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Title: Clofazimine for the treatment of multidrug-resistant tuberculosis: Multicenter, randomized controlled study

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Body: Objective: To evaluate the clinical efficacy and safety of using clofazimine to treat MDR-TB. Methods: We enrolled 92 patients who had sputum-culture-positive MDR-TB in 8 major tuberculosis specialized hospital. Patients were randomly assigned to clofazimine therapy group (n=46) and control group (n=46). All patients had positive sputum-smear microscopy results at the time of MDR-TB diagnosis. Patients in two groups were adopted individual-based chemotherapy regimens based on the patient medication history and drug susceptibility test results. Meanwhile, clofazimine therapy group was added to 100 mg of clofazimine once daily for 21 months. Results:3 Patients in each group discontinued therapy because of side effects or other reasons. The sputum culture conversion rates of clofazimine therapy group were 74.41%(32/43) in 21th months after treatment, higher than those of control group (58.13%,25/43). The lesions absorption rates of clofazimine therapy group were 81.39%(35/43) in 21th months after treatment, higher than those of control group (60.46%,26/43). Of clofazimine therapy group, 39 had cavitary changes noted on initial chest computed tomography, and of control group, 38 had cavitary changes. The cavity closure or reduced rates of clofazimine therapy group were 71.79% (28/39) in 21th months after treatment, higher than those of control group (57.89%, 22/38). Side-effects of skin such as skin discolouration, ichthyosis only occurred in 40 patients of clofazimine therapy group. Conclusions: Using clofazimine to treat MDR-TB can significantly improve clinical symptoms, promote lesion absorption and cavity closure, and accelerate sputum negative conversion.