

Effectiveness of Color Coded Diabetic Control Monitoring Charts among Elderly Diabetics Attending Outreach Primary Care Geriatric Clinics in Rural Karnataka: An Open Label Randomized Control Trial

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Abstract

Introduction: Type 2 diabetes mellitus problem is progressively rising every day. The adherence to the treatment approaches and health-seeking make major difference in case of diabetics particularly elderly. Visual tools improve the involvement of patients in their care, especially among populations with low health literacy. **Objective:** To evaluate the effectiveness of color-coded diabetic control monitoring charts on glycemic control among elderly diabetics. **Methodology:** 144 elderly diabetic patients attending rural primary care geriatric clinics were randomized into two groups. Those randomized to the intervention group received the color-coded diabetic monitoring chart and a health education package in addition to the usual consultation services. Baseline and 1-year follow-up glycated hemoglobin (HbA1C) values were used to assess the effectiveness of the intervention. **Results:** The results of multivariate linear regression analysis showed that there was an average reduction of 0.265% in HbA1C value in the intervention group when compared to the nonintervention group when adjusted for baseline HbA1C and number of visits during the intervention period (β coefficient = 0.265, $P < 0.05$). **Conclusion:** Color-coded diabetes charts are effective in achieving glycemic control among elderly diabetics, and steps should be made to inculcate visually appealing management approaches in case of elderly diabetic patients.

Keywords: Color-coded diabetic control monitoring chart, diabetes mellitus, glycated hemoglobin

INTRODUCTION

Diabetes mellitus is a common and serious global health problem with its prevalence among adults rising at an alarming rate.^[1] The International Diabetes Federation reports the global prevalence of diabetes among adults in 2011 as 8.3% which is projected to increase to 9.9% by 2030.^[2]

Demographic changes have resulted in an increasing proportion of elderly individuals in populations worldwide, including India.^[3,4] The proportion of elderly population is expected to increase to 12.6% by 2025 from 8% in 2011.^[4] Several studies done in India report high prevalence rates for diabetes mellitus among the elderly ranging from 10% to 28%.^[5,6]

The goal of diabetes management is to attain and maintain good glycemic control which is associated with reduced risk

of macro- and micro-vascular complications of diabetes.^[7,8] Worldwide, clinical trials of diabetes have demonstrated the value of glycated hemoglobin (HbA1c) as the gold standard in the assessment of glycemic control.^[9-12] Studies done in India indicate that more than 50% of people with diabetes have poor glycemic control, and a large percentage have diabetic vascular complications.^[13,14] The main reasons for poor

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glycemic control is lack of adherence to pharmacological and nonpharmacological prescriptions.^[15]

Participation of patients in their own care increases the rates of achievement of glycemic goals.^[16] Health literacy is low in elderly people particularly with long-standing illness like diabetes mellitus and can affect health outcomes.^[17,18]

The use of visual tools like color-coded charts is one way of improving communication among populations with low health literacy. There are many examples for the use of charts in medicine to promote and monitor health such as partogram, WHO charts for child growth standards, and cardiovascular risk prediction charts.^[19-21]

Keeping in mind the sociocultural characteristics of rural elderly in Southern Karnataka state of India, we developed a color-coded chart to monitor glycemic control among patients with diabetes. The aim of our study is to evaluate the effectiveness of color-coded diabetic control monitoring charts in achieving glycemic control among elderly diabetics attending outreach geriatric clinics in rural primary care settings.

METHODOLOGY

The Senior Citizens Health Service, Department of Community Health, St John's Medical College, conducts monthly outreach geriatric clinics in villages in Bangalore Urban District, Karnataka state. Elderly were recruited for the study after obtaining informed consent and was conducted for a period of 1 year from September 2015.

We designed an open-label block randomized control trial with 1:1 allocation among elderly patients with diabetes mellitus and was registered with the Clinical Trial Registry of India. Ethical clearance was taken from Institutional Ethics Committee of St John's Medical College.

Inclusion criteria

Patients aged 60 years or more and currently treated for type 2 diabetes mellitus with a single or combination of oral anti-diabetic drugs with or without insulin therapy.

Exclusion criteria

Patients with diabetic ketoacidosis and/or hyperosmolar hyperglycemic state or severely ill.

We calculated the sample size required for the study based on the findings of a study by Wayne *et al.*^[22] who reported a reduction of 0.62% in HbA1c following 3 months of health coaching intervention among patients with type 2 diabetes mellitus. Since we did not find any intervention using a color coded for diabetes, we used the above as a reference expecting a similar reduction in HbA1c value in our study. We calculated the minimum sample size required for our study to be 35 participants per group, at a significance level of 5% (two-tailed), a standard deviation of 1.3%, and a statistical power of 90%. By considering an attrition rate of 30%, minimum target sample size was 50 participants per group. However, a total of 144 patients who sought care at the rural

elderly clinics over 1-month duration were randomized into two groups for the study.

Baseline data on sociodemographic details, diabetic status, lifestyle-related risk factor patterns, medication, and glycated hemoglobin levels were captured initially. The 144 study participants were randomized into intervention and nonintervention groups using block randomization. Block randomization technique with 24 blocks and a block size of 6 were derived with computer assistance using a Microsoft Excel spreadsheet. In each block, randomization was in an allocation ratio of 1:1 so that there were 3 individuals in interventional group and 3 in control group. Concealment of randomization was ensured using sealed envelopes.

The intervention consisted of the use of a color-coded diabetic monitoring chart [Figure 1] developed at the Department of Community Health, St John's Medical College. The dates of each successive patient visit are marked on the X-axis. The Y-axis represents the Glucometer Random Blood Sugar (GRBS) values. The chart depicts the current random blood sugar level of the patient. Participants are classified into those at "good control" (GRBS <140), "fair control" (GRBS 140–199), and "poor control" (GRBS >200) depicted by green, yellow, and red colors, respectively, which is in line with standard guidelines.^[23] Participants who were randomized to the intervention group received this chart in addition to the standard care for diabetes.

The providers of care at the geriatric clinics included faculty members and postgraduate students from the Department of Community Health all of whom were oriented to the study and the intervention. At the first visit following recruitment, for each participant in the intervention arm, the GRBS reading for the month was plotted on the color-coded chart. Using the colors in the chart, the current blood glucose control status was discussed with the patient. Those who were categorized under "good control" were encouraged to maintain good lifestyle patterns and medication adherence practices. Those who are categorized as "fair control" and "bad control" were offered a customized health education package to identify behavioral changes that will enable them to bring their sugar levels to

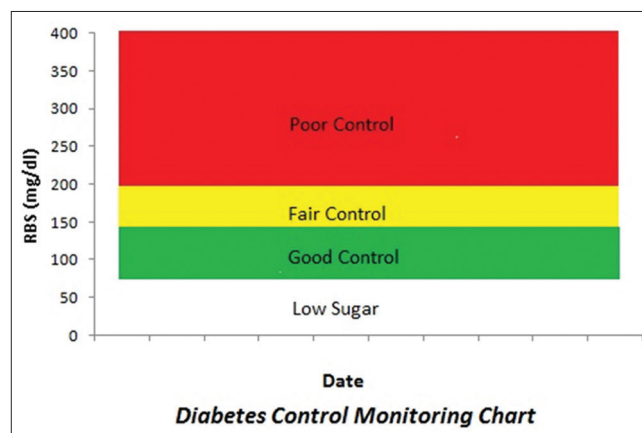


Figure 1: Color-coded diabetes control monitoring chart

the good control category. The health education package included advice on dietary modification, medication adherence, exercise, stress, and identification of barriers to optimal control in that individual. In addition, the current blood glucose level was compared to that recorded in the previous month, and the direction of change in the GRBS reading was indicated to the patient. The nonintervention group received standard treatment and health education for diabetics.

The protocol used for delivery of the customized health package in the intervention group is depicted in Figure 2.

The participants in the intervention and in the nonintervention groups were followed up monthly for a total duration of 1 year with GRBS monitoring. After 1 year, HbA1c was done to assess the glycemic control.

All the data were entered in Microsoft excel and analyzed using SPSS version 19 (Armonk, NY: IBM Corp). Descriptive statistics such as frequencies, percentages, mean, median, standard deviation, and interquartile range were used to describe the sociodemographic and morbidity characteristics of the study sample. Appropriate tests were used to test whether the characteristics of the study individuals in the intervention and the nonintervention group were similar postrandomization. Multivariate analysis done using multiple linear regression was to predict the change in HbA1c in the intervention group compared to the nonintervention group. $P < 0.05$ was taken as significant for all analyses. Intention to treat method was used for analysis.

RESULTS

Of the 144 participants (72 intervention and 72 nonintervention) who enrolled in the study, 59 (40.97%) were males and 85 (59.03%) were females. In both the groups, majority of the participants (77.78%) belonged to the age group of 60–69 years with mean age of 67.42 ± 6.54 years. The baseline characteristics of the sample [Table 1] were similar in both the groups which indicate the success of randomization.

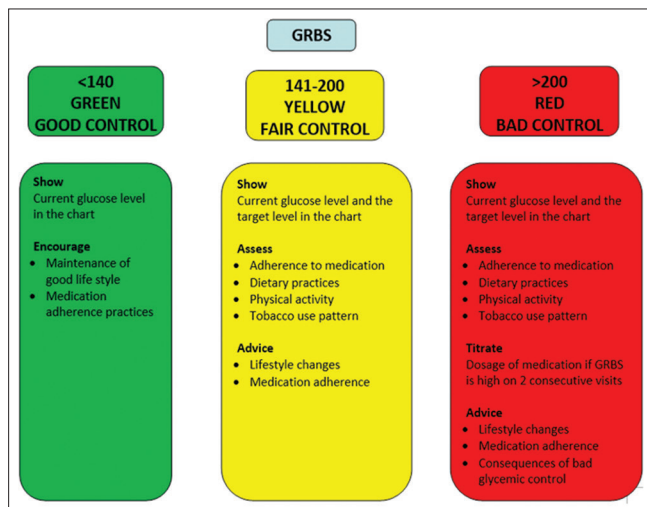


Figure 2: Protocol for advice using the charts

After the initial assessment, both the groups were followed up for a period of 1 year for every month and mean difference in HbA1C value was assessed. In our study, we had attrition rates of 20.8% (72 vs. 57) and 29.2% (72 vs. 51) in the intervention and nonintervention groups, respectively.

We did a multiple linear regression analysis with HbA1C value at the end of 1 year as the outcome variable, the intervention as the predictor variable, and baseline HbA1C and number of visits during intervention as covariates. The results of multivariate linear regression analysis [Table 2] showed that there was an average reduction of 0.265% in HbA1C value in the intervention group when compared to the nonintervention group when adjusted for baseline HbA1C and number of visits during the intervention period (β coefficient = 0.265, $P < 0.05$). This reduction in HbA1C was found to be statistically significant.

On further analysis, we categorized follow-up HbA1C value as controlled (<7) and uncontrolled (>7). We found that 75%

Table 1: Baseline characteristics of the study sample

Variables	Intervention group (n=72), n (%)	Nonintervention group (n=72), n (%)	P
Age (years), mean±SD	67.61±6.97	67.24±6.12	0.09 ^a
Gender			
Female	42 (49.4)	43 (50.6)	0.87 ^b
Male	30 (50.8)	29 (49.2)	
Education			
No formal education	38 (58.5)	27 (41.5)	0.19 ^c
Primary school	14 (48.3)	15 (51.7)	
Middle school	7 (38.9)	11 (61.1)	
High school	13 (44.8)	16 (55.2)	
PUC	0	3 (100)	
Occupation			
Employed	20 (51.3)	19 (49.7)	0.53 ^b
Unemployed	31 (44.9)	38 (55.1)	
Complications			
No complications	30 (45.5)	36 (54.5)	0.61 ^b
Peripheral neuropathy	23 (59)	16 (41)	
Eye problems	14 (58.3)	15 (51.7)	
Combination of both	5 (50)	5 (50)	
Family type			
Nuclear	18 (46.2)	21 (53.8)	0.87 ^c
Joint	34 (51.5)	32 (48.5)	
Extended	6 (60)	4 (40)	
Three generation	14 (48.3)	15 (51.7)	
Marital status			
Currently married	62 (48.4)	66 (51.6)	0.13 ^c
Widow	9 (75)	3 (25)	
Widower	1 (25)	3 (75)	
Duration of disease, years (median, IQR)	5 (2,8)	5.5 (2,10)	0.14 ^d
Baseline HbA1c (%), mean±SD	7.79±1.69	7.54±1.45	0.18 ^a

*Statistically significant $P < 0.05$. ^aIndependent *t*-test, ^bChi-square test, ^cFisher's exact test, ^dMann-Whitney U-test. SD: Standard deviation, IQR: Interquartile range, HbA1c: Glycated hemoglobin

Table 2: Effectiveness of color-coded chart intervention in reduction of glycated hemoglobin: multiple linear regression

Group	Before	After	Mean change	β coefficient (95% CI)	P
Intervention	7.79±1.69	7.58±1.39	-0.11	0.265 (0.18-1.53)	0.045*
Nonintervention	7.54±1.45	7.77±1.55	+0.23	Reference	

*Statistically significant $P < 0.05$. Adjusted for baseline HbA1c and number of visits ($n=57$) for intervention group, ($n=51$) for nonintervention group (at the end of 1 year). CI: Confidence interval, HbA1c: Glycated hemoglobin

of the participants who had 6 visits or less during intervention period had uncontrolled HbA1C value, compared to 42.4% who had more than 6 visits. Thus, patients who had received more than 6 intervention visits appeared to have better glycemic control (Chi-square value = 5.99, $P < 0.05$).

DISCUSSION

Our study shows that the color-coded diabetes control monitoring charts are effective in bringing about a significant reduction in the HbA1c value in the intervention group compared to the control group when adjusted for covariates.

The use of the color-coded charts in diabetes mellitus in our study was a pioneer attempt among elderly diabetics. The use of the color-coded diabetes control monitoring chart offers many advantages. First, at a glance, it is easy to understand even by illiterate patients since the colors used are those used commonly to depict different stages of alert with red color indicating danger, yellow indicating time for action, and green indicating good effort by the patient. This warns a patient with high sugars to put in more efforts while simultaneously encourages a patient under control to continue with his/her current efforts. Second, it adds a personal dimension to the care of the individual as it enhances the involvement of the patient in his/her own health since he/she can visualize the results of his/her efforts in control of his/her sugars. Third, it can be used for longitudinal follow-up and monitoring of the patients' blood sugar levels. Finally, it is cost-effective with no repetitive costs except for the initial cost of color printing of the chart. These qualities make it a locally acceptable and easy to use tool even by a nonphysician health worker, thereby making it a good example of appropriate technology for health.

We used random blood sugar (GRBS) for monthly follow-up as it was part of the standard care provided at the clinics and used HbA1c as a measure of glycemic control. GRBS is more sensitive than HbA_{1c} in detecting variations of shorter duration. HbA_{1c} changes occur in 4–8 weeks as the glucose binding with the hemoglobin is mostly irreversible.^[8-10] HbA1c can be used as a reliable and objective method to check long-term glycemic control, as it does not take daily variations into account^[8,9] and is the gold standard for monitoring glycemic control on follow-up.^[8-12]

In our study, we found a difference in the mean HbA1c of 0.265% between the two groups at the end of 1 year. WHO Global status report 2011 states that a 1% drop in HbA1c leads to a reduction of 30% in microvascular complications.^[24]

A study done by Duckworth *et al.* among military veterans demonstrated an absolute reduction of 1.5% in HbA1c level in the intensive-therapy group as compared with the standard-therapy group.^[25] However, this reduction in the mean HbA1c levels in older patients with poorly controlled type 2 diabetes had no significant effect on the rates of major cardiovascular events, death, or microvascular complications. This finding emphasizes on the need for good glycemic control in the early stages of diabetes. The 0.265% difference in HbA1c that was seen in our study is unlikely to translate into reduction of risk of developing clinical endpoints as our study sample consisted of elderly diabetics. Despite this, the chart has potential to bring about reduction in the risk of complications when used in younger diabetic patients.

There can be different probable explanations for the mechanisms by which the color-coded diabetes chart brings about reduction in HbA1c levels. From the healthcare providers' perspective, constant blood sugar levels in the red category urge the healthcare providers to take actions such as titration of medication doses and placing emphasis on adherence to medication and lifestyle changes. From the patients' perspective, the red category alerts the patient about his/her blood sugar control status and pushes him/her to initiate and sustain lifestyle changes in addition to being adherent to medication. The reduction in HbA1c levels is possibly an indirect effect of the combined actions by the healthcare provider and the patient.

In our study, we had attrition rates of 20.8% (72 vs. 57) and 29.2% (72 vs. 51) in the intervention and nonintervention groups, respectively. The study was conducted in outreach clinics where patients were not regular in their monthly visits which caused attrition and might have affected the result. Our intervention was delivered through multiple providers, which might have decreased the overall efficiency. Less perceived severity and reduced complications among the individuals would have affected their health-seeking behavior thus strained the results. Furthermore, the time period of intervention was 1 year without any intermediate training to the providers which may also have had an effect on the results.

Optimal management of diabetes involves patients taking their medication as prescribed and following lifestyle changes in a sustained manner. The use of color-coded diabetes control monitoring charts is a simple, innovative, and cost-effective method of improving glycemic control rates in resource-constrained settings. There is a need to design further studies in younger populations and to look at the effectiveness of these charts in improving glycemic control.

CONCLUSION

Our study shows that the color-coded diabetes' monitoring

charts were effective in achieving glycemic control among elderly diabetics. This simple tool is an example for the use of appropriate technology for health and has potential to be used in primary care settings to improve diabetic outcomes among patients by involving them in understanding their glycemic control goals.

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Conflicts of interest

There are no conflicts of interest.

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