Original Article

Gynecologic and Obstetric Investigation

Gynecol Obstet Invest
DOI: 10.1159/000381544

Received: March 31, 2014
Accepted after revision: March 9, 2015
Published online: April 25, 2015

Building a Prediction Model for Vacuum-Assisted Operative Vaginal Delivery Risk

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Key Words
Operative vaginal delivery · Vacuum extraction · Prediction model · Nomogram

Abstract
Aim: The objective of this study was to evaluate the risk factors for operative vaginal delivery and to propose a new nomogram for predicting the risk. ***Methods:*** We retrospectively analyzed the data of 1,955 pregnancies that occurred in our clinic between the years 2007 and 2008. Included were singleton pregnancies with labor diagnosis after the 36th gestational week in which spontaneous or operative vaginal deliveries occurred. In this study, the operative delivery was carried out exclusively by vacuum extraction. ***Results:*** After univariate analysis and multivariate logistic regression stepwise model selection, maternal age, nulliparity, medically assisted procreation, gestational age at birth, male fetus, epidural analgesia and medical induction of labor were found to be the most predictive variables for operative vaginal delivery. Considering these factors we propose a new nomogram for an objectified determination of the risk of operative vaginal delivery. ***Conclusions:*** The new nomogram we propose could be an important tool for an objectified determination of the risk of operative vaginal delivery by vacuum extraction in individualized patient counseling.

Introduction

Operative vaginal delivery is one of the most challenging obstetrical procedures provided in order to facilitate and expedite vaginal delivery. Its incidence has been described to be around 10–15%, with variations among different countries [1, 2]. Despite attempts to minimize maternal and neonatal morbidity through correct indication and adequate obstetrics skill training, there is an increasing awareness of the short- and long-term morbidity of pelvic floor injury as well as of neonatal complications following operative vaginal delivery [3, 4]. Several studies report an increased maternal morbidity for operative vaginal delivery, mainly related to deep perineal lacerations or episiotomy extensions. According to a meta-analysis, the relative risk for a third- or fourth-degree perineal tear (with or without episiotomy) is higher for forceps compared to vacuum delivery (RR 1.89, 95% CI 1.51–2.37) [5]. Due to the objective of a reduction of maternal pelvic floor injuries, vacuum extraction was advocated as the instrument of first choice for operative vaginal delivery by the American College of Obstetricians and Gynecologists (ACOG) already in 1989. This probably contributed

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to an increased incidence of vacuum-assisted vaginal deliveries in the last decades [6]. Furthermore, the decrease in overall forceps vaginal deliveries and the need for a longer learning curve for forceps compared to vacuum contributed to the progressive reduction in trained obstetrical personal [1, 7, 8].

Even if reduced compared to forceps delivery, vacuum extraction significantly increases the incidence of maternal perineal laceration. A recent retrospective population-based register study considering a sample of 16,802 women whose infants had been delivered by vacuum extraction reported an incidence of obstetrical anal sphincter injuries of 3.4% among nulliparous women compared to 1.4% among multiparous women [9]. However, the advantage of a lower incidence of maternal injuries should be counterbalanced by a higher failure rate of vacuum delivery compared to forceps (RR of failure for forceps 0.65, 95% CI 0.45–0.94) [5].

Furthermore, when considering an operative vaginal delivery by vacuum extraction, considerable neonatal complications, even higher if compared to forceps delivery, should be taken into account. A recent population-based study considering 913 successful vacuum-assisted, full-term deliveries reported scalp edema, cephalhematoma and skull fracture in 18.7, 10.8 and 5.0% of cases, respectively. Intracranial hemorrhage occurred in 0.87% of cases [10]. In theirs meta-analysis comparing forceps and vacuum extraction delivery, O'Mahony et al. [5] reported for forceps an augmented risk of death or severe morbidity (RR 1.65, 95% CI 0.65–4.21), scalp injury (RR 1.36, 95% CI 0.75–2.48), facial injury (RR 5.10, 95% CI 1.12–23.25), intracranial injury (RR 4.83, 95% CI 0.20–115.98) and skull fracture (RR 3.07, 95% CI 0.13–74.99), while there was a lower risk of cephalhematoma (RR 0.64, 95% CI 0.37–1.11), retinal hemorrhage (RR 0.68, 95% CI 0.43–1.06), jaundice (RR 0.79, 95% CI 0.59–1.06) and admission to a neonatal intensive care unit (RR 0.85, 95% CI 0.52–1.42).

Thus, fear of maternal and fetal complications and consequent medical litigation can in general lead to an increase in the medicalization of vaginal delivery, for example through the choice of avoiding a home childbirth or a childbirth in a second- or third-level hospital setting, or even the choice of an elective cesarean delivery [11–13]. For these reasons, quantification of the risk of undergoing an operative delivery could be very helpful when counseling a woman before the onset of labor, or even in the early phase of labor.

The objective of this study was to evaluate the risk factors for operative delivery and to propose a nomogram for predicting this risk.

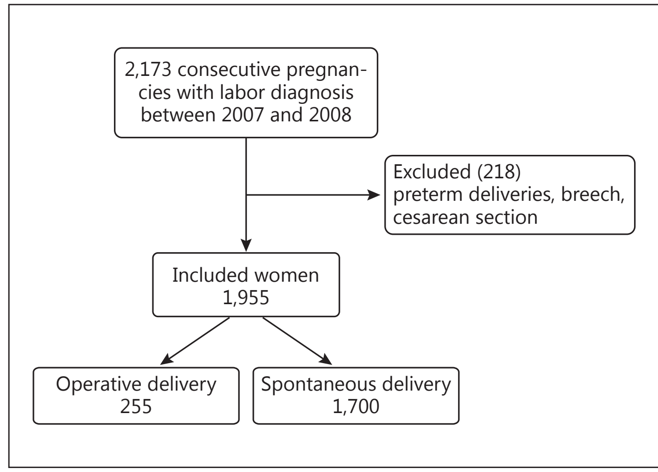

Fig. 1. Flow chart of the study population.

Materials and Methods

The study was a retrospective cohort study conducted at the University Hospital of Udine. We considered the data on maternal and neonatal outcomes of 2,173 consecutive singleton pregnancies between 2007 and 2008 that were admitted with a diagnosis of labor and of patients who were delivered after the 36th week of gestation (fig. 1). The inclusion criteria were singleton pregnancies with a diagnosis of labor (uterine contractions accompanied by cervical dilatation ≥3 cm) [14] giving birth vaginally after the 36th week of gestation. Exclusion criteria were preterm deliveries before the 36th week of gestation, deliveries by cesarean section and fetal breech presentation. A total of 1,955 pregnancies met the inclusion criteria and were included in the study. In this study, the birth operation was carried out exclusively by vacuum extraction and after execution of mediolateral episiotomy as previously described [15]. Furthermore, even if not specified in the clinical files during the study period, usually vacuum-assisted delivery was applied at low or mid planes. The low plane is intended when the leading point of the fetal skull is located at a station ≥+2 cm from the ischial spine and with a head rotation of less or more than 45°, while the mid plane is intended when the fetal skull station is <+2 cm from the ischial spine but the head is engaged.

In this study we considered the following variables: maternal age at the time of admission, pre-pregnancy body mass index (BMI), weight gain during pregnancy, any previous cesarean section, parity, medical history of the previous and current pregnancy (pregestational or gestational diabetes, hypertension in pregnancy, preeclampsia, eclampsia, intrauterine growth restriction, fetal malformations, type of pregnancy [physiological or assisted], gestational age at birth). The population was stratified into pre-pregnancy BMI according to the categories covered by the IOM (IOM 2009) in its guidelines (<18.5, 18.5–24.9, 25–29.9, ≥30). In this study we considered under the heading pregnancy-related hypertensive disorders the following conditions as previously defined: preeclampsia, gestational hypertension, and preeclampsia superimposed on chronic hypertension [16, 17]. The gestational age was estimated on the basis of the date of the last menstrual period, con-

Table 1. Description of the study population and outcomes

	Operative vaginal delivery (255)	Spontaneous vaginal delivery (1,700)	p value
Mother's age, years	31.65±5.39	31.56±5.27[a]	0.807
Nulliparous, years	31.17±5.41	29.97±5.39	<0.05
Multiparous, years	35.00±3.84	33.00±4.73	<0.05
Weight gain during pregnancy, kg	13.52±4.12	12.83±4.54	<0.05
Pre-pregnancy BMI	21.46±2.73	22.04±3.64	<0.05
Pre-pregnancy BMI classes			
<18.5	9.4% (24/255)	7.6% (130/1,700)	0.329
18.5–24.9	80.4% (205/255)	78.4% (1,332/1,700)	0.459
25–29.9	9.0% (23/255)	10.2% (173/1,700)	0.566
≥30	1.2% (3/255)	3.8% (65/1,700)	<0.05
Medically assisted procreation	2.0% (5/255)	0.7% (12/1,700)	0.060
Nulliparity	87.5% (223/255)	47.3% (804/1,700)	<0.05
Pregnancy-related hypertensive disorders	1.6% (4/255)	0.9% (16/1,700)	0.353
Pre-pregnancy diabetes mellitus	0.8% (2/255)	0.2% (3/1,700)	0.073
Gestational diabetes mellitus	2.4% (6/255)	2.3% (39/1,700)	0.953
Mode of labor			
Spontaneous	66.7% (170/255)	83.5% (1,420/1,700)	<0.05
Medical induction of labor	25.1% (64/255)	13.5% (229/1,700)	<0.05
Oxytocin use	8.2% (21/255)	3.0% (51/1,700)	<0.05
Epidural analgesia	51.0% (130/255)	20.2% (344/1,700)	<0.05
Gestational age at delivery, weeks	39.65±1.12	39.34±1.14	<0.05
Neonatal weight, g	3,412.58±409.01	3,399.81±418.89	0.643
Large for gestational age neonate	8.2% (21/255)	10.1% (172/1,700)	0.347
Small for gestational age neonate	10.2% (26/255)	8.7% (148/1,700)	0.436
Male gender	56.1% (143/255)	50.4% (857/1,700)	0.091
Outcomes			
Apgar score at 1 min	7.8±1.44	8.36±0.9	<0.05
Apgar score at 5 min	8.86±0.62	9.05±0.48	<0.05
NICU hospitalization	1.2% (3/255)	0.8% (13/1,700)	0.496
Neonatal intracranial hemorrhage	0.0% (0/228)	0.1% (1/1,457)	0.692
Perineal tears of 3rd or 4th degree	0.8% (2/255)	0.1% (2/1,700)	0.085

NICU = Neonatal intensive care unit.

[a] The significance was lost considering nulliparous and multiparous women together because multiparous women were older and almost all delivered spontaneously, thus significantly increasing the age of spontaneous delivery in comparison to nulliparous women alone. Conversely, only 32 multiparous women delivered by vacuum extraction, leading to a lower increase in the age of the general population in comparison to the nulliparous group.

firmed or corrected by ultrasonography at the first week of gestation.

Also reported were data regarding the neonate: infant sex, birth weight, Apgar scores (at 1 and 5 min), intensive care, neonatal respiratory distress syndrome of the newborn and any other related complications and neonatal outcomes during hospitalization. We considered the 10th percentile to define fetuses small for gestational age [18]. We also defined fetuses large for gestational age as those with a birth weight above the 90th percentile. Macro-geographical and cultural areas of origin were considered stratifying the population by macro-regions and cultural backgrounds as previously described in the following groups: Italy and Western Europe, Eastern Europe, Sub-Saharan Africa, Arabian Countries, Asia, and Other countries [19].

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria for accurate reporting of observational studies were considered [20].

Statistical Analysis

Statistical analysis was performed by R (version 3.0.1) and was considered as significant a $p < 0.05$. The normality of distribution was assessed using the Kolmogorov-Smirnoff test. The data were presented by mean ± standard deviation or median and interquartile range. We also used odds ratio and 95% CI or a specified reference value (e.g. area under the curve) and 95% CI. During the analysis we used the following statistical tests: in case of continuous variables, Student's t test or Wilcoxon test; in case of categorical variables, χ^2 or Fisher's exact test where appropriate. In addition,

Table 2. Prevalence of vaginal operative delivery among women from different macro-regions

Macro-geographical and cultural areas of origin	Prevalence of operative vaginal delivery	p value
Italy and Western Europe	13.8% (226/1,635)	reference
Eastern Europe	11.5% (15/130)	0.465
Sub-Saharan Africa	4.1% (3/74)	<0.05
Arabian countries	13.3% (8/60)	0.914
Asia	3.3% (1/30)	0.097
Other countries	4.8% (1/21)	0.230

Table 3. Logistic regression multivariate analysis

	OR (95% CI)	p value
Initial model		
Mother's age	1.04 (1.01–1.07)	<0.05
Nulliparous women	6.30 (4.18–9.5)	<0.05
Medically assisted procreation	2.30 (0.72–7.27)	0.158
Sub-Saharan Africa	0.49 (0.15–1.66)	0.253
Weight gain during pregnancy	1.01 (0.97–1.04)	0.645
Pre-pregnancy BMI	0.97 (0.92–1.01)	0.172
Gestational age at delivery	1.23 (1.08–1.41)	<0.05
Epidural analgesia	2.31 (1.71–3.12)	<0.05
Medical induction of labor	1.42 (0.99–2.04)	0.054
Large for gestational age neonate	1.1 (0.65–1.87)	0.730
Male gender	1.36 (1.02–1.82)	<0.05
PRHDs	1.56 (0.45–5.35)	0.481
Pre-pregnancy diabetes mellitus	3.2 (0.34–30.51)	0.312
Gestational diabetes mellitus	1.26 (0.5–3.2)	0.628
Final model proposed to predict vaginal operative delivery by vacuum extraction		
Mother's age	1.04 (1.01–1.07)	<0.05
Nulliparous women	6.74 (4.5–10.09)	<0.05
Medically assisted procreation	1.88 (0.61–5.82)	0.271
Gestational age at delivery	1.20 (1.05–1.36)	<0.05
Male gender	1.33 (1.00–1.77)	<0.05
Epidural analgesia	2.36 (1.76–3.18)	<0.05
Medical induction of labor	1.41 (0.99–2.01)	0.053

PRHDs = Pregnancy-related hypertensive disorders.

multivariate logistic regression analysis was also performed. In the multivariate logistic regression models all potentially influencing factors and their interactions were accommodated in a single analysis, except when the interaction term was non-significant (in which case we analyzed the no-interaction model). Furthermore, we included in the initial multivariate model all the factors that had a p value <0.200 in univariate analysis and then performed a stepwise selection to obtain the final multivariate logistic regression model. Based on the final multivariate logistic regression model we developed a nomogram [21].

Results

The average age of the women evaluated in this study was 31.57 ± 5.29 years with a pre-pregnancy BMI of 21.96 ± 3.54. In 99.1% (1,938/1,955) of cases pregnancies were spontaneous, 0.3% (6/1,955) became pregnant following induction of ovulation/intrauterine insemination and 0.6% (11/1,955) after in vitro fertilization/intracytoplasmic sperm injection. Most of the women were from Italy and Western Europe (83.6%, 1,635/1,955), but there was a large proportion of women from Eastern Europe, Sub-Saharan Africa and Arab countries.

The majority of women had given birth spontaneously (87.0%, 1,700/1,955) while 13.0% (255/1,955) had been subjected to operative vaginal delivery. The indications for operative delivery were arrest of the presenting part (58.6%), a prolonged second stage of labor combined with a pathologic or non-reassuring fetal heart pattern (20.7%), prolonged second stage of labor combined with occiput posterior head position or peridural analgesia (12.7%), lack of cooperation of the women during the second stage of labor (5.3%) and other indications (2.7%).

We then proceeded to a comparative analysis of spontaneous and operative delivery risks. In table 1 the characteristics of the two populations are compared. We noted significant differences with regard to maternal age, anthropometric characteristics, parity, type of labor, use of peridural analgesia and gestational age at delivery. We also saw a higher incidence of pre-pregnancy diabetes mellitus and neonatal male gender among women undergoing operative delivery.

In table 2 we provide an analysis of the prevalence of operative delivery in the different macro-geographical and cultural areas, and it can be seen that among women from Sub-Saharan Africa there was a significantly lower incidence of operative delivery compared to women from Italy and Western Europe ($p < 0.05$). There was also a higher prevalence of medically assisted procreation in the operative vaginal delivery group (2.0%, 5/255) than in the spontaneous vaginal delivery group (0.7%, 12/1,700) ($p = 0.060$).

In table 3 (upper part) we show the results of multivariate logistic regression analysis (dependent variable = operative vaginal delivery) considering the significant factors found in univariate analysis. In table 3 (lower part) we show the final model of multivariate logistic regres-

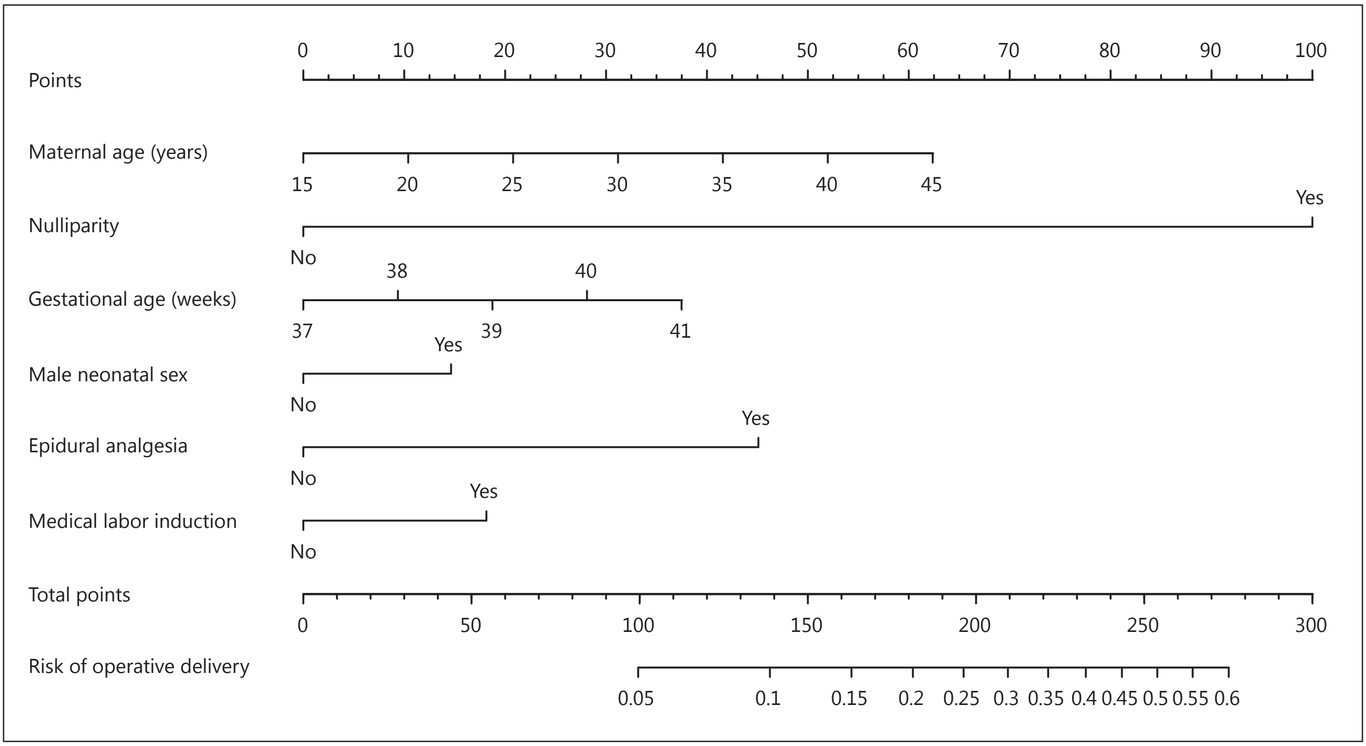

Fig. 2. Nomogram derived from multivariate logistic regression for the final model considering operative delivery as dependent variable. To read the nomogram, draw a vertical line from each tick mark indicating the status of a predictor to the top axis labeled 'Points'. Sum the points and find the corresponding number on the axis labeled 'Total points'. Then, draw a vertical line down to the axes showing the probability for an operative vaginal delivery.

sion analysis that considered only the most predictive factors for operative vaginal delivery. The most significant variables helpful for developing a predictive model by multivariate logistic regression and included in the final model shown were maternal age, nulliparity, gestational age at birth, male fetus, epidural analgesia and medical induction of labor. This model had a good prediction with an area under the curve of 78.3% (95% CI 75.5–80.9). Finally, in figure 2 we report the nomogram derived from the final model of multivariate logistic regression.

Discussion

The need of providing as much objective and individualized counseling as possible to the patient undergoing labor is getting more and more important in recent obstetrics. In this study we propose a nomogram for evaluating and predicting the risk for operative vaginal delivery.

In our institution, operative delivery was carried out exclusively by vacuum extraction, as the internal rules of our hospital no longer support forceps use. This is in line with the current trend in the world, due to the increased risk of damage to the maternal perineum in association with operative delivery with forceps, and the largest learning curve in the use of forceps rather than the vacuum extractor [22]. The prevalence of operative delivery in this study could be considered quite high (13.0%), but this is due to the selection of eligible patients in this study, excluding patients undergoing cesarean section or delivering before the 36th week of gestation. In fact, in our clinic the mean annual incidence of operative deliveries was 8.0% of all deliveries (Internal Audit 2010). The low incidence of operative delivery in patients from Sub-Saharan Africa may be due to the higher prevalence of low gestational age at delivery, small for gestational age babies and multiparous women [23].

In univariate analysis, considering multiparous and nulliparous women together, maternal age did not achieve a significant p value. However, we found a significantly higher maternal age in the operative vaginal delivery groups considering separately the nulliparous and multiparous subgroups. In fact, nulliparous and multiparous women are two different populations in terms of age. Considering the population of nulliparous and multiparous women together, all the nulliparous women will fall inside the range of age of spontaneous delivery age distribution of multiparous women, and this will result in the inability to finding a statistically significant difference in maternal age. This is probably due to the fact that in multiparous women age acts in a different way compared to nulliparous ones on the need to apply operative delivery.

Furthermore, in univariate analysis there was a significantly greater weight gain in operative deliveries. These data match with data reported in a previous study where a greater weight gain during pregnancy was statistically associated with an increased risk of cesarean section during labor [13]. However, in this study, the weight gain during pregnancy lost significance in multivariate analysis.

According to the final multivariate model, this study shows that we are able to predict the risk of operative delivery with some simple parameters: maternal age, nulliparity, medically assisted procreation, gestational age at birth, male fetus, labor analgesia and medical induction of labor. This becomes clearer by analyzing the nomogram included in the study (fig. 2). In our reference population the basal risk of operative delivery was equal to the prevalence of operative delivery (13% = 0.13). For instance, when this nomogram shows us a risk lower than 0.13 we can say that the woman has a low risk profile for operative vaginal delivery. Anyway, in our view it is an important risk of operative delivery that a woman should be willing to take. For example, a possible scenario is a 40-year-old woman with a previous operative delivery that would like to try again to labor, even if she would not like to repeat an operative delivery. With the use of this nomogram, in case of spontaneous labor up to 40 weeks gestation, we can reassure the woman of the low probability of an operative delivery, and even if, she will benefit from the use of epidural analgesia (risk <0.10). The scenario will change with the need of labor induction after 41 weeks (risk of about 0.17).

Comparing our results with the current literature we find a substantial overlap with risk factors considered. In a recent study Mazouni et al. [24] described the most important risk factors related to operative vaginal delivery by forceps. The strongest risk factors for forceps delivery were birth weight >4,000 g, occiput posterior position of the fetal head and epidural analgesia. Other significant risk factors for forceps delivery were age >35 years, induction of labor as well as a prolonged first and second stage of labor. A less recent study, conducted among pregnant women in New South Wales, Australia, describes the trend of delivery by vacuum extraction and forceps between 1990 and 1997 and the associated risk factors. These again include, among primiparous women, epidural analgesia, age >34 years and induced or augmented labor. Interestingly, private care insurance was also reported among risk factors [25]. A further interesting study considered the risk factors for operative vaginal delivery and cesarean section that can be evaluated already at admission. Independent predictors were maternal age and height, pregnancy weight gain, smoking status, gestational age and cervical dilatation at admission. Further risk factors occurring during labor were evaluated. These included the presence of dystocia, epidural analgesia and fetal heart rate tracing abnormalities. Similar to our study, the authors concluded that this model, may help to predict the need for operative vaginal delivery or cesarean section in low-risk nulliparous women already at admission [26].

Study Limitations

The main limitation of this study is its retrospective design. For this reason it will be necessary to evaluate the predictive value of the nomogram created in a prospective observational study to better prove its clinical utility.

Conclusions

As operative delivery can significantly affect the maternal-fetal outcomes, we believe it is important to provide as much objective and individualized counseling as possible to the patient, possibly even before the onset of labor. With our study we propose the use of a new nomogram for an objectified determination of the risk of operative delivery.

Disclosure Statement

The authors have no conflicts of interest to declare.

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