Clinical performance of intrauterine device TCu-380 A in Benghazi, Libyan Arab Jamahiriya

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المردود السريري للولب TCu-380A في بنغازي بالجماهيرية العربية الليبية راتان سينغ وميلود العماري

خلاصة: بحثت هذه الدراسة الصورة الإنجابية والصحية لنساء بنغازي اللاتي يستعملن اللولب في منع الحمل، وقيّمت أحد هذه اللوالب وهو TCu-380A. فأجريت دراسة طولية تاريخية استعملت فيها بيانات من عيادة تنظيم الحصوبة في عيادة كيش المجمّعة ببنغازي. وغملت الدراسة 457 امرأة مسجّلة بين مستعملات اللولب TCu-380A بين سنة 1995 وسنة 1998، وخضعن للمتابعة لمدة ستة شهور على الأقبل. وكانت غالبيتهن ليبيات (87.8%) من الفئة العمرية 20-29 سنة (63.4%)، ويتراوحن في الإنجابية بين مولود واحد إلى ستة موالهد (67.1%) وغير مرضعات (64.3%). وكان نصفهن مصابات بمرض وغير مرضعات (64.3%). وكان نصفهن مصابات بمرض مزمن. وبعد متابعة تراكمية بلغت 36 شهراً لمستعملات اللولب TCu-380A تبين أن معدل الفاعلية كان 8.98%. وكان معدل الاستمرار 1.6%. وحدثت مضاعفات في 5.5%. وهكذا يبدو أن اللولب TCu-380A، يمثل وسيلة رحمية فعالة ومأمونة ومضمونة الاستمرار، لمنع الحمل.

ABSTRACT The study examined the reproductive and health profile of Benghazi women using intrauterine contraceptive devices (IUDs) and evaluated one such device, the TCu-380 A. An historical longitudinal study was carried out using data from the Fertility Regulation Clinic, Keish Polyclinic, Benghazi. The subjects were 457 women registered for TCu-380 A insertion between 1995 and 1998, who had been under follow-up for at least 6 months. The majority were Libyan (87.8%), aged 20–29 years (63.4%), of parity 1–6 (67.1%), non-lactating (64.3%) and with normal delivery at last conception (95.1%). Half had a chronic disease. The cumulative 36-month follow-up of those using TCu-380 A revoaled an effectiveness rate of 99.8%, a continuation rate of 96.1% and complications in 3.5%. TCu-380 A appears to be an effective, durable and safe IUD.

Performance clinique du dispositif intra-utérin TCu-380 A à Benghazi (Jamahiriya arabe libyenne) RESUME L'étude a examiné le profil en matière de santé et de reproduction des termes de Benghazi qui utilisent des dispositifs contraceptifs intra-utérins (DIU) et a évalué un de ces dispositifs, le TCu-380 A. Une étude longitudinale historique a été réalisée à l'aide des données provenant de la Clinique pour la régulation de la fécondité, Polyclinique Keish, Benghazi. Les sujets étaient 457 femmes inscrites pour l'insertion du TCu-380 A entre 1995 et 1998, lesquelles étaient suivies depuis 6 mois au minimum. La majorité de ces femmes étaient des Libyennes (87,8%), âgées de 20 à 29 ans (63,4%), ayant de 1-6 enfants (67,1%), qui n'allaitaient pas (64,3%) et qui avaient eu un accouchement normal lors de la dernière conception (95,1%). La moitié d'entre elles avaient une maladie chronique. Le suivi cumulatif sur 36 mols de celles qui utilisalent le TCu-380 A a révélé un taux d'efficacité de 99,8%, un taux de poursuite de 96,1% et des complications chez 3,5%. Le TCu-380 A semble être un DIU efficace, durable et sans danger.

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Introduction

In the past 4 decades the Libyan Arab Jamahiriya has undergone rapid socioeconomic and demographic growth and development. Its population has increased from 1.1 million in 1954 to 4.7 million in 1997 [I,2], while the population growth rate has declined from 4.2% to 3.5% over the same period [I,2] after peaking in 1987. This downward trend in fertility in the Libyan Arab Jamahiriya is noteworthy because it has occurred in the absence of any policy on population control or any organized fertility control programme.

Modern contraceptives are an important component of family planning services and intrauterine devices (IUDs) are excellent contraceptive choices for properly screened women, providing contraception that is safe, effective, long-lasting and costeffective [3-6]. The rate of contraceptive use among married women in the Libvan Arab Jamahiriya increased from 5% in the 1950s to 9% in the 1980s, rising to 45.1% by 1995 [3,7,8]. By 1981, this increasing demand gave rise to the establishment in Benghazi of the first fertility regulation clinic (FRC) for married women [7]. The most popular method of contraception reported at the Benghazi FRC has been the oral contraceptive pill followed by IUDs. All 574 insertions during 1981-84 at the Benghazi FRC were of copper IUDs, except one, which was a Lippes Loop [9]. The types of IUDs inserted included the TCu-200 Ag. TCu-380 S and Ag, Cu7. The ML Cu-250 and 375 were also used until 1995 when they were replaced by the TCu-380 A.

The new registration and follow up for insertion with TCu-380 A has been considered an important factor for facilitating their regular use and for the protection of women of reproductive age from side-effects and complications. Up to the present

time, the only report available on IUD users has been for the period 1981–84 [9]. It was therefore, considered appropriate to identify the profile of Benghazi IUD users and to analyse the complications, continuation and effectiveness rates of the TCu-380 A IUD and compare the differences with the earlier experience in Benghazi and elsewhere.

Subjects and methods

The FRC at Keish Polyclinic, Benghazi is well connected to other parts of the city and can be reached within 15–20 minutes by car from any part of the city. The clinic was founded to meet the needs and demands of married women of reproductive age—to prevent unwanted pregnancies, to increase their interconceptional period, to screen for medical and gynaecological disorders and to provide contraceptive information and services.

Since July 1995, women having an IUD inserted are given a registration number and IUD identity card which provides information about the user's name, date of IUD insertion, time of next check-up and the address of the clinic. The IUD files maintained at the clinic contain detailed information regarding personal data, health status, reproductive history, menstrual history, gynaecological examinations, laboratory investigations, follow-up observations and management strategies. Women who show recent evidence of urogenital infections, pelvic inflammatory disease, recurrent vaginal bleeding, abnormal cervical pap smears or genital cancer are not eligible for IUD insertion. The IUD is inserted at any time during the menstrual cycle provided pregnancy is not a factor. However, most women were provided with the IUD during the first 5 days of the menstrual cycle.

The present study, an historical longitudinal study with cross-sectional data based on clinic records, was conducted at the Keish Polyclinic FRC in Benghazi. The subjects were 457 women who had had a TCu-380 A inserted between July 1995 and May 1998 and who had completed at least 6 months of use since initial insertion. The data, analysed using *Epi-Info* 6, included profiles of the women, and clinical performance of the TCu-380 A regarding side-effects and complications, continuation, removal and effectiveness in prevention of conception. The results were compared with the previous study at the FRC in 1981–84 and with studies from other countries.

Results

The results are presented in Tables 1, 2 and 3. As shown in Table 1, most of the women were Libyan, 37.6 % were under 30 years of age and 72.7% were parity 1-6. A majority had delivered normally in their latest childbirth, with one-third currently breast-feeding and approximately half having a chronic disease.

Discussion

Profile of subjects

Nationality

A majority of women using IUD contraception during both periods (1981–84 and 1995–98) were Libyan, approximately reflecting their proportion in the city's population (Table 1). Thus, Libyan women seem to be concerned about contraception and willing to accept IUDs for controlling and postponing the reproductive process. The proportion of Libyan women using IUDs increased between the two study periods.

Maternal age

In the latest study, over two-thirds of the women were under 30 years of age—a dra-

matic increase from the 37.2% of the previous study (Table 1). Worldwide, the age range with the highest proportion of contraceptive users is 30–39 years [8,10], suggesting that Libyan women are using IUDs at a younger age than women elsewhere. In the Libyan Arab Jamahiriya, the proportion of 30–39-year-olds using IUDs is likely to increase in the future as education, employment opportunities, status and personal choices for women improve.

Parity

In the present study, almost a third of the women were of low parity (1-3) and a third were of medium parity (4-6). This is similar to the situation reported in the previous (1981-84) study (Table 1). Globally, contraceptive prevalence is known to increase sharply as parity increases from 0 to 3, and thereafter to remain fairly steady. The fertility of married women of reproductive age in the country has also declined from 6.5 to 4.1 during the past 40 years [1,2]. In several studies, age and parity strongly influenced the rate of contraception in general and IUD use in particular [5,6,10].

The apparent preference in the present study for IUD use among women of younger age or medium to low parity may be due to greater modernization and urbanization in the Libyan Arab Jamahiriya. Global communication and transportation are likely to have further influenced the trend towards younger age and lower parity.

Outcome of last conception

A majority of the women attending the Benghazi FRC had a normal delivery at their last childbirth. This was similar to the previous study (Table 1). Thus, women with successful reproduction, at least of their last conception, are adopting IUDs probably to delay, space or limit the reproductive

process. The improved quality and coverage of antenatal, natal and postnatal care and the resultant safe reproduction and better child health are also likely to have increased the acceptance of contraceptives, including IUDs, during the period of study.

Lactation status

Only one-third of the women studied were breastfeeding their babies. However,

breastfeeding can be successfully carried out during IUD use. In fact, IUD contraception has a distinct advantage for lactating women over oral contraceptive pills.

Health status

Health screening revealed that 51.0% of the women in the present study and 58.5% in the previous study had chronic disease (Table 1). The prevalence rate of medical and

Table 1 Comparison of the profiles of women using intrauterine contraceptive devices in Benghazi, Libyan Arab Jamahiriya (1981–84 and 1995–98)

Profile		us study 31–84)	Present study (1995–98)	
	No.	%	No.`	%
All women	574	100.0	457	100.0
Nationality				
Libyans	441	76.8	402	88.0
Non-Libyans	133	23.2	55	12.0
Age group (years)				
15–19	35	6.1	2	0.4
20–29	364	63.4	170	37.2
30–39	154	26.8	230	50.3
40-49	21	3.7	55	12.0
Parity				
1- 3	182	31.7	169	37.0
4-6	202	35.2	163	35.7
7– 9	126	22.0	87	19.0
10–12	64	11.1	38	8.3
Outcome of last conception	1			
Normal delivery	546	95.1	427	93.4
Caesarean delivery	28	4.9	30	6.6
I actation status				
Breastfeeding	NA	NA	163	35.7
Not breastfeeding	NA	NA	294	64.3
Current health status				04.0
Chronic disease	336	58.5	233	51.0
No disease	238	41.5	224	49.0
History of major		_		
surgery	39	6.8	7	1.5

Source: [7]. NA = not available. gynaecological disorders in the present study was 40.3% and 10.7% respectively, compared to 19.2% and 39.4% previously, indicating that reduction in morbidity has mainly been for gynaecological disorders. This may be due to better personal hygiene and improved gynaecological services. However, our study does not definitively explain the improvement and confirmation of the reasons should be sought in future studies.

Women seeking IUD insertion during both study periods had very high rates of morbidity for chronic disorders. This might not be representative of the general population. The women were a self-selected group who had achieved a certain level of fertility and/or were suffering from a chronic disorder, and were adopting IUDs for one or both of these reasons. The health problems of the women in both studies were (in descending order of frequency): long-standing varicose veins, cervical erosion, cardiovascular disorders and diabetes mellitus (Table 2). In addition, 6.3% of all women attending the FRC in the present study were found to be anaemic (haemoglobin < 10 g/dL), compared to 0.5% previously [9]. The reasons for the higher prevalence of anaemia in the present study are unknown. It may be due to inadequacy of testing for anaemia during the previous study period. Alternatively, the co-

Table 2 Comparison of chronic morbidity problems among women using intrauterine contraceptive devices in Benghazi, Libyan Arab Jamahiriya (1981–84 and 1995–1998)

Disorder	(198	us study 31–84) = 574)	Present study (1995–98) (n = 457)	
	No. `	%	No.	%
Medical disorders		•		
Varicose veins	46	8.0	90	19.7
Anaemia (Hb < 10 g/dL)	3	0.5	29	6.3
Diabetes mellitus	24	4.2	26	5.7
Cardiovascular				
disorders	33	5.7	22	4.8
Migraine	-	_	б	1.3
Other	4	0.7	11	2.4
Total	110	19.2	184	40.3
Gynaecological disorders				
Cervical erosion	105	18.3	42	9.2
Vaginitis	45	7.8	3	0.7
Cystocele	34	5.9	1	0.2
Pathological cervical				
cytology	8	1.4	_	_
Other	34	5.9	3	0.7
Total	226	39.4	49	10.7

Chronic morbidity was found in 336/574 (58.5%) women in the 1981–84 study and in 233/457 (51.0%) women in the 1995–96 study.

Hb = haemoglobin.

hort of women adopting IUDs in the 1981–84 period may simply have been healthier. Previous experience of surgical intervention was significantly higher for the women in the previous study period compared to the present. To confirm or refute the findings of health status in both studies, a population-based control group would be required.

Clinical performance

Side-effects and complications

The overall rate of side-effects and complications was 3.5 per 100 women in the present study compared to 43.7 in 1981–84 (Table 3). The main medical complications in the study were increased nonspectific vaginitis (NSV) followed by bleeding and pain, whereas previously, increased bleeding and pain, NSV and pelvic inflammatory disease (PID) were in equal proportions [9]. It is noteworthy that even in a multicentre WHO study, the overall complication rate for a similar period was 14.3 per 100 women, 12.5 due to bleeding and pain, 1.7 due to other medical disorders and 0.1 due to infection [5,10].

In general, copper IUDs increased the volume of menstrual bleeding per cycle, probably by disturbing the blood vessels or altering the clotting mechanism in the lining of the uterus [5]. This increased volume may be within normal range, without having any detrimental health effect or personal consequences. However, bleeding and pain are not necessarily always due to the IUD itself, but may be caused by PID, ectopic pregnancy (EP) or some other condition. Health care providers need to investigate the underlying causes of any bleeding and pain immediately. Bleeding and pain were the most common reasons for IUD removal, in both the present and previ-

Table 3 Comparison of the distribution of women after 36 months of follow-up by side-effects, continuation, removal/expulsion and effectiveness of the intrauterine device in Benghazi, Libyan Arab Jamahiriya (1981–84 and 1995–98)

Variable	Previous study (1981–84)		Present study (1995–98)		χ² (P-value)	
	No.	%	No.	%		
Side-effects (all types)	251	43.7	16	3.5	212.45 (P<0.001)	
Increased bleeding and pain	87	15.2	12	2.6	- (/	
Non-specific vaginitis	85	14.8	4	0.9		
Pelvic inflammatory disease	79	13.8	0	0.0		
Continuation	449	78.2	439	96.1	66.29 (P<0.001)	
Removal/expulsion	102	17.8	16	3.5	55.1 (P < 0.001)	
Self-expulsion	23	4.0	2	0.4	(,	
Removal due to:						
increased bleeding and pain	41	7.1	7	1.5		
non-specific vaginitis	18	3.1	_	_		
pelvic inflammatory disease	16	2.8	_	_		
accidental pregnancy	17	3.0	1	0.2		
planned pregnancy	8	1.4	7	1.5		
social	2	0.3	1	0.2		
Effectiveness: pregnancy prevented	525	91.5	456	99.8	36.37 (P < 0.001)	

ous studies. This is influenced by the type of counselling and support women receive, together with their own attitudes towards using IUDs [5,6]. There was no case of PID in the present study, compared to 13.8% of women (79 women) previously [9]. Thus, the TCu-380 A appears safer as regards PID than the IUDs used previously at Benghazi FRC.

Continuation and removal

The IUD continuation rate in the present study was 96.1% compared to 78.2% previously. According to multicentre trials in developing countries, the continuation rate among women using various types of IUDs a year after insertion ranged from 70% to more than 90% [1,5]. In a WHO study, 6 years after insertion 47% women were still using the TCu-380 A [10]. Both in trials and in practice, IUD continuation rates have been shown to be higher than for other reversible methods of contraception, with TCu-380 A rates higher than for all other IUDs [5].

In the present study, 18 women (3.9% of all subjects) discontinued: 16 (3.5%) had the IUD removed and in 2 (0.4%) the IUD was spontaneously expelled. The rates of discontinuation, removal and self-expulsion in the previous study were 21.8%, 17.85% and 4% respectively [9]. In a multicentre WHO study the corresponding discontinuation, removal and self-expulsion rates for the same duration of time for the TCu-380 A were 36.3%, 29.4% and 6.9% respectively [10]. Thus, the discontinuation rate in the present study was relatively low for the TCu-380 A. This may reflect the greater safety of the TCu 380 A compared to other copper IUDs used at the Benghazi FRC previously.

There was no case of ectopic pregnancy in the present study and a single case previously [9]. Among IIID users an esti-

mated 1 in 30 pregnancies (3%-4%) is ectopic compared with 1 in 125 pregnancies in general [11,12]. For most of the second generation of IUDs, fewer than 1.5 ectopic pregnancies occur per 100 women years of IUD use [13,14]. Two of the most effective IUDs, the TCu-380 A and ML Cu-375, have the lowest ectopic pregnancy rates, 0.25 and 0 per 100 women years respectively [5, 10]. Meta-analysis of case-control and cohort studies published between 1978 and 1994 have found that both current and past IUD users were at moderately higher risk of ectopic pregnancy [15]. All IUD users should, as a matter of routine, have explained to them the symptoms of ectopic pregnancy and the importance of early reporting to the clinic or hospital gynaecologist in the event of a suspected ectopic pregnancy.

Of the 16 women in the present study who had their IUD removed, the reasons were: increased bleeding and pain (7 women), planned (wanted) pregnancy (7 women), accidental pregnancy (1 woman) and social reasons (1 women) (Table 3). The reasons for removal of the TCu-380 A in a WHO study were (in the descending order of frequency): bleeding/pain, other medical disorders, accidental pregnancy and infection [8,10]. In the 1981–84 study for other types of copper IUDs, removal due to sideeffects or accidental pregnancy was much higher than for the TCu-380A in the present study. Similarly, the expulsion rate in the present study was 0.4% compared with 4% previously [7]. Most expulsions occurred during the first year, a finding similar to other studies [16-19]. Several factors, including type and size of IUD, maternal age, parity and health personnel skills, affected expulsion rates. Correct insertion and new types of IUDs (i.e. the T Cu-380A) were found to reduce the chances of expulsion [19,20]. IUD users

were expected to be familiar with the method of checking the string in order to make sure the devices were properly positioned.

Effectiveness

Of the 457 women who had TCu-380 A inserted, only 1 had conceived during a 36month period, giving an effectiveness rate of 99.8%. Previously at the FRC, when mostly Nova-T (73.9%) and Orthogynae R (13.4%) IUDs were used, the effectiveness was 97.0% [9]. The effectiveness of four of the newer copper IUDs (the TCu-380 A, TCu-380 Ag, TCu-220 C and ML Cu-375) is slightly greater than for other devices [5]. Pregnancy protection rates for these devices of more than 99 per 100 women per year have been reported [21]. In a WHO international study, after 6 years of use, the cumulative pregnancy rate with the TCu-380 A was 1.4 per 100 women [10]. Thus, the TCu-380 A remains one of the most effective reversible contraceptive methods available to the Benghazi FRC, an observation which conforms with the conclusions of other longitudinal studies [5, 10, 21].

For a number of years the action of copper IUDs in pregnancy prevention has been the subject of research. Recent results from Australia have shown that copper at concentrations similar to those released from copper IUDs affects the fertility capacity of human gametes (both sperms and oocytes) in vitro and interferes with the sperm-oocyte interaction leading to fertilization [22]. These effects suggest that the principle action of Cu2+ (ions) released from the copper IUD is to act as a preconception contraceptive agent when delivered in the endometrial and oviductal fluids. The action of copper IUDs could facilitate their acceptance by all Arab countries, including the Libyan Arab Jamahiriya, as with no embryos formed, deaths of live fetuses are not involved in using these devices.

Recommendations

Health care providers must thoroughly screen prospective IUD users by way of medical history checks, clinical and gynaecological examinations and laboratory tests, including Pap smear examinations. They should also manage acute or chronic health problems before IUD insertion. Women should use a suitable alternative method of contraception during transition and should select an IUD by matching their health status, personal needs and reproductive expectations. For the best outcome, a family planning programme must carefully screen users and provide informative and empathetic counselling, practical clinical training for health providers and regular follow-up and back-up medical care in case of complications. The programme should offer IUDs together with other methods of contraception through the 'cafeteria approach', so that clients can choose the most suitable methods for themselves. Once a woman decides to use an IUD, the provider should explain the insertion procedure, common side-effects, the chance of more serious complications and expulsion or unintended pregnancy, and advise on the warning signs of serious complications. When a woman has an IUD inserted, she and the provider should plan for follow-up visits (the first within 3 months), although it should be explained to the client that she can return at any time if she has questions or problems or wants the IUD removed.

Copper IUDs should be removed every 3-5 years depending on the approved life span. It is essential, in Benghazi and in other parts of the Libyan Arab Jamahiriya, that only trained health personnel remove the IUD or treat any related problems. The IUD user should be advised that her menstrual period will probably be heavier and last longer than usual, and that, while this is

rarely of such severity as to be harmful, she must visit the clinic if the menstrual bleeding lasts twice the normal period. The provider should give her an IUD card containing information about the type of IUD inserted and dates of insertion and of replacement. The client should also be told that she can have sex as usual, and that she should check the strings, preferably after each menstruation. She should also understand that she can choose an alternative method of contraception in case of complications, inconvenience or preference. All contraceptive users, including IUD users, should have long-term follow-up studies. There is a need for a national database on

the magnitude, trends and experience of all types of contraceptive use throughout the country.

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