Prediction of Success of External Cephalic Version after 36 Weeks

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ABSTRACT

We aimed to develop a predictive model for the chance of a successful external cephalic version (ECV). We performed a prospective cohort study of women with a singleton fetus in breech presentation with a gestational age of 36 weeks or more. Data on parity, maternal age, body mass index, ethnicity, gestational age, placental location, fetal position, estimated fetal weight, and amniotic fluid were recorded in all participants. Multivariable logistic regression analysis with a stepwise backward selection procedure was used to construct a prediction model for the occurrence of successful ECV. We included a total of 310 women. Multivariable logistic regression analysis demonstrated that multiparity, increasing estimated fetal weight, and normal amniotic fluid were favorable predictors of successful ECV. Anterior placenta location was an unfavorable predictor for ECV outcome. Discrimination of the model was fair (area under the curve 0.71), and the calibration of the model was acceptable. Our prediction model appears to discriminate between women with a poor chance of successful ECV (less than 20%) and women with a good chance of success (more than 60%). When this model is validated externally, it could be used for patient counseling and clinical decision making.

KEYWORDS: External cephalic version, prognosis, prediction model, breech

External cephalic version (ECV) at or near term is a safe procedure that effectively reduces the risk of cesarean section in pregnancies with breech presentation.[1,2] It is recommended that all women with an uncomplicated breech pregnancy at term should be offered an ECV attempt.[3,4] Nevertheless, acceptance for an attempt at ECV by women and doctors varies. Reported rates of maternal refusal of ECV range from 18 to 76%.[5–7] Conversely, the number of women potentially suitable for ECV who were not offered an attempt range from 4 to 33%.[7–9]

The reported success rate of ECV varies from 35 to 86%.[2] Previous studies have shown that the success or failure of an ECV procedure is associated with clinical characteristics such as parity and the engagement of fetal presenting part.[10] Thus far, four studies have assessed the predictive value of these indicators in a multivariable approach.[11–14] Two of these studies used predictive indicators to develop a scoring system.[11,14] Both studies used relatively small data sets ($n = 128$ and $n = 108$) of retrospective collected data, and neither study performed an internal validation nor assessed the discriminative capacity of the scoring system. In view of these issues, a reliable prediction of the outcome of an ECV attempt is still not possible but could be of use in counseling women for an ECV attempt. The aim of this study

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was therefore to develop a model to predict the outcome of an ECV attempt.

MATERIALS AND METHODS

The current study is based on data that had been prospectively collected as part of a multicenter randomized controlled trial that assessed the effectiveness of nifedipine as a uterine relaxant in ECV.[15] In this randomized controlled trial, all women presenting between August 2004 and December 2006 with a singleton in breech presentation at 36 weeks' gestational age and beyond were eligible for the study. All participants were allocated to ECV with uterine relaxation with nifedipine or placebo. Patients allocated to uterus relaxation with nifedipine received a capsule of 10 mg nifedipine sublingually 30 and 15 minutes before the ECV attempt. For each patient, we recorded parity, maternal age, body mass index (BMI), ethnicity, gestational age, placental location, fetal position, estimated fetal weight (EFW) and amniotic fluid. Multiparity was defined as having delivered vaginally or abdominally. Amniotic fluid was recorded as normal or decreased amniotic fluid; decreased amniotic fluid was defined as an amniotic fluid index (AFI) <10 cm. EFW was calculated with the Hadlock formula.[16]

The ECV procedure was performed by experienced obstetricians, midwives, or a resident supervised by experienced clinicians in all hospitals. Annual ECV rates of the clinicians performing the ECV ranged from 15 to 50, and ECV success rates ranged from 20 to 60%. Fetal well-being was established by electronic fetal heart rate monitoring for at least 30 minutes preceding and after the procedure. The fetal heart rate was monitored intermittently by ultrasound scanning during the procedure, followed by electronic fetal heart rate monitoring after the procedure. Nonsensitized rhesus-negative women received anti-D immunoglobulin (1000 IU intramuscularly) following the ECV procedure. For the ECV procedure, a forward and a backward roll were allowed.

Data Analysis

We used successful ECV as the end point of the study. Missing data of the predictive variables were imputed ("filled in"), because deleting them would lead to a loss of statistical power in multivariable analysis and, more seriously, potentially biased results.[17,18] We generated a single imputed dataset, using the first step of the "aRegImpute" multiple imputation function in Splus 6.0 (MathSoft, Seattle, WA). This is an efficient implementation of Bayesian multiple imputation, a recommended state-of-the-art method.[19] We generated an imputed data set, using the aRegImpute imputation function in S-plus® 6.0. We checked the linearity of the association between the continuous variables parity, maternal age, gestational age, BMI, and EFW, using visual inspection and spline functions. Based on these spline functions, the continuous variables were transformed to better approach linearity. For both dichotomous and continuous variables, univariate odds ratios (ORs), beta coefficients (β), and 95% confidence intervals (CIs), as well as p values, were calculated.

Subsequently, multivariable logistic regression analysis with a stepwise backward selection procedure was used to construct a prediction model for the occurrence of successful ECV. Selection of variables was usually performed with a significance level of 5%. As the incorrect exclusion of a factor would be more deleterious than including too many factors, our multivariable analysis considered all predictive variables reaching a significance level of 30% in the univariable analysis.[20]

To reduce the overfit of the created model, internal validation was performed with bootstrapping. Bootstrapping is a technique to create comparable populations. We bootstrapped 200 times. In each of these 200 new data sets, the same multivariable logistic regression was assessed. By analyzing the difference among the predictive models, a shrinkage factor was calculated. The model was corrected by this shrinkage factor, and the prediction formula was extracted from the data.

To evaluate the discriminative performance of the logistic model, the area under the receiver operating characteristic (ROC) curve was calculated. Sensitivity was defined as the fraction of successful ECV attempts that was predicted correctly, whereas specificity was defined as the fraction of ECV attempts that result in a failed ECV that was predicted correctly.

To measure the agreement between predicted and observed outcomes, the calibration of the model was assessed. The predicted probability and the observed proportion of the successful ECV attempts were compared by plotting the observed successful ECV rate compared with the predicted successful ECV rate as calculated from the model in five different categories. Women qualified for a category based on their prognosis. Finally, the reliability of the model was estimated with the Hosmer and Lemeshow test for goodness of fit.

The randomized controlled trial form that we used the data for this study was approved by the Institutional Review Board of the Academic Medical Centre, Amsterdam. The boards of each participating hospital granted local approve.

RESULTS

Overall, 310 women were included and had undergone 310 ECV attempts. Baseline characteristics are summarized in Table 1. The overall ECV success rate was 39%.

Imputation was done on all patients who had at most three missing values in the nine core predictive

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Table 1 Results of the Univariable and Multivariable Analysis of Predictors of Successful ECV

	Missing Data	Overall Cohort (n = 310)	Successful ECV (%) (n = 122)	Univariate Analysis		Multivariate Analysis*	
				OR	95% CI	OR	95% CI
Parity (min–max)	0	0.67 (0–4)					
Nulliparous (%)		161 (52)	42 (26)	1.00		1.00	
Multiparous (%)		149 (48)	80 (54)	3.29	20.4–5.29	2.85	1.74–4.67
Maternal age, y (min–max)	0	33 (20–43)		1.07	1.01–1.13		
BMI, kg/m^2 (min–max)	89	24.7 (17–42)					
BMI ≤24(%)		121 (39)	50 (41)	1.06	0.92–1.23		
BMI >24(%)		100 (32)	40 (40)	0.98	0.91–1.06		
EFW, g (min–max)	51	2703 (1609–4046)					
EFW ≤3000 (%)		208 (67)	76 (37)	1.15	1.05–1.26	1.14	1.04–1.25
EFW >3000 (%)		51 (16)	30 (59)	0.97	0.81–1.15		
Gestational age, wk (min–max)	0	259 (250–280)		1.24	0.97–1.59		
Ethnicity	0						
Caucasian (%)		259 (84)	99 (38)	1.00			
Non–Caucasian (%)		51 (16)	8 (17)	1.33	0.72–2.43		
Placental location	29						
Posterior (%)		103 (33)	44 (43)	1.00		1.00	
Anterior (%)		87 (28)	31 (36)	0.80	0.48–1.34	0.73	0.42–1.27
Fundal (%)		63 (20)	25 (40)	1.01	0.55–1.87		
Lateral (%)		28 (9)	14 (50)	1.54	0.68–3.49		
Fetal position	27						
Frank breech (%)		233 (75)	90 (39)	1.00			
Non–frank breech (%)		50 (16)	23 (46)	1.47	0.81–2.67		
Amniotic fluid	94						
Normal amniotic fluid (%)		159	75 (47)	2.54	1.43–4.53	2.28	1.24–4.18
Decreased amniotic fluid (%)		57	14(25)	1.00		1.00	

*Constant−5.106.
BMI, body mass index; CI, confidence interval; EFW, estimated fetal weight; OR, odds ratio.

factors mentioned in Table 1 for successful ECV. In total, 9.4% data points were missing and subsequently imputed. The association between the continuous variable BMI and the occurrence of a successful ECV is shown in Fig. 1. The plot shows a positive and linear relationship until a BMI of 24 kg/m^2. For this reason, we divided the BMI into two groups (BMI ≤24 kg/m^2 and BMI >24 kg/m^2), of which only the first one was analyzed as a continuous linear variable. Figure 2 shows the association between EFW and the occurrence of a successful ECV. There was a positive linear relationship until an EFW of 3000 g; because of this, we divided the EFW into two groups (EFW ≤3000 g and EFW >3000 g), of which only the first one was analyzed as a continuous linear variable. Figure 3 shows the association between the variable parity and the occurrence of a successful ECV. This figure shows a clear difference between primiparity and multiparity. For this reason, we dichotomized this group into primiparity and multiparity. The category ethnicity was divided into six different groups. As the non-Caucasian group consisted of five small groups, and one review on ethnicity in relation to ECV outcome showed the Caucasian race to be associated with failed ECV, we classified ethnicity as Caucasian or non-Caucasian.

Amniotic fluid was categorized as normal amniotic fluid or decreased amniotic fluid (AFI <10 cm). In the univariable analysis, multiparity, increasing maternal age, increasing EFW until 3000 g, lateral placenta location, non–frank breech presentation, and normal amniotic fluid were significantly associated with increase in successful ECV (Table 1).

Four predictive factors were identified with the stepwise selection procedure: parity, EFW ≤3000 g, placental location, and amniotic fluid (Table 1). Internal validation by bootstrapping showed a slope of 0.84, indicating a possible overfit up to 16% in an external population. The chance of a successful ECV can be calculated from the multivariable model with the formula: $\text{Probability} = 1/[1 + \exp(-\beta)]$ where $\beta = -5.1 + (\text{multiparity} \times 1.05) + (\text{EFW} \leq 3000\ \text{g} \times 0.13) + (\text{anterior placental location} \times -0.32) + (\text{normal amniotic fluid index} \times 0.82)$.

In Fig. 4, the ROC curve of the model is shown. The area under the ROC curve was 0.71

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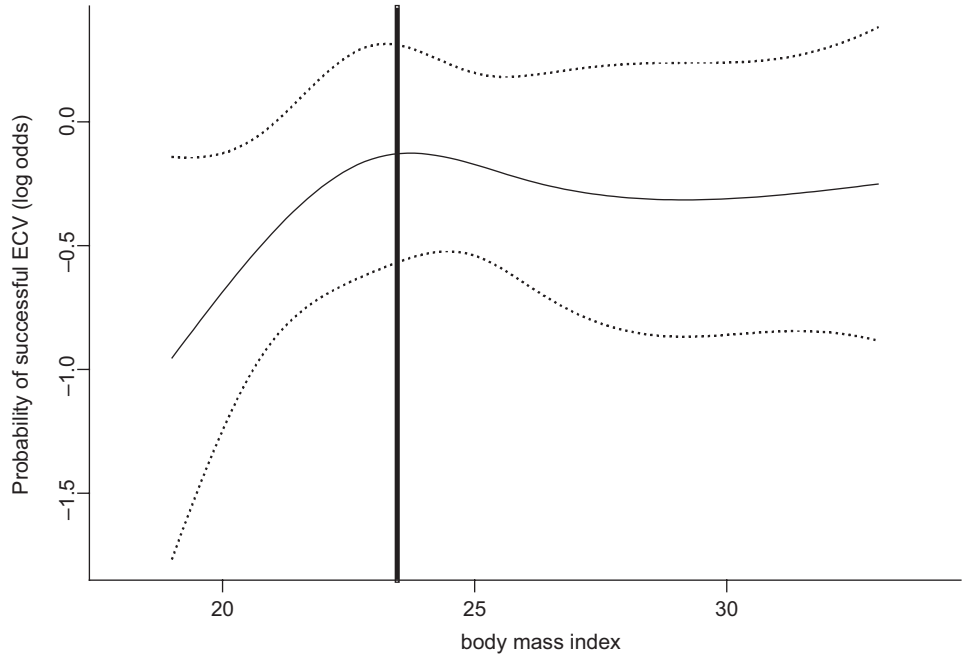

Figure 1 Spline function that illustrates the association of the prediction of a successful external cephalic version (ECV) and the continuous variable body mass index.

(95% CI 0.66 to 0.77). Figure 5 shows that there is no overlap between the group with a poor prognosis (less than 20% chance of successful ECV) and the group with a good prognosis (more than 60% chance of successful ECV), thereby indicating that distinction between these groups is possible. The goodness-of-fit test (Hosmer-Lemeshow) confirmed this analysis with a value of 0.66, indicating a good overall performance of the model.

DISCUSSION

In this study, we present a prediction model for the outcome of an ECV procedure. At internal validation,

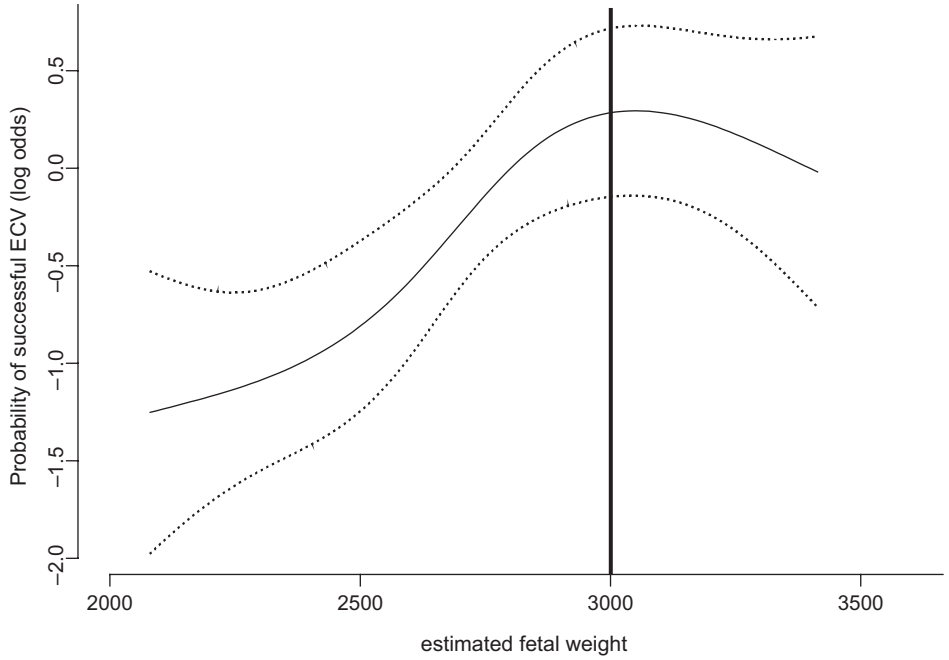

Figure 2 Spline function that illustrates the association of the prediction of a successful external cephalic version (ECV) and the continuous variable estimated fetal weight.

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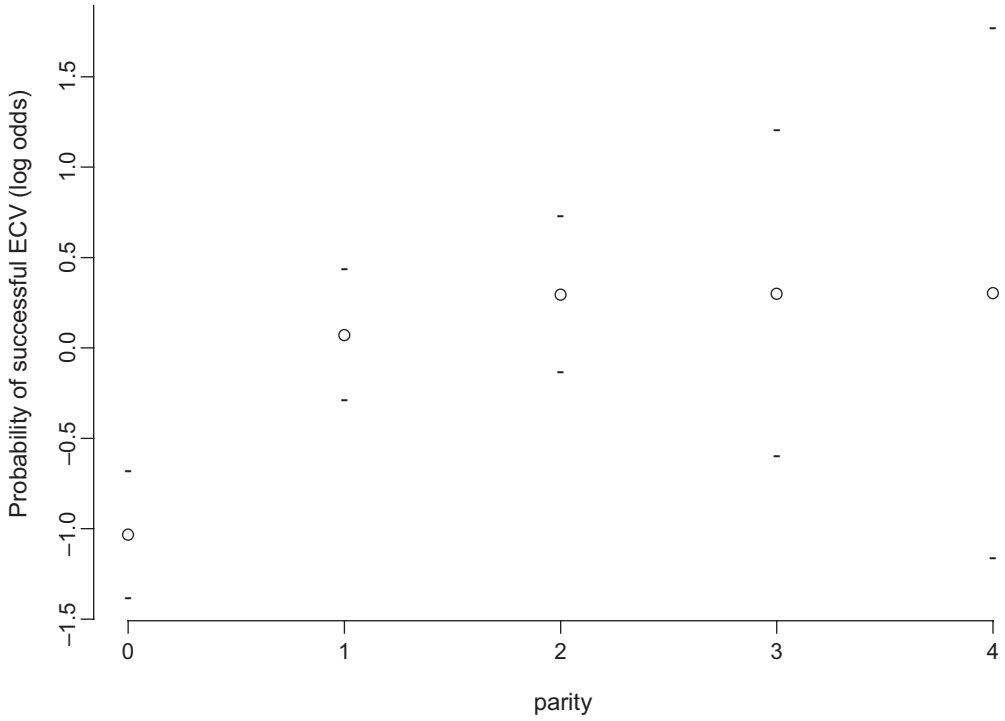

Figure 3 Spline function that illustrates the association of the prediction of a successful external cephalic version (ECV) and the continuous variable parity.

our model had a fair discriminative ability and was well calibrated. We were able to discriminate between women with a poor chance of successful ECV (less than 20%) and women with a good chance of success (more than 60%).

Our study has some limitations. First, engagement and palpation of the fetal head were not recorded as baseline characteristics in our study. According to a recent meta-analysis, these phenomena are important for

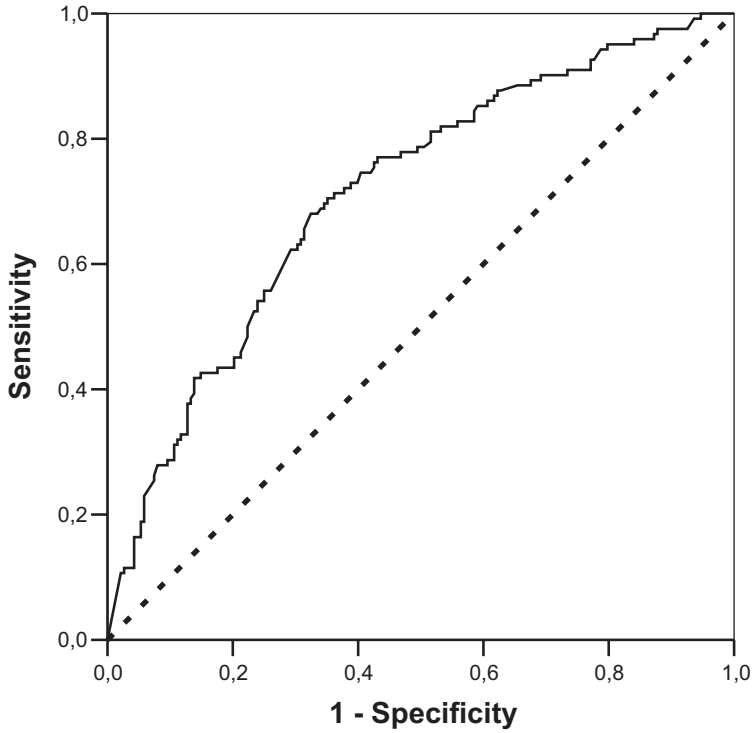

Figure 4 Receiver operating curve of the multivariable logistic regression model for the prediction of a successful external cephalic version.

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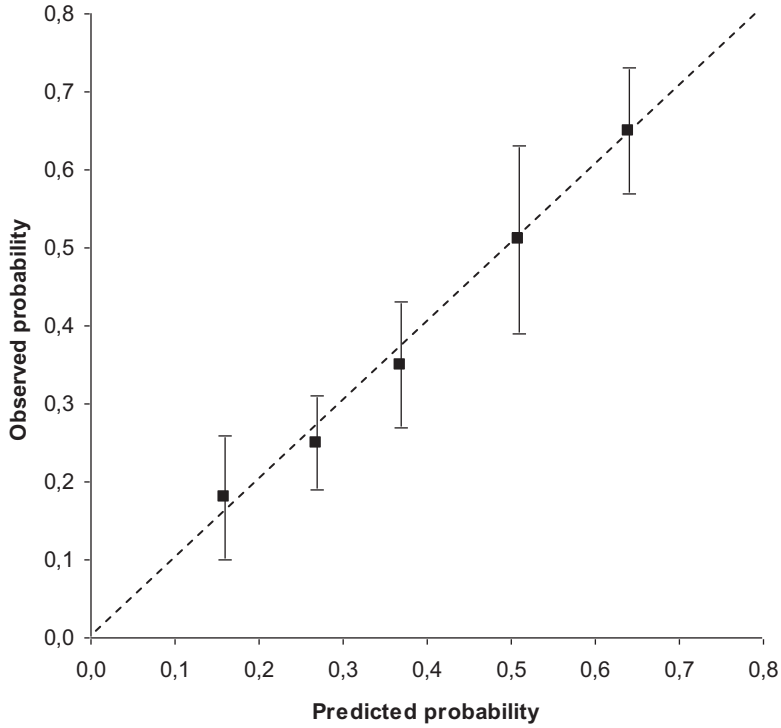

Figure 5 Error bar demonstrating the association between the chance of a successful external cephalic version (ECV) as predicted by the prediction model (x-axis) and the observed chance of a successful ECV (y-axis).

ECV.[10] These factors might improve the performance of our model.

Another limitation is the fact that half of the included women received the uterine relaxant nifedipine whereas the other half received placebo. However, because we did not find a treatment effect of nifedipine (RR 1.1, 95% CI 0.85 to 1.5),[15] this will not have affected our prediction model.

A strength of this study is its large sample size. Previous studies on prediction models for ECV consisted of small groups.[11,14] The performance of an internal validation of our model is another strength of our study compared with earlier studies. We found a fair discriminative capacity and a good calibration of our model. The importance of discrimination and calibration depends on the clinical application of the model. This model is intended to counsel women with a breech-presenting fetus, thus the accuracy of the numeric probability (calibration) is important, as patients want to know the probability that their ECV will be effective. Consequently, the clinical aim of the model is to differentiate between women with a poor prognosis and women with a good prognosis.

External validation of predictive models is a vital step, which has to be performed before the model can be used in clinical practice.[21] One previous study presenting a prediction model on ECV tested their model on a second data set.[14] However, this study did not address the calibration or the discriminative capacity of the model. For prediction models in other fields of medicine, external validation has demonstrated lower predictive performance when evaluated in a different population.[22] Thus, our model needs external validation before it can be used in clinical practice.

If the model holds at external validation, the question is whether one should withhold ECV to women with a poor chance of success (less than 20%). In view of the low complication rate of the procedure, one might advocate that even with low success rates, one should attempt ECV. However, the impact of small risks such as emergency caesarean delivery after an ECV attempt or even fetal death becomes stronger when the success rates are relatively low. Future studies should take into account the predictive profile of patients.

In conclusion, the present study demonstrates that in the prediction of a successful ECV, a distinction can be made between women with a good chance of a successful ECV and women with a poor chance. The success of ECV depended mainly on parity, EFW, placenta location, and AFI. If external validation has shown a good performance, we suggest using this model in counseling women.

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