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ORIGINALES

Beers versus STOPP criteria in polyharmacy community-dwelling older patients

Criterios de Beers versus STOPP en pacientes mayores, polimedicados y residentes en la comunidad

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Resumen: *Objetivo:* Evaluar la prescripción potencialmente inapropiada (PPI) mediante la aplicación de los criterios Beers (versión 2012) y STOPP (versión 2008) en pacientes mayores, polimedicados y residentes en la comunidad.
Métodos: A partir de la información recogida en los datos de facturación de recetas y de las historias clínicas electrónicas se seleccionó una muestra de 223 pacientes de 65 o más años, que tomaban simultáneamente 10 o más medicamentos/día. Se aplicaron separadamente los criterios de Beers y STOPP y se compararon los resultados obtenidos con ambos métodos.
Resultados: Un total de 141 pacientes (63,2%) presentaban al menos un criterio de Beers. Los dos criterios de Beers independientes del diagnóstico observados con más frecuencia fueron el uso de benzodiazepinas y el uso de antiinflamatorios no esteroideos no selectivos de ciclooxigenasa-2. Con respecto a los criterios de Beers considerando el diagnóstico, los más frecuentes fueron el uso de anticolinérgicos en pacientes con síntomas del tracto urinario inferior o con hiperplasia benigna de próstata y el uso de benzodiazepinas, antipsicóticos, zolpidem o antihistamínicos H2, en pacientes con demencia o deterioro cognitivo. Un total de 165 (73,9%) pacientes tenían al menos una PPI según los criterios STOPP. La duplicidad terapéutica y el uso prolongado de benzodiazepinas de vida media larga fueron los dos criterios STOPP más comunes.
Discusión: Nuestro estudio identificó una alta frecuencia de PPI en pacientes mayores, polimedicados y residentes en la comunidad. La aplicación simultánea de los criterios de Beers y STOPP constituye una herramienta útil para mejorar la prescripción en este grupo de población.

Palabras clave: Prescripción potencialmente inapropiada, Criterios Beers, Criterios STOPP, Polifarmacia.

Abstract: *Objective:* To assess potentially inappropriate prescribing (PIP) using Beers (2012 version) and STOPP (2008 version) criteria in polypharmacy, community-dwelling, older patients.
Methods: From the information collected in the invoicing data of the prescriptions and the electronic medical records, a sample was selected of 223 ≥ 65-year-old patients who were taking simultaneously 10 or more drugs per day. Beers and STOPP criteria were separately applied, and the results obtained with the two methods were compared.
Results: A total of 141 (63.2%) patients presented at least one Beers criterion. The two most frequently observed Beers criteria independent of diagnosis were the use of

benzodiazepines and the use of non-COX-2-selective non-steroidal anti-inflammatory drugs. With regard to Beers criteria considering diagnosis, the most frequent were the use of anticholinergic drugs in patients with lower urinary tract symptoms or benign prostatic hyperplasia, and the use of benzodiazepines, antipsychotics, zolpidem or H2-antihistamines, in patients with dementia or cognitive impairment. A total of 165 (73.9%) patients had at least one PIP according to the STOPP criteria. Duplicate drug classes and long-term use of long-acting benzodiazepines were the two most frequent STOPP criteria.

Discussion: Our study identified a high frequency of PIP in polymedicated community-dwelling older patients. Simultaneous application of Beers and STOPP criteria represents a useful tool to improve prescribing in this population group.

Potentially inappropriate prescribing; Beers criteria; STOPP criteria; Polypharmacy

Keywords: Potentially inappropriate prescribing, Beers criteria, STOPP criteria, Polypharmacy.

Introduction

Medication prescription in older patients will often be a complex process, due to the fact that they will usua- lly present multiple comorbidities. Moreover, changes in homeostasis, pharmacokinetics and pharmacodynamics derived of aging will render older patients more prone to suffer adverse reactions to medications, therefore increasing morbidity and the need for medical care [1].

Adverse reactions to medications represent around 7.2-16.8% of admissions of elderly patients in Internal Medicine Units [2,3,4], and in many cases, a potentially inappropriate prescription (PIP) of medications is one of the factors leading to hospitalization [5,6,7,8]. This term refers to those situations where the risk to suffer adverse events is superior to clinical benefit, particularly when there are safer and/or more effective therapeutic alternative options. Moreover, the use of drugs with a frequency, duration or dose superior to their indication is also considered inappropriate, as well as the use of medications with a high risk of interactions, and therapeutic duplications. On the other hand, it is also inappropriate to omit the prescription of medications with a clearly demonstrated indication for specific situations [9,10,11].

Implicit and explicit methods have been developed for the assessment of PIP in older patients [12]. Implicit methods are based on the clinical evaluation of patients and their medication, and the most widely used is the "Medication Appropriateness Index" (MAI) Method [13]. Explicit methods measure PIP by means predefined criteria based on evidence and expert consensus. Among these, Beers criteria [14,15,16,17] and "Screening Tool of Older Person´s Prescriptions/Screening Tool to Alert doctors to Right Treatment" (STOPP/START) [18,19] criteria are the most widely used. Beers criteria were developed in U.S. in 1997 [14] and updated in 2003 [15], 2012 [16] and 2015 [17]. In their 2012 update [16], besides the review of molecules, there was an addition of pharmacological groups, and information was included about the reasons upon which PIP criteria are based. The STOPP/START criteria [18] were published in 2008 in

Ireland, due to the limitations of extrapolating Beers criteria to the European setting, and the difficult application of the implicit methods; these have been updated in 2015 [19] . The STOPP/START criteria have demonstrated high reliability among evaluators, and have been adapted to our setting [20,21] . These criteria are focused on potential problems associated with drug treatment, in the setting of the comorbidities inherent to older patients, and they detect not only overprescription and PIP, but also treatment omissions [22,23] .

With the aim to assess PIP in > 65-year-old polypharmacy patients and understand its prevalence, we conducted an analysis of prescriptions and electronic clinical records, applying Beers criteria [16] and STOPP criteria [18] , in the relevant Primary Care Records from the Healthcare Area II of the Principality of Asturias Health System (SESPA).

Method

A descriptive, transversal study was conducted on those prescriptions written at the health centres from the SESPA Healthcare Area II, for polypharmacy≥ 65-year-old patients. In 2011, this Healthcare Area had a population of 28,808 inhabitants, and 8,117 (28%) of them were 65-year-old or older, according to the annual count of Individual Health Insurance Cards.

The study was conducted based on the information from: 1) invoicing data from the SESPA Pharmacy Department, and 2) electronic clinical records (OMI-AP). Based on the prescription invoice data, lists were drawn for drugs prescribed to ≥ 65-year-old patients, who were taking chronically 10 or more drugs/day during 6 or more conse- cutive months (from October, 2010 to March, 2011). Those drugs with topical administration were excluded from the drug count. For each pharmacological treatment, the lists included the name of the molecule, its brand name, the number of packages sold, and the date of invoicing. This information was analyzed and compared with the information from the electronic clinical history of those patients included in the study. For drug analysis, the national codes and the Anatomical-Therapeutical-Chemical (ATC) Classification codes were manually added to the data matrix. Those medications that included combinations of 2 or more active substances were accounted as the number of active substances included.

In order to assess PIP, the following criteria were used:

a) Beers criteria, independent of diagnosis (ID) and considering diagnosis (CD) (2012 version) [16] and b) STOPP criteria (2008 version) [18] , adapted and translated into Spanish by Delgado Silveira *et al.*20. The assessments applied for some of these criteria appear in table 1. In each of the analyzed cases, the presence of any of Beers criteria and STOPP criteria was studied. There was a calculation of the frequencies and percentages of each of the criteria analyzed. Comparisons were conducted through Chi-Square test, using the *IBM SPSS Statistics 22 Program*.

Results

The treatments for 223 patients in total were analyzed; 128 (57%) were female, with a median 78-year-old [range] age [65-96]. The median [range] of medications/day taken by the patients in the study was 12 [10-19] medications.

Beers Criteria

In total, 141 (63.2%) patients had at least one PIP according to total Beers criteria (Table 2). The median [range] of Beers criteria per patient observed was 1 [0-6]. Identified Beers criteria ID and CD are collected in Tables 3 and 4. The highest prevalence of Beers criteria was found in those drugs acting at the Central Nervous System level, followed by those used for pain management, and cardiovascular system drugs. Thus, in the Central Nervous System section, 110 (ID) and 48 (CD) patients had at least one Beers criterion; 35 patients presented some ID criterion associated with pain management, and in the cardiovascular system, 30 (ID) and 10 (CD) patients had at least one Beers criterion.

The 3 most frequent Beers Criteria ID (Table 3) were:

1) use of benzodiazepines (ID 5.5), 2) use of non-COX selective non-steroidal anti-inflammatory drugs (ID 8.2), and 3) the use of alpha-1 adrenergic blockers in the cardiovascular system (ID 4.1). Regarding Beers Criteria

Table 1
Assessment applied for some of Beers and STOPP criteria

	Criterion	Definition
BEERS		
ID 6.5	Insulin (gradual demand)	Constant changes in insulin dosing regimen, without improvement in hyperglycemia and some occasional record of hypoglycemia.
CD 2.4	History of falls and fractures	Any fall or fracture recorded within the last 3 months or during the 6 months of follow-up.
CD 3.1	Chronic constipation	At least 1 constipation period requiring the use of laxatives.
CD 4.1	Chronic renal disease	GFR < 30 ml/min
STOPP		
A1	Digoxin at a long-term dose > 125mg/day with renal impairment (increase in the risk of intoxication)	Renal failure: Estimated GFR < 50 ml/min
A2	Loop diuretics for dependent ankle oedemas, without clinical signs of heart failure (no evidence of their efficacy; support stockings are usually more adequate).	Extended to patients without diagnosis of decompensation due to hepatic cirrhosis, ascites, arterial hypertension, or severe disease.
B12	SSRI with a history of clinically significant hyponatraemia (< 130mmol/l non-iatrogenic in the previous 2 months).	Hyponatraemia: Na^+ < 130 mmol/l, in the previous 2 months.
E2	NSAID with moderate-severe hypertension	In ≥ 1 arterial hypertension measurement.
E4	Long-term use of NSAID (> 3 months) for relief of mild articular pain in osteoarthritis.	Excluding topical NSAID.
E6	NSAID with chronic renal failure (risk of renal function deterioration).	Renal failure: Estimated GFR < 50 ml/min.
J	Any regular prescription of two drugs within the same class: two opiates, NSAID, SSRI, loop diuretics, ACE inhibitors (monotherapy within one single class must be optimized before considering switch to another drug class). This excludes duplicate prescriptions of drugs that can be needed on demand: inhaled $beta_2$ agonists (long and short-acting) for COPD and asthma, or opiates for management of breakthrough pain.	Duplicate medications: molecules included in the same pharmacological subgroup (third level in the ATC Classification). Two concurrent antiaggregant drugs during > 1 year.

GFR: glomerular filtration rate; NSAID: non-steroidal anti-inflammatory drugs; SSRI: selective serotonin reuptake inhibitors: ACE inhibitors: angiotensin converting enzyme inhibitors; ATC: anatomical-therapeutical-chemical; COPD: chronic obstructive pulmonary disease.

Table 2
Distribution of the criteria observed in the analyzed sample

Criteria	Beers		STOPP		Beers vs STOPP p (χ^2)
	n	%	n	%	
None	82	36.8	58	26.1	<0.05
Some	141	63.2	165	73.9	
1	71	31.8	77	34.5	0.61
2	37	16.6	33	14.8	0.70
3	19	8.5	34	15.2	<0.05
4-6	14	6.3	21	9.4	0.29
Patients, total	223	100	223	100	

Table 3.
Identified Beers Criteria Independent of Diagnosis (ID)

Beers criteria (ID)	Patients [n=223]	
	n	%
ID 5 CENTRAL NERVOUS SYSTEM	110	49.3
ID 5.5 Benzodiazepines		
Lorazepam (41), Alprazolam (19), Clorazepate (10), Diazepam (9), Alprazolam + Clorazepate (2), Alprazolam + Flurazepam (2), Clorazepate + Lorazepam (1)	*84*	
ID 5.2 First and Second Generation Antipsychotic Drugs		
Quetiapine (5), Haloperidol (2), Risperidone (2), Aripiprazole (1), Olanzapine (1)	*11*	
ID 5.8 Non-Benzodiazepine Hypnotics		
Zolpidem (9)	*9*	
ID 5.1 Tricyclic Antidepressants		
Amitriptyline (4), Clomipramine (1), Doxepin (1)	*6*	
ID 8 PAIN MANAGEMENT	35	15.7
ID 8.2 Selective Non-COX NSAID		
Ibuprofen (14), Diclofenac (13), Meloxicam (3), Naproxen (1), Diclofenac + Ibuprofen (1), Diclofenac + Naproxen (1), Ibuprofen + Naproxen (1)	*34*	
ID 8.3 Indomethacin	*1*	
ID 4 CARDIOVASCULAR SYSTEM	30	13.4
ID 4.1 Alpha-1 Blockers		
Doxazosin (15), Doxazosin + Terazosin (1)	*16*	
ID 4.3 Class Ia, Ic, III Antiarrhythmic Drugs		
Amiodarone (8), Dronedarone (5)	*13*	
ID 4.6 Spironolactone > 25 mg/day	*1*	
ID 6 ENDOCRINE SYSTEM	3	1.3
ID 6.5 Insulin (gradual demand)	*3*	
ID 1 ANTICHOLINERGIC DRUGS	2	0.9
ID 1.1. First Generation Antihistamines		
Hydroxyzine (2)	*2*	

NSAID: non-steroidal anti-inflammatory drugs; COX: cyclooxygenase.

CD (Table 4), the three most frequently observed criteria were: 1) the use of inhaled anticholinergic drugs or strongly anticholinergic drugs, except for urinary antimuscarinic drugs with lower urinary tract symptoms or benign prostatic hyperplasia (CD 4.3), 2), the use of benzodiazepines, antipsychotic drugs, zolpidem or H2 antihistamines, in patients with dementia or cognitive deterioration (CD 2.3), and 3) selective serotonin reuptake inhibitors, benzodiazepines, zolpidem or antipsychotic drugs in patients with a history of falls and fractures (CD 2.4).

Table 4.
Identified Beers Criteria Considering Diagnosis (CD)

Beers criteria (CD)	Patients [n=223]	
	n	%
CD 2 CENTRAL NERVOUS SYSTEM	48	21.5
CD 2.3 Dementia and cognitive deterioration		
Benzodiazepines (13), Benzodiazepines + Antipsychotic Drugs (3), Antipsychotic Drugs (2), Zolpidem (2), H2 Antihistamines + Benzodiazepines (1)	*21*	
CD 2.4 History of falls and fractures		
Benzodiazepines (10), SSRI (3), Antipsychotic Drugs (1), Benzodiazepines + SSRI (1), Benzodiazepines + Antipsychotic Drugs (1), Benzodiazepines + Zolpidem (1), SSRI + Antipsychotic Drugs (1), Benzodiazepines + SSRI + Antipsychotic Drugs (1)	*19*	
CD 2.5 Insomnia		
Theophylline (5)	*5*	
CD 2.2 Delirium		
Benzodiazepines (3)	*3*	
CD 4 RENAL SYSTEM AND URINARY TRACT	27	12.1
CD 4.3 Lower Urinary Tract Symptoms; Benign Prostatic Hyperplasia		
Inhaled Anticholinergic Drugs (10), Antipsychotic Drugs (5), Paroxetine (4), Amitriptyline (1), Biperiden (1), Tizanidine (1), Inhaled Anticholinergic Drugs + Paroxetine (1)	*23*	
CD 4.4 Stress or Mixed Urinary Incontinence		
Doxazosin (4)	*4*	
CD 1 CARDIOVASCULAR SYSTEM	10	4.4
CD1.1 Heart Failure		
NSAID (6), NSAID + Dronedarone (1)	*7*	
CD 1.2 Syncope		
Doxazosin (1), Doxazosin + Galantamine (1), Doxazosin + Terazosin (1)	*3*	
CD 3 GI SYSTEM	6	2.7
CD 3.1 Chronic Constipation		
Solifenacin (1), Diltiazem (1), Tizanidine (1), Risperidone (1), Solifenacin + Trospium (1), Quetiapine + Solifenacin (1)	*6*	

SSRI: selective serotonin reuptake inhibitors; NSAID: non-steroid anti-inflammatory drugs.

STOPP Criteria

Out of all the patients analyzed, 165 (73.9%) had at least one PIP according to STOPP criteria (Table 2). The median [range] of STOPP criteria observed was 1 [0-6]. The drugs involved affected more frequently the cardiovascular and musculoskeletal system, and the central nervous system (Table 5). Therapeutic duplication, longterm use of benzodiazepines with long half-life, and the use of acetylsalicylic acid at doses> 150mg/day were the 3 STOPP criteria most frequently observed. The most frequent duplications were associated with the use of antiaggregant drugs, non-steroidal anti-inflammatory drugs, benzodiazepines, and antidepressants.

Discussion

The prevalence of PIP observed in our study, by applying both STOPP and Beers criteria, was high compa- red with some previous publications [21,23,24,25,26,27,28]. However, the number of medications received seems to be directly related with PIP frequency [29]. This is probably the reason why PIP

rates are usually superior in hospitalized patients [21,30,31,32,33] *vs.* patients seen by Primary Care [21,24,34]. Our study is focused on the analysis of PIP in patients with a high polypharmacy level, with 12 [10-19] medications/day, which might explain the high prevalence observed. Moreover, we have detected PIP most frequently when applying STOPP criteria than Beers criteria, which coincides with a great part of previous observations [23,35,36]. Thus, an European study published in 2011 [37], which analyzed PIP in hospitals located in Switzerland, Spain, Belgium, Italy, Czech Republic and Ireland, found in all countries a higher number of PIP with STOPP criteria than with Beers criteria. Subsequently, Blanco-Reina *et al.* [34] have analyzed PIP in outpatients, using Beers criteria (2003 version), STOPP criteria, and Beers criteria (2012 version); the PIP rates observed were 24.3%, 35.4% and 44%, respectively. However, our study, where the 2012 version of Beers criteria was used, detectedhigher PIP rates than with STOPP criteria. In our opinion,these differences could

Table 5
STOPP criteria identified with a≤ 6 frequency

STOPP criteria		Patients [n=223]	
		n	%
A	Cardiovascular		
13	ASA with no history of ischemic cardiopathy, cerebrovascular condition or peripheral arterial disease, or arterial occlusive disease (not indicated).	30	13.5
12	ASA at doses>150mg per day (increase in the risk of bleeding, without evidence of higher efficacy).	22	9.9
2	Loop diuretics for dependent ankle oedema, without clinical signs of heart failure (no evidence of their efficacy; support stockings are usually more adequate).	10	4.5
17	ASA, clopidogrel, dipyridamole, warfarin or acenocoumarol with a concurrent bleeding disorder (high risk of bleeding).	6	2.7
5	Non-cardioselective beta-blockers with COPD (risk of bronchospasm).	6	2.7
B	Central Nervous System and Psychotropic Drugs		
7	Prolonged use (>1 month) of long-acting benzodiazepines (chlordiazepoxide, flurazepam, nitrazepam, clorazepate) or benzodiazepines with long-acting metabolites (diazepam) (risk of prolonged sedation, confusion, balance disorders, falls).	54	24.2
E	Musculoskeletal System		
4	Long-term use of NSAID (>3 months) for relief of mild articular pain in osteoarthritis.	23	10.3
6	NSAID with chronic renal failure (risk of renal function deterioration).	10	4.4
3	NSAID with heart failure (risk of worsening heart failure).	7	3.1
H	Drugs that adversely affect fallers (1 or more falls during the past 3 months).		
1	Benzodiazepines (sedatives, they can reduce sensorium, there is balance deterioration).	14	6.3
5	Long-term opiates in those with recurrent falls (risk of somnolence, postural hypotension, vertigo).	12	5.4
I	Analgesic Drugs		
3	Long-term opiates in those with dementia, except when indicated for palliative care or management of moderate/ severe pain syndrome (risk of worsening cognitive deterioration).	7	3.1
J	Duplicate Drug Classes		
	Any regular prescription of two drugs within the same class: two concurrent opiates, NSAID, SSRI, loop diuretics, ACE inhibitors (monotherapy within one single class must be optimized before considering switch to another drug class). This excludes duplicate prescriptions of drugs that can be needed on demand: inhaled beta, agonists (long and short-acting) for COPD and asthma, or opiates for management of breakthrough pain.	58	26

ASA: acetylsalicylic acid; NSAID: non-steroidal anti-inflammatory drugs; SSRI: selective serotonin reuptake inhibitors; ACE inhibitors: angiotensin converting enzyme inhibitors; COPD: chronic obstructive pulmonary disease.

be based on differences in thesample of patients analyzed. Specifically, patients in ourstudy were taking at least 10 medications/day, while inthe study by Blanco-Reina et al. [34], the mean number ofmedications was 4.5 ± 2.9. This also coincides with thefact that the STOPP criteria most frequently observed inour study was medication duplication, while in the studyby Blanco-Reina et al.[34] this was the 5th most frequentSTOPP criteria.

The three pharmacological groups mostly associated with PIP in our study were benzodiazepines, antiaggregant drugs, and non-steroidal anti-inflammatory drugs.

By applying the STOPP criteria we found, similarly to some previous studies [24,27], a high PIP with drugs involving the cardiovascular system, followed by those involving the central nervous system; while when applying Beers criteria, we observed that the first place was for PIP of drugs involving the central nervous system, maybe because these criteria include, besides the prescription of long-acting benzodiazepines, also the prescription of intermediate or short-acting benzodiazepines, which can cause adverse reactions such as falls, fractures, and cognitive deterioration in elderly patients [38]. The second cause of PIP, according to Beers criteria ID, was the use of non-COX-2 selective non-steroidal anti-inflammatory drugs, which coincides with other studies [28,31]. The prolonged use of non-steroidal anti-inflammatory drugs forchronic mild pain in osteoarthritis was also present to ahigh rate in the STOPP Criteria, coinciding with previousstudies [24,39]. Besides, acetylsalicylic acid was involved asthe third most frequent STOPP criteria due to excessiveuse, thus confirming the variability in antiaggreganttreatments for primary and secondary cardiovascularprevention.

Collecting the prescription invoicing data confirmed through OMI-AP electronic clinical records has allowed us to conduct an in-depth study of PIP frequency, and to offer reliable information about patients' chronic treatment. However, our study presents the limitation of the insufficient completion of some clinical records, which made it difficult to identify some criteria. Another limitation was the lack of real assessment of the clinical signs of patients, in order to evaluate, for example, the presence of oedemas or the intensity of articular pain in osteoarthritis.

In 2015, while this study was being conducted, new updates were published for Beers criteria17 and STOPP/ START criteria [19]. If we had applied these new versions, our results might have been different, maybe with an even higher PIP rate detected through both criteria.

In conclusion, we have observed there is a high prevalence of PIP in highly polypharmacyolder patients, detected both with Beers criteria and STOPP criteria, The most frequent causes for PIP were therapeutic duplications, as well as the conditions of use for benzodiazepines, antiaggregant drugs, and non-steroidal anti-inflammatory drugs. In our opinion, the simultaneous application of Beers and STOPP criteria represents a useful tool for PIP screening in polymedicated community-dwelling older patients.

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Información adicional

Contribution to Scientific Literature: Polypharmacy patients represent a population group prone to receiving potentially inappropriate prescriptions. Beers and STOPP Criteria are explicit methods to assess the suitability of pharmacological treatment. This study shows a frequent prescription of therapeutic duplication, benzodiazepines, and

acetylsalicylic acid, without clear indication, as well as non-steroidal anti-inflammatory drugs, in polypharmacy> 65-year-old patients.

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