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A SIMPLIFIED PELVIC FLOOR EXERCISE REGIMEN ADDS NO ADDITIONAL BENEFIT TO DRUG TREATMENT ALONE

Aims of Study

Antimuscarinics are the mainstay of pharmacotherapy for overactive bladder (OAB). The use of pelvic floor muscle exercises (PFME) has been suggested for the treatment of urinary incontinence (1,2) following the hypothesis that contraction of the pelvic floor musculature will result in feedback inhibition of detrusor contraction. However, such training usually requires qualified training and a considerable expenditure of time. It is unknown whether this process can be simplified by the sole use of written instructions. This multinational study assessed whether the addition of a simple written PFME program to drug therapy would augment the therapeutic benefits provided by drug therapy alone in patients with OAB.

Methods

Patients (18–90 years of age) with urge incontinence (≥1 episode/24 h), urgency (defined as a strong and sudden desire to urinate) and urinary frequency (≥8 micturitions/24 h) for ≥6 months were eligible for inclusion. After a 1–2 week run-in period, patients were randomized to receive tolterodine 2 mg bid either alone or in combination with a PFME program for 24 weeks. The PFME program consisted of 2 pages of written information. The primary efficacy variable was change from baseline in the number of incontinence episodes/24 h after 24 weeks of treatment and a patient perception of bladder condition 6-point scale. Efficacy was evaluated using 3-day micturition diary recordings. Results were analysed on an intention-to-treat (ITT) basis.

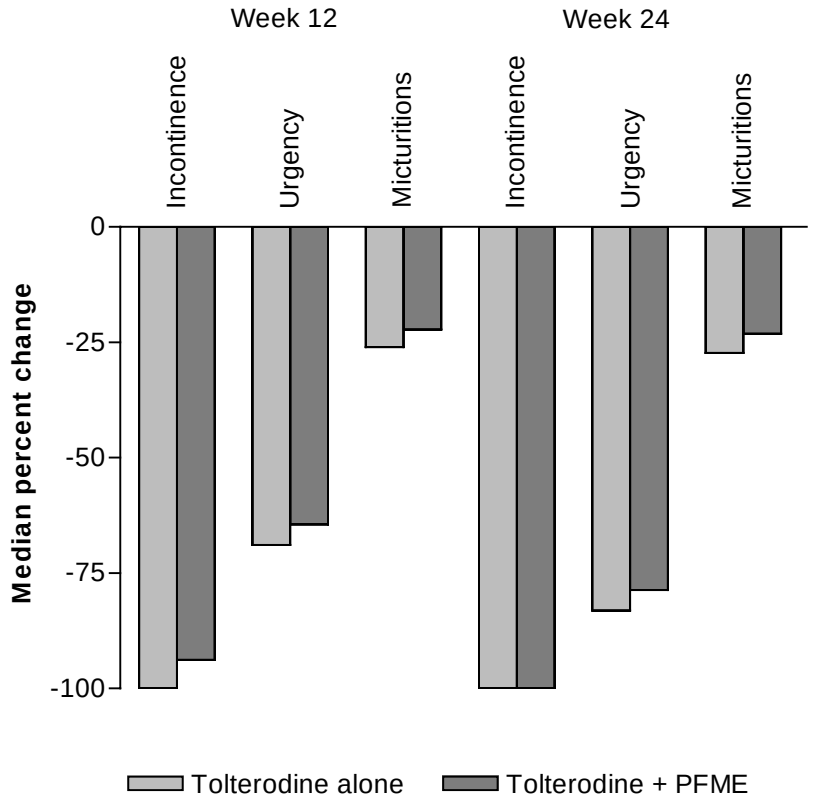
Results

Of the 480 patients randomized to treatment, most were female (75.4%), Asian (79.6%) and naive to anticholinergic therapy (93.1%); patients' mean age was 53.4 years. At weeks 12 and 24, median percent reductions from baseline were statistically significant (p=0.0001) for incontinence episodes/24 h, urgency episodes/24 h and micturitions/24 h in both treatment groups (Figure), but the PFME program did not confirm any additional benefit. The maximal benefit for incontinence and frequency was attained by 12 weeks but urgency continued to improve up to 24 weeks (tolterodine, p<0.0001; tolterodine + PFME, p=0.028). Median volume voided/micturition was also significantly (p=0.0001) increased in both treatment groups at 12 (+17.5 and +20.4 ml for tolterodine and tolterodine + PFME, respectively) and 24 (+19.1 and +21.1 ml, respectively) weeks (no significant differences between groups). There were no significant between-group differences in the percentage of patients who were dry: tolterodine 57.4% vs tolterodine + PFME 51.4%, p=0.2006 at 12 weeks and tolterodine 59.9% vs tolterodine + PFME 53.1%, p=0.1429 at 24 weeks. Improved perception of bladder condition was reported by 85.9% of patients on tolterodine alone vs 81.7% of patients on tolterodine + PFME after 24 weeks (ITT analysis). In total, 75.5% of the tolterodine group and 71.4% of the tolterodine + PFME group completed 24 weeks of therapy.

Conclusions

This study shows that the addition of a simple written PFME program to tolterodine therapy produced no augmentation of the therapeutic benefits achieved by tolterodine alone in OAB patients. This suggests that for PFME to be effective, a more intensive program may be required. Interestingly, urgency was shown to continue to improve between 12 and 24 weeks of therapy, we believe that this is the first demonstration of enhanced efficacy with long-term therapy.

Figure: Median percent change from baseline in incontinence episodes/24 h, urgency episodes/24 h and micturitions/24 h at 12 and 24 weeks



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