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Title: Adverse drug reactions to second line anti tuberculosis drugs: A prospective study in Mumbai, India

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Body: Objective: Patients of drug resistant tuberculosis are on regimens containing multiple drugs and are at risk for adverse drug reactions (ADR). Our aim was to describe the frequency and nature of ADRs in these patients. Methods: A prospective study of sixty patients diagnosed as drug resistant tuberculosis were put on WHO recommended regimen of second line anti tuberculosis drugs. These patients were followed for a period of two years till the completion of treatment and further for a period of one year. Patients were interviewed at monthly intervals for the development of any ADRs. Results: Males 35% (n=21), Females 65% (n=39), Age range 13 to 60 years, Mean 28.5 years. 83% of patients had at least one adverse event (AE) till the completion of study. Commonest AEs were as follows: Nausea and vomiting in 83% (n=50), hypothyroidism in 32% (n=19), reddish hyper pigmentation in 27% (n=16), blood eosinophilia in 13% (n=8), tinnitus and hearing loss in 12% (n=7), peripheral neuropathy in 12% (n=7), psychiatric disturbances in 12% (n=7), urticaria and skin rashes in 8% (n=5), intractable vomiting warranting stoppage of therapy in 7% (n=4), gynecomastia in 3% (n=2). Other AEs seen were deranged creatinine, visual disturbances, convulsion, thrombocytopenia, joint pains and swellings. Severe adverse events (SAE) were seen in 25% of patients (n=15) requiring permanent discontinuation of the offending drug. 10% of patients (n=6) were hospitalized due to SAEs. Persistent AEs even on discontinuation of therapy was seen in 17% (n=10) of patients. Conclusion: Adverse events with second line tuberculosis drugs are common. AEs have an important role in the management and prognosis of these patients.