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RESEARCH ARTICLE

GENDER DIFFERENCE IN GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS: A TRAFFIC SIGNAL COLOR-CODED APPROACH

[1]Nikhita Sarathy, [2]Anitha Rani. A., [3]Satyavani, K. and *[4]Vijay Viswanathan

[1]Research Associate, Prof. M. Viswanathan Diabetes Research Centre
[2]Post Doctoral research fellow, Prof. M. Viswanathan Diabetes Research Centre,
[3]Lab director, M.V. Hospital for Diabetes
[4]Head & Chief Diabetologist, M.V. Hospital for Diabetes & Prof. M. Viswanathan Diabetes Research Centre, (WHO Collaborating Centre for Research, Education and Training in Diabetes)

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ABSTRACT

Aim: To determine the positive impact of a traffic signal color-coded educational tool to improve HbA1c control and to see whether any gender difference exists among patients.
Methods: A total of 700 (385:315) T2DM patients aged between 25 – 65 years with T2DM in South India, attending the Out-Patient Department of a tertiary care centre were screened between January 2016 – January 2017 and followed intensively. Patients with HbA1c of ≤ 8.9%, T1DM, GDM, and patients not willing to give consent were excluded. In the follow up period of 4-5 months from baseline, 140 patients were lost to follow up. Patients were grouped into Group 1 (n=200) and Group 2 (n=360). In Group 1 (Control group), detailed history was recorded and routine counseling was given. While, in Group 2 (Study group), additional education and counseling was given using a color-coded HbA1c thermometer as a motivation tool based on color towards reaching the Target 7% goal. Statistical analysis was carried out using SPSS version 20 software.
Results: The mean age of patients in Group 1 was (Men, 55 ± 11 years; Women, 56 ± 9.7 years) and in Group 2 (Men, 54 ± 10.22 years; Women, 55 ± 11.52 years). Group 1 showed no significant difference among gender in HbA1c, whereas Group 2 showed a higher significant difference in HbA1c values in Men (P = 0.003) as compared to Women (P = 0.008); thereby indicating better glycemic control among Men. Although a percentage decrease was observed in blood sugar levels, serum Creatinine, eGFR, Total Cholesterol and LDL cholesterol values in both groups, statistical significant difference was observed in HbA1c only.
Conclusions: The study highlights the positive impact of the HbA1c thermometer as an educational tool among the people with Type 2 Diabetes, to achieve the Target 7% goal.

INTRODUCTION

In developing countries like India, patients with T2DM have higher risk of developing diabetes related comorbid conditions which pose an economic burden to the individuals as well as to the nation. Presence of a single complication further increases the medical expenses, which in a country like India are usually taken care of by the patients (Satyavani, 2013). One of the most prominent factors taken into account with regard to DM is gender, since a marked difference exists in body composition, behavior, insulin resistance, and energy balance between men and women (Geer, 2009). A projection that a greater number of men in comparison to women were affected by DM was made in 2013 (International Diabetes Federation, 2013) and that incidence rates were directly proportional to increasing ages.

Corresponding author: **Vijay Viswanathan**
Head & Chief Diabetologist, M.V. Hospital for Diabetes & Prof. M. Viswanathan Diabetes Research Centre, (WHO Collaborating Centre for Research, Education and Training in Diabetes)

Globally, in the Asian-Pacific and Western regions, DM incidence of the highest frequencies were discerned in men (Tobias, 2011). The single stop plausible solution to the current situation is that of appropriate DM management and thus, patient care and glycemic control. Factors like poor self-care, untimely meals, physical inactive state and improper personal habits lead to uncontrolled blood sugars, which can further result in the setting of diabetes-related complications. It is necessary to provide the education and tools to patients with DM at critical points where management is essential (Powers, 2015). Nowadays, the care is more patient-centric - patients are capable of making informed decisions - when educated and provided with self-management tools (Marrero, 2013 and http://www.nap.edu/catalog/10027). Unlike the blood sugar measurement which gives an indication towards the day's control, glycated hemoglobin (HbA1c), formed subsequently on interaction of the glucose molecules with hemoglobin during the 120 days lifespan, which reflects on the overall average blood sugar for the past 12 to18 weeks (Goldstein, 1986; Fitzgibbons, 1976). HbA1c, as a result is considered a

much more useful diagnostic tool – as a measure of a diabetic patient's Glycemic control. HbA1c level of < 7% is recommended as the standard goal by the American Diabetes Association (ADA), whereas the International Diabetes Federation (IDF) recommends < 6.5% level as Glycemic control goal (American Diabetes Association, 2010 International Diabetes Federation, 2006). Reducing the HbA1c values from 9% and above to 7.5% and below, post the initial diagnosis will help diminish the susceptibility of the patient to various related complications, including myocardial infarctions and all-cause mortality. Effectiveness of color-coded graphical record for glycemic control in T2DM was reported along with the advancement in mean HbA1c knowledge score; however a reduction in HbA1c levels was not observed (Wong, 2012). Additionally, a positive impact was noted on the maintenance of improved Glycemic control with awareness on HbA1c (Satyavani, 2010). In order to bring attention to the importance of the Target 7% goal in conjunction with HbA1c risk stratification, an HbA1c thermometer was devised. It consisted of a clear depiction of the seriousness of uncontrolled blood sugars and thus, the three month average values (HbA1c) were coded into four color zones. They were mentioned in the increasing levels of risk from Green, Yellow, Orange to Red, which correlates with DM related problems. Green and Red zones indicate good and poor glycemic control, respectively.

Hence an attempt was made to help the patients better understand their present standing with regard to HbA1c value, by educating and creating awareness on the importance of proper glycemic control. The color zones in the thermometer were created to assist in motivating, and gently coercing the patients into thinking along the lines of reaching the green zone (7%) for their betterment. The main aim of this study was to determine the impact of the 'HbA1c Thermometer' in improving glycemic control among T2DM subjects and to see whether there was a gender difference in achieving the HbA1c target of 7%.

MATERIALS AND METHODS

A single centre-based, prospective study was conducted among T2DM patients attending the Out-Patient Department of a tertiary care centre in South India for a period of 13 months (January 2016 to January 2017). T2DM patients (1) aged between 25 and 65 years; (2) with HbA1c ≥ 9% (HbA1c values in 3 consecutive prior visits > 9%) and (3) with creatinine value of < 1.3 and eGFR value of > 60 were included in the study. Patients with T1DM, Gestational diabetes, patients not willing to give consent and patients with HIV and cancer were excluded from the study. Patients' recruitment was based on the inclusion and exclusion criteria. Patients were further randomized into two groups - Control (Group 1) and Study (Group 2). The patients in Group 1 followed the pattern of routine screening and counseling for diet and management. Subsequent review progress data was collected from the centre's database. Group 2 individuals, in addition were intensively educated and counseled on the 'HbA1c Thermometer' and followed telephonically.

HbA1c Thermometer:

An 'HbA1c Thermometer' was designed with specific color codes against the HbA1c values for abnormal level stratification. It comprised of an image of the thermometer in the centre with following two tests on either side with the Laboratory Test on the left (Fig.1). The value on the right provides the average blood glucose level in mg/dl alongside the corresponding values of the Laboratory HbA1c test on the left. The color codes are categorized into four zones with the corresponding HbA1c ranges: Green (6 – 7.5%), Yellow (8.0 – 8.9%), Orange (9.0-9.7%) and Red (9.8% and above). Anthropometric and Biochemical parameters were recorded for all patients in both the groups. Demographic and anthropometric parameters such as age, height, weight and blood pressure was recorded and BMI was calculated accordingly. Biochemical parameters consisted of fasting and post-prandial blood sugars, HbA1c, Lipid profile, Urea and Creatinine. The HbA1c test was performed by HPLC method (Biorad, USA). Data were presented in Mean ± Standard deviation. Chi-square test was used for categorical variables. T-Test was used to compare the study groups. Statistical analysis was carried out using SPSS Software Version 20.

Table 1. Gender-wise demographic and clinical details of the study groups

Demographic Parameters	Group 1		Group 2	
	Men (n= 100)	Women (n = 100)	Men (n= 185)	Women (n= 175)
*Age (years)	55 ± 11	56 ± 9.7	54 ± 10.22	55 ± 11.52
*Duration of DM (years)	10.5 ± 6.32	11.52 ± 6.7	10 ± 6.15	11 ± 7.19
Hypertension	35 (35)	32 (32)	28 (15.14)	26 (14.86)
Dyslipidemia	39 (39)	44 (44)	56 (30.27)	47 (26.86)
Cardiovascular disease	18 (18)	20 (20)	12 (6.5)	9 (5.14)
Thyroid	6 (6)	22 (22)	6 (3.24)	13 (7.43)
Neuropathy	28 (28)	26 (26)	35 (18.92)	27 (15.43)
Retinopathy	19 (19)	11 (11)	13 (7.02)	10 (5.71)
Nephropathy	5 (5)	3 (3)	23 (12.43)	6 (3.42)
Foot Ulcer	14 (14)	14 (14)	17 (9.19)	10 (5.71)

Values are in n (%); * values are mean ± SD

RESULTS

A total of 700 (385:315) T2DM patients, were screened, based on inclusion and exclusion criteria and were grouped into – Control (Group 1) and Study (Group 2) (Fig 2.). While 140 patients were lost-to-follow-up during the follow-up period, the final patient count in Group 1 was 200 and in Group 2 it was 360. Further, patients in both groups were classified based on gender (Group 1: Men = 100, Women = 100 and Group 2: Men = 185, Women = 175). A follow-up of 61% among men and 67% among women was seen in Group 1, however a

Table 2. Gender wise count of HbA1c drop from red to other zones of the study groups

GENDER	Drop from Red zone to	GROUP		P - value
		STUDY	CONTROL	
Male	Red	27 (21.43)	26 (42.60)	0.007*
	Orange	30 (23.80)	13 (21.30)	
	Yellow	30 (23.80)	14 (23.00)	
	Green	39 (31.00)	8 (13.10)	
Female	Red	27 (21.77)	33 (49.30)	0.002*
	Orange	32 (25.81)	15 (22.40)	
	Yellow	33 (26.61)	11 (16.40)	
	Green	32 (25.81)	8 (11.90)	

Values are in n (%); ** P value <0.05 is considered statistically significant.*

Table 3. Biochemical parameters for T2DM men and women in Group 1 and Group 2

Biochemical Parameters	Men				Women			
	Group 1		Group 2		Group 1		Group 2	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
FBS (mg/dl)	222.89 ± 75.37	170.92 ± 59.32	210.73 ± 70.11	172.43 ± 61.08	245.33 ± 74.23	197.51 ± 78.72	214.83 ± 64.91	175.63 ± 68.45
PPBS (mg/dl)	319.42 ± 99.83	256.89 ± 66.59	316.79 ± 92.25	264.80 ± 85.24	335.43 ± 98.69	280.82 ± 107.05	311.38 ± 91.63	256.06 ± 87.48
HbA1c (%)	10.43 ± 1.02	9.34 ± 1.46	10.33 ± 1.36	8.64 ± 1.42**	10.64 ± 1.32	9.77 ± 1.85*	10.38 ± 1.41	9.05 ± 1.48*

P value < 0.005 is considered statistically significant;* Group 1 follow-up Vs Group 2 follow-up.

Fig. 1. HbA1c Thermometer

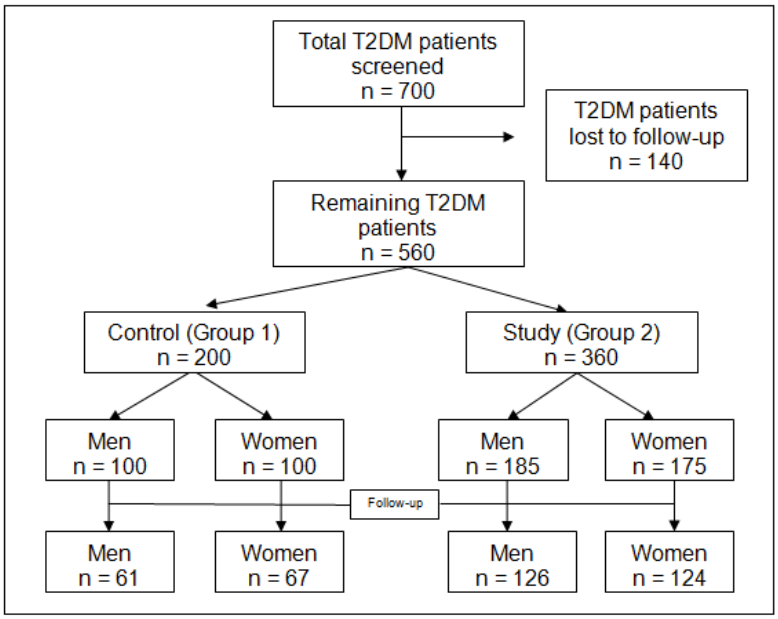

Figure 2. Overall outline flow of the study plan

greater number was observed in Group 2 with 68.11% among men and 70.8% among women. The Demographics of the overall study population is presented in Table 1. In Group 1 the mean age of men was 55 ± 11 years and for women it was 56 ± 9.7 years, while in Group 2 it was 54 ± 10.22 years among men and 55 ± 11.52 years among women. Also, the mean duration of DM in Group 1 was 10.5 ± 6.32 years for men and it was 11.52 ± 6.7 years for women, while in Group 2 it was 10 ± 6.15 years and 11 ± 7.19 years for men and women respectively. Overall, a greater significance (p = 0.001) was noted with regard to the impact of the 4 color zones between Group 1 (standard care) and Group 2 (intervention using HbA1c thermometer). A significance of the color zones in Men (p = 0.007) and in Women (p =0.002) was determined, which signifies the positive outcome of the color-based thermometer (Table 2). Evaluation of the impact of the HbA1c thermometer was based on the drop from red zone to orange, yellow and green zones with green showing Target 7% goal. Conversion of the patients from red zone to green zone were more in group 2 (Men – 31.00%; 25.81% - Women) when compared to group 1 (Men - 13.12%; 11.94% - Women). This showed that to a greater degree, men reached the Target 7% goal than women in Group 2.

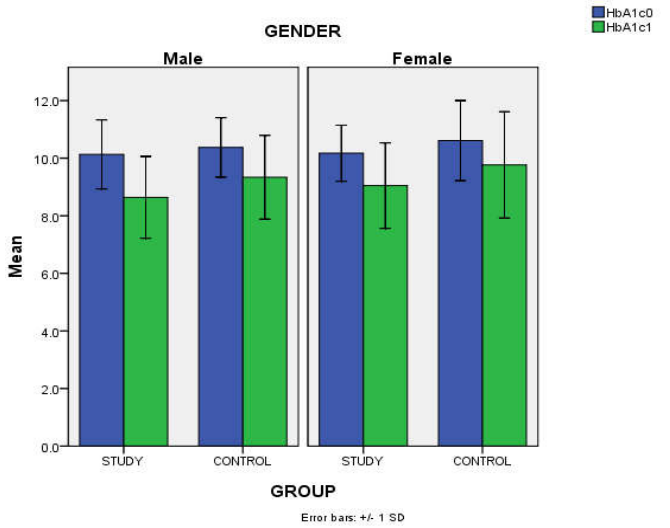

Figure 3. HbA1c Difference based on gender between Group 1 and Group 2

Baseline and follow-up characteristics for Group 1 and Group 2, among men and women are presented in Table 3. Statistical significance was noted only in HbA1c with a higher significance for men than women with a p-value of 0.003 versus 0.008, correspondingly (Fig. 3). This indicated that men fared better with regard to Glycemic control when correlated with women in Group 2.

DISCUSSION

This is one of the first studies, wherein a simple traffic signal based color coding has been used to represent HbA1c stratification to indicate the significance of visual boost by reduction of HbA1c to the Target 7% goal. Secondly, as a result, the determination of gender related disparity in the glycemic control of individuals with T2DM. Following were the subsequent findings from this study: (a) A significance was determined among men and women in Group 2 with regard to the usage of color-coded HbA1c thermometer, (b) Greater reduction in HbA1c among men was seen in Group 2 when compared to Group 1, and (c) A similar HbA1c drop was observed among women in Group 2 than in Group 1. DM in general, as a result of associated metabolic disturbances (World health organization, 1999) is known to affect all parts of the body if left untreated or in case of improper and poor control. Young age at onset, comparably low BMI, higher rates of insulin resistance, and low thresholds of risk associated to DM are factors exclusive to the Indian population (Ramachandran, 2004). Although, a variety of treatment options concerning blood sugar control with oral anti-diabetic (OAD) drugs, insulin and their combinations is present, there prevails a trend of improper management leading towards poor T2DM control. It has been shown that HbA1c and blood glucose levels go hand-in-hand and serve an important purpose in T2DM management (Monnier, 2009).

This in turn supports and shows the significance of linking the average blood sugars to corresponding HbA1c in the thermometer. Self monitoring of blood glucose levels is the main keystone towards DM management, improved patient participation and is beneficial for the individuals with T2DM. The prominent factors with an influence over Glycemic control are gender, obesity and the lifestyle habits of an individual mainly poor diet pattern, reduced or lack of physical activity, smoking and alcohol addiction cessation (Gillies, 2007), and poor compliance to DM management guidelines as advised. Socio-cultural processes are the main reason for the rise of differences among gender (Oertelt-Prigione, 2011; Schenck-Gustafsson, 2012 and Legato, 2010). This occurs along the lines of behaviors, nutrition form, stress pattern, lifestyle habits and treatment related attitudes. Differences were also noted pertaining to quality of diabetes control which was worse in women than men (Pond, 1996) since they simultaneously handle their health and family. Social dynamics ultimately plays an integral role by indirectly influencing both groups in their attitude towards DM, thereby affecting level of compliance. Consequently, women may find it tedious to alter their family's lifestyle to accommodate towards her treatment and management plan (Hentinen, 1992 and Martz, 1995). Overall, poor attitude towards health, low literacy towards diseases and thereby poor adherence has been reported in many Indian studies among the general population (Shobana, 2005; Chew, 2004).

Lifestyle modification is definitely the need of the hour considering the current course of high fat or calorie intake and sedentary lifestyle. It has been proven that intensive lifestyle intervention results in lowering of incidence of T2DM by 58% (Knowler, 2002), when analyzed against individuals under routine care for T2DM. Similarly, this also brought about long term weight loss, fitness improvements and continued favorable effects on CVD risk factors (Look, 2010). According to ADA, aerobic exercise and resistance training is ideal for routine physical activity regimen for individuals with DM (Hayes, 2008). Further WHO recommended that "a far greater impact on the population's health is by increasing the effectiveness of adherence to intervention than by improving specific medical treatments'' (World Health Organization, 2003). Compliance to the treatment plan is necessary for patients with T2DM as prolonged non-compliance can result in associated complications. In addition to the various DM management strategies and treatment plan, compliance is the key to achieving the Target 7% goal and thus a good glycemic control.

Conclusion

Overall, it can be seen that a greater percentage of men than women were able to achieve the target HbA1c level. As a result, the need for the hour is to provide the T2DM women with routine intensive follow-up care including extensive assessments of diet pattern, physical activity, education, psychological well-being and DM management related counseling. Continuous sessions with them in short intervals either in-person or telephonically would further reinforce the importance of complying with the advice of their consultant and educators. Education, when carried out in groups (Implementation tools, 2013), would help in providing a better platform for understanding not only the various management strategies but also similarities in issues faced by others in the process. Also, this would benefit the women in discerning the level of risk and encourage them towards regular treatment, which would probably lead to more women reaching the Target 7% goal.

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Conflict of Interest: The authors declare no conflict of interest.

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