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BEHAVIORAL VERSUS DRUG TREATMENT FOR OVERACTIVE BLADDER IN MEN: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

The objectives of this study were to compare the effectiveness of behavioral treatment compared to antimuscarinic drug therapy for symptoms of overactive bladder (OAB) in men without significant bladder outlet obstruction, and to evaluate the effects of combined behavioral and drug therapy as a way to enhance outcomes in patients who do not achieve satisfactory results with individual therapy alone.

Study design, materials and methods

This study was a 2-site randomized controlled trial. Subjects were 142 men with OAB as manifested by urgency and frequent urination (>8 voids per day), with or without incontinence, and without significant obstruction (< 10 mL/sec on simple uroflowmetry; > 150mL post-void residual urine volume). During a 4-week run-in period, all patients were given an alpha blocker (i.e., tamsulosin 0.4 mg daily or alternative alpha blocker). Patients who continued to experience OAB symptoms were stratified on voiding frequency (> 8 to 15, 16-20, and >20 voids/day) and presence/absence of urge incontinence and randomized to 8 weeks of behavioral treatment or 8 weeks of drug therapy.

The behavioral treatment was a comprehensive training program, which included pelvic floor muscle exercises, delayed voiding, self-monitoring with bladder diaries, and urge suppression techniques to inhibit detrusor contraction and reduce urgency, frequency, and incontinence. Subjects in the drug therapy group received standard antimuscarinic therapy consisting of individually-titrated, extended-release oxybutynin 5 to 30 mg daily. Subjects who did not achieve satisfactory outcomes after 8 weeks of treatment with either behavioral or drug therapy alone were crossed over into a second phase in which they received combined treatment to determine if the treatments together would provide better outcomes than either therapy alone.

Seven-day bladder diaries completed by subjects prior to randomization and following the last treatment session were used to calculate changes in 24-hour frequency of urination. [1] Secondary outcome measures included validated measures of patient satisfaction (Patient Satisfaction Question) [2] and patient's perception of improvement (Global Perception of Improvement). [2]

Results

Subjects ranged in age from 42 to 88 years (mean ±SD = 64.4 ±9.8); 64% were white, 35% African American, and 1% Hispanic. Subjects who completed behavioral treatment (N = 61) demonstrated a reduction in the mean (±SD) number of voids per day from 11.2 (± 2.5) in baseline to 9.0 (± 2.5) post-treatment. The decrease of 2.2 voids per day was statistically significant ($p < 0.001$). Subjects who completed drug treatment (N = 53) demonstrated a reduction in the average number of voids per day from 11.2 (± 2.2) in baseline to 9.4 (± 2.3) post-treatment. This decrease of 1.9 voids per day was also statistically significant ($p < 0.001$). These changes equate to an average 18.4% reduction in frequency of urination in the behavioral treatment group and a 16.0% reduction in the drug treatment group. The reductions in voiding frequency did not differ significantly by group ($p = 0.45$). Post-treatment, 39% of subjects in behavioral treatment and 34% of those in drug therapy had 8 or fewer voids per day ($p = .55$)

On Global Perception of Improvement measured at the end of treatment, 38% of subjects in the behavioral treatment group reported that they were "much better" compared to 28% in the drug therapy group ($p = 0.27$). On the Patient Satisfaction Question, 59% of subjects in behavioral treatment reported that they were "completely satisfied" with their progress in treatment compared to 42% of those in drug therapy ($p = .08$).

At the end of the 8-week intervention period, 37 subjects chose to cross over to combined behavioral plus drug therapy and completed another 8 weeks of treatment (27 who completed drug therapy and added behavioral therapy, and 10 who completed behavioral therapy and added drug therapy). For these individuals, mean frequency of urination decreased from 10.1 (± 2.3) voids per day after single therapy to 9.0 (± 2.2) voids per day after combined therapy. This mean decrease of 1.1 voids per day was statistically significant ($p = .002$). The magnitude of the decreases did not differ by group ($p = 0.92$).

Interpretation of results

Outcomes of behavioral treatment and drug therapy were not significantly different on reduction in 24-hour voiding frequency, satisfaction with treatment, or global perception of improvement. Adding the alternate treatment in subjects who were not satisfied with their first treatment led to modest further reduction in voiding frequency.

Concluding message

The results of this trial demonstrate that behavioral treatment with pelvic floor muscle training, delayed voiding, and urge suppression techniques is effective for reducing frequency of voiding in men with OAB, and yields outcomes at least as good as drug therapy. It also provides evidence that combining behavioral and drug therapy in a stepped manner may add benefit in men not satisfied with an individual therapy.

References

1. Locher JL. Goode PS. Roth DL. Worrell RL. Burgio KL. Reliability assessment of the bladder diary for urinary incontinence in older women. Journals of Gerontology. Series A, Biological Sciences & Medical Sciences. 2001;56(1):M32-5
2. Burgio KL, Goode PS, Richter HE, Locher JL, Roth DL. Global Ratings of Patient Satisfaction and Perceptions of Improvement with Treatment for Urinary Incontinence: Validation of Three Global Patient Ratings. Neurourology and Urodynamics 2006; 25, 411-417

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