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A RANDOMIZED TRIAL COMPARING REHABILITATION AND DRUG THERAPY FOR URGENCY URINARY INCONTINENCE: 1 YEAR FOLLOW UP

Hypothesis / aims of study

Urgency Urinary Incontinence (UUI) is defined by the International Continence Society as a complaint of involuntary loss of urine associated with urgency. UUI is associated with reduced Quality of Life (QOL) and depression, and in the geriatric age is associated with increased social isolation and functional decline. Efforts have been made to find an optimal long term treatment for UUI that will reduce symptoms, with minimal side effects. Bladder Training (BT) and Drug Therapy (DT) have shown better results than no treatment or placebo for UUI. Previous studies found no differences in outcomes between various protocols of DT with or without various protocols of BT and Pelvic Floor Muscles Training (PFMT). It is yet to be determined which of the treatment protocols – PFMT, BT or DT – is more clinically effective for woman with UUI in short, medium and long-term treatments (as indicated by Cochrane systematic review published in 2006 and in 2012). Therefore, the purpose of the present study was to compare long-term clinical efficacy of four conservative treatment protocols: DT, BT, PFMT, and Combined Pelvic Floor Rehabilitation (CPFR), in treating women with UUI symptoms. Based on our previous study [1] we hypothesized that CPFR that includes BT, PFMT and behavioral guidance would be more effective and cost-effective when measured a year later, compared to the other protocols investigated.

Study design, materials and methods

This was an assessor blinded RCT conducted in a public health center from July 2007 to December 2011. Invitation letters were sent to 30,000 women. Over 1,000 women expressed interest in participating in the study, and were screened for the trial. The inclusion criteria were: age 45-75 with at least three episodes of UUI over the previous 4 weeks, without stress urinary incontinence, urinary tract infection, clinical depression or previous pelvic floor surgery. Sample size was calculated based on the primary outcome measure: the reduction of voids per 24 hours. The number of subjects required to detect a reduction of 3 voiding/24 h was 45 in each study arm (with a significance level of 0.05, 80% power and 10% drop out).

One hundred eighty four patients signed an informed consent and participated in our multi-center single blinded randomized controlled trial. Patients were randomized to receive DT, BT, PFMT or CPFR for 3 months. DT consisted of 3-months of Tolterodine SR 4 mg (Detrusitol SR 4 mg, Pfizer). Patients from the BT, PFMT, and CPFR study groups met with one of the 20 female physical therapists specializing in pelvic floor rehabilitation four times, in three week intervals. While the examiners were blinded to the participants' allocation, the participants themselves were not. Outcome measures included number of voiding/24 hours, number of UUI episodes in last week, QOL Related to UUI, EuroQOL, Center of Epidemiology Studies Depression scale and self-reported function and disability, at baseline (t1), 3 months (t2), and 12 months (t3).

Results

The first 20 woman recruited to participate in the pilot study were not included in the final analysis, leaving 164 valid cases (40-42 woman in each group) for final analysis. At baseline, no statistical significant differences were found in patient demographic and health related characteristics. Mean age (SD) was 56.7(8.0). All four groups showed significant improvement over the study period with a significant main effect for time for all primary and secondary outcomes ($p<0.001$). No significant interaction effects between group and time were found. Furthermore, between-group comparison showed a decrease of more than 3 voids/24 h only in the CPFR group (mean −3.4 at t1 and −4 at t2), with a moderate Effect Size (0.35) compared with the DT group (mean −1.3 at t1 and −2.1 at t2). Self reported function related to improvement in lower extremity function was identified at t1 and t2 in the CPFR group only [2].

In addition, 22% of our study population had depressive symptoms (Center of Epidemiology Studies Depression scale<16). The study showed that depressive symptoms and physical symptoms of UUI decreased following rehabilitation and drug treatment protocols [3]. Direct average costs per women related to self-reported monthly utilization of pads, laundry and new underwear at baseline, were $25 (in US dollars). This mean cost was significantly reduced from baseline to 12 months of follow-up to $15.6. The four treatment modalities were equally cost-effective.

The reported adherence to rehabilitation treatment (BT=85%, PFMT=90%, CPFR=95%) was significantly higher than the adherence to DT (64%) ($p=0.01$) at t1. The main reason for dropout from the DT group was dissatisfaction with group allocation. No major side effects were reported.

Interpretation of results

Our study showed that the four treatment modalities for treating women with UUI were equally effective and had comparable costs. It is important that physicians and other healthcare providers be aware of the lower adherence to drug therapy compared to pelvic floor rehabilitation treatment that can be suggested as a primary treatment for UUI.

Concluding message

We recommend that pelvic floor rehabilitation be the first choice of treatment for women with early symptoms of UUI. Based on the results of the study, this treatment can improve QOL in middle-aged women and potentially reduce the risk for additional illness.

References

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