The international debate on Adverse events in multi-drug resistant tuberculosis patients registered at DOTS-Plus site, AIIMS, New Delhi

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**Background:** According to Global Tuberculosis Report 2017, there were an estimated 10.4 million incident cases of TB in 2016 in the world (140 cases per 100,000 population). Drug-resistant TB is a persistent threat, with 490,000 million cases of multidrug-resistant TB (MDR-TB) emerging in 2016 and an additional 110,000 cases that were susceptible to Isoniazid but resistant to Rifampicin (RR-TB). One of the major obstacles in achieving successful treatment outcomes in DR-TB is the adverse events affecting the adherence to the both first-line and second-line TB drugs. Aim of the present study was to evaluate adverse events due to the second-line drugs (SLDs) in MDR-TB patients during first year of treatment.

**Methods:** A prospective cohort study was conducted at DOTS Plus site at AIIMS, New Delhi. Eighty-one MDR-TB patients were recruited consecutively from June 2014 to May 2015 and were given standardized Category IV drug regimen under Revised National Control Tuberculosis Programme (RNCTP). Patients were followed-up till one year after initiation of treatment and adverse events were primarily recognized and documented with clinical evidence and/or laboratory investigations.

**Results:** A total of 91 adverse events were reported in 52 (64.2%) patients. The grouped adverse events were most commonly gastrointestinal (70.6%), arthralgia (10.9%), ototoxicity (6.4%), psychiatric (5.5%), and hypothyroidism (2.1%). Out of 81, 9 (11.1%) patients had serious adverse events requiring discontinuation or substitution of drugs which included psychiatric disturbances and ototoxicity.

**Conclusions & Recommendations:** Adverse events among MDR-TB patients are one of the major areas which is affecting cure rate of DR-TB patients. Further improvement in monitoring and management of adverse events may enhance the cure rate of MDR-TB patients.