Risk factors associated with severe perineal lacerations during vaginal delivery: a 10-year propensity score−matched observational study

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BACKGROUND: Severe perineal lacerations are rare obstetrical complications in high-income countries. However, the prevention of obstetric anal sphincter injuries is crucial because of their long-term consequences on a woman's digestive function, sexual-mental health, and well-being. The probability of obstetric anal sphincter injuries can be predicted by assessing antenatal and intrapartum risk factors.

OBJECTIVE: This study aimed to assess the incidence of obstetric anal sphincter injuries at a single institution for 10 years and to identify women more at risk by evaluating the relationship between antenatal and intrapartum risk factors and severe perineal tears. The main outcome measured in this study was the occurrence of obstetric anal sphincter injuries during vaginal delivery.

STUDY DESIGN: This was an observational retrospective cohort study conducted at a University Teaching Hospital in Italy. The study was conducted from 2009 to 2019 using a prospectively maintained database. The study cohort included all women with singleton pregnancy at term who delivered via vaginal delivery in cephalic presentation. Of note, data analysis was performed in 2 stages: a propensity score matching to balance possible differences between patients with obstetric anal sphincter injuries and those without and a stepwise univariate and multivariate logistic regression. A secondary analysis was performed to further evaluate the effect of parity, epidural anesthesia, and duration of the second stage of labor by adjusting for potential confounders.

RESULTS: Of 41,440 patients screened for eligibility, 22,156 met the inclusion criteria, and 15,992 were balanced after propensity score matching. Obstetric anal sphincter injuries occurred in 81 cases (0.4%), 67 (0.3%) after spontaneous delivery and 14 (0.8%) after vacuum delivery(P=.002). There was an increased odds of severe lacerations of nearly 2-fold for nulliparous women delivering by vacuum delivery (adjusted odds ratio, 2.85; 95% confidence interval, 1.19−6.81; P=.019), with a reciprocal reduction in women with spontaneous vaginal delivery (adjusted odds ratio, 0.35; 95% confidence interval, 0.15−0.84; P=.019) and at least 1 previous delivery (adjusted odds ratio, 0.51; 95% confidence interval, 0.31−0.85; P=.005). Epidural anesthesia was associated with a lower incidence of obstetric anal sphincter injuries (adjusted odds ratio, 0.54; 95% confidence interval, 0.33−0.86; P=.011). The risk of severe lacerations was independent of the duration of the second stage of labor (adjusted odds ratio, 1.00; 95% confidence interval, 0.99−1.00; P=.3), whereas the risk was reduced when mediolateral episiotomy was performed (adjusted odds ratio, 0.20; 95% confidence interval, 0.11−0.36; P<.001). Neonatal risk factors include head circumference (odds ratio, 1.50; 95% confidence interval, 1.18−1.90; P=.001) and vertex malpresentation (adjusted odds ratio, 2.71; 95% confidence interval, 1.08−6.78; P=.033). Induction of labor (adjusted odds ratio, 1.13; 95% confidence interval, 0.72−1.92; P=.6), frequent obstetrical examinations (adjusted odds ratio, 1.17; 95% confidence interval, 0.72−1.90), and women's supine position at birth (adjusted odds ratio, 1.25; 95% confidence interval, 0.61−2.55; P=.5) were further evaluated. Among severe obstetrical complications, shoulder dystocia increased the risk of obstetric anal sphincter injuries by nearly 4 times (adjusted odds ratio, 3.92; 95% confidence interval, 0.50−30.74; P=.2), whereas postpartum hemorrhage occurred 3 times more often in cases of delivery complicated by severe lacerations (adjusted odds ratio, 3.35; 95% confidence interval, 1.76−6.40; P<.001). The relationship among obstetric anal sphincter injuries, parity, and the use of epidural anesthesia was further

confirmed in a secondary analysis. We found that primiparas who delivered without epidural anesthesia had the highest risk of obstetric anal sphincter injuries (adjusted odds ratio, 2.53; 95% confidence interval, 1.46−4.39; *P*=.001).

CONCLUSION: Severe perineal lacerations were found to be a rare complication of vaginal delivery. By using a robust statistical model, such as propensity score matching, we were able to investigate a broad range of antenatal and intrapartum risk factors, including use of epidural anesthesia, number of obstetrics examinations, and patient position at birth, which are usually underreported. Moreover, we found that women who delivered for the first time without epidural anesthesia had the highest risk of obstetric anal sphincter injuries.

Key words: epidural anesthesia, intrapartum care, obstetrical anal sphincter injuries, obstetrical risk factors, obstetrical trauma, perineal tears, sexual and reproductive health, third- and fourth-degree lacerations

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Why was this study conducted?
This study aimed to investigate factors associated with obstetric anal sphincter injuries (OASIs) in a large cohort of pregnant women in Italy.

Key findings
Our study determined that OASIs are more frequent in nulliparous women delivering without epidural anesthesia (EA); that vacuum-assisted delivery has the highest risk, particularly when a mediolateral episiotomy is not performed; and that shoulder dystocia, neonatal size, and vertex malpresentation, confer additional risk.

What does this add to what is known?
Because of their relatively low occurrence, OASI is a neglected topic in obstetrics research, and factors associated with their probability are still controversial. By using a robust statistical model, such as propensity score matching, we were able to investigate a broad range of antenatal and intrapartum risk factors, including use of EA, number of obstetrics examinations, and patient position at birth, which are usually underreported.

Introduction

Perineal tears are frequent after vaginal delivery (VD),[1] and they can be classified on the basis of their extension and the involvement of the anal sphincters and the epithelium. Most obstetrical lacerations are first- and second-degree lacerations, and they do not result in adverse functional outcomes. Severe perineal tears encompass the external and/or internal anal sphincter complex. The American College of Obstetricians and Gynecologists (ACOG) classification system refers to them as third- and fourth-degree lacerations, but they are also known as obstetric anal sphincter injuries (OASIs).[1] The 1998−2010 US Nationwide Inpatient Sample esteemed that a third-degree laceration occurs in 3.3% of women after VD and that a fourth-degree laceration occurs in 1.1% of women after VD.[2] A history of an OASI is the most important contributor to long-term anal incontinence among women. In a recent article from Levin et al,[3] women with fourth-degree lacerations were at the highest risk of developing bowel symptoms 6 months after delivery, and those who had a history of a fourth-degree laceration at the first delivery reported suboptimal bowel control 10 times more frequently than women with a third-degree laceration (30.8% vs 3.6%; *P*=.001). Because of fecal-urinary incontinence and sexual impairment associated with OASIs and the long-term consequences, the prevention of OASIs is of paramount importance. The rate of OASIs among parous women is 3 times lower than among nulliparous women (0.75% −2.30%). Other risk factors for OASIs consistently reported include vacuum and forceps VD, precipitous birth, induction of labor (IOL), and large-for-gestational-age (LGA) fetus, whereas other antenatal and intrapartum factors, including the use of epidural anesthesia (EA), are less clear.[4−11] The primary objective of this study was to assess the incidence of OASIs at a single institution over an observation period of 10 years and to identify women at higher risk of OASIs by evaluating the relationship between maternal, neonatal, and intrapartum risk factors and severe perineal tears.

Materials and Methods
Study design
This was an observational retrospective cohort study conducted at the Department of Women and Child Health, Fondazione Policlinico Universitario Agostino Gemelli (FPUAG), IRCCS, Rome, Italy. The FPUAG is a tertiary university hospital in Italy, with a maternity unit accounting for nearly 4,000 deliveries per year. The study covered 10 years, between October 19, 2009, and November 19, 2019. The study cohort included all women who delivered via VD a single baby in cephalic presentation at term (defined as gestational age [GA] of ≥37 weeks). Deliveries included spontaneous VD (SVD) or vacuum-assisted delivery (VAD) performed with the use of the Kiwi Vacuum Delivery System. The exclusion criteria included maternal age of <18 years, multiple pregnancies, emergency and scheduled (ie, prelabor) cesarean delivery (CD), women who were unconscious or severely ill, women with learning difficulties, and women with serious mental illness.

Data collection
The study was conducted using information contained in a preexisting prospectively maintained electronic database where all women who delivered at the same institution in the past 10 years are

included. The data contained in the database covered all information regarding patient history, labor and delivery parameters, and maternal and neonatal outcomes. Data were extracted from medical records, including admission records, delivery medical records, partographs, and discharge codes from the International Classification of Diseases, Ninth Revision, Clinical Modification. All records were reviewed for this study by a single gynecologist reviewer (V.L.L.). All patients were contacted via phone to be informed about the study and provided informed consent. Only women who agreed to participate in the study were included in the analysis. The study protocol was approved by the internal department review board (approval number DIPUSVSP-03-11-2177).

Study outcomes

The main outcome measured was the occurrence of OASIs in women who delivered via VD. We defined an OASI as any third- or fourth-degree laceration occurring after VD, following the definition adopted by ACOG.[1]

Definition of variables and outcomes

Data on risk factors associated with OASIs were collected, and the propensity scores were adjusted as listed in Table 1. Covariates included in the analysis were screened and grouped into maternal, fetal and neonatal, and intrapartum, as appropriate.

Statistical analysis

The data analysis was performed in 2 stages. A propensity score matching (PSM) was used to balance the possible inherent differences between patients with OASIs and those without. This was followed with logistic regression modeling to assess the relationship between OASIs and background characteristics.

Stage 1: propensity score matching. PSM was first developed in 1983,[12] to predict the probability of receiving treatment or having a condition based on identified covariates and background characteristics. Here, the intention of using a PSM was to create a similar group of patients with OASIs and those without before

regression. To estimate the propensity score for each patient, a logit model was developed. Covariates included in the analysis were grouped into maternal, fetal and neonatal, and intrapartum, as appropriate (Table 1). After the calculation of the propensity scores, a Mahalanobis metric matching with a caliper of 0.1 was used to match OASI cases with non-OASI cases. This matching technique was preferred as it has been found to offer better matches than traditional techniques.[13] Quality of matching was performed through 2 procedures. In the first procedure, summary measures of Rubin's B and R were used. Rubin's B is a measure used in determining bias between matched and unmatched groups, and a value of <25% is an indication that both groups are well balanced, as evidenced in the matched groups. In contrast, Rubin's R is a ratio of variances, and a range between 0.5 and 2.0 suggests a good balance.[14] Here, Rubin's R value was 1.03 after matching. The second balancing procedure was the measurement of standardized differences for each covariate between the matched and unmatched groups. If a variance ratio fell outside the ranges of 0.60 and 1.67,[15] it was dropped, and if a *P* value of the *t* test for the matched groups was statistically insignificant, it was considered as adequately balanced. All covariates satisfied these conditions, although some initial covariates included did not and, thus, were dropped.

Stage 2: logistic regression modeling. Of note, 2 logistic regression models were developed to assess the relationship between OASIs and background characteristics. Statistical significance was considered with a *P* value of ≤.05. All analyses were performed in Stata (version 13.0; StataCorp, College Station, TX).

Results

A total of 41,440 patients were screened for eligibility and included at the baseline as presented in the study flowchart (Figure 1). The original population consisted of 22,156 women with a singleton VD in cephalic presentation at term;

PSM resulted in a matched population of 15,992 women. The sociodemographic characteristics of pregnant women and their association with OASIs are described in Table 2. The mean maternal age at enrolment was 32.0 years (standard deviation [SD], ±5.2). White ethnicity was the most represented (14,648/15,992 [91.6%]). Of note, 1 in 2 women was married (6775/ 15,992 [42.4%]) and received a secondary or higher education (10,353/15,992 [64.7%]). Clinical characteristics of women included in the preliminary analysis and their association with OASIs are presented in Table 3. Mean GA at delivery was 40 weeks (SD, ±1.1), and half of the women were in their first pregnancy (9720 of 15,992 [60.8%] in the nullipara group vs 6272 or 15,992 [39.2%] in the multipara group). The onset of labor was induced in 1 of 3 women (5021/15,992 [31.4%]). Vaginal birth after cesarean delivery occurred in a minority of women (151/ 15,992 [0.95%]). A minority of women had their pregnancy complicated by diabetes mellitus (1422/15,992 [8.9%]) or hypertensive disorders (522/15,992 [3.3%]). Deliveries were equally distributed between day (8:00 AM to 7:59 PM) and night hours (8:00 PM to 7:59 AM), with half of them occurring at night (8397/15,992 [52.5%]). Most of the women were delivered using National Health System services, with only 355 of 15,992 deliveries (2.2%) assisted as part of a private payment scheme.

Delivery characteristics of women included in the analysis are described in Figure 2. Of the 22,156 women included at baseline, 20,421 (92.2%) delivered via SVD, and 1735 (7.8%) delivered via VAD. Among those women, OASIs occurred in 81 cases (0.4%): 67 of 20,421 (0.3%) after SVD (*P*=.002) and 14 of 1735 (0.8%) after a VAD (*P*=.002). After PSM, the incidence of SVD was 92.1% (14,676 /15,992), and the incidence of VAD was 8.2% (1316/ 15,992). There were 61 cases (0.4%) of OASIs: 52 of 1467 (0.4%) after SVD (*P*=.063) and 9 of 1316 (0.5%) after VAD (*P*=.063). The results from univariate and multivariate logistic models of known risk factors for OASIs are shown

TABLE 1
Propensity score−adjusted logistic model of known risk factors for obstetric anal sphincter injury, grouped into maternal, fetal and neonatal, and intrapartum characteristics

Characteristics	Univariate analysis			Multivariate analysis		
	OR	95% CI	P value	Adjusted OR	95% CI	P value
Maternal						
Height (cm)	0.98	0.96−1.01	.326	0.96	0.92−1.00	.063
Age (y)	0.99	0.95−1.04	.869	1.03	0.98−1.09	.216
BMI (numbers)	0.99	0.93−1.05	.736	0.96	0.90−1.02	.185
BMI category 3 (>25 kg/m^2)	1.01	0.59−1.74	.960	0.80	0.45−1.40	.432
White ethnicity	0.71	0.46−1.1	.116	0.68	0.42−1.09	.109
Nulliparous	2.4	1.30−4.41	.005[a]	1.02	0.11−1.58	.198
Multiparous	0.51	0.31−0.85	.005[a]	0.42	0.11−1.58	.198
Gestational diabetes mellitus	0.85	0.37−1.95	.701	0.75	0.32−1.77	.517
Hypertensive disorders	0.38	0.05−2.74	.337	0.33	0.05−2.43	.278
Fetal and neonatal						
Neonatal sex (male)	0.71	0.42−1.19	.194	0.86	0.50−1.45	.568
Neonatal head circumference	1.50	1.18−1.90	.001[a]	1.39	1.03−1.87	.031[a]
Neonatal length	1.16	0.99−1.35	.062	1.24	1.03−1.50	.026[a]
Intrapartum						
Duration of the second stage of labor (min)	1.00	—	—	1.00	0.99−1.00	.264
Obstetrical examinations of >5	1.44	0.87−2.39	.151	1.17	0.72−1.92	.522
Induced labor	1.42	0.85−2.37	.182	1.13	0.71−1.81	.607
Spontaneous delivery	0.52	0.25−1.05	.068	0.35	0.15−0.84	.019[a]
Vacuum-assisted delivery	1.94	0.95−3.94	.068	2.85	1.19−6.81	.019[a]
Epidural anesthesia	0.87	0.53−1.44	.589	0.54	0.33−0.86	.011[a]
Episiotomy	0.34	0.19−0.60	<.001[a]	0.20	0.11−0.36	<.001[a]
Delivery at night	1.48	0.94−2.32	.087	1.54	0.96−2.45	.05[a]
Abnormal fetal head position (occiput anterior vs others)	2.58	1.04−6.42	.041[a]	2.71	1.08−6.78	.033[a]
Fetal head restitution (left vs right)	0.69	0.41−1.14	.150	0.71	0.43−1.19	.191
Patient position at birth (supine vs others)	1.12	0.55−2.27	.760	1.25	0.61−2.55	.539
Complication: hemorrhage	2.48	1.36−4.51	.003[a]	3.35	1.76−6.40	<.001[a]
Complication: shoulder dystocia	5.76	0.78−42.41	.086[a]	3.92	0.50−30.74	.193

BMI, body mass index; *CI*, confidence interval; *OR*, odds ratio.

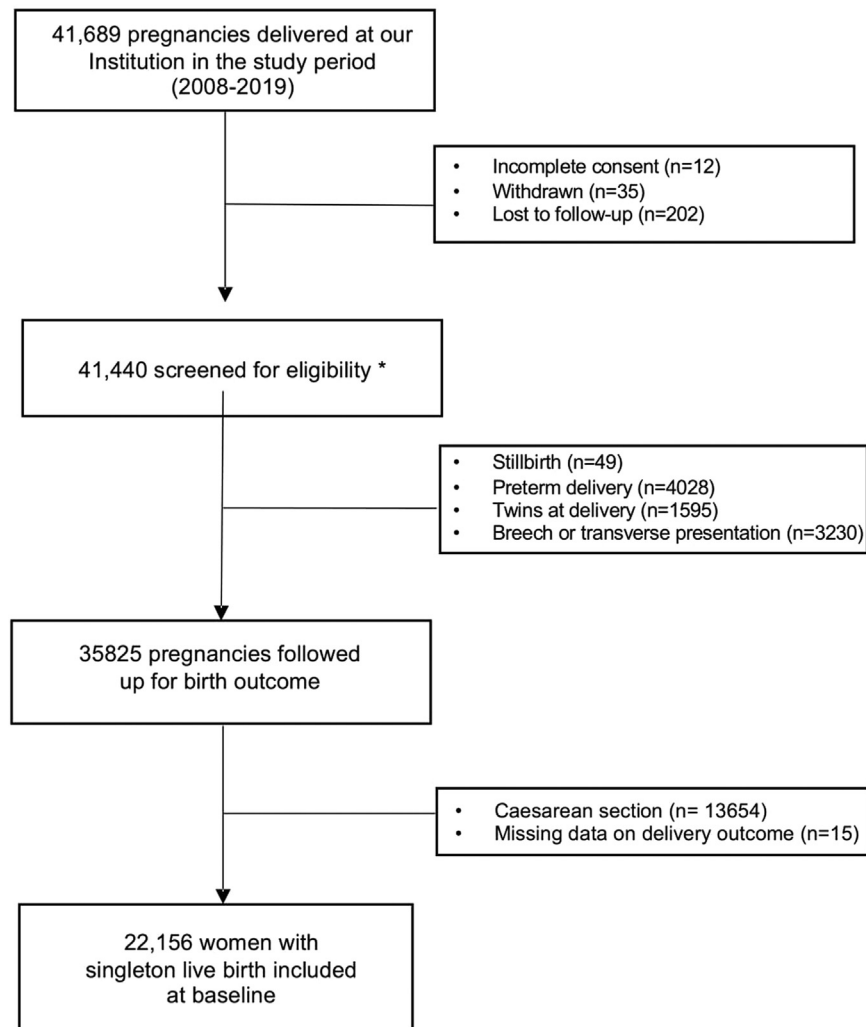[a] Statistical significance was considered at pvalue ≤ 0.05.

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in Table 1. Univariate analysis revealed a positive association with parity, neonatal head circumference (HC), and OASI, as the risk of severe perineal tears was more than doubled in women who delivered for the first time (odds ratio [OR], 2.4; 95% confidence interval [CI], 1.30−4.41; P=.005) and increased along with the size of the fetal head (OR, 1.5; 95% CI, 1.18−1.90; P=.001) (Table 1). In our cohort, an OASI was not significantly associated with maternal age, ethnic origin, and body mass index (BMI) at term. After controlling for potential confounders, the strongest association with OASIs was observed among women who delivered via VAD (adjusted OR [aOR], 2.85; 95% CI, 1.19 −6.81; P=.019) and in deliveries complicated by shoulder dystocia (aOR, 3.92; 95% CI, 0.50−30.74; P=.193). Abnormal vertex presentation, asynclitism, and fetal head presentation in the posterior occiput position were other risk factors for OASIs (aOR, 2.71; 95% CI, 1.08−6.78; P=.033). In contrast, our findings suggested that mediolateral

FIGURE 1
Participant flow chart

Asterisk represents some women have more than 1 exclusion criterion.

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further evaluated the association between severe perineum injuries and another common obstetrical complication, postpartum hemorrhage (PPH), defined as an estimated blood loss of ≥500 mL after VD.[16] There was a robust association between the incidence of OASIs and PPH, as women with an OASI had 3 times the probability of experiencing severe bleeding after delivery (aOR, 3.35; 95% CI, 1.76−6.40; *P*<.001). A secondary analysis was performed to evaluate the strength of the association of OASIs with the use of EA, parity, and the length of the second stage of labor (Table 4). After adjusting for known risk factors, the occurrence of severe perineal lacerations was significantly higher in nulliparous women without EA (aOR, 2.53; 95% CI, 1.46−4.39; *P*=.001) than in women who delivered with EA, whereas multiparity seems to protect from OASIs independent of EA administration (with EA: aOR, 0.26; 95% CI, 0.09−0.72; *P*=.010; without EA: aOR, 0.39; 95% CI, 0.19−0.81; *P*=.012). The duration of the second stage of labor was not associated with OASIs, even in cases of prolonged second stage labor or expedited delivery (aOR, 1.00; 95% CI, 1.00−2.00; *P*=.012).

Structured Discussion
Principal findings
In a large cohort of term pregnant women, severe perineal lacerations were found to be a rare complication of VD (<1%). Over the observational timeframe, there was an increased odds of OASIs of nearly 2-fold for nulliparous women who delivered via VAD, with a reciprocal reduction of the incidence of OASIs for women with SVD and at least 1 previous delivery. The occurrence of OASIs was independent of the maternal age, BMI, and duration of the second stage of labor, although it was markedly reduced when mediolateral episiotomy was performed. The risk of severe perineal lacerations was influenced by the use of EA during labor and delivery, showing a positive effect of EA on preserving the maternal perineum. When EA was administered, the incidence of OASIs was halved. Additional factors found to influence the incidence of

episiotomy and EA are associated with a reduced risk of OASIs. In women who had a mediolateral episiotomy performed, the risk of OASIs demonstrated a 5-fold reduction (aOR, 0.20; 95% CI, 0.11−0.36; *P*<.001). Similarly, in women who delivered with EA, the risk of OASIs showed a 2-fold reduction (aOR, 0.54; 95% CI, 0.33−0.86; *P*=.011). IOL was associated with an increased risk of OASIs (aOR, 1.13; 95% CI, 0.72−1.92), and conversely, spontaneous onset of labor seems to reduce the risk of OASIs (aOR, 0.88; 95% CI, 0.55−1.41). However, these results did not reach statistical significance (*P*=.607).

Women who underwent more than 5 obstetrical examinations were at increased risk of OASIs (aOR, 1.17; 95% CI, 0.72−1.92); however, the strength of association was underpowered (*P*>.05). Maternal comorbidities, such as diabetes mellitus and hypertensive disorders, were not significantly associated with an increased or decreased risk of OASIs in our cohort (diabetes mellitus: aOR, 0.75; 95% CI, 0.32−1.77; *P*=.517; hypertensive disorders: aOR, 0.33; 95% CI, 0.05−2.43; *P*=.278). The incidence of OASIs was higher in nighttime deliveries than in daytime deliveries (aOR, 1.54; 95% CI, 0.96−2.45; *P*=.05). We

TABLE 2
Sociodemographic characteristics of pregnant women and association with OASIs

Sociodemographic characteristics	All women	OASIs (n=61)	Non-OASIs (n=15,931)	P value
Age (y), mean (SD)	32.3±5.2	32.2±4.4	32.3±5.2	.869
BMI, mean (SD)	27.3±4.4	27.1±3.4	27.4±4.4	.678
BMI category 3 (>25 kg/m^2), n (%)	11,010 (68.6)	42 (67.7)	10,968 (68.6)	.889
Height (cm), mean (SD)	164.8±6.8	164.0±6.5	164.8±6.8	.346
Ethnic origin, n (%)				
White	14,648 (91.9)	54 (88.5)	14,594 (91.6)	.692
Black	270 (1.7)	1 (1.6)	269 (1.7)	
Asian	643 (4.0)	5 (8.2)	638 (4.0)	
Hispanic	429 (2.7)	1 (1.6)	428 (2.7)	
Not classified	2 (0.0)	0 (0.0)	2 (0.01)	
Civil status, n (%)				
Single	4152 (26.0)	12 (19.7)	4140 (26.0)	.465
Married	6775 (42.3)	29 (47.5)	6746 (42.4)	
Divorced or separated	192 (1.2)	2 (3.3)	190 (1.2)	
Widowed	12 (0.1)	0 (0.0)	12 (0.1)	
Not declared	4861 (30.4)	18 (29.5)	4843 (30.4)	
Educational status, n (%)				
No formal education	109 (0.7)	0 (0.0)	109 (0.7)	.629
Primary	124 (0.9)	1 (1.6)	123 (0.8)	
Secondary	6002 (37.5)	26 (42.6)	5976 (37.5)	
Higher	4351 (27.2)	18 (29.5)	4333 (27.2)	
Not declared	5406 (33.8)	16 (26.2)	5390 (33.8)	
Employment status, n (%)				
Housewife	1814 (11.3)	5 (8.2)	1809 (11.4)	.781
Employed	5588 (34.9)	21 (34.4)	5567 (34.9)	
Unemployed	722 (4.5)	5 (8.2)	717 (4.5)	
Student	833 (5.2)	3 (4.9)	830 (5.2)	
Retired	21 (0.1)	0 (0.0)	21 (0.1)	
Not declared	7014 (43.9)	27 (44.3)	6987 (43.9)	
Fees n (%)				
NHS	15,637 (97.8)	60 (98.4)	15,577 (97.8)	.758
Private	355 (2.2)	1 (1.6)	354 (2.2)	

BMI, body mass index; *NHS*, National Health Service; *OASI*, obstetric anal sphincter injury; *SD*, standard deviation.

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OASIs in our cohort included neonatal biometry, mainly neonatal HC, and malpresentation of the fetal head at birth, mainly occiput posterior. IOL, frequent obstetrical examinations during labor (>5 inspections), and supine position at birth showed a positive trend toward an increased risk of OASIs, although the results were not statistically significant. Furthermore, nighttime deliveries were more frequently complicated by OASIs than daytime deliveries. Among severe obstetrical complications, shoulder dystocia and PPH were recurrently associated with OASIs; although shoulder dystocia increased the risk of OASIs by nearly 4 times, PPH occurred 3 times more often in cases of delivery complicated by OASIs than in women who delivered with intact perineum or mild perineal

TABLE 3
Clinical obstetrics characteristics of pregnant women and their association with OASIs

Clinical characteristic	All women	OASIs (n=61)	Non-OASIs (n=15,931)	P value
Gestational age, mean (SD)	40.2 (1.1)	40.5 (1.1)	40.2 (1.1)	.010[a]
Parity, n (%)				
Nullipara	9720 (60.8)	48 (78.7)	9672 (60.7)	.002[a]
Multipara	6272 (39.2)	13 (21.3)	6259 (39.3)	
Labor onset, n (%)				
Spontaneous	10,971 (68.6)	37 (60.7)	10,934 (68.6)	.180
Induction of labor	5021 (31.4)	24 (39.3)	4997 (31.4)	
Previous cesarean delivery, n (%)	151 (0.95)	0 (0.00)	151 (0.94)	.445
Time of the day, n (%)				
Day	7595 (47.5)	24 (39.4)	7571 (47.5)	.202
Night	8397 (52.5)	37 (60.7)	8360 (52.5)	
Length of hospital stay (d), mean (SD)	4.3 (1.8)	4.8 (1.4)	4.3 (1.8)	.026[a]
Episiotomy, n (%)	8477 (53.0)	17 (27.8)	8460 (53.1)	<.001[a]
Pregnancy complications, n (%)				
Gestational diabetes mellitus	1422 (8.9)	6 (9.8)	1416 (8.9)	.795
Hypertensive disorders	522 (3.3)	0 (0.0)	522 (3.3)	.151

OASI, obstetric anal sphincter injury; *SD*, standard deviation.

[a] Statistical significance was considered at pvalue $\leq$ 0.05 .

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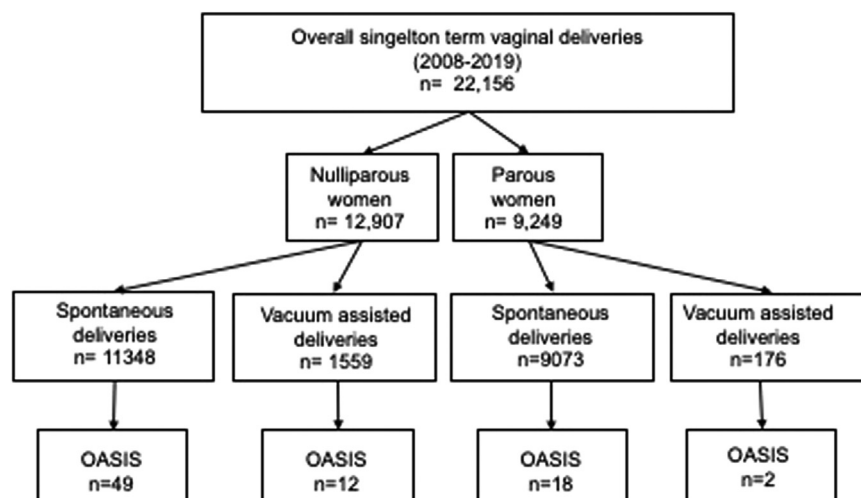
lacerations. The relationship among OASIs, parity, and the use of EA was confirmed in a secondary analysis evaluating the contribution of these factors after adjusting for potential confounders. We found that women who delivered for the first time without EA had the highest risk of OASIs.

FIGURE 2
Delivery outcomes of women included in the analysis

SVD, spontaneous vaginal delivery; *VAD*, vacuum-assisted delivery.

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Results in the context of what is known

The incidence of OASIs observed in our population before and after PSM (0.4%) was similar to what was observed in other studies conducted in other countries. A retrospective study published in 2020 evaluated the temporal trend of OASIs in a broad range of cases (295,668 women) and found a cumulative incidence of 0.2%.[17] OASIs are rare complications of VD in high-income countries with a good level of obstetrical care. Factors that have contributed to the reduction of the prevalence of severe lacerations include the progressive abandonment of instrumental forceps deliveries, the controlled use of midline episiotomy, and the widespread use of preventive strategies and conservative techniques, such as antepartum and intrapartum perineal massage, protection of the perineum during delivery (also defined as "hands-on" method), delayed pushing, and use of warm perineal compresses during pushing.[18−21]

Secondary analysis of the association of obstetric anal sphincter injuries with the use of epidural anesthesia, parity, and duration of the second stage of labor

Variables	Univariate analysis			Multivariate analysis[a]		
	OR	95% CI	*P* value	Adjusted OR	95% CI	*P* value
Nulliparous, epidural	1.30	0.78−2.14	.315	1.79	1.05−3.02	.031[b]
Nulliparous, no epidural	1.82	1.07−3.11	.028[b]	2.53	1.46−4.39	.001[b]
Multiparous, epidural	0.42	0.18−0.97	.041[b]	0.26	0.09−0.72	.010[b]
Multiparous, no epidural	0.58	0.29−1.18	.133	0.39	0.19−0.81	.012[b]
Duration of the second stage of labor (min)	1.00	1.00−1.00	.011[b]	1.00	1.00−1.00	.012[b]

CI, confidence interval; *OR*, odds ratio.

[a] Statistical significance was considered at pvalue ≤ 0.05; [b] Adjusting for maternal age, body mass index category 3 (>25 kg/m^2), gestational age, ethnicity (White vs all the other ethnicities), mode of delivery (spontaneous vs vacuum-assisted delivery), induction of labor, birthweight of >4500 g, obstetrical examinations of >5, and the use of episiotomy.

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The relationship between operative VD and OASIs is well established,[22−25] and our findings have confirmed it. A meta-analysis of 22 studies, including 651,934 pregnancies, established that VAD and LGA were important risk factors for OASIs. In contrast with our results, in the same meta-analysis, the use of EA and midline episiotomy were equally associated with third- and fourth-degree lacerations.[26,27] Previous studies reported an increased risk of severe perineal injuries when midline episiotomy was performed.[26,28] Recent recommendation of good obstetrical practice encourages restrictive use of episiotomy instead of routine episiotomy.[29−31] A study conducted in the Netherlands evaluating the effect of mediolateral episiotomy on perineal integrity underpinned how mediolateral episiotomy should be preferred for its sphincter-saving effect, particularly on high-risk women, as nullipara.[32] At our institution, we perform a mediolateral episiotomy. We believe that in women with a background risk of severe perineal lacerations, including cases of rigid perineum and deliveries complicated by fetal macrosomia or vertex malpresentation, an episiotomy may help to alleviate the trauma caused by the fetal head on the integrity of the maternal tissues and, thus, help in protecting the perineum from severe perineal lacerations. Furthermore, evidence on the relationship between episiotomy and OASIs is

often conflicting and does not distinguish the type of episiotomy performed (midline vs mediolateral) and its indications. Moreover, as in the case of VADs, the same indications for episiotomy could potentially be confounders of the same outcome (ie, OASIs).[1]

Here, women who chose to deliver with EA had a lower incidence of severe perineal injuries. Putative mechanisms to explain the association between EA with a reduction in the occurrence of severe perineal tears may have included a relaxing effect of the anesthetic drugs on maternal tissues and a lower intensity of maternal pushing during the second stage of labor, resulting in fewer sphincter stress. These hypotheses need further investigation to be confirmed. A review of the literature on the effect of EA on severe perineal tears found that, despite prolonging the second stage of labor, the use of EA was not associated with increased odds of OASIs.[33] Another study evaluating the effect of EA on maternal perineum reported no additional risk of perineal lacerations of any extension when EA was used, whereas the use of EA was associated with a higher frequency of episiotomy.[34] Nevertheless, there is a gap of knowledge in evaluating the contribution of EA on maternal perineum, particularly on the occurrence of OASIs. Although the association between EA and VAD has been reported[35] and, conversely, the increased risk of severe perineal tears in

cases of VAD,[22−25] a direct effect of EA on maternal perineum remains unclear. By adjusting for potential confounders, including VAD, our study permitted the assessment of the individual contribution of EA to the risk of OASIs.

A standard obstetrical practice is to examine a woman in active labor approximately every 2 to 4 hours; therefore, a cutoff of ≥5 obstetrical examinations is often used to indicate a high frequency of inspections.[36−39] Here, we assessed the relationship between frequent obstetrical examinations in labor and increased risk of severe perineal trauma and showed a positive trend toward increasing the risk of OASIs; however, our results were underpowered to draw solid conclusions. The study by Gluck et al[40] is, to the best of our knowledge, the only study to examine the association between OASIs and the frequency of obstetrical examinations on a cohort of 22,387 laboring women. Moreover, Gluck's study found that performing ≥5 vaginal examinations was associated with a 2-fold increase in the incidence of severe perineal tears (0.26% vs 0.53%; *P*<.01). In line with the results from Gluck et al,[40] we believe that the number of obstetrical examinations in labor should be carefully considered in women at increased risk of OASIs and that women be encouraged to try alternative positions for delivery other than the standard supine position. In addition, the

influence of birthing position and obstetrical examinations on perineal integrity warrants further research, including a randomized control trial.

A randomized controlled trial of nulliparous term women evaluated the risk of OASIs with prolonged second stage of labor (defined as an extended duration of >1 hour than that defined by the ACOG)[41] and found no additional risk of OASIs in women with an extended length of the second stage of labor.[42] Conversely, an earlier study conducted only on multiparous women showed that the incidence of third- and fourth-degree lacerations increases in parallel with the duration of the second stage of labor, peaking after 3 hours (15%; aOR, 2.56; 95% CI, 1.44−4.50).[43] Moreover, we assessed the relationship between the duration of the second stage of labor and OASIs and found no additional risk for deliveries with a prolonged second stage of labor (aOR, 1.0; P=.012).

Strengths and limitations

A major strength of this study is the inclusion of a large population covering an extended timeframe of 10 years and a broad range of variables. The use of PSM is another important strength of the study. PSM allowed to improve the quality of the results and, together with multivariate regression, to control for potential confounders. The monocentric nature of the study, besides being associated with greater accuracy and uniformity of the data, can at the same time be considered a limitation of the study. The data input into an electronic database by obstetrical personnel not directly involved in the study could be considered a further limitation. Nevertheless, the contemporaneity between the event and data entry could potentially mitigate the effect and reduce the risk of sampling bias.

Conclusions

Our study confirmed that OASIs are rare events occurring during delivery in countries with high standards of obstetrical care. The probability of OASIs can be predicted by assessing antenatal and intrapartum risk factors, as some factors are associated with increased odds of OASIs and others may protect women from experiencing these complications. We found that women who delivered for the first time without EA had the highest risk of OASIs. Awareness of the main contributors to OASIs should always be promoted; these contributors may be useful in antenatal patient counseling and in the training of personnel directly involved in intrapartum care. Further studies, including a meta-analysis of published evidence, should be encouraged as they could help to shed further light on a topic that is still controversial. ∎

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