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RESEARCH

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Midterm complications after primary obstetrical anal sphincter injury repair in France

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Abstract

Background Incidence of complications following obstetrical anal sphincter injury (OASI) during vaginal delivery are poorly defined. They are only studied in high level maternities, small cohorts, all stages of perineal tear or in low-income countries. The aim of our study was to describe complications after primary OASI repair following a vaginal delivery in all French maternity wards at short and midterm and to assess factors associated with complication occurrence.

Methods We conducted a historical cohort study using the French nationwide claim database (PMSI) from January 2013 to December 2021. All women who sustained an OASI repair following a vaginal delivery were included and virtually followed-up for 2 years. Then, we searched for OASIS complications. Finally, we evaluated factors associated with OASIS complication repaired or not and OASIS complication repairs.

Results Among the 61,833 included women, 2015 (2.8%) had an OASI complication and 842 (1.16%) underwent an OASI complication repair. Women were mainly primiparous (71.6%) and 44.3% underwent an instrumental delivery. During a follow-up of 2 years, 0.6% ($n=463$), 0.3% ($n=240$), 0.2% ($n=176$), 0.1% ($n=84$), 0.06% ($n=43$) and 0.01% ($n=5$) of patients underwent second surgery for a perineal repair, a fistula repair, a sphincteroplasty, a perineal infection, a colostomy and a sacral nervous anal stimulation, respectively. Only one case of artificial anal sphincter was noticed. Instrumental deliveries (OR = 1.56 CI95%[1.29;1.9]), private for-profit hospitals (OR = 1.42 [1.11;1.82], reference group "public hospital"), obesity (OR = 1.36 [1;1.84]), stage IV OASIS (OR = 2.98 [2.4;3.72]), perineal wound breakdown (OR = 2.8 [1.4;5.48]), ages between 25 and 29 years old (OR = 1.59 [1.17;2.18], reference group "age between 13 and 24 years old") and 30 and 34 years old (OR = 1.57 [1.14; 2.16], reference group "age between 13 and 24 years old") were factors associated with OASIS complication repairs.

Conclusions Maternal age, stage IV OASIS, obesity, instrumental deliveries and private for-profit hospitals seemed to predict OASIS complications. Understanding factors associated with OASIS complications could be beneficial for the patient to inform them and to influence the patient's follow-up in order to prevent complications, repairs and maternal distress.

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Keywords Wound complication, Anal sphincter repair, Wound breakdown, Wound infection, Perineal trauma, Perineal care

Background

Obstetrical anal sphincter injury (OASI) rates range between 0.25 and 6% in the general population [1]. Wound complications include infection, breakdown, incontinence and rectovaginal fistula [2]. They can affect women's quality of life and prolonged postpartum recovery. In the literature, risk factors for wound complications in women who sustain obstetric anal sphincter injuries are infection and operative vaginal delivery [3, 4].

Some of third- to fourth-degree perineal lacerations following labor will lead to rectovaginal fistula. Usually, fistula appears 7 to 10 days following an apparently normal repair [5]. In such instances, fistulas occur either from infection of the wound or from breakdown of the repair.

Complications following OASIS during vaginal delivery are relatively rare events, with an incidence of approximately 5–13% [2]. A recent study highlighted the lack of a scientific basis for the incidence of wound complications [6]. Studies assessed these complications only in high level maternities, in small cohorts, in all stages of perineal tear or in low-income countries [2, 7–9]. No study has been conducted to determine the epidemiologic incidence of wound complications after primary OASI repair.

Identifying and addressing factors associated with OASI complications is a significant challenge. These complications are probably multifactorial, with contributing elements such as the severity of the initial injury, the quality of the repair, and individual patient factors such as comorbidities [2, 7–9]. In addition, there is often a lack of standardised protocols for follow-up and management, resulting in variable outcomes [10, 11]. Effective identification of women at risk of OASIS complications could greatly improve patient care by providing better information and personalised follow-up strategies. This requires comprehensive data collection and analysis to better understand the predictors of adverse outcomes and improve clinical practice.

Therefore, the aim of our study was to describe complications after primary OASIS repair following a vaginal delivery in all French maternity wards at short and mid-term and to assess factors associated with complication occurrence.

Methods

Study design and data collection

We conducted a historical cohort study using the French nationwide hospital claim database (PMSI, “Programme de Médicalisation des Systèmes d’Information”, which means Information Systems Medicalization Program).

This database contains all discharge reports for every inpatient stay from nonprofit and for-profit hospitals in France. In the present study, “patient stay” denotes complete hospital admission, including daytime hospitalizations. These discharge reports provide administrative, demographic and medical data, initially collected for funding purposes. Medical diagnoses are encoded using the ICD10 (10th International Classification of Diseases) [10]. Medical procedures, whether it be therapeutic or diagnostic, are encoded using the French common classification of medical procedures (CCAM). Each woman over 18 is given a unique anonymous number that follows them throughout their life, regardless of the type of health facility they attend, allowing us to track their path. At the time of the study, the nationwide PMSI database contained all the inpatient stays in France from January 2013 to December 2021.

Study population

We first searched for inpatient stays of women having a diagnosis of OASI (O70.2, and O70.3 codes) and a procedure of OASI suture (JMCA003, and JMCA001 code), from January 2013 to December 2021. For each woman, we only kept the first patient stay matching the inclusion criteria. Then, we excluded patient stays without any diagnosis of delivery (Z37 code). We also excluded patient stays without any procedure of delivery (JQGA002, JQGA003, JQGA004, JQGA005, JQGD001, JQGD002, JQGD003, JQGD004, JQGD005, JQGD007, JQGD008, JQGD010, JQGD012, and JQGD013 codes). The next step was the exclusion of inpatient stays with cesarean section procedures (JQGA002, JQGA003, JQGA004, and JQGA005 codes). We excluded inpatient stays with a medical termination of pregnancy or in utero fetal demise (Z371, Z373, Z374, Z376, Z377, Z3710, Z3711, Z3730, Z3731, Z3740, and Z3741 codes). At the end, we excluded women aged less than 10 or more than 75 years old.

Then, all data from the available hospital stays (during the index stay and following ones) of these women were extracted (nonprofit or for-profit hospitals, medicine surgery or obstetrics). It should be noted that, if a woman encountered two OASIS during the study period, she would be included only once, at the first OASI diagnosis and repair.

Study variables

For every hospital stay, we extracted administrative data, ICD-10 diagnoses and CCAM procedures. We then extracted several features from the available data.

The list of outcomes was defined through a comprehensive review of the literature [2, 4, 6, 7, 12–18]. Outcome variables were OASIS complications (repaired or not) defined by:

- Wound infection with or without surgery (HKPA006, HKPA007, JMPA005 procedures, or O860, L022, M726, K661, N760 diagnoses)
- Suture breakdown (O90.1 diagnosis)
- Secondary perineal repair (JMMA002, JMCA005, JLCA004, JMCA005, JMCA006, JMPA002, JMPA004 procedures)
- Recto-vaginal fistula repaired or not (N829, K604, K605, K603, N828, N824, N823 diagnoses, or HJFA013, HKPA007, HJJA001, HJSA001, HJPA001, HKCA003, HJMA002 procedures)
- Sphincteroplasty (HJMA002, HKCA003, JLCA001, JLCA002, HKMA002, HKMA003, HKMA004, HKMA005 procedures)
- Artificial anal sphincter (HKLA002 procedure)
- Sacral nervous stimulation (AHLA804, AHLA003, AHLB018, HKLA001 procedures)
- Digestive surgery: colostomy (HHCC007, HHCA002 procedures)

OASIS complication repair included colostomy, surgery for wound infection, secondary perineal repair, recto-vaginal fistula repair, sphincteroplasty, artificial anal sphincter and sacral nervous stimulation.

Women follow-up after primary OASIS repair was 2 years in order to take into account late management of OASIS complications. OASIS complications were studied up to one subsequent pregnancy in order to attribute the index OASIS to the complication. In case of multiple OASIS complications, all were reported.

Data analysis

We first described women at inclusion. Then, we reported OASIS complications. Finally, we evaluated factors for OASIS complication repairs.

Statistical analysis

Qualitative, binary, or discrete variables with very few modalities are expressed in numbers and percentages. Quantitative variables are expressed as mean and standard deviation (SD). The relationships between the candidate covariates and a binary outcome are modelled and tested using a logistic regression. The results are expressed in terms of odds ratios (OR) with 95% confidence intervals (CI95%). The available covariates are all included in the analysis, and are selected automatically using a bidirectional stepwise procedure. Only the final model is presented. Studied variables included in the logistic regression model are presented in Appendix 1.

Statistics were computed using R statistical software version 4.0.2, and RStudio. Statistical tests are two-sided. The p values are considered significant at the 5% threshold. P values lower than 10^{-10} are reported as “p=0”. Confidence intervals are computed at 95%.

Regulatory framework

This study complies with French regulations according to the 5th reference methodology of the French National Commission of Informatics and Freedom (CNIL, MR005) [19]. According to French regulation, written consent was not necessary for this research work. In addition, no advice from the internal review board was necessary.

Results

In this study, 61,833 women were included (Fig. 1). Among them, 2015 (2.8%) women had an OASIS complication and 842 (1.2%) women underwent an OASIS complication repair (Fig. 2) during 2 years follow-up. Baseline characteristics of women who underwent an OASIS complication are available in Table 1.

During a follow-up of 2 years, 0.6% (342), 0.6% (463), 0.5% (389), 0.2% (176), 0.5% (349), 0.1% (43) of women had a perineal breakdown, a perineal repair, a genital fistula, a sphincteroplasty, a perineal infection, a colostomy, and a sacral nervous anal stimulation, respectively. Only case of artificial anal sphincter was noticed.

Instrumental deliveries (OR=1.53 CI95%[1.3;1.79]), obesity (OR=1.35 [1.5;1.72]), stage IV OASIS (OR=2.43 [2.01;2.94], reference group “overall stage III OASIS”), obstetrical hematoma (OR=1.81 [1.22;2.67]), ages between 25 and 29 years old (OR=1.27 [1;1.61], reference group “age between 13 and 24 years old”) were statistically independently associated with OASIS complication repaired or not (Fig. 3).

Instrumental deliveries (OR=1.56 [1.29;1.9]), private for-profit hospitals (OR=1.42 [1.11;1.82], reference group “public hospital”), obesity (OR=1.36 [1;1.84]), stage IV OASIS (OR=2.98 [2.4;3.72], reference group “overall stage III OASIS”), perineal wound breakdown (OR=2.8 [1.4;5.48]), ages between 25 and 29 years old (OR=1.59 [1.17;2.18], reference group “age between 13 and 24 years old”) and 30 and 34 years old (OR=1.57 [1.14; 2.16], reference group “age between 13 and 24 years old”) were statistically associated with OASIS complication repair (Fig. 3). Low and mid-cavity instrumental deliveries were independently factors associated with OASIS complication repair (OR=1.6 [1.2;2.13] and OR=1.4 [1.14;1.72], respectively).

In this study, other variables were not statistically significant factors associated with OASIS complication repaired or not (Appendix 1).

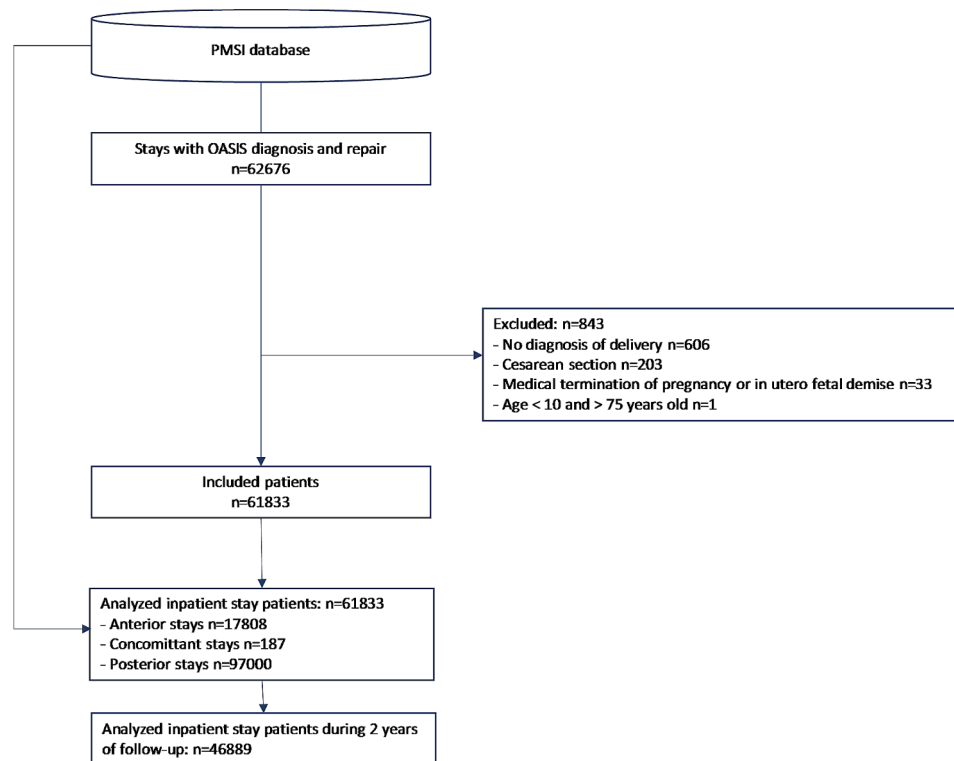


Fig. 1 Flow chart. PMSI: French nationwide claim database; OASIS: Obstetrical anal sphincter injury

Discussion

In this large French historical cohort study, global OASIS complications and OASIS complication repairs rates at midterm were low (2.8% and 1.2%). These rates are lower than those from the literature. In Stock et al. study based on 1629 women who sustained an OASIS in a high-income country, wound complications including infection, breakdown, packing, operative intervention or secondary repair) occurred in 7.3% of women [2]. In Okeahialam et al. meta-analysis, the incidence of wound infection and wound dehiscence were 4.4% and 6.9% respectively [6]. All 10 studies of the meta-analysis were conducted in high-income countries. The difference could be different definitions of complication, study method used, sampling and quotation errors.

Stage IV OASIS was associated with a twofold risk of OASIS complications repaired or not and a nearly threefold risk of OASIS complication repairs. This is similar to findings in a previous study. Stock et al. found that fourth degree of tear was a predictive of perineal wound complication (OR=1.89 95%CI [0.99–3.61] in a retrospective chart review of all women who had a vaginal delivery complicated by an OASIS in a high-income country maternity ward [2]. Unlike Williams and Chames study, episiotomy was not a significant risk factor of perineal wound complications in our cohort probably because of our lower rate: 22.3% versus 47.4% in Williams and Chames cohort [12].

Instrumental delivery was a significant factor associated with OASIS complications repaired or not and of OASIS complication repairs. This is in accordance with the literature [2, 4, 7, 12]. In our study, 19.4%, 14.8% and 2.5% of women had a forceps delivery, a vacuum delivery and combined forceps and vacuum delivery, respectively. No instrument was found to be statistically more at risk of an OASIS complication than another. Likewise, head station during the instrumental delivery or a prolonged second stage of labor were not predictive of an OASIS complication.

Perineal wound breakdown was associated with a nearly threefold risk of OASIS complication repair. Obstetrical hematoma (pelvic hematoma of obstetric origin and obstetric wound hematoma) was associated with a nearly twofold risk of OASIS complication repaired or not. These two factors associated with could be explained by the presence of necrotic tissue, poor perineal hygiene and the formation of a perineal hematoma [15]. Intrapartum antibiotics was described in the literature to be a protective factor [2]. We could not study this factor because common drugs are not traced in the PMSI database.

Ages between 25 and 29 years old were statistically significant factors associated with OASIS complications repaired or not. Plus, ages between 25 and 29 years old and 30 and 34 years old were statistically associated with OASIS complication repair. These facts were not found in

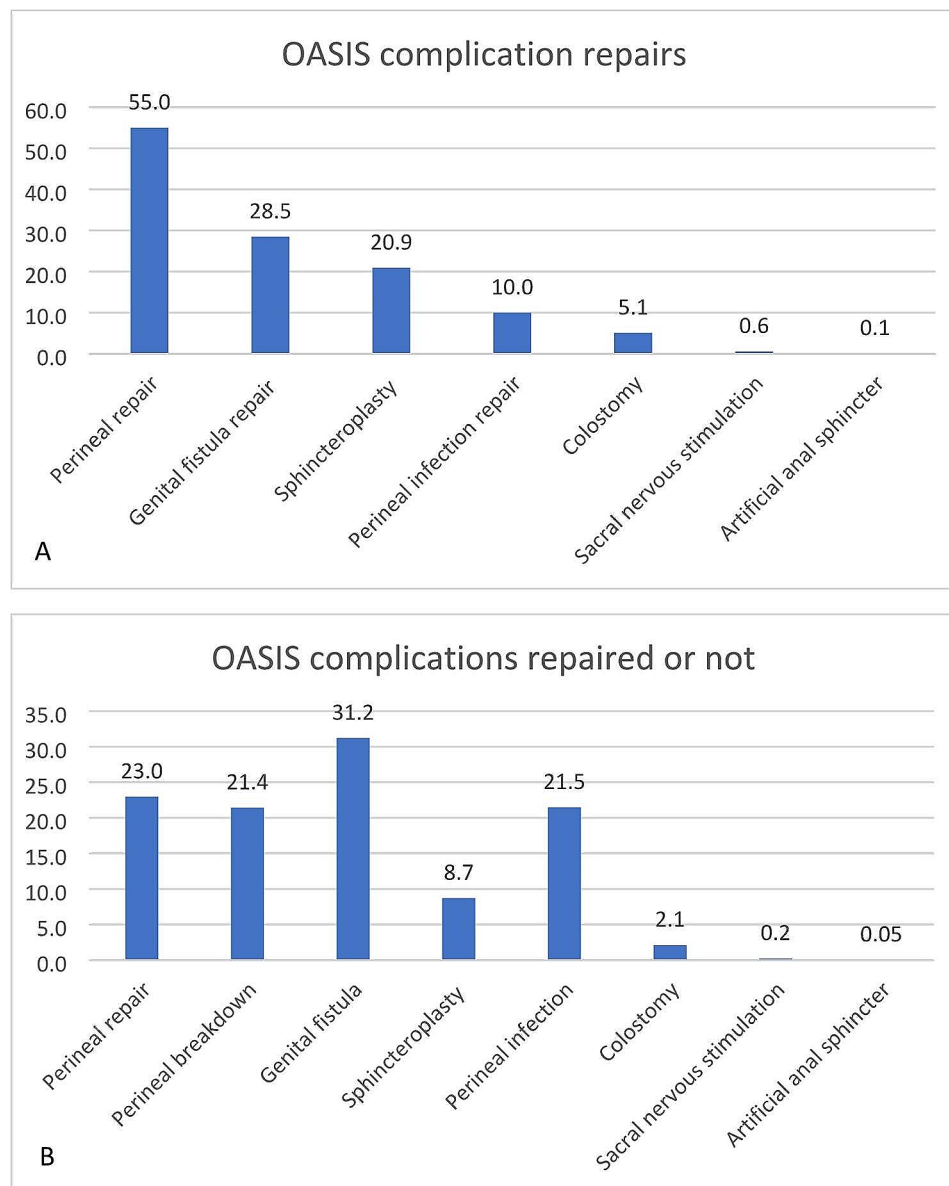


Fig. 2 Distribution of OASIS complication repairs (A) and OASIS complications repaired or not (B). Data are presented as percentage. OASIS: Obstetrical anal sphincter injury

the literature. The hypothesis explaining these results is that younger women will seek for help more easily and more often for perineal complications than older women. Similarly, women from private for-profit hospitals who are probably better off financially, are more likely to consult a doctor for an OASIS complication. Complications may be under-reported and under-treated in older women, and non-profit hospitals.

Obesity was a predictor for OASIS complications in this study. This is in accordance with the literature [20]. Gomesen et al. also showed that BMI > 35 kg/m² increased the risk of wound infection and dehiscence (aOR 7.66 [2.13;27.5] and aOR 3.46 [1.10;10.9], respectively) [7]. Stock et al. also found that obesity was a significant factor

associated with perineal wound complications in women who sustained an OASIS during delivery [2]. Studies has shown an association between obesity and vascular dysfunction in adipose tissue. Indeed, according to Ye et al., in obesity, capillary density and function fail to meet the demand of adipose tissue growth [21]. The failure leads to microcirculation dysfunction from an impaired blood perfusion, which results in a local hypoxia response in adipose tissue. Other explanations include inherent anatomic features of adipose tissue, vascular insufficiencies, cellular and composition modifications, oxidative stress, alterations in immune mediators, and nutritional deficiencies [20].

Table 1 Baseline characteristics of women who sustained an OASIS complication

Demographic and intrapartum variables	Value
Age (years)	29.3 ± 5.0
Nulliparous	44,241 (71.6)
Premature Deliveries	1144 (1.8)
Obesity	5580 (9.0)
Diabetes	6341 (10.3)
Preeclampsia	745 (1.2)
History of sexual mutilation	133 (0.2)
History of cesarean-section	2756 (4.5)
Cephalic delivery	49,035 (79.3)
Singleton delivery	61,446 (99.4)
Prolonged second stage	14,143 (22.9)
Epidural analgesia	51,946 (84.0)
Instrumental deliveries	27,383 (44.3)
Forceps deliveries	12,024 (19.4)
Vacuum deliveries	9125 (14.8)
Combined forceps and vacuum deliveries	1538 (2.5)
Head station during instrumental deliveries	
Mid-cavity	21,402 (34.6)
Low-cavity	6093 (9.8)
Degree of OASIS	
3rd stage	45,676 (73.9)
4th stage	6144 (9.9)
Episiotomy	13,793 (22.3)
Postpartum hemorrhage	6284 (10.2)

Data are mean ± standard deviation or n(%)

OASIS: Obstetrical anal sphincter injury

though it is not recommended during or after an OASIS repair. Colorectal surgeons are not trained in primary OASIS repair [22]. The only indication for colostomy is anal incontinence severely affecting the patient’s quality of life, and as a last resort, after failure of all non-surgical treatments [18].

The major limitation of this study is that it relies on real-world data. Those data were not collected for the present research, but for billing purposes. The data suffer from under-coding bias. For instance, data such as tobacco use, pain or postnatal depression do not have any impact on hospital funding and it is poorly coded. This is the reason why we could not study these potential factor associated with OASIS complications. However, it can be expected that the under-coding bias is non-differential, and risk factors that can be discovered are actual risk factors. But it is the largest real-life retrospective study about OASIS complications. Second, women are not only included from specialized perineal clinics or high-level maternities. They come from all French public and private hospitals, which ensures that they are highly representative of the real population. The methodology induces some limits. The database only includes diagnoses or procedures associated with hospitalization. So, complications treated on an outpatient basis were therefore not included. Moreover, during the 2-year follow-up, the patient could subsequently deliver again. The LOSA complication could not be attributed to the first or second delivery. But this rate is very low.

In this study, 42 cases of colostomy were reported, even

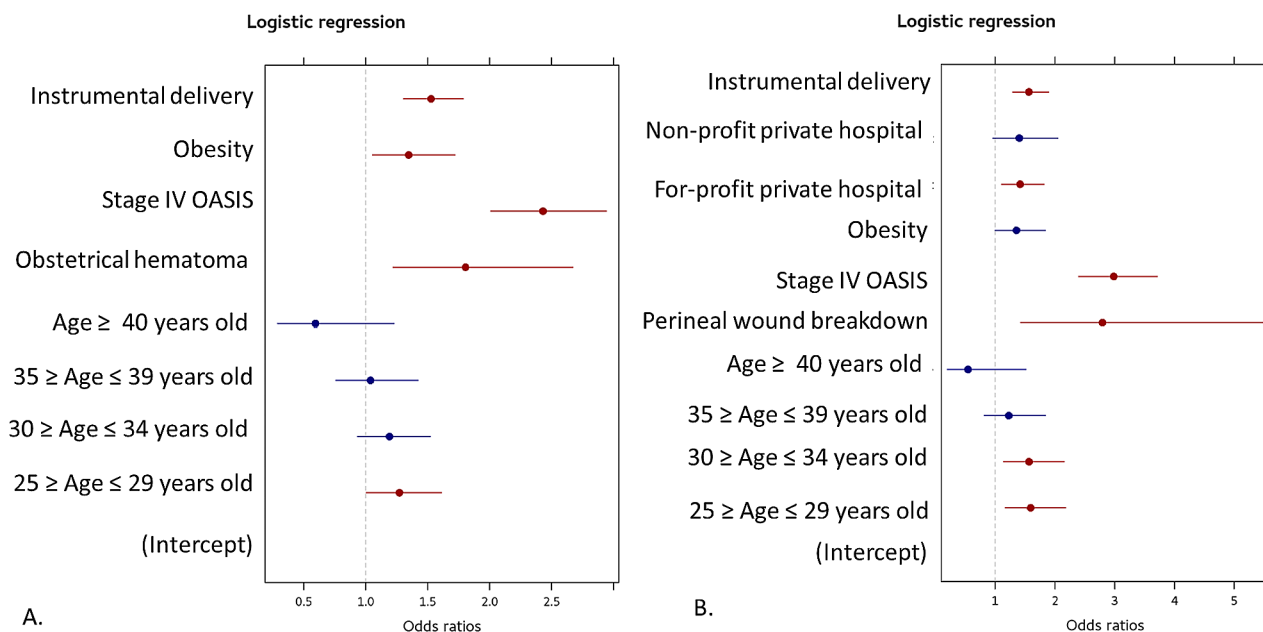


Fig. 3 Risk factors of OASIS complication repaired or not (A) and OASIS complication repair (B) according to the final logistic regression model. Results are expressed as odds ratios (OR) with 95% confidence intervals. OASIS: Obstetrical anal sphincter injury

A positive message can be given to women who delivered with an OASI. Women with an OASI can be reassured about the overall complication rate, which is relatively low. This study provides valuable insights into the factors associated with OASIS complications, enabling healthcare professionals to better identify women at risk of complications and to improve outcomes for women with OASIS and minimize the risk of mid-term complications. For women identified with factors of complications, healthcare providers could provide detailed information about the increased risk of complications and the importance of close follow-up. It might be interesting to schedule more frequent check-ups during the postpartum period to monitor for any potential complications. By focusing on these factors, healthcare professionals can empower these women to actively participate in their care and ensure the best possible outcomes after OASIS repair.

Conclusion

The most common complications after primary OASI repair following vaginal delivery were perineal repair, perineal breakdown, genital fistula and perineal infection. Maternal age, stage IV OASIS, obesity, instrumental deliveries and private for-profit hospitals seemed to predict OASIS complications. OASIS complications can be associated with significant morbidity. Understanding factors associated with OASIS complications could be beneficial for the patient in order to inform them. Plus, we could try to modify them, if possible, to prevent long-term consequences of OASIS complications. Identifying these factors after an OASI repair could influence the patient's follow-up in order to prevent complications, repairs and maternal distress.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12884-024-06691-w>.

Supplementary Material 1

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Not applicable.

Author contributions

ML: protocol/project development, data analysis, manuscript writing/editing; SB: protocol/project development, manuscript writing/editing; LG: manuscript writing/editing; CR: manuscript writing/editing; AFR: manuscript writing/editing; YK: manuscript writing/editing; EC: manuscript writing/editing; protocol/project development, data analysis, manuscript writing/editing; MC: manuscript writing/editing.

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Data availability

Research data are not shared. If details about data are needed, please contact Professor Emmanuel Chazard [emmanuel.chazard\[at\]chu-lille.fr](mailto:emmanuel.chazard[at]chu-lille.fr).

Declarations

Ethics approval and consent to participate

This study complies with French regulations according to the 5th reference methodology of the French National Commission of Informatics and Freedom (CNIL, MR005) <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000037187535> [19]. According to French regulation, written consent was not necessary for this research work. In addition, no advice from the internal review board was necessary. This article is an epidemiological study for which ethical approval does not apply.

Competing interests

Other authors declare that they have no competing interests: Professor M. Cosson has contracts from Ab medica, Promedon, Syliva, Proveday and receives consulting fees from Boston scientific and honoraria for educational events from Boston scientific and Promedon. He is also a founder of Digyne start-up.

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