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PREVENT POSTNATAL URINARY INCONTINENCE BY PRENATAL PELVIC FLOOR MUSCLE TRAINING? FIRST RESULTS OF THE MULTICENTER RANDOMIZED STUDY 3PN, PRENATAL PELVIC FLOOR PREVENTION.

Hypothesis / aims of study

Urinary incontinence (UI) is a frequent trouble in women. UI onset occurs often during pregnancy or postpartum. UI prevalence is maximal during pregnancy with 30-50% women concerned [1]. Pelvic floor muscle training is offered for several years for prevention or treatment of urinary disorders in pregnancy and postpartum. It is usual to advise pregnant women to do "exercises of contraction of the perineum" during their pregnancy to avoid incontinence. Our main objective was to compare prenatal pelvic floor muscle training to written instructions only to prevent postpartum UI.

Study design, materials and methods

This was a multicenter randomized controlled single-blind in two parallel groups: prenatal pelvic floor muscle training versus written information only. The inclusion visit was performed from the fifth month of pregnancy. Inclusion concerned nulliparous women carrying an uncomplicated singleton pregnancy with or without UI. The eight standardised pelvic floor muscle training sessions were conducted between the 6th and 8th month of pregnancy. Each session was supervised by a trained health care professional (mid-wife or physiotherapist) and took 20 to 30 minutes. Personal pelvic floor contractions were encouraged. Written instructions (delivered to the pelvic floor training group and to the control group) give information about UI and how performing pelvic floor contractions. Questionnaires were administered at ninth month of pregnancy, 2 months and 12 months after delivery. We used the ICIQ-SF (International Consultation on Incontinence Questionnaire Short Form), it is the primary endpoint, the Baessler Female Pelvic Floor Questionnaire (FPFQ) that addressed urinary and pelvic floor symptoms. Quality of life was assessed using the Contilife questionnaire and EuroQoL-5D. To show at 12 months postpartum a 1-point difference on the score of incontinence (ICIQ-SF) we need 182 subjects (sd = 2.4, $\alpha = 0.05$, $\beta = 0.20$ and a bilateral formulation). Because of loss of follow-up (estimated at 1/3) it was planned to include 280 women.

Results

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). Their average age was 28.6 years (18-4-48,2) at enrolment. We received 223 responses (79.1%) for late pregnancy questionnaire, 212 (75.2%) 2 months postpartum and 184 (65.2%) 12 months postpartum. The characteristics of women were not different according to the randomization group (Table 1).

Table 1: Characteristics of women included during their first pregnancy

Groups	Pelvic Floor Training	Control	
N	140	142	
Characteristics	% (n/N) / mean (sd; N)		p
Baseline			
UI (ICIQ-SF score>0)	37,88 (50/132)	37,31 (50/134)	1
ICIQ-SF score	2,5 (3,9 ; 132)	2,6 (3,8 ; 134)	0,89
FPFQ urinary score	1,6 (1,3 : 132)	1,6 (1,4 ; 133)	0,55
Pad-test	1,3 (1,9 ; 112)	1,8 (5,5 ; 117)	0,67
QoL-Contilife score	9,3 (1,0 ; 128)	9,3 (1,0 ; 130)	0,57
EuroQoL-5D	78,8 (21,1 ; 131)	77,9 (20,7 ; 133)	0,54
Delivery			
Cesarean section before labor	8,0 (11/137)	8,1 (11/135)	0,56
Cesarean section during labor	18,2 (25/137)	12,6 (17/135)	
Spontaneous vaginal delivery	52,6 (72/137)	53,3 (72/135)	
Instrumental delivery	21,2 (29/137)	25,9 (35/135)	

The UI prevalence defined by a score of ICIQ-SF> 0 was 37.59% at baseline, 44.80% in late pregnancy, 36.19% at two months postpartum and 35.91% at one year of childbirth. There were no significant differences by randomization group in late pregnancy, at 2 months postpartum and at endpoint on the score of the ICIQ-SF and the other secondary endpoints except the generic quality of life to 12 months (Table 2). Performing personal pelvic floor exercises in late pregnancy was similar in both groups (number of exercises, duration, and number of contractions).

Table 2: Results, 12 months postpartum

Groups	Pelvic Floor Training	Control	
N	140	142	
Characteristics	% (n/N) / mean (sd; N)		p
	Late pregnancy		
IU (ICIQ-SF score>0)	45,05 (50/111)	44,55 (49/110)	1
ICIQ-SF score	2,8 (3,7 ; 111)	3,0 (4,0 ; 110)	0,95
FPFQ urinary score	1,7 (1,3 : 111)	2,0 (1,4 ; 111)	0,09
QoL-Contilife score	9,3 (1,1 ; 107)	9,2 (1,3 ; 108)	0,58
EuroQol5D	76,4 (20,5 ; 110)	77,9 (16,3 ; 112)	0,91
	2 months postpartum		
UI (ICIQ-SF score>0)	33,65 (35/104)	38,68 (41/106)	0,48
ICIQ-SF score	1,7 (2,9 ; 104)	2,3 (3,4 ; 106)	0,24
Pad-test	0,9 (1,6 ; 78)	1,3 (3,3 ; 85)	0,93
FPFQ urinary score	0,8 (0,9 : 105)	0,9 (1,0 ; 107)	0,48
QoL-Contilife score	9,6 (0,8 ; 102)	9,5 (0,8 ; 101)	0,06
EuroQol5D	82,6 (18,2 ; 105)	80,4 (17,0 ; 107)	0,13
	12 months postpartum		
UI (ICIQ-SF score>0)	32,18 (28/87)	39,36 (37/94)	0,35
ICIQ-SF score	1,8 (3,3 ; 87)	2,2 (3,3 ; 94)	0,30
FPFQ urinary score	0,9 (0,9 ; 89)	1,0 (1,1 ; 94)	0,76
QoL-Contilife score	9,6 (0,9 ; 84)	9,5 (1,0 ; 87)	0,09
Medical visits since delivery	2,9 (2,3 ; 80)	3,0 (2,2 ; 81)	0,48
EuroQol-5D	86,8 (13,0 ; 90)	82,8 (14,8 ; 94)	0,04

Interpretation of results

Unlike previous similar trials [1,2,3] the results of our randomized antenatal pelvic floor muscle training versus written instructions alone is negative. In our study, prenatal pelvic floor muscle training supervised by a health care professional is not associated with significant less urinary incontinence during pregnancy or postpartum.

The UI prevalence observed is consistent with what was expected, however, the variance of the ICIQ-SF score is greater than what was expected so that the available power is lower than expected. It also seems to be a contamination between pelvic floor training group and control group; women sensitized by preventing urinary leakage due to their inclusion in the study have practiced exercises in both groups.

Concluding message

Prenatal pelvic floor training with a health care professional is not effective to prevent postnatal urinary incontinence.

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