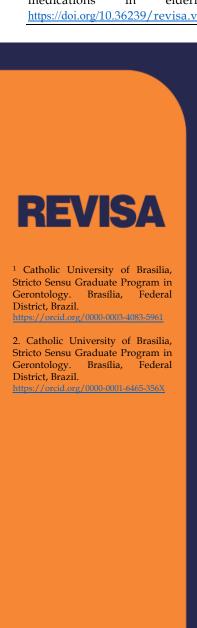# Risk predictors for the consumption of potentially inappropriate medications in elderly people with pain

Preditores de risco para o consumo de medicamentos potencialmente inapropriados em idosos com dor

Predictores de riesgo para el consumo de medicamentos potencialmente inapropiados en ancianos con dolor

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ORIGINAL

RESUMO
Objetivo: Verificar quais as comorbidades podem ser preditoras do risco para uso de medicamentos potenciamente inapropriados para idosos (MPII) e desenvolver um modelo preditor para o consumo de MPII. **Método:** Trata-se de um estudo retrospectivo, transversal, com alocação consecutiva de idosos atendidos ambulatorialmente. Foram desenvolvidos modelos probabilísticos com a utilização de regressões logísticas binárias. **Resultados:** Um modelo contendo as variáveis dor, ansiedade, depressão, escore de Elixhauser, e número de medicamentos atingiu área sob a curva de 0,853 (IC95% 0,813-0,893) para identificar idosos sob risco de receber prescrição de MPII. Os resultados corroboram que a ansiedade [OR 10,6 (IC95% 1,29-87,0), p=0.028] e depressão [OR 40,3 (IC95% 5,05-321), p<0.001] são fatores de risco independentes para o uso de MPII. **Conclusão:** Ferramentas de suporte à decisão clínica podem incorporar modelos preditores como os desenvolvidos no presente trabalho, aumentando o nível de informação e facilitando a sinalização de MPII no ato da prescrição.
Descritores: Idoso; Polifármaco; Comorbidade.

ABSTRACT
Objective: To verify which comorbidities may be predictors of the risk for use of potentially inappropriate medication for the elderly (PIME) and to develop a predictive model for the consumption of PIME. **Method:** It is a study retrospective, cross-sectional study with consecutive allocation of elderly patients treated on an outpatient basis. Probabilistic models have been developed using binary logistic regressions. **Results:** A model containing the variables pain, anxiety, depression, Elixhauser score, and number of medications reached an area under the curve of 0.853 (95%CI 0.813-0.893) to identify elderly people at risk of receiving PIME prescription. The results corroborate that anxiety [OR 10.6 (95%CI 1.29-87.0), p=0.028] and depression [OR 40.3 (95%CI 5.05-321), p<0.001] are independent risk factors for the use of PIME. **Conclusion:** Clinical decision support tools can incorporate predictive models such as those developed in the present study, increasing the level of information and facilitating the signaling of PIME at the time of prescription.
Descriptors: Elderly; Polypharmacy; Comorbidity.

RESUMEN
Objetivo: Verificar qué comorbilidades pueden ser predictoras del riesgo de uso de medicación potencialmente ianpropriada para los ancianos (MPIA) y desarrollar un modelo predictivo para el consumo de MPIA. **Método:** És un estudio retrospectivo, transversal, con asignación consecutiva de ancianos atendidos de forma ambulatoria. Se han desarrollado modelos probabilísticos utilizando regresiones logísticas binarias. **Resultados:** Un modelo que contenía las variables dolor, ansiedad, depresión, puntaje de Elixhauser y número de medicamentos alcanzó un área bajo la curva de 0,853 (IC95% 0,813-0,893) para identificar ancianos con riesgo de recibir prescripción de MPIA. Los resultados corroboran que la nestidad [OR 10,6 (IC95% 1,29-87,0), p=0,028] y la depresión [OR 40,3 (IC95% 5,05-321), p<0,001] son factores de riesgo independientes para el uso de MPIA. **Conclusión:** Las herramientas de apoyo a la decisión clínica pueden incorporar modelos predictivos como los desarrollados en el presente estudio, aumentando el nivel de información y facilitando la señalización del MPIA en el momento de la prescripción.
Descriptores: Ancianos; Polifarmacia; Comorbilidad.

Introduction

With population aging, the main comorbidities (occurrence of two or more diseases simultaneously, in the same person) that affect individuals have changed, with a migration from infectious and parasitic diseases - which mostly affect the youngest - to chronic and degenerative diseases.[1,2]

Considered one of the biggest public health problems in the world, chronic diseases are prevalent in 70% of the elderly in Brazil and are usually accompanied by pain.

Pain makes the elderly more vulnerable, restricting their social interaction, interfering with their independence and autonomy, and may make them anxious or depressed.[3-5] The inverse relationship can also occur, generating bidirectionality and, consequently, diagnostic confusion and a cascade of prescriptions.[3]

Faced with this plethora of chronic diseases prevalent in the elderly, drug treatments become more challenging, because the various changes that occur in the body, and that are a consequence of aging, make pharmacological treatments a challenge regarding efficacy and safety, especially when the patient makes use of polypharmaceuticals. Such factors may increase the chances of drug interactions, causing some medications to be considered as potentially inappropriate medications for the elderly (PIML).[3,6,7]

To assist at the time of medical prescription, and in order to avoid the use of these medications, lists of these PIMLs were created, such as the AGS/Beers Criteria and the Brazilian Consensus on Potentially Inappropriate Medications for the Elderly (CBMPII), which were used in the present study.[8]

The MPII have been highlighted, but there is no clarity as to the main factors associated with their use. Therefore, the main objectives of this research were (i) to verify which comorbidities can be considered as predictors of the risk for the consumption of IPM in cases of chronic pain, in the elderly attended at the Geriatrics Outpatient Clinic of the Integrated Outpatient Center of the Catholic University of Brasília (AG/CIA/UCB); and (ii) develop a predictive model for MPII consumption. As secondary objectives (iii) to know the quantitative differences of pain by sex; (iv) check if there is use of polypharmaceuticals; (v) to observe if there are reports of adverse drug reactions (ADRs); and (vi) whether there is adherence to non-pharmacological therapies for the treatment of pain, and whether it interferes with the development of daily activities.

Method

This is a retrospective, cross-sectional and quantitative study, with the allocation of consecutive elderly participants of a primary health access program.

The study was conducted at the Geriatrics Outpatient Clinic (AG), which is part of the Integrated Outpatient Center (CIA), located at the Catholic University of Brasília - Taguatinga Campus. The CIA uses the KONSIST system, installed in August 2018, and data is collected from the medical records of patients who were seen in the period from August / 2018 to August / 2021 (with care interrupted between June / 2020 and April 2021 due to the pandemic).

We analyzed 565 medical records of male and female patients, aged 60 years or older, whose consultations were carried out specifically in the GA. As inclusion criteria, the medical record should include the comorbidities presented, as well as the record of the medications used. Blank medical records or those without the information pertinent

to the questions of this research and of deceased patients were excluded.

The exploratory analysis of the data included descriptive statistics, mean, median, standard deviation, minimum and maximum value for numerical variables and number and proportion for categorical variables. For the analysis of the behavior of continuous variables, descriptive statistics, histogram and boxplot graphs and the specific test for the theoretical assumption of normality Kolmogorov-Smirnov were considered.[9] The comparison between categorical variables (comorbidities, sex, pain) and MPII treatment (non-use and use) was performed by applying Pearson's chi-square test or Fisher's exact test, where appropriate.[10] For continuous variables (age and number of medications), the Mann-Whitney test was applied in the comparative analysis.[10]

The Elixhauser score was used, which, although originally developed to predict mortality, is an important component of clinical prognosis.[11] After comparative analyses, three probabilistic models were developed using the binary logistic regression technique, with the objective of finding risk predictors for the use of PIML.[12,13]

Initially, those whose p values were lower than 0.05 in the bivariate analyses were considered as candidate variables for the model, in order to develop a parsimonious model, also taking into account the applicability in the study. The finalist variables of the model with p values < 0.05 were considered significant. As performance indicators of the model, we considered the Nagelkerke square R, Cox & Snell square R and the study event classification table (confusion matrix).[12]

The ROC (Receiver Operator Characteristic Curve), constructed with the purpose of evaluating the accuracy of the models in predicting the use of MPII, was determined by measuring the area under the ROC curve (AUROC)[10]. The results of the finalist variables of the models were presented as Odds Ratio and 95% confidence interval.[12,13]

Statistical analysis was performed using IBM-SPSS Statistics software version 28 (IBM Corporation, NY, USA). P values < 0.05 were considered significant.

This research was approved by the Ethics Committee of UCB under opinion number 4.671.785, CAAE 45191521.9.0000.0029, with exemption from the Informed Consent Form (ICF) because it is a retrospective research, without direct contact with the participant.

Results

Observing the inclusion and exclusion criteria, of the 565 medical records collected, 48 were excluded, of which 517 were eligible, and of these, 70.4% (364 medical records) corresponded to the medical records of female patients, and 29.6% (153 medical records) corresponded to the medical records of male patients.

The mean age of the elderly treated without MPII (71 years) and of the patients treated with MPII (73 years) showed no significant difference. Regarding the number of drugs used, the average was 3 for patients who do not use MPII and 4 drugs for those who use MPII. Table 1 shows the bivariate analyses of these demographic data (age, gender) and clinical data (pain) in relation to the use of MPII.

About 130 comorbidities were mentioned in the medical records. However, still in Table 1, it can be verified that there are only 23 comorbidities in the analysis, a fact that is due to the fact that only these have presented citations in the medical records in sufficient numbers to be compared in relation to the use of MPII.

Table 1- Bivariate comparative analysis.

Comparative analysis between gender, pain, age, number of medications and type of treatment (without or with the use of MPII)			
	MPII		
	I do not use	**I use**	P value
Sex Female	62,10%	73,20%	**0,016**
Pain Yes	36,40%	55.80%	**< 0,001**
Age (years)	71 (60 - 98)	73 (60 - 101)	0,263
Number of drugs	3 (1- 4)	4 (1- 4)	**<0,001**
Comparative analysis between comorbidities and type of treatment (without or with the use of PIML)			
Alzheimer 's	0 (100,00%)	17 (95,60%)	**0,009**
Anxiety	1 (0,80%)	27 (7,00%)	**0,006**
Arrhythmia	2 (1,50%)	15 (3,90%)	0,261
Stroke	0 (0,00%)	12 (3,10%)	**0,043**
Chagas	3 (2,30%)	13 (3,40%)	0,772
Depression	1 (0,80%)	69 (17,90%)	**< 0,001**
DM	39 (29,50%)	140 (36,40%)	0,155
GERD	3 (2,30%)	7 (1,80%)	0,721
Hepatic steatosis	2 (1,50%)	8 (2,10%)	1,000
Fibromyalgia	2 (1,50%)	20 (5,20%)	0,071
Gastritis	2 (1,50%)	16 (4,20%)	0,181
Glaucoma	3 (2,30%)	10 (2,60%)	1,000
Has	86 (65,20%)	264 (68,60%)	0,468
Hernia	1 (0,80%)	15 (3,90%)	0,084
Hypothyroidism	17 (12,90%)	55 (14,30%)	0,687
Urinary incontinence	3 (2,30%)	10 (2,60%)	1,000
Insomnia	6 (4,50%)	38 (9,90%)	0,059
Renal failure	1 (0,80%)	10 (2,60%)	0,304
Obesity	5 (3,80%)	15 (3,90%)	0,956
Osteopenia	9 (6,80%)	12 (3,10%)	0,063
Osteoporosis	22 (16,70%)	44 (11,40%)	0,120
Rhinitis	1 (0,80%)	10 (2,60%)	0,304
Dizziness	2 (1,50%)	9 (2,30%)	0,737

Stroke – Stroke; DM – Diabetes Mellitus; GERD – Gastroesophageal Reflux Disease; SAH – Systemic Arterial Hypertension; MPII – Potentially Inappropriate Medications for the Elderly

As for the multivariate model, observed in Table 2, those whose p values were lower than 0.05 in the bivariate analyses were considered as candidate variables, as already mentioned, such variables were: gender, pain, number of medications, in addition to 4 comorbidities: alzheimer, anxiety, stroke and depression.

For model 1, the finalist variables were: pain, anxiety, depression (categorical variables) and number of medications (numerical variable), as shown in Table 2. This model presented, as performance indicators, the Nagelkerke square R = 0.355; R square of Cox & Snell = 0.241. In addition, the proportion of correct answers for the outcome use of MPII was 93.8%, considering the cutoff point of 0.5 for the classification of the probability of the use of MPII. In model 2, also observed in Table 2, pain (categorical variable) and number of medications (numerical variable) are considered as finalist variables. This presented as performance indicators, the Nagelkerke square R = 0.278; Cox & Snell's square r = 0.189, as well as, presented the proportion of correct answers for the outcome use of MPII of 92.5%, considering the cutoff point of 0.5 for the classification of the probability of the use of MPII.

Model 3, also shown in Table 2, considers Elixhauser's comorbidity index[11,14,15] as a covariate, and presents as variables: pain, anxiety, depression (categorical variables) and number of medications. For this model, 468 cases were available, 360 with the event "use of MPII" and presented, as performance indicators, the Nagelkerke square R = 0.401; R square of Cox & Snell 0.265=. In addition, although it presented a wide confidence interval for both comorbidities, model 3 presented the proportion of correct answers for the outcome use of MPII of 93.9%, considering the cutoff point of 0.5 for the classification of the probability of the use of PIML.

Regarding the accuracy of the model, the ROC curve (Receiver Operator Characteristic Curve) was constructed, determined by measuring the area under the ROC curve (AUROC) and its confidence interval, as can be seen in Table 2.

Table 2- Models of risk factors for the use of MPII, according to binary logistic regression.

MODEL 1		
AUROC	CI 95%	
0,823	0,783-0,863	
Variable	OR (CI 95%)	P Value
Pain Yes *	2,290 (1,430-3,680)	**<0,001**
Anxiety Yes *	10,030 (1,240-81,100)	**0,030**
Depression Yes*	23,080 (3,020-176,490)	**0,002**
Number of drugs	Number of drugs	**<0,001**
Constant	Constant	**<0,001**
MODEL 2		
AUROC	CI 95%	
0,784	0,738-0,830	
Variable	OR (CI 95%)	P Value
Pain Yes*	2,270(1,430-3,580)	**<0,001**
Number of drugs	Number of drugs	**<0,001**
Constant	Constant	**<0,001**

MODEL 3		
AUROC	CI 95%	
0,853	0,813-0,893	
Variable	OR (CI 95%)	P Value
Pain Yes*	2,378 (1,409 ; 4,013)	**0,001**
Anxiety Yes*	10,582 (1,287 ; 87,023)	**0,028**
Depression Yes*	40,325 (5,053 ; 321,795)	**< 0,001**
Number of drugs	1,666 (1,455 ; 1,908)	**<0,001**
Elixhauser score	1,199 (1,067 ; 1,347)	**< 0,001**
Constant	0,161	**< 0,001**

*Used in relation to the "No" category. AUROC- area under the Receiver Operator Characteristic Curve; OR, odds ratio; CI, confidence interval.

Of the 517 medical records analyzed, about 275 patients were identified as users of polypharmaceuticals, and of these, 54.6% are patients who reported pain; regarding ADR, there were few records and a predominance in females, with 7 reports among the total of 9 patients. Women also make up the majority of those who adhere to non-pharmacological therapies (physiotherapy, acupuncture, among others), corresponding to 21 of the total of 25 patients. Regarding the interference of pain in the development of daily activities, of the 26 reports, 80% are female patients.

Discussion

Studies suggest that the Elixhauser score, although originally developed to predict mortality, is an important component of clinical prognosis, since data on comorbidities are valuable in the comparison between patient populations, and in risk adjustments to associated outcomes.[11,14,15] In this study, the associated outcome was the use of MPII. Thus, the Elixhauser comorbidity index was inserted in the binary logistic regression, being used as a severity score.[14,15]

It is observed that, of the comorbidities tested, only 4 showed a significant association with the use of PIML, which were: alzheimer, anxiety, stroke and depression.

Because they present a lower p-value in the comparative analysis between comorbidities and the type of treatment without or with the use of MPII, the comorbidities Anxiety and Depression can be considered as predictors of the risk for the consumption of IPM. It was observed that some authors correlate them bidirectionally, that is, they can be both triggers of pain and a consequence.[16-18] This confusion of diagnosis, which can generate unnecessary and incorrect prescriptions, emphasizes the challenge of pain management in the elderly and it is emphasized that, in order to achieve positive results in the treatment, it is necessary to have an understanding of all the particularities of each elderly.[16,18]

Regarding the AUROC results, the three models tested presented good performance, distinguishing well between the use and non-use of MPII, considering the variation of sensitivity and specificity. However, among these models, model 3 denotes a better accuracy in predicting the consumption of MPII in patients with pain, with an AUROC of 0.853.

Considering that longevity is higher among women, studies indicate that women are the majority in the sample (62.6% and 66.8%).[19,20] In the present study, female patients accounted for 70.4% of the sample (364 medical records).

The predominance of females regarding the use of MPII was also verified in this study, as a consequence of being the majority of the sample, in line with other studies.[19] The association of females with higher use of IPM is also pointed out in other studies, where it is observed that, in general, women use more medications than men.[23,25] This fact may be due to the fact that women present "a higher prevalence of pain and symptoms of the neurological affective sphere than men", being related to biological factors, and because they are more concerned with health, as well as social aspects because they use health services more frequently.

It was observed that pain was present in 50.8% of the sample, of which 77.2% corresponded to females, in agreement with a study conducted in the United States.[21] The same study observes the interference of pain in the development of daily activities in 70 to 80% of the elderly, differently from the numbers found in this study (6.7%), denoting that, perhaps, pain is undervalued or underreported in Brazil.

The use of polypharmaceuticals is considered as a factor frequently related to the use of PIML, since it can be triggered by a "cascade" of prescriptions.23 Studies conducted in Natal/RN point to a high prevalence in the use of IPM (54.6%) strongly associated with the use of polypharmaceuticals (47%).[24] Corroborating these authors, the sample of this study presented a profile of polydrug use in 53.19% of patients, with predominance in those treated with IPM (90.55%). In general, although they were identified as polydrug elderly, few reports of ADR were found, which is possibly due to some research bias, due to underreporting or underdiagnosis.

In this research, in line with other published studies, the development of multiple comorbidities increases the risk for the development of pain, as well as there are statistical indicative results to affirm that the amount of drugs used and the type of comorbidities presented is directly related to the presence of pain and the use of PIMP.[16,25]

Based on studies that demonstrate that the reduction of the use of MPII increases the safety in the administration of drugs in general, and considering the variability of responses of the elderly organism to a drug, the standardized lists of MPII to assist in medical prescriptions are considered important tools for the success of treatment and for the preservation of the health of the elderly.[22]

This study has limitations because it is of the retrospective type, and it is not possible to carry out a complete sociodemographic research, covering schooling and socioeconomic level. Another limitation is due to the fact that it was carried out only in the AG/CIA/UCB, thus having its potential for generalization diminished. The wide confidence interval for anxiety and depression comorbidities demands further studies for deepening. Finally, because there was not enough information about the health conditions or daily dose consumed in all medical records, the MPII research was performed based on the lists (AGS/Beers Criteria and CBMPII) using only the name of the drugs.

Conclusion

We inferred that anxiety and depression comorbidities can be considered predictors of the risk for the use of IPM and, together with the use of polypharmaceuticals, should be seen as warning signs for clinicians to reconsider the safety and efficacy of their prescriptions to elderly people in pain. It is noteworthy that clinical decision support tools can incorporate predictive models, such as those developed in the present study, increasing the level of information for clinicians and facilitating the signaling of PIMP at the time of prescription

Acknowledgement

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