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Development and internal validation of a clinical prediction model for external cephalic version

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ABSTRACT

Objective: To develop a prediction model for the chance of successful external cephalic version (ECV).
Study design: This is a secondary analysis of a multicenter, open-label randomized controlled trial that assessed the effectiveness of atosiban compared to fenoterol as uterine relaxant during ECV in women with a singleton fetus in breech presentation with a gestational age of 36 weeks or more. Potential predictors included maternal, pregnancy, fetal, and treatment characteristics and 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. Model performance was assessed using calibration and discrimination.
Results: We included a total of 818 women with an overall ECV success rate of 37%. Ten predictive factors were identified with the stepwise selection procedure to be associated with a successful ECV: fenoterol as uterine relaxant, nulliparity, Caucasian ethnicity, gestational age at ECV, Amniotic Fluid Index, type of breech presentation, placental location, breech engagement, possibility to palpate the head and relaxation of the uterus. Our model showed good calibration and a good discriminative ability with a c-statistic of 0.78 (95% CI 0.75 to 0.81).
Conclusion: Prediction of success of ECV seems feasible with a model showing good performance. This can be used in clinical practice after external validation.

Introduction

Breech presentation occurs in 3 to 4% of all term pregnancies [1,2]. Vaginal delivery of a fetus in breech position is associated with higher rates of neonatal morbidity and mortality compared to a planned caesarean delivery [3]. Consequently, the global rate of term vaginal breech deliveries has declined substantially, while the rate of planned caesarean deliveries increased for fetuses in breech position [4,5]. However, caesarean delivery is associated with short and long-term consequences for maternal and neonatal health [6,7]. External cephalic version (ECV) is a safe and effective procedure to reduce the number of breech presentations at term and consequently the caesarean delivery rate for this indication [8–12]. Considering the global rise in caesarean deliveries in the last decade from approximately 23 to 34%, of which malpresentation is the third indication (approximately 17%) [13], ECV is an important intervention that can contribute to put a hold on this. Even as the complication rate is very low (a pooled risk on fetal death is 0.19% [8]), it is important to weigh these risks of complications with the alternatives to an ECV, namely the risk of perinatal mortality in planned vaginal breech birth (2.0/1000) and planned caesarean delivery (0.5/1000) and with caesarean section and in future pregnancies (1.0/1000) [14]. Therefore, ECV is recommended to all women with an uncomplicated breech pregnancy near term [13].

The success rate of ECV varies from approximately 35% up to 86% with an average of 50–60% [4,15]. Therefore, a more reliable and individualized prediction of successful ECV would be useful to counsel women for an ECV attempt and to improve individualized care and shared decision making. Recently, a systematic review including six prediction models for successful ECV was published [16]. They concluded that one prediction model was validated in an external cohort and had acceptable predictive performance.

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However, none of the models incorporated all important variables in their analysis determined in literature [17,18], thereby potentially limiting the performance of the models. Therefore, the aim of this study was to identify which combination of all important variables in daily clinical practice best predicts the success of ECV.

Materials and methods

The current manuscript was reported according to the TRIPOD reporting guideline [19], and is based on data that had been prospectively collected as part of a multicenter, open-label randomized controlled trial in one academic and seven teaching hospitals in the Netherlands [20]. This study assessed the effectiveness of atosiban compared to fenoterol as uterine relaxant during ECV. Atosiban was associated with a lower success rate (RR 0.73 (95% CI 0.55 to 0.93)). The study was approved by the research ethics committee of the Academic Medical Center in Amsterdam (reference number MEC 08–364) and by the board of directors of each of the participating hospitals. The study was registered in the Dutch Trial register (NTR 1877). In this randomized controlled trial, all women presenting between August 2009 and May 2014 with a singleton fetus in breech position who were scheduled for ECV were eligible for the study. Exclusion criteria were maternal age less than 18 years old, gestational age below 34 weeks, any contra-indication to vaginal birth (e.g. placenta praevia), any contraindication for ECV (scarred uterus other than transverse in the lower segment, known uterine anomalies, placental abruption in history or signs of placental abruption, severe preeclampsia or HELLP syndrome, third trimester blood loss or seven days prior to ECV, ruptured membranes), any known contra-indication to one of the two drugs, suspected intrauterine growth restriction (defined as estimated fetal weight < P5 for gestational age assessed by ultrasonography), severe oligohydramnios (deepest pool < 2 cm), fetal anomalies or non-reassuring fetal heart rate monitoring. Women were randomly assigned to receive atosiban or fenoterol. Fifteen minutes before starting ECV, the participating woman received an intravenous bolus of atosiban (6.75 mg in 0.9 ml (7.5 mg/ml)) or fenoterol (40 μg in 0.8 ml (0.5 mg/10 ml)) administered by a physician.

Experienced obstetricians and midwives performed the ECV procedure, and the procedure was successful if the fetus was still in cephalic position 30 min after the ECV attempt.

Candidate predictors

Based on literature [17,18] and clinical reasoning, we selected candidate predictors that are available in clinical practice. Candidate predictors were: parity, maternal age, body mass index (BMI), ethnicity, gestational age, placental location, fetal position, estimated fetal weight (EFW), amniotic fluid index in cm (AFI), position of the fetal spine, breech engagement, symphysis fundal height defined in weeks, possibility of palpation of the fetal head, and relaxation of the uterus all assessed by the clinician performing the ECV. Ethnicity initially consisted of six different groups, but ethnicity was recorded as Caucasian or non-Caucasian, based on a review on ethnicity. It showed a negative effect of Caucasian race on successful ECV. EFW was calculated with the Hadlock formula [21]. Fetal position was defined as frank breech (reference), non-frank breech, incomplete breech or transvers lie. Placental location was defined as anterior (reference), posterior, fundal or lateral position. Breech engagement was defined as non-engaged (reference), descent into pelvis or fixed in pelvis. Palpation of the fetal head was defined as easy (reference), difficult or unremarkable which is defined as not easy nor difficult to palpate the head of the baby. Relaxation of uterus was defined as relaxed (reference), unremarkable or non-relaxed.

Data analysis

We used successful ECV at 30 min after the attempt as the end point of the study. Various candidate predictors had missing values (Table 1). Because these are often selectively missing, deleting them would lead to a loss of statistical power in multivariable analysis and it is well documented that a complete case analysis probably yields biased results [22]. Hence, we used multiple imputation (ten times) to handle missing values. The imputation model included all potential predictors and the outcome.

Baseline characteristics were analyzed using descriptive statistics and presented as mean with standard deviation (SD) or median with interquartile range (IQR) for continuous variables as appropriate, and as numbers and percentages of the whole population for categorical and dichotomous variables.

To assess potential non-linearity of the association between the continuous variables maternal age, gestational age, BMI, and EFW, and the outcome (i.e. successful ECV) multivariable fractional polynomials were used, and continuous variables were transformed accordingly [23].

First, the univariable associations were assessed for each individual variable with the outcome using logistic regression, resulting in odds ratios (ORs) with 95% confidence intervals (CIs), and corresponding p values. Since selection based on univariable statistics might result in unstable prediction models we chose not to perform any preselection and to include all candidate predictors in the multivariable analyses [24,25]. 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 based on Akaike's Information Criterion. Since results may differ between imputation sets variable selection was repeated within each imputation set. Afterwards the final model was determined based on the majority rule, meaning that variables that were selected in 5 or more imputation sets were included in the final model [26]. Afterwards, the final model was fitted within each imputation set separately and intercept and regression coefficients were pooled using Rubin's rules [27].

With each model development there is a chance of overfitting, meaning that the model is too strongly fit to the data on which it was developed and consequently may perform poorly when externally validated. To assess the degree of overfitting or optimism, we internally validated the model using bootstrapping techniques. One hundred bootstrap samples of equal size to the original data (n = 818) were drawn from the original data set with replacement, allowing for multiple sampling of the same individual. Within each sample the entire modelling process described above was repeated. This yields a shrinkage factor, with which the regression coefficients of the predictors are multiplied (uniformly shrunken) to correct the model for optimism and overfitting [24].

Model performance will be assessed using discrimination and calibration. The discriminative ability of the models, being the ability to distinguish between those with and without a successful ECV, was assessed with the c-statistic [24]. Calibration was assessed graphically using calibration plots.

Furthermore, the following accuracy measures are assessed: sensitivity (or true positive rate), specificity, positive predictive value, negative predictive value, and false positive rate. As no clear relevant cut-off value exists, these measures were presented for different cut-off values based on the deciles of the predicted probabilities.

Table 1
Characteristics of the study population and the univariable associations between potential predictors and successful ECV.

Characteristic	Missing data (%)	Overall Cohort before imputation (n = 818)	Successful ECV (%)	Unsuccessful ECV (%)	Univariable Analysis	
					OR	95% CI
Administration of fenoterol (%)	0	414 (50)	166	242	1.37	1.03 – 1.8
Nulliparous (%)	0	511 (62)	128	383	0.25	0.19 – 0.34
Maternal age, year (SD)	0	32 (4.1)	–	–	1.41	0.99 – 2.0
BMI, kg/m^2 (min - max)	66 (8)	23.1 (16 – 48)	–		1.15	0.84 – 1.6
Caucasian (%)	25 (3)	705 (89)	273	453	1.23	0.76 – 2.0
Gestational age, weeks (SD)	16 (2)	36.2 (0.94)			0.58	0.40 – 0.84
Estimated foetal weight, gr (SD)*	192 (23)	2610 (336)	–	–	2.1	1.30 – 3.4
Amniotic Fluid Index, cm (min – max)	281 (34)	15 (3 - 40)	–	–	0.18	0.08 – 0.42
Type of breech (%)	41 (5)					
- Frank breech		568 (73)	189	409	1.00	
- Non-frank breech		117 (15)	54	69	1.7	1.1 – 2.6
- Incomplete breech		49 (6)	25	26	2.0	1.1 – 3.7
- Transversal		43 (6)	35	12	6.4	3.2 – 13.1
Placental location (%)	52 (6)					
- Anterior		266 (35)	98	186	1.00	
- Posterior		267 (35)	121	165	1.42	0.99 – 2.0
- Fundal		142 (19)	48	103	0.89	0.57 – 1.4
- Lateral		91 (12)	36	61	1.12	0.67 – 1.8
Position of spine (%)	108 (13)					
- Anterior		59 (8)	26	42	1.00	
- Posterior		29 (4)	9	25	0.56	0.21 – 1.5
- Lateral left		346 (49)	135	266	0.80	0.46 – 1.39
- Lateral right		242 (34)	106	171	0.99	0.56 – 1.8
- Transvers up		20 (3)	18	7	4.4	1.5 – 12.8
- Transvers down		14 (2)	12	5	3.7	1.01 – 13.4
Fundal Height, weeks (min – max)	111 (14)	36 (32 – 40)			2.4	0.75 – 7.8
Breech engagement (%)	62 (8)					
- Non-engaged		215 (28)	136	102	1.00	
- Descent into pelvis		440 (58)	160	313	0.38	0.28 – 0.52
- Fixed in pelvis		101 (13)	7	101	0.05	0.02 – 0.11
Palpation of head (%)	132 (16)					
- Easy		606 (88)	276	440	1.00	
- Difficult		66 (10)	21	61	0.55	0.31 – 0.96
- Unremarkable		14 (2)	5	13	0.64	0.20 – 2.0
Relaxation of uterus (%)	130 (28)					
- Yes		541 (79)	261	379	1.00	
- Unremarkable		135 (20)	40	122	0.47	0.30 – 0.74
- No		12 (2)	2	14	0.23	0.05 – 1.17

Data were analyzed using R version 3.0.1, package RMS for prediction modelling purposes and MICE for multiple imputation (The R Foundation for Statistical Computing, 2013, http://www.r-project.org/). Data and codes are available upon request from the corresponding author.

Results

Between August 2009 and May 2014, 818 women were enrolled (410 received atosiban (intervention group) and 408 fenoterol (control group)). The overall ECV success rate was 37%. The multifractional polynomial analyses indicated a linear association between the outcome and all continuous variables except for AFI and gestational age at ECV. AFI was transformed to 1/AFI. The suggested transformation for gestational at ECV was complex and difficult to interpret, thus we decided to dichotomize this variable to term (gestational age from 37 weeks onwards) and preterm (gestational age <37 weeks).

Predictors related to the outcome in the univariable analysis were fenoterol as uterine relaxant, nulliparity, gestational age at ECV < 37 weeks, EFW, AFI, type of breech presentation, position of the fetal spine, breech engagement, possibility to palpate the head and relaxation of the uterus (Table 1). In the multivariable analyses ten predictive factors remained after the stepwise selection procedure: fenoterol as uterine relaxant, nulliparity, Caucasian, gestational age at ECV, AFI, type of breech presentation, placental location, breech engagement, possibility to palpate the head and relaxation of the uterus (Table 2). Of these predictors, the most important are breech engagement, nulliparity and performing an ECV at term. All three predictors contribute negatively on the chance of success. Administration of fenoterol, posterior placenta and amniotic fluid are the most important predictors with a positive effect on the chance of success.

For our model, internal validation showed good calibration (Fig. 1) and a good discriminative ability with a c-statistic of 0.78 (95% CI 0.75 to 0.81). The mean predicted chance for success was 36.9% and this chance ranged from 1.7 to 93.6%. The mean observed success was 37.0%.

The predicted chance of successful ECV can be calculated using the following formula:

$$\text{Predicted chance} = (1 + e^{-LP})^{-1},$$

LP = −0.382 + (administration of fenoterol * 0.26) + (nulliparious * −1.008) + (Caucasian * 0.360) + (Gestational age at ECV from 37

Table 2
Multivariable associations for our prediction model.

Predictor	β*	Odds ratio	95% CI
Intercept:	−0.382		
Administration of fenoterol	0.261	1.30	0.93 – 1.8
Nulliparous	−1.008	0.37	0.26 – 0.51
Caucasian	0.360	1.43	0.83 – 2.5
Gestational age at ECV from 37 weeks onwards	−0.388	0.58	0.40 – 0.84
1/Amniotic fluid in cm:	0.449	1.6	1.01 – 2.4
Position of fetus:			
- Frank breech	Ref	Ref	Ref
- Non-frank breech	0.282	1.33	0.83 – 2.1
- Incomplete breech	0.423	1.5	0.80 – 2.9
- Transversal	0.583	1.8	0.80 – 4.0
Placental location:			
- Anterior	Ref	Ref	Ref
- Posterior	0.349	1.5	1.00 – 2.2
- Fundal	−0.007	1.0	0.60 – 1.6
- Lateral	0.150	1.2	0.67 – 2.0
Breech engagement			
- Above pelvis	Ref	Ref	Ref
- Descent into pelvis	−0.440	0.64	0.44 – 0.94
- Fixed in pelvis	−1.935	0.14	0.06 – 0.35
Palpation of head			
- Easy	Ref	Ref	Ref
- Difficult	−0.448	0.64	0.33 – 1.22
- Unremarkable	0.705	0.49	0.12 – 2.0
Relaxation of uterus			
- Yes	Ref	Ref	Ref
- Unremarkable	−0.401	0.70	0.40 – 1.10
- No	−0.340	0.71	0.12 – 4.1
Mean shrinkage factor 0.83			

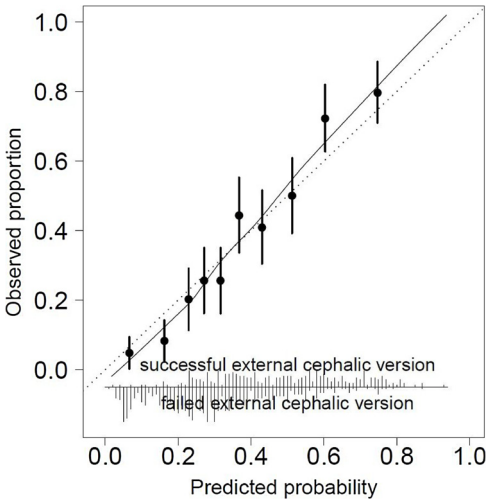

Fig. 1. Calibration plot with the observed chance of a successful ECV by predicted probabilities. The dots indicate deciles of women grouped by similar predicted chance of a successful ECV. The vertical bars through the dots indicate the 95% confidence interval of the observed chance of a successful ECV.

weeks onwards * −0.388) (1/(AFI/10) * 0.449) + (non-frank breech * 0.2817) + (incomplete breech * 0.4227) + (transversal * 0.5833) + (posterior placenta * 0.349) + (fundal placenta * −0.007) + (lateral placenta * 0.583) + (breech descent into pelvis * -0.440) + (breech fixed in pelvis * −1.935) + (difficult palpation of the fetal head * −0.448) + (unremarkable palpation of the fetal head * 0.705) + (unremarkable relaxation of the uterus * −0.401) + (no relaxation of the uterus * −0.340)

In the formula, in categorical variable (administration of fenoterol, nulliparous, Caucasian and gestational age at ECV from 37 weeks onwards), the value '1' should be used if a women belongs the reference group and '0' if she belongs to the non reference group. For the categorical variables, the value '0' should be used if the woman belongs to the reference category and '1' if she belongs to the non reference category. For breech presentation, frank breech is reference. For placental location, anterior placenta is reference. For breech engagement, above pelvis is reference. For palpation of the head, easy to palpate is reference. For relaxation of the uterus, a relaxed uterus is reference. For amniotic fluid index, the cm must be fulfilled.

For example, a Caucasian, multiparous, preterm, with 15 cm of amniotic fluid, incomplete breech, posterior placental location, breech is descent and not fixed in pelvis with a unremarkable possible palpation of the head, a relaxed uterus and administration of fenoterol has a predictive chance of 50.8% for a success full ECV.

Discussion

In this study we developed and internally validated a prediction model for the outcome of an ECV procedure. Our model showed good calibration and a good ability to discriminate between women with a successful and unsuccessful ECV.

Our study has several strengths. First, this is the largest study on the prediction of ECV success and compared to the c-statics of 0.67 (95% CI 0.62 – 0.72) of the study of Burgos et al. [28] and 0.70 (95% CI 0.67 – 0.74) of the study by Kok et al. [29] our performance was better (0.78 (95% CI 0.75 to 0.81)). Second, our study was performed and reported according to established methodology concerning development and validation of a clinical prediction model. Third, we believe our model is generalizable as we used data from a well-described, large, nationwide randomized controlled trial in the Netherlands. This resulted in standardized data collection in high quality [20]. Fourth, we incorporated all identified relevant predictor variables that lacked in previous prediction models [16–18], and all characteristics used in the model are readily available and easy to measure for the clinician who will counsel the patient for ECV. Therefore, the model will be easy and inexpensive to apply in daily clinical practice.

To improve uptake in clinical practice, we present a formula to allow calculation of one's individual chance of success of an ECV attempt. Before this model, seven other models were developed of which only one model was validated externally. Despite the fact that it is usual to use the best model for updating, we have chosen to make a new model. The previous models used a maximum of five possible predictors. Since we designed this study alongside a RCT, after recording the most important predictors, we were able to make a more accurate model. Before our model can be implemented in daily practice at least two additional steps are needed. First, our model needs external validation, and if necessary updating, to assess the model's performance in another population [30]. Thereafter, an impact analysis is needed to test for the model's ability to change and improve shared decision making and evaluate (un)intended effects on patient outcomes.

Our study has some limitations. First, it is possible that our results might be less reliable due to missing data. However, we used multiple imputation including all potential predictors and the outcome to decrease this potential effect. Second, we used data from a comparative study that found a treatment effect in favor of fenoterol, and therefore, we included administration of fenoterol as predictor in the model [31]. Compared to the other predictors in the model, uterine relaxation had a moderate effect on the success rate of ECV. Third, as our model is developed using

data from a RCT, the observed chance of success could be higher compared to the general population as it is being developed in a population who already decided on an ECV attempt. On the other hand, those women with anticipated high chances of successful ECV might not have been included by caregivers in the RCT about uterine relaxants. The baseline characteristics of the patients in this study correspond to a large cluster RCT in the Netherlands in which all women counselled for ECV were included [32]. Nevertheless, inclusion and exclusion criteria for the initial trial were in accordance with common guidelines, which makes that our study population is a representative sample of the general population. However, to further confirm the generalizability of our model we are planning to perform external validation in a cohort of women who are considering ECV. If the model performs well at external validation, impact analysis will additionally be performed. Fourth, ECV attempts were undertaken in centers that perform ECV frequently, this could also contribute to a higher chance of success compared to centers that do not perform ECV frequently as it is strongly believed that experience of the performing gynecologists or midwife and setting are of importance in increasing the success rate of ECV [33,34]. We have not included experience of the operator as a potential predictor. Furthermore, Yun Kim et al. [35] undertook the first step developing a standardized learning curve guideline for ECV. They concluded that a minimal number of 57 ECV attempts need to be performed in order to reach a 50% success rate, which underlines the potential importance of considering operator experience as a potential confounder or predictor for a successful ECV. Unfortunately, this information was not available in our study, meaning that we were unable to account for this. As a result, the current model may overestimate the ECV success rate in a less experienced setting. Further external validation studies in a such a setting are needed to confirm this hypothesis.

ECV is recommended in international guidelines as it prevents caesarean deliveries and related morbidity in current and future pregnancies [14]. A calculated low success rate based on a prediction model might discourage women to give it a try. And this might leave a clinician in conflict whether to use the model in such a situation. We think that the model (after above mentioned additional evaluation) should be used for all women because it contributes to personalized care. It helps to translate data of a large cohort into daily practice on a patient level and truly helps shared decision making on an individual level.

Our model can be applied to demonstrate the increased chance of success if fenoterol is used as treatment, and therefore to better inform women the potential positive effect. It is known that more than 70% of the women receiving fenoterol experience minor adverse side effects such as palpitations, flushing, and dizziness [20]. For some caregivers, this is a barrier to offer uterus relaxants to women, or at least to try a first attempt without medication [36].

From a preference study, we know that women are willing to undergo treatment with possible side effects if it generates an increased success chance [37]. Therefore, before the first attempt counseling about tocolysis must be performed, as we believe that the most optimal attempt must be provided. In light of routine administration of tocolysis, future research should focus on determining who benefits most. Our model may help further facilitate such personalized medicine.

Conclusion

In summary, in women undergoing an ECV attempt for breech presentation, a combination of parity, ethnicity, administration of fenoterol, amniotic fluid index, fetal position, placental position, engagement of the breech in the pelvis, uterine tone, palpitation of the head and gestational age best predicts the chance of ECV success. After external validation, our model can be used in daily obstetric clinical practice, and optimizes personalized medicine and shared decision making for women with a breech presentation near term.

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