

Pharmacovigilance study on the increased use of antibiotics in pediatric treatment

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ABSTRACT

Objective: To conduct the pharmacovigilance study on the increased use of antibiotics in pediatric treatment. **Materials and Methods:** A suitable, simple questionnaire associated with the study of pharmacovigilance assessment, for mainly the adverse drug reactions associated with the increased antibiotic use in pediatric treatment was designed and distributed among 200 families having children in the age groups of <1 to 8 year. This survey was done in Pune region. Amoxicillin, Tetracycline, Cephalexin, Doxycycline were the antibiotics selected for the study. **Results:** About self-medication more than 50% groups said they did self-medication. And major source for it was medicines leftover from previous prescriptions. Maximum response was obtained from 5–8year age group. ADR were detected with the usage of antibiotics in 66 percent of groups. When it comes to the intensity of an adverse drug reaction, 74% of respondents said it was light, 22% said it was moderate, and 4% said it was severe. Around 97 % groups said they went to doctor after occurrence of adverse drug reaction, 98 % percent groups said they were aware of the risks of self-medication. Majority of groups knew about adverse drug reactions reporting system. When it comes to awareness of increased antibiotic use leading to antibiotic resistance, 98% of groups were found aware of the problem. **Discussion:** Survey showed that families having small children experienced adverse drug reactions as a result of using any of the antibiotics Amoxicillin, Tetracycline, Cephalexin, or Doxycycline. **Conclusion:** In conclusion, our study strongly recommends that there is a great need to create awareness among the middleclass families having children to improve the reporting of ADR's.

Keywords: Pharmacovigilance, Pediatrics, Anti-microbial resistance (AMR), Amoxicillin, Tetracycline, Cephalexin, Doxycycline

Antibiotics are medicines used to prevent and treat bacterial infections. Antibiotic resistance is rising to dangerously high levels in all parts of the world. New resistance mechanisms are emerging and spreading globally, threatening our ability to treat common infectious diseases. A growing list of infections such as pneumonia, tuberculosis, gonorrhoea, and foodborne diseases are becoming harder, and sometimes impossible, to treat as antibiotics become less effective [1, 2].

To understand the burden of threat posed by antimicrobial resistance, World Health Organisation (WHO) estimated that every year in the world, infections caused by multidrug resistant (MDR) bacteria result in 700,000 deaths across all ages, of which around 200,000 are newborns in Europe, MDR infections in pediatric patients may represent up to 30% of the total cases in regions of the Middle East, 90% of newborns with sepsis, hospitalized in ICU, had resistant bacteria; in some areas of South East Asia, 83% of children have E. coli resistant to first

line antibiotics; in Sub-Saharan Africa, 66% of neonatal sepsis and meningitis were found to be caused by bacteria resistant to antibiotics [3]. India contribution to the *Uppsala Monitoring Centre (UMC)* database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also due to a lack of the reporting culture among the health care workers [4, 5].

Quoting the joint WHO-UNICEF report of 2006: "Children are not small adults when taking a drug." The capacity of absorption, distribution, metabolism and elimination of a drug are very different between adults and children, and they continue to change during the stage of development. The risks resulting from the administration of a drug that has not been tested and proven in the pediatric population may therefore be due to overdose (increase in adverse reactions), ineffectiveness of the drug (for dosing) and use of a formulation which is not appropriate [6].

Antibiotics are reported as the most troublesome of drugs contributing to approximately 15% - 16% of cases of Adverse Drug Reactions (ADR's), mostly related with the frequency of administration that accounts approximately for 23% of all adverse events recorded. Children are more at risk of having ADR's because many drugs which are prescribed to this population have been marketed with limited or no experience of their efficacy and safety [7].

Rational use of antimicrobials in the long run, therefore, demands continuous survey of antimicrobial use and related ADR monitoring. [8]. Rational use of antimicrobials in the long run, therefore, demands continuous survey of antimicrobial use and related ADR monitoring. [9]

As for antibiotic misuse in pediatrics, although critical, it has rarely been tackled in epidemiological studies. It could be related to several factors, such as the medication itself (e.g. taste acceptability, dilution and conservation), or the treating pediatrician (e.g. watchful waiting approach) or even the pharmacist (e.g. referral to pediatricians). The occurrence of adverse drug reactions (ADR's) is an-other problem with antibiotic use. ADR's in pediatric population may have relatively more severe effect than adults leading to significant morbidity among children [10].

Inappropriate antibiotic-prescribing practices have been well described in developed nations [11]. Therefore, using antibiotics to treat these viral infections is considered misuse or overuse of antibiotics. This misuse/overuse is common in children, and is currently considered to be one of the major public health issues worldwide [12].

MATERIALS AND METHODS

This was a cross-sectional, questionnaire-based survey which was conducted in Pune region. This survey done in 200 families (Groups); where in number of responses: 111 offline responses and 89 online responses were taken. It was conducted in middleclass families having children age group <1 to 8 years [13, 14]. A standardized questionnaire was made in order to identify the antibiotic prescription practices in common childhood diseases and attitudes towards pharmacovigilance [15].

The questionnaire was divided into several parts. The first part, included self-medication practices questions later part the names of antibiotics and adverse drug reactions observed. The last part include about awareness about pharmacovigilance program in India and antibiotic resistance. The families were requested to complete the questionnaire and to return it within 1 day to RJSPM'S College of Pharmacy Students' team. This survey deals with pharmacovigilance issues like ADR's due to

antibiotic administration and the reporting rates of these. The method of self-administered questionnaire was implemented for data collection purposes [16, 17].

RESULTS

Figure 1 represents for question have you ever treated yourself (self-medicated) with antibiotics? 56% of group response was yes and 44% of groups response was no.

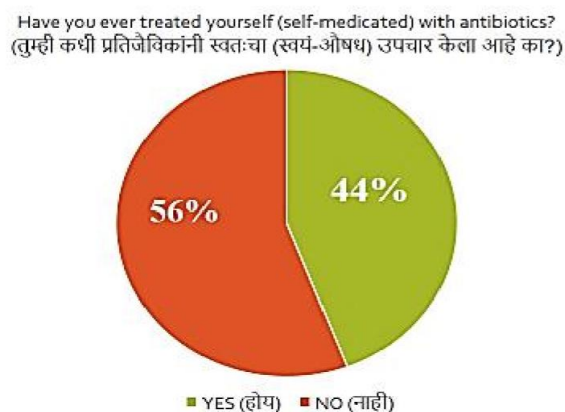


Fig. 1 - Have you ever treated yourself (self-medicated) with antibiotics?

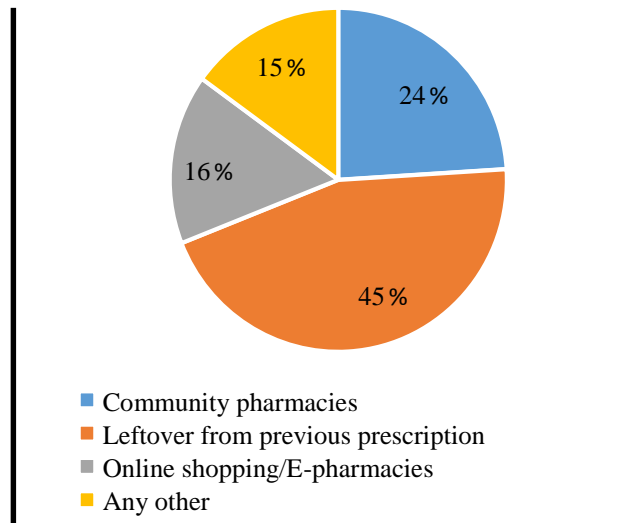


Fig. 2 - Where did you usually obtain antibiotics for self-medication?

Figure 2 represents for question, where did you usually obtain antibiotics from for self-medication? groups response 45% positive for leftover from previous prescription and for community pharmacies, it was 24%, while, 16% groups responses gone in favor of online shopping /E-pharmacies and responses for any other option were only 10%.

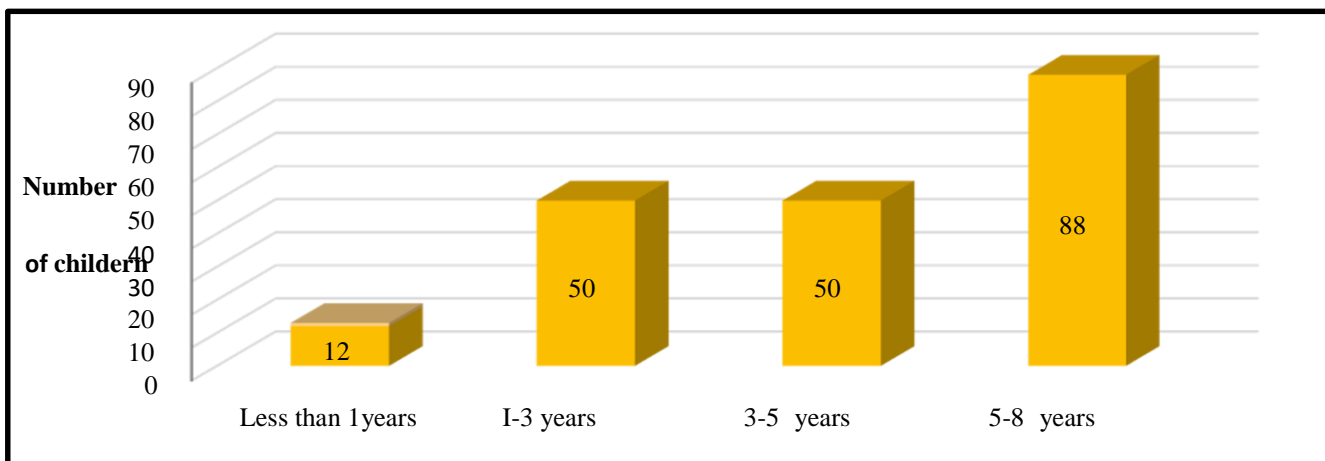


Fig. 3 - What is age group of children?

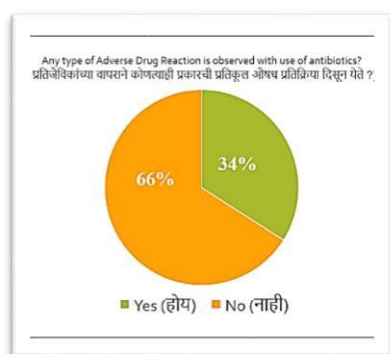


Fig. 4 - Any type of adverse drug reaction is observed with use of antibiotics?

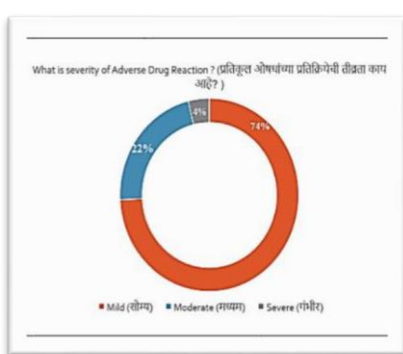


Fig. 5 - What is severity of adverse drug reaction?

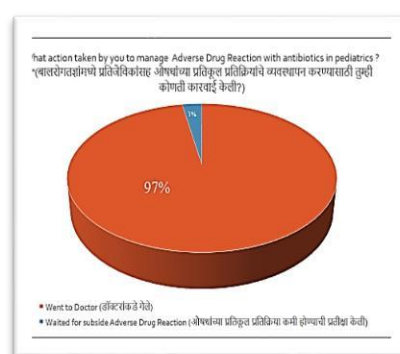


Fig. 6 - What action taken by you to manage ADR with antibiotics in pediatrics?

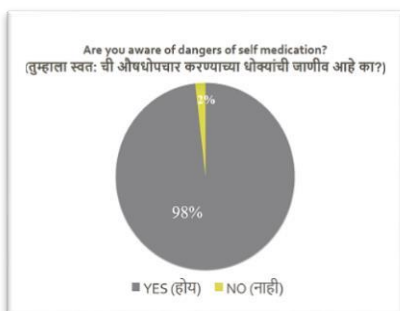


Fig. 7 - Are you aware of dangers of self-medication?

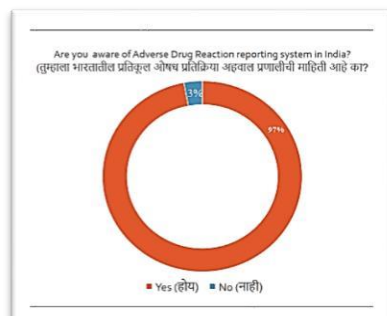


Fig. 8 - Are you aware of adverse drug reaction reporting system in India?

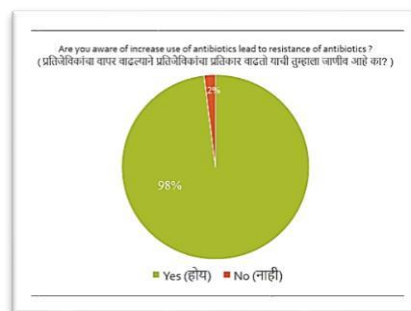


Fig. 9 - Are you aware of awareness of increase use of antibiotics leading to resistance of antibiotics?

Figure 3 represents in case of age group of children, maximum groups gave responses for age group 5-8 years i.e., 88 out of 200, for 1-3 years 50 responses were recorded and for 3-5 years age group 50 were there, and for 0-1-year age group 12 responses were recorded.

Figure 4 represents for question, any type of adverse drug reaction is observed with use of antibiotics 66% groups said yes and 34% family said no.

Figure 5 represents in case of severity of adverse drug reaction 74% responses were for mild ADR, 22% were for moderate ADR and 4% were for severe type of ADR.

Figure 6 represents in case of what action taken by you to manage ADR with antibiotics in pediatrics, maximum responses

i.e., 97% groups said they went to doctor and only 3% were waited for subside adverse drug reaction.

Figure 7 represents for question are you aware of dangers of self-medication, 98% groups said yes and 2% said no.

Figure 8 represents in case of awareness of adverse drug reaction reporting system in India, 97% groups are aware of the ADR reporting system and 3% are unaware of ADR reporting system.

Figure 9 represents in case of awareness of increase use of antibiotics leading to resistance of antibiotics, 98% groups are aware of resistance and 2% are unaware.

DISCUSSION

For Fig 1 thus, it is seen that almost 50% of the surveyed sample have done self-medication at some point of time with antibiotics. Verma et al indicates self-medication is very common problem in India [18].

Fig. no.2 which discuss about where did you usually obtain antibiotics from for selfmedication? People are understandably unwilling to submit to the inconvenience of visiting a doctor for what they rightly feel they can manage for themselves. Reasons for wide variations may be due to differences in education, socio-economic status, nonavailability of medical facilities and easy availability of drugs [19].

Community pharmacy, E pharmacy is responsible factor for self-medication according to our study. Fig. 3 tells us current study indicates majority population falls between 5 and 8 years of age. Fig. no. 4 deals with question, any type of adverse drug reaction is observed with use of antibiotics 66% groups said yes and 34% family said no. In our study occurrence of ADR is 34 % indicate higher incidence might be due to poor patient compliance. One of the cited research paper results reveal that the estimated average ADR incidence in all selected studies was 9.52%. According to the study which was conducted in 38 different Italian hospitals and recruited 1332 hospitalized patients reported that the onset of at least 1 ADR [6].

Fig. 5 talk about in case of severity of adverse drug reaction 74% responses were for mild ADR, 22% were for moderate ADR and 4% were for severe type of ADR. Only serious ADRs are needed to be reported in pediatric care, seems to be the most significant factor of no reporting, according to Mary et al. [20].

Current study lowest score for severe ADR shows awareness about reporting any type of ADR. This might be due to survey done in urban part where majority of people are literate. The reasons for occurrence of ADR in children may be due to immature drug metabolizing organ system in newborn and infants that put them at a higher risk of developing an ADR [14].

Fig. no. 6 tell about almost all groups went to doctor for ADR treatment. Fig. no. 7 almost all groups aware about dangers of self-medication which is a general indication. Fig. 8 deals about in case of awareness of adverse drug reaction reporting system in India, 97% groups are aware of the ADR reporting system and 3% are unaware of ADR reporting system. In northern India, study done in year 2013 showed little awareness about the ADR reporting system among the doctors in a tertiary care hospital [5]. Due to increased use of social media past few years 2022 may resulted in increase in awareness about ADR reporting in current study. Fig. no. 9 indicates all groups aware about increase use of antibiotics leading to resistance of antibiotics which indicates people are well trained about use of antibiotics.

Table 1 shows us about many groups experienced adverse reaction with antibiotics indicates importance of ADR monitoring system. In order to generalize our results, similar

studies be done in other parts and paramedical colleges of the city and other states of the country. Training sessions must clarify the roles of the various healthcare professional's doctors, nurses, pharmacists and paramedical workers in pharmacovigilance. There should be closer relationship between the common public and the pharmacovigilance centers. Results showed to be published and discussed in the public domain to spread awareness. To the best of our knowledge, this is one of the few attempts to explore antibiotics prescribing practices and attitudes on pharmacovigilance of hospital pediatricians in Pune region.

Table 1 - Names of the group and the adverse drug reactions they experienced as a result of using a certain antibiotic

Group Number	Antibiotic	Adverse Drug Reaction
Group 1	Azithromycin	Diarrhoea
Group 2	Azithromycin	Abdominal pain
Group 3	Amoxicillin	Nausea
Group 4	Amoxicillin	Fever
Group 5	Tetracycline	Yellowing of teeth
Group 6	Amoxicillin	Rashes, fever
Group 7	Doxycycline	Nausea
Group 8	Cephalexin	Rashes
Group 9	Amoxicillin	Rashes, itching

CONCLUSION

In conclusion, our study strongly recommends that there is a great need to create awareness among the middle-class families having children to improve the reporting of ADR's. The ADR reporting should be made an integral part of the clinical activities in order to improve the patient care.

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