ORIGINAL ARTICLE

Mobile Phone Intervention to Improve Diabetes Care in Rural Areas of Pakistan: A Randomized Controlled Trial

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Abstract

Objective: To determine the effect of mobile phone intervention on HbA1c in type-2 Diabetes Mellitus (DM) patients living in rural areas of Pakistan.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of Endocrinology, Liaquat National Hospital, Karachi, from December 2013 to June 2014.

Methodology: A total of 440 patients in intervention and control groups were enrolled. All patients between 18 - 70 years of age, residing in rural areas of Pakistan, HbA1c ≥ 8.0% and having personal functional mobile phone were included. The intervention group patients were called directly on mobile phone after every 15 days for a period of 4 months. They were asked about the self-monitoring blood glucose, intake of medications, physical activity, healthy eating and were physically examined after 4 months. However, the control group was examined initially and after 4 months physically in the clinic and there were no mobile phone contacts with these patients.

Results: Patients in intervention group showed improvement ($p < 0.001$) in following diet plan from 17.3% at baseline to 43.6% at endline, however, the control group showed insignificant increase ($p=0.522$) from 13.6% at baseline to 15.9% at endline. Intervention group (RR = 2.71, 95% CI = 1.18 - 6.40) showed significant positive association with normalization of HbA1c levels. The relationship was adjusted for age, gender, socio-economic status, ethnicity, education, hypertension, medication, BMI, diet, LDL levels and physical activity. Dietary restriction and low LDL levels also showed significant associations with reduced HbA1c levels on multivariate analysis.

Conclusion: Mobile phone technology in rural areas of Pakistan was helpful in lowering HbA1c levels in intervention group through direct communication with the diabetic patients. Lowering LDL and following diabetic diet plan can reduce HbA1c in these patients and help in preventing future complications.

Key Words: *Mobile phone. Diabetes mellitus. Rural areas. Pakistan. HbA1c.*

INTRODUCTION

Diabetes Mellitus (DM) is currently a disease of epidemic magnitude at both national and international level. It threatens to reach pandemic levels by the year 2030, especially in low income countries.[1] Around 382 million people of the world are suffering from DM and the number will increase to 592 million by the year 2035.[2] The incidence of DM has increased to 170% in the developing countries as compared to 47% in the developed countries.[3] The prevalence, complications and cost of this problem is increasing day by day.[4] There has been a rapid increase in the prevalence of DM in South Asian countries in the last two decades.[5] This estimates for 2013 showed that in Pakistan there were 3,777, 000 people suffering from DM in rural settings as compared to 2,934, 000 in urban settings; thus there has been an increase of this problem in rural areas.[2] The risk factors for DM (obesity, smoking, hypertension, family history) in young adults have also been observed to increase over time in rural areas of Pakistan.[6]

DM patients in rural areas are not visiting the endocrinologist regularly to get the treatment. They are either lost to follow-up or get inappropriate management of type-2 DM when they reach their home towns. Close monitoring of these patients are important for long-term care. It is also true that Self Monitoring Blood Glucose (SMBG) levels are associated with a better glycaemic control regardless of type of diabetes or medications used.[7] The risk of complications due to type-2 DM is likely to be reduced by reduction in glycosylated haemoglobin (HbA1c).[8] Therefore, the endocrinologist always advises diabetic patients to monitor their blood glucose levels, take medications regularly along with proper diabetic diet and exercise to keep blood sugars under control.

Health facilities are limited especially in the rural areas of Pakistan. There is hardly any trained endocrinologist working in the rural areas of the country. DM is a very common public health problem in these regions. Rural areas of Pakistan are geographic regions located outside the cities and towns, with a low density population and are not included within urban settle-

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ments. Patients cannot come from the far-flung rural areas on a regular basis to cities. Therefore, it is important that mechanisms should be devised to control the blood glucose levels of type-2 diabetic patients living in these areas using modern technology. One can use mobile phone technology for the management and education of this chronic disease in the rural areas of the country. The rationale of the study was that this modern technology can help in the long-term better treatment of DM in less developed regions of Pakistan, where medical facilities are scarce. The objective of the study was to determine the effect of mobile phone intervention on HbA1c in type-2 DM patients living in rural areas of Pakistan. The hypothesis of the study was that after telephonic intervention HbA1c will be reduced to 7.0% or less. Primary outcome was to achieve HbA1c ≤ 7.0% and the secondary outcome was the reduction of Low Density Lipoprotein (LDL) < 100 mg/dl in the intervention group.

The objective of this study was to determine the effect of mobile phone intervention on HbA1c in type-2 Diabetes Mellitus (DM) patients living in rural areas of Pakistan.

METHODOLOGY

This was a two-arm prospective randomized controlled trial. All patients between 18-70 years of age, residing in rural areas of Pakistan, willing to participate in the study, type-2 DM of ≥ 3 months, ability to understand Urdu and HbA1c ≥ 8.0% presenting to the outpatient services of Department of Endocrinology, Liaquat National Hospital (LNH) were included in the study from December 2013 to June 2014. Ethical approval was obtained from LNH (0122-2013 LNH-ERC), before conducting the study. Patients with complications of DM like diabetic nephropathy, diabetic foot, status post-amputation of limb, diabetic retinopathy, psychiatric illness, pregnant females, patients using insulin, patients who do not have mobile phone facilities and those having other chronic illnesses were excluded from the study. Informed written consent was taken prior to enrolling the patients in the study.

The Principal Investigator called the intervention arm patients directly after every 15 days for a period of 4 months. Each patient, therefore, received a total of 8 calls during the entire period of study. Patients were asked about the SMBG, intake of medications, physical activity and healthy eating. These patients were examined in the clinic at the end of the study along with the investigations. At the time of appointment, before randomization, participants were having height, weight, Body Mass Index (BMI) and blood pressure as baseline measurements. Patients were randomly distributed in the intervention and non-intervention groups based on gender. Patients in both the arms were seen by the healthcare professionals and delivered equal services according to the standard guidelines of managing this disease. Before randomization into groups, baseline data was taken by the staff of the clinic, however, it was not possible to blind the patients and the clinicians to the allocation groups.

Both the groups were given SMBG form to monitor their blood glucose levels. Users in the intervention group received regular (15 days) feedback based on their blood glucose over the past readings of 15 days on phone. Participants were trained by the diabetes educationist in the correct use of the glucometer and to correctly write the readings in the form. The written information leaflets related to information regarding diet given by the nutritionist, initiating and maintaining healthy lifestyles, symptoms of hypoglycemia and hyperglycemia and complications of DM were provided to both the groups on the visit of randomization. Both the groups were also educated about going to the local physician if their blood glucose remains very high or very low. Patients were also advised to eat or take sweet drink if the blood sugar is less than 60 mg/dl. Intervention group were asked to provide atleast total seven blood glucose readings in 15 days including fasting and random measurements. Patients in the control group were advised regarding their medications, diet, lifestyle changes, care and SMBG levels by the physician, nutritionist and diabetes educator. They were asked about the SMBG at baseline and at regular follow-up. They were also advised to come for the usual follow-up visit.

Both the groups were asked to come after 4 months of the recruitment to the clinic with all the investigations, SMBG, recent HbA1c report and LDL results. Staff collected the information including height, weight, blood pressure and body mass index. Sample size was calculated by using open epi-calculator considering P1 = 20%, P2 = 10%, β of 20% and α 95% confidence level. A total of 440 study subjects (220 in each group) were included in the study. Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 19. Baseline socio-demographic and clinical characteristics in intervention and control group were compared using independent t-test for quantitative variables and chi-square test for categorical variables. Wherever appropriate, Fisher's Exact Test was applied to compare the categorical variables. Baseline and endline clinical outcomes at the end of 4 months follow-up in intervention and control groups were compared using paired t-test for quantitative variables and McNemar's Test for categorical variables. P-value of less than 0.05 was considered significant.

The association between intervention and outcome was analyzed using multiple Cox regression in which results were expressed as a Relative Risk (RR) with corresponding 95% Confidence Interval (CI). The relationship was adjusted for age, gender, socio-economic status, ethnicity, education, hypertension, medication, BMI, diet, LDL levels and physical activity.

RESULTS

Comparison of baseline socio-demographic characteristics of intervention and control groups is shown in Table I. There were 135 (61.4%) males and mean age of the patients was 48.95 ± 8.83 years in the intervention group, however, there were 135 (61.4%) males and mean age of the patients was 49.21 ± 7.92 years in the control group. No statistically significant difference was found in any of the recorded variables.

Comparison of baseline clinical characteristics of intervention and control groups is shown in Table II. There was no statistically significant difference in BMI, mean HbA1c levels, mean LDL levels, medication intake, physical activity and dietary intake. However, hypertension was recorded significantly more (p = < 0.001) in intervention group (27.3%) as compared to control group (11.4%) and medicine intake was better (p = < 0.001) in control group (96.8%) as compared to intervention group (81.4%).

There was a significant reduction (p < 0.001) in hypertension, BMI, mean LDL levels and mean HbA1c levels in both groups. Reduction in mean HbA1c levels was more pronounced in intervention group (-1.46) as compared to control group (-0.48). Patients in intervention group showed significant improvement (p < 0.001) in following diet plan from 17.3% at baseline to 43.6% at endline while in the control group there was an insignificant increase (p=0.522) from 13.6% at baseline to 15.9% at endline. The intervention group also showed significant (p < 0.001) increase in physically active patients from 16.4% to 44.5% whereas an insignificant improvement (p=0.472) was observed in control group from 14.1% to 16.4% (Table III).

Unadjusted and adjusted relationship of demographic and clinical characteristics with normal HbA1c levels is shown in Table IV. On univariate analysis, intervention group (RR=5.28, 95% CI=2.38-11.85), physical activity (RR=7.76, 95% CI = 3.85 - 15.71) and diet restriction (RR=10.61, 95% CI = 4.93 - 22.83), showed a significant positive association while high LDL levels > 100 mg/dl showed a significant negative association (RR=0.09, 95% CI=0.02-0.40) with controlled HbA1c levels. Intake of medication, although showed a positive impact, it was statistically insignificant (RR=1.35, 95% CI = 0.76 -2.54). BMI and hypertension status also showed no significant association. None of the socio-demographic variables including age, gender, socio-economic status, ethnicity and education showed any significant association.

On multivariate analysis, intervention group (RR=3.09, 95% CI = 1.33 - 7.33) and dietary restriction (RR=6.53, 95% CI = 1.80 - 23.63) remained significant while physical activity became insignificant (RR=1.25, 95% CI = 0.38 - 4.07). Patients with LDL levels of > 100 mg/dl had significantly less chance of good HbA1c control (RR=0.20, 95% CI = 0.04 - 0.87). All the other variables remained insignificant.

Table I: Comparison of baseline socio-demographic characteristics of intervention and control groups.

Variable	Intervention (n=220)	Control (n=220)	p-value
Age (years)			
Mean±SD	48.95±8.83	49.21±7.92	0.742
Gender			
Male	61.4% (135)	61.4% (135)	1.00
Female	38.6% (85)	38.6% (85)	
Regions			
Sindh	30% (66)	29.1% (64)	0.834
Baluchistan	70% (154)	70.9% (156)	
Marital status			
Single	2.3% (5)	1.8% (4)	0.644
Married	95% (209)	97.3% (214)	
Others	2.7% (6)	0.9% (2)	
Education			
No education	37.3% (82)	32.7% (72)	0.318
Educated	62.7% (138)	67.3% (148)	
Socio-economic status			
Low	18.6% (41)	18.6% (41)	0.747
Medium	73.6% (162)	75.5% (166)	
High	7.7% (17)	5.9% (13)	
Employment			
Yes	55.5% (122)	59.1% (130)	0.076
No	8.2% (18)	3.2% (7)	
Housewife	36.4% (80)	37.7% (83)	

Table II: Comparison of baseline clinical characteristics of intervention and control groups.

Variable	Intervention (n=220)	Control (n=220)	p-value
Blood pressure (mmHg)			
Systolic Mean ± SD	120.88 ± 10.1	121.09 ± 8.99	0.823
Diastolic Mean ± SD	81.15 ± 7.37	74.54 ± 5.91	< 0.001
Hypertension	27.3% (60)	11.4% (25)	< 0.001
BMI			
Mean ± SD	27.08 ± 4.54	27.57 ± 3.16	0.188
< 25	28.6% (63)	22.7% (50)	-
25 and above	71.4% (157)	77.3% (170)	0.156
HbA1c			
Mean ± SD	10.09 ± 1.71	9.85 ± 1.37	0.10
LDL			
Mean ± SD	111.7 ± 31.35	108.33 ± 21.8	0.187
Normal (< 100 mg/dl)	35.9% (79)	39.1% (86)	0.491
Following diet plan	17.3% (38)	13.6% (30)	0.291
Physically active	16.4% (36)	14.1% (31)	0.507
Medications			
No intake	18.6% (41)	3.2% (7)	< 0.001
Taking medications	81.4% (179)	96.8% (213)	-
Hypoglycemia	0.9% (2)	0.5% (1)	0.642

DISCUSSION

The authors believe this to be the first randomized controlled trial in Pakistan that has observed the effect of mobile phone health technology through direct communication with rural area diabetic patients and listening to their problems. Mobile health technology is a method of patient care particularly important for the management of chronic diseases like DM.[9] A meta-analysis has shown that mobile phone intervention has

Table III: Comparison of baseline and endline clinical outcomes in intervention and control groups.

Variable	Intervention (n=220)				Control (n=220)			
	Baseline	Endline	Difference	p-value	Baseline	Endline	Difference	p-value
Blood pressure (mmHg)								
Systolic Mean±SD	120.8±10.1	118±9.14	-2.88±0.5	<0.001	121.09±8.99	119.8±7.61	-1.22±0.65	0.062
Diastolic Mean±SD	81.15±7.37	75.72±6.54	-5.43±0.5	<0.001	74.54±5.91	75.1±5.85	0.59±0.59	0.321
Hypertension	27.3% (60)	8.2% (18)	-19.1%	<0.001	11.4% (25)	4.1% (9)	-7.3%	< 0.001
BMI								
Mean±SD	27.08±4.54	28.6% (63)	0.96±.09	<0.001	27.57±3.16	28.6±3.11	1.02±0.09	< 0.001
< 25	28.04±4.7	22.3% (49)			22.7% (50)	8.6% (19)		
25 and above	71.4% (157)	77.7% (171)	6.3%	0.001	77.3% (170)	91.4% (201)	14.1%	< 0.001
HbA1c								
Mean±SD	10.09±1.71	8.63±1.29	-1.46±.07	<0.001	9.85±1.37	9.36±1.15	0.48±0.04	< 0.001
LDL								
Mean±SD	111.7±31.3	88.68±18.06	-23±1.4	< 0.001	108.33±21.8	99.29±19.5	-9.04±0.77	< 0.001
Normal (<100 mg/dl)	35.9% (79)	78.2% (172)	42.3%	< 0.001	39.1% (178)	56.4% (201)	17.3%	< 0.001
Following diet plan	17.3% (38)	43.6% (103)	26.3%	<0.001	13.6% (30)	15.9% (35)	2.3%	0.522
Physically active	16.4% (36)	44.5% (107)	28.1%	<0.001	14.1% (31)	16.4% (36)	2.5%	0.472

Table IV: Unadjusted adjusted relationship of demographic and clinical characteristics with normal HbA1c levels .

Variable	Unadjusted RR (95% CI)	p-value	Adjusted RR	p-value
Group				
Control group	1.00	<0.001	1.00	
Intervention group	5.28 (2.35-11.85)		2.71 (1.18-6.40)	0.023
Age group				
28 - 49 years	1.00		1.00	0.49
50 and above	0.86 (0.47-1.56)	0.63	0.80 (0.43-1.50)	
Gender				
Male	1.00		1.00	
Female	0.74 (0.39-1.39)	0.35	0.77 (0.36-1.65)	0.50
Socio-economic status				
Rs. < 20000	1.00		1.00	
Rs. 20000 - 100,000	0.99 (0.46-2.17)		0.87 (0.38-1.98)	
Rs. > 100,000	1.36 (0.41-4.53)	0.83	1.16 (0.33-4.02)	0.85
Regions				
Sindh	1.00		1.00	
Baluchistan	0.81 (0.43-1.51)	0.50	0.91 (0.47-1.75)	0.79
Education	1.14 (0.61-2.17)	0.65	1.05 (0.48-2.30)	0.89
Hypertension	0.72 (0.17-3.00)	0.66	0.85 (0.19-3.62)	0.82
BMI (> 25)	0.93 (0.43-2.16)	0.93	1.49 (0.65-3.43)	0.34
Following diet plan	10.61 (4.93-22.83)	<0.001	5.15 (1.50-17.46)	0.008
Taking proper medications	1.35 (0.76-2.54)	0.35	0.83 (0.42-1.62)	0.58
Physically active	7.76 (3.85-15.71)	<0.001	1.30 (0.42-3.96)	0.64
LDL (>100 mg/dl)	0.09 (0.02-0.40)	0.001	0.20 (0.04-0.87)	0.032

a significant improvement in glycaemic control and self-management in diabetes care, especially in type-2 diabetes patients.[10]

This study has highlighted that direct interaction with patient and reinforcing good behaviors has a strong impact on the control of DM. Similarly, Kim *et al*. had seen the effect of Short Message Service (SMS) by cellular phone or wire internet for 6 months follow-up and showed promising results.[11] A randomized controlled trial through telephonic intervention to improve type-2 diabetes care was done in Australia showed that interactive telephone intervention had improved the glycaemic control.[12] SMS reminders to diabetic patients have been suggested for future self-care management of DM due to its cost effectiveness,[13] however, in Pakistan Ali showed that there was no effect of SMS on the dietary compliance of type-2 DM patients.[14] This might be due to the reason that rural area people of Pakistan want more discussion of their problems as compared to simple reminders through SMS. One of the strengths of the study was that the communication with the patients was done directly by a Physician which provided extra confidence to the patients in sharing their problems. It is important to stay in touch with the patients on regular basis on cell phone; this can cause an extra motivation in these patients to

take care of their disease. The course of DM worsens if the patient does not take good care of his/her illness and can ultimately result in future complications.[15] Hence control of DM through continuous counselling is important either directly or indirectly using recent technologies. Face-to-face interaction with the physician is not possible in patients living in rural areas, therefore, alternative method such as use of mobile phone has shown promising results in this study.

Despite of limitations, this study highlights some interesting findings. The intervention group has shown improvement in HbA1c and dietary restriction was significant. Al-Shookri *et al*. found similar results that those type-2 Omani diabetic patients who followed the nutrition care guidelines provided by the dietitian had significant improvement in anthropometric and bio-chemical outcomes including HbA1c than controls.[16] In India, those type-2 diabetic patients who visited the dietitians were associated with consumption of diabetic diet.[17] Amano *et al*. also reinforced the importance of diet and exercise in type-2 diabetic patients, with a mean decrease of HbA1c of 0.9% at 6 months.[18] Thus every diabetic patient must visit the dietitian and follow the instructions seriously in order to improve the HbA1c levels.

This study has also shown that patients with LDL levels of < 100 mg/dl had significantly good chance of good HbA1c control. It is important to reduce LDL levels, as LDL lowering therapy decreases the risk of future cardiovascular events.[19] Subanayagam *et al*. conducted a population-based study in Singapore in 3000 individuals and found that lowering LDL levels were associated with good glycaemic control in diabetic patients.[20] Similarly, in another study on 2,220, type-2 diabetic patients, it was found that worse HbA1c has been associated with increase in LDL levels.[21] In Pakistan, there is a high prevalence of poor glycaemic control and dyslipidemia in diabetic patients as they have a poor knowledge regarding their disease hence LDL levels should be controlled in order to reduce the complications related to the problem.[22] BMI and physical activity did not show any significant association, this might be due to short duration of follow-up. Intake of medications showed a positive impact, however, it was statistically insignificant.

This study has certain limitations. Patients were followed for 4 months. It is very difficult to change certain parameters like BMI in such short time duration. Only patients presenting to one hospital in Karachi and patients who were from two rural regions of Pakistan were studied due to defined catchment area of the hospital. Hence these findings may not be generalizable to other parts of the country. Similar studies from both public and private hospitals with a longer follow-up time period and representation from all the provinces need to be done in future.

CONCLUSION

Modern technologies like mobile phone use in clinical setting are a good way to control blood glucose levels in a cost effective way. This can help in preventing the future deadly complications of this disease. Taking medications at proper time, following instructions of the dietitian by taking diabetic diet and lowering LDL levels have shown a good impact on the glycaemic control of DM patients.

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