

Spirolactone in Psoriatic Arthritis: Safety, Efficacy and Effect on Disease Activity

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Abstract : Therapeutic approaches used previously relied on disease-modifying antirheumatic drugs (DMARDs) that had only partial clinical benefit and were associated with significant toxicity. Spirolactone, an oral aldosterone antagonist, suppresses inflammatory mediators. Clinical efficacy of spiro lactone compared with placebo in patients with active psoriatic arthritis despite treatment with prior traditional DMARDs. In the 24-week, placebo-controlled study patients (n=31) were randomized to placebo and spiro lactone (2 m/kg/day). Patients on background concurrent DMARDs continued stable doses (methotrexate, leflunomide, and/or sulfasalazine). Primary outcome measures were the assessment of disease activity measures i.e. 28-joint disease activity score (DAS28) and diseases activity in psoriatic arthritis (DAPSA) at week 24. The key secondary endpoint was change from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at week 24. Additional efficacy outcome measures at week 24 included improvements in the markers of inflammation (ESR and CRP) and pro-inflammatory cytokines TNF- α , IL-6 and IL-1. At week 24, spiro lactone significantly reduced disease activity measure DAS-28 ($p<0.001$) and DAPSA ($p=0.001$) compared with placebo. Significant improvements in key secondary measures HAQ-DI (disability index) were evident with spiro lactone ($p=0.02$) versus placebo. After week 24, there was significant reduction in pro-inflammatory cytokines level TNF- α , IL-6 ($p<0.01$) as compared with placebo group. However, there was no significant improvement in IL-1 in both treatment and placebo groups. There were minor side effects which did not mandate stopping of spiro lactone. No change in any biochemical profile was noted after spiro lactone treatment. Spirolactone was effective in the treatment of PsA, improving disease activity, physical function and suppressing the level of pro-inflammatory cytokines. Spirolactone demonstrated an acceptable safety profile and was well tolerated.

Keywords : spiro lactone, inflammation, inflammatory cytokine, psoriatic arthritis

Conference Title : ICBMJD 2014 : International Conference on Bone, Muscle and Joint Diseases

Conference Location : Bangkok, Thailand

Conference Dates : December 18-19, 2014