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Non Adherence and its Contributing Factors Among type Two Diabetic patients with Anti Diabetic treatment in a Rural Tertiary care teaching Hospital, Tamil Nadu, India.

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ABSTRACT

Diabetes is a chronic incurable disease affecting worldwide. It is more prevalent these days due to obesity and increased life expectancy. India is regarded as the diabetic capital of the world. Adherence to drug therapy is a major factor that supports proper glycemic control. The study was performed to access the adherence of the patients towards their anti-diabetic therapy and also to find out the reasons for non-adherence. This descriptive observational study was carried out among patients with diabetes mellitus admitted in Perundurai Medical College Hospital. Every other patient was selected and data regarding their medication adherence was collected using a structured interview. Data analysis was carried out using SPSS-22. Of all respondents, 736 (77.96%) were male. 684 (72.44%) of the patients were above 50 years of age. 484 (51.27%) of the study population were diagnosed within last 1 to 10 years. 532 (56.35%) patients were non-adherent with prescribed medication. 446 (47.24%) patients skipped there drugs for more than 5 days; forgetfulness and busy life were reported to be the most common reasons for non-adherence. 608 (64.40%) patients did not have a proper drug knowledge regarding their prescribed medications. Greater than half of the patients were non adherent to their therapy. This can be improved through education, counseling and reinforcement of self- care. The factors like increasing age, male sex, literacy, concomitant illness were significantly associated with the non-compliance. The prescriber before prescribing and pharmacist before dispensing drugs for diabetic patients, he/she should negotiate about the treatment plan that the patient understands and to which he or she commits.

Keywords: *Diabetes mellitus, Non-adherence, Drug knowledge.*

INTRODUCTION

Diabetes mellitus is one of the most common chronic diseases affecting worldwide [1]. It is a serious and incurable disease but mostly invisible [2]. The prevalence of diabetes has increased significantly due to obesity and increased life expectancy [1]. Epidemiological data indicates that all nations, whether rich or poor, are suffering the impact of the diabetic epidemic. The scenario is even worst in socially and economically backward countries [3]. India is regarded as the diabetic capital of the world. This disease is a complex disorder which requires constant attention to diet, regular monitoring of blood glucose and drug therapy for glycemic control [1]. Management of diabetes mellitus involves both pharmacological and non-pharmacological approaches [3]. Adherence to drug therapy is a major factor that supports proper glycemic control [4]. Non-pharmacological approaches include dietary modification, life style changes and physical exercises [3]. It has been reported that approximately one in four people is not adherent to his or her prescribed drug regimen [5]. Understanding how patient's beliefs about their disease and its treatment affect health behaviours such as medication adherence represent important opportunities for improving diabetes medication adherence [6].

According to WHO, "Adherence is the extent to which a person's behaviour; taking medication, following a prescribed diet, and/or executing life style changes corresponds with agreed recommendations from the health care provider"[7].

Rational drug use is a complex issue with a goal which is difficult to achieve, defined as follows: "that patients receive medications appropriate to their medical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community" [8].

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The WHO has shown that adherence to long term therapy for chronic illness in developed country averages only around 50%[9]. This is much less in developing countries like India.
Individual with poor diabetic management are at a higher risk of developing long-term micro and macro vascular complications[10]. It can in-turn lead to end organ damage such as kidney, brain, heart and eyes; which affect the overall quality of life and increases direct and indirect health care costs [11, 12].

There are several factors that lead to medication non-compliance. These include beliefs about the medication, side effects, complex regimens, lack of adequate knowledge and costs associated with the medications [10].

Treatment adherence can be measured using direct and indirect methods. Direct methods used to measure treatment adherence include the measurement of serum drug concentration or the use of chemical markers in tablets. These methods are expensive and have known limitations. Indirect method includes electronic monitoring (which is the gold standard) and pill counting techniques [13].

MATERIALS AND METHODS

This study was conducted in PMC Hospital Perundurai, which is a rural tertiary teaching hospital in Tamil Nadu. The study was conducted from April 01 to August 30, 2015. A prospective observational study was conducted among patients with type II diabetes mellitus. Direct patient interview was conducted and their responses were collected in a well-designed data collection form. Relevant data were also collected from patient case files, previous medical records, interviewing patient caretakers etc. Adult type 2 diabetes patients who were admitted in the hospital during the study period were interviewed on their adherence towards the hypoglycaemic drugs.

A structured questionnaire with open and closed-ended questions was used to record the patient responses. The questionnaires were prepared in English language and translated to local language Tamil for data collection. The questionnaires contain socio-demographic characteristics, reasons for non-adherence,

knowledge and attitude of patients, concomitant illness, treatment regimen etc.

The structured questionnaire was pre-tested in 15 patients to check for its simplicity, clarity, coherency and understandability. The feedback was obtained and correction was made accordingly. For confusing words and phrases, locally known and comparable terms were used.

Statistics:

Data was analyzed using SPSS Statistical software version 22.

RESULTS

A total of 944 patients were interviewed to access the adherence and knowledge towards the treatment.

Gender:

In our study, 736 of the respondents were male whereas 208 were female.

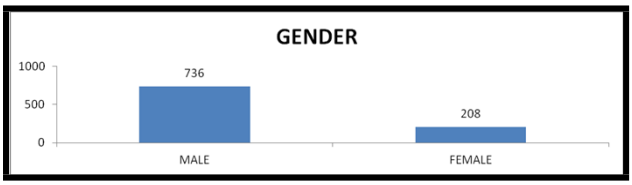

Fig. 1: Gender distribution.

Age:

Patients were included irrespective of their age. Among the 944 respondents, the majority were above 50 years of age. 20 patients were from the age group of 15-30 years, 240 patients were from the age group of 31-50 years.

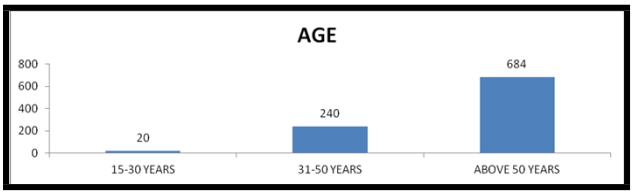

Fig. 2: Age in years

Economic status:

On analyzing the economic status of the patient, 480 patients were affordable to pay for the treatment whereas 464 patients were economically backward and received free treatment.

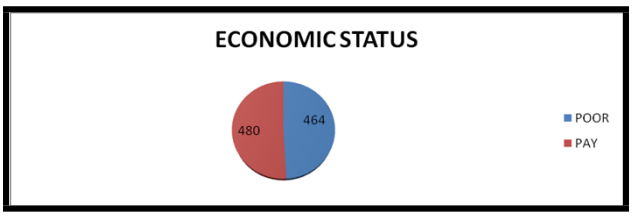

Fig. 3: Economic status

Educational status:

Among the respondents, majority reported of having primary school education, which included 558 patients. 314 patients reported to have an education of high school or more. 72 patients reported to be illiterate.

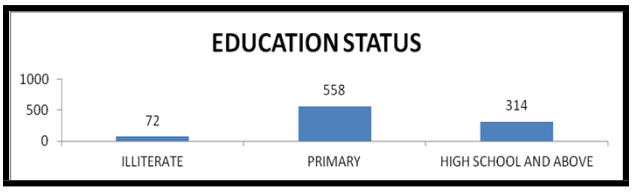

Fig. 4: Educational status

Marital status:

804 patients who took part in the interview were married, 88 patients were divorced/widow whereas 52 patients were single.

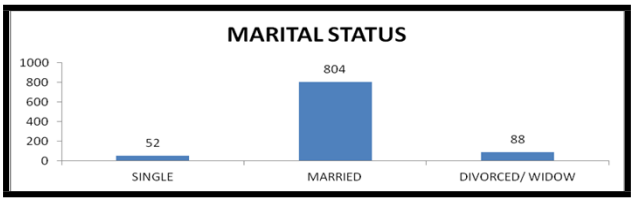

Fig. 5: Marital status

Concomitant illness:

The most common concomitant illness found in association with diabetes was hypertension. It was found in 272 of the study subjects, followed by tuberculosis in 168 patients. 128 patients did not have any concomitant illness.

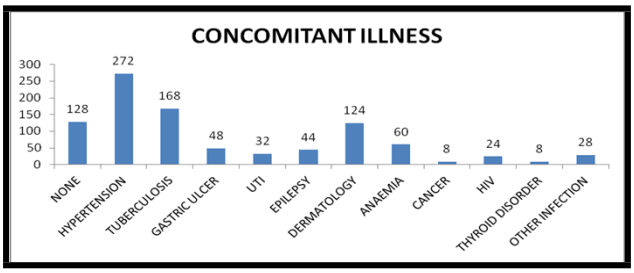

Fig. 6: Concomitant illness

Years of diagnosis:

The patients were enquired regarding the age of diagnosis. Majority of them were diagnosed within a period of past 1 to 10 years, which comprised of 484 patients. It was followed by 232 patients diagnosed within the past 11 to 20 years. 176 patients were newly diagnosed, whom were identified to be diabetic within the past 12 months.

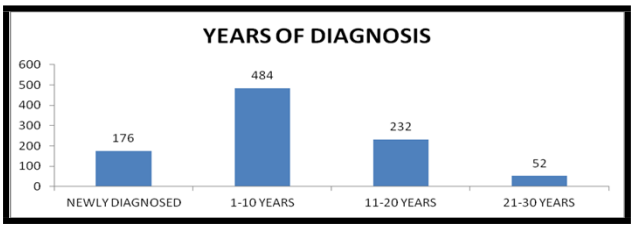

Fig. 7: Years of diagnosis

Blood glucose monitoring:

The study subjects were monitored regarding various blood parameters to determine the blood glucose level. We recorded the levels of fasting blood glucose, HbA_1c, random blood sugar and post prandial blood sugar. It was noted that each patient was performed with at least 2 of these parameters.

- ***Fasting blood glucose:***

  Out of 944 patients interviewed, 116 of them did not undergo the FBG test. Majority of the patient's blood glucose level falls within the range of 140-200mg/dl, which includes 292 patients; followed by 156 patients with uncontrolled blood sugar level of >250 mg/dl.

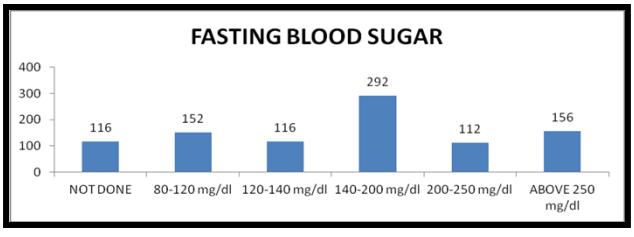

Fig. 8.1: FBS Level

- ***HbA$_1$c:***

HbA$_1$c levels were not recorded in 636 patients. Among 208 patients whom were monitored with HbA$_1$c, 152 patients recorded a higher level between 7 to 10%, whereas 56 patients fell in the normal range.

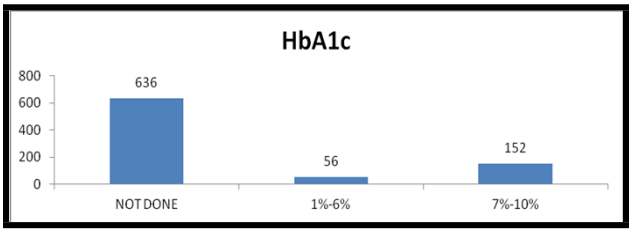

Fig. 8.2: HbA$_1$c Level

- ***Random blood sugar:***

540 patients did not undergo the test. Among those who were performed with the test, majority recorded an uncontrolled level of more than 250 mg/dl of blood glucose; followed by 112 patients in the range of 140-200 mg/dl.

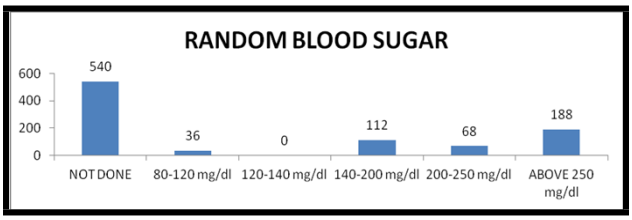

Fig. 8.3: RBS Level

- ***Post prandial blood sugar:***

164 patients were not performed with the test. Among 780 patients who performed the test, 316 patients had elevated levels of more than 250 mg/dl, followed by 184 patients falling in the 200-250 mg/dl level.

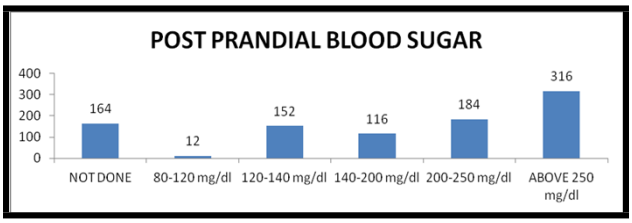

Fig. 8.4: PPBS Level

Treatment regimen:

We noted that majority of the patients were treated with single insulin (260 patients). It was followed by 216 patients treated with a single oral hypoglycemic drug (OHA). 176 patients were treated with 1 insulin plus 1 OHA. 36 patients with severely uncontrolled diabetes were treated with combination of 1 insulin plus 3 oral hypoglycemic drugs. We also noted that 36 patients were not administered with any drug, but were advised with diet modifications only.

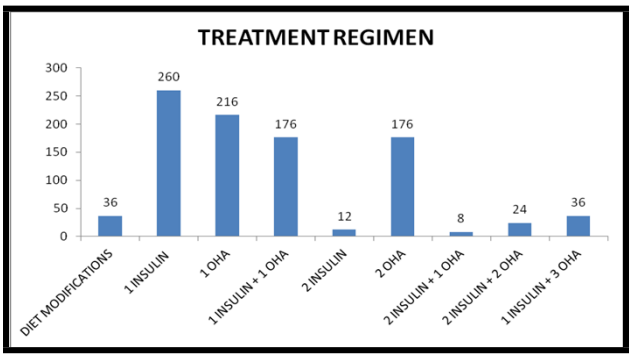

Fig. 9: Treatment regimen

Treatment adherence:

The patients were analyzed with their adherence to drug therapy. This included timely administration of drugs as well as adherence to diet modifications. It was noted that majority of them (532 patients) have poor adherence to the treatment provided. Meanwhile, 412 patients showed good adherence pattern to the treatment.

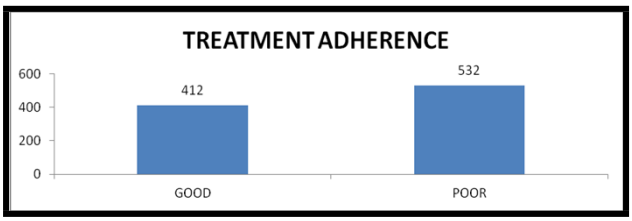

Fig. 10: Treatment adherence

Drug knowledge:

The participants were assessed with the knowledge of hypoglycemic drugs administered to them. It included basic knowledge regarding name of the drug, dose, frequency, duration, and route of administration of the drug.

It was noted that majority of them (608 patients) had poor knowledge of their drugs. Only 336 patients responded correctly to all the questions asked by the interviewer.

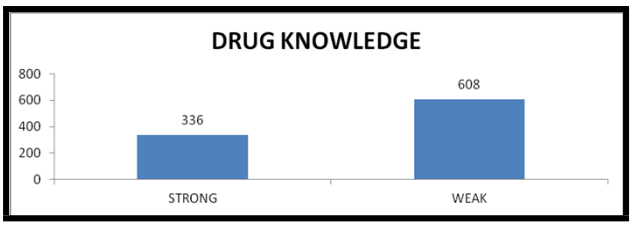

Fig. 11: Drug knowledge

Diabetic foot ulcer:

The prevalence of diabetic foot ulcer among the patients admitted with diabetes mellitus were assessed in the study.

It was noted that 340 patients had the complication of diabetic foot, whereas 604 patients did not had diabetic foot ulcer.

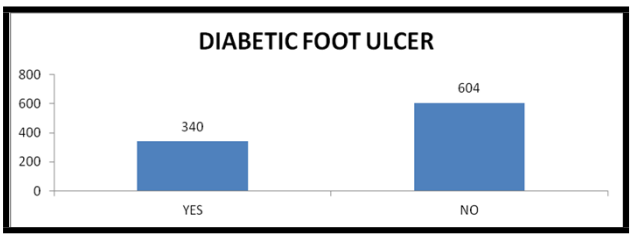

Fig. 12: Patients with diabetic foot

Diet modifications:

The patients were interviewed about their habit of control over the diet and 572 patients responded to have a diet modification while, 372 reported that they do not have the practice of diet modification.

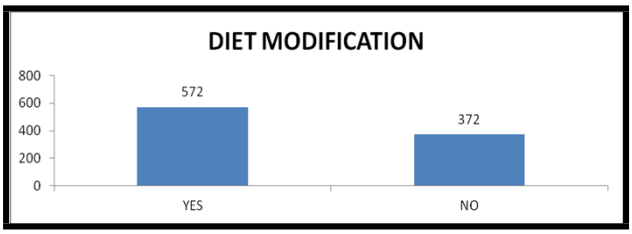

Fig. 13: Diet modification

Insulin adherence:

Out of 516 patients who took insulin, 388 patients said that they were adherent towards the insulin therapy while 128 of them responded negatively.

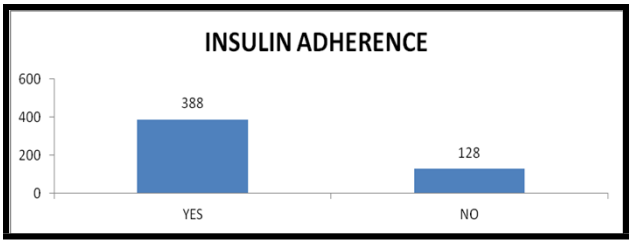

Fig. 14: Insulin adherence

Alteration of the injection site:

Alteration of the injection site is very important in the diabetic patients who are been prescribed with insulin. This question was asked during the interview with the patients and a majority of them (348 patients) responded that they have the practice of altering the injection site regularly and 168 patients responded negatively.

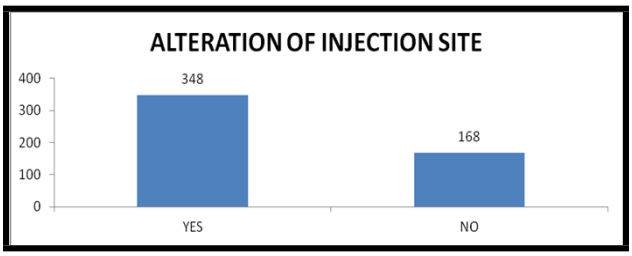

Fig. 15: Patients altering injection site

Frequency of blood glucose monitoring:

The patients were enquired regarding the frequency of blood glucose monitoring. Maximum number of patients responded of checking blood glucose every 3- 6 months, while 292 patients monitored it every month. 20 patients responded they never monitored blood glucose for the past 1 year.

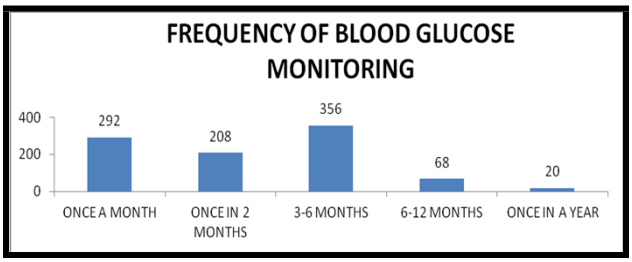

Fig. 16: Frequency of glucose monitoring

Habit of "fast sugar":

752 patients said that they do not have the habit of carrying "fast sugar" and only 192 patients responded that they do carry "fast sugar".

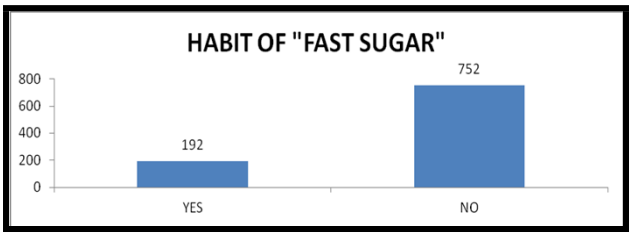

Fig. 17: Habit of fast sugar

Exercise:

Exercise is very important for the proper control of the diabetes but only 184 of the patients interviewed responded that they have the habit of exercise while the majority of them (760 patients) reported that they do not exercise.

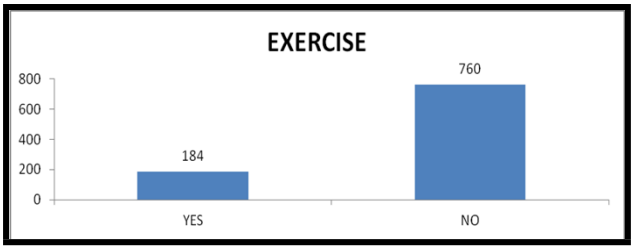

Fig. 18: Habit of exercise

Occurence of hypoglycemia:

140 patients reported to experience hypoglycemia while 804 patients reported that they have never experienced any hypoglycemic events with the drug regimen.

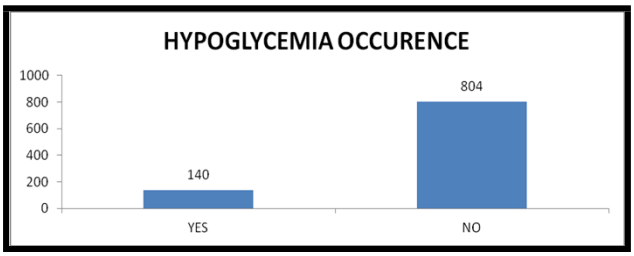

Fig. 19: Patients with hypoglycemia episodes

Diabetic chart:

The patients were interviewed on their habit of maintaining a diabetic chart and 220 of them responded positively while 724 patients reported not to have the practice of maintaining a diabetic chart.

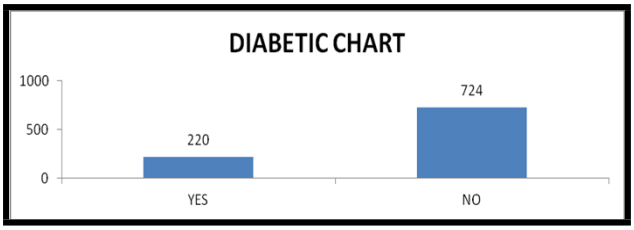

Fig. 20: Maintenance of diabetic chart

Care giver:

Care giver represents the one who take care of the physician appointments, drug administration etc.

520 patients responded that they managed these aspects by themselves. 424 patients responded that others (includes parents, siblings, wife/husband, son/daughter, home nurse etc.) were responsible for taking care of these aspects.

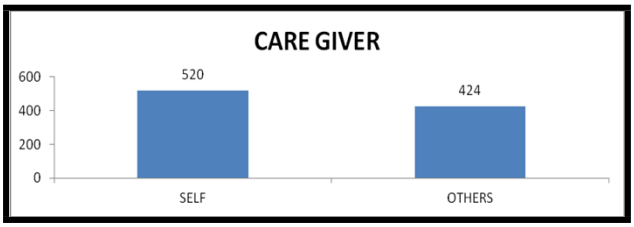

Fig. 21: Care giver

Medication skipping behaviour:

On this question 412 patients said that they regularly take their, medications and never skip the drugs. 446 patients responded that they skip the drug more than 5 days and 86 patients reported that they have completely stopped taking the drugs.

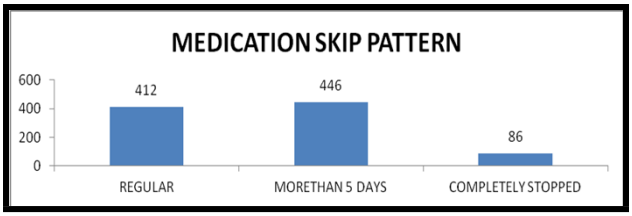

Fig. 22: Medication skip pattern

Reason for non- adhernce:

Out of 532 patients who were non-adherent towards the therapy, the reason was non-adherence was asked and 208 of them responded that they are non-adherent because they forget to take the drugs followed by 192 patients who responded that they are non-adherent because of their busy life.

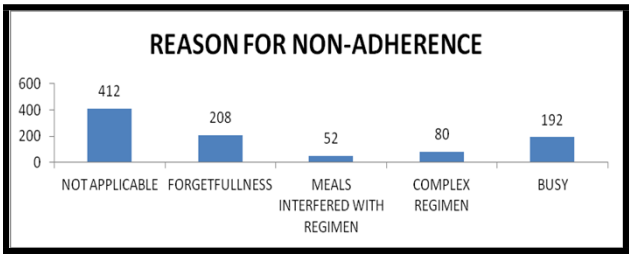

Fig. 23: Reason for non-adherence

Other systems of medicine:

The patients were enquired regarding the habit of using other system of medicine to manage diabetes mellitus. It included Ayurveda, Homeopathy, Unani, Siddha etc. 804 patients reported not to use them while 140 patients reported to have using other system of medicines along with allopathy.

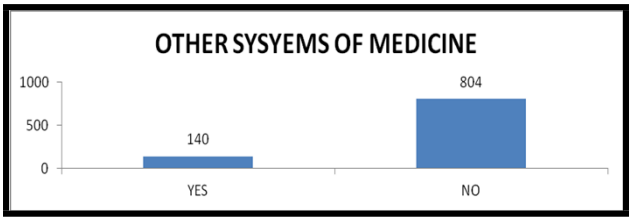

Fig. 24: Patients using other systems of medicine

Data was analyzed in SPSS Statistical software version 22 comparing the means of various parameters with treatment adherence which showed p value>0.05 indicating non adherence to the treatment.

DISCUSSION

Poor medication adherence seems to be a significant barrier to attainment of positive clinical outcome among type 2 diabetes patients [14].

This study found that 43.64% of patients with diabetes had good adherence with their therapy. Similar results were seen in study performed in France (39%) [15]. But a higher adherence of 65% was found in Yelena et al 2008[16], 57.7% in Shuvankar Mukherjee et al 2013 [17], and 84% in Mohammed Arifulla et al [18].

Majority of the patients were males, which comprised 77.96% and female were only 20.03%. It was found that males were more adherent to their drug therapy. Among the males, 46.19% had good adherence while only 34.61% were adherent among the females. In contrast, Grant RW et al [19] documented non-adherence to be more common among male patients, whereas Muhammed et al [18], reported similar adherence rate in both genders.

72.45% were from the age group of more than 50 years. In them only 50% of the patients were found to be adherent to the prescribed treatment regimen. This is particularly low since diabetes is a chronic disease which demands strict adherence to avoid future complications.

49.15% of the study population was from poor economic backgrounds, among which 55.17% were non adherent to the treatment. On the other hand, 57.5% of the patients with sound economic status were non-adherent to the therapy.

Of the total study population, 59.11% obtained primary school education. 33.26% patients reported to have received an education of high school and above. 7.62% patients participated in our study were illiterate. The adherence was found to be low among the illiterate and it increased among those with higher education. This was consistent with other studies like Suliasnaia et al 2014 [20].

On assessing the civil status of the patients, it was found that 85.16% were married, while 9.32% were widow/divorced and 5.5% of them were single.

The status of patients with any concomitant illness associated with diabetes mellitus was studied. This revealed that 86.44% suffered with some concomitant illness. Only 13.55% were free from other diseases. On assessing the association of adherence with concomitant illness, only 40.19% with concomitant illness were adhere to their diabetic medications. On the other hand, the proportion of adherent patients was quite high among those without any other illness (65.62%). The most common concomitant illness found in association with diabetes mellitus was hypertension. This is similar to the study performed by Nasir et al 2011 [21].

Majority of the patients were diagnosed to be diabetic in the past 1 to 10 years. It included 51.27% of the total study population. 18.64% among them were newly diagnosed; within the last 12 months period. On assessing the relation between years of diagnosis and medication adherence, it was found that the proportion of adherence increased with increase in years of diagnosis. Adherence was found to be quite similar among those diagnosed in last 11-20 years and 21-30 years (56.89% and 53.84% respectively). This is quite high as compared to the adherence of the ones diagnosed below 10 years (22.31%). This may be explained with the long experience of therapy, which would result in improved drug knowledge, and knowledge regarding importance of adherence. This is in contrary with the study of Gimenes et al [22] and Mohammed et al [18], where adherence was higher among those diagnosed below 10 years.

On assessing the treatment regimen of the study patients, we noted that 27.54% patients were treated with single insulin. It was followed by 22.88% patients being treated with a single oral hypoglycemic drug. 18.64% patients were treated with a combination of insulin and single OHA. 3.81% were prescribed with 1 insulin plus 3 OHA. 3.81% other patients were only given diet modifications and were not prescribed with any drug. There was a significant but inverse correlation between the total number of oral antidiabetic drugs taken daily and medication adherence. This is similar to the study performed by Dailey et al [23] and Suliasnaia et al [20].

The knowledge of patients regarding hypoglycemic prescribed to them were assessed during our study. It was noted that only 35.59% had strong knowledge regarding their drugs. 64.4% lacked complete knowledge regarding their drugs. On comparing the relationship between drug knowledge and adherence, it was found that drug adherence was strong among those with good drug knowledge. 63.09% among those with good drug knowledge were well adhere to their drugs, whereas only 49.01% were adherent among those with poor drug knowledge.

It was found that the prevalence of diabetic foot ulcer was quite high among those with diabetes mellitus. About 36.01% among the study population had the complaints of diabetic foot. This is quite high and it was found that the patient's had poor knowledge regarding diabetes complications and management.

60.59% of the study population responded that they were strictly adhering to the diabetic diet advised by the physician. In Taruna Sharma 2014 [14] only 23.3% of study population was found to be maintaining a diabetic diet.

Of 516 patients who are on insulin 388 patients (75%) reported to be adherent to their insulin therapy and 67.44% of the patients reported to have the habit of altering the site of injection.

Majority of the patients (37.71%) had the practice of monitoring the blood glucose once in 3 to 6 months, followed by 30.93% who monitored the blood glucose regularly once in a month. 2.11% never monitored their blood glucose level in the last one year. This signifies periodic monitoring of blood glucose is quite low among the patients. The patients should be made aware of the importance of periodic blood glucose monitoring, which could be done either by the physician or a clinical pharmacist.

760 patients responded that exercise is not a part of their daily routine. This signifies that more than 85% of those affected with diabetes lead a sedentary life style. It is important to educate the patients regarding the importance of exercise. This is higher

than the results of Taruna Sharma et al 2014 [14] (31.7%), and Shuvankar Mukherjee et al 2013 [17] (27%).

Only 15.41% responded to have experienced episodes of hypoglycemia. But, none of them had reported the incidence to the consulting physician. These patients were educated regarding the importance of reporting such incidence; certain cases would require alteration in the treatment regimen.

Maintenance of diabetic chat is important since it gives an idea regarding success/failure of the therapy, treatment adherence etc. Only 23.3% patients had the habit of maintaining a proper diabetic chart. It is important for all diabetic patients and we recommend the health care team to help the patient maintain a chart and track the changes during every visit.

The practice and knowledge of basic diabetes self-management practices was quite low among the study patients. But, it was significantly higher among those who never missed their medication and those who reported good adherence to their prescribed anti diabetic medications. These findings stress out the important role played by practice of diabetes self-management behaviors and patient awareness in improving medication adherence, ensuring adequate glycemic control, and minimizing the incidence of diabetic complication [21, 24, 25].

The study patients were enquired regarding the reason for non-adherence. 39.09% responded that they "forget" to take their drug. 36.09% responded their busy life was the reason behind non-adherence. 15.03% had the problem with complex drug regimen so as to be non-adherent to the therapy. Shuvankar Mukherjee et al [17] also reported the most common reason for non-adherence being forgetfulness. Pascal et al [26], (2012) from eastern Nigeria reported the most common reason being financial constraints. The other reasons included forgetfulness and a feeling of being well [17].

In our study, 14.83% patients responded to have using other system of medicines (Ayurveda, homeopathy, etc.) for the treatment of diabetes mellitus. No significant association was found with patients taking alternative medicines and non-adherence although patients not taking alternative medicines seemed to be at a lower risk of non-adherence. These findings were similar to study done by Blanca et al, 2001 [27]. However, such patients should be made aware of the adverse effects and interactions while using other system of medicines along with their current regimen.

Limitations of the study:

The present study was not without limitations. Firstly, HbA1c is a more reliable parameter to assess glycemic control over a period of 3 months but this was not used in every patient in the study population. Secondly, there was no way of determining the sincerity of the respondents even with the use of structured questionnaire and/or patients' interview. Nevertheless, this study has left scope for a future research in these areas.

CONCLUSION

Type 2 diabetes mellitus being a chronic disorder requires multiple therapeutic approaches including dietary and lifestyle modifications. Overall, the study indicated low adherence among people treated with anti-diabetic medications. This can be improved through education, counseling and reinforcement of self-care. The factors like increasing age, male sex, literacy, concomitant illness were significantly associated with the non-compliance. Lack of knowledge about the disease and the drugs was found to be the major reason behind non adherence. Patients' with single drug therapy were seen to be more adherent than patients with multiple drug regimens. Forgetfulness was the most common reason for non-adherence, which can be overcome by pillboxes, alarms and assistance by family members. The prescriber before prescribing and pharmacist before dispensing drugs for diabetic patients, he/she should negotiate about the treatment plan that the patient understands and to which he or she commits.

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