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Indices for studying urinary incontinence and levator ani function in primiparous women

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Summary

• Urinary incontinence (UI) is a complex phenomenon that is prevalent in pregnant and parous women and requires the use of sophisticated measures to adequately reflect functioning of the continence system.

• The purpose of this study was to develop reliable and valid measures of UI and levator ani function for use in research and clinical settings.

• A Leakage Index (LI) and a Levator Ani Function Index (LAFI) were developed using data from a longitudinal study of primiparous women. Reliability and validity tests were conducted to: (i) estimate the internal consistency reliability of each index, (ii) determine whether the indices captured change in continence status and pelvic floor function during pregnancy through 1 year postpartum, and (iii) estimate association between the indices as a test of predictive validity.

• Cronbach's alpha ranged from 0.72 to 0.84 for the LI and from 0.53 to 0.79 for the LAFI across the six data collection time points of the study. Average LI scores increased late in pregnancy and decreased postpartum, though not significantly. Average LAFI scores decreased significantly at 35 weeks gestation ($t = 4.84$, $P = 0.000$) and increased significantly at 12 months postpartum ($t = -3.51$, $P = 0.002$) relative to baseline. The LI and LAFI were significantly associated at 20 weeks gestation (Pearson $r = -0.40$, $P = 0.007$) and at 6 weeks postpartum (Pearson $r = -0.33$, $P = 0.029$).

• The findings suggest the LI and LAFI are reliable and valid measures of UI and levator ani function in primiparous women, which can be used with confidence in clinical and research settings.

Keywords: female incontinence, Levator Ani Function, urine leakage.

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Introduction

Urinary incontinence (UI) is a prevalent and costly outcome of pregnancy and childbirth, requiring use of sophisticated measures to reflect adequate functioning of the continence system. This paper reports on the construction of a Leakage Index (LI) and a Levator Ani Function Index (LAFI), and on tests conducted to estimate their reliability and validity. The LI is a simple, unobtrusive assessment tool for evaluating continence status, constructed from questionnaire items. The LAFI combines objective measures of levator ani function and a clinician's subjective assessment of levator ani strength and control in a single index. Combining measures of similar phenomena can provide more accurate measurement through cancelling of random error, and can enhance the breadth and depth of measures (Nunnally, 1994). If reliable and valid measures of UI and pelvic floor function are made known to clinicians and researchers, then it may be possible to evaluate risk factors, and assess and treat incontinence with greater consistency and effectiveness.

Birth-related changes in the levator ani portion of the pelvic floor muscles are hypothesized to cause incontinence, and several studies have examined the link between birth-induced levator ani dysfunction and urine leakage (Doherty *et al*., 1993; Morkved & Bo, 1997; Sampselle *et al*., 1998). These studies used simple measures of incontinence and pelvic floor function that were not evaluated for reliability and validity. For instance, Sampselle *et al*. (1998) used a measure of simple stress UI that was based on four items related to specific activities (cough, laugh and sneeze). Yet episodes of incontinence may occur under many circumstances, and it is our belief that a sensitive and reliable measure of leakage should include questions that also capture urge-related episodes of leakage. Doherty *et al*. (1993) used a diary method to assess any leakage, while Morkved & Bo (1997) and Bear *et al*. (1997) used a pad test to evaluate urine leakage. These methods are not simple for clinicians to apply. Further, Miller *et al*. (1999) found no significant correlation between clinical cough tests used to induce leakage and women's self-reported frequency of incontinence and voiding using a diary method, and Morkved & Bo (1999) found differences between self-reported incontinence and results of a pad test. Though these studies were not all conducted on primiparous women, they clarify the need for comprehensive measures of urine leakage with demonstrated reliability and validity.

To measure levator ani strength, Sampselle *et al*. (1998) used force during a voluntary contraction of the pelvic floor measured with an instrumented speculum (US Patent No. 6 468 232 B1; Ashton-Miller *et al*., 2002). Considering the many measures of pelvic floor function collected in a thorough evaluation of the health of the continence system, we felt additional measures would better reflect the strength and functioning of the levator ani muscles. Doherty *et al*. (1993) and Morkved & Bo (1997) obtained an objective measure of pelvic floor strength using a vaginal balloon catheter connected to a pressure transducer. Morkved & Bo (2000) later assessed pelvic floor function and strength by vaginal palpation and vaginal squeeze pressure. Brink *et al*. (1994) assessed pelvic floor function using the Digital Measure, which involves a clinician's subjective assessment of performance on several tests. None of the studies have combined objective (instrumented) and subjective (clinician's) assessments of levator ani function in an index. The reason it is important to do so is that women are known to vary in their ability to isolate and control the levator ani contraction. The clinician's expert assessment incorporates an appraisal of correct isolation and control and may reduce the artefact of technique inconsistency.

We hypothesize that reliable measures of urine leakage and pelvic floor function used to assess physiological change as a result of childbearing and delivery will demonstrate internal consistency over the course of the pregnancy and postpartum, and that valid measures will reflect changes in physiology associated with childbearing and delivery, consistent with findings from a longitudinal study of primiparous women (Sampselle *et al*., 1998). We tested these hypotheses through secondary analysis of the data collected by Sampselle *et al*. (1998), while recognizing that the trends we expected our new measures to reveal were uncovered in prior analysis of the same sample, with use of much simpler measures. In part, our impetus to develop better measures came from a conceptual model developed prior to the start of this study. That model was guided in part from unpublished analyses of failures to find statistical significance when testing hypothesized associations between simpler measures. We did not statistically compare the indices developed here with the simpler measures used previously on the same data set, as the measures are linearly related, and results of those tests would be biased.

Method

SAMPLE

A total of 66 primigravidas were recruited for this study. The subjects were 18 years of age or older, <20 weeks gestation, expecting vaginal birth, and expecting to reside

in south-east Michigan for 1 year following the birth of the infant. Candidates were excluded from the study if they had a history of genito-urinary or neuro-muscular pathology, or previous pregnancy carried beyond 20 weeks gestation. Consent forms approved by the Institutional Review Board of the University of Michigan Hospital were reviewed by the women and signed at their first clinical visit (20 weeks gestation). Demographics and data on the participant's history of UI were collected at baseline. Longitudinal data – including a urine loss questionnaire and tests of pelvic muscle strength and function – were collected at the six time points of the study (20 and 35 weeks gestation, 6 weeks, 6 months and 12 months postpartum). Birth event data were collected through direct observation of the labour and delivery and from reviews of medical charts. The average age of women in the study was 29.2 years (SD = 5.3, range: 19–40, $n = 66$). Most of the women were White Americans and a majority delivered vaginally (Table 1).

Table 1 Subject characteristics

	n (%)
Race ($N = 66$)	
African American	4 (6.1)
Asian	5 (7.6)
White American	52 (78.8)
Other	5 (7.6)
Treatment status ($N = 66$)	
Treatment	35 (53.0)
Control	31 (47.0)
Delivery type ($N = 50$)	
Vaginal	36 (72.0)
C-section	14 (28.0)
Second stage of labour duration ($N = 46$)	
0–40 minutes	11 (23.9)
41–100 minutes	15 (32.6)
>100 minutes	20 (43.5)
Epidural ($N = 45$)	
Yes	33 (73.3)
No	12 (26.7)
Episiotomy ($N = 44$)	
Yes	9 (20.5)
No	35 (79.5)
Forceps ($N = 36$)	
Yes (low)	2 (5.6)
No	34 (94.4)
Vacuum ($N = 40$)	
Yes	5 (12.5)
No	35 (87.5)

Nineteen subjects dropped out of the study, leaving a sample of 47 participants with longitudinal data for analysis. Subjects who dropped from the study did not differ significantly from subjects retained on age, urine leakage or levator ani function at 20 weeks gestation. Study participants who delivered vaginally or by caesarean section were included in this analysis as were participants with a prior history of incontinence as a young woman, women who leaked on the baseline paper towel test, and women who were unable to contract the pelvic floor muscles at baseline. Including these women in the analysis enabled us to develop and test the indices using data from a sample of women who varied in severity of incontinence and pelvic floor support, independent of challenge to the pelvic floor from the passage of the infant through the birth canal.

When we analysed trends over time we used a constant sample, that is, cases with no missing data on the variables of interest across all time points of the study. The number of cases included in a particular analysis depends on the amount of missing data on specific items in that analysis. Constraining the sample to complete cases removed concerns about the potential influence of particular cases that would 'come and go' across the study time points. This constraint was not used for tests of reliability or associations between variables, as these analyses did not involve examining trends.

INDEX CONSTRUCTION

Leakage index

The LI was constructed to capture the most common subjective experiences of UI in a manner sensitive enough to detect change over time. The LI is the sum of eight measures of urine leakage reported through surveys completed at each clinical visit. The LI includes one general measure of urine leakage and seven items that measure symptoms typically associated with stress and urge leakage under specific circumstances (Fig. 1). Other survey items that asked about UI such as 'Do you ever find yourself wet after you have fallen asleep at night?' and 'Do you leak when you are bending over?' were excluded from the index because very few women indicated they experienced leakage under those conditions.

The LI survey items are scored 0 for no leakage, 1 for any leakage, and summed (Fig. 1). The LI ranges from 0 for a person who reported no leakage on all items, to 8 for a person who reported leakage on all items (Table 2). As six of the eight items (items 2 through 7) specify under what condition leakage actually occurred, the index gives more weight to incontinence experienced under specific circumstances.

Leakage Index Questionnaire

Other than the few drops right after urinating, have you involuntarily lost or leaked any amount of urine or been unable to hold your water and wet yourself?

	YES	NO
	❑1	❑0

Next is a list of things that some people say can cause them to leak urine and wet themselves. Tell me whether each one has caused you to lose urine since we last saw you [date of last visit]

	YES	NO
Coughing hard.....	❑1	❑0
Laughing.....	❑1	❑0
Sneezing.....	❑1	❑0
Not being able to wait at least 5 minutes until it is convenient to go to the toilet.....	❑1	❑0
Arriving at your door or putting your key in the lock	❑1	❑0
Suddenly finding that you are losing or about to lose urine with very little warning.....	❑1	❑0

Imagine that you are standing in the check-out line at the grocery store with a full bladder that you would like to empty as soon as possible. Now imagine that you have to sneeze or cough several times very hard. What is most likely to happen about urine leakage?

Check One

❑0	Stay dry
❑1	Leak a few drops, *or* Wet underpants but not soak through, *or* Possibly drip onto the floor

TOTAL SCORE (Sum All Items) ☐

Figure 1 Leakage index questionnaire.

Table 2 Reliability analysis

	Leakage index		Levator Ani Function Index	
Study time point	α	*n*	α	*n*
20 weeks gestation	0.78	59	0.69	53
35 weeks gestation	0.74	47	0.53	46
2 weeks postpartum	0.84	41	0.79	35
6 weeks postpartum	0.75	46	0.76	49
6 months postpartum	0.72	45	0.66	46
12 months postpartum	0.82	40	0.68	41

LAFI

The LAFI was constructed from four measures of levator ani strength and functioning to reflect overall function of the levator ani muscles. The four measures are: maximum voluntary contraction (MVC) force, cough force, digital displacement and digital pressure. The LAFI is consistent in content with other measures of pelvic floor function and strength that have been published in studies about female incontinence (Bishop *et al*., 1992; Morkved & Bo, 2000). A single, trained clinician obtained items in the LAFI. We selected items to include in the index on the basis of use in prior studies, our evaluations of the consistency of application of clinical protocols in this study, and our subjective confidence in the accuracy of measures that were fairly exploratory at the time of the study. For example, although we intended to include measures of bladder neck stability obtained by ultrasound, we decided not to on the basis of results of reliability tests that demonstrated that the ultrasound measures were not strongly associated with other measures in the index.

The MVC force and cough force were obtained using an instrumented speculum. The instrumented speculum

was a new device developed at the University of Michigan for a series of studies about the pelvic floor. It was adapted from a standard gynaecological speculum and is positioned in a similar manner. Data on calibration and reliability testing of the instrumented speculum are reported in Sampselle *et al.* (1998).

The MVC force indicates the strength of the levator ani muscles and ability to contract the pelvic floor, while cough force indicates the strength of the response of the pelvic floor during a cough. The MVC force and cough force were measured twice during each clinical visit and the highest value (patient's strongest effort) for each measure was used to construct the LAFI. Using the highest value was consistent with our reasoning behind collecting two measures, namely, that we wanted to capture the woman's best effort to estimate her maximum strength.

A trained clinician also measured pressure, displacement and duration, taken from the Digital Measure (Brink *et al.*, 1994). The measures of pressure and displacement are included in the LAFI. The duration measure was excluded because of a highly skewed distribution across the study time points and inconsistent association with other items in the LAFI. The clinicians who assessed digital duration also expressed little confidence in their ability to judge accurately the end of a voluntary contraction. This was perhaps reflected in our finding that the Cronbach's alpha for the index was lower when digital duration was included.

To construct the LAFI index score, each item was standardized to its 20-week (baseline) time point. The four standardized measures were then averaged to obtain the scale score. We allowed up to one of the four items to be missing when calculating the baseline scale score. The baseline scale score for the total sample has a mean slightly different from zero, and a SD different from 1.0 (Table 3). This is mostly because of allowing some missing data when averaging items to calculate the scale score, and is in part due to rounding error. Scale scores at time points following baseline are not expected to have a mean of zero and SD of 1, as they are standardized to the 20-week time point. As intended, the data following baseline reflect change in the LAFI relative to baseline.

Table 3 Leakage index summary statistics ($n = 27$)

	Mean (SD)	Per cent incontinent	t (P-value)
20 weeks gestation	1.74 (1.79)	63.0	–
35 weeks gestation	2.26 (1.91)	66.7	−1.66 (0.110)
2 weeks postpartum	1.93 (2.34)	55.6	−0.40 (0.690)
6 weeks postpartum	1.04 (1.87)	37.0	1.80 (0.084)
6 months postpartum	1.22 (1.45)	52.0	1.57 (0.129)
12 months postpartum	1.19 (1.94)	37.0	1.56 (0.130)

t-Tests are paired comparisons with baseline (20 weeks gestation).

RELIABILITY TESTS

The internal consistency reliability of the LI and the LAFI were estimated using Cronbach's alpha (Carmines & Zeller, 1979). Finding good alphas in the range of 0.7 or better for all time points in the study would enhance our confidence in the reliability of the measures for use during pregnancy through 1 year postpartum (Landis & Koch, 1977).

VALIDITY TESTS

Tests to evaluate validity included: examining changes in LI and LAFI scores over time; testing for differences and estimating associations between early and later data points for each index separately; and estimating associations between the LI and the LAFI over time through causal modelling (Asher, 1983).

Leakage index

We expected leakage to increase at 35 weeks gestation and early postpartum relative to baseline and to decrease at later postpartum time points. We expected leakage to increase just prior to birth because of pressure from the foetus on the pelvic floor, and to remain elevated just following birth as a result of damage to the pelvic floor related to labour and delivery. Later postpartum, we expected recovery of the pelvic floor to result in a decrease in leakage, which would result in higher associations between baseline and the 6-month and 12-month leakage. t-tests and Pearson's correlations were used to investigate these expectations.

LAFI

We expected the LAFI to decrease immediately postpartum relative to baseline and 35 weeks gestation because of damage to the pelvic floor during labour and delivery, and we expected the LAFI scores to increase relative to baseline at later postpartum time points, reflecting recovery of the pelvic floor structures (Sampselle *et al.*, 1998). t-Tests and Pearson's correlations were used to investigate these expectations.

Association between LI and LAFI

To test the predictive validity of the LAFI and the LI we examined the associations between these measures over

time using Pearson's correlations. We expected levator ani function to be negatively correlated with leakage at every time point in the study. That is, better levator ani function (higher LAFI) would be associated with less incontinence (lower LI).

We also examined the relationship between leakage and levator ani function by estimating a causal model of the effect of levator ani function on leakage at 6 months postpartum, controlling for baseline LAFI and baseline leakage (Fig. 2). Regression analysis was used to test the model (Asher, 1983). All paths in the model were tested because we were interested in the relationship between leakage and levator ani function within and across time points. Paths from the LI at 20 weeks gestation to the LI at 6 months postpartum, and from the LAFI at 20 weeks to the LAFI at 6 months, were included to estimate the stability of these factors.

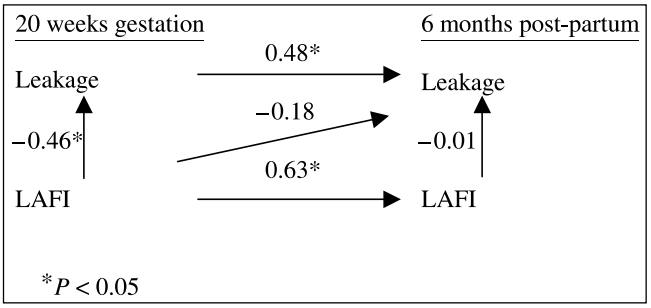

Figure 2 Association between leakage index and Levator Ani Function Index.

Results

RELIABILITY

Leakage index

Reliability tests conducted for each time point of the study indicate good reliability among the measures in the LI with Cronbach's alpha ranging from 0.72 to 0.84 (Table 2).

LAFI

Reliability tests on the LAFI ranged from 0.53 to 0.79 across the time points of the study, indicating fair to good reliability during gestation and postpartum (Table 2).

VALIDITY

Leakage index

Using a constant sample across the study time points, we found leakage was highest on average at 35 weeks gestation and lowest on average at 6 weeks postpartum (Table 3). The SD was fairly constant across time with the greatest variance at 2 weeks postpartum. The largest percentage of women reported leakage at 35 weeks gestation, and the smallest percentage reported leakage at 12 months postpartum.

Paired *t*-tests comparing baseline leakage to other time points were not significant, though the difference at 6 weeks postpartum approached significance ($P = 0.084$) (Table 3). Pearson's correlations between baseline leakage and leakage at subsequent time points (Table 5) show the lowest associations between baseline and 2 and 6 weeks postpartum, and stronger associations between baseline and 6 and 12 months postpartum. Leakage at 35 weeks gestation was strongly associated with leakage at 20 weeks gestation, which was unexpected. When these correlations were run on a constant sample ($n = 27$) across all study time points, the associations were similar in magnitude and pattern.

LAFI

Across the time points of the study, the LAFI was lowest on average at 2 weeks postpartum and highest at 12 months postpartum (Table 4). Paired *t*-tests comparing the baseline LAFI to other time points showed significant differences at 2 weeks postpartum and at 12 months postpartum (Table 4). Pearson's correlations showed a moderate association between LAFI scores at baseline and 35 weeks gestation, but higher associations between baseline and postpartum LAFI scores (Table 5). Very similar associations were obtained in a constant sample ($n = 22$).

Association between levator ani function and leakage

Using Pearson's correlations, we found significant negative associations between the LI and the LAFI at 20 weeks gestation and at 6 weeks postpartum (Table 6).

Table 4 Levator Ani Function Index summary statistics ($n = 22$)

	Mean (SD)	Range	*t* (*P*-value)
20 weeks gestation	−0.04 (0.81)	−1.34–2.32	–
35 weeks gestation	−0.04 (0.62)	−1.04–1.37	−0.02 (0.981)
2 weeks postpartum	−0.76 (0.82)	−1.83–1.16	4.84 (0.000)
6 weeks postpartum	−0.33 (0.93)	−1.50–1.82	2.02 (0.056)
6 months postpartum	0.09 (0.81)	−1.36–1.32	−0.91 (0.371)
12 months postpartum	0.46 (0.68)	−0.95–1.56	−3.51 (0.002)

t-Tests are paired comparisons with baseline (20 weeks gestation).

Table 5 Association with baseline

	Leakage index			Levator Ani Function Index		
	Pearson *r*	*P*-value	*n*	Pearson *r*	*P*-value	*n*
35 weeks*	0.72	0.000	43	0.33	0.047	36
2 weeks	0.30	0.073	36	0.65	0.000	30
6 weeks	0.29	0.074	40	0.67	0.000	40
6 months	0.55	0.000	40	0.63	0.000	37
12 months	0.60	0.000	36	0.57	0.001	33

*Gestation time point.

At 6 months postpartum, the association was modest but approached significance.

Results of the causal analysis revealed significant associations between leakage at 20 weeks gestation and leakage at 6 months postpartum. The LAFI at 6 months postpartum was only weakly, negatively associated with 6-month postpartum leakage. The baseline LAFI had only a modest, negative association with leakage postpartum. Similar results were obtained in a sample excluding women with caesarean birth.

Discussion

In general, these findings show changes in the LI and LAFI across the time points of the study that are consistent with our concept of physiological change. Cronbach's alphas for the measures across the time points of the study are good, demonstrating that the measures are internally consistent both during pregnancy and postpartum. Birth-related changes as a result of hormonal fluctuations, birth canal injuries and subsequent recovery are reflected in the average LI and LAFI scores. Changes in association between baseline at 20 weeks gestation and later time points are largely consistent with our expectations. The negative associations between the LI and the LAFI at 20 weeks gestation and at 6 weeks postpartum are also as would be expected during pregnancy and postpartum, lending confidence in the validity of the measures.

Several results were not expected. The alpha for the LAFI at 35 weeks gestation was 0.53, which may reflect the weight of the baby on the pelvic floor reducing a woman's ability to contract the levator ani muscles. Leakage at 20 weeks gestation was strongly associated with leakage at 35 weeks gestation. It may be that the less functional pelvic floor at 20 weeks is showing further dysfunction at 35 weeks, because of the added weight of uterine contents. The moderate association between the baseline and 35-week LAFI scores may also reflect the added uterine weight in conjunction with genetic differences in the pelvic floor. The association of the baseline LAFI with all postpartum time points suggests that, despite birth-related effects, the initial genetic endowment may play a role postpartum.

The lack of association between the LI and the LAFI at 2 weeks postpartum and 12 months postpartum was also unexpected. At 2 weeks postpartum there may be confusion on the part of the participant between lochia and urine leading to greater measurement error at this time point. At 12 months, the full effect of pelvic floor rehabilitation may be operating, for example, learned supplementary stabilization of the urethra known as the 'knack' (Miller *et al.*, 1999).

The finding in the causal analysis that the baseline LAFI had a weak negative association with postpartum leakage may be due in part to the small sample and partitioning of variance between several measures. Yet the direction of association was as expected. This model should be tested again in a larger sample of women.

Findings of this study may have been influenced by aspects of the study design, or by limitations of the variables measured. For instance, study participants received pelvic muscle exercise training (Miller *et al.*, 1994) that may have raised their awareness of the pelvic floor, though this effect was not measured. The effect of pelvic muscle training practised by participants was also not measured. Yet, the level of pelvic muscle exercise practised may have influenced leakage at postpartum time points. The LI captured data about observed or actual leakage, with the exception of one item that presented a hypothetical scenario in which the woman might experience urine leakage. The study did not collect data on whether women felt a general threat or burden related to urine loss under a variety of conditions. That information might contribute additional content to the LI regarding

Table 6 Association between leakage and levator ani function

	20 weeks* ($n = 48$)	35 weeks* ($n = 43$)	2 weeks ($n = 33$)	6 weeks ($n = 46$)	6 months ($n = 44$)	12 months ($n = 40$)
Pearson *r*	−0.40	−0.21	−0.01	−0.33	−0.28	−0.07
P-value	0.007	0.116	0.800	0.029	0.055	0.339

*Gestation time point.

the severity of UI, thus creating a measure with more depth and sensitivity. Beverage intake and voiding frequency were also not measured. It is plausible that many women at 12 months postpartum may control UI by limiting beverage intake or by voiding frequently. Further, the measures of UI during specific activities that were included in the LI were scored on a binary scale, limiting the variance captured by these items, and failing to reflect frequency or the amount of leakage. Many of these issues are being addressed through revisions to the data collection protocols in the current continuation study.

Conclusion

This paper represents a first attempt to develop and test comprehensive measures of urine leakage and levator ani function using longitudinal data from pregnancy through 1 year postpartum. Most of the results were as expected and the measures demonstrated reliability and validity across the time points of the study. This study population was mostly healthy and young and a large percentage of the subjects demonstrated minor leakage or absence of leakage following birth. Work remains to test the reliability and validity of the indices in other samples such as nulliparous, multiparous and older parous women. Overall, the findings of this study suggest that the LI and the LAFI can be used clinically and in research to assess patients' UI and levator ani function.

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