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Impact of Selective vs Routine Midline Episiotomy and Lacerations of the Anal Sphincter

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Abstract

Introduction: Obstetric anal sphincter tear (OAST) is associated with anal incontinence. Episiotomy was proposed as a form of protection of the anal sphincter at delivery; however, several studies have shown that routine use of episiotomy does not reduce the risk of OAST. **Objective**: This study aims to analyse whether the reduction in the rate of episiotomy in a school hospital in Brazil was associated with an increase in the incidence of obstetric lacerations of the anal sphincter, in addition to associated factors. **Methods**: Observational, cross-sectional and retrospective study. We included all vaginal deliveries of single pregnancies, cephalic presentation, from 34 weeks of gestational age, performed in 2011-2012 (liberal episiotomy) and 2015-2016 (restricted episiotomy), and compared in relation to the rate of mediolateral episiotomy and OAST. **Results**: 4268 births were analysed (2043 in 2011-2012 and 2225 in 2015-2016). The episiotomy rate decreased from 59.4% to 44.2% ($p \leq 0.0001$). In 2011-2012, there were 10 obstetric anal sphincter lacerations in 2043 births (0.48%), while in the period 2015-2016 there were 31 lacerations in 2225 births (1.39%). There was interaction when comparing the two periods in relation to the episiotomy and the occurrence of OAST ($p \leq 0.0001$). Factors associated with OAST were labor induction and shoulder dystocia. **Conclusion**: There was an increase in the rate of lacerations of the anal sphincter with use of restrictive episiotomy. However, this increase occurred both in deliveries with and in deliveries without episiotomy.

Keywords

Restrictive Episiotomy; Third-Degree Perineal Laceration, Fourth-Degree Perineal Laceration, Obstetric Anal Sphincter Tear

1. Introduction

Vaginal birth can cause lacerations of the vagina and perineum. While smaller lacerations can heal quickly without the need for intervention, larger lacerations, involving muscles of the perineal body and sometimes the anal sphincter, require suturing and can cause complications later [1]. The obstetric anal sphincter tear (OAST) is a heterogeneous group of lesions, ranging from the involvement of some fibers to laceration of the total thickness of the external and internal anal sphincter, as well as the anorectal epithelium. They are considered severe perineal lacerations [2]. Non-recognition and proper repair can lead to serious long-term morbidity, especially anal incontinence [3]. The incidence of OAST is 0.5% to 3.5% in Europe and 4.5% in the United States [4]. The main risk factors described include nulliparity, newborn weighing more than 4 kilograms, shoulder dystocia, occipito-posterior position and instrumented delivery with forceps with and without episiotomy [5].

Episiotomy has been suggested as one of the strategies for reducing obstetric anal sphincter rupture, and its routine use is common to avoid the aforementioned adverse outcomes. However, randomized clinical trials and other observational studies have shown that episiotomy performed routinely has no protective effect on the pelvic floor, in addition to increasing the risk of complications. From these studies, the episiotomy was considered restrictive only, and the routine performance of this practice was discouraged [6] [7] [8] (Carroli e Lede, 1993; Murphy *et al.*, 2008; Rodriguez *et al.*, 2008).

In a Cochrane [1] review of 12 randomized controlled trials (6177 patients) comparing restrictive episiotomy with routine use, restrictive use resulted in 30% fewer severe perineal lacerations. However, this analysis included both medial and mediolateral episiotomy. In addition, the rate of episiotomy in these studies ranged from 8% to 59% in the restrictive group, and 61% to 100% in the routine group. Other studies have reported that routine episiotomy may be a protective procedure, especially among nulliparous women, in preserving the integrity of the anal sphincter. Among the types of episiotomy, it was found that mediolateral episiotomy may be associated with a considerable reduction in the incidence of severe perineal lacerations compared to median episiotomy [9].

Based on these findings, the objective of the present study is to analyze whether the reduction in the rate of episiotomy at the Hospital de Clínicas in Porto Alegre was associated with an increase in the incidence of obstetric anal sphincter lacerations, in addition to factors associated with them.

2. Methods

This cross-sectional and retrospective observational study was performed at the Hospital de Clínicas, Porto Alegre, Rio Grande do Sul, Brazil. The Hospital de Clínicas (HCPA) is a tertiary and university hospital, which serves women of the public health system. The Maternity of the Hospital is one of the main ones in southern Brazil with 300 to 350 births/month. We analyzed all vaginal deliveries performed at two distinct periods of episiotomy protocol, since as of 2014, the restrictive episiotomy was instituted at the Hospital, with the objective of reducing the rate of episiotomy. Period 1 corresponds to the births occurred in 2011-2012, period with liberal episiotomy; while period 2, to those in 2015-2016, period with restrictive use. In both groups, the indication for episiotomy was defined by obstetricians. Because it is a school hospital, episiotomies were performed by physicians training in obstetrics area. All deliveries followed the same protocol for performing the episiotomy instituted at the service. The incision is routinely performed at the time the fetal head is visible in the vaginal introitus during a contraction. A left medio-lateral incision is made, with an angle of 60˚ to the midline. In all instrumented deliveries forceps were used. Third degree laceration was defined as an injury involving partially or totally the external and/or internal anal sphincter, and fourth degree laceration involving the rectal mucosa, according to Sultan criteria [5]. The identification of the type of laceration was performed by the obstetrician. Data were reviewed from the electronic medical records.

The inclusion criteria were: 1) vaginal deliveries performed at HCPA between January 2011 and December 2012, and 2) all vaginal deliveries between January 2015 and December 2016. In the first period there was no restriction for performing episiotomy, whereas in the second period it was performed only in selected cases. In both periods, all patients with single gestation and gestational age higher or equal to 34 weeks were included. Cases of vaginal delivery with pelvic presentation, intrauterine fetal death, multiple gestation, delivery at a position other than lithotomy and delivery outside the hospital setting were excluded.

Statistical analyses were conducted at individual level using the SPSS program, version 18.0 [SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.]. The descriptive analyses were performed for all variables, considering the periods of years (period 1: from 2011-2012, period 2: from 2015-2016), the episiotomy groups (group 1: with episiotomy, group 2: no episiotomy) and possible interactions. Analyses were also performed considering the groups of OAST.

Continuous variables were expressed as means ± standard errors of the means (SEM) or medians and 95% confidence intervals [95% CI]—as normality by the Shapiro-Wilk test, while the categorical variables were expressed in absolute (n) and relative frequencies (n%). Comparisons considering the periods of years and the episiotomy groups were performed by non-parametric tests for independent samples (Mann-Whitney test). In addition, analyzes of distributions (Chi-square

test with adjusted residual values) were conducted for comparisons between categorical variables. On the other hand, interactions between the years' factors and episiotomy were analyzed by non-parametric tests for independent samples (Kruskal-Wallis test with Dunn post hoc) or by analysis of distributions (Chi-square test with adjusted residual values). The same comparisons were made with the groups in relation to the obstetric lacerations of the anal sphincter. The level of significance was set at 5% ($p \leq 0.05$) for all analyzes.

The study followed the STROBE Guidelines (Strengthening the Reporting of Observational Studies in Epidemiology) in its elaboration. There was approval of the Research Ethics Committee of the Hospital de Clínicas of Porto Alegre (CAAE: 52635116.4.0000.5327). All participants signed the Data Use Consent Term.

3. Results

Of 4275 births that met the inclusion criteria, 7 were excluded due to lack of data in the medical record. Of the 4268 births analyzed, 2043 occurred between 2011 and 2012, and 2225 between 2015 and 2016 (Figure 1). In the period 2011-2012, the rate of episiotomy was 59.4%; while in the period 2015-2016, the rate was 44.1%.

Sample characterization and comparisons between years, episiotomy and interactions (among years and episiotomy groups) are displayed in Table 1. The

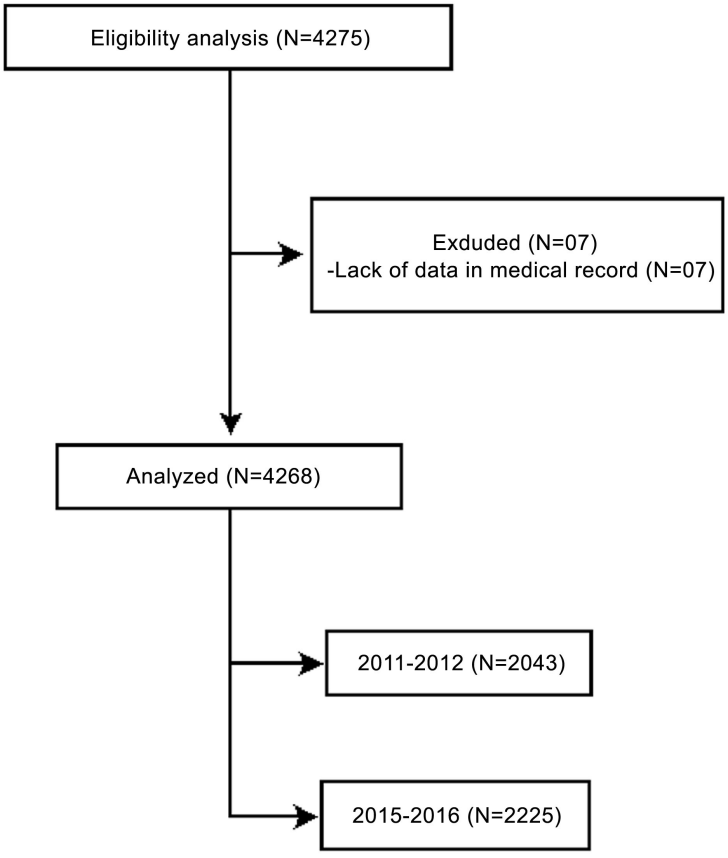

Figure 1. Patient selection flowchart.

Table 1. Sample characterization—maternal characteristics.

Variables	2011-2012			2015-2016			*p1	*p2	*p3
	Total *N* = 2043	Episiotomy *n* = 1214	No Episiotomy *n* = 829	Total *n* = 2225	Episiotomy *n* = 983	No Episiotomy *n* = 1242			
Age (in years)—md [95% CI]	24.00 [24.66 - 25.23]	22.00 [26.69 - 27.60][a]	26.00 [26.69 - 27.60][b]	24.00 [24.88 - 25.44]	22.00 [23.13 - 23.90][a]	26.00 [26.19 - 26.96][b]	**0.204**	**≤0.0001**	**≤0.0001**
Number of Previous Gestations—md [95% CI]	2.00 [2.20 - 2.38]	1.00 [1.59 - 1.81][a]	3.00 [3.06 - 3.33][b]	2.00 [2.02 - 2.13]	1.00 [1.44 - 1.54][c]	2.00 [2.48 - 2.65][d]	**0.004**	**≤0.0001**	**≤0.0001**
Number of Previous Deliveries—md [95% CI]	1.00 [0.91 - 1.04]	0.00 [0.37 - 0.46][a]	1.00 [1.72 - 1.95][b]	0.00 [0.74 - 0.84]	0.00 [0.21 - 0.28][c]	1.00 [1.17 - 1.32][d]	**≤0.0001**	**≤0.0001**	**≤0.0001**
Number of Previous Cesareans—md [95% CI]	0.00 [0.06 - 0.09]	0.00 [0.06 - 0.09]	0.00 [0.05 - 0.09]	0.00 [0.07 - 0.10]	0.00 [0.07 - 0.10]	0.00 [0.07 - 0.10]	0.241	0.803	0.707
Number of Previous Abortions[#]—md [95% CI]	0.00 [0.18 - 0.24]	0.00 [0.13 - 0.19][a]	0.00 [0.23 - 0.33][b]	0.00 [0.18 - 0.22]	0.00 [0.13 - 0.19][ac]	0.00 [0.21 - 0.27][bd]	0.553	**≤0.0001**	**≤0.0001**
Weight (in kg)—md [95% CI]	75.00 [75.97 - 77.21]	74.40 [74.93 - 76.50][a]	76.10 [77.01 - 79.03][bc]	76.50 [78.05 - 79.37]	75.00 [76.03 - 77.92][ab]	78.00 [79.27 - 81.08][c]	**≤0.0001**	**≤0.0001**	**≤0.0001**
BMI (in kg/m^2)—md [95% CI]	29.10 [29.43 - 29.87]	28.60 [28.93 - 29.48][a]	29.70 [29.97 - 30.69][b]	29.50 [29.94 - 30.40]	29.00 [29.28 - 29.94][a]	30.00 [30.32 - 30.96][b]	**0.009**	**≤0.0001**	**≤0.0001**
GA (in weeks)—md [95% CI]	39.43 [39.12 - 39.26]	39.43 [39.18 - 39.36][ab]	39.29 [38.95 - 39.19][a]	39.43 [39.15 - 39.29]	39.57 [39.22 - 39.44][b]	39.43 [39.03 - 39.23][a]	0.333	**≤0.0001**	**0.001**
Ethnicity—*n* (*n*%)									
White	1511 (74.0)	927 (76.4)	584 (70.4)	1689 (76.0)	**782 (79.6)**	907 (73.1)	0.137	**≤0.0001**	**≤0.0001**
Not white	532 (26.0)	287 (23.6)	**244 (29.6)**	534 (24.0)	201 (20.4)	333 (26.9)			

Sample characterization and comparisons considering year (p1), presence of episiotomy (p2) or interactions (p3). Legend: GA—Gestational Age; md—median; 95% CI—95% Confidence Interval; kg—kilograms; m—meter; *n*—Absolute Frequency; *n*%—Relative Frequency; p—Statistical significance; p1—Year Group; p2—Episiotomy Group; p3—Interaction among Year and Episiotomy Groups. Significance set as 5% for all analysis. *p1 and p2—Mann-Whitney test for independent samples or Chi-Square test with standardized adjusted residuals; *p3—Kruskal-Wallis test for independent samples or Chi-Square test with standardized adjusted residuals. [ab]Different letters indicate statistical significance. [#]Includes abortions and ectopic pregnancies.

sample was characterized in age, ethnicity, obstetric history, weight and BMI—all factors that may be related to sphincter lacerations. Maternal median age [95% CI] was higher in no episiotomy group (26.00 [26.49 - 27.08] years) when compared to episiotomy group (22.00 [23.25 - 23.76] years) (*data not shown*, Mann-Whitney test, $p \leq 0.0001$) in both year groups. Considering the median frequencies of gestations and of deliveries, a year effect (Mann-Whitney test, $p = 0.004$ and $p \leq 0.0001$, respectively) was observed, since women in 2015-2016 (2.00 [2.02 - 2.13] and 0.00 [0.74 - 0.84], respectively) had lower frequencies when compared to 2011-2012 (2.00 [2.20 - 2.38] and 1.00 [0.91 - 1.04], respectively). Additionally, an interaction was found among year and episiotomy groups (Kruskal-Wallis, $p \leq 0.0001$ and $p \leq 0.0001$, respectively). No year (Mann-Whitney test, $p = 0.241$), episiotomy (Mann-Whitney test, $p = 0.803$) and interactions (Kruskal-Wallis test, $p = 0.707$) was found on the number of previous cesareans. Considering the body mass index (BMI), a year effect (Mann-Whitney test, $p = 0.009$) indicated that women in 2011-2012 had higher median BMI (29.10 [29.43

- 29.87] kg/m^2) when compared to women from 2015-2016 group (29.00 [29.28 - 29.94] kg/m^2). An episiotomy effect and an interaction effect with year group were also observed (Mann-Whitney test, $p \leq 0.0001$; Kruskal-Wallis test, $p \leq 0.0001$), since no episiotomy women had higher median BMI (29.88 [30.28 - 20.76] kg/m^2) when compared to episiotomy group (28.70 [29.17 - 29.60] kg/m^2).

Maternal clinical characteristics were also compared between year groups, episiotomy groups and possible interactions among year and episiotomy groups. A year group effect was observed on Gestational Hypertensive Disorder (Chi-Square test, $p = 0.030$), since there was a reduction of this condition in 2015-2016 group (6.0%) when compared to 2011-2012 (7.2%). On the other hand, it was observed an increase in the frequency of Type 2 Diabetes mellitus in 2015-2016 group (0.3% when compared to 2011-2012 group (0.0%) (Chi-Square test, $p = 0.045$). HIV/AIDS frequencies were also increased in 2015-2016 group (1.9%) when compared to 2011-2012 group (0.9%) (Chi-Square test, $p = 0.006$). An episiotomy group effect was observed on HIV/AIDS (Chi-Square test, $p = 0.001$), since HIV/AIDS was strongly related to no episiotomy (2.1%), while not having HIV/AIDS was related to episiotomy (99.1%). Effects of year and episiotomy groups' interactions were highlighted on gestational Diabetes mellitus (Chi-Square test, $p = 0.001$ and $p = 0.008$, respectively), since this condition was strongly related to 2015-2016 group with no episiotomy (7.0%), while not having this diagnosis was related to 2011-2012 group with episiotomy (95.3%). Furthermore, HIV/AIDS analysis revealed an interaction among time and episiotomy groups (Chi-Square test, $p = 0.001$), since it was strongly related to 2015-2016 group with no episiotomy (2.6%), while not having this diagnosis was related to 2011-2012 group with episiotomy (99.3%). There was no effect of year, episiotomy or interaction on maternal hypertensive disorder, Diabetes mellitus type 1, Thrombophilia and Intrauterine Growth Restriction (Chi-Square test, $p > 0.05$ for all). This data is shown in **Table 2**.

Regarding maternal clinical characteristics related to delivery (**Table 3**), an interaction effect was on the frequency of premature rupture of membranes (Chi-Square test, $p = 0.017$), since this condition was strongly related to 2015-2016 group with episiotomy (24.0%), and not having this diagnosis was related to 2015-2016 group with no episiotomy (81.3%). An episiotomy effect and an interaction effect with year groups were observed on labour induction (Mann-Whitney test, $p = 0.001$; Kruskal-Wallis test, $p = 0.013$) and on oxytocin augment (Mann-Whitney test, $p \leq 0.0001$; Kruskal-Wallis test, $p \leq 0.0001$), as both were strongly associated with episiotomy (31.3% e 45.9%, respectively). Similarly, labour analgesia (epidural or spinal anesthesia) was strongly related to episiotomy (34.9%). In relation to third degree perineal injury, a year group effect was observed (Chi-Square test, $p = 0.034$), since there was an increase in this type of laceration in 2015-2016 (3.3% of all lacerations) compared to 2011-2012 (1.5% of all lacerations). In addition, an episiotomy effect was observed, and third degree perineal injury was strongly associated to episiotomy (9.5%). There

Table 2. Sample characterization—maternal clinical characteristics.

Variables—*n* (*n*%)	2011-2012			2015-2016			*p1	*p2	*p3
	Total *N* = 2043	Episiotomy *n* = 1214	No Episiotomy *n* = 829	Total *n* = 2225	Episiotomy *n* = 983	No Episiotomy *n* = 1242			
Hypertensive Disorder									
Yes	47 (2.3)	31 (2.6)	16 (1.9)	51 (2.3)	15 (1.5)	36 (2.9)	0.985	0.363	0.141
No	1996 (97.7)	1183 (97.4)	813 (98.1)	2174 (97.7)	968 (98.5)	1206 (97.1)			
Gestational Hypertensive Disorder									
Yes	148 (7.2)	87 (7.2)	61 (7.4)	125 (5.6)	59 (6.0)	66 (5.3)	**0.030**	0.494	0.160
No	1895 (92.8)	1127 (92.8)	167 (92.6)	2100 (94.4)	924 (94.0)	1176 (94.7)			
Gestational *Diabetes Mellitus*									
Yes	90 (4.4)	57 (4.7)	33 (4.0)	150 (6.7)	63 (6.4)	**87 (7.0)**	**0.001**	0.638	**0.008**
No	1953 (95.6)	**1157 (95.3)**	796 (96.0)	2075 (93.3)	920 (93.6)	1155 (93.0)			
Diabetes Mellitus Type2									
Yes	1 (0.0)	1 (0.1)	0 (0.0)	7 (0.3)	5 (0.5)	2 (0.2)	**0.045**	0.183	0.052
No	2042 (100.0)	1213 (99.9)	829 (100.0)	2218 (99.7)	978 (99.5)	1240 (99.8)			
Diabetes Mellitus Type1									
Yes	2 (0.1)	1 (0.1)	1 (0.1)	3 (0.1)	2 (0.2)	1 (0.1)	0.75	0.703	0.827
No	2041 (99.9)	1213 (99.9)	829 (99.9)	2222 (99.9)	981 (99.8)	1241 (99.9)			
Thrombophilia									
Yes	2 (0.1)	1 (0.1)	1 (0.1)	2 (0.1)	2 (0.2)	0 (0.0)	0.932	0.346	0.473
No	2041 (99.9)	1213 (99.9)	828 (99.9)	2223 (99.9)	981 (99.8)	1242 (100.0)			
Intrauterine Growth Restriction									
Yes	16 (0.8)	10 (0.8)	6 (0.7)	14 (0.6)	5 (0.5)	9 (0.7)	0.548	0.871	0.850
No	2027 (99.2)	1204 (99.2)	823 (99.3)	2211 (99.4)	978 (99.5)	1233 (99.3)			
HIV/AIDS									
Yes	19 (0.9)	8 (0.7)	11 (1.3)	41 (1.9)	11 (1.1)	**32 (2.6)**	**0.006**	**0.001**	**0.001**
No	2024 (99.1)	**1206 (99.3)**	818 (98.7)	2182 (98.1)	972 (98.9)	1210 (97.4)			

Sample medical characterization and comparisons considering year, presence of episiotomy or interactions. Legend: HIV—Human Immunodeficiency Virus; AIDS—Acquired Immunodeficiency Syndrome; *n*—Absolute Frequency; *n*%—Relative Frequency; p—Statistical significance; p1—Year Group; p2—Episiotomy Group; p3—Interaction among Year and Episiotomy Groups. Significance set as 5% for all analysis. *Chi-Square test with standardized adjusted residuals.

Table 3. Sample characterization—maternal clinical characteristics related to delivery.

Variables—*n* (*n*%)	2011-2012			201-2016			*p1	*p2	*p3
	Total *N* = 2043	Episiotomy *n* = 1214	No Episiotomy *n* = 829	Total *n* = 2225	Episiotomy *n* = 983	No Episiotomy *n* = 1242			
Premature membrane rupture									
Yes	440 (21.5)	254 (20.9)	186 (22.40	468 (21.0)	**236 (24.0)**	232 (18.7)	0.688	0.091	**0.017**
No	1603 (78.5)	960 (79.1)	643 (77.6)	1757 (79.0)	747 (76.0)	**1010 (81.3)**			
Labour Induction									
Yes	611 (29.9)	**380 (31.3)**	231 (27.9)	632 (28.4)	207 (31.2)	325 (26.2)	0.280	**0.001**	**0.013**
No	1432 (70.1)	834 (68.7)	598 (72.1)	1593 (71.6)	676 (68.8)	**917 (73.8)**			
Oxytocinaugmentation									
Yes	564 (37.7)	**398 (46.1)**	166 (26.1)	619 (36.4)	**328 (45.6)**	291 (29.6)	0.454	**≤0.0001**	**≤0.0001**
Labour Analgesia									
Yes	**588 (28.8)**	**458 (37.8)**	130 (15.7)	465 (20.9)	**308 (31.3)**	157 (12.6)	**≤0.0001**	**≤0.0001**	**≤0.0001**
No	1454 (71.2)	755 (62.2)	699 (84.3)	**1760 (79.1)**	675 (68.7)	1085 (87.4)			

Continued

Use of Forceps									
Yes	83 (4.1)	**83 (6.8)**	0 (0.0)	80 (3.6)	**79 (8.0)**	1 (0.1)	0.426	**≤0.0001**	**≤0.0001**
No	1960 (95.9)	1131 (93.2)	829 (100.0)	2145 (96.4)	904 (92.0)	1241 (99.9)			
Grade of laceration									
Third degree injury	9 (1.5)	4 (5.3)	5 (1.0)	**31 (3.3)**	**10 (14.1)**	21 (2.4)	**0.034**	**≤0.0001**	**≤0.0001**
Fourth degree injury	2 (0.3)	1 (1.3)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0.074	**0.050**	0.128

Maternal clinical characterization related to delivery and comparisons considering year (p1), presence of episiotomy (p2) or interactions (p3). Legend: md—median; 95% CI—95% Confidence Interval; *n*—Absolute Frequency; *n*%—Relative Frequency; p—Statistical significance; p1—Year Group; p2—Episiotomy Group; p3—Interaction among Year and Episiotomy Groups. Significance set as 5% for all analysis. *p1 and p2—Mann-Whitney test for independent samples or Chi-Square test with standardized adjusted residuals; *p3—Kruskal-Wallis test for independent samples or Chi-Square test with standardized adjusted residuals.

were only two cases of fourth degree perineal injury (both in 2011-2012 group), one with and the other without episiotomy.

Newborn's clinical characteristics were also compared and are shown in Table 4. An episiotomy effect was observed related to birth weight (Chi-Square test, p = 0.008), since birth weight less than 2500 g and between 3501 and 4000 g was strongly associated to no episiotomy (6.5% and 24.5%, respectively). An episiotomy effect and an interaction effect with year group were observed in relation to APGAR score greater than 7 in the first minute (Chi-Square test, p ≤ 0.0001), since it was strongly associated to episiotomy (89.6%). An episiotomy effect was also observed in shoulder dystocia and clavicle fracture (Chi-Square test, p = 0.008 and p = 0.024, respectively), since both were strongly associated to episiotomy (5.1% and 1.8%, respectively).

Univariate analysis of the factors associated with obstetric anal sphincter tear in year groups 1 (2011-2012) and 2 (2015-2016) are shown in Table 5. In the 2011-2012 period, 10 obstetric lacerations of the anal sphincter occurred in 2043 deliveries (0.48%). The number of previous vaginal deliveries (p = 0.284), maternal diabetes (p = 0.927), labor induction (p = 0.176), oxytocin use (p = 1.00), analgesia (p = 1.000) and episiotomy (p = 0.539) were not associated with its occurrence.

In the period 2015-2016, there were 31 lacerations in 2225 births (1.39%), and only the induction of labor was associated with the occurrence of OAST (p = 0.008). In this period, the episiotomy did not present any association either (p = 0.205). Factors associated with obstetric anal sphincter tear were also compared between year groups, OAST groups and possible interactions among them. Grade 1 lacerations were corrected only if bleeding or distortion of the anatomy occurred. Grade 2, 3 and 4 lacerations were always corrected. No patient had complaint of incontinence during hospitalization. The study did not perform post-discharge follow-up.

An interaction effect was noted on gestational *Diabetes mellitus* (Chi-Square test, p = 0.003), since this condition was strongly associated to OAST group and no OAST group in 2015-2016 (12.9% and 6.7%, respectively), and not having this diagnosis was associated to no OAST group in 2011-2012 (95.6%). An interaction effect was observed on induction of labour (Chi-Square test, p = 0.010),

Table 4. Sample characterization—newborn's clinical characteristics.

Variables—*n* (*n*%)	2011–2012			2015–2016			*p1	*p2	*p3
	Total *N* = 2043	Episiotomy *n* = 1214	No Episiotomy *n* = 829	Total *n* = 2225	Episiotomy *n* = 983	No Episiotomy *n* = 1242			
Sex									
Male	1020 (49.9)	619 (51.0)	410 (48.4)	1116 (50.2)	508 (51.7)	608 (49.0)	0.880	0.092	0.391
Female	1023 (50.1)	595 (49.0)	428 (51.6)	1109 (49.8)	475 (48.3)	634 (51.0)			
Weight									
<2500 g	**133 (6.5)**	69 (5.7)	**64 (7.7)**	107 (4.8)	37 (3.8)	70 (5.6)			
2501 - 3000 g	515 (25.2)	318 (26.2)	197 (23.8)	530 (23.8)	245 (24.9)	285 (22.9)	**0.015**	**0.008**	**0.003**
3001 - 3500 g	863 (42.2)	528 (43.5)	335 (40.4)	958 (43.1)	426 (43.3)	532 (42.8)			
3501 - 4000 g	436 (21.3)	244 (20.1)	192 (23.2)	**543 (24.4)**	228 (23.2)	**315 (25.4)**			
>4000 g	96 (4.7)	55 (4.5)	41 (4.9)	87 (3.9)	47 (4.8)	40 (3.2)			
APGAR score 1st minute									
>7	1902 (93.1)	1111 (91.5)	**791 (95.4)**	2033 (91.4)	858 (87.3)	**1175 (94.6)**	0.056	**≤0.0001**	**≤0.0001**
7	140 (6.9)	102 (8.4)	38 (4.6)	192 (8.6)	**125 (12.7)**	67 (5.4)			
<7	1 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)			
Newborn's Complications									
Shoulder dystocia	**104 (5.1)**	**71 (5.8)**	33 (4.0)	81 (3.6)	42 (4.3)	39 (3.1)	**0.020**	**0.008**	**0.010**
Clavicle fracture	31 (1.5)	20 (1.6)	11 (1.3)	28 (1.3)	19 (1.9)	9 (0.7)	0.469	**0.024**	0.080
Brachial plexus injury	3 (0.1)	1 (0.1)	2 (0.2)	2 (0.1)	2 (0.2)	0 (0.0)	0.587	0.703	0.348

Newborn's clinical characterization and comparisons considering year (p1), presence of episiotomy (p2) or interactions (p3). Legend: md—median; 95% CI—95% Confidence Interval; *n*—Absolute Frequency; *n*%—Relative Frequency; p—Statistical significance; p1—Year Group; p2—Episiotomy Group; p3—Interaction among Year and Episiotomy Groups. Significance set as 5% for all analysis. *p1 and p2—Mann-Whitney test for independent samples or Chi-Square test with standardized adjusted residuals; *p3—Kruskal-Wallis test for independent samples or Chi-Square test with standardized adjusted residuals. [ab]Different letters indicate statistical significance.

Table 5. Univariate analysis of the factors associated with obstetric anal sphincter tear in year groups 1 (2011-2012) and 2 (2015-2016).

Variables	2011-2012		p	2015-2016		p	#p1	#p2	#p3
	No OAST* *n* = 2033	OAST* *n* = 10		No OAST* *n* = 2194	OAST* *n* = 31				
Age (in years)—md [95% CI]	24.00 [24.73 - 25.27]	22.50 [17.96 - 29.44]	0.479	24.00 [24.98 - 25.52]	25.00 [23.70 - 28.75]	0.484	0.204	0.745	0.455
GA (in weeks)—md [95% CI]	39.43 [39.08 - 39.22]	39.71 [38.25 - 40.55]	0.687	39.43 [39.13 - 39.27]	39.43 [39.08 - 39.86]	0.644	0.333	0.500	0.718
Number of Deliveries—md [95% CI]	1.00 [0.95 - 1.07]	0.00 [−0.01 - 1.01]	0.284	0.00 [0.77 - 0.87]	0.00 [0.28 - 0.95]	0.428	**≤0.0001**	0.156	**≤0.0001**
Diabetes Mellitus							**0.001**	0.135	**0.003**
Yes	89 (4.4)	1 (10.0)	0.927	146 (6.7)	4 (12.9)	0.309			
No	1944 (95.6)	9 (90.0)		2048 (93.3)	27 (87.1)				
Induction of Labour							0.281	**0.003**	**0.010**
Yes	606 (29.8)	5 (50.0)	0.176	**616 (28.1)**	16 (51.6)	**0.008**			
No	1427 (70.2)	5 (50,0)		1578 (71.9)	**15 (48.4)**				
Oxytocin Augmentation							**0.001**	0.773	**0.009**
Yes	582 (37.6)	2 (40.0)	1.000	613 (36.4)	6 (35.3)	1.000			
No	931 (62.4)	3 (60.0)		1072 (63.3)	11 (64.7)				

Continued

Labour Analgesia							**≤0.0001**	1.000	**≤0.0001**
Yes	585 (28.8)	3 (30.0)	1.000	458 (20.9)	7 (22.6)	0.992			
No	1447 (71.2)	7 (70.0)		1736 (79.1)	24 (77.4)				
Episiotomy							**≤0.0001**	0.078	**≤0.0001**
Yes	1209 (59.5)	5 (50.0)	0.539	973 (44.3)	10 (32.3)	0.205			
No	824 (40.5)	5 (50.0)		1221 (55.7)	21 (67.7)				
Newborn Shoulder Dystocia							**0.025**	**0.036**	**0.004**
Yes	102 (5.0)	2 (20.0)	0.153	78 (3.6)	3 (9,7)	0.185			
No	1931 (95.0)	8 (80.0)		2116 (96.4)	28 (90.3)				
APGAR Score 1st minute							0.056	0.889	0.211
>7	1894 (93.2)	8 (80.0)	0.256	2004 (91.3)	29 (93.5)	0.664			
7	1 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)				
<7	138 (6.8)	2 (20.0)		190 (8.7)	2 (6.5)				
Birthweight							**0.015**	0.054	**0.017**
<2500 g	132 (6.5)	1 (10.0)	0.225	107 (4.9)	0 (0.0)	0.168			
2501 - 3000 g	513 (25.2)	2 (20.0)		524 (23.9)	6 (19.4)				
3001 - 3500 g	860 (42.3)	3 (30.0)		947 (43.2)	11 (35.5)				
3501 - 4000 g	434 (21.3)	2 (20.0)		532 (24.2)	11 (35.5)				
>4000g	94 (4.6)	2 (20.0)		84 (3.8)	3 (9.7)				

Clinical characterization and comparisons considering year (p1), presence of Obstetric Anal Sphincter Tear (p2) or interactions (p3). Legend: md—median; 95% CI—95% Confidence Interval; *n*—Absolute Frequency; *n*%—Relative Frequency; OAST—Obstetric Anal Sphincter Tear, NICU—Neonatal Intensive Care Unit; p—Statistical significance, p1—Year Group; p2—OAST Group; p3—Interaction among Year and OAST Groups. Significance set as 5% for all analysis. *Mann-Whitney test for independent samples or Chi-Square test with standardized adjusted residuals. #p1 and p2—Mann-Whitney test for independent samples or Chi-Square test with standardized adjusted residuals; #p3—Kruskal-Wallis test for independent samples or Chi-Square test with standardized adjusted residuals.

since induction was strongly associated to OAST in 2015-2016 group (51.6%). Oxytocin augmentation analysis revealed an interaction among time and OAST groups (Chi-Square test, p = 0.009), since it was strongly associated to no OAST in 2011-2012 group (89.1%), and its non use was strongly associated to no OAST in 2015-2016 group (17.4%). An interaction effect was observed on labour analgesia (Chi-Square test, p ≤ 0.0001), since it was strongly associated to no OAST in 2011-2012 group (28.8%), and not having analgesia was strongly associated to no OAST in 2015-2016 (79.1%). A year group effect was noted on episiotomy (Chi-Square test, p ≤ 0.0001), since there was a reduction of episiotomies in 2015-2016 group (44.2%) when compared to 2011-2012 (59.4%). An interaction effect on episiotomy was also observed (Chi-Square test, p ≤ 0.0001), since it was strongly related to 2011-2012 group with no OAST (59.5%), while not having an episiotomy was related to both OAST (67.7%) and no OAST (55.7%) group in 2015-2016. No effects were observed in maternal age and gestational age.

Regarding newborn's characteristics, there was a year group, an OAST group and an interaction effect on shoulder dystocia (p = 0.025 and p = 0.004, respec-

tively), since there were more cases in 2011-2012 group (5.1%) than in 2015-2016 (3.6%). This condition was strongly associated to OAST group (12.2%). In addition, it was strongly associated to OAST group (20.0%) and no OAST group (5.0%) in 2011-2012, and its absence was strongly associated to no OAST group in 2015-2016 (96.4). An interaction effect was also observed on birth weight ($p = 0.017$). Newborn weight less than 2500 g was strongly associated to no OAST in 2011-2012 group (6.5%), while newborn weight more than 4000 g was associated to OAST in the same year group (20.0%). Newborn weight was associated to both OAST and no OAST 2015-2016 group (35.5 and 24.2%). No effects were observed concerning APGAR scores in first minute and neonatal Intensive Care Unit admission.

4. Discussion

The primary reason for performing episiotomy is to avoid large and irregular spontaneous lacerations of the perineum, with the reason that the episiotomy incision would be easier to repair than spontaneous lacerations. It could also be performed to increase the way out size of soft pelvic tissue, which is useful in macrosomic fetus. However, in a systematic review of interventions related to perineal trauma, Eason *et al.* [10] found that avoiding routine episiotomy significantly reduced perineal trauma.

The association of OAST and episiotomy remains controversial. The limited evidence from randomized clinical trials suggests that the restrictive use of episiotomy leads to better healing, less need for suturing and reduction of perineal trauma. On the other hand, a large observational study [11] suggested that medial-lateral episiotomy is associated with a reduced risk of OAST. In Finnish study [12], both nulliparous and multiparous women, had an increase in the incidence of OAST with a decrease of episiotomy. A positive association between OAST and episiotomy was observed, when it was used in a restricted way. The work suggests that episiotomy rates can be safely reduced in women with low OAST risk, without increasing rates of perineal injury. The risk is established based on the newborn birth weight, number of previous vaginal deliveries, previous cesarean before the first vaginal delivery and mode of birth.

In our study, compared to the two periods, the rate of episiotomy fell from 59.4% to 44.2% ($p \leq 0.0001$). Although the fall was statistically significant, a greater reduction in the rate of episiotomy was expected in the period 2015-2016. There was an increase in the rate of anal sphincter injury with a decrease in the rate of episiotomy. This increase occurred in both the episiotomy and non-episiotomy groups. Third degree laceration rate was 0.48% in period 1 (2011-2012), and 1.39% in period 2 (2015-2016). This is probably due to the failure to perform episiotomy when there would be indication or insufficient and late incision in the cases in which episiotomy were performed, due to delay in the decision in performed the procedure. The fact of the study was carried out in a school hospital also serves as an explanation, because with the decrease of episiotomy, the

learning curve increases, leading to an increase of insufficient and late episiotomies. However, the association between episiotomy practice and reduction in the occurrence of laceration remains controversial. It is not possible to affirm that the routine use of episiotomy actually reduces OAST. Furthermore, the fact that our study is observational only allows us to propose this association. Randomized clinical trials should be made to confirm if there is an association between episiotomy practice and OAST reduction. Considering the two periods, there was an association with OAST and labor induction ($p = 0.003$) and shoulder dystocia ($p = 0.025$).

In our study, the restricted use of mediolateral episiotomy was not an anal sphincter protective factor. Yamasato *et al.*, in a retrospective study analyzing 22,800 deliveries, found that episiotomy was associated with increased risk of OAST, regardless of parity ($p < 0.0001$) [13]. Similarly, a Cochrane review of 2017 [1] analysed 12 randomized clinical trials (6177 patients) comparing restricted use of episiotomy with the liberal one. Restricted use resulted in 30% fewer severe perineal lacerations (RR = 0.70, 95% CI = 0.52 - 0.94, 5375 women, 8 clinical trials). However, the analysis included both medial and mediolateral episiotomy, and the rate of episiotomy in these studies ranged from 8% to 59% in the selective use group, and 61% to 100% in the routine group. EPITRIAL study [14] randomized nulliparous patients to standard or non-episiotomy and observed a higher incidence of OAST in the standard care group (3.9% versus 1.3%, OR = 0.33, 95% CI = 0.06 - 1.65). However, in this study, the rate of episiotomy was similar in both groups ($p = 0.35$). Conversely, some studies have observed mediolateral episiotomy as a protective factor for OAST. Zafran and Salim [15], in a retrospective study comparing selective and routine use of episiotomy, found that the incidence of OAST was significantly higher with selective use (OR = 2.23, 95% CI = 1.16 - 4.29, $p = 0.02$) Gundabattula and Surampudi [16], in a retrospective study, evaluated the occurrence of OAST and identified episiotomy as a protective factor (OR = 0.57, 95% CI = 0.40 - 0.83, $p = 0.003$) and Verghese *et al.* [17], in a systematic review comparing OAST rates, found that episiotomy was a protective factor (RR = 0.67, 95% CI = 0.49 - 0.92). In this review, all the studies evaluated were non-randomized, population-based or retrospective.

Revicky [18] and colleagues analyzed a number of risk factors for OAST, including primiparas, maternal age, use of sintocinone (synthetic form of oxytocin), and shoulder dystocia. In that study, there was an increase in the incidence of OAST in the comparison between 2005 and 2007. Authors believe it is related to a better ability of physicians in detect lesions, rather than changes in risk factors. Furthermore, episiotomy was associated with a lower risk of OAST, but this is probably due to the fact that only high risk women (older and more difficult delivery) had episiotomies. After multivariate analysis, the episiotomy remained as a protective factor for OAST. Vaginal births without mediolateral episiotomy had 1.4 times higher risk of OAST than those with it. Authors, however, recommend caution and believe a randomized clinical trial is necessary to confirm

these findings.

Our study found that the occurrence of obstetric anal sphincter tear was strongly associated with restrictive mediolateral episiotomy. The technique of the incision in relation to the length, depth and angle in relation to the midline was not evaluated in this study. Eogan *et al.* [19], in a case-control study, compared the angle of episiotomy 3 months after delivery in patients with and without OAST. The mean angle of the episiotomy was significantly lower in the cases of OAST (30˚, 95% CI = 28˚ - 32˚) than in the controls (38˚, 95% CI = 35˚ - 41˚, $p < 0.001$). This could justify the occurrence of obstetric lacerations of the anal sphincter found in both periods of our study, since this data was not evaluated. Another important fact to note is that, because it is performed by physicians in obstetric training, the restriction of episiotomies has led to less experience in the adequate performance of these. When indicated, it may not have been performed at the appropriate size, depth and angle. Episiotomy could decrease the incidence of lacerations, provided that it is done following criteria. Indications of this procedure should be accurate and the technique should be improved using mannequins. Since HCPA is a school hospital, the presence of a preceptor is mandatory, which helps improving the technique of medical students. The indications for episiotomy in the Hospital de Clínicas of Porto Alegre are: perineal body smaller than 3 cm; non-reassuring fetal condition; fetal macrosomia; shoulder dystocia; posterior varieties of presentation (relative indication); instrumental delivery (relative indication); pelvic presentation and maternal diseases that prevent vigorous pulling (such as myocardiopathy) [20]. All operative deliveries were performed with episiotomy and forceps in our study. De Leeuw *et al.* [21], in a population-based observational study, found that mediolateral episiotomy was a protective factor in instrumental delivery with forceps (OR = 0.08; 95% CI = 0.07 - 0.11) (De Leeuw *et al.*, 2008). Another population-based retrospective study found similar data in which mediolateral episiotomy in forceps delivery was associated with a 5-fold reduction in the risk of OAST in primiparous and multiparous women [22].

Steiner and associates [23] investigated whether episiotomy decreases OAST in specific conditions of higher risk: shoulder dystocia, occipito-posterior position variation, pelvic presentation, non-reassuring fetal condition, macrosomia, instrumental delivery, oligodrhamium, pre-eclampsia, rupture of premature ovary membranes and epidural anesthesia. Even under these conditions, restricted use of episiotomy is independently associated with OAST.

There was no increase in OAST in cases of analgesia. Loewenberg-Weisband *et al.* [24] find association between analgesia and sphincter laceration (OR = 1.78; 95% CI = 1.34 - 2.36); however, the association was no longer observed after adjustment for parity.

In 2006, the American College of Obstetricians and Gynecologists released a newsletter discouraging the routine use of episiotomy [25]. However, studies more recent and after restricted use of episitomy have shown that this behavior increased OAST [12] [21].

The present study found no association with oxytocin and OAST. Few studies evaluate the use of oxytocin during labor to correct uterine dynamics as the main outcome. In a case-control study conducted by Rygh *et al.* (2014), oxytocin use was associated with an increased risk of OAST in births weighing more than 4 kilograms (OR = 1.8, 95% CI = 1.5 - 2.2) [26].

The association between OAST and birth weight greater than 4000 g was observed only in the period 2011-2012. This period presented a higher proportion of newborns weighing more than 4000 g (4.7%) when compared with the period 2015-2016 (3.9%) (p = 0.015). In both periods, newborns weighing more than 4000 g were strongly associated with episiotomy. Studies evaluating risk factors for OAST describe birth weight as an associated factor. Sooklim *et al.* [9], in a prospective cohort, found the newborn weight greater than 3500 grams as an independent risk factor for severe perineal laceration (RR = 2.22, 95% CI = 1.46 - 3.38).

There were more cases of dystocia in the period 2011-2012, and this condition was strongly associated with OAST. Hehir *et al.* [4] in a retrospective study found that episiotomy was a protective factor in cases of shoulder dystocia (p = 0.006). Likewise, Gundabattula and Surampudi [16] demonstrated an association between dystocia and OAST (OR = 7.81, 95% CI = 4.30 - 14.18; p = 0.000).

The positive aspects of our work include the number of patients analyzed, all the episiotomies followed the same technique (mediolateral) and the fact that there are few studies done in this model with the Brazilian population. Our study can evaluate the factors associated with episiotomy and the occurrence of OAST.

Some limitations may be cited. Because it is a study carried out by reviewing medical records, data may have been incomplete or incorrectly filled in. Some partial lacerations may not have been identified at the time of delivery, and therefore have not been described. The procedure was performed by physicians in training in the area of obstetrics, with great variation in technique. In the second period of analysis, by doing the procedure less, doctors may tend to perform episiotomies of insufficient size, failing to achieve the desired goal of preventing severe perineal lacerations.

Other information not described in medical records is the indication of the episiotomy and the data such as depth, length and angulation. Moreover, because it is a retrospective analysis, this type of study does not allow the identification of causality

5. Conclusion

Literature is still controversial about the role of episiotomy in OAST. Restricted use has increased the incidence of 3rd and 4th degree lacerations, according to studies in northern European countries. In our study, the restricted use of episiotomy increased OAST rates, both in the group with and without the procedure. With the changes of indication for performing episiotomy, it takes time to train

new protective measures for lacerations, which may have contributed to its increased incidence in both groups. However, in most analyses, no study considers the incision technique of episiotomy in relation to depth and angle, which may be a confounding factor.

Author Contribution

EG Valério, J Vettorazzi, FS Grossi, S Schneider conceptualized/designed the study. S Schneider, NM da Silva and AV Perez worked on data collection. M Sabraini revised the manuscript. S Schneider, J Vettorazzi, FS Grossi, SH Martins-Costa, EG Valério and AV Perez carried out the initial analyses, drafted the initial manuscript, critically reviewed and revised the manuscript. All authors read and approved the final manuscript as submitted.

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Conflicts of Interest

All authors read and approved the submitted manuscript. None of the authors has any conflicts of interest related to this study, whether financial or of any other nature.

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