ORIGINAL RESEARCH

# Physiotherapy for Persistent Postnatal Stress Urinary Incontinence: A Randomized Controlled Trial

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**OBJECTIVE: The aim of this study was to compare the effectiveness of multimodal supervised physiotherapy programs with the absence of treatment among women with persistent postnatal stress urinary incontinence.**

**METHODS: This was a single-blind randomized controlled trial. Sixty-four women with stress urinary incontinence were randomly assigned to 8 weeks of either multimodal pelvic floor rehabilitation (n = 21), multimodal pelvic floor rehabilitation with abdominal muscle training (n = 23), or control non–pelvic floor rehabilitation (n = 20). The primary outcome measure consisted of a modified 20-minute pad test. The secondary outcome measures included a Visual Analog Scale describing the perceived burden of incontinence, the Urogenital Distress Inventory, the Incontinence Impact Questionnaire, and pelvic floor muscle function measurements.**

**RESULTS: Two patients dropped out, leaving 62 for analysis. At follow-up, more than 70% of the women in the treatment groups (14/20 in the pelvic floor and 17/23 in the pelvic floor plus abdominal group) were continent on pad testing compared with 0% of women in the control group. Scores on the pad test, Visual Analog Scale, Urogenital Distress Inventory, and Incontinence Impact Questionnaire improved significantly in both treatment groups (all $P < .002$), whereas no changes were observed in the control group. Pelvic floor muscle function, however, did not improve significantly in either active group.**

**CONCLUSION: Multimodal supervised pelvic floor physiotherapy is an effective treatment for persistent postnatal stress urinary incontinence. (Obstet Gynecol 2004;104: 504–10. © 2004 by The American College of Obstetricians and Gynecologists.)**

**LEVEL OF EVIDENCE: I**

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Postnatal stress urinary incontinence is an important social and hygienic health problem affecting between 3% and 24% of adult women.[1,2] Those in whom stress urinary incontinence develops during pregnancy or puerperium without remission 3 months after delivery have a very high risk of symptom persistence 5 years later.[3] Pelvic floor muscle physiotherapy is generally recommended to reduce postnatal urinary incontinence. This therapy involves graded muscle training, either alone or in combination with biofeedback, electrical stimulation, and vaginal cones and is designed to rehabilitate and strengthen the pelvic floor muscle.[4] Although pelvic floor muscle physiotherapy after childbirth has proven effective in the prevention of urinary incontinence,[5–8] few trials have addressed the treatment of persistent postnatal stress urinary incontinence.[9,10] In addition, although these trials produced good results, the dropout rates were high (52% and 25%, respectively).[9,10]

Recent experimental data suggest that deep abdominal exercises may be used to improve the effect of a pelvic floor muscle rehabilitation program.[11,12] However, no clinical trial has evaluated their potentiating effects.

This article reports the results of a randomized controlled trial in which the primary objective was to assess the effectiveness of pelvic floor muscle physiotherapy programs in the treatment of persistent postnatal stress urinary incontinence. The secondary objective was to compare pelvic floor rehabilitation programs with and without deep abdominal muscle training in the treatment of persistent postnatal stress urinary incontinence.

## MATERIALS AND METHODS

Young parous women were recruited by means of a urinary incontinence questionnaire handed out at the



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obstetrics clinic of Sainte-Justine Hospital to patients during their annual gynecologic visit. If incontinence was reported, the women were screened by telephone to determine their eligibility. To be eligible, participants had to be younger than 45 years, premenopausal, still presenting symptoms of stress urinary incontinence at least once per week 3 months or more after their last delivery, and willing to participate in the study. Women who had experienced urinary incontinence before pregnancy, who had had previous surgery for stress incontinence, a neurologic or psychiatric disease, or a major medical condition, or those who were taking medication that could interfere with their evaluation or treatment were excluded. Current pregnancy and inability to understand French or English instructions were also causes for exclusion.

A total of 120 potential participants met the initial criteria. The local ethics committee approved the study and all participants provided their written informed consent to enrollment. The study was conducted between January 2001 and April 2003. Subjects were scheduled for evaluation by a gynecologist. Those with moderate to severe urogenital prolapse (Pelvic Organ Prolapse Quantification System stage II or higher)[13] were excluded. After remaining subjects emptied their bladders, the amount of residual urine was measured to exclude those with a high postvoid residual urine volume (more than 50 mL). The bladder was then refilled by catheter with 250 mL of sterile water at ambient room temperature. To confirm the diagnosis of stress urinary incontinence, subjects performed a 20-minute pad test, substituting 10 jumping jacks[14] for the standard jumping exercises.[15] Those with less than 5 g of leakage measured by the 20-minute pad test with fixed bladder volume were excluded. Urodynamic testing was then performed in the remaining candidates. Those with involuntary detrusor contraction on cystometry were excluded from the study.

Sixty-four women were randomly allocated to a pelvic floor rehabilitation group, a pelvic floor rehabilitation plus abdominal training group, or a control group. Stratified randomization was performed using a balanced block randomization schedule generated from a table of random numbers.[16] Because severity of incontinence and parity are factors that may affect the outcomes of treatment,[4] subjects were stratified into 4 groups according to the results of the pad test (5–10 g of urine loss and more than 10 g of leakage) and parity (primipara and multipara). The evaluators and clinicians involved with the treatment groups had no access to the randomization procedure. A research investigator who was not involved in any intervention or outcome assessment informed all participants of their group allocation, which was preestablished by the randomization schedule. The participants were asked not to disclose their group allocation to the evaluators.

Five physiotherapists were trained to conduct both standardized reeducation programs. The women in the pelvic floor rehabilitation group had weekly sessions under the supervision of an experienced physiotherapist for 8 consecutive weeks. Each session consisted of a 15-minute electrical stimulation of the pelvic floor muscle (stimulating-current characteristics: biphasic rectangular form; frequency 50 Hz; pulse width 250 microseconds; duty cycle, 6 seconds on and 18 seconds off for the first 4 weeks and 8 seconds on and 24 seconds off for the last 4 weeks; maximal tolerated current intensity[14]), followed by a 25-minute pelvic floor muscle exercise program with biofeedback, which included strengthening and motor relearning exercises,[17,18] and a home exercise program to be done 5 days per week.[17,18] The UROSTIM Unit (Laborie Medical Technologies, Brossard, Quebec, Canada) was used for the electrical stimulation and electromyographic biofeedback during the whole supervised treatment.

The women in the pelvic floor rehabilitation plus abdominal training group followed weekly sessions under the supervision of an experienced physiotherapist for 8 consecutive weeks. Each session consisted of the multimodal pelvic floor rehabilitation protocol described previously plus 30 minutes of deep abdominal muscle training consisting of isolation, reeducation, and functional retraining of the transversus abdominis.[19] Complete deep abdominal muscle training protocols are available from the first author.

The women in the control group had 8 weekly sessions of relaxation massage for the back and extremities performed by a physiotherapist. They were asked not to exercise their pelvic floor muscles at home during the study, but were offered the possibility of receiving a treatment at trial completion.

The primary outcome measure consisted of a modified 20-minute pad test with standardized bladder volume.[14] A nurse-assessor who was unaware of the treatment allocation of the participant administered the test twice, once during the initial evaluation and again the week after treatment ended. Participants with pad weight gains of less than 2 g were considered continent.[14]

The secondary outcome consisted of 4 different measures. The subject's perceived burden of incontinence was evaluated using a Visual Analog Scale (VAS) that proved to be valid, reproducible, and responsive to treatment for urinary incontinence in women.[20] Assessment of symptoms associated with incontinence was performed using a French version of the Urogenital Distress Inventory, a 19-item questionnaire about lower

urinary tract symptoms.[21] Assessment of the psychological impact of urinary incontinence was performed using the French Canadian version of the Incontinence Impact Questionnaire, 26 items focusing on daily living, social interaction, sex life, and self-perception.[22] Both questionnaires have acceptable levels of reliability, validity, and responsiveness and have been used in several clinical trials.[21–23]

Finally, pelvic floor maximum strength and rapidity of contraction were measured using a new static pelvic floor muscle dynamometer[24] designed to evaluate the pelvic floor muscle function. The psychometric properties of the measurements taken with the new device have been studied in young parous women in a large research program, which included an acceptability study, a test-retest reliability trial, and a construct validity study.[24–26] All secondary outcome measures were taken during the preintervention evaluation and during the postintervention evaluation the week after the intervention ended.

The sample size was initially set at 29 subjects per group. This sample size would provide 80% power to detect a statistically significant group by time interaction effect at the .05 significance level if the active treatments induced medium to large effect sizes. The expected effect sizes were based on a pilot study on physiotherapy for postnatal stress urinary incontinence, with urine loss on the pad test as the primary outcome measure.[13] In that study, we observed a difference in the pretreatment and posttreatment mean of the order of 0.60 standard deviation, which corresponds to a medium-to-large effect.[27]

Analysis was done on data from treated participants, excluding those without a final evaluation of the outcome variables. First, the experimental and control groups were compared for background (age, body mass index, parity, duration of symptoms) and outcome variables to determine the comparability of the groups at baseline. A nonparametric Kruskal-Wallis test was used because several outcome variables were not normally distributed and sample sizes were small. Pretreatment and posttreatment scores for primary and secondary outcome measures were compared to evaluate change in each of the three groups with the Wilcoxon signed rank test. Then, the change scores (pretreatment − posttreatment scores) for the experimental and control groups were compared to determine whether they varied between groups. The Kruskal-Wallis test was performed for this purpose. Finally, the Mann-Whitney test was used to detect differences between the control group and each experimental group and between each experimental group. Two-tailed $P$ values of .05 were considered statistically significant. All analyses were performed using SPSS 11.0 (SPSS Inc., Chicago, IL).

## RESULTS

The flow of participants through each stage of the randomized trial is presented in Figure 1. The characteristics of the three groups were comparable at baseline (Table 1). Furthermore, the outcome measures at baseline were not significantly different among the 3 groups (Table 2).

Pad test scores improved significantly ($P < .001$) in both the pelvic floor and the pelvic floor plus abdominal treatment groups but not in the control group ($P = .243$). More than 70% of the women in both treatment groups (14/20 in the pelvic floor group and 17/23 in the pelvic floor plus abdominal group) showed objective cure as defined by less than 2 g urine on the pad test, whereas none in the control group were cured (Fig. 2). Approximately 90% of the women in the active treatment groups showed a greater than 50% reduction in leakage compared with 10% among the women in the control group (Fig. 2). Scores on the VAS, Urogenital Distress Inventory, and the Incontinence Impact Questionnaire improved significantly (all $P < .002$) in both treatment groups but not in the control group (all $P > .589$). However, the pelvic floor muscle maximum strength and rapidity of contraction did not improve significantly in any of the 3 groups.

Statistical analyses comparing change scores among the 3 groups showed statistically significant results for all outcome measures (all $P < .028$) except the pelvic floor muscle function tests. In addition, there were statistically significant differences in scores on the pad test, VAS, Urogenital Distress Inventory, and Incontinence Impact Questionnaire in 2 compared groups: control versus pelvic floor (all $P < .019$) and control versus pelvic floor plus abdominal (all $P < .021$) (Table 3). No statistically significant difference in change scores was observed, however, for scores on the pad test, VAS, Urogenital Distress Inventory, and Incontinence Impact Questionnaire between the 2 treatment groups.

No adverse effects or difficulty using electrical stimulation were reported by the subjects of this study. Finally, the results of the intention-to-treat analyses were virtually the same as those of the treatment analysis for all outcomes.

## DISCUSSION

Multimodal supervised pelvic floor physiotherapy reduces persistent postnatal stress urinary incontinence. This study demonstrates that multimodal supervised pelvic floor physiotherapy programs are more effective than no treatment in parous women with persistent stress urinary incontinence. The choice of a control group in which no treatment was offered was made in terms of the population studied; namely, women with

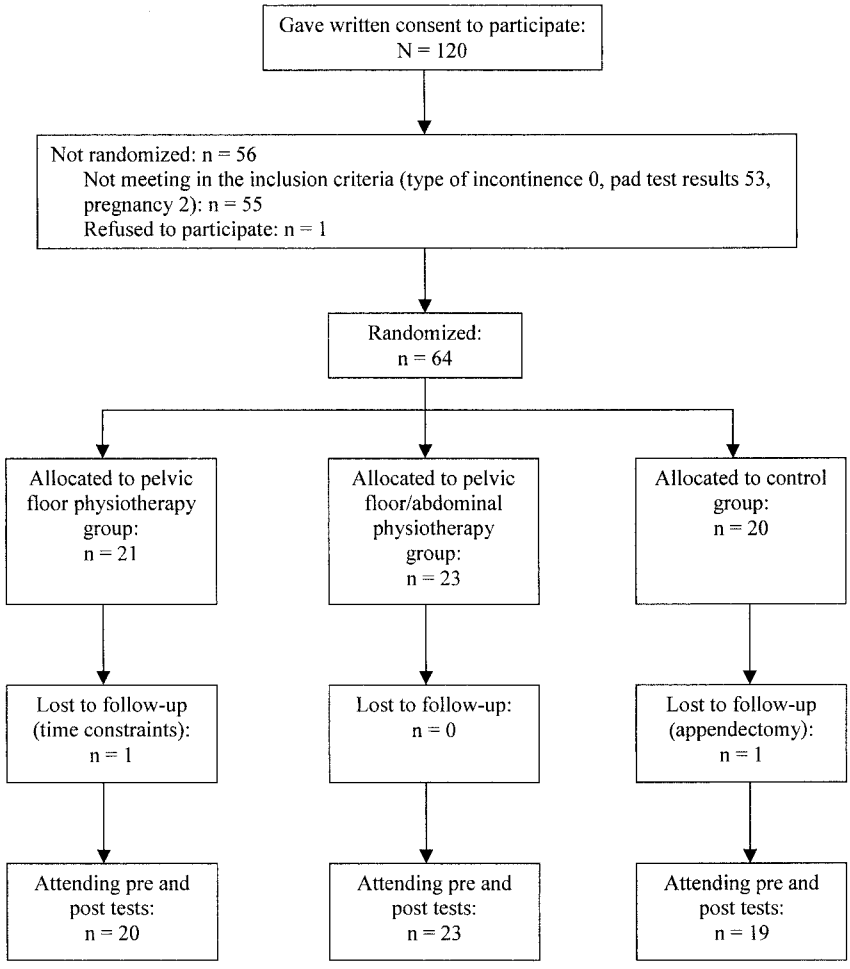


**Fig. 1.** Trial profiles showing the flow of participants through each stage of the randomized trial comparing trainings and control groups.

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persistent postnatal stress urinary incontinence 3 or more months after delivery who could show a spontaneous reduction of symptoms with time. By giving massage to the control group, we controlled for the response of subjects to the special attention they received from physiotherapists.

Our results corroborate those from the randomized controlled trials of Wilson and Herbison[9] and Glazener et al,[10] who reported that 7 and 9 months of pelvic floor rehabilitation significantly reduced persistent stress urinary incontinence. In-depth comparison between the results of the present study and those of the previous studies is difficult, because the training protocol and its duration differed among studies.

It is important to point out that marked objective and subjective improvement in continence status was observed after only 8 weeks of pelvic floor rehabilitation with high adherence to treatment. Our dropout rate was only 6% compared with 52% in Wilson and Herbison's study and 25% in Glazener et al's study. Interestingly,

**Table 1.** Background Characteristics at Baseline

| | Pelvic floor group (n = 20) | Pelvic floor plus abdominal group (n = 23) | Control group (n = 19) | *P** |
|---|---|---|---|---|
| Age (y) | 36.00 (23.25–39.00) | 37.00 (34.00–39.00) | 35.50 (33.75–38.25) | .802 |
| Body mass index (kg/m$^2$) | 24.20 (22.83–26.19) | 22.17 (20.62–24.15) | 24.32 (21.92–26.07) | .469 |
| Parity | 2.00 (2.00–3.00) | 2.00 (2.00–2.00) | 2.00 (1.00–3.00) | .995 |
| Duration of symptoms (mo) | 62.00 (31.00–78.50) | 51.00 (30.00–91.00) | 64.50 (32.25–100.25) | .545 |

Values are medians and 25th to 75th percentiles.

* Kruskal-Wallis test.

**Table 2.** Outcome Measures at Baseline

| | Pelvic floor group (n = 20) | Pelvic floor plus abdominal group (n = 23) | Control group (n = 19) | P* |
|---|---|---|---|---|
| Pad test (g) | 12.50 (7.00–26.75) | 20.00 (6.00–32.00) | 13.00 (8.75–42.25) | .870 |
| VAS (/10) | 8.00 (6.00–8.00) | 7.00 (4.75–8.00) | 7.00 (6.00–8.00) | .768 |
| Urogenital Distress Inventory (/57) | 12.00 (9.25–14.75) | 10.00 (7.00–15.00) | 10.00 (6.75–18.75) | .483 |
| Incontinence Impact Questionnaire (/90) | 25.50 (15.00–39.75) | 19.00(6.00–28.00) | 15.50 (9.00–31.00) | .173 |
| Pelvic floor muscle maximum strength (N) | 5.17 (4.24–7.80) | 5.12 (2.86–7.33) | 5.38 (2.90–8.28) | .952 |
| Maximum rate of force development (N/s) | 3.29 (1.69–5.03) | 3.44 (1.35–5.61) | 3.24 (2.68–6.75) | .636 |

VAS, Visual Analog Scale.
Data are presented as medians and 25th to 75th percentiles.
* Kruskal-Wallis test.

more than 30% of the withdrawals from Wilson and Herbison's study[9] were related to time constraints and work. It is possible that the much shorter intervention time and close supervision of the intervention by a trained physiotherapist in our study contributed to the patients' strong adherence to the treatment. We recognize, however, that the extent of symptom duration after delivery was somewhat different from that in the study by Wilson and Herbison and Glazener et al, which may also have contributed to the difference in dropout rates.

Many factors may have contributed to the marked objective and subjective improvement in continence status observed in a shorter period. First, pelvic floor muscle exercises conducted under the close supervision of a trained professional have proven more effective than pelvic floor exercises performed at home.[4] In addition, the present protocol, with the use of electrical stimulation, biofeedback in conjunction with pelvic floor muscle training, and timed pelvic floor contractions, may have contributed to rapid continence improvement. How-

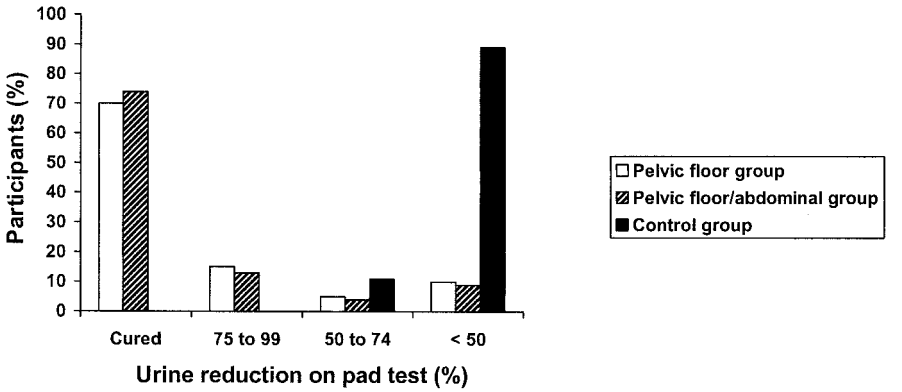


**Fig. 2.** Objective cure (less than 2 g of leakage on the pad test with standardized bladder volume) and percentage of reduction of urine after treatment.
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**Table 3.** Change of Scores in Outcome Measures From Baseline to After Treatment

| | Pelvic floor group (n = 20) | Pelvic floor plus abdominal group (n = 23) | Control group (n = 19) | P* |
|---|---|---|---|---|
| Pad test (g) | 8.00 (4.00–25.25) | 19.00 (6.00–25.00) | 0.00†‡ (−3.00 to 9.75) | .000 |
| VAS (/10) | 2.50 (0.75–5.0) | 3.00 (2.00–4.00) | 0.00†‡ (−0.05 to 0.02) | .000 |
| Urogenital Distress Inventory (/57) | 7.00 (3.00–8.00) | 4.00 (1.00–10.00) | 0.00†‡ (−2.25 to 6.50) | .027 |
| Incontinence Impact Questionnaire (/90) | 13.00 (6.00–25.00) | 10.00 (2.00–16.00) | 0.50†‡ (−6.50 to 5.00) | .000 |
| Pelvic floor muscle maximum strength (N) | 0.49 (−0.58 to 2.54) | 0.69 (0.24–2.34) | −0.48 (−1.68 to 1.00) | .109 |
| Maximum rate of force development (N/s) | 0.31 (−1.11 to 1.93) | 0.82 (−1.05 to 2.92) | −0.46 (−2.05 to 0.76) | .213 |

VAS, Visual Analog Scale.
Data are presented as medians and 25th to 75th percentiles.
* Kruskal-Wallis test.
† Significantly different from pelvic floor group at the 5% level (Mann-Whitney test).
‡ Significantly different from pelvic floor plus abdominal group at the 5% level (Mann-Whitney test).

ever, the relative contribution of each factor cannot be determined in our study. Whether these results will translate into long-term cure or improvement of persistent posturinary stress incontinence is unknown at this point.

Although the objective and subjective continence outcomes improved significantly after implementation of both pelvic floor rehabilitation programs, it appears that these effects are not related directly to changes in the pelvic floor muscle function. Factors other than strength and rapidity of contraction may have contributed to continence. Motor learning phenomena not related to change in maximal strength, such as better timing of the pelvic floor contraction and increased perception of pelvic muscle contraction encouraged by the present rehabilitation protocol, may have contributed to the rapid change in continence status. Nonetheless, the results do not exclude the possibility that the small sample size in this study (n = 20, n = 23, and n = 19) was a limiting factor and that any nonsignificant results may be due to type II errors. A larger sample size would be needed to make a good pelvic floor muscle function comparison between groups.

Finally, the present results suggest that the addition of abdominal training does not further improve the outcome of pelvic floor muscle rehabilitation. Although we were unable to recruit 29 subjects per group as planned initially, the improvement in the pelvic floor group as measured by the pad test was higher than expected, making additional improvement in the pelvic floor rehabilitation plus abdominal training group virtually undetectable and clinically nonsignificant.

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