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ORIGINAL ARTICLE

DETECTION OF POTENTIALLY INAPPROPRIATE PRESCRIPTIONS USING TIME AND STOPP/START LISTS IN TURKISH GERIATRIC PATIENTS: A SINGLE CENTER EXPERIENCE

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Abstract

Introduction: Screening Tool of Older Person's Prescriptions (STOPP) / Screening Tool to Alert Doctors to the Right Treatment (START) is among the most forthcoming lists developed to detect potentially inappropriate prescribing, which consists of potentially inappropriate medications and potential prescription omissions. Turkish Inappropriate Medication Use in the Elderly (TIME) was developed based on STOPP/START version 2 for the eastern European population. We aimed to compare the effectiveness of STOPP/START and TIME in detecting potentially inappropriate prescribing, potentially inappropriate medications, and potential prescribing omissions.

Materials and methods: Eighty-five patients who presented to Gazi University Hospital's Geriatrics Outpatient Clinic between November 2020 and March 2022 were included in this study. The patients' detailed clinical records were evaluated according to TIME and STOPP/START. The numbers of potentially inappropriate prescribing, potentially inappropriate medications, and potential prescribing omissions were determined.

Results: Median number of potentially inappropriate prescribing detected according to TIME was significantly higher than according to STOPP/START (6 [IQR 4-7] vs. 3 [IQR 2-5], $p<0.001$). However, no significant difference was observed in the number of potentially inappropriate medications detected. The number of patients meeting potentially inappropriate prescribing criteria according to the TIME was significantly higher than START, which was attributable primarily to the disparity in the vaccination category.

Conclusion: Our results suggest that TIME is more successful in detecting potentially inappropriate prescribing than STOPP/START in Turkish geriatric patients. This success was probably due to the better performance of TIME in detecting potential prescribing omissions. Further studies are needed to confirm these findings.

Keywords: Potentially Inappropriate Medication List; Polypharmacy; Drug Therapy; Geriatric Assessment; Drug Interactions.

INTRODUCTION

Comorbidities and polypharmacy in elderly patients are serious issues that health-care professionals must address. Increased interactions between diseases and medications escalate adverse drug reactions. Furthermore, medication effects differ in older patients, which creates the need for careful clinical practice evaluation. The adverse drug reactions that result from the interplay of these elements lead to an increase in hospital and emergency department admissions. Medication-related issues in the elderly continue to harm patients and strain health-care systems.

Given these negative circumstances, older people's drug use must be monitored. In response to this need, the concept of potentially inappropriate prescribing (PIP) has been introduced. This concept covers two issues: potentially inappropriate medications (PIMs) and potential prescription omissions (PPOs). PIMs are drugs that a patient is using that are potentially inappropriate. PPOs refer to medications that the patient should be using based on their clinical condition but that have not been prescribed. Various lists of criteria have been developed to anticipate potentially inappropriate prescriptions and prevent potential adverse effects (1).

Among these lists, one of the most important consists of the Screening Tool of Older Person's Prescriptions (STOPP) and the Screening Tool to Alert Doctors to the Right Treatment (START). Studies have demonstrated the association between the potentially inappropriate medications identified by this list and adverse drug reactions (2-4). This list was developed by 18 experts in geriatric pharmacology, who used the Delphi method for this task. In the first version of the list there are 65 criteria in the STOPP section (for PIMs) and 22 criteria in the START section (for PPOs). The list has been expanded to 114 criteria in the second version, including 80 STOPP criteria and 34 START criteria. (5). Researchers in different countries have adapted this list to their national contexts (6, 7). The third version of this list, with an expanded scope and number of criteria, was published in 2023 (8).

Prescription habits and drug-market products vary widely by country (9). As a result, new lists of criteria, or the adaptation of existing ones, are necessary. To meet this need, the Turkish Inappropriate Medication Use in the Elderly (TIME) list was developed for use in eastern Europe. This list contains two sections: TIME-to-STOP and TIME-to-START. The first version of the list was published in 2020. The next year, the list was validated and updated internationally with minor changes using the Delphi method (10, 11). The methodology and format of STOPP/START were used to prepare TIME. Therefore, TIME-to-STOP addresses PIMs, and TIME-to-START deals with PPOs. The first section comprises 101 criteria, while the second one contains 33, which amounts to a total of 134 criteria. As indicated by the number of criteria, STOPP/START and TIME differ significantly in content (10, 11). According to the relevant consensus study, the TIME list should be considered a separate list; also, as noted by Lee et al. in their systematic review, the literature features TIME as a separate entity (1, 11).

The TIME list addresses the needs of a population living in a more localized geographical area. It represents a pioneering effort in terms of the target population and country context. Accordingly, we aimed to compare the effectiveness of STOPP/START and TIME in patients attending a university hospital geriatric outpatient clinic through a descriptive study. To the best of our knowledge, the present study is the first of its kind.

MATERIALS AND METHOD

Approval was obtained from the Gazi University Clinical Research Ethics Committee (meeting date: October 2, 2020; decision no.: 684). The study was conducted cross-sectionally at the Gazi University Hospital Geriatric Outpatient Clinic and

the Department of Medical Pharmacology. Written informed consent was obtained for the detailed examination of all the clinical data of 85 patients who applied to the clinic between November 2020 and March 2022. The patients' demographic information, complaints, comorbidities, medical histories, medications being used, and relevant laboratory and imaging results were recorded in case report forms. Subsequently, these forms were examined to check the adherence of the patients' medications to the TIME and STOPP/START version 2 lists. When evaluating the clinical information of the patients, the most recent medications prescribed on the date of informed consent were taken as reference. PIMs and PPOs were identified, and the criterion class on the basis of which they were identified was recorded.

Since the TIME list is based on STOPP/START v2, we preferred to use the second version. On the other hand, it was considered appropriate to use the most recent and available lists at the time the patients were evaluated.

In our research, when TIME is specified as a list, it means that TIME to STOP and TIME to START are evaluated together. If there is a separate evaluation involving distinct subsections, they will be identified as TIME to STOP or TIME to START. Similarly, if the STOPP/START list was evaluated as a whole, it will be named as such, if distinct sub-sections were evaluated, it will be specified as STOPP or START.

An a priori power analysis was conducted using G*Power version 3.1.9.7 to determine the minimum sample size required to test the study's hypothesis (12). This analysis indicated that the required sample size to achieve 80% power to detect an effect size of 0.3, with a significance criterion of α=0.05, was N=176 for the Mann–Whitney U test. Thus, the obtained total sample size of N=170 (85 patients for each of the tests) was adequate to test the hypothesis.

All the statistical analyses were performed using IBM SPSS Statistics version 23. Descriptive statistics were expressed as percentages, means, standard deviations, interquartile ranges, and minimum and maximum values. The data were evaluated for normality using the Kolmogorov–Smirnov test. Parametrically distributed data were analyzed using independent t-tests, while non-parametrically distributed data were analyzed using the Mann–Whitney U test. A significance level of $p<0.05$ was considered statistically significant.

RESULTS

Demographic Data

In the sample, 37% of the participants were male, and 63% were female. The mean age was 74.5±6.0. The participants had an average of 4.5±2.1 comorbidities. The most commonly observed comorbidities were hypertension, diabetes mellitus, coronary artery disease, osteoporosis, and hyperlipidemia (the prevalence of comorbidities in the population was n=65, 76.5%; n=43, 50.6%; n=26, 30.6%; n=21, 24.8%; and n=16, 18.9%, respectively). There was no significant difference in the number of comorbidities between males and females. The participants used an average of 7.5±3.5 medications. There was no significant difference in the mean number of medications used between the two genders (Females: 7.9±3.6 vs. Males: 6.8±3.6; p=0.141).

Meeting at Least One Criterion

When evaluating which criteria the participants met, it was observed that all of them met at least one criterion of the TIME list, while 96.5% met at least one criterion of the START/STOPP list. Looking at the subgroups, 55.3% of the participants met at least one PIM criterion according to TIME to STOP, while 44.7% met at least one PIM criterion according to STOPP. All the participants met at least one PPO criterion of the TIME to START list, while the figure for the START list was 95.3%. In terms of gender, 64.2% of female participants met at least one PIM

criterion based on TIME to STOP, while 54.7% of them met at least one PIM criterion based on STOPP. Among the male participants, these rates were 40.6% (TIME to STOP) and 28.1% (STOPP). Furthermore, 96.2% of female participants met at least one PPO criterion according to the START list, while this rate was 93.9% in males.

Number of Criteria Met According to List

When evaluating the medications used by the participants, the number of criteria met was found to be significantly higher for the TIME list, as shown by the median (Mdn) values (TIME Mdn: 6[IQR 4–7]; STOPP/START Mdn: 3[IQR 2–5]). No significant difference existed between the number of PIM criteria met according to the TIME to STOP list and the number met according to the STOPP list (p=0.056). The number of PPO criteria met based on the TIME to START list was significantly higher than that met based on the START list (TIME to START Mdn: 4[IQR 4–5]; START Mdn: 2[IQR 2–3]) (Table 1, Figure 1).

Comparisons Between Females and Males

According to the TIME list, females met more PIP criteria than males (Female Mdn: 6[IQR 5–8]; Male Mdn: 5[IQR 4–6]; p=0.009). However, there was no significant difference between the total number of PIP criteria met in females and that met in males according to the STOPP/START list. Based on both TIME to STOP and STOPP, females met more PIM criteria than males (TIME to STOP Female Mdn: 1[IQR 0–2] vs. TIME to STOP Male Mdn: 0[IQR 0–1.75], p=0.02; STOPP Female Mdn: 1[IQR 0–2] vs.

Table 1. Number of criteria met in general patient population

	TIME median, [IQR]	STOPP/START median, [IQR]	P value
PIM	2, [0-2]	0, [0-1]	0.056
PPO	4, [4-5]	2, [2-3]	<0.001
PIP (TOTAL)	6, [4-7]	3, [2-5]	<0.001

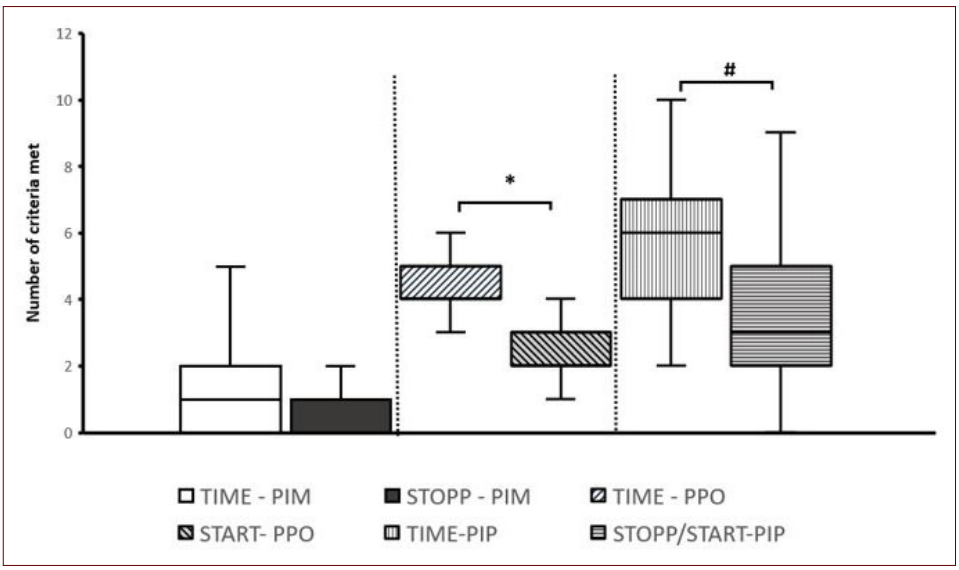

Figure 1. Number of PIMs, PPOs and PIPs covered by TIME and STOPP/START lists (*<0.001, #p<0.001, Mann Whitney-U Test).

STOPP Male Mdn: 0[IQR 0–1], p=0.02). There was no significant difference between the number of PPO criteria met in females and males according to both the TIME to START and START lists (Table 2).

The number of criteria met based on the TIME and STOPP/START lists was compared separately for females and males. In both genders, the total number of PIP criteria met according to TIME was significantly higher than that met according to STOPP/START (TIME Female Mdn: 6[IQR 5–8] vs. STOPP/START Female Mdn: 3[IQR 2–6], p<0.001; TIME Male Mdn: 5[IQR 4–6] vs. STOPP/START Male Mdn: 3[IQR 2–4], p<0.001). Both among males and females, the total number of PIM criteria met based on the TIME to STOP list did not significantly differ from that met according to the STOPP list. In both genders, the total number of PPO criteria met according to TIME to START was significantly higher than that met according to START (TIME to START Female Mdn: 5[IQR 4–5] vs. START Female Mdn: 2[IQR 2–3.5], p<0.001; TIME to START Male Mdn: 4[IQR 4–5] vs. START Male Mdn: 2.5[IQR 2–3], p<0.001).

Comparisons by Organ System Category

The TIME and STOPP/START lists were also compared based on the organ system categories they contain.

When examining the PIM criteria from this perspective, it was noted that STOPP listed two subsets of criteria under the categories Cardiovascular System and Coagulation System; in contrast, TIME to STOP list had only the category Cardiovascular System. Therefore, Cardiovascular System in the TIME to STOP list was compared to Cardiovascular System and Coagulation System in the STOPP list. The number of criteria met was significantly higher in the combined category Cardiovascular System and Coagulation System in the TIME to STOP list compared to the STOPP list (TIME to STOP Mdn: 0[IQR 0, 1] vs. STOPP Mdn: 0[IQR 0, 0]; p<0.001). No significant difference was observed between the two criteria lists in the categories Central Nervous System, Gastrointestinal System, Respiratory System, Musculoskeletal System, Urogenital System, Endocrine System, and Antimuscarinic Drugs.

When examining the PPO criteria in terms of organ system subcategories, it was noted that in Gastrointestinal System Drugs and Vaccines, the TIME to START list had a significantly higher number of met criteria compared to the STOPP list. Regarding Musculoskeletal System Drugs, however, the START list had a considerably higher number of met criteria compared to the TIME to START list (Table 3). No significant difference was observed between the two lists in the categories

Table 2. Number of criteria met in males and females.

	Male median, [IQR]	Female median, [IQR]	P value
TIME PIP	5, [4-6]	6, [5-8]	0.009
STOPP/START PIP	3, [2-4]	3, [2-6]	0.072
TIME PIM	0, [0-1.75]	1, [0-2]	0.02
STOPP PIM	1, [0-1]	1, [0-2]	0.02
TIME PPO	4, [4-5]	5, [4-5]	0.058
START PPO	2.5, [2-3]	2, [2-3.5]	0.524

Table 3. Number of PPO criteria for organ system subcategories

	TIME median, [IQR], (min, max)	STOPP median [IQR], (min, max)	P value
Cardiovascular System	0, [0-1], (0, 3)	0, [0-1], (0, 3)	0.626
Central Nervous System	0, [0-0], (0,1)	0, [0-0], (0, 1)	1.000
Gastrointestinal System	0, [0-0], (0-1)	0, [0-0], (0, 0)	<0.001
Respiratory System	0, [0-0], (0, 2)	0, [0-0], (0, 2)	0.655
Musculoskeletal System	0, [0-0], (0, 2)	0, [0-0], (0, 3)	0.007
Urogenital System	0, [0-0], (0, 1)	0, [0-0], (0, 2)	0.081
Endocrine System	0, [0-0], (0, 0)	0, [0-0], (0, 1)	0.173
Vaccines	4, [4-4], (2, 4)	2, [2-2], (0, 2)	<0.001
Vaccines Excluded From Total	1, [0-2], (0, 5)	1, [0-1.5], (0, 4)	0.705

Cardiovascular System, Central Nervous System, Respiratory System, Endocrine System, and Urogenital System. Furthermore, excluding the significant difference observed in the Vaccines category, all the other criteria were also evaluated within their own categories. No significant difference was observed in this comparison between the two lists (Table 3).

DISCUSSION

The potentially inappropriate medication use and PPOs of patients attending a university hospital geriatric outpatient clinic were evaluated using the TIME and STOPP/START lists.

The first notable result of the study is that according to the TIME list, all the participants met at least one criterion, while according to the STOPP/START list, almost all the participants met at least one criterion. Reviewing the literature, evaluations using the STOPP/START list typically show a criterion-met rate of 50%–70% (13-16). However, some studies report lower rates (17).

Moreover, in our study, the rates of patients with at least one PIM determined using the TIME to STOP and STOPP lists appear to be in line with the literature. However, the PPO rates are higher than previously documented (14-16).

The reason for this discrepancy could be the composition of the study population, which consisted of patients from a university hospital clinic. The complexity of comorbidities in patients visiting a university hospital may lead to more challenging polypharmacy scenarios. However, in their multicenter cross-sectional study published in 2022, Zeng et al. reported that PIMs were prescribed more frequently in primary care settings (18). Thus, further research is needed to evaluate the possible high rates of PPOs in the population of university hospitals in Türkiye.

When the medications used by the participants were evaluated, the average number of criteria met (the number of identified instances of PIP) according to the TIME list was found to be significantly higher than that based on the STOPP/START list. Hence, it could be suggested that TIME is more effective in detecting PIP in the Turkish population. Additionally, the mean number of instances of PIP identified by STOPP/START in our study is consistent with the literature (19, 20). However, to the best of our

knowledge, no data are available on the mean number of instances of PIP determined by TIME.

Although the TIME to STOP list identified more PIMs than STOPP, this difference was not statistically significant. Also, the rate of PPOs identified by TIME to START was significantly higher. However, this significance was lost when the Vaccines category was excluded.

In the TIME to START list, the Vaccines category has been expanded compared to the START, and the varicella-zoster virus (VZV) and tetanus–diphtheria vaccines have been added to the list. Therefore, it can be said that the difference in effectiveness between TIME to START and START largely stems from this expansion. Nowadays, vaccination against VZV, tetanus, and diphtheria is considered a necessity in routine geriatric health-care services (21-23). Thus, it can be concluded that the TIME list draws attention to an essential aspect of geriatric care in Türkiye and has the potential to raise considerable awareness about vaccination in geriatric health-care practice.

The TIME to STOP list detected significantly more PIMs in the categories regarding cardiovascular drugs and the coagulation system compared to the STOPP list. In the TIME to STOP list, the categories Cardiovascular System and Coagulation System from the STOPP list are grouped under a single heading. However, it should be noted that there are 30 criteria under a single heading for these two systems in the TIME to STOP list, while there are 23 under two headings in the STOPP list. Furthermore, 14 criteria present under the single heading in question in TIME to STOP are not found in STOPP, and eight criteria have been changed compared to STOPP. Both the expansion of the criteria and the changes made to them suggest that considerable differences have occurred in the detection of inappropriate drug use in the Turkish patient population (5).

When evaluating PPOs, it was observed that the TIME to START list discovered significantly more cases with reference to the Gastrointestinal System category. In the TIME-to-START section, which assesses PPOs, only one criterion recommends fiber use in everyone with symptomatic constipation who does not respond to dietary therapy. The START list has a criterion for proton pump inhibitor use and a second criterion recommending fiber support in individuals with diverticulosis and symptomatic constipation. Thus, the success of the TIME to START list in this regard may be attributed to its more liberal approach to recommending fiber use. Two significant articles published after STOPP/START version 2 have been cited in the TIME list regarding this issue. These publications recommend fiber use in symptomatic constipation (5, 10, 24, 25). This issue has been expanded in the third version of the STOPP/START list, with a recommendation added for the use of osmotic laxatives in elderly individuals with idiopathic or secondary benign constipation. However, in the newer version, the presence of diverticulosis is still deemed necessary for the use of fiber supplementation (8). This can be interpreted as an indication that STOPP/START version 3 has incorporated the current approach of TIME.

Upon reevaluation of the PPO results, it was found that more cases were identified concerning the Musculoskeletal System category in START. In this list, there are seven criteria under this category, while in the TIME to START list, there are eight criteria. In TIME to START, three criteria from START were preserved; two were preserved but modified, and one criterion from START's Analgesics category was transferred to the Musculoskeletal System category. Two criteria included in the START list but not in the TIME to START list are related to prescribing vitamin D in elderly individuals receiving long-term corticosteroid therapy, those at risk of falls, or those with osteopenia (20). The detection of more PPOs related to Musculoskeletal System Drugs in START could indicate a deficiency in prescribing vitamin D to elderly individuals in Türkiye.

In our study, more instances of PIP were detected in females according to the TIME list, while no gender difference was observed in the STOPP/START list. However, more PIMs were identified in females based on both the TIME to STOP and STOPP lists. Regarding PPO rates, no gender difference was observed between TIME to START and START. These findings suggest a tendency for more PIM prescriptions in females. A similar trend has been reported in the literature (15, 16). Furthermore, in our study, a higher rate of PIM detection was observed for females according to both lists, but no significant difference was found between males and females in terms of PPO rates. Thus, the higher prevalence of PIP detection for females may be due to more PIM prescriptions. More studies are needed to investigate why higher PIM rates are observed in females.

The present study also examined the differences in terms of PIP identified by TIME and START/STOPP in the male and female populations. A similar pattern emerged in both genders, with the TIME list detecting considerably more instances of PIP and PPOs among all participants. This suggests that the effectiveness of the TIME and START/STOPP lists in identifying instances of PIP does not vary between the genders.

The fact that all the participants visited the geriatric outpatient clinic during the COVID-19 pandemic is another important aspect of this study. The data are crucial for determining the frequency of PIP in the patient population during the pandemic.

The most significant aspect of this study is the comprehensive evaluation of detailed clinical data for all the participants. Given their content, the TIME and STOPP/START lists require full access to patient data.

The main limitation of the study is its small sample size. More comprehensive results could be obtained in a more extensive study where patients are selected from a clinic's patient pool through full randomization rather than voluntary participation. Furthermore, studies conducted in multiple institutions could advance our understanding of the phenomenon. Another limitation of the study is its observational design. More complete data can be obtained from prospective studies that correlate PIP data with adverse event and morbidity occurence.

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