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Prevalence Of Polypharmacy Among Elders And Screening For Inappropriate Prescriptions Using STOPP/START Criteria In Tertiary Care Teaching Hospital In Mumbai, India

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Abstract:
Polypharmacy is a rising global issue, affecting both primary and secondary care. Contributing factors are the increase in ageing and multimorbid population along with the increased use of evidence-based clinical guidelines. Polypharmacy refers to the use of multiple medicines for individuals with multiple morbidity. It is associated with adverse outcome ranging from mortality, falls, drug interaction, increase duration of hospital stay and re-admission following discharge.[1,2] The word "polypharmacy" has been derived from the ancient Greek 'polús' which means 'many', and 'pharmakeía' which means 'the use of drugs'. This broad meaning is a linguistic perspective and there is no consensus on the clinical definition of polypharmacy.[3] There are several definitions for polypharmacy ranging from two or more to five or more drugs intake in general or disease specific intake of drug. A systematic review by Masnoon et. al. [4] stated the definition of polypharmacy as the intake of five or more medication on daily basis to be most commonly used by researcher. Hence the present study has included the same definition.

INTRODUCTION

Physicians can do little to alter the characteristics of individual older patients to affect the kinetics or dynamics of drugs, however the decision whether to prescribe any drug, the choice of drug, and the manner in which it is to be used such as dose and duration of therapy, are all factors that are under control of the prescriber. Therefore, clinicians have be aware of consequences of polypharmacy and ensure the benefits of administering multiple medications versus the potential harms. Western countries have developed several tool kits to screen elders on the risk of drug interaction due to polypharmacy and also the need to initiate certain medication depending on the need. There is paucity of studies on the prevalence of polypharmacy and also the use of these screening tools in our setting. The present study aims to assess the prevalence of polypharmacy and its risk factors. Additional we also used STOPP/START criteria to screen the prescriptions for potentially inappropriate medication and identify the necessity to initiate certain medications.

MATERIAL AND METHODOLOGY

A cross-sectional study was done among elders aged above 60 years, visiting the Geriatric OPD between June to November 2023 at a Teaching Hospital in Mumbai. The study was conducted after obtaining Institutional Review Board and Ethics Committee approval. Based on prevalence of polypharmacy as 45.8% (P) from a previous study [5] and 8% (d) precision, the sample size was calculated using the formula $Z^2P(1-P)/d^2$. Taking into consideration 15% non-response rate the final sample was calculated to be 186. Inclusion criteria were all elders aged more than 60 years attending the geriatric OPD during the study period. Patients without their drug prescription and those not willing to give consent were excluded. Consecutive sampling was done till desired sample size was reached.

Operational definition for polypharmacy in this study was intake of five or more medication for the past 2 weeks. All drugs mentioned on their prescription was included to assess for polypharmacy excluding drugs taken for acute condition. A questionnaire was used to collect data on sociodemographic profile and the presence of co-morbidities. A total of 198 elders were examined for their prescription, of which 180 were included based the inclusion and criteria.

Risk factors included for association with polypharmacy were age (≥75 years vs <75 years), sex (male versus female), residence (rural vs urban), marital status (married vs unmarried/widowed), educational status (illiterate vs literate), occupational status (working vs non-working), family type (living alone vs nuclear/joint family, socioeconomic status (Class 4 & 5 vs Class 1,2 & 3) and number of co-morbidities (≥ 2 vs <2).

The STOPP/START medication review tool [6] was used to screen the elders for inappropriate medication and detect drugs that should be initiated based on the checklist. The STOPP criteria contains a total of 45 inappropriate drug prescription under 9 subheadings (e.g cardiovascular, Central Nervous System & Psychotropics, gastrointestinal etc.) The START criteria comprises a list of 22 medication which needs to be initiated based on the presence of chronic disease.

Statistical analysis: Data entry was done in Microsoft excel 2021 and analysis in Statistical Package for the Social Sciences (SPSS) version 26.0 IBM Corporation. Continuous data was expressed in mean and standard deviation while discrete data in frequency and percentage. Chi-square test was used to assess the association between polypharmacy and risk factor with a p-value < 0.05 considered to the statistically significant.

RESULTS

Sociodemographic details

A total of 180 elders aged more than 60 years and fulfilling the selection criteria were included in the analysis. Most of them (36.1%) belonged to the age group of 65 to 69 years with mean age of study participants was 69.47 ± 6.93 years. Male to female ratio was 1.2:1 with majority from the rural area (63.3%). The other sociodemographic details are given in table 1.

Comorbidities

Table 2 shows the comorbidities among the elders in the present study. The most common comorbidities were hypertension and other cardiovascular related disease (73.9%) followed by diabetes (50.6%) and respiratory illness such as COPD/asthma (23.3%). The average number of comorbidities among elders was 1.78 ± 1.03 with most (35.6%) having at least two chronic illness.

Medication intake

The mean number of medication intake among the study participants was 5.11 ± 2.9 drugs. The minimum and maximum drugs intake was 0 and 15 respectively. Intake of more than 10 medication was documented among 2.8% while none among 1.7%. [Table 3] Polypharmacy as per the operational definition was documented among 105 elders i.e 58.3% (95% Confidence interval: 50.8 -65.6).

Risk factors for polypharmacy

Among the several risk factors assessed for association with polypharmacy, only type of family i.e belonging to nuclear or joint family (X^2 =15.28, df=1, p<0.001) and having two or more co-morbidities (X^2=77.89, df=1, p<0.001) was found to be statistically significant [Table 4].

Potentially inappropriate medication

A total of 897 medication taken by the 180 elders were screened for their prescription this study. Of these 71 out of 897 drugs among 69 elders (38.3%) had inappropriate prescription as per STOPP criteria. The details of potentially inappropriate medication are given in table 5. The most common drug that given inappropriately was calcium channel blockers i.e amlodipine (21.1%) for elder with constipation followed by deflazacort and naproxen (8.4% each).

Drugs needed to be added

Among the 180 elders screen for their prescription, 42 elders (23.3%) needed to be started on a drug based on START criteria [Table 6]. The commonly started drugs were statins (23.7%) for elders with high risk of cardiovascular disease followed by calcium and vitamin D (16.6%) and pantoprazole (9.5%).

Table 1: Sociodemographic details of study participants (N=180)

Variable	Category	Frequency, n (%)
Age	60-64	39 (21.7)
	65-69	65 (36.1)

	70-74	22 (12.2)
	75-79	38 (21.1)
	>80	16 (8.9)
Sex	Male	99 (55.0)
	Female	81 (45.0)
Residence	Rural	114 (63.3)
	Urban	66 (36.7)
Marital status	Unmarried	8 (4.4)
	Married	134 (74.4)
	Widow	38 (21.1)
Educational status	Illiterate	81 (45.0)
	Primary school (1st to 5th class)	32 (17.7)
	Middle school (6th to 8th class)	24 (13.4)
	High school (9th and 10th class)	20 (11.2)
	Higher secondary (11th and 12th class)	15 (8.3)
	Graduate/Postgraduate/diploma	8 (4.4)
Occupation	Employed	101 (56.2)
	Not employed	79 (43.8)
Family type	Living alone	75 (41.7)
	Joint	68 (37.8)
	Nuclear	37 (20.6)
Socioeconomic status	Class V	45 (25.0)
	Class IV	52 (28.9)
	Class III	36 (20.0)
	Class II	28 (15.6)
	Class I	19 (10.5)
Number of co-morbidities	Nil	12 (6.7)
	1	57 (31,7)
	2	64 (35.6)
	3	36 (20.0)

	4	11 (6.1)

Table 2: Co-morbidities present among the study participants (N=180)

Disease	Frequency, n (%)
Diabetes	91 (50.6)
HT/CVA/CAD	133 (73.9)
COPD/Asthma	42 (23.3)
Thyroid disorder	20 (11.1)
Cirrhosis	7 (3.9)
Seizure	9 (5)
Psychiatric illness	20 (11.1)
Others	6 (3.3)

HT-Hypertension, CVA-Cardiovascular disease, CAD-Coronary artery disease, COPD-Chronic Obstructive pulmonary disease, Others include arthritis, Parkinson's disease, skin disease, autoimmune disease.

Table 3: Number of medication intake among study participants (N=180)

Number of medications	Frequency, n (%)
Nil	3 (1.7)
1-2	42 (23.3)
3-4	30 (16.7)
5-6	50 (27.8)
7-8	28 (15.6)
9-10	22 (12.2)
>10	5 (2.8)
Total	180

Table 4: Factor associated with polypharmacy (N=180)

Variable	Polypharmacy		Chi-square	df	P value
	Absent (n=75)	Present (n=105)			
Age					
≥75 years (n=54)	21 (38.9%)	33 (61.1%)	0.24	1	0.62

<75 years (n=126)	54 (42.8%)	72 (57.2%)			
Sex					
Female (n=81)	33 (40.7%)	48 (59.3%)	0.05	1	0.81
Male (n=99)	42 (42.4%)	57 (57.6%)			
Residence					
Rural (n=114)	45 (39.5%)	69 (60.5%)	0.61	1	0.43
Urban (n=66)	30 (45.5%)	36 (54.5%)			
Marital status					
Married (n=134)	54 (40.3%)	80 (59.7%)	0.40	1	0.52
Unmarried/widow (n=46)	21 (45.7%)	25 (54.3%)			
Educational status					
Illiterate (n=81)	33(40.7%)	48 (59.3%)	0.05	1	0.81
Literate (n=99)	42 (42.4%)	57 (57.6%)			
Occupation					
Employed (n=101)	47 (46.5%)	54 (53.5%)	0.96	1	0.34
Not employed (n=79)	31 (39.2%)	48 (60.8%)			
Family type					
Alone (n=75)	44 (58.7%)	31 (29.5%)	15.28	1	0.00*
Nuclear/Joint (n=105)	31 (29.5%)	74 (70.5%)			
Socioeconomic status					
Class V and IV (n=161)	65 (40.4%)	96 (59.6%)	1.05	1	0.30
Class III, II and I (n=19)	10 (52.6%)	9 (47,4%)			
Number of co-morbidities					
≥2 (n=111)	19 (17.1%)	92 (82.9%)	77.89	1	0.00*
<2 (n=69)	58 (84.1%)	11 (15.9%)			

*Statistically significant at $p<0.05$

Table 5: Potential inappropriate medication identified on STOPP criteria. (n=71)

Drugs to be stopped	Frequency
Cardiovascular	
Diuretic (monotherapy) with hypertension	2

Thiazides (bendroflumethiazide) with gout	1
Non-cardioselective Beta-blocker (propranolol, carvedilol, sotalol etc with COPD/Asthma	3
Calcium channel blockers with chronic constipation	21
Aspirin with peptic ulcer or >150mg/day	1
Aspirin, clopidogrel, dipyridamole or warfarin with any bleeding disorders	1
Central Nervous System & Psychotropics	
Tricyclic antidepressants (amitriptyline, imipramine etc) with cognitive impairment or glaucoma or cardiac arrhythmia or constipation or in addition to opiate or calcium channel blockers	1
Neuroleptics >1 month (haloperidol, risperidone etc) with hypnotic or parkinsonism	10
Selective serotonin re-uptake inhibitors (SSRIs, fluoxetine etc) with Hyponatraemia	2
Gastrointestinal	
Prochlorperazine (Stemetil) or metoclopramide with Parkinsonism	1
Chest	
Theophylline (monotherapy) with COPD	1
Systemic corticosteroids (instead of inhaled) with COPD	7
Ipratropium (nebulised) with Glaucoma	2
Musculoskeletal	
Non-steroidal anti-inflammatory drugs (NSAIDs) (ibuprofen, naproxen, diclofenac etc) with Mod-severe hypertension or Heart failure or >3 months in mild osteoarthtitis or Chronic kidney disease or along with warfarin	7
Corticosteroids (>3 months, monotherapy) with Rheumatoid Arthritis	3
NSAIDs or colchicines to prevent gout	2
Urogenital	
Bladder antimuscarinics (oxybutinin, tolterodine, solifenacin etc) with Cognitive impairment or Glaucoma or Constipation or chronic prostatism	1
Alpha-blockers (doxasocin, tamsulosin, terazocin etc) with Male & urinary incontinence >1 daily	2

Endocrine	
Glibenclamide or chlorpropamide with Type 2 diabetes mellitus	2
Falling	
Neuroleptic drugs with Recurrent falls disorder	1

Table 6: Potential prescribing omission based on START criteria (n=42)

Drugs to be initiated	Frequency
Cardiovascular	
Anticoagulant for atrial fibrillation	1
Aspirin or clopidogrel for vascular disease & in sinus rhythm	2
Statin for vascular disease with independent for activities of daily and life expectancy >5 years	3
ACE inhibitors for chronic heart failure	1
Beta- blockers for chronic stable angina	1
Chest	
Inhaled B2 agonist or anticholinergic for mild to moderate asthma or COPD	1
Neuro	
Levo dopa for Parkinson's Disease with definite functional impairment & resultant disability	2
Anti-depression for depression, moderate-severe <3 months	5
Gastro	
Proton Pump Inhibitor for severe gastro-oesophageal acid reflux disease	3
Proton Pump Inhibitor for Peptic stricture requiring dilatation	1
Fibre supplement for diverticular disease with constipation	2
Musculoskeletal	
Disease-modifying anti-rheumatic drug for Active moderate-severe rheumatoid disease > 12 weeks	1
Bisphosphonates for Maintenance corticosteroid therapy	2
Calcium & Vitamin D for osteoporosis	7
Endocrine	
Metformin for Type 2 diabetes +/- metabolic syndrome	1

ACE inhibitor or Angiotensin Receptor Blocker for Diabetes + proteinuria or microalbuminuria + GFR <50ml/min	2
Statin for Diabetes mellitus + major cardiovascular risk factors	7

DISCUSSION

The present observational study was conducted in a Geriatric department of a tertiary care hospital among 180 elders aged more than 60 years. The objective of study was to identify the prevalence of polypharmacy and assess the risk factors contributing towards the same. Additionally, we also screened the elders for potentially inappropriate medication using STOPP START medication review tool kit.

The operational definition of polypharmacy in our study was the intake of five or more medication for any chronic illnesses. Based on this, the prevalence of polypharmacy in our present study was very high i.e. 58.3% (95% CI: 50.8 -65.6). Studies done in India by Subeesh VK et. al.,[7] Rakesh et. al. [8] and Rathod et. al. [9] reported similar findings ranging from 58.2% to 66.2%. While others studies by Priya et. al.,[10] Agrawal et.al. [11] and Bhatt et. al. [12] reported a lower prevalence ranging between 26% and 45.8%. A study by Mohammad et. al. [13] from Tamil Nadu documented a very high prevalence of polypharmacy i.e. 81.3%. But this study was done elders admitted in the General medicine ward of a teaching college, hence could be the reason for high prevalence since most of the other studies were done among OPD patients were the number of medications would have been comparatively less due to less severity of illness. Ideally community-based studies should be done to access the real burden of polypharmacy. International studies done in Iran, [14] Italy [15] and Korea [16] reported 23.1%, 39.4% and 86.4% of polypharmacy respectively. This finding shows a wide range of difference in the prevalence of polypharmacy not only in India but across the world. Few studies [12,16,17] have further categorized polypharmacy as minor (5 to 6), major (7 to 9) or hyperpolypharmacy (10 and more). Overall, most of the studies have included five or more medication to be classified as polypharmacy.

The mean age of geriatric patients in our study was 69.47 ± 6.93 years with a range of 60 to 89 years. Age was not a significant risk factor contributing to polypharmacy in our study. Similar findings were also reported by Al Meida et. al. [18] But other studies by Hoesseine et. al. [14] found those aged 65 to 69 years and 75 to 79 years to be a greater risk for polypharmacy. Kin et. al., [16] Dutta et. al. [19] and Rakesh et. al. [8] found those aged between 70 to 79 years at a risk while Priya et. al. [10] found those aged between 60 to 65 years at greater risk. Most of the studies reported elders aged in their 70s to be at greater risk. This could be due to the fact that most of the elders develop chronic disease around this age and as they enter their 80s either the physician decreases the drug prescription or patients themselves avoid taking medication for side effects or non-improvement of the health illness. Moreover, most of these studies are hospitals-based studies, hence the true effect of age on polypharmacy cannot be assessed.

Gender was not statistically associated with polypharmacy in our study. Dutta et. al. [19] also reported similar finding in their study on risk factors of polypharmacy. Hossiene et. al. [14] documented female elders to be at a greater risk for polypharmacy while Kim et. al. [16] reported males. Hence, there is need for further studies to assess the role gender in polypharmacy.

Most of the geriatric patients i.e. around 63% in our study were from rural areas. Residence was not associated with polypharmacy in our study, similar to a study by Priya et.al. [10] Most of the other studies have not analyzed residence to be a factor contributing to residence. It is important study the effect of residence on polypharmacy since in India there is a prevalent practice alternative medicine which generally more common among the rural than urban. Despite this assumption our study did not find any association between residence and polypharmacy thus indicating the absence of alternative medicine practice in our setting.

Socioeconomic status was not associated with polypharmacy in our study. But Dutta et. al. [19] study found elders belonging to middle class to be a greater risk of polypharmacy. Carvalho et. al.'s study found high income group and being employed to have polypharmacy among the elders.[20] Kin et. al. [16] found lower income elders to be at greater risk. There is gross difference in role of socioeconomic in contributing to polypharmacy. Further studies with larger sample size to represent individuals from all socioeconomic status are needed to draw valid conclusion in our settings.

Educational status was also not associated with polypharmacy. Almeida et. al. [18] also reported similar finding, but Dutta et, al. [19] found elders with less than primary school to have more polypharmacy than the counterpart. There is a need to identify whether polypharmacy is mainly initiated from the patient's side of the physician side. Seeking treatment from multiple physicians increases the risk of polypharmacy. Our study found no effect of marital status on polypharmacy similar to results obtained by Almeida et. al. [18] and Priya et.al. [10] Family type was the only sociodemographic variable that statistically significantly associated with polypharmacy in our study. Elders living in joint or nuclear family had more incidence of polypharmacy than those living alone. This difference could be due to the fact that in joint or nuclear family, elders live with family member who take extra care or spend more money in buying medicine ensuring they take all the prescribed medication and also additional vitamins and minerals supplements. Several medical conditions such as diabetes, hypertension and cardiovascular disease, COPD/asthma, cirrhosis and psychiatric illness were associated with polypharmacy except for thyroid disease and seizures. It was also noted that elders with greater number of chronic illnesses had more polypharmacy. The mean number co-morbidity in our study was 1.78 ± 1.03. A study by Subeesh et.al. [7] the mean number co-morbidity was 2.54 ± 1.86, and their study also found elders with more chronic illness to have more risk of polypharmacy. Hosseine et. al. [14] in their study found elders with hypertension, angina, myocardial infarction, diabetes, pulmonary disease, depression, hypothyroidism and arthritis were significantly associated with polypharmacy in our study.

Almeida et. al. [18] reported elders with circulatory system disorders to have 4.88 times more risk of polypharmacy, while endocrine, nutritional, metabolic diseases and digestive tract to be at 3.78 times. This study also reported elders taking treatment at public health service were having more polypharmacy than those getting treated at private clinic. In our study, almost all patients had been taking medication from our hospital and we did not have a comparison group.

Using the STOPP START medication review tool for our study patients, a total of 71 drugs had to be stopped. Of these cardiovascular related drugs were the maximum of 40.8%, followed by central nervous system drugs (18.3%), musculoskeletal drugs (16.9%), chest drugs (14.2%) and urogenital drugs (4.2%). Other drugs relating to gastrointestinal system, endocrine system and falls were less than 2%. Among the drugs that had to be started using STOPP START tool were majority (23.8%) belonged to each muscular skeletal and endocrine system. The commonly started drugs were statins for elders with high risk of cardiovascular disease followed by calcium and vitamin D.

Keche et.al. [21] had conducted a study to assess the usefulness of STOPP START and Beers' criteria for prescribing medication in the elders at a tertiary care center. Among the 331 elders prescription that was examined, a total of 78 drugs were suggested to be stopped based on STOPP START criteria and 137 based on Beer's criteria. But only 18 out 78 drugs (based on STOPP START) and 34 out 137 (based on Beer's) was approved to be stopped by the treating physician. The study concluded that the quality of primary care to the elders can be improved by using these screening tools.

A study by Ryan et. al. [22] in Ireland also compared the potentially inappropriate drugs among elders between STOPP START and Beers criteria among 1329 records. They reported 21.4% of drugs were inappropriate based on STOPP START criteria and 18.3% based on Beers' criteria. The stated that the prevalence potentially harmful medication was very high in the community and suggested the need for training primary care physicians and community pharmacist as a preventive strategy. Beers criteria was not used in our study since the screening checklist to lengthened as compared to STOPP START. Moreover, a systematic review documented that STOPP/START criterion is more sensitive than the Beers criteria. [23]

Gollarte et.al. [24] had compared the inappropriate drug prescription between STOPP START and Australian criteria. Of the 100 patients studied 79% of subjects had at least one inappropriate drug while 95% with Australian criteria. The most common potentially inappropriate drugs that was prescribed were proton-pump inhibitors, anticholinergic drugs, benzodiazepines and antipsychotic drugs. Many elders had duplicate medications and also drug interactions. Statins and aspirin were underused in patients having high cardiovascular risk, and of calcium and vitamin D in elders with osteoporosis. The most frequent potentially inappropriate medication detected by the STOPP criteria was proton-pump inhibitor (PPI) without any clear indication (52%). Other findings were, use of benzodiazepines (35%) and antipsychotic drugs (26%) in patients with a history of falls, prolonged use of long-acting benzodiazepines (13%), and

the use of antipsychotics for sleep induction (23%). In 9% of their study subjects, duplication of medications was detected which mostly belonged to central nervous system activating drugs.

CONCLUSION

In conclusion, our study found that polypharmacy to be a prevalent health issues of great concern among elders and need for primary care physician and pharmacist to be trained in the screening for drugs using the STOPP START toolkit.

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