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Compliance with the treatment of diabetes mellitus and the factors associated

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Abstract---Background: The prevalence of diabetes mellitus is growing rapidly worldwide and is reaching epidemic proportions. Epidemiological data indicate that all nations, rich and poor, are suffering from the impact of the diabetes epidemic. Effective care of diabetes with pharmacological and non-pharmacological methods is required, but it is impossible to control diabetes and its complications, as well as mortality, without strong compliance or adherence to therapy. Aims & Objectives to study the compliance rate of the patients with type 1 & 2 diabetes to the prescribed medications and to find out its association with different socio-demographic factors and other patient characteristics affecting compliance. Methodology: A cross sectional observational study was done using a pre-designed, semi-structured, and pre-tested questionnaire. Patients' clinical and socio-demographic data, were obtained. The Morisky medication adherence scale (MMAS-8) was used to assess adherence to prescribed medications. Results: Overall compliance was very low (6%) and it was associated with education, Rural or urban dwellings, female gender and lower socio economic class. High compliance was associated with better glycaemic control. Conclusion: The study reveals a low overall rate of medication and physical activity compliance, which helps to explain the high prevalence of Diabetes and the rising morbidity associated with it. Medication compliance was found to be linked to gender, education level, socioeconomic status, family type, disease duration, and medication route and amount.

Keywords---diabetes, comppliance, adherence, medications.

Introduction

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. It is spreading rapidly over the world and has reached epidemic proportions. According to epidemiological data, the diabetes epidemic is affecting all nations, rich and poor alike. The impact is exacerbated in socially and economically deprived countries. Diabetes is described by the American Diabetes Association (ADA) as a collection of illnesses characterized by hyperglycemia caused by abnormalities in insulin secretion, insulin action, or both.(1) This definition has been accepted by other international bodies like World Health Organization (WHO). But a more comprehensive & relevant definition of diabetes is as follows: The term diabetes mellitus describes a metabolic cum vascular syndrome of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat & protein metabolism resulting from defects in insulin secretion, insulin action, or both leading to changes in small blood vessels (microangiopathy) and large blood vessels (macroangiopathy).(2)

Nearly 1/5th of all adults with diabetes in the world live in the south east Asia region. Mauritius having the highest prevalence among adults (14.8%) in the region followed by India (9.1%). People with diabetes in India, Bangladesh and Sri Lanka make up 98.8% of the region's total Diabetes Population. Current figures say that 72.1 million people have diabetes, among those 65.1 million are from India and it has been projected that around 109 million Indians will be affected from Diabetes in 2035.(3) Effective care of diabetes with pharmacological and non-pharmacological methods is required, but level of adherence or compliance to the therapy is a critical element in diabetic control. It is impossible to control diabetes and its complications, as well as mortality, without strong compliance or adherence to therapy. As a result, this study was conducted to identify compliance with medication and other treatment options, as well as socio-demographic factors associated with non-compliance to anti-diabetic therapy, which will aid physicians and health care providers in making decisions to reduce the same, as well as help type 2 diabetes mellitus patients achieve their glycemic targets. Understanding the patient's response to the treatment supplied will surely benefit physicians/healthcare professionals, and may aid in the future strict and successful management of this chronic illness.

Objectives

The objectives of the present study are:

- To study the compliance rate of the patients with type 1 & 2 diabetes to the prescribed medications.
- To find out its association with different socio-demographic factors and other patient characteristics affecting compliance

Materials and Methods

This study titled "Factors affecting compliance with the treatment of diabetes mellitus among young adults attending a tertiary care hospital in Bhubaneswar city" was carried out in the Department of community Medicine, Kalinga Institute

of Medical Sciences, - Kalinga Institute of Industrial Technology(KIIT), University, Bhubaneswar, Odisha. The field of this study was a tertiary care hospital , Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital (PBMH), Bhubaneswar, Odisha. This hospital is a super-speciality centre and is having specialized consultative care by specialists in each subject including endocrinology. The patient load is very good in the department of endocrinology may be because of the location of the institute and the specialized care as well. The geographical location of the institute, Northern part of the city, was an additional advantage because it serves urban, nearby rural and slum population also or we can say a more representative sample of the city. A hospital based cross sectional study was carried out to find out the compliance rate of the patients with type 1 & 2 diabetes to the prescribed medications, and the treatment ,find out its correlation with different socio-demographic factors and other patient characteristics affecting compliance.

Study Population

The Study population was all the patients with diagnosed Diabetes Mellitus (1 & 2) in the age group of 21-45 years of age, attending the tertiary care hospital.

Sample Size

The minimum sample size required for a cross sectional study is calculated by the following statistical formula.(4)

$$n = \frac{Z^2_{1-\alpha/2}Pq}{d^2}$$

Where n = minimum required sample size, Z = Reliability coefficient at required confidence interval (1- α), α = Type 1 error taken as 0.05 (5%), the level of confidence = (1- α) =0.95 (95%). Value of Z obtained from a normal curve table = 1.96,P = It is the proportion of the population having the event of interest i.e. taking compliance rate to the anti-diabetic drugs as 57% , in a study by *Shuvankar Mukherjee et al*, (5). q = 100-P, it is the proportion of population without the event of interest i.e. q = 100 – P, = (100 – 57%) = 43, d = Absolute allowable error,taken as 0.05 (5%) as per usual convention. Putting all these values in the above equation we got the sample size n as 376.63 . Rounding it off to the nearest integer we get it as 377.adding 10 % non-respondents i.e. 38, the final size came out to be 377+38 = 415.

Inclusion Criteria

All Patients with type 1 & 2 diabetes of at least 3 months duration following the initial diagnosis, aged 20 - 45 years, non-pregnant , non-lactating or non-puerperal at the time of the interview (for female patients), and those who had a recent (last 3 Months) laboratory report on the glycosylated hemoglobin (HbA1C) levels. Also those who were not seriously ill, those who gave informed consents to participate in the study and who were not previously interviewed by the researchers on a previous occasion during the study period were included in the study.

Informed Consent

The written and informed consent was taken from all the study subjects enrolled after explaining them in detail the nature and purpose of this study. They were taken into confidence about the anonymity of the results. Participation was purely voluntary and participants had the choice of not answering any question in which they were not comfortable. Ethical Clearance was obtained from the the Institutional Ethics Committee (IEC) of the institute.

Study Tool

A pre designed, semi structured and pretested Interview schedule was prepared after thorough literature review. It was then pre tested in the similar setup of Out patient department (OPD) and the necessary modifications were done. The information was collected on the socio-demographic data of patients such as their age, sex, religion, type of family etc. Education status , Occupation and income were taken to assess the socioeconomic class of the subjects. Relevant Medical and Surgical history and findings were recorded to identify the co morbidities along with drug history. A validated scoring system i.e. Morisky medication adherence scale (MMAS-8) was used to assess the adherence to the prescribed medications. Accordingly, individuals were classified as low-adherence if the mean score was 3-8, medium adherence if the mean score was 1-2, and high adherence if the mean score was 0. (6)(7). A portable stadiometer, weighing machine, and sphygmomanometer were used for measurements.

Methodology

All the patients attending the endocrine OPD having a pre diagnosed diabetes of at least 3 months duration were considered for the study purpose as per the inclusion and exclusion criteria. The data was collected during OPD hours, The process of registering the study subjects and interview was continued till the desired sample was obtained. The interview was done using a pre design, semi structured and pre tested schedule. The information was recorded regarding socio-demographic variables of the participants such as age education income and occupation. Family history, medical and surgical history as well as the available latest lab parameters were also recorded followed by the Morisky medication adherence scale (MMAS-8). After the interview general examination of the patient was done along with blood pressure management. Anthropometric measurements were also taken. Body mass index and waist to hip ratio were also calculated. The latest available lab values including fasting and post prandial Blood sugar, HBA1C as well as Renal function tests and Thyroid profile (if available) were copied from their available lab reports. The complications (if any) and comorbidities were also recorded along with the lab or radiological evidence. Dietary habits along with the last 24 hours meal history was also recorded.

Analysis

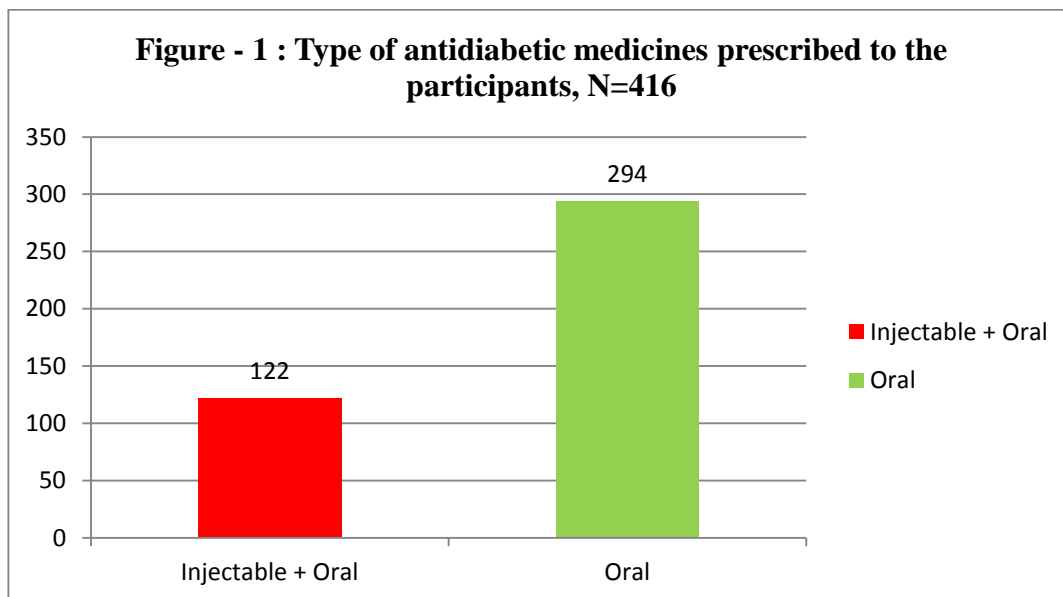
Analysis was done by SPSS (Statistical Package for the Social Sciences) version 20.0 software, provided by PHFI (Public Health Foundation of India). Mean, Proportions and appropriate statistical tests were used for drawing inference as

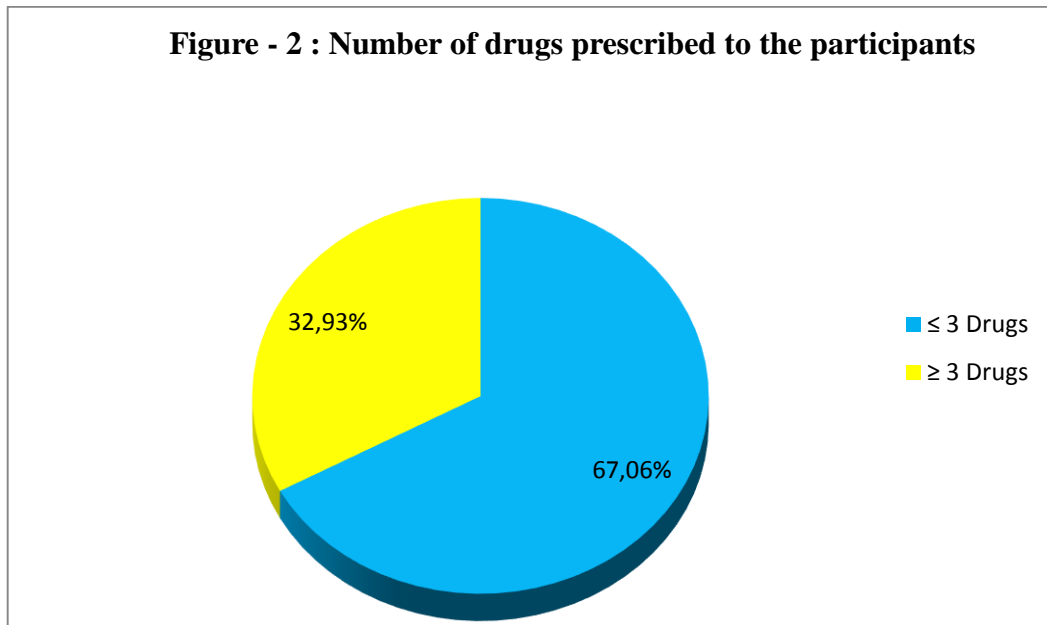
required. Tests of significance such as Chi-square test and Fisher exact tests were used as applicable. Any value found to be significant or highly significant was analyzed for probable factors affecting the same.

Sources of funding: none

Results

The mean age of participants was found to be 39.42 ± 5.21 years (Mean \pm SD). Out of the 416 participants 207 (49.75%) were male and 209 (50.24%) were female. Most (88.20%) of the participants were Hindus while 9.61% were Muslims and very few (1.92%) belonged to other religion. It was observed that most (57.5%) of the participants were having nuclear family while 42.50 % were having Joint family. The higher percentage of nuclear family reflects the urban Culture where most of the families are nuclear. Most (73.07%) of the participants in our study were from urban areas while around 26.92% were from the rural areas. It was found that majority (71.88%) of the participants were literates while 28.13 % were illiterates. The modified kuppuswamy scale was used as it is applicable to the urban population. It was found that 66.1% of the study participants were from the upper middle class while upper and lower middle class had almost the same percentage of participants (13.7% & 13.5%) respectively. Very few (6.7 %) participants were from the upper lower class.





The above figure (1) shows the type of anti-diabetic medicines prescribed to the study subjects. Most i.e. 294 (70.67%) of them were prescribed Oral drugs only while 122 (29.32%) of them were given oral plus injectable medications. The average no. of drugs prescribed (figure 2) to the most participants was ≤ 3 (67.06%), while around 32.93% were prescribed ≥ 3 drugs. The reason for prescribing maximum patients with less no of drugs might be the less duration of diabetes as all the participants were young (≤ 45 years) in our study. Also now a days combined formulations are available for two, three drugs which was also one of the reasons for less no of drugs being prescribed to the patients.

Table 1
Morisky medication adherence scale (MMAS – 8) scores obtained by the study participants, N=416

Scores	Frequency	Percent
0	8	1.9%
1	57	13.7%
2	80	19.2%
3	97	23.3%
4	69	16.6%
5	32	7.7%
6	36	8.7%
7	25	6.0%
8	12	2.9%
Total	416	100%

The 8 item Morisky medication adherence scale was used for accessing the compliance among the participants. The above table (Table – 1) shows the frequency of different scores obtained by the study participants. It

was observed that most common score was, scored by 97 participants followed by 2 (scored by 80 participants). Maximum participants, 97 (23.3%) got a score of 3, followed by 71 (17.06%) of the participants who got a score of 2 and 69 (16.58%) having a score of 4. Only 25 participants scored 0 (6.00%) which indicates full compliance and around 12 (2.88 %) scored 8 which indicates zero compliance. Overall an ordinal parameter of high, medium & low compliance was defined on the basis of scores of MMAS-8 scale which is as follows :- High : 0, Medium : 1-2 & Low : 3-8. It was found that most (65.06 %) of the study participants were poorly adherent to the medications and only 6.02% of the participants were highly adherent while around 28.91% were having medium adherence.

Table 2
Association of Adherence with various Socio-demographic factors

Characteristics		Compliance				p-Value
		High	Medium	Low	Total	
Age	<35 years	02(3.70 %)	10(18.51%)	42(77.77%)	54(100%)	P=0.11
	>35 years	23(6.35 %)	110(30.38 %)	229(63.25 %)	362(100 %)	
Gender	Male	15(7.28 %)	70(33.98%)	121(58.73 %)	206(100 %)	P=0.02
	Female	10(4.76 %)	50(23.80%)	150(71.4%)	210(100 %)	
Religion	Hindu	25(6.79 %)	108(29.34 %)	235(63.85 %)	368(100 %)	P=0.113
	Others	0(0.00%)	12(25.00%)	36(75.00%)	40(100%)	
Marital Status	Married	19(6.29 %)	86(28.47%)	197(65.23 %)	302(100 %)	P=0.9
	Unmarried	6(5.26%)	34(29.82%)	74(64.91%)	114(100 %)	
Family Type	Nuclear	9(3.76%)	52(21.75%)	178(74.47 %)	239(100 %)	P<0.0001
	Joint	16(9.03 %)	68(38.41%)	93(52.54%)	177(100 %)	
SE Class	Upper	23(6.92 %)	98(42.24%)	211(63.55 %)	332(100 %)	P=0.20
	Lower	2(2.38%)	22(26.19%)	60(71.42%)	84(100%)	
Literacy	Illiterate	2(1.70%)	18(15.38%)	97(82.90%)	117(100 %)	P<0.0001
	Literate	23(7.69 %)	102(34.11 %)	174(58.19 %)	299(100 %)	
Residence	Rural	7(6.25%)	26(23.21%)	79(70.53%)	112 (100%)	P=0.30
	Urban	18(5.92 %)	94(30.92%)	192(63.15 %)	304(100 %)	

Table 3
Association of adherence to glycemc control

Adherence	HbA1C		
	>6.5	<6.5	
High	24(96.00%)	1(4.00%)	<i>p=0.04</i>
Medium	113(94.16%)	7(5.83%)	
Low	235(86.71%)	36(13.28%)	
Total	372(89.42%)	44(10.57%)	

Discussion

It was found that most (65.06 %) of the study participants were poorly adherent to the medications and only 6.02% of the participants were highly adherent while around 28.91% were having medium adherence. In a study done by *Parveen Singh et al* in Kangra, Himachal Pradesh it was found that 50 % of the participants were having good drug compliance while 23.5% & 26.4% were having fair and poor drug compliance respectively.(8). The difference in the findings of the studies might be due to different age group taken as population (the later study took geriatric people).In a study done by *Suhana Banu et al* in Mangalore the over all adherence level was found to be 71.3% and non adherence was 28.7%.(9), While *Sontakke, et al* in their study found that 74 % of the participants were having low adherence while 26 % of them were having medium adherence and none (0.00%) were having high adherence.(10)

The analysis showed that there was not much difference in the compliance age wise (Compliance increased with age) which is contrary to a study done in Thiruvananthapuram which shows that compliance was higher 49.4 % in the age group of 30-40 as compared to 45.3 % in the age group of 40-50 years age group.(11). Considering the gender, it can be observed that low adherence was higher (71.4%) in the females as compared to 58.73% in the male participants. Similar findings were there in a study done in Thiruvananthapuram where the females had more 88% poor adherence as compared to the 68.5 % among males,(11) while In a study done by *Shuvankar Mukherjee et al* in Kolkata it was found that females were more compliant (66.5%) as compared to 53.2% among males.(5)

In a study done by *Manjusha sajith et al* in Pune ,high compliance was found to be more in males (43.33%) as compared to females (37.78%), which was similar to our study.(12) The association of religion with adherence to medications was not found to be significant statistically. Adherence was higher, 35.08% (5.26% + 29.82%) among unmarried participants as compared to those who were married i.e 34.76% (6.29% + 28.47%) , although the association was not significant statistically. Similar findings, were there in a study done in Kolkata by *Shuvankar Mukherjee et al*. i.e. Compliance was more (64.7%) among unmarried as compared to married (55.7%) participants. (5) It was found that the adherence level was more (9.03%) among the participants who were having joint family as compared to the participants from nuclear families (3.76%). The association was found to be highly significant. It shows that low adherence was more among classes III & IV, and high adherence was higher (5.26%) in Upper class and upper middle class II

(7.27%). Hence it can be said that over all adherence was higher in upper classes as compared to lower classes. The association was found to be statistically highly significant ($p < 0.001$). Affordability might be the reason behind adherence being higher in the upper classes.

In a study done by *Nadia M. Taha et al* in Cairo, Compliance was found to be higher among the participants having lower income (35.3%) as compared to those who were having higher income (58.6%).(13) While a study done by *Abebe et al* in Ethiopia found that adherence was higher (58.9%) among the rich as compared to the poor (55.8%) which is similar to our study.(14). The table-3 shows the association of adherence level with glycemic control in the study participants. It was observed that among the highly adherent participants most (96%) were having poorer glycemic control when compared to 86.71% of those who were having lower adherence level. The association was found to be statistically significant. In contrast to our study *Manjusha sajith et al* in their study found that the participants with high adherence were having better glycemic control (53.49%) as compared to those who were less adherent (13.04%) to medications.(12)

Conclusion

The study discovers an overall low compliance rate with medications and physical activity, which explains the high prevalence of Diabetes and the rising morbidity associated with the disease. Gender, education level, socioeconomic status, family type, disease duration, and route & amount of medicines were all found to be associated with medication compliance. Because compliance was low among the lower socioeconomic classes, it was inferred that the cause was the high cost of the medicines, necessitating actions such as a hospital supply of free medicines and the establishment of fair price shops in government-run hospitals to make drugs affordable to all. Patients in rural areas are also under-educated about diabetes and its crippling long-term effects, which, according to other studies, increases morbidity and death. The overall medication adherence rate among them was poor. As a result, the medical community requires health practitioners to educate patients about their illness conditions and drug compliance. Because illiteracy has been identified as a significant obstacle to compliance, education, knowledge, and counselling about the importance of adhering to prescribed medications is critical for reducing disease-related morbidity and mortality.

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