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Research Article

USE OF THE PHARMACEUTICAL CARE PROGRAM IN THE MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS IN DHULE CIVIL HOSPITAL

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ABSTRACT

Aim & Objective: The study was planned to evaluate the effectiveness of pharmaceutical care on the control of medical parameters, such as Fasting plasma glucose, Glycosylated hemoglobin (HbA1c) and BMI also to evaluate drug therapy problems in patients with type 2 diabetes mellitus. Setting: the study was conducted at SBHGM College, Civil Hospital in Dhule MS.

Research design and Methods: A prospective, Open label and randomized control study was conducted with 200 type 2 diabetes patients with glycosylated haemoglobin of higher than 7.5%, they were divided into two groups: (I) control group without pharmaceutical care program (n=100), and (II) pharmaceutical care program (intervention) group (n=100). They were monitored for 3 consecutive visits. Patients in the control group received usual medical care, but patients in the intervention group received both standard medical care and pharmaceutical care.

Results: At the end of the study, a statistically significant fall was observed in the glycemic levels, BMI of patients in the intervention group as a small reduction, which is statistically not significant, was observed in the control group. Additionally, the follow-up of the intervention group by a pharmacist contributed to the resolution of 118 drug therapy problems identified.

Conclusion: pharmaceutical care program provide by pharmacist to patients with type 2 diabetes mellitus can give up measurable improvements in the glycemic control, BMI & resolute of drug therapy problems and improvements in the adherence to antidiabetic medication.

Keywords: Type 2 Diabetes mellitus, Pharmaceutical care program, and Fasting plasma glucose, Glycosylated hemoglobin (HbA1c) and Body mass index (BMI).

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INTRODUCTION

Diabetes mellitus is a chronic disease condition characterized by hyperglycemia, that is associated with high morbidity and mortality from its complications which if uncontrolled leads to various short terms and long-term complications. Diabetes mellitus with its associated complications such as cardiovascular diseases, retinopathy, nephropathy, and neuropathy is a serious health problem^{1,2}. Type 2 Diabetes mellitus account for 90-95% of those with Diabetes mellitus The

prevalence rate of Type 2 Diabetes mellitus is high in India and is expected to rise. This rise is due to low literacy rate, lack of public awareness, lack of advanced healthcare facilities and sedentary lifestyle.^{3,4} in this study also the high prevalence rate of type2 diabetes in Dhule Maharashtra due to low literacy rate, lack of public awareness, lack of advanced healthcare facilities and inactive lifestyle. The contribution of pharmacists in diabetes management is so far not documented in India.⁵

The complication danger is directly related to high blood glucose levels.^{3,5} however, as most patients with type 2 diabetes mellitus have a combination of risk factors together with obesity, hypertension, and hyperlipidemia⁴. The result of the Diabetes Control and Complication Trials⁸ and the United Kingdom Prospective Diabetes study^{8,9} The critical issues for managing of diabetes are patient's adherence to exacting dietary, exercise, self care actions, and medication regimens. The greater the number of medications, the more drug related problems such as adverse drug reaction, drug interaction, medication non-adherence, no valid medical indication, and so on.^{8,9} Poor medication adherence seems to be a significant barrier to the accomplishment of positive clinical outcomes among type 2 diabetes patients in both developed and developing countries.⁹ Increased pharmaceutical compliance was associated with fewer emergency department visit and patient admissions. Increased medication adherence was associated with decreased medical care cost.¹⁰ in recent years; pharmacists in many practice settings have begun providing patient centered services with the goal of improving drug therapy outcomes through practices such as pharmaceutical care. These PC programs have been found useful in improving the quality of care of patients with various diseases. Pharmacist's interventions in diabetes have also resulted in beneficial outcomes.^{11, 12, 15} This study intended to address this gap. Diabetes is a disease that needs more pharmacist involvement. Pharmacists possibly will contribute to such programs through pharmaceutical care. This Pharmaceutical care study will improve the quality of life, health-related quality of life. Pharmaceutical care decreases the fasting plasma glucose, Glycosylated hemoglobin (HbA1c) and Body mass index (BMI). Pharmaceutical care is the straight, responsible situation of medication-related care with the purpose of achieving definite outcomes that improve a patient's quality of life in Type 2 Diabetes mellitus. The generally Pharmaceutical care program improves patients' outcomes, reduce cost, and promote patients quality of life.

MATERIALS & METHODS

Study design:

The study was a prospective, open label and randomized control. It was conducted at SBHGM College, Civil hospital in Dhule Maharashtra. In this study, patients were divided into two groups by simple randomization technique; the first group is control group who only received only medical care, while the second one is intervention group, who received pharmaceutical care. The intervention group was followed up for 3 visits. The interval between each visit ranged from 8-9 weeks with for the follow up. Data Collection: The following data of each patient were recorded in the patient data collection forms (Patient Proforma).

Study population:

A total of 200 Type 2 diabetic patients were enrolled in the study, on the basis of inclusion & exclusion criteria after getting approval from Institutional Human Ethics Committee of SBHGM College. Civil hospital in Dhule

Maharashtra. Patients were included into to the study if Patients with type 2 diabetes mellitus of either sex, Patients with age more than 38 yrs, Patients with HbA1c more than 7.5% and Patients with blood sugar level more than 140 mg / dl. Patients were excluded from the study if Patient with end stage kidney disease, Patient with heart failure, with chronic Diabetes problem and orthopedic problem, pregnant women with type 2 diabetes.

Ethical Consideration

The protocol of study approved from Institutional Human ethical Committee of SBHMG civil hospital Dhule Maharashtra. clearance was obtained from the Ethical Committee. The study aim & objectives were explained to the patients and informed written consent was obtained in local language from them before the data collection.

Study materials:

Patient data collection Form

"As per standard guidelines, Patient data collection Form was set and got approval from diabetologist for composed patient data and Pharmaceutical care issues". The form which contain demographic data like Name, file number, weight, height, address, telephone number age, sex, social history, Medical Data Family history of diabetes, food or drug allergies, past medical history, past medication history, hypertension and hyperlipidemia, current treatment regimen, change of prescription drugs and current status of blood glucose level.

Clinical outcome data Fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), Body mass index (kg/m²).

Process evaluation data Drug therapy problems and adherence by pill count and Morisky-Green test that consists of the following questions.¹⁸ "Do you ever forget to get your medicine, "Are you careless at times about taking your medicine, "When you experience better, do you sometimes stop taking your medicine, Sometimes if you feel worse when you take the medicine, do you stop taking it.

Data and statistical analysis

The data were entered into a Microsoft Excel Spreadsheet, after data cleanout the data were transported into SPSS. Statistical Package for the Social Sciences-version 1.6 package software program for statistical analysis.¹³ Descriptive statistics (numbers and percentage) were calculated for all variables, as well as analytical statistics was done to find the relations between variables.

RESULTS

A total 223 patients were involved in the study out of which 23 patients didn't complete study Out of 223 patients, these patients were distributed into different two such as control group I (n-100) without pharmaceutical care program and Pharmaceutical care program (intervention) group II (n-100). there were 200 patients who completed the study. The other 23 patients

were excluded because they came too late after first or second visits. All patients were counseled after the selection into the study regarding Disease information, medication, diet, exercise and personal hygiene and motivate to improve life style modification. All patients

baseline parameter were recorded before the pharmaceutical care program counseling as control values and recorded at each follow up. Demographic characteristics of patients As Shown in **Table 1**.

Table 1: Demographic characteristics of patients

Parameter	Control Group-I (N=100)	Pharmaceutical care GroupII (N=100)
Sex :Male/ Female	63/37	60/40
Age(yrs)		
40-49	13(13%)	12(12%)
50-59	43(43%)	49(49%)
≥60	44(44%)	39(39%)
Mean ±S.D.	56.53±5.96	56.87±6.72
Diabetes duration (yrs)		
0-5	83(83%)	71(71%)
≥ 6	17(17%)	29(29%)
Mean ±S.D.	4.12±2.09	5.06±1.92
BMI (Kg/m ²)	26±2.9	26± 3.1
Family history of DM		
Yes	52(52%)	49(49%)
No	48(48%)	51(51%)
Hypertension.		
Normal	57(57%)	53(53%)
Hypertensive	43(43%)	47(47%)

Effect of pharmaceutical care program on fasting plasma glucose level (FPG) (Given in Table No.2):

The baseline value of FPG of Group-I was 213.6±42.87 and it no reduced significantly 220.0±43.18 after 6 month. The baseline value of FPG Group-II of was 201 ±41.40 and it reduced significantly upto 160±0.8 after 6 month.. There were statistical significant differences in FPG found only in intervention Group- II. P-value < 0.05 considered as statistical significant differences. Shown in Table No 2.

Effect of pharmaceutical care program on glycosylated hemoglobin: (Given in Table No. 2)

The statistical significant difference reductions in the glycosylated hemoglobin level were observed among in intervention Group- II. The HbA1c was found to be reduced more significantly in group II patients from 9.41 ± 1.06 to 8.23 ± 0.85. P-value < 0.05 considered as statistical significant differences .shown in Table No 2.

Effect of pharmaceutical care program on BMI: (Given in Table No. 2)

The baseline values of BMI of G-I and Group-II were 26±2.9, 26± 3.1 after 6 month final values BMI of G-I and Group-II were 26 ± 2.9, 24 ± 1.8 There were statistical significant differences in BMI found only in intervention Group- II. P-value < 0.05 considered as statistical significant differences shown in Table No 2.

Table 2: Comparative analysis of baseline and final values between patients in the Pharmaceutical care program and control groups.

Parameter	Control group N=(100)		PC Intervention group N=(100)	
	Baseline Values	Final Values	Baseline Values	Final Values
FPG(mg/dl)	213.6± 42.87	220.0± 43.18	201 ± 41.40	160.8± 26.43
HbA1c (%)	9.38 ± 1.4	9.62 ± 1.35	9.41 ± 1.06	8.23 ± 0.85
BMI(kg/m ²)	26±2.9	26 ± 2.9	26± 3.1	24 ± 1.8
P value	0.197	0.001	0.341	0.000

Values are expressed as Mean ± SD (n=100 for each group)

P-value < 0.05 considered as statistical significant differences

Medication Adherence There are many methods for the assessment of medication compliance. In this study, indirect methods have been used (interview and pill count technique) for the evaluation of Adherence among

patients in the intervention group. Medication Adherence from the first visit until the end of the study is summary in Table 3.

Table 3: Mean adherence change at each visit for intervention group.

Adherence change	Visiting time			P value
	First visit N (%)	Second visit N(%)	Third visit N (%)	
NonAdherence	49(77.4)	28(41.9)	15(19.0)	0.000
Adherence	14(22.6)	39(58.1)	51(81.0)	0.000

There is an improvement in the Medication Adherence which is statistically significant (p value < 0.05).

Drug Therapy Problems: Drug therapy problems (DTPs) were identified in the intervention group during the study. It is discussed in literature review 16. DTPs are classified into 7 categories. In order to identify and resolve DTPs 7 points are considered among patients in the intervention group that include the followings. Unnecessary drug therapy, needs addition drug therapy,

Dosage too low, Dosage too high, Drug therapy ineffective, adverse drug reaction, and Non adherence.

At the first visit, 25 patients have one DTP, 17 patients have two DTPs, and 5 patients have three DTPs, at the second visit two DTPs were identified among three patients and at the third visit just one DTP is found in one patient, considerable resolving and prevention of DTPs have been found that is statistically significant (P-value less than 0.05).

Table 4: Mean Drug therapy problems (DTPs) for the intervention group during the study.

DTP options	Visiting time			P value
	First visit N (%)	Second visit N (%)	Third visit N (%)	
No DTP	23(33.9)	61(95.2)	63(98.4)	0.000
One DTP	25(37.1)	3(4.8)	1(1.6)	
Two DTP	17(24.2)	0(0.0)	0(0.0)	
Three DTP	5(4.8)	0(0.0)	0(0.0)	

DISCUSSION

Pharmacist is main part in a health care team. This team normally consists of pharmacist, physician, nurse, technician, and other health care professions. All of the members in health care team have important roles in diabetes management in accomplishing the goal of treatment, improving quality of life, controlling disease and its complications, detaining complication, and decreasing mortality and morbidity.^{1,4,5} In this present study pharmacist is main role in pharmaceutical care program. Pharmacists' interventions are an important factor to improve glycemic control in diabetic type2 patients. Pharmacists' interventions include diabetes education and counseling on disease, drug, diet, exercise, life style modification, and self management, identifying and solving drug-related problems, improving glycemic control, more recent studies, all these interventions used in present study. HbA1c levels, Fasting Blood Glucose levels and Body Mass Index values significantly reduced with pharmacists' interventions compared with usual care.¹⁴ Mean difference in the change of HbA1c, FPG and BMI This would help patients meeting the target of their treatment. In This present study significant fall in the values of HbA1c, FPG and BMI in the intervention group II as compared to control group I. differences is 1.18±0.75, 41±14.97, & 2.13 respectively. The data analysis showed there were significant reductions in FPG, HbA1c, and BMI (160± 0.8mg/dl, 8.23 ± 0.85%.and 24 ± 1.8kg/m²respectively) obtained in the intervention

group at the end of the study period. But there is no significant FPG, HbA1c, and BMI reduction in the control group. Our result complied with those of other similar studies.¹³ The pharmacist's interventions in more recent studies also resulted in beneficial outcomes. In the study^{14,15} studied the quality of care of a pharmacist-managed diabetes clinic. This inconsistent result could be explained by various reasons, for example: noncompliance to dietary control and exercise might explain this result.¹⁵ reported that poor compliance to dietary recommendations, missed appointment, and medication noncompliance were found in 56.69%, 13.33% and 5.55% of patients, respectively vast numbers of the diabetic patients suffer from poor dietary control. these may suggest that diabetic patients may need dietary modification specialists to assist them.¹⁸ The present study shows that better pharmacist education sessions, pill count, use of dietary chart and follow up calls and activities prove beneficial in falling mean FPG and HbA1cs significantly. To our knowledge, this type of intervention is first of its kind to be reported in Dhule Maharashtra region and shows that pharmacists could have added significance in "diabetes care management" through pharmaceutical care program.

Medication Adherence: Medication Adherence was assessed in this study by direct methods, which include: question method and pill count method. In the first visit 49 (77.4%) patients were non-adherence by question (Morisky-Green test). According to the protocol of the

Morisky-Green test, patients are considered Adherence to the treatment when they get a maximum score of four points, and non-adherence when they get three points or less 21. At the second visit, the number of non-adherence patients was reduced to 28(41.9%) patients by using Morisky-Green test and pill count technique. For the pill count technique, the percentage of each antidiabetic medication compliance was calculated for each patient; then the average percentage of all medication adherence was calculated, according to Sackett D.L if the result is more than or equal to 80% the patient is considered adherence.¹⁸ At the third visit, compliance rate was assessed by Morisky-Green test and pill count technique, the number of non-adherence patients was reduced to 15(19%) patients.^{17,18} Our results show that the major cause of non-adherence is forgetting to take medications (at the end of the study), the reasons of forgetting to take medications were mainly due to forgetfulness, being too busy, hard working and uneducated. These causes may be solved if patients educate the importance of taking medicine at correct time and punctuality. This study disclosed that, the pharmacist may play an important role to teach patients about diabetic drugs and disease, to reduce the rate of non-adherence among diabetic patients.

Drug Therapy Problems: Drug therapy problems (DTPs) were adapted from the definition of Cipolle and Strand and it was classified into four categories indication, efficacy, safety and non-adherence.^{5,10}

In this study, the non-adherence problems were the highest among DTPs. During the 2nd and 3rd visits for the intervention group, the intervention was accepted and the DTPs were solved in 98 cases (231 cases of DTP were not solved) and DTPs were solved in 17 cases (13 cases of DTP were not solved), respectively.

REFERENCES

1. International Diabetes Federation. Diabetes Atlas. 4th ed. Brussels; 2010; 100 p. 71-73
2. World Health Organization. "Definition, diagnosis and classification of diabetes mellitus and its complications: Report of a WHO Consultation. Part 1. Diagnosis and classification of diabetes mellitus". Retrieved 29 May 2007.
3. Matzer S, Leiter L, Daneman D, Gerstein H, Lau D, Ludwig S, et al. Clinical practice guidelines for the management of diabetes in Canada. CMAJ. 1998; 159:1-29.
4. American Diabetes Association: Implications of the diabetes control and complications trial. Diabetes Care 2002; 25:25-27.
5. Diabetes care, net.
6. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990; 47(3):533-543.
7. Abuissa H, Bel DS, O'Keefe JH Jr. Strategies to prevent type 2 diabetes. Curr Med Res Opin. 2005; 21:1107-14.
8. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993; (329):977-986.
9. United Kingdom Prospective Diabetes Study Group. Intensive blood - glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes mellitus (UKPDS 33). Lancet 1998; (352):837-853.
10. Cipolle RJ, Strand LM, Marley PC. Pharmaceutical care practice. New York:McGraw-Hills; 1998. p. 1110.
11. Dinesh KU et - Evaluation of the Impact of a Pharmaceutical Care Program for Diabetes Patients in Nepal: A Preliminary Study Indian Journal of Pharmacy Practice 2011; 4(4).
12. Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash). 2003; 43(2):149-159.
13. HepKe, K.L., Martus, M.T., & Share, D.A. Costs and utilization associated with pharmaceutical adherence in a diabetic population. The AJMC; 10:144-151.
14. Coast-Senior EA, Kroner BA, Kelley CL, Trilli LE. Management of patient with type 2 diabetes by pharmacists in primary care clinics. Ann Pharmacother. 1998; 32:636-41.
15. Anaya JP, Rivera JO, Lawson K, Garcia J, Luna J Jr, Ortiz M. Evaluation of pharmacist-managed diabetes mellitus under a collaborative drug therapy agreement. Am J Health Syst Pharm. 2008; 65:1841-5.
16. Rothman R, Malone R, Bryant B, Horlen C, Pignone M. Pharmacist led, primary care-based disease management improves hemoglobin HbA1c in high-risk patients with diabetes. Am J Med Qual. 2003; 18(2):51-8.
17. Suppapatiporn S, Chindavijak B, Onsanit S. Effect of diabetes drug counseling by pharmacist, diabetic disease booklet and special medication containers on glycemic control of type 2 diabetes mellitus: a randomized controlled trial. Med Assoc Thai 2005; 88 Suppl 4:S134-41.
18. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of self-reported measure of medication adherence. Med Care. 1986; 24(1):67-74.

CONCLUSION

In this study result showed that there are significant reductions in glycemic levels i.e. FPG, HbA1C and BMI for the intervention group this result recommended that, the implementation of the pharmaceutical care program might result in good Glycemic control compared to usual medical care. In term of medication adherence, this study showed that, pharmaceutical care program can increase the rate of medication adherence among patients in the intervention group. Drug therapy problem is also one of the important objectives for this study, the study findings showed that the numbers of patients who do not have any DTPs from the 1st visit to the 3rd are significantly improved. In This present study we conclude that Pharmaceutical care program study will improve the quality of life, "health-related quality of life". The study, therefore, recommended that the pharmaceutical care program on the total care of the patients should be established in all chronic disease. The Pharmaceutical Care provided by the pharmacist to the type 2 diabetic patients was effective in reducing the blood glucose levels and in improving their overall quality of life.

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