

Pharmacist intervention in outpatients with hypertension, type 2 diabetes mellitus, ad impact on cardiovascular risk

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Abstract

About 80% of CVDs are linked to behavioral risk factors. The effects of physical inactivity and unhealthy diet may present in an individual as overweight and obesity, high blood pressure, elevated blood glucose levels, and elevated blood lipid levels. Aim: This study aims to assess the impact of pharmacist interventions focusing on the medical risk factors for primary prevention in outpatients with Hypertension, Diabetes and their impact on Cardiovascular risk. Material and Methods: The selected patients were grouped randomly into interventional and usual care groups. The different intervention steps and the protocol of the study were explained to the patients included in the interventional group whereas the normal care group will be directed to follow their normal treatment protocol. Results & Conclusion: In both interventional group (61.3%) and usual care group (57.7%) majority were females. The age group of the patients varied from 41 to 70. There were significantly results in the Interventional group in clinical outcomes, biomedical outcomes and adherence of medication compared with the Usual care group.

Keywords: Pharmacist Intervention; Cardiovascular risk; Adherence; Hypertension

1. Introduction

Cardiovascular disease (CVD) represents a leading health problem worldwide. Several risk factors have been reported to be associated with CVDs[1]. Although some are simply nonmodifiable (e.g., age, sex, family history of CVD, genetic links, and ethnicity), others are modifiable [2]. The risk of CVDs can be reduced by adopting a healthy lifestyle such as regular physical activity, consumption of fruits and vegetables, moderation of alcohol intake, dietary sodium reduction, avoiding tobacco use, avoiding foods rich in fat, and maintaining a healthy body weight [3]. About 80% of CVDs are linked to behavioral risk factors. The effects of physical inactivity and unhealthy diet may present in an individual as overweight and obesity, high blood pressure, elevated blood glucose levels, and elevated blood lipid levels [4]. Early detection, intervention and management of these risk factors, are among some of the primary prevention strategies that can reduce the burden of CVD worldwide [5,6].

The involvement of the pharmacist in optimizing medication in a patient care setting can solve the problems which are particularly related to the use of the medication [7,8]. However, all these studies focused on ambulatory care settings [9]. ADR is mainly reported from the patient discharged from acute care centers, where the risk for these events are reported high [10,11]. In majority of the incidents, the unwanted drug effects are reported due to inappropriateness in the prescribing pattern of drugs, poor adherence, and the discrepancies between regimens [12-14]. Several studies focused on hospitalization due to adverse drug effects of the prescribed medications. It was reported that an inadequate therapeutic drug regimen for the patient is one of the main reasons for the hospitalization of the patients due to drug related issues[15-17]. The involvement of clinical pharmacists demonstrated to have a significant role in the achievement of the clinical goals by solving these medication-related problems [18].

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Among the hospital readmission rate, it is estimated that 14% of the patients are readmitted due to the problems associated with discrepancies while 6% of cases are without any such issues [19]. The World Health Organization (WHO) estimated that approximately 50% of chronic disease patients comply to the prescribed therapeutic regimen worldwide [20].

This study shows the involvement of pharmacist in the intervention outcomes in Type 2 diabetes and Hypertension patients and its impact on Cardiovascular risk by assess the parameters, medication adherence, quality of life.

2. Material and methods

2.1. Study Type

Prospective study

2.2. Study Duration

4 months

2.3. Selection criteria

Patients above 18 years of age belonging to either gender, diagnosed with type – 2 diabetes mellitus and hypertension for not more than 2 years were selected. Patients above 70 years are not included due to comorbid conditions and inability to adhere to the therapeutic regimen due to psychological factors.

Patients with severe renal and hepatic dysfunctions were also excluded.

2.4. Methodology

Patients diagnosed with the disease Diabetes and Hypertension in the Tertiary care hospital were selected from the outpatient department.

Patients who expressed willingness to participate in the study and otherwise satisfied the eligibility requirements was selected and the study details was well explained to all the participating patients and the duly signed informed consent will be obtained.

The selected patients were grouped randomly into interventional and usual care groups. The different intervention steps and the protocol of the study were explained to the patients included in the interventional group whereas the normal care group will be directed to follow their normal treatment protocol.

Intervention procedures were applied to the selected interventional group, while the usual care group was not given any special attention or care in addition to normal care and information given by the healthcare team and pharmacist in the outpatient pharmacy department regarding the medications and therapeutic regimen.

The multifaceted interventions for the patients in the interventional group will be comprised of two sessions, a face-to-face care by an interview and counseling followed by telephonic follow up program. The interventional group will be given regular 2 face-to-face informative sections during a period of 4 months during their regular visit to the outpatient department for review. During this session the clinical pharmacist was performed a 30 minutes face to face interaction and counseling. This included the following

- Evaluation and providing basic knowledge about the diabetes, hypertension and cardiovascular diseases which included factors that are found to be seriously affect and possible occurrence of cardiac events.
- Evaluation of the previous medication uses and the experiences, if necessary, it was tailored with advices.
- Utilizing medication administration supports like pill counter and leaflets containing the detailed information about the drug.
- Patient information leaflets containing information regarding the disease, symptoms, laboratory tests required and life style modifications to be made were prepared and supplied. and pictures showing health educations, and
- Correcting any misunderstandings about the disease or medications and associated life style modification.

During this interview the evaluations was made regarding the progress of the intervention and detailed counseling and education were given regarding the medications, adherence, selfcare activities and also the life style modifications recommended. The patients were also given time to ask questions related to their disease, therapy and clear the doubts.

During the second session the patients were given regular 4 follow up interventions during the course of study. The patients will contacted over telephone and guidance will be given regarding the rational use of medications. Telepharmacy was mainly focused on adherence of the patient to the medications.

Patient counselling is performed by the clinical pharmacist utilizing the telepharmacy pursuance and performed the following: -

- Assessment of the medication adherence,
- Encouragement and reminders with tailored advices, and
- Clarifying any misunderstandings or misconcepts. All the patients participated in all the proceedings.

At the starting and ending of the research work, blood samples was collected to evaluate the biomarkers such as fasting blood sugar, HbA1c, TC, LDL-C, HDL-C, and TG.

Arrangements were made to measure the Systolic Blood Pressure and Diastolic Blood Pressure during the visit of the study population at the outpatient department. At the beginning and end of the proceedings of the study questionnaires were given and explained to answer for the adherence and selfcare activities. Adherence was measured using Morisky adherence test and selfcare activities by using standardized questionnaire formats. Measurements were taken for the body mass of the patient in the outpatient department. The main outcomes were measured with respect to the chronic diseases. Impact of these disease conditions on cardiovascular diseases was studied. The hospitalization due to cardiovascular complications was also be recorded. The changes in quality of life will be closely monitor. Measurements was made in the outcome of the interventions from baseline to the completion of the study evaluated using statistical analysis.

2.5. Data Analysis

All the data collected were analyzed using SAS software. The demographic data and the baseline characteristics were summarized descriptively. Continuous variables were analyzed using unpaired t test and categorical data were analyzed by using chi square test at the baseline as well as by the end of the study at 5% significance. All differences were tested at $p=5$.

3. Results

A total of 220 eligible patients attending outpatient clinic of the department of general medicine of a tertiary care hospital were participated in the study voluntarily after submitting the official informed consent for the study. Among the 220 participants, 110 each were randomly selected in the interventional patient's group and in the usual care patients' group. Four patients from intervention group and six patients from usual care group were discontinued during the study due to personal reasons. Therefore, 106 patients in the interventional group there was 106 patients and the usual group consists of 104 patients accounting to 210 patients successfully participated till the end of the study.

In gender wise accounting, females were more than males in both the groups. There were 61.3% females in the interventional group while 57.7% participants were females in the usual care group.

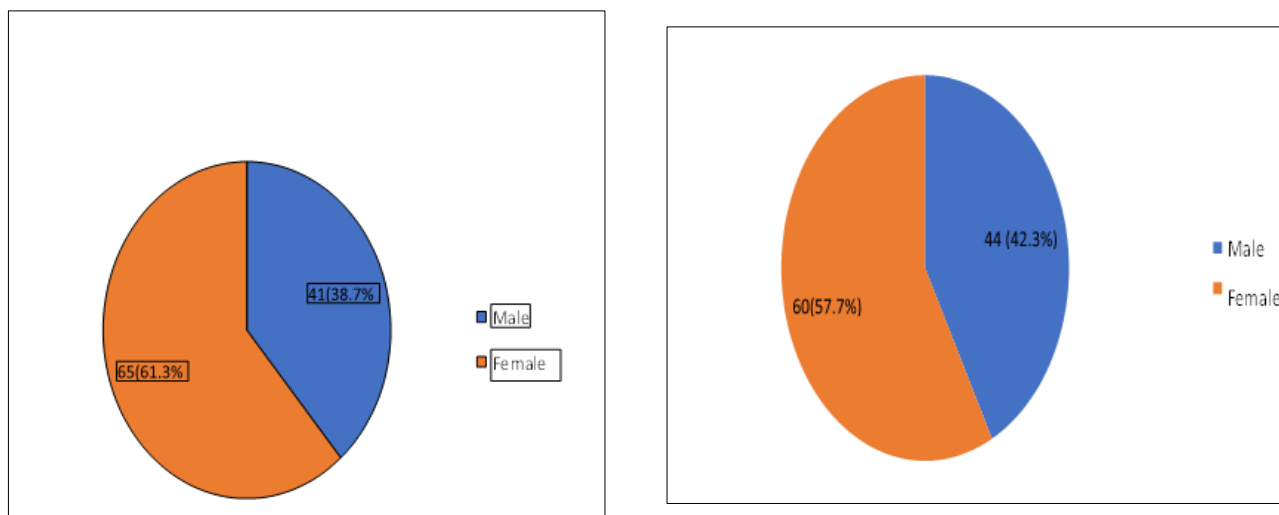


Figure 1 Summary of Gender Interventional group and Usual Care Group

Table 1 Outcomes in key Biomedical Values at Baseline and End of Study Within& Between Groups

Outcome measures	Interventional		Group		Usual care group				Group mean difference
	Baseline Mean +SD (Median)	End of Study Mean +SD (Median)	Mean Difference	p Value	Baseline Mean+SD (Median)	End of study Mean+SD (Median)	Mean Difference	p Value	
Fasting Blood Sugar (mg/dL)	209.62 ± 0.60 (208.0)	182.571 ± 4.91 (186.0)	27.06	0.00	211.831 ± 1.91 (212.0)	200.68 ± 17.19 (198.0)	11.144	0.001	-15.912
HbA1c (%)	8.56 ± 0.69 (8.5)	7.360 ± 0.76 (7.2)	01.196	0.00	8.710 ± 0.74 (8.7)	8.570 ± 0.95 (8.5)	0.136	0.136	-1.061
Systolic BP (mm Hg)	140.86 ± 5.05 (141.0)	125.81 ± 4.51 (126.0)	15.05	0.00	143.00 ± 6.19 (142.0)	134.78 ± 5.57 (134.0)	8.221	0.001	-6.826
Diastolic BP (mm Hg)	91.031 ± 0.84 (91.0)	82.043 ± 0.25 (82.0)	08.99	0.00	91.19 ± 1.96 (91.0)	85.273 ± 0.35 (86.0)	5.923	0.000	-3.067
Total Cholesterol (mg/dL)	209.53 ± 6.17 (209.0)	188.59 ± 8.71 (190.0)	20.93	0.00	209.71 ± 6.81 (209.0)	197.24 ± 15.14 (195.0)	7.904	0.000	-8.463
Triglycerides (mg/dL)	157.58 ± 8.91 (157.0)	138.25 ± 15.22 (137.0)	19.32	0.00	155.04 ± 4.86 (155.0)	154.88 ± 4.91 (155.0)	0.150	0.117	-11.417
LDL-C (mg/dL)	124.516 ± 0.89	111.58 ± 8.95	12.93	0.00	127.86 ± 9.57	121.66 ± 13.56	6.191	0.001	-6.742

	(124.0)	(112.0)			(127.0)	(120.0)			
HDL-C (mg/dL)	42.08 ± 6.29 (41)	48.993 ± 0.70 (49.0)	- 06.92	0.005	39.894 ± 0.89 (40.0)	39.98 ± 4.91 (40.5)	0.087	0.07	6.829
BMI (kg/m ²)	28.753 ± 0.60 (27.0)	24.792 ± 0.99 (25.0)	01.95	0.005	26.46 ±3.14 (27.0)	26.54 ±3.01 (27.0)	0.087	0.06	-2.039
Waist Circumference (cm)	105.76 ± 6.90 (105.0)	102.69 ± 5.28 (101.5)	03.08	0.000	104.68 ±5.32 (104.5)	106.97 ±5.10 (108.0)	2.952	0.00	-5.364

HbA1c= Glycosylated haemoglobin A1c, BP=Blood Pressure, LDL-C Low-Density Cholesterol, HDL- C= High-Density Cholesterol, BMI=Body Mass Index

As shown in Table 1: The fasting blood glucose levels were 208mg/dl for the intervention group and 211mg/dl and the usual care group at the baseline. The values were 198mg/dl for the usual care and 186mg/dl for the interventional group by the end of the study. In both group the reduction was statistically significant. The percentage of patients in interventional group achieved the ADA goals for SBP/DBP (140/90) significantly higher than the usual care group in this study.

At the end of the study the difference in the TC also statistically significant between groups. The difference in triglyceride between Baseline values were significant at the end of study in the usual care group. But at the end of the study, a significant reduction (157mg/dL to 137mg/dL) in the triglyceride was found in the interventional group. The LDL-C values showed a significant decrease in both interventional (124 mg/dL to 112mg/dL and usual care (127mg/dL to 120mg/dL) groups. But significant decrease in the interventional group in comparison to normal care group was observed in the group analysis. The difference HDL-C values (40mg/dL to 40.5mg/dL) in the usual care group were not significantly increased. But it was significant in the intervention group (41mg/dL to 49mg/dL) and between the groups at the end of the study. No reduction in the BMI values in the usual care group (27 kg/m²) during the study period. The difference was found significant in the interventional group (27 to 25) and the difference between the groups also showed significant difference at the end of the study.

3.1. Adherence

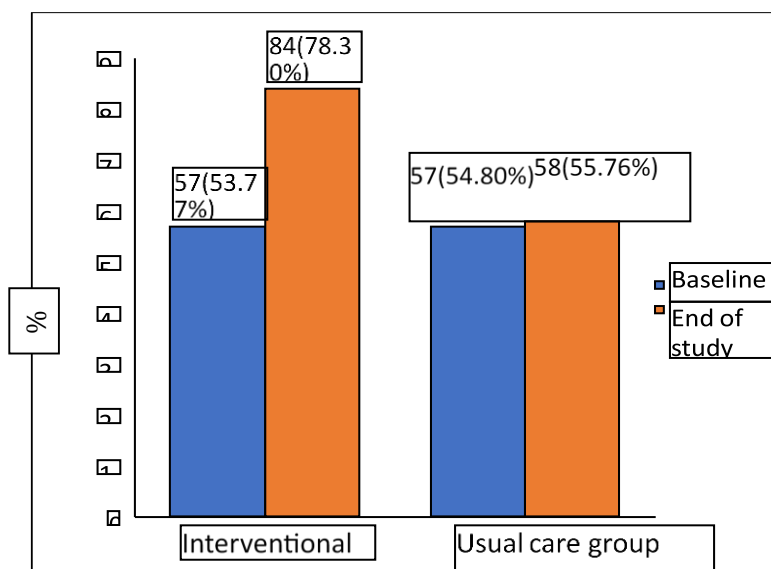


Figure 2 Summary of Adherence in Interventional and Usual care group

At the baseline 53.77% of the interventional group and 54.8% of the normal care group were compliant to the medication orders as per the Morisky Adherence Test. At the end of the study the adherence was increased to 78.3% and 55.76% in the intentional and the normal care group respectively as shown in figure 2.

4. Discussion

In both interventional group (61.3%) and usual care group (57.7%) majority were females. The age group of the patients varied from 41 to 70. Most of them belonged to the age group 56 to 60 indicated the complications of the chronic diseases and associated complications starts after 50 years and before 60 years. The inclusion criteria allowed participants above 18 years, but there was no candidate with all the three chronic disease conditions in the age group less than 41 years. Some patients were available, but they were admitted in other wards like pulmonology regularly for their comorbid conditions and found to be not available for regular interventions and follow up studies. Majority of the participants were educated and therefore the communication regarding the interventions were conveyed properly. The standard of the participants was reflected in the adherence and selfcare management outcomes. Since majority were housewives, the employment rates were estimated as 41% and 31% in the interventional category and in the usual care category respectively.

A study performed showed that three months sustained education resulted to improved adherence in comparison to a single educational session. Patients belonging to the intervention group exhibited greater decrease compared to usual care group in the event of hospital admission. This may be due to the fact that the pharmacist acquired and utilized a pharmaceutical care plan for the patients in the interventional group. This intervention supported in preventing and resolving several problems associated with therapy which resulted in acute health complications such as hypoglycemia and subsequent hospital admissions [21]. Numerous very closely related studies concluded that frequency of hospital admission and diabetic associated complications were minimized by pharmacist mediated patient counseling and self care practice training on awareness. The healthcare costs related to diabetes including the expenses of hospital admissions as a result of various microvascular and macrovascular obstacles in diabetes mellitus patients in 2011 were more than 450 billion USD globally [22].

5. Conclusion

Pharmacist intervention resulted in a significant improvement in HbA1c, fasting blood glucose, blood pressure and lipid profile. This has reduced the occurrence of associated heart diseases and the related hospitalization. During the study the clinical pharmacist was involved in the patient counselling and patient education to optimize the pharmacotherapy. It was achieved through personal face to face interactions, supply of literatures and telephonic follow up. This has created an awareness on the patient not only in the appropriate use of medication but also the life style modifications. The study also made an impact on the usual care group with their personal contacts with the intervention group members. Therefore, improved clinical outcomes were also observed in the usual care group.

Compliance with ethical standards

Disclosure of conflict of interest

There are no conflicts of interest by the researchers to declare.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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