# External validation of a prediction model on vaginal birth after caesarean in a The Netherlands

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# External validation of a prediction model on vaginal birth after caesarean in a The Netherlands: a prospective cohort study

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**Abstract**

**Objectives:** Discussing the individual probability of a successful vaginal birth after caesarean (VBAC) can support decision making. The aim of this study is to externally validate a prediction model for the probability of a VBAC in a Dutch population.

**Methods:** In this prospective cohort study in 12 Dutch hospitals, 586 women intending VBAC were included. Inclusion criteria were singleton pregnancies with a cephalic foetal presentation, delivery after 37 weeks and one previous caesarean section (CS) and preference for intending VBAC. The studied prediction model included six predictors: pre-pregnancy body mass index, previous vaginal delivery, previous CS because of non-progressive labour, Caucasian ethnicity, induction of current labour, and estimated foetal weight ≥90th percentile. The discriminative and predictive performance of the model was assessed using receiver operating characteristic curve analysis and calibration plots.

**Results:** The area under the curve was 0.73 (CI 0.69–0.78). The average predicted probability of a VBAC according to the prediction model was 70.3% (range 33–92%). The actual VBAC rate was 71.7%. The calibration plot shows some overestimation for low probabilities of VBAC and an underestimation of high probabilities.

**Conclusions:** The prediction model showed good performance and was externally validated in a Dutch population. Hence it can be implemented as part of counselling for mode of delivery in women choosing between intended VBAC or planned CS after previous CS.

**Keywords:** caesarean section; external validation; prediction model; vaginal birth after caesarean.

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## Introduction

Contemporary guidelines propose that pregnant women who have had a previous cesarean section (CS) should be counselled about their choice of mode of delivery [1–3]. One of the key aspects in this counselling is discussing the probability of a successful vaginal birth after CS. Of all women who attempt a vaginal birth after CS (VBAC), it is postulated that 49–87% achieve successful vaginal delivery [4]. However, this broad range makes challenging

counselling based upon maternal personalised risk factors. Calculating the individual probability of a successful VBAC personalizes counselling and can support decision making. Women can take this individual probability into consideration when making an informed choice of mode of delivery.

Several models for predicting successful VBAC have been developed. Some of these models only include variables known early in pregnancy [5–7]. Other models also include variables known only close to delivery [8, 9]. Earlier studies showed that the models that include close-to-delivery predictors discriminate better between success and failure of VBAC than the models only containing the predictors that are measured early on in pregnancy [8, 10–12]. Schoorel et al. developed a prediction model including both variables known early in pregnancy and variables only known just before delivery. This model was developed and internally validated in a sample of 515 women from a Western European cohort [13]. Subsequently, the prediction model was included in a decision aid (DA) for counselling with regards mode of delivery [14] (Supplemental Material). Implementation in a study setting showed an unchanged VBAC rate, but a better risk selection with a 40% reduction in the unplanned caesarean section rate [15].

Before any prediction model is implemented in daily practice, it needs to be externally validated to assess the performance of the prediction model in an independent sample. We aimed to externally validate this prediction model for the probability of a VBAC in a Dutch population. If proven externally valid, the model can be implemented in daily practice for women choosing between intended VBAC en planned CS to individualize counselling for mode of delivery after one previous CS and help to improve case selection.

# Materials and methods

## Prediction model

The development of the prediction model and internal validation is described in the original article by Schoorel et al. [13]. In brief, all potential predictors of a successful VBAC were included in a multivariable logistic regression model with successful VBAC (yes or no) as the outcome variable. With backward stepwise elimination based on the Wald test, the number of predictors was reduced. Finally, six predictors were selected and combined into a prediction model. These six predictors were pre-pregnancy body mass index (BMI), previous vaginal delivery, previous CS because of non-progressive labour, Caucasian ethnicity, induction of current labour, and estimated foetal weight ≥90th percentile. The model was internally validated and assessed by calculating the area under the curve (AUC) from receiver operating characteristic (ROC) curve analysis. The AUC was 70.8%, indicating good discriminative ability. Visual inspection of the calibration plot showed that the model was well calibrated.

## Setting and design

The current study is part of the Caesarean Section IMPLEmentation (SIMPLE) II study, a study to evaluate the use of a DA including the prediction model for mode of delivery after CS [15]. In this prospective cohort study in 12 Dutch hospitals, six hospitals in one region were assigned to use the DA [14] including the aforementioned Schoorel et al. prediction model [13] as part of the counselling for mode of delivery. These hospitals were compared with six matched (based on type and VBAC-rate) hospitals offering counselling without DA [15]. Different types of hospitals were represented: university hospitals (n=2), teaching hospitals (n=6) and non-teaching hospitals (n=4). Furthermore, the hospitals had different intended VBAC-rates prior to the start of this study ((≤60% (low), 60–80% (mean) and ≥80% (high)). This design was chosen to prevent bias caused by caregivers working in different hospitals in one region during the study period. As all these hospitals earlier recruited the women for the cohort study in which the prediction model was developed [13], this external validation can be seen as temporal validation. This shows the performance of the model in the setting in which the prediction model was developed, but on subsequent patients. The index study was a prospective cohort study performed between September 2012 and September 2014 including all patients from the SIMPLE II study opting for VBAC and intending VBAC to externally validate the Schoorel at al. prediction model [13].

## Study population

The inclusion criteria for the current study were comparable to those of the cohort of Schoorel et al. [13] Eligible for inclusion were women with a singleton pregnancy with a foetus in cephalic position beyond 37 weeks of gestation and with a history of one previous CS. Furthermore, the women had to opt for an intended VBAC after counselling. Women were excluded if they were not able to read Dutch, if they preferred a planned CS or if there was a contra-indication for an intended VBAC. The contra-indications were defined as a previous classical vertical incision or other significant uterine scar, a previous uterine rupture, a suspected abruption of the placenta, impossibility of vaginal birth, e.g. cervical myoma, placenta praevia, vasa praevia or a primary infection with genital herpes simplex virus. All women meeting the inclusion criteria were recorded in an anonymised study database. Since the DA with the prediction model was used to improve guideline adherence [15], the Medical Ethical Committee of the MUMC + agreed that obtaining individual informed consent was not necessary.

## Sample size

There are no formulas available to compute the required sample size for an external validation study. Some simulation studies on sample size exist and results are often transformed into a generic rule-of-thumb that states that at least 100 events and 100 non-events should be available for the analysis [16]. Because of the size of the available

cohort we had ample precision to compute estimates of model performance. An event was defined as an unsuccessful trial of labour, which occurred 166 times in this cohort. Hence, both the number of successes and failures were well over 100.

### Data collection

Data on patient characteristics (ethnicity, age, BMI, obstetric history and features of the current pregnancy) the variables contained in the prediction model (see above), and mode of delivery were collected from the birth registration in each hospital by trained staff and research nurses. Regarding the patient characteristic ethnicity, in birth registrations in the Netherlands seven categories of ethnicity are used: Dutch, Mediterranean, other European, African, Asian, Hindu, and "other". In both the development and external validation cohorts, Caucasian ethnicity was defined as "Dutch" and "other European". Because data were collected from the same type of birth registrations, converting or redefining of the other collected data was not necessary. A successful VBAC is defined by a woman starting intended VBAC and ending having a vaginal birth. When a woman starts intended VBAC, but finally has an unplanned CS is defined as a failed VBAC. This was consistent at all the participating hospitals

### Statistical analyses

Missing covariate data were imputed using stochastic regression imputation, since complete case analysis decreases statistical power and may induce bias if data are not missing completely at random [17]. The performance of the prediction model was quantified by several measures. The ability to discriminate between women who will succeed and those who will not was expressed as the area under the receiver operating characteristic (ROC) curve (AUC). The difference between the average predicted probability and observed frequency was used to determine calibration in the large. Furthermore, a calibration plot was made to visually assess the models' agreement between predicted probabilities and actual probabilities. The Hosmer-Lemeshow-statistic was used to determine the goodness of fit of the prediction model. This is a goodness of fit test for logistic regression, showing how well the data fits the prediction model. Specifically, the HL test calculates if the observed event rates match the expected event rates in population subgroups. All statistical analyses were performed using SPSS version 21. The calibration plot was constructed using R version 3.2.3.

### Ethical approval

Ethical approval for this study was obtained from the Medical Ethical Committee of the Maastricht University Medical Centre+ (MUMC+) in The Netherlands (MEC number 12-4-091) (18-04-13).

### Trial registration

This study is registered at ClinicalTrials.gov: Current Dutch Practice on Caesarean Sections: Identification of Barriers and Facilitators for Optimal Care (SIMPLE), NCT01261676, https://clinicaltrials.gov//show/NCT01261676?term=cesarean&rank=18

# Results

## Study population

Of the 924 women pregnant after previous CS and eligible for VBAC in the original cohort, 586 (63%) women opt for and started intended vaginal delivery and were hence included for this study. Four hundred and 20 women had a successful VBAC (72%) and 166 (28%) had an unplanned CS. Baseline characteristics are shown in Table 1. Women who had a successful VBAC had a lower BMI, had more often a previous vaginal delivery and were less likely to have a foetus with an estimated foetal weight >90th percentile or a previous cesarean section because of failure to progress. Furthermore, they were less likely to have an induction.

## External validation

The area under the ROC curve was 0.73 (CI 0.69–0.78) (Figure 1), expressing the discriminative ability of the prediction model for VBAC. The average predicted probability of a VBAC according to the prediction model was 70.3% (range 33–92%). The actual VBAC rate in this cohort was 71.7%. Therefore, as calibration in-the-large was close to zero, we did not observe evidence of systematic under- or overestimation of the probability. The calibration plot did show some proportional miscalibration: a small overestimation for low probabilities of VBAC and an underestimation of high probabilities (Figure 2). Interpretation of Figure 2 shows a slight overestimation of the probability of a successful VBAC when the probability of success is lower than 60%. The HL statistic to assess the goodness of fit, showed a p-Value of 0.11, indicating sufficient calibration of the prediction model.

# Discussion

## Main findings

This study shows the external validation of a prediction model for VBAC developed by Schoorel et al. [13]. The discriminative performance of the model is good and even improved slightly in the validated model to an AUC of 73%, compared to an optimism-corrected AUC of 71% in the developed model [13]. The HL-statistic was non-significant, indicating good calibration. Temporal validation is proven, because the model was validated in the same setting in which

**Table 1:** Baseline characteristics.

| | Successful VBAC n=420 n (%) or mean (± SD) | Failed VBAC n=166 n (%) or mean (± SD) | Missing[a] n Successful VBAC/ n failed VBAC 3/0[b] | p-Value |
|---|---|---|---|---|
| Caucasian ethnicity | 327 (78.6) | 119 (73.0) | 1/3 | 0.16 |
| Maternal age, years (mean) | 33.6 (4.3) | 33.9 (4.4) | 13/5 | 0.51 |
| Pre-pregnancy BMI (mean) | 25.1 (5.2) | 26.6 (5.2) | 80/31 | |
| <18.5 | 13 (3.9) | 1(0.7) | | 0.08 |
| 18.5–24.9 | 189 (56.1) | 59 (43.7) | | 0.02 |
| 25.0–29.9 | 81 (24.0) | 41 (30.4) | | 0.16 |
| >30 | 54 (16.0) | 34 (25.2) | | 0.026 |
| Obstetric history | | | | |
| Parity (median) | 1 (0.9) | 1 (0.4) | 2/1 | 0.00 |
| Indication previous CS failure to progress | 132 (33.8) | 88 (55.0) | 27/6 | 0.00 |
| Previous vaginal birth | 125 (30.5) | 9 (5.4) | 7/0 | 0.00 |
| Previous vaginal birth after CS | 91 (22.5) | 4 (2.4) | 12/2 | 0.00 |
| Current pregnancy | | | | |
| Gestational diabetes | 13 (3.1) | 6 (3.6) | 3/0 | 0.80 |
| Pre-existent or pregnancy induced hypertension | 32 (7.7) | 14 (8.4) | 3/0 | 0.74 |
| Pre-eclampsia/HELLP | 7 (1.7) | 7 (4.2) | 5/0 | 1.29 |
| Estimated foetal weight from GA 32 p≥90 | 15 (3.9) | 17 (10.8) | 35/9 | 0.00 |
| Estimated foetal weight from GA 32 ≤p10 | 19 (5.0) | 7 (4.4) | 35/8 | 1.00 |
| Induction of labour | 117 (31.5) | 55 (38.7) | 46/24 | 0.14 |

VBAC, vaginal birth after caesarean; BMI, body mass index; CS, cesarean section; HELLP, syndrome of hemolysis, elevated liver enzymes, and low platelet count; GA, gestational age; p, percentile; [a]number of patients with missing data; [b]number of patients missing data in all baseline characteristics.

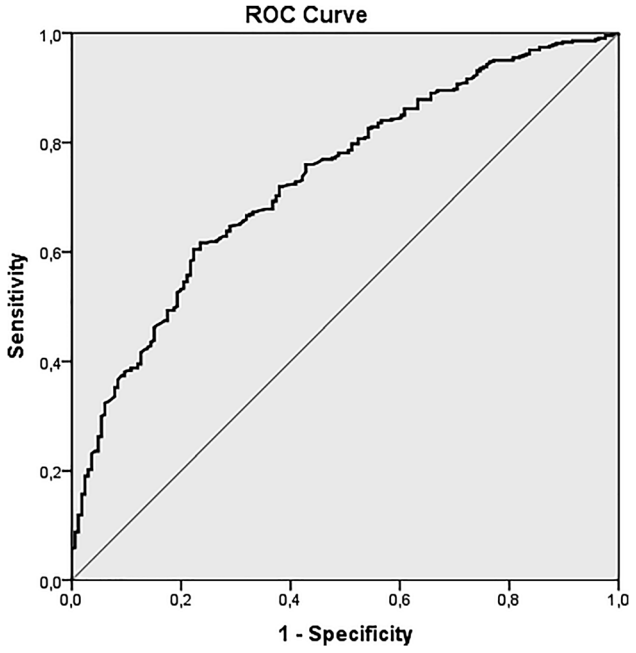
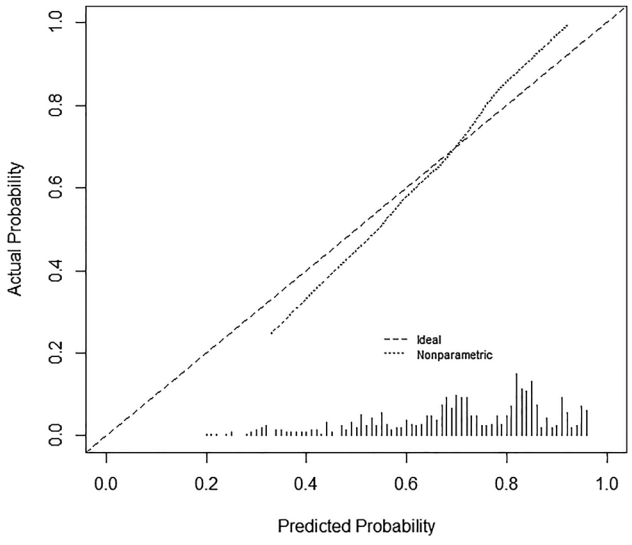



**Figure 1:** Receiver operating characteristic curve.




VBAC: vaginal birth after caesarean

**Figure 2:** Calibration plot with the observed probability of a vaginal birth after caesarean by the predicted probability of a vaginal birth after caesarean by the prediction model.

the model was developed. In women with a high probability of VBAC, the prediction model on average slightly underestimates their probability and conversely, in women with a low probability of VBAC, their VBAC probability was slightly overestimated by the prediction model. At internal and external validation, the model showed a slight overestimation of the probability of a successful VBAC when the probability of success is lower than 60%.

## Strengths and limitations

One of the strengths of this study is that this model has been used in a prospective setting as part of the counselling for mode of delivery after a previous CS in eligible women. In the prospective setting, use of the model suggests a risk reduction in unplanned cesarean [15]. By showing the prediction model is externally valid we proved that it can be implemented in daily practice for a personalized counselling of women pregnant after a previous CS in the third trimester of pregnancy choosing mode of delivery.

Furthermore, this study was performed in a prospective setting in multiple centres, which contributes to a higher validity of the study results. The externally validated model was previously developed in a Dutch sample. Because the external validation took place in the same hospitals but after the development of the model, there was no need to convert or redefine variables because of differences in definitions or measurements.

A limitation of this study was that the model has only been validated in Dutch hospitals, a population with a high VBAC rate (38–46%) [15, 18]. The discriminative performance may change when applied to samples from other populations because of other patient characteristics and preferences and other policies concerning mode of delivery after previous CS [6, 12]. Besides, the clinical impact of this model used in a prospective setting on VBAC rate and risk reduction has not been studied in other countries yet.

Self-selection bias based on women with a high risk on an unplanned CS cannot be ruled out. Women with a low chance on VBAC might prefer a planned CS. Hence, women opting for intended VBAC possibly have a higher chance on VBAC. When we compare the baseline characteristics of this study cohort with the control group of the SIMPLE II study [15], women in this cohort seem to have more often a BMI lower than 25, less often had a previous CS because of failure to progress and more often had a previous vaginal birth. These factors are positive predictors for VBAC. However, age and parity were comparable and women in this cohort more often had an induction of labour, which is a negative predictor for VBAC. Besides, it is unknown if these differences are significant. The intended VBAC rate (63%) is comparable with the intended VBAC rate in the cohort study in which the prediction model was developed (67%) [13]. Further research of the impact of the predicted chance on VBAC on the decision for mode of delivery is necessary.

## Interpretation

A model with a good discriminative performance between patients with a high probability of a VBAC and those with a low probability can contribute to a decrease in unplanned CS and consequently a decrease in maternal and foetal morbidity [19]. Vankan et al. already showed a reduction in unplanned CS when this prediction model is used as part of a decision aid, without a clear change in VBAC rate [15].

To make a distinction between a high and a low probability of VBAC and, consequently between equal or less and more maternal morbidity than with an elective (planned) repeat caesarean section, a cut-off point might be helpful in counselling patients and risk estimation. Several studies researched this issue; however a clear cut off point has not been defined yet. Grobman et al. [20] showed increased total and minor maternal morbidity when the probability of VBAC was lower than 70% and increased major maternal and neonatal morbidity when the probability of VBAC was lower than 60%. These results were derived when using a prediction model with factors known early in pregnancy. When the same model was used in a different population, increased maternal morbidity was demonstrated when the probability of VBAC was lower than 60% and there was increased neonatal morbidity when the probability of VBAC was lower than 70% [21]. Metz et al. used a model with close to delivery variables and made a distinction between a low probability (<50%) and a high probability (>85%) [22]. However, these cut off points were not directly related to morbidity rates. Our cohort is likely too small to draw conclusions about morbidity rates. Furthermore, the risk of morbidity is only one factor contributing to women's choices. Previous experiences and personal preferences are different and are likely to result in different risk appreciation. For some women a 60% chance of vaginal birth is considered high while others find it low.

The model performance in predicting a successful VABC, indicated by the AUC, was 0.733. If we compare this to other developed models, most of them had a similar or lower discriminative ability when they were externally validated [5, 6, 9–11, 21, 23]. A few had a higher discriminative ability [10, 12, 22].

Metz et al. validated their own model in a retrospective study in multiple hospitals, which included early known variables and a variable known close to delivery and found a concordance statistic of 0.80 at external validation [22]. However, the close-to-delivery variable was only known at admission for delivery, which makes this model less suitable for counselling in the third trimester. Yokoi et al.

externally validated the entry-to-care model of Grobman in Japanese women in one tertiary referral hospital and found a concordance-statistic of 0.81, but these results are not applicable for a Western European population [12]. Constantine et al. [10] found a concordance statistic of 0.76 when validating the close-to-delivery model of Grobman at one university hospital in the United States.

In both the studies of Metz and Yokoi a high percentage of VBAC was found in their population as we found in our study [12, 22]. The models were only tested in populations of patients who choose a trial of labour. This could indicate selection-bias, because patients with a low probability of VBAC might not choose an intended VBAC. Our model showed an overestimation for low probabilities of VBAC. The model of Metz and the close-to-delivery model of Grobman also showed more variance in the low probabilities of VBAC [8, 21]. These findings make the models less accurate for patients with a low probability of VBAC. Fagerberg et al., who validated an adapted version of the entry-to-care model of Grobman showed a better correlation between predicted and observed VBAC-rates in women with low probabilities of VBAC compared to the original model of Grobman [6]. The discriminative ability of this model was comparable to the discriminative ability of our model.

Several studies show that validating the same model in different countries can change the discriminative ability of a prediction model [5, 6, 10–12, 21, 23]. Further research is necessary to explore if similar results can be achieved in different settings.

## Conclusions

This study externally validated a prediction model for mode of delivery after a previous CS in a Dutch population, showing good performance. The prediction model can be implemented as part of counselling in women choosing mode of delivery after previous CS in the Netherlands.

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**Ethical approval:** Ethical approval for this study was obtained from the Medical Ethical Committee of the Maastricht University Medical Centre+ (MUMC+) in The Netherlands (MEC number 12-4-091) (18-04-13).

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