

Outcomes of Different Protocols of Pelvic Floor Physical Therapy and Anti-Cholinergics in Women With Wet Over-Active Bladder: A 4-Year Follow-Up

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Aims: We investigated the 4-year outcomes of three protocols of pelvic floor physical therapy and anticholinergic drug in women with wet over-active bladder (OAB). **Methods:** One hundred and sixty-four women were randomly allocated to one of four interventions: drug therapy (DT), bladder training (BT), pelvic floor muscle training (PFMT), or combined pelvic floor rehabilitation (CPFR) that includes BT, PFMT, and behavioral advice. The active treatment in each group lasted 3 months. Of the 132 women who completed a 1-year follow-up, 120 women (90%) responded to our questionnaires and therefore were included in this study. Outcome measures were the number of voids per day, number of urgency urinary incontinence (UUI) episodes per week, completely dry rate and Incontinence Quality of Life questionnaire (I-QOL) at 4 years. **Results:** After 4 years of follow-up, the outcome measures improved significantly and equally in all four groups. The median number of UUI episodes/week dropped by 3, 1, 2, and 2 in the DT, BT, PFMT, and CPFR groups, respectively ($P = ns$). The dry rates were 25%, 31%, 44%, 34% in the DT, BT, PFMT, and CPFR groups, respectively ($P = ns$). I-QOL scores improved significantly in all four groups. **Conclusions:** Women who suffer from wet-OAB may experience the same degree of long-term improvement following various pelvic floor physical therapy protocols as they would from drug therapy. *NeuroUrol. Urodynam.* 36:755–758, 2017. © 2016 Wiley Periodicals, Inc.

Key words: bladder training; overactive bladder; pelvic floor muscle training; pelvic floor rehabilitation; urgency urinary incontinence

INTRODUCTION

Overactive bladder (OAB) is characterized by urinary urgency accompanied by frequency and nocturia. One-third of patients experience urgency urinary incontinence (UUI) as well. The quality of life of these patients is considerably impaired.¹ Efforts have been made to find an optimal long-term treatment for UUI that will reduce symptoms while entailing minimal side effects. Conservative treatments for OAB include: fluid management, bladder training, bladder control strategies, and pelvic floor muscle training. First-line treatment with behavioral therapy presents essentially no risks to patients and should be offered to all patients. Second-line treatment with anticholinergic drugs, though not invasive, presents the risk of side effects that primarily compromise quality of life.² Data on the long-term effect of these treatments are sparse.^{2,3}

In this study, we evaluated the 4-year outcomes of three different protocols of pelvic floor physical therapy and drug treatment in OAB women who suffer from UUI (wet-OAB).

MATERIALS AND METHODS

One hundred and sixty-four women aged 45–75 who experienced at least three episodes of UUI per week were recruited for the original randomized controlled study.⁴ Patients were randomly allocated to one of the four study groups by randomly permuted blocks of four, with random assignment concealed in tamper-proof envelopes: Drug therapy (DT)—Tolterodine SR 4mg, bladder training (BT), pelvic floor muscle training (PFMT), and combined pelvic floor

rehabilitation (CPFR). BT comprised three components: (i) patient education on bladder function and on how continence is usually maintained; (ii) increasing intervals between voids; and (iii) positive reinforcement through psychological support and encouragement. The PFMT protocol included, during each of the appointments, three sets of 8–12 slow maximal contractions sustained for 6–8 sec in different functional body positions, progressing from lying to standing. Participants then continued a daily PFMT home-based program and recorded their home exercise sessions using an exercise log. Participants were trained to contract these muscles repeatedly to diminish urgency and prevent UUI, as well. The CPFR protocol included BT, PFMT, and behavioral advice, including bowel education to avoid constipation, modification of fluid intake, increasing daily activity, and posture consultation. Patients from the BT, PFMT, and CPFR groups participated in four sessions, once every 3 weeks, given by 1 of 20 female physical therapists who specialize in pelvic floor rehabilitation. The examiner was blinded to the participant's allocation.⁴

Outcome measures were: number of voids per 24 hr as recorded in one's bladder diary,⁵ self-recording of UUI episodes during the

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previous week,⁶ dry rates, and the Incontinence Quality of Life questionnaire (I-QOL) score.⁷ Outcomes were recorded at baseline, 3 months after active treatment, and at a 12-month follow-up. The main focus of our study was physical therapies rather than medications. Since physical therapies are safe, lacking in known adverse events, we did not document side effects.

The same questionnaires were posted 4 years after the end of the active treatment to 132 women who completed the 12-month follow-up. The questionnaires were sent back to us by e-mail, fax, or in an envelope by post.

Patients' clinical data as well as physician encounters, dispensed prescriptions, and physical therapy treatments were documented in a detailed computerized database.⁸ The study protocol was approved by the local ethics committee for experiments in humans and all subjects signed an informed consent form prior to study enrollment.

Categorical data are presented as frequencies and percentages, and continuous data as mean (standard deviation) or median (interquartile range, iqr). Normal distribution was evaluated using the Kolmogorov–Smirnov test and a histogram. Comparison of baseline characteristics between responders and non-responders were evaluated using the Mann–Whitney test, Chi-Square test, or Fischer's exact test. Comparison of baseline characteristics and in 4-year follow-up between treatment groups were evaluated using the Kruskal–Wallis test, Chi-Square test, or Fischer's exact test. When 20% or more of the expected counts in the Chi-Square test were less than five we used the Monte Carlo simulation. To compare the baseline status and 1-year outcome with 4-year outcomes, we used the Wilcoxon Signed Rank Test. Multivariate Logistic Regression was made to evaluate the treatment success between four treatments modalities. The regression included known risk factors (age and body mass index) for UUI. A 2-tailed $P < 0.05$ was considered statistically significant. Analyses were performed with SPSS software (statistical package for the social sciences, version 22, Chicago, IL).

RESULTS

The flow of participants through each phase of the trial is presented in Figure 1. Out of 164 women who participated in the original randomized trial, 135 (82.3%) women completed 1-year of follow-up.⁴ One hundred and twenty women (90%) responded to our questionnaires and completed a 4-year follow-up and therefore were included in this study.

Baseline demographic and clinical characteristics were similar across the groups (Table 1). Baseline characteristics were similar among patients who responded and those who did not respond to our questionnaires.

After 4 years of follow-up, all outcome measures improved significantly compared to the baseline. No significant differences between the four groups were found in the number of voids/24 hr ($P = 0.635$), the number of UUI episodes/week ($P = 0.206$), and the I-QOL score ($P = 0.354$). The dry rates (no incontinence) were similar ($P = 0.616$) across the four groups (Fig. 2), adjusted to age ($P = 0.370$, OR = 0.978; 95%CI 0.933–1.026) and body mass index ($P = 0.424$, OR = 0.975; 95%CI 0.916–1.038). Statistically significant correlation ($r = -0.499$, $P < 0.001$) was found between number of UUI per week and I-QOL scores.

During the follow-up period, 14 patients (11.6%) had used anti-cholinergic drugs: 7, 6, 1 and none of the patients in the DT, BT, CPFR, and PFMT groups, respectively. Thirteen women (10.8%) had practiced pelvic floor physical therapy during the follow-up period: 4, 3, 4 and three patients in the DT, BT, CPFR, and PFMT groups, respectively.

Only one patient who continued with anti-cholinergic drugs was completely dry (7%), compared to five patients who continued practicing pelvic floor physical therapy (38.5%, $P = 0.032$).

Interestingly, 54% of the study population ($n = 65$) suffered from musculoskeletal pain such as low back pain and extremities pain. The presence of pain was significantly associated with the number of UUI/week but not with age, number of voids/24 hr, body mass index or I-QOL score.

DISCUSSION

Anticholinergic drugs are one of the main treatments for OAB. However, the adherence rate of these drugs is considered to be very low. After 1 month from commencing the therapy, the discontinuation rate is more than 40% and after one year less than 20% of patients will continue to consume the drug.^{9,10} One of the main reasons for the low adherence rate is adverse events. Despite the relatively large number of randomized controlled trials, the overwhelming majority of the trials have short-term follow-up of only 12 weeks.²

Behavioral and pelvic floor physical therapies are appealing options since they have no significant potential risks or side effects. Yet, it is not clear whether physical therapies have

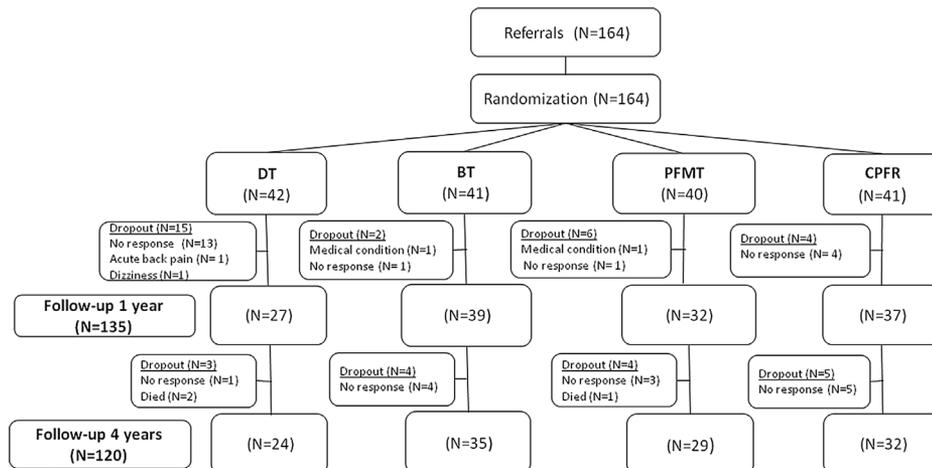


Fig. 1. Trial profile showing the flow of participants through each stage of the trial.

TABLE I. Comparison Between the Four Groups of Baseline Demographics, Co-Morbidities, and Clinical Variables in Women Who Have Completed 4 Years of Follow-Up (N = 120)*

| | DT (N = 24) | BT (N = 35) | PFMT (N = 29) | CPFR (N = 30) | P-value |
|--|-------------|--------------|----------------|---------------|---------|
| Median age (iqr) | 58 (51–68) | 63 (52–68) | 59 (54.5–64.5) | 58 (54–67) | 0.841 |
| Median education (years) (iqr) | 15 (12–16) | 15 (12–17) | 15 (12–17) | 15 (12–16.7) | 0.987 |
| Median body mass Index (iqr) | 29 (25–32) | 27.3 (25–32) | 28.2 (25–32) | 25.4 (23–31) | 0.346 |
| Median parity (iqr) | 2 (1.2–3) | 3 (2–4) | 2 (1.5–3) | 3 (2–4) | 0.175 |
| No. physically active (<2 a week) n (%) | 15 (62.5) | 23 (65.7) | 22 (76) | 23 (72) | 0.702 |
| No. smoking (%) | 4 (17) | 4 (11) | 3 (10) | 3 (10) | 0.372 |
| No. pts DM (%) | 0 (0) | 1 (3) | 2 (6) | 3 (10) | 0.375 |
| No. pts HTN (%) | 2 (8) | 6 (17) | 5 (17) | 4 (13) | 0.747 |
| No. pts taking anti cholinergic drugs (%) | 7 (29) | 7 (20) | 0 (0) | 1 (3) | <0.001 |
| No. pts received pelvic floor physical therapy (%) | 4 (17) | 3 (11) | 3 (10) | 4 (12) | 0.911 |
| Median voids/24 hr (iqr) | 8 (6.3–14) | 9 (7–12) | 9 (6–11) | 7 (8–10) | 0.635 |
| Median I-QoL (iqr) | 95 (79–105) | 98 (82–104) | 99 (88–106) | 93 (69–102) | 0.354 |
| Median UUI episodes/week (iqr) | 2 (0–4) | 2 (0–5) | 1 (0–3) | 1 (0–4) | 0.206 |

DT, drug therapy; BT, bladder training; PFMT, pelvic floor muscle training; CPFR, combined pelvic floor rehabilitation; I-QoL, incontinence quality of life; UUI, urgency urinary incontinence; DM, diabetes mellitus; HTN, hypertension.

*Data presented as median (inter quartile range [iqr]) or numbers (%).

long-term benefits and whether they are as effective as anticholinergic drugs.¹¹

Very few studies have investigated the efficacy of pelvic floor physical therapies in patients with OAB. The treatments that have been tested include bladder training, Kegel exercises, biofeedback-assisted pelvic floor muscle training, and electrical stimulation. The reported subjective improvement/cure rates ranged from 33% to 51%.^{12–14} However, these studies have been hampered by considerable disadvantages: small populations

(25–71 patients) with heterogeneous clinical symptoms (diverse lower urinary tract symptoms, mixed urinary incontinence) and short follow-up ranging from 3 to 6 months.

Behavioral training with or without assistance of biofeedback (verbal feedback based on vaginal palpation) showed a mean 60% reduction in incontinence episodes in 222 women who suffer from urgency or mixed incontinence.¹⁵ Yet, the main flaws of this study were heterogeneous clinical symptoms and very short follow-up (8 weeks).

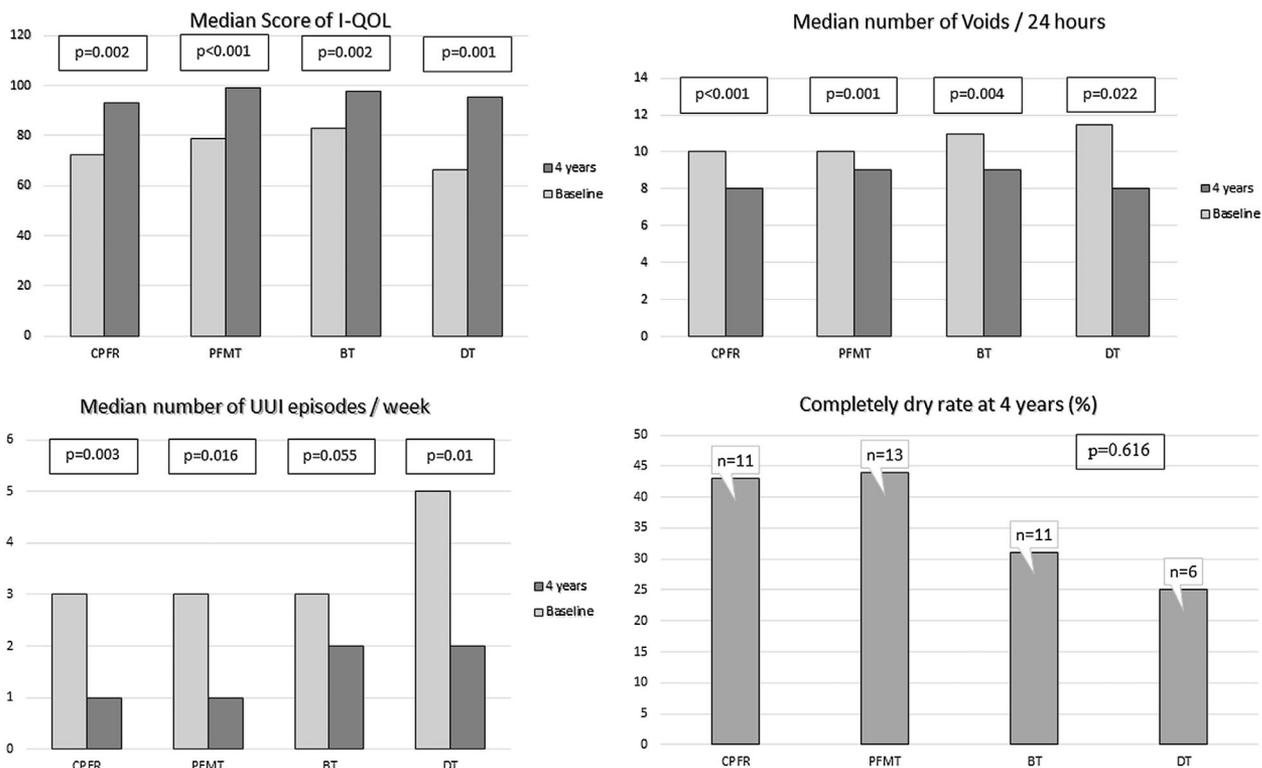


Fig. 2. Comparison of the outcome measures across the 4 groups: I-QoL score, number of voids/24 hr, number of UUI episodes/week, and completely dry rates. I-QoL, Incontinence quality of life; UUI, Urgency urinary incontinence; CPFR, Combined pelvic floor rehabilitation; PFMT, Pelvic floor muscle training; BT, Bladder training; DT, Drug therapy.

Comparisons between anticholinergic medications and pelvic floor physical therapies were performed in very few studies. Burgio KL et al. investigated 197 women aged 55–92 with predominantly UUI. Patients were randomized to receive biofeedback-assisted behavioral treatment (three sessions of anorectal biofeedback, urge strategies with PFM contractions), medication (Oxybutynin), or placebo. After 8 weeks, the mean incontinence episodes reduced by 81%, 68%, and 39% in the behavioral, medication, and placebo group, respectively ($P < 0.05$).¹⁶ Lauti M et al. randomized 57 women to BT ($n = 21$), Oxybutynin ($n = 16$), or a combination of both ($n = 19$). After 12 months of follow-up, the number of urinary incontinence episodes per day decreased from 2.2 to 0.9 in the BT group, from 1.0 to 0.9 in the Oxybutynin group, and from 1.8 to 0.8 in the combined treatment group. The difference between the groups was not significant.¹⁷

In this study, we evaluated the 4-year outcomes of three different protocols of physical therapy and anticholinergic drug in OAB women who suffer from UUI. We found that the four treatments are effective, without significant differences between them, in the number of UUI episodes per week, number of voids per day, I-QOL score, and dry rates. Interestingly, although the active treatments lasted 3 months the favorable outcomes were preserved even after 4 years of follow-up. To the best of our knowledge, this is the first study examining long-term outcomes of different physical therapies in women with UUI.

Our study has several strengths: women were randomized at baseline, the patients' characteristics were similar across the four groups thus minimizing the risk of bias due to occult confounding factors, and the response rates to our questionnaires were relatively high (90%).

One of the limitations of this study is that the number of the participants allocated to each group was relatively small, thus limiting our ability to perform extensive post-hoc analyses. From 164 cases at baseline, the retention rate was 83.5% at 3 months and 82% at the 1-year follow-up. Another limitation is that due to ethical reasons, a non-treatment group was not included. Finally, in our study, the treatment protocol was confined to 3 months and the clinical evaluation was performed 4 years later. Life style modifications are hard to maintain, so it is possible that most of the patients were exposed to other unknown confounding factors.

Although this was not one of the aims of this study, our computerized medical administrative database showed that 54.2% of our women suffered from orthopedic problems and had physical treatment for musculoskeletal pain. It was described earlier that UUI symptoms are associated with reduced QOL, depression, self-reported impairment of lower extremity function, and falls.^{18–22} The association between orthopedic pain and the number of UUI episodes may represent the horrendous functional status of these women, and it certainly should be investigated and addressed in future studies.

CONCLUSIONS

Pelvic floor muscle training, bladder training, and behavioral advice provided by pelvic-floor physical therapists in four sessions over 3 months should be considered as the first line of treatment in women with wet-OAB. Long-term follow-up has shown that physical therapies reduced the number of voids per day, the number of UUI episodes per week, and improved the quality of life of these women. The long-term efficacy was equal to that of drug therapy.

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