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STUDY ON THE IMPACT OF CLINICAL PHARMACY INTERVENTIONS ON DIABETES MELLITUS WITH OR WITHOUT COMPLICATIONS IN A TERITARY CARE TEACHING HOSPITAL AT PALAKKAD

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ABSTRACT

Diabetes Mellitus is a progressive, chronic and multifactorial endocrine disorder characterized by elevated serum glucose levels.Clinical pharmacist through medication therapy management and patient counselling can render services by guiding, identifying and monitoring disease and drug related issues faced by the patients. This study evaluated the impact of clinical pharmacy intervention on diabetes mellitus with or without complications. This study assessed medication adherence and the therapeutic outcome of the patients and to educate the patients regarding the self monitoring of blood glucose. This prospective intervention study was conducted in 2021 among patients who had diabetes with or without complications aged >20 years at Karuna Medical College Hospital, chittur India. Patients were randomly assigned to the study population and were matched for sociodemographics, clinical and laboratory results and their life routines which were entered in a self designed data collection form. All participants were responding to Morisky Medication Adherence scale. The fasting blood sugar (FBS) and Post Prandial blood sugar (PPBS) were analysed. Clinical pharmacist intervention emphasized on Modifiable risk factors like diet, exercise, smoking and alcohol cessation, need for timely follow-up and importance of medication adherence. The data was analysed and reliability were assessed using paired T test. Out of 160 patients, 53.13% were males, 28.125% of people are of age group 51-60 with a mean age of (55.57±3.34).The medication adherence, sleep pattern and quality of life of patients improved significantly after pharmacist intervention in study population at the follow-up time (p <0.0001).The medication adherence of the patients increased from 15%-30% (5.22±1.86 to 6.23±1.29) at the follow-up. Thus the above results suggests the importance of clinical pharmacist activities which had a positive impact on sleep pattern, medication adherence and quality of life of diabetic patients with or without complications.

Key words: Medication Adherence, Glycemic Control, Self Monitoring of Blood Glucose.

INTRODUCTION

Diabetes is an increasing global health challenge affecting 8% of the adult population worldwide. The International Diabetes Federation (IDF) estimates that there will be 578 million adults living with diabetes by 2030 and 700 million by 2045[1]. The greatest numbers of people with diabetes are between 40 and 59 years of age. Lifestyle modification alone or in combination with anti-

diabetes medicines may be prescribed lifelong to significantly reduce it's morbidity and mortality. Antidiabetic medicines are not designed to cure diabetes, but they help diabetes patients to keep their blood glucose under control and lower the risk of complications. There are currently six classes of Oral Anti-diabetes Agents (OAAs) namely biguanides, sulphonylureas,

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thiazolidinediones, alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors and meglitinides [2].Injectables including Rapid-acting insulins, Short-acting insulins, and Intermediate-acting insulin's (NPH), Long-acting Insulins, Premixed Insulins, Other injectable preparations.

Non-pharmacological therapy involves treatment for a person with diabetes includes advice on: Nutrition, physical activity, weight loss, smoking cessation. Structured education programmes: Help them manage their diabetes themselves on a day-to-day basis. Examples of such programmes include DAFNE (Dose Adjustment for Normal Eating) in type 1 diabetes and DESMOND (Diabetes Education for Self-Management in the On-going and Newly Diagnosed) in type 2 diabetes [3].

In addition, the long-term adverse effects of the disease reduce the self-care behaviors of patients and result in poor health state. Monitoring and control of blood glucose is a viable tool to determine disease control and rational therapy .Self-care ,including self-monitoring of blood glucose ,showed a positive effect on controlled glycaemic levels, considering the fact that diabetes related knowledge plays a vital role in association with self care behaviors of a patient [4].

METHODOLOGY
Study designs and settings
A prospective interventional study has been carried out in both inpatients and outpatients with diabetes mellitus with or without complications from General Medicine Department at Karuna Medical College Hospital, vilayodi, chittur, Palakkad district Kerala for a period of six months from February 2021 to July 2021 in 160 patients.

Study participants
The sample size was calculated based on Cochran's formula and was found to be 160 patients, who are treated with oral hypoglycemics, insulin or both aged above 20 years with or without diabetic complications were included in the study . Patients who are critically ill, not willing to give informed consent and those with psychiatric issues are excluded from the study.

Study procedure
Patients were approached and screened at study sites .Eligible patients were invited to participate upon signing of informed consent .We interviewed them by using validated and semi-structured questionnaire and self deigned data collection form to collect information .We interviewed the participants twice for the study and each interview took approximately 10-15 min. The questionnaire captured data on sociodemographic details such as gender, age, family history. We also collected information on behavioural factors such as alcohol use and tobacco use diabetes treatment details such as duration, type of medications comorbidities and complications. We counselled and also provided patient information leaflet (PIL) among the study population to attain glycaemic control by providing awareness related to the importance of self monitoring of blood glucose during their first visit.

Study tool
Medication adherence was assessed using Morisky's Medication Adherence Scale (MMAS) [5] which contains 8 questions. The answers for MMAS scale captured as yes or no .An answer of 'yes' is scored as zero and 'no' is scored as one for the first 7 questions except for the fifth question, were yes is scored as one and no is scored as zero.

Statistical analysis
The collected data was entered in MS-Excel 2019 for calculating the percentage of various parameters. Paired student t-test was used for comparison of MMAS, FBS, PPBS during the first and second visit. The relationships between these variables were expressed as Mean± SD.

Ethics policy
The study protocol was reviewed by the Institution Ethics Committee (IHEC // 2020) of Karuna Medical College Hospital, Vilayodi, Chittur and the information collected during the study will be kept in high confidentiality.

Table 1. Distribution based on age

Age Group	No of patients(n=160)	Percentage (%)
20-30	1	0.625
31-40	12	7.5
41-50	35	21.875
51-60	45	28.125
61-70	44	27.5
>70	23	14.375

Table 2. Distribution Based On Social Habits

Social habits	No of Participants(n=160)	Percentage (%)
Smoker	54	33.75
Alcoholic	34	21.25
Both smoker and alcoholic	32	20
No social history	103	64.375

Table 3. Distribution based on physical activity.

Exercise	No of patients (n=160)	Percentage (%)
YES	21	13.125
NO	139	86.875

Table 4. Distribution of variation in Fasting Blood Sugar (FBS)&Post Prandial Blood Sugar(PPBS)values.

Parameter	No of patients with increased level (n=160)	Percentage (%)	No of patients with decreased level(n=160)	Percentage (%)
FBS (mg/dl)	16	10	144	90
PPBS(mg/dl)	16	10	144	90

Table 5. Statistical analysis of Fasting Blood Sugar during follow-up and base line

Parameters	FBS (Baseline)	FBS (Follow-Up)	P Value	CI
MEAN	185.68	140.88	0.0001	34.73-54.85
SD	60.79	50.33		
SEM	4.81	3.98		
N	160	160		

Table 6. Statistical analysis of Post Prandial Blood Sugar during follow-up and base line

| Parameters	PPBS (baseline)	PPBS (follow-up)	P Value	CI
MEAN	268.73	204.13	0.0001	52.77 - 76.44
SD	73.14	58.04		
SEM	5.78	4.59		
N	160	160		

Table 7. Distribution based on Morisky's Medication Adherence Scale (MMAS).

| MMAS	Baseline no of patients(n=160)	Percentage (%)	Follow up no of patients (n=160)	Percentage (%)
Low adherence	88	55	21	13.13
Medium adherence	48	30	90	56.25
High adherence	24	15	48	30

Table 8. Statistical analysis of Morisky's Medication Adherence Scale during baseline and follow-up(MMAS)

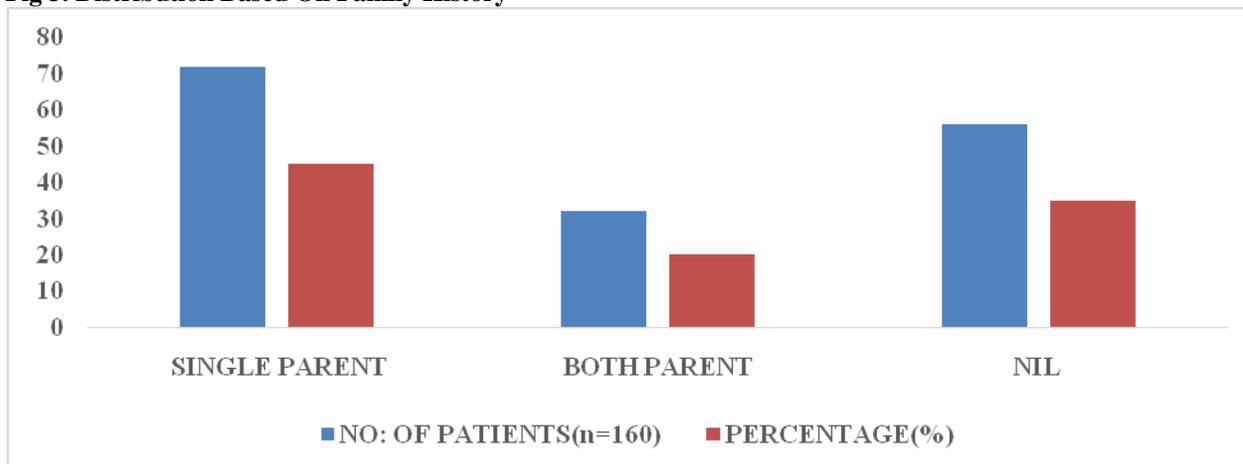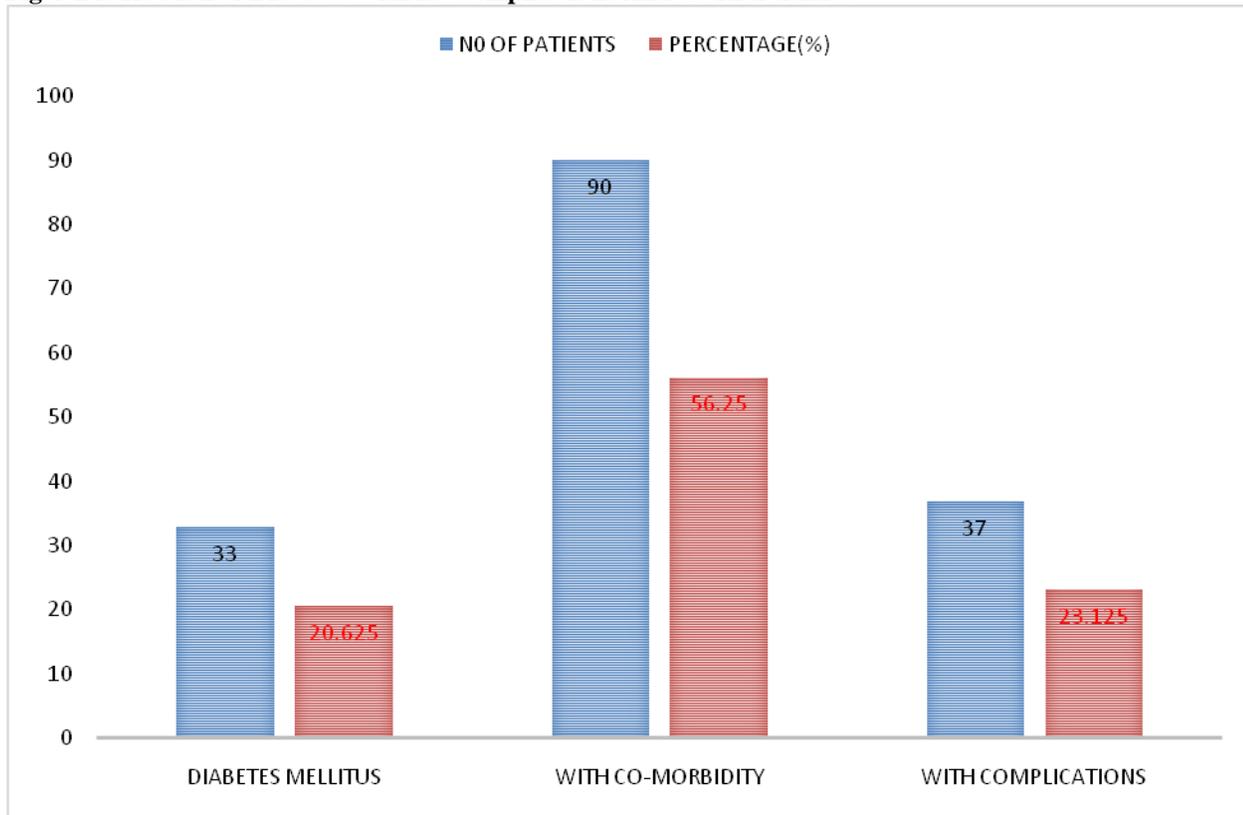| Parameters	MMAS(baseline)	MMAS(follow-up)	P VALUE	CI
MEAN	5.22	6.23	0.0001	-1.67 _ -1.15
SD	1.86	1.29		
SEM	0.15	0.1		
N	160	160		

Fig 1. Gender Wise Distribution
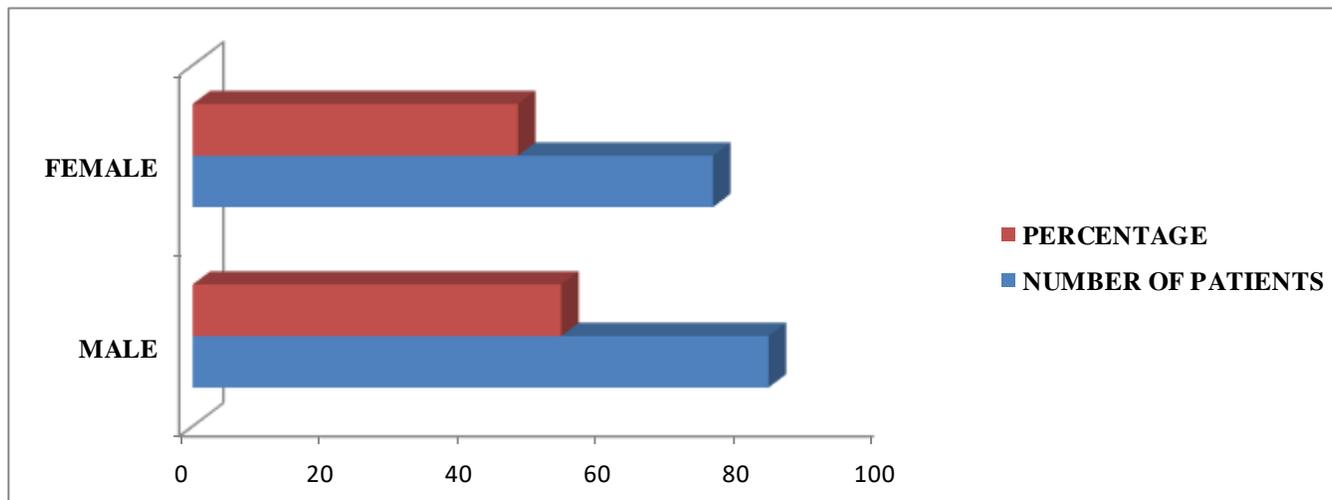
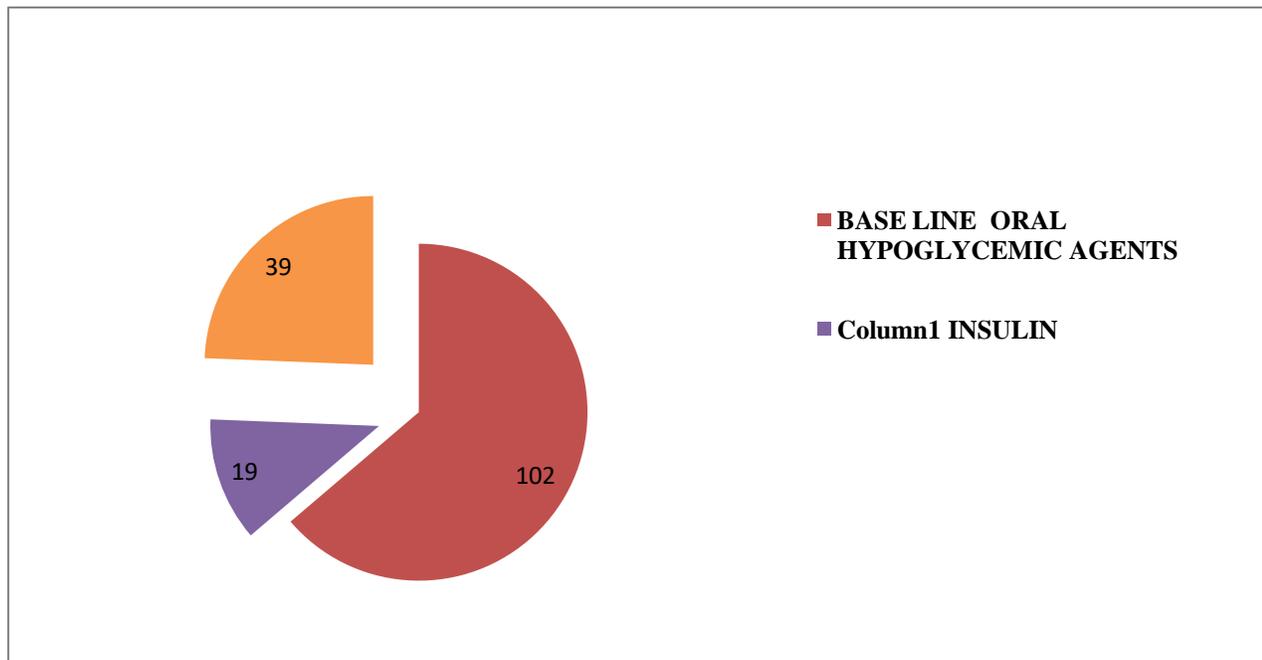**Fig 2. Distribution Based On Diabetic Duration**
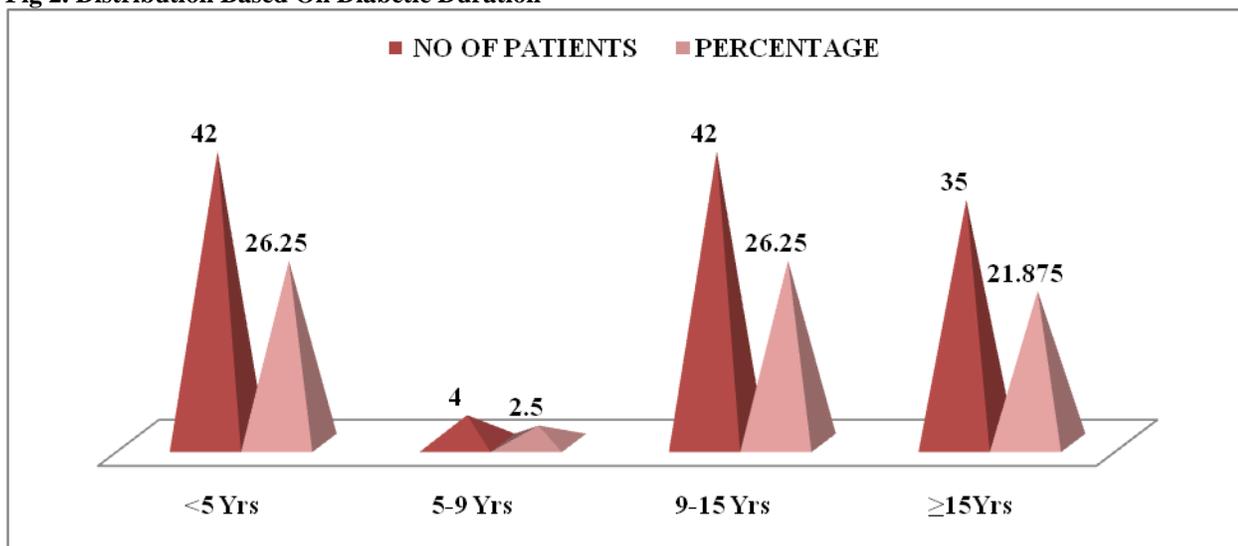
Fig 3. Distribution Based On Family History

Fig 4. Distribution of Diabetes With Its Complications And Co Morbidities

Fig 5. Distribution based on therapeutic drug management for both baseline and follow-up

RESULTS AND DISCUSSION

A total of 160 patients with diabetes with or without complication were enrolled in the study out of which 33(20.63%) were inpatient cases and 127(79.37%) were outpatient cases.

Figure 1: Among the study population 53.13% (n=160) male patients were more in number (83) when compared with female patients 46.88% (n=75).

In Table 1: The data related to the age of onset of diabetes or age of diagnosis of diabetes versus the number of patients were illustrated in which the majority of patients (45 patients, 28.125%) diagnosed belong to the age group of 51-60 years (28.125%), followed by 44 patients (27.5%)belongs to the age group of 61-70,below 20-30 years of age shows only less diagnosis of diabetes.

Figure 2: while observing 160 patients based on duration of diabetes 42 (26.25%) patients were suffering from diabetes in each of the categories less than 5years and 9-15 years respectively followed by 35(21.875%) patients were suffering for greater than or equal to 15 years and 4(2.5%) patients for 5-9 years.

Figure 3: Out of 160 patients 72 (45%) had family history of single parent (father/mother). The study shows there is no family history for 56 patients (35%).

Table 2: Out of the 160 patients, 54(33.75%) were smokers followed by 34(21.25%) were alcoholics and 32(20%) were both smokers and alcoholics .103 patients (64.38%) had no social habits.

Table 3: Among the total study population (n=160), 139 (86.88%) were physically inactive whereas 21(13.13%) were physically active. Figure 4 : out of 160 patients 34 patients (21.25%) had only diabetes . About 89 patients (55.625%) were having comorbidities, while 37 patients (23.125%) had complications .

Figure 4: Out of 160 patients 34 patients (21.25%) had only diabetes. About 89 patients (55.625%) were having co morbidities, while 37 patients (23.125%) had complications.

Figure 5 :Out of 160 patients 102 patients (63.75%) were prescribed with only oral hypoglycaemic agents followed by 39 patients (24.38%) were prescribed with both insulin and oral hypoglycaemic agents therapy , 19 patients (11.88%) were prescribed only insulin therapy during their baseline and follow-up.

Table 4: Out of 160 patients 114 patients (90%) showed a decrease in their Fasting Blood Sugar(FBS) value and 16 patients (10%) had no change in their Fasting Blood Sugar(FBS) value.

Table 5: Out of 160 patients, there was a decrease in the Fasting Blood Sugar (FBS) value of the patients from their baseline to the follow-up visit of 185 ± 60.79 to 140 ± 50.33 respectively (p<0.0001).

Table 6: Out of 160 patients 144 patients(90%) had a decrease in Post Prandial Blood Sugar(PPBS) their value from 268.73 ± 73.14 to 204.13 ± 58.04 during their initial and follow up visits (p<0.0001) respectively.

Table 7: The medication adherence of the patients was studied using Morisky's Medication Adherence Scale. On assessing the baseline adherence of the out of 160 patients 88 patients (55%) were having low adherence, 48 patients (30%) had medium adherence and 24 patients (15%) had high adherence respectively. After proper follow intervention done the adherence in the baseline got changed in the follow-up to 21 patients (13.13%) with low adherence, 90 patients (56.25%) and 48 patients (30%) with high adherence.

Table 8: Out of 160 patients an increase in medication adherence observed with their value from 5.22 ± 1.86 to 6.23 ± 1.29 during their initial and follow up visits (p<0.0001) respectively.

CONCLUSION

The evidence highlights the effectiveness of clinical pharmacist activity on medication adherence and self monitoring behavior of diabetes patients with or without complications.

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