Impact of periodic counselling of diet and lifestyle modification on glycaemic index in patients with Type 2 Diabetes Mellitus

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ABSTRACT

Background- Lifestyle modification and therapeutic nutrition are widely regarded as fundamental strategies in the prevention and management of type 2 diabetes. **Aim assnd Objective**- To determine the effect of periodic counselling on lifestyle changes and its impact on HbA1c levels of patients with Type 2 Diabetes Mellitus. **Methodology-** A randomised controlled trial with a 1:1 allocation ratio was conducted in the medicine department at a tertiary care centre in northern India. Type 2 diabetes Mellitus patients between 30 and 65 years were enrolled and randomly assigned to the control group (CG) or the experimental group (EG). Both groups received counselling on diet, exercise (physical activity), lifestyle modification, and disease management. The CG was asked to visit for follow-up after six months, whereas the EG was scheduled for monthly visits for periodic counselling over the six-month study period. **Results**- Among the 110 diabetic study participants, the mean age was 48.24 ± 10.126 years in the control group and 50.87 ± 10.540 years in the intervention group. A significant difference was found between the two groups in fasting and postprandial glucose levels at the fourth and fifth follow-up visits. The HbA1c values at six months differed significantly between the groups (p = 0.008). Within the intervention group, the change in HbA1c from baseline to both follow-up assessments was highly statistically significant (p = 0.0001). **Conclusion-** Periodic counselling on lifestyle modification and diet, along with adherence, can significantly improve diabetes control and management even within 6 months of intervention.

INTRODUCTION

Diabetes Mellitus, a metabolic disorder with diverse etiologies characterised by a state of chronic hyperglycaemia and disruption of the balanced metabolism of carbohydrate, protein and fat resulting from either insulin resistance or defects in insulin secretion or both.(1) In long-standing untreated diabetes, development of nephropathy, retinopathy and neuropathy are the closely related effects seen.(1,2)However, diabetics are also at heightened risk of cardiac, peripheral vascular and cerebrovascular disease.(3)

At present, Diabetes is among the substantial global health emergencies, ranking with respiratory disease, cardiovascular disease (CVD) and cancer among the 10 principal causes of mortality worldwide.(4,5) As per the World Health Organisation (WHO), non-communicable diseases (NCDs) accounted for 74% of global deaths in 2019, with diabetes responsible for 1.6 million of these deaths, making it the ninth leading cause of

mortality worldwide. (5) It is expected that by the year 2035, diabetes alone will be accountable for nearly 592 million deaths. (6) In countries like China and India, the diabetes prevalence has reached epidemic proportions (4,7), and the prevalence is rising rapidly in countries with low to middle income levels.(8)

For more than 40 years, Glycosylated haemoglobin (HbA1c) has been recognised as an 'atypical' haemoglobin in diabetics. (1) In the 1980s, HbA1c was introduced clinically and has since become a mainstay for diagnosing diabetes. (9) It indicates average plasma glucose over the 3 months. (10) It is easy to perform, with no fasting required and can be done at any time of the day. Hence, it is the preferred blood test for assessing glycaemic control in people with diabetes. (1,10)

For almost 4 decades, lifestyle modifications have been the main focus in treating diabetes (11), but as per recommendations of the Diabetes and Nutrition Study Group (DNSG) in 2004, re-emphasis was made to prevent type 2 diabetes, DNSG is the part of the European Association for the Study of Diabetes (EASD) (12). Since 2004, several randomised controlled trials (RCTs) have demonstrated that it's not impossible to prevent Type 2 Diabetes, or to markedly delay its occurrence, by lifestyle modifications, i.e., increased physical activity, changes in dietary habits, and weight reduction. (13)

The rationale for this study is to bring forth the impact of periodic counselling on diet and lifestyle modifications on glycosylated Hb levels in patients with Type 2 Diabetes Mellitus.

MATERIAL & METHODS

Study Type- Experimental (Interventional) Study

Study design: Randomised control trial (RCT). Parallel RCT with 1:1allocation ratio of the two study groups (experimental and control).

Study Setting: Medicine OPD, KGMU UP

Study unit: Type 2 Diabetic Mellitus (Type 2 DM) patients.

Inclusion criteria
- Both male and female
- Age between 30 and 65 years.
- Glycosylated Hb more than 6.5 %
- Type 2 DM patients on hypoglycaemic drugs.
- Can read and understand the patient's consent form.

Exclusion criteria
- Type 2 DM patients on insulin,
- Pregnant and Lactating women
- Patient underwent surgery in the last 1 year.
- Patients with mental illness, physical immobility.

- Diabetic patients with cardiomyopathy, retinopathy, nephropathy and neuropathy.

Sample Size

Sample size was calculated using the formula--

$$n = (Z_\alpha + Z_\beta)^2 *2*\sigma^2 / d^2$$

here Z_α is the critical value of the Normal distribution at α one-tailed, for a confidence level of 95%, α = 0.05 one-tailed, and the critical value = 1.645,

here Z_β is the critical value of the Normal distribution at β, for a power of 80%, β = 0.2, and the critical value is 0.84.

population variance, $\sigma2=1$ and the difference to be detected is d = 1

Thus, putting all the values in the formula:

$$n = \frac{(1.645+0.84)(1.645+0.84)*2*(1)(1)}{0.5*0.5} = 49.4018 = 50/group$$

50 was the sample size 'n' in each group (control and experimental). And 100 is the total sample size (including both groups).

However, to account for dropouts and non-cooperation among study subjects, a 10% dropout margin was included. Thus, taking 10% more of the total sample size, the number of subjects enrolled in the study was 110, i.e., 55 in each group.

Randomisation, Blinding and Allocation Concealment.

This study adopted a 2-arm RCT design with a 1:1 allocation ratio. Firstly, screening and baseline data were collected, and then the eligible and consented participants were randomised into two groups: intervention group A (diet and lifestyle modification, periodic counselling) and control group B (diet and lifestyle modification, one-time counselling). Computer-generated random numbers were used for randomisation.

A sequentially numbered opaque envelope (SNOPES) containing details of either of the two treatment forms was issued to each randomised patient. The treatment allocation details of patients were concealed in an encrypted folder of the computer system. The treatment for each patient in any group was administered by the principal investigator. Study participants were blinded because they were not aware of which group they were being allocated to. As per the schedule, follow-up of patients and assessment of outcomes were conducted. The protocol adhered to the CONSORT guidelines.

Ethical Considerations: ethical approval (Ref code: 93rd ECM II B- Ph.D./P2) was obtained from the Institutional Ethics Committee of KGMU prior to conducting the trial. Written informed consent form was taken from the study participants after a briefing about the study. The study data were anonymised to ensure confidentiality. This study

trial was registered with the Clinical Trials Registry-India (CTRI); registration number is CTRI/2020/07/026780.

Data Collection Procedure: DM TYPE 2 patients on hypoglycaemic drugs as per the inclusion criteria were selected as per the total sample size. (Figure 1) Then, the study patients were randomly assigned to the control and experimental groups. Their Fasting and post-prandial blood sugar, and Glycosylated haemoglobin were recorded at the beginning of the study. Information on demographic profile, biochemical profile, dietary habits, and patients' knowledge of diabetes, lifestyle practices, and stress management was recorded using a pre-structured schedule. Participants in both the intervention and control groups were counselled on diet, exercise (physical activity), lifestyle modification, and the disease condition. The control group was asked for a follow-up visit after six months, whereas the experimental group was asked to visit monthly for counselling up to six months. Data was collected up to six months from baseline in both the control and experimental groups. Periodic telephonic follow-up at every month for compliance and recording glycaemic values was maintained in both groups to minimise dropouts and manage diet plan adherence.

Data Analysis: SPSS version 24.0 was used. Study results were presented as descriptive summaries using frequencies, percentages, graphs, mean, and standard deviation. Probability (p) was calculated to test statistical significance at the 5% level of significance. Study data were normally distributed, as the Kolmogorov-Smirnov test of normality was statistically insignificant ($p>0.05$). Comparison of continuous variables, such as Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), was performed between the intervention and control groups using a parametric test, i.e., an independent t-test. Intra-group comparisons of FBS and PPBS, in the control and intervention groups at various follow-ups, were done using repeated measures ANOVA. Change in HbA1c after six months from baseline was analysed using a paired t-test.

RESULTS

A total of 110 patients with diabetes were studied. After loss to follow-up, 52 in each group were evaluated. In the control and intervention groups, the mean ages were 48.24±10.126 and 50.87±10.540 years, respectively. All baseline parameters were comparable ($p>0.05$) (Table 1)

Table 1- Basic Sociodemographic Characteristics of Study Participants

Characteristics		Control	Intervention	P value
Age (Mean ± SD)		48.24±10.126	50.87±10.540	0.199
Sex	Male	29 (55.8)	24(46.2)	0.327
	Female	23(44.2)	28 (53.8)	
Religion	Hindu	42 (80.8)	37 (71.2)	0.251
	Muslim	10 (19.2)	15 (28.8)	
Marital Status	Married	51 (98.1)	50 (96.2)	1.000
	Unmarried	1 (1.9)	2 (3.8)	
Education	High school	14 (26.9)	12 (23.1)	0.074
	Intermediate	13 (25.0)	15 (28.8)	
	Graduate	24 (46.2)	17 (32.7)	
	Post-graduate	1 (1.9)	8(15.4)	
Occupation	Employed	22 (43.1)	18 (34.6)	0.375
	Unemployed	29 (56.9)	34 (65.4)	
Family Type	Joint	28 (53.8)	29 (55.8)	0.844
	Nuclear	24 (46.2)	23 (44.2)	
Family History of Diabetes	Yes	19 (36.5)	25 (48.1)	0.234
	No	33 (63.5)	27 (51.9)	

Comparing the mean fasting blood sugar (FBS) at baseline and at various follow-ups across both groups was statistically significant at the 4th and 5th follow-up. (p value- 0.005 and 0.002, respectively). (Figure 2)

Comparing the mean post-prandial blood sugar (PPBS) at baseline and at various follow-ups across both groups was statistically significant at the 2nd, 4th and 5th follow-up (p value- 0.028, 0.004 and 0.0001, respectively). (Figure 3)

The comparison of HbA1c at baseline, 3rd-month, and 6th-month follow-up was performed in both groups. It was significant statistically at the 6th month follow-up (p value- 0.008). (Table 2) The difference in HbA1c was also statistically highly significant (P value: 0.0001) among the intervention group at baseline and at both follow-ups. (Table 3)

Table 2- Comparison of HbA1c at baseline and 3 and 6 month follow-up across both groups

HbA1c		Mean	Std Deviation	95% CI		P value
				Lower	Upper	
Baseline	Control	8.31	1.31	-1.10	0.23	0.208
	Intervention	8.74	2.03			
1st Follow Up (3rd month)	Control	7.80	0.91	-.41	0.41	1.000
	Intervention	7.80	1.15			
2ndFollow Up (6th month)	Control	7.70	0.86	0.14	0.87	0.008*
	Intervention	7.19	1.01			

Table 3: HbA1c of intervention group at Various Follow ups

HbA1c	Mean	Standard Deviation	f value	p Value
Baseline	8.741	2.0344	59.323	0.0001*
3 months follow up	7.802	1.1507		
6 months follow up	7.196	1.0056		

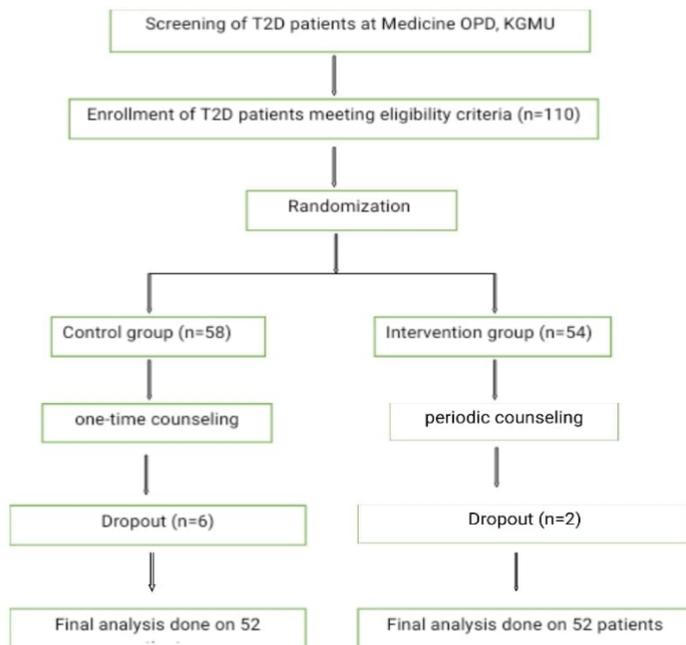**Figure 1 – Patient flow consort diagram**

Figure 2 – Comparison of Mean FBS at baseline and at every follow-up across both groups
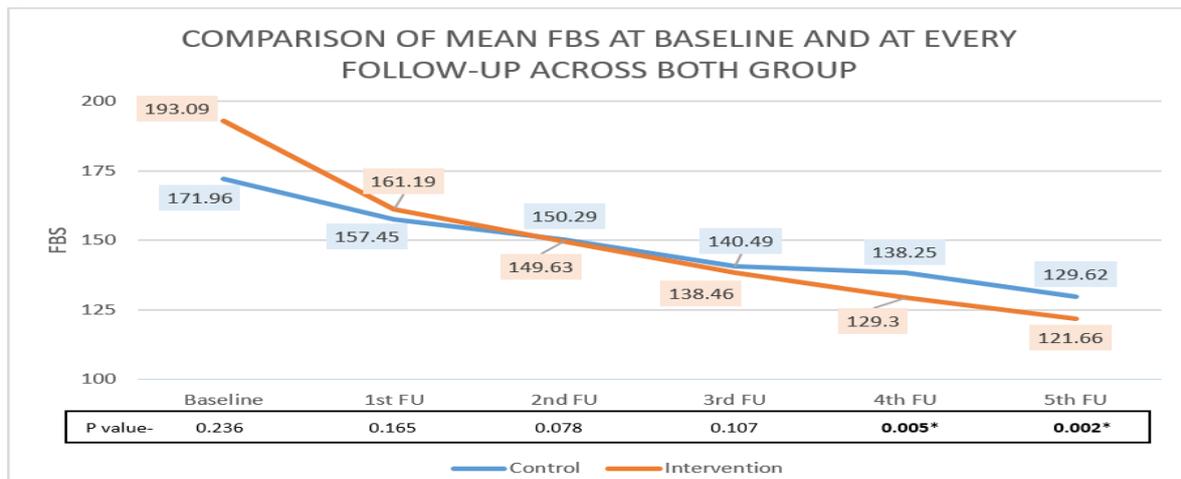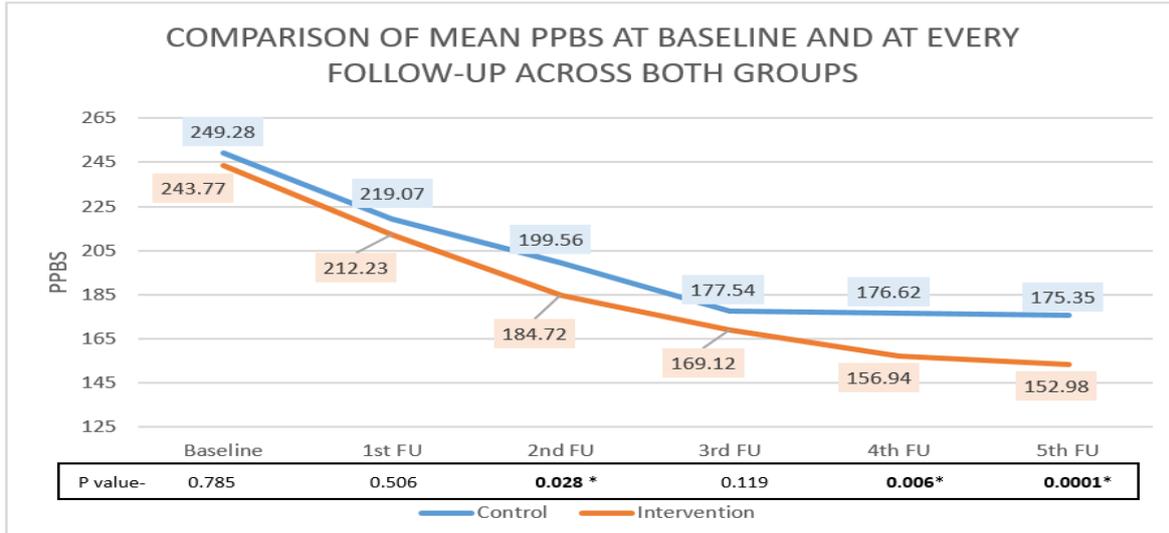
Figure 3- Comparison of Mean PPBS at baseline and at every follow-up across both groups

DISCUSSION

The main focus while managing diabetes is always 'glycaemic control', as it is directly related to improved health outcomes and hence reduces the rate of severe complications and co-morbidities. (14) Application of lifestyle modifications to manage diabetes is a non-invasive and effective approach to establish glycaemic control and manage weight and blood pressure. (15)

The study purpose was to determine the effectiveness of diet and lifestyle modification counseling and its adherence on glycaemic control and physiological parameters among Type 2 DM patients in a 6 months follow-up period. The results of this study show significant reductions in FBS at follow-up at 5th and 6th months, PPBS at 2nd, 5th, and 6th months, and HbA1C at 6th-month follow-up.

A study by Kumari G et al. showed significant decreases in PPBS levels and HbA1c at 6-month follow-up, whereas fasting blood sugar levels decreased significantly after 3 months of intervention. The study continued periodic counselling monthly for 6 months, hence had a significant result, but the next 6-month follow-up period had a steady glycaemic control despite not counselling during this period. Adherence to the intervention plan was also assessed, showing a decline in the second half of the 12-month follow-up period, indicating the need for periodic counselling and motivation towards these lifestyle modifications and a diabetic diet. (16)

Dwibedi C et al, assessed glycemic control in diabetic who followed the intervention at their own pace. Among those who followed the counselling and self-assessing tool biweekly i.e. every two weeks had a higher decrease in HbA1c levels (up to 0.5% or 6mmol/mol) than those who followed monthly, bimonthly or did not follow, at 3 month follow-up. (17)

Similarly, our study had a significant reduction in the intervention group in HbA1c at 6 month follow-up (p value-0.0001) with a reduction of 1.55%. Other similar studies showed significant HbA1c reductions. A study by Kumari G et al, showed decrease in HbA1c levels significantly 0.9%, after counselling for diet and physical activity intervention. (16) Dhandhaliya AK et al. reported that structured lifestyle counselling significantly reduced HbA1c levels from 8.4 ± 1.1% to 7.2 ± 0.9% over six months, compared with minimal change in the control group (p < 0.001) among patients with Type 2 Diabetes Mellitus. (18) Another study showed that participants with better lifestyle showed progressively better glycemic control, with the odds of poor control patients was higher than those patients with healthier and better lifestyle (OR- 0.82 to 0.56), indicating a higher likelihood of achieving HbA1c < 7% in patients with Type 2 Diabetes Mellitus with lifestyle changes. (19) This study had a higher reduction in HbA1c due to periodic counselling.

Limitations of our study could be that the selection of the study population was only from a single centre so the study cannot be generalised. The follow-up period could be long assessing the glycemic control after 6 months of periodic lifestyle and diet counseling. This topic requires further multi-centric randomized control studies with larger population in different groups for a more generalised result and conclusion.

However, the results of this study conclude that periodic counselling on lifestyle modification and diet along with adherence can significantly improve diabetes control and management even within 6 months of intervention.

CONCLUSION

There is strong evidence to suggest that T2DM can be prevented by adopting healthier lifestyle practices, which includes reducing body weight and eating a diet that complies with current recommendations for fruit, vegetables, whole grains, and fat types. Our study results also conclude that diet and life style modification periodic counselling and its adherence can significantly improve diabetes control and management even within 6 months of intervention.

RECOMMENDATION

Periodic lifestyle counselling should be incorporated into routine diabetes care at primary and tertiary health facilities to improve glycemic control and reduce long-term complications.

LIMITATION OF THE STUDY

The study was conducted at a single centre with a relatively short follow-up period, which may limit the generalizability of the findings.

RELEVANCE OF THE STUDY

This study highlights the significant impact of structured and periodic lifestyle counselling on improving glycemic control among patients with Type 2 Diabetes Mellitus.

AUTHORS CONTRIBUTION

All authors contributed to the study concept and design, data collection, analysis, manuscript preparation, and final approval of the manuscript.

FINANCIAL SUPPORT AND SPONSORSHIP

Nil.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

DECLARATION OF GENERATIVE AI AND AI ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

The authors haven't used any generative AI/AI assisted technologies in the writing process.

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