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Correlation between levator ani muscle injuries on MRI and fecal incontinence, pelvic organ prolapse, and urinary incontinence in primiparous women

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For the Pelvic Floor Disorders Network

STRUCTURED ABSTRACT

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Objective—To correlate the presence of major levator ani muscle (LAM) injuries on magnetic resonance imaging (MRI) with fecal incontinence (FI), pelvic organ prolapse (POP) and urinary incontinence (UI) in primiparous women 6–12 months postpartum.

Study design—A published scoring system was used to characterize LAM injuries on MRI dichotomously (MRI−, no/mild versus MRI+, major).

Results—Major LAM injuries were observed in 17/89(19.1%) women who delivered vaginally with external anal sphincter (EAS) injuries, in 3/88(3.5%) who delivered vaginally without EAS injury, and in 0/29(0%) who delivered by Cesarean before labor (p=0.0005). Among women with EAS injuries, those with major LAM injuries trended towards more FI, 35.3% vs. 16.7% (p=0.10) and POP, 35.3% vs. 15.5% (p=0.09), but not UI (p=1.0).

Conclusion—These data support the growing body of literature suggesting that both EAS and LAM are important for fecal continence and that multiple injuries contribute to pelvic floor dysfunction.

Keywords

fecal incontinence; levator ani muscle; magnetic resonance imaging (MRI); pelvic floor muscle; pelvic organ prolapse; urinary incontinence

INTRODUCTION

Vaginal birth increases the likelihood that women will have pelvic floor dysfunction. Recent advances in pelvic floor imaging and neuromuscular testing provide evidence to pinpoint the specific anatomical and functional abnormalities caused by vaginal birth that are associated with increased occurrence of fecal incontinence (FI), pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

Visible damage to the pubic portion of the levator ani muscle (LAM) is one specific injury associated with vaginal delivery.(1–3) Pelvic imaging using magnetic resonance imaging (MRI) can improve our understanding of anatomic observations and clinical conditions that occur after childbirth. In a case-control study, young women with de novo SUI, nine months after a first vaginal birth, were more than twice as likely to have a LAM defect imaged on MRI compared to women without SUI (28% versus 11%).(1) However, using a different case-control mix of middle-aged women with and without stress SUI, the same researchers found similar rates of LAM injury in each group.(4)

The relationship of LAM injury to other known injuries is not entirely clear. In a case control study of primiparous women with and without *de novo* postnatal stress incontinence, LAM injury was more common in those who experienced an anal sphincter rupture at delivery compared to those who did not (62% versus 17%, OR = 8.1).(2) The effect of this injury on fecal incontinence (FI), pelvic organ prolapse (POP) and stress urinary incontinence (SUI) is not fully known.

The Childbirth and Pelvic Symptoms (CAPS) study assessed the prevalence and incidence of FI, POP and UI in a population of primiparous women after primary repair of clinically diagnosed 3rd or 4th degree sphincter tears, compared to women who underwent vaginal delivery without a tear and those who underwent a Cesarean delivery prior to labor. Two hundred and thirty-five women in CAPS (approximately 25% of the CAPS population) underwent a single pelvic MRI at 6–12 months after 1st delivery, for the primary purpose of evaluating the anal sphincter complex. Because of the association between anal sphincter injury and LAM defects in previously described studies, frequent occurrence of levator defects in this cohort would be expected.

The goal of the current study is to determine the presence of major LAM defects on MRI (MRI +) in women with clinically recognized 3rd or 4th degree sphincter lacerations and to correlate its occurrence with FI, POP, and UI at 6–12 months postpartum in the entire cohort of primiparous women that participated in the CAPS imaging study.

METHODS

Study Population

The CAPS study was a multicenter, prospective cohort study conducted by the Pelvic Floor Disorders Network (PFDN) and supported by the National Institute of Child Health and Human Development. This study of primiparous women evaluated FI and UI symptoms at 6 weeks and 6 months after delivery, and has been previously described.(5–7) The CAPS study included three cohorts of primiparous women: Group 1, vaginal delivery with a clinically recognized 3rd or 4th degree anal sphincter tear (sphincter tear); group 2, vaginal delivery without a clinically recognized anal sphincter tear (vaginal control); and, group 3, cesarean delivery without labor (cesarean control). All women with a sphincter tear were invited to participate; the next woman delivered at each institution without a sphincter tear was invited to be a control and therefore many women without sphincter tears were not invited to participate.

A subset of the CAPS subjects was invited to undergo additional evaluations at 6–12 months postpartum. This included pelvic floor imaging using both MRI and endoanal ultrasound, the techniques of which have been described previously.(7–8) The women who participated in this MRI study were similar to the overall CAPS population who did not participate in age, rates of episiotomy and of vacuum or forceps intervention, and fecal incontinence prevalence and severity. However, more African-American women participated in this MRI study. Physical examination using the pelvic organ prolapse quantification (POP-Q) score was performed. (9). Other outcome data gathered 6–12 months after childbirth included the Medical Epidemiologic and Social Aspects of Aging (MESA) and FI Severity Index (FISI) questionnaires to assess UI and FI.(10–11) A separate informed written consent was obtained from all imaging subjects in this IRB-approved study. For the purposes of this study, POP is defined as maximal vaginal descent at or below the hymen, UI as at least one response of urine leakage “sometimes” or more frequently on all 15 MESA items, while stress UI is limited to at least one response of urine leakage “sometimes” or more frequently on the first 6 MESA SUI items. FI is present if the subject’s response on the FISI was anything other than “Never” to questions regarding accidental bowel leakage of liquid, solid or mucus stool within one month. We chose a cut-point of maximal vaginal descent at or below the hymen to define prolapse because of an emerging body of research that suggests that women are more likely to be symptomatic at this level than above the hymen.(12–15)

Image reader training

Three board certified radiologists with 2–10 years of subspecialty experience in abdominal imaging participated in an on-line, case-based training led by the originator of the LAM defect scoring system (JD). Online training and teleconferencing was facilitated using Microsoft Office Live Meeting® (2009 Microsoft Corporation) enabling collective discussion and image review. A centralized Data Coordinating Center (DCC) for the PFDN facilitated these meetings. The training and testing dataset used pelvic floor MRI images from the Michigan Pelvic Floor Research Group’s imaging library, which contains approximately 1,000 MRI scans of subjects with pelvic floor dysfunction and asymptomatic volunteers. The online training was performed during six, two- hour, web-based teleconferences.

In total, 75 examinations obtained from the Michigan data library were reviewed for the training portion of the study, in groups of 15 studies per training session. In the initial session, readers were taught to identify the relevant landmarks and anatomy and to understand and utilize a LAM injury grading system.(16) This technique is known for high interrater reliability in categorical grading of LAM defects, with a reported overall weighted kappa coefficient of 0.86 (95% CI 0.83, 0.89) as determined by investigators at one site.(17) For the next two reader review sessions, the readers prospectively reviewed studies that were collated in a Microsoft PowerPoint® (2004 Microsoft corporation) presentation, with 12 images presented per slide, in both axial and coronal orientations. The readers were blinded to clinical data and outcomes. Scoring and assessment were discussed on a teleconference call, but a final consensus score was neither collected nor recorded. For the final three sessions (45 studies), the readers reviewed and scored the studies prospectively and independently, and then submitted the scores prior to the group review and discussion of the examinations. When it was determined that training was sufficient, based on an analysis of interrater agreement and agreement within one point difference, the two readers who had the highest agreement with the trainer and between themselves went on to score the MRI examinations that were obtained in the CAPS imaging study cohort.

MRI image evaluation

Two radiologist readers at different clinical sites independently scored injury severity to each side of the LAM complex, blinded to all clinical and research data. Each reader received the study images on DVD, and used the Open-Source Apple-Macintosh based OsiriX DICOM viewer platform to review the studies. The readings occurred over a 3-month period, and no additional training or feedback was provided to the readers once the MRI review started.

The right and left LAM muscles were identified on both axial and coronal imaging, and a categorical variable was assigned to grade the muscle defect as follows: 0 = no defect; 1 = < ½ of muscle missing; 2 = > ½ of muscle missing; 3 = muscle absent. The scores for each side were then summed. The threshold for significant injury was met when either the total score was ≥4 or a unilateral grade 3 defect was present. Lesser scores have not been associated with increased occurrence of pelvic organ prolapse (16) or at risk obstetrical parameters.(18). A total score of ≥4 or grade 3 on either side was classified as a major LAM injury (MRI+); and anything less was scored MRI−. The MRI-category included women with both no injury and minor injuries.

Statistical Analysis

The LAM defect score was dichotomized into no major injury (MRI−) versus major injury (MRI+), as described above. Kappa coefficients were computed to evaluate interrater reliability.

A consensus score was then determined: if the two raters agreed on the dichotomous outcome, then the outcome was accepted; otherwise, a third rater (the trainer) evaluated the image set, also blinded to all clinical data, and the dichotomous outcome was determined by the majority (i.e., the trainer and one of the original raters). The consensus score was used in all the analyses.

Analyses were performed for all subjects and then separately for each cohort of the study (the sphincter tear, vaginal control, and cesarean control groups). Since a large majority of major LAM injuries were found in one cohort, it was determined that cohort status would confound tests of association. Therefore, tests were reported separately for each cohort. Fisher's exact test (2-tailed) was used to test for statistical significance; p-values were reported with no adjustment for multiple tests. A p-value < 0.05 was considered statistically significant. Analyses were performed using SAS 9.1 (SAS Institute, Cary, NC).

RESULTS

Population

The population has been previously described.(8) Briefly, the mean age, and standard deviation across all cohorts is 27.8±6.1, with no significant difference in age by cohort (p=0.30). Approximately 75% of the population was Caucasian. Fifty six percent of the sphincter tear group had undergone a forceps or vacuum delivery, compared to 11% of the vaginal control group. Additionally, the birth weight was significantly larger in the sphincter tear group as compared to the vaginal control group or Cesarean control group, at 3602±433 grams, 3410 ±378 and 3415±434 (p=0.005), respectively.

Reader Reliability

The images from 206 MRI examinations were available for review. Twenty-nine of the 235 examinations were not evaluated because either the original data had become unreadable or the identifier on the images could not be verified. Reliability results are presented in Table 1. The readers agreed on 189 scores and disagreed on 17 scores, for overall moderate agreement (Cohen's kappa = 0.59). One reader identified more MRI+ scans than the other (McNemar's test, p=0.013). The third reader then evaluated the 17 examinations with disagreement between the first two readers. This reader classified 5 scans as MRI+, agreeing with 4 of the 14 scans classified by the first reader as MRI+ and the second reader as MRI−, and with 1 of the 3 scans classified by the second reader as MRI+ but by the first reader as MRI−. There were 121 scans that received a score of 0 from both readers (out of 174 that were classified as MRI− by both readers). Of the 32 scans that were MRI+, 28 examinations had at least one side with a score of 3 (complete muscle loss).

Consensus scoring

Scores that reflect the consensus reading are presented in Table 2. Using the same MRI LAM scoring system, major LAM injuries were seen in 17/89 (19.1%) of the sphincter tear subjects, 3/88 (3.5%) of vaginal control subjects and 0/29 (0%) of Cesarean delivery subjects. Major LAM injury was strongly associated with whether the subject had a sphincter tear at delivery (p=0.0005).

Pelvic Floor Symptoms

Of the 206 subjects with MRI LAM injury scores, 203 completed the MESA questionnaire and the POP-Q examination, while 206 completed the FISI. Table 3 demonstrates the relations between LAM injury and clinical measures in aggregate (all) and by cohort. Since only three major LAM defects were found in the vaginal control cohort (with a clinically intact anal sphincter), we focused our analysis on the sphincter tear cohort. Among women with sphincter tears, those with concomitant major LAM injuries (MRI+) showed trends towards more FI symptoms, 35.3% vs. 16.7% (p=0.10); and POP, 35.3% vs. 15.5% (p=0.09); but not SUI, 25.0% vs. 24.3% (p=1.0). Seventeen women in the sphincter tear group had prolapse when defined as maximal vaginal descent at or below the hymen. POP-Q points Ba and Bp were more likely at or below the hymen in women with major LAM injuries than in women without such injury, 29.4% vs. 11.3%, and 5.9% vs. 1.4%, respectively. However, only 13 and 2 women, respectively, had prolapse to this degree. Of women with major LAM injuries, cases of UI and SUI were only seen in the sphincter tear cohort, whereas in the MRI− group, UI and SUI were distributed evenly across all the cohorts.

COMMENT

Six to twelve months after delivery, major LAM injuries were significantly more common in women with sphincter tears than in those who delivered vaginally without sphincter tears or by cesarean. One in five women with a sphincter tear had a major LAM injury on MRI. We found no major LAM injuries in women who delivered by cesarean without labor. Our findings are consistent with a study using endoanal MRI in 105 women with severe FI, which found that LAM defects coexisted with anal sphincter defects in 30% of patients.(19) These observations underscore the importance of vaginal delivery, particularly traumatic vaginal delivery with sphincter tear, as a risk for major LAM injury.

If major LAM injuries are more common in more traumatic vaginal deliveries, it is reasonable to assume such an injury would increase the risk of pelvic floor dysfunction later in life. A recent case-control study demonstrates this pattern of pelvic floor muscular injury with POP. A comparison of 151 women with prolapse matched for age, race, and parity to 135 women with normal pelvic support found major LAM injuries in 55% of the women with prolapse, but only in 16% of the women with normal support.(16) The prevalence of major LAM injury in women with symptomatic prolapse in this published study is substantially higher than the 9.7% we noted in our study. Several factors may contribute to these differences. Our cohort is far younger than the typical age at which most women develop clinically significant POP, so some of the women in our study may develop POP later in life. Our subjects were selected based on obstetrical delivery status while in the case-control study cases were selected based on the existence of POP a centimeter or more below the hymenal ring. Further research will be required to assess the likelihood of a major LAM tear developing as a function of additional deliveries and aging. Whether LAM injuries occur due to direct trauma to the muscle or secondary to potential nerve injury is also currently unknown.

Given the case-control design of our study, our data cannot be used to determine the overall incidence of major LAM injuries after vaginal delivery. The prevalence of clinically recognized grade 3 and 4 sphincter tears, at more than 40% in this research population, is significantly higher than the prevalence in a normal population of primiparous women. Thus, if the incidence of LAM injury is closely correlated with the rate of significant anal sphincter tear, the overall prevalence of LAM injury will vary depending on the proportion of women in a given population that sustain this degree of birth related injury.

Almost all of our observed major LAM injuries occurred in women with a clinical diagnosis of sphincter tear, underscoring the negative effect such a delivery may have on integrity of the pelvic floor, but precluding us from commenting substantively on LAM injury in the absence of sphincter injury. Our study design did provide an opportunity to understand and define specific anatomic factors associated with FI. While we were underpowered to detect changes in pelvic floor symptoms after LAM injury, we did observe trends consistent with other reports.(2) Among women with sphincter tears, there were trends toward higher rates of FI and symptomatic POP, but not UI. This observation emphasizes the need to consider separate mechanisms of injury for various types of pelvic floor dysfunction and not to presume that a given vaginal delivery has a comparable impact on all pelvic compartments.

We are confident in our determination of LAM injury status in these women. The ordinal scoring system for LAM defects used in this study has been previously demonstrated to be highly reliable between raters at one site with a weighted kappa of 0.86.(17) That study tested the scoring system using a dataset with fairly equal numbers of subjects with prolapse versus normal controls. In the current study, our readers had similar training in the same system, but achieved a lesser, moderate overall agreement with a kappa of 0.59. The reason for this difference is not entirely clear, but may be attributable at least in part to the behavior of the kappa index as a measure of clinical agreement. While the kappa coefficient is popularly used to describe observer agreement and variability, it can be dramatically affected by disease prevalence. Two observer pairs measuring two disease processes with equivalent percent of agreement will generate a lower kappa for the disease process in which the prevalence is low (a situation known as "Feinstein's paradox").(20) Our prevalence of major LAM defects in this group of young, primiparous women was 9.7%, far less than the 55% previously reported in women with symptomatic prolapse,(16) and this likely contributed to a lower kappa despite fairly impressive percent agreement between our readers.

CONCLUSION

A higher prevalence of major LAM injury is identified on MRI in women who experience anal sphincter tears during delivery. This study confirms a reliable image scoring system for assessing these LAM injuries on MRI. It is likely that the combination of anal sphincter injuries during delivery and major LAM injury increases the future risk of POP and FI. Patients with such a history may benefit from early surveillance, education, and therapy directed at preventing the later sequelae of pelvic floor dysfunction. Future studies should be designed to look at such preventative or regenerative therapies.

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Table 1

Blinded reader score

	Reader 2		
Reader 1	**MRI −**	**MRI +**	**Total**
MRI −	174	3	177
MRI +	14	15	29
Total	188	18	206

MRI− = No/minor LAM injury
MRI+ =Major LAM injury

Table 2

Major LAM injury relationship to status at delivery

	Treatment Group			
Consensus Reading	**Sphincter Tear**	**Vaginal Control**	**Cesarean Control**	**Total**
MRI− (No/minor LAM injury)	72	85	29	186
MRI+ (Major LAM injury)	17	3	0	20
Total (%)	89 (19.1%)	88 (3.5%)	29 (0%)	206 (9.7%)

LAM= Levator ani muscle

Table 3

Pelvic Floor Symptoms and LAM Injury

Clinical outcome	Group	Proportion with Clinical outcome (%)		p-value
		MRI+ (Major LAM injury)	MRI− (No/minor LAM injury)	
Urinary incontinent based on MESA	All	5/19 (26.3%)	59/184 (32.1%)	0.80
	Sphincter tear	**5/16 (31.3%)**	**23/70 (32.9%)**	**1.00**
	Vaginal control	0/3 (0%)	29/85 (34.1%)	0.55
	Cesarean control		7/29 (24.1%)	
Stress urinary incontinent based on MESA	All	4/19 (21.1%)	40/184 (21.7%)	1.00
	Sphincter tear	**4/16 (25.0%)**	**17/70 (24.3%)**	**1.00**
	Vaginal control	0/3 (0%)	18/85 (21.2%)	1.00
	Cesarean control		5/29 (17.2%)	
Fecal incontinence based on FISI	All	7/20 (35.0%)	19/186 (10.2%)	0.006
	Sphincter tear	**6/17 (35.3%)**	**12/72 (16.7%)**	**0.10**
	Vaginal control	1/3 (33.3%)	2/85 (2.4%)	0.10
	Cesarean control		5/29 (17.2%)	
Any POP measure at or below the hymen	All	8/20 (40.0%)	33/183 (18.0%)	0.035
	Sphincter-tear	**6/17 (35.3%)**	**11/71 (15.5%)**	**0.087**
	Vaginal control	2/3 (66.7%)	17/83 (20.5%)	0.12
	Cesarean control		5/29 (17.2%)	
Ba at or below hymen	All	6/20 (30.0%)	22/183 (12.0%)	0.039
	Sphincter-tear	**5/17 (29.4%)**	**8/71 (11.3%)**	**0.12**
	Vaginal control	1/3 (33.3%)	13/83 (15.7%)	0.42
	Cesarean control		1/29 (3.4%)	
Bp at or below hymen	All	3/20 (15.0%)	1/183 (0.6%)	0.003
	Sphincter tear	**1/17 (5.9%)**	**1/71 (1.4%)**	**0.35**
	Vaginal control	2/3 (66.7%)	0/83 (0%)	0.0008
	Cesarean control		0/29 (0%)	

Sphincter tear = external anal sphincter tear cohort; Vaginal control = vaginal delivery cohort; Cesarean control = cesarean delivery cohort; LAM = Levator ani muscle; MESA = Medical Epidemiologic and Social Aspects of Aging questionnaire; SUI = stress urinary incontinence; FISI = Fecal Incontinence Severity Index; POP = Pelvic organ prolapse, Ba = Point Ba dichotomous; Bp = Point Bp dichotomous.