Obstetric risk factors for urinary incontinence and preventative pelvic floor exercises: Cohort study and nested randomized controlled trial

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Summary
We conducted a cohort study assessing risk factors for developing urinary incontinence following childbirth, and a pilot randomized controlled trial of a physiotherapist-led intervention to reduce incidence of incontinence. A total of 723 women were recruited to the cohort study, of which 234 entered the nested trial and were randomized to intensive training in pelvic floor exercises or standard information. At 6 months post-partum, 45% of women reported some incontinence problems. A pre-existing incontinence problem was the best predictor of future incontinence (odds ratio 4.49, 95% confidence interval (CI) 3.09 – 6.53). Chronic constipation (1.86, 1.03 – 3.34) and episiotomy in at least one delivery (1.96, 1.25 – 3.07) were also independent risk factors, while an epidural or spinal (0.62, 0.42 – 0.92) was protective. The intervention as designed did not help in preventing future incontinence (relative risk 1.28, 95% CI 0.98 – 1.67), but this may be due to the failure to persuade the women to return for the classes. Any intervention aimed at promoting postnatal pelvic floor exercises should be limited to women who have already been experiencing incontinence problems.

Introduction
Urinary incontinence in women is a widespread problem; estimates of prevalence vary considerably according to study methodology, but some are as high as 50% (Cheater and Castleden 2000). Childbirth has long been recognized as a major contributory factor in the risk of developing stress incontinence, but there is no overall consensus regarding which specific aspects of obstetric history constitute important risk (or protective) factors. Many such factors have been suggested, based on a number of cross-sectional surveys, cohort and case-control studies. The most consistently reported are age (Cheater and Castleden 2000; Mason et al. 2001; Dolan et al. 1999), parity (Dolan et al. 1999; Marshall et al. 1996; Persson et al. 2000; Foldsang et al. 1992; Marshall et al. 1998; Mason et al. 1999; Burgio et al. 1996; Jolleys 1988) and a history of vaginal (rather than caesarean) deliveries (Persson et al. 2000; Mason et al. 1999; Wilson et al. 1996; Skoner et al. 1994; Rortveit et al. 2003; Burgio et al. 2003). There is also some support for obesity (Persson et al. 2000; Wilson et al. 1996; Burgio et al. 2003; Mommsen and Foldsang 1994; Burgio et al. 1991), high birth weight (Persson et al. 2000; Chaliha et al. 1999) and previous incontinence (Burgio et al. 1996; Burgio et al. 2003) being risk factors. Other suggested predictors are ethnicity (more prevalent among white than black women, Burgio et al. 1996), smoking (Burgio et al. 2003) and epidural (Persson et al. 2000). Mixed results have been found for family history (Skoner et al. 1994; Chaliha et al. 1999), forceps/vacuum assisted delivery (Persson et al. 2000; Burgio et al. 2003) and episiotomy/tear (Persson et al. 2000; Jolleys 1988; Skoner et al. 1994). Many studies do not attempt multivariate analysis of risk factors, and it is unclear how the various factors might interact and to what extent some associations may simply be the result of confounding. Despite the lack of a comprehensive evidence-base regarding risk factors, some trusts have developed risk-scoring algorithms to attempt to identify women at high risk for targeting with preventative measures (Dandy 1999).

Pelvic floor exercises have been used for over 50 years in the treatment of stress incontinence (Cammu and Van-Nylen 1997) and a systematic review in the Cochrane Library (Hay-Smith et al. 2003) based on 43 randomized controlled trials concluded that pelvic floor muscle training is effective in the treatment of incontinence. However, relatively few studies have examined the use of pelvic floor exercises during pregnancy and the postnatal period as a preventative measure. A recent systematic review (Harvey 2003) included seven randomized controlled trials evaluating exercises for the purpose of prevention: three trials of ante-partum exercises and four trials of post-partum exercises. The ante-partum trials showed a non-significant reduction in urinary incontinence. Of the four post-partum trials, only one (Chiarelli and Cockburn 2002) used urinary incontinence as an outcome (the others using pelvic floor strength), showing a modest but significant effect in preventing incontinence. One randomized trial of post-partum pelvic floor muscle training aimed at both prevention and treatment found a significant effect at 1-year follow-up (Morkved and Bo 1997; Morkved and Bo 2000). Conversely, a randomized trial of standard vs intensive pelvic floor exercises in women following vaginal delivery found no difference at follow-up (Sleep and Grant 1987). Another recent trial suggests that pelvic floor muscle training during pregnancy reduces the likelihood of a prolonged second stage of labour (Salvesen and...
problems of urinary incontinence; a reminder was sent 2 – 3
sent a questionnaire 6 months after delivery to assess
mized trial were then asked to consider this further
not collected; the catchment population of the hospital is
which may be of potential importance. Ethnicity data were
contains several items relating to the present delivery but
not included in SIFCRAT. In particular, SIFCRAT
the SIFCRAT scale plus some other putative risk factors
administered a questionnaire containing all the items in
Following consent to the cohort study, women were
Data collection
For the cohort study aimed at assessing risk factors,
exclusion criteria were: stillbirth; baby considered to be at
high risk (e.g. very low birth weight); mother aged under
insufficient comprehension to complete the study
documentation (e.g. through poor understanding of the
English language, or learning disabilities) and mother or
midwife requesting treatment from physiotherapist for
frank incontinence. Otherwise, all consecutive eligible
women were approached.
For the nested randomized trial, an attempt was made to
identify women at relatively high risk of developing
incontinence, notwithstanding the lack of a comprehensive
evidence base for such purposes. To be eligible for
inclusion in the trial, women had to score nine or higher
on the ‘Sandwell incontinence following childbirth risk
assessment tool’ (SIFCRAT) risk scale (Dandy 1999) and/
or to have already experienced incontinence. The
SIFCRAT contains items on birth weight, parity, pro-
longed pushing in labour, forceps delivery, episiotomy,
third-degree tear, epidual/spinal analgesia, multiple preg-
nancy, chronic constipation, obesity and age (if first baby).

Methods
The overall study design consisted of a cohort study, with a
nested randomized controlled trial. Women were recruited from
those giving birth in Taunton and Somerset Hospital over a 19-week period from November 2001 to March 2002. Recruitment was initially limited to women who were accessible on the postnatal ward during the 5-day working week; half-way through the recruitment period, some weekend recruitment was introduced.

Eligibility criteria
For the cohort study aimed at assessing risk factors, exclusion criteria were: stillbirth; baby considered to be at high risk (e.g. very low birth weight); mother aged under 16; insufficient comprehension to complete the study documentation (e.g. through poor understanding of the English language, or learning disabilities) and mother or midwife requesting treatment from physiotherapist for frank incontinence. Otherwise, all consecutive eligible women were approached.
For the nested randomized trial, an attempt was made to identify women at relatively high risk of developing incontinence, notwithstanding the lack of a comprehensive evidence base for such purposes. To be eligible for inclusion in the trial, women had to score nine or higher on the ‘Sandwell incontinence following childbirth risk assessment tool’ (SIFCRAT) risk scale (Dandy 1999) and/or to have already experienced incontinence. The SIFCRAT contains items on birth weight, parity, prolonged pushing in labour, forceps delivery, episiotomy, third-degree tear, epidural/spinal analgesia, multiple pregnancy, chronic constipation, obesity and age (if first baby).

Sample size
It was anticipated that during the study period about 750 women would be eligible and that about 600 completed assessments would be returned at follow-up with reminders. This number would provide a good basis for assessing the validity of the SIFCRAT in predicting incontinence; for example, the correlation coefficient between the SIFCRAT and the B-FLUTS (if used as a total score) would be estimated with a 95% CI of about ± 0.04. The trial component of the study was only a pilot and was not powered to detect meaningful differences. It was anticipated that about 350 women would be eligible for this part, of which 250 might be recruited (recruitment to the trial component would cease once the timing of the planned group sessions made this non-viable) and 200 might supply full follow-up data.

Randomisation
Eligible women consenting to the randomized trial component of the study were randomized to an intervention or control group using serially numbered opaque envelopes containing codes produced from computer-generated pseudo-random numbers.

Interventions
Women entering the cohort study but not entering the trial part of the study, plus those randomized in the trial to the control group, received local standard care: verbal promotion of postnatal pelvic floor exercises, with a leaflet explaining how to perform these. Those randomized to the intervention group in the trial received one-to-one instruction on pelvic floor function and exercises from a physiotherapist while still in hospital, and were invited to attend a pelvic floor exercise group on two subsequent occasions 2 months and 4 months after delivery. To minimise possible contamination, the patient information sheet for the trial referred only to different methods of preventing incontinence without specifying the detail of the intervention.

Outcomes
Women recruited to the study were sent the Bristol Female Lower Urinary Tract Symptoms questionnaire (B-FLUTS; Jackson et al. 1996) 6 months after delivery. This is an all-encompassing instrument that measures the extent and severity of incontinence and related symptoms and the impact on quality of life. At the time of the present study, there was no agreed way of combining responses to the B-FLUTS into one or more scale scores. A short-form version of the B-FLUTS has since been produced which generates scores in five domains, one of which relates specifically to incontinence (Brookes et al. 2004). However, this domain includes questions pertinent to urge incontinence, and stress incontinence is more specifically relevant for the present study. Therefore, one key question in the original B-FLUTS questionnaire was used for the analyses, which asks whether the woman experiences any loss of urine during coughing, sneezing or exercising.

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Analysis

Although the question from the B-FLUTS used as the outcome measure has a five-point response scale, the responses are dichotomised here into ‘no problems’ and ‘some problem’ for the purpose of analysis. Individual putative risk factors, and the overall SIFCRAT score, are assessed for predictive ability using $\chi^2$ tests as appropriate. Logistic regression is used to assess confounding and to derive a model representing the ‘best’ prediction of incontinence. Predictors are reported with relative risks of developing incontinence wherever appropriate. Throughout the analyses of risk factors, no adjustment is made for the women recruited to the intervention arm of the nested trial: as the results presented later show, very few of the women randomized to the intervention group actually returned for the classes, and the intention to treat analysis showed that the intervention did not have an effect on outcome, with the 95% CI effectively ruling out the possibility of a benefit. Although the trial component is intended as a pilot only, data are presented on outcomes from the two groups with comparisons on an intention-to-treat basis. The conventional $p$ value of $<0.05$ has been taken to mean statistical significance, although caution is exercised in the interpretation, as there are no formal adjustments for the multiple tests employed.

Results

A total of 723 women were recruited to the cohort study, of which 234 participated in the nested trial. Figure 1 illustrates the flow of women through the study. Of the 723 women, 556 (76.9%) provided data at the 6-month follow-up by returning the questionnaire. In the trial, 190 of the 234 women returned the questionnaire (81.2%). Table I shows demographic and related data. Similar distributions are seen for the overall sample recruited and for those returning the 6-month follow-up questionnaire; this applies also for those recruited to the trial (data not shown separately for responders). Likewise, similar distributions are seen for the two arms of the trial; these are however different from the overall sample since the factors shown each had a role in calculation of the SIFCRAT score and hence an influence on eligibility for the trial.

Cohort study results

Of the 556 women responding to the 6-month questionnaire, 552 completed the question used to define incontinence for the main analysis: ‘Does urine leak when you are physically active, exert yourself, cough or sneeze?’ Of these, 301 (54.5%) reported ‘never’, 203 (36.8%) ‘occasionally’, 37 (6.7%) ‘sometimes’, 7 (1.3%) ‘most of the time’ and 4 (0.7%) ‘all of the time’. For the analyses reported here, these responses are dichotomised into never ($n = 301$) and all other responses ($n = 251, 45.5$%). Table II shows the relationship between possible predictors and incontinence at 6 months, defined by this single variable. Of the demographic and related maternal factors, increasing age is a significant predictor (though not strongly so), as is a family history of incontinence and chronic constipation. However, by far the strongest predictor is whether the woman has already previously experienced incontinence problems, especially if they occurred outside pregnancy (i.e. before first pregnancy or between pregnancies). Although there is a suggestion of increasing risk with body mass index (BMI), this reverses for the obese (BMI $>30$) in this cohort. If the same analyses are repeated for the 272 primiparas returning the 6-month questionnaire, a slightly different pattern emerges. Age now ceases to be a significant predictor, with the percentage incontinent for the five age groups being 38, 43, 34, 33 and 36, respectively ($\chi^2$ test for trend $p = 0.94$). This suggests that the increasing incontinence with age seen for all women in Table II might simply be reflecting increasing parity with age, parity being the more direct causative factor; this is explored later in multivariate analyses. For the primiparas, BMI becomes a significant predictor, the percentage incontinent in the five categories being 26, 33, 49, 46 and 41, respectively ($\chi^2$ test for trend $p = 0.03$). The relationship with family history disappears, percentage incontinent being 39, 40 and 39 for the three categories.

The only significant predictor relating specifically to the recent pregnancy and delivery is the use of an epidural or spinal, which is negatively associated with incontinence, i.e. it appears to be protective. Since caesareans have a (non-significantly) lower risk, the reduced risk for epidural/spinal may be related to this; in fact, when only vaginal deliveries are considered, the rates of incontinence for non-use and use of epidural/spinal remain similar to the figures obtained for all women, at 49% and 39%, respectively. Limiting these analyses to primiparas only, the pattern of results is very similar, although the smaller sample size makes the relationship with epidural/spinal non-statistically significant.

In terms of the broader obstetric history, parity is a significant predictor, as is at least one vaginal delivery, i.e. a history of only caesareans would seem to be protective. One or more episiotomies is also a significant risk factor, even though an episiotomy for the recent delivery showed no such effect.

The SIFCRAT scale

Of the numerous items in the SIFCRAT scale, the data from this prospective cohort study provides support only for parity, episiotomy (but only related to previous deliveries) and constipation; in addition epidural/spinal was found to be protective.

Using 9 as a cut-off point, of 237 women considered ‘high risk’ according to the SIFCRAT, 109 (46%) reported incontinence at 6 months, compared with 142 of 315 (45%) at relatively ‘lower risk’ (relative risk = 1.02 (0.85–1.23), $p = 0.86$). The mean SIFCRAT score for those reporting incontinence was 7.55, compared with 7.27 for those reporting no problems.

The original intended use of the SIFCRAT was that existing incontinence would qualify for a woman to be referred immediately, whatever the score. Therefore a fairer analysis here might be to exclude those with existing or previous incontinence and include only those without such problems. This produces identical incontinence rates at 6 months of 31%, whether the woman scored $\geq 9$, or not.

Multivariate analyses

The factors considered above are not independent. Logistic regressions were used to assess any confounding and possible interaction effects among the various predictors. On the basis of the results from the univariate
analyses, the factors included in these analyses were: age group, BMI, family history, previous incontinence (yes/no) epidural/spinal (this delivery), constipation, parity (one/two or more), all deliveries caesarean and at least one episiotomy.

The final model included only those variables shown in Table III. Note in particular that once these factors are included in a predictive model, parity itself does not add significantly to the predictive ability. Although not shown here, when the analysis was repeated without previous incontinence included as a predictor, the same three factors (constipation, episiotomy and epidural) were again the only significant predictors (although family history was borderline).

In consideration of all the variables listed above, there was in fact one significant interaction effect, between constipation and epidural/spinal. However, this has not been included in Table III as it is likely to be a spurious finding: the interaction would suggest that, for people without any constipation, an epidural reduces risk of incontinence (i.e. is protective); while for people with chronic constipation, an epidural increases the risk. This
seems implausible and may well be a chance finding ($p = 0.008$), although this could usefully be examined in future studies.

Pilot trial results

As detailed in Figure 1, a total of 234 women were randomized equally to intervention and control groups. Of the 117 randomized to intervention, 90 returned the 6-month follow-up questionnaire, while 100 of the 117 randomized...
to control returned theirs. Of the 117 in the intervention group, 114 received the one-to-one instruction on pelvic floor function and exercises before leaving hospital, but only 21 returned to attend a group class and only five attended both classes. In an intention-to-treat analysis, 47 (47%) of the control group and 54 (60%) of the intervention group reported incontinence at 6 months (relative risk: 1.28, 95% CI 0.98–1.67, p = 0.10).

**Discussion**

For practical reasons, women were only invited into this study if they were ‘available’ in the maternity unit, and the sample therefore excluded women who returned home soon after delivery and some who delivered (and returned home) over the weekend. It is not clear whether this might be a source of bias in estimating prevalence of incontinence or assessment of risk factors. It is also unclear whether non-responders to the 6-month questionnaire were more or less likely to be suffering incontinence. Certainly some of those contacted by telephone said they did not feel the questionnaire applied to them as they had no problems, but there may be others who were too embarrassed by a problem to respond. Reassuringly, of those who did respond, the ‘late’ responders (i.e. needing a reminder letter) were similar to the early responders in terms of incontinence at 6 months (47% vs 45%, p = 0.77).

The study was designed to provide information for the planning of a larger trial of a physiotherapist-mediated intervention to prevent incontinence in women who have recently given birth. The pilot trial component clearly demonstrated that the delivery of this intervention, in particular involving the women returning to group classes, is likely to be infeasible in practice. The catchment area of Taunton and Somerset NHS Trust is very rural and parking at the hospital is notoriously troublesome; this may have contributed to the disappointing attendance. Other trials have commonly limited the intervention to the antenatal and/or in-hospital postnatal periods (Morkved and Bo 1997; Morkved and Bo 2000). At least two trials have demonstrated effectiveness of an intervention that did involve later contact (Cammu and Van-Bylen 1997; Chiarelli and Cockburn 2002), although in the latter trial, women were given the choice of return to hospital or a home visit. This was conducted in Australia; the earlier trial in the USA. It may well be that postnatal exercises do help to reduce the risk of incontinence, but any intervention designed to promote greater adherence to an exercise programme needs to take into consideration likely uptake. The cost-effectiveness of such interventions remains unproven.

The results of the cohort study provide further insight into possible causative factors. By far the best predictor of incontinence at 6 months post-partum is (perhaps unsurprisingly) pre-existing incontinence problems assessed at delivery. Indeed, given the multiple statistical tests and hence risk of ‘false positive’ results, it is the only consistently convincing predictor identified. Chronic constipation also seems to increase the risk, independently of whether there were previous incontinence problems. The role of episiotomy and epidural are less clear from the results of this study.

This study found episiotomy in the recent delivery not to increase risk, yet a previous episiotomy did. There are several possible explanations for this: (1) the number of women having an episiotomy in the recent delivery was small, and there was therefore limited power to detect an effect; (2) 6 months might possibly be too short a period for any adverse effect of an episiotomy to emerge; (3) it is also conceivable that the adverse effect of an episiotomy does not materialise until a subsequent delivery; (4) techniques for episiotomy and repair may have improved over time, so that they no longer increase risk of incontinence as they once did. Such explanations are necessarily speculative.

The use of an epidural or spinal was found to be negatively associated with the risk of developing incontinence. It has been previously suggested in a study of 424 primiparas that epidural may be protective (Schuessler et al. 1988), although this failed to be replicated in a subsequent study of 208 primiparas (Viktrup and Lose 1993) and a large registry-based study suggested a positive association (Persson et al. 2000), at least with severe incontinence requiring surgery.

Other factors significantly associated with incontinence in univariate analyses failed to remain significantly predictive when these four variables were controlled for. Instead of obtaining the best prediction for development of incontinence problems (in order to target high-risk groups for intervention), interest may lie in identifying risk factors that are amenable to change. In this case previous incontinence is of less interest, but omitting this factor still led to a final model containing the three remaining factors; factors such as parity and BMI were not significant in the model.

This study questions many common perceptions about risk factors for incontinence, particularly regarding obstetric factors. In terms of identifying women who may be at high risk (at whom interventions might be targeted), the study suggests that the most important question to ask is whether they have been suffering incontinence problems prior to, or during, their pregnancy. The inclusion of additional factors may be of relatively marginal significance. Chronic constipation is an additional factor and previous episiotomy is also implicated from this study. Educational interventions designed to help prevent incontinence need to recognize the problem of mothers finding it difficult to attend classes. Any intervention aimed at promoting postnatal pelvic floor exercises is likely to be problematic if it is itself instigated postnatally. Promotion of such exercises is best done antenatally and further attention postnatally should be limited to women who have already been experiencing incontinence problems. Any such interventions need to be assessed for cost-effectiveness.

There would be benefit in further work to identify the optimum set of risk factors that can be ascertained at the time of booking, for targeting antenatal interventions at women at high risk of developing urinary incontinence. There are now many published studies on this issue, of varying design and sample size, and a comprehensive systematic review may be of help.

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