**AN OBSERVATIONAL STUDY OF INAPPROPRIATE MEDICATION USE IN ELDERLY PATIENTS USING HEDIS CRITERIA IN GENERAL MEDICINE AND CARDIOLOGY DEPARTMENTS OF A TERTIARY CARE HOSPITAL IN SOUTH INDIA**

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**T.K.N.V. Raja Kiranmai 1,2\*, Pradeep Devarapalli1,2, G. Swaraj1,2, A.M.S Sudhakar Babu1,2, V. Lokesh Reddy1,2**

1. A.M. Reddy Memorial College of Pharmacy, Guntur, India.

2. Lalitha Super Specialty Hospital, Kothapet, Guntur, India.

***Email ID- editorjohp@gmail.com***

**ABSTRACT**

**BACKGROUND**

National committee on quality assurance, USA convened an expert consensus panel and identified the list of drugs which should be avoided in the .elderly people. This resulting list of drugs after 2006 Health Plan Employer Data and Information Set (HEDIS) to assess the drug prescribing in elderly people.

**METHOD**

The objective of this study was to determine the prevalence of inappropriate drug use and assess their predictors in the hospitalized elderly patients of tertiary care hospital by using HEDIS 2006 criteria. A 6-month prospective study was conducted in medicine & cardiology inpatient department of tertiary care hospital by reviewing prescriptions of 135 elderly patients. The patients of either sex having age more than 60 year were included in this study.

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**RESULTS**

It is found that (2.39%) 12 patients received at least 1 inappropriate drug by 2006 HEDIS measure. Out of 12 inappropriate drugs, short acting nifedipine was prescribed to 4 elderly patients followed by dicyclomine to 2 patients and ketorolac to 2 patients each. Increased number (≥11) of concurrent medications use during hospital stay (OR: 0.015, CI: 0.001–0.199, P = 0.001) and prolonged (≥5 days) length of stay (OR: 0.039, CI: 0.005–0.291, P = 0.002) were found as a predictors of inappropriate medication use.

**CONCLUSION**

In this study, low prevalence (2.39%) of inappropriate drug prescribing was found. Multiple medications and long duration of hospital stay were the risk factors for inappropriate medication use.

**KEYWORD: HEDIS;** Inappropriate; Drug; Hospitalized; Elderly

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1. **INTRODUCTION**

Sickness is as natural as the process of ageing. Since time unknown diseases have been associated with old age. And thus have begun man’s pursuit of healing and health. 1. A WHO report has projected that the elderly population of the world will cross the one billion mark by the year 2020 and by that time, over 700million elderly people will be living in developing countries.2

Appropriateness in healthcare has been defined as “the outcomes of process of decision making that maximizes net health gains within society’s available resources”.3 Inappropriate medication use (IMU) in the elderly population has long been an issue of healthcare quality along with over and under-use of medications.4 This subject has gained attention among health care researchers, providers and policy makers. The effort to reduce inappropriate medication use in elderly patients is likely to have a substantial impact upon reducing drug-related morbidity. It is important that elderly people should not be taken as a burden on society, but rather as an asset.5The assessment of suitability of pharmacotherapy aims to modify the existing geriatric care practice(s).

## 1.1 **AGEING AND HEALTH**

Age is a risk factor for many of the chronic diseases now facing the developed and developing world, making the elderly more likely to be diagnosed and treated for multiple co morbidities.6

Due to the increase in the number of concurrent medications taken by elderly patients there is also an increase in the likelihood of experiencing adverse drug reactions.7 Pharmacotherapy is considered as single most important medical intervention for care in majority of elderly patient.

## 1.2 USE OF MEDICATION IN ELDERLY

Patient safety has become a high priority for hospitals, various national health care advocacy organizations, and health care accrediting bodies. Inappropriate prescribing of medications in this population may lead to adverse effects associated with increase in morbidity and mortality.8 A number of factor increases risk of drug related problem in elderly, including suboptimal prescribing (inappropriateness, drug-drug interaction, drug–disease interaction, adverse drug reaction, prescribing patterns &polypharmacy).

### **1.3 INAPPROPRIATENESS**

Inappropriate medication prescription for elderly is major concern because it increases the risk of adverse events and health care costs.9 Potentially inappropriate prescriptions (PIPs have been estimated to affect 4.8% to 45.6% of the elderly population. 10

 A retrospective study done by *Wawruch and coworkers* has shown that, 20.2% patients were treated with at least one potentially inappropriate drug at the time of hospital admission. 11

**1.4 DISEASE CONDITION AND PRESCRIBING PATTERN**

Medical treatment for any disorder has changed considerably in past decades because of advances in clinical practice and development of new drug(s). In recent years, new drugs that combine high efficacy with low incidence of adverse effect have been developed.

A cross sectional study done in England by *Batuwitage B, Kingham J, Morgan N, Bartlett R* shows that 36/66 (54%) patients the PPI was prescribed for an indication outside those proposed in guidelines. 12

## 1.5 INTERACTIONS

Older patients are at risk due to ageing physiology, drug use patterns, different prescribers and acquiring accurate information. Mechanism of interaction altered absorption, gastric motility, altered gastric pH, altered metabolism, altered renal elimination, pharmacodynamic interactions etc.

**1.5.1 DRUG-DRUG**

Drug interactions are often clinically unrecognized and responsible for increased morbidity in elderly patients. DDI can be prevented by a number of ways: number of drugs used to treat elderly patients must be minimized, prudent use of medication, vigilant drug monitoring are essential in avoiding DIs. In addition, use of hand-held personal digital assistants (PDAs) and other computer applications can be helpful to screen for potential drug–drug interactions.

### A population-based, case-control study13by *Juurlink DN et al* showed that hospital admissions were more likely in patients being co-administered with following drugs: glyburide and co-trimoxazole, digoxin and clarithromycin, and ACE inhibitors and potassium-sparing diuretic, than in patients receiving any one of the drugs.

### **1.5.2 DRUG-DISEASE**

Drug can improve quality of life for many older people, but they may cause adverse health outcomes if used inappropriately. One consequence of both inappropriate and appropriate medication uses is a drug–disease interaction, which is the prescribing of a medication that has the potential to exacerbate a pre-existing disease.

A Study done by *Marie and coworker*14 had shown that the only highly significant predictors of mild cognitive impairment were anticholinergic drug use.

### **1.6 ADVERSE DRUG REACTIONS**

During recent years, the knowledge base relating to adverse drug events in hospitals and in nursing home settings has grown substantially. However, only limited efforts have been made to systematically examine the problem of drug-related injury among the elderly population in the ambulatory setting.

A study done in France by *Laroche M, Charmes J, Nouaille Y* shown that The inappropriate medications most often involved in patients with ADRs were: anticholinergic antidepressants, cerebral vasodilators, long-acting benzodiazepines and concomitant use of two or more psychotropic drugs from the same therapeutic class. 15

## 1.7 ASSESSMENT CRITERIA’S OF INAPPROPRIATE MEDICATION USE

The commonest methods for assessing appropriate or inappropriate prescribing are explicit criteria and implicit professional judgement. Implicit judgements are subject to reviewer variations. However implicit judgements take account of the context of individual patients and easily incorporate new evidences into assessment. They may have greater validity but poorer reliability than explicit criteria. On the other hand, an explicit criterion16,17 used a consensus panel to prepare a set of standards from the literature.

**HEALTH PLAN EMPLOYER DATA AND INFORMATION SET (HEDIS) CRITERIA 2006**

The National Committee on Quality Assurance convened an expert consensus panel and, using a modified Delphi process, developed a quality measure to identify rates of inappropriate prescribing in the elderly based on the most commonly used measure of PIPE. This measure includes drugs that should always be avoided in the elderly and is currently being used in the 2006 Health Plan Employer Data and Information Set (HEDIS) in 2006 to assess quality of care for older Americans.18,19

1. **METHODOLOGY**

To achieve the objectives, a prospective observational study was conducted in an inpatient department of a tertiary care hospital.

**2.1** **PATIENTS**

The patients were recruited in the study were on basis of

1. 60 years or above, patients of either sex
2. Number of drugs prescribed more than one.
3. One or more concurrent diseases
4. Complete information regarding patient

**2.2 DATA COLLECTION**

The patient’s information was studied using chart review method. The patient data was collected from case reports and medicine review charts. The study form was completed when the patient was admitted in the hospital and updated daily until the patient was discharged.

## 2.3 ASSESSMENT USING HEDIS CRITERIA

Each prescription was checked individually for inappropriate drug prescribing by using HEDIS Criteria 2006.Appendix C enlists the inappropriate drugs included in HEDIS Criteria. The criteria used in this study required certain modifications which are necessary in the Indian setting. These modifications are:

* The cut off age considered in this study was 60 years or more instead of age 65 years or more.
* Some medications which were banned after 2002 by the DCGI were removed from the list for e.g. Reserpine, Propoxyphene, and Cimetidine etc.

## 2.4 STATISTICAL ANALYSIS

In this study Relative Risk was used to assess inappropriate medication use by comparing inappropriate with appropriate medication use. The confidence interval and Relative Risk was calculated for determining the predictors of inappropriate medication use. Age, number of medication, number of diagnosis and length of stay in hospital were the risk factors of IMU.

1. **RESULTS**

This prospective observational study included the data of 135 patients which was collected using Chart Review Method during the study period from the medicine and cardiology departments of LSSH. The following results emerged after analysing the data.

## 3.1 POPULATION CHARACTERISTICS

Out of the 135 patients, Cardiovascular disorders like Hypertension and Coronary Artery Disease were highly prevalent in medicine and cardiology IPD. Diabetes Mellitus Type 2 was the second most prevalent chronic disease .

**3.2 PROFILE OF THERAPY& PRESCRIPTION PATTERN**

Approximately 1180 drugs were prescribed in 135 patients. The evaluation of the patterns of medication use showed that 27.40% of the patients received 1-5 medications, 38.5% received 6-10 medications and 31.1% received 11-15 medications while only 2.96% of the patients received more than 16 medications. The average number of medicines prescribed was 8.83±0.16.

## 3.3 ANALYSIS OF IMU USING HEDIS CRITERIA 2006

The analysis of data for inappropriateness using HEDIS 2006 criteria showed that 31 patients received inappropriate medication (6.2%) (Table.1). Digoxin was found to be the most frequently prescribed inappropriate prescription. (Figure.1)

**Table.1 Distribution of Inappropriate Medication Using HEDIS Criteria 2006**

|  |  |  |
| --- | --- | --- |
| Name of Drugs | Severity | No. of patients(%) |
| Digoxin | Low | 17(54.8%) |
| Nifedipine | High | 4(12.9%) |
| Bisacodyl | High | 2(6.4%) |
| Dicyclomine | High | 2(6.4%) |
| Ketorolac | High | 2(6.4%) |
| Nitrofurantoin | High | 2(6.4%) |
| Promethazine | High | 1(3.2%) |
| Chlorpheniramine | High | 1(3.2%) |

**Figure.1**

**3.4 PREDICTORS OF INAPPROPRIATE MEDICATION USE**

The Relative Risk calculated for determining the predictors of inappropriate medication use. (Table.2)

**Table 2: Predictors of IMU Using HEDIS Criteria 2006**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **Variable** |  | **Total (n)** | **Patients with IMU**¤ | **Patients with AMU**• | **Prevalence of IMU**¤ | **OR**® **(95% CI**\***)** |
|  | **All** |  | 135 | 31 | 104 | 22.4% |  |
| **1** | **Age** | 60-69 | 104 | 8 | 96 | 8% | 1 (reference) |
|  |  | 70-79 | 29 | 3 | 26 | 10.3% | 0.74(0.70-0.77) |
|  |  | ≥ 80 | 2 | 0 | 1 | 0% | 0.62(0.57-0.66) |
| **2** | **Sex** | Female | 53 | 4 | 49 | 7.6% | 1 (reference) |
|  |  | Male | 82 | 6 | 72 | 7.31% | 0.75(0.71-0.78) |
| **3** | **No. of medication** | ≤ 5 | 35 | 2 | 33 | 5.71% | 1 (reference) |
|  |  | 5-10 | 52 | 5 | 47 | 9.7% | 0.70(0.66-0.73) |
|  |  | ≥11 | 53 | 3 | 50 | 5.7% | 0.58(0.53-0.62) |
| **4** | **Length of stay** | ≤ 5 | 56 | 2 | 54 | 3.6% | 1 (reference) |
|  |  | 5-10 | 59 | 4 | 55 | 6.8% | 0.68(0.64-0.72) |
|  |  | ≥11 | 20 | 1 | 19 | 5.0% | 0.59(0.54-0.63) |
| **5** | **No. of diagnosis** | 1 | 20 | 1 | 19 | 5.0% | 1 (reference) |
|  |  | 2 | 41 | 2 | 39 | 4.9% | 0.37(0.33-0.41) |
|  |  | ≥3 | 73 | 5 | 68 | 6.9% | 0.45(0.41-0.49) |

\* CI = Confidence interval, ¤ IMU = Inappropriate Medication Use, ® OR = Odds Ratio, • AMU = Appropriate Medication Use

## 3.5 PREVALENCE OF DRUG INTERACTIONS

Severity classification of 116 drug interaction showed that 13(11.3%) were of severe category, while 103 (88.6%) were of moderate category. The most frequently occurring drug interactions were found between Ceftriaxone & Ranitidine (12.5%) followed by Phenytoin & Ranitidine (10.2%) and Aspirin &Clopidogrel (8.3%).

**4. DISCUSSION**

## 4.1 PATIENT CHARACTERISTICS

The findings of this study were based on the data obtained from 135 patients. Of the total patients, the male to female ratio was approximately 2:1. The higher percentage of male patients was observed which was in accordance with findings of the study conducted by

## 4.2 INAPPROPRIATE MEDICATION USE

Inappropriate medication use is a major, common health problem in older people. IMU among the elderly in other countries has been well-documented with the estimated prevalence ranging from 11% to 43%.

NSAIDs should be avoided as they may exacerbate exiting ulcer disease or create new ulcer. The risk of gastrointestinal complications in NSAID users over the age of 65 years is increased approximately 2-3.5-fold when compared with younger patients.14

## 4.3 PREDICTORS OF IMU

One of the objectives of this study was to find the predictors of inappropriate prescribing in elderly patients, using HEDIS Criteria. Being a prospective observational study, Relative Risk was used to find the predictors of IMU.

## 4.4 DRUG INTERACTION

Out of 135 patients, Male patients were more likely to suffer from drug interaction than female patients. Moderate type of DI were common than major type of DI.

## 4.5 LIMITATIONS OF THE STUDY

Criteria were consensus rather than evidence based and explicit process criteria were not measures of actual clinical outcomes. Both the screening tools include many out-dated drugs that were unavailable or are seldom prescribed. The drugs defined as inappropriate were not always inappropriate. Physician(s) considered them appropriate depending upon individual situations.The benefits of some potentially inappropriate medications may outweigh their potential risks in some situations. Proper randomization of the cases could not be achieved. HEDIS Criteria was not arranged in any particular order or structure. Moreover the drugs enlisted are not classified according to the severity.The lack of convincing evidence showing the benefits of using HEDIS Criteria. This study has not explored the issue of adverse drug reaction, drug-disease interactions which also require same level of attention to improve the use of medications in elderly patients.

1. **CONCLUSION**

This prospective observational study was conducted to evaluate the quality of geriatric pharmacotherapy in a tertiary care hospital. Data of 135 patients were used to carry out the analysis. HEDIS(2006)criteria was used as screening tools to determine the inappropriateness of medication use. The average number of medication prescribed and diagnosis were 8.83±0.16 and 2.89±0.06 respectively. The most common inappropriate medications identified according to the first list of inappropriate medications were Digoxin (48.6%) Nifedipine (11.4%),Bisacodyl (5.7%) and indomethacin(5.7%) .Drugs identified according to the second list of inappropriate medications were NSAIDs (2.8%). Males showed higher inappropriateness than females. Inappropriateness in elderly inpatients increased with advanced age, increase in number of medications, number of diagnoses and length of hospitalization. Both the criteria showed identical types of predictors. On analyzing for drug-drug interaction, 58 patients (43.02%) were found to be prescribed with medicines that could result in drug-drug interaction.The most frequently observed drug interactions were Ceftriaxone& Ranitidine (12.5%) followed by Phenytoin & Ranitidine (10.2%) and Aspirin &Clopidogrel (8.3%). Patients receiving atleast one inappropriate medication (according to either/both criteria) had higher possibility of having drug interaction than patients who are not receiving any inappropriate medication.The findings reflect low prevalence of inappropriate medication use in elderly patients, in comparison to other settings and countries, in the concerned setting. This study was undertaken to assess and improve the quality of medication in elderly patients.

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