Effect of Pharmaceutical Care Services Provided by Clinical Pharmacists on Type-2 Diabetes Patients

Komal Choudhary1,*, Monika Mali1, Kamini Bhavsar1, Sunita Pawar2, Arundhati Diwan2, Supriya Barsode2
1Department of Clinical Pharmacy, Poona College of Pharmacy, Bharati Vidyapeeth University, Pune, Maharashtra, INDIA. 2Department of Medicine, Bharati Vidyapeeth University, Pune, Maharashtra, INDIA.

Received: 28 Dec 2018; Accepted: 19 Jan 2019

*Correspondence to:
Dr. Komal Choudhary, PharmD,
Department of Clinical Pharmacy,
Poona College of Pharmacy, Bharati Vidyapeeth University, Pune, Maharashtra, INDIA.
Email: ckomal8087@gmail.com

Abstract

Objectives: The study aimed to provide diabetic pharmaceutical care and evaluate the effect in terms of glycemic control and blood pressure. Methods: Randomized, interventional, controlled and comparative clinical study was conducted recruiting a total of 152 type 2 Diabetes mellitus outpatients. The control group received only common clinical care from medical staff, whereas the intervention group received additional pharmaceutical care from clinical pharmacists. Biochemical data such as blood pressure, fasting and post prandial blood sugar were collected pre and post intervention. Knowledge, Attitude and Practice (KAP) questionnaire was administered to both groups before and after intervention. Changes in outcome were measured using t-test and independent t-test. For statistical significance, P<0.05 was considered. Results: In the intervention group, significant decrease in the FBS from 182.98 ± 33.37 (mean ± SD) to 121.59 ± 17.43, PPBS from 227.15 ± 66.95 to 156.67 ± 18.50, systolic BP from 137.61 ± 22.95 to 118.76 ± 7.89 and diastolic BP from 89.32 ± 10.09 to 80.53 ± 6.91 was observed and increase in the Knowledge, Attitude and Practices (KAP) of patient was observed from pre-questionnaire 24.57 ± 2.8 to post-questionnaire scoring 33.95 ± 3.82, which was statistically significant (p<0.001), but no significant improvement in the control group was observed. Conclusion: Present study outcomes indicate that Pharmaceutical care provided by clinical pharmacists improves the control of diabetes and patient’s knowledge, awareness and attitude about the disease and medicines can do productive changes in the glycemic control. Key words: Diabetes, Pharmaceutical Care, Type 2 Diabetes, KAP, Clinical pharmacists.

INTRODUCTION

Diabetes is one of the world’s leading chronic diseases with serious socio-economic impact that requires a continuous medical care to prevent the risk of complications and associated co-morbidities.[1-3] The International Diabetes Federation (IDF) estimates that 246 million adults worldwide have diabetes mellitus. The global prevalence of diabetes has risen from 108 million in 1980 to 422 million in 2014 with the rapid rise in middle-income and low-income countries.[4]

It has been proposed that age, obesity, regional adiposity, family history, genetic factors, sedentary lifestyle, lack of physical activity along with urbanization, industrialization, globalization can contribute to increase the risk of diabetes with considerable impact on quality of life and limits patient’s routine activities in terms of physical, social and psychological well-being.[5] Increased glucose levels may result in the development of micro and macro vascular complications and are associated with disease progression, hospitalization, premature disability and mortality. Several observational studies have shown that intensive glycemic control will lead to improved outcomes in cardiovascular, cerebrovascular and peripheral vascular diseases.[6-7]

Though Type 1 diabetes is the most common form of diabetes found in children, the availability of patients is less in Indian Scenario. Type 2 diabetes (non-insulin-dependent or adult-onset) resulting from insulin resistance is widely seen in both urban and rural areas.[8] A two to three fold increased risk of cardiovascular disease is associated with type 2 diabetes mellitus. Also, the long-term complications of diabetes are associated with high morbidity, high cost and decreased quality of life. The factors observed in poor glycemic control include poverty, non-compliance, lack of knowledge and poor follow ups.[9] Poor adherence results in the worsening of glucose control and increases the hospital admissions of patients due to diabetes complications.[10]

The increase in the cost of healthcare, disease burden, irrational use of medicines, non-availability of health care providers in sufficient numbers, especially in rural areas are all challenges we have to overcome.[11] These challenges can be overcome by a clinical pharmacists with his/her knowledge and expertise in production, distribution, storage and dispensing of quality medicines and also promoting the rational medicine use, health promotion, managing medicines and drug therapy, providing patient instructions and counselling to patients to improve compliance with therapy, assisting patients in making effective self medicine choices and decisions for their health.[12]

Several studies have reported the positive impact of clinical pharmacist counseling on glycemic control and quality of life outcomes in diabetic population.[3-4,11-12] Studies such as the Diabetes Control and Complication Trail (DCCT)[13] and United Kingdom Prospective Diabetes Study (UKPDS) [14,15] have conclusively demonstrated that a goal of normalization of blood glucose significantly reduces the risk of complications. Therefore pharmacists specialized in this arena can make a significant and positive impact on the patients and health care system and who can provide counseling on disease, drug, lifestyle modifications, including diet and exercise and self-management of disease by periodic monitoring.[14]
Pharmaceutical care is direct, responsible provision of medication-related care with the purpose of achieving definite outcomes that improve a patients' quality of life. The morbidity associated with DM can be reduced by proper knowledge about the disease, appropriate attitude and practices. Thus, this study aimed to evaluate the effects of pharmaceutical care services provided by clinical pharmacist on type-2 diabetes patients.

**MATERIALS AND METHODS**

This study was approved by the Institutional Ethics Committee at Bharti Hospital and Research Centre, Pune. (REFERENCE BVDUMC/IEC/87)

**Study design**

A Randomized, interventional, controlled, comparative study of 8-months duration with one follow-up, was conducted on patients with Type 2 Diabetes Mellitus (T2DM), recruited from the general outpatient department of Bharti Hospital and Research Centre, Pune (Maharashtra, India), with an inclusion of patients with T2DM of either sex above 20 years of age and with hypertension, after an informed consent was obtained. Patients who were diagnosed with type1 Diabetes, pregnant or lactating women, those with physical or mental disability and who were not willing to give an informed consent were excluded. After recruitment, these patients were randomly distributed to Intervention Group (IG) or Control Group (CG). Patients in the control group received only clinical care from medical staff, whereas those in IG received additional pharmaceutical care from a clinical pharmacist. The primary endpoints in this study included improvement in Blood Pressure (BP), Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), Glycosylated Haemoglobin (HbA1c) along with impact on Knowledge Attitude Practice (KAP) of patients post intervention.

**Sample size**

A total of 200 patients were preliminarily assessed and as per the inclusion criteria, 160 patients were recruited into CG and IG, amongst whom, 8 patients dropped out from the study and 152 patients completed the study (76 patients for CG and 76 for IG).

**Data Collection**

Patients’ demographic data, clinical data, medications and biochemical data, such as Blood Pressure, Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS) and Glycosylated Haemoglobin (HbA1c) levels were collected using patient profile form along with the Knowledge, Attitude and Practice (KAP) questionnaire, in accordance with the physician’s order before and after intervention.

**Pharmaceutical care services**

The intervention program included diabetic education to the patients. All patients in the IG were educated twice in this study (at the beginning and at the next follow-up, respectively) depending on the patients’ knowledge, attitude and practice of T2DM, risk of diabetic complications, precautions of oral hypoglycaemic agents and insulin, signs and symptoms of hypoglycaemia, self-management of disease eg. Self-monitoring of blood glucose and a healthy lifestyle. Interviews included a face-to-face interview on the first visit and telephone or face-to-face interview on subsequent follow-up at the end of this study. In the interview, pharmacist discussed with each patient about their disease, medication adherence, self-monitoring of glucose control, exercise; and explained the side effects of anti-diabetic drugs; and reminded them of their next visit of follow-up. Individual patient’s record files were maintained.

**Statistical analysis**

GraphPad QuickCals: t-test calculator was used for statistical analysis and data was expressed as Mean ± Standard deviation. Differences between control and intervention groups were evaluated using independent t-test and differences between baseline and endpoint outcome measures were determined using the paired t-test. P<0.05 was considered statistically significant.

**RESULTS**

Out of 160 patients, there were 152 patients who completed the study (76 patients in the intervention group and 76 patients in the control group). The other 8 patients were excluded from the study due to lost to follow-up. Figure 1 illustrates the flow of patients through the study and describes various stages at which data were collected. The age, gender, duration of diabetes, family history of diabetes, occupation, level of education and civilization for both the groups are presented in Table 1. Statistical analyses indicated that the groups were well matched (P>0.05 in all cases).

**Clinical outcome measurements**

Among 152 patients, there was a significant decrease in fasting blood glucose in both the groups from 184.36 ± 38.83 to 180.82 ± 15.26 and 182.98 ± 33.37 to 121.59 ± 17.43 between the baseline and final interview respectively with a difference considered to be statistically significant (P<0.001) in the intervention group. In the control group there was a significant increase in post prandial blood glucose from 219.61 ± 52.47 to 222.46 ± 53.43 (P>0.05); while in the intervention group there was a significant decrease in PPBG from 227.15 ± 66.95 to 156.67 ± 18.50 between the baseline and final interview, this difference is considered to be statistically significant (P<0.001); presented in Table 2.

There was a significant decrease in Systolic blood pressure in both the groups from 140.71 ± 22.94 to 136.42 ± 23.8 and 137.61 ± 22.95 to 118.76 ± 7.89 between the baseline and final interview respectively and this difference is considered to be statistically significant (P<0.001) in the intervention group. According to the Diastolic blood pressure readings there was a significant decrease in both the groups from 90.79 ± 7.79 to 88.82 ± 8.79 and 89.32 ± 10.09 to 80.53 ± 6.91 between the baseline and final interview respectively, with a statistically significant difference (P<0.001) in the intervention group; presented in Table 3.

There was a significant decrease in knowledge, attitude and practices from 23.84 ± 2.52 to 23.18 ± 2.81 in the control group (P>0.05) while in intervention group there was significant increase in knowledge, attitude and practices from 24.57 ± 2.8 to 33.95 ± 3.82 between the baseline and final interview respectively and this difference is considered to be statistically significant (P<0.001); presented in Table 4.

![Figure 1: Flowchart of participants’ screening for this study.](image-url)
In this study, there was a significant decrease in fasting blood sugar (FBS) in both the groups between the baseline and final interview. In the
intervention group, this difference is considered to be statistically significant \((p<0.001)\), which is in line with the study conducted by Hua Shao et al.\(^\text{[25]}\) and Chidambaram Dhandapani et al.\(^\text{[26]}\) and that showed a significant improvement in FBS, in intervention group, compared to those in the control group. These results provide clinical evidence that pharmaceutical care has a positive role in T2DM management and suggest that routine participation of clinical pharmacist in medical teams for outpatients is of high therapeutic value.\(^\text{[26]}\)

The findings showed that there was a significant increase in Post Prandial Blood Sugar levels (PPBS) in the control group while in the intervention group there was a significant decrease in PPBS between the baseline and final interview. The statistical analysis showed that the intervention group was statistically significant \((p<0.001)\) which is in agreement with the study conducted by Chidambaram Dhandapani et al.\(^\text{[26]}\) which showed that better glycemic control was obtained in the intervention group and that the pharmacist education sessions and follow up calls proved beneficial in reducing mean PPBS levels significantly.

This study showed that there was a significant decrease in systolic and diastolic blood pressure in both the groups between the baseline and final interview and thus revealed a positive conclusion of pharmaceutical care to control hypertension in patients with diabetes. Moreover, in the intervention group, this difference is considered to be statistically significant \((p<0.001)\) for both systolic and diastolic blood pressure, which is consistent with the studies conducted by Hua Shao et al.\(^\text{[25]}\) and Winifred Atigbelle Ojiehu et al.\(^\text{[28]}\) these studies demonstrated that the mean values of systolic and diastolic blood pressure were significantly decreased in both groups, but in the control group there was an increase of about 1 unit from the baseline in the mean value of systolic blood pressure.

KAP scoring showed that, there was a significant decrease in knowledge, attitude and practices between the baseline and final interview in the control group, whereas, in the test group there was a significant rise in knowledge, attitude and practices between the baseline and final interview. The statistical analysis presented the intervention group to be statistically significant \((p<0.001)\) and were in accordance with studies conducted by Hua Shao et al.\(^\text{[25]}\) that showed that better knowledge acquisition was obtained in the intervention group and that the pharmacist education sessions and follow up calls proved beneficial in reducing mean PPBS levels significantly.

CONCLUSION
Pharmaceutical care provided by the pharmacist to T2DM patients improved the overall clinical outcomes in diabetic patients. Education and counseling by clinical pharmacist results in better care of patients with chronic, long term diseased conditions and helps them improve their quality of life. This study provided evidence on the value of clinical pharmacist as a critical member of the medical team who can effectively provide Pharmaceutical care and help in achieving positive clinical outcomes.

ACKNOWLEDGEMENT
Authors would like to thank Vincy Kurian (Pharm D), Anju Thomas (Pharm D) and Sophia Mathew (Pharm D) for their critical review and support.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

ABBREVIATIONS
Nil.

REFERENCES