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POTENTIALLY INAPPROPRIATE MEDICATIONS IN GERIATRIC HEMODIALYSIS PATIENTS

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Abstract: Concerns about inappropriate drug use are increasing in geriatric patients. Potentially inappropriate medication (PIM) lists are being updated accordingly. The aim of this study is to determine the prevalence of PIM in elderly Turkish hemodialysis patients and to assess the association of patient's characteristic as risk factors for PIMs in this population. Patients aged 65 years and over who were treated at two different hemodialysis centers were included in the study. Medical and sociodemographic information of the patients was obtained from patient's files and medical records. Patients' files and SGK-Online Medulla System were used to identify medications used by patients. PIMs were defined by using the modified Beers' criteria independent of diagnosis and Beers' Kidney-List. A total of 110 patients (mean age 73.31±6.4 years) were included in the study. 69 of the patients were male (62.7%) and 41 female (37.3%). Only 47.3% of the patients were independent in daily functioning. The average number of medications received by the patients was 7.3. When the charts in the patient files were examined, it was determined that 54.5% of all patients used PIM. However, when all prescribed drugs were scanned online from the Medulla-SGK system, it was found that inappropriate drugs were prescribed in 70.9% of the patients. A statistically significant relationship was found between the use of PIM and the total number of drugs used and the number of hospital admissions. The prevalence rate of PIM in elderly Turkish hemodialysis patients was higher. It is necessary to raise awareness of this in terms of reducing unwanted drug interactions and contributing economically.

Keywords: Aging, Hemodialysis, Polypharmacy, Inappropriate prescriptions, Potentially Inappropriate medications

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1. Introduction

Drug-related adverse effects are more common in patients with chronic kidney disease (CKD) than in the normal population. Previous studies have demonstrated that almost all hemodialysis patients (98%) experience at least one drug-related problem (Manley et al., 2003). The pharmacokinetics and pharmacodynamics of drugs undergo marked changes as CKD progresses to end-stage renal disease (ESRD) and dialysis. Therefore, safe and effective prescribing becomes more difficult as the risk of drug-disease and drug-drug interactions increase. Drug dosing errors are the leading cause of unnecessary and inappropriate medication in patients with CKD, especially those who are on dialysis (Helldén et al., 2009). In addition to renal insufficiency, elderly dialysis patients have many concomitant chronic diseases, which require long-term drug treatment, such as diabetes, hypertension, cardiovascular disease, mineral and bone disorders and result in polypharmacy (Battistella et al., 2018). To prevent or reduce the drug-related adverse effects, physicians must identify potentially inappropriate drugs, discontinue or avoid prescribing of these drugs and replace them with safer alternatives, if necessary (Eyigör et al., 2012; St Peter, 2015).

The Beers' Criteria have been in use for over 20 years to prevent possible inappropriate prescribing in the elderly. The Beers' Criteria were updated in 1997, 2002, 2003, 2012 and 2015 and, most recently, by the American Geriatrics Society in 2019 (Beers Criteria® Update Expert Panel, 2019). There are a total of 140 different substances listed in the Beers' Criteria as potentially inappropriate medications irrespective of the patients' specific diagnoses or conditions. 98 of these medications are available in Türkiye, all of which are covered by the state-funded health insurance, the Social Security Institution (SGK) (SGK, 2022). New to the Beers' Criteria since the 2015 update is a list of 20 non-anti-infective medications, all of which are available in Türkiye and should be avoided or have their dosage reduced depending on the kidney function in older adults (Beers' Kidney list).

The aims of this study were to determine the prevalence

of PIMs using the Beers' Criteria irrespective of diagnosis and the Beers' Kidney list in elderly hemodialysis patients. In a second step, patients' characteristics were analyzed to identify the relationship with PIM use.

2. Materials and Methods

The prevalence of PIMs among elderly hemodialysis patients (ages 65 years or more) with SGK insurance in two different dialysis centers in Sakarya province was evaluated retrospectively. Medical and socio-demographic information of the patients was obtained from patients' charts and medical records. The Barthel Index and Mini-Nutritional Assessment Short Form are screening methods used routinely in clinical practice at these dialysis centers to assess patients' needs. The Barthel Index (BI) is an ordinal scale used to measure an individual's performance in 10 activities of daily living. The maximum score is 100 points, indicating total independence in daily life. A lower score indicates more dependence and assistance needed for daily functioning (Mahoney and Barthel, 1965). The Mini-Nutritional Assessment Short Form (MNA-SF) is a screening measure of nutritional status. According to this form, a score of 0-7 indicates that malnutrition is present. A score of 8-11 suggests a risk of malnutrition. A score of 12 or higher indicates a normal nutritional status (Kaiser et al, 2009). The Charlson Comorbidity Index was used to assess the burden of comorbid conditions (Charlson et al, 1987). Two data sources were used to identify medications received by patients: medication lists in the patients' charts and linked insurance data via the SGK-Online Medulla System. This system displays all the medicines the patients received from the pharmacy in the past 6 months. Medications administered during the hemodialysis session such as erythropoietin, heparin, intravenous iron and active D-vitamins were not included in the total number of medications for this study. PIMs were defined by using the modified Beers' Criteria irrespective of diagnosis and the Beers' Kidney list.

The normality of the distribution was evaluated with the Kolmogorov-Smirnov test. Descriptive statistics were expressed as median (minimum-maximum) for continuous and intermittent numerical variables, and as percentage (%) for categorical variables. Descriptive statistics for continuous and intermittent numerical variables were expressed as median (minimum-maximum), categorical variables as number of cases and percentage (%). The significance of the difference between the groups among the evaluated parameters was evaluated with the Mann-Whitney U Test. The Continuity Corrected Chi-square test was used when the expected frequencies in the cells of a 2x2 contingency table (a table showing the frequencies of observations in different categories) were between 5 and 25. When the expected frequencies were larger than 25 the Pearson Chi-square test was used. Analyses of categorical data in crosstabiulations of RxC (if at least one of the categorical variables in the row or column were duplicate outcomes) were done using Pearson's Chi-Square test. Statistical Package for Social Sciences (SPSS) 21.0 for Windows was used for statistical analysis. The results were reported with a confidence interval of 95% and an assumed significance level of $P<0.05$.

3. Results

A total of 110 patients (mean age 73.31±6.4 years) were included in the study. 69 of the patients were male (62.7%) and 41 female (37.3%). The age range of the patients was 65-92 years old and the age distribution of the patients was as follows: 40 (36.4%) between 65-69 years, 29 (26.3%) between 70-74 years, 22 (20%) between 75-79 years and 18 (17.3%) over 80 years. The median dialysis duration of study population is 7.7 months (min. 3 months- max. 62 months). The mean BI score of the cases was 82.6±23.1. Only 47.3% of the patients (52 of 110) were independent in daily functioning (Barthel Index score of 91-100).

34.5% of the study population had fallen at least once in the past six months. The mean MNA-SF score of the cases was 12.25±2.81 indicating an adequate nutritional status. The cause of ESRD was found to be diabetes mellitus in 36.4% of cases and hypertension in 33.6% of cases. The mean Charlson Comorbidity Index score, 5.9±1.2, indicating a high burden of comorbid conditions. 50 patients (45.5%) had hypertension and 46 (41.8%) had diabetes mellitus. Other common comorbid conditions and characteristics of study population are listed in Table 1.

Table 1. Patients' characteristics

Characteristics	n	%
Age (years)		
65-69	40	36.4
70-74	29	26.3
75-79	22	20
≥ 80	18	17.3
Gender		
Male	69	62.7
Female	41	37.3
Education Status (year)		
0	26	23.6
1-8	77	70
≥ 9	7	6.4
Primary Cause of ESRD*		
Diabetes Mellitus	40	36.4
Hypertension	37	33.6
Polycystic Kidney Disease	6	5.5
Other causes	27	24.5
Duration of Hemodialysis (months)		
3-6	51	46.3
7-12	29	26.3
13-36	19	17.2
>36	12	10.2

Table 1. Patients' characteristics (continue)

Characteristics	n	%
Comorbidities		
Hypertension	50	45.5
Diabetes Mellitus	46	41.8
Coronary Artery Disease	45	40.9
Cerebrovascular Disease	22	20
Heart Failure	20	18.2
Malignancies	13	11.8
Charlson Comorbidity Index		
0-5	45	40.9
6-7	56	50.9
8-9	9	8.2
BI Scores**		
0-90	58	52.7
91-100	52	47.3
MNA-SF***		
0-11	37	33.6
>11	73	66.4
Hospital Admissions (past 6 months)		
0	14	12.7
1-3	33	30
4-5	41	37.3
>5	22	20
History of Fall (past 6 months)		
Yes	41	34.7
No	77	65.3

*ESRD= end stage renal disease, **BI= Barthel index ***MNA-SF= mini-nutritional assessment- short form.

The average number of medications received by the patients was 7.3±1.9 and the median number of medications was 7 per patient (min. 2 - max. 11). The five most commonly prescribed medications in the patients' charts were: phosphorus binders (69.1% of patients), folic acid (51.8%), aspirin (46.4%), proton-pump inhibitors (PPI) (45.5%) and furosemide (37.3%) of the patients. The number of patients receiving five or fewer medicines was 16 (14.6%); 40 patients (36.4%) received 6-7 medications, 36 patients (32.7%) received 8-9 medications and 18 (16.3%) 10 and more medications. When patients' charts were examined, 72 PIM cases were detected in 60 patients (54.5% of all patients). Only three kind of PIMs were in the patients' charts and they were PPI, insulin and doxazosin. When all medicines prescribed in the SGK Online Medulla system were examined, 164 PIM cases were detected in 73 patients (66.3% of all patients) according to the Beers' Criteria and 27 PIM cases were detected in 25 patients (22.7% of all patients) according to the Beers' Kidney list. The total number of patients, who were prescribed PIMS, determined by both lists was 78 (70.9% of all patients).

Only 5 patients were not using PIM according the Beers' Criteria, but using PIM according to the Beers' Kidney list and these PIMs were H-2 blockers. The most commonly used PIMs in all patients were PPI 50 (45.5%), nonsteroidal anti-inflammatory drugs (NSAIDs) 27 (24.5%), anti-histamines 16 (14.5%) and doxazosin 12 (10.9%) (Table 2).

Table 2. Frequently prescribed medications and PIMs

Features	n	%
Number of Medications		
< 6	16	14.6
6-7	40	36.4
8-9	36	32.7
≥ 10	18	16.3
Frequently Prescribed Medications		
Phosphor Binder	76	69.1
Folic acid	57	51.8
Acetyl Salicylic Acid	51	46.4
Proton-pump inhibitors	50	45.5
Furosemide	41	37.3
Beta Blocker	41	37.3
Statins	31	28.2
Frequently Prescribed PIMs* according to Beers List		
Proton-pump inhibitors	50	45.5
NSAIDs** (Diclofenac-Naproxen-Ibuprufen-Etodolac)	27	24.5
Anti-histamines (Diphenhydramine-Chlorpheniramine-Hydroxyzine-Clemastin-Doxylamine)	16	14.5
Doxazosin	12	10.9
Insulin, sliding scale	10	9
Metoclopramide	9	8.1
Anti-depressants (Amitriptyline-Fluoxetine-Escitalopram)	9	8.1
Chlorzoxazone	7	6.3
Acetyl Salicylic Acid (higher dose than 325 mg/day)	6	5.4
Quetiapine	4	3.6
Aripiprazole	3	2.7
Olanzapine	3	2.7
Frequently Prescribed PIMs according to Beers Kidney List		
H-2 Blockers (Famotidine-Ranitidine)	10	9
Gabapentin	6	5.4
Pregabalin	4	3.6
Tramadol	2	1.8
Colchicine	2	1.8

*PIMs= potentially inappropriate medications, **NSAIDs= nonsteroidal anti-inflammatory drugs.

According to Beers' kidney list most commonly used PIMs in all patients were H-2 blockers 10 (9%), gabapentin 6 (5.4%) and pregabalin 4 (3.6%) (Table 2). According to both criteria, 78 patients (70.9%) received at least one PIM, 54 (49%) two PIMs, 24 (21.8%) three PIMs and 10 (9%) four PIMs.

Factors associated with PIM use were examined. There was no significant difference between PIM use and gender, age, educational status, cause of ESRD, duration of dialysis, BI score, MNA-SF score and Charlson comorbidity score. Although 92.6% of the patients with positive falling history had at least one PIM, there was no statistically significant relation between falls and PIMs. A statistically significant positive correlation was found

between the total number of medications and PIM use. Patients receiving PIMs were prescribed significantly higher numbers of medications in general (P=0.017). There was also a statistically significant positive correlation between hospital admission and PIM (P<0.001) (Table 3).

Table 3. Factors associated with PIM use

Parameter	PIM* Positive		PIM Negative		
	Median	Min-Max	Median	Min-Max	P value
Age	72	65-91	74.5	65-92	0.443
Dialysis duration (months)	7.7	3-61	8	3-59	0.541
Charlson Comorbidity Index	6	3-10	5.5	4-8	0.223
Barthel Index	90	10-100	100	10-100	0.234
MNA-SF**	12	2-15	12	4-15	0.644
Number of Medications	8	5-11	6	2-9	0.017
Hospital Admission (past 6 months)	4	0-9	2	0-9	<0.001

*PIM= potentially inappropriate medication, **MNA-SF= mini-nutritional assessment- short form.

4. Discussion

In our study, the prevalence of PIM received by the elderly Turkish hemodialysis patients as determined by the both Beers Criteria and Beers' Kidney List was 70.9% and little higher than previously reported rates of PIM prevalence among dialysis patients in the literature. Until now, no such study has been done in Turkish elderly hemodialysis patients.

In a recent study conducted in Türkiye, the rates of PIM use were examined in patients with stage 1-5 CKD who were not on dialysis. In this study, PIM was detected in 91% of patients according to Beer's criteria. In the same study, PIM was found in 42% of patients according to the STOPP criteria and in 70% of the patients according to the medication appropriateness index (MAI) criteria (Pehlivanlı et al., 2022). Different criteria have been used in PİM studies in many studies. The reported PIM rates vary accordingly. This may be due to the healthcare system of the country, the variety of drugs available and the prescribing habits of local physicians. For example, in a study conducted in a similar population to our study, the PIM prevalence was 50% according to the Beers criteria and 30% according to the Taiwan criteria (Novaes et al., 2017).

In a study published in 2015, a secondary analysis of the data from the Phase II and III Dialysis Outcome Practice Pattern Study in Japan (DOPPS), PIM status was determined using the modified Beers Criteria for Japanese patients. The prevalence of PIMs in the study populations was 57%. The three most frequently prescribed PIMs were H2 blockers (33%), antiplatelet agents (19%) and α-blockers (13%). However, the medicines that listed in this study came only from patients' study charts (Kondo N. et al., 2015). In our study, we included not only the medications found in patients' charts but also all medications prescribed in dialysis center or in other health institutions and dispensed by pharmacies in the past 6 months. As a matter of fact, the only PIMs detected in the patients' files were PPI, alpha-blocker and insulin. However, when the SGK online database was examined, other PIMs were detected, especially NSAIDs and anti-histamines.

The most frequently prescribed PIM in elderly Turkish hemodialysis patients was PPI and 45.5% of patients were using PPI according to our study. The use of PPI has increased globally over the past few decades. PPIs are beneficial drugs that should be used in patient groups with a history of gastrointestinal bleeding, severe dyspeptic complaints, etc. However, in our country, it is used as a 'stomach protector' in patients who use many drugs without any obvious indication for PPI. The relationship between PPI and osteoporosis is well-described. Other possible adverse side effects of PPIs, such as Clostridium difficile infection, community-acquired pneumonia, vitamin B12 deficiency, kidney disease and dementia, are particularly harmful to elderly patients (Maes et al., 2017).

The most interesting finding of our study is the very high rate of NSAID use in hemodialysis patients. 27 patients (24.5% of all patients) were prescribed NSAID. The frequency of NSAID use is quite different from other studies in the literature. According to 2015 DOPPS study in Japan the incidence of inappropriate NSAID use was as low as 1% but it should be noted that in this study had to meet a criterion of long-term NSAID prescription to be considered an inadequate medication (Pehlivalı et al., 2022). In a study conducted in 2013, PIM use was detected in 56% of patients using the 2012 Beers criteria and the UK National Prescribing Guidelines for Kidney Disease in 100 consecutive inpatients aged 70 years and over, who were not on hemodialysis but had stage 3-5 CKD. The proportion of patients receiving NSAID or codeine-based pain medication in that study was 11% (Jones and Bhandori et al., 2013). In another study published in 2016, the PIM status of 51 elderly hemodialysis patients at a dialysis center in Norway was determined by applying the STOPP criteria to medication lists in the centers' electronic medical records and other medications detected by patient interviews. The PIM prevalence was found to be 64%; notably, no inappropriate NSAID use was detected (Parker et al., 2016).

Although the high rate of NSAID use found in our study is dissimilar to previous studies of PIM prevalence in hemodialysis patients, it is consistent with the rates NSAID use among elderly patients in the literature. NSAIDs are the most commonly prescribed medications for muscle and skeletal system pain in the elderly (Wongrakpanich et al., 2018). In general practice, rates of NSAID use in patients over 65 years of age have been shown to be approximately 96% (Ilotto et al., 2003). In another study, approximately 60% of elderly patients were prescribed NSAIDs despite contradiction for hypertension and / or heart failure drugs (Vandraas et al., 2010). Because mineral and bone disorders in dialysis patients, inadequate exercise, weakness from reduced muscle mass, arthritis and frequent pain complaints are common in elderly patients, especially elderly dialysis patients, physicians have a high tendency to use and prescribe NSAIDs. Although hemodialysis patients are generally anuric, NSAIDs should not be used in elderly hemodialysis patients due to gastrointestinal side effects, adverse effects on blood pressure and fluid control and other side effects. In these patients, paracetamol (acetaminophen) therapy may be a more appropriate treatment option than NSAID to control pain. An important limitation in the interpretation of our data is the prescription's legacy of our old drug payment and insurance systems. While a prescription is written to the patient as a habit from the past, if the relative has a complaint and this situation requires medication, this drug can also be written to the primary patient's prescription. Although this practice is no longer performed, the spouses of the patients in our study may have prescribed NSAIDs.

In our study, it was notable that PPIs were included in the prescription of NSAIDs. This may be an example of the "prescription cascade", a cause of polypharmacy, in which the prescription of drug A leads to the prescription of drug B in order to treat the side effects of a drug A. Similarly, a reduction in the use of NSAIDs would lead to a reduction in the use of PPIs, and thus, an overall decrease in the PIM prevalence. Improving the clinical care of CKD patients will require improved recognition of CKD and a better understanding of the medications that have nephrotoxic potential or risk for drug–drug interactions (Weir and Fink, 2014).

In previous correlation studies, several conflicting factors related to PIMs have been identified. In some studies, the number of PIMs was found to be positively correlated with the number of medications, age, and co-morbidities, while in other studies this relationship was not found (Manley et al., 2003; Kondo et al., 2015; Parker et al., 2016; Chahine, 2020).

In our study, there was no significant difference between inappropriate medication and gender, age, marital status, living situation, educational status, cause of ESRD, duration of dialysis, Barthel Index score, MNA score or Charlson Comorbidity score, but there was a positive correlation between total number of medications and PIM. The frequency of drug side effects increases with the number of drugs prescribed. This increase is especially marked in elderly patients with CKD.

Another finding that is noteworthy in our study is the significant association between hospital admission and PIM. The prescription by more than one physician increases the PIM risk significantly. While coordinating the care of dialysis patients in the chaotic environment of hospital emergency departments or outpatient settings, the risk of PIM may increase due to problems of both time and information access. Transitions of care are also associated with medication errors, which make hospital discharge an opportune time to address potential inappropriate medications (Hajjar et al., 2005). All medications prescribed to the patient require sufficient time and attention. Caution should be exercised especially in dialysis patients or patients with multiple comorbidities.

5. Conclusion

Due to the advances in medical technology combined with the global demographic shift, as more patients reach old age and develop chronic kidney disease requiring replacement therapy, a higher proportion of dialysis patients will be geriatric. Due to their special needs, it is important for physicians in dialysis centers to be cautious about geriatric conditions such as polypharmacy, fragility, neurocognitive disorders and to coordinate these treatments with consideration of geriatric conditions. New and different models in these dialysis approaches will need to be developed to obtain better treatment outcomes.

Author Contributions

The percentage of the author(s) contributions is present below. All authors reviewed and approved final version of the manuscript.

	K.E.Ö.	M.İ.	E.Z.	P.V.	H.D.
C	50	20	10	10	10
D	70	30			
S		50			50
DCP	50		30	20	
DAI	40	30			30
L	20	20	20	20	20
W	20	20	20	20	20
CR	20	20	20	20	20
SR	20	20	20	20	20
PM	20	20	20	20	20
FA	20	20	20	20	20

C=Concept, D= design, S= supervision, DCP= data collection and/or processing, DAI= data analysis and/or interpretation, L= literature search, W= writing, CR= critical review, SR= submission and revision, PM= project management, FA= funding acquisition.

Conflict of Interest

The authors declared that there is no conflict of interest.

Ethical Approval/Informed Consent

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to. The experimental procedures were approved by the Local Animal Care and Ethics Committee of Sakarya University Faculty of Medicine Non-Interventional Ethics Committee (approval date: May 15, 2021, protocol code: E-216255-35).

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