OBSTETRICS

Impact of pushing timing on occult injury of levator ani: secondary analysis of a randomized trial

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BACKGROUND: Evidence of detachment of the levator ani muscle system is seen more frequently in patients with pelvic floor disorders. It has been suggested that passive descent of the fetus before pushing could be used to decrease operative vaginal delivery and levator ani muscle injury.

OBJECTIVE: This planned analysis aimed to determine whether immediate or delayed pushing was associated with an increased proportion of injury to the levator ani muscle system after the first delivery among nulliparous women.

STUDY DESIGN: The Optimizing Management of the Second Stage study was a multicenter randomized trial. Nulliparous women with term pregnancies and neuraxial analgesia were randomly assigned at complete cervical dilation to either immediate pushing or delayed pushing for 1 hour. A subset of participants consented to longitudinal objective pelvic floor assessments: (1) during postpartum stay (initial), (2) at 6 weeks (postpartum 1), and (3) at 6 months (postpartum 2) with transperineal 3-dimensional ultrasound. Following the completion of all visits by all subjects, saved 3-dimensional ultrasound volumes were assessed in a masked fashion. The outcome was "occult" levator ani muscle injury on the right or left, defined as a widening of the attachment of the levator ani to its origin utilizing the levator-urethra gap measurement. Measurements and proportions were compared between the 2 groups by study visit using the χ^2 test or Fisher exact test for categorical variables and the *t* test or Mann-Whitney *U* test for continuous variables as appropriate.

RESULTS: Here, 941 of 2414 randomized subjects (39.0%) participated in the pelvic floor assessments: 452 in the immediate pushing group and 489 in the delayed pushing group. We obtained sonograms on 67%, 83%, and 77% of the pelvic floor assessment participants at the initial, postpartum 1, and postpartum-2 visits, respectively. Demographic and labor characteristics were comparable between the 2 groups; 94% of participants were non-Hispanic, and 50% of participants were Black. Levator ani muscle injury was noted in 77 participants (13.6%) at the initial visit, 99 (13.1%) at PP1, and 72 (10.6%) at PP2. There was no difference in injury between women in the immediate pushing group and women in the delayed pushing group. These findings did not change when the threshold (sensitivity) of levator ani muscle injury was adjusted to a less conservative measure.

CONCLUSION: Among nulliparous women at term with neuraxial analgesia, the rates of occult levator ani muscle injury were not different between women undergoing immediate pushing and women undergoing delayed pushing in the second stage of labor. Further research efforts are needed to understand the development and potential prevention of subsequent pelvic floor disorders.

Key words: labor, puborectalis, pubovisceralis

Introduction

Pregnancy and vaginal delivery have been implicated as main contributors to symptomatic pelvic floor disorders that are noted remote from delivery.[1,2] Levator ani muscle (LAM) injury is almost always occult, and it has been observed using postpartum imaging in 20% to 36% of people who vaginally deliver their first child.[3,4] These injuries are likely a result of passive tissue fatigue[5] or requiring the muscle to stretch beyond its limits during fetal descent.[6] Because LAM injury has been associated with the development of pelvic floor symptoms,[7–9] the detection and potentially prevention of this type of injury are important initiatives.

Certain labor and delivery procedures, outcomes, and strategies may be more harmful to the pelvic floor. Previous investigations have shown that prolonged labor, operative vaginal delivery, age, and recognized anal sphincter lacerations are associated with an increased odds of other pelvic floor injuries.[10,11] A recent large multicenter randomized clinical trial of delayed vs immediate pushing[12] updated relevant data that resulted in a subsequent meta-analysis[13] to conclude that there was no effect of immediate pushing compared with delayed pushing during the second stage of labor on spontaneous or operative vaginal delivery rates or overt severe perineal lacerations. Given the relationship of occult LAM injuries and symptomatic pelvic floor disorders later in life, and to further inform decisions regarding the timing of pushing, this planned secondary analysis aimed to investigate whether immediate or delayed pushing after complete dilation was associated with a different incidence of LAM injury.

Materials and Methods

This was a planned analysis of prespecified secondary outcomes originating from the Optimizing Management of the Second Stage (OMSS) study.[12] Briefly, at 6 geographically separated sites in the United States, 2414 nulliparous pregnant women at term with neuraxial analgesia were randomized at complete cervical dilation to push immediately or delay pushing for 60 minutes. Participants enrolled in the trial were allowed to have pelvic floor

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AJOG at a Glance

Why was this study conducted?

Delayed pushing has been proposed to optimize maternal outcomes, yet recent data do not support it. It is unknown whether there is a difference in the incidence of levator ani muscle (LAM) injury between delayed and immediate pushing.

Key findings

For first-time parturients, LAM injury occurred in at least 13%, possibly higher. There was no difference in LAM injury between women undergoing delayed pushing and women undergoing immediate pushing in this trial.

What does this add to what is known?

Previous assessments of delayed vs immediate pushing were limited to overt severe perineal lacerations and symptoms of anal incontinence, showing no difference. Our findings were consistent. When viewed in context with potential neonatal and other peripartum morbidities, initiating pushing when complete dilation is reached in nulliparous patients with neuraxial analgesia is recommended.

follow-up assessments. Institutional review board approvals were obtained at each site. A separate informed consent was obtained from each participant for this portion of the study. Moreover, 3-dimensional (3D) transperineal pelvic floor sonograms were obtained after delivery while in the hospital (initial), at 6 weeks after delivery (PP1), and 6 months (PP2) after delivery to assess the presence of LAM injury.

Image acquisition

Using "Expert," "Performance," and "Signature" series and Voluson i (BT14) from the GE Voluson System (GE Medical Systems, Zipf, Austria), an RAB 4−8 RS 4D convex transducer was used to obtain multiple 3D volumes of the pelvic floor. Preset pelvic floor settings were created on each machine: maximum field of view of 70° (for acquisition viewing in the sagittal plane), lateral sweep acquisition range of 85°, and depth of 6.8 cm. Other contrast, gain, and speckle reduction settings were preprogrammed to optimize the "write" image quality.

Experienced sonographers from each of the sites underwent centralized training of a standardized transperineal ultrasound protocol and obtained and saved identified image volumes. With the patient in the lithotomy (stirrups) or frog-leg position, a transducer (with sufficient gel for maximum acoustic coupling) was gently placed between the parted labia. Each acquisition was designed to initially visualize structures in the midsagittal plane and use the inferior portion of the pubic bone as a reliable bony reference. A 3D sweep made it possible to assess the distal portions of the pelvic organs, the surrounding supporting muscles, and the intervening aperture (levator hiatus). The anal canal and its sphincters were not reliably in the acquisition plane, and these structures were not evaluated. Multiple volumes were obtained with the subject at rest and after achieving a maximum pelvic floor muscle squeeze. These were saved and uploaded to a central server for later analysis.

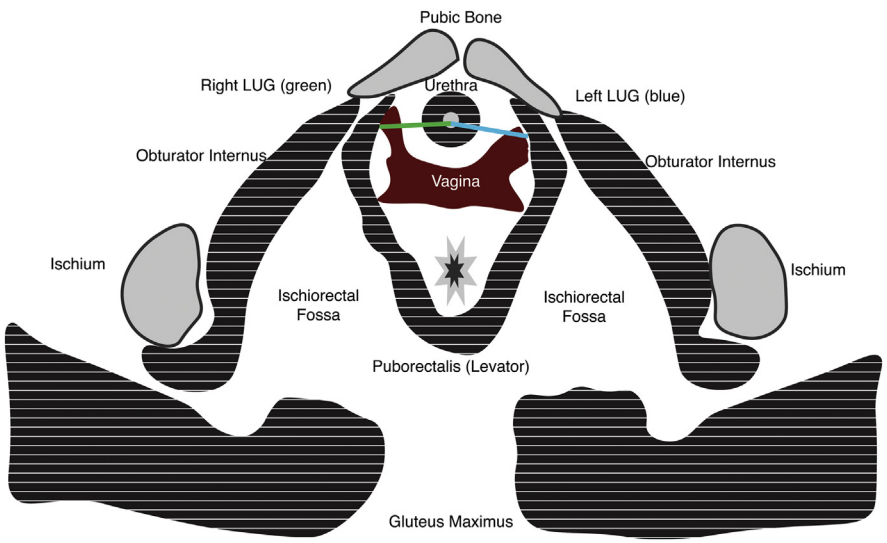
Masking

After the final study participant had completed all study visits, the project biostatistician (C.W.) recoded the files and folders containing the ultrasound volumes, which removed the evidence of the study site and study visit number from the research participant identification. In addition, the identifying meta-data of each file was hidden from the displayed volume by a specific selection in the software used to do the offline measurements and calculations.

Measurements

A centralized team consisting of a sonographer, 2 research nurses, and a

FIGURE 1
Axial view of structures in the plane of minimal hiatal dimensions



The distance between the urethral lumen and the attachment of the puborectalis (levator) muscle, the LUG, is shown in *green* and *blue line segments*, respectively. Permission granted for publication by a license (number 5197210294396) granted by Wolters Kluwer Health, Inc. Originally published in Gregory et al.[16]

LUG, levator-urethra gap.

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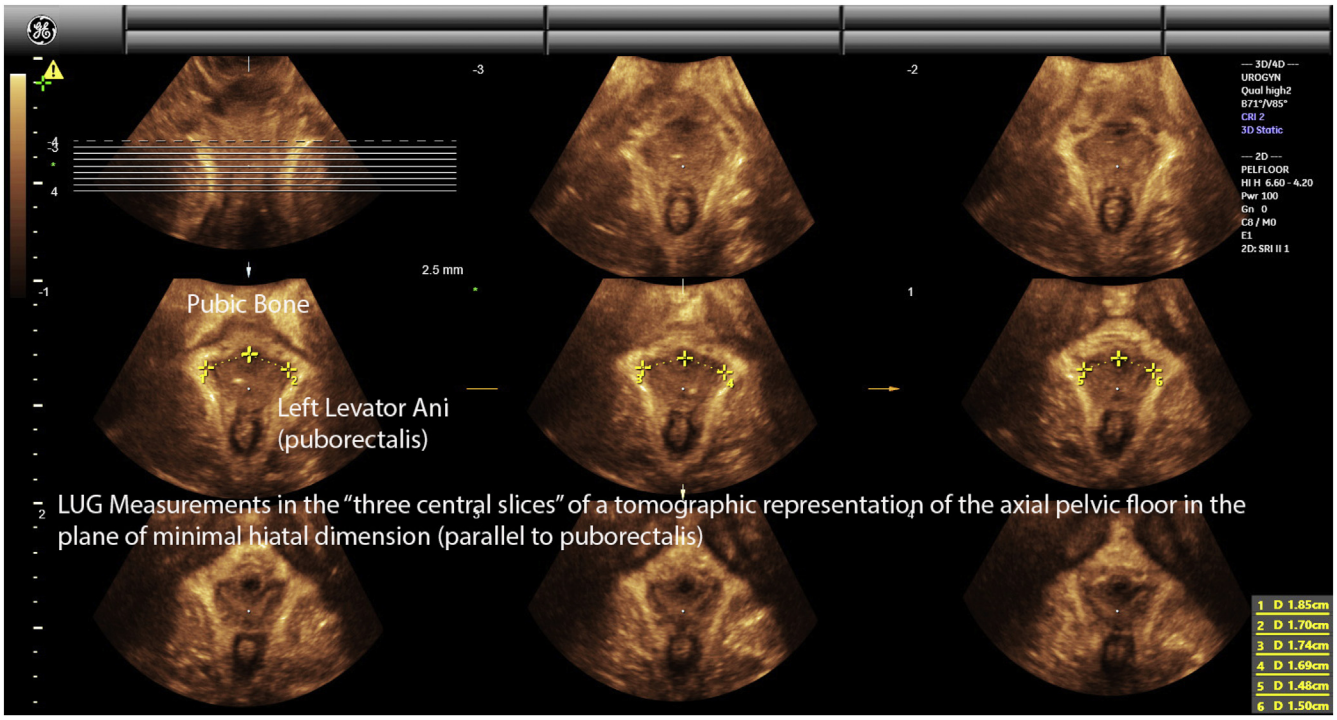
FIGURE 2
Tomographic images separated by 2.5 mm



LUG measurements made on the right and left sides of the 3 central slices indicated by calipers. The upper left corner image represents a coronal view from which the tomographic images were rendered. Distances denoted by number in the bottom right corner.

LUG, levator-urethra gap.

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physician investigator (W.T.G.) with considerable experience in 3D transperineal ultrasound performed the measurements on the masked study volumes. The software program 4D View (GE, version 18.3; GE MedicalSystems, Zipf, Austria) was used to generate the data. For each study visit, the sonographer or research nurse prepared the 3D image volume by identifying the optimal file with the best quality images of the series. Other postprocessing enhancements (gain, bias, hues, and contrasts) were made to optimize the conspicuity of the anatomy. After the volume had been postprocessed and prepared for measurements, an assessment of the image quality (acceptable, moderate, or unreadable) and presence of obscuring artifacts (yes or no) was made.

The volume was first manipulated to generate tomographic images in the plane of minimal hiatal dimensions (parallel to the puborectalis muscle). These tomographic images were set for 2.5-mm slice intervals, which started 5 mm caudal to and extended 12.5 mm cephalad to the plane of minimal hiatal dimension. The 3 central slices in this sequence were used to measure the distance between the center of the urethral lumen and the insertion of the puborectalis, known as the levator-urethra gap (LUG) (Figure 1).

Levator ani muscle injury definition

Based on previous data, a priori, an LUG of ≥2.5 cm in the "rest" images for each of the 3 central slices on either the left or right (Figure 2) was considered to be LAM injury (ie, all 3 slices needed to exceed the threshold).[14,15] From more recent data, a second, potentially more sensitive, definition was explored requiring an LUG threshold of ≥2.25 cm for each of the 3 central slices.[16] Assessments were made and reported separately for each time point.

Other biometry

In the same plane, a rendered volume (slice thickness no greater than 1.0 cm) was used to generate several other measurements: levator hiatus diameters (transverse and anterior-posterior), levator hiatus area, and cross-sectional diameters of the puborectalis muscle (right and left).

All generated measurement markings from each image for each visit of each participant were rereviewed by 1 masked investigator (W.T.G.). When there was a disagreement of measurements or markings, the volume used for the measurements was reopened. Any needed adjustments to the angle or placement of the plane of minimal

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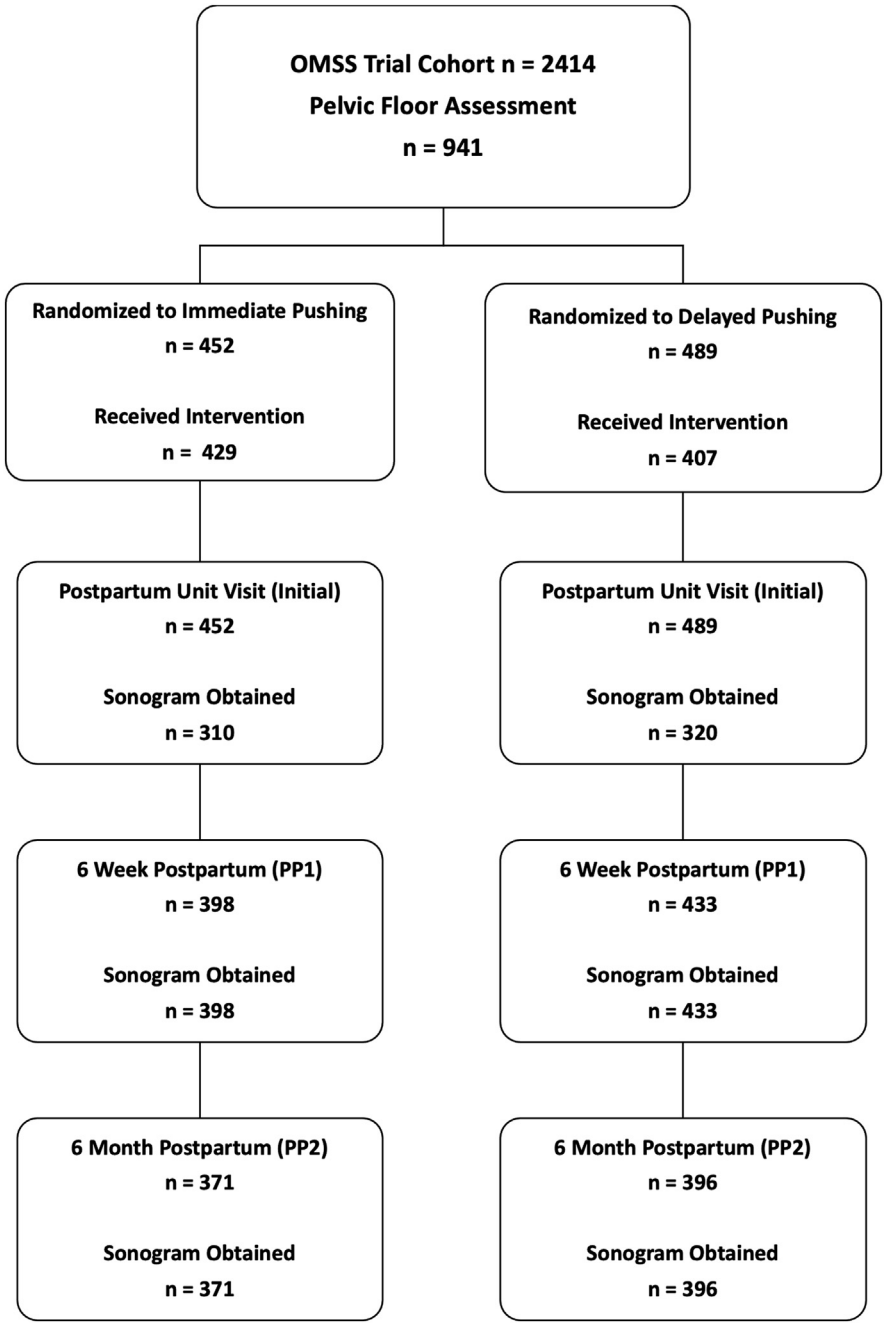
FIGURE 3
Flow of participants



OMSS, Optimizing Management of the Second Stage; *US*, ultrasound.

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hiatal dimensions were applied, and markings were recreated until consensus was achieved between the sonographer or nurse and W.T.G.

Statistical analysis

Participants were analyzed in the group to which they were assigned, whether or not they received the assigned intervention. Baseline and outcome measures were compared between participants in the immediate and delayed pushing groups and by study visit using the χ^2 test or Fisher exact test for categorical variables and the *t* test or Mann-Whitney *U* test for continuous variables as appropriate. Moreover, a sensitivity analysis of baseline measures was performed, comparing participants in the pelvic floor study to nonpelvic floor participants of the larger OMSS study. A *P* value of.05 was used to assess significance, and there was no adjustment for multiple comparisons. All analyses were conducted using SAS (version 9.4; SAS Institute. Cary, NC).

Results

Here, 941 of 2414 participants (39.0%) in the primary trial of immediate vs delayed pushing consented to the pelvic floor assessments: 452 in the immediate pushing group and 489 in the delayed pushing group (Figure 3). Consistent with the study design's planned intervention, overall second-stage length was shorter in the immediate pushing group than in the delayed pushing group (94.8 [standard deviation (SD), 78.6)] vs 132.6 [SD, 80.4] minutes; $P<.01$); however, active pushing time was equivalent between the 2 groups (78.7 [SD, 77.0] vs 73.5 [SD, 75.8] minutes; $P=.3$) (Table 1). Furthermore, Table 1 demonstrates that most relevant demographic and labor and delivery characteristics were comparable between the 2 groups. There were more participants with an occiput-posterior position at delivery in the immediate pushing group than in the delayed pushing group (49 [10.8%] vs 19 [3.9%]; $P<.01$), but there were also nearly 50% of participants with an unknown position (221 [48.9%]) vs 246 [50.3%]). Participants who participated in the pelvic floor assessment were younger (24.9 [SD, 5.8] vs 26.7 [SD, 6.1]; $P<.01$] years old), were more likely to be Black (49.7% vs 39.9%, $P<.01$), and had a slightly greater body mass index (BMI) (31.1 [SD, 6.6] vs 30.5 [SD, 6.0] kg/m^2; $P<.01$) than those who did not participate in the pelvic floor assessment (Table 2). In addition, the pelvic floor assessment participants had lower mean birthweight (3222.3 [SD, 460.4] vs 3297.3 [SD, 440.8] g; $P<.01$) and fewer second-degree lacerations (36.8% vs 43.5%; $P<.01$).

Figure 3 depicts the number of randomized participants in each group, those who received the intervention as randomized, and the number of

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TABLE 1
Baseline and delivery characteristics among pelvic floor participants

Characteristics	Immediate pushing (n=452)	Delayed pushing (n=489)	*P* value
Maternal age (y)	24.90±5.70	24.81±6.00	.74
Gestational age (wk)	39.00±1.20	39.01±1.20	.94
BMI at delivery (kg/m^2)	31.60±6.90	30.71±6.50	.05
Obese (BMI>30 kg/m^2)	229 (50.80)	232 (47.50)	.32
Race			
White	207 (45.80)	209 (42.70)	.58
Black or African American	220 (48.70)	248 (50.70)	
Other or mixed	25 (5.50)	32 (6.50)	
Ethnicity, not Hispanic or Latina	426 (94.30)	463 (94.70)	.64
Spontaneous labor	236 (52.20)	255 (52.20)	.98
Length of second stage of labor (min)	94.80±78.60	132.60±80.40	<.01
Duration of active pushing (min)	78.70±77.00	73.50±75.80	.30
Birthweight (g)	3237.90±485.40	3207.90±436.00	.32
Mode of delivery			
Spontaneous vaginal delivery	405 (89.60)	424 (86.70)	.60
Forceps-assisted vaginal delivery	15 (3.30)	21 (4.30)	
Vacuum-assisted vaginal delivery	6 (1.30)	8 (1.60)	
Cesarean delivery	26 (5.80)	36 (7.40)	
Perineal lacerations			
Second-degree laceration	164 (36.30)	182 (37.20)	.77
Third-degree laceration	23 (5.10)	17 (3.50)	.22
Fourth-degree laceration	3 (0.70)	0 (0)	.11
Third- or fourth-degree laceration	26 (5.80)	17 (3.50)	.09
Fetal station at complete dilation	1 (1−2)	1 (1−2)	.42
Fetal head position at delivery			<.01
Occiput-anterior	180 (39.80)	214 (43.80)	
Occiput-posterior	49 (10.80)	19 (3.90)	
Occiput-transverse	2 (0.440)	10 (2.00)	
Unknown	221 (48.90)	246 (50.30)	
Occiput-posterior position at delivery	49 (10.80)	19 (3.90)	<.01
Occiput-anterior position at delivery	180 (39.80)	214 (43.80)	.22
Prostaglandin use	66 (14.60)	95 (19.40)	.04
Oxytocin use	371 (82.10)	392 (80.20)	.60

Data are presented as mean±standard deviation, number (percentage), or median (interquartile range), unless otherwise indicated.

BMI, body mass index.

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participants who had a study visit at each time point. One of the study sites did not obtain sonograms at the initial visit. In addition, not every participant completed each study visit. Of the 941 originally enrolled pelvic floor participants, 630, 778, and 722 of initial, PP1, and PP2 visit participants, respectively, were capable of having ultrasound images created during their study visit. Central readers reviewed 2130 individual masked image sets. From those enrolled participants who underwent an ultrasound at a given study visit, images were found to be of moderate or greater

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TABLE 2
Baseline and delivery characteristics between pelvic floor participants and nonpelvic floor participants

Characteristics	Pelvic floor participants (n=941)	Nonpelvic floor participants (n=1473)	*P* value
Maternal age (y)	24.9±5.8	26.7±6.1	<.01
Gestational age (wk)	39.0±1.2	39.2±1.1	<.01
BMI at delivery (kg/m^2)	31.1±6.6	30.5±6.0	.04
Obese (BMI>30 kg/m^2)	461 (49.0)	655 (44.5)	.13
Race			<.01
White	416 (44.2)	703 (47.7)	
Black or African American	468 (49.7)	587 (39.9)	
Other or mixed	57 (6.1)	183 (12.4)	
Ethnicity, not Hispanic or Latina	889 (94.5)	1379 (93.6)	.25
Spontaneous labor	491 (52.2)	804 (54.6)	.18
Birthweight (g)	3222.3±460.4	3297.3±440.8	<.01
Mode of delivery			.16
Spontaneous vaginal delivery	829 (88.1)	1253 (85.1)	
Forceps-assisted vaginal delivery	36 (3.8)	75 (5.1)	
Vacuum-assisted Vaginal delivery	14 (1.5)	22 (1.5)	
Cesarean delivery	62 (6.6)	123 (8.4)	
Length of second stage (min)	114.6±84.0	121.2±78.0	.07
Duration of active pushing (min)	76.0±76.4	81.1±72.4	.10
Perineal lacerations			
Second-degree laceration	346 (36.8)	640 (43.5)	<.01
Third-degree laceration	40 (4.3)	75 (5.1)	.34
Fourth-degree laceration	3 (0.3)	5 (0.3)	1.00
Third- or fourth-degree laceration	43 (4.6)	80 (5.4)	.35

Data are presented as mean±standard deviation or number (percentage), unless otherwise indicated.

BMI, body mass index.

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quality without an obstructing artifact in 568 of 630 (90%), 725 of 778 (93%), and 682 of 722 (94%) of initial, PP1, and PP2 participants, respectively. There was no systematic difference in the quality between rest and squeeze image sets (data not shown).

LAM injuries were noted in 77 participants (13.6%) at the initial evaluation, 99 (13.1%) at PP1, and 72 (10.6%) at PP2 (Table 3) with no difference between the groups. Using the LUG threshold of 2.25 cm, 235 participants (41%) at the initial evaluation, 355 participants (49%) at PP1, and 286 participants (42%) were deemed to have LAM injury, with no difference between the intervention groups at this more sensitive threshold (Table 3). None of the levator hiatus measurements or the puborectalis muscle diameters obtained at rest were different between the 2 intervention groups (Table 4).

Comment

Principal findings

In this randomized trial of nulliparous women with neuraxial analgesia who agreed to participate in postpartum pelvic floor assessments, it was found that approximately 13% of participants had evidence of LAM injury at the 6-week postpartum visit. Furthermore, neither pushing immediately nor delaying for 60 minutes after complete cervical dilation resulted in a different extent of LAM injury. Although a more sensitive definition of injury did not change the conclusion about pushing strategy, not surprisingly, it did suggest that musculoskeletal injury following a first delivery could occur in more than 40% of parturients.

Results in the context of what is known

Previous studies have evaluated several labor and neonatal characteristics associated with immediate vs delayed pushing; however, few have focused on pelvic

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TABLE 3
Number and percentage with complete levator ani muscle injury based on levator-urethra gap threshold

	Right			Left			Bilateral (left and right injury)			Unilateral (left or right injury)		
	Imm	Del	*P* value	Imm	Del	*P* value	Imm	Del	*P* value	Imm	Del	*P* value
LUG≥2.5 cm												
Visit												
Initial	20 (7.2)	26 (9.0)	.46	27 (9.7)	31 (10.7)	.72	12 (4.3)	15 (5.2)	.65	35 (12.5)	42 (14.5)	.53
PP1	29 (8.5)	28 (7.3)	.55	28 (8.2)	45 (11.7)	.12	15 (4.4)	20 (5.2)	.61	42 (12.4)	53 (13.8)	.55
PP2	24 (7.4)	25 (7.0)	.81	22 (6.8)	30 (8.4)	.45	15 (4.6)	14 (3.9)	.63	31 (9.6)	41 (11.4)	.45
LUG≥2.25 cm												
Visit												
Initial	63 (22.6)	85 (29.4)	.06	96 (34.4)	112 (38.8)	.28	51 (18.3)	70 (24.2)	.08	108 (38.7)	127 (43.9)	.21
PP1	112 (32.9)	127 (33.0)	.83	136 (40.0)	171 (44.4)	.16	84 (24.7)	107 (27.8)	.27	164 (48.2)	191 (49.6)	.53
PP2	102 (31.6)	95 (26.5)	.22	117 (36.2)	113 (31.5)	.30	76 (23.5)	65 (18.1)	.12	143 (44.3)	143 (39.8)	.40

Data are presented as number (percentage). The chi-square test was used. Initial indicates visit on the postpartum unit, PP1 indicates 6-week postpartum visit, and PP2 indicates 6-month postpartum visit.

Del, delayed pushing by 60 minutes; *Imm*, immediate pushing; *LUG*, levator-urethra gap.

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floor outcomes. For those that did, the assessment was limited to perineal lacerations and symptoms of anal incontinence.[17,18] This report focused on the direct injury of the LAM complex assessed with imaging by 3D transperineal ultrasound.

The rate of injury seen in this large group of previously nulliparous women was 13%, which is slightly less than the 20% determined in a previous study using magnetic resonance imaging (MRI) assessments,[3] but much less than in a similar, but much smaller cohort of women whose LAM injury was assessed using transperineal 3D ultrasound[4] as was done in our study. Although MRI can depict pelvic musculoskeletal anatomy in a high resolution, it is less readily available and more costly. In addition, 3D ultrasound has been shown to be equivalent to MRI in its ability to resolve the distal levator biometry and assess levator ani injuries.[19–21] None of the previous studies have evaluated the effect of timing of pushing on LAM injury evaluated early in the postpartum period.

Previous efforts used solely subjective assessments of injury (partial and complete), whereas the current study used the measurement of the LUG. The gap threshold of 2.5 cm that was used a priori to define LAM injury was directly based on retrospective assessments of parous patients referred for symptoms of pelvic floor disorders and diagnoses of injury made via the previously mentioned sonographic assessments.[8,22] In the current study, it was decided to compare LUG measurements using lower thresholds (2.25 cm) established in nonpregnant nulliparous community participants and other studies of parous participants or symptomatic patients.[14,16,23,24] Although the lower threshold yielded higher overall injury rates, it did not alter the conclusion that neither immediate nor delayed pushing conferred an advantage on LAM injury seen by ultrasound.

Clinical and research implications

The data presented in this study supported the findings that in pregnant patients who reach complete cervical dilation and intend to have a vaginal delivery, injury to the levator ani system is common, which is consistent with previous assessments. Because LAM injury has been associated with the development of pelvic floor symptoms,[7,8] assessing whether or not a putative labor and delivery strategy has benefits or harms to the pelvic floor is an important effort to undertake. In the original larger portion of this trial,[12] neither the spontaneous vaginal delivery rates nor the operative vaginal delivery rates were different, but the question remained open as to whether the underlying pelvic floor support structure may have been affected differentially. Although there were more participants with occiput-posterior position in the immediate pushing group, the distribution of positions in each group had almost 50% unknown, making that data less useful. There was no difference in the time of active pushing between the 2 groups. Looking at the potential differences between participants and those who declined participation, the observations are mixed. One would hypothesize that the older participants, with a slightly larger mean birthweight, could lead to a higher likelihood of levator ani injury; however, nonparticipants also had lower mean BMIs. Regardless, our strategy of considering different LUG

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TABLE 4
Levator hiatus and muscle diameters at rest

Variable	Immediate	Delayed	*P* value
Levator hiatus—anterior-posterior in centimeters			
Initial	5.62 (0.89)	5.60 (0.84)	.80
PP1	4.90 (0.76)	4.87 (0.73)	.61
PP2	4.72 (0.77)	4.70 (0.73)	.69
Levator hiatus—transverse in centimeters			
Initial	3.25 (0.61)	3.33 (0.65)	.13
PP1	3.68 (0.65)	3.68 (0.70)	.98
PP2	3.45 (0.59)	3.45 (0.60)	.93
Levator hiatus—area in centimeter squared			
Initial	13.07 (3.44)	13.06 (3.30)	.97
PP1	12.01 (3.06)	11.91 (3.08)	.65
PP2	11.62 (2.96)	11.48 (3.05)	.55
Right puborectalis diameter in centimeters			
Initial	1.02 (0.29)	1.03 (0.33)	.56
PP1	0.78 (0.24)	0.81 (0.25)	.10
PP2	0.92 (0.32)	0.92 (0.33)	.99
Left puborectalis diameter in centimeters			
Initial	1.02 (0.28)	1.06 (0.32)	.09
PP1	0.81 (0.24)	0.82 (0.25)	.60
PP2	0.91 (0.28)	0.90 (0.30)	.58

Data are presented as mean (standard deviation), unless otherwise indicated. Initial indicates visit on the postpartum unit, PP1 indicates 6-week postpartum visit, and PP2 indicates 6-month postpartum visit.

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thresholds (as discussed below) accounted for a wider range of potential injury rates.

This study did confirm that using LUG as a marker of LAM injury (whether at a 2.50- cm or 2.25-cm threshold) could potentially direct the clinician to encourage secondary preventive strategies against the development of pelvic floor disorders, including urinary and fecal incontinence and pelvic organ prolapse. Further research clarifying which postpartum patient has greater odds of LAM injury (and therefore may benefit from earlier intervention) is needed.

Overall, the results from these secondary analyses did not provide evidence to suggest a preferred timing of a pushing strategy to benefit the pelvic floor. When viewed in context with potential neonatal and other peripartum morbidities,[12] when complete dilation is reached in nulliparous patients with neuraxial analgesia, initiating pushing without delay is recommended. Certainly, further research regarding the pushing strategies on pelvic floor anatomy and neurophysiology and pelvic floor symptoms remote from delivery continues to be warranted.

Strengths and limitations

This study has several strengths. Results were derived from participants in a randomized, yet pragmatic, design. There is significant geographic practice diversity, which amplifies the benefit of the pragmatic design. Furthermore, in this planned secondary analysis, we noted a balance in demographic and several relevant clinical features, which enhances the generalizability. The images were obtained in a standard fashion, by trained researchers, and the data were sent to a centralized server and data steward. The investigators who reviewed the image volumes and performed the measurements were fully masked to all data, including research site, randomization assignment, and delivery method, which limited both bias and error.

The study limitations included no predelivery pelvic examinations or pelvic floor ultrasounds being collected. Furthermore, not every participant in the larger trial was followed in the pelvic floor assessment component of the study. In addition, the participants in this trial were previously nulliparous and had received epidural analgesia, making the findings not necessarily generalizable to multiparous patients or those without epidurals. Moreover, the studied population has a much lower proportion of Hispanic persons and a much higher

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proportion of Black persons than the overall US population. Although there were a few differences between those who participated and those who did not, it is unclear how the constellation of different characteristics would lead to different conclusions. Finally, although LAM injury at the insertion near the pubic bone was assessed by ultrasound, occult anal sphincter injury was not concomitantly assessed.

Conclusions

There was no difference in LAM injury between women undergoing delayed pushing and those undergoing immediate pushing. When viewed in context with potential neonatal and other peripartum morbidities, when complete dilation is reached in nulliparous patients with neuraxial analgesia, initiating pushing without delay is recommended. Strategies to reduce LAM injury during labor and delivery need further study. ■

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Data sharing of individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices), beginning 9 months and ending 36 months after the parent study is complete, is available per the 2003 NIH Data Sharing Policy.

There are investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for individual participant data meta-analysis.

Proposals may be submitted up to 36 months following article publication. After 36 months, the data will be available in the data warehouse but without investigator support other than the deposited meta-data.

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