



SELF MONITORING OF BLOOD GLUCOSE & ITS EFFICACY

General Medicine

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ABSTRACT

Introduction: Diabetes mellitus is a chronic metabolic disorder which leads to complications especially when not properly managed. The role of self-monitoring of blood glucose (SMBG) in type 2 diabetic patients treated with Insulin helps in adjusting the dose required to normalise blood glucose level. Proper adherence to SMBG decrease the progression of disease and emergence of complications

Objectives: To determine the efficacy of Self-monitoring blood glucose triweekly vs weekly basis in bringing down the HbA1C in insulin treated patients with type 2 diabetes mellitus.

Methodology: 60 insulin treated Diabetes Mellitus patient (mean age of 18-70 years) who attended Diabetic OPD with a mean HbA1C > 8 were randomised into 2 groups. The first arm of 30 patients were doing SMBG on three days of a week (pre meal/ 2 hr post meal) based on three discreet meals (breakfast, lunch, dinner) Total of six readings per week (Sunday, Wednesday, Friday). The second arm of 30 patients were doing SMBG on weekly once basis a total of six SMBG readings in a day of a week. (FBS/ 2 hr PPBS, Pre-lunch/ 2 hr post-lunch, pre-dinner/ 2 hr post dinner) on Sundays. Baseline sugars, HbA1C, fasting lipid profile, Serum creatinine, blood urea, Blood pressure and Body mass index were measured in both control and test group at the beginning of the study. Difference in FBS, PPBS, HbA1C were compared in the end of three months between both the test and control group. Data were entered into Microsoft excel sheet and analysed using SPSS version 16. Continuous variables like age, height, weight, BMI, Systolic and Diastolic BP, Renal Function tests, Lipid profile, Fasting and Post Prandial Blood Sugar were depicted as mean and standard deviation. Paired sample t test was done to assess the mean difference in FBS, PPBS, HbA1C after 3 months in both groups.

Results: The minimum age was 42 years among the thrice weekly SMBG group and 43 years among once weekly SMBG. The mean (SD) of thrice weekly SMBG was 59.60(11.38) years and that of once weekly SMBG was 59.57(11.14) years. Both of the groups had maximum number of male subjects. 18(60%) and 16(53.3%) among pregabalin and placebo group respectively.

The mean (SD) SBP of thrice weekly SMBG was 137.06(13) mm of Hg and that of once weekly SMBG was 136.6(14.43) mm of Hg. The mean (SD) DBP of thrice weekly SMBG was 88.47(9.58) mm of Hg and that of once weekly SMBG was 87.27(8.04) mm of Hg. The mean (SD) BMI of thrice weekly SMBG was 30.63(6.39) Kg/m² and that of once weekly SMBG was 29.69(6.31) Kg/m². The mean (SD) FBS of thrice weekly SMBG was 195.6(43.29) mg/dl and that of once weekly SMBG was 195.13(43.84) mg/dl. The mean (SD) height of thrice weekly SMBG was 286.5(48.3) mg/dl and that of once weekly SMBG was 379.5(51.98) mg/dl. The mean (SD) HbA1C of thrice weekly SMBG was 9.76(1.25) and that of once weekly SMBG was 10.39(1.19). There was a statistically significant improvement, that is decrease in FBS, PPBS, HbA1C after thrice weekly Self-Monitoring of Blood Glucose for 3 months. In FBS [195.60±43.291 to 177.80±24.395 (p value-0.04)], in PPBS [286.50±48.319 to 246.67±35.170 (p value<0.001)], in HbA1C [9.763±1.25 to 8.9300±1.029 (p value-0.002)]. All these were statistically significant. The mean difference between pre and post 3 months FBS, PPBS, HbA1C among once weekly SMBG was not statistically significant.

Conclusion: The use of regular and frequent use of SMBG (thrice weekly) among type 2 DM patients lead to better glycaemic control compared with patients who had less frequent SMBG. This can be used for improved physical quality of life by adjusting medications.

KEYWORDS

INTRODUCTION:

Diabetes Mellitus (DM) is a non-communicable disease of numerous risk-factors manifested as chronic hyper-glycaemia with disorder of carbohydrate, protein and fat metabolism caused by diminished insulin secretion, insulin action, or both.¹ Chronic-hyperglycaemia can lead to damage to organ-systems causing life-threatening health-complications both microvascular (retinopathy, nephropathy, and neuropathy) and macrovascular. All these lead to 2- 4-fold increased risk of cardiovascular diseases.²

Diabetes is defined on the basis of a fasting hyperglycaemia (≥ 126 mg/dl), glucose levels being greater or equal to 200 mg/dl at 120 min after an oral glucose tolerance challenge or a random glucose test showing levels to be greater or equal to 200 mg/dl on two or more occasions. Impaired fasting glucose (IFG) typically precedes diabetes and is defined by fasting blood glucose being in the 100–125 mg/dl range.³ HbA1c is considered the golden standard in the management of type 2 diabetes mellitus (T2DM). Although HbA1c is the target, it is measured once every 3 months, and day-to-day self-management of diabetes to achieve and maintain the individualized target HbA1c is facilitated by self-monitored blood glucose (SMBG) values, especially in patients treated with insulin. HbA1c does not provide details about the daily glycaemic values and the amplitude of glycaemic variability (frequency and magnitude of the glycaemic excursions) to which the patient is exposed daily.^{4,5} Self-monitoring of blood glucose is supposed to assist people with diabetes in handling

their disease and in sustaining blood glucose at levels that may prevent diabetic problems⁶.

OBJECTIVES:

To compare the pattern of monitoring on triweekly vs weekly basis in bringing down the HbA1C in insulin treated patients with type 2 diabetes mellitus.

METHODOLOGY:

- A Randomised control trial was done among 60 patients, satisfying inclusion criteria (Both sexes of age 18-70 years, Out-patient based type 2 diabetes patients on insulin and OHAS management, Patients who are willing to self-monitor their blood glucose on weekly and triweekly basis, Patients with HbA1C > 8), were included in the study in a tertiary hospital, after obtaining IEC protocol. The first arm of 30 patients were ng SMBG on three days of a week (pre meal/ 2 hr post meal) based on three discreet meals (breakfast, lunch, dinner) Total of six readings per week (Sunday, Wednesday, Friday). The second arm of 30 patients were doing SMBG on weekly once basis a total of six SMBG readings in a day of a week. (FBS/ 2 hr PPBS, Pre-lunch/ 2 hr post-lunch, pre-dinner/ 2 hr post dinner) on Sundays. Baseline sugars, HbA1C, fasting lipid profile, Serum creatinine, blood urea, Blood pressure and Body mass index were measured in both control and test group at the beginning of the study. Difference in FBS, PPBS, HbA1C were compared in the end of three months between both the test

and control group. Data was entered in MS excel sheet and analysed using SPSS software version 16 using paired or dependant T test with P value less than 0.05 were considered statistically significant.

RESULTS:

A Pubmed, MEDLINE, INDMED, ADA data basis analysis was performed to identify studies describing the efficacy of self monitoring blood glucose in diabetes. Search terms "self monitoring blood glucose, type 2 diabetes". Selected articles referenced in these publications were also examined. Using the search strategy described above, few below articles met the inclusion criteria and were included, clinical and experimental studies, cohorts, meta analysis and systematic reviews of great impact and scientific relevance to the topic.

- Baltaci D et al (2012)**⁶² did a study to evaluate effectiveness of SMBG on metabolic control in Turkish patients with type 2 DM. The participants were assigned to three groups according to status of SMBG: group 1- regular, group 2 - irregular and group 3 - never SMBG implementation. A total of 349 patients were enrolled. There was no significant difference in mean fasting and post-prandial blood glucose, lipid profile values between the groups. The number of patients with high education level in group 1 was higher than groups 2 and 3 ($p = 0.001$). HbA1c level was higher in groups 2 and 3 than group 1, but not significantly ($p = 0.285$). Mean spot urinary albumin- creatinine ratio (ACR) in group 1 is significantly lower than in groups 2 and 3 ($p = 0.008$ and $p = 0.044$, respectively), but no significant difference was observed between group 2 and 3 ($p = 0.473$). They concluded that regular use of SMBG was not superior to irregular/never use of SMBG on glycaemic control, but it seemed to be good intervention for prevention of diabetic nephropathy.
- Hou et al (2014)**⁶³ did a meta-analysis to evaluate the efficacy of blood glucose self-monitoring on glycaemic control in patients with non-insulin-treated type 2 diabetes. The results indicated that blood glucose self-monitoring significantly reduced the glycated haemoglobin (HbA1c) level by 0.41%. Subgroup analysis showed that while implementation of a diabetes management regimen based on the blood glucose self-monitoring results effectively reduced the HbA1c level by 0.42%, no significant improvement in HbA1c level control was observed with the implementation of blood glucose self-monitoring alone.
- McIntosh et al (2010)**⁶⁴ identified in their review that there was a statistically significant improvement in the HbA1c concentration across RCTs that compared self-monitoring of blood glucose levels with no self-monitoring among patients taking oral anti-diabetes drug therapy (weighted mean difference -0.25% , 95% confidence interval -0.36% to -0.15%). Subgroup analysis indicated that results from RCTs that provided patients with education on how to interpret and apply self-monitoring test results were similar to those from RCTs that did not.
- Tura et al (2015)**⁶⁵ did a double-blind, randomized, placebo-controlled crossover study to identify the utility of four-point pre-prandial glucose self-monitoring to calculate several indices of glycaemic control and variability in a study adding the DPP-4 inhibitor vildagliptin to ongoing insulin therapy. They found that vildagliptin improved the glycaemic condition compared to placebo: mean glycaemic levels, and both GRADE and M-VALUE, were reduced by vildagliptin (< 0.01). Indices also showed that vildagliptin reduced glycemia without increasing the risk for hypoglycaemia.
- Zhu et al (2016)**⁶⁶ found that the SMBG intervention improved glycated haemoglobin (HbA1c) (mean difference -0.33 ; 95% CI -0.45 to -0.22 ; $p=3.0730e-8$; $n=18$), body mass index (BMI; -0.65 ; -1.18 to -0.12 ; $p=0.0164$; $n=9$) and total cholesterol (TC; -0.12 ; -0.20 to -0.04 ; $p=0.0034$; $n=8$) more effectively than the control in overall effect. SMBG improved HbA1c levels in the short term (≤ 6 -month follow-up) and long term (≥ 12 -month follow-up) in patients with T2D who were not using insulin.
- Lee et al (2016)**⁶⁷ did a study with an objective to investigate the effect of patient engagement in self-monitoring with a telemonitoring device on glycaemic control among patients with type 2 diabetes. After 6 months, change in HbA1c was $-2.4 \pm 1.6\%$ among frequent users and $-1.5 \pm 1.5\%$ among infrequent users ($p=0.003$). The proportion of patients achieving target HbA1c level at 6 months was significantly higher among frequent users than among infrequent users. An increased frequency of SMBG

was significantly correlated with a reduction in HbA1c at 6 months.

- Allemann et al (2009)**⁶⁸ assessed the effect of self-monitoring of blood glucose (SMBG) on glycaemic-control in non-insulin treated patients by means of a systematic review and meta-analysis. Fifteen trials (3270 patients) were included in the analyses. SMBG was associated with a larger reduction in HbA_{1c} compared with non-SMBG.
- Kim (2018)**⁶⁸ did a study to evaluate effectiveness of SMBG among patients with insulin-treated T2DM. Compared to baseline (HbA1c, $8.5\% \pm 1.3\%$), significantly decreased HbA1c ($8.2\% \pm 1.2\%$) was observed at the end of follow-up (median, 6.1 months). Baseline HbA1c and fasting serum glucose levels showed moderate-to-strong inverse correlations with changes in HbA1c respectively.
- Malanda et al (2012)**⁶⁹ did a study to analyse the effects of SMBG in patients. SMBG induced decrease in HbA1c at up to six months follow-up (-0.3 ; 95% confidence interval (CI) -0.4 to -0.1 ; 2324 participants, nine trials), yet an overall statistically non-significant SMBG induced decrease was seen at 12 month follow up.
- Karter et al (2001)**⁷⁰ found that self-monitoring among patients with type 1 diabetes ($> \text{or} = 3$ times daily) and pharmacologically treated type 2 diabetes (at least daily) was associated with lower HbA1c levels than less frequent monitoring.
- Martin et al (2006)**⁷¹ conducted a study to investigate the relationship of SMBG with disease-related morbidity and mortality. The total rate of non-fatal events, micro- and macrovascular, was lower in the SMBG group than in the non-SMBG group (7.2 vs 10.4%). A similar difference was found for the rate of fatal events (2.7 vs 4.6%).

The study was done among 60 subjects (30 subjects in each group). One group was Thrice weekly SMBG and other was Once weekly SMBG. The minimum age was 42 years among the thrice weekly SMBG group and 43 years among once weekly SMBG. The mean (SD) of thrice weekly SMBG was 59.60(11.38) years and that of once weekly SMBG was 59.57(11.14) years.

Both of the groups had maximum number of male subjects. 18(60%) and 16(53.3%) among pregabalin and placebo group respectively. The minimum SBP was 110 mm Hg among the thrice weekly SMBG group and once weekly SMBG group. The mean (SD) SBP of thrice weekly SMBG was 137.06(13) mm of Hg and that of once weekly SMBG was 136.6(14.43) mm of Hg. The minimum DBP was 70 mm Hg among the thrice weekly SMBG group and 110 mm of Hg once weekly SMBG group. The mean (SD) DBP of thrice weekly SMBG was 88.47(9.58) mm of Hg and that of once weekly SMBG was 87.27(8.04) mm of Hg. The minimum weight was 55 Kg among the thrice weekly SMBG group and once weekly SMBG group. The maximum weight was 89 Kg in both groups. The mean (SD) weight of thrice weekly SMBG was 68.97(8.74) Kg and that of once weekly SMBG was 69.2(8.73) Kg. The minimum height was 130 cm among the thrice weekly SMBG group and 132 among once weekly SMBG group. The maximum height was 171 cm in thrice weekly SMBG group and 172 cm among once weekly SMBG group. The mean (SD) height of thrice weekly SMBG was 148.5(12.9) cm and that of once weekly SMBG was 148.73(12.35) cm. The minimum BMI was 20 Kg/m² among the thrice weekly SMBG group and 21 Kg/m² among once weekly SMBG group. The maximum BMI was 42.79 Kg/m² in thrice weekly SMBG group and 42.78 Kg/m² in once weekly SMBG group. The mean (SD) BMI of thrice weekly SMBG was 30.63(6.39) Kg/m² and that of once weekly SMBG was 29.69(6.31) Kg/m². The mean (SD) of creatinine among thrice weekly SMBG was 1.44(.68) mg/dl and that of once weekly SMBG was 1.45(.65) mg/dl. The mean (SD) of blood urea was 59.87(15.09) mg/dl among thrice weekly SMBG and 60.03(15.32) among once weekly SMBG.

The mean (SD) of Total Cholesterol among thrice weekly SMBG was 201.2(43.15) mg/dl and that of once weekly SMBG was 203.73(35.054) mg/dl. The mean (SD) of Triglycerides was 150.73(31.21) mg/dl among thrice weekly SMBG and 153.77(42.4) mg/dl among once weekly SMBG. The mean (SD) of HDL was 42.13(8.26) mg/dl among thrice weekly SMBG and 42.4(8.4) mg/dl among once weekly SMBG. The mean (SD) of LDL was 113.03(36.72) mg/dl among thrice weekly SMBG and 113.87(36.9) mg/dl among once weekly SMBG. The mean (SD) of VLDL was 21.1(5.38) mg/dl among thrice weekly SMBG and 21.03(5.47) mg/dl among once weekly SMBG.

The minimum FBS was 135 mg/dl among the thrice weekly SMBG group and 134 mg/dl among once weekly SMBG group. The maximum FBS was 280 mg/dl in thrice weekly SMBG group and once weekly SMBG group. The mean (SD) FBS of thrice weekly SMBG was 195.6(43.29) mg/dl and that of once weekly SMBG was 195.13(43.84) mg/dl.

The minimum PPBS was 192 mg/dl among the thrice weekly SMBG group and 187 mg/dl among once weekly SMBG group. The maximum PPBS was 360 mg/dl in thrice weekly SMBG group and 370 mg/dl among once weekly SMBG group. The mean (SD) height of thrice weekly SMBG was 286.5(48.3) mg/dl and that of once weekly SMBG was 379.5(51.98) mg/dl.

The minimum HbA1C was 8.2 among the thrice weekly SMBG group and 9 among once weekly SMBG group. The maximum HbA1C was 12.7 in thrice weekly SMBG group and 13 among once weekly SMBG group. The mean (SD) HbA1C of thrice weekly SMBG was 9.76(1.25) and that of once weekly SMBG was 10.39(1.19).

Figure: Frequency distribution of FBS, PPBS, HbA1C among two groups

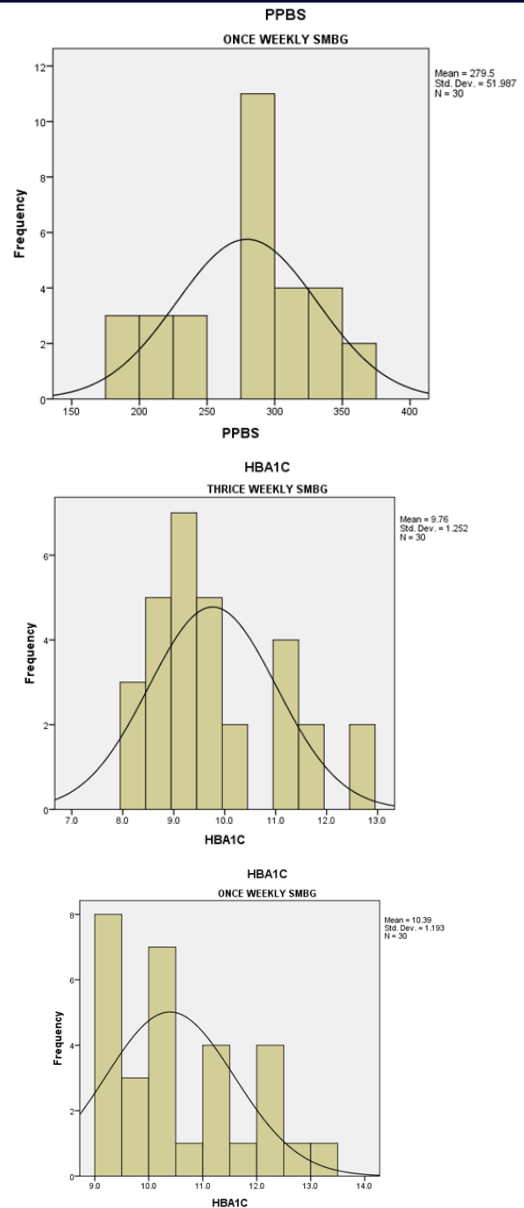
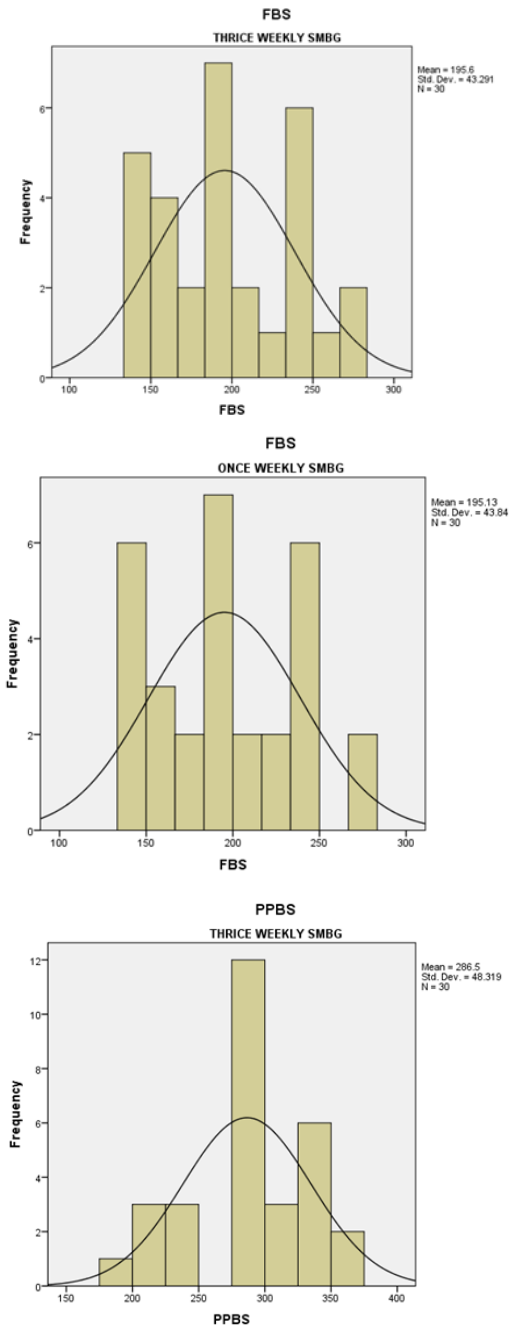


Table: Comparison of socio-demographic variables between group

	GROUP	Mean	Std. Deviation	F value	p value
Age	Thrice weekly SMBG	59.60	11.38	0.015	.904
	Once weekly SMBG	59.57	11.14		
SBP	Thrice weekly SMBG	137.07	13.0	0.44	.509
	Once weekly SMBG	136.6	14.42		
DBP	Thrice weekly SMBG	88.47	9.58	0.24	.623
	Once weekly SMBG	87.27	8.04		
Weight	Thrice weekly SMBG	68.97	8.743	0.07	0.786
	Once weekly SMBG	69.20	8.731		
Height	Thrice weekly SMBG	148.50	12.591	0.006	.94
	Once weekly SMBG	148.73	12.351		
BMI	Thrice weekly SMBG	30.63	6.39	0.007	.93
	Once weekly SMBG	29.69	6.31		

Table: Mean difference between FBS, PPBS, HbA1c among group in two different times

GROUP		Mean	Std. Deviation	p value
Thrice weekly SMBG	FBS	195.60	43.291	0.04*
	FBS after 3 months	177.80	24.395	
	PPBS	286.50	48.319	<0.001*
	PPBS after 3 months	246.67	35.170	
	HbA1C	9.763	1.25	0.002*
HbA1C after 3 months	8.9300	1.029		

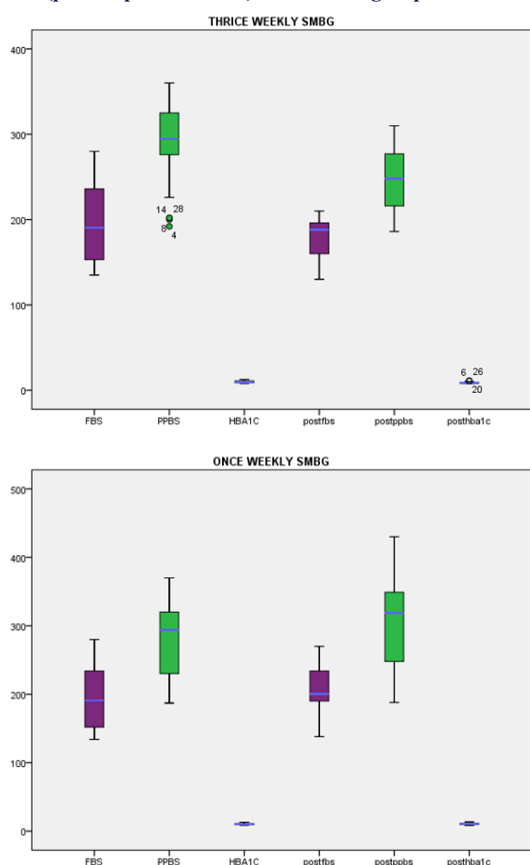
Once weekly SMBG	FBS	195.13	43.84	0.21
	FBS after 3 months	205.07	33.59	
	PPBS	279.50	51.99	0.065
	PPBS after 3 months	306.73	60.30	
	HbA1C	10.393	1.19	0.16
	HbA1C after 3 months	10.7133	1.189	

***Paired t test
p value <0.05 was significant**

The above table showed that there was a statistically significant improvement, that is decrease in FBS, PPBS, HbA1C after thrice weekly Self-Monitoring of Blood Glucose for 3 months. In FBS [195.60±43.291 to 177.80±24.395 (p value-0.04)], in PPBS [286.50±48.319 to 246.67±35.170 (p value<0.001)], in HbA1C [9.763±1.25 to 8.9300±1.029 (p value-0.002)]. All these were statistically significant.

The mean difference between pre and post 3 months FBS, PPBS, HbA1C among once weekly SMBG was not statistically significant.

Figure: Box plot showing the mean difference among FBS, PPBS, HbA1C (pre and post 3 months) between two groups



The above box plot showed that there was a significant decrease in FBS, PPBS, HbA1C after thrice weekly Self-Monitoring of Blood Glucose for 3 months. In FBS [195.60±43.291 to 177.80±24.395 (p value-0.04)], in PPBS [286.50±48.319 to 246.67±35.170 (p value<0.001)], in HbA1C [9.763±1.25 to 8.9300±1.029 (p value-0.002)].

The mean difference between pre and post 3 months FBS, PPBS, HbA1C among once weekly SMBG was not statistically significant.

DISCUSSION

The main objective of the study is to determine the efficacy of Self-monitoring blood glucose triweekly vs weekly basis in bringing down the HbA1C in insulin treated patients with type 2 diabetes mellitus.

The minimum age was 42 years among the thrice weekly SMBG group and 43 years among once weekly SMBG. The mean (SD) of thrice weekly SMBG was 59.60(11.38) years and that of once weekly SMBG

was 59.57(11.14) years. Both of the groups had maximum number of male subjects. 18(60%) and 16(53.3%) among pregabalin and placebo group respectively.

The mean (SD) SBP of thrice weekly SMBG was 137.06(13) mm of Hg and that of once weekly SMBG was 136.6(14.43) mm of Hg. The mean (SD) DBP of thrice weekly SMBG was 88.47(9.58) mm of Hg and that of once weekly SMBG was 87.27(8.04) mm of Hg. The mean (SD) BMI of thrice weekly SMBG was 30.63(6.39) Kg/m² and that of once weekly SMBG was 29.69(6.31) Kg/m². The mean (SD) FBS of thrice weekly SMBG was 195.6(43.29) mg/dl and that of once weekly SMBG was 195.13(43.84) mg/dl. The mean (SD) height of thrice weekly SMBG was 286.5(48.3) mg/dl and that of once weekly SMBG was 379.5(51.98) mg/dl. The mean (SD) HbA1C of thrice weekly SMBG was 9.76(1.25) and that of once weekly SMBG was 10.39(1.19).

There was a statistically significant improvement, that is decrease in FBS, PPBS, HbA1C after thrice weekly Self-Monitoring of Blood Glucose for 3 months. In FBS [195.60±43.291 to 177.80±24.395 (p value-0.04)], in PPBS [286.50±48.319 to 246.67±35.170 (p value<0.001)], in HbA1C [9.763±1.25 to 8.9300±1.029 (p value-0.002)]. All these were statistically significant. The mean difference between pre and post 3 months FBS, PPBS, HbA1C among once weekly SMBG was not statistically significant.

Limitation:

Factors like Fasting Lipid Profile, Renal function tests and BMI were not followed up after 3 months. Smaller sample size decreased the chance of generalisability of the study. Hospital based study in a tertiary care setting may lead to underrating community related factors determining the progression of the disease.

CONCLUSION:

In conclusion our study results shows a statistically significant improvement, that is decrease in FBS, PPBS, HbA1C after thrice weekly Self-Monitoring of Blood Glucose for 3 months. In FBS [195.60±43.291 to 177.80±24.395 (p value-0.04)], in PPBS [286.50±48.319 to 246.67±35.170 (p value<0.001)], in HbA1C [9.763±1.25 to 8.9300±1.029 (p value-0.002)]. All these were statistically significant. The mean difference between pre and post 3 months FBS, PPBS, HbA1C among once weekly SMBG was not statistically significant.

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