International Journal of Basic & Clinical Pharmacology
Kodam L et al. Int J Basic Clin Pharmacol. 2020 Jan;9(1):134-137
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20195775

Original Research Article

Adverse drug reactions observed in treatment of gastro intestinal and respiratory tract infections: a prospective analysis

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Received: 19 October 2019
Revised: 02 December 2019
Accepted: 03 December 2019

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ABSTRACT

Background: The aim of the study was to observe common adverse drug reactions in treatment of gastro intestinal and respiratory tract infections in a tertiary care hospitals.
Methods: A prospective observational study was conducted by Departments of Pharmacology for a period of one year from prescriptions and case sheets of medical record section. Adverse drug reaction reporting forms and alert cards were used for reporting.
Results: The drugs most commonly used for gastrointestinal tract and respiratory diseases are tablets norflox 400 mg, norflox-tz, taxim 200 mg, IV amikacin and IV amoxicillin (500 mg) and clavulanic acid (125 mg) combination. Systems affected by use of above drugs were skin and gastrointestinal tract. Urticaria on skin, abdominal pain, itching in genital area, ulcer on oral mucosa are the common adverse drug reactions observed.
Conclusions: Drugs used for common gastrointestinal tract and respiratory tract infections alert cards should be issued to patients when prescribing and adverse drug reactions should be reported to higher centres. Brand names causing adverse reactions should be monitored regularly and their further usage should be based on signals from other centres. All tertiary care hospitals should have antimicrobial guidelines policy to reduce adverse drug reactions.

Keywords: Health care professionals, Adverse drug reactions, Respiratory tract infections

INTRODUCTION

Pharmacovigilance is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems." Most countries in the world have established adverse drug reaction (ADR) reporting.

ADRs have been a global problem of major concern, causing both morbidity and mortality, affecting both children and adults with varying magnitude.

When a drug is marketed little is known about its safety in clinical use because only about 1500 patients are likely to have been exposed to it. Thus drug safety assessment should be considered an integral part of everyday clinical practice since detection and diagnosis often depend on clinical acumen.

A number of complexities interfere with recognition and reporting of ADRs in nearly all cases the patient is already ill and the specific event could result of the underlying disease rather than medication, many patients especially those hospitalized or in the institutions are taking multiple medications, there is lack of practical

definition to what to collect and many reports lack a standard approach to reporting and even clinical pharmacologist with an interest in ADRs often cannot agree on whether specific event was drug related or which drug was the causative agents.[1,2]

ADR reporting programs on an institutional basis can provide valuable information about potential problems in drug usage in that institution.

There is a need to inform the treating doctors about the importance of observing for ADR following pharmacotherapy, recording them meticulously and reporting them to the concerned authority. This practice will prove to be very valuable in making the drug therapy safer and rational. Setting up of ADR monitoring centers at a more regional or hospital level and integrating them with a sound network can reveal unusual or rare ADRs prevalent in Indian population.

Prevention of adverse effects to drugs can be minimized but not altogether eliminated by observing the following practice: avoid all inappropriate use of drugs in context to patient clinical condition, use appropriate dose, route and frequency of drug administration, elicit and take in to consideration previous history of drug reactions, rule out possibility of drug reactions when more than one drug is prescribed.[3]

The objectives of the present study was to examine the prevalence of ADRs for drugs used in treatment of common gastro intestinal and respiratory tract infections and reporting of incidence that helps to improve the clinical condition of patients and reduce cost of treatments.

METHODS

The present study was prospective study conducted by department of pharmacology in Rajiv Gandhi Institute of Medical Sciences, Adilabad and Mahavir Institute of Medical Sciences, Vikarabad, Telangana a tertiary care hospitals after approval by the institutional ethical committee.

The study was done for period of one year from May 2018 to April 2019. Patients of either sex and any age group were include in the study sex and exclusion criteria are suspected ADRs due to drug overdose.

Data was collected from out patient's prescriptions and case sheets of inpatient departments. Adverse drug reporting forms and alert cards were used for the conduct of study.

Statistical analysis

Statistical analysis was done by SPSS software version.

RESULTS

A total of 52 ADRs were identified during one year of study from May 2018 to April 2019. Majority of ADRs occurred in age group of 20-75 years, more common in geriatric age and patients receiving monotherapy and combination therapy.

In Table 2, general medicine (35) reported maximum number of ADRs followed by dermatology (10), pulmonology (5) and casuality (2). ADRs were reported following single and combination therapy.

Risk factors for gastrointestinal and respiratory tract infections identified in this study are poor feeding practice, overcrowding, malnutrition, poor socio-economic status,

Table 1 describes common adverse reactions observed due to use of brand name for gastrointestinal and respiratory tract infections.

Table 1: Drugs and type of ADRs.

Drugs	ADR	No of patients	%
Norflox and tinidazole tablet combination.	Mucosal eruptions over mouth	10	19.2
Norflox tablets	Urticaria rash over trunk and upper and lower limbs.	8	15.3
Taxim 200 mg tablet	Urticarial rash all over body.	6	11.5
Inj amoxicillin (500 mg) and clavulanic acid (125 mg) combination	Itching in genital area and ulcer on genitalia and oral mucosa.	4	7.6
Metrogyl suspension	Steven johnsons syndrome	8	15.3
Anti TB drugs H75, R150, E 2	Eythematous rash with pustules over body surface area.	5	9.6
Vitamin B12 injection	Itching and burning sensation all over body, swelling of face and tongue	3	5.7
Amikacin IV	Severe skin rash at the site of injection	4	7.6
Tab betamethasone one year usage	Abdominal pain	4	7.6

Table 2: ADRs reported from clinical departments.

Department	No. of ADRs
General medicines	35
Dermatology	10
Pulmonology	5
Casualty	2

DISCUSSION

Spontaneous reporting of ADRs to the regional monitoring centre or National monitoring centre via the ADR reporting form is crucial for safety surveillance of the marketed drugs.[4,5]

Major problem in India is under reporting of ADRs due to lack of proper system of pharmaco-vigilance. Ability to anticipate and prevent ADRs can be facilitated by establishment of standard approaches by all health care professionals.

In Table 1, the drugs most commonly used for gastrointestinal tract and respiratory diseases are tablets norflox 400 mg, norflox-tz, taxim 200 mg, IV amikacin and Inj amoxicillin (500 mg) and clavulanic acid (125mg) combination. Systems affected with use of above drugs are skin and gastrointestinal tract. The results were comparable with international study conducted by suhetal.[6]

Cephalosporins and fluoroquinolones were the commonly used antibiotics in the study and the reported ADRs were also more in these drug classes. A study conducted by Stavreva et al also revealed the predominance of cephalosporins whereas fluoroquinolones were most accounted in a study conducted by Hussain et al.[7,8]

Causality assessment was done by using Naranjo scale and severity of ADRs by modified Hartwig and Siegal scale. The severity of 52 cases of ADRs showed 32% as possible (norflox and tinidazole combination, metrogyl suspension, tab betamethasone and injections of vitamin B12) and the remaining drugs 68% as propable. In 18 cases (norflox and tinidazole combination and metrogyl suspension) the ADRs was managed by withdrawl of drug and specific treatment given. In 34 patients the dose of drug was altered and patients recovered from the reaction. The suspected ADRs were reported to the regional pharmacovigilance centre through on line and by mailing.

ADRs observed with use of norflox and its combination are mucosal eruptions over mouth, urticaria rash over trunk, upper and lower limbs compared to previous study by Roberge et al, Theoharides etal and Ratikanta et al.[9-11] Hypoglycemia caused by some fluoroquinolones is well established in literature. Published reports are available for ciprofloxacin, gatifloxacin, and clinafloxacin. Hypoglycemic stress can activate the release of corticotrophin-releasing hormone (CRH) by postganglionic sympathetic neurons as well as the hypothalamus. CRH-stimulated mast cell degranulation could lead to urticaria.[9-11]

Cefotaxim use has caused urticarial rash all over body which was comparable to review of literature from Petz and from management of rash by Kim et al studies.[12,13]

Itching in genital area and ulcer on genitalia and oral mucosa with use of inj amoxicillin (500 mg) and clavulanic acid (125 mg) combination.[12,13]

Steven johnsons syndrome with use of metrogyl suspension as reports from Chen et al and from Bolognia et al.[14,15]

Eythematous rash with pustules over body surface area with use of antitubercular drugs as done by studies done by Sameeretal and Dhingra et al.[16,17]

Vitamin B12 injection has caused itching and burning sensation all over body, swelling of face and tongue as reports from Rajendran et al and James et al.[18,19]

Amikacin IV has resulted in severe skin rash at the site of injection which was comparable to studies by Suken et al and Bensaid et al.[20,21]

Long term use of corticosteroid tab betamethasone few patients has complained of abdominal pain. The results were comparable to Mulchand et al and Conn et al.[22,23]

ADR forms should be available in outpatient, inpatient departments and drug alerts cards should be issued to patients for reporting possible adverse effects. Drugs causing adverse reaction by brand names should be reported to manufacturer and through vigiflow sent to higher centres. If the reactions are severe in nature can be withdrawn from market based on signals from other hospitals. Antimicrobial guidelines common to all tertiary care hospitals should be framed to reduce ADRs, and economic burden on patient. Regular sensitization of health care professionals regarding importance of ADRs can reduce reactions due to drugs.

CONCLUSION

While using drugs for common gastrointestinal tract and respiratory tract infections treating doctors should issue alert cards to patients and ADRs should be reported to higher centres. Brand names causing adverse reactions should be monitored regularly and their further usage should be based on signals from other centres. All tertiary care hospitals should have antimicrobial guidelines policy to reduce ADRs and economic burden on patients.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kodam L, Tamma NK, Marupaka J, Karedla S. Adverse drug reactions observed in treatment of gastro intestinal and respiratory tract infections: a prospective analysis. Int J Basic Clin Pharmacol 2020;9:134-7.