Unmoderated Posters: BPH

UP-01

Clinically Meaningful Improvement of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia with Tadalafil: Integrated Analyses from 4 Double-blind Placebo-controlled Studies

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Introduction and Objectives: In 4 large double-blind, placebo-controlled studies, tadalafil 5 mg once daily significantly improved lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH). This post-hoc analysis evaluated the proportion of patients achieving a clinically meaningful improvement using 2 different definitions of response.

Methods: Men ≥45 years old with LUTS/BPH, an International Prostate Symptom Score (IPSS) ≥13 and Qmax ≥4 to ≤15 mL/sec at baseline, were randomized to tadalafil (n=752) or placebo (n=747) for 12 weeks. Baseline values for analyses were established after the 4-week placebo-run-in and before randomization. A patient was classified as a responder if total IPSS improvement was ≥35 or if a total IPSS improvement ≥25% from baseline to endpoint was observed. Response status was calculated per patient, and relative benefit (95% CI) of placebo versus tadalafil was calculated.

Results: At baseline, mean (SD) age was 63.1 (8.34) and 63.1 (8.65) years, mean IPSS was 17.6 (5.72) and 17.3 (5.94), the proportion of patients with severe symptoms (IPSS ≥20) was 35.1% and 34.9% and the proportion with Qmax <10 mL/sec was 45.4% and 48.2% for tadalafil and placebo, respectively. Overall, mean (SD) IPSS improvement for tadalafil was -5.8 (6.36) and for placebo was -3.4 (6.03). Tadalafil 5 mg once daily as compared to placebo resulted in a significantly greater proportion of: 1) patients achieving at least a 3-point total IPSS improvement: 71.1% and 56.0% for tadalafil and placebo patients respectively (relative benefit [95% CI]: 1.26 (1.16, 1.37), and 2) tadalafil patients (61.7%) compared to placebo patients (45.5%) achieving a clinically meaningful response using a ≥25% improvement in total IPSS from baseline to endpoint as a threshold (relative benefit [95%CI]: 1.37 (1.24, 1.52).

Conclusions: Using total IPSS improvement ≥3 or a total IPSS improvement ≥25%, a statistically significantly greater proportion of tadalafil-treated patients as compared to placebo-treated patients achieved a clinically meaningful improvement in LUTS/BPH symptoms.

UP-02

Prostate Specific Antigen as a Predictive Tool for Prostate Volume in New Brunswick Men without Prostate Cancer

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Introduction and Objectives: Prostate-specific antigen (PSA) is used in the diagnosis of prostate cancer (PCa) and monitoring of its treatment. Research suggests a role for PSA in the assessment of prostate volume (PV) to assist with therapeutic decision-making for men with symptomatic benign prostatic hyperplasia (BPH). This has influenced the Canadian Urological Association Guidelines for the management of BPH, which notes that PSA may be a useful surrogate marker for PV.

Objectives:
- Assess PSA and age as variables in the prediction of PV.
- Determine critical PSA values that predict PVs >40 mL for patients in their 50s, 60s, and 70s.
- Assess the utility of PSA as a clinical tool to guide treatment with 5α-reductase inhibitors.

Methods: A prospectively collected Prostate Database of 2175 patients was reviewed. Patients with evidence of PCa were excluded, only those with benign conditions were analyzed. Patients with PSA > 0 ng/mL were excluded. Patients >80 and <50 years old were excluded. Patients were stratified by decade of life (50s, 60s, 70s).

Results: A total of 1111 patients were evaluated. Multiple regression analysis showed PSA value and age stratification by decade of life as significant predictors of PV (R2 = 0.23, F[3, 1013] = 100.7, p<0.001). Patients with higher PSA values had higher log-PV (Unit increase of PSA = 8.4% increase in log-PV). Also, increases in age were associated with increases in log-PV (patients in their 60s and 70s had a 20% increase in log-PV compared to those in their 50s).

Receiver Operating Characteristic (ROC) curves showed PSA had good predictive value for PV with areas under the curve ranging 0.69 - 0.75 for select PV (30, 40, 50 mL). Our findings support PSA values of 1.6 ng/ml, 2.0 ng/ml, and 2.3 ng/mL for predicting PV of >40 mL in men in their 50s, 60s, and 70s, respectively.

Conclusions: Our results are consistent with Roehrborn et al, adding to the evidence of PSA and age being significant variables in predicting PV in men with BPH. These predictors may be useful in therapeutic decision-making with 5α-reductase inhibitors.