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**Title:** Safety and benefit of adjunctive systemic corticosteroid therapy in the management of severe, smear positive pulmonary tuberculosis (SSP-PTB); an interim analysis of a randomized controlled trial

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**Body:** Objective To assess the safety and benefit of adjuvant steroid therapy in SSPPTB. Method SSPPTB patients were randomized to 2 groups. All were given standard category I anti-tuberculosis therapy(ATT). Test group was given a tapering 3 week course of oral prednisolone. Interim analysis done at 8 weeks. Results Steroid arm had 38 (36 males; mean age 49y) while control arm had 26 (19 males; mean age 46y) patients. Night sweats and appetite showed a faster subjective improvement in the steroid arm. A weight gain within the initial 2 months was seen in 74% (average 1.7 kg) in steroid arm and in 76% (average 2.6 kg) of controls. A higher rate of sputum non-converters (18% vs.12%) was noted in steroid arm. The average, percentage improvement of ESR from pre-treatment value was higher in controls (39.2% vs.59.3%). Pre-treatment and two month CXR average scores were 60.5 and 59.5 in the steroid arm and 52.4 and 43.4 in the control arm respectively (AP Ralph, et al. Thorax 2010;65:863-9). Mean improvement of CXR score was higher among controls, but without statistical significance (0.99 vs.8.97; t=-1.40; p=0.17). Complications were noted in 5(13%) patients on steroids (hepatitis 1, itching 2, coronary ischemia 1, venous thrombosis 1) and in 2(8%) of controls (hepatitis 1, gastropathy 1). Conclusion Adjunction of oral prednisolone to ATT in SSPPTB showed inferior results in the initial two months, with regard to weight gain, sputum conversion, percentage ESR and CXR improvement. Furthermore, patients treated with steroids showed an overall higher incidence of adverse drug effects and disease complications.