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LETTER TO THE EDITOR

ADVERSE DRUG REACTIONS TO FLUOROQUINOLONES IN PEDIATRIC PATIENTS IN A TERTIARY CARE HOSPITAL

Sir,

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Fluoroquinolone antibacterial agents are widely prescribed for the control of various infections. They have a wide spectrum of activity (1) and are generally well tolerated. But with increasing use, their adverse effects are being reported (2). They are recommended with caution in children and pregnant women (3). The present study reports the frequency of administration and adverse drug reactions (ADRs) to fluoroquinolones in the pediatric patients hospitalised in the Postgraduate Institute of Medical Education and Research, Chandigarh.

A prospective drug surveillance program was used to monitor the patients. Children aged upto 12 years of age under fluoroquinolone treatment, hospitalised between June 1997 and July 1998, were selected randomly and studied prospectively. The data were compiled and causality assessment was done by the method of Karch and Lasagna (4) with some modification. Patients were followed up for a minimum period of 7 days.

Of the 1836 random patients studied, 107 patients received quinolones, 38 of these were below the age of one year. Ciprofloxacin (106 patients) and norfloxacin (1 patient) were the fluoroquinolones admisnitered. Out of 106 patients treated with ciprofloxacin, four (3.7%) developed ARD during the hospital skin reactions (maculopapular rash in 2 and erythma with pruritus in 1) were seen in 3 patients and vomiting with heart burn in one patient. This data is in agreement with previous reports (5, 6). No other serious adverse event was detected. All the patients recovered on withdrawal of ciprofloxacin (de-challenge).

Though ciprofloxacin is not recommended for use in patients under 12 years of age and in pregnant woman due to its possible toxicity to growing cartilage at the end of long bones (3), use of this drug to treat life threatening illnesses caused by multiple drug resistant organisms, even in children, may be ethically justified (7).

Our study was specific to identify ADRs to ciprofloxacin in patients below 12 years of age. After comparing our results with known ADRs to ciprofloxacin (4, 8), we conclude that the incidence of ADRs to ciprofloxacin in children is no greater than in adults. The ADRs observed in our study were only during the course of treatment in the hospital. However, the long term

effect of the drug on linear growth and joint structure integrity, or any other structure or organ can only be judged by follow up over many years. Hence, we advocate use of ciprofloxacin only for selected cases where the benefit from ciprofloxacin use will outweigh the potential risk of damage to juvenile cartilage.

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REFERENCES

1. Nerurkar RP, Nadkar MY, Bichile SK. Need for monitoring adverse drug reactions (Editorial) *J Assoc Phys India* 1998;46(8):673-674.
2. Domagala JM. Structure-activity and side effect relationship for the quinolone antibacterials. *J Antimicrob Chemother* 1994;33:685-706.
3. Stahlmann R. Safety profile of the quinolones. *J Antimicrob Chemother* 1990;26(Suppl D):31-44.
4. Karch FE, Lasagna L. Toward the operational identification of adverse drug reactions. *Clin Pharm Ther* 1977;21(3):247-254.
5. Karande SC, Kshirsagar NA. Adverse durg reaction monitoring of ciprofloxacin in pediatric practice. *Indian Pediatr* 1992;29:181-188.
6. Uppal R, Jhaj R, Malhotra S. Adverse drug reaction to fluoroquinolones at a tertiary care hospital in Northern India. *J Assoc Phy India* 1998;46(11):946-947.
7. Adam D. Use of quinolones in pediatric patients. *Rev Infect Dis* 1989;11(Suppl 5):S113-S116.
8. Schacht P, Arcieri G, Hullmann R. Safety of oral ciprofloxacin. An update based on clinical trial results. *Am J Med* 1989;87 (Suppl 5A): S98-S102.

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