

# Changing associations of episiotomy and anal sphincter injury across risk strata: results of a population-based register study in Finland 2004–2011

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## ABSTRACT

**Objectives:** To evaluate the changing association between lateral episiotomy and obstetric anal sphincter injury (OASIS) for women with low and high baseline risk of OASIS.

**Design:** A population-based register study.

**Setting:** Data gathered from the Finnish Medical Birth Register for the years 2004–2011.

**Participants:** All women with spontaneous vaginal or vacuum-assisted singleton births in Finland (n=384 638).

**Main outcome measure:** OASIS incidence.

**Results:** During the study period, the incidence of OASIS increased from 1.3% to 1.7% in women with first vaginal births, including women admitted for first vaginal birth after a prior caesarean section and from 0.1% to 0.3% in women with at least one prior birth, whereas episiotomy rates declined from 56.7% to 45.5% and 10.1–5.3%, respectively. At the study onset, when episiotomy was used more widely, it was negatively associated with OASIS in women with first vaginal births, but as episiotomy use declined it became positively associated with OASIS. Women with episiotomy were complicated by OASIS with clearly higher risk scores than women without episiotomy suggesting that episiotomy was clearly protective against OASIS. OASIS occurred with lower mean risk scores among women with and without episiotomy over time. However, OASIS incidences increased only among women with episiotomy, whereas it decreased or remained among women without episiotomy.

**Conclusions:** The cross-over effect between episiotomy and OASIS could be explained by increasing disparity in baseline OASIS risk between treated and untreated women, since episiotomy use declined most in women at low OASIS risk. Episiotomy rate can be safely reduced in low-risk women but interestingly along with the policy change the practice to cut the episiotomy became less protective among high-risk women.

## INTRODUCTION

Obstetric anal sphincter injury (OASIS) is a serious complication of vaginal delivery with

## ARTICLE SUMMARY

### Article focus

- To re-evaluate the association between obstetric anal sphincter injury (OASIS) and lateral episiotomy, for women at varying baseline risk of OASIS based on number of prior vaginal births, mode of delivery (spontaneous vaginal or vacuum assisted) and birth weight.
- To assess whether increasing OASIS incidence was mostly attributable to secular changes in risk factors for OASIS, and whether there was measurable confounding by indication, with an association between use of episiotomy and baseline risk of OASIS.

### Key messages

- During 2004–2011 total episiotomy rates declined, while OASIS incidences increased among both women with first vaginal births and women with prior vaginal births.
- An increasingly positive association between episiotomy and OASIS was observed, as episiotomy was used increasingly restrictively.
- The cross-over effect between episiotomy and OASIS could be explained by increasing disparity in baseline OASIS risk between treated and untreated women, since episiotomy use declined most in women at low OASIS risk.
- The observed statistical association between lateral episiotomy and OASIS was profoundly modified by episiotomy rate, serving here as a surrogate for unmeasured confounding by indication.

### Strengths and limitations of this study

- The strength was that data source was a mandatory national database that covers the entire Finnish population.
- We were not able to include all known risk factors for OASIS in the models such as length of the second stage of labour, episiotomy indications and fetal distress.

up to two-thirds of women affected by it suffering from anal incontinence.<sup>1</sup> Although there is an overall increase in the incidence

of OASIS, there are substantial differences in incidence between countries, ranging from 0.2% to 4.0% in 2010 in Europe<sup>2</sup> and from 3.5% to 5.9% in the USA<sup>3 4</sup> in the last decade. It is unclear whether such trends reflect differences in populations, in diagnosis and registration, or differences in management of delivery between and within countries.<sup>5 6</sup> The association between episiotomy and OASIS remains a controversial source of debate. The available evidence from randomised controlled studies suggests that restrictive use of episiotomy leads to less need for suturing, better healing outcomes and reduced severe perineal trauma (RR 0.67, 95% CI 0.49 to 0.91, 7 trials, n=4404).<sup>7</sup> However, further, large observational studies have suggested that although the midline type of episiotomy is associated with increased OASIS risk,<sup>8</sup> the mediolateral episiotomy technique is associated with substantially decreased OASIS risk.<sup>9</sup>

Lateral episiotomy, the exclusive episiotomy technique practiced in Finland, is when an incision is made to the vaginal introitus 1 or 2 cm lateral to the midline and directed towards the ischial tuberosity.<sup>10</sup> Our previous work demonstrated that lateral episiotomy was associated with a lower OASIS incidence in first births and a higher rate in second and subsequent births,<sup>11</sup> but use of episiotomy had declined substantially over the decade to 2007 among both women with first vaginal births and multiparous women as the incidence of OASIS increased.<sup>12</sup> As the use of episiotomy has become even more restrictive, the aim of this retrospective case-control study was to re-evaluate the association between OASIS and lateral episiotomy, for women at varying baseline risk of OASIS based on number of prior vaginal births, mode of delivery (spontaneous vaginal or vacuum assisted) and birth weight. We wished to assess whether increasing OASIS incidence was mostly attributable to secular changes in risk factors for OASIS, and whether there was measurable confounding by indication, with an association between use of episiotomy and baseline risk of OASIS.

## MATERIALS AND METHODS

### Data and population

The data were gathered from the Finnish Medical Birth Register (MBR) that includes information on maternal and neonatal birth characteristics and perinatal outcomes during seven postnatal days for all births after the 22nd gestational week or weighing 500 g or more. The authorisation to utilise a sensitive health register data for the period from 2004 to 2011 was granted by THL National Institute for Health and Welfare, the current register keeper, according to national data protection legislation.

Incidence of OASIS is defined by the International Classification of Diseases (ICD-10) codes O70.2 (3rd degree) and O70.3 (4th degree), and has been captured in the MBR since 2004, as well as the Hospital Discharge Register (HDR). The two data sources were linked together using encrypted unique personal identification numbers. We used only anonymised data, and

accordingly informed consent of the registered individuals was not needed. The HDR also provided information on other medical interventions and surgical procedures during pregnancy and birth. Women with a second or subsequent OASIS (n=34) were excluded from analysis.

The study population included all women with singleton vaginal spontaneous or vacuum-assisted delivery (n=384 638) during the study period from 2004 to 2011. The deliveries were categorised into two groups based on number of prior vaginal births; women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section (CS), that is, first vaginal birth (n=168 081) and women with at least one prior vaginal birth (n=216 557). The study period was grouped into four 2-year periods to compute the secular trends in OASIS incidences, episiotomy rates and risk profiles during the study period.

### Variables and definitions

The degree of OASIS was classified according to standard definitions; a third-degree injury involves the external anal sphincter and a fourth-degree injury affects both the anal sphincter and the anorectal mucosa.<sup>13</sup> Third-degree injuries and fourth-degree injuries were pooled for all the analyses. Mode of delivery was classified either vaginal spontaneous or vacuum-assisted; forceps and breech were excluded from the analytic dataset due to low number of cases. Breech, forceps and CS rates are presented as additional information. Gestational age was estimated based on data for the last menstrual period, unless there was a discrepancy of more than 7 or 14 days at the first-trimester or second-trimester ultrasound measurements, respectively. Smoking during pregnancy was self-reported and grouped as non-smoking, given up smoking during the first trimester and continued smoking after the first trimester.

### Statistical analyses

To assess association of episiotomy and OASIS over time and risk group, we computed risk scores for OASIS based on OASIS incidences for all years pooled for subgroups of women, by number of prior vaginal births, mode of current delivery (vaginal spontaneous or vacuum assisted) and mode of prior delivery (CS or vaginal), separately for four birth weight strata (<3000, 3000–3499, 3500–3999 and ≥4000 g). We calculated risk scores separately for women with first vaginal births, including women admitted for first vaginal birth after a prior caesarean section, and women with at least one prior vaginal birth. For both groups, women with the lowest OASIS incidence were assigned a risk score of 1.0 and those with higher risks had each risk factor multiplied by the relative increase in the OASIS incidences compared to this reference group. Thus, risk scores did not allow comparison between the two groups of women. Factors used in the risk scores (number of prior vaginal births, prior CS before first vaginal delivery, birth

weight and mode of delivery) were chosen as recognised independent risk factors for OASIS from previous analyses of this register. We defined two risk strata (low and high) for OASIS during the entire study period separately for both groups of women, to assess possible changes in OASIS risk profiles over time based on receiver operator characteristic (ROC) curves (not shown). The best thresholds to maximise sensitivity and specificity were 1.85 (sensitivity 49% and specificity 72%) in women with first vaginal births and 2.50 (sensitivity 50% and specificity 76%) in women with at least one prior vaginal birth that were chosen as cut offs between low-risk and high-risk strata for both groups. Risk scores ranged from 1.0 to 4.9 in women with first vaginal birth and from 1.0 to 14 in women with at least one prior vaginal birth.

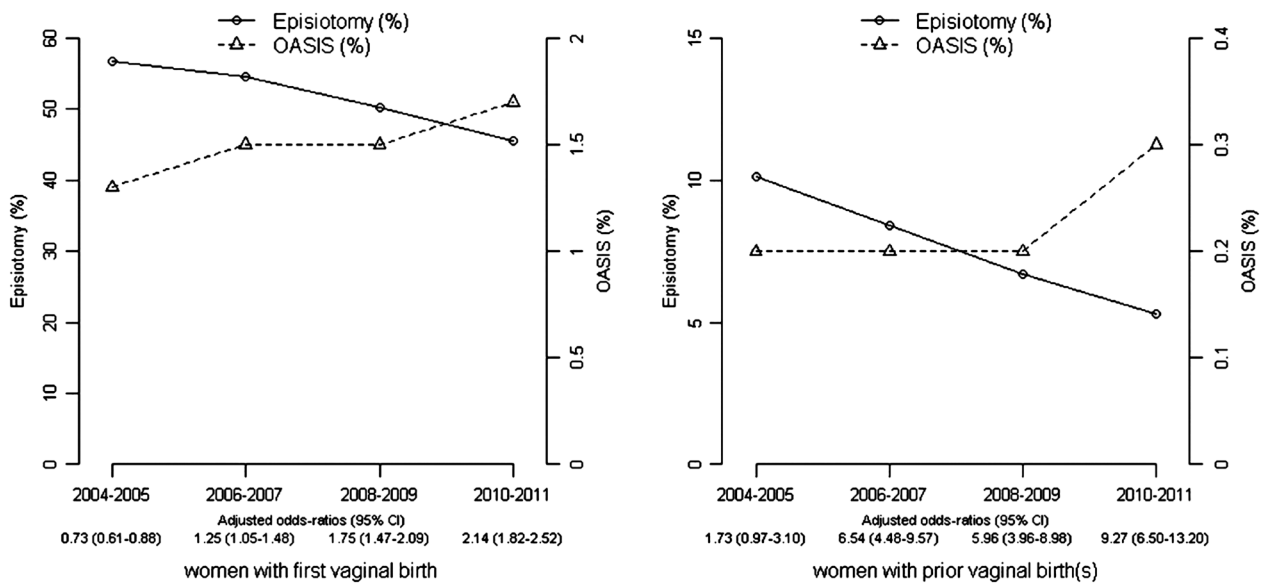
Statistical tests were performed separately for both groups of women with and without OASIS or with and without episiotomy. Statistical differences in categorical variables were evaluated by  $\chi^2$  test and differences in continuous variables by Mann-Whitney U, Kruskal-Wallis, Student's t or analysis of variance (ANOVA) tests as appropriate. Logistic regression analyses were used to calculate OR of OASIS with 95% CI adjusting for statistically significant independent and clinically important risk factors for OASIS ( $p < 0.1$ ) including maternal age, gestational age, prior CS, birth weight, mode of delivery, episiotomy, epidural analgesia and maternal smoking. Information on length of active second stage of birth was missing in 83 156 (21.7%) cases and thus this variable was not included in analyses. The data were analyzed using Predictive Analytics SoftWare V.19.0.

**Table 1** Demographics and delivery characteristics were compared between four 2-year time periods separately in singleton women with first vaginal birth including women admitted for first vaginal birth after a prior caesarean section (n=168 081) and women with at least one prior vaginal birth (n=216 557) in 2004–2011 in Finland

	2004–2005	2006–2007	2008–2009	2010–2011	*p Value	Pooled 2004–2011
<b>Women with first vaginal birth</b>						
Mean maternal age (SD) (year)	27.2 (5.2)	27.4 (5.1)	27.5 (5.1)	27.7 (5.2)	≤0.001	27.4 (5.2)
Mean gestational weeks (SD)	39.9 (1.7)	39.9 (1.7)	40.0 (1.7)	40.0 (1.7)	0.08	40.0 (1.7)
Epidural analgesia (%)	67.6	59.7	69.9	71.3	≤0.001	67.2
Episiotomy (%)	56.7	54.6	50.3	45.5	≤0.001	51.7
OASIS (%)	1.3	1.5	1.5	1.7	≤0.001	1.5
OASIS without episiotomy (% (n))	1.3 (227)	1.2 (226)	1.0 (212)	1.1 (247)	0.04	1.1 (912)
OASIS with episiotomy (% (n))	1.3 (312)	1.8 (419)	2.1 (447)	2.5 (485)	≤0.001	1.9 (1663)
<b>Mode of delivery (%)</b>						
Vaginal spontaneous	63.4	61.5	60.9	60.5	≤0.001	61.6
Vacuum	12.7	14.4	14.9	15.0		14.3
Breech†	0.6	0.6	0.6	0.8		0.6
Forceps†	0.1	0.1	0.1	0.1		0.1
Caesarean section†	23.2	23.4	23.4	23.7		23.4
Prior caesarean section (%)	8.3	8.4	8.6	9.0	0.001	8.6
Mean birth weight (SD) (g)	3464.2 (494.5)	3443.4 (495.7)	3436.9 (492.1)	3438.4 (490.3)	≤0.001	3445.5 (493.2)
<b>Women with at least one prior vaginal birth</b>						
Mean maternal age (SD)	30.8 (5.1)	30.8 (5.1)	30.8 (5.0)	30.8 (4.9)	0.11	30.8 (5.0)
Mean gestational weeks (SD)	39.9 (1.6)	39.9 (1.5)	39.9 (1.5)	39.9 (1.5)	0.17	39.9 (1.5)
Epidural analgesia (%)	22.8	19.1	23.9	25.4	≤0.001	22.9
Episiotomy (%)	10.1	8.4	6.7	5.3	≤0.001	7.6
OASIS (%)	0.2	0.2	0.2	0.3	≤0.001	0.2
OASIS without episiotomy (% (n))	0.1 (62)	0.1 (70)	0.2 (80)	0.2 (98)	0.15	0.2 (310)
OASIS with episiotomy (% (n))	0.3 (17)	1.2 (53)	1.2 (46)	2.1 (61)	≤0.001	1.1 (177)
<b>Mode of delivery (%)</b>						
Vaginal spontaneous	87.9	88.1	88.3	88.1	≤0.001	88.1
Vacuum	2.1	2.4	2.4	2.7		2.4
Breech†	0.5	0.5	0.6	0.6		0.5
Forceps†	0.0	0.0	0.0	0.0		0.0
Caesarean section†	9.5	9.1	8.7	8.6		8.9
Prior caesarean section (%)	5.6	5.7	5.6	5.6	0.90	5.6
Mean birth weight (SD) (g)	3637.7 (510.8)	3625.2 (500.9)	3610.6 (499.3)	3612.1 (497.9)	≤0.001	3621.1 (502.2)

\* $\chi^2$  or analysis of variance (ANOVA) tests.

†Additional information.



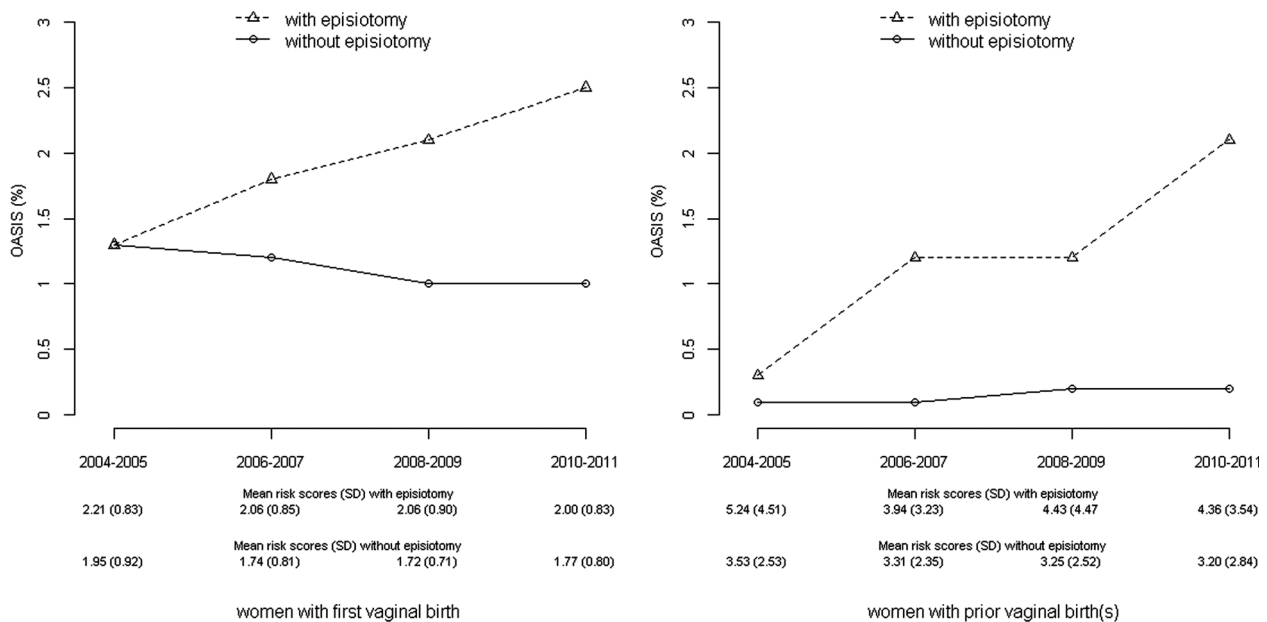
**Figure 1** Changes in episiotomy rate and obstetric anal sphincter injury rate and their adjusted association, stratified by number of prior vaginal births 2004–2011.

**RESULTS**

For the women with first vaginal births, including women admitted for first vaginal birth after a prior caesarean section (n=168 081), with singleton vaginal spontaneous or vacuum-assisted births, episiotomy rate decreased between 2004–2005 and 2010–2011 from 56.7% to 45.5% while OASIS incidences increased from 1.3% in 2004–2005 to 1.7% in 2010–2011 (table 1). For women with at least one prior vaginal birth (n=216 557), episiotomy rate almost halved from 10.1% to 5.3% while OASIS incidences increased from 0.2% in 2004–2009 to

0.3% in 2010–2011. As episiotomy use became more restrictive, OASIS incidences increased. After adjustment episiotomy was positively associated with OASIS among both groups (figure 1). Furthermore, OASIS incidences decreased in women who gave birth without an episiotomy while increased in women with episiotomy among both groups of women (figure 2).

Secular trends of demographics and obstetric interventions were modest (table 1) with the exception of a slight increase in use of vacuum assistance (unadjusted OR (uOR) 1.24, 95% CI 1.20 to 1.29 and uOR 1.28,



**Figure 2** Obstetric anal sphincter injury incidences in women with and without episiotomy in women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section and women with at least one prior vaginal birth women in 2004–2011.

**Table 2** Risk scores\* of OASIS among women with first vaginal birth without and with a prior caesarean section (CS) and women with at least one prior vaginal birth according to birth weight groups in spontaneous vaginal and vacuum-assisted births

Characteristics according to birth weight groups	Women with first vaginal birth Risk scores	Women with first vaginal births after a prior CS Risk scores	Women with at least one prior vaginal birth Risk scores
<3000 g			
Vaginal spontaneous	1	1.3	1
Vacuum assisted	1	3.7	3
3000–3499 g			
Vaginal spontaneous	1	1.3	1
Vacuum assisted	2.2	2.3	8
3500–3999 g			
Vaginal spontaneous	1.5	2.3	2
Vacuum assisted	2.8	2.8	10
≥4000 g			
Vaginal spontaneous	2.5	3.9	4
Vacuum assisted	3.2	4.9	14

\*The references for the risk score are women with the lowest OASIS incidence in women with first and with prior vaginal births, and therefore, the estimated OASIS risks are valid only within the groups, not allowing the comparison of risk between the groups.

95% CI 1.19 to 1.38 in 2010–2011 compared with 2004–2005 in women with first vaginal births and women with prior vaginal births, respectively, data not shown) and epidural analgesia (uOR 1.15, 95% CI 1.12 to 1.18 and uOR 1.18, 95% CI 1.15 to 1.22, respectively in 2010–2011 compared with 2004–2005, data not shown). Furthermore, risk scores (table 2) among those women with first vaginal births (mean 1.60, range 1.00–4.90) were constant across the 8-year period, whereas the women with prior vaginal births showed a slight but statistically significant difference in risk profile across the 2-year time periods (mean 2.23 to 2.28, range 1.00 to 14.00; table 3).

Episiotomy use declined both among women at low and high risk of OASIS in both groups but most among women at low risk (table 4). Use of episiotomy decreased significantly by 27% (uOR 0.58, 95% CI 0.56 to 0.60) and 9% (uOR 0.74, 95% CI 0.70 to 0.79) among women with first vaginal births with low-risk and high-risk scores, respectively. Among women with prior vaginal births, episiotomy use decreased by 52% (uOR 0.45, 95% CI 0.43 to 0.48) and 36% (uOR 0.60, 95% CI 0.56 to 0.65) among women with low-risk and high-risk scores, respectively. Correspondingly, OASIS incidences increased most among women at low risk of OASIS among both groups but also among women with prior vaginal births at high risk of OASIS. The incidence of OASIS increased significantly by 63% (uOR 1.60, 95% CI 1.37 to 1.88) in women with first vaginal delivery at low risk, but not in women with first vaginal births at high risk, and doubled in women with prior vaginal births at both low risk and high risk (uOR 2.24, 95% CI 1.51 to 3.35) and (uOR 1.69, 95% CI 1.17 to 2.45), respectively. Furthermore, in both groups regardless of risk group OASIS incidences increased in women with episiotomy, whereas decreased or remained the same in women without episiotomy.

Table 3 shows the mean risk scores of OASIS, episiotomy and OASIS with and without episiotomy. The mean risk scores of women who underwent episiotomy increased over time and were significantly higher than in women without episiotomy. The mean risk scores of women affected by OASIS decreased during the study period among both groups. Further, women with episiotomy were complicated by OASIS with higher mean risk scores than women without episiotomy in both groups as an indication of a protective effect brought about by episiotomy.

## DISCUSSION

During the study period in 2004–2011 total episiotomy rates declined, while OASIS incidences increased among both women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section and women with at least one prior vaginal birth women. Paradoxically, we observed an increasingly positive association between episiotomy and OASIS, as episiotomy was used increasingly restrictively. Across a wide range of known risks for OASIS, we observed that the OASIS risk profile for the overall population was constant during the years studied, not explaining this increased OASIS incidence. However, episiotomy use declined sharply among women at low baseline risk, while conversely OASIS incidences increased among women with episiotomy while decreasing or remaining the same among women without episiotomy. Thus, the observed statistical association between lateral episiotomy and OASIS was profoundly modified by episiotomy rate, serving here as a surrogate for unmeasured confounding by indication. These results, in parallel with those from randomised trials, suggest that the episiotomy rate can be safely reduced in low-risk women, without any increase in OASIS rate.

**Table 3** Distribution of low and high baseline risk of obstetric anal sphincter injury (OASIS) and the mean risk scores of OASIS separately among women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section and in women with at least one prior birth between four 2-year periods in 2004–2011

	2004–2005	2006–2007	2008–2009	2010–2011	p Value	Pooled 2004–2011
<i>Women with first vaginal birth</i>	40 995	41 664	42 684	42 738		168 081
Risk score range 1.0–4.9						
Mean risk scores among all nulliparous (SD)	1.60 (0.73)	1.60 (0.73)	1.60 (0.73)	1.60 (0.74)	0.88*	1.60 (0.73)
Mean risk scores (SD) with OASIS (n=2575)†	2.10 (0.88)	1.95 (0.85)	1.95 (0.86)	1.92 (0.83)	0.001**	1.97 (0.85)
Mean risk scores (SD) without OASIS	1.59 (0.72)	1.60 (0.73)	1.59 (0.72)	1.60 (0.74)	0.92	1.59 (0.73)
Mean risk scores (SD) with episiotomy‡	1.72 (0.78)	1.75 (0.79)	1.78 (0.80)	1.82 (0.81)	≤0.001*	1.76 (0.80)
Mean risk scores (SD) without episiotomy	1.43 (0.62)	1.42 (0.62)	1.41 (0.59)	1.43 (0.62)	≤0.001	1.42 (0.61)
Mean risk scores (SD) with OASIS (n=1663) and with episiotomy‡	2.21 (0.83)	2.06 (0.85)	2.06 (0.90)	2.00 (0.83)	0.007**	2.07 (0.86)
Mean risk scores (SD) with OASIS (n=912) and without episiotomy	1.95 (0.92)	1.74 (0.81)	1.72 (0.71)	1.77 (0.80)	0.01**	1.80 (0.82)
uOR (95% CI) of episiotomy associated with OASIS	1.05 (0.89 to 1.25)	1.55 (1.32 to 1.83)	2.10 (1.78 to 2.48)	2.39 (2.05 to 2.79)		
aOR (95% CI) of episiotomy associated with OASIS§	0.73 (0.61 to 0.88)	1.25 (1.05 to 1.48)	1.75 (1.47 to 2.09)	2.14 (1.82 to 2.52)		
<i>Women with at least one prior vaginal birth</i>	52 274	53 338	55 180	55 765		216 557
Risk score range 1.0–14.0						
Mean risk scores among all multiparous	2.28 (1.73)	2.26 (1.78)	2.23 (1.77)	2.26 (1.81)	≤0.001*	2.26 (1.78)
Mean risk scores (SD) with OASIS (n=487)†	3.90 (3.11)	3.59 (2.77)	3.68 (3.40)	3.65 (3.17)	0.46**	3.68 (3.11)
Mean risk scores (SD) without OASIS	2.28 (1.73)	2.26 (1.78)	2.23 (1.77)	2.26 (1.81)	≤0.001	2.26 (1.77)
Mean risk scores (SD) with episiotomy‡	3.14 (2.90)	3.33 (3.19)	3.55 (3.36)	3.85 (3.64)	≤0.001**	3.41 (3.23)
Mean risk scores (SD) without episiotomy	2.18 (1.52)	2.16 (1.55)	2.14 (1.56)	2.17 (1.62)	≤0.001	2.16 (1.56)
Mean risk scores (SD) with OASIS (n=177) and with episiotomy‡	5.24 (4.51)	3.94 (3.23)	4.43 (4.47)	4.36 (3.54)	0.67**	4.34 (3.80)
Mean risk scores (SD) with OASIS (n=310) and without episiotomy	3.53 (2.53)	3.31 (2.35)	3.25 (2.52)	3.20 (2.84)	0.88**	3.31 (2.58)
uOR (95% CI) of episiotomy associated with OASIS	2.45 (1.43 to 4.20)	8.32 (5.82 to 11.91)	8.07 (5.61 to 11.61)	11.33 (8.21 to 15.63)		
aOR (95% CI) of episiotomy associated with OASIS§	1.73 (0.97 to 3.10)	6.54 (4.48 to 9.57)	5.96 (3.96 to 8.98)	9.27 (6.50 to 13.20)		

\*Analysis of variance (ANOVA) or \*\*Kruskal-Wallis tests.

†Differences between the groups were statistically significant ( $p \leq 0.001$ ) in each time period (Student's t-test).‡Differences between the groups were statistically significant ( $p \leq 0.001$ ) among women with first vaginal birth in each time period and among women with at least one prior vaginal birth only in 2010–2011 (Mann Whitney U test).

§OR of OASIS adjusted for maternal age, gestational age, prior caesarean section, birth weight, mode of delivery, episiotomy, epidural analgesia and maternal smoking associated with OASIS. aOR, adjusted OR; uOR, unadjusted OR.

**Table 4** Differences in episiotomy rates and OASIS incidences among women with low and high baseline risk of OASIS\* separately among women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section and among women with at least one prior birth women between four 2-year time period in 2004–2011 in Finland

Characteristic	2004–2005	2006–2007	2008–2009	2010–2011	p Value	Pooled 2004–2011
<i>Women with first vaginal birth</i>						
n	40 995	41 664	42 684	42 738		168 081
Distribution of risk groups*						
Low risk (%)	72.3	71.6	71.6	71.1	0.002	71.6
High risk (%)	27.7	28.4	28.4	28.9		28.4
Low risk, risk scores <1.85						
Episiotomy use (%)	50.4	47.4	41.9	36.9	≤0.001	44.1
Change in episiotomy use (uOR, 95% CI)	1 (reference)	0.88 (0.86 to 0.91)	0.71 (0.69 to 0.73)	0.58 (0.56 to 0.60)		
OASIS (% (n))	0.8 (242)	1.1 (336)	1.1 (348)	1.3 (396)	≤0.001	(1322)
OASIS with episiotomy (% (n))	0.7 (111)	1.3 (189)	1.6 (210)	2.1 (236)		1.4 (746)
OASIS without episiotomy (% (n))	0.9 (131)	0.9 (147)	0.8 (138)	0.8 (160)		0.9 (576)
Change in OASIS (uOR, 95% CI)	1 (reference)	1.38 (1.17 to 1.63)	1.40 (1.19 to 1.65)	1.60 (1.37 to 1.88)		
High risk, risk scores >1.85						
Episiotomy use (%)	72.8	72.7	71.5	66.6	≤0.001	70.8
Change in episiotomy use (uOR, 95% CI)	1 (reference)	0.99 (0.94 to 1.05)	0.94 (0.88 to 0.99)	0.74 (0.70 to 0.79)		
OASIS (% (n))	2.6 (297)	2.6 (309)	2.6 (311)	2.7 (336)	0.89	2.6 (1253)
OASIS with episiotomy (% (n))	2.4 (201)	2.7 (230)	2.7 (237)	3.0 (249)		2.7 (917)
OASIS without episiotomy (% (n))	3.1 (96)	2.4 (79)	2.1 (74)	2.1 (87)		2.4 (336)
Change in OASIS (uOR, 95% CI)	1 (reference)	1.00 (0.85 to 1.17)	0.98 (0.83 to 1.15)	1.04 (0.89 to 1.22)		
<i>Women with at least one prior vaginal birth</i>						
n	52 274	53 338	55 180	55 765		216 557
Distribution of risk groups*						
Low risk (%)	75.2	76.2	77.2	76.7	≤0.001	76.4
High risk (%)	24.8	23.8	22.8	23.3		23.6
Low risk, risk scores <2.50						
Episiotomy use (%)	8.4	6.9	5.3	4.0	≤0.001	6.1
Change in episiotomy use (uOR, 95% CI)	1 (reference)	0.80 (0.76 to 0.84)	0.60 (0.57 to 0.64)	0.45 (0.43 to 0.48)		
OASIS (% (n))	0.1 (34)	0.1 (59)	0.2 (68)	0.2 (83)	0.001	0.1 (244)
OASIS with episiotomy (% (n))	0.2 (7)	0.9 (26)	1.2 (26)	1.5 (25)		0.8 (84)
OASIS without episiotomy (% (n))	0.1 (27)	0.1 (33)	0.1 (42)	0.1 (58)		0.1 (160)
Change in OASIS (uOR, 95% CI)	1 (reference)	1.68 (1.10 to 2.56)	1.85 (1.22 to 2.79)	2.24 (1.51 to 3.35)		
High risk, risk scores >2.50						
Episiotomy use (%)	15.0	13.4	11.6	9.6	≤0.001	12.4
Change in episiotomy use (uOR, 95% CI)	1 (reference)	0.88 (0.82 to 0.94)	0.75 (0.69 to 0.80)	0.60 (0.56 to 0.65)		
OASIS (% (n))	0.3 (45)	0.5 (64)	0.5 (58)	0.6 (76)	0.04	0.5 (243)
OASIS with episiotomy (% (n))	0.5 (10)	1.6 (27)	1.4 (20)	2.9 (36)		1.5 (93)
OASIS without episiotomy (% (n))	0.3 (35)	0.3 (37)	0.3 (38)	0.3 (40)		0.3 (150)
Change in OASIS (uOR, 95% CI)	1 (reference)	1.46 (0.99 to 2.14)	1.33 (0.90 to 1.96)	1.69 (1.17 to 2.45)		

$\chi^2$ -test or logistic regression analyses.

\*The best thresholds to maximise sensitivity and specificity; 1.85 (sensitivity 49% and specificity 72%) in women with first vaginal births including women admitted for first vaginal birth after a prior caesarean section and 2.50 (sensitivity 50% and specificity 76%) and in women with at least one prior birth.

uOR, unadjusted OR.

Despite the positive associations between episiotomy and OASIS, the likely confounding by indication, our results suggest that episiotomy still had a protective role since women with episiotomy were complicated by OASIS with higher mean risk scores than women without episiotomy as shown in table 3. However, it appeared that mean risk scores among women with OASIS and with episiotomy decreased over time suggesting that along with the policy change in episiotomy use the technique became less protective also among high-risk women. Other data have suggested that narrow-angled episiotomy increases the risk of OASIS and measures such as point of incision, episiotomy length and depth might reduce the OASIS risk.<sup>14</sup> However, due to observational study design we were able to reveal only associations between the role of episiotomy and OASIS, and therefore well-designed randomised controlled trials of restrictive versus routine lateral episiotomy among high-risk women are still needed.

The most important strength of this study was that the data covered the total population of women with vaginal births over an 8-year period in Finland. Differences in registration routines might have affected OASIS incidences, but both national registers used for this study have extensively validated data quality.<sup>5 15 16</sup> The possible limitation was that we were not able to include all known risk factors for OASIS in the models, including the prolonged second stage of birth and abnormal presentation. Furthermore, the data also lack information on all possible indications for episiotomy, including fetal distress, slow crowning and condition of the perineum at birth that might have biased our results. The study results are likely generalisable only to lateral episiotomy.

## CONCLUSIONS

Using an 8-year population-based data we showed that the highest risk of OASIS was associated with high birth weight with vacuum-assisted birth regardless of number of prior vaginal births but the incidences of OASIS were in the order of sevenfold after the first vaginal birth compared to subsequent vaginal births. The observed association between lateral episiotomy and OASIS, was profoundly modified by episiotomy rate, serving here as a surrogate for unmeasured confounding by indication.<sup>17</sup> Variation in episiotomy rate must contribute to the heterogeneity in previous estimates of this association, both between observational studies in different countries with different episiotomy policies, and studies within the same countries over time. Randomised trials are required to assess the optimal rate of lateral episiotomy for women at high risk of OASIS.

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