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A Prospective And Observational Study: Assessment Of Drug Related Problems To Increase The Patient Safety In Rural Tertiary Care Teaching Hospital

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ABSTRACT

Background: Advances in medication therapy have both enhanced patient care and contributed to an apparent increase in the number of drug-related issues documented in the last 40 years. Most drug-related problems may be prevented, and clinical pharmacists have been demonstrated in several trials to aid in the detection and prevention of such problems.

Aim: To determine whether or not patients admitted to hospital have drug-related concerns and strategy to increase the patient safety.

Methods: A prospective observational research involving inpatients at the medical unit. Patients were enrolled in the trial if they met the inclusion criteria. Details about demography, treatment, and other relevant information were collected using a specially designed patient data collecting form. Any drug-related concerns were discussed with the physician during ward rounds, and confirmed DRPs were recorded.

Results: From 232 patients, a total of 171 DRPs were found. Patients who were female accounted for 88 (51.5%) of the total, while men accounted for 83 (48.5%). Patients aged 51 to 60 years old were more likely to have DRPs. The majority of DRPs found in this study are the outcome of CVS. Antibiotics contained the greatest number of DRPs. Drug interactions (38%) were identified as the most common type of DRP, followed by ADR (14.6%).

Conclusion: The greatest significant health-care burden in the entire population is drug-related disorders. A large number of DRPs were discovered in the hospital's medicine wards during this investigation.The clinical pharmacist's

suggestions were also warmly received by the physician throughout the intervention. This demonstrates that clinical pharmacists are accepted and recognised as members of the health-care team during the treatment of patients.

Key words: Drug related problems; Polypharmacy; ADR, DDI.

INTRODUCTION:

There were fewer medications accessible and drug-related disorders were not thoroughly assessed prior to the 1960s. Over the last 40 years, advances in pharmacological therapy have improved patient care while also appearing to increase the number of drug-related disorders identified[1]. A drug-related problem (DRP) is defined as an incident or scenario involving drug therapy that, directly or indirectly, interferes with anticipated health results[2]. The most prevalent types of DRPs are adverse drug responses, drug interactions, drug consumption without indication, failure to get pharmaceuticals, improper medication selection, drug overdose, subtherapeutic dosage, or neglected indication[3]. Drug-related problems are frequent, and they can result in decreased quality of life as well as increased morbidity and mortality. Drug-related problems can arise at any stage of the drug's life cycle, from prescription to follow-up. The bulk of problems include the administration, dispensing, and patient use of a medicinal product, but a lack of follow-up and evaluation of medical treatment is also a big problem[4-9]. Because of the intricacy of pharmacotherapy, health-care personnel's lack of training and understanding, and medicine users' behaviour, it is preferable to prevent drug-related issues rather than correct them. Some pharmaceutical problems, like as allergies, are the result of an individual's unanticipated reaction and cannot always be avoided.Even if drug and patient-related factors could be analysed during a medication review before a medicine is administered to a patient, post-initiation pharmacotherapy evaluation is still necessary to find DRPs and improve outcomes. Prescription, dispensing, and drug usage are the three main stages at which a drug-related problem can arise during the implementation of pharmacotherapy. Problems with prescriptions typically begin at the doctor's office, but they can also occur at the patient's bedside. Negligence or a lack of expertise, as well as a lack of information about the patient's entire treatment profile and maybe missing laboratory results, are the most common causes of such difficulties. External factors, such as the pharmaceutical business, may sway a doctor's decision to prescribe the optimal treatment option. DRPs can also be induced by nurses who misrepresent a physician's orders on a record or prescription form, or who neglect to provide medication as directed. Dispensing problems are frequently caused by human error. Misreading a physician's handwriting, neglecting to conduct a medicine usage check, or taking the wrong box or bottle can all result in DRPs. There are a number of factors that can contribute to the high prevalence rate, but polypharmacy and advanced age are two that have been widely mentioned as key risk factors. Polypharmacy is the use of numerous drugs by a single patient, which is prevalent among geriatric patients. Older age has been associated to a considerably increased likelihood of developing an ADR among the risk variables. ADRs (adverse drug reactions) were found in several studies (Bergman and Whilom 1981b;Veehof et al 1999; Fattinger et al 2000), provides baseline data characterising the problem of DRPs among hospitalised patients receiving polypharmacy in Singapore, and helps to develop and implement risk management strategies[8].

DRPs were found to be more common in India than in industrialised countries, according to a study[7].There is currently no widely accepted management system for the definition, collection, documentation, and management of drug-related problems at the international level (DRPs)[11].

Clinical pharmacists are experts in therapeutics and provide patients with comprehensive medication management with main responsibility to use medicines safely and effectively. Clinical pharmacists

are frequently involved in the monitoring of a patient's drug therapy by questioning the prescriber and the patient as needed. During ward rounds, the physicians were informed of the detected drug-related issues. The majority of DRPs are preventable, and clinical pharmacists are taking a proactive role in preventing and resolving them[12-15]. Therefore DRPs can be addressed by clinical pharmacists both during and after hospitalisation. They can provide post-discharge counselling, identify and resolve medication inconsistencies, and monitor for non-adherence. In this study our main aim is to determine whether or not patients admitted to hospital have drug-related concerns and if so what is the pharmacist role for the same to increase their safety.

METHODOLOGY

Study Site:

Study was conducted at medicine department of Sri Adichunchanagiri Hospital and Research Centre (AH & RC), B.G.Nagara, Karnataka, which is a 1050-bedded tertiary care teaching hospital located in rural area of India.The hospital has various departments, like medicine, surgery, orthopaedics, Ophthalmology, ENT, paediatrics, obstetrics and gynaecology, Radiology, Skin and STD.

Study Period

From December 2012 to August 2013, a nine-month study was conducted

Study Approval

The ethical committee of the (AH & RC), B.G. Nagara, gave their approval with registration number AIMS/ECC/50/13-14.

Study Criteria

Inclusion Criteria:

In-patients aged 18 and up, of either gender, in medicine units, and patients who are willing to engage in the study

Exclusion Criteria:

Women who are pregnant or breastfeeding

Study Materials:

Patient case notes (containing case records, treatment charts, laboratory reports, and other relevant sources), Medication/Treatment chart, Properly constructed documentation form, Laboratory data reports, and other pertinent sources.

Study Procedure: Patients who matched the inclusion criteria were invited to participate in the trial after signing a signed consent form. A specially designed patient data collection form was used to collect all relevant data for intervention from inpatients, including patient demographics, admission complaints, previous medication and medical history, social history, history of allergy, diagnosis, laboratory data, drug treatment charts (including drug prescribed, doses, route of administration, frequency, and duration of treatment), progress report, discharge medication, and follow up notes, among other things (case records, medication chart and laboratory reports etc).Drug Related Problems (DRPs) (such as incorrect drug selection, compliance, untreated condition, drug use, interaction, ADRs, and so on) were reviewed and followed up on

in the data. The different forms of DRPs discovered were discussed and documented on the wards with the doctors concerned. DRPs were identified and investigated using standard text books [Roger Walker, Drug Interaction Facts-5, WHO- Naranjo's Causality Assessment, Herfindahl Gourley, and others], and the results were communicated with physicians to help them reduce DRPs.

Statistical Methods: The statistical analysis utilised in this study was descriptive and inferential. Continuous measurements' results are shown as Mean SD (Min-Max), while categorical measurements' results are shown as Number (%).

Statistical Software: The data was analysed using SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0, and R environment ver.2.11.1, while graphs, tables, and other graphics were created using Microsoft Word and Excel.

RESULT & DISCUSSION

Gender & Age Distribution

In this study,from 232 patients, a total of 171DRPs were found. The patients has provided their consent and participated after being approached and educated about the study. The majority of subjects were female (51.5%) and male (48.5%). Subject were higher at the age group between 51-60 (24%) followed by 61-70 (22.2%) and lower at the age 81-90 (1.25%). The DRPs patients were higher in female 88 (51.5%) when compare to the male 83 (48.5%). Female patients have been demonstrated to be more vulnerable to DRPs, despite the fact that they are frequently lighter in weight and smaller in build than their male counterparts who receive the same therapeutic doses. The study's findings are comparable to those of another study (Bergman and Wiholm 1981b;Veehof et al 1999; Fattinger et al 2000)[9].

Disorders Associated With DRPs

The distribution of illnesses was shown that the majority of the patients had cardiovascular issues 66 (38.5%) followed by ischemic heart disease, hypertension, myocardial infarction, dilated cardiomyopathy and unstable angina.

Endocrine disorders: Diabetes Mellitus and Hypothyroidism accounted for 21.3% of the total, followed by pulmonary diseases. There were 13(7.6%) individuals with tuberculosis and 9(5.3%) patients with CNS illnesses such epilepsy and Parkinsonism.

A minor percentage of patients had other disorders and diseases involving other body systems, such as gastrointestinal infections (7.1%), UTI and Renal disorders (6.5%), malaria, dengue, liver disorders, and numerous other disorders 22(12.9%). As numerous body systems are engaged, the risk of drug-related disorders increases, particularly in geriatrics with weakened bodily functions and systems.

Table 1: Disorders Associated With DRPs

Diagnosis	No. of Patients	Percentage(%)	DRPs identified & %
Cardiovascular disorders	76	32.7	66 (38.5)
Endocrine disorders	31	13.3	21 (12.3)
Pulmonary disorders	31	13.3	22 (12.9)

GI disorders & infection	12	5.6	7 (4.1)
Poisoning	10	4.3	6 (3.5)
UTI & Renal disorders	10	4.3	6 (3.5)
CNS disorders	16	6.4	9 (5.3)
Pulmonary Infections	19	8.9	13 (7.6)
Others	26	11.2	22 (12.9)
Total	232	100	171

Drug class associated DRP's

While assessing the drugs class associated with DRP's in our study, majority of DRP's was found to be in Antibiotics 52 (30.4%), DRPs were discovered as medication interactions in the majority of cases20 (11.6%), ADR 6 (3.5%), drug used without indications 8 (4.7%). And the second class of drugs was Antihypertensive 30 (17.5%) i.e., drug-interaction 16 (9.4%), ADR's 2 (1.2%), Poly-pharmacy 9 (5.3%) followed by followed by Analgesics 27 (15.5%), in that drug-interaction 8 (4.7%), ADR's 3 (1.8%), including both narcotics 6 (3.5%), and NSAIDs (Diclofenac and Aceclofenac) 21 (12.3%). When ADRs were investigated, it was determined that only a small percentage of the study population had ADRs as a result of their therapy, but that the strength of the ADRs was moderate and readily controlled.

Table 2: Drug class associated DRP's

Classes of Drugs	No. Of DRPs	Percentage(%)
Antibiotics	52	30.4
Corticosteroids	13	7.6
Antihypertensive	30	17.5
Antidiabetics	14	8.2
Antitubercular	01	5.8
Analgesics	27	15.8
Vasodilators	09	5.3
Drugs acting on GI system	04	2.4
Others	21	12.3
Total	171	100.0

Drug-Drug Interaction

Drug-Drug Interactions are also considered amongst an important drug related problem, which may give rise to a variety of effects, showed in another study[8]. Drug-drug interactions can occur in geriatric patients due to polypharmacy, improper medication use, and various pharmacokinetic and pharmacodynamic changes. More drugs were prescribed to inpatients than to outpatients, which could explain why there were more drug-drug interactions. The DDIs were determined to be 38% percent in our study, which requires small adjustments and optimization to therapy, which were not expected to significantly alter hospital stay, resource utilisation or clinical outcome. It was observed that a majority of prescriptions does not contain the interacting drugs while a significant proportion showed the presence of one or more interacting drugs in the prescription, however, majority of the interactions were moderate (27.5%) in nature and followed by major (9.9%), could be managed without any major intervention. Drug-Drug interaction varies in their clinical significance, and the pharmacist needs to make a professional judgment whether a change in drug therapy is necessary.

A couple of illustrations Drug interactions discovered in this study shown in table no.3

Table 3: Illustrations Drug interactions

Drug Interactions	No. of patients	Percentage (%)
Metformin + Enalapril	4	2.4
Clopidogrel + Asprin	3	1.8
Sorbitrate + Asprin	3	1.8
Clopidogrel + Rabeparazole	3	1.8
Clopidogrel + Amlodipne	3	1.8
Amlodipine + Asprin	3	1.8
Metformin + Rifampicin	3	1.8
Norfloxacin + Insulin	3	1.8
Digoxicin + Norephinephrine	2	1.2
Dexamethasone + Phenytoin	2	1.2
Furosemide + Hydrocortisone	2	1.2
Losartan + Asprin	2	1.2
Isoniazide + Acetaminophen	2	1.2
Ceftriaxone + Amikacin	2	1.2
Asprin + Insulin	2	1.2
Asprin + Enalaril	2	1.2
Furosemide + Ramipril	2	1.2
Ciprofloxacin + Pribinacid2	1.2	

Asprin + Streptokinase	2	1.2
Norfloxacin + Asprin	2	1.2
Furosemide + Diclofenac	2	1.2
Rifampicin + Prednisolone	2	1.2
Dugoxcin + Furosemide	1	0.6
Asprin + Heparin	1	0.6
Budosenide + Clopidogrel	1	0.6
Aspirin + Glipzide	1	0.6
Norephenephrine + Dopamine	1	0.6
Furosemide + Theophyline	1	0.6
Clopidogrel + Amlodipine	1	0.6
Levofloxacin + Aspirin	1	0.6
Budosenide + Hydrocortisone	1	0.6
Heoarin + Nitroglycerine	1	0.6
Budosenide + Metronidazole	1	0.6
Budosenide + Domperidone	1	0.6

Requirement Of Dose Adjustment [Sub Therapeutic Dose, Low Dose& High Dose]

DRPs may result from failures to select the dosage or duration of treatment. Dose of a drug plays a vital role in deciding its effect on the patient. In this study it was observed that a higher dose 15 (8.8%), can precipitate the toxic effects while a sub-therapeutic dose 10 (5.8%), may lead to failure of therapy due to inappropriate serum concentration of the drug and a low proportion of patients were prescribed low dose 1 (0.6%), which required dose adjustments to their medications, including phenytoin, digoxin, and oral iron supplements. Because lowered stomach secretions and achlorhydria may lower the capacity for iron absorption, these patients who were given oral iron supplements needed a greater dose. Because of the decreased build-up of metabolism leads, phenytoin and digoxin required dose adjustments, and they may be required at a lower dose. The clinical pharmacist gave this information, although it was regarded as a minor concern by health care experts.

Failure To Receive Medication

In our study showed that only a small proportion of patients failed to receive the prescribed drugs 13 (7.6%), reason was some patients are not able to purchase prescribed drugs 9 (5.3%), some patients forgot to take prescribed medicines 4 (2.3%). This information collected during counselling the patients. The major factor/reason observed was manual mistakes and ignorance by the patients.

Adverse Drug Reaction

In our investigation, the number of adverse drug reactions seen and monitored was 25 (14.6%), with Definite 3 (1.8%), Probable 11(6.4%) and Possible 11(6.4%) connected to the medication molecule. On the third day of treatment, the patient had Jaundice (Hepatitis-E virus) and a Bilirubin has raised drastically, thus the doctor recommended Trental.400 mg (Pentoxyfylline) after which patient had nausea, itching, and vomiting. When the clinical pharmacist identified him, he gave his approval and stopped taking the Trental.400 mg tablet (Pentoxyfylline) and suggested for alternative.

Table 4: Patient distribution on Adverse drug reaction

Type of ADR	No. of patients (n=171)	%
Nil	146	85.4
Yes	25	14.6
• Definite	3	1.8
• Possible	10	5.8
• Probable	9	5.2
• Unlikely	3	1.8

Number Of Drugs Prescribed & Polypharmacy

In our study, the practice of Polypharmacy 29 (17%) i.e. more than 5 drugs per prescription may lead to the risk of pharmacokinetic/pharmacodynamics drug interactions. More than 10 drugs were noticed in 7 (4.2%) patients, more than 8 drugs were noticed in 10 (5.8%). In 12 (7%) of the patients, there were more than six medicines. Only 29 patients tested positive for the polypharmacy. The majority of the patients had more than three medical problems, symptomatic therapy and a multiple/co-morbid disease state, polypharmacy could be the reason. Polypharmacy is only used by a small percentage of the population, according to the current study. There are a number of factors that contribute to the high incidence rate, but polypharmacy and advanced age are frequently cited as major risk factors[9].

Table 5: Patients distribution on Poly pharmacy

Poly pharmacy	No. of patients	%	No. of drugs used		
			>6	>8	>10
No	142	83.0	-	-	-
Yes	29	17.0	12(7.0%)	10(5.8%)	7(4.2%)
Total	171	100.0			

Drug Used Without Indication

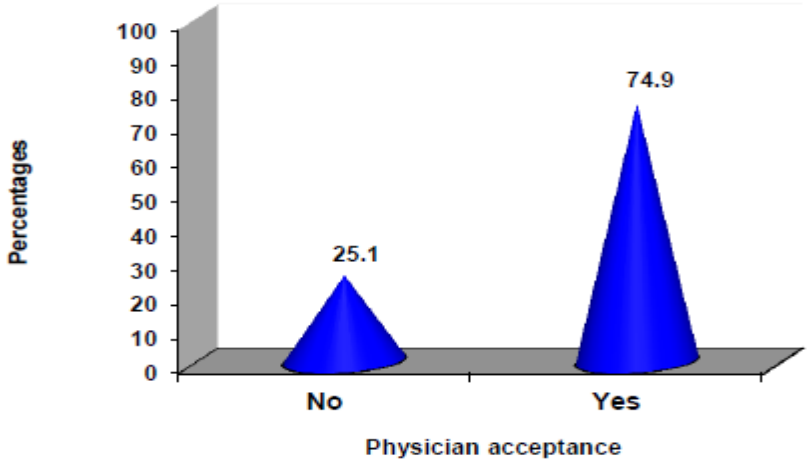
In our study 38 (22.2%) patients were identified as drug used without indication. The enrolled in patients were prescribed with more medication. The drugs which was used without indication were Proton pump inhibitors 20 (11.6%), multivitamins 6 (3.5%) and NSAID's 12 (7.0%).

Physician Acceptance Rate

Clinical pharmacist suggestions and prescription modifications were accepted in 74.9% of cases. The 22.8% of the dose was adjusted, 34.5% was cut, 7.6 percent was increased and 9.9% medications were stopped. During the study, the majority of physicians said that the advice given was too helpful in terms of updating their expertise for improved patient care, wellbeing and lower prescribing errors.

Table 5 & Figure 1: Physician Acceptance and changing the treatment

Physician acceptance	No. of patients (n=171)	%
No	43	25.1
Yes	128	74.9
• Drug therapy changed	39	22.8
• Dose decreased	59	34.5
• Dose Increased	13	7.6
• Drugs stopped	17	9.9



CONCLUSION

The greatest significant health-care burden in the entire population is drug-related disorders. A large number of DRPs were discovered in the hospital's medicine wards during this investigation. In this investigation, multiple treatment regimens, patient age, and drug interactions were found to be the most common causes of DRPs. According to the findings, including clinical pharmacist services into patient care can significantly aid in the detection, resolution, and prevention of DRPs in hospitals, thus improving patient outcomes.The clinical pharmacist's suggestions were also warmly received by the physician throughout the

intervention. This demonstrates that clinical pharmacists are accepted and recognised as members of the health-care team during the treatment of patients. Better patient care and treatment outcomes can be achieved when physicians and pharmacists work together. This study proves that the clinical pharmacist have enormous role to play in the health care management and also represents the need and strength of clinical pharmacist services at hospital in India.

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