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Original Article
Intrapartum care

Obstetric anal sphincter injury after episiotomy in vacuum extraction: an epidemiological study using an emulated randomised trial approach

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Objective To emulate a randomised controlled trial investigating whether lateral or mediolateral episiotomy compared with no episiotomy reduces the prevalence of obstetric anal sphincter injury (OASIS) in nulliparous women delivered with vacuum extraction.

Design A population-based observational study.

Setting Sweden.

Population 63 654 nulliparous women delivered with vacuum extraction derived from the Swedish Medical Birth Register 2000–2011, with a live singleton baby with no known malformations in cephalic presentation in gestational week $\geq 34^{+0}$, and subject to lateral or mediolateral episiotomy or no episiotomy.

Methods The effect of episiotomy was calculated using a causal doubly robust estimation method based on propensity scores. Results are presented as the average treatment effect and numbers needed to treat (NNT).

Main outcome measures OASIS (third- and fourth-degree perineal injury) in nulliparous women delivered with vacuum extraction.

Results Episiotomy was associated with a reduction in OASIS from 15.5% to 11.8%, average treatment effect of −3.66% (95% CI −4.31 to −3.01) and NNT 27. Third-degree perineal injuries were reduced from 14.0% to 10.9% (−3.08, 95% CI −3.71 to −2.42) with NNT 32. Fourth-degree perineal injuries were reduced from 1.6% to 1.0 % (−0.58%, 95% CI −0.79 to −0.37) with NNT 172.

Conclusions Lateral or mediolateral episiotomy reduced the prevalence of OASIS in nulliparous women delivered with vacuum extraction, compared to women with no episiotomy.

Keywords Causal inference, inverse treatment probability weighting, obstetric anal sphincter injury, propensity score.

Tweetable abstract To prevent one case of OASIS in first-time mothers delivered with vacuum, 27 episiotomies had to be performed.

Linked article This article is commented on by AH Sultan and JW deLeeuw, pp. 1672–1673 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.16783.

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Introduction

Obstetric anal sphincter injury (OASIS) is a severe complication of vaginal delivery and the most important cause of female anal incontinence.[1] OASIS is associated with dyspareunia, perineal pain and impaired quality of life.[2] In nulliparous women, OASIS is reported in 0.1–5% of spontaneous vaginal deliveries,[3] and 1.5–28.1% of vacuum extractions (VE).[3,4] The prevalence of third-degree injuries, involving the anal external or internal sphincter, and fourth-degree perineal injuries, involving the anal sphincters and/or rectal mucosa, are rarely reported separately. Fourth-degree perineal injuries have been observed in 1.0% of spontaneous vaginal deliveries and 2.3–6.1% in VE (mixed parity).[5]

Lateral or mediolateral episiotomy has been observed to reduce the rate of OASIS in VE in nulliparous women and is generally recommended.[4,6] Despite this, the use of episiotomy is highly variable between countries and hospitals, reflecting lack of consensus.[7] The Nordic countries, excluding Finland, have a restrictive use of episiotomy in operative vaginal delivery, likely influenced by the feeble effect and risk of harm in spontaneous vaginal delivery.[6-8]

Whether routine or restrictive episiotomy may reduce OASIS in operative vaginal delivery in nulliparous women was studied in a pilot randomised controlled trial (RCT) in Great Britain in 2008, although it was underpowered to show a significant difference.[9] Furthermore, it has proven difficult to adhere to the planned use of episiotomy in RCTs.[9,10] When an RCT cannot be performed, causal inference from large observational databases can be used to emulate an RCT.[11,12] To balance the baseline characteristics among different treatment groups, propensity score-based methods can be used.[13,14] The propensity score is defined as the likelihood of receiving a treatment given a set of characteristics, and this can be modelled using a logistic regression. The causal average treatment effect can be evaluated using the potential outcome framework and propensity score-based methods. In this study, we use a doubly robust method, which has the advantage of being correct when either the outcome regression model (traditional way of obtaining treatment effect) or the propensity score model (i.e. treatment selection model) is correct.[15,16] For our purpose, we examine the average treatment effect in the total population, rather than the treatment effect in the treated, which allows us to examine the effect of routine episiotomy for a general population.[12,14]

The aim of our study was to emulate an RCT to investigate whether routine lateral or mediolateral episiotomy compared with no episiotomy reduces the prevalence of OASIS at VE in nulliparous women.

Methods

We used data from the Swedish Medical Birth Register from 2000 to 2011. Information is collected prospectively from standardised antenatal, obstetric and neonatal records at all midwifery antenatal clinics and hospitals. The Swedish Medical Birth Register is validated and contains information on 98% of all births, including demographic data, reproductive history, maternal diseases and pregnancy complications classified using the International Classification of Diseases version 10 (ICD-10).[17,18]

Study population and exposure

We included nulliparous women in gestational week $\geq 34^{+0}$ with a singleton, live fetus in occiput anterior or occiput posterior presentation delivered with VE, with a lateral or mediolateral episiotomy or no episiotomy (Figure 1). The type of cup was not available in the register. Most VEs in Sweden are performed with a metal cup, but silastic cups and kiwi cups are also used. Episiotomy was identified using marked checkboxes indicating a left, right or median episiotomy or by using the procedure code (TMA00). We excluded women with a median or unclassified episiotomy. A left or right episiotomy was considered a lateral or mediolateral episiotomy, as the incision point, angle or length was not available. The two types, lateral or mediolateral, can also be considered similar in effect,[19] and a distinction based on clinicians' description is difficult.[20] We excluded delivery by forceps and sequential techniques because they were rare (Figure 1). The rate of conversion to forceps is presented in Figure 1 (n = 888) and constituted 1% of all vacuum attempts (caesarean sections, n = 3182, 4%). We excluded deliveries with malformation diagnoses (ICD-10, chapter Q).

Covariates

The baseline characteristics were categorised as follows: maternal age (<19, 20–24, 25–29, 30–24, 35–39, ≥40 years), maternal continent of birth (Europe and USA, Canada, New Zealand and Australia as one category, and Asia, Africa and Latin America as separate categories), maternal height (<160 or ≥160 cm), maternal body mass index (BMI; <18.5, 18.5–24.9, 25.0–29.9, 30.0–34.9, ≥35.0), smoking (yes or no at any timepoint during pregnancy), cohabitation (yes or no), diabetes (pregestational and gestational, yes or no), pre-eclampsia or hypertension (pre-gestational and gestational, yes or no), Crohn's disease or ulcerative colitis (yes or no), female genital mutilation (yes or no), onset of labour (spontaneous or induction), gestational age (34–36 , 37–40 or ≥41 weeks), neonatal sex (boy/girl), epidural anaesthesia (yes or no), labour dystocia (yes or no), intrapartum fetal distress (yes or no), fetal head station at VE (outlet, mid-cavity, unspecified), fetal head position (occiput anterior or occiput posterior), fetal head circumference (<38 or ≥38 cm, which corresponds to the 95th percentile), birthweight (<3000, 3000–3499, 3500–3999, 4000–4499 or ≥4500 g), Apgar at 1 minute (≥4 and <4) (which served as a proxy for severely abnormal CTG during the VE), shoulder dystocia (yes or no) and year of delivery. Hospital of delivery was limited to hospitals with at least 100 VEs during this 12-year period. Continuous covariates were categorised based on what is customarily done in the literature for ease of modelling and interpretation. Missing data regarding continent of birth, maternal height, BMI, smoking, cohabitation, fetal head station and head circumference were categorised as unspecified to ensure including women with frequently missing data. For all other covariates, missing data occurred in <1% of the treated or nontreated women, and these observations with missing covariate information were not included in the analysis. For details on ICD codes, see Table S1.

Main outcome measures

A core outcome set for OASIS prevention and treatment is under planning but has not yet been established.[21] The primary outcome in our study was OASIS which included a third-degree perineal injury involving the anal sphincters or a fourth-degree perineal injury also involving the rectal

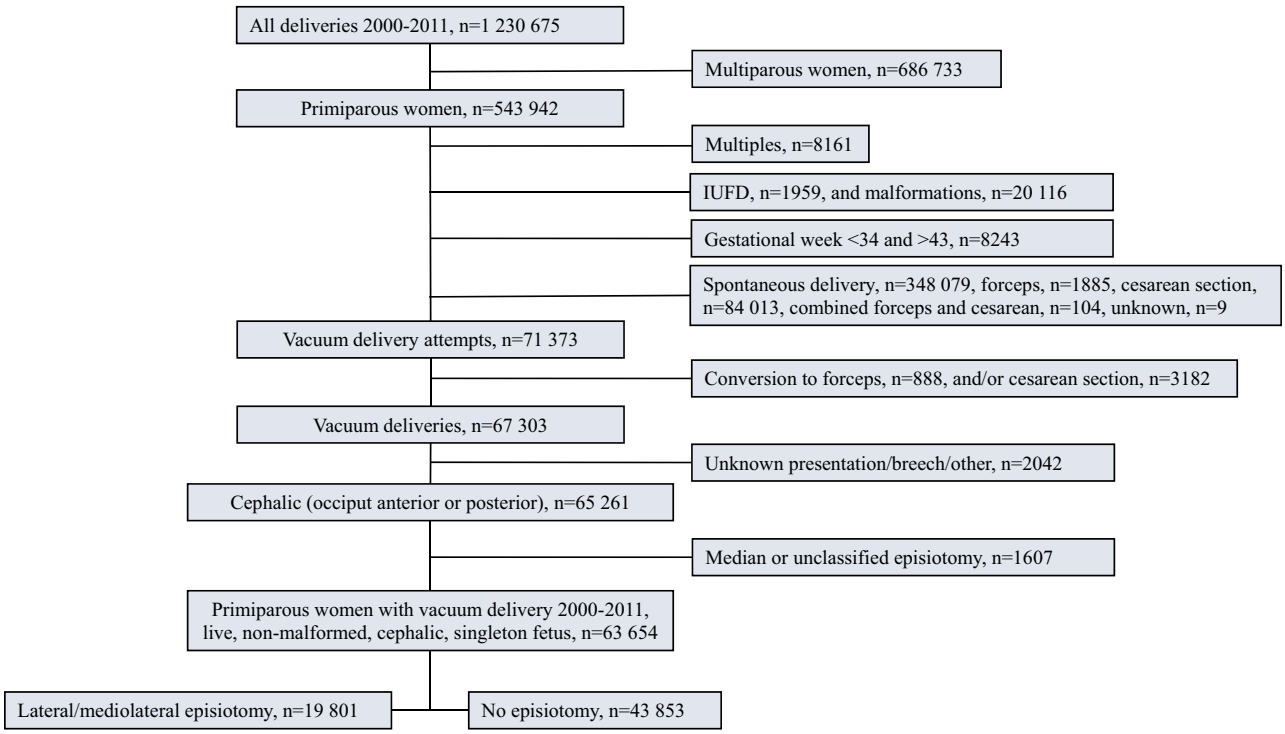

Figure 1. Flowchart.

mucosa. OASIS was defined by ICD-10 codes O70.2A-F, X and O70.3, marked checkboxes indicating injury to the sphincters or rectum, or the procedure code indicating repair of a third- or fourth-degree perineal injury (MBC33). The secondary outcome was a fourth-degree perineal injury defined by ICD-10 code O70.3 or a marked checkbox (injury to the rectum). The remaining OASIS were regarded as third-degree perineal injuries.

Patient involvement and funding

Patients were not involved in the development, design, conduct or analysis of this study. The study was partly funded by The Swedish Research Council through a grant for an ongoing randomised controlled trial.[22] The funding body had no part in the design or conduct of this study.

Statistical analyses

Statistical analyses were made using STATA 16.1 (StataCorp, College Station, TX, USA). First, we presented maternal characteristics and delivery characteristics in eligible women without and with episiotomy, as well as in women without and with the outcome OASIS. Next, we performed chi-square tests to determine whether there is a statistical difference in the maternal characteristics and delivery characteristics between the women without and those with episiotomy. We also performed chi-square tests to determine what characteristics might contribute to the difference in the outcome OASIS.

Subsequently, we calculated the propensity score for each woman. The propensity score is the probability of receiving treatment given certain characteristics. We entered all characteristics that could be associated with either treatment or outcome, here defined as a *P*-value <0.20 in the bivariate analyses (Tables 1 and 2).[13,16] The primary analysis was performed by calculating the average treatment effect using a doubly robust method, combining inverse probability weighting (IPW, weight each person by the inverse of their propensity score) and the outcome regression method (using the same set of covariates). The average treatment effect estimates the treatment effect in the total population, were everyone to receive the treatment. The IPW creates a synthetic population assigned to each of the two treatment groups, with balanced patient characteristics. The doubly robust method will provide correct inference when either the treatment selection model is correct or when the outcome regression model is correct.[15] We used the doubly robust method as the primary method, but also examined the data using the IPW method as well as regression adjustment (Table 3). We checked for the positivity assumption by examining propensity scores overlap between the two treatment groups. We also checked for the balance of baseline characteristics after IPW of each observation (Tables S2 and S3). The results are presented as the average

Table 1. Maternal characteristics

	Treatment			Outcome		
	No episiotomy ***Total n* = 43 853** ***n* (row %)**	**Episiotomy** ***Total n* = 19 801** ***n* (row %)**	***P*-value***	**No OASIS** ***Total n* = 54 626** ***n* (row %)**	**OASIS** ***Total n* = 9028** ***n* (row %)**	***P*-value***
Maternal age						
<19 years	875 (68.5)	402 (31.5)	<0.001	1198 (93.8)	79 (6.2)	<0.001
20–24 years	6791 (67.3)	3301 (32.7)		8978 (89.0)	1114 (11.0)	
25–29 years	15 400 (68.2)	7169 (31.8)		19 189 (85.0)	3380 (15.0)	
30–34 years	14 591 (69.6)	6363 (30.4)		17 728 (84.6)	3226 (15.4)	
35–39 years	5145 (70.9)	2112 (29.1)		6235 (85.9)	1022 (14.1)	
≥40	858 (69.3)	380 (30.7)		1073 (86.7)	165 (13.3)	
Missing	193 (72.3)	74 (27.7)		225 (84.3)	42 (15.7)	
Continent of birth						
Europe, USA, Canada, NZ, Australia	38 273 (68.7)	17 399 (31.3)	<0.001	47 904 (86.0)	7768 (14.0)	<0.001
Asia	3871 (70.7)	1603 (29.3)		615 (90.7)	63 (9.3)	
Africa	662 (61.0)	422 (39.0)		4577 (83.6)	897 (16.4)	
Latin America	533 (78.6)	145 (21.4)		890 (82.1)	194 (17.9)	
Unspecified	514 (68.9)	232 (31.1)		640 (85.8)	106 (14.2)	
Maternal height						
<160 cm	5490 (67.2)	2676 (32.8)	0.002	6905 (84.6)	1261 (15.4)	<0.001
≥160 cm	35 557 (69.0)	16 008 (31.0)		44 349 (86.0)	7216 (14.0)	
Unspecified	2806 (71.5)	1117 (28.5)		3372 (86.0)	551 (14.0)	
Maternal BMI						
<18.5	996 (66.1)	510 (33.9)	0.18	1287 (85.5)	219 (14.5)	<0.001
18.5–24.9	25 465 (68.8)	11 535 (31.2)		31 817 (86.0)	5183 (14.0)	
25.0–29.9	8864 (68.9)	3997 (31.1)		10 951 (85.1)	1910 (14.9)	
30.0–34.9	2330 (69.5)	1023 (30.5)		2869 (85.6)	484 (14.4)	
≥35.0	872 (69.8)	378 (30.2)		1108 (88.6)	142 (11.4)	
Unspecified	5326 (69.9)	2358 (30.1)		6594 (85.8)	1090 (14.2)	
Smoking						
Yes	2627 (68.8)	1191 (31.2)	0.86	3418 (89.5)	400 (10.5)	<0.001
No	37 330 (68.7)	17 035 (31.3)		46 483 (85.5)	7882 (14.5)	
Unspecified	3896 (71.8)	1575 (28.2)		4725 (86.4)	746 (13.6)	
Cohabitation						
Yes	38 652 (68.5)	17 800 (31.5)	0.003	48 343 (85.6)	8109 (14.4)	<0.001
No	2808 (70.7)	1162 (29.3)		3529 (88.9)	441 (11.1)	
Unspecified	2393 (74.0)	839 (26.0)		2754 (85.2)	478 (14.8)	
Diabetes, all types						
Yes	588 (66.0)	303 (34.0)	0.06	762 (85.5)	129 (14.5)	0.80
No	43 265 (68.9)	19 496 (31.1)		53 864 (85.8)	8899 (14.2)	
Pre-eclampsia/hypertension						
Yes	2444 (69.8)	1051 (30.2)	0.17	3030 (86.7)	465 (13.3)	0.13
No	41 409 (68.8)	18 750 (31.2)		51 596 (85.8)	8563 (14.2)	
Crohn's/ulcerative colitis						
Yes	339 (67.4)	164 (32.6)	0.47	442 (87.9)	61 (12.1)	0.19
No	43 514 (68.9)	19 637 (31.1)		54 184 (85.8)	8967 (14.2)	
Female genital mutilation						
Yes	42 (43.4)	55 (56.7)	<0.001	72 (74.2)	25 (25.8)	0.001
No	43 811 (68.9)	19 746 (31.1)		54 554 (85.8)	9003 (14.2)	

*Test of proportions (χ^2).

Table 2. Delivery characteristics

	Treatment		*P*-value*	Outcome		*P*-value*
	No episiotomy ***Total n* = 43 853** ***n* (row %)**	**Episiotomy** ***Total n* = 19 801** ***n* (row %)**		**No OASIS** ***Total n* = 54 626** ***n* (row %)**	**OASIS** ***Total n* = 9028** ***n* (row %)**	
Episiotomy						
Yes	0	19 801	n/a	17 361 (87.7)	2440 (12.3)	<0.001
No	43 853	0		37 265 (85.0)	6588 (15.0)	
Onset of labour						
Spontaneous	36 758 (69.0)	16 549 (31.0)	0.42	45 772 (85.9)	7535 (14.1)	0.55
Induction	6897 (68.3)	3165 (31.7)		8617 (85.6)	1445 (14.4)	
Missing	198 (69.5)	87 (30.5)		237 (83.2)	48 (16.8)	
Gestational age						
34-36 weeks	1111 (71.1)	452 (28.9)	<0.001	1461 (93.5)	102 (6.5)	<0.001
37-40 weeks	26 815 (70.0)	11 498 (30.0)		33 225 (86.7)	5088 (13.3)	
≥41 weeks	15 927 (67.0)	7851 (33.0)		19 940 (83.9)	3838 (16.1)	
Neonatal sex						
Boy	24 110 (67.9)	11 396 (32.1)	<0.001	30 283 (85.3)	5223 (14.7)	<0.001
Girl	19 742 (70.1)	8404 (29.9)		24 341 (86.5)	3805 (13.5)	
Missing	1 (50)	1 (50)		2 (0)	0	
Epidural						
Yes	28 392 (70.2)	12 059 (29.8)	<0.001	34 729 (85.9)	5722 (14.1)	0.72
No	15 461 (66.6)	7742 (33.4)			3306 (14.2)	
Labour dystocia						
Yes	27 403 (68.4)	12 526 (31.4)	0.06	33 867 (84.8)	6062 (15.2)	<0.001
No	16 450 (69.3)	7275 (30.7)		20 759 (87.5)	2966 (12.5)	
Intrapartum fetal distress						
Yes	19 050 (69.9)	8275 (30.1)	<0.001	24 078 (88.1)	3247 (11.9)	<0.001
No	24 803 (68.3)	11 526 (31.7)		30 548 (84.1)	5781 (15.9)	
Fetal head station						
Outlet	21 097 (69.7)	8748 (30.3)	<0.001	25 818 (86.5)	4027 (13.5)	<0.001
Mid-cavity	14 519 (65.7)	7577 (34.3)		18 591 (84.1)	3505 (15.9)	
Unspecified	8237 (70.3)	3476 (29.7)		10 217 (87.2)	1496 (12.8)	
Head position						
Occiput ant	41 075 (71.2)	17 460 (28.8)	<0.001	50 414 (86.1)	8121 (13.9)	<0.001
Occiput post	2778 (54.4)	2341 (45.6)		4212 (82.3)	907 (17.7)	
Head circumference						
<38 cm	39 851 (69.7)	17 332 (30.3)	<0.001	49 314 (86.2)	7869 (13.8)	<0.001
≥38 cm	2830 (66.9)	1400 (33.1)		3372 (79.7)	858 (20.3)	
Unspecified	1172 (52.3)	1069 (47.7)		1940 (86.6)	301 (13.4)	
Birthweight						
<3000 g	5371 (72.6)	2027 (27.4)	<0.001	6875 (92.9)	523 (7.1)	<0.001
3000–3499 g	14 789 (71.1)	6014 (28.9)		18 593 (89.4)	2210 (10.6)	
3500–3999 g	15 991 (68.2)	7467 (31.8)		19 875 (84.7)	3583 (15.3)	
4000–4499 g	6442 (64.5)	3544 (35.5)		7869 (78.8)	2117 (21.2)	
≥4500 g	1195 (62.9)	704 (37.1)		1318 (69.4)	581 (30.6)	
Missing	65 (59.9)	45 (40.1)		96 (87.3)	14 (12.7)	
Apgar at 1 minute						
≥4	42 545 (69.2)	18 915 (30.8)	<0.001	52 727 (85.8)	8733 (14.2)	0.16
<4	1237 (59.8)	830 (40.2)		1796 (86.9)	271 (13.1)	
Missing	71 (55.9)	56 (44.1)		103 (81.1)	24 (18.9)	
Shoulder dystocia						
Yes	303 (58.5)	215 (41.5)	<0.001	342 (66.0)	176 (34.0)	<0.001
No	43 550 (69.0)	19 586 (31.0)		54 284 (86.0)	8852 (14.0)	
Year of delivery*			<0.001			<0.001
Hospital of delivery***			<0.001			<0.001

*Test of proportions (χ^2). **,***See Tables S4 and S5.

Table 3. Unadjusted analysis and causal inference results using different methods

	No episiotomy	Episiotomy	ATE (95% CI)	NNT
Unadjusted analysis	*n* = 43 853	*n* = 19 801		
OASIS	15.02%	12.32%	−2.70 (−3.27 to −2.13)	37
4th degree perineal injury	1.51%	0.99%	−0.52 (−0.70 to −0.35)	192
3rd degree perineal injury	13.51%	11.89%	−2.18 (−2.72 to −1.63)	46
Adjusted analyses				
Doubly robust				
OASIS	15.50%	11.84%	−3.66 (−4.31 to −3.01)	27
4th degree perineal injury	1.58%	1.00%	−0.58 (−0.79 to −0.37)	172
3rd degree perineal injury	13.95%	10.87%	−3.08 (−3.71 to −2.45)	32
IPW				
OASIS	15.57%	11.95%	−3.62 (−4.28 to −2.97)	28
4th degree perineal injury	1.59%	1.01%	−0.58 (−0.79 to −0.37)	172
3rd degree perineal injury	13.98%	10.93%	−3.05 (−3.68 to −2.42)	33
RA				
OASIS	15.51%	11.82%	−3.69 (−4.32 to −3.06)	27
4th degree perineal injury	1.58%	1.00%	−0.58 (−0.78 to −0.37)	172
3rd degree perineal injury	13.93%	10.82%	−3.11 (−3.72 to −2.50)	32

ATE, average treatment effect; CI, confidence interval; IPW, inverse treatment probability weighting; NNT, numbers needed to treat; OASIS, obstetric anal sphincter injury; RA, regression adjustment.

treatment effect of episiotomy on OASIS with 95% confidence intervals (CI) and numbers needed to treat (NNT) calculated as 100/ATE.

Results

We identified 63 654 eligible nulliparous women delivered with VE, of which 43 853 (68.5%) did not receive an episiotomy and 19 801 (31.5%) women did (Figure 1). Women without and with episiotomy differed significantly in most aspects (Tables 1 and 2). Characteristics associated with a more frequent prevalence of episiotomy were African origin, female genital mutilation, fetal head in occiput posterior position, an unspecified head circumference, a birthweight ≥4500 g, Apgar at 1 minute <4 and shoulder dystocia. Characteristics associated with a more frequent prevalence of OASIS were maternal age, Latin American or African origin, body mass index (BMI) <35, no smoking, cohabitation with the other parent, female genital mutilation, no episiotomy, gestational age ≥41 weeks, neonatal sex, labour dystocia, absence of fetal distress, mid-cavity VE, fetal head in occiput posterior position, fetal head circumference ≥38 cm, increasing birthweight, especially ≥4500 g, and shoulder dystocia. Year of delivery and hospital of delivery influenced both the prevalence of episiotomy and the prevalence of OASIS (Tables S4 and S5).

In the total population of 63 654, the prevalence of OASIS was 15.02% in women without an episiotomy and 12.32% in women with an episiotomy (Tables 2 and 3). Unadjusted analysis shows that episiotomy was associated with a 2.70% (95% CI −3.27 to −2.13) reduction of the prevalence of OASIS (Table 3). To prevent one case of OASIS, 37 episiotomies would be required. Third-degree perineal injuries constituted most of the OASIS, while fourth-degree perineal injuries were rare (Table 3).

After statistical balancing using propensity score, a synthetic population of 62 806 women for each treatment group was created, with one group not receiving an episiotomy and another group receiving an episiotomy. In this synthetic population, the average treatment effect estimate using doubly robust method was −3.66% (95% CI −4.31 to −3.01) (Table 3). The prevalence of OASIS was reduced from 15.5% to 11.8% (Table 3). To prevent one case of OASIS, 27 episiotomies would be required. The effect on third-degree perineal injuries was similar, requiring an NNT of 32, whereas fourth-degree perineal injuries would require an NNT of 172 (Table 3). The average treatment effect was also calculated using regular inverse probability weighting and regression adjustment, with similar results (Table 3).

Discussion

Main findings

This study showed that the prevalence of OASIS at VE in nulliparous women could be significantly reduced by routine lateral or mediolateral episiotomy. To prevent one case of OASIS, 27 episiotomies would be required. Routine episiotomy also reduced third-degree and fourth-degree perineal injuries alone, although requiring a higher number of episiotomies to prevent one case of fourth-degree perineal injuries due to its relative infrequency.

Strengths and limitations

This is the first epidemiological study aiming to emulate an RCT of episiotomy or not in VE using a propensity score-based method to estimate the treatment effect. Observational, non-randomised studies are often subject to selection bias, due to the differences in patient characteristics between treated and untreated subjects. Propensity score-based methods can minimise the influence of selection bias and enable checking for balance between exposure groups, without the risk of overestimation of results and overadjustment associated with multivariate logistic regression modelling.[23] The maternal and delivery characteristics contributing to OASIS coincide with the characteristics leading to episiotomy. Therefore, causality versus confounding will be difficult to detangle. The doubly robust method allowed us to adjust for characteristics irrespective of their relation to the treatment or outcome. However, the results did not differ much between the propensity score methods used in our study. The propensity score-based methods, as well as multivariate logistic regression, are limited by the assumption that all the confounders are measurable and included in the model. We admit that unmeasured residual confounding such as operator experience and specific episiotomy technique may influence the result.[24-26] Data on operator experience is not available in the Swedish Medical Birth Register, although operator experience may significantly alter the risk of OASIS.[25] The distinction between mediolateral and lateral episiotomies is also not available, nor are the angle, length or incision point, which impairs the evaluation of different techniques.[24,26,27] Furthermore, the register does not supply information on the duration of second stage of labour, perineal support technique or type of scissors, although these factors may also affect the risk of OASIS.[28,29]

Another strength is the large sample size, which is needed to confirm or reject small differences. Our study included a nationwide sample of women with high quality, prospectively collected data in a setting with comprehensive obstetric care, free of charge, ensuring an almost full coverage, eliminating recall bias and loss of power. The included time period reflects previous register studies, facilitating comparison of results.[4,30] The use of episiotomy has been unchanged but the prevalence of OASIS is reported to be lower in the recent years, which may affect the validity of the results.[31]

Interpretation

An adequately sized RCT to establish the effect of episiotomy in VE has not yet been published and has proved difficult to complete.[9,32] Our study, using a doubly robust method balancing the treated and untreated population similar to the effect of randomisation, supports previous traditional register studies using multivariate logistic regression.[4,14,16,30] Nonetheless, the protective effect of episiotomy was smaller than in many previous register studies.[4,30] The meta-analysis by Lund et al. (n = 321 459) showed an overall treatment effect of −5.55% (no episiotomy 9.1% OASIS versus episiotomy 3.6% OASIS), ranging from a reduction of 13.1% to an increase of 14.1%, presented as an odds ratio of 0.53 (95% CI 0.37–0.77) and NNT of 18.3.[4] No data from Sweden were included in the meta-analysis.

Apart from methodological differences, a possible explanation discussed by Lund et al. is that an episiotomy rate exceeding 75% may be more protective.[4] Van Bavel et al.[30] presented an episiotomy rate of almost 90% in 130 000 Dutch primiparous women delivered with VE, which reduced OASIS from 14% to 2.5% (NNT 8). Jangö et al.[33] presented an episiotomy rate of 29% in 39 000 Danish primiparous women delivered with VE, which reduced OASIS from 15% to 11% (NNT 23), similar to our results. The correlation between a low episiotomy rate and a higher rate of OASIS in operative vaginal deliveries was also observed in the Euro-Peristat Project comparing data from 20 European countries.[7] The Euro-Peristat collaborators hypothesised that a low episiotomy rate may result in a poor episiotomy technique and thereby a smaller protective effect, pointing especially at the Scandinavian countries.[7] The episiotomy incision point, length and angle may all be of importance to prevent tearing toward the anus.[24,26,27] We recognise that a poor episiotomy technique due to little practice could explain why our study showed a lower protective effect. Another possible explanation, when episiotomy rates are low, is confounding by indication. If episiotomy is applied only when there is fetal distress or additional risk factors for OASIS, the protective effect of episiotomy may be underestimated. Operator preferences, perceived episiotomy indications and episiotomy technique in Sweden are under investigation in an ongoing project.

The results from our study add to the growing body of evidence from several observational studies that a lateral or mediolateral episiotomy is protective of OASIS at VE in nulliparous women.[4,30] Some authors argue that an RCT is no longer needed or feasible.[6,30] Given the treatment effect in our study, an RCT would require 2808 nulliparous women with VE allocating 1404 women to each treatment arm. In the British pilot RCT (n = 200), Murphy et al. estimated that a total of 1600 women would be needed to demonstrate the non-significant difference they observed (restrictive episiotomy 10.9% OASIS versus routine episiotomy 8.1% OASIS).[9] Such sample sizes would be challenging in most settings and must be balanced against what is deemed the clinically significant difference. An ongoing RCT in Sweden is powered to demonstrate a 50% reduction in OASIS (n = 710, 12.4% versus 6.2%),[22] based on a

clinical appraisal of a relevant treatment effect and the meta-analysis by Lund et al.[4] This RCT has the potential to isolate the effect of episiotomy at a realistic sample size, due to favourable trial conditions, such as a high rate of OASIS, a defined episiotomy technique and a specific treatment allocation (routine episiotomy versus no episiotomy). Until the results of this or another RCT can guide practice, we recommend liberal use of a correct lateral or mediolateral episiotomy at VE in nulliparous women. This should include clinical situations with additional risk factors for OASIS, such as occiput posterior presentation,[34] macrosomia,[35] short maternal stature[25] or an inexperienced operator.[25] These and other specific risk factors should be established by further research. Future research should also include long-term outcomes. A recommendation to perform routine episiotomy at VE in all nulliparous women can first be issued when short- and long-term outcomes favour routine episiotomy.

Conclusion

Lateral or mediolateral episiotomy reduced the prevalence of OASIS in nulliparous women delivered with VE, but the treatment effect was slightly smaller than in previous studies. Based on this and previous studies, clinical recommendations should include a liberal use of lateral or mediolateral episiotomy at VE in nulliparous women. In the advent of an adequate RCT, future research should identify specific risk factors at VE in nulliparous women when episiotomy is especially beneficial.

Disclosure of interests

All authors declare no conflict of interest. Completed disclosure of interests forms are available to view online as supporting information.

Contribution to authorship

SBW and VA conceived the study. SBW, VA and BJ acquired the data and managed the dataset. SBW, VA and HZ planned and performed the analysis. SBW and VA wrote the first draft, with critical and technical input from HZ and BJ. All authors approved the final version of the manuscript.

Details of ethics approval

The study was approved on 12 September 2018 by the Regional Ethical Review Board of Stockholm (2018/1627-31/2) and on 23 November 2015 by the Regional Ethical Review Board of Gothenburg (092-06, T885-15).

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Data availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Diagnosis (ICD-10) and procedure codes used to identify cases with chosen diagnoses or surgical procedures

Table S2. Balance summary after IPW (outcome OASIS).

Table S3. Balance summary after IPW (outcome OASIS) continued.

Table S4. Year of delivery.

Table S5. Hospital of delivery. ■

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