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A RANDOMISED CONTROLLED TRIAL COMPARING THE EFFICACY OF WITHDRAWING ALPHA BLOCKER FOLLOWING INITIAL COMBINATION THERAPY WITH DUAL 5 ALPHA-REDUCTASE INHIBITOR (5ARI) DUTASTERIDE COMPARED TO CONTINUATION OF COMBINATION THERAPY IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study
To compare the efficacy of withdrawing alpha blocker following initial combination therapy with dual 5 alpha-reductase inhibitor (Dutasteride) compared to continuation of combination therapy in patients with symptomatic BPH.

Study design, materials and methods
The study was conducted from January 2010 to June 2011 on moderate and severe benign prostate hyperplasia (BPH) patients in a tertiary institution, who had been on combination therapy for 52 weeks duration. One hundred and three patients were then randomised to continuation of alpha blocker and dutasteride (DT64) or withdrawal of alpha blocker for another 12 weeks (DT52+D12). Patients' assessment of symptoms based on International Prostate Symptom Score (IPSS) and peak urinary flow rate (Qmax) were evaluated at the end of 4,8 and 12 weeks from baseline.

Results
Of those subjects with an IPSS<20 who changed to dutasteride monotherapy at week 52, 89% switched without a noticeable deterioration in their symptoms. In the 26% of men with severe baseline symptoms (IPSS≥20) who had withdrawal of alpha-blocker therapy at week 52, 34% reported a worsening of their symptoms compared with 20% in the DT64 group. Peak urinary flow measurements (Qmax) among both DT52+D12 and DT64 groups showed significant improvements (72.5% and 89.2% respectively). However, among the patients with improved IPSS, only 77% and 94% of patients in DT52+D12 and DT64 groups showed concurrent improvement in Qmax. There were no significant associations between both the groups in terms of clinical BPH progression as assessed by IPSS (moderate symptoms p=0.12, severe symptoms p=0.33) and Qmax (moderates symptoms p=0.45, severe symptoms p=0.28).

Interpretation of results
Dutasteride can be used in a 52-week combination with alpha-blocker, to achieve rapid onset of symptom relief in patients at risk of underlying disease progression. This symptom relief is maintained in the majority of patients after the alpha-blocker is stopped.

Concluding message
Alpha-blocker can be stopped safely after 52 weeks of combination therapy.

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