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# Maternal and neonatal morbidity after attempted operative vaginal delivery according to the instrument type: a prospective study using a propensity score analysis

Alizée Froeliger

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**Thèse pour l'obtention du DIPLOME d'ETAT de DOCTEUR EN MEDECINE**

**DES GYNÉCOLOGIE-OBSTÉTRIQUE**

Présentée et soutenue publiquement le 30 Septembre 2021

Par **Alizée FROELIGER**, née le 06 mai 1992 à Paris 14<sup>ème</sup> (75)

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D'EXTRACTION INSTRUMENTALE EN FONCTION DE L'INSTRUMENT UTILISE :  
UNE ETUDE PROSPECTIVE AVEC ANALYSE PAR SCORE DE PROPENSION.**

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VAGINAL DELIVERY ACCORDING TO THE INSTRUMENT TYPE : A PROSPECTIVE  
STUDY USING A PROPENSITY SCORE ANALYSIS.

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Madame le Professeur Karen LEFFONDRE.....Juge

Monsieur le Docteur Hugo MADAR.....Juge

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Ancien Chef de service de Gynécologie-Obstétrique,  
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# I. LISTE DES ABREVIATIONS

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**95%CI** : 95% Confidence interval

**ACOG** : American College of Obstetricians and Gynecologists

**AI** : Anal incontinence

**(a)OR** : (Adjusted) Odds Ratio

**(a)OVD** : (Attempted) Operative vaginal delivery

**BFLUTS** : Bristol Female Lower Urinary Tract Symptoms

**BMI** : Body Mass Index

**CNGOF** : French National College of Obstetricians and Gynecologists

**FHR** : Fetal heart rate

**FISI** : Fecal Incontinence Severity Index

**IQR** : Interquartile range

**NICU** : Neonatal intensive care unit

**PPH** : Postpartum hemorrhage

**RCT** : Randomized controlled trial

**RR** : Relative risk

**UI** : Urinary incontinence

## II. ARTICLE

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### **MATERNAL AND NEONATAL MORBIDITY AFTER ATTEMPTED OPERATIVE VAGINAL DELIVERY ACCORDING TO THE INSTRUMENT TYPE: A PROSPECTIVE STUDY USING A PROPENSITY SCORE ANALYSIS.**

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## Abstract

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**Objective:** To assess severe short-term maternal and neonatal morbidity and pelvic floor disorders at 6 months postpartum after attempted operative vaginal deliveries (OVD) according to type of instrument.

**Study design:** Prospective study of women with live singleton term fetuses in vertex presentation who underwent attempted OVD in a French tertiary-care university hospital from December 2008 through October 2013. We used multivariable logistic regression and propensity score methods to control for indication bias and compare outcomes associated with vacuum- or forceps-/spatula-assisted deliveries. Severe maternal and neonatal morbidity were composite primary endpoints. Symptoms of urinary incontinence (IU) and anal incontinence (AI) were assessed 6 months after delivery by validated self-administered questionnaires.

**Results:** Among 2,138 attempted OVDs, 30.7% (n=654) used vacuum, and 69.3% (n=1474) forceps/spatulas. Severe maternal morbidity occurred in 5.4% (n=35; 95%CI 3.8-7.4) of vacuum attempts and 10.5% (n=154; 95%CI 8.3-12.1) of forceps/spatula attempts ( $P<.001$ ); and severe neonatal morbidity in 8.4% (n=55; 95%CI 6.4-10.8) and 10.2% (n=155; 95%CI 8.7-11.8) respectively ( $P=.2$ ). Although forceps/spatula attempted OVD was significantly associated with more frequent severe maternal morbidity (aOR 1.99 95%CI 1.27-3.10) in multivariable logistic regression analysis, this association was no longer significant after propensity score matching (aOR 1.46 95%CI 0.72-2.95). Forceps/spatula attempted OVD was not significantly associated with more frequent severe neonatal morbidity after multivariable logistic regression or propensity score matching. Among the 934 women (43.9%) who responded to questionnaires at 6 months, the prevalence of symptoms of UI was 22.7% and of AI 22.0%, with no significant differences between the two groups.

**Conclusion:** In singleton term pregnancies, neither severe short-term maternal or neonatal morbidity nor urinary or anal incontinence was more frequent after attempted OVD by forceps or spatulas than by vacuum after controlling for indication bias with a propensity score analysis.

**Keywords:** operative vaginal delivery; instrumental vaginal delivery; forceps; Kiwi Omni Cup vacuum; Thierry's spatulas; maternal morbidity; neonatal morbidity; pelvic floor disorders; urinary incontinence; anal incontinence; propensity score; cohort study.

# Main text

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## Introduction

Operative vaginal delivery (OVD), a safe alternative for avoiding cesarean birth in the late second stage, enables vaginal birth for maternal or fetal indications.<sup>1-5</sup> OVD rates range from 3% to 15% worldwide,<sup>1,6-9</sup> and its practice patterns vary widely, especially instrument choice (vacuum, forceps, or spatulas). When OVD is necessary, operators must choose their instrument rapidly, based on factors including characteristics of the woman and her labor, clinical circumstances such as fetal head station and occipital position, local practices, and their own experience and skills.

Comparing international guidelines from the USA,<sup>1</sup> the UK,<sup>7</sup> Australia and New Zealand,<sup>8</sup> Canada,<sup>9</sup> and France<sup>10</sup> shows no consistent strategy for this choice.<sup>11</sup> They all note that vacuum-assisted deliveries appear most likely to be associated with both neonatal trauma and failure, but maternal morbidity occurs more often after forceps/spatula deliveries, with elevated rates of severe perineal lacerations and vaginal trauma.<sup>1,11,12</sup> Long-term outcomes, notably urinary or anal incontinence, do not appear to differ, although results are inconsistent.<sup>12</sup>

Previous studies of maternal or neonatal complications after OVD by instrument type have important limitations: retrospective design, confounding bias without important details to permit adjustment, changes in practices over time, and no control for indication bias.<sup>13</sup> Previous randomized controlled trials (RCTs) comparing vacuum versus forceps delivery had methodological weaknesses and relatively few participants, and date from two or more decades ago.<sup>12</sup> Although RCTs should provide the best evidence, ethical and feasibility considerations prevent their performance today. Observational prospective studies using appropriate statistical methods might thus be the best way to evaluate outcomes after OVD.

We therefore sought to assess severe maternal and neonatal morbidity after attempted vaginal operative delivery (aOVD) by type of instrument (vacuum versus forceps/spatulas) as primary endpoints, and

urinary and anal incontinence symptoms at 6 months after aOVD as secondary endpoints. Propensity score analyses ensure the comparability of the study groups while minimizing indication bias.

Our primary endpoints were to assess severe maternal and neonatal morbidity after attempted vaginal operative delivery (aOVD) by type of instrument (vacuum versus forceps/spatulas). Our secondary endpoints were to assess urinary and anal incontinence symptoms at 6 months after aOVD. Propensity score analyses ensure the comparability of the study groups while minimizing indication bias.

## **Materials and methods**

### ***Study design***

This study was an ancillary prespecified analysis of data collected from a prospective cohort study that took place from December 2008 to October 2013 at a French tertiary-care university hospital with more than 4,000 deliveries annually. It was designed primarily to assess the effect of fetal head station on short-term maternal and neonatal morbidity and prospectively analyze maternal complications at 6 months: pelvic floors disorders, sexual dysfunction, and postpartum depressive symptoms.<sup>14-16</sup>

### ***Study population***

This study included all women with a live singleton pregnancy in vertex presentation at term (37 weeks of gestation or more) and an aOVD, defined by the placement of at least one blade for forceps or spatula, or an attempt to place a vacuum, regardless of whether delivery was finally vaginal or cesarean. Exclusion criteria were multiple gestations, a known congenital anomaly, noncephalic presentation, or small-for-gestational-age status, defined as birthweight below the 10<sup>th</sup> percentile for gestational age on the Hadlock curves.<sup>17-18</sup>

Our study population comprised all women in the primary cohort with data for type of instrument used for aOVD. All women received information about our study and consented to the collection of their data. The Research Ethics Committee of the University of Angers, France, approved the study (no. 2008).

### ***Clinical procedures***

The decision to attempt an OVD, the choice of instrument (forceps, Kiwi OmniCup vacuum, or Thierry's spatulas), and the place of delivery (operating room or not) were up to the attending obstetrician. OVDs were performed by either the attending obstetrician (with 5 or more years of experience with OVD) or the obstetric resident (with less than 5 years of such experience) under the

supervision of an experienced obstetrician, always present in the delivery room. The attending obstetricians always chose the instrument used and determined whether they needed to check the instrument placement personally before traction. All women were offered epidural analgesia. The bladder was emptied by catheter before delivery. In accordance with French guidelines,<sup>10</sup> and again at the attending obstetrician's discretion, ultrasound could be performed to assess fetal head position if doubts remained after examination. It was recommended that rotational forceps-assisted deliveries (>90° rotation) be avoided: only vacuum instruments were recommended for rotation; midpelvic delivery could be performed in selected appropriate cases by trained, experienced obstetricians. If OVD failed, the same resident performed the cesarean under the supervision of the same attending obstetrician.

The medical records of women with aOVD were assessed and discussed on working days at the daily morning staff meeting. Attending obstetricians regularly reviewed with residents the ACOG classification of fetal head station,<sup>19</sup> academic knowledge about OVD, and the clinical practice guidelines for this type of delivery issued by the French National College of Obstetricians and Gynecologists (CNGOF).<sup>10</sup> Specifically, station was defined by the level of the leading bony point of the fetal head in centimeters at or below the level of maternal ischial spines (0 and +1 = midpelvic; +2 and +3 = low; +4 and +5 = outlet).<sup>19</sup> Indications for aOVD included nonreassuring scalp pH and fetal heart rate (FHR) abnormalities (defined by any prolonged deceleration, bradycardia, or decreased variability)<sup>20</sup> and/or prolongation of the second-stage pushing phase due to inadequate expulsive efforts or failure to progress.<sup>10,21</sup> All women underwent continuous FHR monitoring. Episiotomy was left to the practitioner's discretion and was always mediolateral. A pediatrician examined the newborn in all cases within 2 hours after delivery. These clinical procedures have previously been reported.<sup>14,22</sup>

### ***Data collection***

The midwife or obstetrician and pediatrician responsible for the delivery and the neonate prospectively collected details of procedures used to manage the labor and all clinical outcomes identified during the immediate postpartum period. Other short-term data were collected by a research assistant, independent

of the local medical team, from a prospectively maintained database of women who underwent attempted (or completed) OVD. Intermediate-term data of pelvic floor disorders were prospectively collected from a questionnaire sent 6 months after delivery. A second mailing was sent to the women who did not respond to the first.<sup>14-16</sup>

### ***Endpoints***

The primary endpoints were composite variables of severe maternal and neonatal morbidity.

*Severe short-term maternal morbidity* was defined by at least one of the following: third- or fourth-degree perineal laceration, perineal hematoma, cervical laceration, extension of uterine incision in cesarean delivery, postpartum hemorrhage exceeding 1,500 ml (blood loss was routinely assessed with a collector bag placed just after birth),<sup>23,24</sup> surgical hemostatic procedures, uterine artery embolization, blood transfusion, infection (endometritis, episiotomy infection, or wound infection requiring surgery), thromboembolic events, admission to the intensive care unit, and maternal death.<sup>14</sup>

*Severe neonatal morbidity* was defined by at least one of the following criteria: 5-minute Apgar score less than 7, umbilical artery pH less than 7.00 (umbilical artery blood gas values were routinely measured), need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage greater than grade 2, neonatal intensive care unit admission for more than 24 hours, convulsions, sepsis, and neonatal death.<sup>14</sup>

The secondary endpoints were the presence of pelvic floor disorders at 6 months after delivery. Appendix 1 describes the details of procedures used to assess them.<sup>15</sup>

*Urinary incontinence* (UI) was assessed by the French version of the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) validated questionnaire<sup>25-27</sup> about the frequency, amount, and circumstances of leakage and if and to what extent UI bothered women.

*Anal incontinence* (AI) was assessed with the French version of the American Society of Colon and Rectal Surgeon's Fecal Incontinence Severity Index (FISI),<sup>28,29</sup> based on type of incontinence and frequency matrix. A high FISI score indicated severe perceived symptoms.

### ***Exposure variable***

Our exposure variable was the type of instrument used for the aOVD, classified into two groups: vacuum and forceps/spatulas. When two instruments were used sequentially, women were analyzed by the last instrument used.

### ***Adjustment variables***

All variables that might influence both the choice of instrument for aOVD and the endpoints were considered potential confounding variables and used as adjustment variables.

These variables included : maternal baselines characteristics such as age, body mass index (BMI) before pregnancy based on height and weight before pregnancy, parity, history of cesarean delivery, adverse events during previous delivery (birthweight >4,000g, shoulder dystocia, OVD, third- or fourth-degree perineal laceration or postpartum hemorrhage >1,500mL) ; characteristics of pregnancy, labor and delivery such as diabetes mellitus during pregnancy (preexisting or gestational), gestational weigh gain, prenatal suspicion of macrosomia (determined by fundal height measurement at delivery >37cm, ultrasonographic fetal abdominal circumference >90<sup>th</sup> percentile for gestational age on Hadlock curves,<sup>17,18</sup> or both), gestational age at delivery (determined by craniocaudal length at a 1<sup>st</sup>-trimester ultrasound examination or by the date of the last menstrual period, a second or third trimester ultrasonogram, or both if the 1<sup>st</sup>-trimester ultrasonogram was not performed),<sup>30</sup> type of labor (spontaneous or induced by prostaglandins, amniotomy, or oxytocin), epidural analgesia, fetal head position (occiput anterior, posterior or transverse), duration of the second stage of labor (complete dilatation to birth) and of the active second stage (from the beginning of expulsive efforts to birth [pushing time]), indication for

aOVD, station at attempted delivery according ACOG classification,<sup>19</sup> and operator for delivery (attending obstetrician or resident).

### *Statistical analysis*

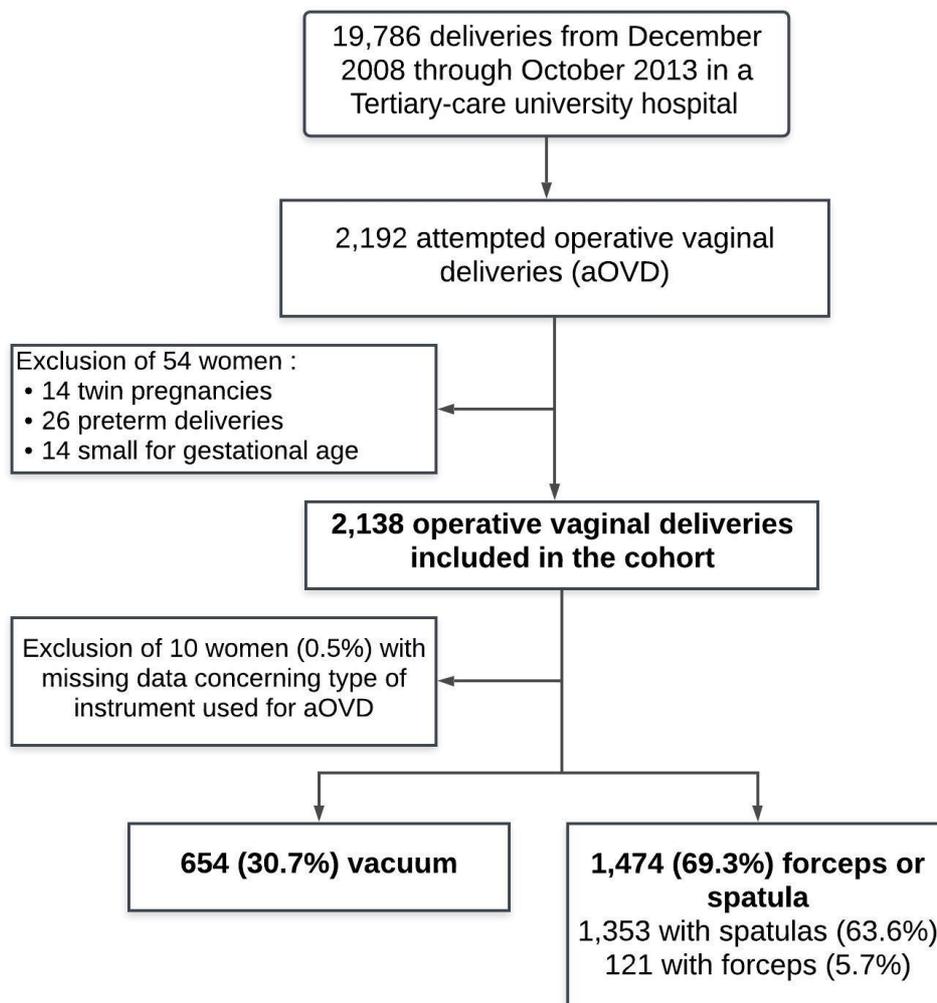
Continuous variables were described by their means and standard deviations or medians and interquartile ranges as appropriate, and compared between groups by a Student or Kruskal-Wallis test. Categorical variables were described by proportions and compared by Chi2 tests or Fisher's exact test, as appropriate. To control for confounding factors that might influence both the choice of instrument and the endpoints, we began with logistic regression models with multiple adjustments to estimate crude and adjusted odds ratios (aORs) and their 95% confidence intervals (CIs). We used theoretical hypotheses to select the potential confounders for the multivariable analysis and interaction terms between modes of delivery and the covariates considered to test for clinically relevant interactions. Because instrument choice was probably guided by characteristics of the women, their pregnancy and labor, rather than chance, we used a propensity score as a sensitivity analysis to limit potential indication bias.<sup>31</sup> Women's propensity scores were defined as their probability of undergoing aOVD by forceps or spatulas, based on their individual covariates measured before delivery. A 1:1 matching algorithm was used within a caliper of 0.2 standard deviation of the logit of the propensity score<sup>31,32</sup> (31) (32) to match women for the selected baseline maternal and obstetric characteristics. We checked imbalances after matching by propensity score distribution and standardized mean differences.<sup>33</sup> In the matched set, paired conditional generalized estimating equation logistic regression was used to estimate ORs and their 95% CIs to quantify the association between instrument type and short-term severe maternal and neonatal morbidity. The same procedures were used for the secondary endpoints. **Appendix 2** details the propensity score construction and matching procedures. A sensitivity analysis used multiple imputation of missing data. The proportion of women with missing data for any covariate included in the main multivariable model ranged from 1% to 5% for primary and 1% to 8% for secondary endpoints. We performed multiple imputation chained equations for the missing data and pooled estimates

according to Rubin's rules (10 datasets imputed).<sup>34</sup> Differences were considered significant at  $P < .05$ .  
Stata SE 15 was used for all analyses.

## Results

### *Study population*

During the study period, the hospital had 19,786 deliveries: 15,836 (80.0%) vaginal, including 2,153 (13.6%) successful OVDs, and 3,950 (20.0%) cesareans, including 39 (0.2% of all deliveries and 1% of all cesarean deliveries) after failed OVD. This study analyzed the 2,192 deliveries with aOVD (98.2% successful and 1.8% failures), but first excluded 54 women meeting exclusion criteria (14 twin pregnancies, 26 preterm, i.e., <37 weeks, and 14 small for gestational age) and 10 for missing data about the instrument used for the aOVD. Our final sample for the main analysis comprised 2,128 births with an aOVD: 654 (30.7%) by vacuum, and 1,474 (69.3%) by forceps or spatulas (**Figure 1**).



**Figure 1.** Study flow chart.

### ***Primary endpoints***

**Table 1** reports maternal and labor characteristics by type of instrument. Nulliparity, prenatally suspected macrosomia, induced labor, second stage of labor exceeding 3 hours, high oxytocin doses, epidural analgesia, manual rotation of the presentation, persistent occiput posterior position, midpelvic delivery, and attempted delivery by the attending senior obstetrician were significantly more frequent in forceps- or spatula-assisted deliveries (**Table 1**).

**Table 2** reports maternal and neonatal morbidity by type of instrument. The severe maternal morbidity rate after aOVD was 5.4% (n=35, 95%CI 3.8-7.4) by vacuum and 10.5% (n=154, 95%CI 8.3-12.1) with forceps or spatulas. It differed significantly between the groups ( $P<.001$ ) (**Table 2**). In the univariate analysis, women with severe morbidity more often had a higher mean prepregnancy BMI, previous cesareans and OVDs, prenatally suspected macrosomia, had a higher median oxytocin dose, cesarean delivery after failed aOVD, and delivery performed by a senior attending obstetrician (**Table 3**). The severe maternal morbidity rate was higher among OVDs attempted with forceps or spatulas than vacuum in the univariate analysis (crude OR 2.06, 95%CI 1.41-3.01) and the multivariable logistic regression analysis (aOR 1.99, 95%CI 1.27-3.10), after adjustment for potential confounders (**Table 4**). These results were consistent with the first sensitivity analysis, based on multiple imputation (aOR 1.93, 95%CI 1.25-2.99) (**Figure 2a**).

The rate of severe neonatal morbidity after aOVD was 8.4% (n=55, 95%CI 6.4-10.8) with vacuum and 10.2% (n=155, 95%CI 8.7-11.8) with forceps or spatulas and did not differ significantly between the groups (**Table 2**), in either the univariate (crude OR 1.23, 95%CI 0.89-1.71) or multivariable (aOR 1.04, 95%CI 0.69-1.56) analyses (**Table 4**). These results were consistent with the first sensitivity analysis based on multiple imputation (aOR 1.10, 95%CI 0.74-1.65) (**Figure 2a**).

The propensity score matching process analyzed 594 cases: 297 matched deliveries in each group, including 45.4% of the aOVDs with vacuum and 20.1% of those with forceps or spatulas. The two matched groups were well balanced for all variables (**Figure 3**). After propensity score matching, aOVD with forceps or spatulas was no longer associated with a higher rate of severe maternal (aOR 1.46, 95%CI 0.72-2.95) or neonatal (aOR 1.08, 95%CI 0.63-1.85) morbidity (**Figure 2a**).

### ***Secondary endpoints***

Six months after delivery, 934 women (43.9%) among the 2,128 who had an aOVD completed the questionnaires: 276 (29.5%) had had an aOVD by vacuum and 658 (70.5%) by forceps/spatulas ( $P=.3$ ). Respondents and nonrespondents differed for several characteristics. Nonrespondents were younger, more of them had gestational weight gains >20 kg, sequential use of two instruments and severe neonatal morbidity (11.5% versus 7.5%;  $P=.002$ ); fewer had a prolonged second stage of labor and epidural analgesia. The type of instrument used for aOVD did not differ between these groups (**Appendix 3**).

**Table 2** reports the pelvic floor disorders 6 months after delivery by type of instrument. Among women with aOVD, the prevalence of UI symptoms at 6 months was 22.7% (212/933, 95%CI 20.1-25.5) and that of AI symptoms 22.0% (202/918, 95%CI 19.4-24.8); 13.7% (127/924, 95%CI 11.6-16.1) reported perineal pain. UI symptoms (19.6% for women with vacuum and 24.1% for those with forceps/spatulas), AI symptoms (19.2% versus 23.2%, respectively) and perineal pain (11.6% versus 14.6%) did not differ significantly between these groups. Similarly, the median FISFI score in women with AI did not differ between these two groups (11 IQR [7-12] versus 11 IQR [7-16] respectively;  $P=.3$ ) (**Table 2**).

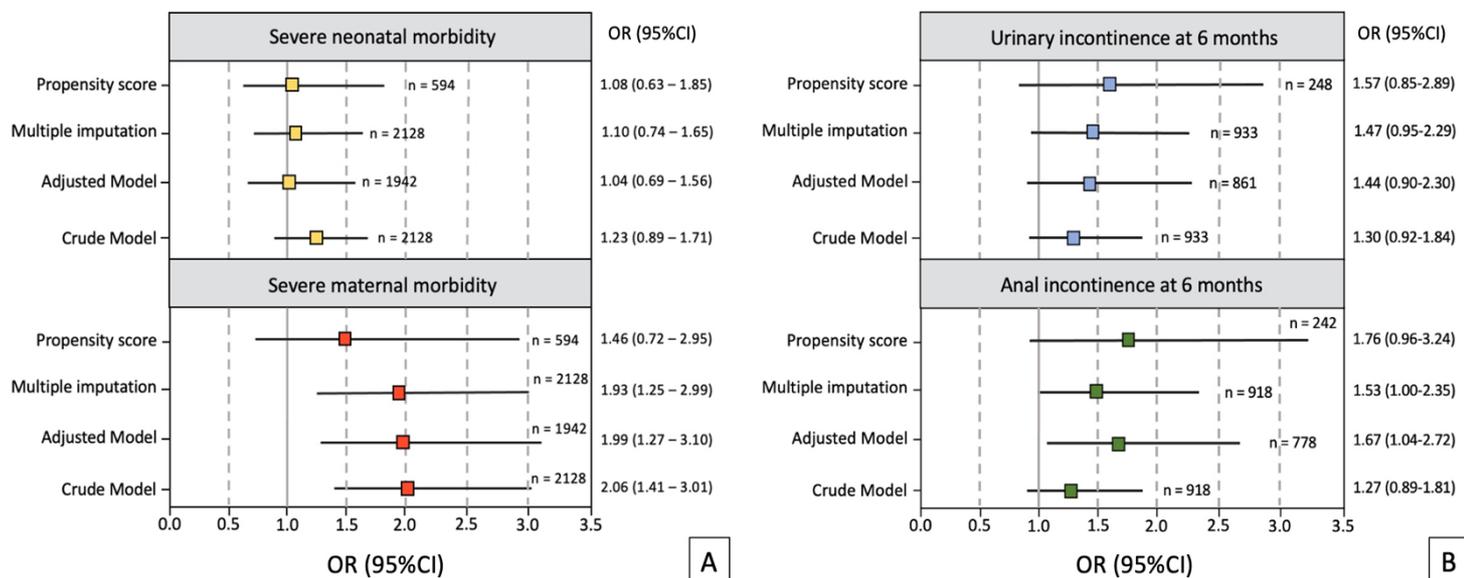
Compared with women without UI, those with it were older, had higher rates of third- and fourth-degree perineal lacerations, and breastfed more often. Comparisons for AI showed that women with AI were older, more often multiparous, and had higher rates of a previous infant and the index infant born weighing >4000 g, and of gestational diabetes mellitus, prenatally suspected macrosomia, induced labor,

third- or fourth-degree perineal lacerations, severe maternal morbidity, and breastfeeding. Episiotomy was not significantly associated with UI or AI at 6 months (**Appendix 4**).

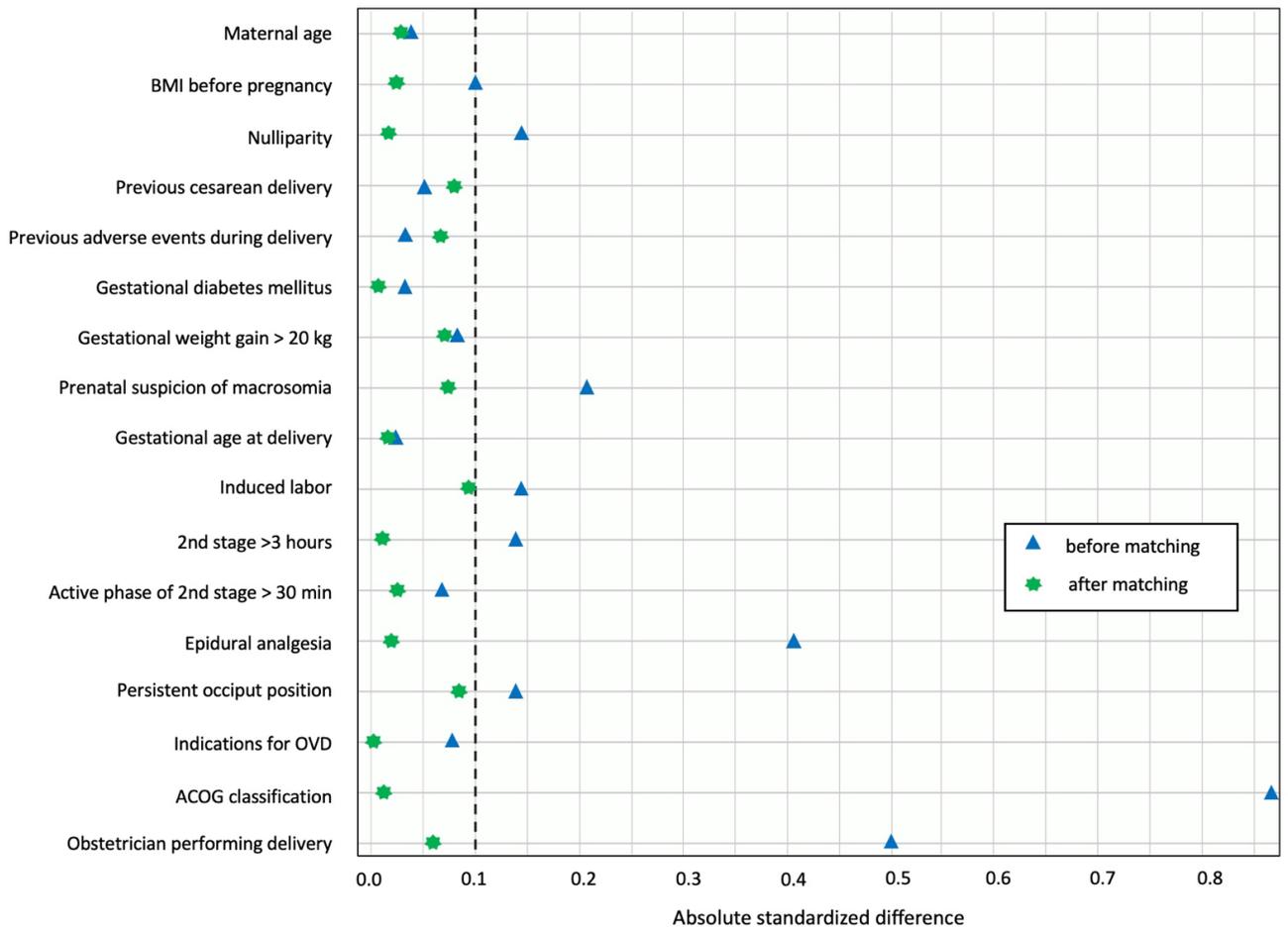
Operative vaginal delivery attempted with forceps or spatulas compared with vacuum was not significantly associated with a higher rate of urinary incontinence, either in multivariate analysis (aOR, 1.44; 95%CI 0.90-2.30) (**Appendix 5**), after multiple imputation (aOR, 1.47 95%CI 0.95-2.29), or after propensity score matching (aOR, 1.57 95%CI 0.85-2.89) (**Figure 2b**).

Inversely, it was significantly associated with a higher rate of anal incontinence in the multivariable logistic regression analysis (aOR 1.67, 95%CI 1.04-2.72) (**Appendix 5**). The first sensitivity analysis, based on multiple imputation, reached a similar result (aOR 1.53, 95%CI 1.00-2.35), but no difference remained after propensity score matching (aOR 1.76, 95%CI 0.96-3.24) (**Figure 2b**).

The propensity score matching process analyzed 248 cases for UI and 242 for AI, and the matched groups for each analysis were well balanced for all variables (**Appendix 6**).



**Figure 2.** Severe maternal and neonatal morbidity (2a) and pelvic floor disorders at 6 months (2b) after attempted operative vaginal delivery by to type of instrument (reference: vacuum). CI, confidence interval; OR, odds ratio



**Figure 3.** Absolute standardized differences between women with vacuum- and forceps-/spatula-assisted deliveries, for the variables included in the propensity score, before (total population) and after matching (propensity score-matched population).

*BMI, body mass index ; OVD, operative vaginal delivery ; ACOG, American College of Obstetricians and Gynecologists*

*Absolute standardized difference is a measure of effect size between two groups that is independent of sample size. It is the absolute value of the mean difference divided by the pooled standard deviation.*

**Table 1.** Maternal and labor characteristics for operative vaginal deliveries, by the type of instrument used (n=2128).

	<b>Vacuum (n=654)</b>	<b>Forceps/Spatulas (n=1474)</b>	<b>P</b>
Maternal age (years)	28.1 ± 5.1	28.2 ± 5.1	.8
≤ 30	451 (69.0)	1032 (70.0)	.6
> 30	203 (31.0)	442 (30.0)	
BMI before pregnancy (kg/m <sup>2</sup> )	23.0 ± 16.3	23.0 ± 4.3	.9
<18.5	68 (10.5)	125 (8.5)	.1
[18.5-25[	455 (70.5)	1000 (68.3)	
[25-30[	86 (13.3)	234 (16.0)	
≥ 30	36 (5.6)	105 (7.2)	
Gestational weight gain > 20 kg	55 (8.8)	155 (11.2)	.1
Nulliparous	455 (69.6)	1115 (75.6)	.003
Previous cesarean delivery	62 (9.5)	161 (10.9)	.3
Previous operative vaginal delivery	41 (6.3)	81 (5.5)	.5
Previous birth > 4,000 g	6 (0.9)	18 (1.2)	.5
Previous shoulder dystocia	3 (0.5)	5 (0.3)	.7
Previous PPH	10 (1.5)	13 (0.9)	.2
Gestational diabetes mellitus			.5
Preexisting	1 (0.2)	6 (0.4)	
Treated by diet	30 (4.6)	83 (5.7)	
Treated by insulin	13 (2.0)	24 (1.7)	
Prenatally suspected macrosomia ‡	27 (4.1)	138 (9.4)	<.001
Gestational age at delivery (weeks)	39.9 ± 1.3	39.7 ± 1.6	.06
Gestational age at delivery ≥ 41 weeks	155 (23.7)	336 (22.8)	.6
Induced labor	91 (13.9)	284 (19.3)	.003
2 <sup>nd</sup> stage >3 hours	70 (10.7)	224 (15.2)	.005
Active phase of 2 <sup>nd</sup> stage > 30 min	191 (29.4)	476 (32.9)	.1
Dose of oxytocin (mIU) median [IQR]	594 [18-1630]	1090 [280-2520]	<.001
Epidural analgesia	556 (85.1)	1428 (96.9)	<.001
Manual rotation	49 (7.6)	179 (13.3)	.001
Persistent occiput position			.01
Anterior	594 (91.4)	1277 (87.1)	
Posterior	40 (6.2)	147 (10.0)	
Transverse	16 (2.5)	43 (2.9)	
ACOG classification			<.001
Mid	25 (3.8)	353 (24.1)	
Low	467 (71.7)	1076 (73.5)	
Outlet	159 (24.4)	36 (2.5)	
Indications for OVD			.1
Non-reassuring FHR only	292 (44.7)	618 (42.0)	
Arrested progress only	223 (34.1)	568 (38.6)	
Non-reassuring FHR and arrested progress	139 (21.3)	287 (19.5)	
Obstetrician performing delivery			<.001
Senior attending obstetrician	74 (11.4)	458 (31.4)	
Obstetric resident	575 (88.6)	999 (68.6)	
Sequential use of two instruments	67 (10.0)	15 (1.0)	<.001
Rotational forceps delivery	0 (0)	2 (0.1)	.3

*BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate.*

Continuous data are expressed as means  $\pm$  standard deviations or medians [IQR] when specified ; discrete data are expressed as n (%). Student t test,  $\chi^2$  test, Kruskal-Wallis test, and Fisher's exact test were used as appropriate. A *P* value of .05 was considered significant.

‡ Prenatally suspected macrosomia: fundal height measurement at delivery  $> 37$  cm and/or ultrasonographic fetal abdominal circumference  $> 90^{\text{th}}$  p. for gestational age on Hadlock curves.

**Table 2.** Maternal and neonatal outcomes for operative vaginal deliveries, by the type of instrument used (n=2128).

	<b>Vacuum (n=654)</b>	<b>Forceps/Spatulas (n=1474)</b>	<b>P</b>
<b>Maternal outcome</b>			
Caesarean delivery after failed OVD	3 (0.5)	36 (2.5)	.002
Extension of uterine incision in cesarean	0 (0)	7 (0.5)	.08
Episiotomy	462 (70.6)	1390 (94.5)	<.001
3 <sup>rd</sup> or 4 <sup>th</sup> -degree perineal lacerations	11 (1.7)	46 (3.1)	.05
Perineal hematomas	1 (0.2)	1 (0.1)	.6
Manual removal of retained placenta	45 (15.2)	220 (23.7)	.002
Blood loss (mL) median [IQR]	200 [100-300]	300 [200-500]	<.001
PPH (blood loss >500 mL)	62 (9.5)	281 (19.1)	<.001
Severe PPH (blood loss>1,500 mL)	6 (0.9)	23 (1.6)	.2
Need for an additional uterotonic agent	10 (3.4)	33 (3.6)	.9
Second-line therapies §	2 (0.7)	4 (0.4)	.6
Blood transfusion	6 (0.9)	32 (2.2)	.04
Infections§	9 (1.4)	20 (1.4)	.9
Thromboembolic event	1 (0.2)	3 (0.2)	.8
Admission to intensive care unit	1 (0.2)	1 (0.1)	.6
Maternal death	0	0	-
<b>Severe maternal morbidity *</b>	<b>35 (5.4)</b>	<b>154 (10.5)</b>	<b>&lt;.001</b>
<b>Neonatal outcome</b>			
Birth weight ≥ 4,000 g	22 (3.4)	87 (5.9)	.01
5-min Apgar score < 7	3 (0.5)	19 (1.3)	.08
pH < 7.00	12 (1.9)	21 (1.5)	.4
Transfer to NICU	39 (6.0)	104 (7.1)	.3
NICU hospitalization > 24 h	38 (5.8)	100 (6.8)	.4
Respiratory distress syndrome	20 (3.1)	61 (4.2)	.2
Scalp laceration	14 (2.1)	104 (7.1)	<.001
Scalp hematoma	8 (1.2)	47 (3.2)	.008
Pain necessitating drugs	36 (5.5)	186 (12.7)	<.001
Neonatal trauma #	3 (0.5)	20 (1.4)	.06
Fracture of the clavicle	0 (0)	9 (0.6)	.04
Fracture of a long bone	0 (0)	0 (0)	-
Brachial plexus injury	1 (0.2)	5 (0.3)	.4
Cephalhematoma	2 (0.3)	6 (0.4)	.7
Skull fracture	0 (0)	0 (0)	-
Intraventricular hemorrhage>grade 2	0 (0)	0 (0)	-
Need for resuscitation or intubation	3 (0.5)	11 (0.8)	.4
Sepsis	4 (0.6)	17 (1.2)	.2
Seizures	1 (0.2)	4 (0.3)	.6
Neonatal death	0 (0)	0 (0)	-
<b>Severe neonatal morbidity **</b>	<b>55 (8.4)</b>	<b>150 (10.2)</b>	<b>.2</b>
<b>Variables recorded at 6 months postpartum</b>			
Breastfeeding	185/276 (67.0)	401/658 (60.9)	.08
Pelvic floor muscle training	210/272 (77.2)	526/654 (80.4)	.3

	Vacuum (n=654)	Forceps/Spatulas (n=1474)	P
Urinary incontinence <sup>¶</sup>	54/276 (19.6)	158/654 (24.1)	.1
Stress urinary incontinence	5/54 (9.3)	18/158 (11.4)	.7
Urge urinary incontinence	20/54 (37.0)	49/158 (31.0)	.5
Mixed urinary incontinence	24/54 (44.4)	63/158 (39.9)	.6
Severe urinary incontinence	1/54 (1.9)	0/158 (0)	.09
Difficulty voiding	36/54 (66.7)	105/158 (66.5)	.9
Anal incontinence <sup>¶¶</sup>	52/271 (19.2)	150/647 (23.2)	.2
FISI score	11 [7-12]	11 [7-16]	.3
Perineal pain <sup>¶¶¶</sup>	32/275 (11.6)	95/649 (14.6)	.2
Episiotomy complications <sup>§</sup>	70/260 (26.9)	218/605 (36.0)	.01
Sexually active	240/253 (94.9)	571/602 (94.9)	.9
Dyspareunia	83/240 (34.6)	196/571 (34.3)	.9

*OVD, operative vaginal delivery ; IQR, interquartile range ; PPH, postpartum hemorrhage NICU, neonatal intensive care unit ; FISI, Fecal Incontinence Severity Index.*

Continuous data are expressed as means  $\pm$  standard deviations or medians [IQR] when specified ; discrete data are expressed as n (%). Student t test,  $\chi^2$  test, Kruskal-Wallis test, and Fisher's exact test were used as appropriate. A P value of .05 was considered significant.

§ Second-line therapies: uterine compression sutures, uterine artery embolization, and peripartum hysterectomy for management of massive primary postpartum hemorrhage after failure of uterine massage and uterotonic agents to stop bleeding.

£ Infections were defined by at least one of the following: endometritis, episiotomy infection, or wound infection requiring surgery.

\* Severe maternal morbidity was defined by at least one of the following criteria: third or fourth-degree perineal lacerations, perineal hematomas, cervical laceration, extension of uterine incision in cesarean delivery, PPH > 1,500 mL, surgical hemostatic procedure, uterine artery embolization, blood transfusion, infections (endometritis, episiotomy infection, wound infection requiring surgery), thromboembolic event (deep vein thrombophlebitis or pulmonary embolism), admission to intensive care unit, and maternal death.

# Neonatal trauma was defined by the existence of at least one of the following criteria: fracture of the clavicle or a long bone, brachial plexus injury, cephalhematoma, and skull fracture.

\*\* Severe neonatal morbidity was defined by at least one of the following criteria: 5-minute Apgar score < 7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for > 24 hours, convulsions, sepsis, and neonatal death.

¶ Symptoms of urinary incontinence defined as the answer "yes" to the question "Do you have involuntary loss of urine?"; Stress urinary incontinence (SUI) was assessed by responses to the question "Does urine leak when you are physically active, cough or sneeze?". Women who answered "often" or "all the time" were considered to have severe SUI; Urge incontinence by any positive response to "Does urine leak before you go to the toilet?"; Mixed incontinence by a positive response to both of the previous questions; Voiding difficulty by response to the question "Do you have difficulties in emptying your bladder?".

¶¶ Symptoms of anal incontinence were defined as the answer "yes" to the question "Do you have involuntary loss of flatus or stool?".

¶¶¶ Perineal pain was assessed by the question: "Do you have chronic perineal pain (perineum designates the skin and muscle around the vaginal and anal outlets)?".

§ Episiotomy complications were defined by the existence of at least one of the following criteria: hematoma, abscess, scar disunion, or required surgery for episiotomy.

**Table 3.** Univariate analysis of severe maternal and neonatal morbidity after attempted operative vaginal delivery by the type of instrument used (n=2128).

	Severe maternal morbidity *			Severe neonatal morbidity **		
	No (n=1939)	Yes (n=189)	P	No (n=1923)	Yes (n=205)	P
Maternal age (years)	28.2 ± 5.1	28.1 ± 5.3	.6	28.2 ± 5.1	27.8 ± 5.4	.9
> 30	1350 (69.6)	130 (68.8)	.9	1331 (69.2)	149 (72.7)	.3
BMI before pregnancy (kg/m <sup>2</sup> )	22.8 ± 4.2	25.0 ± 4.1	.001	22.7 ± 4.1	25.3 ± 4.1	<.001
<18.5	175 (9.0)	19 (10.1)	.7	175 (9.1)	19 (9.3)	.07
[18.5-25[	1345 (69.2)	125 (66.1)		1343 (69.7)	127 (65.3)	
[25-30[	296 (15.2)	29 (15.3)		288 (14.9)	37 (18.1)	
≥ 30	127 (6.5)	16 (8.5)		122 (6.3)	21 (10.3)	
Gestational weight gain > 20 kg	188 (10.1)	26 (14.0)	.1	196 (10.5)	18 (10.1)	.8
Nulliparous	1441 (73.5)	146 (76.4)	.4	1438 (74.0)	149 (72.0)	.5
Previous cesarean delivery	196 (10.0)	30 (15.7)	.01	202 (10.3)	24 (11.6)	.6
Previous operative vaginal delivery	117 (6.0)	5 (2.7)	.06	106 (5.5)	16 (7.8)	.2
Previous birth > 4,000 g	1 (0.5)	23 (1.2)	.4	21 (1.1)	3 (1.5)	.6
Previous shoulder dystocia	7 (1.4)	1 (2.2)	.6	7 (1.4)	1 (1.7)	.8
Previous PPH	19 (1.0)	4 (2.1)	.1	21 (1.1)	2 (1.0)	.9
Gestational diabetes mellitus			.6			.8
Preexisting	7 (0.4)	0 (0)		7 (0.4)	0 (0)	
Treated by diet	108 (5.6)	8 (4.3)		105 (5.5)	11 (5.1)	
Treated by insulin	36 (1.9)	2 (1.1)		35 (1.8)	3 (1.5)	
Prenatally suspected macrosomia ‡	147 (7.5)	22 (11.5)	.05	156 (8.0)	13 (6.3)	.4
Gestational age at delivery (weeks)	39.8 ± 1.5	40.1 ± 1.3	.003	39.9 ± 1.3	38.9 ± 2.7	.01
Gestational age at delivery ≥ 41 weeks	439 (22.4)	56 (29.3)	.03	450 (23.2)	45 (21.7)	.6
Induced labor	345 (17.6)	35 (18.3)	.8	332 (17.1)	48 (23.2)	.03
2 <sup>nd</sup> stage > 3 hours	268 (13.7)	32 (16.8)	.2	284 (14.6)	16 (7.7)	.007
Active phase of 2 <sup>nd</sup> stage > 30 min	614 (31.8)	59 (31.1)	.8	618 (32.2)	55 (27.6)	.2
Dose of oxytocin (mIU) median [IQR]	880 [188-2220]	1300 [380-2920]	<.001	900 [200-2280]	918 [214-2470]	.6
Epidural analgesia	1831 (94.5)	175 (91.6)	.3	1813 (93.3)	193 (93.2)	.9
Manual rotation	206 (10.7)	26 (13.7)	.2	208 (10.8)	24 (11.9)	.6
Persistent occiput position			.9			.3
Anterior	1719 (88.2)	166 (87.4)		1713 (88.4)	172 (84.7)	
Posterior	176 (9.0)	19 (10.0)		171 (8.8)	24 (11.8)	
Transverse	55 (2.8)	5 (2.6)		53 (2.7)	7 (3.5)	
ACOG classification			.2			.6
Mid	348 (17.7)	43 (22.6)		349 (18.0)	42 (20.8)	
Low	1418 (72.8)	133 (70.0)		1408 (72.7)	143 (70.8)	
Outlet	183 (9.4)	14 (7.4)		180 (9.3)	17 (8.4)	
Indications for OVD			.05			.003
Non-reassuring FHR only	851 (33.4)	66 (34.6)		832 (42.8)	85 (41.3)	
Arrested progress only	720 (36.8)	84 (44.0)		742 (38.2)	62 (30.1)	
Non-reassuring FHR and arrested progress	388 (19.8)	41 (21.5)		370 (19.0)	59 (28.6)	
Caesarean delivery after failed OVD	29 (1.5)	10 (5.2)	<.001	33 (1.7)	6 (2.9)	.2
Obstetrician performing delivery			.03			.001
Senior attending obstetrician	481 (24.8)	60 (32.1)		470 (24.4)	71 (35.3)	
Obstetric resident	1456 (75.2)	127 (67.9)		1453 (75.6)	130 (64.7)	

	Severe maternal morbidity *			Severe neonatal morbidity **		
	No (n=1939)	Yes (n=189)	P	No (n=1923)	Yes (n=205)	P
Instrument type			<.001			.2
Vacuum	619 (31.9)	35 (18.5)		599 (31.2)	55 (26.8)	
Forceps or Spatula	1320 (68.1)	154 (81.5)		1324 (68.9)	150 (73.2)	
Sequential use of two instruments	73 (3.7)	9 (4.7)	.5	70 (3.6)	12 (5.8)	.1
Rotational forceps delivery	2 (0.1)	0 (0)	.7	2 (0.1)	0 (0)	.6
Episiotomy	1700 (87.2)	162 (85.3)	.5	1692 (87.4)	170 (82.9)	.07
Birth weight ≥ 4,000 g	96 (4.9)	14 (7.4)	.1	99 (5.1)	11 (5.4)	.9

*BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate.*

Continuous data are expressed as means ± standard deviations or medians [IQR] when specified ; discrete data are expressed as n (%). Student t test,  $\chi^2$  test, Kruskal-Wallis test, and Fisher's exact test were used as appropriate. A P value of .05 was considered significant.

\* Severe maternal morbidity was defined by at least one of the following criteria: third or fourth-degree perineal lacerations, perineal hematomas, cervical laceration, extension of uterine incision in cesarean delivery, PPH>1,500 mL, surgical hemostatic procedure, uterine artery embolization, blood transfusion, infections (endometritis, episiotomy infection, or wound infection requiring surgery), thromboembolic event (deep vein thrombophlebitis or pulmonary embolism), admission to intensive care unit, and maternal death.

\*\* Severe neonatal morbidity was defined by at least one of the following criteria: 5-minute Apgar score<7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for >24 hours, convulsions, sepsis and neonatal death.

‡ Prenatally suspected macrosomia: fundal height measurement at delivery >37 cm and/or ultrasonographic fetal abdominal circumference > 90<sup>th</sup> p. for gestational age on Hadlock curves.

**Table 4.** Univariate and multivariate analysis of severe maternal and neonatal morbidity after attempted operative vaginal delivery by the type of instrument used (n=1942).

	Severe maternal morbidity *			Severe neonatal morbidity **		
	Crude OR (95% CI)	Adj. OR (95% CI)	P <sup>†</sup>	Crude OR (95% CI)	Adj. OR (95% CI)	P <sup>†</sup>
<b>Instrument type</b>						
Vacuum	Ref	Ref		Ref	Ref	
Forceps or Spatula	2.06 (1.41-3.01)	1.99 (1.27-3.10)	<.01	1.23 (0.89-1.71)	1.04 (0.69-1.56)	.9
<b>Maternal age (years)</b>						
> 30	1.00 (0.76-1.45)	1.00 (0.69 -1.44)	.9	0.85 (0.62-1.17)	0.73 (0.49-1.08)	.1
<b>BMI before pregnancy (kg/m<sup>2</sup>)</b>						
<18.5	1.17 (0.71-1.95)	1.17 (0.68-2.03)	.6	1.15 (0.69-1.91)	1.09 (0.60-1.97)	.8
[18.5-25[	Ref	Ref		Ref	Ref	
[25-30[	1.03 (0.67-1.58)	0.94 (0.60-1.48)	.8	1.34 (0.90-1.98)	1.37 (0.89-2.13)	.2
≥ 30	1.37 (0.79-2.39)	1.25 (0.68-2.29)	.5	1.85 (1.12-3.04)	2.15 (1.22-3.80)	.01
<b>Gestational weight gain &gt; 20kg</b>	1.48 (0.95-2.30)	1.34 (0.84-2.14)	.2	0.91 (0.54-1.53)	0.81 (0.46-1.45)	.5
Nulliparous	1.15 (0.81-1.63)	1.76 (0.94-3.31)	.07	0.89 (0.65-1.23)	1.14 (0.64-2.03)	.6
Previous cesarean delivery	1.71 (1.12-2.60)	2.92 (1.47-5.79)	<.01	1.15 (0.73-1.80)	1.38 (0.71-2.70)	.3
Previous adverse events during delivery <sup>&amp;</sup>	0.70 (0.56-1.36)	0.88 (0.40-1.91)	.7	1.18 (0.70-2.01)	1.24 (0.60-2.54)	.6
Gestational diabetes mellitus <sup>§</sup>	0.68 (0.35-1.32)	-	-	0.91 (0.52-1.61)	-	-
Prenatally suspected macrosomia <sup>‡</sup>	1.65 (1.03-2.66)	1.37 (0.81-2.32)	.2	0.79 (0.44-1.42)	0.54 (0.25-1.14)	.1
<b>Gestational age at delivery (weeks)</b>						
< 39	0.83 (0.55-1.24)	0.87 (0.56-1.34)	.5	2.42 (1.74-3.37)	1.80 (1.21-2.67)	.01
[39-41[	Ref	Ref		Ref	Ref	
≥ 41	1.44 (1.02-2.03)	1.40 (0.96-2.05)	.08	1.27 (0.87-1.85)	1.10 (0.72-1.69)	.6
<b>Induced labor</b>	1.07 (0.73-1.57)	0.90 (0.59-1.38)	.6	1.45 (1.02-2.04)	1.58 (1.05-2.38)	.03
2 <sup>nd</sup> stage>3 hours	1.26 (0.84-1.89)	1.02 (0.64-1.62)	.9	0.46 (0.27-0.80)	0.42 (0.22-0.82)	.01
Active phase of 2 <sup>nd</sup> stage > 30 min	0.98 (0.71-1.35)	0.60 (0.39-0.93)	.02	0.79 (0.57-1.10)	0.95 (0.59-1.51)	.8
Epidural analgesia	0.76 (0.44-1.30)	0.42 (0.22-0.79)	<.01	0.98 (0.55-1.74)	1.55 (0.69-3.49)	.3
Manual rotation	1.29 (0.83-2.02)	-	-	1.14 (0.73-1.79)	-	-
<b>Persistent occiput position</b>						
Anterior	Ref	Ref		Ref	Ref	
Posterior	1.18 (0.71-1.94)	1.10 (0.64-1.87)	.7	1.47 (0.93-2.33)	1.19 (0.70-2.04)	.5
Transverse	0.96 (0.38-2.44)	0.76 (0.26-2.17)	.6	1.35 (0.60-3.01)	1.28 (0.53-3.09)	.6
<b>ACOG classification</b>						
Mid	1.80 (0.94-3.43)	1.08 (0.51-2.32)	.8	1.27 (0.70-2.31)	0.77 (0.37-1.60)	.5
Low	1.31 (0.73-2.36)	1.05 (0.54-2.03)	.9	1.06 (0.63-1.80)	0.87 (0.47-1.59)	.6
Outlet	Ref	Ref		Ref	Ref	
<b>Indications for OVD</b>						
Non-reassuring FHR only	0.66 (0.47-0.92)	0.50 (0.32-0.79)	<.01	1.23 (0.87-1.74)	1.03 (0.62-1.70)	.9
Arrested progress only	Ref	Ref		Ref	Ref	
Non-reassuring FHR and arrested progress	0.91 (0.61-1.35)	0.74 (0.47-1.19)	.2	1.89 (1.29-2.76)	1.67 (1.02-2.72)	.04
Caesarean delivery after failed OVD	3.68 (1.76-7.67)	-	-	1.73 (0.71-4.17)	-	-
<b>Obstetrician performing delivery</b>						
Senior attending obstetrician	Ref	Ref		Ref	Ref	
Obstetric resident	0.68 (0.49-0.94)	0.84 (0.58-1.21)	.3	0.59 (0.43-0.80)	0.66 (0.45-0.97)	.04
Sequential use of two instruments	1.28 (0.63-2.60)	-	-	1.65 (0.88-3.09)	-	-
Episiotomy	0.83 (0.54-1.26)	-	-	0.68 (0.46-1.01)	-	-
Birth weight ≥ 4,000 g	1.56 (0.87-2.79)	-	-	1.07 (0.56-2.02)	-	-

*OR, Odds Ratio ; CI, confidence interval ; BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate.*

‡ Adjusted logistic regression analyses. Adjustment on maternal age, BMI, gestational weight gain, nulliparity, previous caesarean delivery, previous adverse event during delivery, prenatal suspicion of macrosomia, gestational age, induced labor, duration of second phase of labor, epidural analgesia, occiput presentation, ACOG classification, indication for OVD, and operator for OVD.

\* Severe maternal morbidity was defined by at least one of the following criteria: third or fourth-degree perineal lacerations, perineal hematomas, cervical laceration, extension of uterine incision in cesarean delivery, PPH>1,500 mL, surgical hemostatic procedure, uterine artery embolization, blood transfusion, infections (endometritis, episiotomy infection, wound infection requiring surgery), thromboembolic event (deep vein thrombophlebitis or pulmonary embolism), admission to intensive care unit, and maternal death.

\*\* Severe neonatal morbidity was defined by at least one of the following criteria: 5-minute Apgar score<7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for >24 hours, convulsions, sepsis, and neonatal death.

‡ Prenatally suspected macrosomia: fundal height measurement at delivery > 37cm and/or ultrasonographic fetal abdominal circumference > 90<sup>th</sup> p. for gestational age on Hadlock curves.

\$ Preexisting or gestational diabetes mellitus

& History of birth weight >4,000g, shoulder dystocia, operative vaginal delivery or PPH.

## **Discussion**

### ***Principal findings***

Our results after controlling for indication bias with a propensity score analysis suggest that among women with singleton term pregnancies, aOVD with forceps/spatulas versus vacuum was not associated with greater severe maternal or neonatal morbidity or with higher rates of UI and AI symptoms at 6 months postpartum.

### ***Results***

To our knowledge, our study is the first using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that is, the same probability of forceps-assisted delivery.

A Cochrane review examined 32 RCTs of aOVD by different instruments, including 3,338 women from 13 trials, performed mainly before 2000 (n=10) comparing forceps with vacuum delivery. Forceps were more often associated with maternal morbidity, especially for third- and fourth-degree perineal tears (relative risk [RR] 1.89, 95%CI 1.51-2.37), vaginal trauma (RR 2.48, 95%CI 1.59-3.87), and flatus incontinence or impaired continence (RR 1.77, 95%CI 1.19-2.62). Vacuum-assisted deliveries were associated with a higher rate of failed vaginal birth and a trend toward higher neonatal morbidity.<sup>12</sup> All had notable methodological limitations: small (median: 210 participants, range: 36–637), single-center studies, some only quasi-randomized, and mostly underpowered to assess adverse events.

Observational studies have reported discordant results regarding the association between maternal and neonatal morbidity and forceps-, spatula- and vacuum-assisted deliveries. They also were limited by methodological flaws — sample size, retrospective designs, limited data quality and availability, and absence of propensity score analysis to limit the indication bias affecting in the operator's choice of instrument.<sup>4,35-39</sup> Any statistical approaches were limited to multivariable analyses controlling for some

potential confounders. In these cases, results were consistent with our adjusted OR showing higher maternal morbidity with forceps- than vacuum-assisted delivery.<sup>13</sup>

Previous studies assessing pelvic floor disorders following an aOVD were limited by the same weaknesses as previously described.<sup>40-43</sup> Nevertheless, our results are consistent with other findings in the literature, regarding the prevalence of UI and AI (around 20% the first months after OVD<sup>44-46</sup>), the maternal or pregnancy-related characteristics at risk of UI or AI (advanced age,<sup>47-48</sup> high pre-pregnancy BMI,<sup>40,41,44,48</sup> gestational diabetes mellitus,<sup>47,49,50</sup> and breastfeeding<sup>15,44</sup>), and the trend to a higher rate of urinary and anal incontinence after aOVD with forceps or spatulas compare than with vacuum.<sup>41,43,46,48</sup>

### ***Clinical and research implications***

Choice of instrument for OVD remains a controversial topic. Previous data suggest the interests of mother and fetus conflict: forceps appear to be associated with maternal morbidity and vacuum with more frequent and severe neonatal complications. Our study, using a propensity score analysis to limit indication bias, shows no difference between vacuum and forceps/spatulas in maternal and neonatal morbidity until hospital discharge and in pelvic floor disorders at 6 months. The choice of instrument should be determined principally by the operator's or woman's preference. Future studies should determine whether some circumstances or subgroups of women might benefit from one instrument or another.

### ***Strengths and limitations***

Our study presents several strengths. First, the data came from a large prospective cohort in a center with a policy of planned vaginal delivery, demonstrated indirectly by its OVD (13.6%) and cesarean (20%) rates. These prospectively collected data, often unavailable in retrospective population-based studies, include maternal and obstetric characteristics, notably during the second stage of labor, and describe clinical situations affecting the aOVD decision (e.g., prenatally suspected macrosomia, fetal

head station, and occiput position). Second, these data are robust: a collector bag was routinely used to estimate blood loss after delivery, neonatal arterial blood gases were systematically measured, and all neonates were examined by a qualified neonatologist. Our previous results have been consistent with other well-established findings in the literature, especially for short- and mid-term maternal morbidity and short-term neonatal morbidity after vacuum or forceps deliveries.<sup>14,15,22</sup> Third, we studied all attempted OVDs, including failures, because their exclusion might mask a negative effect.<sup>3</sup> Fourth, to control for indication bias (which would otherwise be this study's major limitation), we performed propensity score analysis and made rigorous adjustments for confounding factors, specifically for maternal and obstetric characteristics (including prenatally suspected macrosomia, fetal head station and occiput position, physician experience with aOVD, and its indications) to minimize the likelihood of incorrectly attributing any association to forceps/spatulas. Our univariate analysis showed that forceps/spatulas were used in the most difficult conditions, and vacuum for lower-risk, less complicated deliveries. Lastly, we used validated instruments to assess symptoms of UI and AI at 6 months postpartum.<sup>25-29</sup>

Our study has some limitations. First, despite our careful statistical approaches with sensitivity, multivariable, and propensity score analyses, unmeasured confounders may still persist. An RCT would undeniably be the best study design to compare the effects of the instrument used for aOVD, but its feasibility today seems very doubtful. Second, the rate of respondents at 6 months was only 43.9%. This response rate is nonetheless similar to other studies assessing postpartum pelvic floor disorders by mailed questionnaires after birth.<sup>49,51,52</sup> Although respondents and nonrespondents differed for some characteristics, nothing suggests that this potential selection bias produces a higher or lower risk of pelvic floor disorders. Moreover, the nonrespondents differed mainly for severe neonatal morbidity, a factor unrelated to UI or AI. Third, the infrequency of neonatal morbidity such as scalp hematoma, trauma or seizures, limited our statistical power to detect potentially clinically meaningful differences between vacuum and forceps/spatulas. Moreover, due to the sample size of our propensity score analysis

(n=594 for short-term neonatal and maternal outcome), some might argue that it was underpowered. However, we have to underline that our results show a trend to a higher rate of short- and long-term maternal morbidity possibly obscured by a loss of power. Nonetheless, this increase appears moderate. Furthermore, a post-hoc calculation found that with a sample size of 594 patients and 5-10% of deliveries with adverse maternal or neonatal outcomes, we would have had a power of 80% and an alpha of 0.05, so that an OR >2.1 have been detected by univariate logistic regression. Lastly, the time frame of UI and AI assessment at 6 months is considered as very short term in the context of the development of pelvic floor disorders. Urogynecologic evaluation over the second year after the childbirth appears to be the most meaningful to patients and physicians.<sup>42-49</sup> As in previous cohort studies of incontinence, our study used self-report of incontinence, rather than diagnoses reached using urodynamics. If the self-report of symptoms of UI provides the most patient-relevant outcomes, symptomatic incontinence may show limited correlation with urodynamic diagnosis, and thus these findings should not be generalized to diagnoses of urodynamic UI.<sup>41</sup>

## **Conclusion**

These limitations notwithstanding, in our study, aOVD managed by forceps or spatulas compared with vacuum was not associated with a higher rate of severe maternal and neonatal morbidity or with maternal pelvic floor disorders. These results support the use of vacuum or forceps/spatulas, depending mainly on the operator's preference.

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## Appendices

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### Appendix 1. Assessment of pelvic floor disorders at 6 months postpartum.

Information about pelvic floor disorders was obtained from a questionnaire sent 6 months after delivery. A second mailing was sent to the women from whom we had received no response. The questionnaire asked about postpartum pelvic floor exercises and pelvic floor symptoms during the preceding 4 weeks. The women who answered "yes" to the entry question "Do you have involuntary loss of urine?" were considered to have symptoms of UI and were then asked further questions from the French version of the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) validated questionnaire<sup>25-27</sup> about the frequency, amount, and circumstances of leakage, and if and to what extent incontinence bothered women. Stress urinary incontinence (SUI) was assessed by responses to the question "Does urine leak when you are physically active, cough or sneeze?" Possible responses were as follows: never, occasionally, sometimes, often or all the time. "Occasionally" was defined as less than one-third of the time; "sometimes" as between one and two-thirds of the time; and "often" as more than two-thirds of the time but less than "all the time". Women who answered "often" or "all the time" were considered to have severe SUI.<sup>25-27</sup> Urge incontinence was assessed by any positive response to "Does urine leak before you go to the toilet?" and mixed incontinence by a positive response to both of the previous questions. Voiding difficulty was assessed by the response to the question "Do you have difficulties in emptying your bladder?"<sup>25,26</sup>

As previously reported,<sup>25</sup> perineal pain was evaluated with the question "Do you have chronic perineal pain (perineum designates the skin and muscle around the vaginal and anal outlets)?" This question was dichotomous (possible answers: "yes" and "no").<sup>25</sup> Episiotomy complications were evaluated with the question "Did you have any complications of your episiotomy (hematoma, abscess, scar disunion, surgery)?" They were defined by the existence of at least one of the following criteria: hematoma, abscess, scar disunion, or surgery required for episiotomy.



Never  
Occasionally  
Sometimes  
Most of the time  
All of the time

4) Do you have difficulties in emptying your bladder?

Never  
Occasionally  
Sometimes  
Most of the time  
All of the time

5) Do you have to rush to the toilet to urinate?

Never  
Occasionally  
Sometimes  
Most of the time  
All of the time

6) To what extent have your urinary symptoms affected your ability to perform daily tasks (eg, cleaning, "Do It Yourself", lifting objects)?

Not at all  
A little  
Somewhat  
A lot

7) How often do you leak urine?

Never  
Once or less per week  
2-3 times per week  
Once per day  
Several times per day

8) To what extent do you feel that your life has been spoiled by your urinary symptoms?

Not at all  
A little  
Somewhat  
A lot



## **Appendix 2. Propensity Score Matching construction.**

To control for confounding factors that might influence both the choice of vacuum or forceps/spatulas for the attempted OVD and the occurrence of severe maternal and neonatal morbidity, we used a propensity score approach. A woman's propensity score was defined as her probability of undergoing aOVD by forceps/spatulas, based on her individual covariates measured before delivery. A propensity score was estimated for all women, by a logistic regression model with attempted OVD by forceps/spatulas as the dependent variable in relation to the following baseline maternal and obstetric characteristics: maternal age older than 30 years (binary variable), BMI before pregnancy over 30 kg/m<sup>2</sup> (binary variable), nulliparity (binary variable), previous cesarean delivery (binary variable), previous adverse event during delivery (binary variable), gestational diabetes mellitus (binary variable), gestational weight gain exceeding 20 kg (binary variable), prenatally suspected macrosomia (binary variable), gestational age at delivery (<39, 39-41 or ≥ 41 weeks), induced labor (binary variable), second stage of labor exceeding 3 hours (binary variable), active second phase of labor more than 30 minutes (binary variable), epidural analgesia (binary variable), persistent occiput position (binary variable: anterior or posterior/transverse), indications for OVD (nonreassuring FHR only, arrested progress only, or both), ACOG classification of the fetal head position (mid, low, outlet), and the obstetrician performing the delivery (binary variable). The choice of variables that were included in the propensity score model was made after analysis of the literature and careful thought.

Exposed (with attempted OVD by forceps/spatulas) and unexposed (with attempted OVD by vacuum) women were matched with a one-to-one nearest neighbor matching algorithm without replacement for the average propensity score,<sup>31</sup> within a caliper of 0.2 standard deviation of the logit of the propensity score.<sup>31</sup> Imbalances after matching were checked by propensity score distribution and calculation of standardized mean differences.<sup>33</sup>

Paired conditional statistical methods were used to assess the effect of exposure on the matched sample. In the matched set, odds ratios (OR) and their 95% confidence intervals (95% CI) were estimated to quantify the association between the choice of vacuum or forceps/spatulas for the attempted OVD and

the occurrence of severe maternal and neonatal morbidity by Generalized Estimating Equation logistic regression.

### Appendix 3. Comparison of respondents and nonrespondents to the questionnaires at 6 months.

**Table 5.** Maternal and labor characteristics and maternal and neonatal outcomes for operative vaginal deliveries of respondents and nonrespondents to the questionnaires at 6 months (n=2,128).

	Respondents (n=934)	Non-respondents (n=1,194)	P
<b>Maternal and labor characteristics</b>			
Maternal age (years)	29.0 ± 4.8	27.5 ± 5.2	<.001
> 30	325 (34.8)	318 (26.6)	<.001
BMI before pregnancy (kg/m <sup>2</sup> )	22.7 ± 3.9	22.9 ± 4.5	.1
<18.5	68 (7.3)	123 (10.3)	.01
[18.5-25[	676 (72.7)	798 (66.8)	
[25-30[	136 (14.6)	180 (15.1)	
≥ 30	50 (5.4)	93 (7.8)	
Gestational weight gain > 20kg	78 (8.6)	142 (11.9)	.02
Nulliparous	701 (75.1)	872 (73.0)	.3
Previous cesarean delivery	87 (9.3)	135 (11.3)	.1
Previous operative vaginal delivery	50 (5.4)	72 (6.0)	.5
Previous birth>4,000 g	9 (1.0)	16 (1.3)	.5
Previous shoulder dystocia	2 (0.2)	6 (0.5)	.3
Previous PPH	7 (0.8)	17 (1.4)	.2
Gestational diabetes mellitus			.8
Preexisting	4 (0.4)	4 (0.3)	
Treated by diet	54 (5.8)	60 (5.0)	
Treated by insulin	16 (1.7)	21 (1.8)	
Prenatally suspected macrosomia ‡	66 (7.1)	98 (8.2)	.4
Gestational age at delivery (w)	39.8 ± 1.4	39.7 ± 1.6	.1
Gestational age at delivery ≥ 41 weeks	213 (22.8)	284 (23.8)	.6
Induced labor	154 (16.5)	227 (19.0)	.1
2 <sup>nd</sup> stage>3 hours	151 (16.2)	134 (11.7)	.003
Active phase of 2 <sup>nd</sup> stage > 30 min	322 (34.9)	350 (29.3)	.01
Dose of oxytocin (mIU) median [IQR]	920 [200-2220]	900 [200-2380]	.8
Epidural analgesia	882 (94.5)	1101 (92.2)	.03
Manual rotation	110 (11.8)	120.6 (10.1)	.2
Persistent occiput position			.01
Anterior	831 (89.3)	1043 (87.4)	
Posterior	75 (8.1)	115 (9.6)	
Transverse	25 (2.7)	36 (3.0)	
ACOG classification			.2
Mid	152 (16.4)	232 (19.4)	
Low	690 (74.6)	851 (71.3)	
Outlet	83 (9.0)	111 (9.3)	

	<b>Respondents (n=934)</b>	<b>Non-respondents (n=1,194)</b>	<b>P</b>
Indications for OVD			.01
Non-reassuring FHR only	394 (42.2)	517 (43.3)	
Arrested progress only	382 (40.9)	406 (34.0)	
Non-reassuring FHR and arrested progress	158 (16.9)	265 (22.2)	
Obstetrician performing delivery			.3
Senior attending obstetrician	243 (26.4)	293 (24.5)	
Obstetric resident	677 (73.6)	901 (75.5)	
Sequential use of two instruments	26 (2.8)	57 (4.8)	.02
Rotational forceps delivery	0 (0)	2 (0.2)	.3
<b>Maternal outcome</b>			
Caesarean delivery after failed OVD	16 (1.7)	24 (2.0)	.6
Episiotomy	824 (88.2)	1028 (86.1)	.2
3 <sup>rd</sup> or 4 <sup>th</sup> -degree perineal lacerations	27 (2.9)	30 (2.5)	.6
PPH (blood loss >500 mL)	164 (17.6)	179 (15.0)	.1
Severe PPH (blood loss >1,500 mL)	17 (1.9)	13 (1.1)	.2
<b>Severe maternal morbidity *</b>	81 (8.7)	111 (9.3)	.6
<b>Neonatal outcome</b>			
Birth weight ≥4,000 g	52 (5.6)	60 (5.0)	.5
<b>Severe neonatal morbidity **</b>	70 (7.5)	137 (11.5)	.002

*BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate.*

Continuous data are expressed as means ± standard deviations or medians [IQR] when specified ; discrete data are expressed as n (%). Student t test,  $\chi^2$  test, Kruskal-Wallis test, and Fisher's exact test were used as appropriate. A P value of .05 was considered significant.

‡ Prenatally suspected macrosomia: fundal height measurement at delivery > 37 cm and/or ultrasonographic fetal abdominal circumference > 90<sup>th</sup> p. for gestational age on Hadlock curves.

\* Severe maternal morbidity was defined by at least one of the following criteria: third or fourth-degree perineal lacerations, perineal hematomas, cervical laceration, extension of uterine incision in cesarean delivery, PPH > 1,500 mL, surgical hemostatic procedure, uterine artery embolization, blood transfusion, infections (endometritis, episiotomy infection, wound infection requiring surgery), thromboembolic event (deep vein thrombophlebitis or pulmonary embolism), admission to intensive care unit, and maternal death.

\*\* Severe neonatal morbidity was defined by at least one of the following criteria: 5-minute Apgar score < 7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for > 24 hours, convulsions, sepsis, and neonatal death.

#### Appendix 4. Univariate analysis for the secondary endpoints.

**Table 6.** Univariate analysis of urinary and anal incontinence at 6 months after attempted operative vaginal delivery by type of instrument used (n=934).

	Urinary incontinence			Anal incontinence		
	No (n=721)	Yes (n=212)	P	No (n=716)	Yes (n=202)	P
<b>Maternal and labor characteristics</b>						
Maternal age (years)	28.7 ± 4.7	30.0 ± 5.0	<.001	28.7 ± 4.7	30.4 ± 4.6	<.001
> 30	233 (32.3)	91 (42.9)	<.001	225 (31.4)	97 (48.0)	<.001
BMI before pregnancy (kg/m <sup>2</sup> )	22.6 ± 3.8	23.0 ± 4.2	.1	22.5 ± 3.7	23.0 ± 4.1	.1
<18.5	57 (8.0)	11 (5.2)	.4	51 (7.1)	14 (7.0)	.2
[18.5-25[	521 (72.7)	154 (72.6)		530 (74.2)	137 (68.5)	
[25-30[	103 (14.4)	33 (15.6)		102 (14.3)	33 (16.5)	
≥ 30	36 (5.0)	14 (6.6)		31 (4.3)	16 (8.0)	
Gestational weight gain > 20kg	56 (8.1)	21 (10.2)	.3	60 (8.7)	16 (8.3)	.9
Nulliparous	542 (75.2)	158 (74.5)	.8	553 (77.2)	137 (67.8)	.01
Previous cesarean delivery	62 (8.6)	25 (11.8)	.2	63 (8.8)	23 (11.4)	.3
Previous operative vaginal delivery	43 (6.0)	7 (3.3)	.1	31 (4.3)	15 (7.4)	.08
Previous birth > 4,000 g	8 (1.1)	1 (0.5)	.4	3 (0.4)	6 (3.0)	.001
Previous shoulder dystocia	2 (1.1)	0 (0)	.4	2 (1.2)	0 (0)	.4
Gestational diabetes mellitus			.4			.01
Preexisting	4 (0.6)	0 (0)		3 (0.4)	1 (0.5)	
Treated by diet	38 (5.3)	15 (7.1)		33 (4.6)	20 (10.0)	
Treated by insulin	11 (1.5)	5 (2.4)		10 (1.4)	6 (3.0)	
Prenatally suspected macrosomia ‡	55 (7.6)	11 (5.2)	.2	42 (5.9)	20 (9.9)	.04
Gestational age at delivery (weeks)	39.8 ± 1.4	39.9 ± 1.3	.8	39.8 ± 1.4	40.0 ± 1.3	.2
Induced labor	116 (16.1)	38 (17.9)	.5	108 (15.1)	44 (21.8)	.02
2 <sup>nd</sup> stage > 3 hours	118 (16.4)	33 (15.6)	.8	112 (15.7)	38 (18.8)	.3
Active phase of 2 <sup>nd</sup> stage > 30 min	244 (34.2)	78 (37.5)	.4	243 (34.3)	76 (38.2)	.3
Epidural analgesia	686 (95.3)	195 (92.0)	.06	676 (94.6)	192 (95.1)	.8
Manual rotation	91 (12.7)	19 (9.0)	.1	84 (11.8)	24 (11.9)	.9
Persistent occiput position			.2			.3
Anterior	639 (88.8)	191 (91.0)		634 (88.9)	183 (90.6)	
Posterior	58 (8.1)	17 (8.1)		62 (8.7)	12 (5.9)	
Transverse	23 (3.2)	2 (1.0)		17 (2.4)	7 (3.5)	
ACOG classification			.1			.7
Mid	111 (15.5)	41 (19.6)		120 (16.9)	29 (14.5)	
Low	534 (74.7)	155 (74.2)		525 (74.1)	153 (76.5)	
Outlet	70 (9.8)	13 (6.2)		64 (9.0)	18 (9.0)	
Indications for OVD			.8			.3
Non-reassuring FHR only	308 (42.7)	86 (40.6)		310 (43.3)	76 (37.6)	
Arrested progress only	292 (40.5)	90 (42.5)		292 (40.8)	86 (42.6)	
Non-reassuring FHR and arrested progress	121 (16.8)	36 (17.0)		114 (15.9)	40 (19.8)	
Obstetrician performing delivery			.5			.4
Senior attending obstetrician	190 (26.9)	52 (24.5)		180 (25.6)	58 (28.9)	
Obstetric resident	517 (73.1)	160 (75.5)		523 (74.4)	143 (71.1)	
Instrument type			.1			.2
Vacuum	222 (30.8)	54 (25.5)		219 (30.6)	52 (25.7)	
Forceps/Spatulas	499 (69.2)	158 (74.5)		497 (69.4)	150 (74.3)	
Sequential use of two instruments	18 (2.5)	8 (3.8)	.3	18 (2.5)	7 (3.5)	.5
Rotational forceps delivery	0 (0)	0 (0)	-	0 (0)	0 (0)	-

	Urinary incontinence			Anal incontinence		
	No (n=721)	Yes (n=212)	P	No (n=716)	Yes (n=202)	P
<b>Maternal outcome</b>						
Caesarean delivery after failed OVD	14 (2.0)	2 (1.0)	.3	13 (1.8)	3 (1.5)	.8
Episiotomy	639 (88.6)	184 (86.8)	.5	628 (87.7)	183 (90.6)	.3
3 <sup>rd</sup> or 4 <sup>th</sup> -degree perineal lacerations	16 (2.2)	11 (5.2)	.02	14 (2.0)	12 (5.9)	.003
PPH (blood loss >500 mL)	124 (17.2)	40 (18.9)	.6	116 (16.2)	44 (21.8)	.07
Severe PPH (blood loss >1,500 mL)	13 (1.8)	4 (1.9)	.9	10 (1.4)	7 (3.5)	.06
Severe maternal morbidity *	61 (8.5)	20 (9.4)	.7	55 (7.7)	25 (12.4)	.04
<b>Neonatal outcome</b>						
Birth weight (g)	3320.8 ± 430.6	3299.3 ± 409.4	.5	3296.4 ± 426.9	3398.7 ± 419.1	.01
Birth weight ≥ 4,000 g	41 (5.7)	10 (4.7)	.6	37 (5.2)	14 (6.9)	.3
Cephalic perimeter (cm)	34.4 ± 1.4	34.5 ± 1.3	.8	34.4 ± 1.4	34.7 ± 1.4	.01
Severe neonatal morbidity **	58 (8.0)	12 (5.7)	.2	57 (8.0)	13 (6.4)	.5
<b>Variables recorded at 6 months postpartum</b>						
Breastfeeding	434 (60.2)	151 (71.2)	.004	434 (60.6)	142 (70.3)	.01
Pelvic floor muscle training	153 (21.4)	37 (17.5)	.2	553 (77.9)	172 (86.0)	.01
Urinary incontinence †	-	212 (100)	-	135 (18.9)	72 (35.6)	<.001
Stress urinary incontinence	-	21 (10.2)	-	18 (13.4)	5 (6.9)	.2
Urge urinary incontinence	-	68 (32.5)	-	51 (37.5)	19 (26.0)	.09
Mixed urinary incontinence	-	87 (41.0)	-	71 (9.9)	52 (25.7)	<.001
Severe urinary incontinence	-	1 (0.5)	-	1 (0.7)	1 (1.4)	.7
Difficulty voiding	-	141 (68.5)	-	105 (75.5)	41 (56.2)	.004
Anal incontinence ††	130 (18.3)	72 (34.8)	<.001	-	202 (100)	-
FISI score	11 [7-15]	12 [7-18]	.2	-	11 [7-15]	-
Perineal pain †††	625 (87.4)	171 (82.2)	.06	91 (12.8)	34 (17.0)	.1
Episiotomy complications †	451 (67.5)	126 (64.3)	.4	216 (32.6)	69 (36.5)	.3
Sexually active	638 (95.1)	172 (94.0)	.5	627 (95.4)	170 (92.4)	.1
Dyspareunia	428 (67.1)	103 (59.9)	.08	218 (34.8)	56 (32.9)	.7

*BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate ; FISI, Fecal Incontinence Severity Index.*

Continuous data are expressed as means ± standard deviations or medians [IQR] when specified ; discrete data are expressed as n (%). Student t test,  $\chi^2$  test, Kruskal-Wallis test, and Fisher's exact test were used as appropriate. A P value of .05 was considered significant.

‡ Prenatally suspected macrosomia: fundal height measurement at delivery >37 cm and/or ultrasonographic fetal abdominal circumference > 90<sup>th</sup> p. for gestational age on Hadlock curves.

\* Severe maternal morbidity was defined by at least one of the following criteria: third or fourth-degree perineal lacerations, perineal hematomas, cervical laceration, extension of uterine incision in cesarean delivery, PPH > 1,500 mL, surgical hemostatic procedure, uterine artery embolization, blood transfusion, infections (endometritis, episiotomy infection, or wound infection requiring surgery), thromboembolic event (deep vein thrombophlebitis or pulmonary embolism), admission to intensive care unit, and maternal death.

\*\* Severe neonatal morbidity was defined by at least one of the following criteria: 5-minute Apgar score < 7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma,

intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for >24 hours, convulsions, sepsis and neonatal death.

¶ Symptoms of urinary incontinence defined as the answer “yes” to the question “Do you have involuntary loss of urine?”; Stress urinary incontinence (SUI) was assessed by responses to the question "Does urine leak when you are physically active, cough or sneeze?". Women who answered “often” or “all the time” were considered to have severe SUI; Urge incontinence by any positive response to "Does urine leak before you go to the toilet?"; Mixed incontinence by a positive response to both of the previous questions; Voiding difficulty by response to the question "Do you have difficulties in emptying your bladder?".

¶¶ Symptoms of anal incontinence were defined as the answer “yes” to the question “Do you have involuntary loss of flatus or stool?”.

¶¶¶ Perineal pain was assessed by the question: “Do you have chronic perineal pain (perineum designates the skin and muscle around the vaginal and anal outlets)?”.

§ Episiotomy complications were defined by the existence of at least one of the following criteria: hematoma, abscess, scar disunion, or required surgery for episiotomy.

## Appendix 5. Univariate and multivariable analysis for the secondary endpoints.

**Table 7.** Univariate and multivariable analysis of urinary and anal incontinence at 6 months after attempted operative vaginal delivery according to the type of instrument used (n=934).

	Urinary incontinence † (n=861)			Anal incontinence †† (n=778)		
	Crude OR (95% CI)	Adj. OR (95% CI)	P‡	Crude OR (95% CI)	Adj. OR (95% CI)	P‡
Instrument type						
Vacuum	Ref	Ref		Ref	Ref	
Forceps/Spatulas	1.30 (0.92-1.84)	1.44 (0.90-2.30)	.1	1.27 (0.89-1.81)	1.72 (1.07-2.75)	.02
Maternal age > 30 (years)	1.58 (1.15-2.76)	1.56 (1.08-2.45)	.02	2.02 (1.47-2.77)	1.58 (1.08-2.31)	.02
BMI ≥ 30 before pregnancy (kg/m <sup>2</sup> )	1.34 (0.71-2.53)	1.55 (0.75-3.18)	.2	1.92 (1.03-3.58)	2.29 (1.11-4.75)	.03
Gestational weight gain > 20kg	1.30 (0.77-2.20)	1.48 (0.81-2.70)	.2	0.95 (0.53-1.69)	0.87 (0.45-1.67)	.7
Nulliparous	0.97 (0.68-1.37)	1.14 (0.75-1.72)	.5	0.62 (0.44-0.88)	0.64 (0.42-0.98)	.04
Prenatally suspected macrosomia ‡	0.66 (0.34-1.29)	-	-	1.76 (1.01-3.08)	-	-
Gestational diabetes mellitus §	1.31 (0.77-2.25)	1.29 (0.71-2.34)	.4	2.25 (1.36-3.72)	1.92 (1.09-3.40)	.03
Induced labor	1.14 (0.76-1.70)	1.20 (0.76-1.91)	.4	1.57 (1.06-2.32)	1.33 (0.84-2.11)	.2
2 <sup>nd</sup> stage >3 hours	0.94 (0.62-1.43)	0.82 (0.49-1.36)	.4	1.25 (0.83-1.87)	1.26 (0.76-2.07)	.4
Active phase of 2 <sup>nd</sup> stage > 30 min	1.16 (0.84-1.59)	1.31 (0.79-2.18)	.3	1.18 (0.86-1.64)	1.19 (0.71-1.98)	.5
Epidural analgesia	0.57 (0.31-1.04)	0.44 (0.21-0.93)	.03	1.11 (0.54-2.26)	0.52 (0.23-1.17)	.1
Manual rotation	0.68 (0.40-1.14)	-	-	1.02 (0.63-1.65)	-	-
Persistent occiput position			.3			.6
Anterior	Ref	Ref		Ref	Ref	
Posterior	0.98 (0.56-1.72)	1.09 (0.60-1.99)		0.67 (0.35-1.27)	0.70 (0.39-1.56)	
Transverse	0.29 (0.07-1.25)	0.34 (0.08-1.53)		1.43 (0.58-3.49)	1.20 (0.40-3.60)	
ACOG classification			.1			.3
Mid	1.99 (1.00-3.97)	2.08 (0.99-4.94)		0.86 (0.44-1.67)	0.54 (0.23-1.28)	
Low	1.56 (0.84-2.90)	1.44 (0.69-2.99)		1.04 (0.60-1.80)	0.78 (0.39-1.56)	
Outlet	Ref	Ref		Ref	Ref	
Indications for OVD			.9			.5
Non-reassuring FHR only	0.91 (0.65-1.27)	0.97 (0.57-1.65)		0.83 (0.59-1.18)	0.95 (0.55-1.65)	
Arrested progress only	Ref	Ref		Ref	Ref	
Non-reassuring FHR and arrested progress	0.97 (0.62-1.50)	1.22 (0.69-2.15)		1.19 (0.77-1.84)	1.29 (0.72-2.29)	
Obstetrician performing delivery						
Senior attending obstetrician	Ref	Ref		Ref	Ref	
Obstetric resident	1.13 (0.79-1.61)	1.21 (0.80-1.84)	.4	0.85 (0.60-1.20)	0.88 (0.58-1.34)	.6
Sequential use of two instruments	1.53 (0.66-3.57)	-	-	1.39 (0.57-3.38)	-	-
Episiotomy	0.84 (0.53-1.33)	0.83 (0.47-1.46)	.4	1.35 (0.80-2.28)	1.30 (0.69-2.47)	.4
3 <sup>rd</sup> - 4 <sup>th</sup> degree perineal lacerations	2.41 (1.10-5.26)	-	-	3.16 (1.44-6.94)	-	-
Birth weight ≥ 4,000 g	0.82 (0.40-1.67)	0.71 (0.33-1.54)	.4	1.36 (0.72-2.58)	0.84 (0.38-1.86)	.7
Cephalic perimeter > 36 cm	0.56 (0.30-1.06)	-	-	1.73 (1.04-2.86)	1.64 (0.91-2.94)	.09
Breastfeeding	1.64 (1.17-2.28)	1.85 (1.27-2.69)	.001	1.54 (1.10-2.15)	1.64 (1.12-2.42)	.01

OR, Odds Ratio ; CI, confidence interval ; BMI, body mass index ; PPH, postpartum hemorrhage ; ACOG, American College of Obstetricians and Gynecologists ; IQR, interquartile range ; OVD, operative vaginal delivery ; FHR, fetal heart rate.

‡ Adjusted logistic regression analyses. Adjustment on maternal age, BMI, gestational weight gain, nulliparity, prenatal suspicion of macrosomia, gestational diabetes mellitus, induced labor, duration of active second phase of labor, epidural analgesia, occiput presentation, ACOG classification, 3<sup>rd</sup>- 4<sup>th</sup> degree perineal lacerations, birth weight, breastfeeding and cephalic perimeter of the newborn for anal incontinence.

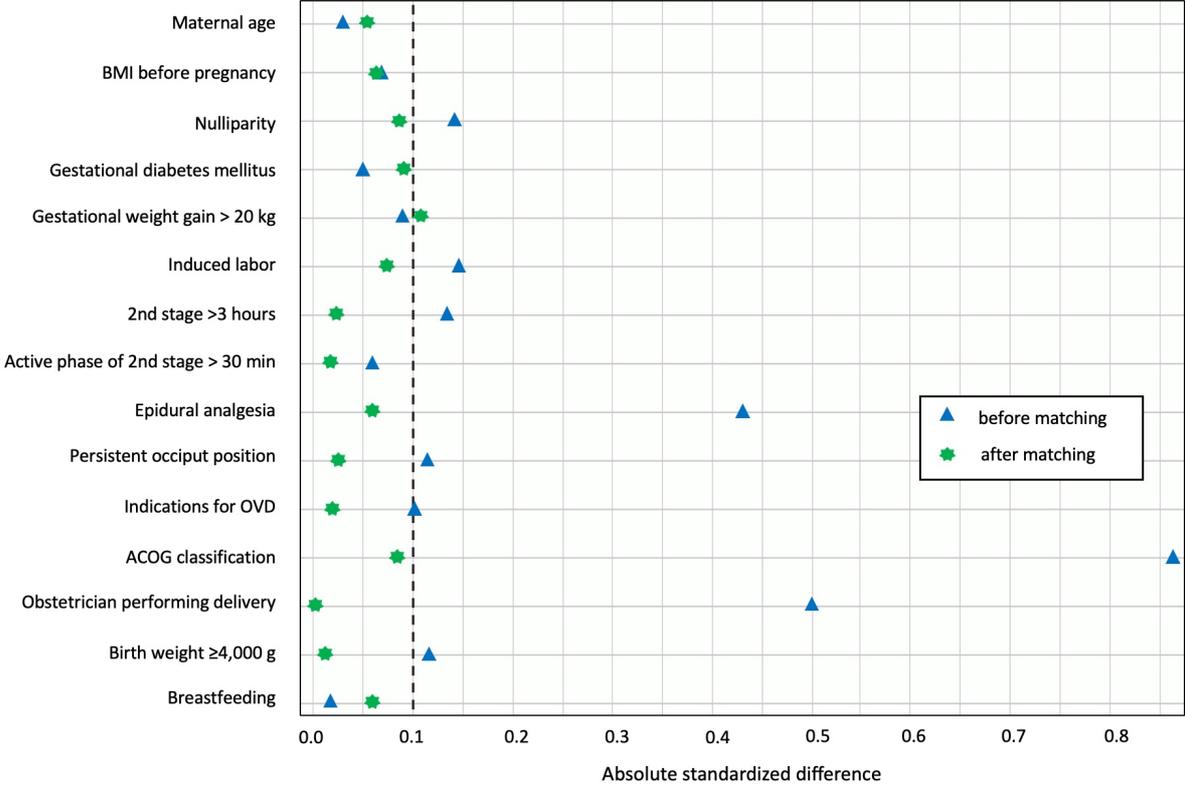
‡ Prenatally suspected macrosomia: fundal height measurement at delivery > 37cm and/or ultrasonographic fetal abdominal circumference > 90<sup>th</sup> p. for gestational age on Hadlock curves.

\$ Preexisting or gestational diabetes mellitus

¶ Symptoms of urinary incontinence defined as the answer “yes” to the question “Do you have involuntary loss of urine?”.

¶¶ Symptoms of anal incontinence defined as the answer “yes” to the question “Do you have involuntary loss of flatus or stool?”.

**Appendix 6.** Absolute standardized differences after propensity score matching.



**Figure 4.** Absolute standardized differences between women with vacuum and forceps/spatulas deliveries, for the variables included in the propensity score, before (total population) and after matching (propensity score-matched population).

*BMI, body mass index ; OVD, operative vaginal delivery ; ACOG, American College of Obstetricians and Gynecologists*

*Absolute standardized difference is a measure of effect size between two groups which is independent of sample size. It is the absolute value of the mean difference divided by the pooled standard deviation.*

# SERMENT D'HIPPOCRATE

---

Au moment d'être admis à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs. Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré et méprisé si j'y manque.



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## Maternal and neonatal morbidity after attempted operative vaginal delivery according to the instrument type : a prospective study using a propensity score analysis.

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**Objective:** To assess severe short-term maternal and neonatal morbidity and pelvic floor disorders at 6 months postpartum after attempted operative vaginal deliveries (OVD) according to type of instrument.

**Study design:** Prospective study of women with live singleton term fetuses in vertex presentation who underwent attempted OVD in a French tertiary-care university hospital from December 2008 through October 2013. We used multivariable logistic regression and propensity score methods to control for indication bias and compare outcomes associated with vacuum- or forceps-/spatula-assisted deliveries. Severe maternal and neonatal morbidity were composite primary endpoints. Symptoms of urinary incontinence (IU) and anal incontinence (AI) were assessed 6 months after delivery by validated self-administered questionnaires.

**Results:** Among 2,138 attempted OVDs, 30.7% (n=654) used vacuum, and 69.3% (n=1474) forceps/spatulas. Severe maternal morbidity occurred in 5.4% (n=35; 95%CI 3.8-7.4) of vacuum attempts and 10.5% (n=154; 95%CI 8.3-12.1) of forceps/spatula attempts (P<.001); and severe neonatal morbidity in 8.4% (n=55; 95%CI 6.4-10.8) and 10.2% (n=155; 95%CI 8.7-11.8) respectively (P=.2). Although forceps/spatula attempted OVD was significantly associated with more frequent severe maternal morbidity (aOR 1.99 95%CI 1.27-3.10) in multivariable logistic regression analysis, this association was no longer significant after propensity score matching (aOR 1.46 95%CI 0.72-2.95). Forceps/spatula attempted OVD was not significantly associated with more frequent severe neonatal morbidity after multivariable logistic regression or propensity score matching. Among the 934 women (43.9%) who responded to questionnaires at 6 months, the prevalence of symptoms of UI was 22.7% and of AI 22.0%, with no significant differences between the two groups.

**Conclusion:** In singleton term pregnancies, neither severe short-term maternal or neonatal morbidity nor urinary or anal incontinence was more frequent after attempted OVD by forceps or spatulas than by vacuum after controlling for indication bias with a propensity score analysis.

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## MORBIDITE MATERNELLE ET NEONATALE APRES TENTATIVE D'EXTRACTION INSTRUMENTALE EN FONCTION DE L'INSTRUMENT UTILISE : UNE ETUDE PROSPECTIVE AVEC ANALYSE PAR SCORE DE PROPENSION.

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**Objectifs :** Évaluer la morbidité maternelle et néonatale sévère et les troubles du plancher pelvien à 6 mois du post-partum, après une tentative d'extraction instrumentale en fonction du type d'instrument utilisé.

**Matériel et méthodes :** Étude prospective monocentrique dans une maternité universitaire de niveau 3 conduite de décembre 2008 à octobre 2013. Cette étude incluait des femmes avec une grossesse monofœtale en présentation céphalique ayant une tentative d'accouchement par voie basse instrumentale (TAVBI) après 37 semaines d'aménorrhée. Nos critères de jugement principaux étaient des variables composites de morbidité maternelle et néonatale sévère. Nos critères de jugement secondaires étaient la présence de symptômes d'incontinence urinaire (IU) et d'incontinence anale (IA) et étaient évalués à 6 mois après l'accouchement par des auto-questionnaires validés. Les associations entre le type d'instrument utilisé (ventouse ou forceps/spatules) pour la TAVBI et les critères de jugement ont été analysées par modélisation multivariée logistique puis par score de propension afin de diminuer le biais d'indication.

**Résultats :** Parmi 2138 TAVBI, 30,7% (n=654) étaient par ventouse, et 69,3% (n=1474) étaient par forceps/spatules. La prévalence de morbidité maternelle sévère était de 5,4% (n=35; IC95%, 3,8-7,4) après TAVBI par ventouse et de 10,5% (n=154; IC95%, 8,3-12,1) après forceps/spatules (p<0,001). La prévalence de morbidité néonatale sévère était de 8,4% (n=55; IC95%, 6,4-10,8) après ventouse et de 10,2% (n=155; IC95%, 8,7-11,8) après forceps/spatules (p=0,2). La TAVBI par forceps/spatules était significativement associée à un sur-risque de morbidité maternelle sévère après analyse multivariée (ORa 1,99 IC95% 1,27-3,10) mais ne l'était plus après analyse par score de propension (ORa 1,46 IC95% 0,72-2,95). La TAVBI par forceps/spatules n'était pas significativement associée à un sur-risque de morbidité néonatale sévère après analyse multivariée ou par score de propension. Parmi les 934 femmes (43,9%) ayant répondu aux questionnaires à 6 mois du post-partum, la prévalence de symptômes d'IU était de 22,7% et d'IA de 22,0%. Il n'existait pas de différence significative entre les deux groupes.

**Conclusion :** Parmi les femmes ayant une TAVBI à terme, l'utilisation de forceps/spatules par rapport à l'utilisation de ventouse ne semble pas être associée à un sur-risque de morbidité maternelle ou néonatale sévère, ni à une prévalence plus élevée d'incontinence anale ou urinaire, après contrôle du biais d'indication par analyse par score de propension.

**Mots-clés :** accouchement par voie basse instrumentale ; extraction instrumentale ; forceps ; ventouse de Kiwi ; spatules de Thierry ; morbidité maternelle ; morbidité néonatale ; incontinence anale ; incontinence urinaire ; score de propension.

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**Discipline :** Médecine, Gynécologie-Obstétrique

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