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Comparison of Murraya koenigii- and Tribulus terrestris-Based Oral Formulation Versus Tamsulosin in the Treatment of Benign Prostatic Hyperplasia in Men Aged >50 Years: A Double-Blind, Double-Dummy, Randomized Controlled Trial.

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Abstract

BACKGROUND:

Drug treatment can defer surgical intervention in benign prostatic hyperplasia (BPH), a common disorder in elderly men, and is widely practiced. Various herbal formulations have been used for the treatment of BPH, but few have been compared with established modern medicines in head-to-head clinical trials.

OBJECTIVE:

We compared the effectiveness and tolerability of an oral formulation, comprising standardized extracts of Murraya koenigii and Tribulus terrestris leaves being marketed in India under Ayurvedic license, versus tamsulosin in the treatment of symptomatic BPH.

METHODS:

A double-blind, double-dummy, parallel-group, randomized controlled trial was conducted with treatment-naive ambulatory patients with BPH aged >50 years. Patients received either the plant drug in a dose of 2 capsules BID or tamsulosin 400 μg once daily for 12 weeks with 2 interim follow-up visits at the end of 4 and 8 weeks. The double-dummy technique was used to ensure double-blinding. The primary effectiveness measure was reduction in the International Prostate Symptom Score (IPSS). Proportion of patients becoming completely or relatively symptom free (IPSS <8), change in prostate volume (assessed by using ultrasonography conducted by a radiologist blinded to the nature or duration of treatment), and peak urinary flow rate (assessed by using uroflowmetry) were secondary measures. Treatment-emergent adverse events, changes in weight, vital signs, and routine laboratory safety parameters were recorded.

RESULTS:

Forty-six patients were randomized (23 per group); 19 completed all study visits in the plant drug group and 21 in the tamsulosin group. However, applying modified intention-to-treat criterion, 23 and 21 patients, respectively, were considered for effectiveness analysis. Mean (SD) age and baseline weight were 58.5 (14.0) years and 57.5 (10.5) kg in the plant drug arm, and 62.9 (6.3) years and 59.8 (9.9) kg in the tamsulosin arm, respectively. Median (interquartile range) symptom duration was 12.0 (12.0-24.0) months and 15.0 (12.0-24.0) months, respectively, in the 2 arms. These differences were not statistically significant. IPSS (median [interquartile range]) declined from 17.0 (12.0-19.0) to 9.0 (5.0-13.0) with the plant drug and from 14.0 (11.0-18.0) to 8.0 (6.0-13.0) with tamsulosin after 12 weeks of treatment. The decline was individually significant in both groups (both, $P < 0.001$), but intergroup values showed no statistically significant difference at any point of time. IPSS <8 at study end was achieved by 10 and 7 patients, respectively, in the 2 arms ($P = 0.548$). The plant drug reduced prostate volume from 33.5 (26.2-45.9) mL to 31.6 (26.1-37.5) mL ($P = 0.040$). The corresponding reduction with tamsulosin, from 41.3 (29.4-51.3) mL to 39.9 (32.6-52.3) mL, was not statistically significant. Peak urinary flow rate did not change appreciably. Mild joint pain was the most common adverse event in both arms. No serious events were encountered. Compliance was satisfactory.

CONCLUSIONS:

These findings suggest that the M koenigii- and T terrestris-based formulation significantly lowered IPSS scores in the initial treatment of symptomatic BPH. Further trials are needed to determine if the beneficial effect is sustained beyond the 12-week observation period of this trial.