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Predictors for failure of vacuum-assisted vaginal delivery: a case-control study☆

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ABSTRACT

Objective: To identify potential predictors for failed vacuum-assisted delivery.
Study design: Retrospective case-control study conducted in two perinatal centers in the Netherlands. Cases were women who underwent a failed vacuum-assisted delivery between 1997 and 2011. A failed vacuum extraction was defined as a delivery that was started as vacuum extraction but was converted to a cesarean section because of failure to progress. As controls we studied two successful vacuum extractions that were performed before the failed one. We used multivariable logistic regression to assess the risk for failed vacuum extraction.
Results: Between 1997 and 2011, 6734 trials of vacuum extraction were performed of which 309 failed (4.6%). These 309 cases were compared to the data of 618 women who underwent a successful vacuum extraction. Predictors for failed vacuum-assisted vaginal delivery were increasing gestational age (OR 1.2 per week), maternal height (OR 0.97 per cm), previous vaginal birth as compared to nulliparae (OR 0.32), estimated fetal weight ≥3750 g as compared to <3250 g (OR 5.7), epidural analgesia (OR 3.0), augmentation (OR 1.4), failure to progress as indication for trial of vacuum delivery (OR 1.7), station of descent of the fetal head (OR 0.31 per station more descended), and occiput posterior position (OR 2.6). The area under the receiver-operating characteristic curve of a prediction model integrating these indicators was 0.83.
Conclusion: Failed vacuum extraction can be predicted accurately using both ante- and intrapartum characteristics. There is a strong need for prospective studies on the subject.

Introduction

Vacuum-assisted operative vaginal delivery is used to facilitate childbirth and to avoid cesarean delivery and its associated morbidities in case of non-progression of the second stage of labor or fetal distress.

Cesarean delivery rates increase, affecting 33% of all births in the United States (US) in 2011, while rates of operative assisted vaginal deliveries have been declining since the mid-1990s. In the US use of operative delivery with forceps or vacuum extraction was 3.5% in 2011 [1].

In literature, failure rates for vacuum-assisted delivery vary between 5% and 8% [2,3]. There is however a wide range of operative delivery rates (1–23%), both across and within geographic regions in the US [4]. A failed vacuum extraction is associated with adverse maternal and fetal outcomes [5–7], and may be a negative experience for the mother [8].

The guidelines of the British and American Colleges emphasize the importance of adequate training and operator experience but do not specify criteria for the attempt or abandonment of a trial of operative delivery [9,10]. Four or more pulls at attempted vaginal operative delivery has been associated with increased neonatal trauma and admission to special-care baby-unit [8].

☆ This study was conducted in Veldhoven and Alkmaar, the Netherlands.

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Knowledge of indicators that are related to failed vacuum-assisted delivery can potentially improve clinical decision-making, but systematic information on the subject is lacking. The objective of this study was to identify and quantify potential predictors of failed vacuum extraction.

Materials and methods

We performed a case-control study in the Departments of Obstetrics and Gynecology of Maxima Medical Center, Veldhoven and Medical Center Alkmaar, in the period 1997–2011. We included women with a singleton pregnancy of at least 37^{+0} weeks and a vacuum-assisted vaginal birth. Women who underwent cesarean section after the vacuum extraction had failed (cases) were compared with the characteristics of women who had a successful vacuum-assisted birth (controls). For each case we selected as controls the last two women with a successful vacuum-assisted vaginal birth who delivered before the selected case. In both hospitals the indications for vacuum-assisted vaginal delivery were prolonged second stage of labor and nonreassuring fetal heart rate. According to national guidelines an episiotomy was performed in all cases.

Through retrospective chart review, we collected data on maternal age, height, pre-pregnancy body mass index (BMI), parity, gestational age, estimated fetal weight (EFW), labor induction, epidural analgesia, indication for vacuum-assisted delivery, the use of a Malmström or soft cup, position and descent of the fetal head, the number of tractions and neonatal outcomes (i.e. birth weight, Apgar score, umbilical artery pH, neonatal admission). BMI was categorized as <20, 20–25 (reference category), 25–30, >30. EFW was categorized as <3250 (reference category), 3250–3500, 3500–3750 g, and ≥3750 and was defined as the fetal weight before delivery, estimated either by palpation or by ultrasound. In both participating hospitals ethics committee approval was not required for a retrospective study.

The association between potential risk indicators and the occurrence of failed vacuum-assisted delivery was assessed using logistic regression analysis, the measure of association was an odds ratio (OR) with a 95% confidence interval (CI). In the univariable analysis we investigated the association between each individual risk indicator and the occurrence of failed vacuum. Multivariable logistic regression analysis was used to estimate the independent contribution of potential risk indicators for the occurrence of failed vacuum. The univariable analysis was conducted as a complete case analysis; women with a missing value for the variable investigated were omitted from the analysis. Since such an approach would lead to a large number of excluded women in the multivariable analysis, we used multiple imputation (ten times) for variables with missing values, which ranged from 0.6% (augmentation during labor) to 59% (EFW), to obtain complete data [11]. Only variables known before the actual performing of a vacuum-assisted delivery were eligible for inclusion in the analysis. Additional pre-selection of predictors for inclusion in the multivariable logistic regression analyses was not done as such selection based on univariable statistics often results in unstable prediction models [12–15]. Predictors of the multivariable models were identified by backward stepwise selection using Akaike Information Criterion in each imputation set separately to account for differences between imputation sets. The predictors for the final multivariable model were selected using the majority method, meaning that predictors were selected in at least 5 of 10 imputed data sets [16]. Afterwards the regression coefficients of this model were estimated in each imputation set separately and combined using Rubin's rules to obtain the regression coefficients of the final model [17].

The prognostic performance of the identified multivariable model was also investigated. The discriminatory ability of the model was assessed by the area under the receiver operating characteristic (AUC) analysis. Calibration was assessed by comparing the predicted probabilities with the observed frequencies of failed vacuum-assisted deliveries in a calibration plot [13]. Furthermore, the following accuracy measures were assessed: sensitivity, specificity, positive and negative predictive values, and false positive rate. Since no clear relevant cut-off value exists, these measures were presented for different cut-off values based on the deciles of the predicted probabilities. To facilitate clinical applicability of the model we created a nomogram.

To adjust for a possibly over-fitted model, we (internally) validated the model with bootstrapping techniques in which the predictor selection was repeated [18]. This yielded a shrinkage factor which was used to perform uniform shrinkage of the regression coefficients to adjust for optimism. Statistical analyses were performed using SPSS (SPSS Inc, Chicago, Il), and R for Windows, version 2.15.2 (The R Foundation for Statistical Computing).

Results

Between 1997 and 2011, 6734 trials of vacuum extraction were performed of which 309 failed (4.6%). These 309 cases were compared to the data of 618 women who had a successful vacuum extraction (Fig. 1).

The neonates born after failed vacuum-assisted delivery more often had a low Apgar score after 1 min (17% versus 8%, OR 2.1 (95% CI 1.4–3.2)) and an arterial umbilical pH under 7.05 (4% versus 1%, OR 4.7 (95% CI 1.7–13)). Furthermore, a failed vacuum-assisted delivery was associated with increased admission to special care baby unit (30% versus 19%, OR 2.0 (95% CI 1.3–2.9)) (Table 1).

Table 2 shows the characteristics of the study population at the start of labor. There was no significant difference in maternal age or labor induction rate between cases and controls. The characteristics of the study population at the start of vacuum-assisted delivery are shown in Table 3.

Univariable analysis (Tables 2 and 3) showed that maternal height (OR 0.97 (95% CI 0.95–0.99) per cm) and previous vaginal

Table 1
Neonatal outcome.

Characteristics	Failed vacuum-assisted delivery $n=309$ (%)	Successful vacuum-assisted delivery $n=618$ (%)	Odds ratio (95% CI)	*P*-value
Birth weight in g, mean (±SD)	3714 (460.8)	3517 (43.18)	1.1 (1.1–1.1)	<0.001
Apgar score after 1 min				
<7	52 (16.8)	52 (8.4)	2.1 (1.4–3.2)	<0.001
≥7	257 (83.2)	551 (89.2)	Ref	
Missing	0	15 (2.4)		
Apgar score after 5 min				
<7	17 (5.5)	10 (1.6)	3.5 (1.6–7.6)	0.002
≥7	292 (94.5)	593 (96)	Ref	
Missing	0	15 (2.4)		
Umbilical artery pH				
<7.05	12 (3.9)	6 (1.0)	4.7 (1.7–13)	0.003
7.05–7.20	27 (8.7)	67 (10.8)	1.2 (0.73–2.1)	0.451
≥7.20	45 (14.6)	103 (16.7)	Ref	
Missing	225 (72.8)	442 (71.5)		
Admission special care baby unit				
Yes	96 (31.1)	129 (20.9)	2.4 (1.7–3.6)	<0.001
No	213 (68.9)	489 (79.1)	Ref	

CI, confidence interval.