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AN OBSERVATIONAL STUDY TO EVALUATE THE ADVERSE DRUG REACTIONS SECONDARY TO THE USE OF ANTI-MICROBIAL AGENTS IN PATIENTS ADMITTED TO SURGERY WARD AT TERTIARY CARE HOSPITAL

Pharmacology

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ABSTRACT

Antimicrobials are widely used in surgical patients, for prophylaxis and treatment of infections. Common problems associated with their use include, the antimicrobials resistance and adverse drug reactions.

The prospective study aimed to evaluate the occurrence of adverse drug reactions due to antimicrobials in surgical cases. A total of 10 ADRs were reported among 90 participants with predominance in men (14.03 %) and elderly (60 %) with incidence of 11.11 %. Meropenem (30 %) caused highest ADR involving mostly the GI system (78.57 %).

It was observed that most of them were of Type A reactions, of which 90 % were preventable. On causality assessment the 50% of the reactions were possible and 50% probable. About 60% showed complete recovery, however no mortality was recorded

Use of antimicrobials is inevitable. Since it is observed for 90 % of ADRs to be preventable, care should be administered in their judicious use.

KEYWORDS

Adverse drug reactions, antimicrobials, surgical prophylaxis

INTRODUCTION

Antimicrobials are one of the few medicines used for prophylaxis, palliation and treatment of various infective diseases with significant importance in the developing countries where infective diseases predominate. These are the class of medicines most frequently used and misused [1].Antimicrobials can save life or worsen the disease condition due to their inappropriate use, thus contributing as a major cause of mortality and morbidity worldwide[2].

They are mostly prescribed for prophylaxis in pre and post operative surgical patients which accounts to a total of 20-50% of drug expenditure thus, adding to the economic burden for the patients and the health care system [3]. Non compliance and inappropriate use has been observed in many patients regarding the use of antibiotics which is found to be a major contributor for development of antibiotics resistance, super infection and adverse drug reactions. John JF et al have shown that, more than 50% of the antibiotic prescriptions used for treatment and prophylaxis were irrational[4,5].

A large number of antimicrobials are used for prophylactic management in pre, intra and post-operative stages, as the surgical site infections are most common and result in prolongation of hospitalizations and increased financial burden [6].The incidence of surgical site infection has been observed to have reduced in the last three decades due to prophylaxis use of the anti-microbial agents [7]. However, it has also been observed through several other studies that inappropriate and injudicious use of the antimicrobial agents, has led to the development of resistance, super infection and adverse drug reactions [8].Adverse drug reactions due to the use of antimicrobial agents are of great concern as they increase the economic burden to the individual and the health care set up [9].

There are very few studies that have focused on the adverse drug reactions due to the antimicrobial usage in surgical patients. Hence, the present study was taken up to evaluate the occurrence of adverse drug reactions secondary to the use of the antimicrobials in the surgical ward with the objectives to identify the common antimicrobial agent used in the surgical ward, demographic profile of the patients who suffer with adverse drug reactions due to antimicrobial therapy to find out the prevalence of the adverse drug reactions, the causality and severity of the recorded adverse drug reactions, to find out the cost-effectiveness and the duration of hospital stay post adverse drug reactions.

MATERIAL AND METHODS

The prospective study was conducted in the serially admitted patients to the male and female surgical wards of Dhiraj hospital and was initiated after obtaining permission from Sumandeep Vidyapeeth Institutional Ethics Committee. A total of 90 patients of either gender above 18 years of age, treated with antimicrobials for the surgical procedure who willingly signed the informed consent were included in the study. The patient's personal information along with the relevant medical and surgical history, diagnosis and treatment were obtained following the personal interview and the hospital case files. In case of the suspected adverse drug reactions all information pertaining to the adverse drug reactions were recorded in the ADR reporting form (white form) and subjected to the causality assessment by WHO-UMC and Naranjo's scale and their severity was assessed by Hartwig's scale Preventability score of the ADR was assessed as per the Schumock and Thornton's scale.

RESULTS

Out of the 90 participants enrolled in the study 57 (63.33%) were men and 33 [36.67%] were women who were grouped into three groups depending on their age. Group I, included patients between age of 18-39 years, Group II, 40-59 years while, Group III 60 and above.

The incidence rate of adverse drug reactions (ADR) recorded were 11.11% as indicated in figure 1. A total of 10 patients suffered with adverse drug reactions of which 8 (80%) occurred in men while, 2 (20%) occurred in female as indicated in figure 2, while the reactions were found to be maximum in men who belong to Group III (>60 years of age) followed by Group II and Group I.

FIGURE 1:

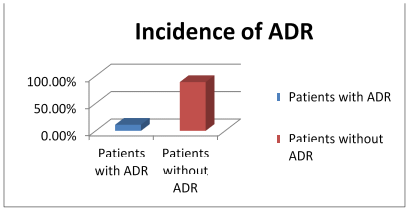
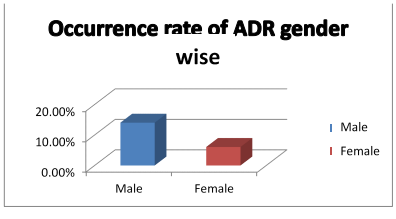
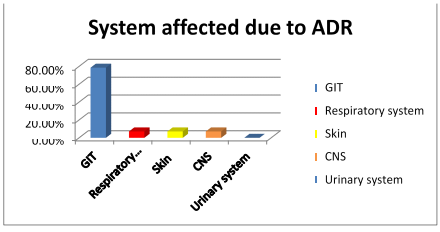


FIGURE 2:



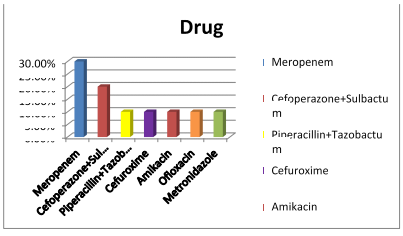
The common systems affected with the adverse drug reactions, followed by the use of antimicrobials included gastrointestinal system, which affected the maximum 10 (76.92%) affecting 8 men and 2 women followed by skin (7.69%), respiratory system (7.69%) and central nervous system (7.69%) as indicated in figure 3. The maximum and minimum number of drugs used in patients with ADR including antimicrobial was 10 and 3 respectively where as the average number of drug used in these patients was 6.6. However, the maximum number of antimicrobials used in patients with ADR was 4 and minimum 1 which had an average of 2.9.

FIGURE 3:



In the present study meropenem caused highest 3 (30%) of the adverse drug reactions, cefoperazone + sulbactum combination was the second highest which caused 2 (20%) of ADRs followed by piperacillin + tazobactum combination 1 (10%) cefuroxime 1 (10%), amikacin 1 (10%), ofloxacin 1 (10%) as indicated in figure 4.

FIGURE 4:



Total cost incurred in managing 10 patients before development of ADR was Rs 42179.00 whereas, cost incurred post ADR was Rs 43916.66. There was 4.12% increase in total cost of treatment post-ADR. The average cost involved in treating ADR per patient was around Rs 4391.60.

We have observed that of the recorded 10 ADRs 9 (90%) were of Type A (Augmented) and 1(10%) was of Type 2 (Bizarre) while all the 10 ADRs were moderate in severity according to the Hartwig's scale. Subjected to the causality analysis by Naranjo's and WHO-UMC scale it was observed that 5 (50%) were of 'probable' type and remaining 5 (50%) were of 'possible' type. On assessment by the Schumock and Thornton preventability scale we observed 9 (90%) of these were 'definitely preventable' while 1 (10%) was 'not preventable' in nature.

However, during our study we observed that 6 (60%) 'Recovered' from the adverse drug reactions while 4 (40%) were 'continued' to suffer with ADR till the follow up period.

DISCUSSION

Antimicrobials are the commonest preparations used among the surgical patients, in pre-operative, operative and post-operative stages of surgery. In the present study we have recorded a total of 10 adverse drug reactions among the enrolled 90 patients making the incidence rate of 11.11%. These observations of ours were similar with the study conducted by Embase and Medline in surgical hospitalized patients who found an occurrence of 2-27% per 100 patients [10]. Further, the observation made was that, the adverse drug reactions were maximum in men belonging to Group III (patients above 60 years of age) thus, indicating that the degenerative changes, comorbid conditions with the practice of polypharmacy make the elderly person suffer more with the adverse drug reactions. Similar studies conducted by Jimmy Jose et al and Suthar and Desai also showed the male predominance but the age group in which ADR was most frequent was adults in both the studies [11,12]. While, the study conducted by Stavreva et al showed adult age group and female predominance [13].

We have observed that the gastrointestinal system was most affected with adverse drug reactions due to antimicrobial use followed by skin, respiratory and central nervous system. These results of ours were in line with the study conducted by Benjamin Horen et al and Annie. Their study also revealed the predominance of the gastrointestinal system followed by the skin in ADR occurrence [14]. Four other studies showed the predominance of cutaneous manifestations [15,16,17,18].

The present study has shown that beta lactam group of antimicrobials were maximum used. Hence, meropenem was found to cause the maximum number of adverse drug reactions followed by cefoperazone + sulbactum combination, piperacillin + tazobactum combination, cefuroxime, amikacin, ofloxacin and metronidazole. These observations were similar to that observed by Starvera et al [13]. However, Hussain et al., have accounted fluroquinolones to cause the maximum adverse drug reactions while Priyadarshini et al attributed for the use of vancomycin and penicillin.

The predominance of Type A ADRs was similar to those observations made by Oshikoya et al [16]. Our observations of the reactions being moderate in severity according to Hartwig's severity scale were similar to the observations of Jimmy Jose et al and Priyadarshini et al. While, Oshikoya et al have shown that the recorded adverse drug reactions in their study were more of severity grade followed by moderate grade of severity [13,16,19].

On causality assessment by WHO-UMC scale and Naranjo's scale 50% were probable and 50% were of possible nature. These observations of ours were similar to observed by Jimmy Jose et al, Stavreva et al and Priyadarshini et al while, the study conducted by Oshikoya et al shows that more number of reactions were of definite type. With 90 % of the reactions found to be preventable similar to those observed by Oshikoya et al and Jimmy Jose et al. However, there were no fatal outcomes for the recorded reactions. About 60 % recovered completely while 40 % were continued to suffer with the adverse drug reactions as observed during the study period. However, their post discharge outcome could not be assessed due to the feasibility issues.

CONCLUSION

Adverse drug reaction is an unavoidable reaction occurring to any drug and has been more important when they occur with the antimicrobials. Use of antimicrobials is inevitable but their judicious use, rational use, could reduce the incidence and consequence as well. With several causes for the occurrence of antimicrobials resistance, being vigilant and meticulous with their use can reduce the adverse drug reactions and resistance to the antimicrobial agents. Further, communications with the entire healthcare professional at the periphery (rural) and in urban set ups through telemedicine and regular faculty development programmes could help reduce the problem of adverse drug reactions following the use of antimicrobial agents [20].

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Conflict of interest: None declared

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