VALUE IN HEALTH REGIONAL ISSUES 17C (2018) 119–125

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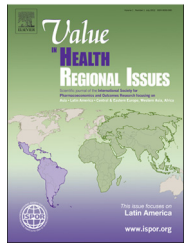

Potentially Inappropriate Medications in Elderly Ambulatory Patients: A Comparative Study between a Primary Health Care Center and a Community Pharmacy

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ABSTRACT

Objective: This study aims to compare, both qualitatively and quantitatively, the medication dispensed to elderly patients in a primary health care center (PHC) and a community pharmacy (CP) in Argentina and to identify the prescription of potentially inappropriate medications (PIMs). **Methods:** A cross-sectional observational study. Data were acquired from 886 prescriptions in the PHC and 2368 in the CP between February and April 2015. Dispensed medications were coded according to the Anatomical, Therapeutic, and Chemical (ATC) classification system. The frequency of prescriptions for each of them was determined. The number and monthly average of drugs dispensed were calculated for each patient. The use of PIMs was identified using Beers Criteria. **Results:** In both institutions, the means of medications dispensed per individual and month were similar: 3.69 ± 1.93 in the PHC and 3.46 ± 2.18 in the CP. Most of the medications corresponded to cardiovascular system agents. In the CP, 111 prescriptions (4.69%) dispensed to 51 patients (19.39%) were identified as PIMs. In the PHC, 72 prescriptions (8.13%) dispensed to 27 patients (28.42%) were identified as PIMs. In patients with major polymedication the possibility of consuming these drugs was 2.55 times higher in the CP and 2.60 times higher in the PHC. The percentage of PIM prescriptions was significantly higher in the PHC, although the percentage of patients receiving them did not differ significantly. **Conclusions:** The prevalence of PIMs found in this population is relevant enough to implement measures that address the problem in an integral way, to improve the quality of prescriptions and the health outcomes of patients.

Keywords: aged, drug use, inappropriate medication, polypharmacy, prescription of drugs.

Introduction

The World Health Organization has recognized the need to establish a national drug policy and the importance of an associated research strategy that includes studies on the use of medicines [1]. This policy should aim at reaching a rational use of drugs, understood as the one with the greatest benefit to the patient, at the lowest cost possible for both the patient and the community.

Medicines are therapeutic tools to cure acute diseases, stabilize chronic conditions, and sometimes save a patient's life or improve its quality. Medications can, however, also cause adverse reactions, interact with other drugs, and sometimes in some patients be contraindicated.

In particular, elderly people form a population that requires special attention as to the quality of drug prescription. This group is characterized by pluripathology, functional and cognitive impairment, and physiological changes developing with age, which modify the pharmacodynamics and pharmacokinetics of drugs. This leads to an increase in the consumption of medications, which in turn enhances the probability of the presence of unfavorable pharmacological interactions and adverse reactions [2]. It has also been reported that as many as 31% of hospital admissions of geriatric patients are directly related to problems with drug therapy. Such drug-related morbidity represents a substantial economic burden [3].

Agents in which the risk of adverse events in older adults exceeds the expectations of clinical benefits (although there are more effective and safer alternatives) are usually denominated potentially inappropriate medications (PIMs) [4,5]. Several criteria have been developed to identify PIM usage in older people, with Beers Criteria [4] being the most widely used. These criteria require low-level training and do not need a review of the clinical records of the patients [6].

It has been reported that polypharmacy increases the risk of consuming PIMs and that some drug interactions may intensify the risk of problems related to the health of the users [7]. In Argentina, there has been a fast growth in the elderly population

The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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2212-1099$36.00 – see front matter © 2018 Published by Elsevier Inc. on behalf of International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

https://doi.org/10.1016/j.vhri.2017.12.009

(according to the 2010 Census, they represented approximately 12.8% of the total population, whereas, according to recent estimates [8], they represent approximately 17.4%) and only a few studies, in institutionalized elderly people, have focused on the evaluation of the prescription of PIMs in this population [9].

Based on the importance of identifying PIMs and associated factors, as well as on the lack of published articles in Argentina and South America in general, in the present study, we aimed to compare, both qualitatively and quantitatively, the medications dispensed to elderly patients in a primary health care center (PHC) and in a community pharmacy (CP) in the city of Rosario, Santa Fe, Argentina. For this purpose, in the first section of this article, we describe the characteristics of patients. Second, we determine the frequency of prescription of dispensed drugs and describe the medication consumption. Finally, we identify PIMs, estimate their prevalence, and evaluate their possible relation with polypharmacy, sex, and age of patients.

Methods

Design and Data Collection

A cross-sectional observational study was conducted between February and April 2015. Data were acquired from 2368 prescriptions in the CP from 263 patients affiliated with the National Institute of Social Services for Retirees and Pensioners (INSSJP)—the Argentine public agency specializing in the care of the elderly—and 886 prescriptions corresponding to 95 patients treated in a PHC that did not have trade union–run medical insurance. All patients were 60 years old and older (the cut-off age for elderly people in developing countries), and data recorded from each prescription were year of birth and sex of the patient, date of dispensation, and medications dispensed. The prescriptions of psychotropic drugs were excluded because they are not dispensed at PHCs.

The medications prescribed at the PHC are included in the Provincial Therapeutic Formulary of Santa Fe, Argentina [10], which consists of a list of essential medicines based on recommendations of the World Health Organization and are available for free. In the case of the dispensations made at the CP to members of the National Institute of Social Services for Retirees and Pensioners, doctors may prescribe any medication within the National Vademecum [11], an official source in permanent update, in which all the medicines currently marketed in Argentina are published. These patients must receive their medicines for free or with a 50% discount at the pharmacy.

Classification of Drugs and Identification of PIMs

The dispensed medications were coded according to the Anatomical, Therapeutic, and Chemical classification (the ATC code), version 2016 [12]. For each patient, the number of drugs dispensed monthly and the monthly average were determined. A mean value of two to four drugs was considered minor polymedication, whereas a mean value of five or more drugs was considered major polymedication [13].

To detect the use of PIMs, we used the Beers Criteria corresponding to the review published in 2012 [4]. The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, commonly called the Beers List, are guidelines for health care professionals to help improve the safety of prescribing medications for older adults. They emphasize deprescribing medications that are unnecessary, which helps to reduce the problems of polypharmacy, drug interactions, and adverse drug reactions, thereby improving the risk–benefit ratio of medication regimens in at-risk people. They include 53 medications and medication classes divided into three categories: PIMs and classes to avoid in all older adults, PIMs and classes to avoid in older adults with certain diseases and syndromes that the drugs listed may exacerbate, and medications to be used with caution in older adults. In this study, we considered drugs not recommended for use in the elderly, with high and moderate quality of evidence and independence of diagnosis.

Statistical Analysis

Descriptive statistics were used to summarize the characteristics of patients and the use of medications.

Quantitative variables were reported as means ± SDs and median (min–max), and categorical variables as proportions (%). For quantitative variables, Student's t test for two independent samples was used to compare means, and the Mann–Whitney U test was performed to contrast medians between patients for both dispensation sites. Pearson's chi-square test was used to analyze the possible relation between qualitative variables. If the association was statistically significant ($P < 0.05$), logistic regressions were used to determine the odds ratio (OR) [14] and their confidence interval (95% CI).

To contrast the characteristics of PIM users and nonusers within each dispensation sites, we used the same methods described in the foregoing. Multivariate logistic regressions were used to determine patient factor associated with the use of at least one PIM, considering the variables that were found to be significant ($P < 0.1$) in the bivariate analysis. We also calculated the OR and its 95% CI to describe the significant associations between the use of PIM and the characteristics of the patients. Statistical analysis was performed using SAS University Edition.

Results

Patients' Characteristics

We analyzed 886 prescriptions from the PHC and 2368 from the CP. The mean age of the 95 patients of the first group was 67.47 years old (SD = 6.85 years old), with values between 60 and 94 years old, and 50% of the patients were aged 65 or younger. In the CP, the mean age of the 263 patients was 75.84 years old (SD = 7.90 years old), with values between 60 and 94 years old, and 50% of the patients were aged 75 or younger. The differences between the mean ages as well as the median were statistically significant ($P < 0.001$ in both cases). Of the patients who attended the PHC, 56.84% were women, whereas 65.40% of those who attended the CP were women. The data did not provide sufficient evidence to reject the hypothesis that the proportion of women attending both institutions is the same ($P = 0.145$).

At the PHC, one to nine drugs per patient were dispensed monthly, with an average of 3.69 medications per individual and month (SD = 1.93) and a median of three drugs. Considering the levels defined by Bjerrum et al. [13], 58.95% of the patients presented minor polymedication (two to four drugs), whereas 29.47% presented major polymedication (five or more drugs). At the CP, 1 to 14 medications were dispensed per month and patient, with an average of 3.46 medications per individual and month (SD = 2.18) and a median of three drugs. Considering the levels defined by Bjerrum et al. [13], 53.61% of the individuals presented minor polymedication and 27.00% presented major polymedication.

No significant differences were found in the average number of medications dispensed monthly per patient or in the median ($P = 0.338$ and $P = 0.210$ respectively). Also, no significant difference was detected in the percentage of patients in each level of

Table 1 – Characteristics of the elderly population studied.

Characteristics	Primary health care center (N = 95)	Community pharmacy (N = 263)
Gender: Female	54 (56.84%)	172 (65.40%)
Age: ≥75 years	12 (12.63%)	133 (50.57%)*
Mean (SD)	67.47 (6.85)	75.84 (7.90)*
Median (min–max)	65 (60–94)	75 (60–94)*
Monthly mean number of drugs:		
2–4	56 (58.95%)	141 (53.61%)
≥5	28 (29.47%)	71 (27.00%)
Mean by individual/ month (SD)	3.69 (1.93)	3.46 (2.18)
Median (min–max)	3.00 (1–9)	3 (1–14)

* $P < 0.001$.

polymedication ($P = 0.226$). These data are shown in detail in Table 1.

Medication Consumption

Table 2 shows the 10 groups of drugs with the highest relative frequency of prescription, considering the third level of the ATC code. As expected, at both institutions, most of the groups corresponded to drugs that act on the cardiovascular system (group C), followed by those that act on the digestive system (group A). Nine out of the 10 most prescribed pharmacological groups were the same at both the CP and the PHC. Group C03A (low-ceiling diuretics, thiazides) was not present at the CP and was in the third position at the PHC. Similarly, group C09C (angiotensin II antagonists, plain) was not present at the PHC and was in the fourth position at the CP. Also, at the PHC, the 10 groups concentrated 86% of the prescriptions, whereas at the CP these represented 57% of the prescriptions. The possible relationship between the chance to use one drug of the nine coincident pharmacological groups and the sex of the patients was evaluated. At the PHC, the odds ratio of using drugs for peptic ulcer and gastroesophageal reflux disease (group A02B) was 3.59 times higher for women than for men (OR = 3.59, 95% CI 1.21:10.74), whereas at the CP, this odds ratio was 1.81 higher for women than for men (OR = 1.81, 95% CI 1.01:3.25). Similarly, at the PHC, the chance of using nonsteroidal anti-inflammatory drugs (NSAIDs, group M01A) was eight times greater for women than for men (OR = 8.00, 95% CI 1.01:65.79), whereas no significant effect of sex on this group was found at the CP. Regarding lipid-modifying agents (group C10A), the odds of consumption at the CP was 1.88 higher for men than for women (OR = 1.88, 95%CI 1.07:3.29). No relationship was found between the use of NSAIDs and antacids (group A02B) ($P = 0.972$ for the CP and $P = 0.060$ for the PHC).

The 10 most dispensed drugs are presented in Figure 1A,B. Enalapril was the most dispensed drug at both dispensation sites, followed by losartan at the CP and hydrochlorothiazide at the PHC. These results are in agreement with those shown in Table 2. At the PHC, the 10 most dispensed medications represented 81% of the dispensations, whereas at the CP, these concentrated only 32% of the dispensations. This fact may be related to the greater availability of drugs that can be prescribed by physicians whose patients obtain their medication at the CP. At the PHC, the most prescribed drugs from group A02B (agents for peptic ulcer) were ranitidine and omeprazole, whereas at the CP, the most prescribed agents for peptic ulcer were pantoprazole, omeprazole, ranitidine, lansoprazole, esomeprazole, rabeprazole, and dexlansoprazole. Similar results were obtained for group C10A (lipid-modifying agents). Simvastatin and fenofibrate were exclusively prescribed at the PHC, whereas atorvastatin, rosuvastatin, simvastatin, gemfibrozil, fenofibrate, ezetimibe, and cholestyramine were exclusively prescribed at the CP (data not shown). It is important to note that the drug of group A10B (oral blood glucose lowering drugs) most dispensed at the CP was metformin, whereas those most dispensed at the PHC were metformin and glibenclamide.

Use of PIMs

Table 3 reports the PIMs recorded at the CP and the PHC. By following Beers Criteria, 111 (4.69%) of the prescriptions made at the CP, which included 21 different drugs dispensed to 51 patients (19.39%), were identified as PIMs for the elderly. Considering the established degree of polypharmacy, the possibility of consuming these drugs was 2.52 times higher in patients with major polymedication than in those with minor polymedication (OR = 2.52, 95% CI 1.33:4.78, $P = 0.005$). At the PHC, 72 out of the 886 prescriptions dispensed, which included three different drugs and corresponded to 27 patients (28.42%), were identified as PIMs (8.13%). The possibility of receiving PIMs was 2.60 times larger in patients

Table 2 – Frequency of the dispensing of the 10 most prescribed pharmacological groups.

Primary health care center			Community pharmacy		
Code	Group	N (%)	Code	Group	N (%)
C09A	ACE inhibitors, plain	179 (20.20)	C07A	Beta-blocking agents	196 (8.28)
A10B	Oral blood glucose lowering drugs	126 (14.22)	A02B	Drugs for peptic ulcer	180 (7.60)
C03A	Low-ceiling diuretics, thiazides	95 (10.72)	C10A	Lipid-modifying agents. Plain	178 (7.52)
C10A	Lipid-modifying agents, plain	82 (9.26)	C09C	Angiotensin II antagonists. plain	149 (6.29)
C07A	Beta-blocking agents	67 (7.56)	A10B	Oral blood glucose lowering drugs	140 (5.91)
B01A	Antithrombotic agents	63 (7.11)	B01A	Antithrombotic agents	138 (5.83)
A02B	Drugs for peptic ulcer	59 (6.66)	M01A	Anti-inflammatory and antirheumatic products, nonsteroids	118 (4.93)
C08C	Selective calcium channel blockers	38 (4.29)	C09A	ACE inhibitors, plain	106 (4.48)
H03A	Thyroid preparations	29 (3.27)	C08C	Selective calcium channel blockers	89 (3.76)
M01A	Anti-inflammatory and antirheumatic products, nonsteroids	27 (3.05)	H03A	Thyroid preparations	89 (3.76)

ACE, angiotensin-converting enzyme inhibitors.

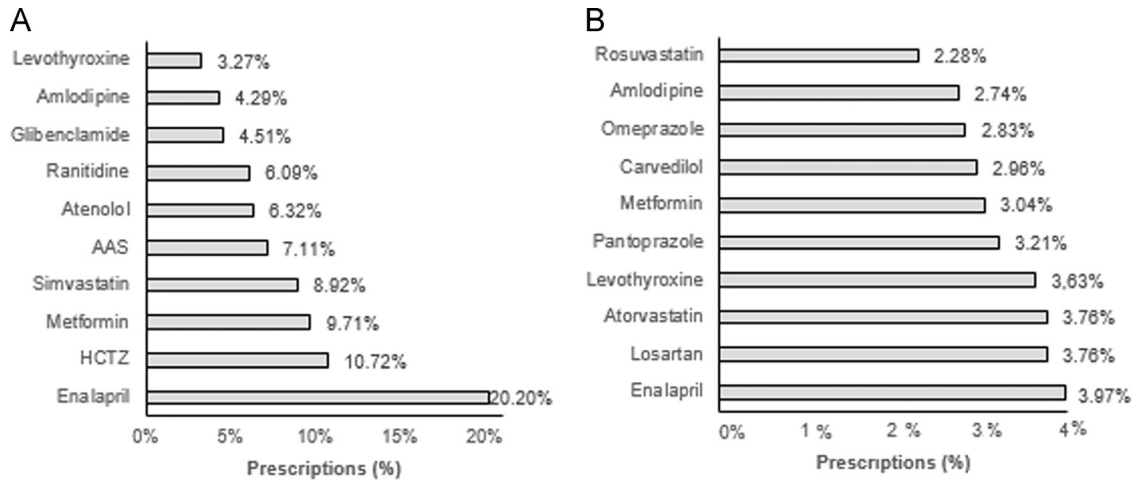

Fig. 1 – Frequency of dispensing of the 10 most prescribed drugs. (A) PHC; (B) CP.

with major polymedication than in the rest of the elderly (OR = 2.60, 95% CI 1.01:6.68, P = 0.044). The percentage of PIMs prescriptions was significantly higher at the PHC (P = 0.001), although the percentage of patients receiving them did not differ significantly (P = 0.068).

At the PHC, the most frequently prescribed PIM was glibenclamide, followed by ibuprofen and digoxin (Table 3). At the CP, the variety of pharmacological groups that can cause PIMs was greater, and the most frequently prescribed drugs were diclofenac, meloxicam, digoxin, amiodarone, and glibenclamide.

Table 4 shows a comparison of the individual characteristics of PIM users versus nonusers for both dispensation sites. In both cases, the mean and the median of the individual monthly average of medications, and the percentage of patients who showed major polymedication, were significantly higher for PIM users. The average age and the percentage of patients older than 75 years of age who were PIM users were higher at the CP than at the PHC.

To evaluate the impact of patient characteristics on the probability of using PIM, within each dispensation site, logistic regressions were used considering the variables that were found

Table 3 – Prescribed drugs included in Beers Criteria 2012.

PIM	Community pharmacy		Primary health care center	
	Prescriptions (%)	Patients (%)	Prescriptions (%)	Patients (%)
Anticholinergics				
Chlorpheniramine	2 (0.08)	2 (0.76)		
Cyproheptadine	1 (0.04)	1 (0.38)		
Diphenhydramine	1 (0.04)	1 (0.38)		
Oxybutynin	3 (0.13)	1 (0.38)		
Cardiovascular drugs				
Amiodarone	8 (0.34)	4 (1.52)		
Flecainide	1 (0.04)	1 (0.38)		
Digoxin >0.125 mg/d	9 (0.38)	3 (1.14)	5 (0.56)	2 (2.11)
Nifedipine	7 (0.30)	3 (1.14)		
Spironolactone >25 mg/d	1 (0.04)	1 (0.38)		
NSAIDs				
Diclofenac	32 (1.35)	15 (5.70)		
Ibuprofen	2 (0.08)	2 (0.76)	27 (3.05)	10 (10.53)
Meloxicam	25 (1.06)	15 (5.70)		
Piroxicam	1 (0.04)	1 (0.38)		
Naproxen	4 (1.17)	4 (1.52)		
Ketorolac	1 (0.04)	1 (0.38)		
Dexketoprofen	1 (0.04)	1 (0.38)		
Others				
Nitrofurantoin	1 (0.04)	1 (0.38)		
Glibenclamide	7 (0.30)	4 (1.52)	40 (4.51)	16 (16.84)
Carisoprodol	1 (0.04)	1 (0.38)		
Chlorzoxazone	1 (0.04)	1 (0.38)		
Metoclopramide	2 (0.08)	2 (0.76)		
Total	111 (4.69)	51 (19.39)	71 (8.13)	27 (28.42)

PIM, potentially inappropriate medication.

Table 4 – Characteristics of users of PIMs versus nonusers.

Characteristic	Primary health care center		Community pharmacy	
	PIMs users	PIMs nonusers	PIMs users	PIMs nonusers
N	27 (28.41%)	68 (71.59%)	51 (19.39%)	212 (80.61%)
Age (years)				
60–74	25 (92.59%)	58 (85.29%)	24 (47.06%)	106 (50.00%)
≥75	2 (7.41%)‡	10 (14.71%)	27 (52.94%)	106 (50.00%)
Mean (SD)	67.15 (6.17)‡	67.60 (7.14)	75.55 (7.36)	75.91 (8.05)
Median (min–max)	64.00 (60–84)‡	65.50 (60–94)	75.00 (64-93)	74.50 (60–94)
% Female	18 (66.67%)	36 (52.94%)	39 (76.47%)†	133 (62.74%)
Monthly mean number of drugs				
2–4	15 (55.56%)	41 (60.29%)	26 (50.98%)	115 (54.25%)
≥5	12 (44.44%)	16 (23.53%)	22 (43.14%)*	49 (23.11%)
Mean (SD)	4.63 (2.00)*	3.32 (1.78)	4.59 (2.49)*	3.22 (2.01)
Median (min–max)	4 (2–8)*	3 (1–9)	4 (1–14)*	3 (1–11)

PIM, potentially inappropriate medication.
PIM users versus nonusers: *$P < 0.05$; †$P < 0.10$.
Primary health care center PIM users versus community pharmacy PIM users: ‡$P < 0.001$.

to be significant ($P < 0.1$) in the bivariate analysis. In the case of CP, the model included as covariates the sex of patients and the number of drugs used. The results for both variables were statistically significant. The possibility of receiving PIMs was 2.17 times higher for women than for men (OR = 2.17, 95% CI 1.04:4.55, $P = 0.03$). An increase in one unit in the number of drugs used implies that the odds of using PIMs increase 1.32 times (OR = 1.32, 95% CI 1.15:1.52, $P < 0.001$). For the PHC, the model included only the quantity of drugs used. An increase in one unit in this value, implies that the odds of using PIMs increase 1.43 times (OR = 1.43, 95% CI 1.12:1.83, $P = 0.003$).

Discussion

Polypharmacy is usually observed in the elderly population [2,15,16]. However, both polypharmacy and its incidence can be defined in different ways [17–19]. In this study, the proportion of patients with major polypharmacy (defined here as five or more drugs) was 29.47% at the PHC and 27% at the CP. These values were similar, although the average age was higher for patients from the CP. Some recent studies on the drugs used by older people have shown that the percentage of patients with major polypharmacy varies between 35% and 90% [20–23]. We believe that this difference between our results and the ones observed in the cited literature may be due to the fact that we did not consider the dispensation of psychoactive drugs or the self-medication of these patients. The mean and median of medication by month found in our study are similar to those observed in other studies [20,21,24].

Nine out of the 10 pharmacological groups with the highest frequency of dispensation were similar at both places. The pharmacological group with the main proportion of dispensation, both at the PHC and the CP, was the one related to the cardiovascular system. This was an expected outcome because elderly people have a high index of cardiovascular comorbidity [15,20,23,24]. In some patients, we found an association of two or more drugs for cardiovascular disease. It is important to note that the most frequent association at the PHC was that of enalapril with hydrochloride, while that at the CP was that of losartan with amlodipine (data not shown). Although we are not aware of the existence of other risk factors associated with the underlying pathologies, because the design of the study did not include the consultation of medical records, these results show that, although international guidelines for the treatment of primary hypertension (in patients aged 55 years or older) consider that low doses of thiazides are the first choice of therapy—alone or in combination with other drugs [25]—diuretics remained underutilized by patients whose prescriptions were dispensed at the CP.

The percentage of PIM users found in the present study was slightly lower than that found in other studies [20,21,23,26]. This could be because we excluded the prescriptions of psychotropic drugs—not dispensed at the PHC—and self-medication. However, both at the CP and at the PHC, the differences in the mean and median number of medications per month between PIM users and nonusers were statistically significant. In addition, in the two cases, the percentage of polymedicated patients was higher among PIM users. This is in line with other studies suggesting that the risk of inappropriate is greater in patients with polypharmacy [5,27,28]. In addition, at the CP, we found an association between female sex and the use of PIM, in agreement with other studies [5,22,26]. However, we found no correlation with age.

Although only three drugs from the Beers Criteria were detected at the PHC—as compared to the 21 drugs detected at the CP—the percentage of PIM prescriptions at the PHC was much higher than that at the CP. This is partly due to the fact that more than half of the PIM prescriptions dispensed at the PHC corresponded to glibenclamide, one of the most frequently prescribed oral antidiabetic medicines for patients with type 2 diabetes in primary health care centers in Argentina and a drug included with metformin in the Provincial Therapeutic Formulary. This formulary does not provide gliclazide as an alternative to the same class (sulfonylurea), which is indicated for elderly patients because of its lower adverse reaction profile [29,30]. At the CP, the more used oral blood glucose lowering drugs were gliclazide, saxagliptin, vildagliptin, and metformin (data not shown).

This study has some limitations. First, although the results obtained can be generalized to ambulatory elderly patients in Argentina, they cannot be generalized to hospitalized patients. Second, it would be interesting to investigate whether the prevalence of PIMs is similar in the same population if other criteria, such as the STOPP/START or Priscus Criteria, is used [31,32]. Beers Criteria are the gold standard to study inappropriate medication [6], but present a number of disadvantages such as the fact that each drug is evaluated independently of the therapeutic context, and the need for continuous updating of criteria according to the available evidence [33,34].

On the other hand, the PHC studied uses a limited list of medicines—because patients do not have trade union–run medical insurance—and is thus not completely adapted to the specific needs of the elderly. This represents a significant restriction on the availability of drugs that professionals can prescribe to select a better therapeutic option. Based on these findings, it would be important to contemplate the incorporation of some drugs into the Provincial Therapeutic Formulary.

Despite the aforementioned limitations, this study is valuable to reconsider the prescription of certain drugs in elderly patients and, in the future, we envision the development of a specific screening tool for the detection of PIMs in our country.

Also, from an economic point of view we have perceived that increased information and education at the pharmacy (pharmaceutical care) could produce large cost savings because of the reduced incidence of drug-related problems.

Conclusion

In this study, we described and compared the profile of dispensing medications to older people at a PHC and a CP in Rosario, Argentina. Cardiovascular and alimentary drugs were the principal classes used by the elderly, who showed a high prevalence of polypharmacy, although we had no information about their self-medication or use of psychotropics. We also verified the prescriptions of PIMs and their relationship with a greater amount of medicines used.

It is important to highlight that in CP we found a higher number of PIM users in patients older than 75 years with greater polymedication. These conditions could increase the risk of hospitalization through drug adverse effects, drug interactions, or intolerability and should be considered by the prescribing physician.

In conclusion, the prevalence of PIMs found according to the Beers Criteria in this population is relevant enough to implement measures that address the problem in an integral way, to improve the quality of prescription and the health outcomes of the patient. There is also an urgent need for the health care authorities to work toward the development of a national screening tool based on the many existing criteria.

Acknowledgments

This study was supported by Universidad Nacional de Rosario (N° 445/2015) and a grant from Secretaría de Estado de Ciencia, Tecnología e Innovación -SECTEI- (N°2010-174-14), Santa Fe, Argentina. The authors would like to thank the Association of Pharmacists of the 2nd Circumscription of the Province of Santa Fe for the collaboration provided for the realization of this work.

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