as a major task assigned to LHWs but in practice counselling was not provided to couples, but involved female clients only. In a society less open to talk about issues like family planning, the service providers described it as difficult to provide counselling to men. However, they stressed effective engagement of men during counselling and decision-making because men require more awareness of their role for better uptake of contraceptives. The sehat (health) committee at village level included male members, but their primary focus was on general health issues. The service providers stressed that in addition to creating awareness on primary health issues, they should also address issues like FP, especially for men.

“Similarly, male members of the sehat committee should work with us. They may conduct continuous meeting with husbands or at least once a month to create awareness for FP. This will be helpful in counselling men as we mostly counsel women but not men.”

Revisions in curriculum and refresher training

The participants mentioned that there were instances when the LHWs felt less capable to satisfy clients. For example, when the clients enquired more information about FP than the LHWs had already shared. To be more

confident and able to satisfy clients, participants urged revisions to existing curricula, with inclusion of recent research and methods along with locally appropriate communication strategies to enhance knowledge and counselling skills of LHWs, focusing on creating more awareness among men regarding use and benefits of family planning. They further expressed their dissatisfaction on frequency and quality of training sessions being held. Generally, LHSs conducted classroom sessions with the purpose of revision of certain topics. Since LHSs have limited information, qualification and skills, it was suggested to involve qualified trainers for conducting training for LHWs and LHSs.

“I think in this changing context, the current curriculum is not sufficient for us as we have confined our clients mostly to condom use only.”

“Our curriculum needs revision with updated information and new research. The focus should be on providing adequate knowledge/information to men and women and motivating clients to use family planning.”

“I joined the programme in 1994 and received training from trainers who were experts in the field. They taught us everything in such a way that we became ‘half doctors’. If frequent and expert training is done, we can achieve 90–95% positive results.”

Inadequate supervision and oversight

Generally, LHWs agreed that LHSs are supportive, while few mentioned that LHWP should discourage induction of young LHSs with less field experience. For better performance of LHWs, the LHSs should also be evaluated on a regular basis for their supervisory and monitoring skills. Previously, the district and regional coordinators of the programme used to have field visits, but the current programme structure lacked a regular system for supportive supervision of LHSs. If included, this would encourage service providers to execute quality work, with increased sense of responsibility and accountability.

“If LHSs think that they may have surprise visits from higher authorities, then they [LHS] will deliver the job with more sense of accountability and responsibility. In this way, they will be held answerable for performance of their LHWs.”

Supply shortages and failures

Nonavailability of medicines, family planning supplies and stationary items was reported as a chronic issue in the past few years, and frequent medicine and supply failures were reported by most of the LHWs. The most commonly used contraceptives were condoms, but LHWs stressed that the quantity of condoms provided was insufficient to meet demand. This has resulted in increased pregnancies, for which the community blamed LHWs.

“The supplies are not sufficient for the whole community. For example, we get a low supply of condoms. If we can just have

a proper supply of condoms only, this will help us a lot.”

Overall low motivation level of LHWs and LHSs

Frequent delays in salary disbursement and low job security were the main reasons reported for demotivation and eventually underperformance by LHWs and LHSs. It was difficult to meet household expenses with such low and frequently delayed incentives, especially for those who were sole bread winners (widows or divorced). Even after the decision by the authorities to make LHWs a permanent cadre, the service providers were still waiting for implementation of the orders.

“It was in 2012 when the Court declared LHWs as a permanent cadre with increased salary, to be paid with arrears. However, to date, we do not have written proof of whether we are permanent or not. The Court’s orders should be carried out quickly as there is no implementation on the ground.”

Discussion

There is a great sense of encouragement demonstrated by female clients towards use of contraceptives. Regardless of fear of side effects and other barriers, they are still inclined to practice family planning. In contrast, despite having a country-wide family planning programme, the intra-family dynamics (influence of husband and mother-in-law) are acknowledged as significant in shaping the decision-making and choice of family planning methods. The opportunity to discuss the use of contraceptives with their husband not only empowers wives but also affects maternal and child health outcomes in the long run. Therefore, spousal concordance and communication are key for effective uptake of contraceptives – a finding supported by existing literature (17–21).

The influence of the mother-in-law is still voiced as a challenge at the household level. The underlying reason is considered to be rooted in different mind sets within the family dynamics such as: (1) mothers-in-law who were less inclined to use family planning themselves tend to influence their sons and daughters-in-law to do likewise; (2) if the husband is the only son; and (3) families in which there is a desire for a son due to the birth of more daughters. Our findings are consistent with previous studies in Pakistan and neighbouring countries (22,23).

Counselling is one of the key components of the FP programme and affects the knowledge, use and spousal communication for use of contraceptives (24,25). Although counselling is reported to be the major task performed by LHWs, it is only for female clients without involvement of their husbands. Male engagement in counselling is an area not effectively addressed by the current programme structure. It can be ensured through revitalization and involvement of male members of existing health committees, and by conducting awareness sessions for men regarding family planning. This significant finding is supported by available evidence from other low- and middle-income countries (26,27) where male engagement

in counselling increases uptake of contraceptives by creating awareness of methods, services (28,29) and improving spousal communication for method preference (30,31). In comparison to no counselling, couple counselling reported a 54% increase in uptake of contraceptives in a recent randomized control trial conducted in another Muslim country, Jordan (28).

Insufficient curricular revisions and trainings to service providers, weak supportive supervision, interrupted flow of FP commodities and delayed salary disbursements are other key programme areas not sufficiently addressed by the LHWP. These findings are supported by a recent external evaluation of the LHWP, which highlighted key programme impediments to be seriously addressed (32). Despite the current low strength of LHWs, there is a significant community acceptance of LHWs since they have demonstrated potential to deliver services.

Therefore, appropriate curricular revision, shifting from theory to a more practical approach and addition of effective interpersonal communication skills can better equip service providers for counselling clients. In-service training and professional development are important contributors towards maintenance of competencies for delivery of quality services by community workers, especially in low- and middle-income countries (33). This can be achieved with appropriate modifications to delivery and design of in-service training with revisions to curricula, and overall assessment of performance (14,33). Simultaneously, effective supervision by LHSs through improved skills assessment, feedback and reinforced regular supervisory visits, along with good district management practices for timely availability of supplies and salaries, are important for improving overall productivity of service providers and hence uptake of modern contraceptives. When supply of essential commodities is disrupted, not only will the productivity of LHWs decrease, but there may be other consequences such as losing respect from the community, without which the desired tasks cannot be executed.

The criteria of Lincoln and Guba were followed in order to achieve trustworthiness of the study (34). Credibility was obtained by selection of appropriate participants, context, interview guides for FGDs and IDIs, and by choosing representative quotations from the transcriptions. Dependability was assured by conducting the FGDs and IDIs over a period of 1 month, so that phenomena under study would not change in the communities. All the FGDs and IDIs were conducted in the local language and moderated by researchers well versed in language and context. Conformability was achieved by separate coding of teams followed by discussion on similarities and dissimilarities.

Our analysis suggests a comprehensive and integrated approach involving individual, community and management level stakeholders in order to address the challenges identified by the study participants, for enhanced uptake of modern contraceptives in the LHWP.

The LHWs play a pivotal role in the healthcare system in

Pakistan. There is strong potential to enhance counselling and interpersonal communication skills of LHWs and LHSs – a major contributing factor for acceptance and practice of family planning. It is the basic right of couples to decide freely the number and birth spacing of their children. Thus, effective counselling and communication are the way to provide adequate information, education and the means to do so.

Since family planning/birth-spacing choices are more often decided by couples rather than women alone, revitalization of the health committees at community level is strongly needed to promote effective male engagement in RHC initiatives designed to improve women and child health and particularly family planning services. Integrated and well-targeted behavioural change communication activities and community mobilization/awareness campaigns can help address sociocultural issues and misconceptions about contraceptive use. This has a considerable positive impact on awareness

and acceptability of family planning among community members as part of efforts to create demand. Moreover, the involvement of relevant stakeholders, such as community leaders, religious clerics and health activists in the health committees and various behavioural change communication modalities, will lead to substantial community ownership.

The above has to be combined with strategies to strengthen the existing programme structure, such as adequate and periodic needs-based assessment of LHWs and LHSs, sufficient training, and effective supportive supervision (both technical and supervisory) of LHSs. Furthermore, giving greater financial control to district health departments with oversight by provincial level stakeholders could potentially improve availability of funds for salaries, supplies and stationary. Lastly, a significant period of time has elapsed since the last evaluation (32), therefore, re-evaluation of the LHWP may be carried out in order to track the progress and shortcomings.

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Difficultés liées à la faible utilisation prolongée des méthodes de contraception modernes au Pakistan

Résumé

Contexte : Les efforts pour élargir l'accès aux soins de santé génésique au Pakistan remontent au début des années 1950. En dépit de ces efforts, le taux de fécondité a baissé à un rythme plus lent que celui des pays voisins.

Objectifs : Étudier les raisons et les difficultés sous-jacentes expliquant la faible utilisation prolongée des contraceptifs par les clientes et les principaux prestataires des programmes de planification familiale à base communautaire.

Méthodes : Une étude qualitative a été réalisée au moyen d'un total de dix discussions thématiques de groupe et de sept entretiens approfondis avec des clientes et les principaux prestataires de services. Les données ont été analysées en utilisant une analyse de contenu qualitative.

Résultats : Les dynamiques intrafamiliales, à savoir l'influence des maris et des belles-mères, jouaient un rôle déterminant dans la prise de décision et le choix relatifs aux méthodes de planification familiale. De plus, les compétences de conseil inadéquates, la formation insuffisante des prestataires de services, le faible degré d'encadrement bienveillant, l'interruption de l'approvisionnement en contraceptifs et les retards dans le versement des salaires faisaient partie des principales difficultés liées aux programmes de planification familiale.

Conclusions : Malgré un programme de planification familiale à base communautaire bien pensé, les compétences de conseil des prestataires doivent être améliorées. En outre, il importe qu'elles soient associées à une formation adéquate, un encadrement bienveillant et une meilleure disponibilité des contraceptifs.

مكافحة انخفاض استعمال وسائل منع الحمل الحديثة فترةً طويلةً في باكستان

نسيم زاهد شاه، تزين علي، امتياز جيهان، زاهر جول

الخلاصة

الخلفية: تعود جهود التوسع في إتاحة الرعاية الصحية الإنجابية في باكستان إلى أوائل الخمسينيات من القرن الماضي. وعلى الرغم من هذه الجهود، فإن معدل الخصوبة قد انخفض بوتيرة أبطأ، مقارنةً بما حدث في البلدان المجاورة.

الأهداف: هدفت الدراسة إلى استكشاف الأسباب والتحديات المتعلقة بانخفاض استعمال وسائل منع الحمل فترةً طويلةً على مستوى العملاء الإناث، ومقدمي الخدمات الأساسية للبرامج المجتمعية المعنية بتنظيم الأسرة في باكستان.

طرق البحث: أجريت دراسة كيفية من خلال عقد مناقشات ضمن ١٠ مجموعات بؤرية، وعقد ٧ مقابلات مُعمقة مع العملاء الإناث ومقدمي الخدمات الأساسية. وخضعت البيانات للتحليل باستخدام تحليل المحتوى النوعي.

النتائج: كان للديناميات الأسرية، أي تأثير الأزواج والحملات، دوراً أساسياً في تشكيل عملية صنع القرار واختيار وسائل تنظيم الأسرة. وبالإضافة إلى ذلك، فإن هناك مجموعة من التحديات التي يواجهها برنامج تنظيم الأسرة، مثل: قصور المهارات الإرشادية، وعدم توافر التدريب الكافي لمقدمي الخدمات، وضعف الإشراف الداعم، وعدم توافر وسائل منع الحمل باستمرار، وتأخر صرف المرتبات.

الاستنتاجات: على الرغم من جودة تصميم البرنامج المجتمعي لتنظيم الأسرة، فإنه يلزم تحسين المهارات الإرشادية لمقدمي الخدمة. ولكن، ينبغي أن يكون ذلك جنباً إلى جنب مع التدريب الكافي، والإشراف الداعم، وتوافر وسائل منع الحمل.

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Hypertension and associated factors in the Islamic Republic of Iran: a population-based study

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Abstract

Background: Hypertension is a major risk factor for cardiovascular diseases and has a high prevalence in the Eastern Mediterranean Region.

Aims: To estimate the prevalence and awareness of hypertension and its associated factors in a central province of the Islamic Republic of Iran.

Methods: This cross-sectional study was conducted among 2320 adults aged 40–80 years in Yazd, Islamic Republic of Iran, in 2010–2011. Multivariable logistic regression analysis was performed to calculate the odds ratios (ORs) for exploring the association between hypertension and associated risk factors. Of eligible subjects, 2098 participated in clinical examinations (response rate: 90.4%).

Results: The sex- and age-standardized prevalence of hypertension was 52.8% [95% confidence interval (CI): 49.6–56.1%]. Of 1170 participants with hypertension, 421 were diagnosed for the first time in this survey; therefore, the unawareness proportion was 36.0% (95% CI: 33.2–38.8%). Among known cases (749 of 1170), 68.5% (95% CI: 65.0–71.8%) had uncontrolled blood pressure. Age (OR 70–80 vs. 40–50 years=7.01, 95% CI: 4.01–12.24), obesity (OR=2.78, 95% CI: 2.06–3.75), diabetes (OR=1.46, 95% CI: 1.12–1.89), hyperlipidaemia (OR=1.60, 95% CI: 1.26–2.03) and living in a rural area (OR=1.57, 95% CI: 1.0–2.45) were significantly associated with hypertension.

Conclusions: Although age is an inevitable risk factor for hypertension, the high unawareness proportion, uncontrolled hypertension and modifiable risk factors such as obesity, hyperlipidaemia and diabetes demand effective preventive and curative strategies.

Keywords: hypertension, Islamic Republic of Iran, prevalence, risk factors

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Introduction

Hypertension is a major risk factor for cardiovascular diseases, including coronary heart disease, heart failure, arrhythmia and cardiomyopathy. There is also an increased risk of chronic kidney disease and stroke among hypertensive patients (1,2). According to The Global Burden of Disease Study, hypertensive heart disease accounted for 17.5 million disability-adjusted life years in 2015 (3). Research-based evidence has demonstrated an increased risk of hypertension with older age, male sex, and hyperlipidaemia (4).

The World Health Organization (WHO) reported that 30.7% of men and 29.1% of women in the Eastern Mediterranean Region were estimated to have hypertension in 2008 (5). The prevalence of hypertension in the Islamic Republic of Iran among adults aged > 25 years was estimated at 31% in men and 27% in women. Previous studies conducted in different provinces of the Islamic Republic of Iran (6–8) showed a large variation of hypertension prevalence among different provinces. A study in Yazd revealed that 53.7% of people with hypertension were aware of their disorder, 24% of them were under treatment, and only 8% had

controlled hypertension (7). As prevalence of hypertension is probably increasing in low- and middle-income countries (9) including the Islamic Republic of Iran (10), it is important to conduct additional studies to evaluate the trends and associated factors. In addition, population-based surveys on prevalence and risk factors of hypertension are important in settings where routine health monitoring systems are not in place. Due to limited research resources in these settings, most studies of hypertension are performed at subnational level; therefore, collecting data from different geographic areas may be more practical and can later be combined to give a more general picture of hypertension in a country or region. The aim of this study was to estimate the prevalence, awareness and associated factors of hypertension in a central district of the Islamic Republic of Iran.

Methods

Study population

The present study was part of a multidimensional population-based study, as described previously (11). This cross-sectional study was conducted in an urban and

rural area of Yazd District, Islamic Republic of Iran in 2010–2011. The sample size was 2320 adult residents of Yazd aged 40–80 years, who were recruited with a systematic cluster sampling method. The Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran approved the study protocol. Written informed consent was obtained from the participants prior to data collection.

Data collection

A general practitioner conducted general medical assessments including blood pressure measurement. After 5 minutes of rest, blood pressure was taken using a standard mercury sphygmomanometer (nova-presameter; Riester, Jungingen, Germany) in a sitting position twice at the same session and the average measurement was recorded. Fasting blood sugar (FBS) was measured first during the home visit using a glucometer (ACCU CHEK Active Meter; Roche Diagnostics, Indianapolis, IN, USA). A complete blood test from the venous blood sample was conducted after overnight fasting prior to blood sampling at a standard laboratory to measure FBS, haemoglobin A1c and lipid profile. Body weight was measured with indoor clothing using a Balas Miracle Scale (Karaj, Islamic Republic of Iran) and standing height was measured without shoes using a measuring rod (Balas). In addition, self-reported information on tobacco use, physical activity and education level was collected.

Definitions

Hypertension was defined according to the definitions of the Joint National Committee 7 (JNC 7) as: (1) systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg (12); or (2) self-reported history of hypertension and/or taking any antihypertensive medication. A summary of blood pressure definitions that

were used in this study is presented in Table 1. Diabetes mellitus was defined as two independent FBS measurements ≥ 126 mg/dl (7.0 mmol/l), and/or previous history of diabetes diagnosed by a physician, and/or glucose lowering agent medication. Hyperlipidaemia was based on lipid profile in a fasting blood sample, that is, triglyceride > 150 mg/dl (1.7 mmol/l), low-density lipoprotein > 130 mg/dl (3.4 mmol/l), high-density lipoprotein < 35 mg/dl (0.9 mmol/l), cholesterol > 150 mg/dl (3.9 mmol/l), previously diagnosed by a physician, or taking lipid lowering medication. For BMI, participants were classified into 3 groups: normal weight, overweight ($25 \leq \text{BMI} < 30$ kg/m²) and obese (BMI ≥ 30 kg/m²). Age of participants was recorded according to their birth certificate and it was measured as the number of full years they had lived at the time of study enrolment. In addition, age was categorized into 4 10-year intervals of 40–49, 50–59, 60–69 and 70–80 years old. Education was based on number of complete years of formal education and it was categorized as illiterate, incomplete primary education (< 6 years), primary to secondary education (6–12 years), and higher education at a college or university. Physical activity was defined as any kind of regular exercise at least 3 times per week or having physically active occupations.

Statistical analysis

The sex and age standardized prevalence of hypertension was calculated considering demographic composition of people aged 40–80 years who lived in the survey area based on the National Census 2006. In evaluation of the relations, we considered the clustering effect by multilevel analysis within logistic regression. First, we evaluated the univariate relations in a simple multilevel logistic regression. Then, to consider the clustering effect and confounders in the evaluation of the relations, we used multilevel multivariable logistic regression. In this model age, sex, education, diabetes, smoking, BMI, hyperlipidaemia, physical activity and living area were independent variables and covariates (for other variables in the model). The main outcome (dependent) variable was a binary variable with 1 for hypertension and 0 for not hypertension. We used similar models for other outcome measurements including awareness, control status, and stage of hypertension. Within these models, we calculated adjusted odds ratios (ORs) to evaluate association of different factors with hypertension and other outcomes. We considered duration of smoking and amount of smoking as quantitative variables and all other variables were considered as categorical variable in all models. $P < 0.05$ was considered statistically significant at 95% confidence intervals (CIs). We used Stata version 12.0 for statistical analysis.

Results

Of 2320 invited residents, 2098 participated (response rate: 90.4%) with a mean age (standard deviation) of 54.1 (10.0) years. Eighty-nine percent of the study population were urban dwellers and 53% were women. Among participants, 15.7% reported a history of smoking and ~20% had no

Table 1 Definitions of hypertension in the current study

Total study population		
SBP/DBP mmHg	Antihypertensive medication	Considered status
<120/80	No	Normotensive
	Yes	Hypertensive
120–139/80–89	No	Prehypertensive
	Yes	Hypertensive
$\geq 140/\geq 90$	No	Hypertensive
	Yes	Hypertensive
Participants with newly diagnosed hypertension		
140–159/90–99		Stage I hypertension
$\geq 160/\geq 100$		Stage II hypertension
Participants with known hypertension		
< 140/< 90		Controlled hypertension
$\geq 140/\geq 90$		Uncontrolled hypertension

DBP = diastolic blood pressure; SBP = systolic blood pressure.

level of education. The mean BMI was 27.4 (4.7) kg/m² and nearly 25% of participants had a physically active lifestyle. The crude proportion of diabetes and hyperlipidaemia was 25.8% (n = 539) and 34.4% (n = 731), respectively. Prevalence of hypertension and more details of participants' characteristics are provided in Tables 2 and 3.

Age- and sex-standardized prevalence of hypertension and prehypertension was 52.8% (95% CI: 49.6–56.1%) and 35.1% (95% CI: 31.9–38.4%), respectively (Table 2). Of these, 19.5% (95% CI: 17.4–21.7%) were newly diagnosed with hypertension and among known cases, 68.5% had uncontrolled blood pressure ($\geq 140/90$ mmHg).

Urban dwellers had a hypertension prevalence of 54.4%, while prevalence of hypertension among rural residents was 67% (Table 3). Prevalence of hypertension among illiterates was 74.2%, while 45.7% people with > 12 years of education had hypertension. Prevalence of hypertension was greater in non-smokers (58.1% vs. 43%). Among individuals with normal BMI, just 48.5% had hypertension, whereas 69% of obese participants had hypertension. Prevalence of hypertension in patients with hyperlipidaemia and diabetes was 69.6% and 70.1%, respectively.

By sex, prevalence of hypertension was 52% in men and 59.1% in women. Prevalence of hypertension was higher in women, but hypertensive men were more likely to have undiagnosed hypertension. Prevalence of hypertension increased with age in both sexes. Prevalence of hypertension among men and women aged 40–49 was 33.7% and 41.4% and this increased to 54.7% for men and 63.8% for women aged 50–59 years, 66.8% for men and 79.2% for women aged 60–69 years, and 69.7% for men and 89.9% for women aged 70–80 years.

Older age, obesity, diabetes, hyperlipidaemia and living in a rural area were significantly associated with hypertension (Table 4). In addition, older people, women, people with diabetes, and people with hyperlipidaemia were more aware of their hypertension. Uncontrolled hypertension was significantly higher in age group 60–69 years and in people with diabetes. Age had a strong relationship with hypertension, in that people aged 70–

80 years had > 7-fold odds of hypertension compared to those aged 40–50 years. On the contrary, we did not find a significant association between hypertension and the sexes, physical activity, level of education or smoking (Table 4).

Discussion

We measured prevalence of hypertension and its associated factors in a central district of the Islamic Republic of Iran. Age- and sex-standardized prevalence of hypertension in this representative sample of the population aged 40–80 years in Yazd was 52.8%. Previous studies reported a wide range of hypertension prevalence in the Islamic Republic of Iran, ranging from 7.21% among 7–12-year-old children in Ghazvin Province (13) to 41.8% in 40–75-year-old residents in Golestan Province (6). A systematic review of 29 studies in the Islamic Republic of Iran in 1996–2004 reported prevalence of hypertension around 50% in the population aged ≥ 55 years (10). A recent study in Yazd Province revealed that prevalence of hypertension in men and women aged 20–74 was 27.6% and 23.9%, respectively (7). The higher percentage of hypertension in our study was probably due to the older age of the study population.

Hypertension is a common health problem and its prevalence is increasing in low- and middle-income countries. Migration to urban areas, population ageing, dietary patterns and stressful lifestyles are reasons for the increasing prevalence (9). As observed in the current study, age is a strong independent risk factor for hypertension (14) and might have resulted in the higher prevalence of hypertension in our study compared to others. A study among people aged ≥ 65 years in Taiwan reported prevalence of 60.4% hypertension (15). Table 5 compares prevalence of hypertension in different studies by sex and age.

In our study, prevalence of hypertension was higher among women; however, the association was not significant after adjusting for confounders. According to WHO, total prevalence of hypertension is globally higher among men (5). Similarly, studies conducted in

Table 2 Crude and standardized prevalence of hypertension

	n	Crude	Std ^a	95% CI	
				Lower	Upper
Normal	231	11.0%	12.0%	9.5%	14.6%
Prehypertension	697	33.2%	35.1%	31.9%	38.4%
Hypertension	1170	55.8%	52.8%	49.6%	56.1%
New case	421	20.1%	19.5%	17.4%	21.7%
Stage I	106	5.1%	5.0%	3.8%	6.1%
Stage II	315	15.0%	14.6%	13.0%	16.2%
Known	749	35.7%	33.3%	30.7%	35.9%
Controlled	188	9.0%	8.5%	7.1%	9.8%
Uncontrolled	513	24.5%	22.5%	19.8%	25.2%

^aSex- and age-standardized prevalence of hypertension based on the National Census 2006. CI = confidence interval.

Table 3 General characteristics of study population and prevalence of hypertension by variables

Characteristics	Total ^a		Hypertension (-)			Hypertension (+)				
	Total	Non-hypertensive	Pre-hypertensive	Total	Total	Newly diagnosed cases	Known cases	Uncontrolled		
Age, yr	Mean (SD)	54.1 (10.1)	50.6 (8.5)	50.9 (8.9)	50.5 (8.4)	56.9 (10.3)	54.6 (9.7)	56.9 (10.9)	58.2 (10.5)	58.5 (10.2)
	Median (IQR)	52 (46–60)	49 (44–55)	49 (44–55)	49 (44–55)	55 (49–64)	53 (48–60)	55 (48.5–65)	57 (50–67)	57 (50–67)
Age groups, yr		806 (38.4%)	497 (61.7%)	119 (14.8%)	378 (46.9%)	309 (38.3%)	137 (17.0%)	57 (7.1%)	172 (21.3%)	104 (12.9%)
	40–49	705 (33.6%)	288 (40.9%)	76 (10.8%)	212 (30.1%)	417 (59.1%)	169 (24.0%)	58 (8.2%)	248 (35.2%)	182 (25.8%)
	50–59	339 (16.2%)	94 (27.7%)	21 (6.2%)	73 (21.5%)	245 (72.3%)	67 (19.8%)	35 (10.3%)	178 (52.5%)	127 (37.5%)
	60–69	248 (11.8%)	49 (19.8%)	15 (6.0%)	34 (13.7%)	199 (80.2%)	48 (19.4%)	38 (15.3%)	151 (60.9%)	100 (40.3%)
	70–80	994 (47.4%)	477 (48.0%)	137 (13.8%)	340 (34.2%)	517 (52.0%)	236 (23.7%)	69 (6.9%)	281 (28.3%)	190 (19.1%)
Sex		1104 (52.6%)	451 (40.9%)	94 (8.5%)	357 (32.3%)	653 (59.1%)	185 (16.8%)	119 (10.8%)	468 (42.4%)	323 (29.3%)
	Male	1871 (89.2%)	853 (45.6%)	222 (11.9%)	631 (33.7%)	1018 (54.4%)	360 (19.2%)	163 (8.7%)	658 (35.2%)	449 (24.0%)
	Female	227 (10.8%)	75 (33.0%)	9 (4.0%)	66 (29.1%)	152 (67.0%)	61 (26.9%)	25 (11.0%)	91 (40.1%)	64 (28.2%)
Area		418 (20.1%)	108 (25.8%)	22 (5.3%)	86 (20.6%)	310 (74.2%)	69 (16.5%)	55 (13.2%)	241 (57.7%)	167 (40.0%)
	Illiterate	851 (40.9%)	384 (45.1%)	86 (10.1%)	298 (35.0%)	467 (54.9%)	174 (20.4%)	77 (9.0%)	293 (34.4%)	201 (23.6%)
	< 6 yr	584 (28.0%)	306 (52.4%)	89 (15.2%)	217 (37.2%)	278 (47.6%)	123 (21.1%)	40 (6.8%)	155 (26.5%)	106 (8.2%)
	6–12 yr	230 (11.0%)	125 (54.3%)	31 (13.5%)	94 (40.9%)	105 (45.7%)	48 (20.9%)	16 (7.0%)	57 (24.8%)	37 (16.1%)
	> 12 yr	330 (15.7%)	188 (57.0%)	56 (17.0%)	132 (40.0%)	142 (43.0%)	65 (19.7%)	24 (7.3%)	77 (23.3%)	47 (14.2%)
Smoking		1768 (84.3%)	740 (41.9%)	175 (9.9%)	565 (32.0%)	1028 (58.1%)	356 (20.1%)	164 (9.3%)	672 (38.0%)	466 (26.4%)
	Yes									
	No									

Table 3 General characteristics of study population and prevalence of hypertension by variables (concluded)

Characteristics	Total ^a			Hypertension (-)			Hypertension (+)					
	Total	Non-hypertensive	Pre-hypertensive	Total	Stage I	Stage II	Total	Controlled	Uncontrolled			
Duration of smoking, yr	Mean (SD)	24.9 (11.8)	25.3 (11.7)	26.3 (11)	25 (12)	24.4 (11.9)	23 (11)	21.7 (10.4)	23.6 (11.4)	25.4 (12.5)	24.9 (13)	26.4 (12.3)
	Median (IQR)	25 (20–30)	25 (20–30)	25 (20–30)	25 (20–30)	20 (15–30)	20 (15–30)	20 (15–30)	20 (15–30)	25 (15–30)	25 (20–30)	30 (15–32.5)
Amount of smoking per day	Mean (SD)	10.1 (9.4)	10.1 (9.3)	7.6 (7.7)	11.3 (9.7)	10 (9.6)	12 (10.2)	13.4 (10.4)	11.4 (10.2)	8.1 (8.7)	8.6 (8.0)	8.8 (9.6)
	per day	6 (2–20)	8 (2–20)	4 (1–12)	10 (2–20)	6 (2–20)	10 (2–20)	16 (2–20)	16 (2–20)	9 (3–20)	4 (1.5–15)	5 (2–20)
BMI	Mean (SD)	27.4 (4.7)	26.3 (4.5)	26.7 (4.6)	26.3 (4.5)	28.2 (4.6)	27.8 (4.4)	27.9 (4.6)	27.7 (4.3)	28.5 (4.8)	27.8 (4.1)	28.7 (4.9)
	Median (IQR)	27.2 (24.2–30.2)	26.1 (23.2–29.2)	26.9 (23.7–29.5)	26 (23.2–29.1)	27.8 (24.9–30.9)	27.5 (24.5–30.3)	26.9 (24.3–30.9)	27.8 (24.7–30.2)	28.1 (25.1–31.2)	27.7 (24.6–30.7)	28.1 (25.3–31.4)
Weight status	Normal	594 (31.5%)	306 (51.5%)	27 (4.5%)	279 (47.0%)	288 (48.5%)	119 (20.0%)	37 (6.2%)	82 (13.8%)	169 (28.5%)	53 (8.9%)	116 (19.5%)
	Over weight	790 (41.8%)	310 (39.2%)	37 (4.7%)	273 (34.6%)	480 (60.8%)	184 (23.3%)	39 (4.9%)	145 (18.4%)	296 (37.5%)	82 (10.4%)	214 (27.1%)
Obesity	Obese	504 (26.7%)	156 (31.0%)	19 (3.8%)	137 (27.2%)	348 (69.0%)	116 (23.0%)	30 (6.0%)	86 (17.1%)	232 (46.0%)	52 (10.3%)	179 (35.5%)
	Hyperlipidaemia	No	1377 (65.6%)	709 (51.5%)	187 (13.6%)	522 (37.9%)	668 (48.5%)	305 (22.1%)	79 (5.7%)	226 (16.4%)	363 (26.4%)	92 (6.7%)
Physical activity	Yes	721 (34.4%)	219 (30.4%)	44 (6.1%)	175 (24.3%)	502 (69.6%)	116 (16.1%)	27 (3.7%)	89 (12.3%)	386 (53.5%)	96 (13.3%)	269 (37.3%)
	No	522 (25.6%)	236 (45.2%)	47 (9.0%)	189 (36.2%)	286 (54.8%)	109 (20.9%)	30 (5.7%)	79 (15.1%)	177 (33.9%)	44 (8.4%)	123 (23.6%)
Diabetes	Yes	1516 (74.4%)	667 (44.0%)	166 (10.9%)	501 (33.0%)	849 (56.0%)	300 (19.8%)	71 (4.7%)	229 (15.1%)	549 (36.2%)	141 (9.3%)	375 (24.7%)
	No	1551 (74.2%)	763 (49.2%)	208 (13.4%)	555 (35.8%)	788 (50.8%)	325 (21.0%)	84 (5.4%)	241 (15.5%)	463 (29.9%)	131 (8.4%)	301 (19.4%)
Diabetes	Yes	539 (25.8%)	161 (29.9%)	22 (4.1%)	139 (25.8%)	378 (70.1%)	95 (17.6%)	22 (4.1%)	73 (13.5%)	283 (52.5%)	56 (10.4%)	210 (39.0%)

^aPercentage calculated column wise, other row wise. BMI = body mass index; IQR = interquartile range; SD = standard deviation.

Table 4 Multivariable logistic regression model for association of hypertension and different variables

Variables	Hypertension (+)			Awareness (+)			Control (uncontrolled)			Stage (II)							
	OR	95% CI Lower	Upper	P*	OR	95% CI Lower	Upper	P*	OR	95% CI Lower	Upper	P*	OR	95% CI Lower	Upper	P*	
Age category, yr	1.00				1.00				1.00				1.00				
40–49		1.85	2.98	0.001	1.02	0.72	1.45	0.915	1.73	1.00	3.01	0.051	1.40	0.76	2.61	0.277	
50–59	2.35																
60–69	4.01	2.88	5.58	0.001	1.86	1.12	3.11	0.018	1.96	1.10	3.50	0.023	1.03	0.45	2.33	0.951	
70–80	7.01	4.01	12.24	0.001	1.73	1.06	2.84	0.029	1.43	0.74	2.78	0.280	0.55	0.25	1.22	0.139	
Sex	1.00				1.00				1.00				1.00				
Male																	
Female	0.98	0.75	1.28	0.860	2.21	1.56	3.12	0.001	0.77	0.48	1.26	0.293	1.39	0.85	2.27	0.182	
Area	1.00				1.00				1.00				1.00				
Urban																	
Rural	1.57	1.00	2.45	0.049	0.82	0.53	1.26	0.360	0.99	0.55	1.80	0.977	1.12	0.48	2.61	0.796	
Education	1.00				1.00				1.00				1.00				
Illiterate																	
< 6 yr	0.91	0.65	1.28	0.581	0.62	0.40	0.98	0.040	0.87	0.55	1.35	0.522	1.07	0.46	2.51	0.868	
6–12 yr	0.88	0.63	1.23	0.449	0.60	0.34	1.06	0.080	0.90	0.49	1.64	0.720	1.48	0.56	3.90	0.417	
> 12 yr	0.75	0.48	1.15	0.181	0.71	0.36	1.38	0.303	0.73	0.29	1.81	0.490	1.30	0.50	3.40	0.584	
Duration of smoking, yr	0.99	0.97	1.00	0.065	1.02	1.00	1.04	0.020	0.99	0.97	1.02	0.629	1.00	0.96	1.04	0.966	
Amount of smoking per day ^a	0.99	0.96	1.02	0.469	0.94	0.90	0.98	0.009	0.97	0.91	1.03	0.274	0.99	0.93	1.05	0.765	
BMI	1.00				1.00				1.00				1.00				
Normal																	
Over weight	1.97	1.53	2.56	0.001	1.01	0.69	1.48	0.967	1.11	0.72	1.71	0.628	1.57	0.89	2.77	0.118	
Obese	2.78	2.06	3.75	0.001	1.17	0.79	1.73	0.418	1.59	0.94	2.71	0.084	1.24	0.63	2.45	0.524	
Hyperlipidaemia	1.00				1.00				1.00				1.00				
No																	
Yes	1.60	1.26	2.03	0.001	2.36	1.71	3.25	0.001	0.81	0.54	1.21	0.305	1.06	0.63	1.80	0.811	
Physical activity	1.00				1.00				1.00				1.00				
Yes																	
No	1.02	0.80	1.30	0.874	0.97	0.67	1.41	0.878	0.93	0.63	1.38	0.715	1.41	0.71	2.80	0.324	
Diabetes	1.00				1.00				1.00				1.00				
No																	
Yes	1.46	1.12	1.89	0.005	1.63	1.24	2.16	0.001	1.61	1.06	2.42	0.025	1.16	0.65	2.07	0.615	

^aBased on logistic regression considering the cluster effect by multilevel analysis

^bNumber of cigarettes per day.

BMI = body mass index; CI = confidence interval; OR = odds ratio.

Table 5 Prevalence of hypertension in different studies, by sex and age

Study area	Study design	Publication date	Study population	Total		Prevalence of hypertension						
				M	F	By age, yr						
Current study (Yazd)	Cross-sectional Study	—	2320 adult residents of Yazd aged 40–80 yr	52.8%	59.1%	40–49: 38.3%	50–59: 59.1%	60–69: 72.3%	70–80: 80.2%			
Islamic Republic of Iran (Isfahan, Najafabad and Arak) (33)	Cross-sectional Study	2004	Participants aged > 19 yr from Isfahan, Najafabad and Arak	—	18.8%	19–25: M: 4.3% F: 3.8%	26–35: M: 7.2% F: 7.8%	36–45: M: 16.5% F: 22.6%	46–55: M: 29.2% F: 41.1%	56–65: M: 47.7% F: 57.4%		
Iran (Yazd) (7)	Cross-sectional Study	2011	Yazd urban population aged 20–74 yr	25.6%	23.89%	20–34: 10%	35–44: 27%	45–54: 40.2%	55–64: 64.5%	65–74: 70.1%		
Iran (Golestan) (6)	Cross-sectional Study	2014	50 045 healthy subjects from Golestan Province in Northeastern Islamic Republic of Iran	41.8%	46.4%	< 50: 31.6%		50–60: 49.3%		> 60: 61.8%		
Iran (East Azerbaijan) (8)	Cross-sectional Study	2016	Adults aged 15–65 yr from Lifestyle Promotion Project	—	24.3%	15–25: M: 3.5% F: 10.2%	26–35: M: 7.6% F: 5.6%	36–45: M: 12.1% F: 12.3%	46–55: M: 22.9% F: 29.6%	56–65: M: 38.6% F: 53.6%		
Argentina (34)	Cross-sectional Study	2004	People aged over 20 from Dean Funes, Oncativo, Pehuajó and Venado Tuerto	36%	—	20–29: 9.8%	30–39: 13.6%	40–49: 34%	50–59: 49.2%	> 60: 75.5%		
Germany (35)	Population-based cohort study	2015	Men and women aged 45–83 years from CARLA-Cohort Study	—	70.2%	< 55: M: 58.7% F: 55.4%	55–64: M: 78.8% F: 65.7%	65–74: M: 83.8% F: 84.2%		> 75: M: 83.6% F: 86.5%		

F = female; M = male.

East Asia have shown higher prevalence of hypertension among men (16). A systematic review of 33 studies in South Asia indicated that the male sex is associated with a higher prevalence of hypertension, and only 8 studies showed that hypertension is more prevalent among women (17). Some studies in the Middle East have shown that prevalence of hypertension among both sexes is almost identical or slightly higher among women (18). Likewise, a recent systematic review among the Iranian population revealed that prevalence of hypertension is similar in both sexes (19). The sex difference in our study could be explained by the older age of the study population, since we found that the effect of older age on hypertension was more substantial among women. It could also be explained by other factors such as vitamin D deficiency, which is common among women in the Middle East, and this vitamin plays an important role in pathophysiology of hypertension (20). In addition, hormonal changes in postmenopausal women and decreased levels of estrogen cause vasoconstriction (21).

Similar to some other studies (7), women and people aged ≥ 60 years were more likely to know that they had hypertension in the current study. Men are less likely to seek healthcare services. Therefore, they have a greater risk of being unaware about their health problems in some settings because they pay less attention to their medical condition or have outdoor occupations (22). Moreover, history of diabetes and hyperlipidaemia showed an association with awareness of hypertension in our study. Naturally, older people and those with other medical conditions are more likely to have contact with healthcare professionals during their lifespan, which could explain the higher proportion of awareness in these groups.

The current study showed that both obesity and hyperlipidaemia were associated with hypertension. These results are supported by other studies (23). A study in Macao Special Administrative Region revealed that obese people have 4.5 times higher risk of hypertension compared to normal weight population (24). In addition, there are studies demonstrating that 78% of essential hypertension in men and 65% in women is related to excess weight gain (25). It has also been postulated that stimulation of sympathetic activity by high dietary fat and carbohydrate (26) and obesity-induced overactivation of the renin-angiotensin-aldosterone system (RAAS) are major biological causes of hypertension in obesity and hyperlipidaemia (25). These all emphasize the importance of weight control in prevention of hypertension.

Our results revealed no significant association between physical activity and hypertension: 45.2% of normotensive and 54.8% of hypertensive individuals reported some level of exercise. A recent meta-analysis of prospective cohort studies demonstrated a decreased risk of hypertension in people with increased recreational physical activity. However, the risk did not change with occupational physical activity (27). Physical

activity may play a role in decreasing blood pressure by reducing vascular resistance and by influencing the level of activity in the catecholamine and renin-angiotensin-aldosterone system (28). Although having a physically active lifestyle was more common in patients with hypertension, the association between exercise and hypertension was not significant.

According to our results, people who live in rural areas have a greater risk of hypertension. The geopolitical variation in the distribution of hypertension is diverse. In the Islamic Republic of Iran, different studies have reported conflicting results. Esteghmati et al. reported higher prevalence of hypertension in urban dwellers in 2007 (29), while a cohort study in Golestan Province conducted by Malakzadeh et al. (2004–2008) showed lower risk of hypertension in urban dwellers (6). In addition, some Iranian studies have shown no difference in prevalence of hypertension between urban and rural residents (30). Yazd Province in the centre of the Islamic Republic of Iran has an arid climate and farming is less developed. Migration of most people to cities, fewer job opportunities, lack of welfare resources, and a more stressful lifestyle could be causes of higher prevalence of hypertension in rural areas (31). In addition, lack of systematic programmes to promote general knowledge about appropriate lifestyles in rural areas could be another reason.

Higher level of education has been demonstrated to reduce risk of hypertension in the Islamic Republic of Iran and other countries (6). Education can increase people's awareness about their health, including hypertension, and encourage them to pay more attention to it. Although our multivariable analysis showed no significant association between hypertension and education, the descriptive data showed a considerably higher prevalence of hypertension among people who were illiterate. It should be mentioned that about 25% of participants in our study were illiterate and only 11% had an academic education. The number of people who had higher education levels might have been insufficient to show any differences in our study.

In the current study, 17% of participants reported that they were current smokers and we could not find any significant association between smoking and blood pressure. Nevertheless, many studies have revealed that smoking increases prevalence of hypertension (32). The measurement of tobacco consumption is specific and our data collection procedure did not provide an opportunity for collecting precise information. Anecdotally, smoking tobacco is generally disapproved of in the survey area; therefore, data gathering based on self-reported information may have had a reporting bias.

This study had some limitations. First, this was a cross-sectional study and it cannot predict causality. In addition, we included people aged 40–80 years, and the results cannot be generalized to all age groups living in the study area. Moreover, some risk factors for hypertension such as alcohol consumption, psychological problems and dietary intake were not evaluated. Finally, some of

our results such as smoking, education, medication and physical activity were based on self-reported information that may have had a reporting bias.

Conclusion

Hypertension is a major health problem in Yazd. The proportion of those who are not aware of their disorder

and the number of cases of uncontrolled hypertension among known cases are considerable. Age, obesity, diabetes, hyperlipidaemia, and living in a rural area are associated with hypertension. Although older age is the main inevitable risk factor for hypertension, there is potential to improve the situation through controlling manageable factors, increasing public awareness and improving care for people with hypertension.

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Hypertension et facteurs associés en République islamique d'Iran : étude en population

Résumé

Contexte : L'hypertension est un facteur de risque majeur de maladies cardio-vasculaires. Elle a une forte prévalence dans la Région de la Méditerranée orientale.

Objectifs : Estimer la prévalence de l'hypertension et le niveau de connaissance à cet égard ainsi que les facteurs associés dans une province centale de la République islamique d'Iran.

Méthodes : La présente étude transversale a été réalisée auprès de 2 320 adultes âgés de 40 à 80 ans dans la province de Yazd (République islamique d'Iran), en 2010-2011. L'analyse de régression logistique multivariée a été employée pour calculer les odds ratio (OR) permettant d'étudier le lien entre l'hypertension et les facteurs de risque associés. Parmi les sujets remplissant les critères de l'étude, 2 098 ont participé aux examens cliniques (taux de réponse : 90,4 %).

Résultats : La prévalence standardisée de l'hypertension selon le sexe et l'âge était de 52,8 % (intervalle de confiance à 95 % [IC] : 49,6-56,1). Sur les 1 170 participants souffrant d'hypertension, 421 avaient été diagnostiqués pour la première fois lors de cette étude. Par conséquent, la proportion de méconnaissance était de 36,0 % (IC à 95 % : 33,2-38,8). Parmi les cas connus (749 sur 1 170), 68,5 % (IC à 95 % : 65-71,8) avaient une tension artérielle non contrôlée. L'âge (OR 70-80 ; 40-50 ans=7,01, IC à 95 % : 4,01-12,24), l'obésité (OR=2,78, IC à 95 % : 2,06-3,75), le diabète (OR=1,46, IC à 95 % : 1,12-1,89), l'hyperlipidémie (OR=1,60, IC à 95 % : 1,26-2,03) et l'implantation en zone rurale (OR=1,57, IC à 95 % : 1,0-2,45) étaient fortement associés à l'hypertension.

Conclusions : Bien que l'âge soit un facteur de risque d'hypertension inévitable, la proportion élevée de méconnaissance, l'hypertension non contrôlée et les facteurs de risque modifiables tels l'obésité, l'hyperlipidémie et le diabète requièrent des stratégies préventives et curatives efficaces.

ارتفاع ضغط الدم والعوامل المرتبطة به في جمهورية إيران الإسلامية: دراسة سكانية

مرضيه كاتبا، علي مقدم، مهدي ياسري، دنيس نوبين، بير كاليستراب، حميد أحمديه

الخلاصة

الخلفية: يُعد ارتفاع ضغط الدم أحد عوامل الخطر الرئيسية للإصابة بأمراض القلب والأوعية الدموية، وهو منتشر بنسبة مرتفعة في إقليم شرق المتوسط.

الأهداف: هدفت الدراسة إلى تقييم مدى انتشار ارتفاع ضغط الدم والعوامل المرتبطة به ومستوى الوعي بشأنه في إحدى المناطق الوسطى في جمهورية إيران الإسلامية.

طرق البحث: شملت هذه الدراسة المقطعية ٢٣٢٠ بالغاً تتراوح أعمارهم بين ٤٠-٨٠ عاماً في يزد، جمهورية إيران الإسلامية، وذلك في الفترة من ٢٠١٠-٢٠١١. وأجري تحليل الانحدار المنطقي المتعدد المتغيرات لحساب نسب الأرجحية لاستكشاف العلاقة بين ارتفاع ضغط الدم وعوامل الخطر المرتبطة به. ومن بين الأشخاص المؤهلين للاشتراك في الدراسة، شارك ٢٠٩٨ شخصاً في الفحوص السريرية (معدل الاستجابة: ٩٠,٤ %).

النتائج: بلغ معدل الانتشار المعياري لإرتفاع ضغط الدم حسب العمر ونوع الجنس ٨, ٥٢٪ [فاصل الثقة ٩٥ ٪ = ٦، ٤٩-١، ٥٦] ومن بين ١١٧٠ مشاركا مصابا بارتفاع ضغط الدم، شخّص ٤٢١ شخصاً منهم لأول مرة في هذا المسح؛ وهو ما يعني أن نسبة عدم الوعي بالمرض كانت ٣٦, ٠٪ [فاصل الثقة ٩٥ ٪ = ٢، ٣٣-٨، ٣٨]، ومن بين الحالات التي يُعرّف إصابتها بارتفاع ضغط الدم (٧٤٩) من بين ٦٨, ٥، (١١٧٠)٪ منهم كانوا غير متحكمين في ضغط الدم [فاصل الثقة ٩٥ ٪ = ٠، ٦٥-٨، ٧١]. وقد ارتبط ما يأتي بالإصابة بارتفاع ضغط الدم ارتباطاً كبيراً: العمر (نسبة الأرجحية للبالغ أعمارهم ٧٠-٨٠ مقابل ٤٠-٥٠ عاماً = ٧, ٠١، فاصل الثقة ٩٥ ٪ = ٤، ٢٤-١٢، ٠١)، والبدانة [نسبة الأرجحية = ٢, ٧٨، فاصل الثقة ٩٥ ٪ = ٢, ٧٥-٢، ٠٦، ٢]، والسكري [نسبة الأرجحية = ١, ٤٦، فاصل الثقة ٩٥ ٪ = ١, ١٢-١، ٨٩]، وزيادة شحُمِيَّات الدم [نسبة الأرجحية = ١, ٦٠، فاصل الثقة ٩٥ ٪ = ٢, ٢٦-١، ٠٣، ٢] والعيش في منطقة ريفية [نسبة الأرجحية = ١, ٥٧، فاصل الثقة ٩٥ ٪ = ١, ٤٥-٠، ٢].

الاستنتاجات: على الرغم من أن العمر أحد عوامل الخطر المرتبطة حتمياً بارتفاع ضغط الدم، إلا أن ارتفاع نسبة عدم الوعي بشأن ارتفاع ضغط الدم، وعدم التحكم فيه، بالإضافة إلى بعض عوامل الخطر الأخرى القابلة للتغيير مثل البدانة، وزيادة شحُمِيَّات الدم، والسكري، تتطلب جميعها استراتيجيات وقائية وعلاجية.

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Acute coronary syndrome: factors predicting smoking cessation

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Abstract

Background: Few randomized controlled trials have examined the efficacy time of smoking cessation in hospitalized patients with acute coronary syndrome, either during hospitalization or after discharge.

Aims: To assess smoking cessation rates at 24 weeks among patients with acute coronary syndrome. Group A had begun nicotine replacement therapy during hospitalization, and Group B after discharge. We also determined factors predicting success.

Methods: We conducted a randomized controlled trial in the Cardiology Department and Smoking Cessation Service at University Hospital of Monastir, Tunisia from January 2015 to June 2016. Participants were randomly assigned to the above 2 groups. The endpoint assessment was smoking abstinence at 24 weeks, defined as self-reported abstinence in the past week, confirmed by measured exhaled carbon monoxide (CO) \leq 8 ppm. We analysed data by intention to treat. We used a binary logistic regression model to determine factors predicting abstinence.

Results: All participants were male and mean (standard deviation) age was 55 (11) years. At 24 weeks there was no significant difference in smoking cessation rate between the 2 groups: 54.5% [95% confidence interval (CI): 44.7–64.3%] in Group A and 45.5% (95% CI: 35.7–55.3%) in Group B ($P = 0.81$). High level of nicotine dependence [odds ratio (OR): 0.72; 95% CI: 0.54–0.96] and good compliance during follow-up (OR: 6.56; 95% CI: 2.07–20.78) were predictive factors for abstinence.

Conclusions: Smoking cessation rate after acute coronary syndrome was high regardless of the start date. Good compliance during follow-up was the key predictive factor for success.

Keywords: acute coronary syndrome, clinical trial, predictive factors, smoking cessation, Tunisia

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Introduction

Smoking is the main preventable cause of morbidity and premature death worldwide (1) and is a major and independent risk factor for coronary heart disease (CHD) (2). More than two thirds of sudden cardiac death resulting from acute thrombus occurs in smokers (3). Compared to nonsmokers the odds ratio (OR) for myocardial infarction is \sim 2.5, and for cardiovascular diseases overall the OR is \sim 2 (2, 4). Smoking cessation in persons with known CHD reduces the risk of recurrent myocardial infarction or cardiovascular death from 30 to 50% (5) during the subsequent 3–7 years (6). Nevertheless, although smoking cessation is potentially the most effective CHD prevention strategy, quitting smoking is difficult and two thirds of patients return to smoking within 1 year of their acute coronary syndrome (ACS) (7,8). Therefore, being hospitalized for a major cardiac condition, such as ACS, can be an opportunity to prompt many individuals to stop smoking.

Exploitation of this opportunity immediately after ACS may make it possible to increase smoking abstinence in this high-risk population (8). Cessation rates among smokers hospitalized for ACS range from 31% without

intervention to 60% with sustained intervention after hospitalization at 1-year follow-up (9). Nicotine replacement therapy (NRT), bupropion and varenicline, compared to placebo, have demonstrated efficacy for smoking cessation, yet most smokers consider smoking to be a voluntary behaviour and declined to be treated. Currently, smoking cessation remains a secondary concern in cardiology departments and there are few strategies offered to smokers with established CHD.

NRT improves smoking cessation rates without major adverse events (1), with equal rates of cessation in the general population and patients with CHD, as well as improving clinical outcomes among CHD patients (10). Many studies have examined the benefits of smoking cessation after ACS and the efficacy of smoking cessation pharmacotherapy in hospitalized patients with ACS. However, few randomized controlled trials have examined the efficacy time of smoking cessation in hospitalized patients with ACS either during hospitalization or after discharge. We compared among patients with ACS smoking cessation rates with NRT when begun in hospital or after discharge.

Methods

Design and study population

A randomized controlled trial was conducted simultaneously in the Smoking Cessation Service and the Department of Cardiology at the University Hospital of Monastir, Tunisia. The study was performed from January 2015 to June 2016 with a mean 24 weeks of run-up and 24 weeks of follow-up. There were 99 patients, all male, with a mean (standard deviation) age of 55 (t) years, range 25–81 years. Patients were hospitalized with ACS. Patients were actively smoking at the time of inclusion, motivated to quit smoking, able to provide informed consent, and willing to participate in a clinical study including a follow-up examination every 2 weeks after hospital discharge. Active smoking was defined as smoking at least 1 cigarette (or water pipe) per day during the month preceding hospitalization. Exclusion criteria were refusal of assistance for smoking cessation, inability to attend follow-up clinical visits (professional, regional or physical hindrance), or diagnosis of depression or other serious health condition at admission (e.g., ventilatory support or cardiogenic shock).

Sampling

We hypothesized that NRT after ACS during hospitalization would improve smoking cessation rate compared to NRT after discharge. Previous studies reported a rate of 51% among smokers who received NRT for smoking cessation in hospital (11) and 32.7% among patients receiving treatment after discharge (12). An expected sample size of 68 participants was calculated with a power of 0.80 and 2-sided $P < 0.05$. The proportion of patients who dropped out or withdrew was expected to be 30%. Hence, a minimum sample size of 89 was necessary, and the final sample was 99 consecutive patients.

Randomization was performed after consent was obtained (Figure 1). There were 54 patients in Group A and 45 in Group B ($P = 0.366$). Participants were randomized to Group A, who received counselling and NRT during hospital stay 1 day after SCA. Those in Group B benefited from counselling during hospital stay, but NRT was offered at a mean 14 days after SCA at the first clinical visit after discharge. All patients attended regular follow-up visits at the Smoking Cessation Service every 2 weeks. Forty-four (81.4%) and 30 (66.6%) patients completed the follow-up smoking cessation in Group A and Group B, respectively. Loss to follow-up was equal in both groups ($P = 0.931$).

Study protocol and data collection

During hospitalization

All patients in the sample received individual therapeutic education including a motivational interview. Patients were asked about their sociodemographic status, history of tobacco use, level of nicotine dependence (Fagerstrom test for nicotine dependence) (13), psychological state (using Hospital Anxiety and Depression Scale) (14), coaddiction (alcohol, drugs or cannabis), and level of motivation to quit smoking (QMAT scale). The scale consists of 4 questions whose response modalities generate a score

of 0–20: ≤ 6 , insufficient motivation; 6–13, average motivation; and > 13 , very good motivation. Participants in Group A started NRT patches and gum during hospitalization. The first appointment was scheduled at 1 week after hospital discharge.

After hospital discharge

Participants in Group B started NRT patches and gum after hospital discharge. At the first clinical visit, 2 weeks after their SCA event, adverse effects, symptoms of withdrawal, medication adherence and smoking status were assessed. Smoking status was assessed by self-reporting of smoking in the preceding 7 days and confirmed by exhaled CO (ECO). The threshold of ECO was < 8 ppm. Follow-up involved clinical visits every 2 weeks and telephone calls were made to patients who missed their meeting, for whom a new consultation was organized as soon as possible.

A reduction of NRT dose by one third was required every 28 days and NRT dose was adjusted according to signs of under- or overdose. During the processing time, there was close collaboration with a team comprising a psychiatrist, addictologist and clinical psychologist to manage more complicated cases such as dual addiction, depression and type A personalities.

Follow-up assessment

The primary endpoint was 7-days smoking abstinence at 24 weeks following randomization, defined as self-reported abstinence in the past week before the 24-week clinical visit, confirmed by measured $\text{ECO} \leq 8$ ppm. Participants with self-reported abstinence who had $\text{ECO} > 8$ ppm, or who reported any smoking in the last week and $\text{ECO} \leq 8$ ppm, were classified as current smokers. Secondary endpoints included measures by face-to-face survey; compliance with medication; occurrence of adverse effects of NRT patches (e.g., allergic skin reaction) (15); withdrawal symptoms (nervousness, headache, lack of concentration, insomnia, and craving); and benefits of smoking cessation (improvement of respiratory signs, increased appetite, sleep quality, and enhanced physical activity). Compliance with treatment was defined as good if the wearing of nicotine patches was on a regular basis.

Endpoint assessment

Smoking cessation status was assessed during visits at 24 weeks. A telephone survey was performed for patients who had missed appointments.

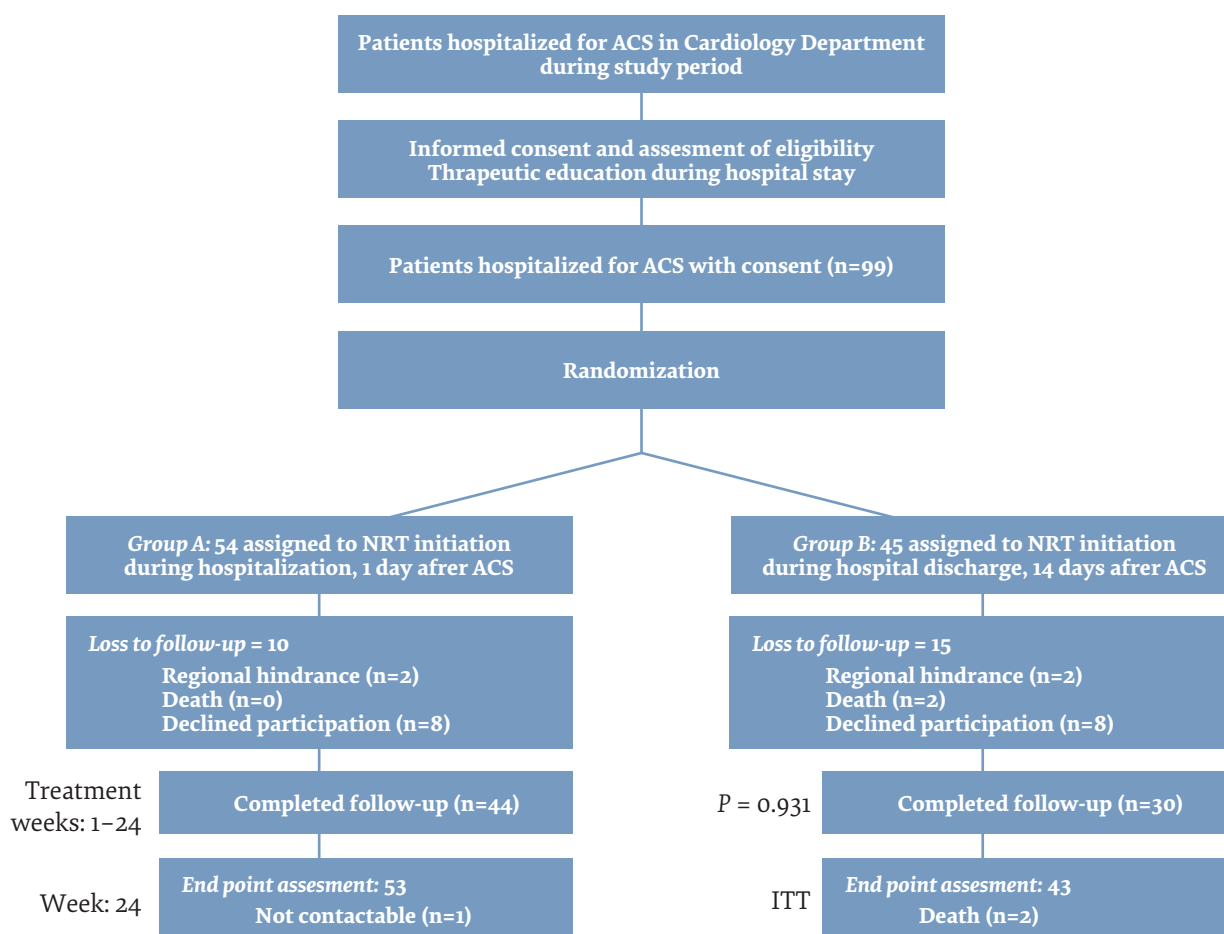
Ethical considerations

Written and informed consent was obtained from all study participants. Participants were given the opportunity to ask questions and decide whether to participate. This trial is registered with Clinical Trials.gov, number: NCT03209622.

Statistical analysis

Statistical analyses were performed using SPSS version 19.0. The primary data analysis examined point prevalence

Figure 1 Flow diagram demonstrating follow-up of enrolled patients



ACS = acute coronary syndrome; ITT = intention to treat; NRT = nicotine replacement therapy

smoking abstinence at 24 weeks. All analyses were intention-to-treat adjusted by ACS type [ST segment elevation myocardial infarction (STEMI) or non-STEMI (NSTEMI)]. Binary logistic regression was used to determine the factors that were independent predictors of smoking cessation success ($P < 0.05$). Variables with $P < 0.2$ in the univariate analysis were included in the multivariate analysis. $P < 0.05$ was considered statistically significant.

Results

Patient characteristics at baseline

At baseline, 93 patients (94%) used cigarettes with a mean 32 (14) cigarettes per day. A high nicotine dependence was found among 49 patients. Two thirds of patients had 2 or more major cardiovascular risk factors other than smoking. Half of patients (49.5%) had NSTEMI. The participant characteristics in the 2 groups are summarized in Table 1. Despite randomization, NSTEMI was found in 18 (37.5%) and 31 (62.5%) patients in Group A and B, respectively ($P = 0.002$). Length of stay in the cardiac intensive care unit was longer in Group B ($P = 0.007$).

Smoking abstinence at 24 weeks

Successful smoking cessation rates, with intention-to-treat analysis, were 57.1% [95% confidence interval (CI): 39.6–74.6%] in Group A and 42.9% (95% CI: 20.8–64.9%) in Group B. OR adjusted by length of stay in cardiac intensive care unit and SCA type was 0.824 (0.334–2.032) ($P = 0.674$).

Predictors of smoking cessation success

Factors associated for successful smoking cessation are shown in Table 2. The likelihood of success was associated with good follow-up compliance, living in a tobacco-free family environment, NSTEMI, history of diabetes and good motivation to quit. Smokers with high nicotine dependence had less chance of success.

Discussion

This study was designed to compare 2 protocols of smoking cessation immediately after ACS. There was no significant difference between initiation of smoking cessation by NRT during hospitalization or after discharge. To our knowledge, there have been no previous

Table 1 Characteristics of smokers with ACS at baseline by treatment group

Demographic variables	Group A	Group B	P
Number	54	45	0.366
Mean (SD) age, year	55 (11)	55 (10)	0.76
Level of education, n (%)			
Analphabet/primary	29(53.7)	18(40.0)	
Secondary/university	25(47.3)	27(60.0)	0.18
Working status, n (%)			
Employed, n (%)	39(72.2)	33(73.3)	0.902
Smoking variables			
Type (cigarettes), n (%)	51(98.1)	42(89.4)	0.10
Cigarettes per day, mean (SD)	29.4 ± 14.9	34.3 ± 13.3	0.09
Prior attempt to quit: n (%)	28(51.9)	21(46.7)	0.607
Motivation score to quit (QMAT scale) mean (SD)	19.2 ± 2.6	19.04	0.752
FTNDS, mean (SD)	6.13 (2.2)	6.31 (2.1)	0.690
≥ 7 (severe), n (%)	25(48.1)	24(53.3)	0.606
Alcohol consumption	11(20.4)	9(20.0)	0.964
Other household smokers	11(20.4)	9(20.0)	0.964
Clinical characteristics	15 (28.3)	14 (31.1)	0.761
Presence of CVRF other than smoking, n (%)	20(42.6)	13(26)	0.17
Diabetes	20(42.6)	17(33.8)	0.64
Hypertension	16(34)	13(28.9)	0.59
Hyperlipidaemia	21(44.7)	18(40)	0.65
Obesity (BMI ≥ 30)	6(12.8)	9(20.5)	0.32
PAOD	4(8.5)	2(4.4)	0.67
History of CVD (prior to baseline event)	12(23.1)	16(34)	0.22
History of depression	0	0	
Admission event, n (%)			
STEMI	30(68.9)	14(31.1)	
NSTEMI	18(37.5)	31(62.5)	0.002
Presence of complication yes, n (%)	11(22.9)	13(28.9)	0.51
Length of stay in Cardiology Department (weeks), Median (IQR)	8 (6–11)	9 (7–12)	0.121
Length of stay CICU (week), Median (IQR)	3 (0.5–4)	4 (3–4)	0.007
Follow up duration (week) Median (IQR)	24 (11–31)	17.5 (11.25–27.5)	0.250
Treatment, n (%)			
No intervention	11 (23.9)	9 (20)	
PCI/CABG	35 (76.1)	36 (80)	0.65
Number of clinical visits, n (%)			
≥ 4	16 (30.1)	22 (46.8)	0.10
Compliance, n (%)			
Good ^a	24 (46.2)	21 (44.7)	
Poor ^b	28 (53.8)	26 (55.3)	0.88

Table 1 Characteristics of smokers with ACS at baseline by treatment group (concluded)

Demographic variables	Group A	Group B	P
Occurrence of adverse effects of NRT, n (%)			
Allergic skin reaction	2 (7.1)	3 (10.3)	1
Withdrawal symptoms, n (%)			
None	21 (40.4)	14 (29.8)	
Nervousness	5 (9.6)	12 (25.5)	0.10
Others ^c	26 (50)	21 (44.7)	
Benefits of smoking cessation, n (%)			
Improvement of respiratory signs	28 (57.1)	30 (60)	
Increased appetite	10 (20.4)	11 (22)	0.99
Others ^d	7 (14.2)	8 (16)	

^aWearing nicotine patches on a regular basis.

^bWearing nicotine patches on an irregular basis.

^cHeadache, lack of concentration, insomnia, craving.

^dSleep quality improvement, enhancement of physical activity.

BMI = body mass index; CAD = coronary artery disease; CABG = coronary artery bypass grafting; CICU = cardiac intensive care unit; CVD = cardiovascular disease; CVRF = cardiovascular risk factor; FTNDS = Fagerstrom test for nicotine dependence score; NRT = nicotine replacement therapy; NSTEMI = non-ST segment-elevation myocardial infarction; PAOD = peripheral arterial occlusive disease; PCI = percutaneous coronary intervention; STEMI = ST segment-elevation myocardial infarction.

trials on smoking cessation performed in patients with ACS in Tunisia.

Patients included in our study were all male. The average age of our coronary population was close to that found in previous studies of smoking cessation in the same population (16–20). Most patients were heavy smokers. Our results were similar to those described in other studies of smoking cessation after ACS (21). These findings are encouraging for the promotion of effective awareness-raising actions for heavy smokers. During the study period, no women developed ACS related to smoking. In fact, in Tunisia, female smoking is considered a social taboo, thus limiting tobacco use in women.

Smoker psychology and ability to change behaviour were described in the Prochaska and Di Clemente model (22). After a cardiac event, the successive stages of the Prochaska cycle are “short circuited” (22) and the patients are often highly motivated to quit smoking (8). In the current study the majority of patients were already highly motivated to quit smoking and hospitalization in the Cardiology Department could be a good opportunity to initiate smoking cessation (23). Also, coronary revascularization such as angioplasty or coronary artery bypass surgery is an alarming event for patients hospitalized for ACS and increases intention to quit (24,25). Previously, the safety and effectiveness of NRT for patients immediately after ACS were unclear because of potential haemodynamic effects of nicotine (26). Recently, safety and efficacy of NRT in patients with recent SCA were documented (1,2,16,27) and the use of NRT to quit smoking roughly doubles the success rate in long-term abstinence by reducing withdrawal symptoms (16).

Smoking abstinence rates at 24 weeks were 54.5% in Group A and 45.5% in Group B. Our results were equivalent to those reported in the literature, particularly in randomized controlled trials with rates ranging from 30.4 to 62% (7,9,10,17–20,24). This result could be explained by the effectiveness of a multidisciplinary management team and the intensive intervention adopted in this protocol. This finding was supported by the literature, which shows that intensive intervention is more effective (28). The difference in smoking abstinence rates from those in the literature could be explained by the pharmacotherapy used: NRT, varenicline or bupropion, with NRT being the only available treatment for smoking cessation in Tunisia. Cardiologists have to be more effective in promoting

Table 2 Factors predicting smoking cessation at 24 weeks among patients with acute coronary syndrome (logistic binary regression model analysis)

Predictive factors	OR	95% CI	P
Good compliance ^a	6.56	2.07–20.78	0.001
No other household smokers	6.10	1.67–22.24	0.006
Type of acute coronary syndrome: NSTEMI	5.01	1.57–15.99	0.006
Diabetes	4.42	1.50–12.95	0.007
Motivation score to quit smoking (QMAT scale: 0–22)	1.29	1.06–1.57	0.009
High level of nicotine dependence (Fagerström test ≥ 7)	0.72	0.54–0.96	0.028

^a> 3 visits (5 weeks) and correct use of nicotine replacement therapy.

CI = confidence interval; NSTEMI = non-ST segment-elevation myocardial infarction; OR = odds ratio.

quitting motivation (29); offering brief advice and encouragement to patients is insufficient (27,28) and they must start NRT as soon as possible.

According to our findings and regardless of treatment groups, patients with STEMI and no other household smokers were significantly associated with smoking cessation. Likewise, smoking cessation rate was related to good treatment compliance (10,11,30,31). These results suggest that such a programme should be applied as a main part of the post-ACS routine following the recommendations of the European Society of Cardiology (32). Diabetes increased the chances of smoking cessation in our study population, which was consistent with the study of Kim et al. (33). However, the presence of other diseases such as stroke (30), previous cardiac events (5), diseases related to smoking, depression (30,34) and a history of anxiolytic use (34) is significantly associated with smoking cessation failure. Concomitant with other studies, a high level of nicotine dependence was significantly associated with smoking cessation failure (30). Finally, a high motivation score to quit is a significant predictive factor for smoking cessation (35), showing that the period of hospitalization is an opportunity to help these patients.

The main limitation in our study was sample size. Also, the exclusion criteria (refusal of assistance for smoking cessation, inability to attend follow-up clinical visits, or diagnosis of depression or other serious health condition at admission) may constitute selection bias that may overestimate our results. However, the study determined the effect of early NRT after ACS. This study is continuing to determine the long-term effect of treatment.

Conclusions

At 24 weeks there were no significant differences in smoking cessation rates between initiating smoking cessation during hospitalization or after discharge. Diabetes, NSTEMI, good motivation for smoking cessation, good treatment compliance and living in a tobacco-free family environment were predictive factors for successful smoking cessation. High nicotine dependence decreased the likelihood of smoking cessation.

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Syndrome coronarien aigu : facteurs prédictifs de la réussite du sevrage tabagique

Résumé

Contexte : Peu d'essais contrôlés randomisés ont examiné la durée garantissant l'efficacité du sevrage tabagique chez les patients hospitalisés atteints d'un syndrome coronarien aigu, soit pendant leur hospitalisation, soit après leur sortie.

Objectifs : Évaluer les taux de sevrage tabagique à 24 semaines chez les patients atteints d'un syndrome coronarien aigu. Les patients du groupe A avaient entamé une thérapie de substitution nicotinique lors de leur hospitalisation, et ceux du groupe B, après leur sortie. Nous avons aussi déterminé les facteurs prédictifs de la réussite du sevrage.

Méthodes : Nous avons mené un essai contrôlé randomisé dans le département de cardiologie et le service de sevrage tabagique de l'hôpital universitaire de Monastir, en Tunisie, de janvier 2015 à juin 2016. Les participants ont été répartis dans les deux groupes susmentionnés de manière aléatoire. Le critère d'évaluation final était le sevrage tabagique à 24 semaines, défini comme l'abstinence auto-déclarée au cours de la semaine écoulée, confirmé par la mesure du monoxyde de carbone expiré (inférieur ou égal à 8 ppm). Nous avons effectué une analyse en intention de traiter sur les données. Un modèle de régression logistique binaire a été employé pour déterminer les facteurs prédictifs de l'abstinence.

Résultats : Tous les participants étaient de sexe masculin, pour un âge moyen (écart type) de 55 (11) ans. À 24 semaines, on ne notait pas de différence significative dans le taux de sevrage tabagique des deux groupes : 54,5 % (intervalle de confiance à 95 % [IC] : 44,7-64,3 %) dans le groupe A et 45,5 % (IC à 95 % : 35,7-55,3 %) dans le groupe B ($p = 0,81$). Un niveau élevé de dépendance nicotinique [odds ratio (OR) : 0,72 ; IC à 95 % : 0,54-0,96] et une bonne observance en phase de suivi (OR : 6,56 ; IC à 95 % : 2,07-20,78) étaient des facteurs prédictifs de l'abstinence.

Conclusions : Le taux de sevrage tabagique suivant un syndrome coronarien aigu était élevé, indépendamment de la date de début d'abstinence. Une bonne observance en phase de suivi était le facteur prédictif clé pour la réussite du sevrage.

المتلازمة التاجية الحادة: العوامل التي تُنبئ بالإقلاع عن التدخين

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الخلاصة

الخلفية: لم تُجر سوى بضع تجارب عشوائية مضبوطة لقياس المدة الزمنية الفعالة للإقلاع عن التدخين لدى المرضى المصابين بالمتلازمة التاجية الحادة الموجودين في المستشفيات، سواء أثناء فترة إقامتهم بالمستشفى أو عقب خروجهم منه.

الأهداف: هدفت الدراسة إلى تقييم معدلات الإقلاع عن التدخين في الأسبوع ٢٤ بين المرضى المصابين بالمتلازمة التاجية الحادة. وقد بدأ أفراد

المجموعة أ العلاج بدائل النيكوتين أثناء فترة إقامتهم بالمستشفى، بينما بدأ أفراد المجموعة ب العلاج عقب خروجهم من المستشفى. كذلك حددنا العوامل التي تنبئ بإحراز النجاح.

طرق البحث: أجرينا تجربة عشوائية مضبوطة في قسم أمراض القلب وخدمات الإقلاع عن التدخين في المستشفى الجامعي بالمنستير، تونس، في الفترة من يناير/ كانون الثاني ٢٠١٥ إلى حزيران/ يونيو ٢٠١٦. ووُزِعَ المشاركون عشوائياً بين المجموعتين المشار إليهما سابقاً. وجاء التقييم النهائي بالامتناع عن التدخين في الأسبوع ٢٤، وعُرفَ بأنه التبليغ الذاتي عن الامتناع عن التدخين في الأسبوع الذي يسبق التقييم، وجرى التأكد منه بقياس تركيز أول أكسيد الكربون الناتج أثناء الزفير الذي يكون ≥ 8 أجزاء في المليون. وحللنا البيانات بقصد العلاج. واستخدمنا نموذج الانحدار اللوجستي الثنائي لتحديد العوامل التي تنبئ بالامتناع عن التدخين.

النتائج: كان جميع المشاركين من الذكور، وكان متوسط أعمارهم (الانحراف المعياري = ١١) ٥٥ عاماً. وفي الأسبوع ٢٤، لم يكن هناك اختلاف ملحوظ في معدل الإقلاع عن التدخين بين المجموعتين: ٥٤، ٤ [فاصل الثقة ٩٥ = ٤، ٤٤ - ٦٤، ٣] في المجموعة أ، و ٤٥، ٥ [فاصل الثقة ٩٥ = ٧، ٣٥ - ٥٥، ٣]؛ وفي المجموعة ب (القيمة الاحتمالية = ٠,٨١). ومستوى مرتفع من إدمان النيكوتين [نسبة الأرجحية: ٠,٧٢؛ فاصل الثقة ٩٥ = ٠,٥٤ - ٠,٩٦]، وكان الالتزام الجيد أثناء فترة المتابعة (القيمة الاحتمالية: ٠,٥٦؛ فاصل الثقة ٩٥ = ٠,٧ - ٢,٨٧) من بين العوامل التي تنبئ بالامتناع عن التدخين.

الاستنتاجات: كانت معدلات الإقلاع عن التدخين مرتفعة عقب المتلازمة التاجية الحادة، بغض النظر عن تاريخ البدء. وكان الالتزام الجيد أثناء فترة المتابعة هو أهم العوامل التي تنبئ بالنجاح.

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Attitudes and behaviours of physicians towards the relationship with the pharmaceutical industry in Saudi Arabia

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Abstract

Background: The relationship and interactions between physicians and the pharmaceutical industry can affect patient care. A physician's practice can be influenced by this relationship. It is believed that these interactions are common among doctors in Saudi Arabia.

Aims: This study was undertaken to assess the frequency of such relationships and physicians' attitudes and behaviours toward them.

Methods: This was a cross-sectional questionnaire survey completed by practicing physicians at four Saudi government and private tertiary care centres in Riyadh, Saudi Arabia. The questionnaire addressed the frequency of meetings with representatives of pharmaceutical companies (PRs) and of receiving gifts and considered the physicians' attitudes and behaviours towards PRs.

Results: A total of 300 completed questionnaires were obtained. Among the physicians surveyed, 223 (74.3%) met PRs one to three times per month. Up to 191 (64%) of physicians admitted receiving gifts. More than two thirds of physicians-192 (63%) have been invited to activities sponsored by pharmaceutical companies. Among the physicians, 239 (80%) agreed that PRs use promotional techniques in their approach and 251 (84%) of them stressed the need for expert physicians to attend presentations by PRs to correct the facts.

Conclusion: The frequent meetings between physicians and PRs and the use of promotional techniques by PRs are concerning. Future studies should assess the impact of this involvement on medical practice and drugs prescription in Saudi Arabia.

Keywords: Physicians; pharmaceuticals, physician, relationship, Saudi Arabia

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Introduction

Interactions between physicians and the pharmaceutical industry are widespread practice (1,2). In the early 1950s and 1960s, contacts between pharmaceutical representatives (PRs) and physicians were seen as a positive relationship; PRs were considered to be important sources of information for physicians. However, since 1980, these relationships have been subjected to major criticism and condemnation by many healthcare professionals. Physicians may be influenced, directly or indirectly, by the profit-seeking behaviour of pharmaceutical companies (3). There may be a conflict of interest between the physician's duty to the patient and the interests of the pharmaceutical industry, leading to the physician recommending or promoting certain products or drugs (4).

PRs, through their relationship with healthcare providers, may influence prescribing patterns and stimulate requests for the addition of drugs to hospital formularies. Wazna (2000) reported in Montreal, Canada that physicians met with PRs on average four times per month and residents accepted six gifts per year (5). Another survey, from the United States of America (USA) in 2001, reported 92% of physicians

received drug samples, 61% received meals, tickets to events, or free travel, 13% received financial or other kinds of benefits, and 12% received incentives for participation in clinical trials (6).

Another recent study by Campbell EG et al. (7) surveyed more than 3000 physicians in the USA, and revealed that most physicians (94%) reported some type of relationship with the pharmaceutical industry, and most of these relationships involved receiving food in the workplace (83%) or receiving drug samples (78%). More than one third of the respondents (35%) received reimbursement for costs associated with professional meetings or continuing medical education, and more than one quarter (28%) received payments for consulting, giving lectures, or enrolling patients in trials (7).

Another study also reported that physicians are now meeting more frequently (up to 16 meetings per month) with PRs than the average of 4.4 meetings per month (5). This increase in the number of visits and the closer relationship raise concerns regarding violations of professional codes of ethics. Recently, many studies and reports have been published confirming industry influence on the objectivities and behaviors of physicians

(8–16). Many physicians frequently do not recognize that their decisions have been affected by commercial gifts and services and may in fact deny or minimize such influence. The continuing increase in the influence of industry on physicians' practice, research and education has prompted the American College of Physicians to issue a statement addressing industry relations with individual physicians and medical professional groups (17).

We have observed that the relationship between physicians and the pharmaceutical industry is increasing in Saudi Arabia. However, we are not certain of the extent of this relationship and the physicians' attitudes towards it. Therefore, this study has been designed to assess the attitudes and behaviours of physicians toward their relationship with PRs.

Methods

Study subjects

This is a cross-sectional survey conducted from March to September 2015. The study sample comprised physicians of all ranks and different specialties from three governmental tertiary care hospitals and one private tertiary care hospital in Riyadh, Saudi Arabia. The physicians were recruited after conferences and academic clinics or activities. Physicians were divided into five groups based on their specialties or subspecialties. These groupings were internal medicine, surgery, obstetrics and gynaecology, paediatrics and others (including family medicine). Positions of physicians were identified as consultants, non-consultants and in training. Non-consultants were defined as associate consultants, assistant consultants and staff physicians. The in-training groups comprised fellows, residents and medical interns. Years of experience were taken as more or less than 15 years. Ethical approvals were obtained from the participating hospitals and the identities of the subjects were kept anonymous. Informed consent was obtained from participants taking part in the study. The sample size required was estimated to be 325 physicians for a confidence level of 95%, and a predicted positive response of 0.25 based on previous studies (16).

Questionnaire

The questionnaire was developed based on published literature (Saito et al.) to explore the relationship between physicians and pharmaceutical companies (16). The survey consisted of 39 questions covering demographic data, frequency of meetings with PRs, receiving gifts from PRs, the physicians' attitudes and behaviours towards PRs and the medical knowledge gained from the meetings.

The questionnaire addressing the physicians' attitudes and behaviours used a Likert scale: 1-agree, 2-neutral, or 3-disagree with the statements. Individual physicians were visited in their offices and on the wards and the questionnaires completed immediately. The questionnaires were in English as all physicians in Saudi Arabia speak English.

Statistical analysis

Comparisons between categorical variables were performed using Chi-square and statistical significance was set at P -value < 0.05 . Years of practice was categorized into >15 years and <15 years. The Statistical Package for Social Sciences software (SPSS 21.0, Chicago, IL, USA) was used for the analysis.

Results

During the study period 514 questionnaires were distributed and 325 questionnaires returned, giving a response rate of 63.2%. Twenty-five of these were excluded owing to incomplete data and a total of 300 questionnaires were analyzed. The majority of the participants, 219 (73%) were of Saudi nationality, 155 (52%) were consultants and 176 (58%) of all physicians were from internal medicine (Table 1).

Table 1 Demographics characteristics (300)

	No (%)
Gender	
Male	231(77)
Female	69(23)
Nationality	
Saudi	219(73)
Non-Saudi	81(27)
Hospital setting	
Private hospital	40(13.3)
Government hospital	260(86.7)
Institution	
Academic	242 (80.7)
Non-academic	58(19.3)
Year of practice	
Less than 15	131 (43.7)
15 or more	169(56.3)
Position of physician	
Consultant	155(51.7)
Non-consultant	64(21.3)
In-training	81(27)
Specialties	
Internal medicine	176(58.7)
Pediatrics	35(11.7)
Obstetrics/gynecology	19(6.3)
General Surgery	40(13.3)
Others	30(10)

Attitudes and behaviours of physicians towards pharmaceutical representatives (PRs)

A majority of physicians (190, 63%) agreed that pharmaceutical companies played an important role in supporting continuing medical education (CME) in their institute. On the other hand, 139 (46%) of physicians stated that PRs did not have a teaching role in their institute and 136 (45%) felt that PRs should not be banned from giving lectures. Pharmaceutical companies were acknowledged to support speakers at conferences (234, 78%). However, 239 (80%) believe that PRs use lecture time to advertise their products and 251 (84%) believed that it is necessary to have expert faculty attending such lectures to redress the balance.

Over three quarters of respondents 230 (77%) had received no training, whether at medical school or later, on how to interact with pharmaceutical companies and their representatives. Out of the participants, 135 (45%) and 142 (47.3%) agreed that the information supplied by the PRs regarding both new and old drugs was accurate. Nevertheless, 184 (61%) stated that discussions with PRs and gifts received did not have any impact on their prescribing behavior. However, 116 (39%) stated that such discussions and interactions influenced the prescribing behavior of other physicians (Table 2).

Meetings and receiving of gifts from pharmaceutical representatives (PRs)

Physician exposure to PRs was very frequent, occurring one to three times per month, and 223 (74%), and 147 (49%) physicians had received drug samples up to three times monthly.

More than half of the physicians (60.3% and 55.3%) received stationery and industry sponsored CME events within the workplace from one to three times per month (Table 3).

Comparison between categorical variables

Demographic variables, including sex, nationality, years of experience, position held, specialty, type of hospital (governmental or private, academic or non-academic) were considered and categories compared. Table 3 shows that more physicians with 15 years of experience or more (156, 92%) had regular meetings with PRs and invitations to industry sponsored CME events. In addition, while meetings with PRs are commonplace, significantly more physicians working in private hospitals (37, 93%) had regular meetings with PRs than was seen in government hospitals (211, 82%) ($P = 0.014$). Similarly, drug samples were given to more physicians in the private sector than in government hospitals; 39 (98%) compared with 116 (45%) respectively ($P < 0.001$). Most government physicians believe that PRs employ marketing techniques in their approach; 220 (85%) compared to 19 (48%) of private sector physicians ($P < 0.001$). Only 100 (38%) of the government physicians compared to 35 (88%) of private sector physicians believed that the information provided by PRs was accurate ($P < 0.001$). Table 4 shows statistically significant changes in prescribing behaviour between experienced and less experienced physicians, with 123 (73%) experienced physicians believing that their prescribing behaviour was not impacted after meetings with PRs, compared to 61 (47%) less experienced physicians ($P < 0.001$). The information provided and any gift given to the physician was related to the influence of PRs on prescribing behaviors.

Table 2 Attitude and behaviors of physicians towards PRs

Parameters	Agree N (%)	Neutral N (%)	Disagree N (%)
Attitude of physicians towards PRs			
PR plays important role in CME for physicians	190 (63)	50 (17)	60 (20)
PR perform important teaching function	78 (26)	83 (28)	139 (46)
PR should be banned from presentation in hospitals	79 (26)	85 (28)	136 (45)
I was given sufficient training during my pre and post graduate training on interacting with PR	42 (14)	28 (9)	230 (77)
PR supports important conferences and speakers.	234 (78)	44 (15)	22 (7)
PR employs marketing techniques in their interactions	239 (80)	46 (15)	15 (5)
An expert faculty member should be present at all presentation by PR	251 (87)	35 (12)	14 (5)
Behaviors of physicians towards PR			
PR provides accurate information about new medications	135 (45)	62 (21)	103 (34)
PR provides accurate information about old medications	142 (47)	83 (28)	75 (25)
Discussion with PR have an unfavorable impact on my prescription behaviors	75 (25)	41 (14)	184 (61)
Gifts from PR have an unfavorable impact on my prescription behaviors regardless of the monetary value	76 (25)	42 (14)	182 (61)
Gifts from PR have an unfavorable impact on other physicians' prescription behaviors regardless of the monetary value	116 (39)	93 (31)	91 (30)
I would have some degree of contact with PR weather or not promotional gifts were given	183 (61)	67 (22)	50 (17)
It is appropriate to receive gifts of low monetary value from PR	65 (22)	57 (19)	178 (59)
It is appropriate to receive gifts of high monetary value from PR	39 (13)	35 (12)	226 (75)

Table 3 Meetings and Gift receiving between years of experience (N=300)

N(%)		Total	Years of Experience		P value	Hospital Affiliation		P value
			<15 years (N=131)	>15 years (N=169)		Private Hospital (N=40)	Governmental Hospital (N=260)	
Average meetings with pharmaceutical rep (PR)	Never	52 (17)	39 (30)	13 (8)	< .001	3 (8)	49 (19)	.014
	Once to three times a month	223 (74)	88 (67)	135 (80)		37 (93)	186 (72)	
	One a week or more	25 (8)	4 (3)	21 (12)		0	25 (10)	
Drug Samples	Never	145 (48)	74 (56)	71 (42)	.045	1 (3)	144 (55)	< .001
	Once to three times a month	147 (49)	54 (41)	93 (55)		39 (98)	108 (42)	
	One a week or more	8 (3)	3 (2)	5 (3)		0	8 (3)	
Stationery such as pens and notepads	Never	109 (36)	62 (47)	47 (28)	.002	6 (15)	103 (40)	.008
	Once to three times a month	181 (60)	65 (50)	116 (69)		33 (83)	148 (57)	
	One a week or more	10 (3)	4 (3)	6 (4)		1 (3)	9 (3)	
Industry-sponsored CME events inside the workplace	Never	108 (36)	70 (53)	38 (22)	< .001	14 (35)	94 (36)	.299
	Once to three times a month	178 (59)	59 (45)	119 (70)		26 (65)	152 (58)	
	One a week or more	14 (5)	2 (2)	12 (7)		0	14 (5)	
Meals outside the workplace	Never	158 (52)	86 (66)	72 (43)	< .001	9 (23)	149 (57)	< .001
	Once to three times a month	96 (32)	40 (31)	94 (56)		31 (78)	103 (40)	
	One a week or more	4 (1)	5 (4)	3 (2)		0	8 (3)	
Industry-sponsored CME events outside the workplace	Never	158 (53)	91 (69)	67 (40)	< .001	10 (25)	148 (57)	< .001
	Once to three times a month	134 (45)	40 (31)	94 (56)		30 (75)	104 (4)	
	One a week or more	8 (3)	0	8 (5)		0	8 (3)	
Financial subsidies to attend CME events	Never	167 (56)	89 (68)	78 (46)	< .001	11 (28)	156 (60)	< .001
	Once to three times a month	127 (42)	42 (32)	85 (50)		29 (73)	98 (38)	
	One a week or more	6 (2)	0	6 (4)		0	6 (2)	

Discussion

Most of the participants (223, 74%) met with PRs frequently, which is concerning. However, this is almost similar to other international studies; for example 77%–84% of German physicians were visited at least once a week (18,19) and up to 95% according to another study by De Ferrarai A, et al. (20). In our study the majority of physicians believe that PRs did not influence their practice, but did influence other physicians. This concept is difficult to prove among our participants due to the nature of our study, which is not designed to assess this question. However, it has been reported in many other studies (21–23). Never the less, there are several studies documenting the negative effect of PR on physicians clinical practice (5,24,25).

More than 135 (45%) physicians agreed that PRs provided accurate information about new drugs and 142 (47%) agreed about the accuracy of information for old drugs. This is similar to a previous study by Leib et al. (19) where 43% of German physicians believed PRs provided adequate and accurate information. Of greater concern in our study is that 239 (80%) of physicians agreed that PRs use promotional techniques in their approach and 251 (84%) affirmed the need for the presence of an expert physician at PR presentations to ensure factual accuracy.

In this study, more than two thirds of our physicians (192, 64%) received gifts, most of which were industry sponsored CME events. This also has been reported in other studies where 31%–98% received gifts, and 32%–85% received material, equipment or drugs sample for professional use (16,20,26). Prescribing behaviors have been shown in many studies to be influenced by this practice, despite denials by participating physicians (17). Lurie et al. (27) found that in one institution 25% of internal medicine faculty and 32% of residents reported that they had changed their practice at least once in the preceding year because of a discussion with a PR.

Approximately two thirds of participants (192, 64%) had been invited to activities sponsored by pharmaceutical companies – in some cases to be promotional (7) – and studies have shown the prescribing pattern of physicians changed after they attend such conferences (17). One study of psychiatry residents (28) showed the influence increased to 50%. Many physicians (193, 63%) believe that PRs contribute to academic activities. Two-thirds of physicians (184 61%) denied any influences of PRs on their prescribing patterns. This result concurs with Saito et al. (16) where 69% of physicians denied any impact from PRs on their prescribing behaviour. However, this

Table 4 Behaviors and attitude of Physicians towards PRs between experience years and practice sittings (N=300)

Questions	Behaviours of physicians				Attitude of physician			
	Yrs of experience		Hospital Affiliation		Hospital Affiliation		P value	
	<15 (N=131)	>15 (N=16)	Private Hospital (N=40)	Gov Hospital (N=260)	Private Hospital (N=40)	Gov Hospital (N=260)	P value	
PRs provide accurate information about new medications.	Agree	68 (52)	67 (40)	35 (88)	100 (38)	35 (88)	155 (60)	.003
	Neutral	22 (17)	40 (24)	3 (8)	59 (23)	3 (8)	47 (18)	
	Disagree	41 (31)	62 (37)	2 (5)	101 (39)	2 (5)	58 (22)	
PRs provide accurate information about old (established) medications	Agree	63 (48)	79 (47)	33 (83)	109 (42)	23 (58)	55 (21)	< .001
	Neutral	35 (27)	48 (28)	5 (13)	78 (30)	12 (30)	71 (27)	
	Disagree	33 (25)	42 (25)	2 (5)	73 (28)	5 (13)	134 (52)	
Discussions with PRs have an unfavorable impact on my prescribing behaviors.	Agree	41 (31)	34 (20)	32 (80)	43 (17)	16 (40)	63 (24)	.001
	Neutral	29 (22)	12 (7)	5 (13)	36 (14)	17 (43)	68 (26)	
	Disagree	61 (47)	123 (73)	3 (8)	181 (70)	7 (18)	129 (50)	
Gifts from PRs have an unfavorable impact on my prescribing behaviors, regardless of the monetary value	Agree	45 (34)	31 (18)	27 (68)	49 (19)	22 (55)	20 (8)	< .001
	Neutral	27 (21)	15 (9)	9 (23)	33 (13)	14 (35)	14 (5)	
	Disagree	59 (45)	123 (73)	4 (10)	178 (68)	4 (10)	226 (87)	
Gifts from PRs have an unfavorable impact on other physicians' prescribing behaviors, regardless of the monetary value	Agree	59 (45)	57 (34)	29 (73)	87 (33)	25 (63)	209 (80)	.003
	Neutral	38 (29)	55 (33)	9 (23)	84 (32)	13 (33)	31 (12)	
	Disagree	34 (26)	57 (34)	2 (5)	89 (34)	2 (5)	20 (8)	
I would have the same degree of contact with PRs whether or not promotional gifts were distributed	Agree	68 (52)	115 (68)	26 (65)	157 (60)	19 (48)	220 (85)	< .001
	Neutral	39 (30)	28 (17)	12 (30)	55 (21)	20 (50)	26 (10)	
	Disagree	24 (18)	26 (15)	2 (5)	48 (18)	1 (3)	14 (5)	
It is appropriate to receive gifts of low monetary value from PRs	Agree	35 (27)	30 (18)	23 (58)	42 (16)	28 (70)	223 (86)	.003
	Neutral	31 (24)	26 (15)	15 (38)	42 (16)	11 (28)	24 (9)	
	Disagree	65 (50)	113 (67)	176 (68)		1 (3)	13 (5)	

finding needs to be examined carefully and objectively. The majority of the respondents (230, 77%), did not receive any education in how to deal with PRs or ethical impact of such relationships, and this issue should be addressed as early as medical school.

These issues need to be regulated. In some countries, the code of marketing also regulates the function of drugs representative. For example, in Canada, this code requires PRs to provide full and factual information on products without misrepresentation or exaggeration. Representatives' statements must be accurate and complete and must not be misleading, either directly or by implication (29). In the USA, the Pharmaceutical Research and Manufacturers of America (PhRMA), in 2009, implemented a new code of conduct governing physician–industry relationships among its members (30). This code states that these interactions must benefit patients and enhance the field of medicine. It also discourages pharmaceutical companies from giving physicians gifts that do not carry benefit to patients.

Limitations

The limitation of the study is that respondent bias may be present, as physicians were more likely to answer the survey in a more ethically acceptable manner. We tried to minimize this issue by conducting the survey completely anonymously. In addition, we did not assess the effect of

PRs on the cost of prescribing medication because of the nature of our study design. However, this issue has been studied before (31–33).

Conclusion/recommendations

The frequent meetings and the use by PRs of promotional techniques such as drug samples, gifts and CME events, are concerning. PRs have shown they are involved in academic activities by sponsoring CME events and by sponsoring speakers to such events who may have an influence on physicians and their prescribing behaviours. This study did not cover the influence of PR activity on the actual prescribing of the physicians concerned, but there is an urgent need for future research to assess the impact and influence of this involvement PR on medical practice in Saudi Arabia.

Currently, we do not know the extent of this relationship and its effects on healthcare or healthcare providers. Physicians should be educated to deal with PRs early in their careers; possibly at medical school. The relationship between the pharmaceutical industry and physicians must be regulated by institutions and local health professional organizations to assure the best healthcare is being provided to patients.

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Attitudes et comportements des médecins vis-à-vis du lien avec l'industrie pharmaceutique en Arabie saoudite

Résumé

Contexte : Le lien et les interactions entre les médecins et l'industrie pharmaceutique peuvent avoir une incidence sur la prise en charge des patients. En effet, ce lien peut influencer la pratique d'un médecin. On estime que ce type d'interactions est courant chez les médecins en Arabie saoudite.

Objectifs : La présente étude a été menée afin d'évaluer la fréquence de ces liens ainsi que les attitudes et les comportements des médecins vis-à-vis de ces interactions.

Méthodes : La présente étude transversale consistait en un questionnaire rempli par des médecins en exercice dans quatre centres de soins tertiaires publics et privés à Riyadh (Arabie saoudite). Le questionnaire portait sur la fréquence des réunions avec des représentants de compagnies pharmaceutiques et des cadeaux reçus. Il s'intéressait aussi aux attitudes et comportements des médecins vis-à-vis de ces représentants.

Résultats : Au total, 300 questionnaires remplis ont été collectés. Parmi les médecins interrogés, 223 (74,3 %) rencontraient un représentant de compagnie pharmaceutique une à trois fois par mois. Non moins de 191 médecins (64 %) ont admis recevoir des cadeaux. Plus des deux tiers des médecins – à savoir 192 (63 %) – ont été invités à des activités parrainées par les compagnies pharmaceutiques. Parmi les médecins interrogés, 239 (80 %) s'accordaient pour affirmer que les représentants de ces compagnies utilisaient des techniques promotionnelles dans leur approche et 251 (84 %) d'entre eux insistaient sur la nécessité pour les médecins experts d'assister aux présentations des représentants afin de corriger les faits mentionnés.

Conclusions : Les réunions fréquentes entre les médecins et les représentants des compagnies pharmaceutiques, ainsi que l'utilisation de techniques promotionnelles par ces derniers, sont inquiétantes. De prochaines études devraient évaluer l'impact de cette implication sur l'exercice de la médecine et sur la prescription de médicaments en Arabie saoudite.

مواقف الأطباء وسلوكياتهم إزاء علاقتهم بالصناعة الدوائية في المملكة العربية السعودية

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الخلاصة

الخلفية: يمكن أن تؤثر علاقة الأطباء بدوائر الصناعة الدوائية وتفاعلاتهم على الرعاية المقدمة للمرضى، كما يمكن أن تؤثر هذه العلاقة على ممارسة الطبيب لعمله. ويُعتقد أن هذه التفاعلات أمر شائع بين الأطباء في المملكة العربية السعودية.

الأهداف: هدفت الدراسة إلى تقييم تواتر هذه العلاقات ومواقف الأطباء وسلوكياتهم إزاءها.

طرق البحث: أجريت دراسة مقطعية باستخدام استبيان أجاب عنه مجموعة من الأطباء الممارسين في أربعة مراكز سعودية حكومية وخاصة للرعاية الصحية الثالثية في الرياض، المملكة العربية السعودية. وتناول الاستبيان وتيرة عقد اجتماعات مع ممثلي شركات الأدوية، وتلقي هدايا، مع الأخذ في الاعتبار مواقف الأطباء وسلوكياتهم تجاه هؤلاء الممثلين.

النتائج: بلغ إجمالي عدد الاستبيانات المكتملة التي حُصل عليها ٣٠٠ استبياناً. ومن بين الأطباء الذين شملهم الاستبيان، قابل ٢٢٣ طبيباً (٧٤,٣٪) ممثلي شركات الأدوية من مرة واحدة إلى ثلاث مرات في الشهر. وأقر ١٩١ طبيباً (٦٤٪) بتلقي هدايا. كذلك تلقى أكثر من ثلثي الأطباء، أي ١٩٢ طبيباً (٦٣٪)، دعوة لحضور أنشطة أقيمت تحت رعاية شركات الأدوية. ومن بين الأطباء، وافق ٢٣٩ طبيباً (٨٠٪) على أن ممثلي شركات الأدوية يستخدمون أساليب ترويجية في النهج الذي يتبعونه، وأكد ٢٥١ طبيباً (٨٤٪) ضرورة الاستعانة بأطباء يتمتعون بالخبرة لحضور العروض التقديمية الخاصة بـ ممثلي شركات الأدوية لتصحيح الحقائق.

الاستنتاجات: الاجتماعات المتكررة بين الأطباء وممثلي شركات الأدوية واستخدام هؤلاء الممثلين لأساليب ترويجية أمر يستحق الاهتمام. وينبغي أن تُقيم الدراسات المستقبلية تأثير هذه العلاقة على الممارسات الطبية ووصف الأدوية في المملكة العربية السعودية.

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Health-related quality of life of parents of children with phenylketonuria in Tehran Province, Islamic Republic of Iran

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Abstract

Background: Parents of children with phenylketonuria are at risk of reduced quality of life.

Aims: This study determined the quality of life of parents of children with phenylketonuria in Tehran Province.

Methods: The study was conducted in 2015 and included parents of children with phenylketonuria referred to three government children's hospitals in Tehran Province that provide phenylketonuria services. Data were collected using the Farsi version of the World Health Organization Quality of Life-Bref questionnaire. Analysis of variance, t-test, Pearson correlation coefficient and multiple linear regression were used to assess the relationship between quality of life domains and sociodemographic characteristics of the parent and child.

Results: The study included 240 parents; 55% were mothers. Quality of life of parents in psychological, social relationships and environment domains was low. Significant relationships were found between: physical domain and age of child at phenylketonuria diagnosis ($P = 0.044$); psychological domain and parent's age ($P = 0.019$), child's age ($P = 0.007$) and parent's education ($P = 0.015$); social relationships domain and parent's age ($P = 0.003$), and education ($P = 0.002$), household income ($P = 0.025$) and child's age ($P = 0.004$); and environmental domain and residence ($P = 0.034$), parent's education ($P = 0.007$), household income ($P = 0.002$) and child's age ($P = 0.049$). In the multivariable analysis, parent's age and education, child's age, and household income were significantly associated with parent's quality of life.

Conclusion: Given the low levels of quality of life in the parents, education and more financial support are recommended.

Keywords: quality of life, parents, phenylketonuria, Iran

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Introduction

Phenylketonuria is an autosomal recessive disorder of amino acid metabolism. The enzyme phenylalanine hydroxylase is necessary to metabolize the amino acid phenylalanine to tyrosine in liver. This enzyme is defective in people with phenylketonuria. It leads to an increase of phenylalanine in the blood and the brain (1). High levels of phenylalanine in the plasma cause mental retardation, seizures, behavioural difficulties, motor delay and slow language development. Although children with phenylketonuria who are treated early have average intelligence, they differ in cognitive performance when compared with their peers without phenylketonuria. Academic and cognitive functions of children with phenylketonuria are significantly lower than peers in the control group (2). It has also been reported that children with phenylketonuria may have low self-esteem, less motivation, loss of independence and reduced social confidence. Adolescents and adults may be at risk of depression, anxiety and social isolation (3).

Lifelong dietary treatment from birth is required to prevent mental retardation for all patients with phenylketonuria. Treatment includes severe restriction of natural protein, and supplementation with the phenylalanine-free formula (4). Adhering to the diet for people with phenylketonuria is a burden for patients and health staff, and management of phenylketonuria can be time-consuming for both adult patients and caregivers of children. In addition, phenylalanine intake should be monitored carefully by regular blood tests. Phenylketonuria may also impose an economic burden on patients and caregivers. These costs include direct costs related to the resources needed for the management of phenylketonuria, such as low-protein foods, supplements, medications, laboratory monitoring and visits to health care services, and also indirect costs in loss of productivity (5).

In the past two decades, studies to assess the quality of life (QoL) of people with chronic conditions have increased (6). Health-related QoL is the effect of disease

and treatment on physical, psychological, social and welfare dimensions of life (7). Health-related QoL can be used in the evaluation of disease outcomes, the use of interventions, assessment of the effectiveness of different treatments, and evaluation of health care services and health policies (8).

With early detection and treatment, phenylketonuria is a relatively benign disease, without physical symptoms and with few hospitalizations (9). However, the need to regularly monitor blood and adapt to a more complex diet, and the occurrence of neurological symptoms and stigma associated with a congenital metabolic disorder are likely to affect the QoL of people with phenylketonuria and their parents (10).

Assessment of QoL in these parents can help identify those with undiagnosed disorders as a result of the chronic burden of caring for a child with phenylketonuria. In addition to the usual stress associated with caring for a newborn baby, parents have to cope with the grief and worry of having a sick child and having to learn how to manage the diet (11). Parents of children with chronic diseases are at risk of psychological disorders and mental problems and have lower health status than parents of healthy children (12). In addition, a study that compared the QoL of parents of sick children and parents of healthy children showed that more than half of the parents of children with chronic diseases were at risk of decreased QoL (13).

The incidence of phenylketonuria in the Islamic Republic of Iran is relatively high (2) and studies on the QoL of parents of children with phenylketonuria are lacking. Therefore, this study aimed to determine the QoL of parents with children with phenylketonuria in Tehran Province.

Methods

This was a cross-sectional study conducted in three hospitals in Tehran Province in 2015: Children's Medical Centre, Mofid Hospital and Aliasghar Hospital. These three government hospitals are the only children's hospitals that provide specialized services to patients with phenylketonuria in Tehran Province. Using census sampling, all 240 parents (mother or father) referred to these hospitals from March to December 2015 were included in the study. The inclusion criteria were: Iranian nationality, father or mother of children with phenylketonuria, residence in Tehran Province, and ability to respond to the questionnaire. Exclusion criteria were: unwillingness to participate in the study and inability to remember events that had occurred in the past four weeks which were asked about in the questionnaire.

The World Health Organization Quality of Life-Bref (WHOQOL-BREF) was used to evaluate QoL. This 26-item questionnaire includes four domains: physical health (seven items), psychological health (six items), social relationships (three items) and environment (eight items). It also has two general questions about the individual's overall perception of his/her QoL and overall

perception of his/her health. Each item is rated on a five-point Likert scale from 1 to 5 and, to convert domain scores to a 0–100 scale, raw scores are converted to transformed scores (14). As per the WHOQOL-BREF manual, the mean score of items was used to compute the domain score. A higher score indicates a better QoL. The validity and reliability of the Farsi version of this questionnaire have been demonstrated (15–17). In our study, the validity of the instrument was confirmed by expert opinion and its reliability was acceptable (Cronbach alpha = 0.95).

Statistical analysis

Data were analysed using SPSS, version 22.0. A P-value less than 0.05 was considered statistically significant. Means and standard deviations (SD) were computed for demographic variables. Analysis of variance (ANOVA), t-test, Pearson correlation coefficient and multiple linear regression were used to assess the relationship between quality of life domains and sociodemographic characteristics of the parent and child.

Ethical considerations

The study was approved by the Committee for Ethics of Faculty of Public Health of Shahid Beheshti University of Medical Sciences (Code SBMU.REC.1393.812). The purpose of the study and procedures that would be carried out were explained to the parents of the children and verbal informed consent was obtained.

Results

A total of 240 parents completed the questionnaires, 55% were mothers and 45% were fathers. The mean ages of the parents and their children were 36.82 (SD 7.8) and 8.73 (SD 8.1) years respectively. Most of the parents (89.6%) were married, 49.8% were housewives, 42.2% had high-school education, 49.3% earned US\$ 295 or less a month and 51% lived in Tehran city. As regards the number of children with phenylketonuria in the family, 90.5% had one child, 9.1% had two children and one family had four children with phenylketonuria. Most of the children (55.8%) were boys. Only 52.8% of the patients had been diagnosed early; the mean age at diagnosis was 14 (SD 26) months (range 1 day–9.8 years). The demographic characteristics of parents and their children with phenylketonuria are shown in Table 1.

Most of the parents (43.6%) had an average perception of their overall QoL and a low perception of their health status. The mean score for overall perception of QoL was 2.92 (SD 1.1, range 1–5), and mean score for perception of health was 2.51 (SD 1, range 1–5).

The mean scores of the parents for physical health, psychological health, social relationships and environment were 21.23 (SD 2.5), 17.40 (SD 3.8), 7.96 (SD 2.4) and 19.79 (SD 2.9) respectively (Table 2). The highest mean score was for physical health (transformed score 50) and the lowest mean score was for environment (transformed score 38) (Table 2).

There was a significant relationship between

psychological dimension and parent’s age ($P = 0.019$, $r = -0.158$), child’s age ($P = 0.007$, $r = -0.183$) and education level of the parent ($P = 0.015$). There was also a significant relationship between social relationships dimension and parent’s age ($P = 0.003$, $r = 0.2$), education ($P = 0.002$), child’s age ($P = 0.004$, $r = -0.188$), and household income ($P = 0.025$). There was a significant relationship between the environment dimension and residence ($P = 0.034$), household income ($P = 0.002$), education level of the parent ($P = 0.007$), and child’s age ($P = 0.049$, $r = -0.130$). No significant relationship was found between QoL domains and the hospitals, relation of parent to the child, sex of child, employment and number of children with phenylketonuria. Variables associated with QoL domains are shown in Table 3.

In the multivariable linear regression analysis, parent’s age was a predictor of the physical dimension of QoL; Parent’s education level and child’s age were predictors of the psychological and the social relationships dimensions of QoL; and household income was predictor of QoL in the environment dimension (Table 4).

Discussion

Our study found a low level of QoL in parents of children with phenylketonuria in Tehran Province. A study in the Netherlands also found low health-related QoL in the parents of children with phenylketonuria (18). In a survey conducted in the Islamic Republic of Iran, caregivers of patients with phenylketonuria had a lower QoL level than the general population (19). In contrast to our study, other results were not consistent (7,12). Having mentally impaired children in the family, in addition to causing psychological stress, can cause physical illness, such as pain, and mental disorders, such as depression and anxiety, in families, which lead to reduced QoL of mothers (20,21). The reasons for differences between our study and others could be variations in the population, social and cultural conditions of communities, and the presence of support organizations.

Our findings indicate that parents with older children had lower QoL with regard to psychological health. This is not consistent with the results of other studies which found older age of the child was associated with a better health-related QoL in parents (7,12). With increasing patient age, controlling and caring for the disease can become costly and tedious. Most of the time, adherence to treatment decreases with increasing age because of low awareness of dietary restrictions, weak motivation and inability to comply with treatment (22). Non-compliance with diet in low- and middle-income countries can be due to a lack of experienced support centres, larger families, neglect of parents, financial constraints, low perception of risk in parents, and limited availability of low-protein products (23). Parents with children who had been diagnosed early had better QoL for physical and psychological health. Patients who are treated early generally have a favourable outcome with normal development (24). People with phenylketonuria

Table 1 Distribution of the parents and patients with phenylketonuria according to demographic characteristics

Variable	No. (%) (n = 240)
Parents	
Hospital	
Children’s Medical Centre	91 (37.9)
Mofid	81 (33.8)
Aliasghar	68 (28.3)
Age (years)	
≤ 30	49 (20.4)
31–40	121 (50.4)
41–50	51 (21.3)
> 51	19 (7.9)
Relation to child	
Father	108 (45.0)
Mother	132 (55.0)
Marital status	
Married	215 (89.6)
Divorced or widowed	25 (10.4)
Education^a	
Illiterate	3 (1.3)
Elementary school	26 (11.2)
Middle school	41 (17.7)
High school	98 (42.2)
University	64 (27.6)
Monthly household income^a (US\$)	
≤ 295	104 (49.3)
295–442.5	44 (20.8)
442.5–590	19 (9)
> 590	44 (20.9)
Residence	
Tehran city	122 (50.8)
Outside Tehran city	118 (49.2)
Number of children in family with phenylketonuria	
1	210 (90.5)
2	21 (9.1)
4	1 (0.4)
Employment^a	
Housewife	113 (49.8)
Former employee	45 (19.8)
Manual worker	22 (9.7)
Other	47 (20.7)
Patients	
Age (years)	
≤ 1	36 (15.0)
1–5	66 (27.5)
6–10	65 (27.2)
15–11	33 (13.8)
16–20	19 (7.9)
> 20	21 (8.7)

Table 1 Distribution of the parents and patients with phenylketonuria according to demographic characteristics (concluded)

Variable	No. (%) (n = 240)
Sex	
Male	134 (55.8)
Female	106 (44.2)
Age at diagnosis of phenylketonuria	
3–5 days	122 (52.8)
> 5 days	109 (47.2)

*Total is less than 240 because of missing values.

who are treated at an early age generally have an IQ in the normal range (25). Therefore, patients with late diagnosis are faced with mental and physical disabilities that affect all family members.

Tehran residents had a lower QoL in the environmental dimension compared with other towns of Tehran province. Another Iranian study found the environmental dimension scores in different age groups in Tehran city population were significantly lower than in other parts of the world (26). A study in 2008 indicated that personal security and public services have an important role in people's QoL (27). According another Iranian study, the quality of life will

Table 2 Mean scores of the parents of children with phenylketonuria in the World Health Organization Quality of Life-BREF (WHOQOL-BREF) domains

Domain	Raw score	Min–Max	95% confidence interval	Transformed score	
	Mean (SD)			4–20	0–100
Physical	21.23 (2.5)	14–27	20.92–21.55	12	50
Psychological	17.40 (3.8)	8–27	16.89–17.84	11	44
Social relationships	7.96 (2.4)	3–14	7.46–8.27	11	44
Environment	19.79 (2.9)	11–27	19.41–20.16	10	38

SD: standard deviation.

Table 3 Variables associated with quality of life domains of parents of children with phenylketonuria

Variable	Domains			
	Physical Mean (SD)	Psychological Mean (SD)	Social relationships Mean (SD)	Environment Mean (SD)
Hospital				
Children's Medical Centre	21.07 (2.4)	17.19 (5)	8.13 (2.4)	19.65 (2.7)
Mofid	21.28 (2.6)	17.82 (4.1)	7.85 (2.6)	19.82 (3.1)
Aliasghar	21.37 (2.6)	17.63 (3.7)	7.86 (2.2)	19.92 (2.9)
P-value ^a	0.749	0.630	0.757	0.836
Parent's age (years)				
≤30	21.08 (2.7)	17.91 (3.5)	7.44 (2.4)	19.8 (3.1)
31-40	21.7 (2.2)	17.81 (3.9)	7.73 (2.3)	20.2 (3.0)
41-50	20.42 (2.2)	16.08 (4.0)	8.55 (2.6)	18.91 (2.5)
> 50	20.47 (2.2)	16.76 (2.4)	9 (1.8)	19.23 (1.9)
P-value ^a	0.143	0.019	0.003	0.074
Parent's relation to child				
Father	21.41 (2.5)	18 (3.8)	7.98 (2.6)	19.89 (2.8)
Mother	21 (2.5)	17.1 (4.8)	8.02 (2.3)	19.65 (2.9)
P-value ^b	0.916	0.109	0.227	0.747
Marital status				
Married	21.23 (2.5)	17.72 (4.5)	7.85 (2.5)	19.86 (2.8)
Divorced/widowed	20.83 (2.4)	15.7 (3.2)	9.29 (1.7)	18.87 (2.8)
P-value ^b	0.379	0.025	0.714	0.654
Parent's education				
Illiterate	22 (2.6)	17.33 (2.0)	8.66 (2.0)	20.33 (2.5)
Elementary school	21.65 (2.4)	16 (3.9)	9.3 (2.1)	18.88 (2.5)
Middle school	20.8 (3.1)	15.97 (4.9)	8.68 (2.5)	18.7 (2.9)
High school	20.7 (2.4)	17.74 (4.5)	7.85 (2.4)	19.8 (2.7)

Table 3 Variables associated with quality of life domains of parents of children with phenylketonuria (concluded)

Variable	Domains			
	Physical Mean (SD)	Psychological Mean (SD)	Social relationships Mean (SD)	Environment Mean (SD)
Parent's education				
University	21.8 (2.2)	18.64 (3.9)	7.28 (2.3)	20.6 (2.7)
P-value ^a	0.066	0.015	0.002	0.007
Parent's employment				
Housewife	21.06 (2.5)	16.78 (3.7)	8 (2.3)	19.67 (2.9)
Former employee	21.53 (2.0)	18.5 (3.8)	7.5 (2.3)	20.52 (2.5)
Manual worker	20.13 (3.0)	18.04 (8.4)	9.27 (2.6)	18.54 (3.3)
Other	21.69 (2.6)	18 (3.2)	7.82 (2.5)	19.82 (2.6)
P-value ^a	0.127	0.167	0.44	0.61
Monthly household income (US\$)				
≤ 295	20.92 (2.7)	17.41 (4.9)	8.24 (2.5)	19.35 (2.8)
295–442	21.53 (2.1)	18.65 (3.8)	6.97 (2.3)	21.15 (2.7)
442.5–590	21.26 (2.3)	16.57 (3.5)	8.52 (2.4)	20.36 (2.2)
≥ 590	22 (3.0)	17.55 (3.0)	8 (1.8)	18.77 (2.6)
P-value ^a	0.439	0.312	0.025	0.002
Residence				
Tehran city	21.37 (2.4)	16.9 (3.9)	8.29 (2.4)	19.44 (2.6)
Outside Tehran city	21.01 (2.6)	17.77 (3.8)	7.74 (2.4)	20.08 (3.2)
P-value ^b	0.707	0.474	0.796	0.034
Number of children in family with phenylketonuria				
1	20.31 (2.9)	18.02 (4.1)	8.01 (2.4)	22.54 (2.9)
2	21.09 (3.1)	16 (3.1)	8.04 (2.3)	22.09 (2.4)
4	20	18	7	24
P-value ^a	0.51	0.1	0.918	0.702
Child's age (years)				
< 1	21.77 (2.5)	20.17 (6.3)	7.28 (2.7)	20.71 (2.5)
1–5	21.37 (2.7)	17.6 (3.6)	7.57 (2.5)	19.69 (3.0)
6–10	21.24 (2.4)	16.88 (4.0)	8.04 (2.3)	19.72 (2.9)
11–15	20.34 (2.6)	16.96 (4.1)	8.62 (2.5)	19.59 (3.5)
16–20	21.33 (2.2)	16.77 (3.8)	8.55 (2.1)	19.5 (3.5)
> 20	20.85 (2.4)	16 (3.0)	8.9 (1.9)	18.9 (2.2)
P-value ^a	0.157	0.007	0.004	0.049
Child's sex				
Male	21.24 (2.6)	17.27 (3.9)	8.12 (2.4)	19.47 (2.8)
Female	21.23 (2.4)	17.9 (4.9)	7.86 (2.5)	20.15 (2.8)
P-value ^b	0.525	0.520	0.412	0.611
Child's age at diagnosis of phenylketonuria				
3–5 days	21.69 (2.2)	17.52 (4.0)	7.88 (2.6)	20.04 (2.9)
> 5 days	21.07 (2.6)	17.46 (4.5)	8.06 (2.4)	19.67 (2.8)
P-value ^b	0.299	0.773	0.458	0.878

SD: standard deviation.

^aANOVA.

^bt-test.

be different with difference in access to facilities and services and required security and hygiene (28). The parents in our study who were married had a better QoL compared with the divorced and the widow parents.

The social support of a spouse and in a good family environment can help reduce the problems and ease the caring and support of affected children.

Our results indicate that older parents had better QoL

Table 4 Predictors of health-related quality of life in multivariable regression analysis

Domain	Variable	Category	Unstandardized coefficients		P-value
			B	SE	
Physical	Parent's age (years)	≤ 30	1.963	0.8465	0.020
		31–40	2.095	0.7823	0.007
		41–50	0.282	0.7965	0.723
		> 51 (Ref)	–	–	–
Psychological	Parent's education level	Illiterate	0.138	2.2938	0.952
		Elementary school	–2.009	1.0409	0.054
		Middle school	–1.773	0.8662	0.041
		High school	–0.773	0.6796	0.255
		University (Ref)	–	–	–
	Child's age (years)	< 1	2.484	1.2465	0.046
		1–5	1.285	1.1266	0.254
		6–10	0.523	1.1780	0.657
		11–15	0.367	1.2422	0.768
		16–20	0.396	1.4219	0.781
> 20 (Ref)	–	–	–		
Social	Child's age (years)	< 1	–1.485	0.7996	0.063
		1–5	–1.466	0.7371	0.047
		6–10	–0.996	0.7525	0.186
		11–15	–0.193	0.7883	0.807
		16–20	–0.064	0.9255	0.945
		> 20 (Ref)	–	–	–
	Parent's education level	Illiterate	0.132	1.5479	0.932
		Elementary school	1.560	0.7242	0.031
		Middle school	0.694	0.6029	0.250
		High school	0.324	0.4677	0.489
University (Ref)	–	–	–		
Environment	Monthly household income (US\$)	≤ 295	2.024	1.0391	0.051
		295–442	3.303	1.0630	0.002
		442.5–590	3.101	1.2226	0.011
		≥ 590 (Ref)	–	–	–

SE: standard error of the mean.

with regard to the social dimension. These parents had more experience and can build better social relationships. Better educated parents had better QoL for psychological and environment dimensions. A study in the United Kingdom found a positive relationship between higher educated parents and lower level of blood phenylalanine in children (29). A study in Sweden also found that parental education level was significantly associated with blood phenylalanine concentration (30). It appears that better educated parents are better able to manage anxiety, fear and depression, and usually live in a better environment. Parental education with multiple sources of psychosocial support and a positive home environment are likely to be associated with protection against depression (23).

The study had some limitations. Some data were missing for certain demographic variables, such as income and employment, because of the unwillingness

of the parents to share such information. These problems were largely resolved by repeated follow-up visits that explained the objectives of the study to parents and reassured them of the confidentiality of information. On the other hand, despite the rareness of the disease, we were able to recruit a large number of parents in the study which adds to its strength. In addition, as a cross-sectional study the associations found cannot be taken as causality.

Conclusions

The QoL of parents of children with phenylketonuria was low. Interventions are needed to help such parents to cope better with the problems of dealing with a child with phenylketonuria. Family education can increase awareness and improve attitudes of parents. In addition,

more financial support for families, more involvement by support organizations to help fund people with phenylketonuria, and agreement of insurance organizations to cover the medical costs associated with phenylketonuria would be beneficial.

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Qualité de vie liée à la santé des parents d'enfants atteints de phénylcétonurie dans la province de Téhéran (République islamique d'Iran)

Résumé

Contexte : Les parents d'enfants atteints de phénylcétonurie sont exposés au risque d'avoir une qualité de vie réduite.

Objectifs : La présente étude visait à déterminer la qualité de vie des parents d'enfants atteints de phénylcétonurie dans la province de Téhéran.

Méthodes : L'étude a été menée en 2015 sur des parents d'enfants atteints de phénylcétonurie, qui ont été orientés vers trois hôpitaux pédiatriques publics dotés de services prenant en charge la phénylcétonurie dans la province de Téhéran. Les données ont été recueillies à l'aide de la version abrégée en farsi du questionnaire de l'Organisation mondiale de la Santé sur la qualité de vie (WHOQOL-Bref). L'analyse de la variance, le test t, le coefficient de corrélation de Pearson et la régression linéaire multiple ont été employés pour évaluer le lien entre les domaines de la qualité de vie et les caractéristiques sociodémographiques des parents et des enfants.

Résultats : L'étude incluait 240 parents, dont 55 % étaient des mères. La qualité de vie des parents dans les domaines psychologique, environnemental et des relations sociales était faible. Des liens significatifs ont été établis entre les éléments suivants : le domaine physique et l'âge de l'enfant au moment du diagnostic de la phénylcétonurie ($p = 0,044$) ; le domaine psychologique et l'âge des parents ($p = 0,019$), l'âge de l'enfant ($p = 0,007$) et le niveau d'études des parents ($p = 0,015$) ; le domaine des relations sociales et l'âge des parents ($p = 0,003$), leur niveau d'études ($p = 0,002$), le revenu du ménage ($p = 0,025$) et l'âge de l'enfant ($p = 0,004$) ; et le domaine environnemental et le lieu de résidence ($p = 0,034$), le niveau d'études des parents ($p = 0,007$), le revenu du ménage ($p = 0,002$) et l'âge de l'enfant ($p = 0,049$). Dans l'analyse multivariée, l'âge et le niveau d'études des parents, l'âge de l'enfant et le revenu du ménage étaient fortement liés à la qualité de vie des parents.

Conclusion : Compte tenu des faibles niveaux de qualité de vie des parents, il est recommandé de favoriser l'accès à l'éducation et d'accroître le soutien financier.

جودة الحياة الصحية لآباء الأطفال المصابين ببييلة الفينيل كيتون في مقاطعة طهران، جمهورية إيران الإسلامية

كوروش اعتماد، علي رضا حيدري، آريا ستوده، أمير شايخانراد، أتوسا أخلاوي، مريم عزيزي، روبا نيجات نجسن، مريم بجلار، منصوره لطفي

الخلاصة

الخلفية: آباء الأطفال المصابين ببييلة الفينيل كيتون معرضون لخطر انخفاض جودة الحياة.

الأهداف: حددت هذه الدراسة جودة حياة آباء الأطفال المصابين ببييلة الفينيل كيتون في مقاطعة طهران.

طرق البحث: أُجريت الدراسة في عام ٢٠١٥، وشملت آباء الأطفال المصابين ببييلة الفينيل كيتون الذين أُحيلوا إلى ثلاثة مستشفيات حكومية للأطفال في مقاطعة طهران تُقدم خدمات الرعاية الصحية لحالات بييلة الفينيل كيتون. وقد جُمعت البيانات باستخدام النسخة الفارسية من استبيان منظمة الصحة العالمية بشأن جودة الحياة. واستُخدم تحليل التباين، واختبار «تي»، ومعامل ارتباط بيرسون، والانحدار الخطي المتعدد لتقييم العلاقة بين مجالات جودة الحياة والخصائص الاجتماعية السكانية للأبوين والطفل.

النتائج: شملت هذه الدراسة ٢٤٠ أباً وأماً؛ ٥٥٪ منهم من الأمهات. وكانت جودة حياة الأبوين منخفضة في العلاقات النفسية والاجتماعية ومجالات البيئة. كذلك تبين وجود علاقات مهمة بين: المجال البدني وعمر الطفل عند تشخيصه ببييلة الفينيل كيتون (القيمة الاحتمالية = ٠,٠٤٤)؛ والمجال النفسي وعمر الأب/ الأم (القيمة الاحتمالية = ٠,٠١٩)، وعمر الطفل (القيمة الاحتمالية = ٠,٠٠٧) والمستوى التعليمي للأب/ الأم (القيمة الاحتمالية = ٠,٠١٥)؛ ومجال العلاقات الاجتماعية وعمر الأب/ الأم (القيمة الاحتمالية = ٠,٠٠٣)، والمستوى التعليمي (القيمة الاحتمالية = ٠,٠٠٢)، ودخل الأسرة (القيمة الاحتمالية = ٠,٠٢٥) وعمر الطفل (القيمة الاحتمالية = ٠,٠٠٤)؛ ومجال البيئة والإقامة (القيمة الاحتمالية = ٠,٠٣٤)، ومستوى تعليم الأب/ الأم (القيمة الاحتمالية = ٠,٠٠٧)، ودخل الأسرة (القيمة الاحتمالية = ٠,٠٠٢)، وعمر الطفل (القيمة الاحتمالية = ٠,٠٤٩). وفي التحليل المتعدد المتغيرات، تبين وجود ارتباط كبير بين عمر الأبوين ومستواهما التعليمي، وعمر الطفل، ودخل الأسرة وبين جودة حياة الآباء.

الاستنتاجات: نظراً لانخفاض مستويات جودة حياة الآباء، يُوصى بمزيدٍ من الدعم التعليمي والمادي.

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Mapping stakeholders of the Palestinian Health Research System: a qualitative study

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Abstract

Background: There is a growing international and regional interest in Health Research Systems (HRSs) in light of a global strategy for HRS stakeholders' (HRSSHs) active involvement. HRSSHs in Palestine have rarely been investigated with regard to uncertainties.

Aims: This study aimed to analyse perceptions of HRSSHs in order to understand their roles and involvement, identify gaps, and offer policy solutions for stakeholders' engagement in the Palestinian HRS.

Methods: This qualitative study targeted three local Palestinian health sectors, government, academia, and local and international agencies. Data were collected through 52 in-depth interviews (IDIs) and 6 focus group discussions (FGDs) and then analysed using MAXQDA 12 software. Participants and institutions were selected purposively based on a set of criteria and peer review.

Results: The overall HRS stakeholders' roles were unsatisfactory, with low involvement from society, the private sector, local and international sectors. The role of academia and the Ministry of Health is vital but observed moderate in health research while that of international agencies is weak due to conflicting agendas and lack of a guiding body. Most universities have poor representation in public decision-making and scarcity in health research potential and capacity. Interest–power imbalance among stakeholders is reported where political, organizational, and technical shortfalls were indicative of weak roles and low involvement, along with a lack of health research culture, structure, resources, defined roles, and network.

Conclusions: Tackling the inadequate roles, interests' disparity, and poor involvement of HRSSHs is imperative for HRS strengthening. Redefining HRSSHs' roles and involving all stakeholders is key through strategic dialogue, consolidated leadership, and resource mobilization.

Keywords: Health experts, health research system, stakeholders, Palestine

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Introduction

Health Research System (HRS) is a system encompassing people, institutions and activities to generate high-quality knowledge to be utilized in health improvement (1). HRS involves not only the health sector but also key sectors such as science, education, economy, technology or development systems, or indeed aspects of international or private research systems (2). Stakeholders are a key pillar of the HRS who gain in terms of research regulation, production and utilization. This pillar is interconnected and indispensable for any successful HRS, and it is essential to tackle it in system analysis and mapping. Therefore, the World Health Organization (WHO) definition of HRS has delineated two levels of stakeholders – people and institutions (1). Such people are officially engaged in health research (HR) across different institutions of the Palestinian healthcare system. Their primary task is to

boost the capacity and productivity of the HRS to be utilised in health decision-making (3).

HRS is a complex issue with diverse actors and contexts (4) and the lack of common understanding is rooted in its multi-disciplinary nature. Since it has impacts on, and relationships with other key systems, a holistic building and analysis approach is required to fulfill the system's potential in order to attain health and comprehensive development (5). HRS stakeholders (HRSSHs) are the dynamic engine of all HR operations; consequently, grasping their roles, relationships and level of involvement is essential. They can affect or be affected by the HRS and are considered an important source of information and critical perspectives (2).

For system understanding and strengthening, different conceptual HRS frameworks that identified HRS boundaries were used (6,7). In addition, a wide-

range analysis approach was employed using a stakeholder analysis technique (8) to map HRSSHs. This useful combination technique was adopted to identify stakeholders' influence and importance that may significantly impact HRS success (2,9). The technique was also applied to examine stakeholders' engagement across the HR process, from setting up priorities to disseminating results (10). The advantage of HRSSHs' involvement increases the utilization of HR to support the healthcare system's performance and subsequently promote population health (11,12). By contrast, stakeholders' disengagement creates gaps in the formulation of HR policies and priorities (12).

Even though the support of international HRSSHs, particularly donors' support, is indispensable and needs to be used effectively to build proper research institutions (13), their contribution is often inadequate and conflicting (14). For example, one concern that should be addressed in Palestine as a main aid recipient country is the negative influence of donors on the local research and policy agenda (15,16). Therefore, understanding the role of international HRSSHs as aid suppliers is important to ensure effective use of their contribution to strengthen the HRS in Palestine.

As a central pillar of HRS, this study addresses the HRSSHs issue as the first national study in Palestine and the region (17). The study is the fourth study of a larger research project that investigated all HRS components, which is a necessity not only for the healthcare system but also for Palestine in general as an emerging state. The overall aim is to understand the roles and contributions of HRSSHs in order to bridge the knowledge gap and provide demonstrable strengthening insights to decision-makers. Four objectives were formulated to achieve this aim:

1. Explore the roles, functions and responsibilities of local HRSSHs in the Palestinian HR arena.
2. Assess the role of international agencies and institutions with regard to HR support and contributions.
3. Map the level of involvement and influence of national and international HRSSHs.
4. Determine weaknesses and propose improvements to promote active involvement of HRSSHs.

Methods

This qualitative study used a similar design to other local studies relying on different system analysis frameworks developed by Pang et al. (2,3) framework, system thinking, and comprehensive HRS assessment. The same tools were used and included a set of dedicated questions on HRSSHs. The study targeted a diverse group of stakeholders including experts, policy-makers, academics, and directors from the three relevant Palestinian sectors: government, academia, and local and international non-governmental organizations (NGOs). The methods of data collection, management and analysis were similar to other national studies (18,19). Data were collected through 52 in-depth interviews (IDIs) and 6 focus group

discussions (FGDs) and then analysed using MAXQDA 12 software (VERBI GmbH, Berlin, Germany). Participants and institutions were selected purposively based on a set of criteria and peer review.

In order to obtain a precise realization of HRSSHs involved in HR in Palestine and map appropriately their roles and influence, the study approached the participatory stakeholders' analysis through three methods relying on experts' perspectives, the principal investigator's knowledge, and pertinent literature. The analysis was completed through the three approaches of analysis: the conceptual context of experts (participants' perceptions), the HRSSHs involvement-roles continuum, and the HRSSHs power-interest grid.

Ethics clearances

The Research Commission of Swiss TPH approved the study (FK No. 122; approval date: 21 October 2015). Ethical approval was also obtained from Ethikkommission Nordwest und Zentralschweiz (EKNZ) in Switzerland (reference No. UBE-15/116; approval date: 23 January 2016). Ethical and administrative approval was received from the Palestinian Ministry of Health (approval date: 28 April 2016); the institutional review board of Helsinki Committee in Palestine (reference No. PHRC/HC/73/15; approval date: 7 December 2015); and the institutional review board (IRB) at Najah National University (NNU) (reference No. 112/Nov./2015 (approval date: 6 December 2015).

Results

The findings cover two domains: 1) socio-demographic characteristics of study participants; and 2) the overall status of local and international HRSSHs.

Socio-demographic characteristics of study participants

This aspect was clearly illustrated elsewhere in the literature, which addressed other HRS topics in Palestine (18,19). Overall, the study participants had diverse backgrounds and leadership positions. The majority were educated to doctoral level and held more than 20 years of experience, particularly those participants from NGOs. One third of the participants were female. Participants and their institutions were distributed as follows: 18 experts from 8 academic institutions, 19 participants from 15 NGOs (10 local and 5 international), and 15 participants from governmental institutions.

The status of HRSSHs

There were four aspects related to HRSSHs: 1) the role and responsibilities of HRSSHs; 2) their level of involvement; 3) power/interest factor; and 4) the role of international actors in HR.

The role and responsibilities of HRSSHs

As indicated in Table 1, the findings on the role of the HRSSHs were combined where national stakeholders' roles were not appreciated by the majority of experts. Most of the responses were distributed into two catego-

ries: negative perceptions and positive perceptions. Responses to the first category were the most frequent and reflected a conservative and unfavorable perception of the role of HRSSHs and reflected by a diverse spectrum of remarks, such as: “non-robust and weak”, “fragmented and seasonal”, “unsatisfactory and inadequate”, “unfulfilled”, “competitive and non-integrative”, and few echoed, “there are no stakeholders”. In contrast, the positive and more specific category was less frequent. Responses included: “somewhat cooperative”, “impressive at the micro-institutional level”, “a pivotal and good academic role while weak at the governmental level”, and “all roles are improving and can be better”. Three specific quotes reflected this, with a government expert stating: “All HRSSHs are working independently”; an academic added: “weak role due to the producer–user gap where HR production is personal”; while an NGO expert echoed “each party does its best but the overall role is not as wished”.

In a relevant context, a number of experts agreed principally on the importance of the binary-role of the Ministry of Health (MoH) and academia in HR. Experts emphasized the unilateral regulatory and governing role of the MoH through the Palestinian National Institute of Public Health (PNIPH), and to remain a major reference, funder and user of HR. However, some NGOs experts in focus group discussions strikingly disagree on the mandate and capacity of the institute with regards to HR. Alongside some academics, they criticized the government’s role in managing, funding and directing HR. Although a few praised the role of the Ministry of Higher Education (MoHE) in embedding scientific research in curricula and supporting research initiatives, some described these initiatives as individualistic. The question of who can share the role of MoH and other government ministries was controversial. Some suggested that academia could take up this role, others referred to WHO, and a few expressed the opinion that all relevant parties need to be involved. Some experts argued that the academic role is limited to HR production only, although two academics criticized the low level of this role. Remarkably, the financing role of both private, local and international NGOs sectors is criticized by a group of experts among the three sectors. An NGO expert echoed that the INGOs are important in the HR scope. In contrast, an expert from the same sector refuted this perception.

The pattern of stakeholders’ involvement

Figure 1 illustrates the involvement level of HRSSHs, which also reinforces many of the aforementioned pertinent perceptions. The continuum figure represents the actors through three dimensions: institutional and societal, individual, and assigned roles. The continuum has a dualistic explanation: 1) depicts the current level of engagement of the HRSSHs according to the demonstrated three dimensions; and 2) indicates that the current representation is a factual reflection of a successful HRS, but on condition that the scaling up of the three dimensions to a higher level is ensured. In other words, tri-involvement, society–institution–individual, needs to be constantly maximized, so that each role becomes representa-

Table 1 Perception of experts towards the role of HRSSHs

HRSSHs role	
Government	<ul style="list-style-type: none"> - Not strong - Vital academic role - Still weak - A great at the micro-institutional level - To some extent cooperative role - Cannot evaluate their disorganized role due to no system - All stakeholders are working independently - Overall role is not satisfying
Academia	<ul style="list-style-type: none"> - Their roles are negatively performed - Not good due to disorganized and unvalued HR among care providers - Competitive roles rely on personal interests - Insufficient role with unclear tasks - Limited and need empowerment - All do not perform their role as required due to individualism and system gap - Their roles are dispersed - Weak roles due to the producer-user gap and producing HR for personal goals - There are no stakeholders - Individual roles and agendas
NGOs	<ul style="list-style-type: none"> - Each party do its best but the overall role is not as wished - Disintegrated sectorial work with a shortage in their assigned roles - Inadequate where most of their role is just services provision - Lacking a good linkage among all with unsatisfactory roles of gov. and academia - Vague roles, care provider or HR regulator - Difficult to evaluate their roles while no structure or system - Academia role is good but the government is inefficient - Fragmented and seasonal efforts - All Stakeholders are playing an important role - They do not work collaboratively - Their role is improving and can be better - A competitive role rather than complementary teamwork - No, they are not well-performing with a server performance shortage - Many attempts but unsatisfactory roles - Current roles are completely fragmented

tive and weighted in HRS. Certainly, the first dimension showed government and academia as the most involved parties, while the private sector and community were insufficiently involved. Finally, as experts delineated, most of the assigned roles of the HRSSHs in the continuum are almost identified realistically, with varying levels of government and academic involvement in HR, but both actual roles remain weak.

Mapping HRSSHs in accordance to Power/interest Grid

Figure 2 displays the distribution grid of HRSSHs in Palestine. This analytical grid aims for a better understanding of the actors’ interactions and influence and it comprises four quadrants. Four national bodies, academia, and WHO are almost located in the first quadrant, high power–high interest, where most Palestinian academic institutions are national NGOs. The second quadrant shows high power–low interest, and includes most of

Figure 1 Current HRSSH's involvement, individual, and their roles

Involvement Continuum					
Low				High	
Institutional and Society Involvement					
Community	Banks, companies, pharmaceuticals industries, private sector, financial institutions, private hospitals, Palestinian businessmen	All international health agencies, INGOs, International research centers, donors, development partners, UN agencies, UNRWA, WHO, UNICEF	All local health NGOs, professional associations, health providers, hospitals	National universities, medical colleges, Public health schools, University hospitals, research centers, educational institutions	MOH, MOE, MOHE, MOFP, MOW, MOA, MOL, MOJ, MOSA, PHDs, PCBS, National Councils & Centers, Hospitals, Ministries, PSIs, HIS, PNJPH
Individual Involvement					
Members	Businessmen, capitalists, representatives	Decision makers, representatives, researchers	Policy makers, all health professionals, care providers, representatives, researchers	Policy makers, academics, researchers, deans, students	Policy and decision makers, strategic planners, care providers, all health professionals
Involved Stakeholders Roles					
Feedback giver, facilitator	Funder, partner	HR supporter, funder, technical advisor	Facilitator, user, funder, producer	Producers, data user, responsible HR producer, important player	Facilitator, main governor, user, strategies developer, regulator, producer, fundamental reference

MOH: Ministry of Health, MOE: Ministry of Environment, MOHE: Ministry of Higher Education, MOFP: Ministry of Finance and Planning, MOW: Ministry of Water, MOA: Ministry of Agriculture, MOL: Ministry of Labour, MOJ: Ministry of Justice, MOSA: Ministry of Social Affairs, PHDs: State Public Health Departments, PCBS: Palestinian Central Bureau of Statistics, PSIs; Palestinian Standards Institution, HIS: State Health Information System, National Councils & Centres (SRC: Scientific Research Council, SPHC: The Supreme Palestinian Health Council, PCHR: Palestinian Council for Health Research, HCIE: Higher Council for Innovation & Excellence, PNIPH: Palestinian National Institute of Public Health, PMC: Palestine Medical Council), NGOs: Non-governmental Organizations, INGOs: International NGOs, UN: United Nations, WHO: World Health Organization, UNRWA: The United Nations Relief and Works Agency for Palestine Refugees in the Near East, UNICEF: United Nations Children's Fund

the government ministries and the highest sovereign institutions, headed by the president, Palestinian legislative council (PLC), Cabinet, and MoH. Low power–high interest is the third quadrant, which shows the lowest stakeholders' representation, excluding certain academic institutions and INGOs. The last quadrant is low power–low interest, where few national bodies, most INGOs, local NGOs, the private sector, professional associations, and community are situated. Importantly, the overall reflection is that the majority of national and governmental bodies dominate the power structure, but with a low interest in HR. Unlike international and local NGOs, private and community institutions that have low power, as well as academia and some INGOs who possess moderate power and a prominent interest, contribute best to HR.

The role of international actors in health research in Palestine

As demonstrated in Table 2, the general perception indicates that the international role in supporting HR is currently indispensable but ineffective. This is evidently shown in the majority of experts' beliefs that this role is still at a low level; a few experts hailed the financial and technical role, but on an ad-hoc basis with a non-strategic motive and value. A substantial agreement across the three sectors was observed with regards to the factors behind the weakness of this role, which were:

1. Political – fund conditions, donor agendas, and political mandates.
2. Opaque factors influencing donor's roles; unsustain-

able, unpredictable and inadequate resources, and essentially low interest to HR.

3. Factors related to their operational role, as mainly emergency-based, humanitarian-oriented and project-driven and with a short-term scope. Donors' activities do not meet local needs, and their selective support for HR is often related to evaluating their own implemented programmes.

Two policymakers delineated “plays a positive role but insufficient and unsystematic in supporting advanced HR”; an academic viewed that, “this role is not efficient and unsustainable, and far from our interest”; while NGOs noted that, “the role is majorly humanitarian-focused”.

The findings came with a range of thoughts for solutions to enhance this role. One important solution, which was frequently expressed by experts, is the need to speed up forming a unified national advisory policy entity for HR; a few suggested the PNIPH for this assignment. This body's mission with the involvement of all HRSSHs would be to formulate a national strategy, including a national fund for regulating, prioritizing and funding HR. In light of this strategy, it is important to focus on revitalizing the leadership role of MoH and/or PNIPH to allocate and manage the international fund appropriately towards HRS components, primarily investing in human and infrastructure capacity building. Furthermore, a strategic dialogue led by MoH with local and international donors needs to be

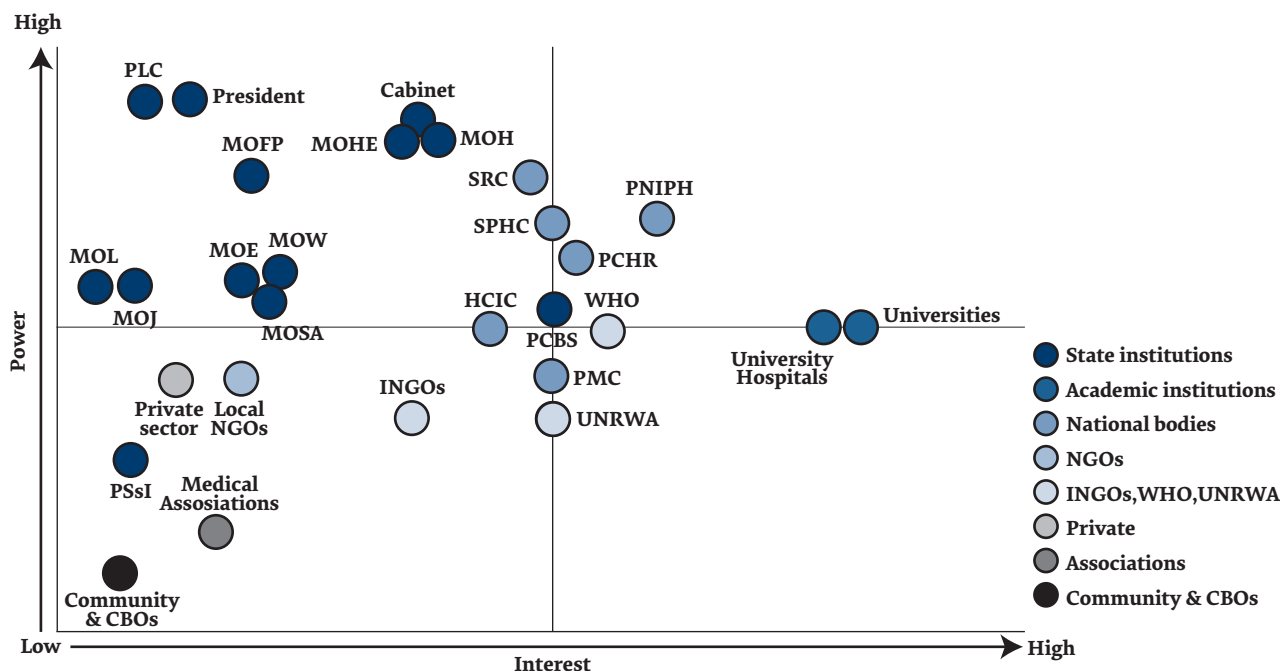
Table 2 The international role in health research (HR) in Palestine

Sector	Description of the role	Enhancing factors
Government	<ul style="list-style-type: none"> - Supports some HR, clearly, their role does not reach the required level - No remarkable role and their HR minimally address our needs - Unclear role and performed according to their agendas - They fund some scientific events and selective HR with limit involvement depending on their agendas - Do not know sufficiently about their role, but generally based on initiatives and remains inadequate - Do not know well but I think they fund HR based on need - A valued role but focuses only on finance assistance - Plays a positive role but insufficient in supporting advanced HR such as radiation exposure, oncology, etc - Plays an important role but in unsystematic approach - Their role depends on their agenda - Essential role and indispensable sponsor - The national HR relies on donors due to no state budget and body 	<ul style="list-style-type: none"> - Agreed national HR vision and agenda is a priority to gear this role - Their role is crucial to help institutions in HR utilization and benefiting from their experience - Regular prioritization exercise is crucial - Technical and financial support together are needed - Optimal use of resources should be adopted
Academia	<ul style="list-style-type: none"> - The majority of actors implement relief projects rather than HR - Their fund is decreasing, health is not a priority instead of the security sector and projects-based - Their role seeks to fulfill their agenda, should not be relied on - Funding their own agenda and HR is not their priority - A fundamental role but influences HR priorities - It is not that efficient and sustainable, the role is far from our interests - Their fund is the main source but the role is questionable - They play a key role but insufficient - Conditioned fund according to their goals - It is supportive concerning the technical assistance - Funding HR that are related to their projects and serves their ideologies - It is emergency and relief-oriented - Relies on donor goals with a lack of attention to HR does not meet our needs - It is selective and based on projects meeting their priorities - Supports HR but according to their ideologies 	<ul style="list-style-type: none"> - Urge to promote the role of the influential role and guiding duty - Establish long-term funding with solid commitment based on national HR developmental strategy - A reform HR strategy to improve its operations - Collective national involvement is a demand includes international players in HR planning and implementation relying on national health needs - A national health institute or council could be the PNIPH, to be a body to manage the international efforts - A strategic dialogue is required to find a common point gaping the donor agenda and the national priorities - A need for fund diversification not relying on one source and maximizing the national funding through companies, banks, diaspora Palestinian communities, and associations. Etc. - Urge the donor's fund to be invested in capacity building programs and resources provision - Partnerships with internal and international players
NGOs	<ul style="list-style-type: none"> - I do not think that it is important where their goals are political - Political and does not consistent with the Palestinian population needs - Mentioning their role makes me nervous where Palestine is out of their priorities - It is a prominent role - Actually, do not know but there are some research projects supported externally - An important role but imposes their agenda where HR is not in their scope - Has its own agendas - Most of the donors work on relief and emergencies and support HR to evaluate their programmes - Provides the government technical and financial support related to the health system and research - It has a major role mainly in humanitarian crises - It neglects to establish HR body without attention from MOH - I do not think that it has a major role in HR where the huge fund goes to the MOH operations - It is the second source works on agendas and directed for relief projects not purely for HR - Finances HR according to its agenda - It is limited and does not meet the scientific research 	<ul style="list-style-type: none"> - Promote their role in getting a state political independence - Using it in empowering our human resources - Founding a national supervisory committee to guide this fund appropriately - This fund needs to be linked with a clear strategic vision reflects the society needs and - Government leaders should build a collective body and national HR network and need to settle HR and to be guided by other abroad successful experiences - A solid agreed HR vision which must not be changed by all kinds of funding while this funding should serve this vision - Donors duty is to monitor and evaluate the fund but not to impose agendas - Palestinian institutions and donors should focus on needs not on finding and irrelevant agendas - Institutional HR units across local and donors need to be established.

launched in order to formulate a common and long-term vision linking their fund structurally with the local HR needs and priorities. Other perceptions emphasized that maximizing and diversifying fund sources for a sustainable funding pledge is indispensable and should

be managed by appealing to national institutions, individuals and communities abroad. Furthermore, optimizing the use of resources and prioritizing HR on a regular basis through solid technical and governance procedures. Another reported enhancing factor was

Figure 2 Current HRSSHs Power/interest grid



PCL: Palestinian Legislative Council, MOHE: Ministry of Higher Education, MOFP: Ministry of Finance and Planning, MOL: Ministry of Labour, MOJ: Ministry of Justice, MOE: Ministry of Environment, MOW: Ministry of Water, MOSA: Ministry of Social Affairs, PCBS: Palestinian Central Bureau of Statistics, PSSi: Palestinian Standards Institution, SRC: Scientific Research Council, SPHC: The Supreme Palestinian Health Council, PCHR: Palestinian Council for Health Research, HCIE: Higher Council for Innovation & Excellence, PNIPH: Palestinian National Institute of Public Health, PMC: Palestine Medical Council, NGOs: Non-governmental Organizations, CBOs: Community Based Organizations, INGOs: International NGOs, WHO: World Health Organization, UNRWA: The United Nations Relief and Works Agency for Palestine Refugees in the Near East

defining the role of the donors in the supervision, monitoring and evaluation of this fund, which should be done under state leadership. Lastly, donors should be urged to establish HR units associated with the national HR body and, more importantly, their technical assistance and fund should be harnessed for establishing sustainable HRS in Palestine.

Discussion

This study dealt with one of the most important pillars of the HRS (3) – analysing the involved HRSSHs in the Palestinian HR arena. As HRS has a complex and diverse context (2,4) and is under growing attention (1,5,19), the findings of this study can be helpful to Palestinian policy-makers with regard to understanding the pattern and network of stakeholders in order to move forward towards a successful HRS based on active participation.

As a substantial pillar, HRSSHs forms the primary driving force of the HRS; analysing their views gives a better understanding of how to improve their roles and performance (20). The study found that the overall role of the Palestinian HRSSHs is below the required level (21), evidently described as unsatisfactory and scattered. In other words, such roles have been criticised as being severely deficient in terms of HR funding, production and application. Such findings largely intersect with another pertinent study (22) that found fragmented HRS roles are assumed to be a leading problem and resulting in system under-performance. The proposed bilateral functional roles, such as the MoH with academia or other bodies, are not an effective solution

under various system contexts. Hence, as the literature suggests (4,21), a participatory, representative and inclusive approach would be more appropriate under an agreed governing framework.

In the Palestinian HR context, the government and academia – whether institutional or individual – are clearly involved, but still play an insufficient role, which hinders the strengthening of HR outputs for translation into sound health policy (8). In return, the less involved stakeholders such as private NGOs and the community are likely related to structural system problems. This indicates that all parties have different and sometimes conflicting agendas. These results were notably inconsistent with WHO’s HR strategy that calls for sectorial inclusiveness and strategic partnerships among all HRSSHs (23). Likewise, the literature urges for harmony between the system and HRSSHs goals (4) and HRS values and principles (21), as HR agendas are increasingly shaped by players’ involvement (2).

In fact, a power–interest interface is a valuable supplementary approach for a better understanding of the actors’ interaction in HRS. In this study, it was observed that the government bodies own the power factors with a significant low interest. This may be interpreted as the need to consult and satisfy these bodies carefully to meet their needs. However, actors with a moderate power and a good HR interest, such as academia, PNIPH, and WHO, are required to expand their roles and involvement (24). The overall indication on this issue is the lack of official attention, orientation, and investment in HR, which is consistent with previous studies from Palestine (18) and

elsewhere (6,25–28). Importantly, the community, private industry, and INGOs, which are inactive when it comes to HR, are also important groups to be involved due to their untapped influence (1,2,8,21,28,29).

Undoubtedly, the donors' role in supporting HRS in fragile settings is crucial as long as it is directed meaningfully to serve crisis management (30). Their role in building proper research institutions is perceived as weak and unclear in Palestine (15,31,32); consequently, donors rarely run HR. Their investment in HR is selective, driven by external agendas with unsustainable funding (28), and mostly emergency-based projects. Because Palestine faces unstable political, economic and social pressures, this fund should be harnessed jointly and optimally in HR as a vital development pillar to meet long-term national needs. To achieve this, a collective national body, which may be led by the MoH or another national entity such as PNIPH, should harness this fund and technical aid and usefully align with a national vision (33) supported by a collaboration strategy. The Paris Declaration–Accra Agenda for Action and ESSENCE are initiatives dedicated to donors' efforts alignment on HR. Such international decrees are needed in the Palestinian HRS to improve the coordination and harmonization of research capacity investments (14,34).

Limitations

Although this study contributes to bridging the knowledge gap, a scarcity of literature and reports was noted. Furthermore, movement restrictions due to political instability and study time constraints were also a limitation to capture more participants and institutions. Eventually, gathering quantitative data on HR stakeholders was hindered

by the lack of data availability, quality and accessibility.

Conclusion

Stakeholders are a central component of the HRS where it forms the functional driving force. Therefore, understanding their roles is a prerequisite for any strengthening effort. The performance of the HRSSHs is generally below the required level, although both academia and MoH moderately play important roles. Distinctly different from the development and services NGOs, it is worth mentioning that the majority of universities in Palestine are national NGOs, where their poor representation in public decision-making and potential scarcity hinders a growing academic interest in HR. In summary, the weakness of HRSSHs roles and involvement is the result of political, organizational and technical shortfalls. Imbalance in the interest–power pattern among stakeholders is considerably reported. The critical need is to enhance the involvement balance and correcting pattern of a power–interest factor among all stakeholders to get them all involved, interested and influential. All HRSSHs roles should be appropriately redefined and invested at the official level and work synergistically to reach a high power–interest. Undoubtedly, as it is also applied to the capacity components of HRS, establishing a clear strategy with a collective involvement is a serious demand. It is clear that the role of external donors in supporting HR is substantially inadequate given the paucity of domestic resources and instability. This role needs to be strengthened through a long-term plan that reflects the national needs and a comprehensive strategic dialogue among local and international parties is important and desirable.

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Cartographie des parties prenantes du système de recherche en santé palestinien : étude qualitative

Résumé

Contexte : Il existe un intérêt croissant, aux plans régional et international, pour les systèmes de recherche en santé du fait de la stratégie mondiale consistant à impliquer activement les parties prenantes desdits systèmes. Ces dernières ont rarement fait l'objet d'études portant sur leurs incertitudes en Palestine.

Objectifs : La présente étude visait à analyser les perceptions des parties prenantes des systèmes de recherche en santé, afin de comprendre leurs rôles et leur implication, d'identifier les éventuelles lacunes et d'offrir des solutions politiques à leur engagement dans le système de recherche en santé palestinien.

Méthodes : Cette étude qualitative ciblait trois secteurs locaux de la santé en Palestine, les agences gouvernementales, universitaires, et locales et internationales. Les données ont été recueillies par le biais de 52 entretiens approfondis et de six discussions thématiques de groupe, puis analysées à l'aide du logiciel MAXQDA 12. Les participants et les établissements ont été sélectionnés intentionnellement sur la base d'un ensemble de critères et d'un examen collégial.

Résultats : Globalement, les rôles des parties prenantes du système de recherche en santé n'étaient pas satisfaisants. Ils démontraient en effet un faible degré d'implication de la part de la société, du secteur privé et des secteurs local et international. Le rôle des universités et du ministère de la Santé est vital, mais on observe qu'ils jouent un rôle modéré dans la recherche en santé. Celui des agences internationales est mineur en raison de la divergence de leurs programmes et de l'absence d'organe directeur. La plupart des universités sont mal représentées dans les processus de prise de décision publique et doivent faire face à la pénurie des potentiels et des capacités en matière de la recherche en santé. Un déséquilibre entre intérêt et moyens a été relevé parmi les parties prenantes, avec des déficits politiques, organisationnels et techniques indicatifs de la faiblesse des rôles et de l'implication. On note par ailleurs des insuffisances en termes de culture, de structure, de ressources, de définition des rôles et de réseau relativement à la recherche en santé.

Conclusions : Il est impératif de s'attaquer à l'inadéquation des rôles, à la divergence des intérêts et au faible degré d'implication des parties prenantes des systèmes de recherche en santé si l'on veut renforcer ces systèmes. Pour ce fait, il importe de redéfinir les rôles des parties prenantes et de les impliquer toutes par la voie d'un dialogue stratégique, d'un encadrement renforcé et d'une mobilisation des ressources.

تحديد أصحاب المصلحة في النظام الفلسطيني للبحوث الصحية: دراسة نوعية

محمد الخالدي، عبد السلام الخياط، كونستانزي بيفير، سليم حاج يحيى، حمزة مغاري، حسن أبو عبيد، علي شعار، يوسف الجيش، مارسيل تانر، يحيى عابد

الخلاصة

الخلفية: يتنامى الاهتمام الدولي والإقليمي بنظم البحوث الصحية في ضوء الاستراتيجية العالمية لإشراك أصحاب المصلحة بفعالية في نظم البحوث الصحية. وفي حالات نادرة فقط جرى الاستقصاء بشأن أصحاب المصلحة في نظم البحوث الصحية في فلسطين فيما يتعلق بأوجه عدم اليقين.

الأهداف: هدفت الدراسة إلى تحليل تصورات أصحاب المصلحة بشأن نظم البحوث الصحية لاستيعاب أدوارهم، وكيفية إشراكهم، وتحديد الثغرات، وعرض حلول للسياسات بخصوص إشراك أصحاب المصلحة في نظم البحوث الصحية الفلسطينية.

طرق البحث: استهدفت هذه الدراسة النوعية ثلاثة قطاعات صحية فلسطينية، وهي الحكومة، والأوساط الأكاديمية، والهيئات المحلية والدولية. وقد جُمعت البيانات من خلال عقد ٥٢ مقابلةً معمقة، و٦ مناقشات ضمن مجموعات بؤرية، ثم خضعت للتحليل ببرنامج تحليل البيانات النوعية MAXQDA ١٢. واختير المشاركون والمؤسسات اختياراً عمدياً، استناداً إلى مجموعة من المعايير ومراجعة الأقران.

النتائج: كانت الأدوار التي يضطلع بها أصحاب المصلحة في نظم البحوث الصحية غير مرضية عامةً، بالإضافة إلى انخفاض مستوى المشاركة من جانب المجتمع، والقطاع الخاص، والقطاعات المحلية والدولية. وكان الدور المهم الذي تؤديه الأوساط الأكاديمية ووزارة الصحة متوسطاً، بينما كان دور الهيئات الدولية ضعيفاً نظراً لتضارب الخطط وعدم وجود هيئة توجيهية. أيضاً فإن تمثيل الجامعات ضعيف في عملية صنع القرار، علاوةً على ندرة الإمكانيات في مجال البحوث الصحية. ويوجد اختلال في توازن المصالح والقوى بين أصحاب المصلحة، ويُستدل من أوجه القصور في النواحي السياسية، والتنظيمية، والتقنية على ضعف الأدوار والمشاركة، بالإضافة إلى الافتقار إلى ثقافة البحوث، وهيكلية لمنظومة البحث الصحي، الموارد وأدوار مُحددة لشبكة الأطراف ذات العلاقة.

الاستنتاجات: من المحتمل معالجة عدم كفاية الأدوار، وتباين المصالح، وضعف مشاركة أصحاب المصلحة في نظم البحوث الصحية بغية تعزيز هذه النظم. ويلزم أساساً إعادة تعريف أدوار أصحاب المصلحة وتحديدها في نظم البحوث الصحية من خلال حوار استراتيجي، وقيادة موحدة، وتعبئة الموارد.

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Prevalence of overweight and underweight in schoolchildren in Constantine, Algeria: comparison of four reference cut-off points for body mass index

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Abstract

Background: Algeria is experiencing a nutritional transition and increasing overweight in children.

Aims: This study aimed to determine the prevalence of overweight and underweight in children aged 6–10 years in Constantine city, Algeria using four international reference cut-offs for body mass index.

Methods: A cross-sectional study was conducted between February and May 2015 with a sample of 509 schoolchildren aged 6–10 years. Height and weight were measured according to World Health Organization (WHO) recommendations. The body mass index cut-offs of WHO, International Obesity Task Force, Centers for Disease Control and Prevention (CDC) and French national references were used to classify the sample as underweight and overweight according to age and sex. The kappa coefficient was used to assess agreement between the reference cut-offs.

Results: Based on the of different reference cut-offs, the prevalence of underweight in the children varied from 1.4% to 8.8%. The prevalence of overweight varied from 22.8% to 28.3%. The WHO cut-off gave a significantly higher prevalence of overweight in boys than girls (32.6% versus 24.0%, $P = 0.03$). The kappa values (between 0.251 and 0.954) indicated a fair to excellent agreement between the different reference cut-offs.

Conclusion: The prevalence of overweight and underweight differs in the Constantine children depending on the reference cut-off used, suggesting international references should be used with care to avoid potential misclassification of children's nutritional status.

Keywords: child, body mass index, nutritional status, overweight, underweight, Algeria

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Introduction

Overweight is increasing in children worldwide while underweight is decreasing in many countries. Among children in developing countries, underweight is still a greater problem than overweight. However, many countries have experienced a rising trend in the prevalence of overweight children (1,2). This shift is attributed to marked changes in lifestyles including increased sedentary behaviour and the introduction of westernized poor-quality diets and drinks. This nutritional transition is underway, at varying rates, in most developing countries, including Algeria.

In Algeria, we do not have representative nationwide studies on the prevalence of overweight and obese children older than 5 years. Local studies conducted in some regions do not allow defining the nationwide prevalence. However, they raise awareness that overweight and obesity in children in Algeria is increasing and could become a real public health problem. In Constantine, based on a sample of 19 263 children aged 6–10 years, the prevalence of overweight including obesity increased from 6.8% in 2001 to 9.5% in 2006 and the prevalence of underweight decreased from 34.3% to 24.5% (3).

Body mass index (BMI) is used extensively to measure malnutrition. Various international BMI reference cut-offs are available to determine the prevalence of malnutrition, particularly overweight and underweight in children. These include reference cut-off points of the International Obesity Task Force (IOTF) (4), the United States Centers for Disease Control and Prevention (CDC 2000) (5), French reference cut-off points published in 1982 and revised in 1991 (6), and the World Health Organisation (WHO), 2007 (7) and IOTF-2007 (8).

Our study aimed to determine the prevalence of overweight including obesity and underweight in a sample of children aged 6–10 years living in Constantine city using different international reference cut-off points for BMI to allow comparison between different studies and countries.

Methods

Study setting

The study was conducted in the city of Constantine, which is the capital of the province of Constantine (in the north-east of Algeria). Constantine is located 439 km

from Algiers, the capital of Algeria. It is the third largest city of Algeria in terms of population. In the last census of 2008 (9), the resident population of the city of Constantine was 448 374. The population of children aged 6–10 years was 32 937.

Study sample

This cross-sectional study was conducted between February and May 2015, and covered a sample of 509 children (254 girls and 255 boys) aged 6–10 years attending primary schools in the city of Constantine. Four schools were selected. These schools were chosen for their location in different geographical areas of Constantine. We could not assess other schools as we did not have permission from the Primary Education Department of Constantine to include more schools. In Algeria, school education is free and obligatory, so children of all social categories are present. All children aged 6–10 years attending these four schools were chosen.

BMI criteria

Height and weight were measured according to WHO recommendations (10) by a trained student. The body weight (in kilograms) was measured to the nearest 0.1 kg using regularly calibrated electronic scales (Seca, Germany). Height was measured in a standing position without shoes to the nearest 0.1 cm using a stadiometer (Seca, Germany). BMI was calculated as weight (kg) divided by height squared (m^2). The 2007 WHO reference cut-off is based on the sample used to construct the original charts of the American Department of Health, Education and Welfare (11). The 2007 WHO reference allows unrestricted calculation of BMI centiles and z-score curves on a continuous age scale from 5 to 19 years. A score of > 1 standard deviation (SD) is considered the overweight cut-off point, a score of < -2 SD is considered the underweight cut-off point (7). The IOTF reference has published a series of sex- and age-specific BMI cut-offs (from 6 to 18 years) which were developed from sex-specific BMI age curves that pass through a BMI of 25 kg/m^2 for overweight and 30 kg/m^2 for obesity at age 18 years (4). For the detection of underweight, IOTF constructed reference cut-offs based on the WHO definition of underweight for adults (8). The CDC 2000 reference is the revised version of the 1977 (American) National Center for Health Statistics growth charts. Here, the 85th centile is considered the cut-off for overweight and the 5th centile the cut-off for underweight (5). According to the French reference published in 1982 and revised in 1991, underweight and overweight are defined as < 3 rd centile and > 97 th centile respectively (6).

Statistical analysis

Statistical analysis was done using Statview software, version 5 (Abacus ConceptsTM, Berkeley, USA). Data were analysed using the chi-squared and Student t-tests to assess differences by age and sex. The kappa coefficient was used to assess the inter-variation between the references. A kappa value > 0.4 was considered moderate

agreement, and a value > 0.75 was considered good agreement (12). The significance level was set at $P < 0.05$.

Results

The mean BMI of the children according to age and sex increased with age between 6 and 10 years with no statistically significant difference by sex (Table 1).

Table 2 shows the prevalence of underweight and overweight by age of the children. The four reference cut-offs all indicated a low prevalence of underweight. The IOTF cut-off showed the highest prevalence of underweight in all age. The new reference cut-off of WHO showed no underweight in children younger than 8 years. For overweight, the French reference indicated a comparatively low prevalence of overweight compared with the other reference cut-offs. The WHO reference showed the highest prevalence of overweight in all ages.

The prevalence of underweight and overweight by age and sex according to various references are presented in Table 3. The overall prevalence of overweight as determined by IOTF and French cut-offs followed a similar trend in both sexes. IOTF and French references classified 21.3% and 18.9% of the girls and 24.3% and 22.0% of the boys, respectively, as overweight. The WHO reference showed a significantly higher prevalence of overweight in boys than girls (32.6% versus 24.0%, $P = 0.03$). This was because 39.6% of 7-year-old boys were classified as overweight with the WHO reference cut-off compared with 18.8% of 7-year-old girls ($P = 0.01$) as were 43.2% of 10-year-old boys compared with 22.6% of 10-year-old girls ($P = 0.03$). The prevalence of overweight according to the CDC reference cut-offs was much higher in boys compared with girls, even though overall the difference was not statistically significant (26.3% versus 19.3%, $P = 0.06$). However, the CDC reference cut-offs showed a significantly higher prevalence of overweight in 7-year-old boys than in girls (37.5% versus 17.4% respectively, $P = 0.01$). The IOTF reference shows the highest prevalence of underweight for girls (10.6%) and boys (7.1%).

The kappa coefficients comparing overweight and underweight between the different reference cut-offs are presented in Table 4. With regard of the detection of underweight, the kappa coefficient values (boys = 0.89, girls = 0.95) suggest an excellent agreement between

Table 1 Mean body mass index of the children by age and sex

Age (years)	Mean body mass index (SD)		P-value
	Girls	Boys	
6	23.47 (3.44)	24.28 (4.80)	0.33
7	25.75 (5.15)	27.41 (5.55)	0.09
8	31.46 (9.37)	29.58 (6.73)	0.24
9	32.66 (7.58)	33.94 (8.57)	0.47
10	36.38 (8.99)	38.98 (9.04)	0.16

SD: standard deviation.

Table 2 Prevalence of underweight and overweight in the children by age according to the international reference cut-offs

Variable	Prevalence (%)					
	6 years (n = 111)	7 years (n = 117)	8 years (n = 101)	9 years (n = 83)	10 years (n = 97)	Total (n = 509)
Underweight						
WHO	0.0	0.0	2.0	2.4	3.1	1.4
IOTF	9.0	11.1	4.9	8.4	10.3	8.8
CDC	2.7	2.6	3.0	2.4	6.2	3.3
French reference	1.8	1.7	2.0	2.4	3.1	2.2
Overweight						
WHO	28.8	27.3	27.7	25.3	31.9	28.3
IOTF	23.4	22.2	23.8	20.5	23.7	22.8
CDC	23.4	25.6	22.8	19.3	21.6	22.8
French reference	20.7	17.9	19.8	20.5	23.7	20.4

WHO: World Health Organization, IOTF: International Obesity Task Force, CDC: Centers for Disease Control and Prevention.

WHO and French references for both sexes (kappa = 0.77). An excellent agreement was also found between the French and CDC references (boys, kappa = 0.91 and girls, kappa = 0.93). However, the kappa values show very low agreement for boys between IOTF and WHO reference cut-offs (kappa = 0.35), IOTF and CDC (kappa = 0.48) and IOTF and French (kappa = 0.42).

In terms of overweight, in girls, an excellent agreement between all references was found (kappa between 0.76 and 0.94). For boys, an excellent agreement was found between WHO and CDC references (kappa = 0.85) and between IOTF and CDC (kappa = 0.95) and IOTF and French references (kappa = 0.93).

Discussion

In our sample, the prevalence of underweight using different reference cut-offs varied from 1.4% to 8.8%.

This prevalence is lower than that observed in India (13) and Morocco (14) but close to that found in Algeria (Si-di-bel-Abbes) in 2008 (15).

Few studies have reported the prevalence of obesity, which has reached epidemic proportions among children in developing countries (16,17). Using the CDC and IOTF reference cut-offs, 22.8% of our sample of children were overweight. This prevalence is considerably lower than that found in Saudi Arabia (40.6%) (18), Libya (45%) (19), Abu Dhabi (33.6%) (20), Egypt (31.2%) (21) and South Africa (30.7%) (22). However, it is higher than that found in the Islamic Republic of Iran (19.7%) (23), India (13.2%) (24), and Turkey (13.3%) (25). It is similar to the prevalence found in Jordan (24.4%) (26). Using the WHO reference cut-offs we found a prevalence of overweight of 28.3%. This prevalence is higher than that in Yemen (20.7%) (27) and Nigeria (13%) (28) but close to that in Saudi Arabia (28.7%) (29) and lower than that in Dubai (40.9%) (30).

Table 3 Prevalence of underweight and overweight by age and sex according to international reference cut-offs

Variable	Prevalence (%)												P-value
	Girls						Boys						
	6 years (n = 46)	7 years (n = 69)	8 years (n = 44)	9 years (n = 42)	10 years (n = 53)	Total (n = 254)	6 years (n = 65)	7 years (n = 48)	8 years (n = 57)	9 years (n = 41)	10 years (n = 44)	Total (n = 255)	
Underweight													
WHO	0.0	0.0	0.0	2.4	3.8	1.1	0.0	0.0	3.5	2.4	2.3	1.6	0.71
IOTF	8.7	13.0	4.5	9.5	15.1	10.6	9.2	8.3	5.3	7.3	4.5	7.1	0.15
CDC	4.3	2.9	2.3	2.4	9.4	4.3	1.5	2.1	3.5	2.4	2.3	2.4	0.21
French reference	4.4	1.5	0.0	2.4	3.8	2.4	0.0	2.1	3.5	2.4	2.3	2.0	0.75
Overweight													
WHO	23.9	18.8*	34.1	23.8	22.6*	24.0*	32.3	39.6	22.8	26.8	43.2	32.6	0.03
IOTF	21.7	18.8	29.5	19.0	18.9	21.3	24.6	27.1	19.3	21.9	29.5	24.3	0.41
CDC	21.7	17.4*	27.3	16.7	15.1	19.3	24.6	37.5	19.3	21.9	29.5	26.3	0.06
French reference	17.4	14.5	27.3	19.1	18.9	18.9	23.1	22.9	14.0	21.9	29.5	22.0	0.39

WHO: World Health Organization, IOTF: International Obesity Task Force, CDC: Centers for Disease Control and Prevention.

*Significant at P < 0.05.

Table 4 Agreement of different reference cut-offs in classifying underweight, overweight and obesity in a sample of Algerian children in Constantine

Variable	Kappa coefficient							
	Underweight			Overweight			Obesity ^a	
	IOTF	CDC	French reference	IOTF	CDC	French reference	IOTF	CDC
Boys (6–10 years combined)								
WHO	0.347	0.796	0.887	0.799	0.850	0.737	0.715	0.934
IOTF		0.482	0.417		0.948	0.934		0.736
CDC			0.907			0.882		
Girls (6–10 years combined)								
WHO	0.711	0.884	0.954	0.900	0.840	0.828	0.760	0.917
IOTF		0.819	0.753		0.940	0.928		0.734
CDC			0.930			0.912		
Total children (6–10 years combined)								
WHO	0.251	0.575	0.774	0.846	0.846	0.778	0.733	0.928
IOTF		0.525	0.371		0.944	0.930		0.737
CDC			0.780			0.896		

IOTF: International Obesity Task Force, CDC: Centers for Disease Control and Prevention, WHO: World Health Organization.

^aThere is no cut-off for obesity in French reference.

In Algeria, representative nationwide studies on the prevalence of overweight and obese children are not yet available. Using IOTF reference, in Constantine, the prevalence of overweight in children 6–10 years was 9.5% in 2006 (3). In Tébessa (eastern Algeria), between 2005 and 2007, the reported prevalence was 8.5% (31). In Oran city (western Algeria), 13% of children aged 6–11 years were overweight (32), while, in Sidi-bel-Abbes (also western Algeria), in 2008, the prevalence of overweight using IOTF, French and CDC references in 8–15-year-old children was respectively 7.9%, 7.7% and 7.2% (15). In Constantine, using WHO reference cut-offs, the prevalence of overweight in 7–11-year-old children in 2013 was reported to be 26.4% (33).

The higher prevalence of overweight in our study might be explained by the recent trend of socio-economic transition coupled with the nutrition transition in Algeria. This prevalence of overweight is a challenge for public health interventions because overweight children are at a higher risk of noncommunicable and degenerative diseases in adulthood. It is not only the availability of and household access to food that determines the nutritional status of children. Factors such as education, sanitation, accessibility and quality of health services, and cultural attitudes and beliefs are equally important. In the area of Constantine, we showed in 2003 that watching television, time spent in sedentary activities and food quality were risk factors for overweight in a sample of schoolchildren aged 6 to 12 years (34). In the current sample, we also collected information on risk factors for overweight and found that overweight children did less sport, ate breakfast less often, and watched 2 hours more television than normal weight children (35). We also observed a link between parental and child obesity, and that the prevalence of overweight was more common

in children who were not exclusively breastfed whose mothers worked.

The differences in the prevalence of underweight and overweight using the different references can be explained by the setting different cut-offs used by the references, which can be influenced by factors such as time period, country of data source and design of the study. Thus, it is advisable to know the basis on which a reference cut-off was calculated before applying it to any population-based study.

Conclusion

The considerable prevalence of overweight and a persistent burden of underweight found in our sample suggests the existence of nutrition transition in Constantine. The prevalence of malnutrition differs depending on the reference used, which suggests international references should be used with care to avoid any potential misclassification of children. The differences obtained by using different cut-off points at the individual and population level need further research to answer questions as to whether certain cut-off points are linked or not with morbidity or mortality endpoints. No Algerian national standard or reference is available to define overweight or underweight in Algerian children. It may be that Algerian children have different growth characteristics from the populations that were selected to develop the international references. Thus local age-specific BMI references and cut-offs for children are needed that can provide accurate predictions of the risk of metabolic morbidity and disease burden throughout life.

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Prévalence du surpoids et du déficit pondéral chez les écoliers de Constantine (Algérie) : comparaison de quatre valeurs de référence utilisées comme seuils pour l'indice de masse corporelle

Résumé

Contexte : L'Algérie connaît une période de transition nutritionnelle et une augmentation un surpoids chez l'enfant.

Objectifs : La présente étude visait à déterminer la prévalence du surpoids et du déficit pondéral chez les enfants âgés de 6 à 10 ans à Constantine (Algérie), au moyen de quatre valeurs internationales de référence utilisées comme seuils pour l'indice de masse corporelle (IMC).

Méthodes : Une étude transversale a été réalisée entre février et mai 2015 dans un échantillon de 509 écoliers âgés de 6 à 10 ans. Leur taille et leur poids ont été mesurés selon les recommandations de l'Organisation mondiale de la Santé (OMS). Les valeurs utilisées comme seuils pour l'IMC par l'OMS, le groupe spécial international sur l'obésité, les Centers for Disease Control and Prevention (CDC) et les valeurs de référence nationales françaises ont été employées pour classer l'échantillon selon les catégories « surpoids » et « déficit pondéral » en fonction de l'âge et du sexe. Le coefficient kappa a été utilisé pour évaluer la concordance entre les valeurs de référence.

Résultats : Sur la base des différentes valeurs de référence utilisées comme seuils, la prévalence du déficit pondéral chez les enfants était comprise entre 1,4 % et 8,8 %. La prévalence du surpoids variait de 22,8 % à 28,3 %. La valeur de référence utilisée comme seuil par l'OMS donnait une prévalence du surpoids considérablement plus élevée chez les garçons que chez les filles (32,55 % contre 24,0 %, $p = 0,03$). Les valeurs du coefficient kappa (entre 0,251 et 0,954) indiquaient une correspondance allant de bonne à excellente entre les références.

Conclusion : La prévalence du surpoids et du déficit pondéral diffère chez les enfants de Constantine selon la valeur de référence utilisée comme seuil, ce qui semble indiquer que les valeurs internationales de référence devraient être utilisées avec prudence afin d'éviter toute erreur de classification de l'état nutritionnel des enfants.

انتشار زيادة الوزن ونقص الوزن لدى طلاب المدارس في قسنطينة، الجزائر: مقارنة أربع نقاط فاصلة مرجعية لمنسب كتلة الجسم

حياة اولعامرة، وسيلة علام، فوزية تباي، عبد الناصر عقلي

الخلاصة

الخلفية: تشهد الجزائر تحولاً في أساليب التغذية وزيادة في الوزن بصورة متنامية بين الأطفال.

الأهداف: هدفت الدراسة إلى تحديد زيادة الوزن ونقص الوزن لدى الأطفال الذين تتراوح أعمارهم ما بين 6-10 سنوات في قسنطينة، الجزائر، وذلك باستخدام أربع نقاط فاصلة مرجعية لمنسب كتلة الجسم.

طرق البحث: أجريت دراسة شاملة لعدة قطاعات في الفترة بين فبراير/ شباط ومايو/ أيار 2015 وشملت عينة ضمت 509 من طلاب المدارس الذين تتراوح أعمارهم ما بين 6-10 سنوات. وقد قيس طول الأطفال ووزنهم وفقاً لتوصيات منظمة الصحة العالمية. وصُنفت العينة حسب نقص أو زيادة الوزن وفقاً للعمر ونوع الجنس، وذلك من خلال استخدام النقاط الفاصلة لمنسب كتلة الجسم الخاصة بمنظمة الصحة العالمية، وفريق العمل الدولي المعني بالبدانة، ومراكز الوقاية من الأمراض ومكافحتها، والمرجع الوطني الفرنسي. واستُخدم معامل كبا لتقييم التوافق بين النقاط الفاصلة المرجعية.

النتائج: استناداً إلى النقاط الفاصلة المختلفة، تباينت نسب انتشار نقص الوزن في الأطفال لتتراوح بين 1,4 % إلى 8,8 %. كذلك تباينت نسب انتشار زيادة الوزن لتتراوح بين 22,8 % و 28,3 %. وبيّنت النقاط الفاصلة لمنسب كتلة الجسم الخاص بمنظمة الصحة العالمية ارتفاع نسبة انتشار زيادة الوزن في الفتيات عن الفتيان ارتفاعاً كبيراً (32,55 % مقابل 24,0 %، القيمة الاحتمالية = 0,03). وأظهرت قيم معامل كبا (بين 0,251 إلى 0,954) توافقاً معقولاً أو ممتازاً بين المراجع.

الاستنتاجات: يختلف انتشار زيادة الوزن ونقص الوزن لدى أطفال قسنطينة حسب النقاط الفاصلة المرجعية المستخدمة، مما يشير إلى ضرورة استخدام المراجع الدولية مع الحرص على تجنب أي تصنيف خاطئ محتمل لحالة تغذية الأطفال.

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Magnitude and determinants of interactions between dentists and dental supply representatives in Saudi Arabia

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Abstract

Background: The relationship between dentists and dental supply representatives is not as well known as that between physicians and pharmaceutical sales representatives.

Aims: To estimate the magnitude, associated factors and characteristics of the interaction between dentists and dental supply representatives in Saudi Arabia.

Methods: A cross-sectional survey was conducted among dentists working in major governmental and private hospitals in different regions of Saudi Arabia. A self-administered questionnaire was distributed to all participants, either in electronic or paper format, depending on the proximity of the participants. A total of 672 participants completed the survey (response rate, 67.2%).

Results: Approximately 68% of participants reported an interaction with dental supply representatives. Saudi dentists had a lower interaction with dental supply representatives than non-Saudi dentists (65.1% vs 73.1%). Dentists working in private hospitals had more interactions with dental supply representatives than those working in public hospitals (78.1% vs 63.2%). Compared to residents and interns, dental consultants and specialists had more interactions with dental supply representatives. Dentists who had a prior history of working abroad showed more interactions with dental supply representatives than those with no such history (75.9% vs 63.7%). Multivariate logistic regression analysis showed that the following characteristics were independently associated with greater dentist–dental supply representatives interaction: male sex, older age, living in the eastern region, unsure about income satisfaction, certain job titles (such as specialists), and certain specialties.

Conclusion: Dentists have a high number of interactions with dental supply representatives in Saudi Arabia. Most of the issues identified are common to those seen in other parts of the world.

Keywords: dentists, dental supply representatives, gifts, dental practice, Saudi Arabia

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Introduction

There is an environment of mutual trust between dentists and their patients that forces dentists to provide a good service while adhering to high ethical norms (1). Drawing parallels between the dental product and pharmaceutical industries, the World Health Organization has disclosed that the global pharmaceuticals market is worth US\$300 billion a year with a soaring profit margin of about 30% (2). These companies currently spend one third of their sales revenue on marketing their products; roughly twice what they spend on research and development (2).

Previous studies reported a significant relationship between physicians and the pharmaceutical industry (3–5). There is ample evidence that these relationships significantly affect physicians' decision-making in their clinical practice and research (6–8). There is a high level of interaction between physicians and pharmaceutical sales representatives in many countries in spite of having restrictive guidelines (9–11) and evidence of adverse effects on physicians' behaviour (3–5). Similarly, a recent

study reported a high level of interaction of physicians with pharmaceutical sales representatives in Saudi Arabia (12). Other studies indicated that many physicians in Saudi Arabia often accept gifts from pharmaceutical companies (13), and promotion of pharmaceutical products by physicians is common in Japan (14).

It is clear from the literature that the issue of dental specialists having an unethical relationship with dental supply representatives is not as well known as that of medical specialists with pharmaceutical sales representatives (15,16). With an extensive variety of present day dental products, dental supply companies have begun to develop new procedures to entice dental practitioners to purchase their items and thereby increase their net revenue. Eventually, this has opened the door for advertising practices similar to those in the pharmaceutical industry (17,18).

Some studies have assessed the relationship between physicians and pharmaceutical sales representatives in Saudi Arabia (12,13); however, no such studies have been conducted among dentists in Saudi Arabia. Other studies

have reported the negative effects of these relationships on patient treatment and care (5,19). Therefore, the present study aimed to determine the magnitude, risk factors and characteristics of dentist–dental supply representative interactions in Saudi Arabia.

Methods

The present study was conducted among dentists working in major governmental (public) and private hospitals in Central, Eastern, Western, Northern and Southern Saudi Arabia. A total of 63 public and 50 private hospitals were identified and 25 public and 20 private hospitals were included in the study by simple random sampling. All ranks of dentists, including general and specialists, participated. The dental supply representatives were defined as sales representatives of companies that supply dental equipment and materials to dentists, and who visit dentists to provide information about their products.

A self-administrated questionnaire that comprised 50 items arranged in two sections in the English language was developed and distributed to all participants. The first section included questions related to sociodemographic factors, such as age, sex, nationality, monthly income, income satisfaction, hospital setting, and occupational characteristics, such as job rank, specialty, and working duration. The second section included questions related to the interaction with dental supply representatives, gift acceptance and opinion of dentists regarding gift acceptance in dental practice. The scientific content of the questionnaire was validated by a multidisciplinary committee, including specialists in psychiatry, ethics, dentistry and epidemiology. The questionnaire was piloted on a small number of participants. The required changes in the questionnaire were made based on feedback from the pilot data. The original version of this questionnaire targeting physicians' attitudes towards interaction with the pharmaceutical industry was developed and validated by the first author and reported previously (12). The questionnaires were distributed through email with 2 or 3 reminders at an interval of 1 week to dentists in all 5 regions of Saudi Arabia.

Informed consent was obtained from all the participants after explaining the objectives of the study. The study was approved by the Ethical Committee of the College of Dentistry at King Saud University, Riyadh, Saudi Arabia.

The sample size was calculated using OpenEpi version 2.2 (Copyright 2003, 2007 Andrew G. Dean and Kevin M. Sullivan, Atlanta, GA, USA). It was indicated that ≥ 600 participants were needed to detect a 20% difference in the given characteristics between the two study groups (400 dentists from public hospitals and 200 from private hospitals), with 95% confidence level and 0.8 power. The total number of participants was adjusted to allow 10% of possible missing data.

Data were presented as the mean and standard deviation (SD) for continuous data and frequencies

and percentages for categorical data. The prevalence of interaction was reported as the percentage of dentists that interacted with the dental supply representatives. Sociodemographic, occupational and economic factors were compared between dentists who had an interaction with dental supply representatives and those who did not. Significant differences between the 2 groups were assessed using the χ^2 test for categorical data and Student's *t* test for continuous data. Characteristics that were significantly associated with dentist–dental supply representative interaction in univariate analysis were entered into a multiple logistic regression model to define independent relationships. Variables with $P < 0.05$ were retained in the model using conditional backward stepwise elimination. All data were considered statistically significant at $P < 0.05$. SPSS version 16.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses.

Results

A total of 1000 questionnaires was distributed. A total of 672 participants completed the questionnaire (response rate, 67.2%). Table 1 details the sociodemographic characteristics of the participants. Approximately 56% participants were male and the average age was 35.7 (9.4) years. Table 2 details the occupational characteristics of the study participants. Almost 70% of the participants were working in public (i.e. governmental) hospitals. The average working experience of the participant was 10.6 (9.4) years.

Approximately 68% ($n = 454$) participants reported an interaction with dental supply representatives. As shown in Tables 1 and 2, the frequency of interaction with dental supply representatives was significantly higher for male dentists, older age, non-Saudi nationals, living in eastern region, unsure income satisfaction, studying abroad, having ethical education, lack of knowledge about rules and policies regulating the dentist–industry relationships, working in private hospitals, certain job titles, working duration 10–19 years, working abroad, orthodontic specialty and less-common specialties (such as implantologist), and treating patients of high socioeconomic class. In multivariate logistic regression analysis, the following characteristics were independently associated with more dentist–dental supply representative interaction; male sex, older age, living in eastern region, unsure income satisfaction, certain job titles (such as specialists), and certain specialties (Table 3).

Table 4 details the characteristics of the dentist–dental supply representative interactions. The majority of interactions ($n = 327$, 74.8%) occurred at a rate of once or less in a month. The dental clinic was the commonest ($n = 169$, 39.0%) place of interaction, followed by conference or symposium ($n = 168$, 38.8%), office ($n = 66$, 15.2%) or other places ($n = 30$, 6.9%). Approximately 84% ($n = 354$) of dental supply representatives offered gifts and the majority of dentists ($n = 197$, 56%) often or almost always accepted these gifts. The most common gifts offered

Table 1 Sociodemographic characteristics of study participants

Characteristics	Overall (n = 672)	Interactions with DSR		P
		No (n = 218)	Yes (n = 454)	
Sex				
Male	376 (56.0%)	104 (27.7%)	272 (72.3%)	0.003
Female	296 (44.0%)	114 (38.5%)	182 (61.5%)	
Age (yr)				
Mean (SD)	35.7 (9.4)	33.5 (9.9)	36.7 (9.0)	< 0.001*
20–29	241 (35.9%)	111 (46.1%)	130 (53.9%)	< 0.001
30–39	213 (31.7%)	51 (23.9%)	162 (76.1%)	
40–49	159 (23.7%)	41 (25.8%)	118 (74.2%)	
≥ 50	59 (8.8%)	15 (25.4%)	44 (74.6%)	
Nationality				
Saudi	464 (69.0%)	162 (34.9%)	302 (65.1%)	0.041
Non-Saudi	208 (31.0%)	56 (26.9%)	152 (73.1%)	
Saudi region				
Central	374 (55.7%)	135 (36.1%)	239 (63.9%)	0.005
Eastern	83 (12.4%)	15 (18.1%)	68 (81.9%)	
Western	122 (18.2%)	32 (26.2%)	90 (73.8%)	
Northern	16 (2.4%)	8 (50.0%)	8 (50.0%)	
Southern	77 (11.5%)	28 (36.4%)	49 (63.6%)	
Monthly income (SAR)				
< 10 000	117 (17.4%)	45 (38.5%)	72 (61.5%)	0.273
10 000–19 000	240 (35.7%)	83 (34.6%)	157 (65.4%)	
20 000–29 000	119 (17.7%)	31 (26.1%)	88 (73.9%)	
30 000–39 000	103 (15.3%)	31 (30.1%)	72 (69.9%)	
≥ 40 000	93 (13.8%)	28 (30.1%)	65 (69.9%)	
Additional income				
Yes	118 (17.6%)	35 (29.7%)	83 (70.3%)	0.478
No	554 (82.4%)	183 (33.0%)	371 (67.0%)	
Other income sources				
Private clinic	605 (90.0%)	190 (31.4%)	415 (68.6%)	0.186
Academic or military duties	12 (1.8%)	4 (33.3%)	8 (66.7%)	
Other nonmedical sources	55 (8.2%)	24 (43.6%)	31 (56.4%)	
Income satisfaction				
Satisfied	375 (55.8%)	110 (29.3%)	265 (70.7%)	0.008
Not sure	91 (13.5%)	24 (26.4%)	67 (73.6%)	
Dissatisfied	206 (30.7%)	84 (40.8%)	122 (59.2%)	
Study abroad				
Yes	304 (45.2%)	83 (27.3%)	221 (72.7%)	0.010
No	368 (54.8%)	135 (36.7%)	233 (63.3%)	
Ethical education				
Yes	299 (44.5%)	68 (22.7%)	231 (77.3%)	< 0.001
No	373 (55.5%)	150 (40.2%)	223 (59.8%)	
Types of ethical education				
Lectures	190 (63.5%)	49 (25.8%)	141 (74.2%)	0.132
Workshops	72 (24.1%)	15 (21.4%)	55 (78.6%)	
Courses	37 (12.4%)	4 (10.8%)	33 (89.2%)	
Knowledge of rules and policies				
Yes	162 (24.1%)	63 (38.9%)	99 (61.1%)	0.044
No	510 (75.9%)	155 (30.4%)	355 (69.6%)	

*t test, otherwise χ^2 test.

DSR = dental supply representative; SAR = Saudi riyal; SD = standard deviation.

Table 2 Occupational characteristics of study participants

Characteristics	Overall (n = 672)	Interactions with DSR		P
		No (n = 218)	Yes (n = 454)	
Type of hospital				
Public (governmental)	462 (68.8%)	170 (36.8%)	292 (63.2%)	0.002
Private (nongovernmental)	128 (19.0%)	28 (21.9%)	100 (78.1%)	
Both (working partly in public and private)	82 (12.2%)	20 (24.4%)	62 (75.6%)	
Main dentist assignment				
Clinical	472 (70.2%)	155 (32.8%)	317 (67.2%)	0.735
Academic	200 (29.8%)	63 (31.5%)	137 (68.5%)	
Clinical job rank				
Consultant	59 (8.8%)	13 (22.0%)	46 (78.0%)	< 0.001
Specialist	132 (19.6%)	28 (21.2%)	104 (78.8%)	
Resident	209 (31.1%)	73 (34.9%)	136 (65.1%)	
Intern	44 (6.5%)	25 (56.8%)	19 (43.2%)	
Professor	31 (4.6%)	15 (48.4%)	16 (51.6%)	
Associate Professor	70 (10.4%)	20 (28.6%)	50 (71.4%)	
Assistant Professor	24 (3.6%)	4 (16.7%)	20 (83.3%)	
Demonstrator	64 (9.5%)	20 (31.2%)	44 (68.8%)	
Lecturer	11 (1.6%)	4 (36.4%)	7 (63.6%)	
General practitioner	28 (4.2%)	16 (57.1%)	12 (42.9%)	
Working duration (yr)				
Mean (SD)	10.6 (9.4)	8.9 (9.3)	11.4 (9.3)	0.001*
0–9	365 (54.3%)	146 (40.0%)	219 (60.0%)	< 0.001
10–19	192 (28.6%)	25 (13.0%)	167 (87.0%)	
≥ 20	115 (17.1%)	47 (40.9%)	68 (59.1%)	
Work abroad				
Yes	212 (31.5%)	51 (24.1%)	161 (75.9%)	0.002
No	460 (68.5%)	167 (36.3%)	293 (63.7%)	
Specialty				
Oral and maxillofacial surgery	20 (3.0%)	4 (20.0%)	16 (80.0%)	<0.001
Oral medicine and diagnostics	45 (6.7%)	12 (26.7%)	33 (73.3%)	
Periodontics	50 (7.4%)	21 (42.0%)	29 (58.0%)	
Paediatric dentistry	41 (6.1%)	24 (58.5%)	17 (41.5%)	
Orthodontics	29 (4.3%)	4 (13.8%)	25 (86.2%)	
Prosthetic dentistry	108 (16.1%)	36 (33.3%)	72 (66.7%)	
Restorative dentistry	71 (10.6%)	19 (26.8%)	52 (73.2%)	
Endodontics	80 (11.9%)	26 (32.5%)	54 (67.5%)	
Others	16 (2.4%)	0 (0.0%)	16 (100.0%)	
Not specialized	212 (31.5%)	72 (34.0%)	140 (66.0%)	
Patients' socioeconomic status				
Not sure	76 (11.3%)	40 (52.6%)	36 (47.4%)	< 0.001
Lower	160 (23.8%)	79 (49.4%)	81 (50.6%)	
Middle	389 (57.9%)	91 (23.4%)	298 (76.6%)	
Upper	47 (7.0%)	8 (17.0%)	39 (83.0%)	

*t test, otherwise χ^2 test.

DSR = dental supply representative; SAR = Saudi riyal; SD = standard deviation.

were free instruments samples (n = 162, 55.6%), followed by sponsorship for attending educational training (n = 57, 19.3%) and stationery items such as pens and notepads (n = 32, 10.8%).

Discussion

To the best of our knowledge, the current study is the first to investigate the magnitude, associated factors and characteristics of the interaction between dentists and dental

Table 3 Multivariate logistic regression OR of dentists' characteristics associated with interactions with DSRs

Characteristics	Reference group	OR	CI		P
			Lower	Upper	
Male	Female	1.82	1.16	2.84	0.009
Age (yr)		1.05	1.01	1.08	0.006
Saudi region					
	Central				0.006
Eastern		2.33	1.17	4.61	0.016
Western		1.10	0.59	2.04	0.763
Northern		0.33	0.10	1.10	0.071
Southern		0.55	0.29	1.07	0.077
Income satisfaction					
	Dissatisfied				0.03
Satisfied		1.50	0.96	2.36	0.078
Not-sure		2.32	1.20	4.51	0.013
Job rank					
	Intern / GP / demonstrator				0.002
Consultant / prof / associate prof		0.80	0.30	2.12	0.651
Specialist / assistant prof		2.81	1.27	6.21	0.011
Resident / lecturer		0.88	0.49	1.58	0.677
Specialty					
	Not specialized				0.004
Oral and maxillofacial surgery		0.85	0.23	3.09	0.806
Oral medicine and diagnostics		0.58	0.25	1.39	0.222
Periodontics		0.54	0.25	1.17	0.118
Paediatric dentistry		0.18	0.07	0.48	0.001
Orthodontics		3.83	1.08	13.64	0.038
Prosthetic dentistry		0.71	0.35	1.45	0.341
Restorative dentistry		0.39	0.18	0.83	0.014
Endodontics		0.43	0.20	0.90	0.026
Others		> 10	0.00	—	0.998
Patients' socioeconomic status					
	Not sure				< 0.001
Lower		0.87	0.44	1.74	0.695
Middle		3.40	1.84	6.27	< 0.001
Upper		3.12	1.14	8.55	0.027

CI = confidence interval; DSR = dental supply representative; GP = general practitioner; OR = odds ratio.

supply representatives in Saudi Arabia. The results showed that two thirds of the participants had interaction with dental supply representatives on a regular basis that was comparable to that reported among physicians in Saudi Arabia (72.9%) and other parts of the world (12). In addition, the current study suggested that dentist–dental supply representative interaction varied according to dentists' personal and professional characteristics and their practice setting. For example, orthodontists and specialists were more likely to interact with the dental supply representatives compared to paediatric dentists. Previous studies reported approximately 90% prevalence of physician–pharmaceutical sales representative interaction in surveys of multi-specialty cohorts (20,21) and single-specialty cohorts such as ophthalmology trainees (22) and psychiatrists (23). Similarly, other studies reported a high prevalence of physician–

Table 4 Characteristics of the interactions between dentists and dental supply representatives

Characteristics	
Frequency of interaction	
≤ 1/month	327 (74.8%)
2 or 3 times/month	47 (10.8%)
Once weekly	27 (6.2%)
2–5 times/week	24 (5.5%)
Nearly every day	12 (2.7%)
Place of interaction	
Clinic	169 (39.0%)
During hours	140 (32.3%)
After hours	29 (6.7%)
Office	66 (15.2%)

Table 4 Characteristics of the interactions between dentists and DSRs (concluded)

Characteristics	
Place of interaction	
Conference/symposium	168 (38.8%)
Others	30 (6.9%)
Duration of interactions (min)	
< 5	40 (9.8%)
5–9	155 (38.0%)
10–14	148 (36.3%)
15–30	40 (9.8%)
> 30	25 (6.1%)
Communication methods	
Telephone	128 (45.2%)
Face-to-face	77 (27.2%)
E-mail	58 (20.5%)
More than one method	20 (7.1%)
Gift offer	
No	67 (15.9%)
Yes	354 (84.1%)
Gift acceptance	
Never	33 (9.3%)
Rarely	53 (15.0%)
Sometimes	71 (20.1%)
Often	102 (28.8%)
Almost always	95 (26.8%)
Reasons for accepting gift offers	
Helps me to remember their products	117 (37.9%)
Human nature to accept gifts	61 (19.7%)
Minor gifts are always welcomed	59 (19.1%)
Do not want to say no	49 (15.9%)
Gifts are present in every profession, not only in dentistry	12 (3.9%)
My colleagues are accepting gifts	7 (2.3%)
Salaries of dentists are inadequate	4 (1.3%)
Type of gift	
Free instruments samples	162 (54.7%)
Attend industry-sponsored CME events	45 (15.2%)
Attend non-industry-sponsored CME events	12 (4.1%)
Stationary such as pens or note pads	32 (10.8%)
Funded research	21 (7.1%)
Free meals	20 (6.8%)
Prepaid promotion cards/codes	4 (1.4%)
Gifts with company's name or logo	
Yes	256 (80.8%)
No	32 (10.1%)
Don't know	29 (9.1%)
Reasons for prescribing a dental material	
To benefit patients with economic incapability	87 (31.3%)
Due to availability of these samples	101 (36.3%)
According to the patients convenience	32 (11.5%)
The sample is more effective	58 (20.9%)

CME = continuing medical education; DSR = dental supply representative.

PSR interaction in Libya (24) and Japan (14). However, in the current study, most of the dentist–dental supply representative interactions occurred at a rate of once or less per month, which is lower than reported for physician–PSR interaction. One review states that 80–90% of physicians in the United States of America, United Kingdom of Great Britain and Northern Ireland, Canada, and New Zealand meet pharmaceutical sales representatives twice a month on average (7). Another study reported higher rates of physician–pharmaceutical sales representative interactions ranging from 5 to 10 times per month based on specialty (14).

Most of the dentist–dental supply representative interactions take place at the dental clinic or in the office during clinical hours or later, which is indicative of a tolerant work environment. The fact that most patients belong to middle or lower economic strata means that social responsibility should go hand-in-hand with professional obligation (25,26). Therefore, mutual trust between dentists and patients is important and it should be nurtured at all levels of treatment. When patient rights and interests are protected, dentists also become protected because most of the existing laws fulfil the ethical obligations of dentists to safeguard the patients' best interests as primary (27–29).

Acceptance of gifts by dentists in the current study was lower than that reported previously. In the study of Alosaimi et al. (13), approximately 80% of the physicians had accepted some type of pharmaceutical gift. Similarly, other studies reported a high rate of acceptance of pharmaceutical gifts from the pharmaceutical sales representatives (14,21,30,31). The commonest reason for accepting gifts stated by dentists was that these gifts helped them to remember their products. One of the previous studies reported that physicians considered that small gifts were not ethically wrong (14). In the current study, the most common gifts offered were free instruments samples, followed by sponsorship for attending educational training, and stationery items such as pens and notepads. In a previous study, smaller gifts such as trinkets, meals and books were more commonly given to physicians; however, costly gifts such as air travel and hotel accommodation were given selectively (32).

Multivariate logistic regression analysis showed various characteristics of the dentists that influenced their interactions with dental supply representatives. Male dentists had more interaction with dental supply representatives than female dentists had. In contrast, a previous study reported a nonsignificant effect of sex on physician–pharmaceutical sales representative interaction (12). However, a direct comparison could not be made as the previous study was of physicians rather than dentists. The sex difference could be explained by the fact that more male dentists worked in private hospitals, where they were more likely to interact with dental supply representatives. In the current study, dentists working in Eastern Saudi Arabia had greater interaction

with dental supply representatives than dentists in other regions had. Similarly, a previous study reported greater interactions between physicians and pharmaceutical sales representatives working in the eastern region (12). In the current study, clinical job rank of the dentists was associated with the interactions between dentists and dental supply representatives. For instance, specialists and assistant professors had greater interaction with dental supply representatives compared to others. Similarly, a previous study reported a greater interaction between medical specialists and dental supply representatives (12). In the present study, some of the specialties, such as paediatric dentistry, orthodontics, restorative dentistry, and endodontics, had more interaction with dental supply representatives than others had. Similarly, a previous study reported greater interaction between some medical specialties and pharmaceutical sales representatives in Saudi Arabia (12).

Owing to lack of ethical education in the dental curriculum, there is a possibility that dental professionals may not be aware of the existing rules and policies in Saudi Arabia that regulate dentist–industry relationships, as in many other countries (11,20,33). Therefore, further research that focuses on ethical, clinical, prescription and economic impacts of dentistry is recommended.

The present study had some limitations. Being a

convenience sample, the outcomes ought to be interpreted with caution and not viewed as representative of dental specialists working in Saudi Arabia. Furthermore, it was a self-reported study; therefore, the likelihood of underestimation, because of social desirability bias, could not be avoided, particularly as the association may have included conflicts of interest. Further studies are warranted to assess the impact of dentist–dental supply representative interaction on patients' treatment and care and the overall quality of dental practice in Saudi Arabia.

Conclusion

The rate of interaction of dentists with dental supply representatives in Saudi Arabia was high, as in other countries where similar studies have been conducted. Orthodontists interacted more often with DSRs than other dentists did. Most dentists interacted with DSRs at a rate of once or less per month. A large number of dentists occasionally accepted small gifts such as free instrument samples and stationary items. Further investigations are required to explore the ethical, clinical and economic impact of dentist–DSR interaction.

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Competing interest: None declared.

Ampleur et déterminants des interactions entre dentistes et représentants dentaires en Arabie saoudite

Résumé

Contexte : Les liens entre les dentistes et les représentants dentaires sont moins bien connus que ceux que l'on observe entre les médecins et les représentants commerciaux des sociétés pharmaceutiques.

Objectifs : Évaluer l'ampleur, les facteurs associés et les caractéristiques des interactions entre les dentistes et les représentants dentaires en Arabie saoudite.

Méthodes : Une étude transversale a été menée auprès des dentistes travaillant dans les grands hôpitaux publics et privés de différentes régions d'Arabie saoudite. Un auto-questionnaire a été distribué à l'ensemble des participants, sous format électronique ou papier, en fonction de la proximité de ces derniers. Au total, 672 participants ont répondu à ce questionnaire (taux de réponse de 67,2 %).

Résultats : Près de 68 % des participants ont déclaré avoir des interactions avec les représentants dentaires. Les dentistes saoudiens faisaient état d'un niveau d'interactions moindre avec ces représentants que leurs confrères non saoudiens (65,1 % contre 73,1 %). Les dentistes travaillant dans des hôpitaux privés avaient plus d'interactions avec les représentants dentaires que leurs confrères en poste dans les hôpitaux publics (78,1 % contre 63,2 %). Les dentistes consultants et les spécialistes faisaient état de davantage d'interactions avec les représentants dentaires que les dentistes résidents et internes. Les dentistes qui, au cours de leur carrière, avaient travaillé à l'étranger avaient plus d'interactions avec les représentants dentaires que leurs confrères n'ayant pas eu ce parcours professionnel (75,9 % contre 63,7 %). L'analyse de régression logistique multivariée a montré que les caractéristiques suivantes étaient associées de manière indépendante à de plus grandes interactions entre les dentistes et les représentants dentaires : sexe masculin, âge plus avancé, résidant dans la Région orientale, incertitude quant à la satisfaction du revenu, certains postes (de spécialistes par exemple) et certaines spécialités.

Conclusions : En Arabie saoudite, les dentistes entretiennent un nombre élevé d'interactions avec les représentants dentaires. La plupart des problèmes identifiés sont communs à ceux observés dans d'autres régions du monde.

حجم التعاملات بين أطباء الأسنان وممثلي شركات مستلزمات طب الأسنان في المملكة العربية السعودية ومحددات هذه التعاملات

فهد العصيمي، عبد العزيز البكر

الخلاصة

الخلفية: العلاقة بين أطباء الأسنان وممثلي شركات مستلزمات طب الأسنان ليست معروفة تماماً مثل العلاقة بين الأطباء البشريين وممثلي مبيعات المستحضرات الدوائية.

الأهداف: هدفت الدراسة إلى تقدير حجم التعامل بين أطباء الأسنان وممثلي شركات مستلزمات طب الأسنان في المملكة العربية السعودية، وتحديد العوامل المرتبطة بهذا التعامل وخصائصه.

طرق البحث: أُجري مسح مقطعي بين أطباء الأسنان العاملين في كبرى المستشفيات الحكومية والخاصة في مناطق مختلفة من المملكة العربية السعودية. ووزع على جميع المشاركين في المسح استبيان يملؤه المستجيبون بأنفسهم، وكان الاستبيان إما إلكترونياً أو ورقياً حسب قرب المشاركين. وأكمل الاستبيان ما مجموعه ٦٧٢ مشاركاً (وبلغ معدل الاستجابة ٢, ٦٧٪).

النتائج: أبلغ ما يقرب من ٦٨٪ من المشاركين عن تعاملهم مع ممثلي شركات مستلزمات طب الأسنان. وكان تعامل أطباء الأسنان السعوديين مع ممثلي شركات مستلزمات طب الأسنان أقل من تعامل أطباء الأسنان غير السعوديين معهم (١, ٦٥٪ مقابل ١, ٧٣٪). وارتفع تعامل أطباء الأسنان العاملين في المستشفيات الخاصة مع ممثلي شركات مستلزمات طب الأسنان عن تعامل نظرائهم العاملين في المستشفيات الحكومية (١, ٧٨ مقابل ٢, ٦٣٪). وكان تعامل استشاريي وأخصائيي طب الأسنان مع ممثلي شركات مستلزمات طب الأسنان أعلى من تعامل الأطباء المقيمين وأطباء الامتياز معهم. وأظهر الأطباء الذين عملوا بالخارج في وقت سابق تعاملات أكثر مع ممثلي شركات مستلزمات طب الأسنان مقارنة بالأطباء الذين لم يسبق لهم العمل خارج البلاد (٩, ٧٥٪ مقابل ٧, ٦٣٪). وأظهر تحليل الانحدار اللوجستي المتعدد المتغيرات أن الخصائص التالية ارتبطت بشكل مستقل بتعامل أكبر بين أطباء الأسنان وممثلي شركات مستلزمات طب الأسنان: الذكور، وكبار السن، والعيش في المنطقة الشرقية، وعدم التأكد من الرضا عن الدخل، ومسميات وظيفية بعينها (مثل أخصائيين)، وبعض التخصصات.

الاستنتاجات: يتعامل أطباء الأسنان بكثرة مع ممثلي شركات مستلزمات طب الأسنان في المملكة العربية السعودية. وتتشابه معظم المشكلات التي حددها المسح مع تلك التي نراها في أجزاء أخرى من العالم.

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Annual meeting of the Eastern Mediterranean Research Ethics Review Committee¹

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Introduction

The annual meeting of the Eastern Mediterranean Research Ethics Review Committee (RERC) took place at the WHO Regional Office for the Eastern Mediterranean in Cairo, Egypt, from 17 to 18 November 2019 (1). The meeting was attended by Committee members from Egypt, Lebanon, Palestine and Tunisia, in addition to staff from the WHO Regional Office for Eastern Mediterranean, Cairo, Egypt. The objectives of the meeting were to: review progress on recommendations of the 2018 meeting; plan for the RERC's work during 2020 and beyond; discuss the status of the upcoming regional bioethics summit; and discuss effective means for implementing the expanded agenda for RERC's work in the Eastern Mediterranean Region.

Summary of discussions

The Committee reviewed progress on implementation of the recommendations of the previous RERC meeting in 2018 (2). Extensive discussion took place on sub-dividing proposals submitted for ethical clearance into three categories of review: “full review”, “expedited review” and “exempted from review”. In addition, the Committee felt that proposals that do not involve human participants are beyond the Committee's mandate within its current terms of reference.

The activities of WHO's Collaborating Centre for Bioethics in Karachi, Pakistan, were presented. The need to improve collaboration and networking with other collaborating centres, both in the Region and globally, was the main challenge identified, in addition to the limited available funding and staff. A subcommittee of the RERC, reviewed WHO online ethics-related courses and suggested two courses for ethics review committee members and researchers in the Region regarding ethics and research ethics. The courses are “Essential Elements of Ethics” (3) and “Research Ethics Online Training” (4).

- Planning challenges and the outcomes of a workshop on research during emergencies, which took place in Amman, Jordan, in March 2019, were shared, highlighting several challenges faced by ethics review commit-

tees in humanitarian settings. These include the lack of ethical guidelines specific to humanitarian settings and the role of funding and international agencies in obtaining or providing ethical clearance. The need for capacity-building for ethics review committees was highlighted. There was a suggestion to build a database of all national review committees, or even institutional review committees, and make it publicly available on the WHO Regional Office website.

- The United Nations Educational, Scientific and Cultural Organization (UNESCO)/League of Arab States Charter of Ethics of Science and Technology in the Arab Region was presented and discussed. The Charter is ready for dissemination among countries in the WHO Eastern Mediterranean Region; first dissemination of the Charter will be during the 13th Global Summit of National Ethics/Bioethics Committees, planned to be held in Lisbon, Portugal, during the period 18–20 March 2020.
- Ethics and governance of artificial intelligence for health was also discussed. The development of an ethical framework for artificial intelligence in health is currently in progress. The process has involved several stakeholders, including academics, human rights experts and representatives of civil society, international organizations, industry and government.

Recommendations

To WHO

- Reviewing the name and mandate of the RERC to go beyond “research ethics” to “ethics” in general, which would serve an unmet need within WHO and an important demand within countries of the Eastern Mediterranean Region. If approved, the Committee would have the following terms of reference: to ensure compliance with WHO's operational guidelines for ethics committees that review biomedical research and Council for International Organizations of Medical Sciences (CIOMS)/WHO international ethical guidelines for health research involving humans; to review protocols of health/research projects involving human subjects recommended for WHO funding in the Region, in-

¹ This report is based on the proceedings of the Informal consultative meeting on testing and adopting planning for the global interactive Robson platform in the Eastern Mediterranean Region, 4–5 September 2019, Cairo, Egypt (<http://applications.emro.who.int/docs/IMR-WRH-109-2019-EN.df?ua=1>).

- cluding randomized controlled trials; to support the development and work of ethics review committees/institutional review boards in the Region; and to support interagency work on bioethics (especially with UNESCO), and foster the work of national ethics/bioethics committees in the Region.
- Supporting bioethics/research ethics work in the Region, including capacity building.
- Ethically reviewing WHO-funded proposals/protocols, including Research in Priority Areas in Public Health (RPPH) and Tropical disease Research (TDR) proposals.

- Fostering work with UNESCO on bioethics and research ethics in the Region.

To Member States

- Ensuring that members of research ethics committees have a minimum of bioethics/ethics training.
- Using the appropriate nomenclature when establishing ethic committees, including National Bioethics Committee (NBC), National Ethics Committee (NEC), Ethics Review Committee (ERC), Institutional Review Board (IRB) and Research Ethics Committee (REC).

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