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Original Research Article

A Prospective Study to Evaluate Adverse Drug Reactions in Treatment of Respiratory Tract Infections and Gastro Intestinal Infections in A Tertiary Care Hospital of Telangana.

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Conflict of interest: Nil

Abstract

Aim: To observe common adverse drug reactions in treatment of gastro intestinal and respiratory tract infections in a tertiary care hospital.

Materials and Methods: A prospective observational study was conducted by departments of Pharmacology and Dermatology 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 Ofloxacin- Ornidazole, Norfloxacin –Tinidazole, Cefotaxime 200mg, Amikacin and anti Tuberculosis medicines. 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.

Conclusion: 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, Gastro intestinal, respiratory,

Introduction

The World Health Organization (WHO) defines adverse drug reaction (ADR) as "A response to a drug, which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function [1] But still ADRs have been a global problem of major concern, causing both morbidity and mortality, affecting both children and adults with varying magnitude.

India is a developing country with fourth largest producer of pharmaceuticals in the world with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. It is also emerging as a clinical trial hub exposing larger population to newer drug treatments. Thus it is need of the hour to identify ADRs as early as possible and to prevent them, ensure the well being of the patient at reasonable cost [2].

Cutaneous drug reactions are usually diagnosed clinically. Early diagnosis is the mainstay in the management of severe cutaneous adverse reactions (SCARs) to drugs which includes toxic epidermal necrolysis/ Stevens-Johnson Syndrome (TEN/SJS), drug rash with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP)[3]. However, in the early stages, it may be difficult to differentiate between SCARs as the initial presentation of all these conditions may be a maculopapular exanthem. Besides, it may be difficult to differentiate DRESS from infectious exanthems, SJS/TEN from SLE (systemic lupus erythematosus), immunobullous diseases, and staphylococcal scalded skin syndrome (SSSS) and AGEP from pustular psoriasis in the early phase of the disease [4].

The objectives of the present study was to examine the prevalence of adverse drug reactions 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[5].

Material and methods:

The present study was prospective study conducted by departments of Pharmacology and Dermatology in Rajiv Gandhi institute of medical sciences, Adilabad , tertiary care hospitals after approval by the institutional ethical committee.

The study was done for period of one year from Februar 2020 to February 2021. Patients of either sex and any age group were include in the study. Data was collected from out patients prescriptions and case sheets of in patient departments. Adverse drug reporting forms and alert cards were used for the conduct of study.

Results

A total of 52 adverse drug reactions 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 30-40 years age group and patients receiving mono therapy and combination therapy.

Table 1 : Drugs and type of adverse drug reactions

Drugs	Adverse drug reaction
Ofloxacin and Ornidazole combination tablet	Mucosal eruptions over mouth
Norfloxacin and tinidazole tablet combination.	Urticaria rash over trunk and upper and lower limbs.
Cefotaxime 200mg tablet	Urticarial rash all over the body.
Anti Tuberculosis drugs H75, R150, E 275	Eythematous rash with pustules over the body surface area.
Metronidazole suspension	Steven johnsons syndrome
NSAIDs	Itching in genital area and ulcer on genitalia and oral mucosa.
Inj Amikacin iv	Severe skin rash at the site of injection
Vitamin B12 injectionection	Itching and burning sensation all over body, swelling of face and tongue

Table 2: Percentage of Adverse drug reactions reported from clinical departments

General medicines	60%
Dermatology	25%
Pulmonology	10%
Casuality	1%

Table 3: Percentage of drugs involved in Adverse drug reaction

DRUGS	Percentage of involvement
Ofloxacin and ornidazole	50%
Norfloxacin and tinidazole	20%
NSAIDS	11%
Anti tubercular drugs H75,R150,E275	10%
Metronidazole suspension	4%
Amikacin IV	3%
Vitamin B12 injection	1%
Cefixime	1%

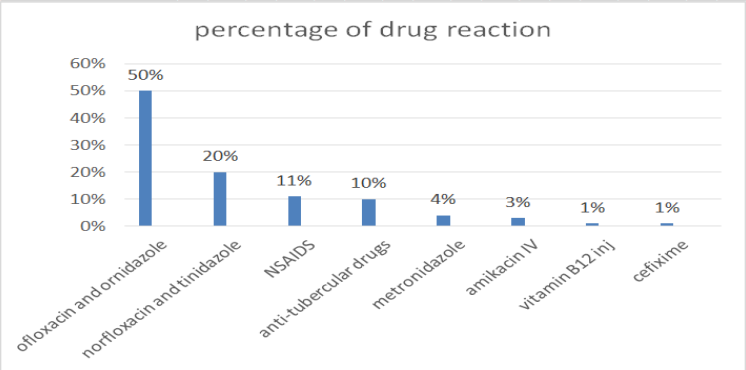

Diagram 1: Bar diagram showing Percentage of drugs involved in Adverse drug reaction

Table 4: Showing gender distribution

MALES	30
FEMALES	22

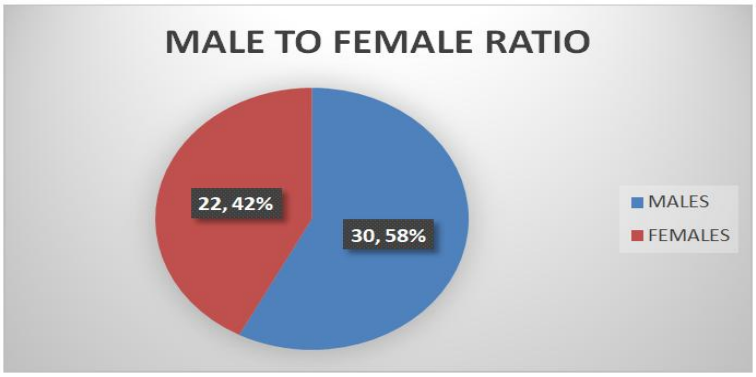

Diagram 2: Pie diagram showing Male Female ratio involved

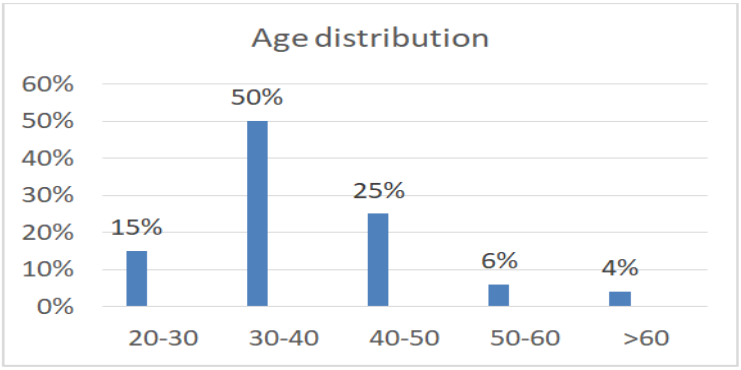

Diagram 3: Bar diagram showing Percentage of drugs involved in Adverse drug reaction

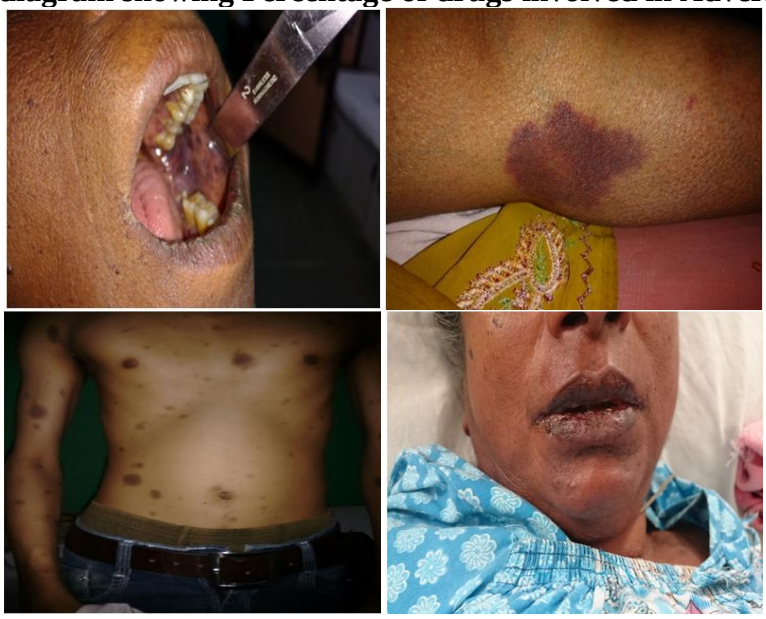

Figure 1:

Discussion

Spontaneous reporting of ADRs to the regional Monitoring centre (RMC) or national monitoring Centre (NMC) via the ADR reporting form is crucial for safety surveillance of the marketed drugs [6].

Major problem in India is under reporting of adverse drug reactions due to lack of proper system of pharmacovigilance. Ability to anticipate and prevent adverse drug reactions can be facilitated by establishment of standard approaches by all health care professionals.

From table 1: the drugs most commonly used for gastrointestinal tract and respiratory diseases are tablets Ofloxacin- Ornidazole, Norfloxacin – Tinidazole, Cefotaxime 200mg, NSAIDs and injection Amikacin. Systems affected with use of above drugs are skin and gastrointestinal tract The results were comparable with international study conducted by suhetal [7].

Adverse drug reactions observed with use of Norfloxacin and its combination are mucosal eryptions over mouth and urticaria rash over trunk and upper and lower limbs. Cefotaxime use has caused urticarial rash all over body. Eythematous rash with pustules over body surface area with use of anti Tubercular drugs. Steven johnsons syndrome with use of Metronidazole suspension. Drug alert with brand name causing the syndrome through vigiflow can prevent the severe adverse reaction. [8] Itching in genital area and ulcer on genitalia and oral mucosa with use of NSAIDs. Long term use of corticosteroid tab betamethasone few patients has complained of abdominal pain. Amikacin iv has resulted in severe skin rash at the site of injection.

Adverse drug reaction forms should be available in outpatient , inpatient departments and drug alerts cards should be issued to patients for reporting possible adverse effects[9]. 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.

Conclusion

While using drugs for common gastrointestinal tract and respiratory tract infections treating doctors should issue alert cards to patients and adverse drug reactions should be reported to higher centres.

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