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Title: Clinical experience of clofazimine in the treatment of MDR-TB

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Body: Objective: In vitro studies have shown good activity of clofazimine against Mycobacterium tuberculosis, including multidrug-resistant strains. However, clinical experience with clofazimine in tuberculosis is scarce. We report, here, our clinical experience with 32 consecutive patients with multidrug-resistant tuberculosis (MDR-TB) treated with clofazimine-containing regimens. Methods: Record review was performed for 32 patients treated with clofazimine as part of a MDR-TB regimen. Patients were enrolled until December 2011. Data were collected on clinical and microbiological characteristics, clofazimine tolerability, and treatment outcomes. The usual dosage of clofazimine was 150mg daily. Results: Patients had isolates resistant to a median of 9 drugs (range, 4-13 drugs). Clofazimine was added to MDR-TB regimens for a median duration of 7 months (range, 1-22). Eleven patients discontinued clofazimine because of out of stock. At data censure (15 February 2013), one patient continued to receive clofazimine-containing regimen. Culture conversion rate was 53.1% (17/32). The treatment success and failure rates were 48.4% (15/31) and 51.6% (16/31), respectively. Of 15 treatment success cases, 10 (66.7%) patients were treated with linezolid, and 3 (20%) patients underwent surgical resection. Skin discoloration occurred in all patients and nine patients stopped clofazimine treatment due to adverse effects: skin discolorization (n=3), liver toxicity (n=3), and gastrointestinal disturbance (n=3). Factors for treatment success were men and concurrent use of linezolid in multivariate analysis. Conclusions: The efficacy of clofazimine in the treatment of MDR-TB was considered limited and concurrent use of linezolid may contribute to treatment success.