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RESEARCH ARTICLE

Improvement in clinical outcomes of type 2 diabetic patients after pharmacist-physician collaborative care for dyslipidemia

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Abstract

Background and aim: The rising prevalence of type 2diabetes poses a major public health challenge. Studies have clearly shown that long-term outcomes for patients with type 2 diabetes can be improved with careful management aimed at controlling glucose, lipid and blood pressure levels. The aim of the study was to evaluate the impact of pharmacist-physician collaborative care for management of dyslipidemia on QOL of type2 diabetic patients.

Methods: This study included 40 diabetic dyslipidemic patients divided into: 20 who received pharmacist-physician collaborative care for management of dyslipidemia as group A and 20 who received the usual medical care by physician only as group B**.** They were subjected to full clinical history, HbA1c, TC, TG, HDL-c , LDL-c at baseline and after 3 & 6 months also QOL was assessed by SF-36 questionnaire at baseline and after 6 months.

Results : There was a highly significant (p value < 0.001) improvement in levels of HbA1c,TC, TG, HDL-c, and LDL-c in patients in group A after 6 months of the study than compared to group B. There was an increase in number of patients who reached HbA1c goal and lipid profile goal after 6 months of group A than in group B. There was significant difference in QOL scores of questionnaire in group A than in group B after 6 months of the study and also there was significant difference in the scores in group A after 6 months than baseline scores, p-value < 0.05.

Conclusion: clinical pharmacist-physician collaborative care leads to improvement in management of dyslipidemia in diabetic patients than those who receive the usual medical care.

INTRODUCTION

Diabetes mellitus (DM) is a chronic disease that leads to various potential complications. Poor diabetes control can lead to multiple complications, including heart disease, stroke, neuropathy, retinopathy, and nephropathy (Haffner, 2004).

Studies have outlined the benefits of glucose control in regard to reduced occurrence of microvascular events. On the contrary, significant reductions in macrovascular complications have been demonstrated with reduction of low-density lipoprotein (LDL) and blood pressure (BP) in T2DM, irrespective of glucose control**.** For this reason, the American Diabetes Association (ADA) clinical practice guidelines not only focused on aggressive glucose control but also on achieving recommended goals for hypertension and hyperlipidemia. ***(ADA, 2014).***

Dyslipidemia is frequent in people with type 2 diabetes mellitus compared to age and sex matched individuals without diabetes. ***(Umpierre et al., 2011)***

Dyslipidemia is poorly controlled despite the increase in use of lipid lowering agents***(Geller et al., 2007).***The impact of clinical pharmacy services on the screening and treatment of patients with dyslipidemia revealed that collaborative care involving clinical pharmacists had led to improved outcomes in patients with dyslipidemia ***(Gerrald et al., 2010)***.

Diabetes care involves more than glycemic control and it is important to manage other cardiovascular risk factors including obesity, hypertension, and dyslipidemia. Along with dietary and pharmacological interventions, exercise is a key element of diabetes management***(Bantle et al., 2008).***Some researches have indicated that a healthy lifestyle that combines a prudent diet, regular physical activity, maintenance of a healthy weight, moderate alcohol consumption, and no smoking decreases the risk for cardiovascular disease, diabetes, and metabolic syndrome.***(Galimanis et al., 2009).***
Under usual physician care, there was already a lipid-lowering effect with the current dyslipidemic management care taking place in the lipid clinic. However, with the involvement of a clinical pharmacist in addition to usual physician care, this lipid-lowering effect became more pronounced. This observation could be due to the close follow-ups provided by the pharmacist via both telephone calls and review of the patient's drug therapy during their clinic visits.***(Wubben and Vivian, 2008***)
Pharmacists work with patients to evaluate and modify medication regimens, perform adherence counseling, discuss lifestyle modifications, review device and disease state education, and enroll patients in medication assistance programs if needed.***(Mitchell et al., 2012)***
Aim of this work: To investigate the impact of pharmacist-physician collaborative care for management of dyslipidemia on QOL of type 2 diabetic patients and To Compare between the pharmacist-physician managed dyslipidemia group versus the physician only managed group.

Patients and methods:

Aprospective, randomized, open label, controlled pilot study was carried on 40 type 2 diabetic patients having dyslipidemia who were randomized into:
Group A: 20 patients who received pharmacist –physician collaborative care and Group B: 20 patients who received the usual standard care by physician only. Both groups were followed up for 6 months, their age ranged from 40 – 70 years old.

Both groups were subjected to the following:

- Patients' data collection including:
- Patient demographics and Clinical characteristics
- Medication history
- Laboratory data was collected at baseline, after 3 and 6 months :
- Glycated Hemoglobin (HbA1c)
- Complete Lipid Profile including:
  Total Cholesterol (TC)
  Triglycerides (TG)
  High density lipoprotein (HDL-c)
  Low density lipoprotein (LDL-c)
- Quality of life assessment: using SF-36 questionnaire at baseline and after 6 months**.(Walters and Campbell, 2004).**

Pharmaceutical care services provided by clinical pharmacist for group A:
Patients in the intervention group were followed by a clinical pharmacist and their physician. The first visit included collecting all relevant information for managing dyslipidemia and ordering lipid profiles. Patients were educated regarding the role of the clinical pharmacist in their dyslipidemia management, their lipid goals, and factors affecting dyslipidemia management.
Patients were provided with brochures on lifestyle modifications, how to increase HDL-c serum levels and a table about types of food to avoid them and what is allowed. The clinical pharmacist also focused on patient education,

reinforcing compliance, nutrition counseling, discussing barriers to compliance and check if there is any drug interactions between the medications taken by the patient.

Inclusion criteria
Patients aged 35 years or older having type 2 diabetes mellitus with dyslipidemia
Exclusion criteria: Pregnant and breast feeding females, Patients with unexplained elevation in serum transaminases or with other serious liver disease, Patients with a serum creatinine level of more than 2.0 mg/dl and also non compliant patients were excluded.

Statistical analysis: It was performed using software packagefor Social Science (SPSS) version 21. Numerical Data were expressed as mean ± standard deviation.Categorical data was summarized as percentages .The Student's t-test was used to compare between 2 groups for normally distributed numeric variables .Chi-square test or Fisher's exact test was used to compare between the groups with respect to categorical data .A two way repeated measures analysis of variance (ANOVA) was performed to compare the difference between the two groups as well as the change with time for normally distributed variables .Mc Nemar exact test was also performed.Significant level measured according to P value (probability), $P \leq 0.05$ is significant.

Results

There was no significant difference between both groups regarding age (p= 0.307) , gender (p= 1.000) and Body Mass Index (p= 0.056)**.**

There was a highly significant change in HbA1c levels (baseline, after 3 months and after 6 months) in Group A(p<0.001) but there was no change in Group B(p=0.483) (Figure 1)

There was significant improvement in levels of TC, TG, HDL-c, and LDL-c in patients in group A who received pharmacist –physician collaborative care.

Highly significant change was found in TC, TG,HDL-c,LDL-c levels (baseline, after 3 months and after 6 months) in group A(p<0.001) while there was no change among group B.(p=0.054,0.195,0.05,0.081 respectively).

There was a significant change in number of patients who achieved goal of HbA1c and goal of lipid profile in patients of group A along 6 months of the study than those patients in group B.(Table 1)

Analysis of the final QOL scores showed that there was no significant difference between both groups at baseline in all items scores of the questionnaire while all item scales had improved in the test group after the 6 months of the study from the baseline. Also, there was significant improvement in the scores of questionnaire at test group than control group after the 6 months of the study(p-value < 0.05).
(Table 2)

Discussion :

The study was conducted on 40 type 2 diabetic patients having dyslipidemia, patients were randomized into 2 groups: Group A**:** 20 patients who received the pharmaceutical care by the clinical pharmacist in collaboration with the endocrinologist who provided the usual medical care. Group B: 20 patients who received the usual medical care by the endocrinologist.

The results of this study showed a significantly greater percent of patients in the intervention group reached their LDL-C and TC goals compared to the control group. These findings were in accordance with other previously published study. **(Ali et al., 2003).**

At baseline, group A patients who were at TC,TG goals were 25%,10% respectively and after 6 months became 70%,50% respectively (p=0.0039,0.0078 respectively). While, in the group B were 60% at baseline and the percent decreased to 30%,55% respectively after 6 months.(p=0.0703,1.000 respectively) .

Patients achieving LDL-c,HDL-c goals in the group A versus group B was 45% versus 5%,80% versus 15% respectively.(p= 0.024,<0.001 respectively).

Highly significant change was found in TC, TG,HDL-c,LDL-c levels (baseline, after 3 months and after 6 months) in the group A(p<0.001) while there was no change among group B (p=0.054,0.195,0.05,0.081 respectively)
There was a highly significant change in HbA1c levels (baseline, after 3 months and after 6 months) in Group A(p<0.001) but there was no change Group B (p=0.483), also HbA1c goal achieved by 40% of patients in Group A versus 10% of patients in Group B (p-value = 0.0313).

QOL assessment of patients showed that all item scales of SF-36 questionnaire had improved in Group A after the 6 months of the study from the baseline. Also, there was significant improvement in the scores of questionnaire at Group A than Group B after the 6 months of the study. (p-value< 0.05).

In 2011 Chung et al. conducted a 24-month prospective controlled trial at the lipid clinic of a public hospital in Hong Kong to assess the clinical and economic outcomes of a clinical pharmacy service (CPS) in dyslipidemic management. A total of 300 patients were recruited into the study (150 in intervention group and 150 in control group). In the interventiongroup, 58.7% patients achieved LDL-C goals compared with 45.3% in the control group (P <0 .05) and their results agreed with the results of our study.**(Chung et al., 2011)**

Also our results agree with another study in which Patients achieved a significant reduction inHbA1c, BP and lipid parameters measured from baseline over a 6-month period of time. Reduction of HbA1c in the cohort of patientsfollowed by the clinical pharmacist was significant with a median reduction of 2.3%. **(Cripps et al., 2011)**

In 2011, a study was conducted to investigate the effectiveness of introducing clinical pharmacy services in achieving goal lipid profile in dyslipidemic patients in North of Jordan. Results showed that after 6 months 94.5% of intervention group patients and 71.2 % of controlgroup patients reached their goal low density lipoprotein and cholesterol levels (P value <0.001) compared to 24.7 and 28.8% respectively at baseline and the results of these results agree with our results**.(Tahaineh et al., 2011)**

Several studies have been conducted in the general population regarding compliance with nutrition recommendations but few similar studies have been conducted in patients with diabetes. A study was conducted in 2013 by Lim et al. showed that adherence to lifestyle recommendations is associated with improved glycemic control and blood lipid levels in people with known diabetes which is consistent with our study as a part of role of clinical pharmacist. (Lim et al.,2013)

In agreement with our study, Farland et al. showed the effect of a pharmacist-physician collaboration on attainment of diabetes-related measures of control. The HbA1c was reduced by an average of 1.16% (p < 0.0001). The proportion of patients with Hb A1c less than 7% increased from 12.75% at baseline to 36.76% at study conclusion (p = 0.0002) **(Farland et al., 2013).**

Also Kiel and McCord conducted a study to evaluate changes in clinical outcomes for patients enrolled in a pharmacist-coordinated diabetes management program. Significant improvements were observed in Hb A1c and LDL values, the percentage of patients with Hb A1c ≤ 7% increased from 19% at baseline to 50% at follow-up (p < 0.001) and the percentage of patients with LDL values < or =100 mg/dL increased from 30% at baseline to 56% at follow-up (p < 0.001) **(Kieland and McCord, 2005).**

In conclusion, collaborative care between clinical pharmacist and physician lead to reduction in level of HbA1c and levels of lipid profile in diabetic patients than those of usual medical care also pharmacist –physician collaborative care leads to improvement in quality of life of patients as indicated by improvement in scores of SF-36 questionnaire after 6 months of the study than baseline.

Table 1: Comparison between HbA1C, lipid profile, BMI levels at baseline and after 6 months in both groups.

Comparison criteria	Group A	Group B	p-value versus control
Number of patients at HbA1c goal at baseline	2	9	0.039[a*]
% at HbA1c goal at baseline	10.0%	45.0%	
Number of patients at HbA1c goal by 6 months	8	2	0.084[a]
% at HbA1c goal by 6 months	40.0%	10.0%	
p-value versus baseline	0.0313[c*]	0.0391[c*]	
Number of patients at TC goal at baseline	5	12	0.075[b]
% at TC goal at baseline	25.0%	60.0%	
Number of patients at TC goal by 6 months	14	6	0.033[b*]
% at TC goal by 6 months	70.0%	30.0%	
p-value versus baseline	0.0039[c*]	0.0703[c]	
Number of patients at TG goal at baseline	2	12	0.003[b*]
% at TG goal at baseline	10.0%	60.0%	
Number of patients at TG goal by 6 months	10	11	0.752[b]
% at TG goal by 6 months	50.0%	55.0%	
p-value versus baseline	0.0078[c*]	1.000[c]	
Number of patients at HDL-C goal at baseline	2	3	1.000[a]
% at HDL-C goal at baseline	10.0%	15.0%	
Number of patients at HDL-C goal by 6 months	16	3	<0.001[b*]
% at HDL-C goal by 6 months	80.0%	15.0%	
p-value versus baseline	0.0001[c*]	1.000[c]	
Number of patients at LDL-C goal at baseline	0	6	0.06[a]
% at LDL-C goal at baseline	0.0%	30.0%	
Number of patients at LDL-C goal by 6 months	9	1	0.024[b*]
% at LDL-C goal by 6 months	45.0%	5.0%	
p-value versus baseline	0.0039[c*]	0.0625[c]	
Number of patients at BMI goal at baseline	1	1	1.000[a]
% at BMI goal at baseline	5.0%	5.0%	
Number of patients at BMI goal by 6 months	2	2	1.000[a]

% at BMI goal by 6 months	10.0%	10.0%	
p-value versus baseline	1.000[c]	1.000[c]	

Statistical test : a Fisher exact test : p-value > 0.05: non-significant
Statistical test : b chi square test : p-value > 0.05: non-significant
Statistical test : c Mc Nemar exact test: p-value > 0.05: non-significant
*Indicates significance
Group A: test patients received pharmacist –physician collaborative care.
Group B: control patients received usual medical care by physician only.

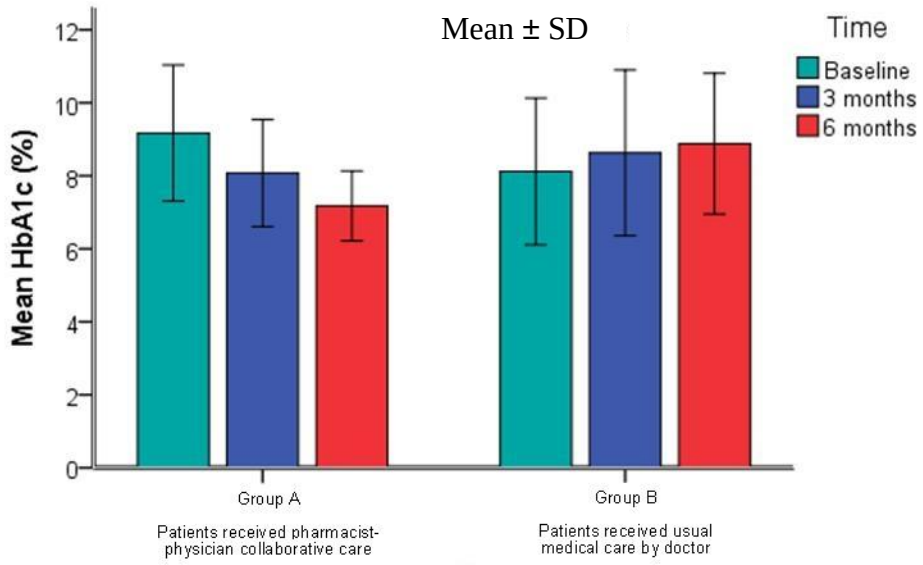
Table 2: Comparison of SF-36 questionnaire scores of patients in the study groups

QOL scores	Group A Mean±SD	Group B Mean ±SD	p-value
Physical functioning: Baseline score After 6 months score	54.5 ± 21.6 72.0 ± 16.6	47.0 ± 19.1 45.3 ± 18.1	0.259# < 0.001*#
p-value	<0.001*##	0.222##	
Role limitations d.t. physical health: Baseline score After 6 months score	30.0 ± 25.1 51.3 ± 20.6	32.5 ± 25.8 25.0 ± 18.1	0.778# <0.001*#
p-value	<0.001*##	0.109##	
Role limitations d.t. emotional problems: Baseline score After 6 months score	31.7 ± 27.5 60.0 ± 25.6	41.7 ± 23.9 38.3 ± 22.4	0.237# 0.014*#
p-value	<0.001*##	0.444##	
Energy/Fatigue: Baseline score After 6 months score	39.5 ± 12.1 50.8 ± 6.9	43.3 ± 11.5 33.8 ± 13.3	0.352# <0.001*#
p-value	0.022*##	0.011*##	
Emotional wellbeing: Baseline score After 6 months score	54.1 ± 11.7 59.2 ± 8.9	54.8 ± 11.2 47.6 ± 8.9	0.870# < 0.001*#
p-value	0.022*##	0.011*##	
Social functioning: Baseline score After 6 months score	53.6 ± 20.9 65.1 ± 13.6	48.3 ± 23.4 40.3 ± 21.2	0.478# < 0.001*#
p-value	0.003*##	0.011*##	
Pain: Baseline score After 6 months score	36.8 ± 14.2 50.4 ± 11.2	36.5 ± 13.5 29.3 ± 12.9	0.880# < 0.001*#
p-value	0.001*##	0.013*##	
general health: Baseline score After 6 months score	38.1 ± 9.3 48.5 ± 9.0	41.0 ± 10.7 36.3 ± 13.5	0.414# 0.012*#

p-value	< 0.001*##	0.128##	

Statistical test: #Mann Whitney test, p-value > 0.05: non-significant
Wilcoxon Signed Ranks test, p-value > 0.05: non-significant
**Indicates significance*
Group A: test patients received pharmacist –physician collaborative care.
Group B: control patients received usual medical care by physician only.

Figure1: HbA1c levels in the studied groups



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