

EDITORIAL

Adverse Drug Reactions Among Paediatrics Population

Vishal R Tandon

The adverse drug reactions are significant health problem across all age groups and gender. However, paediatric age group is considered to enhance the possibility of ADRs.

Aagaard L *et al.* (1) reported that the average incidence rate of ADRs for paediatric inpatients to be 42% & for outpatients 14% and the average prevalence rate to be 24% for paediatric patients hospitalized for outpatients to be 4%. On average, 26% of such reported ADRs are serious in nature.

Priyadharsini R et al (2) in their study observed 60% of the ADRs occurred below the age of 1 year and among them 63% were females and 37% were males. The infants less than one year of age (60%) were most susceptible to ADRs among paediatric patients. The age groups 1-3 years (20%) and 4-6 (20%) years were relatively less susceptible to ADRs compared to infants. There were no ADRs observed in children more than 6 years of age. Antibiotics comprised the major group of drugs causing ADRs (67%). Rashes and urticaria were the most common type of ADR (37%) followed by fever, anaphylactic shock, vomiting, chills, and rigors.

In another study rate of paediatric ADR reports in 2009 was 165 per million, of which nearly half (46 %) were for children (age group 2-11 years). The most frequent ADRs reported were due to vaccines and anti-infectives for systemic use (67 %); nervous system (9 %); respiratory system (9 %). On average, 37 % of ADRs were classified as serious.(3)

Similarly, the annual reporting frequency was about 385 reports per year in another study conducted on paediatric population. The proportion of children that suffered from a serious ADR was 13.0% and that for drug related deaths 0.14%. The most frequently reported reactions were application site reaction (24%) followed by fever (12%) and exanthema (6.7%). The clearly most frequently reported group of drugs were the vaccines (63.8%) followed by antibiotics for systemic use (10.1%). (4)

Digra KK *et al* (5) in their study reported ADRs in 71% of the patients between 1 and 5 years of age, 26% in the age group of 5-10 years, and 3% were more than

10 years old. Anticonvulsants (25.96%) and antibiotics (22.11%) were responsible for majority of ADRs. Rash (55.76%) was the most common presentation of ADR.

All these study depict that variations do exist in patterns and profile of ADRS prevalent among paediatric population. The possible reasons may be growing anatomical body changes, Pharmacokinetic and pharmacodynamic handling of the drug, nutritional status of the child, irrational drug usage and multiple drug prescriptions trends in some particular paediatric population. (6)

Further underreporting ADRs is a big challenge in this age group as only obvious ADRs are only reported and many time this population cant not express and parents and doctors fail to recognise ADRs often in paediatric population. However, the current editorial impress on the need to undertake pharmacovigilance programme specifically in paediatrics population at national level.

References

- Aagard L, Christensen A, Hansen EH. Information about adverse drug reactions reported in children: quantitative review of empirical studies. *Br J Clin Pharmacol* 2010; 70: 481-91
- Priyadharsini R1, Surendiran A, Adithan C, Sreenivasan S, Sahoo FK. A study of adverse drug reactions in pediatric patients. *J Pharmacol Pharmacother* 2011;2(4):277-80. doi: 10.4103/0976-500X.85957
- 3. Aldea A1, García Sánchez-Colomer M, Fernández Quintana E, García Sáiz M. Paediatric adverse drug reactions reported to the Spanish Pharmacovigilance System from 2004 to 2009. *Eur J Clin Pharmacol* 2012;68(9):1329-38.
- Kimland E1, Rane A, Ufer M, Panagiotidis G. Paediatric adverse drug reactions reported in Sweden from 1987 to 2001. Pharmacoepidemiol Drug Saf 2005;14(7):493-99
- Digra KK, Pandita A, Saini GS, Bharti R. Pattern of Adverse Drug Reactions in Children Attending the Department of Paediatrics in a Tertiary Care Centre: A Prospective Observational Study. Clin Med Insights Pediatr 2015; 9:73-8.
- 6. Titchen T, Cranswick N, Beggs S. Adverse Drug Reactions to to non- steroidal anti inflammatory drugs COX-2 inhibitors and paracetamol in a paediatrics hospital. *Br J Pharmacol* 2005; 59:718-23

From the Department of Pharmacology, Govt. Medical College, Jammu J&K- India 1800001

Correspondence to: Dr Vishal R. Tandon, Assistant Prof, Department of Pharmacology, Govt. Medical College, Jammu (J&K) -India 180001