Abstract

Aim: To assess the effect of medical nutritional therapy (MNT) provided by dieticians on medical and clinical outcomes for adults with Type 2 Diabetes Mellitus.

Objective: To compare effectiveness of MNT administered monthly to MNT administered once in 03 months.

Method: The study was conducted at the Department of Endocrinology in a tertiary care hospital. 98 men and women of the age group above 18 years were recruited in the study. 49 consenting individuals were randomly assigned to each of the 02 groups namely Group A and Group B. Group A consisted of 02 visits with dietician (including the initial visit) in the first month and thereafter every month. Group B consisted of initial visit with the dietician and there after every 03 monthly. An additional 49 adults with type 2 Diabetes mellitus at one site who had no facility for a contact with dietician were included as a comparison group.

Medical outcome measures including fasting plasma glucose (FPG), glycated haemoglobin (HbA1c) and serum lipid levels were compared and analysed. Clinical outcomes included Body weight, Height and Body mass index (BMI).

Data was collected at the entry to the study and at 03 and 06 months interval.

Result: In our study, the baseline fasting plasma glucose (FPG), HbA1C, total cholesterol and BMI was more or less similar in all 3 groups. There was a sustained decrease in all the four parameters in Group A which received the maximum nutritional therapy over a period of 06 months (A mean decrease of FPG 15.2 mg/dL, HbA1C 0.59%, total cholesterol 19.6 mg/dL, BMI 0.5 kg/m^2 from baseline at 03 months and a mean decrease of FPG 33.4 mg/dL, HbA1C 1.24%, total cholesterol 40.8 mg/dL, BMI 1.1 kg/m^2 from baseline at 06 months was seen). However, in Group B which received intermitted nutritional therapy, the decrease in these parameters were observed initially but over a period of 06 months, they increased to more or less near the baseline value months (A mean decrease of FPG 12.9 mg/dL, HbA1C 0.73%, total cholesterol 16.1 mg/dL, BMI 0.5 kg/m^2 from baseline at 03 months but a mean increase of FPG 3.2 mg/dL and a mean decrease of HbA1C 0.24%, total cholesterol of 4.3 mg/dL and BMI 0.15 kg/m^2 from baseline at 06 months was seen). In Group C which had no means of access to nutritional therapy, there was a subtle decrease in FPG and gradual increase in HbA1C, total cholesterol and BMI at 03 months but all four parameters increased significantly higher than the baseline value at the end of 06 months months (A mean decrease of FPG 6.2 mg/dL and mean increase of HbA1C 0.31%, total cholesterol 16.0 mg/dL, BMI 0.3 kg/m^2 from baseline at 03 months and a mean increase of FPG 5.9 mg/dL, HbA1C 0.73%, total cholesterol 31.1 mg/dL, BMI 0.81 kg/m^2 from baseline at 06 months was seen).

Conclusion: Our study has clearly indicated that medical nutritional therapy is of great importance in the holistic management of Type 2 Diabetes mellitus in adults. MNT has got the advantage of not only maintaining a strict glycemic control (in terms of FPG and HbA1C reduction) but also in the lowering of cholesterol and BMI which are the main contributors to cardiovascular (CVD) events among people with type 2 Diabetes mellitus. Also, people who were given frequent MNT had a clear advantage over those who received intermittent MNT in terms of all the measured parameters.

Introductin

Diet forms one of the most important aspect in the holistic management of Diabetes. However, the basic principles of nutritional management are nebulous and not adequately understood by both physicians and their patients. We obtain our nutrition through a variety of food we eat. In India, the food habits are very varied and dietary pattern is also quite different. Macronutrients provide energy for the human body to burn or to be stored. Essential calories and nutrients are consumed in the form of carbohydrate, protein, and fat. Carbohydrate and protein each provide 4 calories per gram. Fat provides 9 calories per gram (Alcohol provides 7 calories per gram).1

Studies done have shown certain type of diet regimes like Mediterranean diet can greatly influence diabetic control.2 Cinnamon, a common household spice used in Indian subcontinent is also believed to have diabetic control properties but with mixed opinions.3

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In our country, where there is a huge deficit between clinicians who can confidently handle diabetes to their patients, the importance of medical nutritional therapy (MNT) is rarely given its due credit. Unlike the western world where every individual is given a tailored dietary pattern, the diabetic capital of the world is yet to implement even the basic aspects of MNT. Further, the dietary habits vary vastly among different cultures in our subcontinent. It is therefore not practically feasible for a time constrained physician to provide MNT to his patients. On the other hand, a dietician (or a physician who also plays the role of a dietician) whose sole aim is to provide MNT can make a huge difference in the final outcome of diabetes management.

In our study, we try to bring out the huge benefit MNT offers to diabetes management. Also, we try to compare the effectiveness of MNT over frequent and intermittent visits to dietician. We also try to address the importance of a dietician in each diabetic clinic.

**Material and Methods**

**Place of study**

The study was conducted in the Department of Endocrinology in a tertiary care hospital from 01 Oct 2019 to 31 Mar 2020.

**Study design**

A prospective, randomized, controlled clinical trial.

**Sample size**

Sample size was calculated using GPower computer software using 2x2 factorial ANOVA (2 groups and 2 measures at 2 time periods) and found to be 98 (49 in each group). The power of the study was fixed at 0.80 with alpha error of 0.05 to observe small effect size of 0.25.

**Inclusion criteria**

i. Age above 18 years.

ii. Diagnosed as a case of Type 2 Diabetes mellitus and on treatment with either OADs or insulin or both.

**Exclusion criteria**

i. Age less than 18 years.

ii. Any other type of Diabetes other than Type 2 Diabetes mellitus.

iii. Individuals on concomitant long term steroid therapy (more than 04 weeks).

**Study Design**

The study was conducted at the Department of Endocrinology, at a tertiary care hospital in Bangalore. 98 men and women of the age group above 18 years were recruited in the study. 49 consenting individuals were randomly assigned to each of the 02 groups namely Group A and Group B. Group A consisted of 02 visits with dietician (including the initial visit) in the first month and thereafter every monthly. Group B consisted of initial visit with the dietician and there after every 03 monthly. An additional 49 adults with type 2 Diabetes mellitus at one site who had no facility for a contact with dietician were included as a comparison group.

Medical outcome measures including fasting plasma glucose (FPG), glycated haemoglobin (HbA1c) and serum lipid levels were compared and analysed. Clinical outcomes included Body weight, Height and Body mass index (BMI).

Data was collected at the entry to the study and at 03 and 06 months interval.

**Statistical methods of analysis**

Data collected was checked for normality. Normally distributed continuous data (FPG, HbA1c, lipid levels, body weight, BMI, WHR) were represented as mean standard deviation. Comparison within groups was done by paired t test and between groups by unpaired t test.

**Duration of Study**

06 months, from 01 Oct 2019 to 31 Mar 2020.

**Blinding**

Unblinded study

**Ethical issues**

There was no intervention made in any study subject. Standard care of treatment was not compromised to any individual. Also, even in the comparison group, MNT was not possible since there is no facility available for a trained dietician. Hence, the study did not involve any ethical clearance.

**Result**

A total of 49 individuals were assigned to each of the three groups namely Group A, Group B and Group C. Group A consisted of 02 visits with dietician (including the initial visit) in the first month and thereafter every monthly. Group B consisted of initial visit with the dietician and there after every 03 monthly. Group C had no facility for a contact with dietician and were included as a comparison
group. The various characteristics of the subjects are as follows:

**Discussion**

Medical outcome measures including fasting plasma glucose (FPG), glycated haemoglobin (HbA1c) and serum lipid levels were compared and analysed among the 03 groups. Clinical outcomes included Body weight, Height and Body mass index (BMI).

Data was collected at the entry to the study and at 03 and 06 months interval.

**Fasting Plasma Glucose (FPG)**

In our study, the baseline FPG was more or less similar in all 3 groups (Table 1). There was a sustained decrease in FPG in Group A which received the maximum nutritional therapy over a period of 06 months. There was a mean decrease of 15.2 mg/dL from baseline FPG after 03 months but increased by 5.9 mg/dL from baseline FPG at 06 months (Figure 1).

However, in Group B which received intermittent nutritional therapy, the decrease in FPG was observed initially but over a period of 06 months, the FPG increased to more or less near the baseline value. The mean initial decrease was 12.9 mg/dL from baseline FPG after 03 months but at 06 months, it increased by 3.2 mg/dL from baseline FPG (Figure 1).

Further, in Group C which had no means of access to nutritional therapy, there was a subtle decrease in FPG at 03 months but it increased significantly higher than the baseline value at the end of 06 months. The mean initial decrease was 6.2 mg/dL from baseline FPG after 03 months but increased by 3.2 mg/dL from baseline FPG after 06 months (Figure 1).

The results are in-line with UKPDS trial in which the FPG reduced by 46 mg/dL at the end of 03 months. However, in UKPDS trial, the subjects were newly diagnosed patients with Type 2 Diabetes and hence there was a substantial fall in FPG after initiation of treatment along with nutritional therapy when compare to our study. Franz et al concluded that the FPG decrease was 50-100 mg/dL with more intensive nutritional intervention.

**Glycated Hemoglobin (HbA1C)**

In our study, the baseline HbA1C was more or less similar in all 3 groups (Table 1). There was a sustained decrease in HbA1C in Group A over a period of 06 months. A mean decrease of 0.59% and 6.36% from baseline HbA1C was observed after 03 months and 06 months respectively (Figure 2).

Further, in Group B, the decrease in HbA1C was observed initially but over a period of 06 months, the HbA1C increased to more or less near the baseline value. The mean initial decrease was 0.73% from baseline HbA1C after 03 months but at 06 months, it increased by 0.24% from the baseline HbA1C (Figure 2).

The novelty of our study lies in the fact that the decrease in FPG is well sustained only if the nutritional therapy is given at more frequent intervals. Further, our study also demonstrates that intermittent nutritional therapy loses its significance in the long run as it is evident that FPG values at the end of 06 months is almost the same that of baseline FPG values. Also, it is clearly evident that intermittent nutritional therapy is better than no nutritional therapy as the FPG values at the end of 06 months tend to increase much higher than the baseline FPG in the group receiving no nutritional therapy.
months respectively (Figure 2).

The results are similar to the studies conducted by UKPDS, Franz et al, Kulkarni et al and Glasgow et where HbA1C reduction at the end of 03 months in newly diagnosed Type 2 diabetes was 1.9%, 0.7%, 1.0% and 1.0 -1.3% respectively.5-8

Our study was able to demonstrate that with continuous nutritional therapy, we can achieve a steady reduction in HbA1C. With intermittent nutritional therapy, HbA1C can be maintained at a particular baseline level but will not be able to achieve a sustained decrease. Also, if there is no nutritional therapy given, there occurs a steady increase in HbA1C level.

Total Cholesterol and BMI

In our study, the baseline total cholesterol and BMI were more or less similar in all 3 groups (Table 1). There was a sustained decrease in both total cholesterol and BMI in Group A over a period of 06 months. A mean decrease of 19.6 mg/dL from baseline total cholesterol and 0.5 kg/m² from baseline BMI was observed after 03 months. After 06 months, the decrease was more substantial (mean decrease of 40.8 mg/dL from baseline total cholesterol and 1.1 kg/m² from baseline BMI) (Figure 3).

However, in Group B, the decrease in both total cholesterol and BMI was observed initially but over a period of 06 months, both the values increased to more or less near the baseline value. The mean initial decrease was 16.1mg/dL and 0.5 kg/m² from baseline total cholesterol and BMI respectively after 03 months. But at 06 months, both total cholesterol and BMI increased (mean increase of 11.8 mg/dL from the 03 month value but a net decrease of 4.3 mg/dL from the baseline total cholesterol value; mean increase of 0.4 kg/m² from the 03 month value but a net decrease of 0.15 kg/m² from the baseline BMI value) (Figure 3).

Further, in Group C, there was a gradual increase in both total cholesterol and BMI at 03 months but they increased significantly higher than the baseline value at the end of 06 months. A mean increase of 16 mg/dL from baseline total cholesterol and 0.31 kg/m² from baseline BMI was observed after 03 months. After 06 months, a significant increase was observed as mean total cholesterol and BMI increased by 31.1 mg/dL and 0.8 kg/m² from baseline respectively (Fig 3).

Elevated lipid values and BMI are proven cardiovascular risk factors which increase the mortality in diabetic patients.9 Also, diet and exercise led weight loss causes remission in diabetes.10 The results from our study are similar to the studies conducted by UKPDS,5 Franz et al,6 Glasgow et where nutritional therapy was able to achieve a lean body mass and a better lipid profile compared to patients with type 2 diabetes mellitus having no nutritional therapy.

Our study was able to clearly highlight the importance of nutritional therapy in decreasing both total cholesterol and BMI. With continuous nutritional therapy, we can achieve a steady reduction in both total cholesterol and BMI and with intermittent nutritional therapy; utmost these parameters can be maintained at a particular baseline level but will not be able to achieve a sustained decrease. Also, if there is no nutritional therapy given, there occurs a steady increase in total cholesterol and BMI.

Conclusion

1. Our study has clearly indicated that medical nutritional therapy (MNT) is of great importance in the holistic management of Type 2 Diabetes mellitus in adults. MNT has got the advantage of not only maintaining a strict glycemic control (in terms of FPG and HbA1C reduction) but also in the lowering of cholesterol and BMI which are the main contributors to cardiovascular (CVD) events among people with type 2 Diabetes mellitus.

2. Among Indian patients, the more frequently MNT is provided the better the outcome are. People who were given frequent MNT had a clear advantage over those who received intermittent MNT in terms of FPG, HbA1C, total cholesterol and BMI. On the other hand, people who did not have the opportunity to receive MNT performed poorer on all parameters, showing gradual deterioration in glycemic control and CVD risk than the baseline values over a period of time.

3. Our study concludes that MNT has a huge advantage in the management of type 2 diabetes mellitus and should be provided on every given opportunity. Frequent or continuous MNT has a clear advantage over intermittent MNT which is better than no MNT given.

Recommendations

1. Medical nutritional therapy (MNT) is a vital aspect of type 2 diabetes mellitus management and should be given to all diabetic patients.

2. Frequent or continuous MNT has a clear advantage over those who received intermittent MNT in terms of FPG, HbA1C, total cholesterol and BMI. Hence, MNT should be given at every available opportunity than at fixed intervals. Nevertheless, intermittent MNT is better than no MNT provided.

3. In India, there is a huge deficit between clinicians who can confidently handle diabetes and their patients. Further, the dietary habits vary vastly among different cultures in our subcontinent. It is therefore not practically feasible for a time constrained physician to provide MNT to his patients. Hence, in medical set-ups capable of providing holistic diabetic care, a dietician is must, who can make a huge difference in the final outcome of diabetes management.

References


