Assessment of home glucose monitoring system in primary health care system; where are we?

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Abstract

Introduction: Self Monitoring Blood Glucose system is one of the glycemic control assessment tools. There are many barriers limiting its proper usage. This system is based on three components; availability of the glucometers system, operating skills and knowledge to interpretate its results.

Objectives: To assess the components of self monitoring blood glucose among patients with type 2 diabetes attending primary health care service and its relation to glycemic control.

Methodology: Cross sectional study was designed; one hundred and seventy eight (178; male 72, female 106) were randomly selected from our diabetic registry. All selected patients had type 2 diabetes. Data was collected through a designed questionnaire. The three components of the glucose self monitoring system were assessed. Selected nurses were trained to help patients who could not fill out the questionnaire by themselves. Data was collected and analyzed by SPSS Vers 14.

Results: One hundred and seventy eight (178) subjects ; (40.04% male vs 59.56% female). Eighty eight (88 subjects) were illiterate (49.4%) and most of them were female (38.9% male vs 56.6% female). In the male group only 77.7% had glucometers while in the female group only 52.8% had glucometers (P value <0.0001). In the male group only 61.1% knew how to operate the SMBG while only 39.6% of female group could (P value <0.00001). In the male group only 33.3% stated that they knew the targets of glucose monitoring while it was 68.8% in the female group (P value <0.00001). Only 55.5% of male subjects had the three components of proper home glucose self monitoring compared with 56.1% of female subjects (P value 0.036). Among males with full SMBG components HbA1c was 9.4(+/-)1.9% and 8.1(+/-)1.7 among females with full SMBG components (P value 0.002) .

Conclusion: Lack of proper structured education presented by educators and illiteracy may explain the bad glycemic control in our study sample. Further large studies were recommended.

Key words: Diabetes, glucose monitoring

Introduction

The measurement technology of measuring real time blood glucose has passed through many generation of development. The first self-testing kit for measuring glucose in urine was developed in the 1940s. The advent of capillary blood test strips followed in 1956 and glucose meters in the 1970s and early 1980s. (1) These advances facilitated the adoption of self-monitoring of blood glucose levels as part of the routine diabetes care especially for those on insulin therapy.

The self-monitoring blood glucose is one of the tools used to assess glycemic control and it can contribute to the control process by allowing for adjustments in diet, physical activity and pharmacotherapy in response to test results. The effect of self monitoring in patients taking insulin was well established (2) but its effect on those not on insulin is still controversial (3) but it is still the standard method for glucose assessment. Factors such as economic costs of strips used for tests and patient discomfort and inconvenience may be some of the limitations that have decreased the use of this tool.

Literature review showed some systematic reviews reported marginal advantage of self-monitoring blood glucose levels in terms of controlling HbA1c; interestingly these studies usually did not assess other outcomes such as hypoglycemia, long-term complications of diabetes or quality of life. (4-7)
It was very interesting that many studies did not account for the degree to which participants were educated on how to interpret and act on test results of self-monitoring. This is one of the three components of proper self-monitoring blood glucose systems, since people using test strips must be able to act properly in response to abnormal readings if the system is to be effective. One systematic review and meta analysis showed that self monitoring of blood glucose levels was associated with a modest, statistically significant reduction in hemoglobin A1c concentration (weighted mean difference - 0.25% , confidence interval 0.36% - 0.15%) regardless of whether patients were provided with education on how to interpret and use the test results (weighted mean difference - 0.28% , 95% CI 0.47 - 0.08%) . (8)

The proper self-glucose monitoring needs the availability of a glucose measurement device, skills to operate the device and knowledge to interpret the results. In our study we try to find answers whether, these components are available among our patients and if their presence will affect glycemic control (HbA1c level).

Methodology

Cross sectional study was designed .One hundred and seventy-six (176 subjects) were randomly selected from the diabetic patient registry. Only patients with type 2 diabetes who did two or more HbA1c tests during the year 2014 were included. We select the one that comes each with three components .Questionnaire was designed and distributed to all selected participants after their verbal acceptance to fill out the questionnaires. Two nurses were trained to help participants if they needed help in filling the questionnaire. Each questionnaire-contained questions covering the three components of glucose self-monitoring system; availability of device system, capability to operate the device system and knowledge to interpret results. One hundred and seventy six questionnaires were collected. Patients' medical records were reviewed and mean HbA1c for each patient was calculated. Data was analyzed using SPSS ver 14. One-way ANOVA test analysis was used to find any statistically significant differences between means.

We defined high blood glucose as blood glucose >= 250mg/dl and define low blood glucose as blood glucose =< 70mg/dl.

Results

One hundred and seventy eight (178; 72 male and 102 female) subjects with type 2 diabetes were randomly selected with main age 56.13(+/-) 12.95 and mean HbA1c 8.6(+/-) 2.12 (mean male HbA1c 9.76(+/-) 2.05, female mean HbA1c 8.3(+/-) 1.8) (Table 1).

Eighty eight (88) subjects (50%) were illiterate and most of them were female (57% female vs 38.9% male P value <0.00001) (Table 1). Majority of our subjects receive oral hypoglycemic medication (71.6%; male 66.6% while female 73.5% P value <0.00001) (Table 1).

In the male group only 56 subjects had glucometers while 16 subjects had not (77.7% vs 22.2%, P value <0.00001). In female group 56 subjects had glucometers while 56 had not (52.8% vs 47.1%, P value <0.0001) (Table 2). It was interesting to notice that 44 male subjects could operate their glucometers while 12 could not (61.1% vs 16.6%, P value <0.00001). In the female group, 42 of subjects could operate their glucometers while 32 could not (39.6% vs 30.1%, P value 0.00001) (Table 2). In the male group we noticed 12 patients had glucometers but they cannot operate them while in the female group we found 16 subjects had glucometers but they could not operate them (16.6% vs 15.1% , P value <0.00001) (Table 2) (Figure 1).

In the male group 52 subjects use their glucometers frequently at home while 12 subjects did not (72.2% vs 16.7% ,P value <0.00001). In the female group 48 subjects did frequent use of their glucometers while 28 subjects did not (45.2% vs 26.4% ,P value <0.00001) (Table 3). It was very interesting to note that only 32 male subjects had a glucose test results diary while only 8 females had (42.1% vs 7.5% , P value <0.00001).

In the male group only 24 subjects stated that they knew the targets of glucose monitoring while 20 subjects stated they did not know (33.3% vs 22.2% , P value <0.00001) (Table 4). In the female group 74 stated they knew the targets while 22 did not (68.8% vs 20.7%, P value <0.00001) (Table 4).

Table 1: Bibliography of subjects

	Male N= 72	Female N=106	P value
Age	59.07(+/-)14.13	55.4(+/-)12.4	0.044
Duration of diabetes	11.3(+/-) 4.2 years	10.9(+/-) 5.8 years	0.284339
HbA1c (mean)	9.76(+/-)2.05	8.3(+/-)1.8	<0.00001
Educational level			
Illiterate	38.9% (n=28)	57% (n=60)	<0.00001
Primary	5.5% (n=4)	24.5%(n=26)	<0.0001
Intermediate	22.2% (n=16)	5.7% (n=6)	<0.00001
Secondary	27.7%(n=20)	5.7% (n=6)	<0.00001
University	5.5%(n=4)	7.5% (n=8)	<0.00001
Type of medication			
Oral	66.6% (n=48)	73.5% (n=78)	<0.00001
Insulin	11.1% (n=8)	5.6% (n=6)	<0.00001
Oral + insulin	22.2% (n=16)	20.7% (n=22)	<0.00001

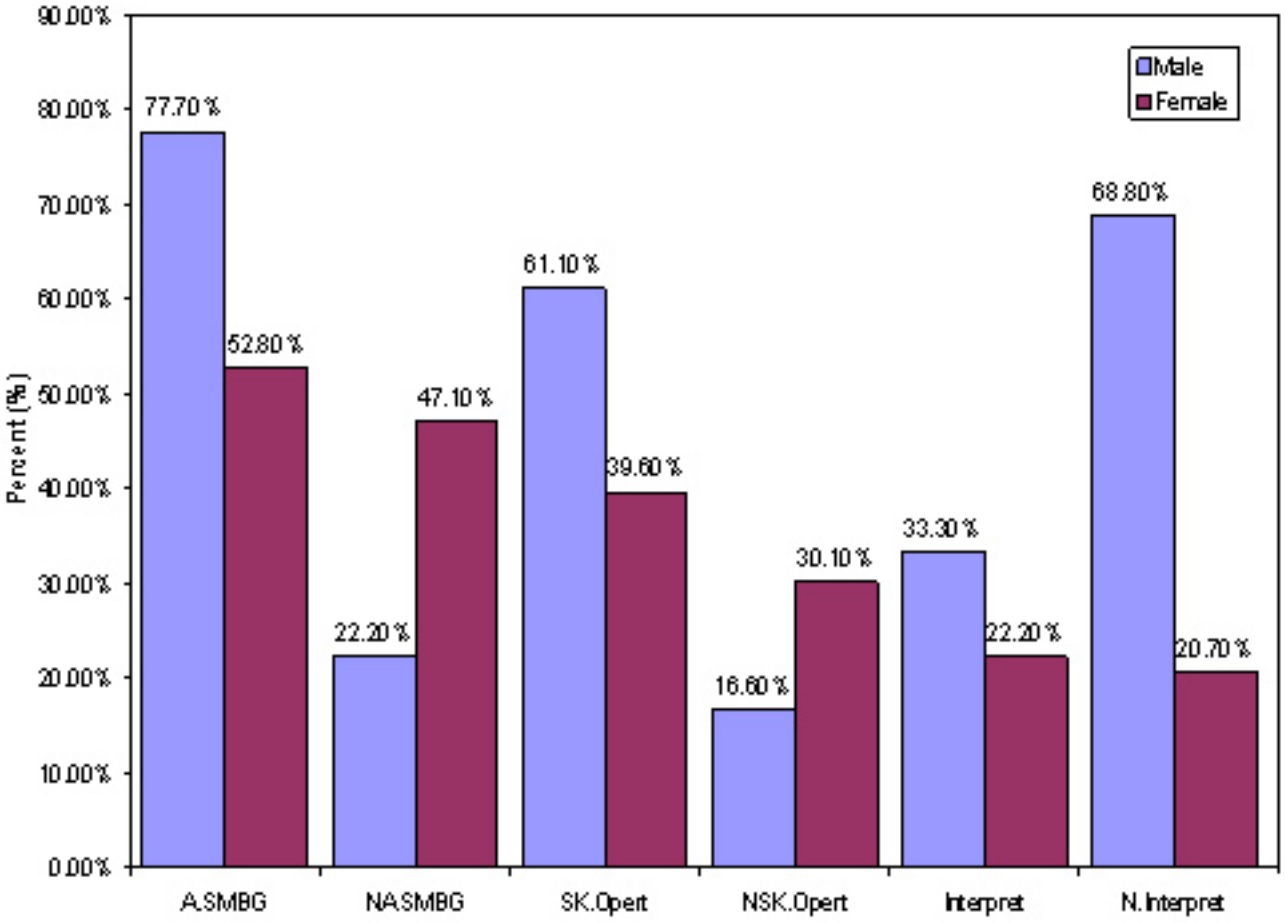
Table 2: Availability of glucometers and operation skills

	Male	Female	P value
Available % (subjects)	77.7% (n=56)	52.8% (n=56)	<0.00001
Not available % (subjects)	22.2% (n=16)	47.1% (n=50)	<0.00001
Can operate % (subjects)	61.1% (n=44)	39.6% (n=42)	<0.00001
Cannot operate % (subjects)	16.6% (n=12)	30.1% (n=32)	<0.00001
Available but cannot operate% (subjects)	16.6% (n=12)	15.1(n=16)	<0.00001

Table 3: Frequency of glucose test at home

	Male	Female	P value
Use glucometer frequently % (subjects)	72.2% (n=52)	45.2% (n=48)	<0.00001
Do not use glucometer frequently % (subjects)	16.7%(n=12)	26.4% (n=28)	<0.00001
Frequency of test (56.8% n=100)			
Daily % (subjects)	46.6% (n=24)	33.3% (n=16)	<0.00001
Weekly % (subjects)	38.4% (n=20)	45.8% (n=22)	<0.00001
Monthly % (subjects)	15.3% (n=8)	20.8% (n=10)	<0.00001
Had glucose test results diary			
Yes % (subjects)	42.1% (n=32)	7.5% (n=8)	<0.00001
No % (subjects)	57.8% (n=44)	93.3% (n=99)	<0.00001

Figure 1: Components of SMBG



A.SMBG = Availability of self-monitoring blood glucose
NA.SMBG = No availability of self-monitoring blood glucose
SK.Opert = Skills to operate glucometer
NSK-Opert = No Skills to operate glucometer
Interpret = interpretation glucometer result
N.Interpret = No interpretation glucometer result

Only 24 male subjects can take action in case of high blood glucose results (> 250mg/dl) while 12 stated they did not know what to do (47.2% vs 30.5% , P value <0.00001). In the female group 60 subjects can take action while 32 subjects did not know what to do (58.8% vs 31.3% , P value <0.00001) (Table 4).

When we compared the male group to female group ,we found that 47.2% male vs 58.8% female can take action if their blood glucose > 250mg/dl (P value 0.00001)

In case of low blood glucose (< 70mg/dl), 50 male subjects can take action and only 14 did not know (55.5% vs 5.6%, P value <0.00001). In the female group 90 subjects can take action while six subjects cannot take action (88.2% vs 5.8%, P value <0.00001) (Table 4). When we compared the male group to female group, we found that 55.5% male vs 88.2% female can take action if their blood glucose <70mg/dl (P value 0.00001).

Only 40 male subjects had the three components of proper home glucose self monitoring while 60 female subjects had them (55.5% vs 56.5%, P value 0.036) (Table 5).

Table 6 explains the relation between the components of SMBG and glycemic control among male and female groups. The differences were statistically different between male and female groups. Neither component was associated with good glycemic control (mean HbA1c <7%).

In (Table 7) we discussed the relation between those with full SMBG components and the type of medication they received. Interestingly HbA1c was 7.6(+/-) 0.75 among females with full SMBG components treated with insulin in comparison with 10.9 (+/-) 1.1 in the male group (P value <0.00001) and there is no statistically difference between male and female groups with full SMBG monitoring components treated with oral medication plus basal insulin (HbA1c 9.8(+/-) 0.4 vs 9.5(+/-)2.11 , P value 0.3085).

Table 4: Knowledge of glucose targets

	Male	Female	P value
Know the targets of home monitoring:			
Yes % (subjects)	33.3% (n=24)	68.8%(n=74)	<0.00001
No % (subjects)	22.2%(n=20)	20.7%(n=22)	<0.00001
Who told you the targets:			
Doctor % (subjects)	83.3% (n=20)	86.4% (n=64)	<0.00001
Educator % (subjects)	0% (n=0)	5.4% (n=4)	<0.00001
Relative(s) % (subjects)	16.7% (n=4)	8.1%(n=6)	<0.00001
Can take action in high blood glucose (> 250mg/dl):			
Yes % (subjects)	47.2% (n=34)	58.8%(n=60)	<0.00001
No % (subjects)	30.5%(n=22)	31.3%(n=32)	<0.022
Can take action in low blood glucose (<70mg/dl):			
Yes % (subjects)	55.5%(n=40)	88.2% (n=90)	<0.00001
No % (subjects)	5.6% (n=4)	5.8% (n=6)	0.119
Did you refer to diabetes educators:			
Yes % (subjects)	8.3% (n=6)	11.7% (n=12)	<0.0001
No % (subjects)	91.6% (n=66)	88.2% (n=90)	<0.0001

Table 5: Subjects who had all components of home glucose self monitoring

Gender	Availability of glucometer	Availability of operation skills	Availability of knowledge to interpret	Subjects	Mean HbA1c
Male	yes	yes	yes	55.5% (n=40	9.4(+/-)1.9%
Female	yes	yes	yes	56.4% (n=60)	8.1(+/-)1.7%
P value				<0.036	0.002

Table 6: Relation of SMG components to HbA1c

SMG component	Mean Male HbA1c	Mean Female HbA1c	P value
System available			
Yes	9.6(+/-)2.25%	8.2(+/-)0.6%	<0.00001
No	9.9(+/-)1.15%	7.7(+/-)2.48%	0.002
P value	0.227	0.0546	
Operation skills			
Yes	9.8(+/-)2.04%	8.4(+/-)1.7%	0.00023
No	9.97(+/-)2.16%	7.7(+/-)1.6%	0.00069
P value	0.421	0.04	
Knowledge to action			
Yes	10.03(+/-)1.8%	8.05(+/-)1.6%	<0.00001
No	7.3(+/-)1.7	8.26(+/-)1.7%	0.027
P value	<0.00001	0.29979	

Table 7: Comparison between subjects with full SMBG based on their type of treatment

	Mean Male HbA1c	Mean Female HbA1c	P value
Oral medications	8.7(+/-)1.8	7.5(+/-)1.4	0.00135
Oral medication+ Basal insulin	9.8(+/-)0.4	9.5(+/-)2.11	0.3085
Insulin only	10.9(+/-)1.1	7.6(+/-)0.75	<0.00001

Table 8: Relation between mean HbA1c and referred patients to structured education by nurse educators among all subjects

	Mean Male HbA1c	Mean Female HbA1c	P value
Not referred to structured education by nurse educators	9.9(+/-)1.97	8.5(+/-)1.6	0.00001
Referred to structured education by nurse educators	8.97(+/-) 1.56	8.24(+/-)1.43	0.000762
P value	<0.0001	<0.00001	

Table 9: Relation between referral to structured education by educators and mean HbA1c in subjects with full SMBG components

	Mean Male HbA1c	Mean Female HbA1c	P value
Referred to structured education by nurse educators	9.58(+/-)1.49	8.43(+/-)1.42	0.041
Not referred to structured education by nurse educators	9.7(+/-)2.18	8.22(+/-)1.84	0.022
P value	0.797	0.719	

Table 10 : Relation with full SMBG components and frequency of SMBG to mean HbA1c

Frequency	Mean Male HbA1c	Mean Female HbA1c	P value
Daily	9.69(+/-)2.05	8.3(+/-)0.45	0.011
Weekly	10(+/-)2.44	8.25(+/-)1.68	<0.00001
Monthly	9.2(+/-)1.13	7.62(+/-)1.25	0.005
P value	0.544	0.445	

In (Table 8) we discussed the effect of referral to structured diabetes education. Interestingly, our results showed that there is no effect of referral to structured education programs by nurse educators on bringing HbA1c towards the target (<7%) . Interestingly there is statistical difference between male and female groups who either referred or not referred; those not referred (9.9(+/-)1,97 vs 8.5(+/-)1.6 , P value 0.00001) and those referred (8.97(+/-)1.56 vs 8.24(+/-)1.43 ,P value 0.000762). When we compared male to male not referred to referred the difference was statistically significant (9.9(+/-)1.97 vs 8.97(+/-)1.56 ,P value < 0.0001) and female to female also the difference was found to be statistically significant (8.5(+/-) 1.6 vs 8.24(+/-)1.43 , P value <0.00001); but all did not drop to the target level (<7%).

In (Table 9) we compared those with full component of SMBG regarding referral or not referral to structured training programs by nurse educators. Among those who referred, there is statistically significant difference (male mean HbA1c 9.58(+/-) 1.49 vs female mean HbA1c 8.43(+/-) 1.42, P value 0.041). Interestingly it was not a statistically significantly difference when we compared the same gender groups; male group (mean HbA1c 9.58(+/-) 1.49 vs 9.7(+/-) 2.18, P value 0.797) vs female group (mean HbA1c 8.43(+/-) 1.42 vs 8.22 (+/-) 1.84, P value 0.719).

In (Table 10) we showed comparison between those with full SMBG components regarding their frequency of SMBG use and their mean HbA1c. Results showed that there are no statistically significant differences in male or female groups regarding the frequency of use and HbA1c; in male group daily, weekly and monthly frequency of test showed HbA1c 9.69(+/-) 2.05, 10(+/-) 2.44 and 9.2(+/-) 1.13 respectively with P value 0.544. While in the female group, it was 8.3(+/-) 0.45, 8.25(+/-) 1.68 and 7.62(+/) 1.25 with P value 0.445. When we compared male to female groups it was significantly statistically different for daily, weekly and monthly frequency (P value 0.001 ,P value <00001 and P value 0.005).

Discussion

Diabetes mellitus is a chronic disease that necessitates continuing treatment and patient self-care education. Monitoring of blood glucose to near normal level without hypoglycemia becomes a challenge in the management of diabetes. The global prevalence of diabetes by International Diabetes Federation (IDF) estimation shows that there are 366 million people with diabetes in 2011, and this is expected to rise to 552 million by 2030. (9)

Self-monitoring of blood glucose (SMBG) has been shown to be as effective in insulin-treated type 1 and type 2 diabetes. Although the effect of SMBG is already demonstrated in some meta-analysis (10-11), it is not recommended as regular use in non-insulin treated type 2 diabetes. SMBG fails to detect nocturnal hypoglycemia and asymptomatic hypoglycemia even in patients with good control of HbA1c values and it needs multiple blood samples throughout the day. In addition, SMBG gives a single instant reading without any information on glucose trends and thus may miss important and significant glucose fluctuations. (12-14)

In our study, we tried to answer some questions related to SMBG. Firstly, we raised the question whether the availability of a SMBG system will affect the glycemic control. Our results showed that availability of the system did not lead to good glycemic control either among male or female groups. The mean HbA1c during the year 2014 did not drop to below 7%, which we considered as good glycemic control, but it was much better among the female group who had a SMBG system (8.2 (+/-) 0.6% vs 9.6(+/-) 2.25%, P value 0.00001). In a randomized control trial done by Wing RR et al (15) the authors also found no statistical difference in HbA1c between those who had SMBG or not. Interestingly this study was done among patients treated with insulin.

On the other hand, another randomized clinical trial (16) in subjects treated with insulin reached a conclusion that presence of SMBG significantly improved HbA1c.

Guerci et al in their randomized control trial (17) concluded that availability of a SMBG system significantly improved HbA1c while Davidson et al (18) did not find any statistically difference in HbA1c. Interestingly Guerci et al was a large trial that included 689 participants while Davidson et al's trial included 88 participants. In sub analysis of our participants we noticed that females with SMBG system treated with insulin have better mean HbA1c than the male group treated with insulin (7.6(+/-)0.75 vs 10(+/-)1.1 , P value <0.00001) . When we work to find an explanation for this result we noticed that compliance to insulin therapy was better among female subjects treated with insulin than male subjects treated with insulin (P value <0.00001).

Then we raised a second question whether the capability to operate the SMBG will affect glycemic control? Our results showed that these skills did not take participants to good glycemic control whether they are male or female (mean HbA1c 9.8(+/-)2.04 vs 8.4(+/-)1.7 , P value 0.00023), but when skills are available with other components mean HbA1c improved (male mean HbA1c 9.4(+/-)1.9 vs female mean HbA1c 8.1(+/-)1.7 , P value 0.002). Brendan M et al (19) found in their systematic review and meta analysis that provided patients with education on how to interpret and apply SMBG system, results were similar to those from RCTs that did not.

Among those who were referred, the male group mean HbA1c was 8.97(+/-)1.56 while in female group mean HbA1c was 8.24(+/-)1.43 with statistically significant difference between the two groups (P value 0.000762). In subjects who were not referred to the structured education program by nurse educator the results showed a statistically significant difference between male and female groups (9.9(+/-) 1.97 vs 8.5(+/-) 1.6, P value 0.00001) with better mean HbA1c in the female group. This finding can be explained by that female patients were more adherent

to educational data and advice. Female patients usually implement more what they learn from educational sessions to their daily life, than male patients.

When we do sub-analysis no those who have the full components of appropriate SMBG and look to their mean HbA1c based on their referral or not referral to structured diabetes program, we found that mean HbA1c dropped more in the male group. It was 9.58(+/-)1.49 vs 8.97(+/-)1.56 P value 0.00001). Interestingly it was not improved in the female group (8.24(+/-)1.43 vs 8.43(+/-)1.42, P value 0.382). This data can be explained by that female patients with full components of SMBG were more reliant on the system itself and did not think that they need multiple structured education sessions. Also the power of culture and the restriction on female movement in the community forces those with full components to hold any participation in such continuous education programs as long as they have the components. Among male patients, the presence of full components of SMBG was a motivation to join a structured educational program, which reflected positively on their mean HbA1c (Table 8-9).

Then we ask ourself if the frequency of SMBG among those with full criteria of appropriate SMBG affected their mean HbA1c? Our results showed no statistically significant difference between male to male and female to female groups who did tests on a daily base, weekly base and monthly base (P value 0.544 vs P value 0.445), but when we compared male to female groups, the difference was statistically significant (daily base, weekly base and monthly base with correspondent P values 0.005, <0.00001 and 0.11) (Table 10). We did not find an effect on frequency of SMBG and mean HbA1 in patients receiving oral, oral plus insulin or insulin only. Schutt M et al (20) did not find effect of frequency of SMBG and level of HbA1c among patients on oral anti-hyperglycemic medications but they found effect among those who use insulin.

Conclusion

The use of SMBG in patients with type 2 diabetes is a complex issue with no clear findings supporting clear recommendations. There are many papers that support its use in patients with type 2 diabetes mellitus especially in the first year of diabetes where its significance starts to decline after 12 months. On the other hand, there are studies that concluded on not to use SMBG in patients with type 2 diabetes due to insignificant effect on glycemic control indicators such as HbA1c as well as the cost of these systems.

In our opinion, the SMBG when individually recommended to selected patients such as type 2 patients on insulin or with add on insulin or on their first year after diagnosis will help these patients very well to improve their HbA1c and the long term metabolic complications. (21)

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Abbreviations:

SMBG = Self Monitoring Blood Glucose
HbA1c = Glycated Haemoglobin

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