



EFFICACY OF SELF MONITORING OF BLOOD GLUCOSE IN IMPROVING THE GLYCEMIC CONTROL (HbA1C) IN INSULIN TREATED PATIENTS WITH TYPE 2 DIABETES MELLITUS

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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.⁴⁻⁸ 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 problems⁹.

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 dependent T test with P value less than 0.05 were considered statistically significant.

RESULTS:

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.

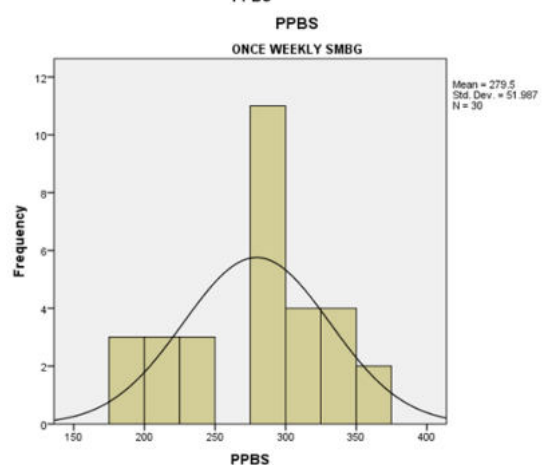
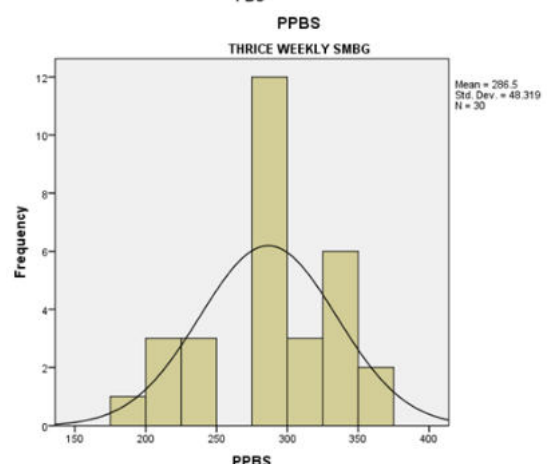
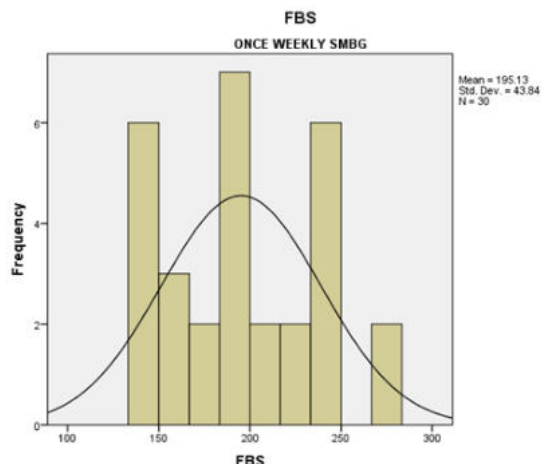
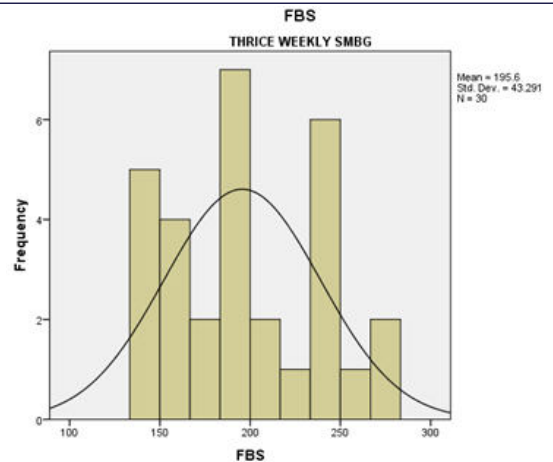
Both of the groups had maximum number of male subjects. 18(60%) and 16(53.3%) among pregabalin and placebo group respectively. The minimum SBP was 110 mm Hg among the thrice weekly SMBG group and once weekly SMBG group. The mean (SD) SBP of thrice weekly SMBG was 137.06(13) mm of Hg and that of once 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 21Kg/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).



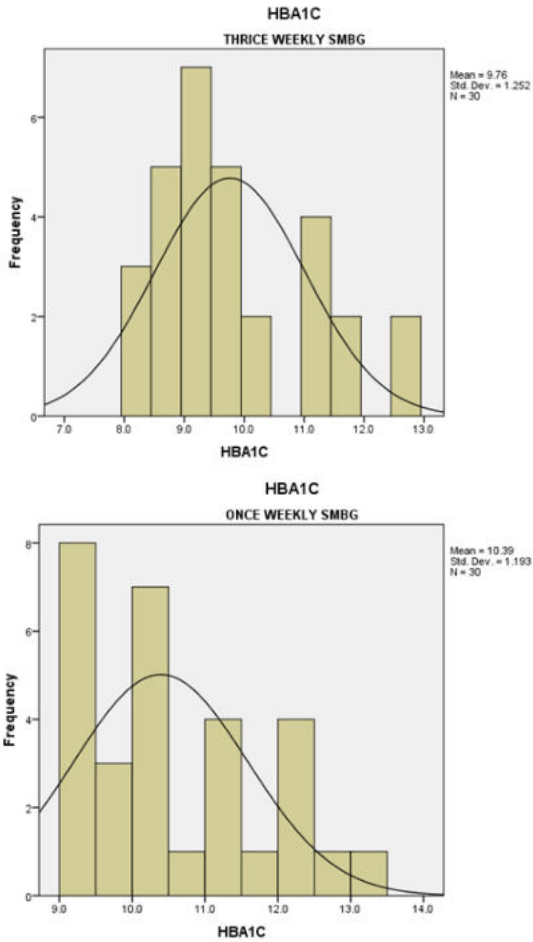


Figure: Frequency distribution of FBS,PPBS, HbA1C among two groups

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.

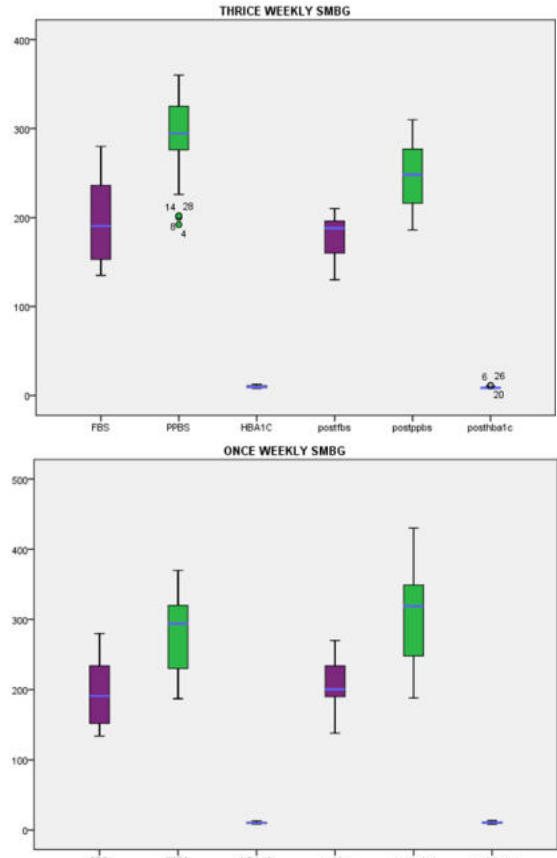


Figure: Box plot showing the mean difference among FBS, PPBS, HbA1C (pre and post 3 months) between two groups

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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