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Title: Supplementary cholecalciferol in recovery from pulmonary tuberculosis

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Body: Introduction: Vitamin D is important for immune homeostasis. In vitro work suggests that 1-alpha-25-(OH)₂ D modulates host cell responsiveness to the T cell cytokine, interferon gamma (IFN γ). IFN γ is one of the key mediators of protective immunity against Mycobacterium tuberculosis infection therefore; vitamin D may enhance the host immune responses against the pathogen. The objectives of this study were to determine whether supplementation of vitamin D in patients with Tuberculosis could impact recovery. Methods: 266 patients were randomized to receive either 600,000 IU of Intramuscular vitamin D3 or placebo for 2 doses. Clinical assessments were done at 4, 8 and 12 weeks from baseline. Blood samples were obtained at 0 and 12 weeks. Statistical comparisons between outcome variables at 0 and 12 weeks were performed. Main Results: 259 patients completed the study. At the end of 12 weeks, the vitamin D arm demonstrated significantly greater mean weight gain; + 4.02 (95%CI 3.18,4.86) v/s + 2.61 (95% CI +1.99,2.23), p 0.007 and increases in BMI; + 1.48 (95% CI 1.17, 1.78) v/s + 0.96 (95% CI 0.72,1.20), p 0.008 as compared with the placebo arm. There was a significant difference in chest radiographic improvement in the vitamin D group; number of zones involved -2.21 (95% CI -1.91, -2.51) v/s -1.77 (95% CI -1.51, -2.03), p 0.031 and resolution of cavitation 73(65.7%) v/s 60 (55%), p 0.05. No differences were seen in TB score or sputum smear conversion. At follow up there was a significant increase in mean Vitamin D levels of the treatment arm; 62.88 v/s -7.30 for the placebo arm, p < 0.0001. Conclusions:Vitamin D supplementation significantly impacted clinical improvement in patients with pulmonary TB.