GYNECOLOGY

Association of levator injury and urogynecological complaints in women after their first vaginal birth with and without mediolateral episiotomy

Leonie Speksnijder, MD; Daniëlla M. J. Oom, MD, PhD; Jeroen Van Bavel, MD; Eric A. P. Steegers, MD; Anneke B. Steensma, MD, PhD

BACKGROUND: Pelvic organ prolapse is a common health problem in women and has a negative influence on quality of life. A major cause of pelvic organ prolapse is levator injury.

OBJECTIVE: The objective of the study was to evaluate the association of mediolateral episiotomy with levator injury (levator avulsion, ballooning, or combined) and urogynecological complaints.

STUDY DESIGN: A prospective observational cohort study was performed in 204 primiparous women with a spontaneous vaginal delivery without anal sphincter tear in a general hospital between 2012 and 2015. One hundred three of these women had had a mediolateral episiotomy. Validated urogynecological questionnaires and transperineal 3-dimensional/4-dimensional ultrasound were completed after delivery. Outcome measures were levator avulsion, ballooning (hiatal area of more than 25 cm^2), and urogynecological questionnaire scores. Statistical analysis was performed using univariate and multiple logistic regression analysis.

RESULTS: The median time at investigation after vaginal delivery was 13 months (range 6–33). Levator injury (avulsion, ballooning, or combined) was identified in 35 of the 103 women who had undergone mediolateral episiotomy (40.0%) and 33 of the 101 women without episiotomy (32.7%) ($P = .69$). No differences were found in the incidence of levator avulsion 27 (26.7%) vs 23 (22.8%) ($P = .53$) or in levator ballooning (20 [19.4%] vs 23 [22.8%] ($P = .58$) between both groups. There was an association between longer duration of the second stage of labor and the incidence of levator avulsion (odds ratio, 1.24 [95% confidence interval, 1.01–1.52]). Nonocciput anterior fetal position increased the risk of levator ballooning and levator injury (odds ratio, 10.19 [95% confidence interval, 1.89–54.91] and odds ratio, 12.16 [95% confidence interval, 1.41–104.38], respectively). No differences in urogynecological complaints were found.

CONCLUSION: Mediolateral episiotomy is not associated with the occurrence of levator injury or urogynecological complaints in women with a spontaneous vaginal delivery who did not obtain an anal sphincter injury. Levator injury was associated with a prolonged second stage of labor and a nonocciput anterior fetal position.

Key words: adult, episiotomy, female, humans, levator ani, levator avulsion, levator ballooning, observational study, obstetric delivery, obstetric labor complications/diagnostic imaging, obstetric labor complications/prevention & control, pelvic floor, pelvic floor/diagnostic imaging, pelvic floor/ injuries, pregnancy, ultrasonography

Pelvic organ prolapse (POP) is a common health problem in women and has a negative influence on quality of life.[1,2] A major cause of POP is pelvic floor injury during delivery. Specific types of pelvic floor injury include levator avulsion and levator ballooning.

Levator avulsion occurs in 13–36% of women after vaginal delivery. Levator ani muscle overextension or levator ballooning can also be related to POP and is strongly associated with symptoms and clinical signs of prolapse.[3–5] This levator ballooning (a hiatal area of more than 25 cm^2 in Valsalva) occurs in 33% of primiparous women.[3,6,7] Both are also associated with a higher recurrence of POP after POP surgery and a decrease in pelvic floor muscle strength.[3–6,8] Attempts to repair levator injuries so far have not been proven successful.[9] Therefore, prevention is important.

Prevention starts with identifying the risk factors and protective factors for levator avulsion. One possible risk or protective factor is the use of a mediolateral episiotomy during vaginal delivery. A mediolateral episiotomy can reduce the incidence of anal sphincter injury.[10] However, while in regard to protecting the levator ani muscle, some studies have found a causative effect of mediolateral episiotomy on levator avulsion, and others have found a protective effect or no effect.[3,11–14] Therefore, the influence of a mediolateral episiotomy on levator injury and urogynecological complaints remains unclear.

If there is a potential benefit of mediolateral episiotomy, this must be weighed against its potential adverse effects. The potential adverse effects include unsatisfactory anatomic results, increased blood loss, increased postpartum pain, higher rates of infection, wound dehiscence, and sexual dysfunction.[15–18]

This uncertainty regarding the benefits of mediolateral episiotomy led us to the following research questions: is a mediolateral episiotomy a risk factor or a protective factor for levator injuries (levator avulsion, ballooning, or combined) and for the occurrence of urogynecological complaints? Furthermore, we examined whether other determinants were involved (ie, age, birthweight, etc). To answer these questions, we used validated questionnaires and transperineal 3-dimensional/4-dimensional (3D/4D) ultrasound in women with and without mediolateral episiotomy after a first, spontaneous

Cite this article as: Speksnijder L, Oom DMJ, Van Bavel J, et al. Association of levator injury and urogynecological complaints in women after their first vaginal birth with and without mediolateral episiotomy. Am J Obstet Gynecol 2019;220:93.e1-9.

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2018.09.025

AJOG at a Glance

Why was this study conducted?

To evaluate the association of mediolateral episiotomy with levator avulsion and/or ballooning and urogynecological complaints in primiparous women without anal sphincter injury.

Key findings

Mediolateral episiotomy has no association with of levator avulsion and/or ballooning or urogynecological complaints. Levator avulsion and/or ballooning are related to a prolonged second stage of labor and a nonocciput anterior fetal position.

What does this add to what is known?

This study resolves the uncertainty about the association between mediolateral episiotomy and occurrence of levator injury (levator avulsion, levator ballooning, or a combination).

vaginal delivery who did not obtain an anal sphincter injury.

Materials and Methods

This was a prospective observational cohort study comparing women who received a mediolateral episiotomy and those who did not. Ethical approval for this study was obtained by the medical research ethics committee of the Erasmus Medical Centre (MEC-2012-058).

All women who underwent a first spontaneous vaginal delivery in our hospital with or without mediolateral episiotomy received a written invitation 3 months after their delivery to participate in this study between 2012 and 2015. Women who delivered prematurely, delivered a fetus in noncephalic position, experienced an instrumental vaginal delivery, median episiotomy, obstetric anal sphincter injury, or secondary Caesarean section were not included in the study. The investigators were not involved in the management of the participants' deliveries.

The women who agreed to participate were scheduled for an appointment no sooner than 6 months after delivery at the outpatient clinic. Participants received compensation for their travel and parking expenses.

After obtainment of written informed consent, the patients completed an anonymized standardized questionnaire on urogynecological complaints. A detailed examination of the perineum and 3D/4D transperineal ultrasound investigation were performed. Antenatal, intrapartum and fetal characteristics were retrospectively obtained from the medical file. In The Netherlands the second stage of labor is defined as the time period from the moment of active pushing onward until the delivery of the baby.

Perineal examination

The scar of the mediolateral episiotomy was studied by the investigator (L.S.). The angle, length, and position of the scar against the midline of the posterior fourchette were measured.

Questionnaire

We used the following validated questionnaires: the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12,[19] Pelvic Floor Impact Questionnaire-7,[20] Urogenital Distress Inventory scale-6,[21] Fecal Incontinence Severity Index,[22] Incontinence Impact Questionnaire-7,[21] and Fecal Incontinence Quality of Life scale.[22]

3D/4D transperineal ultrasound

A 3D/4D transperineal ultrasound was performed in the supine position and after voiding using a Voluson E Expert system using a 4−8 MHz RAB abdominal probe (GE Healthcare, Chalfont St Giles, United Kingdom) as previously described by Dietz.[23] The ultrasound volumes were obtained at rest, pelvic floor muscle contraction, and maximal Valsalva. All volumes were obtained by an experienced investigator (L.S.).

Offline analysis of the recorded 3D/4D transperineal ultrasound volumes were performed by 3 experienced investigators (L.S., D.O., A.S.). The investigators were blinded against all clinical data and therefore unaware of the delivery outcome and whether the participant had or had not had a mediolateral episiotomy. Analysis was done using specialized 3D imaging software, 4D View version 17.0 (GE Healthcare).

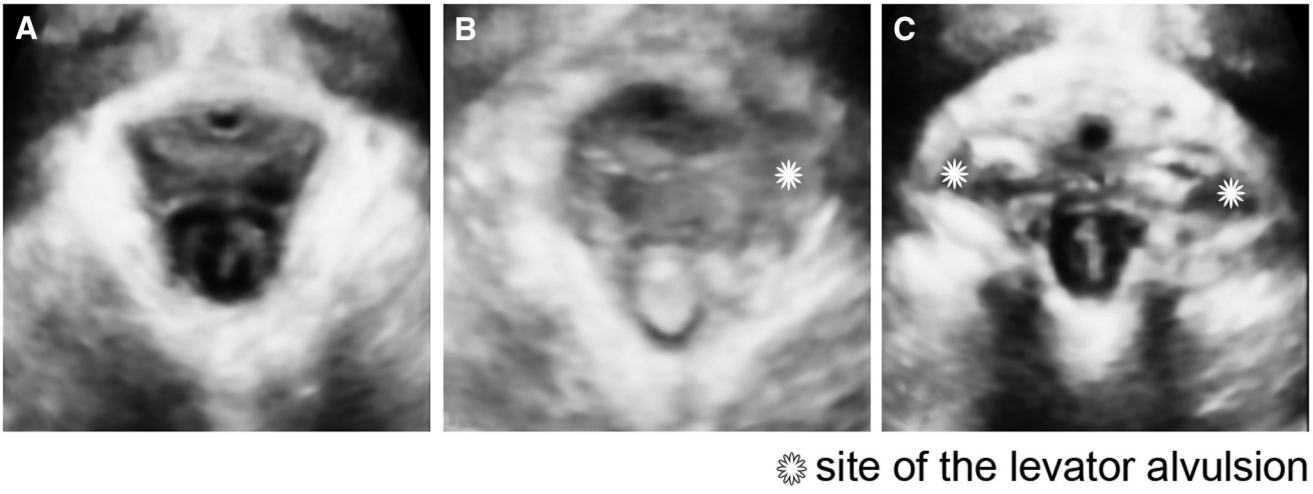
Levator avulsion was scored using a scoring system based on tomographic ultrasound imaging as previously described by Dietz.[24] Levator avulsion was diagnosed when 3 central slices (reference slice and the slices 2.5 and 5 mm cranial) showed an abnormal muscle insertion.[25] Figure 1 depicts a normal, unilateral, and bilateral levator avulsion on 3D/4D transperineal ultrasound.

The hiatal area was measured during maximum Valsalva. Levator ballooning was scored when the levator hiatal area was >25 cm^2. Previous research indicate that a cut of 25 cm^2 can be defined as abnormal distensibility, or ballooning, of the levator hiatus in relation to complains and clinical prolapse.[6,7] Figure 2A gives an example of a normal hiatus during maximal Valsalva. Figure 2, B and C, depicts an example of mild and marked levator ballooning. Women with an avulsion, ballooning, or a combination were scored as having levator injury.

To determine good interobserver and intraobserver reliability of hiatal area measurements, 20 patients were selected at random. All investigators independently performed 3 volume measurements of each data set; the mean measurement was used for comparison. The interobserver intraclass correlations coefficients were above 0.90.

For intraobserver reliability all investigators repeated another 3 measurements at least 2 weeks after the first series in 20 randomly chosen data sets. The mean of these measurements was compared with the mean of the 3 previously obtained measurements from the same 20 data sets. The interobserver intraclass correlations coefficients were above 0.80 (reflects an excellent reliability).[26,27]

FIGURE 1
Normal levator, unilateral, and bilateral avulsion of levator during contraction



Example of a normal levator **(A)**, unilateral **(B)**, and bilateral **(C)** avulsion of the levator during contraction with 3D/4D transperineal ultrasound.
Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

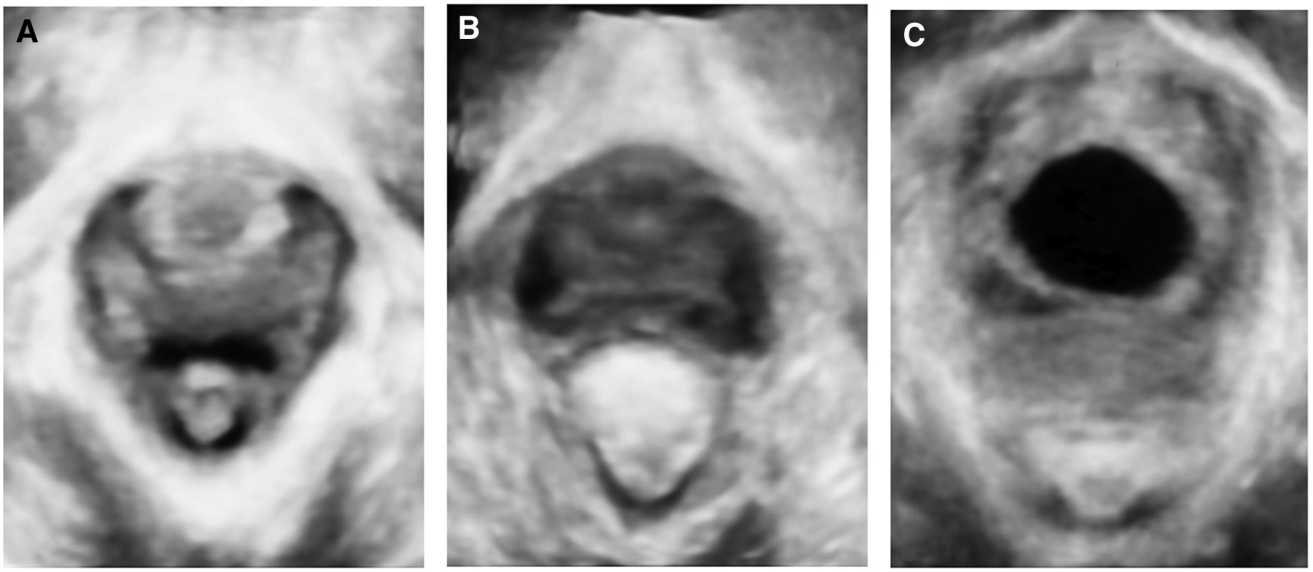
Primary outcome measures were levator avulsion, levator ballooning, and the score of the urogynecological questionnaire.

Statistical analysis

A power analysis was calculated. Previous data regarding the prevalence of a levator avulsion after first vaginal birth have indicated a mean occurrence of approximately 25%.[5] Our hypothesis was that a mediolateral episiotomy reduced the risk of levator avulsion. We considered a difference of 20% to be clinically relevant. We assumed an alpha risk of 5% and a beta risk of 20% (ie, a power of 80%). With these criteria we needed at least 91 women in each group; therefore, we planned to include 100 women in both groups.

Statistical analysis was performed using IBM SPPS Statistics version 20.0. The comparison of means between groups was performed by the Student *t* test after

FIGURE 2
Normal hiatus, mild, and marked levator ballooning during maximal Valsalva



Example of a normal **(A)** hiatus during maximal Valsalva with 3D/4D transperineal ultrasound and mild **(B)** and marked **(C)** levator ballooning.
Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

checking for normal distribution of the variables; otherwise, a Mann-Whitney *U* test was used. Univariate and multiple logistic regression analysis was used for multiple comparisons of quantitative variables between groups.

For the logistic regression, we controlled for known risk or protective factors for occurrence of obstetric trauma like levator avulsion or obstetric anal sphincter trauma including maternal age, mediolateral episiotomy, duration of second stage of labor, fetal birthweight, and nonocciput anterior fetal head position.[5,28–30]

For the study of categorical variables, Fisher exact and χ^2 tests were used as appropriate. For ordinal data the Kruskal-Wallis test was used. A 2-sided value of $P < .05$ was considered to indicate statistical significance.

Results

A total of 2535 women were invited to participate, but only 204 women with a first, spontaneous vaginal delivery (8%) volunteered to participate in our study. Characteristics of participants and nonparticipants are reflected in Table 1. Participants were more likely to be white and had a longer second stage. In nonparticipants more women were induced and received more frequently epidural analgesia.

TABLE 1
Baseline characteristics between participants and nonparticipants

Characteristics	Study participants (n = 204) Mean ± SD or median (IQR) or %	Non-participants (n = 2535) Mean ± SD or median (IQR) or %	*P* value
Age, y	30.1 ± 3.9	29.5 ± 4.8	.05
Caucasian ethnicity[a]	91.7%	80.1%	< .05
BMI, kg/m^2	23.2 (21.3–26.3)	23.0 (20.9–26.1)	.64
Mediolateral episiotomy	51%	51%	.52
Birthweight, g	3362 ± 453	3342 ± 470	.55
Blood loss, mL	300 (200–550)	300 (200–500)	.89
Duration of second stage of labor, min[a]	38 (22–55)	31 (18–48)	< .05
0–30	37%	47%	.09
30–60	42%	39%	.45
60–90[a]	17%	11%	< .05
>90 min	4%	3%	.52
Induction[a]	23%	33%	< .05
Use of oxytocin	64%	69%	.09
Use of epidural analgesia[a]	42%	53%	< .05
Occiput anterior fetal head position	3.4%	4.4%	.34

Depending on normal distribution or not either Student *t* test or Mann-Whitney *U* test was used. For the categorical variables, we used the Fisher exact or χ^2 tests. The Kruskal-Wallis was used for ordinal-level dependent variables. Second stage of labor is defined as the time period from the moment of active pushing onward until the delivery of the baby.

[a] $P < .05$.

Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

The median time at investigation after vaginal delivery was 13 months (range, 6–33 months). Women who received a mediolateral episiotomy had experienced more blood loss and a longer duration of the second stage of labor than women with no mediolateral episiotomy (Table 2).

The mediolateral episiotomy was placed at the left side of posterior fourchette. Indications for performing the mediolateral episiotomy were fetal distress (36.6%), failure to progress (18.8%), tight or short perineum (21.8%), or a combination (22.8%). The median angle of the episiotomy against the midline of the posterior fourchette was 35° (range 10–60°). The median length was 3 cm (range, 1.5- 5 cm).

The episiotomy was placed with a median of 0.5 cm (range 0–2 cm) distance against the midline of the posterior fourchette. Of the women without mediolateral episiotomy, 18% of the women had a first-degree perineal tear, 40% had a second-degree perineal tear, 28% a labial and/or vaginal tear, and 14% had no tear.

Levator injury (avulsion, ballooning, or a combination) was identified in 33.3% of all included patients. No difference in levator injury was found between women with and without mediolateral episiotomy (35 (40.0%) vs 33 (32.7%%) ($P = .69$).

A levator avulsion was identified in 50 of the women (24.5%). Fifty-six percent of the 50 women had an unilateral avulsion, of whom 57% had an avulsion on the left side. There were no significant differences in the incidence of levator avulsion, 27 (26.7%) vs 23 (22.8%) ($P = .53$), between women with and without mediolateral episiotomy.

Levator ballooning was identified in 43 of all women (21%), of whom 41.9% were without levator avulsion. In the majority of patients (51%), ballooning was classified as mild (>25–29.9 cm^2). Twenty-eight percent had moderate ballooning (≥30 to 34.9 cm^2), reasonable (≥35 to 39.9 cm^2) in 14%, and 7% had severe ballooning (≥40 cm^2). There was also no significant difference in the incidence in levator ballooning between both groups (20 (19.4%) vs 23 (22.8%) ($P = 0.58$).

A multiple logistic regression analysis was used to analyze quantitative variables between different groups (Tables 3–5). The first group compared women with and women without levator injury (Table 3). A nonocciput anterior fetal head position remained a risk factor for levator injury (adjusted odds ratio [OR], 12.16 [95% confidence interval (CI), 1.41–104.38).

TABLE 2
Baseline characteristics between women with and without a mediolateral episiotomy

Characteristics	No mediolateral episiotomy n	No mediolateral episiotomy Mean ± SD or median (IQR) or n (%)	With mediolateral episiotomy n	With mediolateral episiotomy Mean ± SD or median (IQR) or n (%)	*P* value
Age, y	101	30.5 ± 4.2	103	29.8 ± 3.6	.19
Caucasian ethnicity	101	91 (90.1%)	102	96 (93.2%)	.29
BMI, kg/m^2	99	22.7 (21.2–26.3)	101	23.4 (21.3–26.0)	.60
Birth with midwife-led care[a]	101	9 (8.9%)	103	2 (1.9%)	.03[a]
Birthweight, g	101	3333 ± 468	103	3392 ± 467	.93
Blood loss, mL[a]	101	200 (150–400)	102	355 (218–585)	< .001[a]
Duration of second stage of labor, min[a]	101	34 (17–52)	103	41 (26–61)	.002[a]
0–30		31 (42%)		19 (30%)	.212
30–60		32 (43%)		27 (43%)	1.00
60–90		9 (12%)		14 (22%)	.168
>90		2 (3%)		3 (5%)	.661
Induction	101	24 (23.8%)	103	23 (22.3%)	.81
Use of oxytocin	101	61 (60.4%)	103	70 (68.0%)	.26
Use of epidural analgesia	101	48 (47.5%)	103	37 (35.9%)	.09
Occiput anterior fetal head position	101	97 (96.0%)	103	100 (97.1%)	.68

Depending on normal distribution or not either Student *t* test or Mann-Whitney *U* test was used. For the categorical variables, we used the Fisher exact or χ^2 tests. The Kruskal-Wallis was used for ordinal-level dependent variables. Second stage of labor is defined as the time period from the moment of active pushing onward until the delivery of the baby.

[a] $P < .05$.

Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

A longer duration of the second stage of labor increased the risk for levator avulsion (OR, 1.24 [95% CI, 1.01–1.52]) (Table 4). Also a non-occiput anterior fetal head position remained a risk factor for levator ballooning (adjusted OR, 10.19 [95% CI, 1.89–54.91]) after correction (Table 5).

TABLE 3
Crude and adjusted estimations for levator injury, meaning women with an avulsion, ballooning, or a combined injury

Characteristics	No levator injury n	No levator injury Mean ± SD or median (IQR) or n (%)	Levator injury n	Levator injury Mean ± SD or median (IQR) or n (%)	*P* value of ANOVA	Nonadjusted OR[a] Odds (95% CI)	*P* value[a]	Adjusted OR[b] Odds (95% CI)	*P* value[b]
Age, y	136	30.0 ± 4.1	68	30.5 ± 3.5	.31	1.04 (0.96–1.11)	.34	1.02 (0.94-–1.10)	.61
Duration of second stage of labor (every 15 min)	136	34 (21–51)	68	45 (25–60)	.05	1.01 (1–1.02)	.07	1.20 (0.99–1.45)	.06
Mediolateral episiotomy	136	70 (51%)	68	33 (49%)	.58	0.89 (0.50–1.59)	.69	0.84 (0.45– 1.55)	.50
Occiput anterior fetal head position	136	135 (99%)	68	62 (91%)	.35	13.07 (1.54–111)	.02[c]	12.16 (1.42– 104.38)	.02[c]
Birthweight (every 500 g)	136	3377 ± 470	68	3334 ± 418	.56	1.00 (1.00–1.00)	.53	0.84 (0.60–1.19)	.33

ANOVA, analysis of variance; *CI*, confidence interval; *IQR*, interquartile range; *n*, number of patients; *OR*, odds ratio.

[a] Crude logistic regression model; [b] Multiple logistic regression analysis adjusted for age, duration of second stage of labor (the time period from the moment of active pushing onward until the delivery of the baby), mediolateral episiotomy, occiput anterior fetal head position, and birthweight; [c] Significant *P* value.

Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

TABLE 4
Crude and adjusted estimations for levator avulsion

Characteristics	No levator avulsion n	No levator avulsion Mean ± SD or median (IQR) or n (%)	Levator avulsion n	Levator avulsion Mean ± SD or median (IQR) or n (%)	*P* value of ANOVA	Nonadjusted OR[a] OR (95% CI)	*P* value[a]	Adjusted OR[b] OR (95% CI)	*P* value[b]
Age, y	154	30.4 ± 3.4	50	30.1 ± 4.0	.56	1.03 (0.94–1.11)	.56	1.01 (0.93–1.10)	.85
Duration of second stage of labor (every 15 min)	154	34 (20–52)	50	45 (32–61)	.02[c]	1.01 (1.00–1.03)	.03[c]	1.24 (1.01–1.52)	.04[c]
Mediolateral episiotomy	154	76 (49%)	50	27 (54%)	.67	1.21 (0.64–2.28)	.57	1.10 (0.56–2.16)	.77
Occiput anterior fetal head position	154	151 (98%)	50	46 (92%)	.12	4.38 (0.95–20.27)	.06	4.17 (0.88–19.90)	.07
Birthweight (every 500 g)	154	3372 ± 422	50	3332 ± 463	.62	1.00 (1.00–1.00)	.58	0.82 (0.56–1.21)	.32

ANOVA, analysis of variance; *CI*, confidence interval; *IQR*, interquartile range; *n*, number of patients; *OR*, odds ratio.

[a] Crude logistic regression model; [b] Multiple logistic regression analysis adjusted for age, duration of second stage of labor (the time period from the moment of active pushing onward until the delivery of the baby), mediolateral episiotomy, occiput anterior fetal head position, and birthweight; [c] Significant *P* value.

Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

No differences in urogynecological complaints on the different validated questionnaires were found between women with and without mediolateral episiotomy or between women with or without levator avulsion and/or ballooning (Table 6).

Comment

A mediolateral episiotomy is neither a risk factor nor a protective factor for levator injury (levator avulsion, levator ballooning, or combined injury). Our results suggest that levator injury in women is a result of a difficult vaginal delivery, in, for example, a longer second stage or nonocciput anterior position.

The greatest stress on the levator ani muscle occurs when the biggest circumference of the head reaches the level of the levator ani muscle. A possible explanation for our finding therefore

TABLE 5
Crude and adjusted estimations for levator ballooning (>25 cm^2)

Characteristics	No levator ballooning n	No levator ballooning Mean ± SD or median (IQR) or n (%)	Levator ballooning n	Levator ballooning Mean ± SD or median (IQR) or n (%)	*P* value of ANOVA	Nonadjusted OR[a] Odds (95% CI)	*P* value[a]	Adjusted OR[b] Odds (95% CI)	*P* value[b]
Age, y	161	30.5 ± 4.1	43	30.6 ± 3.3	.47	1.04 (0.95–1.13)	.43	1.02 (0.94–1.12)	.56
Duration of second stage of labor (every 15 min)	161	37 (22–56)	43	41 (20–55)	.86	1.00 (0.99–1.01)	.94	1.00 (0.80–1.25)	.98
Mediolateral episiotomy	161	83 (52%)	43	20 (50%)	.55	0.82 (0.42–1.60)	.56	0.86 (0.42–1.76)	.68
Occiput anterior fetal head position	161	159 (99%)	43	38 (88%)	.01[c]	10.5 (1.95–55.9)	.01[c]	10.19 (1.89–54.91)	.007[c]
Birthweight (every 500 g)	161	3372 ± 461	43	3325 ± 423	.59	1.00 (1.00–1.00)	.54	0.89 (0.59–1.32)	.55

ANOVA, analysis of variance; *CI*, confidence interval; *IQR*, interquartile range; *n*, number of patients; *OR*, odds ratio.

[a] Crude logistic regression model; [b] Multiple logistic regression analysis adjusted for age, duration of second stage of labor (the time period from the moment of active pushing onward until the delivery of the baby), mediolateral episiotomy, occiput anterior fetal head position, and birthweight; [c] Significant *P* value.

Speksnijder. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

TABLE 6
Differences in urogynecological complaints on the different validated questionnaires between women with or without episiotomy and between women with or without levator injury (levator avulsion, ballooning, or combined injury), levator avulsion, and levator ballooning

	Mediolateral episiotomy		Levator injury		Levator avulsion		Levator ballooning	
Questionnaire	Yes	No	Yes	No	Yes	No	Yes	No
Urogenital Distress Inventory scale-6[20]								
On a scale from 0 to 100, the higher the score, the higher the disability	29 (13–46)	33 (17–46)	33 (17–46)	29 (13–46)	33 (16–46)	29 (13–46)	33 (17–42)	29 (13–48)
Prolapse/Urinary Incontinence Sexual Questionnaire-12[18]								
Maximum: 48 (on a scale from 0 to 48, the lower the score, the higher the disability)	38 (36–41)	38 (34–40)	39 (39–42)	38 (35–41)	39 (35–41)	38 (35–40)	40 (36–42)	38 (35–40)
Pelvic Floor Impact Questionnaire-7[19]								
On a scale from 0 to 300, the higher the score the higher the disability	5 (0–21)	0 (0–14)	5 (0–19)	0 (0–14)	5 (0–14)	0 (0–19)	5 (0–19)	0 (0–14)
Fecal Incontinence Severity Index[21]								
On a scale from 0 to 61, the higher the score, the higher the disability	17 (3–27)	12 (0–27)	16 (16–28)	13 (13–27)	17 (5–27)	12 (0–27)	15 (0–30)	15 (2–27)

Numbers are median (interquartile range [IQR]).

There we no significant differences on the questionnaires with Mann-Whitney U test between the groups ($P < .05$).

Speksnijder et al. Levator injury and mediolateral episiotomy. Am J Obstet Gynecol 2019.

might be that damage to the levator ani muscle already occurs before placement of a mediolateral episiotomy.

Previous studies reported conflicting outcomes. Three studies suggested that levator avulsions were more common after mediolateral episiotomy.[3,12,13] However, multivariable regression analysis revealed a weaker association of mediolateral episiotomy on avulsion rates. Their data revealed that prolonged second stage of labor, forceps delivery, and occipitoposterior position of the fetal head were associated with a higher incidence of levator avulsions.

Two previous studies found similar outcomes as the present study. However, Cassado et al[11] showed a lower number of patients with levator avulsions (12.9%). Possibly their number of studied patients was too small. Our higher proportion of women with levator avulsion (24.5%), is comparable with the study of Valsky et al,[14] which also found no effect of episiotomy on the levator avulsion rates. Based on these previous and the present study, it seems that there is no association between levator avulsion and mediolateral episiotomy.

In our study group, we also analyzed levator ballooning, considered to be another sign of levator injury. We found that women with levator avulsion have a higher risk of levator ballooning, although some women with ballooning had no avulsion. A possible explanation for why women with levator avulsion have a higher risk of levator ballooning is that they are 2 self-contained pelvic floor injuries that are strongly associated with each other. One recently published study that also found no difference in hiatal area during maximal Valsalva in women with and without mediolateral episiotomy.[31] Our measured hiatal area during maximal Valsalva was similar with theirs.

In addition to levator injury, we analyzed other urogynecological complaints and potential adverse effects of episiotomy. Mediolateral episiotomy did not influence the frequency of urogynecological symptoms. A potential adverse effect was a higher amount of blood loss at delivery, which is in line with the findings of a previous study.[32] We found no differences in urogynecological complaints between the women with and without levator injury.

A possible explanation for this could be that the mean time of analysis after delivery was 13 months. As we know, pelvic floor symptoms could exacerbate

at an older age. Our urogynecological complaints scores were comparable with the score of asymptomatic Dutch women in previously studied groups.[19–22]

A key strength of our study is that the 3D/4D transperineal ultrasound was performed on average 13 months after birth. We avoided the risk of an overestimation of the levator avulsions because in examining a patient soon after delivery, a hematoma could be mistaken for a levator avulsion. A study showed that hematomas can dissolve between 6 months and a year after delivery.[33,34] Another strength is that we included urogynecological complaints and pelvic floor injury other than levator avulsion. No other study has addressed these data. A third strength is that we measured angle, length, and position of the scar against the midline of the posterior fourchette.

There were some limitations in our study. The first limitation is selection bias. Only 8% of invited women participated in our study. The fact that our incidence of levator avulsion is comparable with that in previous studies indicates a representative study group. Also, the score on the different questionnaire represents a normal score, suggesting a representative cohort.

The second limitation is that the measurement of the fetal head circumference is not a standard procedure in our department. Therefore, we cannot analyze the influence of head circumference on levator avulsion or ballooning, although Valsky et al[14] have shown that this might be an independent risk factor.

The third limitation is that our mediolateral episiotomy is not a real mediolateral episiotomy when we look at the angle and position of the scar against the midline of the posterior fourchette.[35] The origin of a lateral episiotomy is usually 1−2 cm away from the posterior fourchette and may therefore give less relief of the stretch of the perineum at the point of the posterior fourchette and possibly also on the levator ani muscle.[36]

The fourth limitation is that our results can be generalized only to white women after a first and normal vaginal delivery without anal sphincter tear who have undergone restrictive use of mediolateral episiotomy on the left side.

The possibility remains that our sample size was too small to find a significant difference between women who had a mediolateral episiotomy and women who had not in terms of levator injury or urogynecological complaints. Indeed, a greater population size may well be necessary to detect a possible small protective effect of mediolateral episiotomy in preventing levator avulsion or ballooning or urogynecological complaints. Whether or not this is the case, it should be considered if the intervention is worthwhile, given the potential adverse effects that result from this procedure.

In terms of clinical relevance, we conclude that to prevent levator injury like levator avulsion or ballooning and urogynecological complaints in the future, further research should focus on developing a good prediction model for difficult vaginal deliveries that is applicable in daily practice. ■

References

1. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501–6.
2. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. The prevalence of pelvic organ prolapse symptoms and signs and their relation with bladder and bowel disorders in a general female population. Int Urogynecol J Pelvic Floor Dysfunct 2009;20:1037–45.
3. Durnea CM, O'Reilly BA, Khashan AS, et al. Status of the pelvic floor in young primiparous women. Ultrasound Obstet Gynecol 2015;46:356–62.
4. Schwertner-Tiepelmann N, Thakar R, Sultan AH, Tunn R. Obstetric levator ani muscle injuries: current status. Ultrasound Obstet Gynecol 2012;39:372–83.
5. Dietz HP, Simpson JM. Levator trauma is associated with pelvic organ prolapse. BJOG 2008;115:979–84.
6. Dietz HP, Shek C, De Leon J, Steensma AB. Ballooning of the levator hiatus. Ultrasound Obstet Gynecol 2008;31:676–80.
7. Albrich SB, Welker K, Wolpert B, et al. How common is ballooning? Hiatal area on 3D transperineal ultrasound in urogynecological patients and its association with lower urinary tract symptoms. Arch Gynecol Obstet 2017;295:103–9.
8. DeLancey JO, Morgan DM, Fenner DE, et al. Comparison of levator ani muscle defects and function in women with and without pelvic organ prolapse. Obstet Gynecol 2007;109:295–302.
9. Dietz HP, Shek KL, Daly O, Korda A. Can levator avulsion be repaired surgically? A prospective surgical pilot study. Int Urogynecol J 2013;24:1011–5.
10. Laine K, Rotvold W, Staff AC. Are obstetric anal sphincter ruptures preventable? Large and consistent rupture rate variations between the Nordic countries and between delivery units in Norway. Acta Obstet Gynecol Scand 2013;92:94–100.
11. Cassado J, Pessarrodona A, Rodriguez-Carballeira M, et al. Does episiotomy protect against injury of the levator ani muscle in normal vaginal delivery? Neurourol Urodyn 2014;33:1212–6.
12. Kearney R, Miller JM, Ashton-Miller JA, DeLancey JO. Obstetric factors associated with levator ani muscle injury after vaginal birth. Obstet Gynecol 2006;107:144–9.
13. Shek KL, Dietz HP. Intrapartum risk factors for levator trauma. BJOG 2010;117:1485–92.
14. Valsky DV, Lipschuetz M, Bord A, et al. Fetal head circumference and length of second stage of labor are risk factors for levator ani muscle injury, diagnosed by 3-dimensional transperineal ultrasound in primiparous women. Am J Obstet Gynecol 2009;201:91.e1–7.
15. Combs CA, Murphy EL, Laros RK Jr. Factors associated with hemorrhage in cesarean deliveries. Obstet Gynecol 1991;77:77–82.
16. Hartmann K, Viswanathan M, Palmieri R, Gartlehner G, Thorp J Jr, Lohr KN. Outcomes of routine episiotomy: a systematic review. JAMA 2005;293:2141–8.
17. Sartore A, De Seta F, Maso G, Pregazzi R, Grimaldi E, Guaschino S. The effects of mediolateral episiotomy on pelvic floor function after vaginal delivery. Obstet Gynecol 2004;103:669–73.
18. Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. Am J Obstet Gynecol 2001;184:881–8; discussion 888–90.
19. t Hoen LA, Utomo E, Steensma AB, Blok BF, Korfage IJ. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12): validation of the Dutch version. Int Urogynecol J 2015;26:1293–303.
20. Utomo E, Blok BF, Steensma AB, Korfage IJ. Validation of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) in a Dutch population. Int Urogynecol J 2014;25:531–44.
21. Utomo E, Korfage IJ, Wildhagen MF, Steensma AB, Bangma CH, Blok BF. Validation of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) in a Dutch population. Neurourol Urodyn 2015;34:24–31.
22. t Hoen LA, Utomo E, Schouten WR, Blok BF, Korfage IJ. The fecal incontinence quality of life

scale (FIQL) and fecal incontinence severity index (FISI): Validation of the Dutch versions. Neurourol Urodyn 2017;36:710–5.
23. Dietz HP. Ultrasound imaging of the pelvic floor. Part II: three-dimensional or volume imaging. Ultrasound Obstet Gynecol 2004;23:615–25.
24. Dietz HP. Quantification of major morphological abnormalities of the levator ani. Ultrasound Obstet Gynecol 2007;29:329–34.
25. Dietz H, Shek K. Tomographic ultrasound of the pelvic floor: which levels matter most? Ultrasound Obstet Gynecol 2009;33:698–703.
26. Bartlett JW, Frost C. Reliability, repeatability and reproducibility: analysis of measurement errors in continuous variables. Ultrasound Obstet Gynecol 2008;31:466–75.
27. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. J Clin Epidemiol 2006;59:1033–9.
28. de Leeuw JW, Struijk PC, Vierhout ME, Wallenburg HC. Risk factors for third degree perineal ruptures during delivery. BJOG 2001;108:383–7.
29. Raisanen S, Vehvilainen-Julkunen K, Heinonen S. Need for and consequences of episiotomy in vaginal birth: a critical approach. Midwifery 2010;26:348–56.
30. van Delft K, Thakar R, Sultan AH, Schwertner-Tiepelmann N, Kluivers K. Levator ani muscle avulsion during childbirth: a risk prediction model. BJOG 2014;121:1155–63; discussion 1163.
31. Cassado Garriga J, Carmona Ruiz A, Pessarrodona Isern A, et al. Impact of episiotomy on the urogenital hiatus using transperineal ultrasound. Neurourol Urodyn 2018;37:434–9.
32. Woolley RJ. Benefits and risks of episiotomy: a review of the English-language literature since 1980. Part II. Obstet Gynecol Surv 1995;50:821–35.
33. Shek KL, Chantarasorn V, Langer S, Dietz HP. Does levator trauma 'heal'? Ultrasound Obstet Gynecol 2012;40:570–5.
34. van Delft KW, Thakar R, Sultan AH, IntHout J, Kluivers KB. The natural history of levator avulsion one year following childbirth: a prospective study. BJOG 2015;122:1266–73.
35. Kalis V, Laine K, de Leeuw JW, Ismail KM, Tincello DG. Classification of episiotomy: towards a standardisation of terminology. BJOG 2012;119:522–6.
36. Jansova M, Kalis V, Rusavy Z, Zemcik R, Lobovsky L, Laine K. Modeling manual perineal protection during vaginal delivery. Int Urogynecol J 2014;25:65–71.

Author and article information

From the Department of Obstetrics and Gynecology, Division of Urogynecology, Amphia Hospital (Drs Speksnijder and Van Bavel), Breda, Department of Obstetrics and Gynecology, Division of Urogynecology, Albert Schweitzer Hospital (Dr Oom), Dordrecht, and Department of Obstetrics and Gynecology, Division of Obstetrics and Prenatal Medicine (Dr Steegers), and Department of Obstetrics and Gynecology, Division of Urogynecology (Dr Steensma), Erasmus Medical Center, Rotterdam, The Netherlands.

Received April 14, 2018; revised Sept. 8, 2018; accepted Sept. 21, 2018.

The authors report no conflict of interest.

Presented at the ninth annual congress of the European Urogynaecological Association on Nov. 4, 2016, Amsterdam, The Netherlands.

Corresponding author: Leonie Speksnijder, MD. Ldejong@amphia.nl