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# ASSESMENT OF DRUG RELATED PROBLEMS IN GENERAL MEDICINE INPATIENT DEPARTMENT OF A TEACHING HOSPITAL - A PROSPECTIVE OBSERVATIONAL STUDY

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## ABSTRACT

**Background:** In India very limited research has been conducted on drug related problems in hospital inpatients. Most of the previously published studies addressed either the problem of drug-related hospital admissions or focused only on adverse drug reactions. Majority of drug-related problems can be prevented by the interventions suggested by clinical pharmacists. **Objectives:** To identify the drug related problems in general medicine inpatient department of a teaching hospital. **Methodology:** It is a prospective observational study conducted for a period of six months. Data was collected from the medical records of in-patients and by patient interview. All the prescriptions were checked for errors by the Micromedex Drug-Reax database, online Medscape, CIMS India etc. Data was analyzed using statistical package of social services (SPSS 19.0). Descriptive methods was applied to obtain frequency of drug related problems, chi square test was applied to determine any significant deference between quantitative variables. **Results:** out of 313 cases enrolled in the study, 210(67.1%) patients are having atleast one drug related problem. 335 drug related problems are identified. In that 154(49.2%) drug interaction, 58(18.5%) treatment without indication, 36(11.5%) untreated indications, 28(8.9%) under dose, 24(7.7%) adverse drug reactions, 20(6.4%) improper drug selection, 15(4.8%) over dose are identified. Polypharmacy and age has positive impact on

drug related problems. **Conclusion:** Drug related problems are prevalent in hospital inpatients. Pharmacist can play an important role to identify and resolve drug related problems.

**KEYWORDS:** Drug Related Problems, Adverse Drug Reaction, Drug Interaction.

## INTRODUCTION

Drugs are the most common medical interventions, primarily used to treat sufferings. But it has been recognized long ago that drug themselves can prove fatal; as the saying rightly goes "Drugs are Double Edged Weapons". Drug Related Problems (DRPs) are defined as problems in the pharmacotherapy of the individual patient that actually or potentially interfere with desired health outcomes (definition PCNE 1999).[1]

DRPs are frequent in hospitalization where multiple changes in patient's medication regimens and lack of continuity of care may be accompanied. Problems associated with drug use are many and includes inappropriate medication prescribing, discrepancies between prescribed and actual regimens, poor adherence, drug interactions, inappropriate use, patients monitoring and inadequate surveillance for adverse effects etc. drug related problems may lead to reduced quality of life, increased hospital stay, overall increase health cost and even increase risk of morbidity and mortality.[2] DRPs pose a major challenge to the prescribers by causing significant morbidity and also negatively influencing the quality of life of the patients.[3]

In the case of most diseases drug therapy will enhance health-quality of life. However, inappropriate use of drugs may be harmful and could evoke new adverse symptoms. This has been known for centuries but, it was first when the reports of aplastic anemia following treatment with chloramphenicol and of birth defects after use of thalidomide that the interest in DRPs increased dramatically.[4] DRPs, which include adverse drug reactions (ADRs), unnecessary drug therapy, inappropriate choice of drugs, and untreated conditions, have been shown to prevail in hospitalized patients, with a reported incidence rate as high as 25%. Undeniably, many factors can contribute to the high prevalence rate, but polypharmacy and older age have often been identified as important risk factors.[5] DRPs are the third or fourth leading cause of death in the elderly and can also cause disability, depression, gait disturbances and falls.[6] A recent report of British Medical Association says that least a quarter of a million patients each year from UK are admitted to hospital with an ADR. In US,

the Institute of Medicine and other experts reported that thousands of deaths and millions of hospitalizations were occurred due to medication errors. Medication errors are an unfortunate reality at hospitals approximately, 30% of problems occurring during hospitalization are related to medication errors.[7]

Another interesting observation about the studies relating to DRPs is that there exists little data on comprehensive DRPs among hospitalized patients. Most of the studies have done intentionally, so in India very limited research has been conducted to exemplify the impact of DRP that result for hospital admission. So far, most studies published had addressed either the problem of drug-related admissions to hospitals or focused only on ADRs among hospitalized patients. A more comprehensive study of DRPs in hospitalized patients would provide valuable insights for the healthcare professionals trying to reduce the incidence of DRPs.[5] Studies have shown that the majority (50-80%) of drug-related problems can be prevented. Interventions suggested by clinical pharmacists to solve or prevent drug related problems are to a large degree accepted and acted on by the prescribers.[8]

An assessment of the current situation would assist the healthcare providers in optimizing intervention strategies according to needs and available resources. Keeping these facts in consideration the present study is designed to determine the prevalence of DRPs which includes Adverse Drug Reactions (ADR's), Drug Interactions (DI), High Dose (HD), Low Dose (LD), Treatment Without Indication (TWI) and Untreated Indication (UI), the drugs that most frequently cause drug related problems (DRP's) and to investigate the appropriateness of drug use and the occurrence of DRPs in hospitalised patients in a hospital in India.

## MATERIALS AND METHOD

It is a prospective observational study conducted over a period of six months in General medicine inpatient department of Basaveshwara Medical College Hospital & Research Centre (BMCH & RC), Chitradurga. This study was approved by the "Institutional Human Ethical Committee" of the S.J.M College of Pharmacy, Chitradurga. (SJMCP/IEC/543Q/2014-15 Date-13-10-2014). Inform consent was obtained from each patient. All patients who admitted to the Medicine department of the hospital during study period will be eligible for enrolment. Patients those who were treated from the outpatient departments and who do not require hospital stay and the prescriptions with Incomplete information during date of discharge were excluded from the study.

Information was collected by interviews with the patients/ care takers. The data was collected in a standard data collection form. Name, Age, Sex, IP. No., Unit, Date of admission and discharge, Prescriber name, History of Present Illness (HPI), Past Medical History(PH), Past Medication History (PMH), Allergies, complaints on admission, Final diagnosis, Current drugs, Dose, Frequency, drugs started during the hospital stay, relevant medical history, and results of laboratory tests from all the patients are collected from each patients. Medical charts, medical records and patient's prescriptions are the source used for data collection. The specific factors which increase the risk of DRPs are recorded.

Medication chart review method is used to analyze the prescriptions, which is well suited to identify the prescribing medication errors. The patients with proper diagnosis are selected and the data for identification, medication details and relevant laboratory reports and progress reports were collected. The clinical significance of these DRPs are studied by following the patients throughout the hospital stay.

All the prescriptions were checked for errors by the Micromedex Drug-Reax database, online Medscape, CIMS India etc. The data was entered in Microsoft Excel-2010 version and the results are analysed using Statistical Package for Social Services (SPSS 19.0). Descriptive Methods was applied to obtain the frequency, chi square test was applied to determine any significant difference between quantitative variables.

**RESULTS**

A prospective observational study was conducted in 313 patients (168 (53.7%) males and 145 (46.3%) females) in general medicine inpatient department of a teaching hospital.

The patients were categorized into 6 groups based on their ages. Out of 313 patients, 4(1.3%) patients comes below the age of 18, 54(17.3%) patients are in the age range 18-30, 60(19.2%) patients are in the age range 31-40, 51(16.3%) patients are in the age range 41-50, 61(19.5%) patients are in the age range 51-60, 83( 26.5%) patients are having age above 60. Majority of the patients are in the age above 60 and least are in the age below 18 (Table 1).

Out of 313 patients 210(67.1%) patients are having DRPs and 103(32.9%) patients are not having any DRPs.

Table 2 shows the distribution of patients according to drug interactions. Out 313 patients, drug interaction is present in 154(49.2%) patients.

Table 3 shows the distribution of patients according to over dose. Out of 313 patients, 15(4.8%) patients are over dosed. Most number of drugs which are prescribed over dose are gastrointestinal agents. The details of drugs which are prescribed as over dose are given in Table 4.

Table 5 shows the patient distribution according to under dose. Out of 313 patients, 28(8.9%) patients are under dosed. The frequency of patients which are under dosed in relation to drug class are antimicrobials (8 patients), cardiovascular agents (8 patients), respiratory agents (1 patients), gastro intestinal agents(5 patients), anticoagulants (2 patients), central nervous system agents (1 patients), analgesics and skeletal muscle relaxants one patient each (Table 6).

Table 7 shows the distribution of patients according to Adverse Drug Reactions(ADRs). Out of 313 patients, 24(7.7%) patients are suffered from ADRs. The frequency of patients which are suffered from ADRs in relation to the drug class which cause it are cardiovascular agents (4 patients), antimicrobials (8 patients), respiratory agents(3 patients), corticosteroids, gastro intestinal agents analgesics (2 patients each), skeletal muscle relaxant and anti-diabetic agents one patients each (Table 8). WHO causality assessment scale shows 11, 7 and 6 ADRs are certain probable and possible respectively. While Naranjo causality assessment scale categorize 12 ADRs are probable and 12 ADRs are possible (Table 9).

Table 10 shows the distribution of patients according to treatment without indication (TWI). Out of 313 patients 58(18.5%) patients are taken treatment without any indications. The most number of drugs which are used without any indication are antimicrobials (26 patients) followed by gastro intestinal agents(15 patients) followed by respiratory agents and central nervous system agents 5 patients each, cardiovascular agents (3 patients) and NSAIDs (1 patient), (Table 11).

Table 12 shows the distribution of patients according to untreated indication. Out of 313 patients, 36 (11.5%) patients are left untreated for some indications.

Table 13 shows the distribution of patients according to improper dug selection. Out of 313 patients, 20(6.4%) patients are having improper drug selection.

Table 14 shows the distribution of DRPs in various age groups. The maximum number of drug interactions occurred in the patients of age greater than 60 (51 patients) and least in the

age less than 18. The incidence of ADRs are more in the age greater than 60 (9 patients), 51-60 (6 patients), 41-50 (4 patients), 31-40 (5 patients), 18-30 (16 patients).

The incidence of treatment without indication is more in the age group 18-30 (14 patients) and least in age less than 18. The incidence of untreated indication is more in age group 31-40(12 patients) followed by >60 (9 patients), 41-50(6 patients), 51-60 (5 patients), 18-30 (4 patients). The incidence of over dose based on the age group are >60 (5 patients), 51-60 (2 patients), 41-50 (4 patients), 31-40 (4 patients).

The incidence of under dose based on the age group are >60 (8 patients), 51-60 (9 patients), 41-50 (6 patients), 31-40 (4 patients), 18-30 (1 patient). The incidence of improper drug selection based on the age group are >60 (5 patients), 51-60 (3 patients), 41-50 (4 patients), 31-40 (3 patients), 18 -30 (5 patients). In short incidence of DRP is more in the age >60 (100 patients), followed by 31-40 (71 patients), 51-60 (63 patients), 41-50 (61 patients), 18-30 (40 patients), <18 (no patients). The risk of DRPs increase considerably with age which may be due to increased polypharmacy and comorbidities when age progress. By applying Chi-square test, shows significant relation ($X^2$=18.823, df=5, p:0.002(**sig**).

**Table 1: Distribution of patients according to age.**

| Age in years | No of Patients | % of Patients |
|---|---|---|
| **<18** | 4 | 1.3% |
| **18-30** | 54 | 17.3% |
| **31-40** | 60 | 19.2% |
| **41-50** | 51 | 16.3% |
| **51-60** | 61 | 19.5% |
| **>60** | 83 | 26.5% |

**Table 2: Distribution of patients according to drug interaction.**

| Drug interaction | No of patients | % of patients |
|---|---|---|
| **Present** | 154 | 49.2% |
| **Absent** | 159 | 51.72 |

**Table 3: Distribution of patients according to over dose.**

| Over dose | No of patients | % of patients |
|---|---|---|
| **Present** | 15 | 4.8% |
| **Absent** | 298 | 95.2% |

**Table 4: Identified cases of over dose.**

| Drug class | Drugs | No of patients |
|---|---|---|
| **NSAIDs** | Aceclofenac<br>Paracetamol | 1<br>1 |
| **Gastro intestinal agent** | Rabeprazole | 4 |
| **Anticoagulants** | Heparin | 1 |
| **Respiratory agents** | Montelukast<br>Budesonide<br>Cetrizine | 1<br>1<br>1 |
| **ANS agent** | Pralidoxime | 1 |
| **Corticosteroids** | Hydrocortisone | 1 |
| **Antibiotics** | Amikacin<br>Meropenam | 2<br>1 |

**Table 5: Distribution of patients according to under dose.**

| Under dose | No of patients | % of patients |
|---|---|---|
| **Present** | 28 | 8.9% |
| **Absent** | 285 | 91.1% |

**Table 6: Identified cases of under dose.**

| Drug class | Drug | No of patients |
|---|---|---|
| **Antimicrobials** | Ciprofloxacin<br>Clindamycin<br>Ofloxacin<br>Nitrofurantion<br>Linezolid<br>Levofloxacin | 3<br>1<br>1<br>1<br>1<br>1 |
| **CVS agent** | Amiodarone<br>Carvedilol<br>Metaprolol<br>Amlodipine<br>Verapamil<br>Hydrochlorothiazide | 1<br>2<br>2<br>1<br>1<br>1 |
| **Respiratory agent** | Montelukast | 1 |
| **GI agent** | Ursodiol<br>Loperamide<br>Dicyclomin | 3<br>1<br>1 |
| **Anticoagulant** | Enoxaparin<br>loparin | 1<br>1 |
| **CNS agent** | clonazepam | 1 |
| **Analgesic** | acetaminophen | 1 |
| **Skeletal muscle relaxant** | Baclofen | 1 |

**Table 7: Distribution of patients according to adverse drug reaction.**

| ADR | No of patients | % of patients |
|---|---|---|
| **Present** | 24 | 7.7% |
| **Absent** | 289 | 92.3% |

**Table 8: Identified case of adverse drug reactions.**

| Drug class | Drug | Description of the reaction | No of patients |
|---|---|---|---|
| **CVS agent** | Clinidipine<br>Ramiprill<br>Metaprolol | Tremor<br>Dry cough<br>Constipation | 1<br>2<br>1 |
| **Anti- microbial** | Cefoperazone<br>Ceftriaxone<br>Ofloxacin<br>Azithromycin<br>Metronidazole<br>Isoniazid, pyrazinamide &ethambutol | Bleeding<br>rashes<br>leucopenia<br>running nose<br>hypersensitivity<br>abdominal pain<br>metallic taste<br>jaundice | 1<br>1<br>1<br>1<br>1<br>1<br>1<br>1 |
| **GI agents** | Pantoprazole<br>Rabeprazole | Constipation<br>headache | 1<br>1 |
| **Respiratory agent** | Salbutamol<br>Levocetirizine | Throat irritation<br>Hypokalemia<br>somnolence | 1<br>1<br>1 |
| **Corticosteroids** | Dexamethasone<br>Prednisolone | Diabetes mellitus<br>Cushing syndrome | 1<br>1 |
| **Anti-diabetic agent** | Metformin | Metallic taste | 1 |
| **Analgesic** | Tramadol<br>Acetaminophen | Sedation<br>insomnia | 1<br>1 |
| **Skeletal muscle relaxant** | Baclofen | Head ache | 1 |

**Table 9: Causality assessment by WHO and Naranjo scale.**

| Scale | Severity | No of patients |
|---|---|---|
| **WHO scale** | Certain<br>Probable<br>Possible | 11<br>7<br>6 |
| **Naranjo scale** | Probable<br>Possible | 12<br>12 |

**Table 10: Distribution of patients according to treatment without indication (TWI).**

| TWI | No of patients | % of patients |
|---|---|---|
| **Present** | 58 | 18.5% |
| **Absent** | 255 | 81.5% |

**Table 11: Identified cases of Treatment Without Indication.**

| Drug | Class | No of patients |
|---|---|---|
| **Antimicrobials** | Artesunate&Lumifantrine | 14 |
| | Rifampin | 1 |
| | Isoniazid | |
| | Amoxicillin with cotrimoxazole | 1 |
| | Piperacillin&tazobactam | 2 |
| | Azithromycin | 3 |
| | Ceftriaxone | 2 |
| | Metronidazole | 2 |
| | Fluconazole | 1 |
| **CNS agent** | Phenytoin | 2 |
| | Clonazepam | 1 |
| | Alprazolam | 2 |
| **GI agents** | Domperidone | 3 |
| | Racecadotril | 2 |
| | Ondansetron | 9 |
| | Sennasoft | 1 |
| **Respiratory agent** | Cetirizine | 1 |
| | Pheniramine malate | 1 |
| | Theophylline | 3 |
| **CVS agent** | Furosemide | 1 |
| | Aspirin with atorvastatin | 2 |
| **NSAID** | Diclofenac | 1 |

**Table 12: Distribution of patients according to untreated indication.**

| Untreated Indication | No of patients | % of patients |
|---|---|---|
| **Present** | 36 | 11.5% |
| **Absent** | 277 | 88.5% |

**Table 13: Distribution of patients according to improper drug selection.**

| Improper Drug Selection | No of patients | % of drug selection |
|---|---|---|
| **Present** | 20 | 6.4% |
| **Absent** | 293 | 93.6% |

**Table 14: Distribution of DRPs in various age groups.**

| Age | DI | ADR | TWI | UI | OD | UD | IDS | Total DRPs |
|---|---|---|---|---|---|---|---|---|
| **<18** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **18-30** | 16 | 0 | 14 | 4 | 0 | 1 | 5 | 40 |
| **31-40** | 30 | 5 | 13 | 12 | 4 | 4 | 3 | 71 |
| **41-50** | 26 | 4 | 11 | 6 | 4 | 6 | 4 | 61 |
| **51-60** | 31 | 6 | 7 | 5 | 2 | 9 | 3 | 63 |
| **>60** | 51 | 9 | 13 | 9 | 5 | 8 | 5 | 100 |
| **Total** | 154 | 24 | 58 | 36 | 15 | 28 | 20 | 335 |
| **% of DRPs** | 45.97% | 7.16%% | 17.31%% | 10.74% | 4.47% | 8.35% | 5.97% | 100% |

## DISCUSSION

Drug related problems constitute a major public health problem, because of their consequence on morbidity, mortality and coast. According to the literature they would affect 4% to 22% of hospitalized patients on a given day.[9]

In this study we have enrolled 313 patients among which DRPs are found more in patients aged greater than 60 (26.5%). A similar study conducted by Yvonne *et al.*,[5] shows that, Of 347 patients prescribed Polypharmacy, 58.2% are geriatrics and another study conducted by *Elaine Lau et al.*,[10] shows that the mean number of DRPs identified per geriatric patients was 3.2. Thus it can be assessed as the incidence of DRPs are more in geriatric patients.

A study conducted by Khavane Karna*et al.*,[7] show that A total of 500 cases of the patients were selected, among them 77.4% were male and 22.6% were females. Also in a study by Marimuthu Karthikeyan*et al.*,[11] the study was conducted in 311 patients, where 168 were males (54%) and 143 were females (46%). In our study 53.7% are males and 46.3% are females. It shows the incidence of hospital admission is more in males than females.

A study conducted by pote s *et al.*,[12] Of the 304 cases, 103 (34%) cases had at least one error. The total number of errors found was 157 (51.64%). Also in a study by A .H AL Hajje*et al.*,[9] shows that out of 572 patient, 35% of the patients are having DRPs. In my study, out of 313 patients enrolled in the study 67.1% patients are having DRPs. So the incidence of DRP in hospital inpatients are very high.

A study conducted by Mohammed abbasinzari*et al.*,[13] shows that, 9.9% of the patients are having drug interactions. Another study by Abdulhalim M. mzale[14] shows that Potential drug and abnormal electrolyte interaction was the major error undetected by block pharmacist contributing to 45% . In the present study, out of 313 cases 49.2% of the patients are having drug interaction. It shows drug interaction constitute major proportion of DRPs which may be due to polypharmacy.

A study conducted by Rani Reena Abraham[15] shows that 17.26% of the patients are undergone over dosage. In our study 4.8% of the total patients are undergone over dosing. So the incidence of overdosing is less in our study when compared to other studies.

A.H. AL-Hajje *et al.*,[9] conduct a study shows that 90 patients are having drug related problems, 10% is under dose. Another study by pote s *et al.*,[12] shows the incidence of under

dose is 2.6%. In our study, the incidence of under dose is 8.9% which is close to the results shown by A.H AL-Hajje.

A study by Ayesha Romana*et al.*,[16] shows that 15% of the patients are having ADR. Another study by Kristen k viktil*et al.*,[17] shows that 3.3% of the patients are having ADRs. In our study 7.7% of the patients are having ADR.

A study by Gunarstemer[18] shows 6.8% of the patients are having drug use without indication. In my study 18.5% of the patients are prescribed the drugs without any indication. A study by Gunarstemer[18] shows 7.55 patients are having untreated indication. In our study, 7.5% of the patients are having untreated indications. A study by Ramanath k v *et al.*,[6] shows 19% of the patients are having improper drug selection. Another study by Abdul Halim Mzale[14]shows 23% of the patients are having improper drug selection. The incidence of improper drug selection in our study is 6.4%.

In short DRPs are common in all hospitals. Pharmacist can play a crucial role in the detection and management of DRPs.

## CONCLUSION

According to analyzed results we found that drug related problems are prevalent in hospital inpatients. Incidence of DRPs increases with age and polypharmacy. Out of 313 samples collected, 210 patients are having at least one DRP. In 313 patients, 2091 drugs are prescribed. The incidences of DRPs are more in patients aged greater than 60 when compared to other age groups which may be due to higher incidence of comorbidities and associated poly pharmacy in geriatrics. Out of 313 patients, 154 patients are having DI. Out of all DRPs, drug interaction accounts for greatest frequency.15 patients are over dosed and 28 patients are having drug prescribed as under dose. Antimicrobials and cardio vascular agents are the drugs which are commonly under dosed. 24 patients are having ADR. Majority of the ADRs arise from antimicrobials. 58 patients are having drug use without indication. 36 patients are having untreated indication. 20 patients are having improper drug selection. In our study we concluded that pharmacist can play a crucial role in identifying and resolving DRPs by suggesting interventions to the physician. By regularly monitoring the prescriptions prescribed by the physicians will helps in the reduction of drug related problems. The study suggests that pharmacists and general practicioners (physicians) can work together to identify

and resolve drug - related problems. Additional controlled studies are required to measure the effect of this service on health outcomes.

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