



Pharmaceutical Care Program for Dyslipidemic Patients at Three Primary Health Care Centers: Impacts and Outcomes

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SUMMARY. A pharmaceutical care program for dyslipidemic patients was designed, implemented, and assessed. The study was conducted during 32 weeks, at three Primary Health Care Centers. One hundred and forty two patients were selected. These patients were randomly assigned to intervention or control groups. Intervention group patients received care twice a month and were surveyed to assess their knowledge about their illness and medications, adherence to drug therapy, and quality of life. Possible drug related problems (DRP) were identified, the most frequent being that medication was not taken according to medical indication. Total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides were measured every two months, with results showing significant improvements in the intervention group's total cholesterol, LDL-cholesterol ($p < 0.0001$) and triglycerides ($p = 0.009$), knowledge of the illness ($p < 0.0001$), adherence to pharmacological treatment ($p < 0.0001$), and quality of life ($p < 0.0001$). Pharmaceutical care prevents and solves drug-related problems and improves patients' clinical parameters, adherence to medical treatment and quality of life.

INTRODUCTION

Traditionally, doctors have been responsible for their patients' pharmacological treatment. However, the evolution of health care systems around the world and the varied lifestyles of consumers have made it extremely difficult, if not impossible for them, to undertake on their own, the increasingly complex task of prescribing medication. Thus, a new role in the pharmacy profession has arisen, the concept of pharmaceutical care (PC)¹. In 1993, the WHO held a congress in Tokyo where pharmaceutical care was defined as the outcome of the professional exercise of pharmacy where patients are the ones who mainly benefit from the pharmacist's actions². A drug-related problem (DRP) refers to any undesired event a patient may suffer, where pharmacological treatment is involved or is suspected to be involved, and that may interfere with the patient's evolution³. In this context, pharmacists providing PC use the term

problem to refer to any event related with medications, which can be detected, treated or prevented. DRPs are classified into four categories: 1) indication, 2) effectiveness, 3) safety, and 4) adherence; and, at the same time, into seven types. The clinical goal when preventing and solving DRPs is to avoid or decrease the morbidity-mortality related with medications and their economic consequences⁴ (Table 1).

A frequent clinical problem in Primary Health Care is dyslipidemia, with around 20 percent of the adult population in Chile affected by the disease. Dyslipidemia is defined as a set of metabolic disorders reflected by abnormal plasma concentrations of cholesterol and/or triglycerides that are considered serious cardiovascular risk factors, causing atherosclerosis and myocardial infarction, among others⁵. The impact of atherosclerotic cardiovascular disease has a special importance in epidemiological transition areas, like Chile. Among the associated risk fac-

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DRP		Possible Causes
DRP 1	Unnecessary Pharmacotherapy	No valid health indication exists Patient in similar therapy Therapy is for treating an ARD Non-pharmacological therapy is more appropriate Physical dependence /addiction
DRP 2	Necessary Pharmacotherapy	Health condition needs pharmacotherapy Requires therapy of synergism Requires prophylactic therapy
DRP 3	Wrong drug	More effective drug is available Health condition intractable to a medication Patient's contraindication for a drug Inadequate dosage method Drug interaction
DRP 4	Sub-therapeutic dose	Incorrect dose Administration frequency Inadequate treatment duration Drug administration is incorrect
DRP 5	Adverse Reaction to Drug (ARD)	Drug use places the patient at risk Allergic reaction Not desired effect Drug interaction Wrong drug administration Dose change too fast
DRP 6	Very high dose	Wrong dose Inadequate administration frequency Inadequate treatment duration
DRP 7	Drug not used as prescript	Product not available Product too expensive Patient unable to administer the drug Patient does not understand directions Patient prefers not using the drug

Table 1. Drug-related problems (DRP).

tors, dyslipidemia is one of the most significant etiopathogenic elements ⁶. Epidemiological studies have shown that as cholesterol levels increase in a population, the incidence of death and disability associated with coronary heart diseases (CHD) increases too. The risk of CHD in patients with cholesterol levels above 300 mg/dl is 3-4 times higher than in those with levels below 200 mg/dl ⁵. In recent years, cholesterol levels have increased steadily in the Chilean population, with around half of adults having total cholesterol levels above 200 mg/dl ⁷. The study of the lipid profile includes the measurement of total cholesterol (TC) in the plasma, cholesterol attached to low-density lipoproteins (LDL), cholesterol attached to high-density lipoproteins (HDL), and triglycerides (TG). The relationship between high levels of LDL and a higher risk of coronary disease is

well documented ^{8,9}. To address both demographic and epidemiological changes observed in Chile, the implementation of pharmaceutical care for individuals who use medications recurrently was attempted. Patients who suffer a non-communicable chronic illness, like dyslipidemia, have usually failed to adhere to their drug therapy programs since treatments are recurrent in their nature and, in many cases, cover several medications. Another critical factor for these failures is habits or lifestyle connected with their illnesses, which further interfere with their adherence to treatment. These patients are most in need for PC programs, being the ones who obtain the most benefit from a pharmacist's intervention.

MATERIALS AND METHODS

A 32-week study was carried out in a group

of patients who had been diagnosed with dyslipidemia and who were included in the program for chronic patients at three Primary Health Care centers in the city of Valdivia, Chile. The pre-selection process was made studying patient medical histories, investigating the pharmacies in those centers, and visiting patients' homes.

Patients meeting the inclusion criteria — with a diagnosis of dyslipidemia, with the same pharmacological treatment, and older than 18 years and accepting to participate in the program— signed an informed consent form, and then were randomly divided into an intervention group and a control group. The intervention group received pharmaceutical care, while the control group only participated in the measuring of the assessed parameters.

Data were collected through personal interviews and revision of each patient's medical histories, and personal information such as patient weight, height, life habits, and drug consumption was collected. The lipid profile was measured every two months in both groups; each patient abstained from food for twelve hours before the samples were taken. The samples were processed at the clinical biochemistry laboratory of the Facultad de Ciencias of the Universidad Austral de Chile. Desirable values for the lipid profile were based on recommendations by the Chilean Ministry of Health (MINSAL): total cholesterol <200mg/dl; triglycerides <200 mg/dl; HDL-cholesterol >35 mg/dl; LDL-cholesterol <130 mg/dl.

Data to assess how much patients know about their illness, their pharmacological treatment, and their life habits were collected through surveys, which were conducted during the first and the last session with both groups of patients. Patients' knowledge on different subjects was classified as: Bad: 0-5; Regular 6-10; Good: 11-15, and Very Good: 16-20 points.

To measure patient's quality of life, the Health Survey Short Form-36 was used. This survey covers 36 subjects that research 8 health condition categories: physical function, social function, emotional role, mental health, vitality, pain, and overall health perception, and establishes a graduation for responses to each subject ranging from 0 to 100. The subjects and extension of the survey provide scores that are directly proportional to the quality of life of each patient.

An analog visual scale was used to measure compliance with the pharmacological treatment.

The scale was applied to both groups of patients during all sessions, and each patient self-evaluated with a grade between one and seven, the latter being the highest grade for treatment adherence.

The intervention group attended two monthly sessions lasting thirty minutes each, in which patients received instruction on their illnesses, and pharmacological and non-pharmacological treatment. These sessions were conducted by three pharmacists, one at each center, who used audiovisual aids and flashcards. The pharmacists were previously trained in communication techniques and survey administration.

The statistical analysis of the variables being researched was carried out with the software for epidemiological analysis of tabulated data EPI-DAT 3.1. Data were expressed as means \pm SD. Parametric tests to analyze differences between the means of both groups and the Student's *t*-distribution with a significance level of $p < 0.05$ were used.

RESULTS

A total of 142 patients participated in the study; 85 (59.9%) of them belonged to the intervention group, which were provided with pharmaceutical care. The control group was not provided with any intervention at all. At the beginning of the research no differences existed between the assessed parameters of both groups. During the 32-week research, four patients belonging to the intervention group abandoned the study. In this group, the patient average age was 54 ± 9 years, and 54 ± 7 years for the control group. In both groups, females were predominant, with 64 and 47 individuals respectively.

From the medication armamentarium, 96.5 percent of patients included in the study chose as their only hypolipidemic agent, an HMG-CoA reductase inhibitor (lovastatin), and 3.5 percent of them a fibric acid derivative (gemfibrozil).

Comparing the clinical parameters at the beginning and the end of the intervention we can see the results in Table 2.

When comparing total cholesterol mean values between the beginning and the end of the research in both groups, we see that in the intervention group these values decreased by 18 percent, which corresponds to 43 ± 32 mg/dl, but in the control group, they increased by 9 percent. At the end of the research, 77 (95.1%) intervened patients had lower total cholesterol values, and 4 (4.9%) had higher values; in the

	Intervention Group		Control Group		P- value
	Initial Value (mg/dL) ± SD	Final Value (mg/dL) ± SD	Initial Value (mg/dL) ± SD	Final Value (mg/dL) ± SD	
Total cholesterol	233 ± 32	190 ± 26 **	251 ± 43	230 ± 40 **	0,0001
LDL-cholesterol	141 ± 25	109 ± 27 **	145 ± 39	136 ± 42 **	0,0001
HDL-cholesterol	40 ± 7	48 ± 9	39 ± 9	44 ± 13	> 0,05
Tryglicerides	223 ± 99	166 ± 82 **	233 ± 160	253 ± 199 **	0,009

Table 2. Values of cholesterol and triglycerides (mg/dL) in patients participating, separated by group.

control group, 12 (21.1%) patients had lower cholesterol levels and 45 (78.9%) had higher levels. Concerning LDL-cholesterol, when comparing the mean values between the beginning and the end of the research in both groups, we observe that in the intervention group, their LDL-cholesterol values decreased by 23 percent, which corresponds to 32 ± 14 mg/dl. Meanwhile in the intervention group, 73 (90%) patients had an increase in these levels, and only 8 (10%) had a reduction, it is to note that in the control group, 12 patients (21%) had a reduction in their LDL levels, and 45 (79%) patients had higher levels in both groups, their values of HDL-cholesterol increased at the end of the intervention: in the intervention group, 46 (57%) patients had higher levels, and 35 (43%) had lower levels. In the control group, 16 (28%) patients had an increase levels, and 41 (72%) had a reduction. When comparing mean values of triglycerides between the beginning and the end of the research in both groups, in the intervention group, they decreased by 25 percent, which corresponds to 57 ± 99 mg/dl, in the control group instead, they increased by 8 percent. In the intervention group, 64 (80%) patients had an increase in this parameter; in the control group, 24 (42.1%) patients had a reduction.

During the pharmacotherapeutic follow-up and later study of each patient's situation, 126 (91%) of 138 patients who finished the program showed more than one DRP. A total of 248 DRPs were detected, according to the Cipolle and Strand classification. The most frequent DRP in the intervention group was number seven, corresponding to a medication not taken as prescribed, which occurred 96 times. In the control group, the most frequent DRP was also number seven, occurring 72 times. The second most frequent problem was DRP 4, occurring 55 times in the intervention group and connected with wrong or sub-therapeutic dosage and failures in drug frequency and administration. From the total number of detected DRPs (124) in the

intervention group, 82 percent was solved. In the control group, a solution was reached in 14 percent out of a total number of 74 DRPs. To be able to solve these problems, it was necessary to make pharmaceutical interventions, which were carried out through pharmacist-patient and pharmacist-physician relationships. Interventions to prevent and solve drug related problems were mostly centered on patients (91%), which correspond to 221 interventions. These were generally well accepted, and positive results for such problems were obtained.

Knowledge about illness and medications increased in all intervention patients during the course of the study, with their knowledge rated as "very good," whereas patient knowledge in the control group fell into various classifications, without a marked difference among the knowledge levels ($p < 0.0001$). Regarding patients' diet habits, in the intervention group, 95 % started a balanced diet after receiving instruction; they decreased their consumption of food products rich in saturated fats and increased their consumption of lean meats, fruits and vegetables. Changes in this behavior were not observed in the control group and only 42% ate low-saturated fat foods ($p < 0.0001$).

Regarding healthy life habits, at the beginning of research, 11 (14%) patients in the intervention group were smokers, and 4 (5%) of them quit during the course of the study. The intervention group showed an improvement concerning involvement in physical activities, and the number of patients who exercised daily rose from 6 (7%) to 28 (35%).

The results of the survey SF-36, indicated that 69 (85%) intervention patients improved their quality of life significantly ($p < 0.0001$). The physical and mental health of the intervention group improved over the course of the study to reach 77% and 79% respectively. Physical health improved by 35% in the control group and mental health became worse by 54% in the same group.

DISCUSSION

In this study reductions in the value of some clinical variables were observed. Significant improvements in total cholesterol, LDL cholesterol, and triglycerides were observed in the intervention group as compared with the control group, justifying the effectiveness of the pharmaceutical intervention. Pharmaceutical care helped to improve blood lipid values and thus decreased the risk of cardiovascular disease in the intervention group of patients. Other studies on community pharmacy conducted in Chile and in USA also identify a beneficial effect of pharmaceutical intervention on dyslipidemic patients¹⁰⁻¹². There is a direct relationship between the knowledge of the illness and medical treatment and adherence^{13,14}. In the intervention group the significant improvement in assessment by the patient when using the visual analogue scale is also associated with an improvement in the assessed clinical parameters due to the continuous support provided to these patients in each session concerning their therapy adherence. Studies indicate that the knowledge of some patients increases after participating in an instruction-information session. In our research, patients were given written information through educational brochures, apart from the oral support they received. The study by Vargas and his colleagues also showed positive results, with an increase in patient commitment and treatment adherence when the patient was given verbal instructional and individualized messages, and, as far as possible, written reinforcement¹⁵.

Patient knowledge about the illness and medications was better in the intervention group. The patients in this group were given personalized instruction and at every session their questions were answered. Good communication is critical for proper adherence; therefore, a planned instruction for the patient and his or her family members is required¹⁶.

Changes in non-healthy life habits reduce the risk of acquiring a cardiovascular disease. To change one's lifestyle is not an easy task, but is more easily accomplished following a prescribed drug treatment regimen. Therefore, apart from providing appropriate education about the therapy, a change in the patient's attitude should be sought. With regard to the assessment of healthy life habits, we should point out that it is difficult to change them in an eight-month period. It is easier to acquire a good habit, like exercising, than breaking a bad habit like smoking and alcohol consumption; there were significant

differences in the results when comparing physical activities between both groups^{16,17}.

Eating guidelines help people to meet their nutritional objectives preventing them from acquiring diet-related chronic illnesses. The purpose of this information is to guide patients so that they can choose the healthiest foods and at the same time abstain from consuming foods that possess health risks. All intervention patients succeeded in adopting a well-balanced diet, establishing a significant difference with respect to the control group. These results were obtained thanks to the education provided, concerning the type of food and frequency of consumption, nutrition information labels and the understanding of key words.

A high number of patients experienced drug related problems, with most patients presenting more than one. DRPs are the factors that contribute the most to mortality and morbidity associated with chronic illnesses; they could be modified through simple interventions and are easily assessed among populations. The continuous recording of medications used by patients, changes in their pharmacotherapy, and the assessment of clinical parameters related with dyslipidemia made it possible to identify potential or actual drug-related problems; therefore, it was possible to take measures^{18,19}. The most frequent problem encountered was DRP 7, which refers to the improper use of the prescribed medication. Forgetting to take medication properly is one of the most common reasons for non-adherence to pharmacological therapy, especially with hypolipidemic agents. It is common for patients not use drugs as prescribed for several reasons. One reason is that a patient may feel that the medication has caused or will cause some adverse effect or discomfort; from the patient's point of view, this makes the decision of interrupting the medication seems a logical action. All patients have their own views about health care, knowledge of their illnesses, drug use, expectancies, and concerns. They have negative experiences, fears, cultural influences, habits, or character traits that play an important, often dramatic role, in everyday decision-making. The second most frequent problem encountered was sub-therapeutic dose, DRP 4. According to Porter's study, between 20-71% of those patients do not follow prescribed medical guidelines²⁰.

The high percentage of DRPs solved in this study through pharmacist-patient and patient-physician interactions is coincident with the re-

sults obtained from the Pharmaceutical Care programs implemented in other countries, where DRP solving percentage reaches figures close to 90%. These results show that the implementation of Pharmaceutical Care should be considered essential for supplementing the treatment.

Good communication between pharmacist and patient is a key factor for improving treatment adherence ²¹. To be able to solve DRPs it is necessary to improve communication among pharmacist, patient and physician. These interventions are essential to stimulate and instruct patients on their pharmacological and non pharmacological treatments. Moreover, communication is also promoted among the members of the medical team who take care of the patients ²². Pharmaceutical care may be understood as the responsible provision of pharmacological

treatment with the purpose of obtaining concrete results that improve patients' quality of life. In this sense, the results of health condition survey SF-36 show a favorable change in this aspect in the intervention group. This proves that a pharmaceutical intervention program improves patients' quality of life ²³⁻²⁵.

CONCLUSION

This study showed that a pharmaceutical care program developed at primary health care centers helped to improve values of lipid profiles, cardiovascular risk factors, and quality of life in intervention patients. Pharmacists, as part of multidisciplinary teams, can have a dramatic impact when dealing with patients who need to fully understand their pharmacotherapy. It may be stated that it is possible and necessary to implement these programs in primary health care.

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