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Role of sequential anti-tubercular treatment in patients with tuberculosis meningitis

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Background & Aims: Tuberculosis meningitis (TBM) is associated with high frequency of drug induced hepatitis resulting in treatment interruption. The anti-tubercular (ATT) drugs have to be restarted sequentially in them. In this study, we report the safety and efficacy of sequential anti-tubercular regimen versus standard regimen in treatment naïve TBM patients.

Subjects and methods: This is a single center, open labeled, randomized clinical trial conducted during October 2016 – Feb 2018 in India. Treatment naïve patients with TBM, fulfilling the inclusion criteria were randomized to four drug anti-tubercular treatment (rifampicin, isoniazid, ethambutol and pyrazinamide) administered either simultaneously (standard arm) or one after another (sequential arm) in 1:1 ratio. The liver functions were monitored using serum bilirubin and transaminases. Both the arms were matched for demographic, clinical, and magnetic resonance imaging findings. The primary end point was occurrence of drug induced hepatitis (DIH), and secondary end points were in-hospital deaths, disability at three months, and disability at six months using modified Rankin scale.

Results: 103 patients with TBM were recruited; 15 did not meet the inclusion criteria. A total of 88 patients were eligible for the study. Two of them refused to participate and another six were included in another study; therefore, 80 patients were included. The median age of the patients was 26 (15 - 75) years and 37 (46.2%) were males. The patients in the sequential arm had lower incidence of DIH (20% vs., 42.5%, P = 0.03). In an intention to treat analysis, patients in the sequential arm had lower in hospital mortality (2.5% vs., 17.5% P = 0.025) and better six months outcome (23.1% vs., 51.3%, P = 0.01) compared with the standard arm.

Conclusion: Sequential anti-tubercular treatment was associated with lower frequency of DIH, in hospital mortality and six months disability.

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