The Role of Dutasteride in Preventing BPH-Associated Clinical Progression Among Asymptomatic Men with an Enlarged Prostate

Introduction and Objective: Prostatic enlargement is a risk factor for acute urinary retention (AUR), need for surgery, as well as developing lower urinary tract symptoms (LUTS). Treatment with 5-alpha reductase inhibitors has been studied in men with moderate-severe LUTS. Our study aims to assess the role of dutasteride in preventing clinical progression in asymptomatic men with larger prostates.
Materials and Methods: Using data obtained from the REDUCE study, we assessed the outcomes of men with a prostate size >40 mL and baseline International Prostate Symptom Score (IPSS) <8. Men treated with any medications for benign prostatic hyperplasia (BPH) at time of study entry or who did not complete the end-of-study IPSS questionnaire were excluded. We compared the risk of BPH clinical progression at four years between those randomized to dutasteride versus placebo. BPH clinical progression was defined as a ≥4 point worsening on IPSS, AUR related to BPH, urinary tract infection, or BPH related surgery. A multivariable logistic regression analysis (MVA) assessed the effect of dutasteride on BPH clinical progression adjusting for age, IPSS, prostate volume, post-void residual, and peak urinary flow rate.
Results: Our study cohort consisted of 1617 men; 825 on placebo, 792 on dutasteride. A total of 464 patients (29%) experienced BPH clinical progression; 297(36%) on placebo, 167(21%) on dutasteride (P<0.001). The relative risk reduction (RRR) was 44% and the absolute risk reduction was 15%. Among the 76 patients (4.7%) who had AUR and the 46 patients (2.8%) who had BPH-related surgery, the RRR for dutasteride was 79% and 81%, respectively. On MVA, dutasteride significantly reduced BPH clinical progression with an odds ratio of 0.47(95% CI 0.37-0.59, P<0.001).
Conclusion: This study is the first to explore the benefit of treating asymptomatic or mildly symptomatic men with enlarged prostates. In this cohort, dutasteride significantly decreased the incidence of BPH clinical progression.