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Establishment Of A Diabetic Clinic And Its Effects On Glycaemic Control Among Diabetic Patients In Muar District, Malaysia

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Abstract— Introduction: Diabetes mellitus is one of the major risk factors for cardiovascular disease. In Malaysia, a significant portion of diabetic patients being managed in the primary care setting. However, there is a lack of study done, particularly in the primary care setting in terms of the effect of glycaemic control intensification and early diabetic complications detection. Therefore, this study aims to establish a diabetes clinic in a private medical clinic in Muar, Malaysia, to create better awareness of diabetes, improving the overall glycaemic control, delays complications and subsequently improves the quality of life. **Methodology**: This is a cross-sectional study done on twenty-two diabetic patients over six months. Pre and post values of fasting blood sugar (FBS), glycated haemoglobin (HbA1c), lipid profile and other parameters were taken for comparison, mainly to determine improvement in glycaemic control. A diabetes awareness day was organized before starting the study to improve patient knowledge and awareness. **Results**: The study showed improvement in glycaemic control, especially in obese diabetic patients with a mean improvement of HbA1c by 1.4% over six months. A slight improvement was seen in the lipid parameters; however, paired t-test done indicates no much difference in the pre and post-intervention for all lab parameters **Conclusion**: This study showed that having an awareness campaign and a dedicated diabetes clinic can improve patient's glycaemic control. Further study should be done with a larger sample size and longer duration of follow-up to enhance the validity and reliability of similar studies.

Keywords: diabetes mellitus, Malaysia, primary care.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is an increasingly common disease in most affluent societies with its prevalence is rapidly increasing in many developing countries. The majority (almost 90%) of diabetic patients worldwide are T2DM[1]. Given the progressive nature of the disease, patients would require regular glycaemic monitoring and intensification in order to prevent the devastating associated complications in particular cardiovascular complications[2].

There is a continuous rise in the estimated global burden of diabetes over the years [3,4]. In 1994, the International Diabetes Federation (IDF) Directory estimated that over 100 million people in the world have diabetes [5]. In the same year, Mc Carty et al. analysed data from population-based epidemiological studies and estimated that the global burden of diabetes was 110 million in 1994 and would double to 239 million in 2010 [3]. In 1998, the World Health Organization (WHO) Ad Hoc Diabetes Reporting Group published a standardised global estimate for the prevalence of diabetes and impaired glucose tolerance in adults based on data from 75 communities in 32 countries showed that the estimated prevalence of diabetes was to be around 4.0% (135 million) in 1995 and expected to increase to about 5.4% (299 million) in 2025 worldwide [4]. In South-East Asia, on the other hand, showed almost a quarter of diabetic patients worldwide with an estimated 58.7 million by the year 2010 and around 80 million people by the year 2025 [6,7]. These statistics point towards a linear increase in the prevalence and hence the global burden of diabetes mellitus over two decades, particularly in our region.

According to the Malaysia National Health and Morbidity Survey, it is estimated that 3.4 million Malaysians suffers from diabetes in 2010 [8]. The report also showed a dramatic increase in the prevalence of diabetes from 8.3% in 1996 to 14.9% in 2006 for adults age 30 years and above, i.e. a dramatic increase of 80% within only ten years[8]. Alarmingly, the report also showed that the prevalence of diabetes among adults of 18 years and above was 17.5% mirroring a general increasing trend in prevalence with age, from 5.5% in the 18-19 years age group, reaching a peak of 39.1% among the 70-74 years age group[8,9]. Furthermore, the prevalence of obesity, i.e. one of the main risk factors of T2DM has increased from 4.4% in 1996 to 14.4% in 2006 for adult aged 18 years and above[8]. The risk of developing Type II diabetes significantly increases with increasing obesity in adult population [10]. Moreover, Malaysia has the highest population of obese and overweight people in Asia at 17% and 33% respectively based on the World Health Organization (1998) classification. This alarming prevalence of diabetic risk factors puts a tremendous strain in the already overstretched health services in the country with an estimated cost for providing inpatient diabetic care is RM 119 million per year [11].

Primary health centres and clinics have the highest outpatient turnover and play a crucial role in the prevention, detection and management of diabetes mellitus and its complication. There have not been many studies conducted to estimate the glycaemic control of diabetic patients in primary health clinics in Malaysia. A study conducted in a primary health clinic in Sarawak, Malaysia, showed that only 28% of the study population achieved a good glycaemic control; measured by glycated haemoglobin (HbA1c) level of less than 6.5% [12]. Another study in Nairobi, Kenya, in a primary healthcare clinic focused on diabetes education, able to demonstrate a significant reduction in hospital admission for diabetic-related complications [13].

Treatment of diabetes patients is complex and ever-evolving with patients' compliance and participation being a crucial element in determining the outcome of the treatment. The United Kingdom Prospective Diabetes Study (UKPDS) is the largest study conducted on newly diagnosed diabetic patients over ten years that revolutionized diabetes treatment[14]. The study highlights the

importance of focusing on diabetes control at the early stages of the disease process and its effects at later stages after many years, which is referred to as the 'legacy effect"[15]. The 'legacy effect' is based on the findings that there are significantly lower diabetes-related complications including myocardial infarction and all-cause mortality in the intensive glycaemic control arm compared to the conventional glucose control arm early on in the disease, although the HbA1c was similar in both groups in the 10-year follow up [15]. This finding further emphasizes the importance of early treatment and optimization of glycaemia in order to avert complications later on in the patient's life.

To achieve a good and effective glycaemic control, The International Diabetes Federation (IDF) has recommended that the HbA1c be maintained below 6.5%. Lipid management, on the other hand, showed The optimal level of low-density lipoprotein cholesterol (LDL) should be less than 2.58mmol/L (100mg/dL), high-density lipoprotein (HDL) is more than 1.03mmol/L (40mg/dL) and less than 1.7mmol/L (150mg/dL) for triglycerides (TG)[16,17].

Background and Rationale

Muar is a district in the state of Johor, Malaysia, that covers an estimated area of 2346.12km2 with a population of around 437,164 people with multi-racial demography consisting mainly of Malays, Chinese and Indians. Taj Clinic is a general practice clinic in Muar where chronic diseases such as diabetes and hypertension are among the diseases being treated in the clinic. Currently, more than 120 regular diabetes patients are being treated at the clinic. The pharmacological management of diabetes in the clinic is based on the current Malaysian Clinical Practice Guidelines as well as International Diabetes Federation Guidelines (IDF) for the management of diabetes. The patients who were treated in the clinic include type 1 and type 2 diabetic patients for follow-ups. However, there is no in-house facility that is available for acute emergency cases which require hospitalization most of the time. The clinic sent blood and urine specimens during the follow-ups to a private lab in Muar and therefore provided complete monitoring of the patient's glycaemic control over time.

Diabetes care in Malaysia is mostly treated at primary care level. Thus intensification of glycaemic control and detection of early complication is prudent at primary care level. However, care provided at primary level lacks in many aspects. Average consultation for diabetic patients was only five to ten minutes in a busy clinic setting; thus, proper counselling and intensification of glycaemic control is not possible. Furthermore, most primary care centres are not able to achieve a good diabetic control among their patients. Part of it is due to the lack of availability of specialized drugs and insulin at the primary care level while part of it is due to incomprehensiveness of care for the patient. Patients are managed with a good and comprehensive pharmacological management at study clinic. Therefore, this clinic is chosen to conduct the study since all pharmacological drugs for treating diabetes, including insulin, are readily available.

Objectives

Integrated diabetes care is strongly needed to achieve optimal glycaemic control and better overall health among diabetic patients in Malaysia. Self-management of the disease is an essential aspect of management and should be recommended for all diabetic patients. Diabetes self-management education (DSME) is a critical component of diabetes care as it leads to good glycaemic and metabolic control, which is essential for preventing long-term micro and macrovascular complications. These self-management behaviours include adherence and self-blood glucose monitoring (SBGM) as well as exercise and body mass index (BMI) monitoring [18]. Therefore this is a study conducted at a private clinic in Muar, Malaysia, to achieve an adequate and reliable glycaemic control for diabetic patients.

The main objectives of the study are to measure the effectiveness of a primary care-based behaviour modification program for the optimization of diabetes control among diabetic patients in the district of Muar, Malaysia and to enhance the pharmacological diabetes management. Ultimately, the goal is to promote health education as part of comprehensive diabetes management for the patients and increase the level of awareness among the patients with regards to a healthy diet and living. The study aims to ensure continuous and effective diabetes management utilizing improved record keeping as well as regular biochemical markers analysis as indicators of the effectiveness of diabetes management among patients.

METHODOLOGY

In this project, a cross-sectional study was conducted to understand the effects of glycaemic control at primary care clinics for diabetic patients in Muar, Malaysia. Twenty-two adults (above the age of 18 years) diabetic patients (diagnosed with T2DM) consented to participate in this study and enrolled into Taj Clinic, Muar District in Malaysia, for treatment and follow up for six months. The reason for the small number of patients enrolled in the study is the cost factor. The study is conducted in a private primary care setting whereby patients have to pay for the treatment and lab tests which deterred many patients from enrolling into this study.

This study was conducted in the following sequence; i.e. study was divided into the following main sections:

1. Diabetes Awareness Day

A diabetes awareness day was organized before the beginning of the study to improve the general awareness of diabetes and management and to alleviate the fear of the disease. A total of 100 patients were expected to turn up for the event; however, only sixty-two patients attended.

On the day, participants were offered free blood tests including fasting blood sugar, fasting lipid profile and HbA1c for diabetic patients. Breakfast and lunch meals were provided and prepared by a caterer with a strong background of diabetes food preparation. The main reason for introducing diabetic food is to show that patients can still enjoy tasty and healthy food despite having diabetes. Several talks on diabetes and its management were organized on the day as well, through which patients could interact with speakers and ask any questions they have in mind. The diabetes educator also gave a special talk on dietary modifications and diabetes. The talk highlighted the importance of taking medications regularly within advised timings and their effect on managing diabetes effectively. The Diabetes Awareness brochure is included in Appendix A.

2. Patients' Baseline Assessment

The diabetes clinic is held once every week with a patient load of five to seven patients per session. One week before the first appointment date, patients were required to come to theclinic for baseline assessment which includes the following assessments:

I. Demographic data: the patients were asked to fill up a diabetes awareness questionnaire toassess the level of knowledge, awareness and understanding of the disease process. Thequestionnaire comprises of mainly two sections; the first includes patient's demographicdata such as age, gender, ethnicity, and education level. The second section involvesquestions regarding the awareness of diabetes, and questions assessing the knowledge onrisk factors contributing to diabetes.

II. Medical History: a detailed history taking is done starting with the time of diagnosis, and including osmotic symptoms, any microvascular or macrovascular complications, familyhistory, drug and allergy history, social history and behaviouralrisk factors such as smoking,alcohol consumption, sedentary lifestyle and poor dietary habits.
III. Physical Examination: a thorough physical examination was performed including patient'sheight, weight (with the calculation of body mass index- BMI), blood pressure, resting pulserate, cardiovascular system, respiratory system, gastrointestinal system, 10gmonofilament test, peripheral pulses, vibration using 128Hz tuning fork, and deeptendon reflexes and funduscopy. A baseline electrocardiogram was also done for eachpatient.
IV. Blood Tests: venous blood samples were taken which includes fasting blood sugar (FBS), HbA1c, renal profile, liver function test, lipid profile,urinalysis and full blood count.

3. Patients' Follow Up

Patients follow up for diabetic treatment, and management was carried out for the duration of the study of six months. The follow up was scheduled once a month throughout the study. One day before clinic day, the clinic staff calls up the patients to remind them of their appointment the following day. Each patient is allotted at least half an hour consultation to allow adequate physical examination, review of laboratory results anddiscussion of problems faced by the patients. The follow-up assessment and diabetes management conducted on each patient include the following:

I. Dietary Advice: dietary advice is given to the patients based on the calculation of totalenergy requirement, taking into account the caloric content of the food based on thenational guideline. Glucerna (diabetic milk produced by Abbott company) is introduced as partof medical nutrition therapy. The use of plain sugar and condensed milk in the drinks,which commonly used in Malaysia, is strongly discouraged.
II. Exercise Plan: regular exercise is encouraged to the patients, taking into account patientage and target heart rate. The average duration of exercise was advised to be 150 minutes aweek, or 30 minutes 5 days a week. At the start of the exercise programme, patients wereadvised to start slow and gradually increase the pace and duration of the exercise.
III. General advice on proper footwear was given. Patients were advised to inspect their footregularly every night before going to bed for any developing callus, small ulcers orfungal infections. In future, proper footwear will be introduced in the clinic, which is'diabetic foot-friendly.'
IV. Blood Tests: The same venous blood tests taken during the first visit were repeated afterthe six months period of the study to monitor and assess the effectiveness of behaviourmodification as well as the intensification of pharmacological treatment. The venous blood samples were sent to a private laboratory in Malaysia for analysis. Among the parameters monitored HbA1C and the lipid profile of patients. During the monthly follow-ups, capillary blood tests were done to monitor the fasting blood sugar control with the use of glucometer.
V. Intensification of Medication: Each patients' list of medications were reviewed, and the role of each medication was explained to improve patient compliance. Intensification of therapy is done based on glycaemic control, and new drugs were added, an example being statinsfor dyslipidaemia. The timing of the medications was also advised. Patients were advised to report any side effects of medications to the clinic to allow adjustment of medications and to prevent non-compliance.
VI. Self-Blood Glucose Monitoring (SBGM): the importance of self-blood glucosemonitoring is explained and strongly advised to the patients. Patients were generallyadvised to check the

sugar levels pre and post meals (2 hours postprandial) and to keep a diary on the readings that were shared with the physician during the follow-up visits. Frequency of blood glucose monitoring was tailored individually.

RESULTS AND DISCUSSION

A total of 22 consenting patients were enrolled in the diabetic clinic study for a period of six months. The patients' diabetic treatment is followed up on a monthly basis. It is noted that women outnumbered men (59% to 41%), as shown in Figure 1.

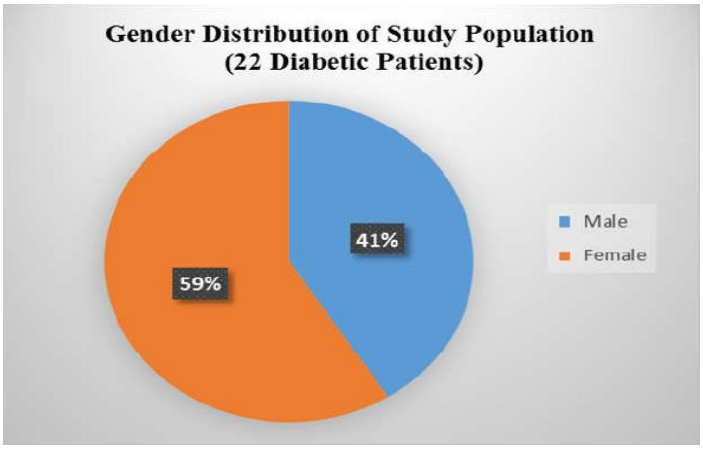

Figure 1 Gender Distribution of Study Population

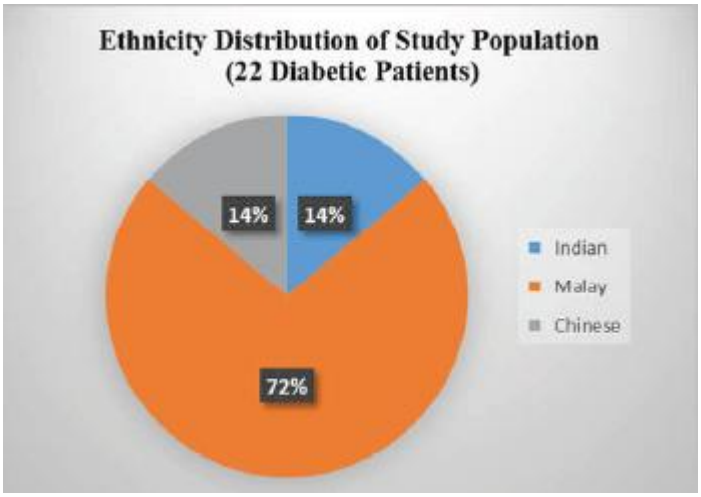

Figure 2 Ethnicity Distribution of Study Population

Figure 2 illustrates the ethnic distribution of patients attending the clinic. Malays made up the majority, followed by Chinese and Indians with an equal percentage. However, this is not representative of the general Chinese and Indian population as the participants from these ethnic groups are small.

Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the

square of the height in metres (kg/m2). The mean BMI for men in this study is found to be 26.9 kg/m2, and the mean BMI for women is 30.3 kg/m2. As such, the mean BMI for men falls into the pre-obese category, and the mean for women falls into the obese category. Table 1 below shows the calculated BMI ranges and associated Obesity categories and FBS and HBA1c values. The participants in this study are mostly in the pre-obese and obese category, as shown in Table 1 and Figure 3.

Table 1 BMI Ranges and Corresponding FBS and HbA1c Values

BMI Range*	No. Of Patients (% of population)	Pre-FBS (%)	Post-FBS (%)	Pre-HBA1c (mmol/L)	Post-HBA1c (mmol/L)
Underweight (>18.5)	0 (0%)	0.0	0.0	0.0	0.0
Normal (18.5-24.9)	5 (22%)	8.18	8.96	9.02	8.72
Pre-Obese (25.0-29.9)	10 (45%)	11.1	8.65	9.48	9.02
Obese (>=30.0)	7 (33%)	9.1	9.4	8.2	6.8

*Adapted from World Health Organization World Health Organization, 1995, 2000, 2004.

Figure 3 shows that an alarming 45% of the study group are in the pre-obese group and 33% areobese. Since the majority of patients are in the pre-obese and obese range, an analysis was doneto look at the correlation between obesity and glycaemic control.

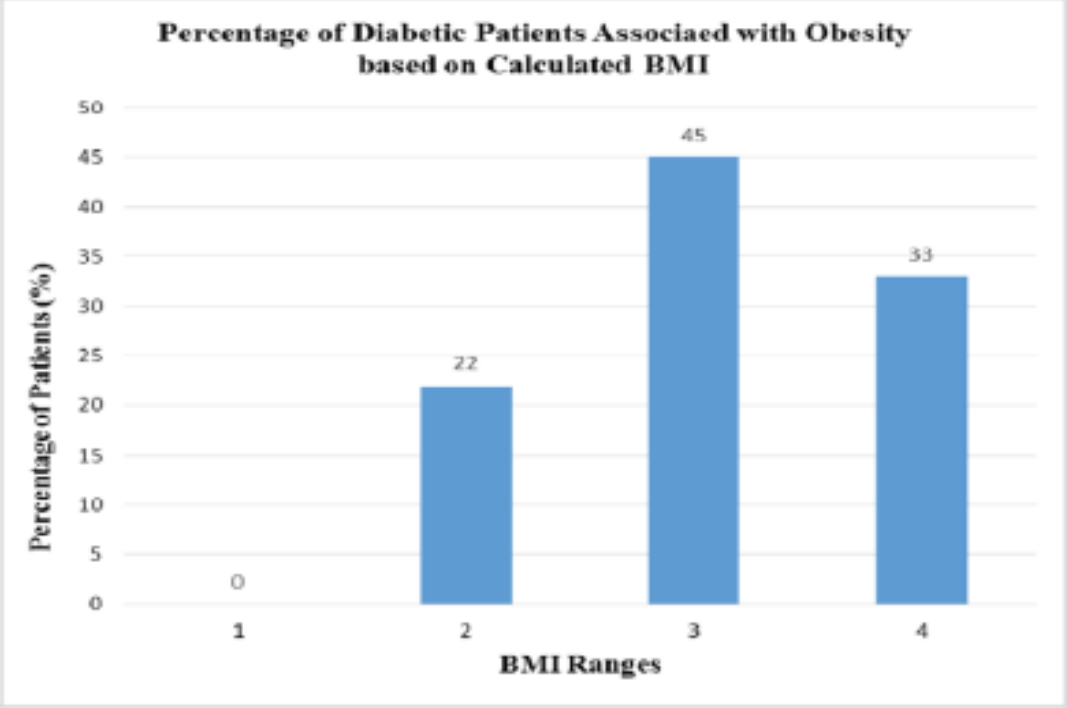

Figure 3 Percentage of Diabetic Patients Associated with Obesity based on Calculated BMI

This study also highlights that the BMI (based on the WHO 2004 criteria), is not a significant factor in the improvement and near normalization of glycaemic control as seen in Figure 4 and 5. This is similar to a study done in Spain looking at the relationship between obesity and glycaemic control, and cardiovascular risk factors concluded that glycemic control was independent of BMI but

associated with abnormal lipid levels [19]. In contrast, a study done in the United States found that for both T1DM and T2DM patients, there were positive and statistically significant associations between being overweight or obese and having suboptimal glycemic control [20].

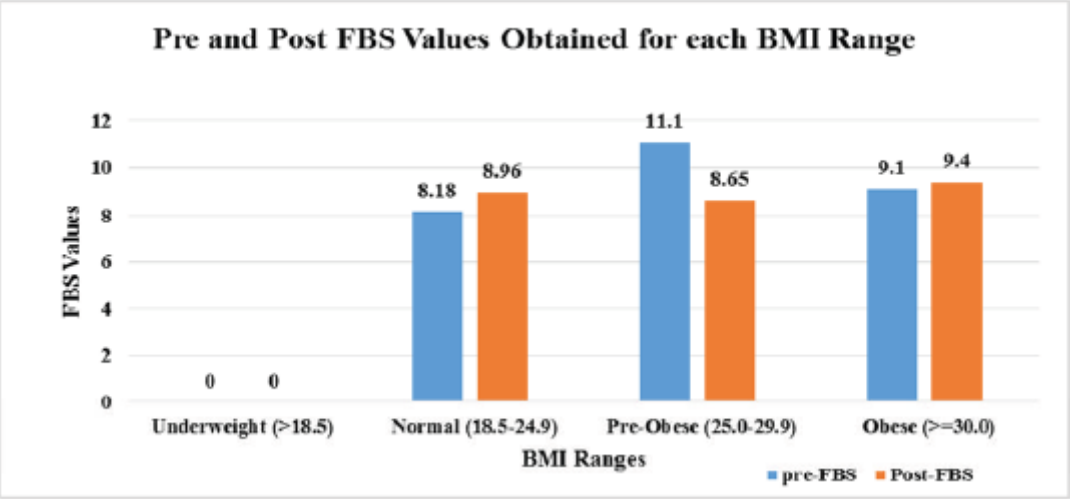

Figure 4 Pre and Post FBS Values Obtained for each BMI Range

Figure 4 describes the pre and post fasting blood sugar among the different BMI ranges. We can see that the normal BMI patients had the lowest baseline fasting blood glucose at a mean of 8.18mmol/L, followed by obese individuals at a mean FBS of 9.1mmol/L. The pre-obese the category had the highest baseline FBS at 11.1mmol/L. Surprisingly, the post-study levels show the pre-obese patients to have the lowest FBS at a mean of 8.65mmol/L, a dramatic improvement from their baseline FBS. This could be due to raised awareness and improved compliance with lifestyle changes and medications.

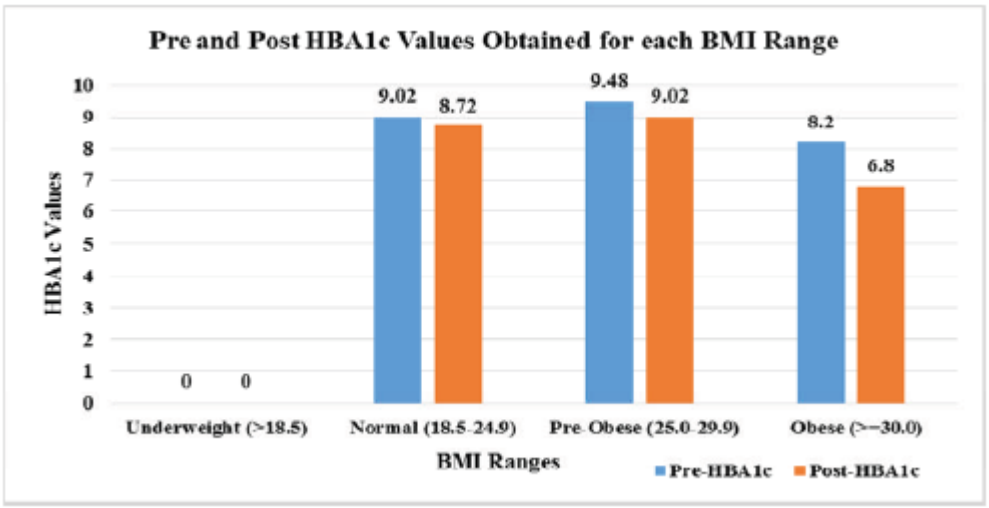

Figure 5 Pre and Post HbA1c Values Obtained for each BMI Range

Figure 5 illustrates the relationship between glycated haemoglobin A1c (HbA1c) through different BMI ranges. We can see here that patients in the pre-obese had the highest baseline mean HbA1c, followed by normal and the obese group having the lowest mean HbA1c at 8.2%. Dramatic improvement in the mean HbA1c is seen in the obese category with an improvement of 1.4% in HbA1c from baseline values. Further study is required to determine the reason for the significant improvement of mean HbA1c seen in the obese category. This is possibly due to heightened diabetes awareness, and the realization that obesity is an added cardiovascular risk factor has contributed to better overall glycaemic control. Further studies with a more extensive study population are required to establish this fact.

One local study stated that there was no correlation between obesity and glycaemic control measured by both glycated haemoglobin level and fasting blood sugar [12]. In this study, patients in the obese category achieved much lower post HbA1c values compared to the other category. This could be explained by better awareness achieved in the obese category patient. The obese group of patients are more self-conscious of their body image, indirectly highly motivated to lose the extra weight, improving the glycaemic control in the process.

Variable	Type	Mean	STDV	Mean difference	Lower CI	Upper CI	t (df)	P value
FBS	Pre	9.72	3	0.77	-0.89	2.43	0.96 (21)	0.347
	Post	8.95	2.7					
HBA1c	Pre	8.92	1.97	0.11	-0.22	0.45	0.71 (21)	0.488
	Post	8.81	1.79					
LDL	Pre	2.54	1	0.11	-0.27	0.5	0.61 (21)	0.546
	Post	2.43	0.9					
HDL	Pre	1.18	0.3	0.07	-0.07	0.21	1.05 (21)	0.306
	Post	1.11	0.3					
TG	Pre	2.22	1.4	0.14	-0.22	0.5	0.79 (21)	0.439
	Post	2.08	1.1					

Table 2 Calculated Mean Values for FBS, HbA1c, LDL, HDL, and TG Pre and Post Intervention

Table 2 shows the mean pre and post values for different blood test lab parameters. Even though paired T-test showed no significant statistical difference, but more detailed study of the mean values showed improvement in all lab parameters. However, the mean glycaemic control of thepatients in this study did not reach the recommended values of FBS and HbA1c less than 6mmol/L and 6.5% respectively. The mean LDL and HDL values are well within the target range.

RECOMMENDATIONS

In the future, the service of a dietitian and diabetic educator will be incorporated into this diabetic clinic which we believe will improve the outcome of patients. Further studies and analysis should be done on non – alcoholic fatty liver disease by monitoring liver function tests and ultrasonography of liver and the impact of lifestyle and diet modification with the intensification of glycaemic control on the fatty liver disease. One patient in the current study presented with elevated liver enzymes with

fatty liver changes observed on ultrasonography showed normalization of liver enzymes at the end of the study. So further analysis of fatty liver disease in diabetes is prudent. The body mass index (BMI) of patients should be repeated to look at the impact of regular physical activity on body weight. Future study should include the measurement of waist circumference as many of these patients may fall into the category of metabolic syndrome.

The clinic also should be better equipped with the professional services of a dietitian and diabetic educators. The incorporation of diabetic foot advice and an able footwear technician will bring about better awareness and understanding regarding foot care and possibly reduced complications related to diabetic foot. A talk on diabetic foot and foot care will help achieve better awareness among patients, translating to better foot care. As part of the foot care, we would like to use the durometer and biothesiometer in our clinic. The introduction of microcellular rubber (MCR) footwear will prevent ulcer and ulcer recurrence. Better awareness must be created among the public on diabetes through talks, campaigns and seminars. It is strongly recommended that this study be continued for a longer period with a larger study sample to see the effectiveness of a dedicated diabetic clinic at the primary care level.

CONCLUSION

Though this study did not yield statistically significant results, the authors wholeheartedly feel that a positive impact will be seen in the management of diabetic patients with proper remedial actions taken (refer to recommendations). Despite the statistical analysis results, scrutiny of the clinical data reveals that small improvement is achieved in the glycaemic control and the lipid profile. The mean lipid profile analysis reveals that most patients' lipid parameters are well within the acceptable range, except for triglycerides. Better awareness of diabetes plays a crucial role with regards to adherence and compliance of diabetic patients to the treatment and management. This also significantly affects the patient's attitude towards diabetes.

The low number of diabetic patients who participated in this study poses a huge challenge. A limited number of participating diabetic patients resulted in insufficient data collection, thus affecting the overall results. Patients' compliance with given treatment and diet as well as regular exercise posed a challenge in their management. The cost factor limited the number of patients using self -blood glucose monitoring (SBGM). Poor awareness and knowledge of the disease process among diabetic patients resulted in poor diabetic management among patients.

Furthermore, the failure of incorporating an expert dietitian, diabetes educator and diabetes foot technician affected the outcome of the study as well.

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