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Qualification en Gynécologie-Obstétrique

Is there still an indication of episiotomy? Results from a French national hospital discharge cohort

Existe-t-il encore une indication à l'épisiotomie ? Résultats d'après les
données du Programme de médicalisation des systèmes d'information

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Sous la direction de M. LEGENDRE Guillaume

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Liste des abréviations

[illegible]

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INTRODUCTION

The episiotomy is a surgical cut made at the opening of the vagina during childbirth, to aid a difficult delivery and prevent severe perineal tear. At first, episiotomy was realised to protect maternal perineum during childbirth and then to protect the foetus of hypoxia.

Several variations of episiotomies are described in literature as medial, mediolateral and lateral. Recent studies indicate that mediolateral episiotomy is protective against obstetric anal sphincter injuries (OASIS) (1) especially compared to medial episiotomy. Mediolateral episiotomy is the recommended episiotomy in both France (2) and United Kingdom (3).

OASIS are a common cause of anal incontinence in women (18). OASIS is a severe perineal tear occurring at vaginal delivery, causing partial or total rupture of the anal sphincter with perineal pain, urinary or anal incontinence and sexual disorder as consequences. This can be physically and mentally devastating.

The severity of OASIS is classified according to standard definition. Third degree rupture of the perineum is divided in three grades: 3a, up to 50% of external anal sphincter involved; 3b, over 50% of external sphincter involved; 3c, complete injury of external and internal anal sphincter. Fourth degree represents injury of anal sphincter and rectum (4).

The prevalence of OASIS is from 0.1% to 5% (5, 6).

The purpose of episiotomy is either to expedite delivery in the case of foetal distress, increase the area of passage in cases of instrumental deliveries or shoulder dystocia, or to minimise the risk of OASIS.

The use of episiotomy and its association with OASIS is a controversial source of debate. Furthermore, although routine episiotomy had been thought to have various advantages such as protection against severe perineal lacerations, two Cochrane systematic reviews of

randomized controlled trials concluded that routine episiotomy increases the risk of severe perineal trauma without any improvement of other outcomes (7, 8, 9).

Because episiotomy could be associated with postpartum haemorrhage, perineal pain and sexual disorder (10), a restrictive practice of episiotomy has therefore been promoted and its use has decrease in many countries but with discordances (6). World Health Organization considers a 10% episiotomy rate a reasonable target (11).

There is a large increase of OASIS incidence recorded in the last two decades (6). Now, studies are not able to tell if this increase is because of the knowledge of OASIS or because of the decrease of episiotomy.

The aim of this study is to determine in a large cohort the impact of the mediolateral episiotomy (gold standard in France) on the risk of OASIS.

METHOD

Data were collected from the French national hospital discharge register PMSI [Programme de médicalisation des systèmes d'information], which is national medico-administrative databases.

In the French PMSI database, data concerning the wholeness of hospital stays are collected, patients characteristics as age, sex or diagnosis according to the ICD-10. The PMSI does not contain any valuable information about clinical results. The data contained in this database are fully anonymized.

1. Study population

Women were included if they were between 18 and 50 years old and if they have stayed in a hospital facility either between the 1st of January 2018 and the 31rd December 2018 with a delivery procedure code [Z37 based on the International Classification of Diseases 10th edition (ICD-10)]. A sensibility analysis was provided among women between the same age range that stayed in a hospital facility within the 1st January 2012 and the 31rd December 2012 or the 1st January 2015 and the 31rd December 2015, with the same delivery procedure code. Women who underwent either a programmed or an emergency cesarean [082 and 084.2 ICD-10 codes] were excluded.

2. Defining variables

The primary outcome was Obstetric Anal Sphincter Injuries (OASIS) during the hospital stay [as third- and fourth-degree perineal lacerations, respectively as ICD-10 O702 or CCAM JMCA003 and ICD-10 O703 or CCAM JMCA001 based on the French Classification Commune des Actes Médicaux (CCAM)].

Variables collected were age, gestational age, episiotomy [CCAM JMPA006], multiple pregnancy [ICD-10 O84], obesity [ICD-10 E66].

Suspected risk-factor for OASIS were collected, primiparity [JQGD013 or JQGD003 or JQGD010 or JQGD002 or JQGD004 according to CCAM], including instrumental delivery [ICD-10 O81 or O841], gestational diabetes [ICD-10 O24], breech delivery [ICD-10 O80.1, O83.1 or CCAM JQGD013, JQGD003, JQGD001, JQGD008, JQGD004, JQGD005] shoulder dystocia [ICD-10 O660], or a long delivery time [ICD-10 O639]. Prolonged pregnancy was defined as a pregnancy longer than 41 weeks and post-term pregnancy for longer than 42 weeks.

3. Statistical analysis

Quantitative variables were expressed as mean and standard deviation and compared using student t-tests. Qualitative variables were expressed as percentage and compared using chi-square tests.

The relationship between OASIS from one hand, and mediolateral episiotomy, age, gestational diabetes, multiple delivery, Crohn disease, primiparity, instrumental delivery, breech delivery, gestational age, prolonged delivery time or shoulder dystocia from the other hand was explored using multivariate logistic regressions. An interaction between episiotomy and gestational diabetes, primiparity, instrumental delivery, multiple pregnancy, shoulder dystocia for studying the variation of episiotomy impact on OASIS depending on whether episiotomy was performed in the presence of OASIS risk-factors or not. For significant interactions, a conditional effect model was realized. The identified conditional effect model was then realized on the year 2012 and 2015 to confirm the results found in the year of interest.

All the tests were two-sided, considering a p-value threshold at 0.05. The statistical analyses were performed using SAS 9.4.

RESULTS

At all, 811 330, 781 998 and 738 835 hospitalizations for delivery were identified from French PSMI, for 2012, 2015 and 2018 respectively. After exclusion of hospitalization in which a cesarean was performed (2012: 131 196, 16.17%; 2015: 124 189, 15.88%; 2018: 115 832, 15.68%), 674 375, 652 935 and 623 003, parturient were included for 2012, 2015 and 2018 respectively.

Mean age at delivery slightly grew from 29.6 ($\pm$ 5.25) in 2012 to 29.9 ($\pm$ 5.20) in 2015 and 30.3 ($\pm$ 5.21) in 2018. OASI percentage grew from 0.79% in 2012 to 0.98% in 2015 and 1.14% in 2018, whereas mediolateral episiotomy percentage decreases from 20.91% in 2012 to 17.75% in 2015 and 10% in 2018.

Percentage of primiparous delivery was consistent though time, with 40.26% in 2012, 39.17% in 2015 and 38.51% in 2018.

The demographic characteristics were reported in the table 1.

1. Factors associated with Obstetric Anal Sphincter Injuries

Primiparity, shoulder dystocia, instrumental delivery and gestational diabetes were highlighted to be risk-factors for OASIS in 2018, confirmed in 2012 and 2015 ($p < 0.001$). Age only in 2015, post-term delivery and prolonged expulsive efforts (≥ 42 weeks) only in 2012 and 2018 and breech delivery only for 2015.

Multiple delivery was identified as protective from OASIS in 2018 (OR: 0.601; IC95% [0.421-0.860]; $p = 0.05$), but no association was found either in 2012 and 2015 (respectively $p = 0.1646$ and $p = 0.731$) (table 2).

2. Effect of mediolateral episiotomy on Obstetric Anal Sphincter Injuries

In our first analysis without interaction, episiotomy is associated with a higher rate of OASIS in 2018 after adjustment for all the included covariates (OR 1.79, IC 95% [1.66-1.92], $p < 0.001$). As an interaction is found significant for primiparity and instrumental delivery in 2018 ($p < 0.001$), we performed a conditional effect model in which episiotomy was identified as a risk factor for OASIS in all cases excepted when performed in primiparous who delivered with instrumental help for whom mediolateral episiotomy was protective.

Sensitivity analysis performed for 2012 and 2015 confirmed the presence of such a protective approach.

Episiotomy performed for non-primiparous women was also identified as a risk-factor for OASIS in 2012 and 2015, with or without instrumental delivery. As for primiparous woman who did not underwent an instrumental delivery, episiotomy was identified as a risk-factor for OASIS (Table 2).

3. Decrease of episiotomy and association with OASIS increase

Percentage of women suffering from OASIS after delivery increases from 0.79% in 2012 to 0.98% in 2015 and 1.14% in 2018. During the same period, mediolateral episiotomy rate decreases from 20.91% to 10% (table 1). The percentage of episiotomy performed decreased through years for women who did not have an instrumental help for delivery but increase for the one with an instrumental help, whatever the parity was (Table 3, Figure 1).

We can assess in 2018, if episiotomy was performed in all primiparous woman who underwent an operative delivery and none in woman multiparous without such an operative delivery, and with similar other parameters, we could have expected 5 070 OASIS, meaning a decrease of 11% of the observed number.

DISCUSSION

Our study gathered 623 003 women who delivered in a French hospital in 2018, along with 674 375 in 2012 and 652 935 in 2015, reporting one largest study based on administrative database exploring episiotomy use and its consequences in the general population.

Our study highlights six risk factors of OASIS, namely primiparity, shoulder dystocia, instrumental delivery, gestational diabetes, prolonged expulsive efforts and post-term delivery.

Regarding the rate of episiotomy, we clearly show a decrease in its use during the study period from 20.91% in 2012 to 10% in 2018, which is correlate to a more restrictive policy and in agreement with the WHO target of 10 % (11).

At the same time, we could observe an increased rate of OASIS (0.79% in 2012, 0.98% in 2015, 1.14% in 2018), as reported by Blondel et al. in 2016, increasing from 0.5% to 4% in Europe (6). This rate increases mainly in women who underwent an instrumental delivery, whatever their parity. For non-primiparous women we find that performing a mediolateral episiotomy increases the OASIS rate.

The six risk factors were identified also in 2012 and 2015, except for post-term delivery and prolonged pregnancy. These factors are congruent with the ones by Pergialiotis et al. in their meta-analysis (1): according to twenty-two studies, 651 934 women, instrumental delivery and primiparity are important risk-factors for OASIS.

Our rates are coherent with the ones reported in a large European study (6) reporting episiotomy rates between 16 and 38% for all vaginal deliveries according to data about the Euro-Peristat indicators in 2004 and 2010 (20 countries).

Our study should be considered with limitations. First, all the known risk-factors for OASIS could not be included in the multivariate model. Indeed, macrosomia is not represented because of mistakes in the coding. In order to have of reflect of such factor, we chose to search for gestational diabetes as a proxy, and it appeared to be a risk factor of OASIS in all the three years investigated. Ethnicity, which is also a known factor as Asian origin is associated with a higher OASIS rate (1) could not be explored as French legislation does not allow to register ethnic characteristics.

In The Netherlands, they use the national registry to analyse the effectiveness of mediolateral episiotomy preventing OASIS with ten years data. According to 170.969 women who underwent vacuum or forceps delivery with the help of a mediolateral episiotomy, they demonstrate a fivefold to tenfold reduction in the rate of OASIS in primiparous (26.7% to 3.4%) and multiparous (14.2% to 2.6%) (14). But this study did not compare such rates with non-instrumental delivery as we demonstrated a significant interaction between those factors.

A clinical trial in Brazil randomized 237 women to a non-episiotomy protocol (115 women) or to a restrictive episiotomy group (control group, 122 women) to evaluate maternal and perinatal outcomes. The episiotomy rate was 1.7% in each group which is not representative of the general population (54%in Brazil). They don't find any difference between the two groups in severe perineal trauma (15;20), probably due to a small sample size.

Pergialotis et al. find an association between episiotomy (every type) and OASIS, but not in the same way: median episiotomy was associated with an increase in OASIS rates whereas mediolateral ones were identified as protective.

Raisanen, using the Finnish Medical Birth Register, analyses the changing associations of episiotomy and OASIS. According to a risk score calculated using the OASIS incidence in groups

(number of prior vaginal birth, birth weight strata, mode of current delivery), he observes an increase of the OASIS rate in patients with episiotomy. This relationship could be explained by a better selection of patients in which episiotomy should be performed (i.e. patients with high risk of OASIS) (12).

In our study, we find a similar result. The increase of OASIS may be due to the decrease of episiotomy. We can observe an increase of the high-risk population of OASIS (women with operative delivery) suggesting the need of a better selection of women who need an episiotomy and the one who don't (multiparous with an instrumental delivery).

With this better selection, we can assess a diminution of 11% of OASIS.

The relationship between episiotomy and OASIS can be also explained by the increasing trend of instrumental delivery.

Indeed, our study found an increase of episiotomy rate from 9.47% to 10.85% in 6 years, congruent with the increase described across many European countries and reported by Blondel. Our results are also in accordance with a Finnish study of 384 638 patients finds similar results with an increase of OASIS from 1.3 to 1.7% in primiparous women meanwhile a similar decrease of 10% the rate of episiotomy (from 56.7 to 45.5%) was observed over the study period (12).

Nevertheless, this important increase in OASIS rate might be attributed not only to this increase of instrumental procedures but also to the new classification of perineal injury used (4) or to the new imaging methods including endoanal sonography, which earlier identifies injuries that previously were occult (16). A better identification of lesions in connection with better awareness and training of caregivers may also be a hypothesis that could explain the increased prevalence of OASIS. Finally, such an increase may be caused by a change in eating

habits within the last decades, leading to maternal obesity and consequently to increase in newborn weight. An increase of newborn weight is known to increase the number of delivery-related injuries of birth canal (13), and OASIS (1).

Our statistical analysis leads to define four groups of patients with episiotomy as, (i) non-primiparous without instrumental delivery, (ii) non-primiparous with instrumental delivery, (iii) primiparous without instrumental delivery and (iv) primiparous with instrumental delivery, which is innovating to study the evolution of the episiotomy-OASIS relationship.

This work clearly showed that the main indication of episiotomy should be the primiparous women who need an instrumental delivery. These results may need to be refined with other risk factors as BMI, ethnicity, macrosomia.

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	2012		2015		2018	
	N =	674 375	N =	652 935	N =	623 003
Age	29.6	5.25	29.9	5.20	30.3	5.21
Crohn disease	486	0.07%	568	0.09%	617	0.10%
Gestational diabetes	39051	5.79%	54490	8.35%	64592	10.37%
Primiparity	271490	40.26%	255753	39.17%	239949	38.51%
Multiple delivery	3720	0.55%	3907	0.60%	3886	0.62%
Post-term delivery	115470	17.12%	117564	18.01%	115317	18.51%
≥ 41 weeks	109706	16.27%	112784	17.27%	110397	17.72%
≥ 42 weeks	5764	0.85%	4780	0.73%	4920	0.79%
Breech delivery	7282	1.08%	7090	1.09%	6902	1.11%
Long delivery time	18482	2.74%	20350	3.12%	22062	3.54%
Prolonged expulsive efforts	14182	2.10%	15371	2.35%	15583	2.50%
Instrumental delivery	63887	9.47%	65807	10.08%	67609	10.85%
Mediolateral episiotomy	141000	20.91%	115894	17.75%	62310	10.00%
Shoulder dystocia	9004	1.34%	8422	1.29%	9300	1.49%
OASIS	5324	0.79%	6392	0.98%	7077	1.14%

Table 1 - Demographic characteristics of the population

	2012		2015		2018	
	Odds ratio [IC95%]	p value	Odds ratio [IC95%]	p value	Odds ratio [IC95%]	p value
Intercept		<.0001		<.0001		<.0001
Age	1.006 [1.001 ; 1.012]	0.0312	1.008 [1.003 ;1.013]	0.003	0.995 [0.990 ;1.000]	0.0392
Gestational diabetes	1.211 [1.082 ; 1.351]	0.0007	1.212 [1.111 ;1.320]	<.0001	1.202 [1.114 ;1.296]	<.0001
Primiparity	3.246 [3.009 ; 3.504]	<.0001	3.444 [3.221 ;3.683]	<.0001	2.972 [2.796 ;3.159]	<.0001
Instrumental delivery	4.198 [3.874 ; 4.545]	<.0001	3.752 [3.497 ;4.024]	<.0001	3.811 [3.587 ;4.050]	<.0001
Multiple delivery	0.762 [0.507 ; 1.094]	0.1646	0.947 [0.685 ;1.272]	0.731	0.601 [0.421 ;0.860]	0.005
Shoulder dystocia	2.786 [2.436 ; 3.174]	<.0001	3.021 [2.672 ;3.403]	<.0001	2.569 [2.293 ;2.878]	<.0001
Prolonged expulsive efforts	1.720 [1.547 ; 1.908]	<.0001	1.460 [1.323 ;1.607]	<.0001	1.534 [1.407 ;1.672]	<.0001
Breech delivery	1.122 [0.848 ; 1.452]	0.3987	1.276 [1.008 ;1.590]	0.036	1.231 [0.982 ;1.543]	0.072
Prolonged pregnancy (>=41Wk)	1.271 [1.189 ; 1.358]	0.9358	1.303 [1.227 ;1.382]	0.010	1.313 [1.242 ;1.388]	0.596
Post-term delivery (>=42Wk)	1.600 [1.275 ; 1.979]	0.0018	1.374 [1.884; 1.715]	0.113	0.234 [0.107 ;0.360]	0.0003
Episiotomy if not primiparous and not an instrumental delivery	2.160 [1.873 ; 2.480]	<.0001	2.017 [1.745 ;2.320]	<.0001	2.418 [2.022 ;2.866]	<.0001

Episiotomy if not primiparous but instrumental delivery	1.260 [1.016 ; 1.548]	0.0313	1.250 [1.020 ;1.520]	0.0281	1.320 [1.068 ;1.616]	0.009
Episiotomy if primiparous but not an instrumental delivery	1.087 [0.996 1.186]	0.0610	0.977 [0.896 ;1.064]	0.5939	1.255 [1.134 ;1.386]	<.0001
Episiotomy if primiparous and instrumental delivery	0.540 [0.489 0.596]	<.0001	0.521 [0.475 ;0.571]	<.0001	0.616 [0.562 ;0.673]	<.0001

Table 2 - Multivariate logistic regression with conditional effects for OASIS

	2012	2015	2018
Episiotomy if not primiparous and not an instrumental delivery	25.0%	23.7%	19,9%
Episiotomy if not primiparous but instrumental delivery	4.2%	5.0%	6.6%
Episiotomy if primiparous but not an instrumental delivery	50.1%	47.4%	42.7%
Episiotomy if primiparous and instrumental delivery	20.6%	23.9%	30.8%

Table 3 - Percentage of mediolateral episiotomy performed on patients according to risk factors for OASIS

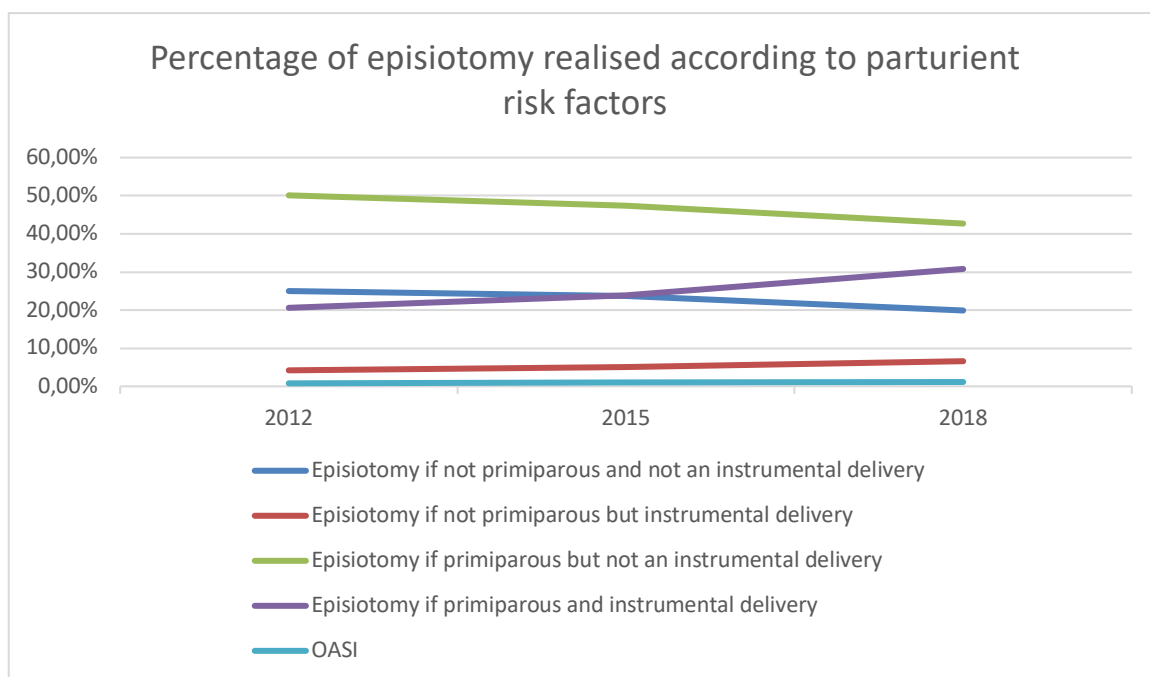


Figure 1 - Percentage of mediolateral episiotomy performed on patients according to risk factors for OASIS

Existe-t-il encore une indication à l'épisiotomie ? Résultats d'après les données du Programme de médicalisation des systèmes d'information

RÉSUMÉ

Introduction : L'épisiotomie est une incision chirurgicale réalisée à l'entrée de du vagin pendant l'accouchement. Les lésions obstétricales du sphincter de l'anus (LOSA) sont une des causes les plus communes d'incontinence anale chez la femme. Le recours à l'épisiotomie et sa relation avec les LOSA sont de plus en plus controversés.

Méthode : Les données utilisées sont collectées via le Programme de médicalisation des systèmes d'information (PMSI). Les femmes incluses ont entre 18 et 50 ans, ont été admises à l'hôpital pour accoucher en 2012, 2015 et 2018. Les accouchements par césarienne sont exclus. La relation entre les LOSA d'un côté, et l'épisiotomie médio-latérale, l'âge, le diabète gestationnel, l'accouchement multiple, la maladie de Crohn, la primiparité, l'extraction instrumentale, l'accouchement par le siège, l'âge gestationnel, le temps de travail prolongé et la dystocie des épaules de l'autre côté est explorée en utilisant une régression logistique multivariée. Une interaction entre l'épisiotomie et le diabète gestationnel, la primiparité, l'extraction instrumentale, l'accouchement multiple, la dystocie des épaules est réalisée pour étudier la variation de l'impact de l'épisiotomie sur les LOSA selon que l'épisiotomie ait été réalisée en présence ou non d'un facteur de risque de LOSA.

Résultats : 674 375, 652 935 et 623 003 femmes sont incluses en 2012, 2015 et 2018. La primiparité, la dystocie des épaules, l'extraction instrumentale et le diabète gestationnel sont mis en évidence comme étant des facteurs de risque de LOSA en 2018, confirmé en 2012 et 2015 ($p < 0.001$).

Dans notre première analyse sans interaction, l'épisiotomie est associée à un plus haut taux de LOSA en 2018 après ajustement (OR 1.79, IC 95% [1.66-1.92], $p < 0.001$). Nous avons réalisé un modèle à effet conditionnel dans lequel l'épisiotomie est identifiée comme facteur de risque de LOSA dans tous les cas sauf chez la primipare accouchant avec extraction instrumentale où l'épisiotomie est protectrice. L'épisiotomie réalisée chez la multipare est identifiée comme un facteur de risque de LOSA en 2012 et 2015 avec ou sans extraction instrumentale.

Le pourcentage d'épisiotomies diminue lors des accouchements sans extraction instrumentale mais augmente lors des accouchements avec extraction instrumentale, quelle que soit la parité (tableau 3, figure 1).

Discussion : Ce travail met clairement en évidence que l'indication première de l'épisiotomie est l'extraction instrumentale chez la primipare. Ce résultat nécessite d'être affiné avec les autres facteurs de risque à savoir l'IMC, l'origine ethnique, la macrosomie.

Mots-clés : épisiotomie, LOSA, PMSI

Is there still an indication of episiotomy? Results from a French national hospital discharge cohort

ABSTRACT

Introduction: Episiotomy is a surgical cut made at the opening of the vagina during childbirth. Obstetric anal sphincter injuries (OASIS) are one of the most common cause of anal incontinence in women. The use of episiotomy and its association with OASIS is more and more controversial.

Methods: Data were collected from the French national hospital discharge register PMSI (Programme de médicalisation des systèmes d'information). Women were included if they were between 18 and 50 years old and if they stayed in a hospital facility in 2018, 2015 and 2012 for a vaginal delivery. The relationship between OASIS from one hand, and mediolateral episiotomy, age, gestational diabetes, multiple delivery, Crohn disease, primiparity, instrumental delivery, breech delivery, gestational age, prolonged delivery time or shoulder dystocia from the other hand was explored using multivariate logistic regressions. An interaction between episiotomy and gestational diabetes, primiparity, instrumental delivery, multiple pregnancy, shoulder dystocia for studying the variation of episiotomy impact on OASIS depending on whether episiotomy was performed in the presence of OASIS risk-factors or not

Results: 674 375, 652 935 and 623 003 parturient were included for 2012, 2015 and 2018 respectively. Primiparity, shoulder dystocia, instrumental delivery and gestational diabetes were highlighted to be risk-factors for OASIS in 2018, confirmed in 2012 and 2015 ($p < 0.001$). In our first analysis without interaction, episiotomy is associated with a higher rate of OASIS in 2018 after adjustment for all the included covariates (OR 1.79, IC 95% [1.66-1.92], $p < 0.001$). We performed a conditional effect model in which episiotomy was identified as a risk factor for OASIS in all cases excepted when performed in primiparous who delivered with instrumental help for whom mediolateral episiotomy was protective. Episiotomy performed for non-primiparous women was also identified as a risk-factor for OASIS in 2012 and 2015, with or without instrumental delivery. As for primiparous woman who did not underwent an instrumental delivery, episiotomy was identified as a risk-factor for OASIS (Table 2). The percentage of episiotomy performed decreased through years for women who did not have an instrumental help for delivery but increase for the one with an instrumental help, whatever the parity was (Table 3, Figure 1).

Discussion: This work clearly showed that the main indication of episiotomy should be the primiparous women who need an instrumental delivery. These results may need to be refined with other risk factors as BMI, ethnicity, macrosomia.

Keywords : episiotomy, OASIS,PMSI