Postpartum pelvic organ prolapse and pelvic floor muscle training Results from a randomized controlled trial of primiparous women

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Abstract

Objectives To study effects of physiotherapist-guided pelvic floor muscle training on pelvic organ prolapse (POP) early postpartum period. Design Assessor-blinded, randomized controlled trial. Setting Physiotherapy Clinic, Reykjavik. Sample Eighty-four primiparous women with a singleton delivery. Methods Participants were screened for eligibility 6-13 weeks postpartum. Women randomized to the training group conducted 12 weekly individual sessions with a physiotherapist, starting on average 9 weeks after childbirth. Outcomes were assessed after the last session (short-term) and at 12 months postpartum (long-term). The control group received no instructions after the initial assessment. Main outcome measures Self-evaluated POP symptoms by the Australian Pelvic Floor Questionnaire. Results Forty-one and 43 women were randomized to the training and control groups, respectively. At recruitment, 17 (42.5%) of the training and 15 (37%) of the control group reported prolapse symptoms (p=0.6). Five (13%) from the training and 9 (21%) controls were bothered by the symptoms (p=0.3). There was a gradual decrease in the number of women with symptoms and no significant short-term (p=0.08 at 6 months) or long-term (p=0.6 at 12 months) differences between the groups regarding rates of women with POP sympoms. No difference was between groups regarding bother in the short (p=0.3) or longer term (p=0.4). Repeated measure analyses using Proc Genmod in SAS did not indicate a significant effect of the intervention over time, p>0.05. Conclusions There was an overall decrease in postpartum symptoms of POP and bother during the first year. Physiotherapist-lead pelvic floor muscle training did not change the outcomes.

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Self-evaluated POP symptoms by the Australian Pelvic Floor Questionnaire.

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Forty-one and 43 women were randomized to the training and control groups, respectively. At recruitment, 17 (42.5%) of the training and 15 (37%) of the control group reported prolapse symptoms (p=0.6). Five (13%) from the training and 9 (21%) controls were bothered by the symptoms (p=0.3).

There was a gradual decrease in the number of women with symptoms and no significant short-term (p=0.08 at 6 months) or long-term (p=0.6 at 12 months) differences between the groups regarding rates of women with POP sympoms. No difference was between groups regarding bother in the short (p=0.3) or longer term (p=0.4). Repeated measure analyses using Proc Genmod in SAS did not indicate a significant effect of the intervention over time, p>0.05.

Conclusions

There was an overall decrease in postpartum symptoms of POP and bother during the first year. Physiotherapist-lead pelvic floor muscle training did not change the outcomes.

Tweetable abstract (up to 110 letters)

An RCT showed that 12 weeks of supervised early postpartum PFMT did not influence POP symptoms up to 12 months postpartum.

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Key words

Pelvic floor muscle training, pelvic floor muscles, pelvic organ prolapse, physiotherapy, postpartum, primiparity, quality of life.

Abbreviations

AI, anal incontinence; APFQ, Australian Pelvic Floor Questionnaire; CG, control group;

CI, confidence interval; PFD, pelvic floor dysfunction; PFM, pelvic floor muscles; PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; CS, cesarean section; RCT, randomized controlled trial; SD, standard deviation; TG, training group; UI, urinary incontinence; VD, vaginal delivery.

Introduction

Pelvic organ prolapse (POP) is a distressing and common symptom in the female population and has been reported in up to 10% of the adult female population when based on a bulging sensation into the vagina.[1] However, the prevalence of anatomic POP is higher; a population-based study which included pelvic examinations showed a prevalence of 31% among women aged 20-59.[2]POP is defined as a loss of support for the vaginal walls, the uterus, bladder, colon and rectum resulting in partial or complete prolapse of the affected organs coming down or through the vagina.[3] The prevalence of POP in the early postpartum period is sparsely investigated. According to Reimers et al,[4] anatomic POP stages [?]2 were found in 9% of primiparous women six weeks postpartum with no significant difference between women after vaginal delivery (VD) or cesarean section (CS). In another study evaluating anatomic POP in primiparous women at 5-22 weeks postpartum stage 2 POP was noted in 35.5% of the women, of whom 7.6% had this after CS vs. 43% for VD .[5] We recently showed an overall prevalence of self-reported POP symptoms 6-10 weeks after first childbirth of 29%, thereof 33% in the VD- and 12% in the CS groups.[6] POP symptoms in the immediate postpartum period have been found to be related to pre-labor maternal characteristics, such as a larger levator hiatal area, a longer distance from the urethral meatus to the anus and a more caudal position of the anterior vaginal wall at mid-pregnancy.[4] Later in life, POP has also been associated with a low body mass index, higher parity, higher birthweights, operative and instrumental VD, levator ani trauma and constipation.[7–10]

The International Consultation on Incontinence concluded that there is 1A level of evidence for pelvic floor muscle training (PFMT) to be useful as first line treatment for POP stages I-III in the general population.[11] However, there is scant knowledge on the effects of PFMT in the early postpartum period. In a systematic review and meta-analysis outcomes with regard to postpartum POP symptoms have been reported.[12] The authors concluded that quality of evidence was low for the primary outcome of POP symptoms, and that the question of whether postpartum PFMT has a beneficial effect on POP symptoms remains unanswered. The aim of this study was to evaluate the effects of individualized, postpartum physiotherapist-guided PFMT on the rate of symptomatic POP and perceived bother.

Materials and methods

Study design

This was a secondary analysis of a parallel-group, assessor-blinded randomized controlled trial (RCT) with the primary aim of examining the effects of postpartum PFMT on the rate of postpartum urinary incontinence (UI) and anal incontinence (AI) in primiparous women.[13] The trial was carried out at a Physiotherapy Clinic in the Reykjavik Capital Area, from March 2016 to January 2018. Baseline assessments and background data of participants were obtained at recruitment 9 weeks postpartum (range 6-13 weeks). Short-term outcomes were completed at the end of treatment at around 6 months (range 5-7), and long-term outcomes were investigated at 12 months (range 11-14) postpartum.

The study was approved by the Icelandic National Bioethics Committee (Ref: VSN-13-189), the Icelandic Data Protection Authority (Ref: 2014030475TS/–) and registered at https://register.clinicaltrials.gov (NCT02682212). The study was conducted according to the Helsinki declaration on human experimentation. All participants provided a signed informed consent. Delivery and maternal data were obtained from the Icelandic Medical Birth Register.

Participants and randomization

Through 2016 and 2017, primiparous women with one live newborn were approached before discharge from the maternity ward of the Landspitali University Hospital in Reykjavik. Women who approved were sent an electronic questionnaire through e-mail about their experiences of pelvic floor dysfunction (PFD) 6-10 weeks postpartum.[6]Of all the women who answered the questionnaire, 95 were invited to participate in an RCT.[13] Eligibility criteria were established for that study, i.e. the presence of self-reported postpartum symptoms of UI. The women had to be generally healthy, aged [?]18 years, able to understand Icelandic and to attend the treatment sessions. Women with a multiple birth, a gestaional length of <32 weeks, a stillbirth or an unwell newborn or those who otherwise had conditions that could interfere with their ability to participate were excluded (inability to contract their pelvic floor muscles (PFM), neurological conditions, previous urogynecological and/or bowel surgery or cognitive disorders). The main outcome assessor (T.S.) evaluated participants initially and before randomization at an outpatient physiotherapy clinic.

At baseline, all the women received instructions about how to correctly contract their PFM, which was confirmed with an observation and vaginal palpation of PFM contractions defined as an inward movement of the perineum and a squeeze around the pelvic openings.[14–16] Subsequently, measurements of PFM variables were done with a vaginal manometer, the Myomed 932 (Enraf Nonius, Netherlands). The results have been reported elsewhere.[13] Following this clinical assessment, the clinics' secretary allocated participants to either a training group (TG) or a control group (CG) using conceiled random sequence numbers from an on-line generator (https://stattrek.com/statistics/random-number-generator.aspx). The Microsoft Excel document containing the randomization code was locked with a password and only accessible to the secretary. She was responsible for booking participants for the short-term and long-term appointments.

Outcome measures

In the present study we aimed to examine the effects of PFMT on rates of POP symptoms as well as bother from symptoms, as assessed by the Australian Pelvic Floor Questionnaire[17,18] (APFQ, Icelandic translation). The questionnaire had previously been rigorously translated and pre-tested,[19] but not validated.

POP was evaluated by the questions "Do you have a sensation of tissue protrusion or a lump or bulging in your vagina¿' and "Do you experience vaginal pressure or heaviness or a dragging sensation¿' Women were considered to have no sympoms if the they answered ,,never" to both questions. Answers of ,,occasionally", ,,frequently" and ,,daily" were considered signs of POP. Bother is a concept used in the APFQ and can in general be defined as trouble, nuisance, worry or something annoying. Bother was considered absent when the answer to the question ,,How much does your prolapse problem bother you¿' was "not at all". Answers of "slightly, moderately and greatly" were considered as bother. According to this approach, data were analyzed as categorical, 0 = no symptoms or no bother and 1 = signs of symptoms and/or of bother.

Intervention

The intervention entailed 12 sessions with a duration of 45-60 minutes for each visit. The exercise period lasted on average 3.7 (range 2.6-6.7) months. The participants met weekly with a physiotherapist. If they cancelled, a new appointment was given in order to accomplish 12 sessions.

The NeuroTrack Simplex(r) biofeedback device with electromyographic vaginal sensors (Quintet, Norway) was used to facilitate the PFMT. Treatment was customized to each woman's capacity within a protocol encouraging 10 close to maximum contractions and 5 second holding periods with a 10 second rest between each contraction. During the first two appointments women were coached to do two exercise sets during every visit with a rest in between and thereafter 3 x 10 contractions if possible. The participants used the biofeedback device to aid progress and to help with relaxation between each contraction. During visits 8-9, the women were asked to add three fast contractions at the end of each contraction and do so in the remaining sessions.[20]

Women in the TG were asked to do home exercises of 10 close-to-maximum PFM contractions, three sets/day and use the ,,knack" (pre-contracting the PFM before coughing and sneezing).[21] They were encouraged to adhere to the home training program and to register daily exercises in a training diary. During each visit they were encouraged to adhere to the home exercises.

The short-term evaluation was done within a week after the last training session. Long-term assessment was one year after childbirth. At both time-points women answered the APFQ. During the long-term appointment participants also answered a questionnaire about PFMT adherence. The CG women had no further follow-up after recruitment, which included general instructions and assessment of PFM contractions, but they were not discouraged from doing PFM exercises. The main assessor was blinded to group allocation throughout the study.

Sample size calculation

Sample size was estimated for the primary study on UI and AI[13] and was based on outcomes from a previous study.[20] No further power calculation regarding POP symptoms was conducted for the present study.

Statistical analysis

We used SPSS, version 24 (IBM, Armonk, NY, USA) for all statistical analysis except for the repeated measure analyses by Proc Genmod which was done in SAS version 9.2. Normally distributed continuous variables are presented as means with standard deviations (SDs). Other participants characteristics are reported as counts with percentages. Rates of POP and bother were analyzed with chi-squared tests. The study was analyzed by intention-to-treat. Additional per-protocol analysis was done. Significance levels were set to 0.05.

Results

In all, 84 Caucasian women entered the study, 41 to the training group and 43 controls, with the initial session occurring at a mean 9 weeks postpartum (range 6-13 weeks). Baseline characteristics are shown in Table 1. Four women (three from the TG) withdrew after the initial evaluation (Figure 1). Characteristics and delivery outcomes did not differ between participating and non-participating women except that women who dropped out were slightly younger and had smaller babies. Five women did not participate in any of the training sessions or did any home PFMT but contributed to the main outcome measures. All 33/41 women who attended the intervention completed all 12 sessions with the physiotherapist. No adverse treatment-effects were reported.

Short-term outcome measures

At recruitment 17/40 (42.5%) and 15/41 (37%) women in the TG and CG respectively reported POP symptoms (p=0.6). Short-term (6 months postpartum) and long-term (12 months postpartum) results of POP are shown in Table 2.

There were no differences in POP rates between the groups measured at 6 months postpartum leaving 8/36

in the TG and 3/38 from the CG symptomatic (p=0.08). There were no significant differences between groups in the rates of women who were bothered by POP symptoms at short-term with five TG women at both timepoints being bothered by POP, but reduced from nine to one woman being bothered in the CG (p=0.08).

Long-term outcomes

POP rates at 12 months after childbirth revealed no difference between the groups, with 4/38 from the TG and 6/42 from the CG still symptomatic (p=0.6). There were no differences regarding the rates of women bothered by symptoms in the TG and CG respectively, leaving 1/37 and 3/42 in the TG vs. CG bothered by POP symptoms (p=0.4).

Repeated measure analyses using Proc Genmod in SAS did not indicate a significant effect of the intervention over time, p>0.05. Analysis per-protocol did not change the outcomes.

Discussion

Main findings

POP symptoms were overall reduced considerably in this group of first-time mothers during the postpartum year, and the feelings of bother were in general mild and not common. This is in line with the results from a cohort study by Reimers et al (2016) which showed good recovery of POP symptoms in primiparous women during the first year postpartum.[22]

Limited data from RCTs are available regarding the treatment effects of PFMT for POP symptoms in the postpartum period despite the wide practice of advising and providing such treatment. Bo et al (2015) did not find improvements for POP symptoms when assessing the effect of a 4-month group-lead PFMT at 6 months postpartum. However, that study included women with diagnosed major levator ani tears which might have reduced the odds for improvement.[23] Yang et al (2013) found significant differences in postpartum POP stages in favour of the two training groups when measured at three months postpartum, where one group included PFMT and the other involved PFMT combined with vaginal electrical stimulation. The combination treatment was superior to PFMT alone when compared to a control group.[24] Both studies had larger sample sizes than our study. A Chinese RCT with only the abstract available in English disclosed positive results regarding postpartum POP symptoms after PFMT with biofeedback combined with electrical stimulation when measured 12 weeks postpartum.[25]

It is, however, difficult to evaluate the information given with regard to how the treatment was conducted. Pelvic floor electrical stimulation can provoke the muscles to contract as well as produce responses from the central nervous system, i.e. increase the awareness of the muscle contractions which could be important for women with a weak PFM.[26–28] However, use of electrical stimulation can be questioned in the early postpartum period and when women are breast-feeding. Low levels of estrogen and thinning of the vaginal mucosa may make electrical stimulation painful. To date, the evidence indicates that in the general female population electrical stimulation of the pelvic floor muscles is better than no treatment, but the low quality of published studies on the matter prevents conclusions when comparing PFMT and electrical stimulation in treatment of UI.[27]

In our study, symptoms were in general benign and women may well have had difficulties in distinguishing between never or occasionally (less than once a week). Women in the TG might also have been more aware of their symptoms during the intervention period as a result of the weekly contacts with a women's health physiotherapist. Conversely, with no contact to treatment providers, women in the CG could have considered themselves as less symptomatic.

The steady decrease in the number of women with symptoms in the TG from recruitment to one year after childbirth did, however, follow a measured increase in PFM strength during the study period. As previously reported, this improvement was significantly better in the TG.[13] The low number of symptomatic women at 6 months postpartum in the CG seems to be an incongruity when looking at the development of symptoms.

Adherence to PFM exercises at home which was encouraged by the physiotherapists for the participants in the TG during the study period has been published in an article reporting the effect of PFMT on postpartum UI and AI.[13] Adherence was in general poor, especially during the latter half of the year which may have influenced the results.

Strengths and limitations

Strengths of the study were the randomized and assessor-blinded design, concealed allocation, a supervised individually tailored program for each participant aiming at treating the symptoms and high adherence to the exercise sessions. Following the participants for one year should also be considered a strength, as long term results are lacking in published studies.[12]

Limitations were the higher drop-out rate in the TG and the low number of women reporting prolapse symptoms in both groups which may have caused a type II error due to small sample size. Five women who were randomized to the TG and contributed to the main outcomes did not participate in the intervention, which also might have influenced the results. The adherence to PFMT after cessation of the intervention is also a limitation of the study.

Interpretation

Our results confer with results from the few other RCTs evaluating effect of PFMT in reduction of POP stage and symptoms in the postpartum period.[12] To date, all studies reported POP as secondary analyses and not all women included in the studies had POP. This may explain the negative results as well as the fact that the studies were conducted in the early postpartum period. Studies indicate that POP symptoms improve for the majority of primiparous women during the first postpartum year.[22,24] Therefore, to enhance our knowledge on the influences of PFMT on postpartum POP symptoms, it might be interesting to conduct an RCT later postpartum, e.g. one year after birth for women who are still symptomatic.

Conclusions

Postpartum symptoms of pelvic organ prolapse and bother decreased during the first year for both controls and exercisers with no difference between the PFMT and the control groups.

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Disclosure of Interest:

The authors report no conflict of interest.

Contribution to Authorship:

Physiotherapist Thorgerdur Sigurdardottir PhD contributed to the design, execution, analysis and interpretation of the study. Obstetricians/gynecologists Thora Steingrimsdottir MD, PhD and Reynir T. Geirsson MD, PhD, FRCOG and Prof. Kari Bo PhD contributed to the design, execution, analysis and interpretation of the study, while statisticians Thorhallur Halldorsson PhD and Thor Aspelund PhD contributed to the design and analysis of the material. All authors have contributed to the writing of the manuscript.

Clinical trial registration:

The trial was registered 30th of March 2015 at https://register.clinicaltrials.gov (NCT02682212). Initial participant enrolment was 16th of March 2016 and reported following CONSORT guidelines for RCTs.

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Figure/table caption list

Figure 1

CONSORT flow diagram of participants.

Table 1

Characteristics of included participants at recruitment and delivery outcomes.

Table 2

Outcome measures at recruitment, short-term (6 months postpartum) and long-term (12 months postpartum).

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