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# PREVENTION OF POSTNATAL URINARY INCONTINENCE BY ANTENATAL PELVIC FLOOR MUSCLE EXERCISES, SECONDARY PER PROTOCOL ANALYSIS OF THE 3PN (PRENATAL PELVIC FLOOR PREVENTION) RANDOMIZED TRIAL.

Hypothesis / aims of study

Pelvic floor muscle training during first pregnancy has been shown in five previous randomized trials to be effective in the prevention of urinary incontinence in the immediate postpartum period [1,2,3]. However, several months after delivery it seems that the preventive effect disappears.

The main objective of the randomized 3PN (PreNatal Pelvic floor Prevention) trial was to compare antenatal pelvic floor rehabilitation versus written instructions alone on the severity of urinary incontinence at 12 months postpartum in a population of nulliparous women carrying an uncomplicated singleton pregnancy. Our first results of the intention- to-treat (ITT) analysis were presented at the last ICS congress (2012). We did not find any significant effect on the various endpoints of pelvic floor muscle training during pregnancy.

The main objective of this secondary analysis was to determine whether or not there was an effect on urinary incontinence when comparing women who actually received antenatal pelvic floor muscle training and women who received only written instructions (per protocol analysis).

Study design, materials and methods

This was a multicenter, randomized, controlled, single-blind study in two parallel groups: antenatal pelvic floor muscle training versus written information alone. The inclusion visit was made from the fifth month of pregnancy. Therapy sessions were conducted between the 6th and 8th month of pregnancy by a skilled health professional (physiotherapist or mid-wife). Each session lasted 20 to 30 minutes, vaginal palpation was used to manage and teach pelvic floor contractions lying down (10 minutes) and standing (5 minutes), women were encouraged to perform voluntary pelvic floor muscle contraction in conjunction with rises in intra-abdominal pressure such as coughing or sneezing, the therapy sessions were repeated once a week for 8 weeks.

Written information was delivered in the 2 groups, it explained how to perform a series of 10 to 20 pelvic floor muscle (PFM) contractions daily. PFM were encouraged at home in both groups.

A questionnaire was administered at the end of pregnancy, two months and 12 months after delivery. The primary endpoint is the score of the ICIQ-UI SF (International Consultation on Incontinence Questionnaire, Urinary Incontinence, Short Form).

The study included 282 pregnant women between November 2007 and June 2009 (140 in the prenatal pelvic floor training group and 142 in the control group). Women who actually received the intervention provided by the protocol were 116 for the therapy group (including 97 who completed the 8 sessions) and 141 for the written information alone group. Our analysis was focused on these 257 women (116+141). We examined whether there were differences in late pregnancy, 2 months and 12 months postpartum between the two groups for urinary incontinence (UI) defined as a score ICIQ-UI SF> 0 and severity of UI measured by the ICIQ-UI SF score.

The analyses were unmatched and matched. In the therapy group we compared the outcome of women who completed all sessions versus those who did not.

Results

We did not find any difference at different visits (late pregnancy, two months postpartum, and 12 months postpartum) for urinary incontinence (Table 1).

Matched analysis (urinary incontinence inclusion / urinary incontinence at 12 months postpartum) is in favor of the rehabilitation group but the difference was not significant (Table 2). Matched analysis of the change in the severity of urinary incontinence as measured by the ICIQ-UI SF score showed no significant difference in late pregnancy (difference between scores at baseline and at the end of pregnancy), 2 months postpartum (difference between the score at baseline and at 2 months postpartum), and 12 months postpartum (difference between the score at baseline and at 12 months postpartum).

Table 1: Results of 3PN (PreNatal Pelvic floor Prevention) trial, analysis per protocol

| Urinary incontinence (UI) | Pelvic Floor Training 116 | Control 141 | p |
|---|---|---|---|
| End of pregnancy | | | |
| UI (ICIQ-UI SF score>0), % (n/N) | 44.2 (46/104) | 45.0 (49/109) | 0.92 |
| ICIQ-UI SF score, median (min-max) | 0 (0-14) | 0 (0-16) | 0.76 |
| 2 months postpartum | | | |
| UI (ICIQ-UI SF score>0), % (n/N) | 35.1 (34/97) | 39.0 (41/105) | 0.56 |
| ICIQ-UI SF score, median (min-max) | 0 (0-15) | 0 (0-16) | 0.30 |
| 12 months postpartum | | | |
| UI (ICIQ-SF score>0), % (n/N) | 30.9 (25/81) | 38.9 (37/95) | 0.26 |
| ICIQ-SF score, median (min-max) | 0 (0-19) | 0 (0-18) | 0.28 |

Table 2: Per protocol matched analysis UI at baseline and 12 months postpartum

| Urinary Incontinence | | Pelvic Floor Training | Control |
|---|---|---|---|
| Baseline | 12 mois postpartum | % (n) | % (n) |
| No | No | 51.9 (41) | 48.9 (45) |
| No | Yes | 13.9 (11) | 13.0 (12) |
| Yes | No | 17.7 (14) | 12.0 (11) |
| Yes | Yes | 16.5 (13) | 26.1 (24) |

The frequency of home PFM exercises, the duration of each exercise, and the number of contractions performed at each PFM exercise were reported similarly (no significant difference) in the rehabilitation and the control group in late pregnancy and 12 months postpartum.
In the rehabilitation group we did not find any difference for urinary incontinence in late pregnancy, 2 months, and 12 months postpartum depending on the number of sessions completed (completion of all sessions versus non-completion).

Interpretation of results

We have not reproduced the positive results of five previous trials [1]. The main differences with previous trials that could explain these negative results are related to the intervention in the control group and in the rehabilitation group. In our multicenter study, many caregivers participated in rehabilitation while in the 2 major previous studies [2,3] this number was limited (1 and 5 respectively). The duration of therapy program (8 weeks) or duration of each therapy session (20-30 minutes) were slightly shorter than in the 5 previous trials (8 to 12 weeks and 30 to 60 minutes) [1,2,3] . We chose written instructions in the control group while they were verbal in four previous studies (note that in the fifth study, the women in this group were asked not to exercise).
In our study, it would appear that having been sensitized to continence promotion by either their inclusion in our study or after having received written instructions, the women in both the pelvic floor training group and the control group had practiced PFM exercises.
Our negative results could be explained either by the effectiveness of the written instructions and by a lower intensity rehabilitation program.

Concluding message

The pelvic floor rehabilitation program taught by health professionals and used in our study failed to show superiority over written information in prevention of urinary incontinence during pregnancy and the first year postpartum.

References

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Disclosures

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