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Effect of pharmaceutical care intervention on blood pressure of elderly outpatients with hypertension

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Uniterms

- Hypertension
- Elderly
- Pharmaceutical Care

The purpose of this study was to evaluate the effect of pharmacist intervention on the prevention and solution of drug therapyproblems (DTP), Body Mass Index (BMI), and blood pressure control in elderly outpatients with hypertension. The instruments were applied to 30 elderly outpatients assisted at the pharmacy of a primary health care unit in Ribeirão Preto (SP), Brazil. The group of patients received follow-up during a period of 12 months. It was observed that Pharmaceutical Care intervention optimized the medication use; reduced symptoms caused by drug therapy and improved the elderly patients' health conditions. The Pharmaceutical Care intervention influenced the care given to elderly people as well as the achievement of positive health outcomes. After this study, the researcher gave training about practice of Pharmaceutical Care to 38 dispensing pharmacists from the Public Health-System of Ribeirão Preto. Nowadays, these pharmacists are perpetuating the practice introduced in the region.

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INTRODUCTION

Hypertension is a common chronic health condition among older people and is the most important risk factor for all subtypes of vascular disease and death. According WHO (2003), the hypertension afflicts approximately 600 million people around the world, including the majority of elderly, and imposes enormous burdens through associated cardiovascular diseases. In Brazil, cardiovascular diseases remain the leading cause of death reaching 32% of all causes of mortality (Muxfeldt *et al.*, 2004).

Although the benefits of antihypertensive medications are clearly established, only 60% of hypertensive patients are currently treated, and only 34%

are adequately controlled (Goodley *et al.*, 2003). Moreover, the high incidence of drug-therapy problems (DTP) in elderly patients with hypertension has been reported in literature (Rollason, Vogt, 2003; Garção, Cabrita, 2002).

The economic impact of DTP is enormous in USA, totaling US\$104 billions annually and rivaling the cost of diseases common in the older population (Erwin, 1999). These preventable negative patient outcomes and their associated costs have caught the attention of patients, healthcare professionals, and governmental agencies (Kohn *et al.*, 1999)

In Brazil, most elderly patients with hypertension are using prescribed drugs by the Public Health Care System (SUS) to control the disease. Despite such therapy, most of patients have inadequate blood pressure (BP) control, with increased risk of associated cardiovascular morbidity and mortality (Zaitune *et al.*, 2006; Muxfeldt *et al.*, 2004). This uncontrolled hypertension is commonly associated with non-adherence to drug therapy and/or lack of access to health care (Chobanian, 2001). Therefore, changes in SUS are necessary to improve the care of these patients.

In recent years, the shift of health care toward an ambulatory has increased the demand for quality outpatient clinical pharmacy services. Pharmacists have been encouraged to provide Pharmaceutical Care to identify, prevent, and resolve DTP and mediate dialogue with patients and physicians, monitoring and alerting them to uncontrolled BP values and optimizing the pharmacotherapy (Lyra Jr. *et al.*, 2007; Lyra Jr. *et al.*, 2006). Pharmaceutical care has been defined as the responsible provision of drug therapy for the purpose of achieving defined outcomes that improve a patient's quality of life (Hepler, Strand, 1990).

In other countries, previous research have shown that pharmacist involvement in the ambulatorial care of hypertensive patients improves BP control (Lee *et al.*, 2006; Zillich *et al.*, 2005; Vivian, 2002; Mehos *et al.*, 2000). Although, primary care units are the entrance of SUS, it almost does not have studies published about Pharmaceutical Care practice in Brazil (Lyra Jr. *et al.*, 2007; Souza *et al.*, 2007; Castro *et al.*, 2006; Lyra Jr. *et al.*, 2005; Oliveira *et al.*, 2005). Thus, the purpose of this study was to evaluate the effect of pharmacist intervention on the prevention and solution of drug therapy-problems (DTP), Body Mass Index (BMI), and blood pressure control in elderly outpatients with hypertension.

METHODS

A longitudinal, prospective study (semi-experimental) was conducted at a primary health care unit (PHCU) in Ribeirão Preto (SP), Brazil, from August, 2003 to July, 2004. This setting was chosen because 300 of the patients had hypertension, and the center's health care providers identified 40% (120) non-adherence as a primary reason for poor outcomes to treatment. At PHCU, the outpatients were attended to by four physicians, two dispensing pharmacists, and one research pharmacist.

Patients

During a week period, all hypertensive outpatients who came to the ambulatory care pharmacy of PHCU to receive their medication were identified as potential candidates for the study. Patients were eligible to participate if they met three or more of the following criteria (Koecheler *et al.*, 1989): five or more drugs in their regimen, twelve or more doses per day, a medication regimen that had changed four or more times in the past year, three or more co-morbidities, a history of medication non-compliance, and the presence of at least one drug that requires therapeutic monitoring (Box 1).

BOX 1 - Drugs requiring therapeutic monitoring

Drug Category β-Blockers
Calcium channel blockers
Thiazide diuretics Angiotensin-converting enzyme inhibitors
Angiotensin II receptor antagonists
α-Antagonists Vasodilators
Biguanides
Sulfonamides Cholesterol and triglyceride reducers

Exclusion criteria were: stage 3 hypertension (systolic e•180 mm Hg and/or diastolic pressure e•110 mm Hg based on JNC-VI criteria), an identified secondary cause of hypertension, such as chronic renal disease, pheochromocytoma, Cushing's syndrome, or had missed more than three appointments during the program.

The nature of the study was described to the patients, and informed consent forms were signed by those eligible and interested in participating.

Pharmaceutical Care program

Patients were scheduled to visit the research pharmacist once per month at PHCU during the period of a year. The research pharmacist (DPLJ) interviewed each patient for forty minutes, using a checklist with essential issues such as socio-demographic variables, health situation, and drug therapy (Currie *et al.*, 2003). The Pharmaceutical Care interview program included: active listening, review of health situation and drug history, identification of needs and problems, assessment, care plan, documentation, and intervention.

Pharmaceutical Care intervention

During the Pharmaceutical Care program, interventions aimed at personal transformation and the awakening of patients' "critical consciousness", and were divided into: health education and drug therapy (Freire, 1983). Such transformation is attributed to three key consciousness-raising experiences: relating to and reflecting on experience; personal exploration and problem solving; and taking thoughtful action. These steps provide a framework for Freire's participatory social orientation approach to the design of effective educational strategies in health. While originally applied to the teaching of basic literacy skills to adults in Brazil, it has been used internationally in health education (Roter *et al.*, 2001; Freire, 1983).

Educative intervention consisted of: counseling concerning chronic health conditions (nature, causes, and treatment) and changes in lifestyle, identification of signs and symptoms caused by medication (effectiveness and safety), and encouragement of patients to participate actively in the proposed drug therapy.

The research pharmacist evaluated patients individually to identify actual and potential DTP. DTP is any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy (Cipolle *et al.*, 2004). It was divided in terms of need, effectiveness, and safety (Comité del Consenso, 2002). All data was recorded on an individual form and updated monthly, thus forming a database. The drug therapy intervention also consisted of: assessment of drug history (current and past medication) and drug-taking ability, solution and prevention of DTP (actual and potential), clarification questions regarding orders, use, and storage of medicines and implementation of adherence-improving strategies.

Statistical analysis

The paired *t* test was used to measure differences in mean of DTP, Body Mass Index (BMI) and systolic and diastolic BP between baseline and end of this study. All analyses used SPSS (version 12, SPSS Inc., Chicago, IL). A significance level of 0.05 was adopted for all statistical tests. All results were validated by means of Wilcoxon's Rank-sum test.

RESULTS AND DISCUSSION

Socio-demographic and health situation profile

The mean age of patients was 66 ± 5 years, 20 of whom were women (n=30). Twenty one (71%) of the patients had low literacy. In Brazil, individuals with reduced education levels are approximately 5 times as likely to have

health problems (Rosa *et al.*, 2003). One of most dramatic problems identified is the extremely poor level of patient knowledge and understanding (Naves, Silver, 2005). In this situation, the educational interventions could contribute to awareness development and to the exchange of experiences, replacing dominant and informative actions that were distant from the patients' reality (Roter *et al.*, 2001). Empowering experiences foster the competence and confidence necessary for personal transformation and the realization of "critical consciousness".

There was a predominance of retirees/pensioners 19 (63%) and housewives 7 (27%) in this study. According to Rosa et al. (2003), retirees and housewives are almost 8 times as likely to present morbidities. The mean chronic health conditions per patient individual corresponded to 3.5 \pm 1.5. In this study, patients presented at least two chronic health conditions (mainly hypertension, diabetes mellitus and hypercholesterolemy); as a consequence they had to be treated by five different specialist physicians, to take multiple medications and to made difficult comprehension about drug therapy. Hypertension, diabetes, and asthma, major causes of morbidity and hospitalization, showed an important therapeutic drug gap (Naves, Silver, 2005). In the literature, it has been demonstrated that the number of drugs prescribed increases with the number of physicians seen (Lyra Jr. et al., 2004; Rollason, Vogt, 2003).

Drug therapy profile

During the study period were consumed 250 medicines, the mean 8.5 ± 4 drugs per elderly, the most of them (81%) prescribed by physicians. Twenty outpatients received more than five different drugs prescribed. In Brazil, the true prevalence of the inappropriateness and redundancy among prescriptions is underestimated (Nóbrega *et al.*, 2006; Gimenes *et al.*, 2006; Lyra Jr. *et al.*, 2004).

Evaluation of Pharmaceutical Care intervention

92 DTP were identified during the study, 3.0 ± 1.5 problems per patient. Twenty one patients showed a mean of 2.6 actual DTP and 0.5 potential DTP. 29% of them were detected by own patients, mainly a higher incidence of problems in the of the Safety category (64%). These DTP had been caused by: diuretics (12 [19%]), analgesics (10 [16%]), calcium channel blockers (9 [14%]) and angiotensin-converting-enzyme (ACE) inhibitors (8 [13%]). The high medication consumption and high incidence of DTP (mainly in the of the Safety category) showed that the medication acted as harmful agent to the

elderly health and caused symptoms such as: orthostatic hypotension, gastritis, dizziness and cramps.

In this study, 590 interventions were performed and documented, for both drug therapy (214) and health education (376). These interventions were equally distributed among the different chronic health conditions that the patients suffered.

Thirty five percent of 214 drug therapy interventions had been solved with the adjustment of medication regimens to elderly patients' daily routine. Other 65% required physician decision and the co-operative working between the research pharmacist, the prescribers and patients. This interaction was a key factor to solve and prevent the DTP in PHCU. Thus, the physicians agreed to change 86% of drug therapy regimen. By the end of the study, the interventions solved 69% of actual DTP and prevented 78.5% potential DTP. The results demonstrated an average of 4 ± 2 Pharmaceutical Care interviews to solve DTP.

All of the health education intervention that were made were accepted by the patients and implemented by them. Other studies showed the positive results of interventions, leading to the solution and prevention of DTP, reduction of treatment costs and satisfaction with Pharmaceutical Care program (Lee *et al.*, 2006; Lyra Jr. *et al.*, 2005; Vivian, 2002, Bernsten *et al.*, 2001).

Some actual and potential DTP remained unresolved or were not prevented. The resolution and prevention of these DTP required modifications in drug regimens that depended exclusively on a medical decision.

Reduction of weight response

At the baseline, 15 (50%) of the elderly presented overweight and 7 (23%) obesity. The category of overweight and obesity was defined as a BMI of 25 kg/m² or greater. According to Ahrens *et al.* (2003), pharmacists can play a role in helping patients to manage their weight and decreasing the BP levels. After the interventions, the patients showed a reduction of 27% in weight (defined as weight loss greater than 7%), but did not observe a significant difference in BMI results (Table I).

Others studies showed no statistically significant differences (p<0,05) of BMI after pharmacist interventions (Castro *et al.*, 2006; Garção, Cabrita, 2002). People, especially the elderly, have difficulty losing weight and maintaining weight loss (Ahrens *et al.*, 2003). The elevated dropout rate suggests a need for other intervention strategies to motivate patients to reduce and maintain their weight loss.

Ahrens *et al.* (2003) suggested that to improve these results it is necessary to have a lengthier intervention

TABLE I – Body Mass Index (BMI) of elderly outpatients, at PHCU Dr. Ítalo Baruffi (Ribeirão Preto – SP), August 2003 to July 2004

BMI	Baseline, <i>f(%)</i>	After, f(%)
Underweight (< 18.5)	0 (0)	0 (0)
Normal weight (18.5 a 25)	8 (27)	9 (30)
Overweight (25 a 29.9)	15 (50)	13 (43.5)
Obese I (30 a 34.9)	5 (17)	7 (23.5)
Obese II (30 a 34.9)	2 (6)	1 (3)

period, training for the pharmacists and the interaction with other health professionals (e.g., physicians and dietitians). Thus, patients with obesity I and II that did not lose weight during this study were referred to physicians and dietitians at PHCU.

Blood pressure response

According to Blenkinsopp *et al.* (2000) the core of the intervention lies in its potential to empower patients to disclose their own concerns and questions about treatment. Empowerment terms implies the ability to take thoughtful action on one's own behalf (Freire, 1983). In this study, interventions such as in increasing the awareness of the importance of BP control were effective in reducing hypertension (Table II).

TABLE II – Changes in Blood Pressure (BP) of patients between baseline and after Pharmaceutical Care interventions, in PHCU Dr. Ítalo Baruffi (Ribeirão Preto – SP), August 2003 to July 2004

BP	Baseline Mean ± SD (mmHg)	After Mean ± SD (mmHg)	p Value
Systolic	$146 \pm 19,5$	128 ± 17	0.0001
Diastolic	86.5 ± 16	74.5 ± 13	0.0001

After empowerment, patients had significant mean reductions from the baseline in systolic (18 mmHg) and diastolic (12 mmHg) pressures (p<0.01). One metaanalysis of 30 clinical trials concluded that 5 mmHg reduction in SBP lowered the risk of cardiovascular events and stroke by 25% to 30% (Staessen *et al.*, 2003). Reduction in DBP of 5 mmHg is associated with 34% less strokes and 21% less coronary heart disease (Piechowski-Józwiak, Bogousslavsky, 2006). At the beginning of the study, only 5 of the patients showed BP control (BP< 120/80 mmHg), and after the Pharmaceutical Care intervention 13 (43.5%) attained a BP below 120/80 mm Hg. At the end of the study, it was also observed that another 13 (43.5%) of the patients achieved improvement (e•5 mm Hg) without the BP control, 2 (6.5%) remained stable, and only 2 (6.5%) worsened. Thus, there was an increase of 26.5% in the control of BP in the elderly group.

These findings are better than in other studies that reported the positive influence of pharmacists on outpatient BP control (Castro *et al.*, 2006; Lee *et al.*, 2006; Garção, Cabrita, 2002). This study is also consistent with three other studies that obtained the same reduction in BP values (Vivian, 2002; Mehos; Saseen; Mac Laughlin, 2000). Furthermore, it is important to highlight that 13 (43.5%) of the hypertensive patients also had diabetes and JNC-VII (2003) guidelines recommend a pressure of <130/85 mm Hg for these patients. Patients with diabetes and hypertension are four times more likely to have a cardiovascular event than patients without diabetes (George *et al.*, 2001).

This study had several limitations as follows: researcher experience and education in Pharmaceutical Care, number of patients (convenience sample), and program conducted in only one setting. The Brazilian pharmacists' lack of experience in Pharmaceutical Care may have prevented the detection of more DTP that increase patient BP (Oliveira *et al.*, 2005). Therefore, a longer training period for the researcher might have produced better results.

Because the population was small, it lacks statistical power to detect a more significant difference in baseline and follow-up BP in patients. Thus, to generalize the results, larger size samples would be needed.

Subjects were recruited from one PCHU, so extrapolating our results to other clinic settings and patient populations may be limited. Furthermore, recruitment and participation of patients was voluntary. Hence, it is possible that patients who did not participate were systematically different from those patients who participated.

CONCLUSIONS

The results demonstrate that although the Pharmaceutical Care program did not observe a significant difference in BMI results after 12 months, the BP control improved in 87% of the patients. Based on these findings, this study concludes that Pharmaceutical Care intervention can be an effective method in improving BP control in elderly outpatients, reducing the risk that hypertension represents for cardiovascular disease. Heightened awareness of the disease as well as increased pharmacistpatient and physician interaction may facilitate drug therapy modifications that are necessary to achieve desired BP goals.

After this study, the researcher gave training about practice of Pharmaceutical Care to 38 dispensing pharmacists from the Public Health-System of Ribeirão Preto. Nowadays, these pharmacists are perpetuating the practice introduced in the region.

Finally, this study provides framework for the future development of other outcomes studies in Brazilian ambulatory care patients.

RESUMO

Efeito de intervenções de atenção farmacêutica na pressão arterial de pacientes idosos com hipertensão

O objetivo deste estudo foi avaliar o efeito das intervenções farmacêuticas na prevenção e solução de problemas relacionados à farmacoterapia, ao índice de massa corporal e ao controle da pressão arterial de um grupo de pacientes idosos portadores de hipertensão arterial. O grupo de 30 pacientes assistidos na farmácia de uma unidade básica de saúde, em Ribeirão Preto (SP), Brasil, foi acompanhado por 12 meses. No estudo foi observado que as intervenções do programa de Atenção Farmacêutica otimizaram o uso dos medicamentos, reduziram os problemas de saúde causados pelos medicamentos e melhoraram as condições de saúde dos pacientes. As intervenções influenciaram tanto no cuidado prestado aos idosos como na obtenção de resultados de saúde positivos. Depois deste estudo, o pesquisador ministrou um curso de capacitação sobre a prática da Atenção Farmacêutica para 38 farmacêuticos da Secretaria Municipal de Saúde de Ribeirão Preto (SP). Atualmente, alguns destes farmacêuticos estão perpetuando a prática introduzida na região.

UNITERMOS: Hipertensão Arterial. Idosos. Atenção Farmacêutica.

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