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Study of Impact of Implementation of Medical Nutrition Therapy on Glycemic Control in Type 2 Diabetes Patients

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Original Research Article

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Abstract: Medical nutrition therapy (MNT) is one of the important cornerstones in the management of glycemic control in type 2 diabetes mellitus (T2DM). Hence, this study was envisioned to evaluate the impact of MNT on glycemic control in type 2 diabetes patients in a medical care centre in North Eastern India. A total of two hundred patients were enrolled for the study. Patients, whose medical back ground, co-morbid condition does not permit MNT, were excluded. Those patients, for whom regular follow up for any cause was not possible, were also excluded. Finally 168 patients were selected for study. After adjusting medical therapy, patients were distributed to Group A and Group B by lottery. Counseling on medical nutrition therapy was given to the subjects of Group A and was termed as intervention group and requested to follow the MNT regimen strictly. Patients of group B were asked to follow the usual conventional diet management and were termed as non-intervention group. All the patients were asked to come for review in every 2 week intervals and dietary practice of MNT was confirmed in every follow up visits to all available subjects of Intervention Group. During the study 7 patients of intervention group and 4 patients of non intervention group had acute medical condition, they were dropped. Those patients did not turn up for at least 2 follow up visit and a visit at the end of study period were also excluded (6 of Group A and 13 of Group B) from final analysis. Thus total of 138 patients were included for the final analysis of the study. Finally, there were 71 patients in Intervention group and 67 patients in Non-intervention group. In this study, we found that there was significant change of weight, body mass index (BMI), waist hip ratio (WHR), fasting sugar, post prandial sugar and glycated hemoglobin (HbA1c) in both the group. Further in the inter-group comparison, though no significant difference could be appreciated in the change of parameters like WHR but reductions in fasting sugar, post prandial sugar and HbA1c were more significantly prominent in the intervention group. Therefore, this study hypothesized that even short term adherence to medical nutrition therapy may bring significant change in glycemic control of type 2 diabetes patients.
Keywords: Fasting Sugar, Post prandial Sugar, HbA1c, BMI, WHR (Waist hip ratio).

INTRODUCTION

Epidemiological studies suggest that there is global increase in the incidence of diabetes, particularly in areas having significant economic improvement with industrialization. In 2002, the prevalence of type 2 diabetes mellitus (T2DM) in India was 2.4 percent in rural populations and 11.6 percent in urban populations [1]. Thirty-six percent of the anticipated global increase of 154 million people with diabetes is projected to occur in India and China alone [2]. Urbanization and rapid industrialization in developing countries is associated with a more sedentary lifestyle tending to increase the diabetes prevalence, so to some extent is a proxy for lifestyle changes. The challenge is to minimize the detriments of urbanization, as the process is unlikely to be reversed [3]. Specific lifestyle intervention programs have been shown to be efficacious in reducing diabetes incidence [4-6]. The American Diabetes Association (ADA) refers to this individualized management plan for the patient as diabetes self-management education (DSME). Medical nutrition therapy (MNT) is a term used by the ADA to describe the optimal coordination of caloric intake with other aspects of diabetes therapy (insulin, exercise,

weight loss etc.). The patients with type 1 or type 2 DM should receive education about nutrition, exercise, care of diabetes during illness and medications to lower the plasma glucose. Patient education should be viewed as a continuing process. More frequent contact between the patient and the diabetes management team may improve glycemic control [7].

In this part of country, paucity of data exists regarding evaluation of effect of dietary regulation on glycemic status. It is also rare again any study reporting on the impact of repeated counseling regarding dietary regulation on glycemic control. Therefore, this study was planned to evaluate the effectiveness of diet management and impact of repeated dietary counseling on glycemic control in type 2 diabetes patients.

METHODS AND MATERIALS

This study was a Randomised Control Trial (RCT), which was conducted at a well-equipped medical clinic at Agartala, Tripura as a part of Distant Fellowship in Diabetes (DFID) programme after ethical committee clearance under the guidance from Christian Medical College, Vellore.

Inclusion criteria

- Adult type 2 diabetes patients (18 to 64 years).
- Agreed to participate in the study.

Exclusion criteria

- Medical background, co-morbid condition requires special diet
- Patients cannot be available for regular follow up.

All the T2DM patients attending the clinic during 01.03.2017 to 31.11.2017 (fulfilling the inclusion criteria) were enrolled for the study. Considering HbA1c difference (effect size of the intervention) of 0.65%, standard deviation of 1.0, α level of 0.05 for a two-tailed test, power of 80%, sample size calculated was 45 (44.58). A loss of follow-up rate of 30% was considered (calculated figure of loss in follow up 13.37), we found that 59 (44.58 + 13.37) participants would be required for each group for statistical significance. For comparison, p value less than 0.05 was considered as significant.

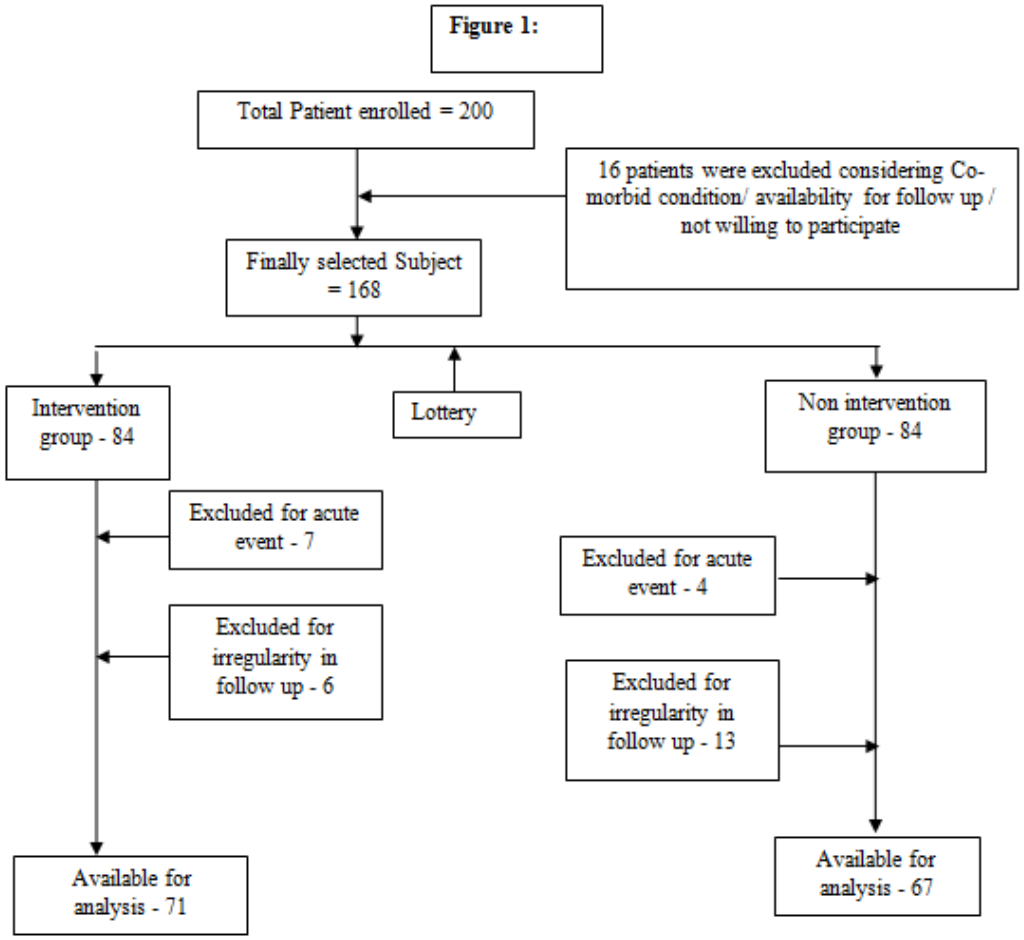
A total of 200 T2 DM patients, attending the clinic during 01.03.2017 to 31.11.2017 were enrolled for the study after taking duly explained written consent For all the patients, history was recorded; physical examination including waist hip ratio (WHR) and body mass index (BMI) was done. BMI was calculated as per Quetelet's Index as weight in kilograms divided by height in meters squared. Basal metabolic rate (BMR) was calculated by applying the formula 24kcal/kg/day in Male and 22kcal/kg/day in Female. Total energy was calculated as BMR added with activity factor (i.e. Sedentary- 25-30% of BMR, Moderate active - 35-50% 0f BMR, Strenuous – 50-100% of BMR). Depending on all these factors, diet chart as per calorie requirement was provided to the patients [8, 9].

After considering the medical background and co-morbid condition of patients, if special nutritional measures were indicated beyond MNT in any patient, they were excluded. Likewise, if it was felt that follow up will not be possible due to work, distance, family, personal or any other issues; they were also not included in the study. Finally we selected 164 patients for the study. At the initiation of the study, adjustment of pharmacotherapy was done after having fresh estimations of glycated hemoglobin (HbA1c) and fasting plasma glucose (FPG) and post prandial plasma glucose (PPPG) values. In the continuation, no change in medication was made thereafter.

This study was a Randomised Control Trial (RCT). After selecting the subjects, they were divided into two groups with each group having 84 patients, using simple lottery. The patients, assigned to Group A, were given counseling regarding medical nutrition therapy on first visit and was named as Intervention Group. Patients of group B were given counseling regarding the disease and personal care and were asked to follow the usual conventional diet as they were on before enrollment in the study, hence mentioned as Non-Intervention Group. All these patients were asked for review visits on biweekly basis for next three months. During follow up visits, dietary habits of patients were again scrutinized and necessary adjustments were advised for patients of intervention group. FPG, PPPG were repeated monthly. HbA1c was again estimated after completion of 3 months.

Seven(7) patients of intervention group had acute crisis during the study period (2 patients had sepsis following urinary tract infection, 2 patients had lower respiratory tract infections, 1 patient had Dengue Shock Syndrome, 1 patient acute pancreatitis, 1 patient had myocardial infarction) and four (4) patients of Non Intervention Group had acute crisis (1 patient had Infero-lateral wall myocardial infarction, 1 patient had Anterior wall myocardial infarction, 1 patient had septic shock following urinary tract infection, and 1 patient had acute pneumonia and needed ventilation) and they were excluded from the study analysis.

For final analysis of the study, we included only those patients who came for at least 2 visits during 3 months and a visit at the end of study period (total 3 follow up visit), therefore 6 patients of intervention group and 13 patents from Non – intervention group were excluded. Ultimately 138 patients were available for final analysis. We had 71 patients in Intervention group and 67 patients in Non-intervention group.



As at least 59 participants were required in each group for the statistical significance of analysis of this study, even after exclusion, there was enough number of participants in both the group (71 in Intervention group; 67 in Non-intervention Group).

STATISTICAL ANALYSIS

Data were checked for normality (Shapiro – Wilk test) and Equality of Variance (Levene's test). Inter-group comparison of parameters like Fasting and Post prandial Plasma Sugar, HbA1c, Weight, Body Mass Index and Waist hip ratio of both the group were compared by Welch's t test, Mann- Whitney U test, Wilcoxon rank test as and when appropriate. Changes in two groups were again compared using unpaired t – test to see significance in difference. Statistical analysis was done using software SPSS version 20.

RESULTS

At the end of study period, a total of 138 patients were available for conclusive data collection. Out of these 138 patients, 71 patients were from Intervention group and 67 patients were from Non-intervention group. Therefore, 51.4% (N = 71) patients of final analysis were from Intervention Group and rests (48.6%, N = 67) were from Non-intervention group. Combining the both groups, 65 patients (47.1%) were male whereas 73 patients (52.9%) were female.

Table-1: Base line characteristics of study participants

Base line characteristics	Intervention Group (N 71, 51.4%)	Non Intervention Group (N 67, 48.6%)	Test value	p value
Age	54.8 ± 14.1€	53.3 ± 7.88€	0.786*	0.43
Weight	57(13)£	68 (11) £	1449**	0.00
BMI	24.4 (5.1) £	26.9(5.5) £	1670**	0.00
Waist Hip ratio	0.976(0.122) £	0.967(0.123) £	2071**	0.19
Fasting Blood sugar	144(49) £	144(50) £	2335**	0.85
Post prandial Sugar	211(99) £	220(103) £	2121**	0.27
HbA1c	7.10(0.95) £	7.40(0.6) £	1877**	0.06

*Welch's t test, ** Mann- Whitney U test , € Mean ± SD, £ Median (IQR)

At the initiation of study, the median of weight of Non Intervention group subjects was 68 kg with standard deviation (SD) of 11kg. In the Intervention group, it was much lower with mean weight of 57 kg with SD of 13 kg (Table No 1). In the Intervention Group, the median BMI was 24.4 with standard deviation of 5.1, whereas median BMI of Non Intervention Group was found to be little higher as 26.9 with standard deviation of 5.5 (Table No 1). Significant difference was found between the study groups regarding parameters like weight and BMI at base line, hence in the final analysis these two parameters were not considered for inter group comparison. In Non Intervention Group, median of waist hip ratio was 0.967(SD 0.123) and in the Intervention group, it was 0.976 (SD 0.122). Median plasma fasting sugar and post prandial sugar of Non intervention group were 144 (SD 50) and 220 (SD 103) mg%, where as in Intervention group these were 144 (SD 49) and 211 (SD 99) mg% respectively. Values in Non Intervention group were marginally higher but the difference was insignificant. The mean HbA1c of Intervention Group and Non Intervention Group, were 7.10 (SD 0.95) and 7.40 (SD 0.6) respectively. HbA1c of Non Intervention Group was comparatively higher (Table No 1).

Table-2: Changes of parameters within the groups

		Initial value	End point value	p-value
Weight (Kg)	Non Intervention Group (N 67)	68(11) £	66(11.5) £	0.02***
	Intervention Group (N 71)	57(13) £	56(12) £	0.00***
BMI	Non Intervention Group (N 67)	26.9(5.5) £	26.8(5.3) £	0.04***
	Intervention Group (N 71)	24.4(5.1) £	23.9(4.5) £	0.00***
WHR	Non Intervention Group (N 67)	0.967(0.123) £	0.966(0.103) £	0.00***
	Intervention Group (N 71)	0.976(0.122) £	0.974(0.133) £	0.00***
Fasting plasma sugar	Non Intervention Group (N 67)	144(50) £	128(35) £	0.00***
	Intervention Group (N 71)	144(49) £	122(26) £	0.00***
PP plasma sugar	Non Intervention Group (N 67)	220(103) £	188(33) £	0.00***
	Intervention Group (N 71)	211(99) £	164(29) £	0.00***
HbA1c	Non Intervention Group (N 67)	7.4(1.15) £	7.1(0.6) £	0.00***
	Intervention Group (N 71)	7.10(0.95) £	6.60(0.40) £	0.00***
BMI – Body Mass Index, WHR – Waist Hip Ratio, PP – Post prandial, HbA1c - Glycated Hemoglobin ** *Wilcoxon signed rank test , € Mean ± SD, £ Median (IQR)				

At the end of the study, it was observed that there were changes in respect of weight, BMI, waist hip ratio, fasting blood sugar, post prandial blood sugar and HbA1c in both the group (Table No 2). Among the Non Intervention Group patients, median of the body weight changed from 68 (SD 11) to 66 (SD 11.5) with a significance level of 0.02. Among the Intervention Group patients, the change in median of body weight was 57(SD 13) Kg to 56 (SD 12) Kg and it was significant (Table No 2). In the Non Intervention Group, change of BMI was from 26.9 (SD 5.5) to 26.8 (SD 5.3) and was found to be statistically significant. Similarly in the Intervention Group, there was statistically significant BMI change [from 24.4 (SD 5.1) to 23.9 (SD 4.5)]. (Table No 2). Changes of median Waist Hip Ratio (WHR) in the Non Intervention Group, from 0.967(SD 0.123) to 0.966(SD 0.103) and in Intervention Group, from 0.98(SD 0.08) to 0.97(SD 0.07) was also statistically significant (Table No 2). There was significant change of fasting plasma sugar in Non Intervention Group as well as in Intervention Group {144(SD 50) to 128 (SD 35) and 144 (SD 49) to 122 (SD 26) respectively}. Changes in regard to post prandial plasma sugar were also similarly significant in both the group {220 (SD 103) to 188 (SD 33) in Non intervention group and 211 (SD 99) to 164 (SD 29) in Intervention group}. (Table No 2). HbA1c changed from 7.4 (SD 1.15) to 7.1 (SD 0.6) in Non Intervention Group, with net change of 0.03. The change was significant (p 0.00). In Intervention Group, HbA1c

changed from 7.10 (SD 0.95) to 6.60 (SD 0.40). This was also statistically significant (p 0.00) (Table No 2).

Table-3: Inter-group comparison (Mann-Whitney U, Independent sample T test)

	Intervention Group (N 71) (Median changes)	Non Intervention Group (N 67)(Median changes)	Intergroup relation (p value)
WHR	0.000 (IQR 0.0109)	0.000 (IQR 0.0153)	0.696
Fasting plasma Sugar	22.000 (IQR- 26.6588)	19.00000(IQR 20.5485)	0.015
PP plasma Sugar	32.000 (IQR 63.0776)	30.000 (IQR 35.0746)	0.321
HbA1c	0.500 (IQR 0.8206)	0.300 (IQR 0.3587)	0.005
WHR – Waist Hip Ratio; PP plasma Sugar – Post prandial plasma Sugar; HbA1c: Glycated Hemoglobin; IQR –Interquirtile range.			

Inter-group comparison of changes in median in parameters like Waist hip ratio, Fasting plasma Sugar, Post Prandial plasma Sugar, HbA1 of both the group were compared by Mann-Whitney U, independent sample T test. No significant difference of changes in these parameters between the two groups could be observed regarding WHR and PP plasma Sugar (Table No 3). Whereas, when a change of Fasting Sugar and HbA1c in both the group was compared, significant difference between groups was observed (Table No 3).

DISCUSSION

In this study we observed that there was significant reduction of body weight in both the groups. As there was significant change of weight, change of BMI was obvious. We observed that both the variables were of higher value for Non Intervention Group at starting point of the study and for both cases of weight and BMI, the difference between two groups was significant. So inter group comparison of change in these parameters were not considered. However in a previous study significant weight loss as well as reduction of BMI after dietary intervention for 90 days was seen [10]. Again, in separate two systemic reviews have there was short time benefit of dietary intervention in regard of weight reduction [11, 12].

In the present study, waist hip ratio of both the group was similar. Changes of median, in the Non Intervention Group as well as in Intervention Group, of WHR were statistically significant. It was very interesting that even within such a short duration, significant change of waist hip ratio occurred. But in inter-group comparison between the two groups, difference in change of WHR was found statistically not significant. Probably this change in WHR also may be explained by the significant weight loss. In a separate study, weight loss preferentially reduced metabolically active visceral adipose tissue. Even moderate weight loss (5–10%) has been associated with disproportionate mobilization of visceral adipose tissue with concomitant decrease in risk. [13] Earlier in a study of overweight British white women, it was demonstrated that weight loss was associated with reduction in waist circumference(WC) and the largest stable reductions in WC after 6 months produced improvements in at least one of several risk factors(e.g., serum cholesterol, low-density lipoprotein cholesterol, and diastolic blood pressure) [14].

Importantly, we found significant reduction in fasting as well as post prandial sugar in both the group and again even with short term dietary intervention, the inter-group difference was also found to be significant. At baseline, HbA1c of the Non Intervention Group was almost similar with that of the Intervention Group. We did adjustment of medication before enrolling patients for the study that likely contributed to improved glycaemic status. Again, probably the reduction of FPG and PPPG had impact on reduction of HbA1c. The HbA1c change from 7.4 (SD 1.15) to 7.1 (SD 0.6) in Non Intervention Group, was significant (p 0.001). In Intervention Group, HbA1c changed from 7.10 (SD 0.95) to 6.60 (SD 0.40) which was also significant (p 0.00). We observed greater reduction of HbA1c in Intervention Group in comparison to Non intervention group. Inter group correlation and comparison confirmed significant difference in HbA1c reduction (Table No **3**) in Intervention Group in comparison to control Group. Hence, our study confirms the benefit of dietary intervention for reducing HbA1c and further improvement of glycemic control. Similarly, in a previous study of 90 days of dietary intervention, significant reduction of HbA1c was observed, [10] other studies also observed significant reduction of HbA1c (0.18 ± 0.16), [15] whereas finding of another study regarding HbA1c of 7.1%±0.6 to 6.8%±0.5) (P = .012), [16] compared to the control group by 0.30%, was marginally higher than our finding. Finding of 0.4±0.14 % change of HbA1c after 72 week of intervention in another study [17] was relatively lower than our study finding. Though one study [18] could not find any significant change of HbA1c with measure of dietary regulation, two other studies, HbA1c reduction of 0.02% [19] and HbA1c change of 1.5 % [20]; found significant change in HbA1c.

Therefore, in conclusion, we may observe that even short term strict adherence to medical nutrition therapy can have significant impact on glycemic control in type 2 diabetes patients. The present study was done for short duration and also the study sample was small like other previous studies. Normalcy of sample

distribution was not present among the groups in this study. So, probably a longer follow up study with large sample may be wished for better understanding of the role of medical nutrition therapy in type 2 diabetes.

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