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Evaluation of suspected adverse drug reactions of antimicrobial drugs commonly prescribed in department of general medicine in a tertiary care hospital

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Abstract
The study on "Evaluation of suspected Adverse Drug Reactions of antimicrobial drugs was conducted at a tertiary care hospital" in north Malabar region in Kerala. The investigation was done for a period of 8 months from May 2017 to January 2018. A total of 21 adverse drug reactions were detected and studied during this period. System most commonly affected by adverse reaction was the gastrointestinal system in 80% patients. The drug class mostly associated with adverse reactions were tetracyclins and oxazolidinediones. The study reveal that female patients 10(52.6%) had more prevalence of ADR over male patients 9 (47.4%). Age wise distribution shows that ADR occurrence in age group 50-59 years (26.3%). Drug was withdrawn in 10 cases 47.61% and symptomatic treatment were given for 11 patients (52.38%). Rate of reporting various health professionals were observed - physicians 12 (57.1%), nurses 7 (33%), pharmacist 2 (9.5%). Causality assessment was done using Naranjo and WHO scale. The result in Naranjo scale reveal that 18 (85%) of reactions was probable, and 3 (14.28%) of possible. While using WHO scale 90% was probable and 9.52% possible, and in modified Hartwig and Seigel scale level of severity mild 9(42.8%) and moderate (54.1%), modified Schumoch and Thornton scale for preventability found that preventable (20) 95.23%, definitely preventable (1) 4.68%. Adverse drug reactions to antibiotics are common in health system and should promote spontaneous reporting of ADR to antibiotics. Proper documentation and periodic reporting to regional pharmacovigilance centres would ensure drug safety.

Keywords: Adverse drug reactions, antibiotics, evaluation

Introduction
Antimicrobial drugs are drugs that kills microorganisms (viruses, bacteria, fungi and protozoa) or inhibit their growth and used commonly in routine practice for treatment and prophylaxis of various disease conditions. Antimicrobial drugs are some of the most widely, and often injudiciously, used therapeutic drugs worldwide. Important considerations when prescribing antimicrobial therapy include obtaining an accurate diagnosis of infection; understanding the difference between empiric and definitive therapy; identifying opportunities to switch to narrow-spectrum, cost effective oral agents for the shortest duration necessary; understanding drug characteristics that are peculiar to antimicrobial agents (such as pharmacodynamics and efficacy at the site of infection); accounting for host characteristics that influence antimicrobial activity; and in turn, recognizing the adverse effects of antimicrobial agents on the host. It is also important to understand the importance of antimicrobial stewardship, to know when to consult infectious disease specialists for guidance, and to be able to identify situations when antimicrobial therapy is not needed. By following these general principles, all practicing physicians should be able to use antimicrobial agents in a responsible manner that benefits both the individual patient and the community [1].

Antimicrobial drugs were classified into 15 different classes including Penicillins, first and second-generation Cephalosporins, third, fourth and fifth-generation Cephalosporins, Monobactams, Carbapenems, Macrolides, Lincosamides, Tetracyclines, Aminoglycosides, Sulphones and Trimethoprim, Quinolones, Glycopeptides, Metronidazole, antifungal agents, and antiviral agents. If several antimicrobial agents were being used at the same time when an ADR developed, the agent most likely to be the cause was identified by the attending physician. If this could not be decided, all agents were regarded as causative agents [2].

WHO defines ADR as any response to a drug which is noxious and unintended and occurs at

doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiologic functions. This WHO definition excludes overdose (either accidental or intentional), drug abuse and treatment failure and drug administration errors.

ADR are recognized hazards of the drug therapy. The problem of adverse drug reaction as significant cause of morbidity and mortality has been recognized since early times. In many countries ADRs rank among the top 10 leading causes of mortality. So there is a need to study ADRs seriously to create awareness about ADRs among patients to motivate health care professionals in the hospital to report ADRs to minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health [3].

Methodology

A prospective spontaneous reporting study involving, active methods (pharmacist actively looking for suspected ADRs) and passive methods (stimulating prescribers to report suspected ADRs) was carried out in general medicine departments of a tertiary care referral hospital, Kerala for a period of eight months. Patients of all age groups who developed Adverse Drug Reactions of antibiotics were included for the study. The data for the study were taken from case sheets, investigation reports of patients who had experienced an ADR, personal interviews with reporting persons or clinicians, personal interviews with patient or patient's attendant, past history of medication use, which were generally obtained from, prescriptions from the past, reports of Medical and surgical interventions, referral letters, etc.

The causality assessment of the reported ADRs was carried out using the Naranjo causality assessment scale. In the Naranjo Algorithm, the drug reaction can be classified as definite, probable, or possible. The modified Schumock and Thornton scale classifies ADRs as definitely preventable, probably preventable and not preventable based on a set of questions for each level. The modified Hartwig and Siegel scale classifies severity of ADR as mild, moderate or severe with various levels according to factors like requirements for change in treatment, duration of hospital stay, and the disability produced by the adverse drug reaction.

Results and Discussion

During the study period 338 patients undergoing treatment with antibiotics were enrolled based on the several inclusion/exclusion criteria. Among the patients 179 were females (53%) and 159 males (47%). In this study age wise distribution shows that the maximum incidence of ADR were in the age group of 50-59 years. Among the 338 patients 115 patients (34.0%) received beta lactum antibiotics either in monotherapy or in combination with beta lactamase inhibitors. The respective number of patients receiving other therapy are as represented in Table 1with macrolides and lincosamides being the other mostly prescribed antibiotics. The incidence of ADR with beta lactum antibiotics was observed in 9 patients accounting for 7.8%. The incidences of adverse effects with other classes of antibiotics in percentage are as represented in figure 1. The result shows maximum incidence of adverse effects in treatment with tetracyclines followed by oxazolidinediones.

Table 1: No. of patients receiving a given drug therapy and incidence of ADR associated with the therapy.

Class of drugs	Drugs prescribed (%)	Incidence of adverse drug reactions (%)
beta lactam antibiotics	34.02	2.61
macrolides	14.3	4.16
aminoglycosides	1.5	40
lincosamides	11.5	5.12
tetracyclines	3.8	15.3
oxazolidinones	3.8	7.69
quinolones	7.4	0
carbapenams	9.5	0
nitriimidazoles	6.8	0
glycopeptides	2.1	0
polymixins	0.9	0
antitubercular agents	1.5	40
azole derivatives	3	0

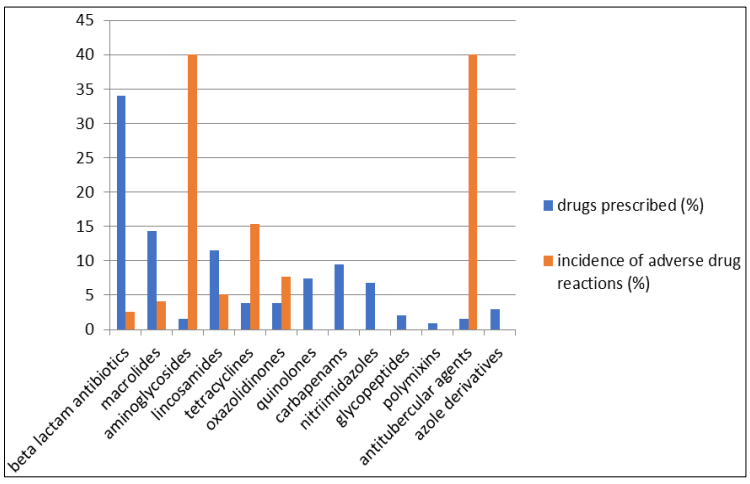

Fig 1: Incidence of ADR with different classes of drug therapy

Gastrointestinal system was the organ system mostly affected by ADR as is represented in figure 2.

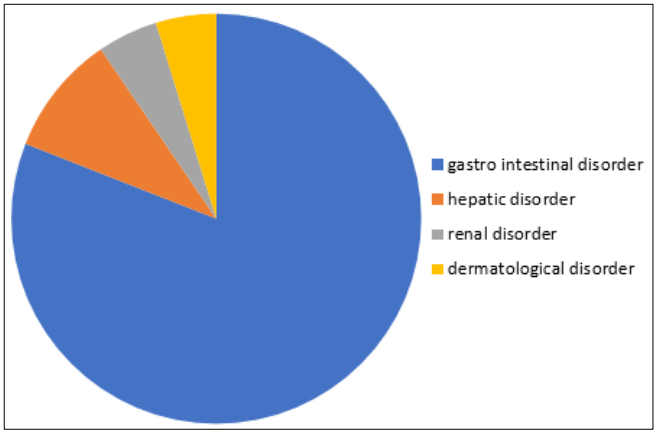

Fig 2: system level of incidence of ADR

Causality assessment with WHO scale revealed that out of 21 cases, 19 cases were probable (90.4) and two were possible (9.5%). In Naranjo scale 18 cases were probable (85.7%) and three were possible (14.3%). Modified Hartwig and Seigel scale showed the incidence of 12 moderate cases (57.1%) and 9 mild (42.9%). In modified Schumock and Thornton scale 28 cars were probably preventable and one definitely preventable. The respective results are as represented in figures 3 to 6.

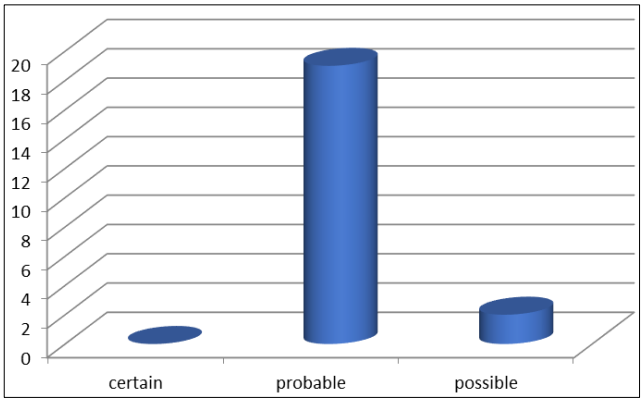

Fig 3: WHO causality assessment scale

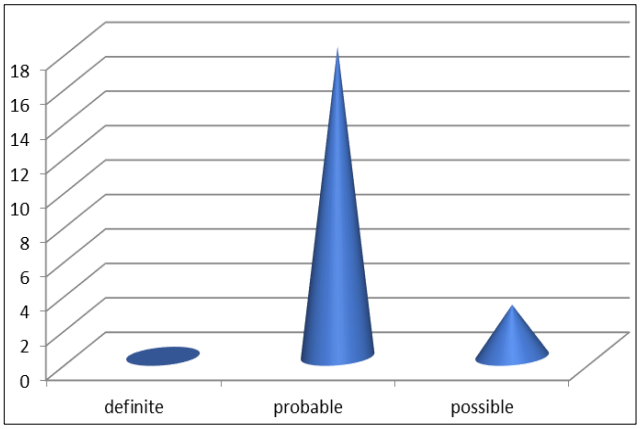

Fig 4: Naranjo causality assessment scale

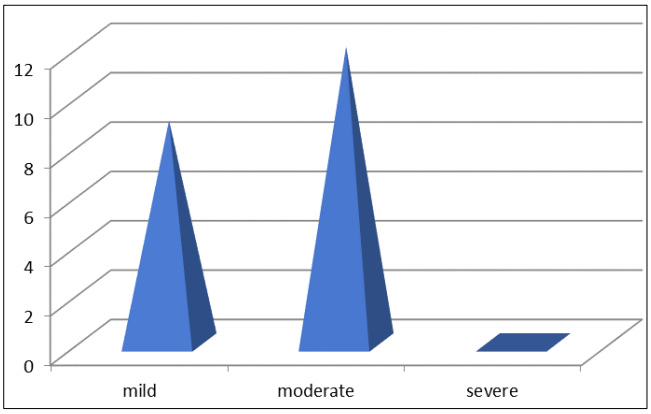

Fig 5: Modified Hartwig & Seigel severity assessment scale

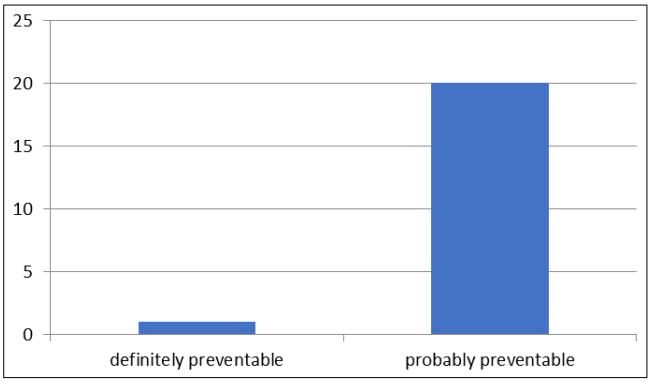

Fig 6: Modified Schumock & Thornton preventability assessment scale

The present study aimed to evaluate the suspected adverse drug reactions of antimicrobial drugs commonly prescribed in in-patients of general medicine department of tertiary health care hospital in northern Malabar region of Kerala. The data for the study were taken from the case sheets, investigation reports of the patients. A total of 338 patients were enrolled in the study, out of this 21 ADRs were identified in 19 patients. The study includes various demographics details of the patients.

In this study the gender wise distribution shows females patients (52.6%) had more prevalence of ADR over males (47.4%), the difference was significant with respect to the male population. Previous studies also reported that the occurrence of ADRs is more common in women, this finding may be because of the difference in weight, body mass index, hormonal changes unique to females (during puberty, menstrual cycles, menopause), and the effect of these changes on drug metabolism. Other possible factors include difference in fat composition (with respect to impact in drug distribution) and genomic constitutional differences influencing the levels of various enzymes involved in drug metabolism. This binding is similar to the findings of V. Brahma Naidu *et al.* [4]. Analysis of age wise distribution shows the ADR occurrence in age group of 50-59 years (26.3%), this result implied that these age group patients were more prone to antibiotic adverse drug reactions due to age related pharmacokinetic and pharmacodynamic changes and the presence of co-morbid illnesses and multiple drugs along with infectious diseases, the similar findings was made by

Kavita Dhar *et al*. [5] In this beta lactam antibiotic drug class, cephalosporins were the most prescribed drug class so that the reported ADRs were also more in these drug classes. When we are comparing the number of drugs prescribed with the ADRs observed, it is found that the incidence rate of ADR with the more commonly prescribed drugs are comparatively less. Here the more number of ADR was seen with Beta Lactam antibiotics but when comparing it with the total number of drugs prescribed the incidence rate of ADR with respect to Beta lactam antibiotics is less. Only type A reactions were reported in all cases. Gastrointestinal system was the most commonly affected organ. This result was similar to the study of Shamna *et al*. [6]

Rate of reporting by various health professionals were observed as physicians 12, 7 by Nurse, and 2 by pharmacist. As part of management of ADR showed that 11 ADR cases require symptomatic treatment and the drug were withdrawn in 10 cases. Majority of patients recovered from ADR because none of the reported reactions were fatal.

Conclusion

The present study has provided baseline information about the prevalence of ADRs and their distribution among different age groups, genders, organ systems affected, and therapeutic classes of medicines. The data presented here will be useful in future, long term and more extensive ADR monitoring in the hospital and will be useful in framing policies towards rational use of drugs. Adverse drug reactions are one of the related problems in the hospital setting and are a challenge for ensuring drug safety. Systematic reporting of ADR help to improve the quality of patient care by ensuring the safety and efficacy of drug use in the daily routine setup.

Antimicrobial drugs are some of the most widely, and often injudiciously, used therapeutic drugs worldwide. Antibiotics comprises the major volume of the drug family and inpatient prescriptions and thus are the most irrationally prescribed drug class. The health system should promote the spontaneous detection of the Adverse Drug Reactions and delivering the awareness classes for the healthcare professionals regarding the need for reporting the incidents, incorporating ADR information in patient charts to improve the scenario in under-reported hospitals. Reporting of Adverse Drug Reactions to antibiotics and other drugs, proper documentation and periodic reporting to regional pharmacovigilance centres will ensure Antibiotics safety.

The simplest way to prevent most adverse drug reactions is to use the minimum dosages of drugs. The simple principle of 'start low and go slow' should be followed. Dosages should be individualised to the patients and drugs should be tailored to patient's need and not the vice versa. Health professionals should periodically be educated about adverse reactions and should be encouraged to report the same. Students should be taught principles of drug safety and rational drug use in their undergraduate and postgraduate curriculum. History of drug allergy should be elicited and renal and hepatic status of the patient should be known before drug use. This is because failure to adjust diug dosages results in adverse drug reactions in cases with renal/hepatic impairment.

Monitoring of the adverse effects of newer drugs and potentially risky drugs is mandatory. Health professionals have an important respons1bility in monitoring the ongoing safety of medicines. The incidence of adverse events is not directly proportional to the number of drugs being taken but increases remarkably as number of drugs rises. It is important to remember that most adverse drug reactions would subside once the offending agent is discontinued or dosage reduced; however, many result in permanent damage. The need is to spread awareness about using minimal doses of the drugs, at least in the beginning of the treatment.

Continuing medical education programmes for physicians and other health professionals should be conducted to make them aware of the methodologies and other technical aspects of the drug monitoring process. The effort of this study revealed the occurrence of comparatively less number of antimicrobial adverse drug reactions.

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