



# Reducing pelvic floor injury by induction of labor

Linda S. Burkett<sup>1,2,3</sup> · Timothy P. Canavan<sup>1,2</sup> · Stephanie M. Glass Clark<sup>1,2</sup> · Lauren E. Giugale<sup>1,2</sup> · Amanda M. Artsen<sup>1,2</sup> · Pamela A. Moalli<sup>1,2</sup>

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## Abstract

**Introduction and hypothesis** We hypothesized that elective induction of labor (eIOL) at 39 weeks is protective of levator ani muscle injury (LAMI) and is associated with decreased pelvic symptoms at 6 weeks postpartum compared to expectant management of labor.

**Methods** Prospective cohort pilot study of uncomplicated, primiparous women with a singleton, vertex gestation enrolled immediately post-vaginal delivery (VD). Subjects were dichotomized into two groups based on labor management: eIOL without complication defined by the ARRIVE trial versus spontaneous VD between 39 weeks<sup>0/7</sup> and 42 weeks<sup>5/7</sup> or no indication for IOL prior to 40 weeks<sup>5/7</sup>. The primary outcome was LAMI at 6 weeks postpartum as evidenced by any of the following ultrasound measures: (1) increased levator hiatal area (LHA) > 2500 mm<sup>2</sup>, (2) increased elasticity index (EI, > 75th quartile) or (3) levator enthesi avulsion.

**Results** Analysis represents 45/102 consented women from July 2019–October 2020 (eIOL  $n = 22$  and spontaneous VD,  $n = 23$ ). Neither maternal, clinical, sociodemographic characteristics nor pelvic symptoms differed between groups. Fewer women had LAMI as defined by the primary outcome with eIOL ( $n = 5$ , 23.8%) compared to spontaneous VD ( $n = 15$ , 65.2%),  $p = 0.008$ . Levator enthesi was more deformable (increased EI) with spontaneous VD as compared to the eIOL [10.66 (8.99) vs. 5.68 (2.93),  $p = 0.046$ ]. On univariate logistic regression women undergoing spontaneous VD had unadjusted OR of 6.0 (1.6–22.5,  $p = 0.008$ ) of sustaining LAMI compared to those undergoing eIOL.

**Conclusions** Composite measures of LAMI though not pelvic floor symptoms were markedly increased in women undergoing spontaneous VD compared to those undergoing eIOL at 39 weeks.

**Keywords** Elective induction · Pelvic floor disorder · Obstetric injury · Transperineal ultrasound · Birth injury · Elastography

## Abbreviations

eIOL Elective induction of labor  
VD Vaginal delivery  
LAMI Levator ani muscle injury  
EI Elasticity index  
ORs Odds ratios  
CIs Confidence intervals  
PFDs Pelvic floor disorders

OASIS obstetric anal sphincter injuries  
TPUS Transperineal ultrasonography  
LHA Levator hiatal area  
EPIQ Modified Epidemiology of Prolapse and Incontinence Questionnaire  
LAS Labor Agency Scale

## Introduction

The female pelvic floor can incur substantial injury at the time of vaginal delivery (VD), which increases the risk of pelvic floor disorders (PFDs) later in life. Nulliparous women are at greatest risk for injury but each subsequent vaginal birth incurs additional risk [1–3]. PFDs negatively impact affected individuals and their families and represent a major public health burden [4, 5].

✉ Pamela A. Moalli  
Moalpa@upmc.edu

<sup>1</sup> Magee-Womens Hospital University of Pittsburgh Medical Center, 300 Halket Street, Pittsburgh, PA 15232, USA

<sup>2</sup> Magee-Womens Research Institute (MWRI), 204 Craft Street, Pittsburgh, PA 15232, USA

<sup>3</sup> Virginia Commonwealth University Health System, 1250 East Marshall Street, Richmond, VA 23298, USA

The multicenter trial (ARRIVE) [6] of low-risk nulliparous women randomized to elective induction of labor (eIOL) at 39 weeks vs. expectant management showed no difference in the primary outcome (neonatal morbidity) but demonstrated decreased risk of cesarean delivery. Although there were no differences in OASIS between the groups (3.4% vs 2.9%; RR- 1.15), the fetal weights (3300 g vs 3380 g) and number of uterine extensions during cesarean (0.9% vs 1.6%; RR- 0.58) were lower in the eIOL group compared to the expectantly managed group. These suggest that earlier delivery may afford lower rates of pelvic floor injury, though these injuries were reported by conventional standards, which do not include evaluation of the levator ani muscles. A study comparing levator ani muscle injury (LAMI) in primiparous women showed that an ~80 g decrease in birthweight was sufficient to protect against LAMI [7], suggesting that the weight difference observed in ARRIVE may be sufficient to meaningfully reduce maternal birth injury. Here, we piloted a study of LAMI in primiparous women managed according to the widely adopted ARRIVE guidelines by comparing women undergoing eIOL at 39 weeks vs expectant management using a comprehensive assessment of LAMI [8].

We hypothesized that eIOL at 39 weeks would be protective against pelvic floor injury compared to delivery after expectant management of labor. We aimed to determine whether women undergoing eIOL at 39 weeks had decreased markers of LAMI relative to those who had spontaneous labor after expectant management measured at 6 weeks postpartum. We further asked whether women undergoing eIOL at 39 weeks had fewer symptoms of PFD and an improved impression of her birth experience compared to women who underwent expectant management of labor.

## Methods

This was a prospective pilot cohort study at a single institution academic medical center with written informed consent obtained 24–48 h postpartum. Subjects were dichotomized into two groups based on labor management: eIOL versus expectant management. The first group underwent eIOL or artificial induction of labor at 39<sup>0/7</sup> to 39<sup>5/7</sup> weeks without any other maternal or fetal indication for delivery. It is standard practice at our institution and a quality measure to offer all women eIOL at 39 weeks. The eIOL group was without maternal or fetal complications defined by the ARRIVE trial [6] and delivered via VD or operative VD. The second group, expectant management, underwent spontaneous labor and VD or operative VD between 39<sup>0/7</sup> weeks and 42<sup>5/7</sup> weeks after declining eIOL at 39 weeks. They had no indication for induction prior to 40<sup>5/7</sup> weeks, at which time they could be induced for late term pregnancy. As these women were selected from the L&D logs following childbirth, we

have no way of knowing how many women at our institution were offered induction and declined. Inclusion criteria were: (1) primiparous without previous delivery < 20 weeks, (2) singleton, vertex VD and (3) available for 4–8 week follow-up. Exclusion criteria were: (1) fetal demise or known major fetal anomaly, (2) cerclage, (3) neonatal complication, (4) maternal complication or comorbidities requiring delivery prior to 40<sup>5/7</sup> weeks and (5) age < 18 years. All eIOL patients were identified from Labor and Delivery logs and were approached for enrollment immediately postpartum after successful VD. Expectant labor patients were identified as the next time-matched primiparous VD and screened for eligibility. If the matched expectantly managed woman declined enrollment, the next eligible individual was approached.

The primary outcome was pelvic floor injury defined by a composite score of (1) increased LHA > 2500 mm<sup>2</sup>, (2) increased elasticity index  $\geq$  75% quartile or (3) levator avulsion on transperineal ultrasonography (TPUS). LHA > 2500 mm<sup>2</sup> is an established cutoff to define LAMI and has been associated with the development of PFDs in postpartum women [9]. Elasticity index is measured as an inverse tissue modulus (stress/strain) at the insertion of pubovisceral muscle into the pubic ramus (enthesis) and represents the amount of deformation of the enthesis relative to bone. A decreased modulus (increased elasticity index) is a sensitive marker for traumatic injury and reflects greater laxity correlated to amount of elastin, collagen and smooth muscle [10]. As this is a relatively novel measure in postpartum women, an increase in ratio into the 75th quartile was used as evidence of injury. Secondary outcomes included POP-Q points, Brink's score, vaginal angle (loss of acute angulation over the levator plate), sociodemographic characteristics, maternal and neonatal clinical characteristics, validated pelvic floor symptoms and subjective birth experience questionnaires. Outcomes were measured by study personnel blinded to the labor management groups.

At 4–8 weeks postpartum, subjects underwent pelvic exams positioned in lithotomy position, with < 30° incline of head. POP-Q measurements, Brink's score [11] and perineal healing were assessed by blinded physician examiner. The timing of study assessments was optimized to assess injury prior to partial or complete recovery, which typically occurs between 3–6 months postpartum. Immediate postpartum ultrasound examination is complicated by edema and hematoma formation and overestimates injury [12].

Three-dimensional transperineal ultrasonography was performed as described [13] by skilled blinded examiners using a GE Voluson E-10 RAB6-D 4D probe. Subjects voided prior to exam and positioned. The plane of minimal hiatal dimensions was identified and the levator ani assessed in the axial, midsagittal and coronal planes. Muscles were assessed at rest, Kegel (contraction) and with maximal strain

(Valsalva) and used to calculate the LHA, circumference, and diameter. Tissue modulus was captured bilaterally with a GE RIC5-9 D endovaginal probe using modified B-wave technique for elastography by trained providers. Evaluation of the puborectal-symphysis plane at the junction of the pubic bone and insertion of pubovisceral muscle (entheses) measured the elastic properties at the common site of levator avulsion. Consecutive gentle pressure in the axis of the transducer angled 30° from the symphysis was applied three times, as described by Masslo [14]. Deformation was standardized to rigid bone and expressed as an elasticity index—an inverse of Young's modulus. Images were rendered and analyzed offline.

During the follow-up study visit, subjects completed the Modified Epidemiology of Prolapse and Incontinence Questionnaire (EPIQ) and the Labor Agency Scale (LAS). EPIQ is a psychometrically validated screening instrument that identifies women at high risk of having PFDs with validated cutoffs in a population of women not seeking care for PFDs [15]. LAS is a validated instrument for measuring expectations and experiences of personal control during childbirth [16]. The score out of 80 represents the inverse relationship between anxiety and control with higher score indicating greater personal control.

In a previous study, women without POP had a smaller LHA measured at 6 weeks postpartum compared to women with POP [15.1 cm (SD 4.7) vs 18.8 cm (SD 2.0)] [17]. For this pilot study, we assumed a mean LHA of 1500 mm<sup>2</sup> in

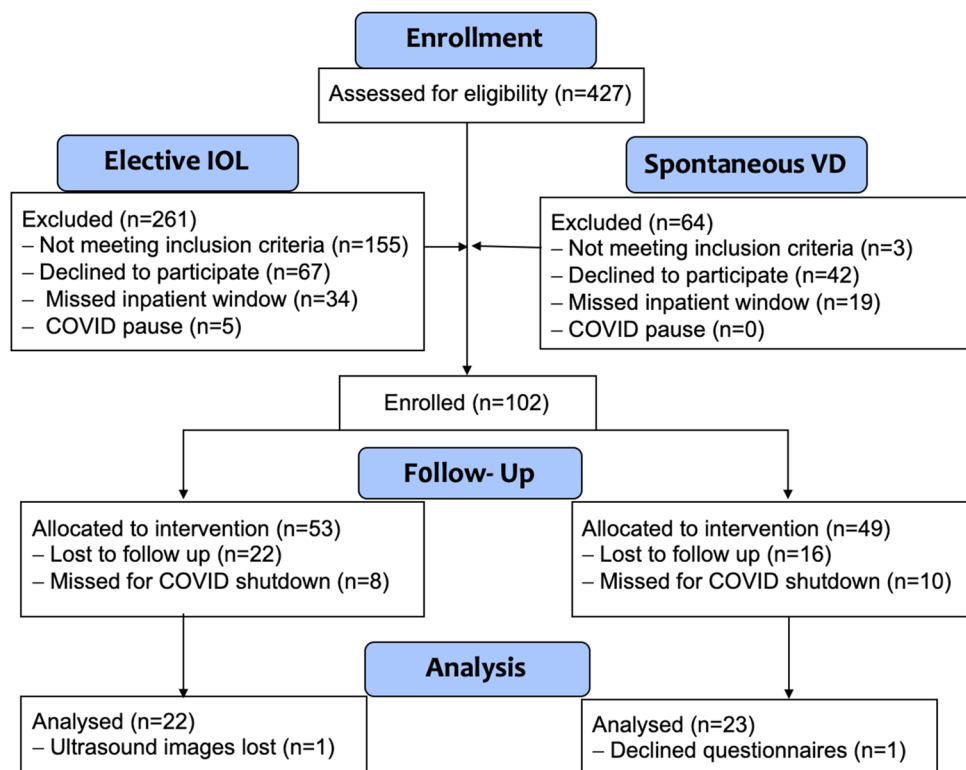
the eIOL group and common SD 335. A sample size of 21 in each group had 80% power to detect a 20% difference in the LHA between the eIOL and spontaneous VD groups based on a two-sided *t*-test,  $\alpha = 5\%$ .

Appropriate statistical analyses were completed using Stata (v16.1) to compare categorical, continuous and non-parametric variables. Multivariable logistic regression was used to identify factors that were independently associated with the primary composite outcome of pelvic floor muscle injury. Selected variables of pelvic injury included POP-Q measures, fetal birth measurements, laceration location and degree, operative delivery, episiotomy and loss of vaginal angulation. Selected socioeconomic variables included race, age, insurance and marital status. Statistical inference was based on the Wald chi-squared test statistic, and odds ratios (OR) were calculated. IRB approval was obtained through the University Medical Center (19030042).

## Results

From July 2019 to October 2020, a total of 427 subjects were screened, 102 were enrolled, and 45 presented for follow-up study visit (Fig. 1). Comparison within all consented subjects of those who did and did not follow up showed that subjects who did not follow-up were more likely to have state insurance (vs private,  $p = 0.006$ ), to be single (vs married,  $p = 0.020$ ) and to have a lower birth

**Fig. 1** CONSORT (Consolidating Standards of Reporting Trials) Diagram



weight [3309.87 g (SD 376.1) vs 3503.9 g (SD 401.2),  $p = 0.014$ ] (Supplementary Table 1). There were no differences in extent of perineal laceration, episiotomy, operative delivery and fetal or maternal complications by follow-up group.

No significant differences were found among sociodemographic and delivery variables between study groups, except in variables used to define the groups (Table 1). The spontaneous VD group had significantly later gestation age and more advanced cervical exam on admission. Five

**Table 1** Comparison of sociodemographic and delivery characteristics between labor groups

Variable	Total ( $n = 45$ )	Elective Induction ( $n = 22$ )	Spontaneous VD ( $n = 23$ )	$p$ -value <sup>a</sup>
Race, $n$ (%)				
Non-Hispanic White or Euro-American	39 (86.67)	19 (86.36)	20 (86.96)	1.000
Black, Afro-Caribbean, or African American	4 (8.89)	2 (9.09)	2 (8.70)	
Hawaiian/Pacific Islander	2 (4.44)	1 (4.55)	1 (4.35)	
Ethnicity, $n$ (%)				
Hispanic or Latino	0	0	0	1.000
Non-Hispanic or Latino	43 (95.56)	21 (91.45)	22 (95.65)	
Unknown	2 (4.44)	1 (4.55)	1 (4.55)	
Marital status, $n$ (%)				
Single	12 (27.27)	5 (23.81)	7 (30.43)	0.192
Partnered (relationship unmarried)	3 (6.82)	3 (14.29)	0	
Married	28 (63.64)	12 (57.14)	16 (69.57)	
Divorced	0	0	0	
Unknown	1 (2.27)	1 (4.76)	0	
Insurance, $n$ (%)				
State	3 (6.67)	2 (9.89)	1 (4.35)	1.000
Private	41 (91.11)	20 (90.91)	21 (91.28)	
Unknown	1 (2.22)	0	1 (4.35)	
Maternal age years, mean (SD)	29.7 (4.38)	28.86 (4.71)	30.52 (3.97)	0.208
Gravity, $n$ (%)				
1	42 (93.33)	21 (95.45)	21 (91.38)	1.00
2	2 (4.44)	1 (4.55)	1 (4.35)	
3	1 (2.22)	0	1 (4.35)	
Gestation age at admission, median (IQR)	39.28 (1)	39.14 (0.287)	40.14 (1.571)	< 0.001
Admission cervical dilation (cm), median (IQR)	2.5 (3)	1 (1)	4 (2)	< 0.001
Admission cervical effacement, median (IQR)	70 (40)	50 (20)	90 (30)	< 0.001
Admission cervical station (cm), median (IQR)	-2 (2)	-3 (1)	-2 (1)	0.002
Length of second stage (minutes), median (IQR)	83 (100)	71.5 (99)	90 (133)	0.256
Length membrane rupture (minutes), median (IQR)	605 (511)	505.5 (373)	708 (678)	0.316
Epidural anesthesia in labor, $n$ (%)	43 (95.56)	22 (100)	21 (91.30)	0.489
Episiotomy, $n$ (%)	5 (11.11)	1 (4.55)	4 (17.39)	0.346
Laceration, $n$ (%) <sup>b</sup>				
Sulcal	4 (8.89)	0	4 (17.39)	0.109
Perineal/vaginal	35 (77.78)	17 (77.27)	18 (78.26)	1
Periurethral	8 (17.78)	3 (13.64)	5 (21.74)	0.699
Perineal degree, $n$ (%)				
1 <sup>st</sup>	10 (28.57)	6 (35.29)	4 (22.22)	0.725
2 <sup>nd</sup>	23 (65.71)	10 (58.82)	13 (72.22)	
3 <sup>rd</sup>	2 (5.71)	1 (5.88)	1 (5.56)	
Estimated blood loss at delivery (ml), median (IQR)	250 (150)	225 (200)	275 (150)	0.335
Delivery fetal weight (grams), mean (SD)	3503.9 (401.2)	3428 (374.3)	3575.7 (420.9)	0.224
Delivery fetal length (cm), mean (SD)	51.9 (2.15)	51.6 (2.38)	52.1 (1.92)	0.41
Delivery head circumference (cm), mean (SD)	34.4 (1.18)	34.6 (1.18)	34.3 (1.19)	0.41

<sup>a</sup> $p$ -values from Fisher's exact, Mann-U Whitney or Student's  $t$ -test, where appropriate. Categorical data are expressed as  $n$  (%); continuous data are expressed as mean ( $\pm$  standard deviation), nonparametric expressed at median (interquartile range)

<sup>b</sup>Subjects could have more than one type of laceration

episiotomies were performed (11%) but did not differ by group. There was one EAS injury in each group—all third-degree lacerations, and no anal sphincter injuries were seen on TPUS. No participants in the spontaneous labor group underwent induction of labor including late term.

Postpartum maternal complications were rare and did not significantly differ between groups (Supplementary Table 2). There were four operative deliveries, three vacuum-assisted VDs in the eIOL group and one forceps-assisted VD in the

spontaneous group. Fetal complications were also rare and did not significantly differ between groups (Supplementary Table 3). Fetal antepartum ultrasounds, obtained at 19–22 weeks, were available for 91% of subjects, and fetal size parameters did not differ between groups.

Pelvic floor injury was present in 45.5%,  $n = 20$ , of subjects and was significantly different between the eIOL and spontaneous VD groups with 5 (23.8%) vs 15 (65.2%),  $p = 0.008$ , respectively (Table 2, Fig. 2). LHA > 2500 mm<sup>2</sup>

**Table 2** Comparison of markers of pelvic floor injury between labor groups

Variable	Total (n=44)	Elective induction (n=21)	Spontaneous VD (n=23)	<i>p</i> -value <sup>a</sup>
Primary composite (LHA > 2500, q75 elasticity index <sup>b</sup> , levator avulsion), <i>n</i> (%)	20 (45.45)	5 (23.8)	15 (65.2)	0.008
LHA > 2500 mm <sup>2</sup> , <i>n</i> (%)	11 (24.44)	3 (13.63)	8 (34.78)	0.096
Any levator avulsion, <i>n</i> (%)	7 (15.91)	1 (4.76)	6 (26.09)	0.062
Elasticity index > 75% quartile, <i>n</i> (%)	8 (27.59)	1 (6.25)	7 (53.85)	0.010
Levator hiatal area rest, mean (SD)	1814.0 (459.9)	1687.5 (400.6)	1929.4 (488.2)	0.081
Levator hiatal area Valsalva, mean (SD)	2131.7 (512.7)	2017.3 (450.0)	2236.0 (523.0)	0.159
Levator hiatal area Kegel, mean (SD)	1678.2 (434.1)	1578 (353.4)	1769.4 (486.4)	0.147
Vaginal angle rest, mean (SD)	59.76 (9.96)	58.76 (10.50)	60.7 (9.55)	0.529
Vaginal angle Kegel, mean (SD)	55.19 (12.16)	52.88 (10.2)	56.45 (13.8)	0.495
Vaginal angle Valsalva, mean (SD)	58.33 (12.84)	54.99 (11.72)	61.55 (13.29)	0.095
Elasticity index <sup>c</sup> , mean (SD)	7.91 (6.76)	5.68 (2.93)	10.66 (8.99)	0.0463

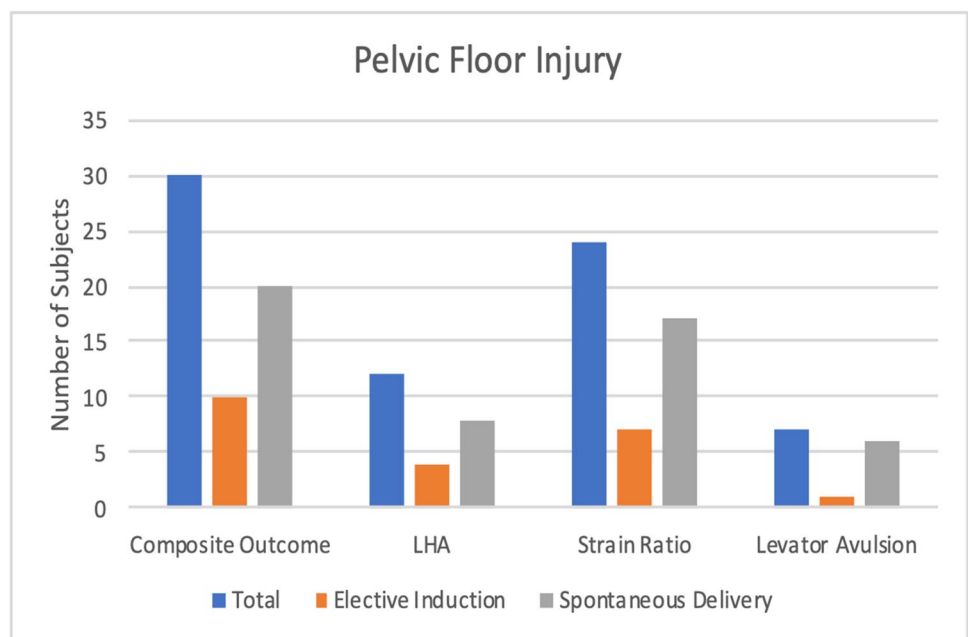
<sup>a</sup>*p*-values from Fisher’s exact or Student’s *t*-test, where appropriate. Categorical data are expressed as *n* (%); continuous data are expressed as mean (± standard deviation)

<sup>b</sup>q75 = 75% quartile value 11.1; elasticity index values above were counted as binary

<sup>c</sup>The deformation was standardized to rigid bone and expressed as elasticity index approximately equal to the inverse of Young’s (tissue) modulus

Abbreviations: LHA = levator hiatal area

**Fig. 2** Primary outcome: composite pelvic floor injury was more common in the spontaneous delivery group. The primary outcome was composite marker for pelvic floor injury; a composite score of (1) increased LHA > 2500 mm<sup>2</sup>, (2) decreased tissue modulus or increased elasticity index > 75% quartile or (3) presence levator avulsion on TPUS. Figure represents composite and individual dichotomous components. LHA = levator hiatal area



trended toward an increased incidence in the spontaneous VD group compared to the eIOL group [8 (35%) vs 3 (13%),  $p = 0.169$ ] but mean LHA was not significantly different. There were ten levator avulsion injuries in seven participants (3 bilateral). Avulsion was more common in the spontaneous VD group [7 (26%) vs 1 (5%),  $p = 0.062$ ] (Fig. 3). Elasticity index (SD) was significantly lower in the eIOL group [5.68 (2.93) vs 10.66 (8.99),  $p = 0.007$ ] consistent with decreased injury to the LAM enthesis with eIOL. Loss of acute vaginal angulation ( $< 45^\circ$ ) was common but did not differ between delivery groups or injury groups [17 (77%) vs 21 (91%),  $p = 0.188$ ].

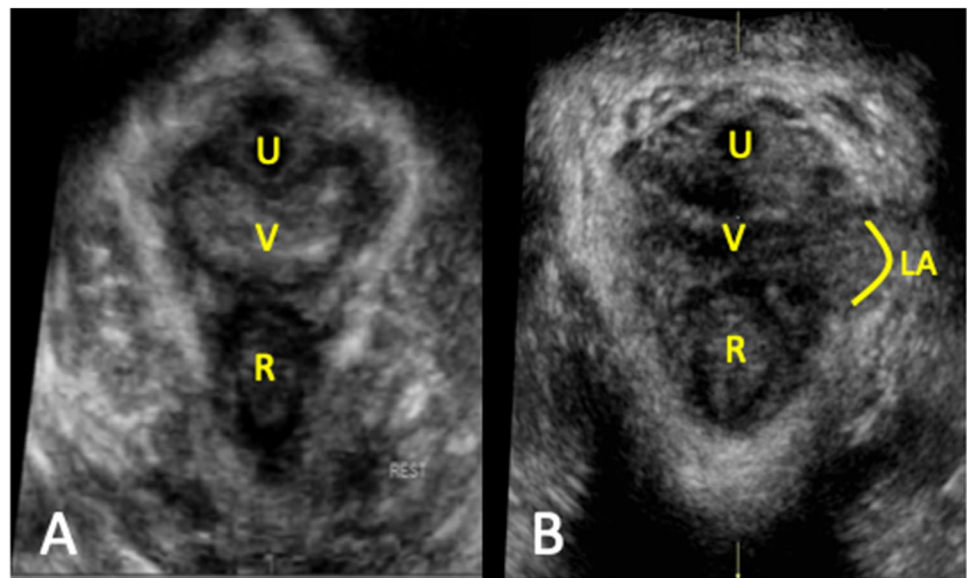
PFD symptoms were uncommon and were not different between groups (Table 3). Pelvic floor muscle injury was not a predictor of PFD symptoms on univariate analysis. The LAS scores revealed that subjects overall felt moderately in control of their labor experience with mean (SD) 56.9 (8.75)

out of 80 for both groups and no difference between groups [56.6 (8.7) vs 56.6 (10.9)  $p = 0.864$ ].

Six-week postpartum POP-Q scores were similar between groups for posterior vaginal wall support (Ba and Bp) and position of the cervix (C) (Table 4). The eIOL group had greater descent of the anterior vaginal wall and point D. Points C and D both trended together but only D reached significance. Both groups had a low incidence of prolapse to hymen or the apex  $\leq \frac{1}{2}$  vaginal length with only one subject in the spontaneous VD and two subjects in the eIOL group ( $p = 0.608$ ) meeting criteria. When comparing injured group to non-injured group, subjects had similar genital hiatus [3.6 cm (0.73) vs 3.2 cm (0.82),  $p = 0.270$ ], apical and anterior wall measurements.

On univariate analysis, only delivery type (eIOL vs spontaneous VD) and sulcal laceration were significantly associated with composite pelvic floor muscle injury

**Fig. 3** Transperineal ultrasound axial plane images with urethra (U), vagina (V) and rectum (R) labeled. **A** Normal postpartum without LHA enlargement or injury. **B** Postpartum injury with left-sided levator avulsion (LA) and enlarged levator hiatal area (LHA)



**Table 3** Comparison of patient reported subjective outcomes between labor groups

Variable	Total (n=44)	Elective induction (n=22)	Spontaneous VD (n=22)	$p$ -value <sup>a</sup>
EPIQ <sup>b</sup> POP, $n$ (%)	2 (4.44)	1 (4.55)	1 (4.35)	1
EPIQ SUI, $n$ (%)	4 (8.89)	2 (9.09)	2 (8.70)	1
EPIQ OAB, $n$ (%)	0	0	0	1
EPIQ AI, $n$ (%)	3 (6.67)	2 (9.09)	1 (4.35)	0.608
LAS <sup>c</sup> , mean (SD)	56.9 (8.75)	55.5 (9.42)	58.4 (7.97)	0.276

<sup>a</sup> $p$ -values from Fisher's exact or Student's  $t$ -test, where appropriate. Categorical data are expressed as  $n$  (%); continuous data are expressed as mean ( $\pm$  standard deviation)

<sup>b</sup>The modified Epidemiology of Prolapse and Incontinence Questionnaire (EPIQ) [15] has validated cutoff points for visual analog scale responses to symptoms of pelvic organ prolapse (POP), stress urinary incontinence (SUI), overactive bladder (OAB) and anal incontinence (AI). If score is above the cutoff, subjects screen positive for symptoms of each pelvic floor disorder

<sup>c</sup>Labor Agency scale (LAS) [16]: The total score out of 80 represents the inverse relationship between anxiety and control with higher scores indicating more control.

**Table 4** Comparison of POP-Q and Brink's score outcomes between labor groups

Pelvic exam outcomes <sup>a</sup> Mean (SD)	Total (n=44)	Elective induction (n=22)	Spontaneous VD (n=23)	<i>p</i> -value <sup>b</sup>
Gh strain	3.3 (0.78)	3.2 (0.62)	3.5 (0.89)	0.161
Pb strain	3.4 (0.59)	3.3 (0.50)	3.5 (0.65)	0.245
Aa	-1.8 (0.64)	-1.5 (0.71)	-2.0 (0.49)	0.011
Ba	-1.8 (0.64)	-1.5 (0.71)	-2.0 (0.49)	0.011
C	-7.0 (1.62)	-6.7 (-7.39)	-7.3 (1.67)	0.187
D	-7.6 (1.59)	-7.2 (1.49)	-8.0 (1.61)	0.008
TVL	8.7 (4.23)	8.3 (4.63)	8.9 (3.89)	0.632
Ap	-2.4 (0.68)	-2.3 (0.65)	-2.4 (0.72)	0.939
Bp	-2.4 (0.62)	-2.4 (0.61)	-2.3 (0.65)	0.742
Vaginal descent (Ab, Aa, Bp or Ap = 0, C > -1/2 TVL), <i>n</i> (%)	3 (6.67)	2 (9.09)	1 (4.35)	0.608
Brinks score <sup>c</sup>	8.42 (1.49)	8.36 (1.65)	8.47 (1.38)	0.801

<sup>a</sup>POP-Q pelvic exam measurements expressed in centimeters relative to hymen with strain

<sup>b</sup>*p*-values from Fisher's exact or Student's *t*-test, where appropriate. Categorical data are expressed as *n* (%); continuous data are expressed as mean ( $\pm$  standard deviation)

<sup>c</sup>Brink's score is a validated measure of pelvic floor muscle function by vaginal palpation, scored from 3 to 12 with higher score indicating better muscle function

Abbreviations: Gh = genital hiatus, Pb = perineal body, TVL = total vaginal length

**Table 5** Univariate relationship of selected factors with composite outcome of pelvic floor muscle injury

Factor	No injury ( <i>n</i> = 24)	Injury ( <i>n</i> = 20)	<i>p</i> -value <sup>a</sup>
Group, <i>n</i> (%)			
Elective induction	16 (66.7)	5 (25.0)	0.008
Spontaneous VD	8 (33.3)	15 (75.0)	
Maternal age (years), mean (SD)	29.2 (4.6)	30.6 (3.9)	0.252
Fetal weight (grams), mean (SD)	3412.7 (420.5)	3611.8 (368.7)	0.156
Fetal length (cm), mean (SD)	51.5 (2.5)	52.2 (1.6)	0.352
Fetal head circumference (cm), mean (SD)	34.7 (1.2)	34.2 (1.1)	0.209
Gh strain, mean (SD)	3.2 (0.8)	3.5 (0.7)	0.270
Ba, mean (SD)	-1.6 (0.7)	-2.0 (0.4)	0.056
C, mean (SD)	-7.0 (1.7)	-7.2 (1.7)	0.705
Sulcal laceration, <i>n</i> (%)	0	4 (20.0%)	0.036
Forceps operative delivery	1 (5)	0	0.455
Vacuum operative delivery	0	3 (12.5)	0.239

<sup>a</sup>*p*-value from Fisher's exact or Student's *t*-test, where appropriate. Categorical data are expressed as *n* (%); continuous data are expressed as mean ( $\pm$  standard deviation)

Abbreviations: VD = vaginal delivery, Gh = genital hiatus, Ba and C = POP-Q score points, SD = standard deviation.

(Table 5). Sulcal laceration perfectly predicted the outcome on univariate analysis and was removed from regression model. Variables remaining in the multivariate logistic regression model were spontaneous VD and POP-Q point Ba. In the adjusted model, Ba was not a predictor; therefore, the only independent predictor of composite pelvic floor muscle injury was spontaneous delivery type [unadjusted OR 6.0 with 95% CI (1.6–22.5), *p* = 0.008] compared to eIOL.

## Discussion

In this pilot study, we asked whether induction of labor at 39 weeks according to ARRIVE guidelines was associated with decreased pelvic floor injury—a known risk factor for PFDs later in life. The most important finding was that subjects in the eIOL group had significantly less evidence of pelvic floor muscle injury when detailed markers

were obtained by blinded examiners. Even with the pilot sample size of the current study, significant differences were observed among LHA, levator avulsion and elasticity index, while traditional markers for injury including degree of laceration and operative delivery did not differ between groups. Not surprisingly, at this early time after delivery, subjective patient-reported symptoms and feeling of control during labor did not differ between groups. POP-Q evaluation showed worsening of anterior vaginal wall and D point in the eIOL group, but overall vaginal descent was uncommon. Fetal weight was significantly different between delivery groups but did not correlate with pelvic injury. There were similar rates of maternal and fetal complications as well continuing to demonstrate safety in both groups.

Severe injury to the pelvic striated muscles even without visible damage or laceration to the perineum is likely much more common than clinically diagnosed, as observational cross-sectional studies using endoanal ultrasound examination have shown anal sphincter injury in 11–35% of primiparous women [18]. MRI studies demonstrate avulsion of the enthesis of the LAM from the pubic ramus in 20–35% of women [1, 19] who have delivered vaginally < 1 year postpartum and 18–30% of parous women have evidence of LAM injury on TPUS [20]. The overall incidence of levator avulsion in our cohort was similar in the spontaneous delivery group to these reported rates (26%) but significantly lower in the eIOL group (5%) demonstrating decreased incidence below baseline risk and a protective effect. Currently, evaluation for LAMI is not part of routine postpartum care despite the known risk for future PFDs.

POP greater than stage II has been reported in 9% of patients within 6 weeks of delivery [21], consistent with our findings of 9% of total subjects with prolapse to hymen or the apex to  $\leq \frac{1}{2}$  vaginal length. We observed greater descent of the anterior vagina and improvement of D point in the eIOL group compared to the spontaneous labor group, and while the sub-centimeter differences may be too small to be considered clinically meaningful, they suggest that the POPQ and TPUS may measure different components of pelvic organ support. Postpartum loss of acute vaginal angulation creating a straighter position of the vagina over the vaginal introitus [22] was demonstrated in both groups with loss of acute angulation in 91% of spontaneous VD compared to 77% eIOL. Improvement in apical measurements (C, D and TVL) is likely due to this loss of vaginal angulation (Table 4) [22, 23].

Previous studies have linked IOL as a risk factor for PFDs, theorizing that this relationship was related to reduced maternal physiologic preparedness for delivery and prolonged labor course. However, most of these studies were retrospective and biased by varied gestational ages and IOL indications including poor maternal health

[2, 24, 25], making them less relevant to healthy low risk nulliparous women at term. More recent data suggest that pelvic floor muscles remodel as early as the first trimester and continue to remodel throughout pregnancy to accommodate VD [26] with IOL not increasing injury risk. This is more consistent with our observed findings that eIOL may be protective. Our finding that pelvic floor injury is decreased with eIOL combined with the decreased Cesarean section rate in the eIOL group in the ARRIVE study suggests that induction of labor may benefit maternal health long term.

As a pilot study, our data were able to provide information about significant differences in pelvic floor injury based on labor management techniques, thus providing a solid platform for a future randomized controlled trial. Further research is needed with larger sample size to determine the mechanistic basis of this protective effect and the long-term consequences for PFDs. Nevertheless, the findings justify further investigation as a potential to decrease the primary risk factors for future PFDs has tremendous implications in terms of future costs of women's healthcare. Any recommendations about obstetric management would have to be balanced with the complex economics, resources and risks involved with safety and quality of peripartum care.

Accumulating evidence suggests that traditional measures of pelvic floor injury at the time of VD likely underestimate the extent of injury. Perineal lacerations are reported in 53–79% of deliveries [27], consistent with our reported 78%, which was similar between groups. OASIS is a measure of severe injury, with a reported clinical incidence of only 1.1–3.3% of VDs and a much higher incidence using imaging outcomes [27]. This cohort had a slightly higher rate of OASIS among all consented subjects ( $n = 3$ , 3.85%). Ultrasound markers identified for the composite outcome increased recognition of significant pelvic floor muscle injury. Our outcomes were designed to capture injury at the enthesis (increased deformation, avulsion) and stretch (LHA). Additionally, evolving measures of injury that assess voluntary muscle function are still highly subjective and dependent on subject effort [28–30]. Although, continued study to define their value in detecting injury is critical. In addition, injured women will need to be followed to define the natural history of pelvic floor injury. While some studies suggest that some women recover from injury with time using imaging criteria [31], it is not clear whether long-term function is regained. Within our study, functional measures including Brink's score, symptoms and vaginal angulation did not differ between groups during the immediate postpartum follow-up period but long-term comparisons may differ. Investigators should continue to evaluate comprehensive measures of pelvic floor injury in the research setting toward the long-term goal of incorporating into an algorithm for clinical risk discussions.



While enriched by multiple modalities of descriptive data for pelvic floor injury, this pilot study has some limitations. We acknowledge that bias may exist between study groups as all women in the spontaneous labor arm have declined eIOL for their own reasons. Further comparison with baseline measures in early pregnancy would have provided a comprehensive comparison for changes that occurred in pregnancy and delivery. In addition, long-term comparison after 6 months would also provide information about healing and presents persistent injury although our primary focus was early injury. Regarding the analysis of mechanical properties of the enthesis, there are currently no established baseline values for tissue modulus. However, standardization against bone to account for force variation provides support for this technique.

We experienced a high lost to follow-up rate, which improved with additional funding to provide participant compensation. Moreover, during the COVID-19 pandemic women were reluctant to return. Differences noted between women who did and did not follow-up indicate a possible source of selection bias. The differences (insurance and marital status) could be related to COVID-19 visitor restrictions, as childcare was required and time away from newborns increased. The relative difference in fetal birthweights between those who did and did not follow up may be multifactorial. It is conceivable that because women who followed up had larger infants and were more symptomatic and sought further assessment. The smaller sample size may not have allowed for adequate comparisons of other maternal and fetal characteristics which can affect pelvic floor injury such as maternal age and prolonged second stage of labor. However, none of these factors were predictive in multivariate analysis.

In conclusion, measures of pelvic floor injury though not pelvic floor symptoms are markedly increased in women undergoing spontaneous VD compared to those undergoing elective induction of labor at 39 weeks.

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Dr. Jacob Larkin MD, Magee-Womens Hospital University of Pittsburgh Medical Center, 300 Halket Street Pittsburgh, PA 15232. No disclosures to report.

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**Author contributions** LS Burkett: Project development, Data collection, Data analysis, Manuscript writing

TP Canavan: Project development, Data collection, Data analysis, Manuscript editing

SM Glass Clark: Data collection, Manuscript editing

LE Giugale: Data collection, Manuscript editing

AM Arsten: Data collection, Manuscript editing

PA Moalli: Project development, Data collection, Data analysis, Manuscript writing

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## Declarations

**Conflicts of interest** None.

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