Factors Associated With a Successful External Cephalic Version in the Early ECV Trial

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Abstract

Objectives: The objective of this research was to determine factors that were associated with a successful external cephalic version (ECV) procedure.

Methods: We undertook a secondary analysis of data from a randomized controlled trial, The Early External Cephalic Version (Pilot) Trial. In this secondary analysis, we included data for the subset of 178 women who had an ECV as part of the pilot trial (123 nulliparous women with any breech presentation and 55 multiparous women with a frank breech presentation only). Using this dataset, we began with two separate univariate analyses, one of characteristics that could be determined before undertaking a procedure, and the other of factors associated with the ECV procedure itself. Variables that had a *P* value of ≤ 0.1 in the univariate analyses were included in two separate logistic regression models, one for preprocedural and one for procedural factors, using a backward elimination approach.

Results: Multiparity and a non-engaged presenting part were significant preprocedural predictors of ECV success. Procedural factors predictive of ECV success included lower reported maternal pain scores during the procedure, a single attempt at ECV, and a more mobile fetus.

Conclusion: Non-engagement of the presenting part was the only modifiable factor predicting ECV success that was identified in this analysis, and it supports the hypothesis that beginning the ECV procedure earlier in pregnancy, prior to engagement, may have merit. The Early ECV 2 Trial is in progress and will further test this hypothesis.

Key Words: Breech, external cephalic version, Caesarean section, predictors of success

Competing Interests: None declared.

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Résumé

Objectifs : Cette recherche avait pour but de déterminer les facteurs qui étaient associés à la réussite d'une intervention de version céphalique par manœuvres externes (VCE).

Méthodes : Nous avons entrepris une analyse secondaire des données issues d'un essai comparatif randomisé, soit l'essai *The Early External Cephalic Version (Pilot) Trial*. Pour cette analyse secondaire, nous avons inclus les données du sous-ensemble de 178 femmes qui avaient subi une VCE dans le cadre de l'essai pilote (123 femmes nullipares connaissant une présentation du siège [quelle qu'elle soit] et 55 femmes multipares connaissant une présentation du siège décomplété seulement). Au moyen de cet ensemble de données, nous avons procédé à deux analyses univariées distinctes : l'une d'entre elles portant sur les caractéristiques qui pourraient être recherchées avant la tenue de l'intervention et l'autre, sur les facteurs associés à l'intervention de VCE elle-même. Les variables qui détenaient une valeur $P \leq 0,1$ dans le cadre des analyses univariées ont été incluses dans deux modèles de régression logistique distincts (l'un d'entre eux portant sur les facteurs préinterventions et l'autre, sur les facteurs associés à l'intervention), au moyen d'une approche d'élimination régressive.

Résultats : La multiparité et une présentation non engagée constituaient des prédicteurs préinterventions significatifs de la réussite de la VCE. Parmi les facteurs associés à l'intervention qui permettaient de prédire la réussite de la VCE, on trouvait le signalement de scores de douleur maternelle moindres au cours de l'intervention, le fait de ne procéder qu'à une seule tentative de VCE et la présence d'un fœtus plus mobile.

Conclusion : Le non engagement de la présentation constituait le seul facteur modifiable pouvant prédire la réussite de la VCE que cette analyse a permis d'identifier; ce qui soutient l'hypothèse selon laquelle il pourrait s'avérer indiqué de débuter l'intervention de VCE plus tôt (avant l'engagement) au cours de la grossesse. L'essai *Early ECV 2 Trial* est en cours et contribuera à déterminer la validité de cette hypothèse.

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INTRODUCTION

External cephalic version effectively reduces the rates of breech presentation and Caesarean section in women with a fetus presenting as a breech at term; however, rates of success are relatively low.[1–3] In order to determine if there were any factors that could be used to predict success of the ECV procedure in our trial population, we performed a secondary analysis on data from a randomized controlled trial. The pilot study, conducted between July 1999 and February 2002, compared early and delayed ECV.[1] It included only women who were most likely to benefit from beginning the procedure early; that is, those who were nulliparous (65%) with any breech presentation or who were multiparous with a frank breech presentation and parity < 5.[4–17] It was considered that multiparous women with other than frank breech presentations were most likely to experience spontaneous version prior to 37 weeks, and they were thus less likely to benefit from the pilot trial intervention. For the 116 women randomized to the early ECV group, the first ECV procedure was planned for between 34 weeks 0 days and 36 weeks 0 days of gestation. For the 116 women randomized to the delayed ECV group, the first ECV procedure was planned for between 37 weeks 0 days and 38 weeks 0 days.[1] Eighty-six percent of women (n = 100) randomized to the early ECV group and 67% of women (n = 78) in the delayed ECV group had had at least one ECV procedure. Of the 178 women who had an ECV as part of the pilot trial, 54 (30.3%) had a successful procedure. Forty-one of the 54 women with successful ECVs (76%) went on to have a cephalic vaginal delivery.

MATERIAL AND METHODS

Data for this secondary analysis were collected as part of the Early External Cephalic Version Pilot Trial, approved by the Office of Research Services at the University of Toronto on September 11, 1998. Approval from the clinical research ethics boards of each participating centre was obtained prior to the recruitment of women into the pilot trial. The data collected were related to potential predictors of success, using the existing literature as a guide to which variables might be important. Additional details about the data collection and methodology used in the EECV Pilot Trial are provided in the published report.[1]

For the secondary analysis of predictors of ECV success, we felt that it was clinically important to consider factors that could be determined prior to the procedure (preprocedural factors) separately from factors that could only be determined as part of the ECV procedure itself (procedural factors). The secondary analysis included 11 preprocedural factors: fundal height, body mass index at the time of randomization, amniotic fluid index at the time of randomization, previous breech birth, parity, placental location, type of breech, fetal position, the condition of abdominal wall musculature, abdominal obesity, and the station of the presenting part at the time of the procedure. The analysis included seven procedural factors: maternal pain experienced during the ECV procedure, number of attempts at ECV, use of tocolytic, uterine tone during the procedure, palpability of the fetal head during the procedure, mobility of the fetus during the procedure as determined by palpation, and gestational age at the time of the procedure. Station was assessed clinically as "floating," "dipping," or "well into pelvis or engaged." Maternal pain was quantified using a visual analogue scale with the endpoints of "pain free/ total comfort" and "most extreme pain imaginable." Uterine tone, palpability of the fetal head, and mobility of the fetus were all assessed clinically by the practitioner at the time of the procedure.

Data were analyzed, using the SPSS version 12 (SPSS Inc., Chicago IL). We began by using univariate analyses to find associations between each of the preprocedural and procedural factors and the success of the woman's first ECV procedure. We used the Student *t* test for continuous data and the chi-square test for categorical data.

In order to determine possible predictors of ECV success in this study population, those variables with a P value of ≤ 0.1 were then included in one of two separate logistic regression models, one including preprocedural factors and the other including procedural factors. Factors were entered using a Wald backward elimination approach.

ABBREVIATIONS

AFI	amniotic fluid index
CI	confidence interval
ECV	external cephalic version
MVP	maximum vertical pocket
OR	odds ratio

RESULTS

The results of the univariate analyses are shown in Table 1. Four preprocedural factors were identified as being associated at a significance level of $P \leq 0.1$ with ECV outcome (0 = ECV failed; 1= ECV succeeded). Nulliparity, muscular abdominal wall, obese abdomen, and engaged presenting part were all associated with failed ECV.

Five procedural factors were found to be associated with the success or failure of the ECV procedure. Higher levels of pain with the ECV procedure and increased numbers of

Table 1. Preprocedural and procedural variables associated with ECV outcome

Predictor	Successful ECV (n = 54)	Failed ECV (n = 124)	*P*
	Preprocedural factors		
Mean fundal height in cm (SD)	34.8 (2.1)	34.4 (1.4)	0.234
Mean body mass index (SD)	27.4 (4.8)	27.5 (3.9)	0.980
	n (%)	n (%)	
Previous breech			0.216
Yes	4 (7.4)	4 (3.2)	
No	50 (92.6)	120 (96.8)	
Parity			< 0.001
Nulliparous	28 (51.9)	95 (76.6)	
Multiparous	26 (48.1)	29 (23.4)	
Amniotic fluid assessment*			0.131
Low	8 (22.2)	32 (36.0)	
Moderate	13 (36.1)	35 (39.3)	
High	15 (41.7)	22 (24.7)	
Placental location†			0.376
Anterior or fundal	23 (45.1)	63 (52.5)	
Posterior or lateral	28 (54.9)	57 (47.5)	
Type of breech‡			0.858
Frank breech	44 (81.5)	93 (75.6)	
Non-frank breech	10 (18.5)	30 (24.4)	
Fetal position§			0.411
Sacrum posterior	3 (6.1)	16 (14.3)	
Sacrum anterior or transverse	46 (93.9)	96 (85.7)	
Abdominal wall musculature			0.046
Muscular	6 (11.1)	30 (24.2)	
Lax or unremarkable	48 (88.9)	94 (75.8)	
Abdominal obesity			0.088
Obese	9 (16.7)	10 (8.1)	
Thin or unremarkable	45 (83.3)	114 (91.9)	
Station of the presenting part¶			< 0.001
Engaged	4 (7.4)	42 (34.1)	
Floating or dipping	50 (92.6)	81 (65.9)	
	Procedural factors		
Mean maternal pain score with ECV (SD)	32.4 (23.5)	49.1 (23.7)	< 0.001
	n (%)	n (%)	
Number of attempts at version			< 0.001
2 or more attempts	20 (37.0)	102 (82.3)	
1 attempt	34 (63.0)	22 (17.7)	
Use of tocolytic			0.700
Yes	30 (55.6)	65 (52.4)	
No	24 (44.4)	59 (47.6)	
Uterine tone during procedure			0.030
Contractile	10 (18.5)	43 (34.7)	
Relaxed throughout	44 (81.5)	81 (65.3)	
Palpability of fetal head			0.088
Difficult	3 (5.6)	18 (14.5)	
Easy or unremarkable	51 (94.4)	106 (85.5)	
Mobility of the fetus during procedure			< 0.001
Not very mobile	10 (18.5)	90 (72.6)	
Very or moderately mobile	44 (81.5)	34 (27.4)	
Timing of the procedure			0.214
≥ 37 weeks' gestation	17 (31.5)	53 (42.7)	
< 37 weeks' gestation	37 (68.5)	71 (57.3)	

*54 women were missing data for the amniotic fluid assessment: 19 with a successful procedure and 35 with a failed procedure. A high AFI was defined as >14.5 cm or an MVP > 6 cm, medium AFI was 12–14.5 cm or MVP 4–6 cm, and low AFI was < 4 cm or MVP < 4 cm.

†7 women had an unknown placental location: 3 with a successful procedure and 4 with a failed procedure.

‡one woman had an unknown type of breech and had a failed procedure.

§17 women had an unknown fetal position: 5 with a successful procedure and 12 with a failed procedure.

¶one woman had an unknown station of the presenting part and had a failed procedure.

Table 2. Logistic regression analyses with ECV outcome as dependent variable and preprocedural characteristics as predictors (N = 178) (All three steps involved in the backward elimination approach are shown, and reference categories for each variable are listed in parentheses.)

Predictor	Beta	*P*	OR	95% CI	R^2
Step 1		< 0.01*			0.217
Parity (Multiparity)	1.02	< 0.01	2.76	1.32, 5.80	
Abdominal Wall Musculature (Lax or unremarkable)	0.61	0.24	1.84	0.67, 5.06	
Abdominal Obesity (Thin or unremarkable)	–0.51	0.35	0.60	0.21, 1.75	
Station of Presenting Part (Floating or dipping)	1.89	< 0.01	6.59	2.15,19.94	
Step 2		< 0.01*			0.211
Parity (Multiparity)	1.05	< 0.01	2.85	1.36, 5.94	
Abdominal Wall Musculature (Lax or unremarkable)	0.67	0.19	1.96	0.72, 5.35	
Station of Presenting Part (Floating or dipping)	1.90	< 0.01	6.66	2.20, 20.17	
Step 3		< 0.01*			0.199
Parity (Multiparity)	1.17	< 0.01	3.23	1.58, 6.61	
Station of Presenting Part (Floating or dipping)	1.89	< 0.01	6.63	2.19, 20.04	

R^2: Nagelkerke R Square
*significance level of each model

attempts at the ECV procedure were associated with failure; having a very or moderately mobile fetus, relaxed uterine tone, and a fetal head that was unremarkable or easy to palpate were associated with ECV success.

When we entered the four preprocedural factors into the logistic regression model, the best predictive model (step 3) found that multiparity (OR 3.23; 95% CI 1.58–6.61) and non-engaged station of the presenting part (OR 6.63; 95% CI 2.19–20.04) emerged as significant preprocedural predictors of ECV success. All steps of the logistic regression model for preprocedural factors are shown in Table 2.

When we entered the five procedural factors into a logistic regression model, we found that increased mobility of the fetus at the time of the procedure (OR 8.35; 95% CI 3.57–19.55), less pain experienced during the procedure ($P = 0.03$), and fewer attempts to perform ECV (OR 4.2; 95% CI 1.80–9.81) were significant procedural predictors of ECV success (see Table 3, step 3).

DISCUSSION

In this study of women with breech presentation, we found that multiparous women and women with a non-engaged presenting part were more likely to have a successful external cephalic version. Women who had more than one attempt at ECV, who experienced more pain during the procedure, or who had a fetus that was not very mobile during the procedure were significantly less likely to have a successful ECV procedure.

Multiparity has been identified in several prior studies as an important predictor of ECV success.[4,8,9,12,15] Even though this study included only those multiparous women who were least likely to have a successful ECV (i.e., those with frank breech presentations), parity still emerged as a significant predictor of ECV outcome. Non-engagement of the fetal presenting part was associated with ECV success in five of six prior studies that included this variable.[6,10,12,14,16] It is possible that starting ECV earlier in pregnancy, before engagement of the fetus, might improve the likelihood of success. The Early ECV 2 Trial,[18] currently in progress, will test the hypothesis that beginning ECV earlier in pregnancy (thus decreasing the likelihood of engagement) will result in fewer Caesarean sections. Although vaginal elevation of the presenting part was not recommended as part of our study protocol, and although it remains an untested method of facilitating ECV, it has been used in other studies,[19,20] and may be useful for enhancing success with ECV when the breech is engaged.

Table 3. Logistic regression analyses with ECV outcome as dependent variable and procedural factors as predictors (N = 178) (All three steps involved in the backward elimination approach are shown, and reference categories for each variable are listed in parentheses.)

Predictor	Beta	*P*	OR	95% CI	R^2
Step 1		< 0.01*			0.461
Pain with ECV (continuous variable with higher scores indicating more pain)	-0.02	0.04	–	–	
Mobility of fetus during the procedure (moderately or very mobile)	2.08	< 0.01	7.96	3.34 –18.98	
Number of ECV attempts (one attempt)	1.42	< 0.01	4.14	1.77–9.70	
Ease of palpating fetal head (easy or unremarkable)	0.08	0.93	1.08	0.21–5.48	
Uterine tone during procedure (relaxed)	0.27	0.59	1.31	0.48–3.56	
Step 2		< 0.01*			0.461
Pain with ECV (continuous variable with higher scores indicating more pain)	-0.02	0.04	–	–	
Mobility of fetus during the procedure (moderately or very mobile)	2.08	< 0.01	8.01	3.39–18.94	
Number of ECV attempts (one attempt)	1.42	< 0.01	4.13	1.77–9.66	
Uterine tone during procedure (relaxed)	0.29	0.58	1.32	0.50–3.53	
Step 3		< 0.01*			0.459
Pain with ECV (continuous variable with higher scores indicating more pain)	-0.02	0.03	–	–	
Mobility of fetus during the procedure (moderately or very mobile)	2.12	< 0.01	8.35	3.57–19.55	
Number of ECV attempts (one attempt)	1.43	< 0.01	4.20	1.80–9.81	

R^2: Nagelkerke R Square

*significance level of each model

Our finding that ECV is more likely to fail when women report higher pain scores associated with the procedure is consistent with earlier findings by a research team in Hong Kong.[21] This finding may be because more vigorous (and thus more painful) attempts at ECV are made when a fetus is not turning readily, or because when pain is reported, the ECV attempt is abandoned. In the pilot study, the ECV procedure was stopped prematurely in 24 women; in 14 of these, the procedure was stopped because of maternal discomfort.[1] Of note, tocolytics were not found to be associated with ECV success in this study. However, tocolytics were used only 47% of the time, and it is possible that in centres where tocolytics were not used routinely they may have been used only when the ECV was expected to be more difficult.

The findings of this secondary analysis may have limited generalizability because the sample included women who had an ECV procedure as early as 34 weeks' gestation; however, we believe the findings are important in helping to estimate the likely success of the procedure. The study's unique feature is its separate consideration of preprocedural and procedural prognostic factors.

CONCLUSION

Non-engagement of the presenting part was the only modifiable factor that was associated with success of ECV in the management of breech presentation. This finding is consistent with the hypothesis that beginning the ECV procedure earlier in pregnancy, just prior to engagement, may have merit. A study is underway to test this hypothesis.

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APPENDIX

The Early External Cephalic Version Trial Group (1999–2002)

Steering committee: Eileen K. Hutton, Mary E. Hannah, Ellen D. Hodnett, Kofi Amankwah, Karyn Kaufman

Canada. Anne Malott, McMaster University Medical Centre, Hamilton; Diane Parkin, Susan Aubin, Sharon Dean, Ottawa Hospital–Civic Campus, Ottawa; Rory Windrim, E. Paul Bernstein, Mary Ellen Salenieks, Mount Sinai Hospital, Toronto; Haidar Mahmoud, Alison Gilmore, Scarborough Hospital–Grace Division, Scarborough; Peter Scheufler, Catherine Cowal, Gail Buss, Tory Tudor Trillium Health Centre, Mississauga; Rose Kung, Sunnybrook and Women's College Health Sciences Centre, Toronto; Jeffrey Pollard, Cheryl Swaby, Foothills Medical Centre (CRHA), Calgary; George D. Carson, Sally Elliott, Regina Health District, Regina; Barbara Parish, Cora Fanning, IWK Health Centre, Halifax; Nestor Demianczuk, Elizabeth Penttinen, Royal Alexandra Hospital, Edmonton; Manon Turbide, Pascale Desautels, Val-d'Or Hospital, Val-d'Or; Quynh Le, Mary Ann Van Os, William Osler Health Centre, Brampton; Ramesh Kulkarni, Joanne Laplante, North Bay General Hospital, North Bay.

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