Nimesulide and adverse drug reactions: Time for a database

Sir,

I read with interest and dismay the report of ‘nimesulide-induced hepatitis and toxic epidermal necrolysis’ by Chatterjee and colleagues. Such reports should provide helpful warning signals and alert authorities to re-analyze drug safety profiles and also develop databases/reporting practices that will allow population-based epidemiological studies to stratify risk profiles. The incidence of hepatopathies and liver injury due to nimesulide has been estimated at 35.2 per 100,000 patient-years and 33.1 per 100,000 patient-years respectively in a population-based study of two million prescriptions, which may be significantly different in India considering the number of over-the-counter non-prescription sales that remain unaccounted for.

The safety profile of nimesulide has been consistently scarred with reports of hepatotoxicity, and the drug remains on the low mid-level profile on risk of upper gastrointestinal toxicity. Usage of nimesulide is contraindicated in patients with hepatic impairment, and as several NSAIDs including nimesulide are metabolized via liver cytochromes P450 (CYP2C9, CYP2C19, CYP1A2), genetic polymorphisms in CYP2C9 that have been associated with NSAID-related complications may also be relevant to nimesulide.

Importantly, the registration of nimesulide was never requested in the US and Canada, and the registration process was withdrawn in Australia and New Zealand. The Irish Medicines Board announced suspension of marketing and sale of oral nimesulide due to six reports of liver failure in May 2007. The WHO database so far has 320 cases of hepatobiliary disorders that have been reported with the use of nimesulide. It is time that the Drug Controller-General of India (DCGI) announced suspension of further use or promotion of nimesulide until at least the European data on safety became available. If the pediatric formulation has truly been withdrawn, it was certainly a step in the right direction in protecting the interests of the patients.

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References