

## Research Article



## The Application of Pharmaceutical Care Program on Patients with Dyslipidemia in Iraqi Community Pharmacy

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### ABSTRACT

Dyslipidemia is an ideal area to demonstrate the value that pharmacists can add to the patient care process through services that can increase patient compliance while improving treatment outcomes and patients quality of life. The aim of this study is to apply a pharmaceutical care program for patients with dyslipidemia within a community pharmacy setting and examine its effects on patients awareness about dyslipidemia, disease control, and quality of life. A randomized, controlled, prospective clinical trial with treatment and follow up periods of 16 weeks. 57 patients who were aged 18 years or older were assigned randomly either to control group (receive usual care) or intervention group (receive pharmaceutical care). Patients were interviewed on a monthly basis where lipid profile was measured. Patients knowledge about the illness and quality of life were assessed. In the intervention group, the knowledge about dyslipidemia score was increased from  $9.68 \pm 2.64$  to  $12.0 \pm 1.87$  which was statistically significant ( $p < 0.001$ ). The comparison of initial and final lipid profile levels between the groups showed significant reduction in total cholesterol with  $p = 0.007$ , LDL with  $p = 0.041$ , triglycerides  $p = 0.023$ , and VLDL with  $p = 0.03$ , but not in HDL levels  $p = 0.222$ . In the intervention group, the reduction in body mass index (BMI) was significant when compared to that in the control group  $p = 0.049$ . Although the percentage increase in quality of life scores of the intervention group was 4 times that of the control group, the improvement was considered statistically not significant. Pharmaceutical care program developed in community pharmacies even for relatively short periods can contribute to: enhance patients' awareness about dyslipidemia and its management and improve clinical parameters of the disease. However, the improvement in quality of life scores did not attain significant level.

**Keywords:** Dyslipidemia; Pharmaceutical care; Quality of life; community pharmacy.

### INTRODUCTION

Dyslipidemia is a state that occurs as a result of abnormalities in the plasma lipids. These abnormalities could be due to elevated plasma total cholesterol (TC), elevated LDL, elevated triglycerides (TG) and reduced HDL levels, occurring either singly or in combinations.<sup>1</sup> Prevalence of dyslipidemia is increasing worldwide.<sup>2-4</sup> Most (80%) lipid disorders are related to diet and lifestyle, although familial disorders (20%) are important as well.<sup>5</sup> Many studies in Arab countries have been conducted: they concluded increased dyslipidemia prevalence and owed this to increased prevalence of both obesity and type 2 diabetes mellitus, which are linked to changes in lifestyle associated with modernization and socioeconomic development.<sup>6-8</sup>

Management of dyslipidemia involves both: Pharmacological treatment<sup>9</sup> and Non-Pharmacological treatment which include life style modifications that aim to educate and reinforce lifestyle activities to reduce cardiovascular disease risk independent of their influence on lipids, these activities include smoking cessation, dietary changes, weight loss (if overweight), and exercise.<sup>10</sup>

Pharmacy practice has changed significantly in the past years from product-oriented to patient-oriented practices which lead to the provision of pharmaceutical care, which is a practice philosophy for pharmacy.<sup>11</sup> The concept deals with the way a patient should receive and use medication

and should receive education on the use of medicines. The concept also deals with responsibilities, medication surveillance, counseling and the evaluation of all the outcomes of care.<sup>12</sup>

Dyslipidemia was considered an ideal area in which to demonstrate the value that pharmacists can add to the patient care process for several reasons:<sup>13</sup>

- Cardiovascular disease (CVD) is considered the most common cause of death in the Arabian Gulf accounting for up to 45% of all mortalities.<sup>14</sup> Risk factors for CVD, like dyslipidemia and smoking, are prevalent in Arab populations.<sup>15</sup>
- Reduction in LDL levels has been shown to produce reductions in coronary artery disease (CAD) events and total mortality.<sup>13</sup>
- Other modifiable CAD risk factors are invariably present in patients with hyperlipidemia, including hypertension, diabetes, obesity, and sedentary lifestyle.<sup>16</sup>
- Community pharmacists are in an excellent position to assist in the management of dyslipidemias. As one of the most accessible health care professionals, community pharmacists are often the first point of contact in the health care system for many patients.<sup>17</sup>

When pharmacists provide direct patient care in outpatient settings there will be significant benefits in achieving hemoglobin A1c, LDL, and blood pressure



targets in addition to reducing adverse drug events.<sup>18</sup> These intermediate health outcome benefits result from enhanced patient knowledge about medications, increased medication adherence, and improved quality of life.<sup>18</sup>

## METHODS

A randomized, controlled, prospective clinical trial with a follow-up period of 16 weeks was carried out at a community pharmacy in Baghdad city, Iraq where 76 patients were included. The inclusion criteria for patients were as follows: both genders, age of 18 years or older, had already been diagnosed and treated for dyslipidemia and who had expressed willingness to abide by the rules of study and provided a written informed consent. While pregnant women, patients with: communication difficulties, nephrotic syndrome, hypersensitivity to any lipid-lowering agent or those who would not be in the geographic area of the study for the entire duration of the study were excluded from participation in our trial.

The Patients engaged in our trial were randomly assigned to either a control or an intervention group. The intervention group received comprehensive pharmaceutical care program while the control group received ordinary (usual counseling) care.

Initial assessment data for both groups were collected through personal interviews and include details about patients' sociodemographics, history of the present illness, information on medications being used, comorbidities and life style habits in addition to measurement of patient's weight and height to calculate Body Mass Index (BMI). For laboratory analysis, patients had been asked to fast for 10-12 hours in order to measure lipid profile (Total cholesterol, LDL, HDL, VLDL, and Triglycerides). Heart Risk Calculator available at <http://www.cvriskcalculator.com/> was used to estimate 10-year risk of heart disease or stroke using the ASCVD algorithm to determine the potency of statin agent needed for each patient. Questionnaires to assess Patients' knowledge about dyslipidemia and quality of life were used at the first and the last session.

### Pharmacist intervention

Patients in both groups were surveyed for 16 weeks during this time period participants attended monthly sessions at the pharmacy, for control group these sessions were of usual care where only laboratory tests were performed to measure lipid profile. This usual care was offered with little or no education of the patients on their diseases and treatment and without empowerment of the patients to be fully involved in the self-management of their illnesses, whereas patients in the intervention group attended a monthly visit that lasted about 15 minutes each and additional on-demand phone calls and visits were performed if required by the patients. A stepwise approach was designed for each patient in order to: set priorities for patient care, assess patient's educational needs, and develop a comprehensive and

achievable pharmaceutical care plan. Patients in the intervention group were also educated on their illness and their medication in a structured manner, including information about dyslipidemia, discussions about the risk of its complications, role of therapy in disease management and treatment goals. Behavioral modifications which involved advice on the following were pursued: Physical exercise, diet, Smoking cessation. Patients were supplied with this information verbally and in a written manner through manuals organized specially for this study. At each visit: lipid profile and body weight were measured for each patient in the intervention group.

### Final measurements and assessments

At the last scheduled visit, patients in both groups received questionnaires to assess their knowledge about dyslipidemia and quality of life. Weight measurement and blood analysis for lipid profile determination were also performed.

### Statistical analysis

SPSS 20.0.0, Minitab 17.1.0, GraphPad Prism 7.0 software package used to make the statistical analysis, p value considered when appropriate to be significant if less than 0.05.

## RESULTS

57 patients completed the follow-up period, 29 patients in the control group and 28 in the intervention group; the mean age was (58.9 ± 9.8). Patients characteristics and details are summarized in Table 1.

Disease characteristics including disease duration, lipid profile and ASCVD scores were assessed for both groups at baseline. The results show that there were significant differences (P value < 0.05) in TC, TG and VLDL values between the groups and the values of these parameters were higher in the intervention group, whereas no significant differences were noticed for the other parameters as shown in Table 2.

At the beginning of the study, there was no significant difference in total knowledge scores. Total scores were (9.68 ± 2.64), (9.48 ± 2.49) in the intervention and the control group respectively. At the end of study, the mean scores were increased significantly in the intervention group and became (12.00 ± 1.87). At the end of the follow-up period, the control group showed no significant difference in total score and in the individual components except in general knowledge which was improved from (0.79 ± 0.77) at baseline to (1.21 ± 0.49) at the end and the change was statistically significant. Table 3 and 4 demonstrate patient's scores regarding different aspects of the disease as well as the total score values.

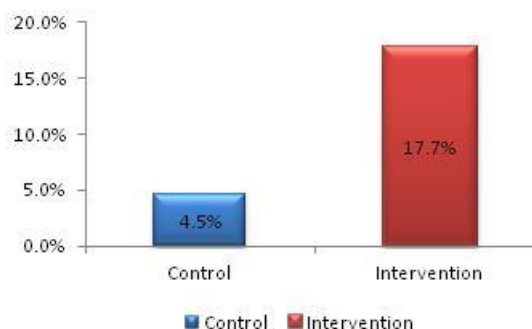
Quality of life was assessed using short form-36 questionnaire (SF-36), and the data obtained are shown in Table 5. It was obvious that the application of our pharmaceutical care program on the intervention group



had improved their mean scores from (50.07 ± 17.38) at baseline to (55.51 ± 17.52) at the end which was statistically significant within the group, however this improvement was not statistically significant when compared to that of the control group (P value > 0.05). The percentage increase in mean quality of life score values at the end of the study was 17.7% in the intervention group vs. 4.5% in the control group as illustrated in Figure 1.

The impact of pharmaceutical care program on different clinical parameters was summarized in Table 6. At baseline, there were significant differences between the groups in the following parameters: total cholesterol, TG and VLDL so adjusted analysis was used to eliminate such confounders. At the end of the study, P of interaction which assessed changes between the 2 groups revealed that all the assessed parameters were significantly improved in the intervention group except HDL values

where no significant difference between the groups was obtained (P value > 0.05). On the other hand, no significant change in any parameter was obtained in the control group at the end of the study.



**Figure 1:** Percentage change in quality of life (from baseline to the end of the study) for each group

**Table 1:** Socio-demographic data for the study subjects

	Control	Intervention	All	P value
<b>Number</b>	29	28	57	-
<b>Age</b>	57.0 ± 10.3	60.8 ± 8.9	58.9 ± 9.8	0.145
<b>BMI</b>	30.0 ± 4.9	30.9 ± 6.1	30.4 ± 5.5	0.532
<b>Sex</b>				
<b>Female</b>	9 (31.0%)	13 (46.4%)	22 (38.6%)	0.233
<b>Male</b>	20 (69.0%)	15 (53.6%)	35 (61.4%)	
<b>Level of education</b>				
<b>Primary</b>	8 (27.6%)	10 (35.7%)	18 (31.6%)	0.626
<b>Secondary</b>	7 (24.1%)	8 (28.6%)	15 (26.3%)	
<b>College</b>	14 (48.3%)	10 (35.7%)	24 (42.1%)	
<b>Smoking</b>				
<b>Smoker</b>	3 (10.34%)	1 (3.57%)	4 (7.01%)	0.611
<b>Not</b>	26 (89.65%)	27 (96.43%)	53 (92.98%)	
Data presented as mean ± SD for age and BMI Sex, level of education and smoking presented as number (percentage)				

**Table 2:** Duration of disease, lipid profile and ASCVD score for the study subjects at baseline

	Control	Intervention	All	P value
<b>Number</b>	29	28	57	-
<b>Disease duration</b>	2 (1 – 5.5)	4.5 (2.0 – 10.0)	3 (1 – 7)	0.060
<b>LDL</b>	103.8 ± 32.2	119.2 ± 37.6	111.4 ± 35.5	0.102
<b>Total Cholesterol</b>	181.3 ± 33.5	207.0 ± 44.8	193.9 ± 41.2	0.017 [S.]
<b>Triglyceride</b>	141.4 ± 35.1	201.8 ± 115.7	171.1 ± 89.4	0.013 [S.]
<b>VLDL</b>	28.9 ± 7.4	40.4 ± 23.1	34.5 ± 17.9	0.018 [S.]
<b>HDL</b>	49.0 ± 5.5	47.1 ± 7.9	48.1 ± 6.8	0.313
<b>ASCVD score</b>	13.1 (5.9 – 33.9)	21.1 (9.7 – 27.7)	18.1 (8.5 – 28.4)	0.429
Lipids panel presented as mean ± SD ASCVD score and disease duration presented as median 50% (interquartile range, 25% to 75%)				

**Table 3:** Assessment of patient's knowledge about dyslipidemia at baseline

	Control	Intervention	All	P value
Number	29	28	57	-
General Knowledge	0.79 ± 0.77	1.29 ± 0.90	1.04 ± 0.87	0.030 [S.]
Habit	1.69 ± 0.76	1.93 ± 0.60	1.81 ± 0.69	0.194
Diet	2.79 ± 0.68	2.82 ± 1.06	2.81 ± 0.88	0.905
Pharmacotherapy	2.10 ± 0.86	1.89 ± 0.79	2.00 ± 0.82	0.339
Complications	2.10 ± 1.42	1.75 ± 0.59	1.93 ± 1.10	0.228
Total score	9.48 ± 2.49	9.68 ± 2.64	9.58 ± 2.54	0.774

**Table 4:** Assessment of patient's knowledge about dyslipidemia at the end of the study

	Control	Intervention	All	P value
Number	29	28	57	-
General Knowledge	1.21 ± 0.49	2.14 ± 0.59	1.67 ± 0.72	<0.001
Habit	1.72 ± 0.65	2.18 ± 0.39	1.95 ± 0.58	0.002
Diet	3.03 ± 0.94	3.43 ± 0.88	3.23 ± 0.93	0.109
Pharmacotherapy	2.03 ± 0.63	2.29 ± 0.71	2.16 ± 0.68	0.164
Complications	1.93 ± 0.59	1.96 ± 0.51	1.95 ± 0.55	0.821
Total score	9.93 ± 2.03	12.00 ± 1.87	10.95 ± 2.20	<0.001

**Table 5:** Assessment of patient's quality of life

	Control	Intervention	All	P value
Number	29	28	57	-
Baseline	49.91 ± 16.22	50.07 ± 17.38	49.99 ± 16.65	0.971
Final	52.18 ± 18.26	58.95 ± 16.34	55.51 ± 17.52	0.146

Data presented as mean ± SD

**Table 6:** Comparison between the intervention and control groups in lipid panel and BMI

Variables	Period	Control	Intervention	All	P value	P of interaction
Number		29	28	57	-	
LDL	Baseline	103.79 ± 32.17	119.57 ± 37.21	111.54 ± 35.33	0.102	0.041
	16 weeks	94.48 ± 25.29	90.89 ± 29.98	92.72 ± 27.50	0.041	
Total Cholesterol	Baseline	177.24 ± 41.23	207.36 ± 44.37	192.04 ± 45.05	0.017	0.007
	16 weeks	173.38 ± 23.61	170.43 ± 43.91	171.93 ± 34.79	0.007	
Triglycerides	Baseline	141.38 ± 35.07	201.25 ± 116.15	170.79 ± 89.62	0.013	0.023
	16 weeks	162.59 ± 61.71	161.79 ± 124.00	162.19 ± 96.53	0.023	
VLDL	Baseline	28.90 ± 7.44	40.25 ± 23.23	34.47 ± 17.91	0.018	0.023
	16 weeks	32.52 ± 12.34	32.36 ± 24.80	32.44 ± 19.31	0.030	
HDL	Baseline	48.97 ± 5.47	47.21 ± 7.92	48.11 ± 6.78	0.313	0.222
	16 weeks	46.07 ± 4.54	47.18 ± 4.97	46.61 ± 4.75	0.222	
BMI	Baseline	29.96 ± 4.88	30.90 ± 6.12	30.43 ± 5.49	0.532	0.049
	16 weeks	30.30 ± 4.79	30.33 ± 5.52	30.31 ± 5.11	0.049	

Data presented as mean ± SD

## DISCUSSION

To our knowledge, this is the first randomized, controlled, clinical trial that examines the impacts pharmacists can have on patients with dyslipidemia within community pharmacy and our results indicate that pharmacists can have a positive contribution in dyslipidemia management and control. The present study showed that oral and written information that had been delivered to patients in the intervention group resulted in (24%) increase in total knowledge score. This significant improvement in patients scores was clearly attributed to the intensive education of intervention patients at each visit during the study period. The usefulness of pharmaceutical care programs in improving patients knowledge about dyslipidemia and its complications was clearly stated by many researchers. Nola K. M. et al. had applied a pharmaceutical care program on (51) patients with hyperlipidemia and after follow-up for 6 months, hyperlipidemia knowledge scores had improved significantly.<sup>19</sup> Similarly, In 2009 and after 32 weeks of follow-up period, Lorenzo A. Villa and his group found significant improvement in patient's knowledge about dyslipidemia ( $p < 0.0001$ ).<sup>20</sup>

Throughout the study period, patients' QOL scores were low. This finding was similar to that reported by Lalonde et al. in 2001 who attributed his results to rigid dietary prescriptions, medication side effects, the need for regular medical care, and the adverse psychological responses that may be caused by the diagnosis and treatment of dyslipidemia.<sup>21</sup> At the end of the study, the (17.7 %) increment in QOL scores achieved by the intervention group was not significant when compared to that of the control group. This may be explained by the fact that dyslipidemia is mostly asymptomatic illness; therefore the modifications that we made in lifestyle and medications may not bear instant feedback about the disease state and its control to the patient. Our finding was different from that obtained by Paulos et al. who reported significant improvement ( P value = 0.002 ) in QOL of 42 hyperlipidemic patients in Chile, however, his finding was not supported by any numbers.<sup>22</sup> The present study was a controlled clinical trial performed on 57 patients and total QOL scores were calculated, while Shibley and Pugh study was a non-comparative clinical trial where 24 hyperlipidemic patients had been involved.<sup>23</sup> The investigators found significant improvements in 3 sections of the SF-36 scale ( role-physical, general health, and vitality) after pharmacist intervention without giving total score values, so this may be the reason behind dissimilarity between our results and theirs. In 2008, a systematic review and meta-analysis in hyperlipidemia management were performed by Machado M. et al, and QOL was considered a possibly sensitive outcome to pharmacists' intervention.<sup>24</sup>

In the current study, a pharmaceutical care program showed favorable results in the control of dyslipidemia, as determined by the significant decrease in the average levels of total cholesterol, LDL-C, VLDL, and TG. These

favorable results can be attributed to changes in pharmacotherapy that had been made to suit each patient's need as well as the provision of education on pharmacological and non-pharmacological treatments.

Our results were similar to what had been confirmed by many other researchers about the role of the pharmacists and their contribution towards patient care through various activities that had made effective improvements in the levels of plasma lipids such as those reported by Chan et al. who performed a prospective, randomized, controlled trial to investigate the impact of pharmacist care program on cardiac risk in patients with type 2 diabetes, and they concluded that pharmacist's managed diabetes care was effective in reducing CHD risk and improving LDL-C level.<sup>25</sup> The impact achieved in the present study was comparable to that obtained by the IMPROVE Study which included 437 dyslipidemic patients and lasted for 12 months, pharmacist's responsibility was in making appropriate adjustments in the patients' drug regimens to improve care and disease control and to identify and prevent drug-related problems and as a result total cholesterol and LDL-C levels were decreased significantly.<sup>26</sup>

Consistent with the findings from earlier research,<sup>27-29</sup> the pharmaceutical care intervention in the present study did not have a positive impact on HDL-C levels. This can be justified by the fact that changes in this parameter are strongly related to lifestyle habits (diet, exercise) which may need longer time to have an obvious effect. Moreover, the baseline HDL-C values were near optimal level ( $48.11 \pm 6.78$ ) making it more difficult for our intervention to have an impact within the timeframe of our study. The mean BMI at the beginning of the study was (30.4) indicating that our patients were obese (BMI > 30), this finding was consistent with the fact that dyslipidemia has been recognized to be strongly associated with overweight and obesity and its co-morbid conditions.<sup>30</sup> Dietary habits of our studied patients which include consumption of high amounts of rice, bread, and food rich in fat beside little (if any) regular physical activity may contribute to their obesity.

After sixteen weeks of follow-up with the intervention group to monitor their weights, educate them about healthy dietary habits, encourage them to be more physically active and reinforce them to lose weight, there was a significant decrease in their BMI when compared to the corresponding value in the control group, however, this reduction was not significant when compared with the mean BMI value in the intervention group at the time of enrollment. The possible explanation for our finding is that the time course of the study was relatively short and insufficient to make notable changes in lifestyle habits of the patients involved, this explanation is supported by results reported by Jaraba. Set al. in 2012 when they applied their pharmaceutical care program on 156 patients with follow-up period for 6 months and found that the change in BMI between the groups was not



significant,<sup>31</sup> while other researchers who performed their programs over 12 months or longer as Al Mazroui N. R et al.,<sup>32</sup> Clifford, R. M et al.<sup>33</sup> and Neto P. R et al.<sup>34</sup> had reported significant changes in BMI at the end of their studies.

### Limitations

Interpretation of this study should be considered in the context of number limitations. First, this study was conducted by only one pharmacist in one pharmacy. Second, the duration of the study was also limited. A longer trial may achieve more lowering in clinical parameter values. So, a larger, longer, multi-center randomized, controlled trial is needed to corroborate results of this study.

### CONCLUSIONS

In conclusion, this study suggests that a pharmaceutical care program may provide important contributions to reduce TC, LDL, TG and VLDL levels providing better disease control beside enhancing patients knowledge regarding their medical condition. Moreover, the application of such program with patient-centred actions could be an important strategy that raise the quality of care provided by pharmacists in the community setting.

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