

Review

Prediction models for successful external cephalic version: a systematic review



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ABSTRACT

To provide an overview of existing prediction models for successful ECV, and to assess their quality, development and performance. We searched MEDLINE, EMBASE and the Cochrane Library to identify all articles reporting on prediction models for successful ECV published from inception to January 2015. We extracted information on study design, sample size, model-building strategies and validation. We evaluated the phases of model development and summarized their performance in terms of discrimination, calibration and clinical usefulness. We collected different predictor variables together with their defined significance, in order to identify important predictor variables for successful ECV. We identified eight articles reporting on seven prediction models. All models were subjected to internal validation. Only one model was also validated in an external cohort. Two prediction models had a low overall risk of bias, of which only one showed promising predictive performance at internal validation. This model also completed the phase of external validation. For none of the models their impact on clinical practice was evaluated. The most important predictor variables for successful ECV described in the selected articles were parity, placental location, breech engagement and the fetal head being palpable. One model was assessed using discrimination and calibration using internal (AUC 0.71) and external validation (AUC 0.64), while two other models were assessed with discrimination and calibration, respectively. We found one prediction model for breech presentation that was validated in an external cohort and had acceptable predictive performance. This model should be used to counsel women considering ECV.

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Introduction

Breech presentation occurs in 3–4% 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, worldwide the rate of term vaginal breech deliveries has declined substantially [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 worldwide general rise in caesarean delivery rate in the last decade [13–15] and the urgency to put a hold to this rise [6,7], ECV is an important intervention that can contribute to this goal.

Even though procedure related complications rarely occur, concerns about safety of the procedure can be a reason for women not to accept an ECV attempt [16,17]. Additionally, knowledge about the effectiveness of ECV also influences acceptance of ECV [16,17]. The success rate of ECV varies from approximately 35% up to 86% in the literature with an average of 50–60% [4,18]. Thus, a reliable more precise and individualized prediction of successful ECV could be useful to counsel women for an ECV attempt. Previous studies have shown that clinical and ultrasound characteristics are associated with success or failure of an ECV procedure [19,20]. There are several prediction models that enable individualized prediction of the outcome of an ECV attempt. However, since the use of poor-quality prediction models could have a negative effect on decision-making [21], careful evaluation is needed before these models can be implemented in clinical practice.

Therefore, the aim of this review is to give an overview of existing prediction models for successful ECV, to evaluate their quality, development and performance and to identify important predictor variables described in the selected articles.

Methods

Study identification

We performed a computerized MEDLINE, EMBASE and Cochrane databases search to identify all studies reporting on prediction models for successful ECV published from inception to April 2015. Language restrictions were not applied. Together with a clinical librarian we developed a search strategy including all known synonyms for the term ‘external cephalic version’ and we performed a search filter for prediction models. References from selected publications were manually searched for additional relevant articles not identified by the computerized search.

Study selection

This review focused on articles that reported on a prediction model to predict the outcome of an ECV attempt. A prediction model was defined as a multivariable model that expressed the chance of successful ECV as a function of at least two predictor variables. In order to be eligible and selected, the articles had to report on a prediction model sufficient to make predictions for individual cases. Two independently working reviewers (JV and FM) selected articles by assessing titles and abstracts. When there were any doubts about the eligibility after reading title and abstract, the article was included for full text reading to make sure no potential eligible article was missed. Any disagreements were resolved by consensus and, if necessary, by a third reviewer (MK).

Study quality assessment

A framework was developed based on the recommended guideline of Hayden et al. [22] in combination with recommendations derived from the Quality In Prognosis Studies tool [23], in order to adequately operationalize items for assessing bias and study quality of the selected articles. The framework was divided into four sections: study participation, predictor variables/prognostic factor measurement, outcome measurement and analysis.

As recommended by Hayden et al., we assessed our four potential bias domains in two steps. During the first step, we assessed the fully operationalized relevant quality items which were scored with ‘yes’, ‘no’, ‘partly’ or ‘unclear’. During the second step, we used these item responses to judge each of the four potential bias domains. Each of these domains was rated as having high, moderate or low risk of bias. This approach to quality appraisal follows a method that has been described by Wortman [24] as ‘mixed-criteria’ quality assessment.

Additionally, we assessed the overall risk of bias and therefore the overall study quality for each study by combining the ratings of the four bias domains of our framework. We took into account the importance of each individual bias domain, with ‘analysis’ and ‘predictor variables’ being the most important domains, which were determined a priori.

Predictor variables

We collected all predictor variables used in the selected articles together with their defined significance, in order to identify the most important predictor variables for successful ECV. Predictor variables are the potential predictors, which were tested both during model development and in the final model. The most important predictor variables were those described as statistically significant input variables in both univariable and multivariable regression analysis in three or more studies. When a predictor variable was only tested in two studies, and not in the other

included studies, both studies had to describe this variable as statistically significant to label it as one of the most important predictors.

Model development assessment

We assessed the development of the prediction models with a published evaluation Scheme [25], which distinguishes three phases of model development: model derivation, model validation and impact analysis. In the model derivation phase, predictors are identified, based on prior knowledge, and the weight of each predictor (regression coefficient) is calculated. Model validation, the second phase, consists of an internal and external validation phase. With internal validation, the ability of the prediction model is evaluated in the group of patients in which the model was developed. Since internal validation consistently gives a too optimistic impression about the predictive accuracy of a model, external validation is a crucial next step in assessing the performance of a model. With external validation, 'generalizability' or 'transportability' of the prediction model is evaluated. This means that the ability of the model to predict the outcome in populations other than the population in which the model was developed, is evaluated.

The third and final phase of model development is impact analysis. During this phase, prediction models are tested for their ability to change and improve clinicians' decisions and patient outcomes.

All prediction models identified in this review are classified into the different phases of model development. We tried to contact all authors of the selected articles by email to investigate if there were new results of model validation or impact analysis, which were not published yet.

Model performance

For the models that were evaluated we quantified the performance of the prediction models by assessing calibration, discrimination and clinical usefulness. Calibration describes the agreement between observed outcomes and predictions of the outcomes. Calibration usually is reported as a calibration plot in which predicted probability is plotted against the actual outcome fraction. Usually reported in a graphical illustration of the Hosmer–Lemeshow goodness-of-fit test.

Overall statistical performance measures incorporate both calibration and discrimination aspects. In this case, discrimination relates to how well a prediction model can discriminate those with the outcome from those without the outcome. Discrimination is commonly reported as the concordance (c) statistic, which indicates the discriminative ability of generalized linear regression models. For a binary outcome, c is identical to the area under the receiver operating characteristic (ROC) curve (AUC). An AUC of 1 implies perfect discrimination, whereas an AUC of 0.5 means that the test does not discriminate at all. For this review, a model is considered to have poor performance if the AUC lies between 0.50 and 0.70. An AUC between 0.70 and 0.80 represents fair performance, and an AUC between 0.80 and 0.90 represents good performance. Another way to evaluate model performance is by assessing its clinical usefulness. Both clinical usefulness and discrimination describe the ability of a model in distinguishing between women with a poor and women with a good chance of successful ECV, which is influenced by the cut-off point used for this classification. Once the cut-off point is chosen, clinical usefulness measures such as accuracy, sensitivity or specificity, positive or negative predictive values or likelihood ratios can be defined.

Results

Study identification and selection

We identified 373 potential eligible articles with the computerized search. After screening titles and abstracts we selected 21 articles for further reading. One paper was retrieved from cross-references. One article was not obtainable in full text version and was therefore excluded since it could not be assessed for study selection. Fourteen articles used univariable and/or multivariable regression analysis to evaluate the significance of predictor variables but did not develop a prediction model in order to express the individual chance of successful ECV. Finally, eight articles met our inclusion criteria and were included in our review [26–33] (Fig. 1).

Study characteristics

Study characteristics are shown in Table 1. We identified eight articles reporting on seven prediction models. One study described the development and internal validation of one prediction model in two separate articles [27,28]. One study [29] described the development and internal validation in a first article and the external validation of the prediction model in a separate article [33]. One study [30] described the development of two separate prediction models in one article.

Patient selection and inclusion criteria were not the same in all articles. Three articles included women with breech presentation with a gestational age of 36 weeks or more in their study [29,30,34] whereas two studies included women with a gestational age of 37 weeks or more [26–28]. One study did not report their inclusion criteria concerning gestational age [35]. Two studies did not mention contraindications to perform ECV [29,30].

Study quality

The results of the study quality assessment are shown in Table 2. Three studies [27–29] were rated of high study quality. The four other studies [26,30,34,35] were rated as having an overall moderate risk of bias and therefore moderate study quality. After critically appraising these four articles by comparing the ratings of each prompting item and bias domain, one study [35] was considered to have the lowest overall study quality. This was due to the fact that, in addition to the ratings of moderate risk of bias for 'analysis' and 'predictor variables', this study did not completely describe inclusion criteria and patient characteristics.

Predictor variables

Table 3 shows a total of 23 different possible predictor variables, which were reported in the seven selected studies. We divided these predictor variables into three groups: patient characteristics, ultrasonographic findings and findings at clinical examination. The variables most commonly described, in four or more articles, were parity, gestational age, type of breech, placental location, estimated fetal weight (EFW) and amniotic fluid index.

The most important predictor variables, described as statistically significant input variables in both univariable and multivariable analysis in three or more studies, were parity, placental location, breech engagement and amniotic fluid index. Parity and placental location were described by all studies included in this review and were found to be statistically significant in both univariable and multivariable analysis in four studies and were incorporated in their final model. Breech engagement was described and found to be significant in three studies and was incorporated in three final prediction models [30,34,35]. Amniotic

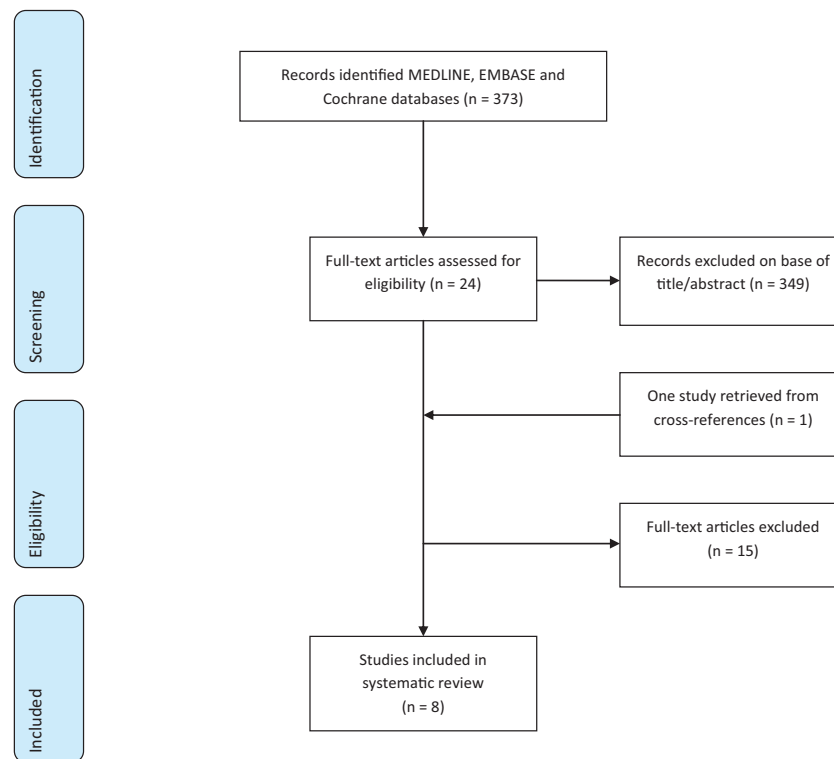


Fig. 1. Flowchart of study selection process.

Table 1
Study characteristics of included articles.

Study (year)	Patients	Exclusion criteria	Outcome	Individuals (N)	Overall success rate (%)	Study design	Ref.
Burgos (2011/2012)	Women with a singleton pregnancy at ≥ 37 weeks, a live fetus in a breech position, and no contraindications to vaginal birth	Placenta praevia, placental abruption, oligohydramnios, fetal compromise, fetal death, severe fetal malformation, multiple gestation, Rhesus sensitization, uterine abnormalities and clotting disorders	Successful ECV	1000 (phase 1 = 500; phase 2 = 500)	Phase 1 = 52.2%; phase 2 = 51.2%; overall = 51.7%	Prospective two-phase study	[27,28]
Kok (2011)	Women with a singleton pregnancy in breech presentation at ≥ 36 weeks of gestation	–	Successful ECV	310	121 (39%)	RCT	[29]
Aisenbrey (1999)	Women with breech presentation at ≥ 37 weeks of gestation	Placenta praevia, history of vaginal bleeding, AFI of at most 5 cm, fetal anomalies, fetal growth restriction, previous uterine scar other than low-transverse, non-reassuring non-stress test, EFW exceeding 4 kg, suspicion of nuchal cord or uterine malformation	Successful ECV	128	78 (64%)	Prospective cohort study	[26]
Wong (2000)	Women with breech presentation at ≥ 36 weeks of gestation	Intrauterine growth retardation, hypertension, placenta praevia, oligohydramnios, previous caesarean section and multiple pregnancy	Successful ECV	140 (phase 1 = 53; phase 2 = 87)	Phase 1 = 64.2%; phase 2 = 61.4%	Prospective two-phase study	[34]
Lau (1997)	Women with breech presentation at ≥ 36 weeks of gestation	Described by Stock et al. [49], full text version not available	Successful ECV	243	169 (69.5%)	Prospective cohort study	[30]
Newman (1993)	Women with singleton gestations	Mentioned contraindications for ECV: abruptio placentae, placenta praevia, premature rupture of membranes, fetal compromise during preliminary fetal heart rate monitoring	Successful ECV	394 (phase 1 = 108; phase 2 = 286 (20 for transverse lie))	166 (62.4%) in phase 2 (success rate transverse lie 18 (90%))	Retrospective and prospective two-phase study	[31]

Table 2

Quality of included studies.

	Burgos et al. (2011/2012)	Kok et al. (2011)	Wong et al. (2000)	Aisenbrey et al. (1999)	Lau et al. (1997)	Newman et al. (1993)
<i>Study participation</i>						
Description of setting and study period	Yes	Yes	Yes	Yes	Yes	Yes
Description of inclusion and exclusion criteria	Yes	Partly	Yes	Yes	Partly	Partly
Consecutive patient selection	Yes	Yes	Yes	Yes	Yes	Yes
Number of patients reported	Yes	Yes	Yes	Yes	Yes	Yes
Success rate of external cephalic version reported	Yes	Yes	Yes	Yes	Yes	Yes
Clear description of patient characteristics	Yes	Yes	Yes	Yes	Yes	Partly
<i>Predictor variables</i>						
Clear definition of all predictor variables evaluated	Yes	Yes	Yes	Yes	Yes	Yes
Description of proportion of participants with complete/missing data	No	Yes	No	No	No	No
<i>Outcome measures</i>						
Clear definition of outcome	Yes	Yes	Yes	Yes	Yes	Yes
<i>Analysis</i>						
Description of evaluation measures	Yes	Yes	Partly	Partly	Partly	Partly
Description of model-building strategies	Yes	Yes	Partly	Partly	Partly	Partly
<i>Overall quality^a</i>	+	+	+/-	+/-	+/-	+/-

^a This only concerns study quality based on operationalized items as mentioned in this table. Other quality aspects will be discussed in the discussion. +, low risk of bias; high study quality; +/-, moderate risk of bias; moderate study quality.

fluid index was described in all selected articles and was found to be statistically significant in three studies [27–29,34]. However, only two studies included amniotic fluid index in their final model [27–29]. Palpation of the fetal head was described and found to be significant in two studies, leading to incorporation of this predictor variable in two final models [30,34].

Phases of model development

All of the included models had completed the phase of model derivation. With the exception of one study [26] all studies passed

the phase of internal validation [26–29,31–33]. One study [30] performed an internal validation by cross-validation, by randomly dividing their dataset in two parts, developing two regression models and testing both models on the other subgroup. Three models were tested by temporal validation, where their model was tested on a group of subsequent patients in the same centre [27,28,34,35]. One study [29] used bootstrapping for internally validating their model and this was also the only study that reached the phase of external validation [33]. After contacting the authors we received one response from the study-group of Burgos et al., who claimed that their model is currently not being externally validated.

Table 3

Predictor variables evaluated and used in prediction models.

	Burgos et al. (2011/2012)	Kok et al. (2011)	Aisenbrey et al. (1999)	Wong et al. (2000)	Lau et al. (1997)	Newman et al. (1993)
<i>Patient characteristics</i>						
Maternal age	3	2		3		
Ethnicity		3				
Parity	1	1	2	3	1	1
Gestational age	3	3	2	3		3
Previous Caesarean Section	3					
<i>Ultrasonographic characteristics</i>						
Type of breech	1		2		2	3
Placental location	1	1	1	3	3 (+)	1
Position of fetal spine			2		3 (+)	
Fetal position		2				
EFW		1	3		2	1
Amniotic fluid (index)	1	1	3	2	2	3
Fetal growth parameters*				3	2 (AC only)	
<i>Clinical examination characteristics</i>						
Maternal weight	3		3			3
Maternal height and weight				3	2 (height only)	
BMI	3	3			3	
Uterine tone			1	1	2	
Palpation of head possible				1	1	
Cervical dilation						1
Breech location			1			
Breech engagement				1	1	1
Symphysis fundal height				1	3	

*: These contain biparietal diameter (cm), femur length (cm) and abdominal circumference (AC) (cm); EFW: estimated fetal weight.

1: Statistically significant in both univariate and multivariate analysis and therefore included in prediction model.

2: Statistically significant in univariate analysis and not included in prediction model.

3: Not statistically significant and not included in prediction model.

+: Not statistically significant variables in univariate analysis but included in multivariate analysis based on prior research.

Table 4
Evaluation of model development and model performance.

Study (year)	Specification of model development				Specification of model performance				Predictive factors used for final model	Ref.
	Type of model and presentation (clinical decision rule)	Development phase	Internal validation (method)	External validation	Calibration	Discrimination (AUC)	Clinical usefulness measures	Result as reported in paper		
Burgos et al. (2011/2012)	Multivariable logistic regression analysis (maximum modelling strategy) <i>Score Chart Rule and index score</i>	Internal validation completed	Prospective group of subsequent patients in same centre $n=500$	–	–	Internal validation 0.67 (95% CI 0.62–0.72)	Used to create ROC-curve	This score can be a useful tool in decision-making, given that it individualizes success probabilities. If the ECV index score is 7/8, the success rate prediction is 56.5% and if it is ≥ 9 , the success is 76.8%. If it is ≤ 6 , the success is 30.9%	Parity Placental location Type of breech Amniotic fluid	[27,28]
Kok et al. (2011)	Multivariable logistic regression analysis and stepwise backward selection procedure <i>Regression formula</i>	Internal and external validation completed	Bootstrapping (200 times)	De Hundt et al. (2012) [33] $n=320$	$p=0.66$, plot shows good overall perfor. $p=0.30$ for ext. validation	Internal validation 0.71 (95% CI 0.66–0.77) External validation 0.66 (95% CI 0.60–0.72)	Used to create ROC-curve	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%)	Parity EFW Placental location Amniotic fluid	[29]
Aisenbrey et al. (1999)	Multivariable logistic regression analysis with backward selection <i>Presentation of regression coefficients and constant; No model presentation</i>	Model derivation and calibration measure completed, no internal validation	–	–	$p=0.92$ for Hosmer and Lemeshow goodness of fit statistic	–	Accuracy of 93%	Of the 78 successful cases, 75 were assigned probabilities greater than 0.50 using our model. With 0.50 as a cut-off, 93% of cases were classified correctly in predicting success/failure	Uterine tone Breech location Placental location	[26]
Wong et al. (2000)	Univariate analysis (χ^2 or Student t test) <i>Score Chart Rule combined with likelihood ratios</i>	Internal validation completed	In the same study, group of subsequent patients in same centre $n=87$	–	–	–	LR ≤ 1.8 for version score ≤ 2 LR = 30 for version score 3 LR = 57.7 for version score 4	Using our scoring system, prediction of successful ECV was possible without ultrasound or vaginal examination, and counselling could be given once breech presentation was diagnosed	Palpable head Breech engagement Symphysis-fundal height (cm) Uterine relaxation	[34]
Lau et al. (1997)	Multivariable logistic regression modelling with stepwise forward selection <i>2 sets of regression coefficients and constants</i>	Internal validation completed	Split-sample; two patient subgroups in same centre; Group 1 $n=129$ Group 2 $n=114$	–	–	–	Overall accuracy of 79.4% in internal validation	The findings confirm that the outcome of ECV is predictable, and that the model derived is reliable and reproducible	Engagement Parity Head easy to palpate	[30]
Newman et al. (1993)	Stepwise linear regression analysis and discriminate analysis and χ^2 and Student t test <i>Score Chart Rule</i>	Internal validation completed	In the same study, group of subsequent patients in same centre $n=266$	–	–	–	LH 21% for version score ≤ 4 ($p < 0.05$), LH 88% for version score ≥ 8 ($p < 0.05$)	We believe that this simple, quantifiable scoring system is a refinement in our ability to predict the likelihood of ECV success	Parity Cervical dilation EFW Breech engagement Placental location	[31]

Performance of the prediction models

An overview and specification of the performance of the models described in the selected articles is presented in Table 4. Discrimination was described for two models [27–29], and calibration was described for two models [26,27,29]. Only the performance of one model [29] was evaluated by calibration and discrimination in both internal and external validation. Aisenbrey et al. [26] did not perform an internal validation of their model, nevertheless they assessed calibration with the Hosmer–Lemeshow test, which had a value of 0.92.

In the study by Burgos et al. [27,28] there are three different AUC described; the discriminative ability of their model was of fair performance in model derivation, 0.74 (95% CI 0.70–0.78) of poor performance in internal validation, (AUC of 0.67 (95% CI 0.62–0.72)), and in total of fair performance 0.70 (95% CI 0.67–0.74). The model by Kok et al. [29,33] had a fair performance in internal (AUC of 0.71 (95% CI 0.66–0.77)) and a poor performance in external validation (0.66 (95% CI 0.60–0.72)). Calibration of the model was visualized in calibration plots. Calibration was good at internal validation. At external validation, overall a slight underestimation of ECV success was seen, with a maximum difference of 14% between observed and predicted probability. However there was no overlap in the confidence intervals between women with a poor prognosis (less than 20% chance of successful ECV) and a good prognosis (more than 50% chance of successful ECV). The Hosmer–Lemeshow test in both internal ($p = 0.66$) and external validation ($p = 0.30$) was not significant.

Three studies [30,34,35], described the performance of their models at internal validation by clinical usefulness, in terms of likelihood ratios or accuracy. Overall, the performance of these three models was fair.

Discussion

We systematically reviewed existing articles reporting on prediction models for successful ECV. We found eight studies reporting on the development of seven prediction models for successful ECV in women with a term or near term fetus in breech position. Five studies [27–30,34,35] described at least one aspect of internal validation, but only one prediction model has reached the phase of external validation [27,29]. Of all seven prediction models, only two models were rated as having an overall low risk of bias [27–29]. None of the studies had reached the phase of impact analysis and none of the models used all important predictors assessed by meta-analysis.

The strength of our findings is based on the fact that our study is performed according to established methodology concerning model development assessment and model performance. For quality assessment, we developed a framework based on recommendation derived from previous studies [22]. Therefore, we effectively reduced the risk of bias by preventing inadequate reporting of quality assessment.

External validation of a prediction model is essential for a model to be implemented in clinical practice. So far the only model of which the performance has been tested by calibration and discrimination in both internal and external validation, was the model developed by Kok et al. [29,33]. There was a good calibration of the model at internal validation. Unfortunately at external validation the model had a slight underestimation of the changes for successful ECV. Nevertheless the model was able to make a distinction between women with a good prognosis and a poor prognosis of successful ECV. The discriminative ability of the model was fair at internal validation but poor at external validation. There is a growing recognition that the discrimination in the evaluation of a prediction model is less important than the calibration. ROC

analysis presumes the capacity to distinguish between successful and unsuccessful ECV. However, the probability of a successful ECV is never 0% or 100% and even seldom above 60%. Consequently discrimination will always be imperfect.

In this review we found five important predictor variables: parity, placental location, breech engagement, amniotic fluid index and palpation of the fetal head. Previous reviews have also indicated palpation of the fetal head, breech engagement, maternal weight, parity, amniotic fluid index, placental location and uterine tone as important predictor variables for successful ECV [19,20]. Another factor related to ECV outcome is the experience of the operator. However, none of the models incorporated all these variables in their analysis. As a consequence, they probably reduced the predictive accuracy of their final model by excluding these variables from their analysis and therefore from their model. Future research should focus on developing a model, or extending the existing models, by incorporating all identified relevant predictor variables by previous research [19,20] and our review.

Our review shows that the probability of success of ECV varies between 20% and 70%. In a process of shared decision making women should be informed with unbiased nondirective information on the advantages, disadvantages and expected risks and outcome of an ECV attempt. A prediction model can guide in this process by for example persuading eligible but otherwise reluctant women with a predicted high success rate.

On the other hand, a predicted chance as low as 20% might still be worth an attempt, considering the safety of the procedure [8,11,12]. It is however unknown whether complications rates are similar for all women, or that complications are more frequent in women with a low predicted success.

Little is known about risk factors for complications during an ECV attempt [8–12]. Therefore, we are currently unable to determine which women have the highest risk of having a complication [8,12]. Future research should focus on identifying possible risk factors associated with the occurrence of complications using large cohort studies. Hopefully, this will provide new insights and an answer to whether or not an ECV attempt should be withheld from subgroups of women with a poor predicted chance of success.

In order to support counselling and clinical decision making regarding an ECV attempt, the question is if one or more of the available prediction models described in this review should be implemented in clinical practice. The use of poor-quality prediction models could have a negative effect on decision-making [21]. Therefore, careful evaluation is needed before these models can be implemented in clinical practice. Unfortunately, currently none of the available prediction models are ready to be implemented in clinical practice as none of the models completed the phase of impact analysis. Furthermore, none used all important predictors assessed by meta-analysis. Future research should focus on the development of a prediction model using a dataset reporting on all important predictors.

Conflicts of interest

The authors did not report any potential conflicts of interest.

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