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Title: Adverse reactions during treatment of multidrug-resistant and extensively drug-resistant tuberculosis

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Body: Introduction Treatment of multidrug-resistant tuberculosis (MDR-TB) and extensively resistant tuberculosis (XDR-TB) is often complicated by adverse reactions. Objectives: To describe the adverse reactions, time of occurrence, attitudes and risk factors among MDR/XDR-TB patients. Methods: Retrospective cohort of all patients with MDR/XDR-TB evaluated at the Regional Referral Center for MDR/XDR-TB in northern Portugal from July 2009 until January 2012. Results We analyzed 29 patients, 19 (65.5%) men, mean age 48 years. Eighteen (62.1%) had co-morbidities of which HIV infection was the most frequent (8 patients). Twenty-two patients (75.9 %) had adverse reactions and 17 (77.3%) had to suspend the drug involved. Median time to occurrence of adverse reactions was 94 days (min=2, max=619). Toxicity related to the injectable drug was the most frequent - 9 (31%) with ototoxicity, and 7 (24.1%) with renal insufficiency. Hypothyroidism was present in 6 (20.7%) of the patients. Psychiatric disorders, associated to cicloserine occurred in 6 (20.7%) patients. Multivariate analysis could not identify independent risk factors in relation to adverse reactions. The occurrence of adverse reactions was not associated with a higher risk of dead or a worse outcome. Conclusions The occurrence of adverse reactions more often correlated with the injectable drug and occurred around the third month. We could not identify independent risk factors for adverse reactions and they did not affect the outcome.