

# Effect of Potentially Inappropriate Medication on Treatment Adherence in Elderly with Chronic Illness

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Non-adherence to treatment has been associated with poor clinical outcomes, especially in vulnerable population like, the elderly. In general, the adherence to medication and use of a potentially inappropriate medication (PIM) may range from 47 to 100% and 20 to 25% respectively, in elderly. PIM is associated with increased risk of adverse drug reactions (ADR) which is a recognized determinant of adherence. The present study was taken up with the primary objective of exploring the influence of potentially inappropriate medication on adherence to drug treatment in elderly patients with chronic illnesses. This cross-sectional study was carried out in the out-patient department of a tertiary care hospital on a convenience sample of 425 elderly patients. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS-8). PIM was assessed as per the American Geriatric Society (AGS) Beers Criteria of 2015. Ordinal regression method was used to analyze the relationship between the ordinal outcome variable (adherence) and the explanatory variables. The study observed that about 48% of the elderly patients were found to be non-adherent to treatment. An inappropriate drug was prescribed in 23.8%. Elderly patients with a potentially inappropriate medication were twice likely be non-adherent to treatment than those without a PIM (OR: 2.089 with CI: 1.277-3.419,  $p = 0.003$ ). The present study concluded that potentially inappropriate medication is an important predictor of medication adherence in elderly. Since, high adherence level to medication among patients is widely reported to be associated with higher treatment efficacy, identifying and preventing the factors that lead to poor medication adherence is essential for the success of a therapy. Prescribers should carefully assess the appropriateness of medications in elderly to improve their adherence to therapy.

**Keywords:** Potentially inappropriate medication (PIM), adherence, elderly, Beers criteria, MMAS-8.

Globally, the elderly population is expected to reach two billion and over 323 million in India by 2050<sup>1</sup>. The disease process in elderly is patho-physiologically complex predisposing them to recurrent, chronic illness and multiple co-morbidities, exposing them to poly-pharmacy (prescribed number of medications), increased risk of drug related problems including ADRs (adverse drug reactions) and non-adherence to treatment<sup>2</sup>. Non-adherence has been associated with poor clinical outcomes, an increased cost of healthcare, a

lower quality of life, and a higher rate of mortality<sup>3</sup>. Various studies have hypothesized, that about 200 factors that influence adherence, some of them are intentional (rational decision-making, secondary effects) and some non-intentional (treatment complexity, inappropriate prescribing)<sup>4</sup>. In general, only 50% of general population has been estimated to adhere to their medications, and this may range from 47 to 100% in elderly<sup>5</sup>. Therefore, medication-using behaviour is extremely complex in elderly and it requires a multifactorial strategy

to improve adherence. Identification of avoidable risk factors that reduce adherence and institution of appropriate interventions is essential for improving medication-taking behaviour and economic outcomes.

Use of potentially inappropriate medications (PIM) in elderly has received substantial research attention in recent years, with researches reporting high prevalence of PIM in developed as well as developing countries<sup>6</sup>. Various studies done in India have reported the prevalence of PIMs in elderly to be in the range of 20 to 25%<sup>7,8</sup>. Prescribing PIM is associated with increased risk of ADRs, morbidity, mortality and healthcare mis-utilization. Studies have reported an 83% increased risk of ADRs in elderly patients receiving a PIM<sup>9</sup>. Since, ADR is a recognized determinant of adherence; it is interesting to study how PIM affects adherence in elderly. Though, numerous studies have been performed to assess the prevalence and predictors of poor compliance, few studies have been done in the Indian population and elsewhere to assess the effect of PIM on medication adherence in elderly. Hence, the present study was taken up with the primary objective of exploring the influence of potentially inappropriate medication on adherence to drug treatment in elderly patients with chronic illnesses.

Researchers interested in assessing the adherence, often have used the eight item Morisky Medication Adherence Scale (MMAS-8), which measures adherence on a 3 level ordinal scale (low adherence = 1-2, medium adherence = 3-4 and high adherence = 5-8)<sup>10</sup>. However, in most of the studies, the outcome variable, in spite of having three ordinal categories, have been considered as dichotomous (adherent vs. non-adherent) and binary/multivariate logistic regression model has been applied resulting in loss of data as well as a substantial loss of statistical power due to the sinking of some groups of the outcome variable<sup>11,12</sup>. The uniqueness of the present study, is to study the effects of independent variables on all the levels of ordered categorical dependent variable, so, special multivariate analysis for ordinal data, like ordinal logistic regression model was used as an alternative and Polytomous Universal Model (PLUM) or the SPSS Ordinal Regression Procedure which is an extension of the general linear model to ordinal categorical data, was used to assess the association

between the ordinal outcome (i.e., different levels of adherence to medication) and the independent variables<sup>13</sup>. AGS Beers criteria 2015, the most widely preferred tool with a high reliability and reproducibility, was used to find out the PIM in elderly<sup>14</sup>.

## MATERIALS AND METHODS

### Study design and setting

This was a hospital based cross-sectional study, carried out in M.K.C.G. Medical College and Hospital, a 1200 bedded tertiary care teaching hospital with 19 out-patients departments in Berhampur, a city in Eastern part of India from March 2017 to May 2017. The hospital caters to the tertiary health care needs of the population of Southern Odisha.

### Sample size calculation and sampling technique

The source population was elderly patients aged 65 years and more attending the out-patients departments (OPD). The sample size was calculated using *nMaster 2.0*, (Designed and Developed by Department of Biostatistics, Christian Medical College, Vellore, India). Assuming, the prevalence of adherence to be 60%, an absolute precision of 5, a desired confidence level of 95%, the sample size was calculated to be 369. Assuming a response rate of 85%, finally 425 elderly patients were included in the study. The OPDs of general medicine, surgery, ENT, ophthalmology, pulmonology, orthopaedics, endocrinology, cardiology, neurology, nephrology, psychiatry were selected for recruiting the study participants based on the assumption that any elderly patient coming to the hospital with one or more chronic illness shall have at least one disease condition that could be treated in the selected OPDs. Convenience sampling technique was adapted to include the participants and the study participants were identified from the different OPDs after reviewing their medical reports and history to confirm that the patient has at least one chronic condition.

### Inclusion and exclusion criteria

Any patients, new as well as repeat, of either gender who had completed 65 years of age as on 31<sup>st</sup> January 2017 and being treated for one or more chronic illness like hypertension, diabetes mellitus, osteoarthritis etc. for at least

six months were included in the study. Patients unable to communicate, seriously ill, mentally unstable, requiring ICU admission, on palliative care or unwilling to participate and those having incomplete information were excluded from the study.

#### **Ethical consideration**

The study was commenced after obtaining ethical clearance from the Institutional Ethics Committee of MKCG Medical College, Berhampur, Odisha (Approval Number 517/2017). All the study participants were explained clearly about the purpose and nature of the study in the local language (odia) or in any other language they could understand. Written informed consent was obtained before including them in the study.

#### **Data collection**

All the participants were interviewed once and their prescriptions were checked for the required information. The data was collected by the investigators in a structured case record form by the investigators. The case record form captured data on various independent variables like socioeconomic and demographic characteristics of the study participants like gender, age, educational status, family income, co-morbidity, duration of disease condition, poly-pharmacy, knowledge about their illness and the prescribed medications, experiencing any side effect or not, physically active or not, presence of care givers, any type of addiction, on-going drug therapy, number of drugs used, name of the drugs, dose, frequency and duration of administration etc. The data were checked for its completeness.

#### **Study tools**

Medication adherence was measured using the Morisky Medication Adherence Scale (MMAS-8). It is a self-report questionnaire, with eight questions, simple to administer, reliable and economical tool. The MMAS-8 was initially designed to identify the barriers and behaviours associated with adherence to chronic medication. The eight questions of MMAS-8 were translated into the local language and the translated version was tested in a group of 20 patients to check for understanding of the questions in accordance with its original meaning. The questions were understood identically by all, and subsequent alterations were not considered necessary. The degree of adherence was determined according to

the score range from 0 to 8, calculated from the sum of all the correct answers: high adherence (eight points), Medium adherence (6 to < 8 points) and low adherence (< 6 points)<sup>15</sup>.

PIM was assessed using American Geriatric Society (AGS) Beers Criteria of 2015, which is a comprehensive set of explicit criteria that categorizes a drug as appropriate or inappropriate for the elderly aged 65 years and above in given conditions. The AGS Beers Criteria 2015 categorizes PIMs based on five criteria – according to organ system, therapeutic category and drug, according to disease or syndrome, according to drugs to be used with caution, according to drug interactions and according to renal function. In the present study a prescription was considered to be inappropriate if it contained one or more drugs included in any of the components of AGS Beers Criteria of 2015 (PIM vs. No PIM)<sup>8, 11</sup>.

Level of adherence, pattern of PIMs and other explanatory variables like gender, age, income of the family, education level of the patient, poly-pharmacy, co-morbidity, physical activity, presence of addiction, occurrence of ADR, presence of care giver and knowledge about the drug were presented using descriptive statistics.

Cross tabulation (Chi square test for linear trends) between adherence and various independent variables was followed by ordinal regression method using PLUM procedure to analyze the relationship between the dependent ordinal outcome variable, i.e. 3-level adherence score and the explanatory variables e.g. PIM and other socio-demographic factors. Initially all the variables were considered for inclusion in the ordinal regression model; however, only the variables with a 'p' value of less than 0.10, observed in univariate analyses were included in the in the final model. The variables were inserted at the same level of analysis using the method of forced entry<sup>16,17</sup>. The data were entered and analysed using SPSS version 16.0 (SPSS Inc. 2007).

## **RESULTS AND DISCUSSION**

In the present study out of 425 elderly patients, 258 (60.7%) were males and 167 (39.3%) were females. The average age of was 72.5±7.6 years (range 65 years to 95 years). The average

**Table 1.** Patients characteristics according to the levels of adherence

Patient characteristics	No. of Patient	Low adherence (MMAS <6)	Medium adherence (MMAS 6- 8)	High adherence (MMAS > 8)	$\chi^2$ value	p value
PIM (AGS Beers criteria 2015)						
Without PIM	324 (76.2%)	146 (34.4%)	147 (34.6%)	31 (7.3%)	6.729	.035
With PIM	101 (23.8%)	60 (14.1%)	32 (7.5%)	9 (2.1%)		
Patient's level of education						
Graduate	23 (5.4%)	11 (2.6%)	7 (1.6%)	5 (1.2%)	14.903	.021
Illiterate	102 (24.0%)	59 (13.9%)	33 (7.8%)	10 (2.4%)		
Primary	212 (49.9%)	104 (24.5%)	92 (21.6%)	16 (3.8%)		
Secondary	88 (20.7%)	32 (7.5%)	47 (11.1%)	9 (2.1%)		
Patient's level of income						
<10000	105 (24.7%)	57 (13.4%)	39 (9.2%)	9 (2.1%)	1.897	.387
>10000	320 (75.3%)	149 (35.1%)	140 (32.9%)	31 (7.3%)		
Age						
≥75-84	122 (28.7%)	84 (19.8%)	29 (6.8%)	9 (2.1%)	82.02	.000
≥ 85	44 (10.4%)	40 (9.4%)	4 (.9%)	0 (0.0%)		
< 75	259 (60.9%)	82 (19.3%)	146 (34.4%)	31 (7.3%)		
Gender						
Female	167 (39.3%)	59 (13.9%)	82 (19.3%)	26 (6.1%)	24.068	.000
Male	258(60.7%)	147 (34.6%)	97 (22.8%)	14 (3.3%)		
Number of medications (poly-pharmacy)						
< 5	106 (24.9%)	26 (6.1%)	67 (15.8%)	13 (3.1%)	32.84	.000
>5	319(75.1%)	180 (42.4%)	112 (26.4%)	27 (6.4%)		
Number of diseases (co-morbidity)						
1	40 (9.4%)	7 (1.6%)	19 (4.5%)	14 (3.3%)	60.137	.000
2	190 (44.7%)	80 (18.8%)	98 (23.1%)	12 (2.8%)		
3	168 (39.5%)	105 (24.7%)	49 (11.5%)	14 (3.3%)		
4	27 (6.4%)	14 (3.3%)	13 (3.1%)	0 (0.0%)		
Occurrence of adverse effect						
Present	258 (60.7%)	122 (28.7%)	105 (24.7%)	31 (7.3%)	5.234	.073
Absent	167 (39.3%)	84 (19.8%)	74 (17.4%)	9 (2.1%)		
Caregiver						
Absent	125 (29.4%)	52 (12.2%)	62 (14.6%)	11 (2.6%)	4.149	.126
Present	300 (70.6%)	154 (36.2%)	117 (27.5%)	29 (6.8%)		
Physical activity						
Not-active	347 (81.6%)	178 (41.9%)	133 (31.3%)	36 (8.5%)	11.423	.003
Active	78 (18.4%)	28 (6.6%)	46 (10.8%)	4 (.9%)		
History of addiction						
Present	53 (12.5%)	27 (6.4%)	26 (6.1%)	0 (0.0%)	6.468	.039
Absent	372 (87.5%)	179 (42.1%)	153 (36.0%)	40 (9.4%)		
Knowledge about treatment						
No	318 (74.8%)	160 (37.6%)	158 (88.3%)	0 (0.0%)	144.017	.000
Yes	107 (25.1)	46 (22.4)	21 (11.8)	40 (9.4%)		
Duration of treatment (Yrs.)						
> 1	294 (69.2%)	160 (37.6%)	98 (23.1%)	36 (8.5%)	32.579	.000
< 1	131 (30.8%)	46 (10.8%)	81 (19.1%)	4 (.9%)		

number of diagnosis per patient was  $2.34 \pm 0.75$ . Forty patients (9.4%) were diagnosed to have one disease, followed by 190 patients (44.7%) having two diseases and 168 (39.5%) and 27 (6.4%) patients had three and four diseases respectively. On the system wise disease analysis, it was observed that cardiovascular disorders like hypertension and dyslipidemia (71.76%) were most common, followed by endocrine system disorders (64%), infectious diseases such as malaria, pneumonia etc. (21.4%), and respiratory system disorders (14.8%). The average number of medicines prescribed per patient was  $7.07 \pm 2.1$ . Three hundred and nineteen (75%) patients were taking  $\geq 5$  medications on a regular basis. Around 76% of patient populations were literate. The clinical-demographic characteristics of patients are presented in Table 1. MMAS-8 was evaluated by using Cronbach's alpha test and was reliable at 0.736. Two hundred six elderly patients (48.5%) were found to be non-adherent (MMAS-8 < 6), while 179 (42.1%) had a medium adherence (MMAS-8 6 to < 8) and 40 (9.4 %) had high adherence (MMAS-8 = 8) to their medication.

According to AGS Beers Criteria of 2015, inappropriate drug was prescribed to 102 (23.8%) elderly patients included in the study, out of which, 72 prescriptions had one PIM, 21 had two and 8 had three or more PIM. AGS Beers Criteria of 2015 classifies the inappropriately prescribed drugs into five components. It was observed that, about 49% of the PIMs belonged to the component that categorized PIM according to the organ system, therapeutic category and drug. [Table 2] Majority of PIMs identified in this study were, psychoactive medications such as benzodiazepines, tricyclic-antidepressants (TCAs). There was a significant association between the level of adherence and number of PIMs prescribed. (Yate's chi Square value = 28.963,  $p < 0.01$ ) [Table 3]

There was no significant association between the patient's levels of income, occurrence of adverse effect, presence of caregiver with adherence therefore, these variables were not included in the ordinal regression model. The result of final ordinal logistic regression models, between the different levels of adherence and the explanatory variables is shown in Table 4.

**Table 2.** Number of prescriptions with inappropriately prescribed drug as per AGS Beers Criteria of 2015

Component of AGS Beers Criteria of 2015	Number of prescriptions (n=102)
According to organ system, therapeutic category and drug	48 (48.96%)
According to disease or syndrome	17 (17.34%)
Drugs to be used with caution	25 (25.5%)
According to drug interactions	5 (5.1%)
According to renal function	7 (7.14%)

**Table 3.** Association between adherence and number of inappropriately prescribed drugs (PIM) for chronic illness in elderly as per AGS Beers Criteria of 2015

Patient characteristics		Total (425)	Low adherence (MMAS <6)	Medium adherence (MMAS 6- 8)	High adherence (MMAS > 8)
Number of PIM (AGS Beers criteria 2015)	0	324 (76.2%)	143 (33.65%)	145 (34.12%)	36 (8.47%)
	1	72 (16.9%)	55 (12.94%)	15 (3.53%)	2 (0.47%)
	2	21 (4.9%)	7 (1.65%)	12 (2.82%)	2 (0.47%)
	3	8 (1.9%)	1 (0.24%)	7 (1.65%)	0 (0.00%)

Yate's chi square value = 28.96,  $p < 0.01$

**Table 4.** Ordinal logistic regression for the association between adherence and PIM

Patient characteristics	Parameter Estimate	OR	95% CI	p value
PIM (AGS Beers criteria 2015)				
Without PIM	.737	2.089	1.277 - 3.419	.003
With PIM	.000	1.000		
Gender				
Female	1.235	3.438	2.216 - 5.335	.000
Male	.000	1.000		
Patient's level of education				
Graduate	.396	1.485	.563 - 3.917	.424
Illiterate	-.742	.476	.258 - .878	.018
Primary	-.427	.653	.388- 1.097	.107
Secondary	.000	1.000		
Age				
≥75-84	-1.328	.265	.163 - .431	.000
≥ 85	-3.602	.027	.009 - .084	.000
< 75	.000	1.000		
Number of medications (poly-pharmacy)				
< 5	.812	2.251	1.408 - 3.599	.001
>5	.000	1.000		

In the ordinal logistic regression models, high adherence had the least number of patients, so, it was taken as the reference. Similarly, the sub-groups of the independent variables with the least number of patients were taken as reference in the ordinal logistic regression model. The independent variables for high adherence as predicted by the ordinal logistic regression model were an absence of PIM, female gender, age less than 75 years, educational level and number of drugs less than five. There was a significant association between the medication with an inappropriately prescribed drug and non-adherence. (OR: 2.089 with CI: 1.277-3.419,  $p = 0.003$ ). Elderly patients with a potentially inappropriate medication as per AGS Beers Criteria of 2015 were twice likely be non-adherent to treatment than those without a PIM. However, this association was not observed when relating to number of PIMs in ordinal logistic regression.

In the present study it was observed that, female gender (OR = 3.438, CI: 2.216 - 5.335;  $p = 0.000$ ) and poly-pharmacy with less than five drugs use in elderly were predictors of high adherence (OR: 2.251, CI: 1.408- 3.599;  $p = 0.001$ ). Patient's age was a predictor of adherence (OR = 0.027, CI: 0.009-0.084;  $p = 0.000$ ), however the negative

parameter estimate indicates that these variables affects adherence negatively. Similarly, illiteracy in patients predicts adherence negatively (parameter estimate: -0.742, OR: 0.476, CI: 0.258- 0.878;  $p = 0.018$ ). The association between co-morbidity and low adherence could not be established in the ordinal logistic regression analysis, though in Chi-square analysis they showed a highly significant association. [Table 4]

The present study has explored the association between potentially inappropriate medication as well as various socio-demographic variables and medication adherence in elderly population with chronic illness in an out-patient setup. Adherence was measured by three levelled MMAS-8, whereas PIM was evaluated by AGS Beers criteria 2015 and the association was analysed by ordinal logistic regression model.

It was observed that, 48.5% of the study participants were not adherent to the prescribed medications (MMAS-8 < 6), while 42.1% had a medium adherence (MMAS-8 6 to <8) and 9.4% were highly adherent to their medication with a MMAS-8 score of 8. These findings were consistent with results reported earlier studies<sup>11,18</sup>. High adherence levels to medication among patients is reported to be associated with

higher treatment efficacy and overall reduction in healthcare wastage. Therefore, identifying the factors that lead to poor medication adherence is essential in any healthcare program. Our results show that PIM, gender, age, educational level, number of drugs are the significant predictors of adherence.

The association between potentially inappropriate medication and non-adherence was significant and elderly patients with a PIM were about twice likely to be non-adherent. It was observed in this study that, 23.8% of elderly patients in our study were prescribed at least one PIM. Similar observations were reported from other studies done in India and elsewhere<sup>9,19,20</sup>. The high prevalence of PIM in elderly may be due to the lack of awareness among physicians about the existence of Beers' criteria<sup>21</sup>. Further, the study participants had at least two chronic co-morbid conditions and were prescribed with an average of seven medications. Multiple medications are often necessary to treat multiple concomitant disease in elderly, however, unnecessary drugs add to the number, complexity and cost of an older person's drug regimen leading to non-adherence. This study also demonstrates that elderly patients with polypharmacy (use of more than five drugs) were twice likely to be non-adherent. Therefore, it is important to ensure that necessary medications are not omitted in the elderly patient. Wherever possible non-pharmacological therapy like, physiotherapy and advice on weight loss for osteoarthritis; psychological / social support for depression due to social isolation or recent bereavement; relaxation exercises like yoga for insomnia should be considered in lieu of prescribing and using medicines.

For improving medication adherence, one of the studies has suggested a combination of educational and behavioural strategies, self-management interventions using medication organisation device like pillboxes or multidrug punch cards which are the least expensive and most widely used adherence aid for patients of chronic diseases<sup>22,23</sup>. Increasing patient's knowledge and providing them with basic skills to manage their disease can result in health benefits and could reduce their dependence on health care services and associated costs<sup>11,18</sup>. It was found that adherence decreased with the increase in the

patient's age, this is in agreement with previous study<sup>4</sup>. Forgetfulness and physical disabilities are common in elderly. This may be the reason for low medication adherence in higher age group. On the contrary, some studies have reported that elderly patients were more adherent. The reason being that, they are suffering chronically, had a better knowledge of their disease condition and that most of the elderly are taken care by some care giver or a family member<sup>15,22</sup>. Another significant predictor of medication adherence was the level of education of the patient. It was observed that there is a negative association between illiteracy and high adherence. This finding corroborates with the observations of other studies which have concluded that uneducated people may not understand the importance of taking medications as advised, and unable to remember and follow the instructions related to medication accurately<sup>10,24</sup>.

There are few limitations of the present study. The foremost being that the study setting being the out-patient of a tertiary care government hospital, it might have captured the adherence level from elderly patients of low socio-economic group who are more likely to come to a government set-up for treatment. So, the study sample may not be representative of patients from other socio-economic backgrounds and from domiciliary care set-up. The present study has excluded patients unable to communicate, comprehend and the very sick, so the findings cannot be extrapolated to this group. MMAS-8 is a self-reported method used to assess medication adherence, where, bias of over estimation is a documented concern. Nevertheless, MMAS-8 is a popular, practical and economical method of data collection, enabling the collection of a large amount of data in a short period of time. Besides, the questions are phrased in a way to avoid the bias of saying 'yes' as it is a common habit of patients to provide healthcare providers with a positive response. In this study, due to the non-availability of Indian criteria to find out the potentially inappropriate medication in elderly, AGS Beers Criteria of 2015 has been used. As such, Beers' criteria are not the gold standard, as they do not identify all the aspects of potentially inappropriate prescribing and are designed for population-based screening. They are not intended to substitute for professional judgment regarding the individualized needs of older adults.

## CONCLUSION

Potentially inappropriate medication is an important predictor of adherence to medication in elderly patients with chronic illness. Low adherence to prescribed medication among elderly patients is a recognized public health concern. Therefore, it is necessary to evaluate factors influencing non-adherence to decrease medication wastage and cost of healthcare as well as to improve disease outcomes. The findings of this study imply that, prescribers should carefully assess the necessity and appropriateness of medications prescribed in elderly to improve their adherence to therapy.

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