A retrospective review of case records of hospitalized patients with the diagnosis of hepatic ADRs (January 1998 to December 2002) in the Department of Gastroenterology, St. John’s medical college, Bangalore was done after obtaining Institutional ethical review board clearance. The hepatic disorders were considered as drug induced when:

1. No alternative explanations for the disorder were available.
2. There was a temporal relation with the drug ingestion and liver disease (5-90 days).
3. Improvement in the condition of the patient after dechallenge.
4. The maximum number of patients were 50 years old and had acute hepatitis with majority under hepatocellular category as reported in the study by Sargo et al. However, all the drugs implicated in the present study were different from that identified by Sargo et al.
5. The major drug class implicated in the present study was ATD (77%) similar to a previous Indian study.
6. Hepatotoxicity induced by metformin, cisplatin, LMWH and leflunomide induced death noticed in this study have been rarely documented in literature. Mortality of 0.4% in the Department of Gastroenterology during the study period was due to serious hepatic ADRs.

Out of 6302 case records screened, 25 cases were included in the study and categorized as certain (two), probable (20) and possible (three). Certain and probable cases were analyzed (22). The median for age was 51 years (interquartile range 45-57). Male to female ratio was 1.7. The major drug class implicated was anti-tuberculous drugs (ATD) (17), followed by cisplatin, metformin, low molecular weight heparin, chlorpromazine and leflunomide (one case each). The median for RT 29.5 days (interquartile range 14-40) and that for resolution was 18.5 days (interquartile range 14.3-24.3). Serum viral markers were negative and base line LFTs were normal for the patients considered for analysis. Pattern of acute hepatitis was hepatocellular in 11, cholestatic in seven and mixed in four patients each. The outcome was recovery in 20 patients and mortality in two patients.

REFERENCES