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IMPACT OF CLINICAL PHARMACIST DELIVERED EDUCATION AMONG TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT: Diabetes mellitus is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia. The aim is to study the impact of clinical pharmacists delivered education among type 2 diabetes mellitus patients in a tertiary care hospital. A prospective, interventional, randomized control study was carried out over a period of 6 months in the general medicine department of a tertiary care teaching hospital. Data was collected from the 129 diabetic patients at the age of 18-60 years using the KAP questionnaire, MMAS-8 item questionnaire, and foot care questionnaire. The mean age having diabetes was found to be 54.42 years. Females were found to be more affected than males. The mean BMI among the participants was found to be 27.33 kg/cm^2. Among the study population, the mean KAP scores after intervention in case was increased by 32.93% for Knowledge, 45.67% for Attitude and 29.67% for Practice; the scores of MA after intervention in case was increased by 30% for high adherence, 23.33% for medium adherence and decreased by 53.33% for low adherence and the results of foot care practices after intervention in case showed an increased by 21.67% for excellent practices, 35% for the good practices and decreased by 56.67% for poor practices while the before and after intervention scores of control remained almost the same. Patients had a lack of knowledge about the disease, attitude and practice toward the disease condition, decreased medication adherence and poor foot care practices, which has shown improvement by the clinical pharmacist delivered education.

INTRODUCTION: The prevalence of diabetes mellitus is dramatically increasing- worldwide and is an epidemic in India as a result of changing lifestyles. Diabetes has been known as a disease of rich man for centuries, but now it has been seen among all groups of population [1]. It is estimated that the number of individuals with diabetes mellitus will continue to increase in the near future. Diabetes is considered as a major global burden that worsens the quality of life of the affected individuals [2]. Epidemiological studies suggest that the incidence of diabetes is increasing globally, particularly in areas with significant economic improvement due to industrialization.

Diabetes mellitus is a metabolic disorder characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and, protein metabolism resulting from defects in insulin secretion, insulin action (sensitivity) or both [3]. The prevalence of diabetes has increased in India over the past decades. The International Diabetes Federation (IDF) has estimated that India will be dubbed as "DIABETIC CAPITAL OF WORLD"

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by 2025. According to the present WHO estimates, around 32 million people are affected by diabetes in India and are expected to increase to 100 million by 2035. By 2030, India will be the country with the largest number of the diabetic population. Presently, 1 in every 12 people in India is suffering from diabetes [1]. Thus, awareness about diabetes, proper medication adherence, and better foot care practices plays an inevitable role in reducing complications. This includes severe macrovascular and microvascular complications (diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy) [4]. The management of diabetes mellitus involves health-related education, a balanced diet, physical activities, self-monitoring, and medications [5].

The aim is to study the impact of clinical pharmacists delivered education among type 2 diabetes mellitus patients in a tertiary care hospital. Continuous education programs and patient counseling helps diabetic patients to emphasize and re-emphasize the importance of risk factors, preventive measures, medication adherence and behavioral changes to prevent recurrences of the disease, its progression and ultimately minimize hospitalization and cost of therapy [6].

A study conducted by Chidambaram *et al.,* in 2014 on Role of Clinical Pharmacist in the Management of Type II Diabetes Mellitus and its Outcomes has clearly demonstrated that counseling program could definitely have an immense impact on the profession of pharmacy, giving it an even greater place in the medical management of patients [7].

Another study conducted by Kishor Khotkar *et al.,* in 2017 on Assessment of Medication Adherence in Type II Diabetic Patients in the Diabetes Clinic of Hospital, Malaysia has concluded that the overall level of medication adherence was low in Type II diabetic patients and need to be improved through better patient counseling and health education of the patients [8].

MATERIALS AND METHODS: A prospective, interventional, randomized control study was conducted in a BGS GIMS tertiary care hospital in Bangalore for a time period of six months from September to February 2019. The study included randomly selected 129 patients who are above 18 years, out of which 60 tested (intervention) group, 60 were the control group, and also had 9 dropouts.

Materials Used:

1. Patient Performa (To study prevalence of diabetes mellitus and collect patient's demographic details).
2. Patient informed consent form (Both English and Kannada).
3. KAP questionnaire (To assess the knowledge, attitude and practice) [9].
4. Morisky Medication Adherence Scale (MMAS)-8 item questionnaire (To assess the medication adherence) [10].
5. Foot care questionnaire (To assess the knowledge and practice of foot care) [11].
6. Pamphlets (Both in Kannada and English).
7. Lab Investigations (FBS, PPBS, GRBS, RBS, HBA1C).

Ethical Approval: The Institutional Research / Ethical Committee approval was obtained from the concerned hospital (IEC/2018-19/35) regarding the study after reviewing the protocol presentation. The purpose of the study was fully explained during the protocol presentation.

Study Procedure: Patients who are diagnosed with type 2 diabetes mellitus were identified through case sheets. Informed consent was collected from the study subjects who are willing to participate.

Patients were interviewed to obtain baseline information such as socio-demographic details, educational qualifications, social habits, food habits, exercise, diabetic history, BMI, co-morbidities, past medical and medication history, and known allergy of patients.

Phase I: Preparation of data collection form, Knowledge Attitude, and Practice (KAP) questionnaire, Medication Adherence (MA) questionnaire, foot care questionnaire, patient consent form, and pamphlets (supportive measures).

Phase II: Includes a random selection of patients and divided into 2 groups:

Group A: Intervention; Receiving one session of counseling at the first visit of the study.

Group B: Control; Receiving one session of counseling at the end of the study.

Phase III: Patients are categorized into two groups, then the KAP, MA questionnaire and diabetic foot care questionnaire were assessed in both groups at 0 months.

Phase IV: The KAP, MA, and foot care questionnaire responses were analyzed and used to develop an appropriate counseling program regarding the disease, medications, diet, exercise, diabetic foot care, diabetic complications, personal hygiene, medication adherence at the first visit.

In our study, counseling was provided both verbally and by distributing pamphlets only for the test group.

Phase V: The patients were asked to come back for follow-up over a period of 3 months. At the end of 3 months, the effect of pharmacist counseling was assessed by means of score variations in KAP, MA, and diabetic foot care questionnaire.

Phase VI: This phase includes statistical analysis. All recorded data were entered using MS Excel software and analyzed using SPSS 22.0 version software for determining the statistical significance. Results were expressed as Percentage, Mean, Standard Deviation and Standard Error Mean for continuous variable. To compare the effect of a before and after the intervention, the paired t-test is used. If the p-value is greater than the 0.05 (*i.e.*,>0.05), we accept our null hypothesis; otherwise, we reject our null hypothesis. The p-value <0.05 was considered statistically significant.

RESULTS: The study was carried out to assess the impact of patient counseling in improving the KAP, MA, and foot care practice of diabetic patients in the general medicine department of a tertiary care teaching hospital over a period of 6 months. A total of 129 people were screened. Out of which, only 120 patients came for follow-up. Among 120 study subjects, 60 were categorized as case groups and 60 as a control group randomly.

TABLE 1: SOCIO-DEMOGRAPHICS OF PATIENTS

Demographic		Case		Control		Total	
		No. of patients (N=60)	%	No. of patients (N=60)	%	No. of patients (N=120)	%
Age distribution (yrs.)	30-39	7	11.67	8	13.33	15	12.5
	40-49	19	31.67	10	16.67	29	24.17
	50-59	17	28.33	19	31.67	36	30
	60-69	10	16.67	11	18.33	21	17.5
	70-79	5	8.33	9	15	14	11.67
	80-89	2	3.33	3	5	5	4.16
Gender	Male	31	51.7	27	45	58	48.4
	Female	29	48.3	33	55	62	51.6
Body Mass Index (BMI) (kg/m2)	Under Weight (BMI 18.5- 25)	11	18.33	21	35	32	26.67
	Normal weight (BMI 25- 30)	33	55	29	48.33	62	51.67
	Obesity (BMI >30)	16	26.67	10	16.67	26	21.66
Physical activity	No Exercise	36	60	38	63.33	74	61.67
	Often Walk	2	3.33	4	6.67	6	5
	Regular Exercise	22	36.67	18	30	40	33.33

TABLE 2: COMPARISON OF LAB INVESTIGATION OF CASE AND CONTROL GROUP

	Lab Investigation	Mean	N	Std. Deviation (%)	Std. Error Mean (SEM)	P-value
	FBS (BI)	188.83	60	49.379	6.375	
	FBS (AI)	170.08	60	55.204	7.127	.034
C	PPBS (BI)	229.72	60	91.983	11.875	
A	PPBS (AI)	204.72	60	75.387	9.732	.017
S	RBS (BI)	290.58	60	69.881	9.022	
E	RBS (AI)	271.80	60	62.481	8.066	.024
	HBA1C (BI)	8.46	60	1.329	0.172	
	HBA1C (AI)	7.78	60	1.642	0.212	.003
	FBS (Baseline)	192.58	60	51.527	6.652	

C	FBS (After 3 Months)	186.77	60	42.865	5.534	.224
O	PPBS (Baseline)	236.13	60	80.014	10.330	
N	PPBS (After 3 Months)	228.78	60	67.589	8.726	.164
T	RBS (Baseline)	276.20	60	79.730	10.293	
R	RBS (After 3 Months)	269.83	60	82.800	10.689	.087
O	HBA1C (Baseline)	9.06	60	2.154	0.278	
L	HBA1C (After 3 Months)	8.99	60	2.266	0.293	.350

(BI- Before Intervention, AI- After Intervention)

TABLE 3: COMPARISON OF KAP SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE AND CONTROL GROUP

	KAP		N	Mean ± SD	p - value
CASE	Knowledge	Before	60	6.98 ± 2.159	
		After	60	11.92 ± 2.884	<0.001
	Attitude	Before	60	1.55 ± 1.016	
		After	60	2.92 ± 0.462	<0.001
	Practice	Before	60	1.63 ± 0.882	
		After	60	2.52 ± 0.596	<0.001
CONTROL	Knowledge	Before	60	6.233 ± 2.086	
		After	60	6.266 ± 2.06559	.157
	Attitude	Before	60	1.133 ± 0.94719	
		After	60	1.166 ± 0.86684	.317
	Practice	Before	60	1.6000 ± 0.80675	
		After	60	1.6500 ± 0.75521	.180

(p-value >0.05, Non-significant; p value <0.05, Significant; p value <0.001, Highly significant)

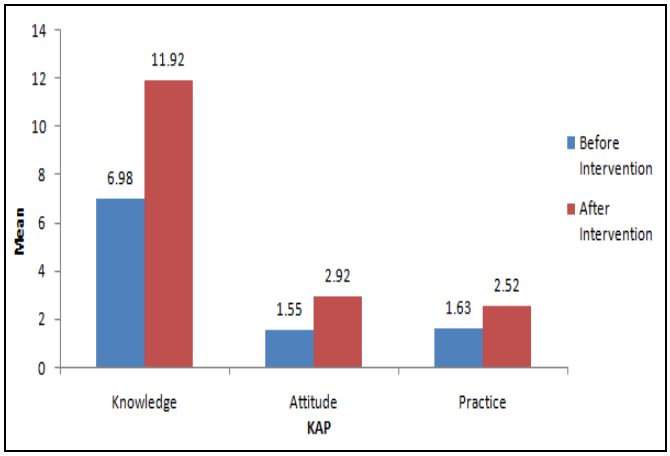

FIG. 1: COMPARISON OF KAP SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE GROUP

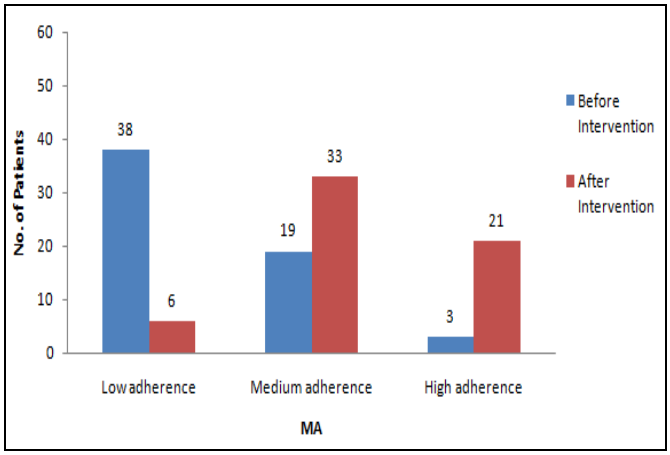

FIG. 2: COMPARISON OF MA SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE GROUP

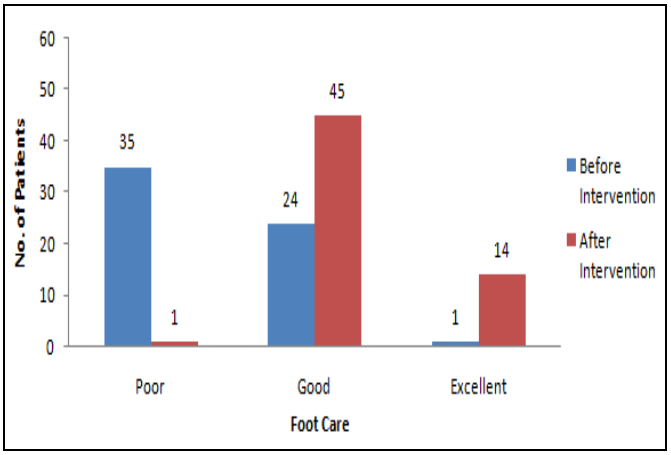

FIG. 3: COMPARISON OF FOOT CARE PRACTICES SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE GROUP

TABLE 4: COMPARISON OF MA SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE AND CONTROL GROUP

	MA	N	Mean ± SD	P-valuee
CASE	Before	60	4.82 ± 1.321	<0.001
	After	60	3.00 ± 1.179	
CONTROL	Before	60	1.22 ± 0.49	.157
	After	60	1.22 ± 0.49	

(p-value >0.05, Non-significant; p value <0.05, Significant; p value <0.001, Highly significant)

TABLE 5: COMPARISON OF FOOT CARE PRACTICES SCORES IN BEFORE INTERVENTION AND AFTER INTERVENTION AMONG CASE AND CONTROL GROUP

	FC	N	Mean ± SD	P- value
CASE	Before	60	5.18 ± 1.642	<0.001
	After	60	9.57 ± 1.511	
CONTROL	Before	60	5.22 ± 1.439	0.317
	After	60	5.25 ± 1.445	

(p-value >0.05, Non-significant; p-value <0.05, Significant; p-value <0.001, Highly significant)

DISCUSSION: Table 1 represents the socio-demographics of patients. The highest incidence of diabetes mellitus occurred among patients of 40-49 years of age was found to be the majority in case group while the highest incidence of diabetes mellitus occurred among patients of 50-59 years of age was found to be the majority in the control group. This result was similar to the result of the study conducted by Ravi *et al.,*[12,] which revealed that the prevalence of DM increases with age, which may be due to lack of time for doing exercise or other sedentary lifestyles and family history.

It was observed that the majority of the patients were male 31 (51.7%) in the case group and female 33 (55%) in the control group. In the context of the total of 120 diabetic patients, females 62 (51.6%) were found to be more affected than male 58 (48.4%). This result was supported by Wallace *et al.,*[13] the association between sex hormone-binding globulin and insulin resistance is stronger in women than in men and stronger in postmenopausal than in premenopausal women. However, it is not clear whether sex hormone-binding globulin leads to insulin resistance or whether the reversal is the case.

According to body mass index (BMI) classification, the major patient populations in the study were of normal body weight with BMI of 25-30. Among which 33 (55%) patients were from the case, and 29 (48%) patients were from the control group. India has a higher prevalence of DM compared to western countries suggesting that DM may occur at a much lower BMI in Indians compared with Europeans. Therefore, relatively lean Indian adults with a lower BMI may be at equal risk as those who are obese [14].

We assessed the physical activity of the individual patients through the patient's interview, and the result showed that more than half of the patients in the study were without regular exercise with 36 (60%) patients in the case group and 38 (63%) patients in the control group. But, after intervention, there was a gradual rise in exercise practice with the regular walk. Lack of exercise among diabetic patients may be due to poor knowledge about its benefit. And the finding was not surprising as one of the key aspects of pharmacist's counseling on the benefit of physical exercise. In general, intense physical activities were reported by younger age groups and more often by men than women. A similar finding was reported by Kufe *et al.* [15]

Table 2 compares the before and after intervention lab investigation values of case group where we found that there was a reduction in the mean values for FBS from 188.83 to 170.08, for PPBS from 229.72 to 204.72, for RBS from 290.58 to 271.80 and for HbA1C from 8.46 to 7.78, which was statistically significant with p<0.05. Also, comparing the before and after intervention lab investigation values of the control group, there was no significant reduction in the values for FBS from 192.58 to 186.77, for PPBS from 236.13 to 228.78, for RBS from 276.20 to 269.83 and for HbA1C from 9.06 to 8.99 with p>0.05. This showed better glycemic control in the patients of the case group than the control group. Similar findings were also reported from Chidambaram *et al.,* [7] in their studies between control and case (interventional) groups.

Table 3 compares the KAP baseline score in case and control group where we noticed that all the scores of Knowledge, Attitude, and Practice were almost equal before intervention. And after Intervention, there was gradual increase in the score for the Knowledge from 6.98 ± 2.159 to 11.92 ± 2.884, Attitude from 1.55 ± 1.016 to 2.92 ± 0.462 and Practice from 1.63 ± 0.882 to 2.52 ± 0.596; which was clinically significant (p<0.001).

We concluded that after intervention *i.e.*, After 3 months from the day of counseling, case group patients got benefits from the pharmacist delivered counseling. This result was supported by Ann Mary Swaroop *et al.,* [16,] which concluded that patient counseling provided by pharmacists helped to improve patient's knowledge about the disease and its management, thereby influencing the patient's attitude and practice towards the disease.

Table 4 shows that the MA baseline scores of the case and control group were found to be 4.82 ± 1.321 and 1.22 ± 0.490, respectively. And after intervention, there was a clinically significant decrease in MA scores for the case group from 4.82 ± 1.321 to 3.00 ± 1.179 ($p<0.01$), representing the increase in high medication adherence compared to the control group ($p=0.157$). This showed the essence of medication adherence related to patient education to the patient in order to get the desired therapeutic outcomes. Similar results were also reported by Kishor Khotkar *et al.,* [8,] which showed a significant improvement in the medication adherence score of the patient at the final follows up in the test group when compared to the control group.

Table 5 indicates that the baseline scores of foot care in the case and control group were almost similar before and after intervention with a score of 5.18 ± 1.642 in case and 5.22 ± 1.439 in control, respectively. The foot care scores before and after intervention in case showed a notable increase from 5.18 ± 1.642 to 9.57 ± 1.511, which was statistically significant ($p<0.001$). This showed the importance of pharmacists delivered patient education regarding proper foot care practices, which was similar to Shyam Kishore *et al.* [11]. According to WHO, QOL is an important health outcome in its own right, representing the ultimate goal of all health interventions, and patients should be benefited from the proper counseling by the clinical pharmacist.

Fig. 1 compares KAP before, and after intervention in Case, all domain scores of KAP among diabetic patients were statistically significant with scores increased from 6.98 to 11.92 (by 32.93%) for knowledge, 1.55 to 2.92 (by 45.67%) for attitude and 1.63 to 2.52 (by 29.67%) for practice respectively.

Fig. 2 compares MA before and after intervention in Case; we found out that the no. of diabetic patients with low adherence was reduced from 38 to 6 (by 53.33%) while there was a gradual increase in no. with medium adherence and high adherence from 19 to 33 (by 23.33%) and 3 to 21 (by 30%), respectively, which were statistically significant.

Fig. 3 compares MA before and after intervention in Case; we found out that the number of diabetic patients with poor foot practice was drastically reduced from 35 to 1 (by 56.67%) while there was gradual increase in no. with good foot practice and excellent foot practice from 24 to 45 (by 35%) and 1 to 14 (by 21.67%), respectively, which were statistically significant.

CONCLUSION: Diabetes is a chronic metabolic disorder or condition which is rapidly increasing worldwide. It has become clinically and epidemiologically a major concern. Our study concludes that the pharmacist's education achieved significant changes in the areas where the patients lack knowledge about the disease, attitude, and practice towards the disease condition, adherence to the medications, and foot care practice. The study emphasizes more on the inevitable role of the pharmacist in providing counseling and education to the patient regarding the health condition and thereby improving the quality of life of the patient, therapeutic outcomes, and reducing the healthcare cost and further complications. Education on lifestyle modifications and diet modification has ultimately given a better glycemic control and prevention of further complications.

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CONFLICTS OF INTEREST: Authors declare no conflict of interest.

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