



Glucose Monitoring and Telemonitoring Pattern among Patients with Diabetes Mellitus

Author

Dr Pradeep Kumar Shukla

Assistant Professor Dept. of Medicine Teerthankar Mahaveer Medical College & Research Centre
Moradabad

Corresponding Author

Dr Pradeep Kumar Shukla

Assistant Professor Dept. of Medicine, Teerthankar Mahaveer Medical College & Research Centre
Moradabad, India

Summary

SMBG and Telemonitoring participants used the Glucometer for blood glucose analysis that enabled patients to record profile on 3 consecutive days prior to each scheduled study visit. ACG used to visit clinic/ hospital for regular blood glucose monitoring and follow-up as per schedule. All Participants received training in the use of the glucometer and instructions how to identify glycemic patterns and how to resolve them by changes in physical activity, portion sizes, and/or meal composition. Telemonitoring means measurement of BG at home and reports are sent by the text message or by email. Patients put on telemonitoring group were instructed to measure their BG, weight at home and report it by email or by telephone. Their data was entered in the Excel sheet and was interpreted. Any minor modification in treatment or in diet was communicated through email or telephone. Data was continuously monitored by the treating physician and instructions were inserted on the excel sheet.

480 patients screened, 374 (SMBG =123, TMG= 125, ACG =126) were eligible and were enrolled in the study. Of these 10 (SMBG =4, TMG= 3, ACG =3) patients doesn't gave consent and 15(SMBG =4, TMG= 6, ACG =5) patients were lost to follow up . So data of total 349 patients was collected, interpreted and analysed. Total 115 patients in SMBG 38.26% were below 50 years age and 61.74% were above 50 years age group, similarly in TMG and ACG group <50: >50 percentage was 41.38%: 58.62% and 41.43%:58.47% respectively.

Male to female percentage in SMBG was 60% and 40 %, while in TMG it was 61.21% and 38.79 % respectively. Percentage in ACG of male and female patients was 62.71% and 37.29% respectively. Percentage of patients put on single drug or on dietary treatment in SMBG, TMG and ACG was 46.96%, 58.62% and 56.78% respectively, while percentage of patients on 2 or more drugs in in SMBG, TMG and ACG was 53.04%, 41.38% and 43.22% respectively.

Introduction

Diabetes is strongly associated with micro- and macro-vascular complications which results in organ and tissue damage in about one-third to one-

half of the diabetic patients¹. The incidence of diabetes is increasing in both the developed and developing countries². Its prevalence is 171,000,000 (2.8%) for all age groups in the

world according to WHO data and it is estimated to reach 366,000,000 (4.4%) by the year 2030. Good control of blood glucose and blood pressure and proper management of dyslipidemia reduces complications and mortality among people with diabetes³. HemoglobinA1c is an excellent population health measure for the risk of vascular complications in diabetes, while continuous glucose monitoring (CGM) is a tool to help personalize a diabetes treatment plan. CGM is a tool for both patients and clinicians to look for the important role that diet, exercise, stress management, and the appropriate selection of diabetes medications can have in managing type 2 diabetes (T2D). Self-monitoring of blood glucose (SMBG) is widely recognized as a core component of effective diabetic self-management⁴.

The increasing prevalence of diabetes, hypertension and other chronic conditions means that traditional models of management in family practice are under extreme pressure and effective approaches like self-monitoring or telemonitoring can be developed to reduce the mortality and morbidity of the disease.

The traditional model of doctor patient relation is face to face consultation for managing diabetes and hypertension, but it can be costly and time consuming in terms of health care professionals. Some reviews indicate that engaging patients in self-monitoring and management can improve clinical outcomes in some chronic disorders⁵.

This study was carried out to investigate the effect of telemonitoring and SMBG intervention on glycemic control in poorly controlled, non-insulin treated type 2 diabetic patients.

Material and Methods

This study was carried out in the Dept. of Medicine in collaboration with Dept. of Biochemistry at Teerthankar Mahaveer Medical College & Research Centre Moradabad. This was more than one year study was the structured Testing programme, multicentre comparison between poorly controlled noninsulin-treated type

2 diabetic patients using structured SMBG in conjunction with enhanced usual care (structured testing group) and an active control group (ACG) that received enhanced usual care. In Enhanced usual care group monthly clinic visits, focusing on diabetes management, blood glucose and A1C testing was done and the third group was telemonitoring group in which patients were having own glucometer, cell phone, email id and can report on phone or on email.

Inclusion criteria

Duration of type 2 diabetes >1 year;

Aged ≥ 25 years;

HbA1C level 7.5–12.0%;

Currently treated by diet, exercise, oral diabetes medication.

Exclusion criteria

Type 1 diabetes managed with insulin, used systemic oral or inhaled steroids more than 14 days within the last 3 month, treated with chemotherapy or radiation therapy; ,pregnant or breast-feeding; major surgery in last 3 months. Severe depression or other severe psychological conditions.

The study protocol was approved by institutional ethical committee. Written informed consent was also obtained from the study participants.

Patients were randomly grouped in SMBG group, telemonitoring group (TMG) and active control group (ACG) that received enhanced usual care. Total of 480 patients were selected in the study and divided in three group.

Data collection

A structured questionnaire was used to take the following information like Age, gender, duration of DM clinic attendance, DM history (duration, type of DM, medication history), possession of glucometer, SMBG practices, frequency of Blood glucose (BG) tests with the glucometer. The case notes of the patients were also reviewed.

Anthropometric indices such as the weight and height were measured. The patients also had blood drawn for fasting plasma glucose (FPG) and HbA1c.

The outcome variable for this study was glycemic control measured by fasting blood glucose and HbA1c. The predictor variable was (SMBG) with a glucometer. SMBG was defined as self-measurement of BG with the aid of a glucometer. SMBG and Telemonitoring participants used the Glucometer for blood glucose analysis that enabled patients to record profile on 3 consecutive days prior to each scheduled study visit. ACG used to visit clinic/ hospital for regular blood glucose monitoring and follow-up as per schedule. All Participants received training in the use of the glucometer and instructions how to identify glycemic patterns and how to resolve them by changes in physical activity, portion sizes, and/or meal composition.

Telemonitoring means measurement of BG at home and reports are sent by the text message or by email. Patients put on telemonitoring group were instructed to measure their BG, weight at home and report it by email or by telephone. Their data was entered in the Excel sheet and was interpreted. Any minor modification in treatment or in diet was communicated through email or telephone. Data was continuously monitored by the treating physician and instructions were inserted on the excel sheet.

The primary goal was change in HbA1C, Treatment modification was calculated using information entered into patient medical records at each clinic visit.

Data management and statistical analysis

Data was entered into Excel worksheet (2013 edition).

Primary aim of the study was to look for the change in HbA1C level from screening to 12 months. Treatment intensification was calculated using information entered into patient medical records. These included starting new medicine, modification of doses, or termination of medication. Also lifestyle modification was advised like change in diet, exercise, or other self-care behaviour.

Observation and Results

Of the 480 patients screened, 374 (SMBG =123, TMG= 125, ACG =126) were eligible and were enrolled in the study. Of these 10 (SMBG =4, TMG= 3, ACG =3) patients doesn't gave consent and 15(SMBG =4, TMG= 6, ACG =5) patients were lost to follow up . So data of total 349 patients was collected, interpreted and analysed.

Table: Distribution of participants

	SMBG		TMG		ACG	
	N	%	n	%	n	%
Total number of participants	115	100	116	100	118	100
Age group						
50	44	38.26	48	41.38	49	41.53
<50	71	61.74	68	58.62	69	58.47
Sex						
Male	69	60	71	61.21	74	62.71
Female	46	40	45	38.79	44	37.29
Diabetic drugs						
0-1	54	46.96	68	58.62	67	56.78
2+	61	53.04	48	41.38	51	43.22

Of the total 115 patients in SMBG 38.26% were below 50 years age and 61.74% were above 50 years age group, similarly in TMG and ACG group <50: >50 percentage was 41.38%: 58.62% and 41.43%:58.47% respectively.

Male to female percentage in SMBG was 60% and 40 %, while in TMG it was 61.21% and 38.79 % respectively. Percentage in ACG of male and female patients was 62.71% and 37.29% respectively.

Percentage of patients put on single drug or on dietary treatment in SMBG, TMG and ACG was 46.96%, 58.62% and 56.78% respectively, while

percentage of patients on 2 or more drugs in in SMBG, TMG and ACG was 53.04%, 41.38% and 43.22% respectively.

Observations at the start of the study

	SMBG			TMG			ACG		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Age (years)	115	58.8	9.8	116	57.6	7.8	118	59.5	6.4
Height (cm)		162.8	7.6		163.5	6.8		164.5	7.4
Weight (Kg)		79.5	22.6		81.4	22.4		80.2	19.6
BMI (kg/m ²)		30.0	8.5		30.5	7.6		29.6	9.1
HbA1C %		8.7	1.3		8.9	1.4		8.8	1.1

At the beginning of the study height and weight was measured for calculation of Body mass index (BMI) and HbA1C was tested. Mean BMI in SMBG was 30.0 kg/m² with SD (standard deviation) of 8.3, in TMG it was 30.5 with SD 7.6

and in ACG BMI was 29.6 while in ACG group BMI was 29.6 with SD of 9.1. Mean HbA1C in SMBG was 8.7 (SD 1.3), in TMG 8.9 (SD 1.4) and in ACG 8.8 (SD 1.1)

Observation after 12 months follows up

	SMBG			TMG			ACG		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Height (cm)	115	162.8	7.6	116	163.5	6.8	118	164.5	7.4
Weight (Kg)		78.5	21.5		78.6	23.5		80.1	20.3
BMI (kg/m ²)		29.6	8.2		28.4	7.1		29.5	7.5
HbA1C %		8.1	1.1		7.2	1.5		8.2	1.3

P value was calculated by using online Social Science Statistics calculated. Paired T test was used to calculate t statistics.

P Value

	SMBG		TMG		ACG	
Weight (Kg)	0.639	Not significant	0.183	Not significant	0.956	Not significant
BMI (kg/m ²)	0.618	Not significant	0.003	significant	0.818	Not significant
HbA1C %	<0.001	Significant	<0.001	Significant	<0.001	Significant

Discussion

Self-monitoring of BG and pattern management require significant commitment from both the patient and the health care provider. Sufficient understanding, training skills and willingness is required to undertake such study in developing country like India. Patients should be appropriately trained in SMBG use and interpretation also patient- health care provider relations should be optimized , because some patients report that health care provider do not show interest in their BG values and rely only on the HbA1C reports⁶.

Several online tools are available to upload data from BG meters for viewing and analysis by health care providers. But this requires at least five days of continuous glucose monitoring over the past week⁷. Technological support has upper hand of improved accuracy and convenience over paper and the ability to store and share findings electronically is very convenient⁸.

Tools that facilitate rapid evaluation of SMBG data by patients or health care provider, either remotely or during shorter clinic visits, may lead to more efficient clinical decisions. The results observed are consistent with evidence from systematic reviews which show that mobile health

interventions can effectively reduce HbA1c⁹. The use of color-coded displays help subjects and health care providers to visualize glucose trends and identify specific low or high BG patterns may contribute to achieving in-range BG results and subsequent decreases in HbA1c¹⁰. Patients find BG targets motivational also enabling them to rectify the problems with control and motivating them to make independent or assisted dose adjustments¹¹.

Most of the patients rely on their health care provider to review SMBG data and determine appropriate actions during their limited number of traditional face-to-face visits.

In this study we observed clinical and statistically significant greater improvements in glycemic control among people with poor glycemic control of diabetes who were offered supported telemonitoring and SMBG. Also in SMBG group significant statistically significant reduction in HbA1C was found. These findings were in contrast to the Meta- analysis review by Farmer AJ et al, which suggest that unsupported self-monitoring of blood glucose does not have clinically significant beneficial effects¹². There was statistically significant reduction in BMI of patients on SMBG and telemonitoring while in ACG group there was no significant reduction in BMI. The lack of change in weight may reflect dietary changes or may be related to shorter follow-up¹³. It is not possible to determine what proportion of the general population with type 2 diabetes would wish to use telemonitoring because most of the patients are not well versed with the modern technologies or cannot use them even if it is available. In a meta-analysis in six clinical trials of self-monitoring of blood glucose among people with type 2 diabetes reported a mean reduction in HbA1c of 2.7¹². In a systematic review and meta-analysis showed a statistically significant and clinically relevant absolute decline in HbA1c level in the intervention compared to control groups similar to our finding¹⁴.

Improved glycemic control is frequently associated with weight, possibly due to failure to

lose calories through glycosuria¹³. We observed statistically insignificant weight change in ACG. But significant reduction in BMR was observed in SMBG and telemonitoring group this may be due to improved self-management, changes in diet and lifestyle or increased adherence to drug treatment.

Conclusion

Telemonitoring and supported self-management of blood glucose can result in clinically meaningful improvements in blood glucose among people with poorly controlled non-insulin dependent type 2 diabetes patients. Further studies are required to support the data also in a developing country application and follow up of telemonitoring may be difficult, especially in rural population and poor people. Further research is required if this intervention is used more widely or to target the specific group of people.

References

1. UK prospective diabetes study (UKPDS). VIII. Study design, progress and performance. *Diabetologia* 1991; 34:877-90.
2. International Diabetes Federation. Diabetes Atlas. 6th ed. Brussels, Belgium: International Diabetes Federation (IDF); 2014.
3. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med*. 2008 Oct 9; 359(15):1577-89.
4. American Diabetes Association. Standards of medical care in diabetes-2010. *Diabetes Care* 2009;32(Suppl. 1):S4-S10
5. Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, Holman R, Kinmonth AL, Neil A. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. *BMJ*. 2007 Jul 21; 335(7611):132.

6. Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *BMJ*. 2007 Sep 8; 335(7618):493.
7. Welsh JB, Myers SJ, Uhrinak AN, Kaufman FR, Lee SW. User acceptability and perceived benefits of new reports in CareLink Pro 3.0 Therapy Management Software for Diabetes. *J Diabetes Sci Technol*. 2012 Mar 1; 6(2):481-2.
8. John C. Choudhary, Stefano Genovese, Gérard Reach. Blood Glucose Pattern Management in Diabetes: Creating Order from Disorder. *J Diabetes Sci Technol*. 2013 Nov; 7(6): 1575–1584.
9. Saffari M, Ghanizadeh G, Koenig HG. Health education via mobile text messaging for glycemic control in adults with type 2 diabetes: a systematic review and meta-analysis. *Prim Care Diabetes*. 2014 Dec; 8(4):275-85.
10. Spollet RS. Self-monitoring of blood glucose: an underutilized tool. *Clin Diabetes*. 2010;28(3):127-129.
11. Rankin D, Cooke DD, Heller S, Elliott J, Amiel S, Lawton J, UK National Institute for Health Research (NIHR) Dose Adjustment for Normal Eating (DAFNE) Study Group. Experiences of using blood glucose targets when following an intensive insulin regimen: a qualitative longitudinal investigation involving patients with Type 1 diabetes. *Diabet Med*. 2012 Aug; 29(8):1079-84.
12. Farmer AJ, Perera R, Ward A, Heneghan C, Oke J, Barnett AH, Davidson MB, Guerci B, Coates V, Schwedes U, O'Malley S. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ*. 2012 Feb 27; 344():e486.
13. Skyler JS, Bergenstal R, Bonow RO, Buse J, Deedwania P, Gale EA, Howard BV, Kirkman MS, Kosiborod M, Reaven P, Sherwin RS, American Diabetes Association., American College of Cardiology Foundation., American Heart Association Intensive glycemic control and the prevention of cardiovascular events: implications of the ACCORD, ADVANCE, and VA diabetes trials: a position statement of the American Diabetes Association and a scientific statement of the American College of Cardiology Foundation and the American Heart Association. *Diabetes Care*. 2009 Jan; 32(1):187-92.
14. Marcolino MS, Maia JX, Alkmim MB, Boersma E, Ribeiro AL. Telemedicine application in the care of diabetes patients: systematic review and meta-analysis. *PLoS One*. 2013; 8(11):e79246.