Focus

Just how unsafe is Ciproxin in paediatrics?

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With the increasing and somewhat controversial use of fluoroquinolones in patients under shared care with GPs, in particular severe chronic urinary tract infection and cystic fibrosis (CF), it was felt timely to undertake a brief literature review of the safety of ciprofloxacin (CFX) in paediatric settings.

Previous observers have indicated the finding of high rates of adverse effects (ADRs) on juvenile animal cartilage. This effect had been noted to be species and dose-specific.

Karande and Kshirsagar (1992) reported a retrospective survey of paediatricians in India who had used CFX in approximately 3340 patients. There had been a reported musculoskeletal adverse reaction rate of 0.3 per cent compared to a general ADR rate of 3.1 per cent. Only 0.3 per cent of all reactions required discontinuation. However, two rare reports were included of sudden death after intravenous CFX and sinus node arrest causing bradycardia.

In one of two studies from Bayer AG (Kubin 1993) there was an analysis of 1500 paediatric patients given CFX, mostly acute infectious *Pseudomonas* exacer-bations of CF. The safety profile of CFX was noted to be very similar to that observed in adult patients. Importantly, reversible arthralgia was only noted in 36 of 1113 patients with CF and there were no abnormal radiographic findings.

The second report from Bayer AG (Hampel et al 1997) documented the safety of CFX in 1795 children. Treatment adverse events were reported in 10.9 per cent (oral) and 18.9 per cent (IV). Arthralgia occurred in 1.5 per cent of cases, most cases being mild to moderate in severity and were reversible. It was felt that the adverse reaction rates in children were not dissimilar to those in adults. Rates of reversible arthralgia were low and consistent with the previously published surveillance data in children.

The Cystic Fibrosis Study Group (Richard et al, 1997) reported on 108 CF paediatric patients in doses of CFX of 15 mg/kg (750mg bid maximum) compared to a control group using IV ceftazidime plus tobramycin. High clinical improvement rates were noted in both groups. Ultrasound and MRI scanning found no evidence of cartilage damage in any of the CFX treated group. Similar rates of musculoskeletal adverse events (7 per cent and 11 per cent) were observed. The group advised that CFX appeared safe and effective for use in young patients.

Conclusion

Although the manufacturers still do not advocate the use of long term treatment of severe infections in children with CFX, the fluoroquinolones are nevertheless widely used internationally in paediatric practice. Most paediatric CF courses averaged three weeks.

In general and with "compassionate" use there has been no significant adverse reaction profile evident in children which would contraindicate the appropriate use of these agents in situations of severe, life-threatening, difficult or chronic paediatric infection such as severe urinary tract infection and cystic fibrosis.

In particular, consideration could be given to reversing the current medical contraindication for use in children.

- *References available on request*