

RETROSPECTIVE ANALYSIS ON
ADVERSE DRUG REACTIONS
INDUCED BY ANTIBIOTICS IN A
TERTIARY CARE CENTRE.

Dr. A. Renuka

Dr. C. Vasanthi

Sri Ramachandra Medical
College

WHO definition of ADR

“Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.”

excludes :

overdose

drug abuse

treatment failure and drug

administration errors.

DRUG INDUCED ADR

Adverse reaction can occur with any class of drugs.

The most troublesome classes of drugs :

antibiotics

antitumor agents.

Over half of all hospitalized patients are treated with antimicrobial agents and their use account for 20–50% of drug expenditures in hospitals. More than 70% of ICU patients receive antibiotics for therapy or prophylaxis.

AIM OF THE STUDY

The main aim of this study was to detect and analyze Adverse Drug Reactions (ADR) to antimicrobial drugs in hospitalized patients of a tertiary care hospital.

Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health.

METHODOLOGY

This is a retrospective study which analyzes the ADRs of antibiotics in inpatients of Sri Ramachandra Medical College for a period of 1 year(May 2013 to May 2014).

Reported ADRs was collected by the pharmacologists in the pharmacovigilance centre.

Causality assessment was done using WHO (UMC) Uppsala Monitoring Centre scale.

The data for the study were taken from records and adverse drug reaction form maintained by the pharmacovigilance centre.

WHO UMC SCALE

CERTAIN

PROBABLE

POSSIBLE

UNLIKELY

UNCLASSIFIED

UNCLASSIFIABLE

CLASSIFICATION OF ADR

Severity of ADR was classified as mild, moderate or severe with various levels according to factors :

1. requirements for change in treatment,
2. duration of hospital stay,
3. and the disability produced by the Adverse Drug Reaction.

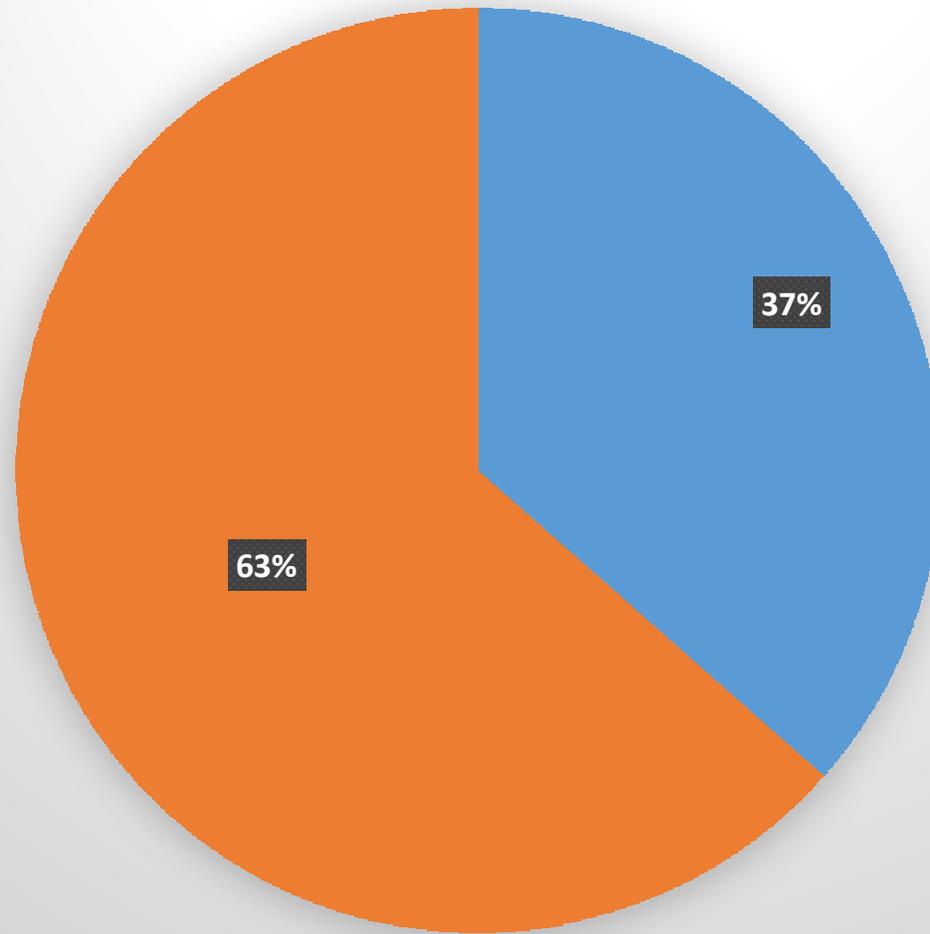
RESULTS

Total number of adverse drug reactions for a period of one year was 136 .

Adverse drug reaction due to antibiotics in our hospital was 97 with the female predominance of 60.

All the reactions were definitely preventable and by causality assessment the reactions were mostly mild and moderate.

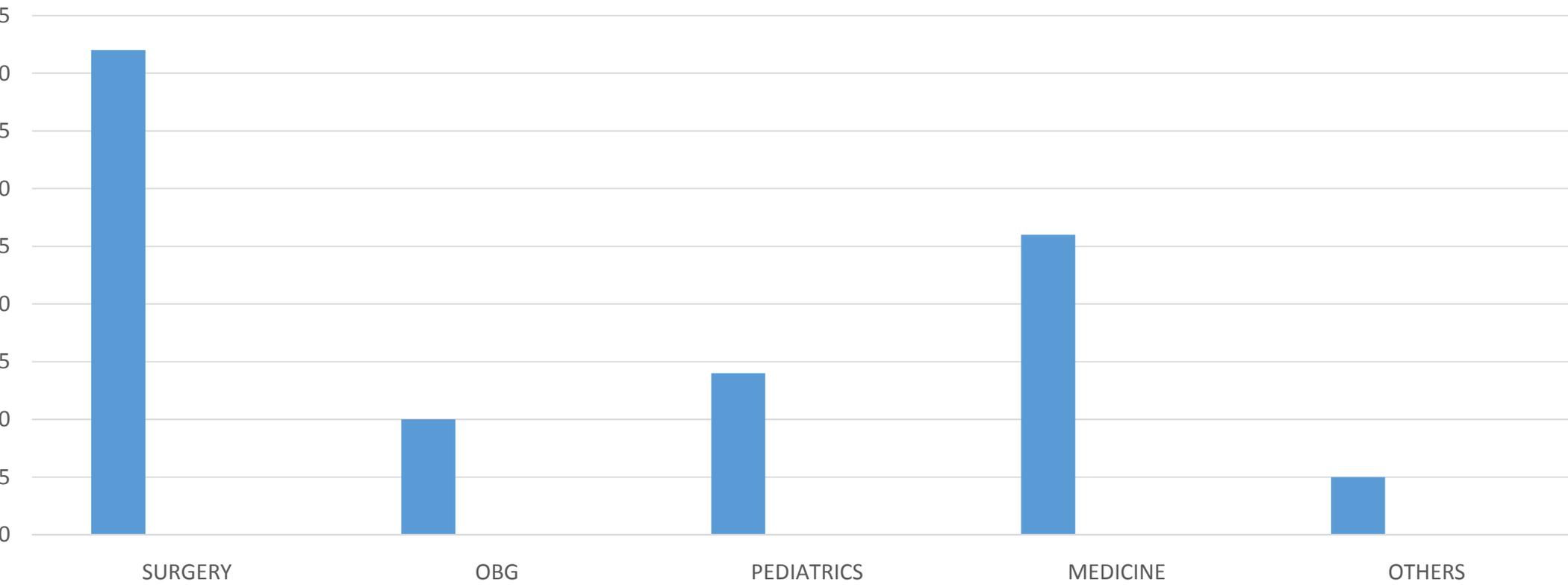
DIVISIONS OF ADR BASED ON AGE GROUP



■ MALE ■ FEMALE

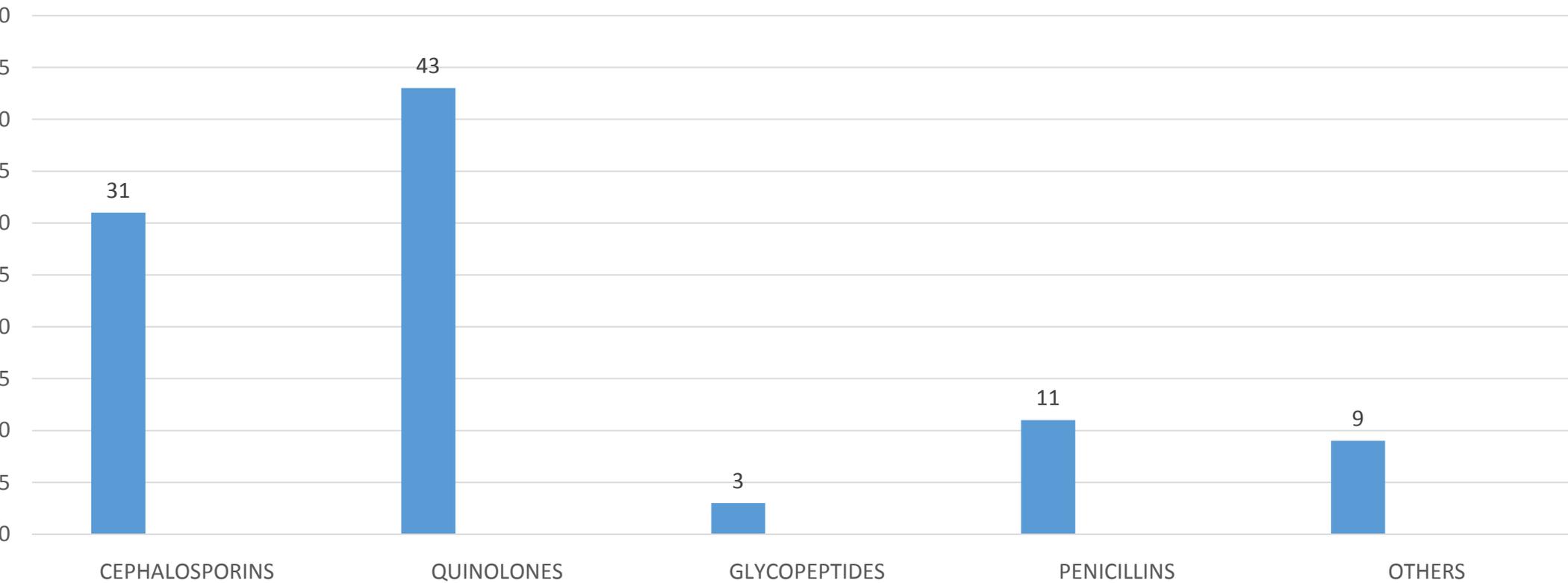
No. of ADRs in DIFFERENT DEPARTMENT

Chart Title



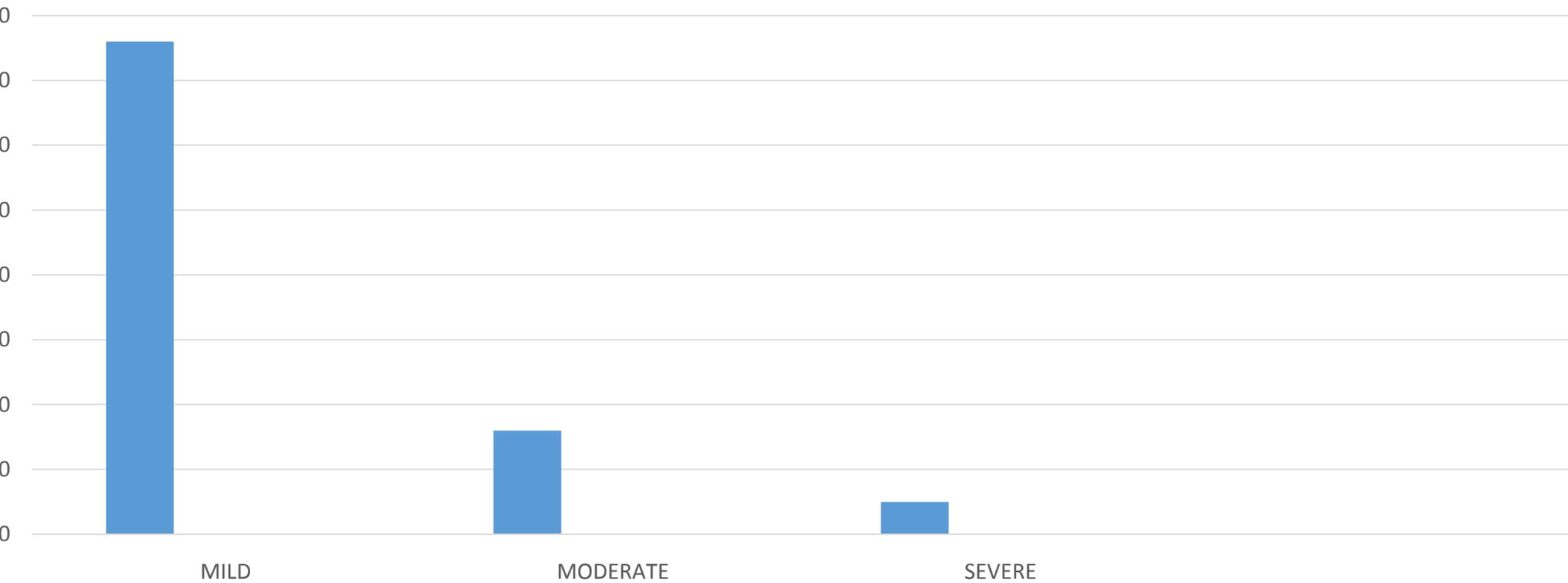
CLASSES OF ANTIBIOTICS -ADR

Chart Title



LEVEL OF SEVERITY OF ADR

Chart Title



RESULTS

From this study, it was found out that there was a recovery from ADR in total of 68 patients although 0% had fatal ADRs.

Specific treatment was given in 16 patients while 13 cases required symptomatic treatment.

RESULTS

Of the reported ADRs moderate reactions accounted for 34% followed by mild reactions 60%. Only 6% of the reactions were severe.

The causality assessment of reported ADRs as per the WHO UMC scale revealed that most of the reactions were probable.

DISCUSSION

The prevalence rate of antibiotic adverse reactions in this study was found to be comparatively low when compared to other studies. This lower prevalence rate was due to the effective intervention of pharmacologists in our hospital such as:

Delivering periodic ADR awareness classes,

and coordination of quality control unit in the hospital.

DISCUSSION

More number of antibiotic Adverse Drug Reactions were detected in General Medicine and Pediatrics departments and may be due to an increased use of antibiotics in these departments for treatment and prophylaxis of various diseases.

DISCUSSION

The analysis of the fate of the suspected drugs showed that the drug was withdrawn in many of the cases and the dose altered in some while no change was made with the suspected drug in others because of considering the risk benefit ratio in specific patients and in some cases, the use of antibiotic was according to the culture and sensitivity reports.

Drug rechallenge was not done in any of the cases.

CONCLUSION

The spontaneous reporting of Adverse Drug Reactions of antibiotics is fairly good in our hospital setting. The effort of this study revealed the occurrence of comparatively less number of antibiotic adverse reactions and their impact on patients of a developing country like India.

The results provided an insight to the healthcare providers on the importance of monitoring and reporting of Adverse Drug Reactions.

CONCLUSION

Antibiotics comprise the major volume of the drug family and inpatient prescriptions and thus are the most irrationally prescribed drug class.

So implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote the rational use.

REFERENCES

- Amrita, P., Singh, S.P., 2011. Status of spontaneous reporting of adverse drug reaction by physicians in Delhi. *Indian J. Pharm. Pract.* 4 (2), 29–36.
- Bates, D.W., Cullen, D.J., Laird, N., et al, 1995. Incidence of adverse drug events and potential adverse drug events. *JAMA* 274 (1)
- Horen, Benjamin., Montastruc, Jean.-Louis., Lapeyre-Mestre, Maryse.,2002. Adverse drug reactions & off-label drug use in paediatric outpatients. *Br. J. Clin. Pharmacol.* 54, 665–670.
- Jonville-Bera, Annie.Pierre., Giraudeau, Bruno., Blanc, Pascal., Beau-Salinas, Frederique., Autret-Leca, Elisabeth., 2002.*Br. J. Clin. Pharmacol.* 53, 207–210.

THANK YOU