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Title Twelve year follow up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial

Short title: 12 year follow up: RCT for postnatal pelvic floor dysfunction

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STRUCTURED ABSTRACT

Objective

To determine the long-term (12-year) effects of a conservative nurse-led intervention for postnatal urinary incontinence.

Design

Follow-up of randomised controlled trial.

Setting

Community-based intervention in three centres (UK and New Zealand).

Population

747 women with urinary incontinence at three months after childbirth, of whom 471 (63%) were followed up at 12 years.

Methods

Women were randomly allocated to active conservative treatment (pelvic floor muscle training and bladder training) after delivery, or a control group receiving standard care.

Main outcome measures

Prevalence of urinary incontinence (primary outcome) and faecal incontinence, symptoms and signs of prolapse, and performance of pelvic floor muscle training at 12 years.

Results

The significant improvements relative to controls that had been found in urinary incontinence (60% vs 69%, risk difference (RD) -9.1%, 95% confidence interval (CI) -17.3% to -1.0%) and faecal incontinence (4% vs 11%, RD -6.1%, 95% CI -10.8% to -1.6%) at one year did not persist for urinary incontinence (83% vs 80%, RD 2.1%, 95% CI -4.9% to 9.1%) or faecal incontinence (19% vs 15%, RD 4.3%, 95% CI -2.5% to 11.0%) at 12 year follow up irrespective of incontinence severity at trial entry. The prevalence of prolapse symptoms or objectively measured pelvic organ prolapse also did not differ between the groups. In the short term the intervention had motivated more women to perform pelvic floor muscle training (83% vs 55%) but this fell in both groups (52% vs 49%) by 12 years.

Conclusions

The moderate short term benefits of a brief nurse-led conservative treatment of postnatal urinary incontinence did not persist. About four fifths of women with urinary incontinence three months after childbirth still have this twelve years later.

Keywords

Pelvic floor dysfunction; urinary incontinence; faecal incontinence; pelvic organ prolapse; randomised controlled trial; pelvic floor muscle training; bladder training

INTRODUCTION

About 20-30% of women have postpartum urinary incontinence,¹ and 3-5% have faecal incontinence.² Controversy exists about how to manage these problems. A Cochrane review on the effects of pelvic floor muscle training for prevention and treatment of incontinence in antenatal and postnatal women suggested that in those who are incontinent after delivery pelvic floor muscle training was better than no treatment, and that more intensive exercising was best.³ These conclusions were based on only three randomised controlled trials,⁴⁻⁶ one of which was the first report of the current trial.⁶ A further three trials investigated the effects of PFMT in antenatal women who were incontinent before delivery.⁷⁻⁹ Overall, whether treatment was started during or after pregnancy, fewer women were incontinent in the PFMT groups (229/735, 31%) than in the control groups (362/806, 45%) at up to a year after delivery (RR 0.58, 95% CI 0.39 to 0.87).³ However, none of the other trials reported follow up after the first year.

We previously reported that significant reductions relative to controls were found in urinary incontinence (60% vs 69%, risk difference (RD) -9.1%, 95% confidence interval (CI) -17.3% to -1.0%) and faecal incontinence (4% vs 11%, RD -6.1%, 95% CI -10.8% to -1.6%) at one year,⁶ but these did not persist at six years for urinary incontinence (76% vs 79%, RD -3.0%, 95% CI -10.2% to 4.1%) or faecal incontinence (12% vs 13%, RD -0.6%, 95% CI -6.4% to 5.1%).¹⁰ At one year, the intervention had motivated more women to perform pelvic floor muscle training (83% vs 55%) but this fell to 50% in both groups by six years. Our objective was to report follow up at twelve years, and we have included prolapse outcomes for the first time.

METHODS

Women were recruited from an original cohort of around 10,000 women who delivered in 1993-94 in three centres (Aberdeen, Birmingham and Dunedin). Ethical approval was obtained in each centre for the original study and follow up at six and twelve years. Information from the remainder of the cohort women who were not randomised (non-trial women) has been published separately.¹¹

All women had urinary incontinence three months after their 'index' delivery and were randomised by remote concealed computer allocation, stratified by delivery mode, parity and frequency of incontinence at trial entry. They received either enhanced conservative management at home or standard care in the control group. The intervention was delivered by trained health care professionals (who were not physiotherapists) and comprised one-to-one pelvic floor muscle training, with bladder training if indicated, on three occasions at 5, 7 and 9 months after the birth. Study methods, interventions and outcomes at one and six years were reported previously.^{6;10}

We contacted the women again at 12 years by postal questionnaire. The primary outcome was the prevalence of urinary incontinence at 12 years after randomisation. Secondary outcomes included practice of pelvic floor muscle training, faecal incontinence, and prolapse symptoms using the Pelvic Organ Prolapse Symptom Score (POP-SS, a 7-item instrument scored 0-28 with higher scores representing more symptoms).¹² Information about prolapse was not obtained at trial entry or at one or six years. Data regarding obstetric history were collected from the women.

We were also able to examine a subsample of women to measure pelvic organ prolapse using the objective Pelvic Organ Prolapse-Quantification system (POP-Q).¹³ These women responded positively to an invitation in the questionnaire, indicating that they were willing to be examined. In total, 35% of the women who responded to the questionnaire were examined, although a few women changed their minds or could not find a convenient time to attend a clinic after volunteering.

Comparisons used the two-sample test for proportions or the Student's t-test for continuous outcomes, with results expressed as either risk differences or mean differences with 95% confidence intervals. Analysis was by original group assignment (intention to treat analysis) without substitution for missing data from non-respondents. . We carried out subgroup analyses amongst women with less and more severe urinary incontinence, and with and without faecal incontinence, at trial entry.

RESULTS

Of the 747 women recruited, 524 (70.1%) had responded one year later⁶ and 516 (69.1%) at six years.¹⁰ At 12 years, the response was 471 women (63.1%), but allowing for women whom we were unable to approach (75 known to have moved, requested no further contact or died, Figure 1), the response rate from those contacted was 471/672 (70.1%). In all, 404 women responded at all three follow up points (54.1%). There were no statistically significant differences at trial entry between the women recruited (n=747) and those who responded at 12 years (n=471) except for age (responders were 1.5 years older, $P < 0.001$, Table 1). The randomised groups were, however, similar to each other at 12 years (Table 1).

Mean length of follow up from index birth was 12.7 years (range 11 to 14). The mean age of the women at this time was 43.3 years (range 30 to 57). Most women had had two children (236, 50%) while 7.9% had had only one child and a further 42% had three or more children. Over half the women (254, 53.9%) had only had spontaneous vaginal deliveries for all their births; 20 (4.2%) had only had caesarean sections; 131 (27.8%) had at least one forceps delivery; and 26 (5.5%) at least one vacuum delivery. The remainder (40, 8.5%) had a mixture of spontaneous vaginal deliveries and caesarean sections.

Pelvic floor exercises

Table 2 describes women's reported practice of pelvic floor muscle exercises at 12 years. The differences in the number performing any exercises, performing exercises every day and number of contractions (which had been present at one year⁶) were not evident at six¹⁰ or 12 years (Table 2).

Urinary incontinence

The difference in any urinary incontinence between the groups seen at one year (60% versus 69%⁶) were no longer apparent by 12 years (83% versus 80%, $P=0.555$, Table 3), although the prevalence had increased in both groups. There was also no difference in the prevalence of more severe incontinence, defined as at least once per week, nor in the proportions using pads (Table 3). More women in the intervention group had already had an operation for urinary incontinence but this finding is based on small numbers (14, 6.5% versus 5, 2.2%, $P=0.028$). Finally there was no evidence that women with more severe incontinence at trial entry were more likely to benefit at 12 years than those with minimal incontinence, although the prevalence at 12 years was marginally lower in the latter group (Table 3). No adverse effects related to the active intervention were reported at any time. Notably, four fifths of the incontinent women were also incontinent 12 years later.

Faecal incontinence

Some women with urinary incontinence at trial entry also had faecal incontinence. The lower prevalence of faecal incontinence in the intervention group (4% vs. 11%, $P=0.012$) at one year was not sustained at 12 years (19% vs. 15%, $P=0.215$, Table 4). The pattern was similar for more severe faecal incontinence (Table 4) and amongst subgroups characterised by whether or not they had faecal incontinence at trial entry (Table 4). A small number of women had received treatment (pads or plugs, constipatory drugs, surgery or physiotherapy) for faecal incontinence: 9 in the intervention group and 7 in the controls, and 12 of the 16 still had some residual faecal loss. Notably, two fifths of the women who did have concomitant urinary and faecal incontinence at trial entry had persistent faecal incontinence at 12 years.

Pelvic organ prolapse

There were no significant differences between the randomised groups at 12 years in terms of prolapse symptoms, severity of symptoms, or number of women having prolapse surgery (Table 5).

We were able to examine a subsample of 35% (165 trial women) to identify objective signs of prolapse,¹¹ using the POP-Q system.¹³ These women were comparable to non-examined trial women on age, parity, proportion with severe urinary incontinence or any faecal incontinence at trial entry, though fewer had a CS as their index delivery (data not shown). They were significantly more likely to have reported symptoms of prolapse in their questionnaire at 12 years than the non-examined trial women (higher score for prolapse symptoms on the POP-SS, 3.72 versus 2.95, MD -0.77, 95% CI -1.41 to -0.12). They were similar in terms of prevalence of urinary or faecal incontinence (data not shown). Nevertheless, there were no significant differences between the trial groups in terms of objectively measured prolapse (Table 5), either defined as: descent to 1 cm above the hymen or worse (Stage 2 or higher: 64.5% versus 64.0%, $P=0.954$); or descent to the hymen or beyond as a marker of a clinically important prolapse (30.3% versus 29.2%, $P=0.883$).

Compared to the original cohort from which the trial women were drawn, the latter had slightly more prolapse symptoms at 12 years (mean score 3.22 on POP-SS amongst trial women compared with 2.58, $P<0.001$ in the non-trial women¹¹) and a higher proportion had objective evidence of prolapse at the hymen or beyond (30% versus 22%, $P=0.061$).¹¹ Similarly, more trial than non-trial women had urinary incontinence (81.5% versus 48.6%, $P<0.001$) and faecal incontinence (16.6% versus 12.4%, $P<0.015$) at 12 years.

DISCUSSION

Main findings

Although at one year follow-up the intervention group had lower rates of both urinary and faecal incontinence, these differences did not persist at six or twelve years. This was also true for the women who initially had more frequent urinary incontinence, and for those who initially had concomitant faecal incontinence.

There were no statistically significant differences in any prolapse outcomes according to the trial groups at 12 years, which was the first time that prolapse was assessed in this study. At least 30% of those examined had objectively measured prolapse at the hymen or beyond, but there was no evidence of difference between the randomised groups.

Four fifths of those wet at trial entry still had urinary incontinence 12 years later. Two-fifths of women with faecal incontinence at trial entry also reported it 12 years later, and another 1 in 10 reported it as a new symptom.

Strengths and limitations

A particular strength of this study was the long length of follow up after randomisation, the inclusion of symptomatic assessment of prolapse symptoms using the POP-SS (which had been developed over the intervening time), and the opportunity to examine a subsample of women for objective evidence of pelvic organ prolapse. The trial women who volunteered to be examined did have some evidence of higher rates of pelvic floor dysfunction based on self-reported symptoms than those who were not examined, although the POP-SS values were low and the small difference (0.77 points) may not be clinically significant.¹⁴

The response rate of 63% at 12 years was slightly lower than at one and six years. However, this did not differ between the trial arms, and those responding were similar to non-responders in terms of age, parity, delivery mode and urinary or faecal incontinence at trial entry (Table 1). The original trial was powered to detect a 10% difference in the urinary incontinence rate. The confidence interval for the difference was within the range -10% to +10% (difference 2.1%, 95% CI of the difference -4.9% to +9.1%): this narrow CI rules out anything but a small effect which is unlikely to be of clinical significance. We are thus confident that the intervention did not have any long term effect in reducing incontinence. The results for the other outcomes also supported this finding of no difference.

Women with faecal incontinence all had co-existing urinary incontinence. A further 7% of women had been continent to urine but incontinent to faeces at trial entry, but they were not eligible for the trial because our inclusion criterion was presence of urinary incontinence. Our trial findings regarding faecal incontinence cannot therefore be generalised to women who do not also have urinary incontinence.

Trial women had a higher prevalence of urinary or faecal incontinence or prolapse at 12 years compared with the women from the original cohort who were not randomised. This may suggest that women who chose to enter the trial because they had some urinary incontinence at 3 months after delivery, no matter how little, were more likely to have symptoms of pelvic floor dysfunction 12 years later.

Interpretation

The moderate short term intervention effect (about 1 in 11 fewer women having urinary incontinence and 1 in 16 fewer having faecal incontinence), did not persist in the long-term. Similarly, the earlier difference in the performance of pelvic floor muscle exercises was not sustained, which is likely to account for the lack of difference in urinary, faecal and potentially prolapse outcomes.

The effect might have persisted for longer if there had been continuing reinforcement or if it had been carried out by pelvic floor physiotherapists rather than trained but non-specialist nurses, but these possibilities would need to be tested by further controlled trials of different strategies to increase adherence to pelvic floor muscle training. These findings are also disappointing because pelvic floor muscle training and bladder training have the merit of being simple to teach and perform (although expensive in terms of teaching time by health professionals), and have few if any adverse effects.

However, the findings are in line with Cochrane reviews of pelvic floor muscle training^{3;15} and bladder training for urinary incontinence¹⁶ and conservative treatment for faecal incontinence.¹⁷ Our results represent the longest follow up of any trial so far.

Further information about the long term follow up in the cohort of women from whom the trial women were recruited is given in other publications.^{11;18;19} The progression and persistence of symptoms in this trial population is similar to that in the rest of the cohort from which the women were drawn. For example, at 3 months after delivery, 33.6% of women had urinary incontinence, compared with 52.7% 12 years later.¹⁹ Faecal incontinence increased from 8.2% to 12.9%: of those who reported FI at 3 months, 43% also reported it at 12 years.¹⁸

Conclusion and recommendations

The moderate short term benefits of a brief nurse-led conservative treatment of postnatal urinary incontinence did not persist. There is therefore a need to identify conservative management strategies for urinary and faecal incontinence and prolapse that have longer term effects than those seen in this study, and then to test them rigorously by randomised controlled trials with long-term follow up.

Contributors

All authors in the ProLong Study Group contributed to the design, conduct, analysis or writing up of the study. CG, CM, SH, AE, RL, PH and DW contributed to the analysis and writing of the current report and approved the final draft.

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STUDY DETAILS

Trial registration number: not applicable (trial run in 1993-94)

Ethics Committee approval

The 12 year follow up study was approved by MREC ref no. 06/MRE10/25.

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Disclosure of interests: None

Protocol: The study protocol was pre-stated in the grant applications and the applications for ethical approval. The protocol for the 12-year follow up study is available and will be uploaded separately.

Assignment: Assignment was concealed by using remote computer randomisation to allocate women to groups (using stratification based on severity of incontinence, parity (up to 3, 4 or more) and Caesarean delivery or not)

Masking: It was not possible to mask treatment once it had been allocated. However, outcome assessment was based on data entry performed from postal questionnaires without knowledge of trial allocation.

Participant flow and follow up: See Figure 1

Analysis: Intention to treat without substitution for missing data.

CONSORT statement: Uploaded separately

Reference List

- (1) Wilson PD, Herbison RM, Herbison GP. Obstetric practice and the prevalence of urinary incontinence three months after delivery. *Br J Obstet Gynaecol* 1996; 103:154-161.
 - (2) MacArthur C, Bick DE, Keighley MR. Faecal incontinence after childbirth. *Br J Obstet Gynaecol* 1997; 104(1):46-50.
 - (3) Boyle R, Hay-Smith EJ, Cody JD, Mørkved S. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. *Cochrane Database Syst Rev* 2012; 10.1002/14651858.CD007471.pub2.
 - (4) Wilson PD, Herbison GP. A randomized controlled trial of pelvic floor muscle exercises to treat postnatal urinary incontinence. *Int Urogynecol J* 1998; 9:257-264.
 - (5) Dumoulin C, Lemieux MC, Bourbonnais D, Gravel D, Bravo G, Morin M. Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. *Obstetrics & Gynecology* 2004; 104(3):504-510.
 - (6) Glazener CMA, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H et al. Conservative management of persistent postnatal urinary and faecal incontinence: a randomised controlled trial. *BMJ* 2001; 323:593-596.
 - (7) Dinc A, Kizilkaya BN, Yalcin O. Effect of pelvic floor muscle exercises in the treatment of urinary incontinence during pregnancy and the postpartum period. *International Urogynecology Journal* 2009; 20(10):1223-1231.
 - (8) Skelly J, Rush J, Eyles P, Burlock S, Morrow C, Fedorkow D. Postpartum urinary incontinence: regional prevalence and the impact of teaching pelvic muscle exercises to pregnant women with UI (Abstract). Proceedings of the Joint Meeting of the International Continence Society (ICS) (34th Annual Meeting) and the International Urogynecological Association (IUGA), 2004 Aug 23-27, Paris, France , Abstract number 552. 2004.
- Ref Type: Abstract
- (9) Woldringh C, van den WM, Albers-Heitner P, Nijeholt AA, Lagro-Janssen T. Pelvic floor muscle training is not effective in women with UI in pregnancy: a randomised controlled trial. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2007; 18(4):383-390.
 - (10) Glazener CMA, Herbison GP, MacArthur C, Grant AM, Wilson PD. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. *BMJ* 2005; 330(7487):337-339.
 - (11) Glazener C, Elders A, MacArthur C, Lancashire R, Herbison P, Hagen S et al. Childbirth and prolapse: long-term associations with the symptoms and objective measurement of pelvic organ prolapse. *BJOG* 2013; 120(2):161-168.

- (12) Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the pelvic organ prolapse symptom score. *BJOG: an International Journal of Obstetrics & Gynaecology* 2009; 116(1):25-31.
- (13) Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *American Journal of Obstetrics & Gynecology* 1996; 175(1):10-17.
- (14) Hagen S, Glazener C, Cook J, Herbison P, Toozs-Hobson P. Further properties of the pelvic organ prolapse symptom score: minimally important change and test-retest reliability [abstract]. *Neurourol Urodyn* 2010; 29(6):1055-1056.
- (15) Dumoulin C, Hay SJ. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev* 2010; 10.1002/14651858.CD005654.pub2.
- (16) Wallace SA, Roe B, Williams K, Palmer M. Bladder training for urinary incontinence in adults. *Cochrane Database Syst Rev* 2004; 10.1002/14651858.CD001308.pub2.
- (17) Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev* 2012; 10.1002/14651858.CD002111.pub3.
- (18) MacArthur C, Wilson D, Herbison P, Lancashire R, Hagen S, Toozs-Hobson P et al. Faecal incontinence persisting after childbirth: a 12 year longitudinal study. *BJOG* 2013; 120(2):169-179.
- (19) MacArthur C, Glazener C, Lancashire R, Herbison P, Wilson D. Exclusive caesarean section delivery and subsequent urinary and faecal incontinence: a 12-year longitudinal study. *BJOG* 2011; 118(8):1001-1007.