DR. FERNANDA PIPITONE (Orcid ID : 0000-0001-5134-8523)

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TITLE: Injury-Associated Levator Ani Muscle and Anal Sphincter Edema Following Vaginal Birth: a Secondary Analysis of the EMRLD Study

Authors:

Fernanda Pipitone, MD. Pelvic Floor Research Group, Michigan Medicine, University of Michigan, 1540 E Hospital Dr, Ann Arbor, MI 48109, USA.

Janis M. Miller, PhD, APRN. University of Michigan School of Nursing and Medical School Department of Obstetrics and Gynecology, 426 N Ingalls St, Ann Arbor, MI 48104, USA.

John O.L. DeLancey, MD. Obstetrics and Gynecology Department, Michigan Medicine, University of Michigan, 1540 E Hospital Dr, Ann Arbor, MI 48109, USA.

Corresponding author: Fernanda Pipitone

1540 E Hospital Dr, Ann Arbor, MI 48109

+1 734 780-0229

fernanda.pipitone@gmail.com

Running Title: Pelvic Floor Muscle Edema Following Vaginal Birth

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ABSTRACT

Objective: To determine if all three components of the levator ani muscle (pubovisceral [=pubococcygeal], puborectal and iliococcygeal) and the external anal sphincter are equally affected by edema associated with muscle injury after vaginal birth.

Design: Observational cross-sectional study.

Setting: Michigan Medicine, University of Michigan.

Population: Primiparous women classified as high risk for levator ani muscle injury during childbirth.

Method: MRI scans obtained 6-8 weeks postpartum were analysed. Muscle edema was assessed on axial and coronal fluid-sensitive MRI scans. Presence of edema was separately determined in each levator ani muscle component and in the external anal sphincter for all subjects. Descriptive statistics and correlation with obstetric variables were obtained.

Main outcome measures: Edema score on fluid-sensitive MRI scans.

Results: Of the 78 women included in this cohort, 51.3% (n=40/78) showed muscle edema in the pubovisceral (one bilateral avulsion excluded), 5.1% (n=4/78) in the puborectal, 5.1% (n=4/78) in the iliococcygeal. No subject showed definite edema on external anal sphincter. Incidence of edema on pubovisceral muscle was 7 times higher than on any of other analysed muscles (all paired comparisons, P-value <0.001).

Conclusions: Even in the absence of muscle tearing, the pubovisceral muscle shows by far the highest incidence of injury, establishing that levator components are not equally affected by childbirth. External anal sphincter did not show edema – even in women with sphincter laceration - suggesting a different injury mechanism. Developing a databased map of injured areas helps understand injury mechanisms that can guide us in honing research on treatment and prevention.

Keywords: levator ani; magnetic resonance imaging; musculoskeletal injuries; pelvic floor; vaginal birth.

Tweetable abstract:

Injury-associated levator ani muscle and anal sphincter edema mapping on MRI reveals vulnerable muscle components after childbirth

Introduction

Women with childbirth-related pelvic floor trauma are present in the everyday practice of obstetricians and midwives. It is, therefore, incumbent on us to know the scientific foundation of these injuries; what type of injury has occurred, how it happened, how different types of injury are best treated, and how they could be prevented. Although progress is being made in this science, our knowledge of injury mechanisms remains incomplete.

Levator ani muscle tearing or avulsion from its pubic origin occurs in 10 to 15% of women[1,2] so a unit that does 10 births daily will have, on average, one injured woman each day. Definitive studies have shown that this gross muscle disruption (a "defect" seen on imaging) results in prolapse in 25% of women followed longitudinally.[3] However, gross disruption, the focus of most research so far, is only one form of muscle injury.[4] Injury within the muscle, known in lay terms as "pulled muscle" can occur in the absence of a torn muscle yet anyone who has pulled a muscle knows how painful and disabling it can be, and how long it takes to fully recover.

In previous work, we documented levator edema following childbirth.[5] We subsequently realized it did not equally involve all 3 components of the muscle (pubovisceral[*], puborectal and iliococcygeal[6]) (Figure 1). As biomechanical modeling studies predict that different parts of the muscle experience different degrees of stretch[7], the edema pattern may give us insight into injury mechanisms and yield a databased map of vulnerable muscles. This could help build a more complete foundation on which to base injury treatment or prevention.

Based on anatomical and functional differences between each levator component and the external anal sphincter[8], it is plausible to think that injury to one muscle may have a different mechanical effect than injury to another. Therefore, we sought to test the null hypothesis that all three components of levator ani muscle and external anal sphincter are equally affected by edema related to vaginal childbirth. In addition, we sought to establish the consequences on hiatal dimensions at 6-8 months after healing was complete.

[*] We have chosen to use the term pubovisceral rather than the *Terminologia Anatomical* term pubococcygeal because the latter term was based on evolutionary grounds, rather than the typical origin-insertion custom. The muscle inserts primarily on the vagina, perineal body, and anus with only a few trivial fibres inserting on the coccyx.

Materials and Methods

This report is a secondary analysis of data from the *Evaluating Maternal Recovery from Labor and Delivery* (EMRLD) project[9], an institutional review board-approved longitudinal study conducted at the University of Michigan (IRB HUM00051193). EMRLD was designed to study patterns of childbirth-related muscle injury, short and longer-term, as evaluated by magnetic resonance imaging (MRI) at 6-8 weeks and again at 6-8 months after delivery. Pertinent demographic and obstetric data were obtained by chart review early postpartum. Ninety primiparous women were recruited for risk of levator ani injury during childbirth. Screening factors were: length of second stage of labour greater than 150 or less than 30 minutes, anal sphincter laceration, forceps use, maternal age greater than 35 years and newborn birth weight greater than 4000 grams, as established in the original study.[10]

In the present report, additional inclusion criteria were the availability of an MRI done at the early time point (6-8 weeks postpartum) using fluid-sensitive sequences. This report's scoring differs from prior EMRLD reports in its focus on identifying variance in distribution of edema by discrete muscles' subdivisions, some of which were not scored previously.

Details of the imaging protocol were previously described.[11] To briefly summarize, MRI was performed using a 3 Tesla Philips Achieva scanner (Philips Medical Systems, Eindhoven, The Netherlands), with an 8-channel cardiac coil positioned over the pelvis, and included coronal, axial and sagittal proton density-weighted sequences. Additional fluid-sensitive sequences in axial and coronal planes were obtained with either proton density-weighted fat saturation or short tau inversion recovery (STIR) sequences.

High-intensity signal on fluid-sensitive scans was used as a marker for muscle injury, as it is a well-established technique for other parts of the body to assess stretch injury that did not result in gross muscle tearing. In brief, musculotendinous strains are a type of muscle injury particularly suitable for MRI assessment with fluid-sensitive sequences because the microscopic fibre disruption present in stretch injuries leads to interstitial edema and sometimes hemorrhage. These altered fluid states are easily identified on fluid-sensitive imaging.[12]

Assessment of each levator ani muscle component (pubovisceral, puborectal and iliococcygeal) and the external anal sphincter was performed on axial fluid-sensitive scans based on muscle subdivision identification previously established.[13] It should be noted that custom in pelvic floor ultrasound uses the term "puborectal" for the injured muscle.

To assess edema, signal was compared with the immediately adjacent obturator internus muscle - known not to be involved in childbirth-related injuries[14] – on fluid-sensitive axial scans. Anatomic landmarks were confirmed on T2 proton density-weighted sequences, and presence of muscle edema were confirmed on coronal plane. Each of the three levator muscle subdivisions and the external anal sphincter were individually analysed on every subject for presence or absence of edema as a dichotomous variable (Figure 2). Whenever presence of edema was uncertain during this review, window and level settings were adjusted until the obturator internus muscle could no longer be identified. If the signal in the levator ani muscle was, then, not visible, edema was judged to be absent; if it was still possible to see some degree of signal, edema was determined to be present. If a discrepancy between sides occurred (left-right), the side with higher score was chosen for comparisons.

Subjects were excluded from the cohort if complete bilateral levator ani avulsion was present. Although the muscle is likely still present after detachment from the pubic symphysis, we have not been able to accurately identify where it has retracted to. Therefore, muscle edema could not reliably be quantified in the pubovisceral component in these instances. In this report, classification of levator ani tears (as observed muscle "defect" on MRI) was done according to the method previously validated and published by the group.[15] Briefly, tears were categorized as none (bilaterally intact muscles), minor (bilateral scores 1-3), or major (bilateral scores 4-6 or score 3 unilaterally). All scans were reviewed independently by two authors (FP and JOLD) who reviewed and discussed all instances when muscle edema score or levator status differed to arrive at consensus.

The difference in fibre direction between pubovisceral and puborectal becomes clearer as they diverge dorsally.[8] For this reason, this was the area chosen for edema assessment. Near the pubic symphysis, their anatomy overlaps and therefore impairs precise identification of structures.

The measurements of urogenital and levator hiatuses were made on mid-sagittal 8-month scans at rest. Six-to-eight-month scans, rather than 6 to 8-week scans, were chosen to reflect hiatus status after completion of the healing process to provide a better long-term assessment of the effect of injury. The levator hiatus was defined as the shortest distance in centimeters from the inferior pubic point to the ventral surface of the levator ani on rest scans. The urogenital hiatus was defined as the shortest distance from the pubic bone to the ventral aspect of the perineal body.[16]

In our obstetrical unit, some providers delay pushing after complete cervical dilation for a period till the head is lower in the pelvis to conserve maternal energy reserves. For this reason, length of second stage of labour is presented here as two different continuous variables: total second stage, defined as the period of time from total cervical dilation to birth; and, active second stage, defined as the length of time during which women were actively pushing.

Statistical Analysis: Descriptive statistics stratified by edema status were obtained for demographic, obstetric data, levator tear status, and hiatus status. Independent samples t-tests and Fisher's exact tests, where appropriate, were used to assess the distributions by edema status of these characteristics. McNemar tests were used to compare edema status for the pubovisceral, puborectal, and iliococcygeal muscles. SPSS (IBM® SPSS® Statistics 26.0) and a 95% confidence level were used for all analyses.

Results

Seventy-nine postpartum primiparous women met inclusion criteria. One woman was excluded for bilateral levator muscle avulsion, leaving 78 women for analysis.

Sample characteristics are shown in Table 1. Women were of childbearing age and with average BMI of 26.4 ± 5.3 kg/m^2 per postpartum status. Six had a discrepancy between right and left side, and in five of these it was the right side that showed greater degree of edema. Among the 78 scans, there were 9 in which there was a difference of opinion between authors; consensus was achieved after discussion.

For the urogenital hiatus and levator hiatus dimensions observed at 6-8 months postpartum, mean (SD) distance was 32.2 (8.1) cm and 52.4 (10.3) cm respectively, with no difference between groups by muscle edema status at 6-8 weeks postpartum (Table 1).

Muscle edema in the pubovisceral was found in 51.3% of women (n=40/78), puborectal in 5.1% (n=4/78), iliococcygeal in 5.1% (n=4/78), and the external anal sphincter in none of the cases (n=0/78). The incidence of edema in the pubovisceral muscle was significantly higher than in any of the other analysed muscles (all paired comparisons yielded a P-value <0.001[†]). Figure 3 details injury-score distribution per muscle. Notably, puborectal and iliococcygeal edema was only present when there was pubovisceral edema and never in its absence.

In women with pubovisceral edema a clear transition between the edematous area and other portions of the levator was often evident. Figure 4 shows examples of subjects in which this transition can be easily seen on fluid-sensitive sequences. It occurred at the junction between the pubovisceral and iliococcygeal muscles.

Edema groups differed significantly in the continuous measures of newborn birth weight and active second stage of labour length (Table 1). Mean newborn weight was 9% greater in subjects with muscle edema. Mean active second stage length was 75% longer in patients with edema. We chose to also analyse total second stage as a dichotomized variable (greater or less than 150 minutes) – per the inclusion criteria cut point of 150 minutes as a one of the risk factors for levator injury considered in recruiting this cohort. When this variable was dichotomized, the edema group showed a 27% higher incidence of total length of second stage greater than 150 minutes (P-value 0.01).

Discussion

Main Findings

These data provide a map of muscle edema in women at high risk for levator tear during vaginal birth. Edema is seven times more incident in the pubovisceral muscle than puborectal or iliococcygeal muscles and occurs in about half the cases. Muscle edema was only found in the two latter muscles when it was also present in the pubovisceral

[†] For the pubovisceral vs. external anal sphincter comparison, the computation was done in R.

component. This suggests an injury pattern that most often affects pubovisceral but can in some cases extend to adjacent muscles. It is consistent with the stretch-induced injury premise from biomechanical modeling[7] that reveals that the pubovisceral muscle undergoes the greatest degree of elongation during birth. It also supports the hypothesis that this injury is caused by stretching rather than compression as the iliococcygeal muscle, being higher in the birth canal, would be subjected to compressive forces for longer than the pubovisceral muscle. The anal sphincter, in turn, moves dorsally during birth but is not subjected to similar degrees of stretching (Figure 1). In this report, the external anal sphincter did not demonstrate clear edema in any subject even though many of these women - selected to be at high risk for injury - had sphincter tears. We, therefore, reject the null hypothesis that all three levator ani muscle components and the external anal sphincter are equally affected by edema, a marker of tissue injury. Although the association of obstetric variables with muscle edema was not our primary objective and is limited by sample size, it parallels, as expected, with what is known about levator tears.[10,17]

As hiatus size and closure mechanism failure are now an established link between childbirth injuries and the consequent pelvic floor disorders[3,16,18], we decided to include in the analysis the measurement for both urogenital and levator hiatuses. A choice was made to use hiatal anteroposterior diameter and not hiatal area as it captures the majority of the variation[18] and the software we had available for window and level adjustment did not allow for plane tipping needed to capture the plane parallel to the puborectal muscle for area calculation[19] at the time of this analysis. On average, smaller hiatal measurements were observed for women with edema. Although this study fails to find statistical differences in hiatal measures between those with and without edema, it is possible that individuals with overall smaller pelvises are at greater risk for pelvic floor trauma. Further research is needed to elucidate these findings.

<u>Interpretation</u>

Why is it important to know about these injuries? Many women have significant pain and disability after vaginal birth. For centuries, no tests were available to document the cause. Ultrasound and MRI have allowed us to determine whether the muscle is visibly torn, but this is only the most severe aspect of the muscle injury spectrum. Muscle strain ("pulled muscle") can be very painful despite not involving gross muscle disruption and may be the reason for pain and dysfunction after birth. Specific treatment regimens are well established for other muscles in the body and should be considered for these injuries. We emphasize that we are not suggesting that women require MRI clinically, but rather that this can help inform us about definite injuries and their mechanisms. Ultrasound is used in other parts of the body for edema assessment[20] and we believe that with proper study it can be applied to the levator edema after birth.

The specific edema pattern can yield insight into injury mechanisms by providing a map of areas under greater risk. Each levator component has its own origin and insertion points[21], and MRI studies in living women have confirmed that they also have different fibre directions and, consequently, different lines of action.[8] The pubovisceral muscle, for instance, attaches to the vagina, perineal body, and anus, generating both a lifting force on these structures and a closure force on the urogenital hiatus. The puborectal muscle passes behind the ano-rectal junction affecting levator hiatus closure but with no significant lifting action. The iliococcygeal muscle has similar line of action to the pubovisceral, although inserted differently, and might mitigate major pubovisceral tears. The external anal sphincter, although not part of the levator, is attached to the anococcygeal ligament and may participate in those actions, aside from its constriction role. Based on these anatomical and functional differences, it is plausible to think that injury to one muscle – and the consequent loss of its specific force vector - may have different mechanical effect than injury to another. In addition, the external anal sphincter is known to undergo laceration and denervation[22–25], but it is unknown whether these are associated with visible edema.

From our new analysis of data within the EMRLD study, it seems likely that the anal sphincter differs in injury mechanism from the pubovisceral muscle. For the 33% of women who came into the EMRLD study with 3rd or 4th degree perineal laceration documented in the delivery room (as it was an inclusion criterion to this high-risk cohort for levator ani injury), edema was nevertheless rarely seen in the external anal sphincter. This suggests that anal sphincter tearing is associated with tearing of the perineal body rather than stretching of the sphincter fibres themselves. This finding raises the important issue of differing injury mechanisms having different consequences and hence should elicit different preventive measures.

As a striated muscle, the levator ani is more likely to be injured if forcibly lengthened.[26] Biomechanical studies simulating childbirth have shown a 3.3 stretch ratio for the pubovisceral muscle, which is 217% greater than the stretch limit established as non-injurious for striated muscles.[7] Therefore, even in the absence of grossly visible muscle tearing, it is logical that at a finer level there is muscle disruption.

Broadening the spectrum of possible injuries and further detailing the mechanisms through which they happen is key in developing effective prevention measures. Women who present muscle edema but not muscle tears, for instance, might benefit from early postpartum physical therapy. Or if we learn how to identify the subset of women who are at higher risk for extensive pelvic floor micro trauma, prenatal counseling on mode of delivery might be conducted differently.

<u>Strengths and Limitations</u>

Our report adds important new information to the growing knowledge about the several different muscle injury mechanisms that affect the levator and provides additional evidence that the pubovisceral injury is stretch induced.

Our findings regarding edema are in parallel with previously reported literature about grossly visible muscle tearing[27] and intact puborectal muscle in subjects with major levator ani tear.[28] Analysis was done on MRI scans with high spatial resolution by individuals experienced with levator anatomy - including identification of the different subdivisions[13] - which provide detailed pelvic anatomy and a powerful tool for edema assessment with fluid-sensitive sequences.

Several limitations must be considered in interpreting the results. This is not a population-based sample. Rather, the sample was purposely enriched to recruit women at high risk for levator injury and so the frequency with which edema is seen is higher than one would expect with normal birth. In addition, our sample size and design limit interpretation of factors associated with muscle injury. Subsequent studies should be performed to confirm the observed associations we have highlighted in this manuscript.

Conclusion

In conclusion, even in the absence of gross muscle tearing, the pubovisceral muscle shows by far the highest incidence of childbirth-related muscle injury. Adjacent muscles only show signs of edema in the presence of edema on the pubovisceral component. External anal sphincter did not show edema, even in the presence of tears, suggesting a different injury mechanism for sphincter laceration. Future studies are necessary to understand what it is that leads to these subclinical injuries, whether they result in symptom variances across women, and delayed or inadequate return to normal function.

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Disclosure of interests: None

Contribution to Authorship:

FP. Study design, acquisition of data, analysis of data, manuscript draft.

JMM. Acquisition of data, Manuscript revision.

JOLD. Study design, acquisition of data, analysis of data, manuscript revision.

Ethics Approval: University of Michigan, Institutional Review Board approved on August 30th, 2011 (HUM00051193).

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Figures/Table caption list

Figure 1. Illustration of pelvic floor muscles at crowning where all three components of the levator ani muscle (pubovisceral, puborectal and iliococcygeal) as well as the external anal sphincter can be seen. Note different fiber directions between different muscles. (© DeLancey).

Figure 2. Fluid-sensitive MRI axial scan illustrating muscle edema scoring. Top and bottom rows display subjects without muscle edema and with muscle edema, respectively. Each column, as labeled, corresponds to one levator ani component indicated by closed arrowheads. The external anal sphincter is not illustrated here as edema was not demonstrated on any subject in this muscle. Obturator internus muscle (closed arrow) is the reference for signal intensity. (B) Bladder; (U) Urethra; (V) Vagina; (R) Rectum.

Figure 3: Edema distribution per levator ani muscle component on the right (R) and on the left (L) sides.

Figure 4. Fluid-sensitive axial MRI scans at the level where the pubovisceral (closed arrowhead) and the puborectal (open arrowhead) fibers diverge. Panels a and b exemplify two different subjects. Open arrow indicates transition between edema in the pubococcygeal and lack of edema in the puborectal muscles. Obturator internus muscle is indicated (closed arrow). (U) Urethra; (V) Vagina; (R) Rectum.

Table 1. Demographic, Obstetric and MRI Characteristics of the Study Population.

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	All subjects	By edema status		
		Edema	No edema	P-value
	N=78	n=40	n=38	
Demograhic data	Mean ± SD			
Age (years)	28.9 ± 5.9	29.3 ± 5.3	28.5 ± 6.5	0.60
BMI (kg/m^2)	26.4 ± 5.3	25.9 ± 5.0	27.0 ± 5.8	0.49
Obstetric data	Subjects (%)			
Forceps	2 (2.6)	2	0	.
Instrumented	7 (9.0)	5	2	0.18
Total 2nd stage >150min	38 (48.7)	25 (62.5)	13 (35)	0.01
OASI*	19 (33.3)	11 (34.4)	8 (32.0)	0.22
NB weight >4000g	7 (9.0)	1 (3)	6 (15)	0.06
Episiotomy	15 (19.2)	10 (27)	5 (13.5)	0.10
	Mean ± SD			
Total 2nd stage length (min)	151 ± 131	171 ± 125	134 ± 137	0.20
Active 2nd stage length (min)	104 ± 88	136 ± 90	77 ± 76	0.01
NB weight (grams)	3372 ± 506	3532 ± 509	3214 ± 470	0.00
MRI data				
Levator ani tears	Subjects (%)			
None	41 (52.6)	18 (23.1)	23 (29.5)	
Minor	28 (35.9)	14 (17.9)	14 (17.9)	
Major	9 (11.5)	8 (10.3)	1 (1.3)	0.02▲
Hiatuses on 2nd scan**	Mean ± SD			
Urogenital hiatus (mm)	32.2 ± 8.1	31.3 ± 9.5	33.4 ± 5.8	0.39
Levator hiatus (mm)	52.4 ± 10.3	50.5 ± 11.9	55.2 ± 7.2	0.11

Continuous variables were analysed with unpaired t-test. Categorical variables were analysed with Fisher's exact test. *n=57; **n=55; ▲levator tears were dichotomized into "major" and "not major" for statistical analysis.

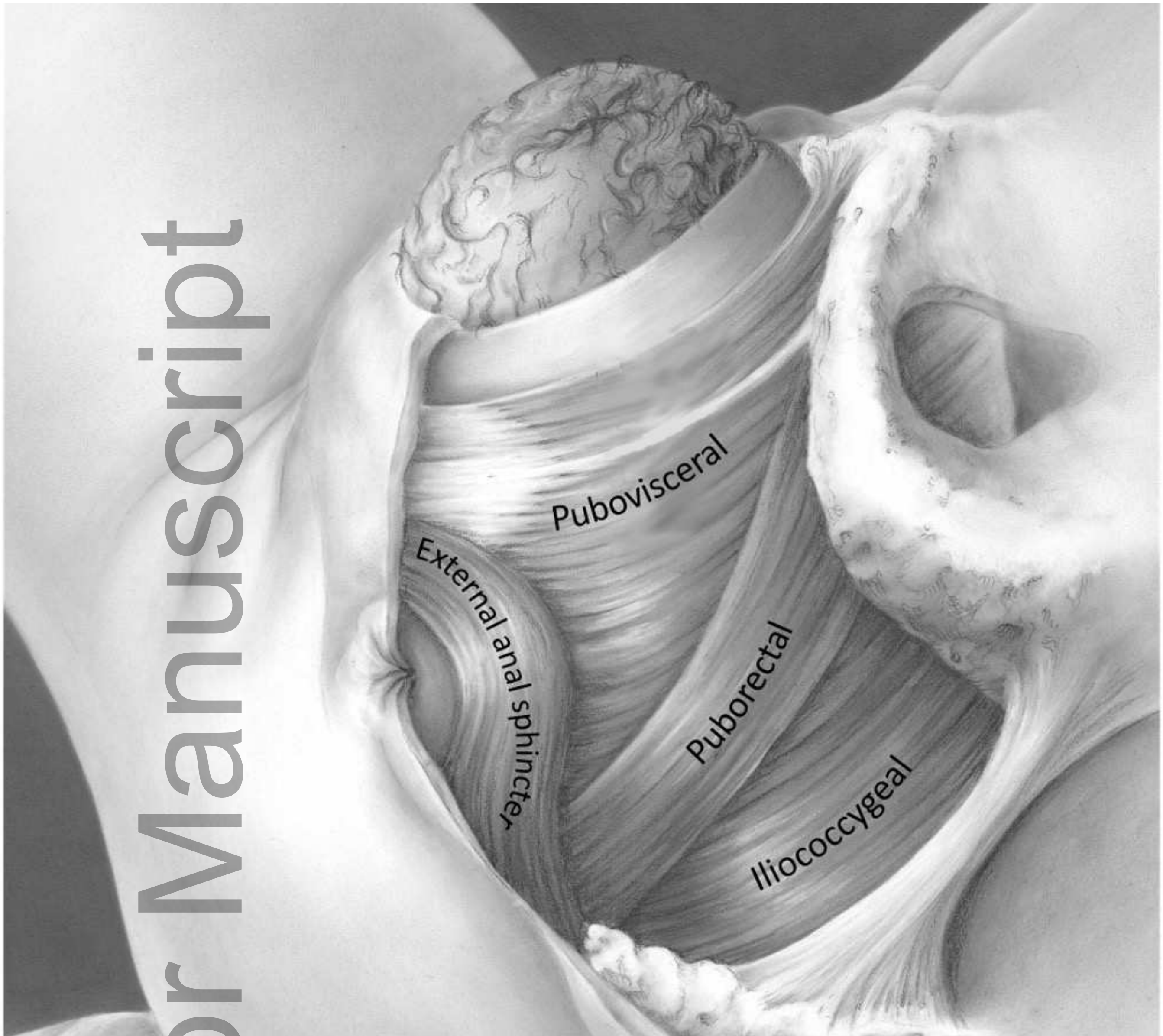

Figure 1. Illustration of pelvic floor muscles at crowing where all three components of the levator ani muscle (pubovisceral, puborectal and iliococcygeal) as well as the external anal sphincter can be seen. Note different fiber directions between different muscles. (© DeLancey).

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Figure 2. Fluid-sensitive MRI axial scan illustrating muscle edema scoring. Top and bottom rows display subjects without muscle edema and with muscle edema, respectively. Each column, as labeled, corresponds to one levator ani component indicated by closed arrowheads. The external anal sphincter is not illustrated here as edema was not demonstrated on any subject in this muscle. Obturator internus muscle (closed arrow) is the reference for signal intensity. (B) Bladder; (U) Urethra; (V) Vagina; (R) Rectum.

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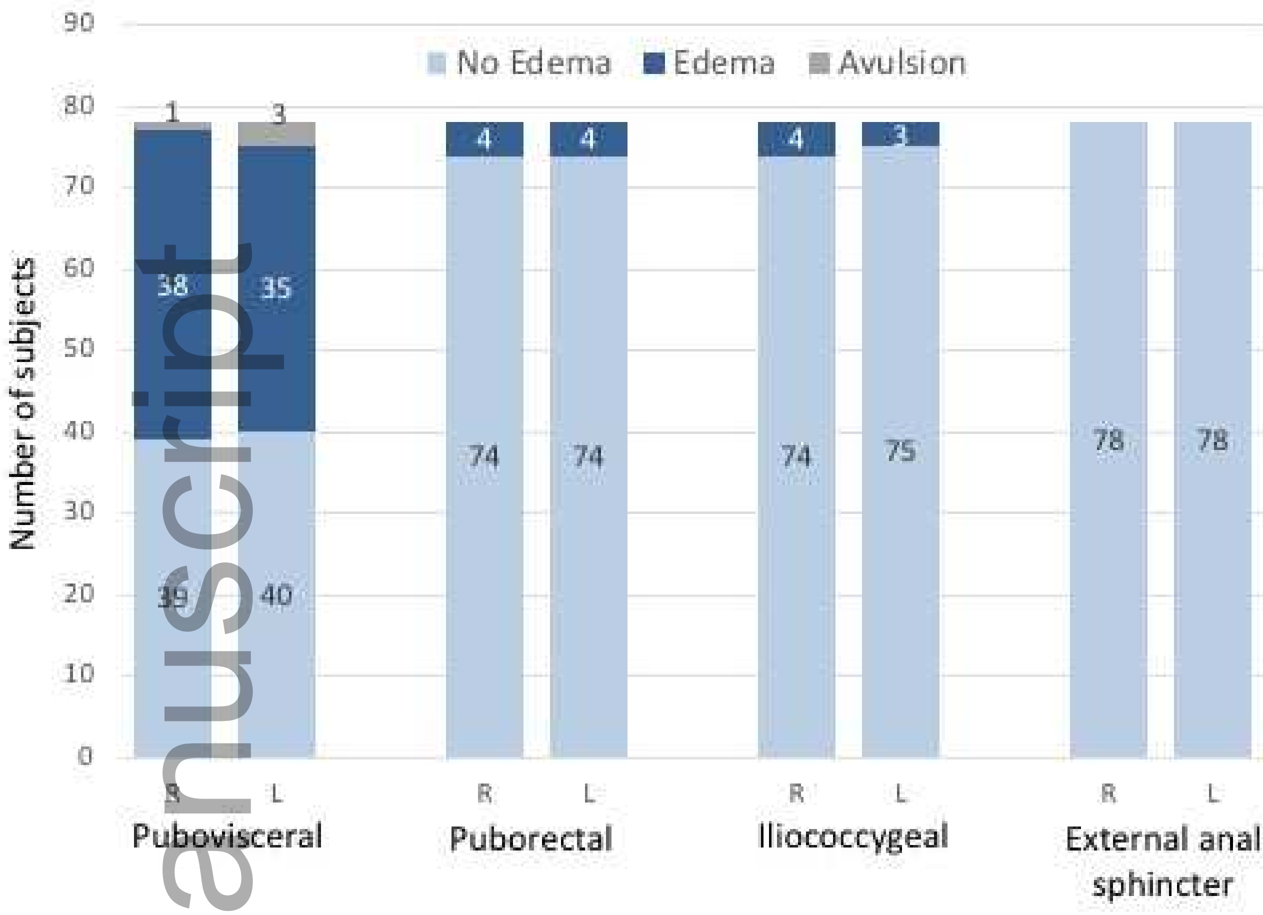

Figure 3: Edema distribution per levator ani muscle component on the right (R) and on the left (L) sides.

bjo_16760_f3.jpg

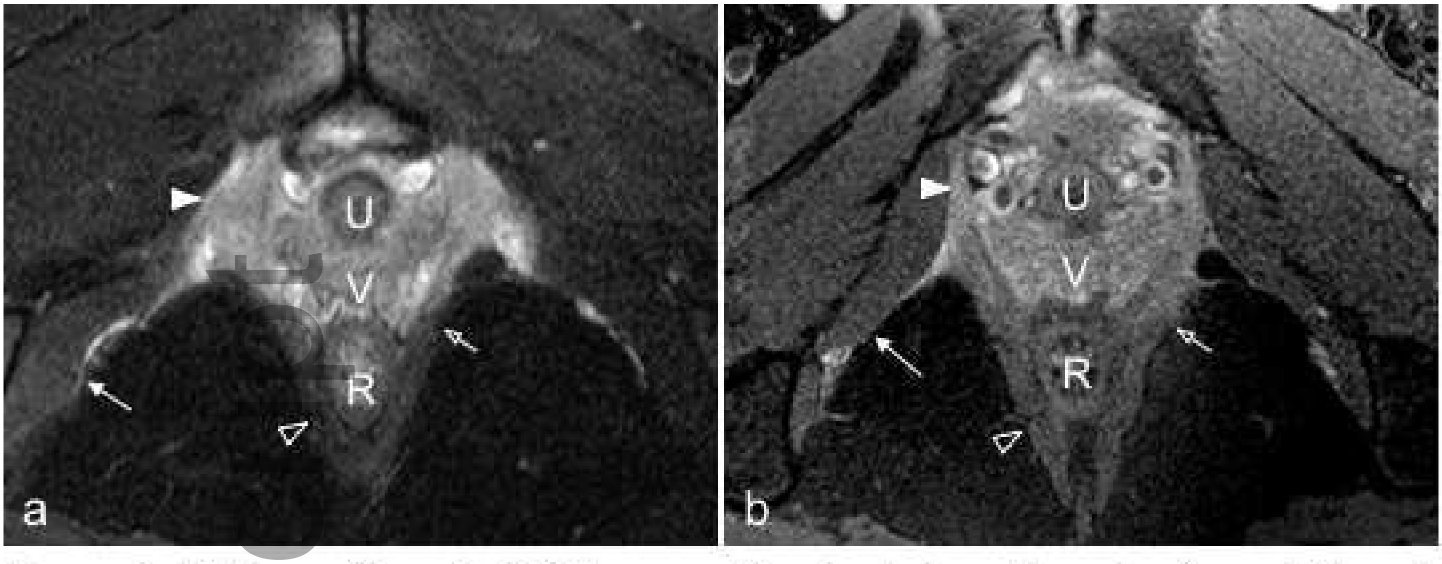

Figure 4. Fluid-sensitive axial MRI scans at the level where the pubovisceral (closed arrowhead) and the puborectal (open arrowhead) fibers diverge. Panels a and b exemplify two different subjects. Open arrow indicates transition between edema in the pubococcygeal and lack of edema in the puborectal muscles. Obturator internus muscle is indicated (closed arrow). (U) Urethra; (V) Vagina; (R) Rectum.

bjo_16760_f4.jpg