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Original Article

Risk factors for obstetric anal sphincter injuries (OASIS) and the role of episiotomy: A retrospective series of 496 cases

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ABSTRACT

Objective: The objective of this study was to determine the prevalence and identify risk factors for obstetric anal sphincter injuries (OASIS), and to determine the prevalence of episiotomy and whether it is protective for the posterior perineum.
Study design: This is a retrospective case-control study carried out in a level 2 maternity unit and a level 3 maternity unit between 1 January 2006 and 31 December 2015. The sample population included all vaginal deliveries at term of a living singleton foetus in cephalic presentation. The case group comprised patients with an OASIS. The control group comprised patients without OASIS. Statistical analysis was subdivided into descriptive and inferential parts.
Results: 42,626 patients were included in the study of whom 496 were cases of OASIS, i.e. a rate of 1.2%. The overall episiotomy rate was 10.0%, which reflects a restrictive practice. Episiotomy doesn't appear to be a statistically significant protective factor for OASIS (OR = 0.89–95%CI [0.68–1.16]).
The principal independent risk factors for OASIS were nulliparity (ORa = 4.19–95%CI [3.03–5.84] - $p < 0.001$), previous caesarean (ORa = 5.59–95%CI [3.68–8.44] - $p < 0.001$), uterine fundal height greater than 32 cm (ORa = 1.35–95%CI [1.03–1.77] – $p = 0.03$), gestational or pre-pregnancy diabetes (ORa = 1.76–95%CI [1.22–2.46] – $p = 0.002$), birthweight of more than 3500 g (ORa = 1.48–95%CI [1.17–1.87] – $p = 0.001$), assisted delivery (ORa = 1.81–95%CI [1.18–2.86] - $p = 0.007$), and use of a second instrument or obstetrical manoeuvre (ORa = 1.93–95%CI [1.05–3.30] - $p = 0.02$).
Conclusion: Episiotomy doesn't appear to be a statistically significant protective factor on the perineal prognosis. A deeper understanding of the factors which promote OASIS and greater awareness of them would improve the perineal prognosis of parturient women.

Introduction

According to the Euro-Peristat Project, obstetric anal sphincter injuries (OASIS) complicated between 0.1% and 4.9% of vaginal deliveries in Europe in 2010, with a mean rate of 0.8% in France [1].

The English-language classification of perineal tears, the most widely used worldwide, has four levels of injury [2]. Third degree is defined as a partial or total involvement of the anal sphincter complex, with a fourth degree further entailing injury to the anorectal mucosa.

Severe perineal tears can have considerable and essentially long-term repercussions on the quality of life of affected women (especially anal incontinence and dyspareunia) and, although they are often unpredictable, it is crucial to understand the factors which prevent or promote their occurrence [3].

The initial rationale for performing an episiotomy was to facilitate difficult foetal expulsions and to prevent severe perineal lesions. Historically, it became more frequent as childbearing became more medicalised. Many reservations are now being expressed about the benefits of episiotomy in terms of protecting the anal sphincter. Studies have attempted to respond to this concern, but the diversity between different practices (episiotomy techniques, restrictive versus liberal policies) make their results difficult to interpret and raise questions about the right course of action [4–10].

In 1996, the World Health Organization (WHO) recommended limiting episiotomy to a rate of around 10% [11]. Since 1998, the episiotomy rate in France has fallen significantly, dropping from a rate of 51% in 1998 to 27% in 2010 according to the National Perinatal Survey [10,12].

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In parallel with the reduction of the episiotomy rate, it is essential to study the evolution of the rate of third- and fourth-degree perineal tears and the factors favouring their occurrence. Risk factors for these perineal tears most commonly found in the literature are nulliparity [13–16], operative vaginal delivery [13–15,17], high birthweight [7,13,15,17], occipito-posterior presentation of the foetal head [7,13,14] and Asian ethnicity of the parturient [15,18–20]. Other features such as the uterine fundal height at the end of pregnancy or the existence of gestational diabetes, both factors which may be linked to possible foetal macrosomia, duration of labour, epidural anaesthesia or the practitioner performing the delivery may also have a role in the occurrence of OASIS. But the implication of these various factors remains little studied in the literature. The objective of this study was to determine the prevalence of OASIS, to identify risk factors, and to determine the prevalence of episiotomy and its impact on the occurrence of an OASIS.

Material and methods

Study population

This is a retrospective case-control study conducted in the two maternity units of the Strasbourg University Hospitals, France (one level 2 maternity and one level 3 maternity). Both sites have the same obstetric protocols and the teams are used to working in both locations. We included all vaginal deliveries at term occurring between January 1, 2006 and December 31, 2015. Deliveries before 37 weeks' gestation (WG), non-cephalic presentations, multiple pregnancies, in utero foetal deaths and medical terminations of pregnancy were excluded.

Data were collated using the DIAMM® digital obstetrical record database after registration at the French National Data Protection Agency (CNIL No.: 1,929,486).

The case group comprised patients with an OASIS. The diagnosis was made immediately following delivery, after exposure of the anal sphincter using digital vaginal and rectal examination. This clinical diagnosis was routinely verified by a senior physician. The control group comprised patients without objective signs of OASIS on the day they delivered.

Study variables

Maternal characteristics studied were age, parity, previous caesarean section, pre-pregnancy body mass index (BMI), weight gain during pregnancy, uterine fundal height and gestational or pre-pregnancy diabetes.

Furthermore, several obstetrical characteristics were assessed such as gestational age, method of initiating labour (spontaneous or artificial induction), use of epidural anaesthesia, maternal position during expulsive efforts (lithotomy, lateral, squatting, on all fours), duration of labour, duration of expulsive efforts, delivery method (spontaneous vaginal delivery, vaginal delivery with obstetrical manoeuvre or vaginal assisted delivery), type of perineal tear, provision of an episiotomy, practitioner performing the delivery (midwife or physician) and occurrence of maternal haemorrhage in the immediate post-partum. The characteristics studied in vaginal delivery with assisted delivery were the type of instrument used (vacuum, spatula or forceps), indication (foetal heart rate anomaly, failure to progress, maternal fatigue), foetal head presentation when the instrument was applied (anterior, posterior or transverse), extraction height (upper, middle or lower part), duration of assisted delivery and the need to use a second instrument or an obstetrical manoeuvre.

Neonatal data included birth weight, sex, arterial pH, and Apgar score at 5 min.

Analytic strategies

Statistical analysis was subdivided into two parts: descriptive and an inferential.

Descriptive statistical analysis of quantitative variables took place by assigning position parameters (mean, median, minimum, maximum) as well as dispersion parameters (variance, standard deviation, spread, interquartile range) to each variable. The Shapiro-Wilk test and quantile-quantile plots were used to test whether data followed Gaussian normal distribution. Qualitative data were described by listing total numbers and proportions for each modality in the sample.

Inferential analysis for qualitative variables was carried out by applying either a Chi 2 test or Fisher's exact test depending on theoretical total numbers. Post hoc tests were conducted with Benjamini-Hochberg correction of the alpha risk. Quantitative variables were compared between groups using either a Student's test when the variable concerned was Gaussian or a non-parametric test if it was non-Gaussian (Mann-Whitney U test). Multivariate analysis was performed for all significant variables ($p < 0.2$) on univariate analysis: nulliparity, previous caesarean section, uterine fundal height, diabetes, maternal position during expulsive efforts, duration of labour, practitioner performing the delivery, use of epidural anaesthesia, duration of expulsive efforts, provision of an episiotomy, delivery method, obstetrical manoeuvre, maternal fatigue, birthweight and sex. A stepwise descending selection method based on AIC minimization was applied.

Analyses were carried out using R software, version 3.2.2, as well as with all the requisite software packages.

Results

42,626 patients were included. Of this number, 496 cases had OASIS, i.e. an overall rate of 1.2%.

A perineal tear was observed in 68% of patients, of whom 34.7% had first-degree, 30.1% second-degree, 1.1% third-degree and 0.1% fourth-degree tears. The evolution of OASIS rates and episiotomy rate between 2006 and 2015 is represented in the Fig. 1.

We observed an increase in the rate of third-degree perineal tears, from 0.6% in 2006 to 1.6% in 2015. The rate of fourth-degree perineal tears remained relatively stable throughout the study period at a mean rate of 0.1%.

The overall episiotomy rate was 10.0%: this rate fell markedly, dropping from 12.3% to 8.7% between 2006 and 2015.

The episiotomy rate in nulliparous women fell from 26.0% to 13.9% during the same period, yielding a mean rate of 17.9%. A fall in the episiotomy rate was also observed in multiparous women: it dropped from 5.3% to 2.8%, yielding a mean rate of 3.7%. An episiotomy was performed in 30.5% of patient undergoing assisted delivery in whom the rate fell from 41.5% to 23.4%. All episiotomies performed were medio-lateral.

With regard to the maternal impact, an immediate post-partum haemorrhage occurred in 4.9% of patients (of whom 59.2% had uterine atony, 34.7% placental retention and 6.1% haemorrhagic tears). The occurrence of an immediate post-partum haemorrhage was more frequent in cases (OR = 2.10–95%CI [1.38–3.11] - $p = 0.001$), with a significantly higher proportion having a haemorrhagic tear (OR = 5.27–95%CI [2.43–10.89] - $p < 0.001$). No significant difference was shown in the haemorrhaged volume between cases and controls.

Episiotomy

Episiotomy was found to be a significant risk factor for OASIS using univariate analysis (OR = 2.08–95%CI [1.64–2.62] - $p < 0.001$),

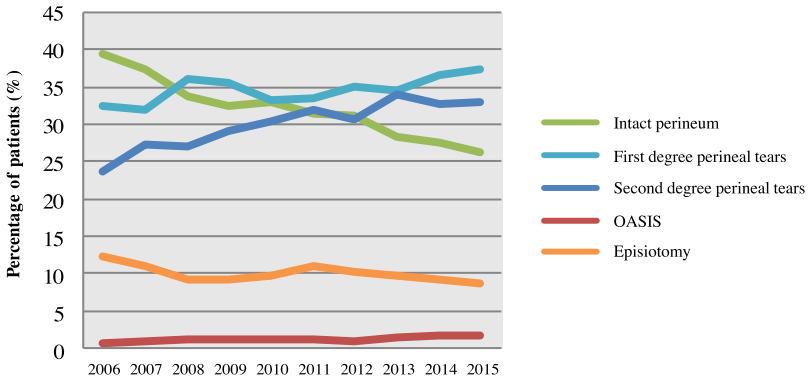

Fig. 1. Evolution of OASIS rates and episiotomy rate between 2006 and 2015.

with a rate of 18.5% in cases versus 9.9% in controls. Multivariate analysis, by contrast, failed to reveal any significant link between episiotomy and the occurrence of OASIS (ORa = 0.89–95%CI [0.68–1.16] - p = 0.39). Gestational age, artificial induction of labour and duration of expulsive efforts were also risk factors on univariate analysis, but not on multivariate analysis. OASIS cases were also more likely to have been delivered by a physician than a midwife, with 55.2% of deliveries by a physician in these cases versus 19.5% in controls (OR = 4.95–95%CI [4.13–5.95] - p < 0.001). This factor disappeared on multivariate analysis.

Maternal risk factors (Table 1)

OASIS were more frequent in the following types of patients:

- Nulliparous patients: present in 73.2% of cases versus 43.8% of controls, with ORa = 4.19 (95%CI [3.03–5.84] - p < 0.001) on multivariate analysis;
- Patients with a history of previous caesarean section: present in 10.1% of cases versus 4.8% of controls, with ORa = 5.59 (95%CI [3.68–8.44] - p < 0.001) on multivariate analysis;
- Gestational or pre-pregnancy diabetes: present in 9.1% of cases versus 4.9% of controls, with ORa = 1.76 (95%CI [1.22–2.46] – p = 0.002) on multivariate analysis;
- Patients in whom the uterine fundal height was greater than 32 cm, with ORa = 1.35 (95%CI [1.03–1.77] – p = 0.03) on multivariate analysis.

No difference was detected between cases and controls with respect to maternal age, pre-pregnancy BMI or weight gain during pregnancy on multivariate analysis.

Obstetrical risk factors (Table 2)

Obstetrical risk factors for OASIS on multivariate analysis were:

- Vaginal assisted delivery: present in 52.2% of cases versus 15.8% of controls, with ORa = 1.81 (95%CI [1.18–2.86] - p = 0.007).
- During assisted delivery, the use of a second instrument or an obstetrical manoeuvre was statistically higher in cases, with ORa = 1.93 (95%CI [1.05–3.30] - p = 0.02).

Epidural anaesthesia appeared to be a risk factor on univariate analysis with a rate of 82.3% in cases versus 73.9% of controls (OR = 1.64–95%CI [1.29–2.09] - p < 0.001) and a protective factor on multivariate analysis (ORa = 0.73–95%CI [0.54-0.99] - p = 0.04). Similarly, a longer labour time was a risk factor on univariate analysis (7.4 ± 3.3 h in cases versus 6.3 ± 3.2 h in controls (OR = 1.10 –95%CI [1.07–1.12] - p < 0.001) and a protective factor on multivariate analysis (ORa = 0.95–95%CI [0.91-0.98] - p = 0.004).

Delivery in the lateral position appeared to be a protective factor against OASIS on univariate analysis, (OR = 0.18–95%CI [0.04-0.48] - p = 0.003), but not on multivariate analysis.

No difference was detected between cases and controls with respect to the type of instrument used, indication, foetal head

Table 1
Maternal risk factors for OASIS on univariate analysis.

	Cases n=496 (1,2%)	Controls n=42,130 (988%)	OR [95%CI]	p
Maternal age (years)	294 ± 5,1	29,8 ± 5,4		0,07
Nulliparity	363 (732)	18,450 (438)	**350** [2,86–4,31]	<**0001**
Previous caesarean section	50 (101)	2044 (4,8)	**220** [1,60-2,96]	<**0001**
Pre-pregnancy BMI (kg/m2)	236 ± 4,4	23,7 ± 4,9		0,78
Weight gain (kg)	128 ± 6,5	12,3 ± 6,7		0,07
Uterine fundal height (cm)	328 ± 2,0	32,4 ± 2,1	**1,10** [105–1,14]	<**0001**
- < 28	1 (0,2)	322 (0,8)		0,35
- 28-32	89 (179)	11,106 (264)	Ref.	–
- 32-36	336 (677)	23,314 (553)	**180** [1,43–2,29]	<0001
- > 36	39 (7,9)	2645 (6,3)	**184** [1,25-2,67]	0002
Gestational or pre-pregnancy diabetes	45 (9,1)	2048 (4,9)	**195** [1,40-2,67]	<0001

OR: Odds Ratio; 95% CI: 95% confidence interval; BMI: body mass index; Ref: reference value.
Continuous variables are given as means and standard deviation, binary variables as number and percentage.

Table 2
Obstetrical risk factors for OASIS on univariate analysis.

	Cases n=496 (1,2%)	Controls n= 42,130 (988%)	OR [95%CI]	p
Gestational Age (WG)	402 ± 1,1	39,9 ± 1,2	**1,20** [1,11–1,30]	<**0001**
Induced labour	122 (246)	8775 (208)	**124** [1,00-1,53]	**0,04**
Duration of labour (h)	7,4 ± 3,3	6,3 ± 3,2	**1,10** [1,07–1,12]	<**0001**
Delivery method				<**0001**
- Spontaneous	232 (468)	35,309 (838)	Ref	–
- Instrumental extraction	259 (522)	6661 (158)	**592** [495-7,08]	<**0001**
- Obstetrical manoeuvre	5 (1,0)	160 (0,4)	**476** [1,68-10,53]	**0,007**
Duration of expulsive efforts (min)	214 ± 12,5	13,6 ± 11,2	**105** [1,04-1,06]	<**0001**
Instrumental extraction Type:				
- Ventouse	249 (961)	6301 (946)		0.24
- Spatula	7 (2,7)	181 (2,7)		
- Forceps	3 (1,2)	179 (2,7)		
Indication:				0,06
- Foetal heart rate anomaly	152 (587)	4241 (637)		
- Failure to progress	106 (409)	2340 (351)		
- Maternal fatigue	0 (0)	63 (0,9)		
- Other	1 (0,4)	11 (0,2)		
Foetal head presentation:				059
- Anterior	178 (687)	3703 (556)		
- Posterior	47 (181)	1124 (169)		
- Transverse	1 (0,4)	50 (0,8)		
Extraction height:				018
- Upper part	21 (8,1)	798 (120)		
- Middle part	154 (595)	2824 (424)		
- Lower part	36 (139)	862 (129)		
Duration of extaction (min)	4,8 ± 3,1	4,9 ± 3,5		059
Use of a second instrument or an obstetrical manoeuvre	16 (6,1)	199 (2,9)	**215** [1,18-3,64]	**0.003**
Delivery by an obstetrician-gynaecologist	277 (558)	8567 (203)	**495** [4,13-5,95]	<**0001**
Maternal position during expulsive efforts				<**0001**
- Lithotomy	470 (948)	34,657 (823)	Ref	–
- Lateral	3 (0,6)	1201 (2,8)	**018** [0.04-0,48]	**0,003**
- Squatting	3 (0,6)	414 (0,9)		0,28
- On all fours	1 (0,2)	350 (0,8)		0,12
- Other	0	425 (1,0)	/	/
Episiotomy	92 (185)	4159 (9,9)	**208** [164-2,62]	<**0001**
Epidural anaesthesia	408 (823)	31,129 (739)	**164** [1,29-2,09]	<**0.001**

OR: Odds Ratio; 95% CI: 95% confidence interval; WG: weeks of gestation; Ref: reference value.
Continuous variables are given as means and standard deviation, binary variables as number and percentage.

presentation, extraction height or duration of assisted delivery. The choice of the instrument depended on the experience of the gynaecologist.

Neonatal risk factors (Table 3)

The rate of OASIS was significantly higher on multivariate analysis when the birthweight was more than 3500 g (3500-4000g: ORa = 1.48–95%CI [1.17–1.87] – p = 0.001 / 4000-4500g: ORa = 2.56–95%CI [1.79–3.61] - p < 0.001 / >4500g: ORa = 3.06–95%CI [1.08–8.69] - p = 0.04). A birthweight of less than 3000 g appeared, however, to be a protective factor against OASIS (ORa = 0.64–95%CI [0.45-0.90] - p = 0.01).

The risk was also higher for male-sex newborn on univariate analysis (OR = 1.50–95%CI [1.26–1.80] - p < 0.001), but this factor disappeared on multivariate analysis.

Discussion

Our study, including 42,626 patients over 10 years (with 496 cases of OASIS), is the largest retrospective study on this topic which compare perineal tears and medio-lateral episiotomies.

Table 3
: Neonatal risk factors for OASIS on univariate analysis.

	Cases n=496 (1,2%)	Controls n= 42,130 (988%)	OR [95%IC]	p
Birthweight (g) *	3505 ± 435	3342 ± 436	**1,01** [1,00-1,01]	<**0001**
- < 3000	54 (109)	8865 (210)	**056** [0,41-0,75]	<**0001**
- 3000-3500	200 (403)	18,384 (436)	Réf.	
- 3500-4000	180 (363)	11,928 (283)	**139** [1,13-1,70]	**0002**
- 4000-4500	54 (109)	2686 (6,4)	**185** [1,35-2,48]	<**0001**
- > 4500	8 (1,6)	248 (0,6)	**297** [1,33-5,69]	**0,003**
Male sex	300 (605)	21,247 (504)	**150** [1,26-180]	<**0001**
Arterial pH	7,22 ± 008	7,25 ± 008		<**0001**
Apgar score at 5 minutes	989 ± 0,47	9,92 ± 053		<**0001**

OR: Odds Ratio; 95% CI: 95% confidence interval; Ref: reference value.
Continuous variables are given as means and standard deviation, binary variables as number and percentage.

With an overall episiotomy rate of 10.0% between 2006 and 2015, reflecting a restrictive practice, our study was unable to find that performing a medio-lateral episiotomy is a protective factor on OASIS. According to the last Cochrane review, there is no current evidence that routine episiotomy reduces perineal/vaginal tears [21]. The meta-analysis by Hartmann et al. in 2005 [22] incorporated 26 studies of which seven were randomised, each also comparing liberal to restrictive episiotomy practices. Only one of these studies dealt with midline episiotomy. The prevalence of liberal episiotomies varied from 44.9% to 93.7%, while the prevalence of restrictive episiotomies varied from 7.6% to 53%. There was also no evidence that a liberal episiotomy practice had any effect on reducing severe perineal tears.

Independently of the reduction in the episiotomy rate, we observed a slight increase in the rate of third-degree perineal tears, but a stable rate of fourth-degree perineal tears. It could be explained by a change in practice in our hospital, in favour of a restriction of episiotomy and by a better screening of OASIS. The study by Chehab et al. [23] investigated changes in perineal tears between 2003 and 2010 within a level 3 maternity unit. With an episiotomy rate which fell from 18.8% to 1.3% and an OASIS rate which dropped from 1% to 0.3%, this retrospective study showed that an ultra-restrictive episiotomy practice was possible without an increase in the rate of severe perineal lesions. Accordingly, the French College of Obstetricians and Gynaecologists don't recommend performing a systematic episiotomy during deliveries to reduce the risk of OASIS, but in case of instrumental deliveries if needed [24]. The literature seems to be in favor of the restrictive practice of episiotomy, but the disparity of frequencies between different series makes interpretation difficult [4–10]. To date, there is no recommended minimum episiotomy threshold, beyond the restrictive practice may have adverse effects. A recent study showed that implementation of a restrictive medio-lateral episiotomy practice for operative delivery seems to be associated with an increase in OASIS incidence with forceps [25]. Routine episiotomy should be avoided, but in some situations, it prevents serious lacerations and may expedite delivery in fetuses thought to be hypoxic [26].

The principal risk factors for OASIS in our study were nulliparity, gestational or pre-pregnancy diabetes and instrumental delivery, as previously described by Thubert et al [27]. OASIS cases were also more likely been attended by a physician than a midwife. Only doctors perform instrumental deliveries and they are generally done on primiparous patient or posterior varieties which increase the risk of tearing. But once these confounding factors are considered, this association disappears. Our study showed that a birthweight of more than 3500 g was significantly associated with an increased risk of OASIS, a result which is replicated in the literature [14,25–27]. A high uterine fundal height and gestational diabetes are also warning signs of the possible existence of a foetal macrosomia. Their link with the occurrence of a severe perineal tear has been very little studied in the literature, with rarely significant results. Our study showed that a uterine fundal height of more than 32 cm and the existence of gestational diabetes significantly increased the subsequent risk of OASIS. The increased rate of diabetes in our patients may also explain the parallel increase in the rate of OASIS during the study period. Vaginal delivery with assisted delivery and the use of a second instrument or obstetrical manoeuvre have been shown to be significant risk factors for OASIS. Groutz et al. [13] also found that vacuum-assisted delivery was an independent risk factor for OASIS (ORa = 2.7–95%CI [1.6–4.6]), similarly to Jangö et al. (ORa = 2.99–95%CI [2.86–3.12]) [30]. Gurol-Urganci et al. [28] found an increased risk with the vacuum (ORa = 1.89–95%CI [1.74–2.05]) and also with the forceps (ORa = 6.53–95%CI [5.57–7.64]).

Our study demonstrated that a prolonged duration of labour has a significantly protective role for the anal sphincter. Date in the literature is very poor and results are inconclusive on this subject. A study in England in 2013 on 1 035 253 nulliparous women [28] failed to find any significant link between a prolonged labour time and the occurrence of a severe perineal tear.

Epidural anaesthesia was also a protective factor for OASIS in our study. The meta-analysis conducted by Pergialiotis et al. in 2013 [29] found an increased risk of OASIS in the event of epidural anaesthesia (ORa = 1.95–95%CI [1.63–2.32]). But the included studies were heterogeneous, with an epidural anaesthesia rate which varied from 7.1% to 81.7%, and there was also a publication bias. A Danish study by Jangö et al. in 2014 on 214 256 nulliparous women showed that epidural anaesthesia had a protective role for anal sphincter (ORa = 0.84–95%CI [0.81–0.88]). The overall rate of epidural anaesthesia was 22.1% [30]. Lastly, with a severe perineal tear rate of 0.3% and an epidural anaesthesia rate of 51.6%, the study by Loewenberg et al. in 2014 on 61 308 patients showed that there was no significant link between these two events [31]. The disparity between the different rates of epidural anaesthesia makes it very difficult to compare these studies.

One of the limitations of our study is that it's a retrospective case-control study. In addition, the antecedent of OASIS could not be analysed, as we didn't have this information for the controls. Yogev et al. showed that OASIS in previous pregnancy is independently associated with increased risk of OASIS in subsequent delivery (OR = 4.6, 95%-CI 1.3–15.3) [32]. Therefore, when there is a previous history of fourth-degree perineal tears, we

usually schedule a caesarean section to prevent recurrence, after discussion with the patient.

Conclusions

With a restrictive episiotomy practice and a rate in constant decline (8.7% in 2015), our study shows that there is no link between performing a medio-lateral episiotomy and the occurrence of a severe perineal tear. Episiotomy is neither protective nor deleterious for the anal sphincter and should not be performed routinely. It should be performed case by case, based on the practitioner's appreciation and good clinical sense in order to improve the conditions of delivery if necessary.

Independent risk factors for OASIS identified in our study were nulliparity, previous caesarean section, gestational diabetes, uterine fundal height greater than 32 cm, birthweight of more than 3500 g, vaginal assisted delivery, and the use of a second instrument or an obstetrical manoeuvre.

Randomized trials are needed to assess the link between a restrictive episiotomy practice and the occurrence of severe perineal tears. A deeper understanding of the factors which promote OASIS and greater awareness of them would improve the perineal prognosis of parturient women.

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