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### Title

# Evaluation of a policy of restrictive episiotomy on the incidence of perineal tears among women with spontaneous vaginal delivery: a ten-year retrospective study

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1 Abstract

Evaluation of a policy of restrictive episiotomy on the incidence of perineal tears among 2 women with spontaneous vaginal delivery: a ten-year retrospective study 3 4 Introduction: Routine episiotomy is no longer recommended to limit obstetrical anal 5 sphincter injuries (OASIs). We aimed to evaluate the effect of a restrictive policy of 6 episiotomy on the risk of OASIs during spontaneous vaginal deliveries. Material and methods: We performed a retrospective single-center observational study 7 8 among women with a term singleton cephalic fetus, with spontaneous vaginal delivery. The occurrence of episiotomy, intact perineum, first, second, third or fourth-degree (OASIs) 9 perineal tears were compared before (period A, from 01/01/2006 to 12/31/2008) and after 10 11 (period B, from 01/01/2012 to 12/31/2016) implementation of the restrictive policy. Odds of perineal tear were estimated using multivariable logistic regression models, stratified by 12 13 parity. **Results:** From 2006 to 2016, the rate of episiotomy decreased, from 14.9% (n/N=200/1141) 14

15 to 4.7% (94/1912). In period B (N=8984) vs A (N=8984), the rates of episiotomy were, 12.9 vs 16 26.6 % for nulliparas (p<0.01) and 2.3 vs 6.8% for multiparas (p<0.01). Odds of OASIs were 17 not different in period B vs A, both for nulliparas (0.9 vs 0.8%, AOR=0.88(0.38-2.05)) and 18 multiparas (0.4 vs 0.2%, AOR=2.28(0.63-8.29). Odds of second-degree tear were higher in period B vs A, both for nulliparas (39.8 vs 17.4%, AOR=2.55(2.11-3.08) and multiparas (26.2 19 vs 12.8%, AOR=2.26(1.95-2.66)); and odds of intact perineum were lower (for nulliparas, 20 21 15.8 vs 24.9%, AOR=0.61(0.42-0.90) and for multiparas, 47.1 vs 56.0%, AOR=0.61(0.49-22 0.76)). No difference was observed for first-degree tears.

- **Conclusion:** The progressive implementation of a restrictive policy of episiotomy during
- spontaneous vaginal delivery was not associated with an increased risk of OASIs over a ten-

25 year period.

**Key words:** episiotomy, OASIs, perineal tear, spontaneous vaginal delivery

#### 28 Introduction

Among women giving birth vaginally, it is estimated that 35% to 75% will suffer from a 29 perineal tear.<sup>1-3</sup> These tears of the perineum may have short, medium- or long-term 30 31 consequences, the importance of which depends on their severity. Obstetrical anal sphincter injuries (OASIs) are the most severe and they affect from 0.8 to 5.9% of women with vaginal 32 delivery.<sup>1-6</sup> OASIs are associated with greater perineal pain, urinary or anal incontinence, 33 sexual disorder, and may have a major impact in women quality of life.<sup>7-9</sup> The principal risk 34 factor of OASIS is instrumental vaginal delivery. In case of spontaneous vaginal delivery, 35 36 nulliparity, macrosomia, obesity, persistent occiput-posterior position have been demonstrated to be associated with the occurrence of OASIS.<sup>2-5, 10-12</sup> 37 The benefit of episiotomy to limit the occurrence of severe perineal tears has been 38 controversial. In the 90's, episiotomy was a frequent obstetric intervention, concerning 39 nearly half of women giving birth vaginally in high income country.<sup>13, 14</sup> Since then, robust 40 41 evidence has shown that a policy of systematic episiotomy was not relevant. Compared to a selective policy, it was not protective against severe perineal tear or maternal and neonatal 42 morbidity.<sup>15</sup> Moreover, episiotomy could also be associated with postpartum hemorrhage, 43 perineal pain and sexual disorder.<sup>16-18</sup> A restrictive practice of episiotomy has therefore 44 been promoted and its use has decreased in many countries.<sup>1, 19</sup> World Health Organization 45 considers a 10% episiotomy rate a reasonable target.<sup>20</sup> 46 In France, the practice of systematic episiotomy is also no longer recommended.<sup>21, 22</sup> In 47 accordance with these recommendations, a sharp reduction in the episiotomy rate was 48 observed between 1998 and 2016, from 71.3% to 34.9% of deliveries in nulliparas and from 49 36.2% to 9.8% of deliveries in multiparas <sup>10</sup>. 50

51 Our objectives were to describe episiotomy rate over a 10-year period following the French 52 recommendations on a restrictive policy of episiotomy and to evaluate the effect of the 53 progressive implementation of a policy of restrictive episiotomy on the risk of severe 54 perineal tears among women with spontaneous vaginal delivery.

#### 55 Material and methods

We performed a single-center comparative retrospective observational study. The study took place at a level III, university maternity unit. All women with spontaneous vaginal delivery and a term singleton cephalic fetus were included over a 10-year period, from 2006 to 2016. Women with medically indicated termination of pregnancy or stillbirth were excluded.

Data were collected retrospectively, from women's medical record completed by the midwives or obstetricians in charge of the women during pregnancy, labor, delivery and immediate post-partum period.

In French practices, episiotomy is usually medio-lateral. The indication of episiotomy was left 64 to the practitioner's discretion during pushing in the second stage of labor. In our center, 65 midwives attend autonomously spontaneous vaginal deliveries. Hands-on perineal 66 67 protection and use of lubricating oil during delivery have been usual practices throughout the study periods. We implemented a policy of restrictive episiotomy during spontaneous 68 vaginal delivery progressively since 2009. The first incentives to reduce the number of 69 episiotomies were provided following the annual review of obstetric practices that usually 70 71 takes place in January. To encourage the restrictive policy, the indication of episiotomy was 72 systematically discussed during the daily obstetrical staff, the rates of episiotomy were 73 regularly reported to the team and peer training in perineal protection was offered to young

midwives. Each year, we dedicated a team meeting to the analysis of episiotomy rates and
the team was strongly encouraged to continue the restrictive policy. The first round lasted 2
years, after which the positive results led us to maintain our efforts.

Perineal tears were classified according to the four-degree classification described by Sultan et al.<sup>23</sup> Third and fourth-degree tear, i.e. OASIs (obstetrical anal sphincter injuries), involving the anal sphincter complex were clinically diagnosed by the midwives and systematically ascertained by an obstetrician. During the 10-year period, there was no change of the diagnostic process of severe perineal tear.

Annual rates of episiotomy were described over the 10-year period, for the whole 82 population and stratified by parity (nulliparas, multiparas). To evaluate the effect of 83 84 implementing a policy of restrictive episiotomy, we performed comparative analyses between two time periods. Before (years 2006 to 2008: period A) and after the 85 86 implementation of the policy (years 2012 to 2016: period B). Because the evolution of practices was gradual, we respected a washout period of three years without evaluation. 87 88 Study population characteristics and perineal status (i.e. intact perineum, without any tears or episiotomy; first-degree perineal tear; second degree-perineal tear; third or fourth-degree 89 90 perineal tear) were compared between the two periods. Univariate analyses were 91 performed using Chi2 test, Student t-test or Mann-Whitney test (non-normal distribution), 92 as appropriate. Independent association between the period and perineal status was 93 estimated using multivariable logistic regression models. Analyses were stratified according to parity (nulliparas, multiparas). Associations were adjusted for potential confounding 94 95 variables, i.e. associated in literature both to practice of episiotomy and risk of OASIs: maternal age, country of birth (European, North African, sub-Saharan African, Asian or 96

other), body mass index (BMI), neonatal weight, maternal position at delivery (lithotomy,

98 adapted lithotomy, i.e. with a foot-rest allowing moderate flexion of the legs, lateral

99 position, or other as squatting, crawling or standing positions), persistent occiput-posterior

100 (OP) position and epidural analgesia. Continuous variables showed no deviation from log-

- 101 linearity when compared to fractional polynomials modelling.
- 102 Sensitivity analyses were performed to select a population of low-risk women, among : (1)

103 nulliparas with spontaneous labor, the selected population corresponding thus to Robson

104 group 1; (2) women without fetal heart rate anomalies during the active second stage of

105 labor (FHRA), as they are the only indication for episiotomy in the French

106 Recommendations.<sup>22</sup>

Significance was set at 0.05. Statistical analyses were performed with Stata software, version108 12.1.

109 Missing data

110 Complete case analyses were performed because less than 4% of data was missing for each

111 variable, and less than 1% for the main criteria (episiotomy, N=21 (0.2%) and perineal status,

112 N=23 (0.2%)). In multivariable models, fewer than 8% of women were excluded from analyses

113 because of missing data for one of the variables considered.

114 Ethical approval: The local Institutional Review Board, CEERB Paris Nord (IRB 00006477) of

115 HUPNVS, Paris 7 University, AP-HP (N ° 2019-0044), approved the research project. The CNIL

approved data collection for this study (n°2216439 v 0).

117 Results

118 Over the 10-year period, episiotomy rates decreased gradually, from 14.9% to 4.7% for all 119 women (p<0.001); from 28.4% to 9.8% for nulliparas (p<0.001); and from 7.6% to 2.2% for 120 multiparas (p<0.001). (Figure 1).

121 Respectively 3978 and 8984 women were included in period A and period B (Figure 2). Study population characteristics and obstetric practices changed over time. In period B, there was 122 123 significantly more multiparas, from non-European country of birth, with advanced maternal 124 age and higher BMI (Table 2). For both nulliparas and multiparas, there was also more induction of labor and epidural analgesia, and women gave birth more frequently in an 125 126 adapted lithotomy position (vs classical lithotomy). For nulliparas, the duration of active 127 second stage of labor was longer in period B. For multiparas, fewer persistent OP position was observed in period B. Rates of episiotomy were lower in period B, both for nulliparas 128 129 (12.9% in period B vs 26.6% in period A, P<0.01) and multiparas (2.3 vs 6.8%, P<0.01).

For nulliparas, period B was not significantly associated with a higher risk of third or fourthdegree perineal tear (0.8 in period B vs 0.9% in period A; adjusted odds ratio, AOR; 95% confidence interval, CI 0.88(0.38-2.05) (Table 3). Period B was significantly associated with more second-degree perineal tear (39.8% *vs* 17.4% in period A, AOR=2.55(2.11-3.08)) and fewer intact perinea (15.8% vs 24.9%, AOR=0.61 (0.42-0.90)). No difference was observed for first-degree perineal tear.

The same results were observed for multiparas. In particular, no association was found
between the period and the risk of OASIs (0.4 vs 0.2%, respectively in period B and A;
AOR=2.28 (0.63-8.29)). Period B was also significantly associated with more second-degree
perineal tear (26.2% vs 12.8%, AOR=2.26 (1.95-2.66)) and fewer intact perinea (47.1% vs
56.0%, AOR=0.61 (0.59-0.76)).

The results of sensitivity analyses were consistent with those of the principal analysis.
Among nulliparas in spontaneous labor (N=2836), no association was found between the
period and the risk of OASIs (0.6 vs 0.9%, respectively in period B and A; AOR=1.36 (0.483.85)). (Table A1) Similar results were observed excluding women with FHRA during active
second stage of labor (Table A2).

- 146 **Discussion**
- 147
- 148 Principal findings

After the progressive implementation of a restrictive policy of episiotomy, the rate of
episiotomy during spontaneous delivery globally decreased, from 14.9 to 4.7%. There were
more second-degree perineal tears and fewer intact perinea in the period following the
restrictive policy. The rate of OASIs was less than 1% and no difference was observed
between the periods.

154 *Strengths and limitations* 

The retrospective before-after design of our study limits its capacity to establish a causal 155 156 pathway between the policy of restrictive episiotomy and the differences observed between the two periods. Being a single-center study can be considered as a limit, but also as a 157 158 strength because we are confident that practices of perineal protection were homogeneous over each of the study periods. Moreover, the rates of cesarean section and instrumental 159 160 delivery in our birth center have not changed much over time (respectively for cesarean and 161 instrumental delivery, period A versus B : 17.1 vs 17.4% and 15.5 vs 17.0%). Yet, other 162 obstetric practices have changed over time that may have an impact on our principal finding. We found less OP positions in period B because the practices evolved favouring to attempt 163 164 manual rotation, as early as possible during the first stage of labor and systematically at the

165 beginning of the second stage of labor. This is the practice recommended to reduce operative delivery.<sup>24, 25</sup> As OP positions are associated with severe perineal tears, we 166 adjusted on that factor.<sup>26, 27</sup> Maternal position during active second stage of labor also 167 evolved, favouring adapted-lithotomy position instead of lithotomy position with the legs 168 169 resting in the stirrups. Lateral positions were also less frequent. That adapted lithotomy 170 position is supposed to decrease the degree of flexion of the legs, in order to limit the 171 stretching of the posterior perineum. Although efficacy of maternal positioning to reduce perineal tears has never been evaluated, we adjusted on it.<sup>25</sup> Another limitation could be the 172 under-screening and reporting of OASIs. If the midwives suspect OASIs, they systematically 173 call the obstetrician for a perineal examination. The contributing factors are sought but the 174 midwife is never charged. We have no information whereas a rectal examination was 175 176 systematically performed for non-superficial tear. However, the frequency of OASIs we found was the same as the one estimated in a recent French national survey.<sup>1</sup> It is unlikely 177 178 that the under-screening was different between the periods and that it biased the results toward the null. 179

#### 180 *Interpretation*

This study adds new evidence regarding the effect of a restrictive policy of episiotomy on 181 perineal status. There was already evidence that a liberal policy of episiotomy is not 182 protective against severe perineal tear.<sup>15</sup> Most of the randomised controlled trials (RCT) 183 were conducted in units performing median episiotomies, and not medio-lateral as in French 184 185 practice. To our knowledge, only one pilot RCT compared restrictive versus routine use of 186 mediolateral episiotomy and found no difference in the risk of third-or fourth degree perineal tears (OASIs).<sup>28</sup> In French cohort studies evaluating selective policy of medio-lateral 187 188 episiotomy, results were consistent with our study. However, neither the study of Chehab et

al., nor the one of Koskas et al. stratified the results among operative and non-operative
vaginal delivery.<sup>29, 30</sup> Moreover, our maternity unit seems to have a very low level of
episiotomy rate for women with non-operative vaginal delivery compared to the national
level. It was estimated at 14.1% in 2014 in a population-based study *versus* 6% in our
maternity.<sup>31</sup>

194 We observed that the frequency of intact perineum decreased between the two periods, 195 contrary to what we expected. In the study of Chehab et al., implementing a restrictive policy of episiotomy permitted to decrease the rate of episiotomy from to 18.8% to 1.3%, all 196 vaginal delivery included, and to increase the rate of intact perineum from 28.2% to 37.5%.<sup>29</sup> 197 198 Both the rates of first and second degree perineal tears increased in their study. This result may be explained by an evolution in the way of reporting the tears in the medical file by the 199 200 midwives in our unit, tending to report more frequently intact perineum instead of first-201 degree tear in period A than in period B for tears not requiring any suture. This hypothesis is 202 supported by the fact that the rate of first-degree tears remained unchanged over time. 203 Another hypothesis is that the trend may have been related to midwives having less seniority in period B. Educational strategies dealing with perineal protection, particularly 204 205 among younger midwives, and companionship could help decreasing the occurrence of perineal tears.<sup>6, 32</sup> Other techniques, such as perineal massage or warm compress application 206 207 should be further evaluated to limit perineal tear, as evidence is still limited to recommend them<sup>21, 33 34</sup>. 208

We had no data about medium and long-term outcomes. In the meta-analysis of Jiang et al.it seemed that restrictive policy was associated with lower immediate postpartum perineal

211	pain, but the evidence was very low. <sup>15</sup> The risks of later perineal pain, urinary or anal
212	incontinence, dyspareunia and genital prolapse were not different.
213	Conclusion
214	The progressive implementation of a restrictive policy of episiotomy for women with
215	spontaneous vaginal delivery was not associated with an increased risk of obstetrical anal
216	sphincter injuries over a ten-year period. Initial and continuous training on perineal
217	protection, specifically among young midwives, should be reinforced to increase the chance
218	of intact perineum.
219	
220	
221	
222	Supporting information: Additional tables A1 and A2
223	Table A1: Multivariable association between the period and perineal status: sensitivity
224	analysis among nulliparas with spontaneous labor.
225	Table A2: Multivariable association between the period and perineal status: sensitivity
226	analysis excluding women with fetal heart rate abnormalities during active second stage of
227	labor, stratified by parity.
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- 232 manuscript and approved the final manuscript as submitted. LM, PB and GM conceived the
- study and contributed to the acquisition of data. PB, LM, GM and JS contributed to its
- design, conducted the analyses, performed the study, drafted the original manuscript,
- reviewed and revised the manuscript.

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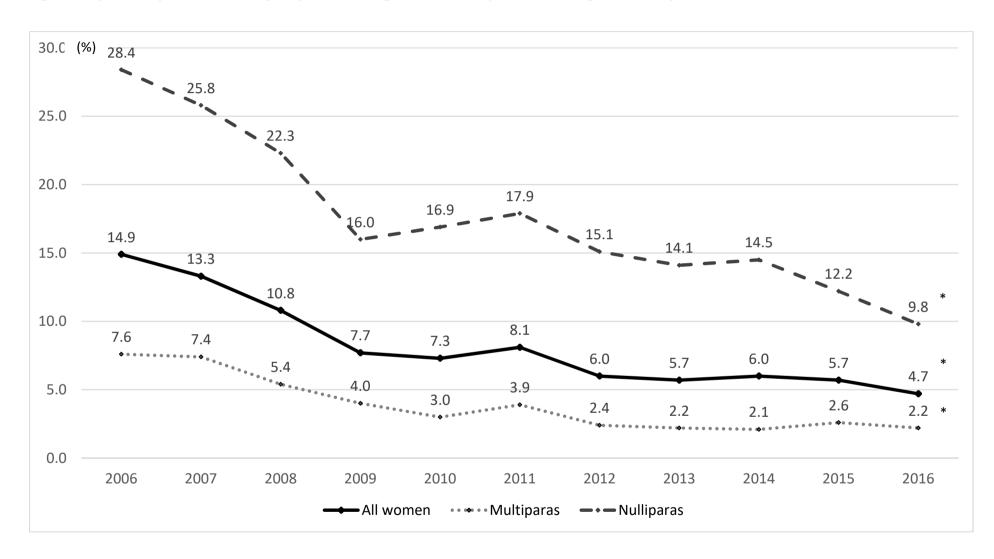
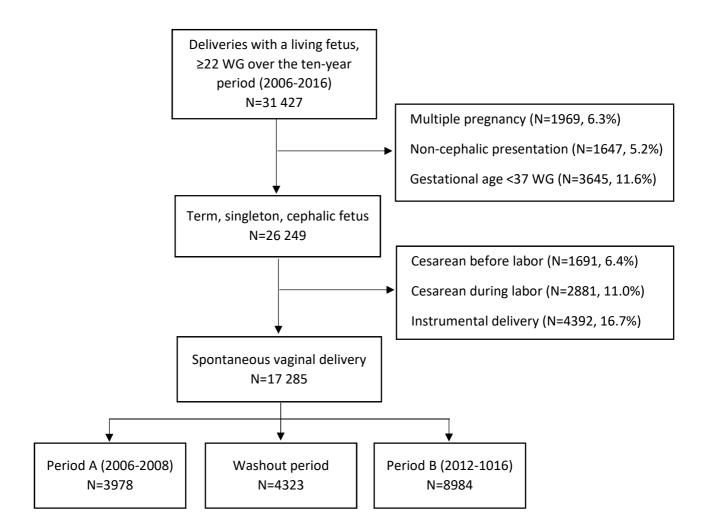


Figure 1: Episiotomy rate over a 10-year period among women with spontaneous vaginal delivery (%)

\**P* for trend < 0.001

#### Figure 2: Flowchart of study population



# Table 1: Characteristics of study population before (period A) and after (period B)

## implementation of a restrictive policy of episiotomy

Characteristics of study population	Period A	Period B	P*
	N=3978	N=8984	
Country of birth			<0.01
Europe	1653 (42.2)	3275 (36.9)	
North Africa	1408 (36.0)	3678 (41.4)	
Sub-saharan Africa	594 (15.2)	1353 (15.2)	
Asia	130 (3.3)	249 (2.8)	
Other	129 (3.3)	327 (3.7)	
Maternal age, y	30.4 (5.4)	31.1 (5.2)	<0.01
BMI, kg/m2	23 [21-27]	24 [21-27]	0.01
Weight gain during pregnancy, kg	12 [8-15]	12 [7-15]	1.0
Nulliparity	1316 (33.1)	2787 (31.0)	0.02
History of C-section			0.21
No	3799 (95.6)	8520 (94.9)	
Yes, with history of vaginal delivery	93 (2.3)	255 (2.8)	
Yes, without history of vaginal delivery	84 (2.1)	207 (2.3)	
Gestational age, WG	39.7 (1.1)	39.7 (1.1)	0.28
Neonatal weight, g	3352 (462)	3361 (435)	0.29
Midwife's seniority, y <sup>a</sup>			<0.01
<1	80 (11.6)	765 (10.5)	
[1-3]	298 (43.1)	2516 (34.5)	
[3-5[	131 (18.9)	2026 (27.8)	
≥5	183 (26.5)	1993 (27.3)	

Data are expressed as n(%) or mean(sd) or med(Q1-Q3). \*Chi2, Student t-test or Mann-Whitney test,

 $^{\rm a}$  22.7% of data were missing in period A and 5.7% in period B.

## Table 2: Comparison of labor and delivery characteristics before (period A) and after (period B) implementation of a selective policy of

## episiotomy

Labor and delivery characteristics		Nulliparas	Multiparas			
	Period A <sup>a</sup>	Period B <sup>a</sup>	<b>P</b> *	Period A <sup>a</sup>	Period B <sup>a</sup>	P*
	N=1316	N=2787		N=2262	N=6197	
Induction of labor	337 (25.8)	922 (33.1)	<0.01	538 (20.3)	1807 (29.2)	<0.01
Peridural analgesia	1162 (88.3)	2576 (92.4)	<0.01	1913 (71.9)	4991 (80.5)	<0.01
Augmentation of labor	864 (65.6)	1389 (49.8)	<0.01	1144 (43.0)	1726 (27.9)	<0.01
Total duration of labor, h	7 [5-9]	8 [6-10]	<0.01	5 [3-6]	5 [3-6]	0.03
Duration of active second stage of labor, min	20 [13-30]	21 [13-33]	<0.01	10 [5-15]	9 [5-15]	1.0
Persistent OP position at delivery	11 (0.8)	17 (0.6)	0.4	48 (1.8)	64 (1.0)	<0.01
FHRA during active second stage of labor	208 (15.8)	679 (24.4)	<0.01	309 (11.6)	1052 (17.0)	<0.01
Meconium-stained AF	319 (24.7)	727 (26.2)	0.29	561 (21.4)	1379 (22.5)	0.26
Maternal position at delivery			<0.01			<0.01
Lithotomy position	505 (43.4)	249 (8.9)		980 (40.8)	515 (8.4)	
Adapted lithotomy position**	557 (47.8)	2378 (85.4)		1012 (42.1)	4518 (74.4)	
Lateral position	44 (3.8)	49 (1.8)		185 (7.7)	218 (3.5)	
Other***	59 (5.1)	109 (3.9)		228 (9.5)	902 (14.7)	
Episiotomy	337 (26.6)	360 (12.9)	<0.01	181 (6.8)	142 (2.3)	<0.01

Data are expressed as n(%) or mean(sd) or med(Q1-Q3). \*Chi2, Student t-test or Mann-Whitney test

\*\*with foot-rest \*\*\*squatting, crawling or standing; WG, weeks of gestation ; OP, occipito-posterior; FHRA, fetal heart rate abnormalities; AF, amnioitc fluid.

Table 3: Multivariable association between the period and perineal status, stratified by parity

		Nulliparas		Multiparas			
Perineal status	Period A	Period B	AOR*(95% CI)	Period A	Period B	AOR*(95% CI)	
	N=1316	N=2787		N=2662	N=6197		
	(Reference)			(Reference)			
Intact perineum	326 (24.9)	440 (15.8)	0.61 (0.42-0.90)	1166 (56.0)	2918 (47.1)	0.61 (0.49-0.76)	
First degree perineal tear	448 (34.2)	925 (33.2)	1.11 (0.94-1.31)	661 (25.0)	1518 (24.5)	1.05 (0.92-1.19)	
Second degree perineal tear	228 (17.4)	1110 (39.8)	2.55 (2.11-3.08)	339 (12.8)	1623 (26.2)	2.26 (1.95-2.66)	
Third- or fourth-degree perineal tear	10 (0.8)	25 (0.9)	0.88 (0.38-2.05)	5 (0.2)	24 (0.4)	2.28 (0.63-8.29)	

Data are expressed as n(%); AOR, adjusted odds ratio; CI, confidence interval; \*all models adjusted for maternal age, country of birth, body mass index,

induction of labor, neonatal weight, persistent OP position, maternal position at delivery and epidural analgesia.

Table A1: Multivariable association between the period and perineal status: sensitivity analysis among nulliparas with spontaneous labor

Perineal status	Period A	Period B	AOR*(95% CI)	
	(Reference)			
	N=971	N=1865		
Intact perineum	224 (23.1)	285 (15.3)	0.52 (0.41-0.66)	
First degree perineal tear	341 (35.1)	627 (33.6)	1.05 (0.86-1.27)	
Second degree perineal tear	179 (18.4)	745 (40.0)	2.49 (2.00-3.10)	
Third- or fourth-degree perineal tear	6 (0.6)	17 (0.9)	1.36 (0.48-3.85)	

Data are expressed as n(%); AOR, adjusted odds ratio; CI, confidence interval; \*all models adjusted for maternal age, country of birth, body mass index,

neonatal weight, maternal position at delivery and epidural analgesia.

Table A2: Multivariable association between the period and perineal status: sensitivity analysis excluding women with fetal heart rate

abnormalities during active second stage of labor, stratified by parity.

	Nulliparas			Multiparas			
Perineal status	Period A	Period B	AOR*(95% CI)	Period A <sup>a</sup>	Period B <sup>a</sup>	AOR*(95% CI)	
	N=1108	N=2108		N=2353	N=5145		
	(Reference)			(Reference)			
Intact perineum	279 (25.3)	327 (15.5)	0.50 (0.41-0.62)	1305 (55.8)	2441 (47.5)	0.67 (0.60-0.75)	
First degree perineal tear	383 (34.8)	720 (34.2)	1.06 (0.89-1.28)	594 (25.4)	1294 (25.2)	1.03 (0.91-1.18)	
Second degree perineal tear	195 (17.7)	842 (39.9)	2.60 (2.12-3.18)	305 (13.0)	1325 (26.8)	2.19 (1.88-2.56)	
Third- or fourth-degree perineal tear	6 (0.5)	20 (1.0)	1.86 (0.67-5.2)	4 (0.2)	17 (0.3)	2.00 (0.45-8.81)	

Data are expressed as n(%); AOR, adjusted odds ratio; CI, confidence interval; \*all models adjusted for maternal age, country of birth, body mass index,

neonatal weight, induction of labor, maternal position at delivery and epidural analgesia.