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A CROSS SECTIONAL STUDY ON ESTIMATING THE PREVALENCE OF POTENTIALLY INAPPROPRIATE MEDICATIONS AMONG ELDERLY PATIENTS ADMITTED TO KING ABDUL-AZIZ MEDICAL CITY EMERGENCY CARE CENTER

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Abstract

Introduction: *Medication management in elderly patients is truly a challenge for all health care professionals. Age-related changes, poly-pharmacy, and co-morbidities are factors for Potentially Inappropriate Medications [PIMs] prescribing that will increase the risk of Adverse Drug Events [ADEs]. STOPP [Screening Tool of Older Persons' Prescriptions] criteria are the most updated screening tool for detecting PIMs in elderly patients.*

Objectives: *To estimate the proportion of potentially inappropriate medications among the elderly visiting Emergency Care Center [ECC] at King Abdul-Aziz Medical City – Central Region [KAMC-CR].*

Methods: *Prospective cross-sectional study has been approved by the Institutional Review Board. The study includes 300 patients, conducted over two months from October-November 2014 at an ECC in KAMC-CR. The inclusion criteria: elderly more than 60 years old, patients from both gender and have polypharmacy [more than 4 medications] prescription. Exclusion criteria: patients who are non-eligible to be treated in KAMC-CR, and who don't have medications history in KAMC-CR pharmacy computer system. The data were collected from the hospital electronic system and patients' charts. The statistical analysis was completed using the Statistical Package for the Social Sciences [SPSS] 19.0 software. Results will be reported in terms of frequency, percent, and p-value.*

Results: *1200 patients who were admitted in ECC at KAMC-CR conducted over two months from October-November 2014. As a result, our study consisted of 300 patients [male 54% female 46%], the majority of patients were between 60-79 years old. PPIs are prescribed to 206 out of 300 patients. The results showed that the most frequent prescriptions resulting in PIPs by STOPP criteria were the PPI [20%], duplicated drug class prescriptions and long-term opiates in those with recurrent falls [11.7%] and vasodilator drugs with postural hypotension [11.4%].*

Conclusion:

> Poly-pharmacy was independently associated with PIMs especially in patients aged over 65.

> These findings have significant implications that will help us identify areas of improvement in the overall medical care of geriatric patients and focus on avoiding inappropriate drug use, reduce unnecessary medication, drug interactions and related adverse events.

> Comparing with other international findings, our institutions need to pay more attention to prescribing in the elderly population.

Keywords: *STOPP, Polypharmacy, PIMs, Elderly, ADE.*

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INTRODUCTION:

For the past few decades, there has been continuous growth of many effective therapeutic agents, which have been able to manage most of the chronic disorders that often accompany elderly patients [≥ 65 years old, about [13%] of world population]. [1,2] Medications often act as a "double-edged sword". Instead of medications being a cure, usually, they can cause other problems that we call Adverse Drug Events [ADEs] especially in the elderly.[1] The elderly are more likely to experience these unpleasant effects as a result of the age-related increase in the amount of drug handling, drug-drug interactions, increased sensitivity to drug effects, and prevalence of predisposing conditions that can enhance the frequency and severity of such events. [3] So, they are at an increased risk of ADEs as a result of co-morbidities, poly-pharmacy, and age-related changes. [4] These factors make older people vulnerable to Potentially Inappropriate Medications [PIMs] and increase the risk of ADRs. [5] PIMs have negative outcomes including a significant risk of ADEs, increased healthcare costs, and hospitalization that increases morbidity and mortality up to 100,000 deaths per year in the United States.

Thus, managing the medications in elderly patients is truly a challenge for all health care professionals. [1] That's why the quality and safety of drug prescribing are becoming a global health problem. [2] Avoiding PIMs represents a strategy aimed at reducing drug-related mortality and morbidity. Several screening tools for the detection of PIMs have been published. [4] In the last 20 years, there has been a focus on the most well-known tool for identifying potentially inappropriate prescribing the Beer's criteria, published in 1991 by Dr. Mark Beers. [5] However, there were some limitations: [7] [i] limited transferability/applicability outside of the United States; [ii] failure to address a number of common Potentially Inappropriate Prescribing [PIP] [e.g. drug-drug and drug-disease interactions]; [iii] failure to include criteria relating to potential under prescribing; and [iv] lack of user-friendly organization [e.g. by physiological systems]. [8] In 1997 these criteria were revised, again in 2003, and finally, in 2012 some of these limitations had been addressed, but not all of them. [7,8] O'Mahony and Gallagher suggested that to overcome the limitations in Beer's new criteria should be developed. A panel of 18 experts in geriatric pharmacotherapy including physicians, pharmacologists, pharmacists, and a psychiatrist made a list of medications that should not be prescribed for this population in specific diseases. [9] These new criteria known as STOPP [Screening Tool of Older Persons' Prescriptions] criteria include 65 medications listed with drug-drug and drug-disease interaction, therapeutic duplication, and increased risk of cognitive deterioration. [7]

STOPP criteria are arranged as most drug formularies according to relevant physiological systems. In addition, concise explanations coexist with each criterion. [10] When comparing the STOPP criteria and the 2002 version of the Beers criteria, some reports give recognition to the STOPP criteria to identify more medications associated with adverse drug events. [8] A Retrospective Study to Describe and Compare the Application of Select Sections of the STOPP/ START and Beers Criteria in Medication Reviews in a Musculoskeletal Specialty Practice [Linder et al., 2013] have shown the following result; A total of 468 medications were prescribed, an average of 7.43 per patient, with [73%] of patients with poly-pharmacy. Beers Criteria identified 32 PIMs in [39.7%] while STOPP Criteria identified 67 PIMs in [58.7%]. High statistical differences were found between the numbers of PIMs identified by the STOPP Criteria compared to the Beers Criteria [P=0.01]. [11] In another retrospective cohort study of 2,051 participants in Ireland [Moriarty et al., 2013], they found after comparison that PIMs defined by the STOPP criteria was more prevalent [61.17 %], followed by the Beers with [37.64 %]. [12] In a primary care setting for older people, the prevalence of PIMs identified by the STOPP criteria was [37.5%]. [13] In primary care in Turkey, they found that 48 patients [14.8%] were using

drugs inappropriately according to STOPP criteria. [2] A university teaching hospital prospectively studied 715 consecutive acute admissions that led to the conclusion that STOPP criteria recognized a significantly higher proportion of patients requiring hospitalization as a result of PIMs-related adverse events than Beers' criteria. This conclusion has notable implications for hospital geriatric practice. [14] STOPP and Beers criteria have several areas of overlap. Both sets of criteria emphasize the higher risk of adverse drug reactions and events in older people. Both sets of criteria focus on several common potential interactions in older people. [15]

Hospital admissions due to Drug-Related Problems [DRPs] have been studied internationally, but local data are limited. In 2006, a prospective observational study was conducted to evaluate all admissions through the Emergency Department of King Abdul-Aziz Medical City, Riyadh, Saudi Arabia, over a period of 28 consecutive days. It included 557 patients admitted through the emergency department; 82 [14.7%] of admissions were due to DRPs [53 definite, 29 possible]. The most common types of DRPs were a failure to receive medications in 25 cases [47.2%], an ADEs in 13 cases [24.5%], and drug overdose in 6 cases [11.3%]. [16] In this study, the average length of stay due to preventable DRPs was 5.6 days/patient and it was estimated that avoiding such admissions could save at least 616,000 Saudi Riyal during the 28 days of the study period. [16] In 2014 another study also linked ADEs and visiting the emergency department at Riyadh Military Hospital [RMH], Saudi Arabia. 300 patients, 56 [18.7%] were presented to the emergency department due to ADEs, and 244 [81.3%] patients were presented to the emergency department due to non-drug related problems. About ninety-three percent [n= 52] of the ADEs group was exposed to hospital admission while only [7.1%] [n= 4] were emergency department visits. [17]

Potentially inappropriate medications in the elderly patient using STOPP criteria have been studied internationally, but local data are limited. International studies showed the effect of using these criteria with ADEs and admission to the emergency department. On the other hand, previous local studies done in the same instruction about emergency department admissions around [47.2%] related to ADEs. The aim of this study is to assess the presence of PIP in elderly polypharmacy patients according to STOPP criteria at ECC in KAMC-CR.

METHODS:

In this study, we prospectively studied 300 patients who presented at tertiary healthcare setting KAMC-CR in ECC for a period of 2 months in 2014. Our targeted patients that were included in our study met our criteria which consist of patients who are 60 years and older, both female and male were also considered, patients who are consuming 4 medication or more. In addition, patients who are admitted to non- Intensive Care Unit [ICU] settings and non-critical care adult admitted at ECC were taken into consideration. However, we have excluded patients who are non-eligible to be treated in KAMC-CR and patient who do not have medications history in KAMC-CR pharmacy computer system. Based on a random sampling the investigators received daily e-mails that provides a list of all patients admitted to the hospital with specific information such as; patient name, Medical Recorded Number [MRN], Most Responsible Physician [MRP] and service under which patient is admitted. The list was received from the Clinical Information Manager [CIM]. STOPP criteria were used to identify inappropriate prescriptions and detect any ADEs after entering standard demographic details, a principal clinical reason for admission, medical co-morbidities, and concurrent medications from each patient's admission document were collected in the data collection sheet. Statistical analysis was performed using SPSS 19.0 software and Statistical Analysis System [SAS] 9.2. Categorical data were expressed as in percentage.

RESULTS:

Statistical analysis was performed using SPSS 19.0 software and SAS 9.2. Categorical data were expressed as in percentage. Furthermore, continuous data such as; age 60 years old and older, patient on more than 4 medications, a patient admitted to non-ICU settings and non-critical care adult admitted at ECC were expressed as mean ± SD. Moreover, all statistical assessment was to be two-tailed and the level of significance was at P = 0.05. When it came to clean the data, the raw data was processed in accordance with the best practices for raw data management to identify any inaccuracies or incompleteness in advance to the statistical analysis. In order to accomplish this task, all interval variables were checked and summarized in terms of maximum and minimum values. Additionally, minimum and maximum values were checked and compared against the nominal maximum and minimum value of each variable and variables with implausible values had been flagged. Furthermore, running a general frequency analysis has been applied to categorical variables such as; gender and age to identify any potential anomalies. To estimate the proportion of potentially inappropriate medication compared against the null value of 0.50 one sample binomial test has been used in our study. Where the results have been reported in terms of proportion, standard error, [95%] confidence interval, p-value, and

significance have been declared at Alfa less than 0.05. Lastly, to conclude the relationship between the findings in our study, Chi-square test/Fisher exact test has been selected to represent our outcomes in term of frequency, percentages, p-value, and significance was declared at alfa less than 0.05.

Depending on the inclusion and the exclusion criteria more than 1200 patients who were admitted in ECC at KAMC-CR conducted over two months from October-November 2014. As a result, our study consisted of 300 patients which were higher than we expected. After statistically analyzing our collected data we concluded that our sample size has a similar distribution between both genders [male 54% female 46%] [Figure 1]. Furthermore, our records showed that the majority of patients that were included in our study were between 60-79 years old in a total of 236 patients out of 300 patients [Figure 2].

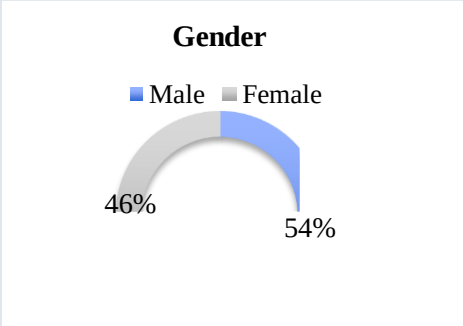

Figure 1Gender

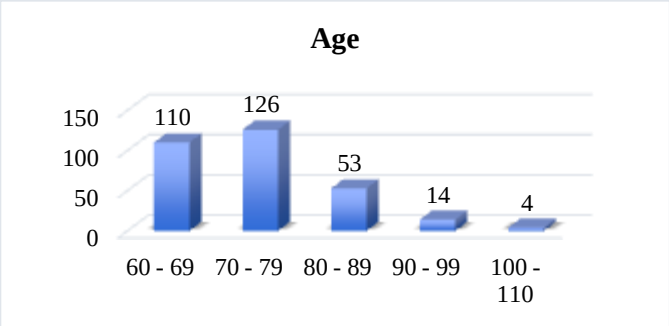

Figure 2 Age

In a serious note, our 300 patients' greatest co-morbidities factors were scoring the highest number when it came to endocrine where 257 out of 300 were suffering from it which makes it the majority of our patients with a percentage of [83.4%]. Second, the cardiovascular system has scored [71.8%] that makes them 221 out of 300 of our patients to be affected by its diseases. Furthermore, the diseases of the central nervous system were affecting our 116 patients who are included in our study with a percent of [37.7%] which makes it the third co-morbidity in our study. The musculoskeletal and the respiratory system have similar scoring where 117 of our patients have respiratory system dilemmas with [38%], and 111 of our patients were scored that they were suffering from the musculoskeletal system with [36%]. Our sixth co-morbidity in our study was the urogenital system [31.2%] which makes them 96 out of 300 patients. Lastly, the gastrointestinal system affected our patients [15.6%] and they are 48 patients out of 300 [Table 1].

Table 1 Co-Morbidities Based on Systems

Co-Morbidities Based on Systems	Population Out Of 300 Patients	%
Endocrine System	257	83.4%
Cardiovascular System	221	71.8%
Central Nervous System	116	37.7%
Respiratory System	117	38%
Musculoskeletal System	111	36%
Urogenital System	96	31.2%
Gastrointestinal	48	15.6%

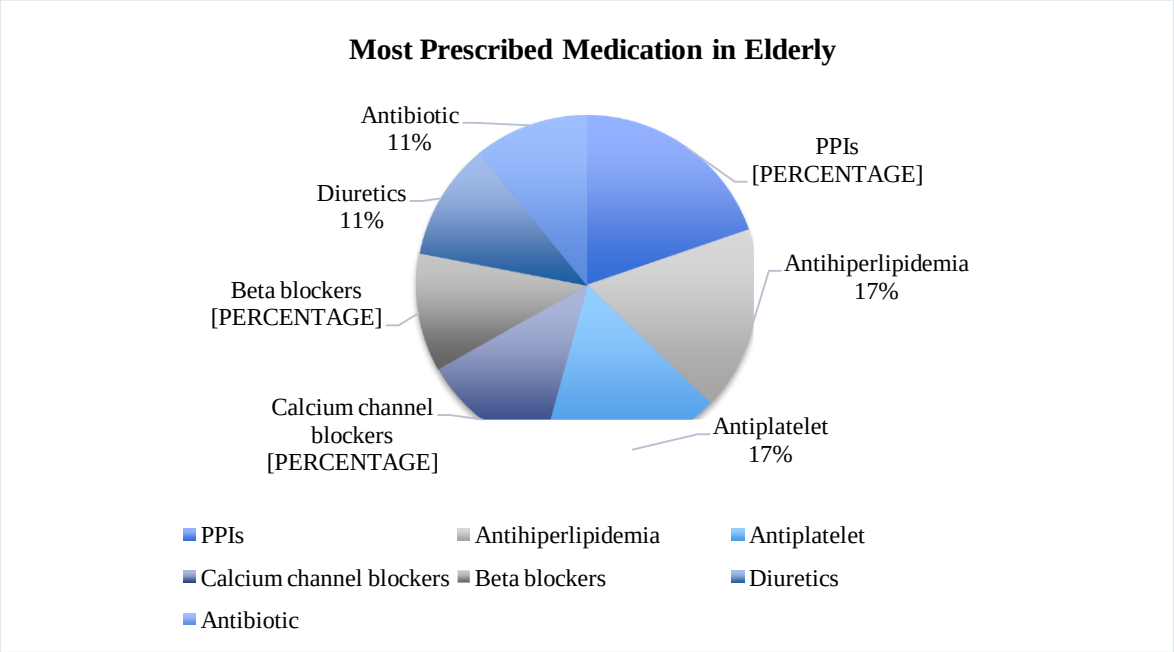

Figure 3 Most Prescribed Medication in Elderly

To be more precise with the high percentages of disease that were affecting our patients in our study were; hypertension [61%], diabetes mellitus [36%], stroke [21%], chronic obstructive pulmonary [16%], and osteoarthritis [14.5%]. Additionally, we discovered from our collected data that the highest prescribing medications in our study were protein pump inhibitor, anti- hyperlipidemia [Staten], and antiplatelet [Figure 3]. Most importantly, in our study, we discovered that PPIs are prescribed to 206 out of 300 patients which are considered a very high number. Despite this remarkable finding, we have investigated the reason behind this huge number on prescribing PPIs in to elderly and according to the data that was collected in ECC at KAMC-CR there was no clear indication that some of these 206 patients need to consume PPIs.

The results showed that the most frequent prescriptions resulting in PIPs by STOPP criteria were the PPI [20%], duplicated drug class prescriptions and long-term opiates in those with recurrent falls [11.7%], vasodilator drugs with postural hypotension [11.4%], neuroleptic drugs with who are prone to fall [9.1%], regular opiates for more than 2 weeks in those with chronic constipation without concurrent use of laxatives [8.5%], beta-blockers in those with diabetes mellitus and frequent hypoglycemia [7.1%], Non-Steroidal Anti-Inflammatory Drugs [NSAIDs] with moderate to severe hypertension [6.8%] [Table 2].

Table 2 Most Frequent Prescriptions Resulting in PIMs by STOPP

Most Frequent Prescriptions Resulting in PIMs by STOPP	%
Duplicate drug class prescriptions	**11.7**
Long-term opiates in those with recurrent falls	**11.7**
Vasodilator drugs with postural hypotension	**11.4**
Neuroleptic drugs with who are prone to falls	**9.1**
Regular opiates for more than 2 weeks in those with chronic constipation without concurrent use of laxatives	**8.5**
β-blockers in those with diabetes mellitus and frequent hypoglycemia	**7.1**
NSAID with moderate to severe hypertension	**6.8**

DISCUSSION:

In our study that depended on STOPP criteria that were used to identify inappropriate prescriptions and detect any ADEs, which is a well-known criterion that involves a 65-item list with therapeutic duplication, drug-drug, and drug-disease interaction, and elevated risk of cognitive deterioration. [7, 14] In our collected data our results have shown that the rate of inappropriate drug use was found to be [11.7%], which compared with other studies who have adopted the same idea on estimating the inappropriate drug prescribed for elderly either by using the STOPP criteria or the Beers' criteria there was a wide range of results. A

study that occurred in Turkey has collected 1019 participants using a face-to-face survey to inspect inappropriate drug use has recorded [9.8%] using Beer's criteria. Furthermore, another study that has been established in Turkey that aims to use STOPP criteria to investigate the rate of inappropriate drug use was reported to be 45 of their patients out of 325 patients which is [14%]. [7,18] Another study has been documented to have a rate of [12.5%] that has been taken in Finland. [19] Furthermore, a close rate to Finland was found in Taiwan with a rate of 10.5%. the study has consisted of 882 patients which only 97 patients over the age of 65 have been recorded to use inappropriate drugs. [20] However, the highest rating was found to be in the United Kingdom with a rate of [25.8%]. [21] Due to the lack of any research in Saudi Arabia that used STOPP criteria on that matter, to our knowledge our study is considered the first study in Saudi Arabia using STOPP criteria, therefore, there are no local results to compare our rating with. Although, with the international studies that have been published our rating is considered to have similarities.

When analyzing our collected data our results showed the most frequent prescriptions resulting in PIMs by STOPP criteria in ECC at KAMC-CR where; PPIs, protein long-term opiates, vasodilator drugs, neuroleptic drugs, regular opiates for more than 2 weeks, beta-blockers, and NSAIDs. With further investigation into the reason behind the high numbers of PPIs being the most prescribed medication in the elderly at KAMC-CR. It was estimated that to 206 patients out of 300 patients that were included in our study were consuming PPIs. Having said that, according to the STOPP criteria the mention of PPIs were stated twice as to be associated with aspirin and warfarin due to the lower risk of gastrointestinal bleeding that will cause, which is considered to be a potential reason on elevated number of its prescribing since the cardiovascular system has scored [71.8%] which they are 221 out of 300 of our patients to be affected by its diseases. Additionally, our sample size has seen to be suffering from hypertension [61%], stroke [21%] which also can be another reason behind it. In addition, it is prescribed for peptic ulcer disease at maximum therapeutic dosage for > 8 weeks. However, our findings showed that the gastrointestinal system affected our patients [15.6%] and they are 48 patients out of 300, and to be more specific only [1.3%] of our patients are suffering from peptic ulcer. Taking all these reasons into consideration our data that consisted of some of our 206 patients who were prescribed PPIs showed no clear indication about the reason behind the prescriptions. A similar outcome was reported in a study that occurred in the United Kingdom that used STOPP criteria to identify inappropriate prescribing among elderly. Their results have shown that the most frequent cases of PIP were therapeutic duplication, the consumption of aspirin with no valid symptom and inappropriate use of PPIs. [22]

Even though our study is limited by poor documentation in the clinical charts especially ADRs related information our reported outcomes showed that the rate of inappropriate drug use was found to be [11.7%]. When comparing with other countries with different PIP it has a variety of percentages different from one another and it may be influenced by explicit regulatory measures. In our study, we suggest that including clinical pharmacists in generating prescribing guidelines will contribute to minimizing the spread of PIP in hospitals. Furthermore, pharmacists by all their levels should play a significant role through the multidisciplinary team to provide safe medication practice to the elderly. In addition, these findings need to be communicated with geriatric medicine in the hospital and to the ministry of health in order to improve the current practice. A study showed that nursing home resident across eight European countries has a remarkably low level of PIP in Denmark among the other countries. The low level was associated with the review of a drug utilization by the National Institute of Health, which involved feedback from healthcare providers. [23] Another study has also suggested that physicians and pharmacists review and input have the ability to develop and improve medication appropriateness in the elderly. [10, 24] Moreover, implementing a customized electronic tool can also be implemented in our hospitals to ensure patient's safety. In other word, STOPP criteria can be applied in areas that aim to treat the elderly to decrease the potential of ADEs that can cause or be associated with morbidity and most importantly exam appropriateness of drug treatment.

CONCLUSION / RECOMMENDATIONS:

In conclusion, comparing with other international findings the findings in our study have highlighted major issues in our current situation in prescribing medication to the elderly. However, identifying these issues with numbers can surely help generate approaches to improve the overall medical care of geriatric patients. Avoiding inappropriate drug use, reduce unnecessary medication, drug interactions and related adverse events are some of the procedures that our healthcare needs to focus on and implements.

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Abbreviations

PIMs	Potentially Inappropriate Medications	PIP	Potentially Inappropriate Prescribing
ADEs	Adverse Drug Events	MRN	Medical Recorded Number
STOPP	Screening Tool of Older Persons' Prescriptions	MRP	Most Responsible Physician
ECC	Emergency Care Center	CIM	Clinical Information Manager
KAMC-CR	King Abdul-Aziz Medical City - Central Region	SAS	Statistical Analysis System
SPSS	The Statistical Package for the Social Sciences	ICU	Intensive Care Unit
DRPs	Drug-Related Problems	PPIs	Proton Pump Inhibitors
RMH	Riyadh Military Hospital	NSAIDs	Non-Steroidal Anti-Inflammatory Drugs