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Impact of Patient Counseling on Medication Adherence in Type II Diabetes Mellitus Patients in a Tertiary Care Hospital, Kerala

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Abstract:-

- ***Background:***

Medication adherence is an important factor in type II diabetic patients to prevent further progression of the disease. Severity of disease and poor adherence to diabetic medication can be minimized by effective patient counseling.

- ***Objective:***

To evaluate the impact of patient counseling on medication adherence in type II diabetes mellitus patients using medication adherence questionnaire.

- ***Method:***

It is a prospective observational study carried out over a six month period in a military based hospital at Thiruvananthapuram, Kerala. A total of ninety six samples were used in the study and assessed the number of patients benefited from patient counseling using paired t test.

- ***Result and Discussion:***

Counseling was provided to the patients initially; and after review, assessed the change in their attitude and knowledge regarding their medications. Dietary and medication related information was provided during counseling. Statistical analysis of adherence, before and after counseling in total samples showed that, there is a statistical difference ($p \leq 0.05$).

- ***Conclusion:***

Majority of the study population attained positive impact regarding the adherence to diabetic medications by counseling. But statistically, demographics and other comorbidities does not have any impact on adherence.

Keywords:- *Adherence, Diabetes Mellitus, Prospective.*

I. INTRODUCTION

Diabetes mellitus is a disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentration of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves [1,2].

Type II diabetes mellitus is a chronic condition which is otherwise known as non-insulin dependent diabetes mellitus that impair the metabolism of glucose. It has an incidence rate of 90-95% [3]. Type II diabetes mellitus has a hereditary origin. It occurs due to either the impairment of β – cells of pancreas to produce sufficient insulin in order to satisfy the demand of the body or due to development of insulin resistance by insulin receptors in the cells or both. Proper exercise, weight reduction and dietary control help in the management of type II diabetes in addition to antidiabetic drugs.

The World Health Organization defines adherence as "the extent to which a person's behavior – taking medications, following a diet and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider". Non adherence to medication is a common controversy in the management of diabetes due to its long term treatment [4,5]. Patient can be made more adhered to diabetic drugs through effective patient counselling. Compliance of patient to medications can be sustained by social and family support, monitoring the number of tablets consumed, lesser frequency of administration and availing healthy communication with physician and pharmacist [6].

Patient counseling is a broad term which describes the process through which health care professionals attempt to increase patient knowledge of health care issues. Patient counseling may be verbal or written performed on an individual basis or in groups, & provide directly to the patient or caregiver[7]. Patient should understand and recognize the importance of each medication given for diabetes. Patient counseling helps to improve medication adherence, self management of adverse effects, improve the quality of life

and provide professional rapport between the patient and pharmacist. Counseling should be given in a private area where confidentiality can be maintained, clear and understandable language must be used and opportunity must be provided for the patients to ask doubts without hesitation.

Maintaining the normal glycemic control can decrease the risk of death and other complications by the good adherence to prescribed therapy and self management by the diabetic patients[8-10]. Pharmacist ensures the patients adherence via regular monitoring, evaluation and health education [11,12]. The study was conducted with an aim to assess the impact of patient counseling on medication adherence in order to control and bring down further diabetic complications.

II. RESEARCH METHODOLOGY

A. Study Site:

The study was conducted in a 300 bedded tertiary care hospital in Thiruvananthapuram, Kerala.

B. Study Design:

It was an observational prospective study conducted over a six months period with the patient's consent and also with the approval of the hospital research and ethics committee. This involved the review of case notes of ninety six randomly selected patients that satisfied the inclusion criteria and with high probability of being available for follow up during the prospective study. Prospective study was done by counseling and educating the selected patients on medication adherence, exercise pattern and dietary modification.

C. Study Procedure

The study was conducted after obtaining the approval from Institutional Ethics Committee (IEC). Standard and relevant indexed articles were collected and conducted the literature review. Medication adherence was assessed using a questionnaire consisting of seven questions (Fig:1) and sample size determination (26,27) along with other statistical evaluations done using the Statistical Package for the Social Sciences (SPSS) software version 21.

The sample size 'n' was calculated using the formula;

$$n= (Z\alpha+\beta)^2 \times (SD)^2 / d^2$$

n= sample size
$Z\alpha$= 1.96
β= 0.84
S.D= 2.1
d= 0.6

Obtained sample size was **≥ 96**

Here, in the study, we assess the medication adherence of patients by using self prepared and self validated relevant questionnaire.

ADHERENCE QUESTIONNAIRE

Cause of nonadherence	Never (0)	Very rare(1)	Sometimes (2)	Often (3)
1. How often do you have difficulty in remembering to take your medications?				
2. How often do you miss taking pills when you feel better?				
3. How often do you decide not to take your medicines?				
4. How often do you run out of your medicines?				
5. How often do you miss the scheduled appointments with doctor?				
6. How often do you put off refilling your medicines due to their high cost?				
7. How often do you miss taking pills when you feel any side effects?				

Fig 1:- Medication Adherence Questionnaire used in Diabetic Patients

After obtaining permission from IEC, study began with data collection. About 200 patients had visited the outpatient diabetology department during the study period from November 2018 to April 2019. The patients were scrutinized based on the inclusion criteria. They were informed about the study and each of them signed an informed consent before enrolling in the study. Patient details were transcribed on a data entry form which comprises of demographic details (age, sex, BMI, literacy, social history, family history, payment pattern, exercise pattern), past medical history (comorbidities), medication history, lab parameters, diabetic history. They were given counseling regarding diabetic diet, foot care, diabetic medications and its administration procedure and the counseling prolonged for 5-10 minutes.

Consequences of non-adherence, importance of clinical visit and methods to incorporate the drug adherence with daily activities were the points given to improve medication adherence. Dietary counseling was provided using a diabetic plate and the administration techniques of insulin was demonstrated to the study populations. Medication adherence questionnaire was modified in such a way that it is intelligible to patients. During the initial visit, the study group was provided with the adherence questionnaire and then was counseled too. The same questionnaires were reintroduced during their next visit after 3 month to assess their improvement. Scoring of questionnaires was done after data collection.

Data collected were analyzed using Statistical Package for Social Science, version 21 (SPSS). Mean and standard deviation for continuous data or as percentage for frequency were obtained from descriptive statistics. The impact of patient counseling on medication adherence was assessed before and after counseling and was compared using paired t-test. Analysis Of Variance (ANOVA) was done to compare the means of qualitative and quantitative variables like demographic details, diabetic details versus medication adherence.

D. Hypothesis

- H_0 : Patient counseling is ineffective in improving medication adherence and QOL in diabetic patients.
- H_1: Patient counseling is effective in improving medication adherence and QOL in diabetic patients.

➢ *Inclusion Criteria:*
- 30 years and above with type II diabetes mellitus
- Both gender
- Should be on anti-diabetic drugs
- Data were collected only from outpatients.
- Presence of co-morbid conditions (Hypertension, CHF, and dyslipidemia) or not.

➢ *Exclusion Criteria:*
- Patients with Type 1 Diabetes.
- Patients visiting the health facility for the first time.
- Patients who could not communicate well with interviewer.

III. RESULT

A prospective observational study was conducted to determine the impact of patient counseling on medication adherence and QOL in diabetic patients. In this study 98 patients were enrolled based on inclusion criteria. These were the results obtained from study:

❖ *Demographic details of study population*

A. Based on age group

AGE GROUP (YEARS)	FREQUENCY	PERCENTAGE (%)
<40	1	1
40-49	4	4.1
50-59	13	13.3
60-69	47	48
70-79	27	27.6
>80	6	6.1
TOTAL	98	100

Table 1:- Categorization of study population according to age group

Patients who were included in the study were in the age range of 25-90. 18(18.4%) of study population came under the age group of 25-59. 74(75.5) of patients were between 60-79 years of age. 6 (6.1%) of the patients belonged to the age group 80-95.

B. Based on gender

GENDER	FREQUENCY	PERCENTAGE (%)
Male	43	43.9
Female	55	56.1
Total	98	100

Table 2:- Categorization of study population according to gender (N=98)

Among 98 patients who were analyzed during the study, 43(43.9%) were male and 55(56.1%) were female.

C. Based on BMI

BMI (kg/m^2)	FREQUENCY	PERCENTAGE (%)
<25	49	50.0
25-29.9	35	35.7
>=30	14	14.3
Total	98	100.0

Table 3:- Categorization of study population according to BMI

The study comprise of 49(50.0%) subjects with BMI <25; 35(35.7%) subjects were having BMI range of 25-29.9. 14(14.3%) were having BMI ≥ 30.

D. Based on Family History

FAMILY HISTORY	FREQUENCY	PERCENTAGE (%)
Present	38	38.8
Absent	60	61.2
Total	98	100.0

Table 4:- Categorization of study population according to family history

In the study 38(38.8%) subjects had a family history of diabetes while 60(61.2%) lacks family history of diabetes.

E. Based on Social History

SOCIAL HISTORY	FREQUENCY	PERCENTAGE (%)
Absent	87	88.8
Present	11	11.2
Total	98	100

Table 5:- Categorization of study population according to social history

Among the patients involved in the study, 87(88.8%) were not having any social history while 11(11.2%) were having social history.

F. Based on duration of diabetes history

AGE GROUP (YEARS)		DM DURATION (YEARS)				TOTAL
		<5	5-9	10-19	≥20	
<40	Frequency	0	1	0	0	1
	Percentage (%)	0	100	0	00	100
40-49	Frequency	2	0	2	0	4
	Percentage (%)	50	0	50	0	100
50-59	Frequency	4	4	5	0	13
	Percentage (%)	30.8	30.8	38.5	0	100
60-69	Frequency	7	12	23	5	47
	Percentage (%)	14.9	25.5	48.9	10.6	100
70-79	Frequency	1	7	10	9	27
	Percentage (%)	3.7	25.9	37.0	33.3	100
80-89	Frequency	0	1	3	2	6
	Percentage (%)	0	16.7	50	33.3	100
Total	Frequency	14	25	43	16	98
	Percentage (%)	14.3	25.5	43.9	16.3	100

Table 6:- Categorization of study population according to the duration of diabetic history

Most of the study population had 10-19 years of diabetic duration(43.9%). 25(25.5%) had 5-9 years of diabetes, 20 patients had 16(16.3%) years and finally only 14 patients had diabetes for less than 5 years.

G. Based on exercise

EXERCISE PATTERN	FREQUENCY	PERCENTAGE (%)
Regular exercise	40	40.8
No exercise	58	59.2
Total	98	100

Table 7:- Categorization of study population according to exercise

Majority of the study subjects (59.2%) exercised regularly (walking, jogging etc.).

H. Based on literacy

LITERACY	FREQUENCY	PERCENTAGE (%)
Literate	85	86.7
Illiterate	13	13.3
Total	98	100

Table 8:- Categorization of study population according to literacy rate (N=98)

The study comprises of 85(86.7%) subjects who were literate and 13(13.3%) who were illiterate

I. Based on co-morbidities

CO-MORBIDITIES	FREQUENCY	PERCENTAGE (%)
Present	77	78.6
Absent	21	21.4
Total	98	100

Table 9:- Categorization of study population according to co-morbidities

In our study, 77(78.6%) out of 96 patients had comorbidities.

❖ *Lab investigations*

LAB VALUES	MEAN (STANDARD DEVIATION)		t SCORE	p VALUE
	Pre intervention	Post intervention		
FBS (mg/dL)	151.49(43.38)	145.17(37.00)	1.85	0.067
PPBS (mg/dL)	228.72 (66.81)	212.53 (66.23)	2.74	0.007**
HbA1c (%)	8.41 (1.81)	7.84 (1.5)	2.74	0.009**

Table 10:- Statistical analysis of lab values before and after counseling
**Statistically significant at P<0.05

There is a statistical difference observed in PPBS and HbA1c levels. Whereas no statistical difference was observed in the FBS values, even though a clinical difference in its value exists.

❖ *Relation of social demographics & clinical variables with adherence*

There was no statistical significance in social demographics & clinical variables with adherence.

A. Relation between adherence and gender

GENDER	MEAN (SD)	t SCORE	p VALUE
Male	5.32 (3.46)	0.636	0.526
Female	4.87 (3.52)		

Table11:- Statistical analysis of relation between adherence and gender **Statistically significant at P<0.05

Gender does not influence adherence in this study which was proved by independent sample t- test.

B. Relation between adherence and age groups

AGE GROUP(YEARS)	MEAN (SD)	f VALUE	p VALUE
<40	7.00(0.00)	0.345	0.884
40-49	6.00(4.08)		
50-59	4.15(3.50)		
60-69	5.25(3.75)		
70-79	4.88(3.04)		
80-89	5.50(3.78)		
Total	5.07(3.48)		

Table 12:- Statistical analysis of relation between adherence and age group **Statistically significant at P<0.05

Age does not influence adherence in our study.

C. Relation between adherence and BMI

BMI (kg/m^2)	MEAN (SD)	f VALUE	p VALUE
<25	4.93 (3.16)	2.338	0.102
25-29.9	4.54 (3.65)		
>=30	6.85(3.79)		

Table 13:- Statistical analysis of adherence with BMI
**Statistically significant at P<0.05

BMI does not influence adherence which was proven by ANOVA.

D. Adherence relation with duration of diabetes

DURATION OF DIABETES (YEARS)	MEAN (SD)	f VALUE	p VALUE
<5	6.28 (3.29)	0.712	0.547
5-9	5.08 (3.39)		
10-19	4.83(3.70)		
>=20	4.62(3.26)		

Table 14:- Statistical analysis of relation between adherence and duration of diabetic history **Statistically significant at P<0.05

Duration of diabetes does not influence adherence

E. Adherence relation with comorbidities

COMORBIDITIES	MEAN (SD)	t SCORE	p VALUE
Present	5.05 (3.55)	0.105	0.916
Absent	5.14 (3.32)		

Table 15:- Statistical analysis of adherence relation with comorbidities. **Statistically significant at P<0.05

Comorbidities does not influence adherence which was statistically proven by independent sample t test.

❖ *Adherence in Diabetic Patients*

ADHERENCE	MEAN (SD)		t SCORE	p VALUE
	Pre Intervention	Post Intervention		
	5.07(3.48)	2.88 (2.70)	7.001	0.000**

Table 16: Statistical analysis of adherence before and after counseling.
**Statistically significant at P<0.05

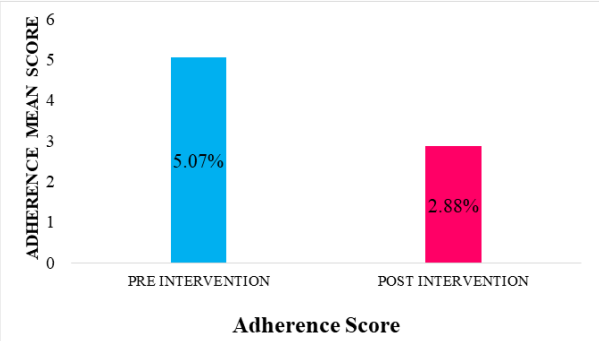

Fig 2:- Comparison of adherence before and after counselling

Statistical analysis of adherence before and after counseling using paired t test showed there is statistical significant difference (P<0.05). As there is statistical significant difference before and after counselling we reject null hypothesis (H_0) and accept alternate hypothesis.

IV. DISCUSSION

The prevalence of type II diabetes mellitus is raising globally. According to 2017 census, International Diabetes Federation (IDF) revealed that about 451 million people are affected with type II diabetes worldwide [4]. Diabetes was known to be rich man's disease but recent studies showed greater occurrence of disease in any age due to the sedentary lifestyle. Diabetes management via counseling on exercise, dietary alterations and self care on medication will improve patient adherence and thereby quality of life [13]. Medication adherence can be improved by asking patients to keep electronic pill count and separating the medication in sachets with particular time and date.

The current study revealed that, female patients (56.1%) were more than males (43.9%) and majority of the study population lies between the age group of 60-69 years (48.0%) that has a close resemblance with the study by Ramesh Adepu et al [14]. Most of the study subjects does not rely on social history (88.8%) and about 60 (61.2%) patients does not have any family history of diabetes mellitus. Patient with body mass index (BMI) more than 25 kg/m^2 are having more chance to develop diabetes [15]. In this study, about half of the diabetic patients (50%) belonged to the category of less than 25kg/m^2 in body mass index. BMI play a vital role in diabetic patients since it was suggested to reduce the weight [16] and do physical activity to lower the blood glucose level that in turn decrease the diabetic progression [17].

Majority of the subjects do not have any exercise habit (59.2%). Another highlight of the study is that majority of the subjects were literate (86.7%) which made answering the questionnaire easy. Cost effectiveness of diabetic drugs were excluded from our study since about 87.8% were under the insurance coverage and only 12 patients paid via cash. Comorbidities such as hypertension, dyslipidemia and CHF can contribute high risk in diabetic patients. 78.6% of the diabetic population had comorbidities that needed to be managed. Study of Nethaji Ramalingam et al; showed the presence of comorbidities in 65% of diabetic patients [18].

Laboratory parameters showed significant difference in PPBS and HbA1c level before and after the patient counseling that is similar with the study of Harith Kh. Al Qazaz et al showed a significantly greater score for knowledge and adherence upon lowering HbA1c [19]. Even though FBS value showed significant difference after intervention, it was not statistically significant at p<0.05 but PPBS and HbA1c level provided statistically significant (p<0.05) result, as same as the study of P.Maheswari et al [20].

By evaluating the relationship of social demographics and clinical variables with adherence, there is no statistical significance obtained showed that adherence is related to social demographics and clinical variables (p >0.05). Statistical analysis of adherence in diabetic patients provided that adherence mean score of 5.07% before counseling decreased to 2.88% after counseling provided positive impact on adherence. As the mean adherence score decreases, the patient compliance with medications increases.

From the total respondents, when we asked about the medication adherence as per the self validated questionnaire, most of them were unaware or not careful in drug administration. Medication adherence can be improved by providing education to patients, enhanced dosing schedule and effective communication between patients and physician [21]. It was proven from the result that, they showed an increase in adherence after patient counseling [22,23]. The study findings gave positive support in patient counseling, that it improves the medication adherence and further follow up is essential for the maximum effect from anti-diabetic medications.

V. CONCLUSION

Pharmacist play an important role in improving the disease condition by providing adequate knowledge regarding daily activities, food habit and supremely, compliance to medications. Adequate care must be given to diabetic patients regarding the rational use of therapy and should check the blood glucose level every 2 weeks. It is mandatory to provide adequate information regarding the drugs to patients while dispensing. Here, the study showed complete benefit from the patient counseling to improve the patient's knowledge as well as their disease state. It is required to have regular appraisal of prescribed diabetic medication and timely monitoring of patient adherence in clinical and homely setting.

SUGGESTION

There is no accurate measurement technique to assess the medication adherence. Nowadays, the role of pharmacist is not confined only in dispensing but also in different public health services. The pharmacist is an ideal person who can know in-depth about patient condition through their direct approach and can correct their belief and knowledge towards medications.

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