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A Study on Cutaneous Adverse Drug Reactions in ADR Monitoring Centre of Tertiary Care Hospital, Guwahati

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ABSTRACT

The observational and cross section study was conducted in the ADR monitoring centre, department of pharmacology, GMCH. The cutaneous adverse drug reactions (CADR) reported by physician of dermatology department of GMCH were collected and then causality, severity and preventability assessment was done. The results were presented as number and percentage. Acne and erythema was commonly reported CADR in our study. Most of the reported CADRs were possible, definitely preventable and mild in nature. Our study suggests that there is a need of intensive monitoring for ADRs in tertiary care hospital for early detection and to ensure the patient safety.

INTRODUCTION

Adverse drug reactions (ADRs) are considered as one of the leading cause of morbidity and mortality. In everyday clinical practice, almost all physicians come across many instances of suspected cutaneous adverse drug reactions (CADRs) in different forms. Although such cutaneous reactions are common and comprehensive information regarding their incidence, severity, and ultimate health effects are often not available as many cases go unreported. In 2010, Central Drugs Standard Control Organization under the aegis of Govt. of India, Ministry of Health and Family welfare has established Adverse Drug Reaction (ADR) Monitoring Centres in pharmacology department of various tertiary care hospitals in all over India (Pharmacovigilance Programme of India, 2010). These hospital-based adverse drug reaction monitoring programmes are aims to identify and quantify the risks associated with the use of drugs in patients. However, the early identification of the condition and identifying the culprit drug and omit it at earliest holds the keystone in management and prevention of a more severe drug reaction. Therefore, not only the dermatologist, but all practicing physicians should be familiar with this condition to diagnose them early and to be prepared to handle them adequately. Thus, the present study was conducted to assess the incidence, causality, severity and preventability of CADRs reported to ADR Monitoring Centre, department of pharmacology, Gauhati Medical College & Hospital (GMCH), Guwahati, India.

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Method

The observational and cross sectional study was carried out in the ADR Monitoring Centre of GMCH. The patient of all age and either sex were included in the study. The study was based on ADRs reported by physicians to ADR Monitoring centre between the periods of 5 month duration from august to december 2011. ADRs identified and reported by physicians of dermatology department of GMCH were considered as an ADR and included in the study. The data was compiled and subjected to descriptive statistical analysis. The assessment of CADRs for causality, severity and preventability were determined by Naranjo **(**Naranjo *et al*., 1981), Hartwig **(**Hartwig *et al*., 1992) and Schumock-Thronton scales **(**Schumock and Thorton, 1992) respectively.

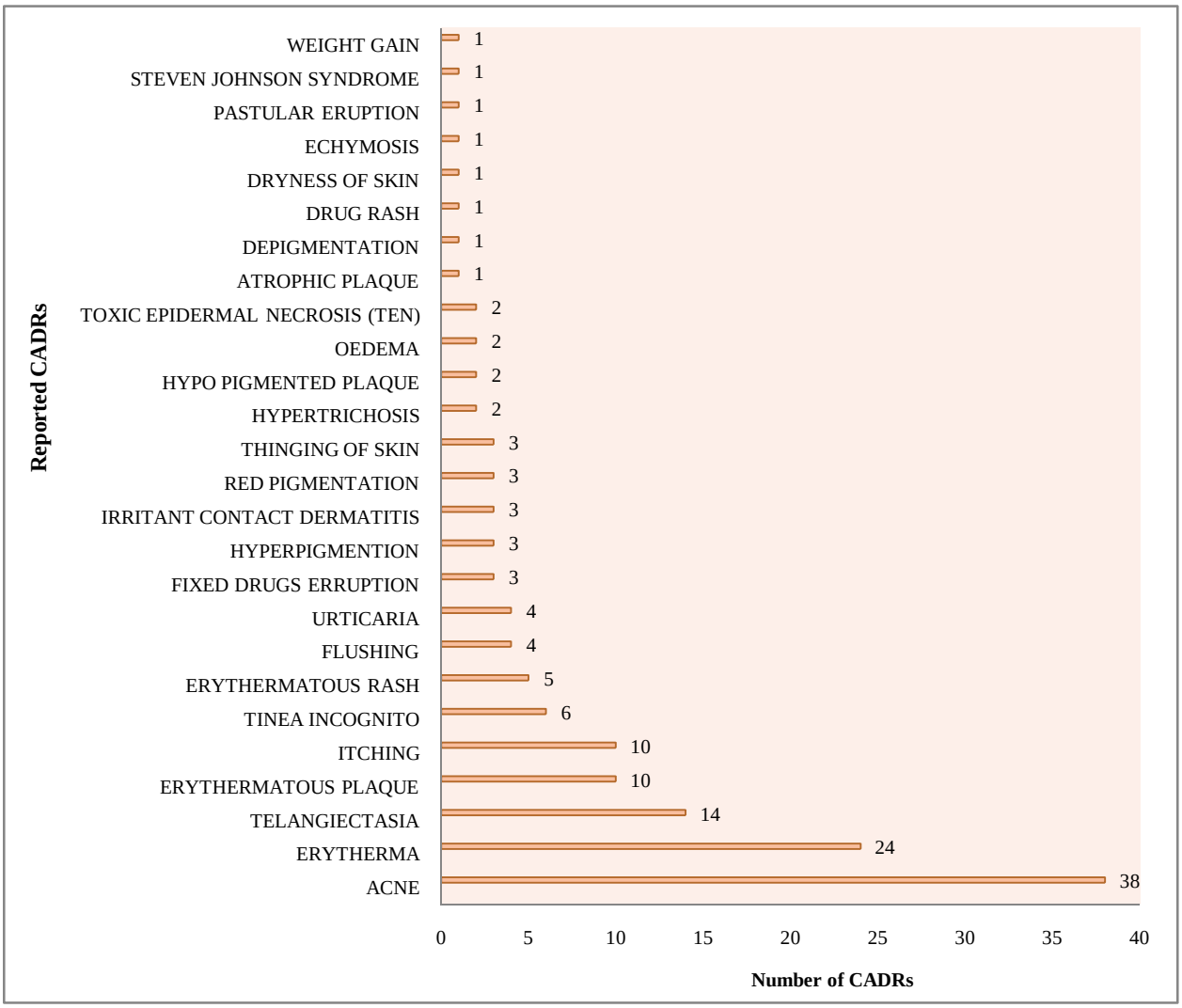

Fig. 1: Total Number of Reported CADRs.

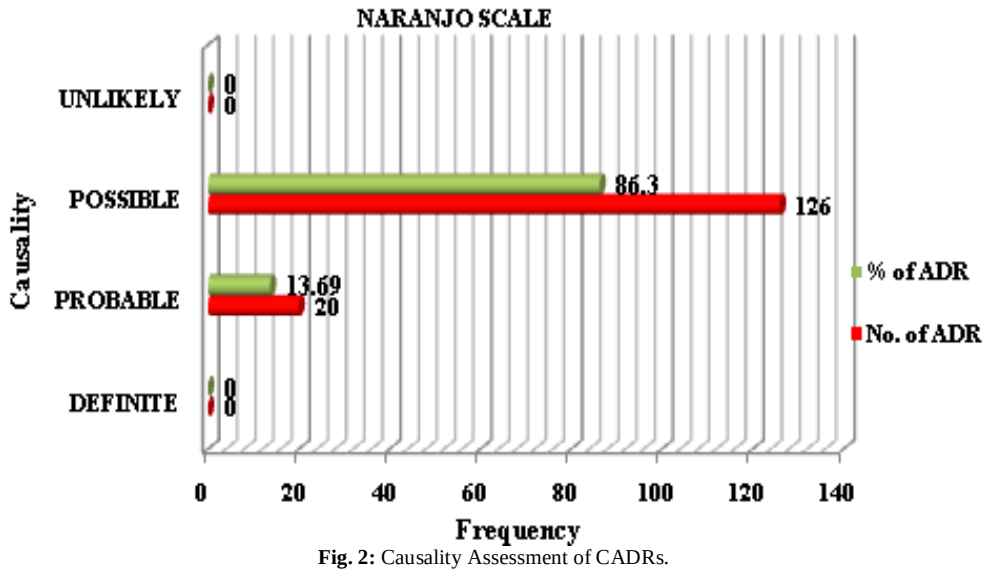

Fig. 2: Causality Assessment of CADRs.

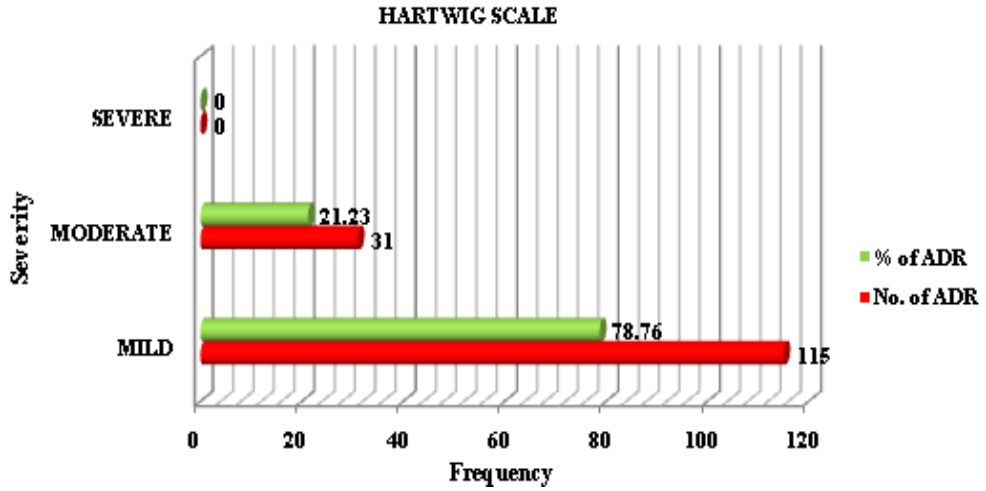

Fig. 3: Severity Assessment of ADRs.

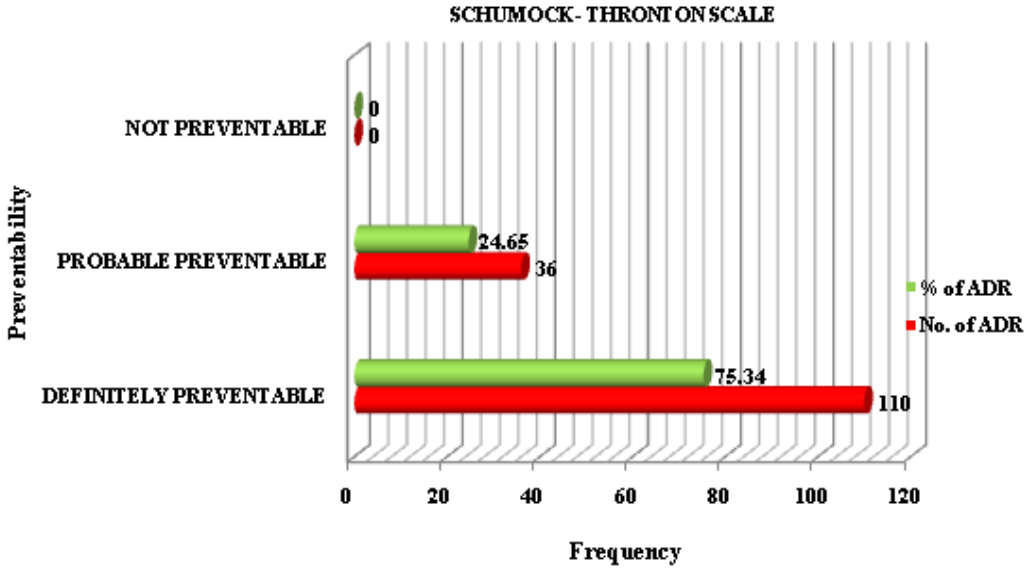

Fig. 4: Preventability of ADRs.

RESULTS

Out of 1537, 108 patients have experienced CADRs in dermatology department of GMCH. Out of these, 42 patients were male and 66 were female patients.146 CADRs were detected and reported to ADR monitoring centre of GMCH during the study period. 97 ADRs were reported from outpatient setting and 11 ADRs were reported from inpatient setting of dermatology department of GMCH. Among various age group, 65 patients have experienced CADRs of age group 21-40 years followed by 30 patients of age group 0-20 years, 8 patients of age group 41-60 years and 5 patients of age group 61-80 have experienced various CADRs. It was found that 77 patients have experienced only 1 ADR, 26 patients were suffered from 2 ADRs and remaining of them was having more than 2 ADRs. Commonly reported CADRs were acne (n=38, 26.02%) followed by erythema (n=20, 16.43%) and telangiectasia (n=14, 9.58%) (Figure1). Out of 146 ADRs, 126 CADRs were found to be possible while the 120 CADRs were classified as probable (Figure 2).115 CADRs were classified as mild while 31 CADRs were found to be moderate (Figure 3). Result has shown that 110 CADRs were belonging to definitely preventable and 36 CADRs were probable preventable (Figure 4).

DISCUSSION

In our study incidence rate of (7.02%) CADR was high as compared to one of the study conducted for 1 year in tertiary care hospital of India where it was 2.6% (Chatterjee *et al*., 2006). It was found that the incidence of CADR was high in women (n=66, 9.88%) than in men (n=42, 4.48%), which was quite similar to the study of Chatterjee *et al*. It was also seen that the patients belongs to age group of 21-40 were more likely to suffer from CADRs which was similar to the study conducted in Chandigarh, India (Sharma *et al*.,2001). Similar study was done in tertiary care hospital of ranchi where they have reported 23% of maculopapular

drug reaction, 14% fixed drug eruption, 13% urticaria and 25% of Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (Mahapatra *et al*.,2012). However, in our study acne (n= 38, 26. 02%) was highly reported CADR followed by erythema (n= 20, 16.43%), telangiectasia (n=14, 9.58%), erythematous plaque (n = 10, 6.84) and itching (n = 10, 6.84). In our study only 2 cases of TEN and 1 case of SJS were reported whereas Sharma *et al*. has shown 11.4% fatal cases of TEN and SJS. In one of the study of north India it was shown that 76.98% ADRs were probable, 19.78 % were possible and 3.29% ADR were definite preventable (Nandha *et al*.,2011) whereas in our study of the 146 ADRs, 126 (86.30%) CADRs were possible and 20 (13.69%) were probable. In this study, preventability assessment has shown that 75.34% CADRs were definitely preventable and 24.65% CADRs were probable preventable. The severity assessment has shown that 78.76% CADRs were mild while 21.23% ADRs were moderate.

LIMITATIONS

Our study has some limitations. CADRs are considered in our study which was reported from only dermatology department of the GMCH. This may exclude the CADRs reported from other departments of hospital. Since our data were cross-sectional, we were able to provide only a snapshot of CADR in Government hospital at one point in time. Our study has not examined the dose, frequency and duration of drug prescribed to patients. In addition, more literature search required to compare and discuss our study with the previous studies. Moreover, further studies required to determine the prevalence, predictor and risk factor of the CADRs in order to improve the drug safety.

CONCLUSION

Results of this study emphasized the need of ADR reporting in tertiary care hospitals to help in assessing the benefit-risk ratio of drugs. From this study, it had been concluded that incidence of CADRs occurrence was high in female patients. Acne was highly reported CADR and most of the reported CADRs were possible, definitely preventable and mild in nature.

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REFERENCES

Chatterjee S., Ghosh AP., Barbhuiya J., Dey SK. Adverse cutaneous drug reaction: A one year survey at a dermatology outpatient clinical of a tertiary care hospital. Indian J Pharmacol.2006;38:429-31.

Hartwig SC., Siegel J., Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J hosp pharm. 1992; 49:2229-31.

Mahapatra S., Keshri Pd U. Adverse cutaneous drug reactions in a tertiary care center patients: A prospective analysis. J App Pharm Sci. 2012; 2:96-8.

Naranjo CA., Busto U., Sellers EM., Sandor P., Ruiz I., Roberts EA., *et al*. A method for estimating the probability of adverse drug reaction. Clin Pharmacol ther.1981; 30:239-45.

Nandha R., Gupta A., Hashmi A. A cutaneous adverse drug reaction in a tertiary care teaching hospital: A North Indian perspective. Int J App Basic Med Res. 2011;1:50-53.

Pharmacovigilance Programme of India (PvPI) 2010. Available on http://www.cdsco.nic.in/pharmacovigilance.htm

Schumock GT., Thorton JP. Focus on preventability of ADRs. Hosp pharm.1992:27;538.

Sharma VK., Sethuraman G., Kumar B. Cutaneous adverse drug reaction: Clinical pattern and causative agents: A 6-year series from Chandigarh, India .J Postgard Med. 2001;47:95-9.

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