

The effect of a mediolateral episiotomy during operative vaginal delivery on the risk of developing obstetrical anal sphincter injuries

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OBJECTIVE: The objective of the study was to evaluate the frequency of obstetrical anal sphincter injuries (OASIS) in women undergoing operative vaginal deliveries (OVD) and to assess whether a mediolateral episiotomy is protective for developing OASIS in these deliveries.

STUDY DESIGN: We performed a retrospective cohort study. Maternal and obstetrical characteristics of the 2861 women who delivered liveborn infants by an OVD at term in the years 2001–2009 were extracted from a clinical obstetrics database and were analyzed in a logistic regression model.

RESULTS: The frequency of OASIS was 5.7%. Women with a mediolateral episiotomy were at significantly lower risk for OASIS compared with

the women without a mediolateral episiotomy in case of an OVD (adjusted odds ratio, 0.17; 95% confidence interval, 0.12–0.24).

CONCLUSION: We found a 6-fold decreased odds for developing OASIS when a mediolateral episiotomy was performed in OVD. Therefore, we advocate the use of a mediolateral episiotomy in all operative vaginal deliveries to reduce the incidence of OASIS.

Key words: mediolateral episiotomy, obstetrical anal sphincter injuries, operative vaginal delivery

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Operative vaginal delivery is a risk factor for obstetrical anal sphincter injuries (OASIS). Other risk factors, identified by several studies, are primiparity, induction of labor, epidural anesthesia, occipitoposterior position, fetal

macrosomia, increased maternal age, and prolonged duration of the second stage of labor.^{1–5} In The Netherlands in 2008, the frequency of OASIS defined as any rupture of the anal sphincter muscle was 2.3% in all vaginal deliveries.⁶

To standardize the classification of perineal trauma, Sultan⁷ proposed a classification that has been adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) with the injury being classified as minor (first and second degree) and major (third and fourth degree) according to the severity of injury.⁸ Knowledge of risk factors and preventive measures may help to reduce the number of anal sphincter injuries.

There is conflicting evidence in the literature about whether episiotomies may prevent OASIS.⁹ A metaanalysis of randomized trials and some earlier studies suggest that the risk of OASIS is increased with the use of a mediolateral episiotomy or was similar with no use of a mediolateral episiotomy.^{10–15} Most of these studies contained only a small number of deliveries and were therefore underpowered or did not use multivariate analysis. Other authors suggest that a mediolateral episiotomy could be pro-

protective for developing OASIS during operative vaginal delivery.^{16,17}

With this study, we hope to present more evidence that a mediolateral episiotomy lowers the odds for developing OASIS in the case of an operative vaginal delivery.

The aim of our study was to evaluate the frequency of OASIS in women undergoing an operative vaginal delivery and to assess whether a mediolateral episiotomy is protective for developing OASIS in these deliveries.

MATERIALS AND METHODS

The Netherlands Perinatal Registry (PRN) is a national database that includes 96% of all approximately 190,000 deliveries per year at more than 16 completed weeks of gestation in The Netherlands, which are under supervision of a midwife or an obstetrician.⁶ After the delivery all the characteristics are recorded by the caregiver using a standardized electronic registration form. All the data are sent regularly to the national registry office, in which checks are conducted to validate the data. In the case of false records, the national registry office returns the data to the obstetrician to

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TABLE 1
General characteristics

Characteristic	MLE+ ^a (n = 2316)	MLE- ^b (n = 545)	P value
Patient characteristics			
Maternal age, y ^c	34.6 ± 5.0	36.7 ± 5.1	< .001
Nationality^e			
Netherlands	2085 (90.0%)	485 (89.0%)	.206
Mediterranean	87 (3.8%)	17 (3.1%)	.206
Other European	42 (1.8%)	7 (1.3%)	.206
Asian	35 (1.5%)	14 (2.6%)	.206
African	23 (1.0%)	11 (2.0%)	.206
Other	39 (1.7%)	9 (1.6%)	.206
Unknown	5 (0.2%)	2 (0.4%)	.206
Gestational age, d ^d	282 (276–288)	282 (276–288)	.243
Primiparity ^e	2026 (87.6%)	399 (73.5%)	< .001
Multiparity ^e	288 (12.4%)	144 (26.5%)	< .001
Delivery characteristics			
OASIS ^e	77 (3.3%)	85 (15.6%)	< .001
Vacuum extraction ^e	1996 (86.2%)	524 (96.1%)	< .001
Forceps extraction ^e	295 (12.7%)	21 (3.9%)	< .001
Both vacuum and forceps extraction ^e	25 (1.1%)	0 (0%)	< .001
Fetal distress is indication for OVD ^e	769 (33.2%)	180 (33.0%)	.960
Occipitoanterior position ^e	1914 (82.6%)	481 (88.3%)	.006
Occipitoposterior position ^e	305 (13.2%)	49 (9.0%)	.006
Other cephalic positions ^e	97 (4.2%)	15 (2.7%)	.006
Usage of epidural anesthesia ^e	517 (22.3%)	75 (13.8%)	< .001
Duration second stage, min ^d	79 (48.5–100)	78 (53–98)	.352
Blood loss, mL ^c	519.7 ± 496.9	437.2 ± 365.5	< .001
Daytime obstetrics ^e	1075 (46.4%)	256 (47.0%)	.849
Neonatal characteristics			
Male ^e	1275 (55.1%)	312 (57.2%)	.363
Birthweight, g ^c	3519.4 ± 453.2	3530 ± 461.4	.630
Gestational age, d ^d	282 (276–288)	282 (276–288)	.243
Apgar score after 1 minute ^d	9 (8–9)	8 (7–9)	< .001
Apgar score after 5 minutes ^d	10 (9–10)	10 (9–10)	.057
pH umbilical cord blood sampling ^c	7.192 ± 0.853	7.189 ± 0.966	.022

Data on blood loss was missing in 11 MLE- and 53 MLE+ patients. Data on pH umbilical cord blood sampling was missing in 312 MLE- and 968 MLE+ patients. The characteristics were grouped by the use of a mediolateral episiotomy (MLE+ and MLE-).

MLE, mediolateral episiotomy.

^a With an MLE; ^b Without an MLE; ^c Mean ± SD; ^d Median (p25–p75); ^e n (%).

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correct them. Previously the validity of the data entered into the PRN, such as perinatal mortality, is checked by comparing it with the Dutch civil registers. The conclusion of this study was that the quality of inputted data of the PRN was high.¹⁸

A retrospective cohort study was performed using data from the (local) PRN database of the Amphia Hospital (Breda, The Netherlands) of deliveries from Jan. 1, 2001, through Dec. 31, 2009. According to Dutch law, the approval of the in-

stitutional review board was not needed because we used anonymous data from an existing clinical database of our hospital.

We selected all women who delivered liveborn infants by an operative vaginal delivery at term. All women with a multiple gestation or a breech delivery and delivered with a median episiotomy were excluded from the analysis.

We defined our primary outcome as OASIS. In our hospital, OASIS is diagnosed by the accoucheur. According to protocol the perineum is examined visually immediately after delivery with performance of a rectal examination. If the accoucheur was not a gynecologist (eg, a midwife or resident), the supervising obstetrician performed a second look to confirm the diagnosis of OASIS. According to the subdivision in the PRN database, perineal ruptures are categorized as none, rupture (first- and second-degree perineal rupture according to the RCOG classification), subtotal rupture (RCOG grade 3A, 3B, and 3C ruptures), and total rupture of the perineum (RCOG grade 4 rupture).⁸

Continuous variables were compared using the Student *t* test or the nonparametric Mann-Whitney *U* test. The χ^2 test was used for categorical variables. Continuous variables were summarized as means with SDs or medians with interquartile ranges (IQRs). $P < .05$ was considered statistically significant.

A logistic regression model was used for the risk assessment of the use of a mediolateral episiotomy on the risk for developing OASIS. Treatment effect was presented as adjusted odds ratio (OR) with 95% confidence interval (CI). The number needed to treat (NNT) was calculated to assess the potential effectiveness of mediolateral episiotomy (MLE) by dividing 1 by the difference in OASIS probabilities between the MLE-positive and the MLE-negative group (eg, $1/(P_{MLE\ negative} - P_{MLE\ positive})$).

RESULTS

The baseline characteristics of the 2 groups are shown in Table 1. Patients in the group with a mediolateral MLE (MLE positive) delivered more frequently by a forceps extraction (12.7% vs 3.9%, $P < .001$), contained more occipitoposterior positions

(13.2% vs 9.0%, $P < .01$), are more often primiparous (87.6% vs 73.5%, $P < .001$), and used epidural anesthesia more often (22.3% vs 13.8%, $P < .001$) compared with the group without a MLE (MLE negative). The MLE-negative group delivered more often by a vacuum extraction (96.1% vs 86.2%, $P < .001$) compared with the MLE-positive group.

A total of 2861 operative vaginal deliveries in the study period were included in the analysis (Figure), and a total of 104 patients were excluded. The overall frequency of OASIS was 5.7%. In women delivered with a vacuum extraction, the frequency of sphincter lesions was 5.9% compared with 3.2% of women delivered with a forceps extraction.

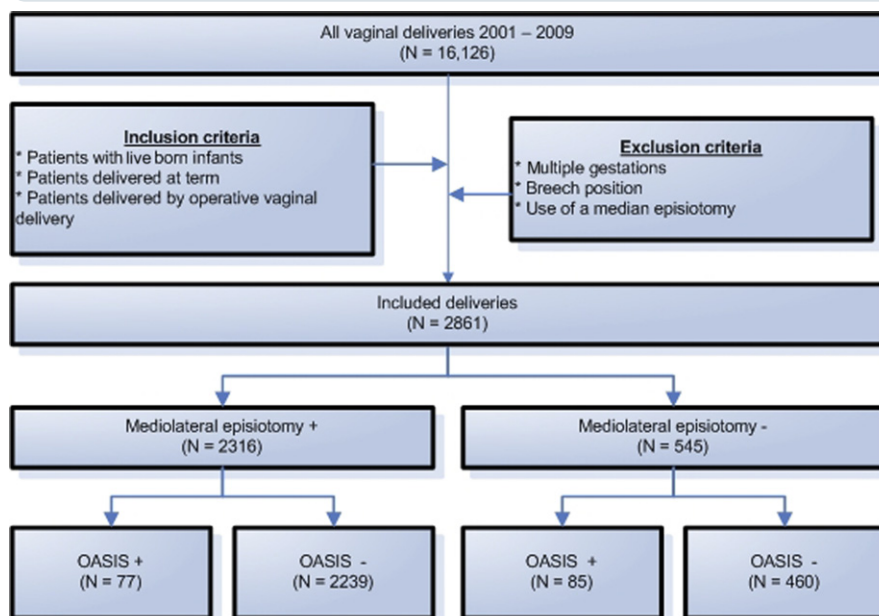
The absolute risk of OASIS was respectively 3.5% in the MLE-positive group, compared with 15.6% in the MLE-negative group (OR, 0.19; 95% CI, 0.14–0.26). After the univariate logistic regression analysis, a multiple logistical model was used to account for the predefined covariates: gestational age at birth, parity, birthweight, maternal age, use of epidural analgesia, indication for operative vaginal delivery, cephalic fetal position, and duration of the second stage this risk estimation remained almost unchanged (adjusted OR, 0.17; 95% CI, 0.12–0.24).

The risk calculation for developing OASIS estimated for different covariates is shown in Table 2. After the logistic regression analysis, controlling for different covariates, MLE showed a strong protective effect for developing OASIS with ORs varying from 0.13 up to 0.26. The protective effect of a mediolateral episiotomy was stronger in women delivered with a forceps extraction compared with women delivered with a vacuum extraction, as shown by the lower adjusted ORs in the group of women delivered with a forceps extraction.

The NNT for the use of a mediolateral episiotomy during vacuum extraction to prevent 1 anal sphincter injury was 8.64, whereas the NNT in a forceps delivery was 5.21. These NNT values are relatively low compared with, for example, 63 for the treatment with magnesium sulphate in severe preeclampsia.¹⁹

FIGURE

Flow diagram of the included patients



The flow diagram of the included patients was divided into 2 groups (MLE positive and MLE negative). MLE, mediolateral episiotomy.

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COMMENT

We analyzed the decreased odds for developing OASIS, associated with the use of a mediolateral episiotomy, in 2861 patients delivered by an operative vaginal delivery.

When a mediolateral episiotomy was performed, the odds for developing OASIS decreased 6-fold.

Our practice is part of one of the largest general teaching hospitals in The Netherlands with more than 3000 deliveries per annum. In our department women are allowed to deliver after 32 weeks' gestational age. As is common in The Netherlands, the use of vacuum extraction is more common in operative vaginal deliveries (OVDs). Only a few trained gynecologists handle the forceps and only in the case of an outlet forceps and occipitoposterior position. Therefore, the number of 321 forceps deliveries in contrast to the 2520 vacuum deliveries is a reflection of Dutch obstetrical practice. Because of the low number of forceps deliveries in our study, the calculated protective effect and NNT have to be interpreted with caution.

Known risk factors for developing OASIS (eg, primiparity, occipitoposterior position, and forceps delivery) are overrepresented in the MLE-positive group, compared with the MLE-negative group. Despite this inequality, the frequency of OASIS is lower in the MLE-positive group, which may indicate that the reducing effect of a mediolateral episiotomy on the risk for developing OASIS is even underestimated.

In our study the use of a mediolateral episiotomy has a strong protective effect on the occurrence of anal sphincter laceration during an operative vaginal delivery, with a 6-fold decreased odds for developing OASIS. Our results are corroborated by the results of previous studies on this subject.^{17,20} Combs et al²⁰ also showed that mediolateral episiotomy was protective against anal sphincter damage after an operative vaginal delivery. de Leeuw et al¹⁷ demonstrated that a mediolateral episiotomy protected significantly for anal sphincter damage in both vacuum extraction and forceps delivery. In that study the number of mediolateral episiotomies needed to prevent 1 sphinc-

TABLE 2
Multivariate analysis on the risk for developing OASIS in vacuum deliveries and forcipal deliveries

Variable	Vacuum extraction (n = 2520)			Forcipal extraction (n = 316)		
	OASIS/n (%)	RR	Adjusted ^a OR (95% CI)	OASIS/n (%)	RR	Adjusted ^a OR (95% CI)
Primiparity						
MLE+	63/1750 (3.60)	0.22	0.18 (0.12–0.26)	3/254 (1.18)	0.05	0.02 (0.00–0.17)
MLE–	64/383 (16.71)	1		4/16 (25)	1	
Multiparity						
MLE+	7/244 (2.87)	0.29	0.26 (0.09–0.69)	1/41 (2.44)	0.06	Not significant
MLE–	14/139 (10.07)	1		2/5 (40)	1	
Occipitoanterior position						
MLE+	53/1655 (3.20)	0.22	0.18 (0.12–0.27)	3/244 (1.23)	0.04	0.02 (0.00–0.13)
MLE–	69/464 (14.87)	1		5/17 (29.4)	1	
Occipitoposterior position						
MLE+	16/260 (5.00)	0.29	0.18 (0.06–0.51)	1/35 (2.86)	0.06	Not significant
MLE–	8/47 (17.02)	1		1/2 (50)	1	
Usage of epidural anesthesia						
MLE+	17/466 (3.65)	0.25	0.19 (0.08–0.44)	1/48 (2.08)	0.02	Not significant
MLE–	11/74 (14.86)	1		1/1 (100)	1	
Birthweight >4000 g						
MLE+	15/289 (5.19)	0.23	0.13 (0.06–0.32)	1/40 (2.5)	0.04	Not significant
MLE–	17/76 (22.37)	1		3/5 (60)	1	
Prolonged pushing (>60 min)						
MLE+	58/1381 (4.20)	0.24	0.20 (0.13–0.30)	3/218 (1.38)	0.03	0.02 (0.00–0.11)
MLE–	59/339 (17.40)	1		6/14 (42.86)	1	
Total						
MLE+	70/1996 (3.51)	0.23	0.18 (0.13–0.26)	4/295 (1.36)	0.05	0.03 (0.00–0.14)
MLE–	79/524 (15.08)	1		6/21 (20.57)	1	

CI, confidence interval; MLE, mediolateral episiotomy; OASIS, obstetrical anal sphincter injuries; OR, odds ratio; RR, relative risk.

^a Adjusted for: maternal age, parity, presence of fetal distress, usage of epidural anesthesia, daytime obstetrics, birthweight >4000 g, fetal head position and prolonged pushing (>60 min).

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ter injury in vacuum extractions was 12, whereas 5 mediolateral episiotomies could prevent 1 sphincter injury in forceps deliveries.¹⁷

The strength of this study is the large number of analyzed deliveries collected in a prospective manner. The weaknesses of this study are the retrospective study design, the inequality at baseline between the 2 groups (although the differences are minimized by using a logistic regression model), and no standardization of how and when a MLE was performed. Also, the database is lacking the registration of adverse effects of the use

of a MLE, which makes it impossible to take these possible effects into account. Despite the weaknesses of this study, the evident and considerable protective effect of the MLE clearly is of clinical importance.

Although adverse effects are not reported in our study, the known adverse effects of the mediolateral episiotomy (eg, short-term healing pain, dyspareunia, etc) are, in our opinion, causing less morbidity compared with the known adverse effects of OASIS (eg, fecal incontinence). Therefore, the significant risk reducing effect of the mediolateral epi-

siotomy warrants its use in OVD, as opposed to the use of median episiotomy, which has a marked risk, increasing effect for the occurrence of OASIS in OVD.²¹

CONCLUSION

We found a 6-fold decreased odds for developing OASIS when a MLE was performed during the operative vaginal delivery. Therefore, we advocate the use of a MLE in all operative vaginal deliveries to reduce the incidence of OASIS. ■

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