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1 **Comparison of maternal and neonatal outcomes after forceps or spatulas-**
2 **assisted delivery**

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1 **Comparison of maternal and neonatal outcomes after forceps or spatulas-**
2 **assisted delivery**

3 **ABSTRACT**

4 **Objective:** The aim of this study was to compare the perinatal outcomes associated with
5 spatulas or forceps assisted delivery.

6 **Study design:** This is a bicentric retrospective cohort study including all assisted deliveries in
7 cephalic presentation after 37 weeks of gestation, performed on singleton pregnancy with
8 forceps and with spatulas in two tertiary centers. The main outcome was the rate of
9 episiotomy. Secondary outcomes included obstetric anal sphincter injuries (OASIS), maternal
10 outcomes and neonatal parameters.

11 **Results:** Out of 37 002 deliveries, the overall rate of assisted delivery was 11.4%, and 1 041
12 (2.8%) assisted deliveries with forceps and 2 462 (6.7%) spatulas deliveries were included.
13 The rate of episiotomy was 90.3% after forceps-assisted delivery and 70.9% for spatulas ($p <$
14 0.001). The rate of OASIS was 7.2% and 5.6% respectively ($p = 0.06$). A slight but significant
15 decrease in neonatal trauma after spatulas was observed.

16 **Conclusion:** In this retrospective cohort study, the episiotomy rate was higher with forceps
17 assisted deliveries than with spatulas. Both instruments have low neonatal morbidity and are
18 similar regarding OASIS.

19 **Keywords:** assisted delivery – spatulas – forceps – maternal and neonatal morbidity -
20 episiotomy – OASIS

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1 **Introduction**

2 In Western Europe, rates of instrumental vaginal delivery vary from 6 to 16%. (1) (2) Three
3 types of instrument are used, with their own obstetrical mechanics: forceps inducing traction,
4 vacuum allowing flexion and rotation, and spatulas allowing propulsion. (3) Vacuum and
5 forceps are the most used instruments in the world, while the use of spatulas is essentially
6 limited to France and Hispanic countries, with a large disparity between maternity units.
7 Assisted birth are associated with a higher incidence of episiotomy, pelvic floor tearing,
8 levator ani avulsion and obstetric anal sphincter injury (OASIS) than spontaneous vaginal
9 birth. Vacuum and forceps are largely described in the literature. Selection of the appropriate
10 instrument depends on both the clinical situation and the operator's level of skill with the
11 specific instrument. The use of vacuum in assisted delivery seems to induce less perineal
12 trauma and less episiotomy than forceps and has thus become the most popular delivery
13 instrument worldwide. (4) However, in our opinion, it's necessary to master at least two
14 instruments to be able to adapt to each obstetrical situation. The role of episiotomy in case of
15 assisted delivery is still debated as its protective effect on severe perineal tears is
16 controversial. (5)

17 To date, no large-scale study has compared spatulas to other instruments in term of perinatal
18 complications. Their supposed benefits would be a low fetal morbidity and their versatility.
19 The aim of the study was to compare maternal and neonatal outcomes associated with forceps
20 and spatulas-assisted delivery.

21

22 **Materials and Methods**

23 *Design of the study*

24 This is a retrospective and bicentric cohort study, led at the University Hospital Center of
25 Toulouse and at the University Hospital Center of Limoges, France, two tertiary care
26 maternity units, from January 2014 to December 2018. This study was approved by the Ethics
27 Committee for Research in Obstetrics and Gynaecology (CEROG 2018-OBST-0501).

28 All pregnant women meeting the following inclusion criteria were included: singleton
29 pregnancy, gestational age ≥ 37 weeks of gestation, cephalic presentation, forceps-assisted
30 delivery at the Hospital Center of Limoges (Forceps Group), or spatulas-assisted delivery at
31 the Hospital Center of Toulouse (Spatulas Group). Spatulas and forceps are the most used

1 instruments in Toulouse and Limoges Hospitals respectively (95 and 81% of all assisted
2 deliveries respectively). Exclusion criteria were multiple pregnancy, caesarean delivery,
3 breech presentation, sequential use of instruments, instrumental delivery using vacuum, intra
4 uterine fetal death, interruption of pregnancy. Sequential uses of instruments were excluded in
5 order to study the outcomes associated with each specific instrument. The choice of
6 instrument was according to the physician's preferences, considering that Spatulas and
7 Forceps are respectively used in first intention in the two centers (Toulouse and Limoges) in
8 case of instrumental vaginal delivery. In both centers, all operative vaginal deliveries were
9 performed on cephalic presentations, with the head engaged and membranes ruptured, by
10 senior physicians or by residents under the direct supervision of a senior obstetrician, after
11 emptying women's bladder. An ultrasound is available in the delivery room and is widely
12 recommended before assisted delivery, especially if there is any doubt about the presentation.

13 ***Outcomes***

14 The primary outcome was the rate of episiotomy (mediolateral episiotomy). Other outcomes
15 included maternal and neonatal parameters. We recorded perineal tears according to the
16 international classification described by Sultan et al, (6) and the incidence of Obstetric Anal
17 Sphincter Injuries (OASIS), including all 3rd and 4th degree tears. (7) The composite criteria
18 including intact perineum or first degree perineal lesion was also notified.(8) (9) Maternal
19 blood loss has been documented. Neonatal outcomes included 1- and 5-minutes Apgar score,
20 umbilical artery pH and birth trauma. Birth trauma included scalp lesions (abrasion,
21 cephalhematoma), wounds, facial injuries, fracture, nerve palsies, intracranial haemorrhage.
22 (9) All data were collected based on medical records and computerized reports.

23 ***Statistical analysis***

24 Qualitative variables were described by numbers and percentage and were compared using the
25 Chi-square test, the corrected Chi-square test or the exact Fisher test according to the expected
26 values under the hypothesis of independence. Quantitative variables were described by
27 numbers, mean and standard deviation and were compared using the Student t-test, Student t-
28 test for unequal variances or the Mann-Whitney-Wilcoxon test depend on the distribution and
29 the variance of the quantitative variables. For each variable, the number of missing data was
30 described. To identify risk factors for OASIS, a logistic regression model was used to adjust
31 on major confounding factors. Assumption of the model (log-linearity of the associations) was

1 checked. All the statistical tests were performed with a type I error rate of 5%. Statistical data
2 analysis was carried out using R 3.5.1 software.

3

4 **Results**

5 Among 37 002 deliveries during the study period, 3 503 (9.5%) were included: 2 462 in the
6 Spatulas Group, 1 041 in the Forceps Group. (Figure 1 flow chart). 55 (0.15%) c-sections
7 were performed for instrumental extraction failure (without any difference between both
8 groups). , The overall rates of caesarean section and of assisted delivery were 20.1% and
9 11.4% respectively.

10 Table 1 summarizes demographic and obstetric data. Maternal age, parity and comorbidities
11 were comparable between the two groups, except for the obesity rate higher in the Forceps
12 Group. The rate of assisted delivery on occiput posterior fetal head position was significantly
13 higher in Forceps Group (12,8% vs 3,4%, $p < 0.001$).

14 Table 2 describes immediate perineal outcomes after assisted delivery in each group. The rate
15 of episiotomy was significantly higher with forceps delivery (90.3% vs 70.9% in case of
16 spatulas delivery, $p < 0.001$). There was no significant difference in the rate of OASIS
17 between the two instruments (7,2% in forceps group vs 5,6%, $p=0.06$). The rate of “intact
18 perineum or 1st degree lesion” was significantly higher in spatulas group than in forceps group
19 (15.6% vs 3.2% respectively, $p = 0.001$).

20 Neonatal parameters are detailed in Table 3. Birthweight was significantly higher in Spatulas
21 Group, with a higher rate of macrosomia ($p=0.01$). Childbirth was complicated by shoulder
22 dystocia for 5.3 % of deliveries in Forceps group and 2.6% in Spatulas group ($p = 0.001$).
23 There was no difference on the 5-minute APGAR score, nor on the umbilical artery pH at
24 birth. Overall, the rate of birth trauma was significantly higher in the forceps group than in the
25 spatulas group (5.2% vs 3.7%, $p= 0.04$), with significantly more scalp wound (1.8% vs 0.9%,
26 $p=0.02$) and clavicular fracture (1.8% vs 0.7%, $p=0.004$). One case of neonatal death was
27 documented in Forceps Group.

28 Significant risk factors for OASIS identified with the univariate analysis were nulliparity,
29 occiput posterior fetal head position, absence of episiotomy. In multivariate analysis
30 significant risk factors (Table 4) were occiput posterior fetal head position (OR 3.06; 95%CI

1 [1.89-4.91], $p < 0.001$) and neonatal weight (OR 1.04, 95%CI [1.01-1.08], $p = 0.02$).
2 Episiotomy was a protective factor (OR 0.51; 95%CI [0.36-0.74], $p < 0.001$).

3

4 **Discussion**

5 The results of this study indicate that spatulas assisted deliveries are associated with a
6 significant lower rate of episiotomy than forceps. There was no significant difference in the
7 incidence of OASIS. However, the rate of intact or first-degree perineum was higher in
8 Spatulas Group. Both instruments are safe for neonates, with a lower rate of shoulder dystocia
9 using Spatulas.

10 In France, the episiotomy rate including spontaneous and assisted vaginal deliveries is about
11 20%, with a decrease observed in recent years (27% in 2010). (1) According to clinical
12 practice guidelines, liberal practice of episiotomy is not recommended because it does not
13 induce any benefit on both maternal and fetal side, comparing to a restrictive use, even in case
14 of assisted deliveries. (10) A systematic review of randomized trials published in 2017
15 comparing systematic and selective episiotomy showed that a restrictive practice reduces the
16 occurrence of severe perineal tears in spontaneous vaginal births. The results did not allow to
17 conclude in case of operative vaginal delivery.(11) In our study, the overall episiotomy rate
18 was high regardless of the type of instrument but with a significant higher rate after forceps
19 delivery. When forceps were compared to vacuum, observational and randomized studies
20 drew similar conclusions. (12) The higher rate of episiotomy in case of forceps might be
21 explained by operator's habits, and the induced increase of diameter.

22 Vaginal birth is often complicated by perineal trauma. Approximately 50% of patients present
23 a first-degree tear after delivery. Regardless of the instrument used, the risk of OASIS is
24 increased compared to spontaneous vaginal delivery, especially for nulliparous women.(13)
25 Our study showed a higher rate of "first degree or intact" perineum after the use of spatulas
26 (15.6% vs 3.2% after forceps delivery, $p < 0.001$). This composite criterion includes intact
27 perineum and 1st degree tears, which are superficial lesions considered to be benign, without
28 any systematic need for suture, and with a very good functional prognosis. (8) (9) A
29 restrictive practice of episiotomy is associated with a higher rate of intact perineum and
30 "benign" perineal tears after spatulas delivery.

1 Data from the literature show a variable prevalence of OASIS, ranging from 0.25 to 6%, or
2 even up to 16% in nulliparous women.(14) Our study found a rate of OASIS about 6%, with
3 no significant difference between the two types of instrument. The consequences of this type
4 of injury are potentially severe due to the risk of perineal pain, dyspareunia and anal
5 incontinence. (15) We thus wanted to evaluate factors associated with the risk of OASIS in
6 our population. Contrary to the data found in the literature, nulliparity was not associated with
7 OASIS. (16)

8 Risk factors for OASIS identified with the multivariate analysis were occiput posterior
9 position and macrosomia. On the other hand, episiotomy appeared to be a protective factor,
10 regardless of the instrument used.

11 The link between OASIS and episiotomy in operative vaginal delivery is still debated. A
12 Canadian retrospective cohort involving about 52 000 instrumental deliveries suggests that
13 episiotomy would protect nulliparous women from OASIS in case of forceps assistance. On
14 the contrary, episiotomy is associated with severe perineal tears in patients with a history of
15 vaginal delivery, or vacuum extraction, according to a French observational study published
16 by Gachon et al in 2019. (5) (17) Moreover, episiotomy is operator-dependent, some
17 unstudied elements could probably influence the occurrence of perineal tears: timing of
18 performing, angle and distance from the vaginal introitus.

19 The rate of OASIS is higher in case of assisted delivery performed on a posterior fetal
20 position, either by forceps or vacuum. (18) (19) In our study, this was the main independent
21 risk factor for OASIS. Instrumental assistance was performed on occiput posterior position for
22 12.8% of births in case of forceps delivery, compared to only 3.4% in case of spatulas
23 delivery ($p < 0.001$). Indeed, the increased risk for OASIS and long-term perineal
24 consequences after assisted delivery in occiput posterior position is well known to
25 practitioners of the Toulouse University Hospital, with a high rate of manual rotation attempt
26 prior to assisted delivery in case of occiput posterior position. (9) (20) (21)

27 In a cohort of 1 065 assisted delivery using Spatulas, Boucoiran et al. reported a rate of 87.3%
28 and 6.2% of OASIS. (22) Macleod et al. reported a rate of 89.6 % of episiotomy and 11.6% of
29 OASIS in a prospective cohort of 904 Forceps assisted deliveries. (23) Recent large studies
30 have shown a lower incidence of episiotomy in the last few years, with a restrictive use of
31 episiotomy even in the setting of operative vaginal delivery. (24) Finally, the results of this

1 study showed that birthweight is an independent risk factor for OASIS, regardless of the type
2 of instrument. Fetal macrosomia is known to provide severe perineal lesions, even in
3 spontaneous delivery. (25)

4 Operative vaginal delivery is a risk factor for postpartum haemorrhage (PPH). (26) Studies
5 have shown that perineal tears and episiotomy also increase maternal blood loss and thus the
6 risk of PPH. PPH was more frequent after spatula (11.5% vs 7.3 % in Forceps group, p
7 <0.001). In the literature, the incidence of this complication is heterogeneous, estimated at
8 about 10% when blood losses are precisely quantified (graduated collection bag, weighing of
9 compresses). (27) Since 2016, there is a protocol of systematic weighing of blood-soaked
10 compresses in Toulouse Hospital Center, in order to avoid under-diagnosis of PPH. This
11 resulted in a significant increase in the detection of PPH. The lack of consideration of soaked
12 compresses in Forceps group may underestimate maternal blood loss. Moreover, risk factors
13 for PPH are multiple, fetal macrosomia is significantly associated with PPH risk and the rate
14 of macrosomia was higher in Spatulas Group. (28)

15 Overall, neonatal morbidity was low in both groups. We found a discrete increase in birth
16 trauma after forceps deliveries, including more scalp wounds, more clavicular fractures and
17 brachial plexus palsies. These results are consistent with the significantly higher rate of
18 shoulder dystocia in the same group despite significantly lower birth weights. The literature
19 shows a limited neonatal morbidity in case of spatulas delivery. (29) Possible neonatal
20 complications related to instrumentation are not specific to the technique, and most often
21 benign. Potentially severe complications such as intracranial hemorrhages have a complex
22 pathophysiology that may involve the cause of instrumental assistance and not just the
23 instrument itself.(30)

24 To our knowledge, this is the largest study comparing perinatal outcomes associated with
25 forceps or spatulas operative vaginal delivery. Only two retrospective studies have been
26 published, involving 77 and 142 patients, with similar conclusions. (31) (32). One of the main
27 limitations of this study is the lack of analysis of the operator's experience. However, all
28 assisted deliveries were performed by a senior physician or a resident under the direct
29 supervision of a senior physician. A retrospective cohort including more than 2000 forceps
30 and vacuum extractor deliveries showed that the rate of severe perineal tears decreased with
31 professional experience, mainly in case of forceps delivery. (33) Moreover, the bicentric
32 nature of the study does not allow the comparison of the two instruments with the same

1 operator and there were more obese women in the forceps group, related to geographical
2 differences. Another bias is the lack of analysis of long-term perineal consequences. Finally,
3 women satisfaction was not evaluated in this study. Involving women during an operative
4 vaginal birth could improve their experience of childbirth, informing them of various possible
5 instruments when it's possible may optimize their management. (34)

6 **Conclusion**

7 In our retrospective cohort study, we found a significantly lower rate of perineal lesions and
8 episiotomy after spatulas assisted delivery compared to forceps. However, spatulas assistance
9 would not prevent the occurrence of OASIS, whose main risk factor is occiput posterior
10 position. The use of Thierry's spatulas seems associated with less neonatal morbidity
11 compared to forceps, with fewer birth trauma and shoulder dystocia. However, these results
12 should be interpreted with caution as they are also related to the practice habits of the two
13 centers included in the study. The absence of specific contraindications to spatulas make them
14 a versatile tool, adaptable to any obstetrical situation but still rarely used.

15

16 **Declaration of interest statement**

17 No potential conflict of interest was reported by the authors.

18

19

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1 Figure 1. Flow chart

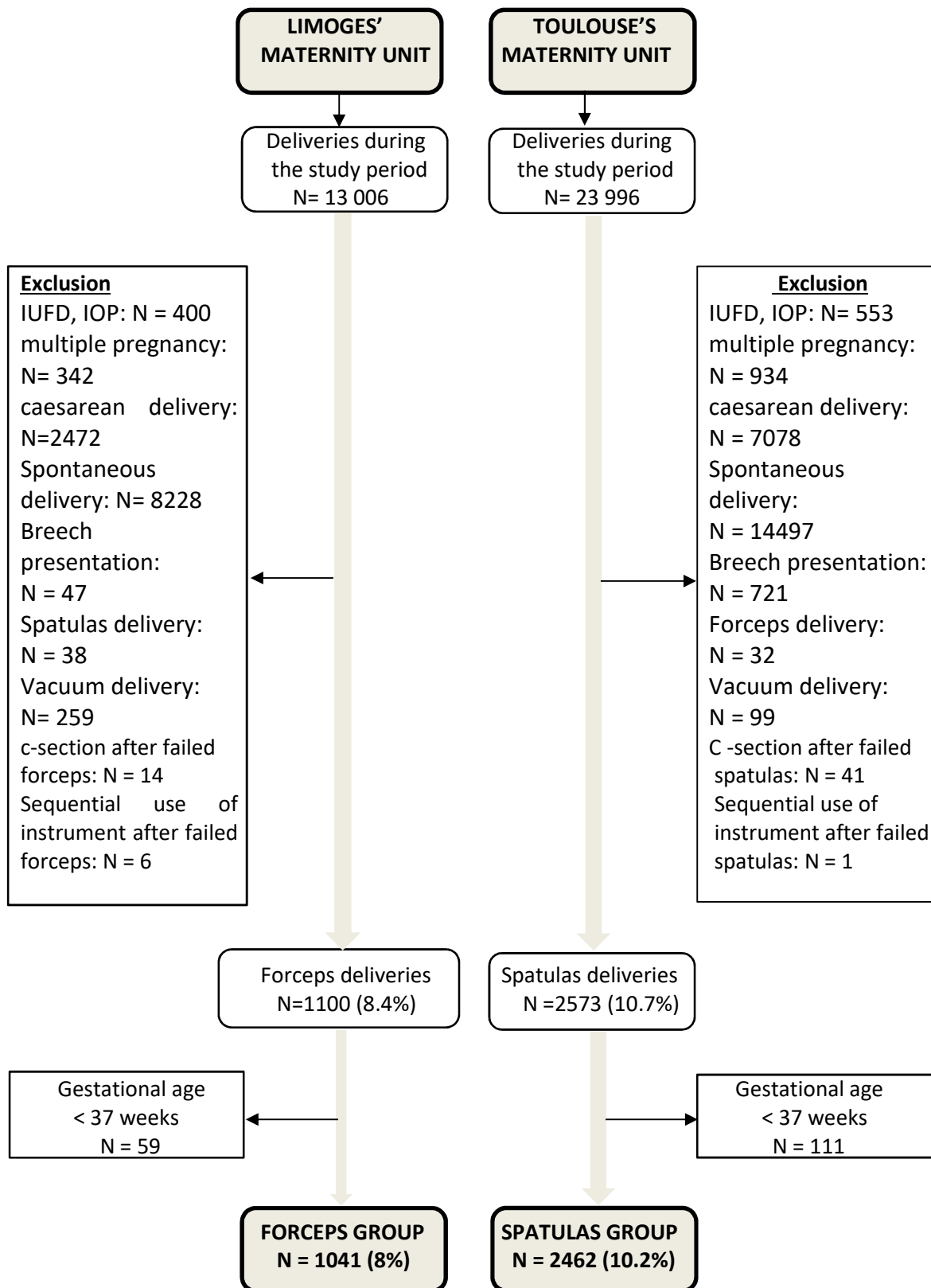


Table 1. Demographic and obstetrical data

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Characteristics	Forceps Group N = 1041	Spatulas Group N = 2462	p-value
Age (years)	29,9 (5,4)	29,8 (5,3)	0,39
BMI	24,2 (4,9)	23,3 (4,9)	0,001
Obesity, N (%)	121 (11,6)	223 (9,1)	0,02
Smoking, N (%)	149 (15,1)	315 (12,8)	0,08
Hypertension, N (%)	10 (0,9)	18 (0,7)	0,49
Diabetes, N (%)	12 (1,2)	44 (1,8)	0,17
Nulliparous, N (%)	802 (77)	1949 (79,2)	0,16
Previous c-section, N (%)	135 (13)	260 (10,5)	0,04
Gestational age, Median [QR]	40 [39; 40]	40 [39; 41]	0,003
Induced Labor, N (%)	312 (30,6)	714 (29)	0,35
Epidural anesthesia N (%)	1017 (98,5)	2394 (97,4)	0,05
Active second stage duration (min)	22 (10,3)	24 (12,4)	0,02
Head position			< 0,001
Anterior, N(%)	905 (87)	2369 (96,6)	
Posterior, N (%)	133 (12,8)	84 (3,4)	
Head station			0,05
Outlet (+5), N (%)	55 (5,3)	140 (5,7)	
Low (+2, +3), N (%)	898 (87,8)	2084 (85)	
Mid (0, +1), N (%)	70 (6,8)	228 (9,3)	

2 *Continuous variables are reported as mean ± standard deviation*

3 Table 2. Maternal outcomes

Perineal Outcomes	Forceps Group N = 1041	Spatulas Group N = 2462	p-value
Intact perineum, N (%)	10 (1)	69 (2,8)	0,001
Episiotomy, N (%)	940 (90,3)	1746 (70,9)	< 0,001
OASIS, N (%)	75 (7,2)	137 (5,6)	0,06
“Intact or 1 st -degree” perineum, N (%)	33 (3,2)	383 (15,6)	< 0,001
Cervical laceration, N (%)	6 (0,6)	7 (0,3)	0,32
PPH (≥500ml), N (%)	76 (7,3)	283 (11,5)	< 0,001
Hospitalizationduration (days)	4,1(0,9)	3,9 (1,9)	< 0,001

4 *OASIS: obstetric anal sphincter injury, PPH: postpartum haemorrhage; Continuous variables are*
 5 *reported as mean ± standard deviation*

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2 Table 3. Neonatal outcomes

Neonatal outcomes	Forceps Group N = 1041	Spatulas Group N = 2462	p-value
Shoulder dystocia, N (%)	55 (5,3)	65 (2,6)	< 0,001
Birth weight, Mean (SD)	3301 (418)	3342 (437)	0,01
Apgar score ≤ 7			
1 min, N(%)	201 (19,4)	280 (11,4)	< 0,001
5 min, N(%)	16 (1,5)	60 (2,4)	0,1
pH Ao < 7,10, N(%)	66 (8,1)	192 (8,6)	0,6
Birth trauma N (%)	54 (5,2)	91 (3,7)	0,04
Neonatal death	1 (0,1)	0	0,1

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4 Table 4. Risk factors for OASIS: multivariate analysis

OASIS RISK FACTORS			
	OR	95%CI [OR]	p-value
Type of instrument			0,08
Forceps	1		
Spatulas	0,73	[0,52 - 1,04]	
BMI	0,99	[0,96 - 1,02]	0,58
Age	1,01	[0,98 - 1,04]	0,58
Smoking	1,04	[0,65 - 1,59]	0,88
Parity ≥1	0,46	[0,15 - 1,5]	0,2
Previous c-section	1,8	[0,54 - 5,7]	0,33
Gestational Diabetes	1,1	[0,71 - 1,73]	0,61
Induction of labor	0,93	[0,65 - 1,30]	0,67
Epidural anesthesia	1,29	[0,46 - 5,37]	0,67
Mid fetal Head station	1,03	[0,54 - 2,24]	0,87
Occiput posterior delivery	3,06	[1,89 - 4,81]	< 0,001
Episiotomy	0,51	[0,36 - 0,74]	< 0,001
Birth weight (100g variation)	1,04	[1,01 - 1,08]	0,02

5 *BMI: Body mass index*