External cephalic version related risks: a meta-analysis

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Abstract

Objective
To systematically review the literature on external cephalic version (ECV) related complications and to assess if the outcome of a version attempt is related to complications.

Data sources
In March 2007 we searched Medline, Embase and the Cochrane Central Register of Controlled Trials.

Methods of study selection
Studies reporting on complications of an ECV attempt for singleton breech pregnancies after 36 weeks of pregnancy were selected. We calculated odds ratios (OR) from studies that reported both on complications as well as on the position of the fetus immediately after the procedure.

Tabulation, integration, and results
We found 84 studies, reporting on 12,955 version attempts that reported on ECV related complications. The pooled complication rate was 6.1% (95% confidence interval (CI) 4.7 to 7.8), 0.24% for serious complications (95% CI 0.17 to 0.34), and 0.35% for emergency caesarean deliveries (95% CI 0.26 to 0.47). Complications were not related to ECV outcome (OR 1.2 (95% CI 0.93 to 1.7).

Conclusion
This study confirms that ECV is a safe procedure. Complications are not related to the fetal position after ECV.
Introduction

Breech presentation occurs in 3% to 4% of all term pregnancies. External cephalic version (ECV) has been clearly shown to reduce the rate of non-cephalic presentations at term and thus the number of caesarean deliveries for breech presentation at term. The high caesarean delivery rate for breech presentation makes ECV an important obstetric intervention and it is therefore recommended by both the American College of Obstetricians and Gynecologists and the Royal College of Obstetricians and Gynaecologists.

Though ECV is a beneficial procedure there are complications reported, such as placental abruption, cord prolapse, fetal heart rate abnormalities, fetal distress, fetomaternal haemorrhage, stillbirth, and vaginal bleeding. Two reviews on the subject reported an overall complication rate of 1.7% to 5.7%. ECV related emergency caesarean deliveries occurred in 0.43%. There are however some shortcomings of these reviews. Firstly, they were incomplete and did not meet current standards of a thorough systematic review. Secondly, they did not report on the fetal position after ECV. It is imaginable that a 180° rotation of the fetus is associated with more complications than no rotation. Therefore, the aim of this review was to provide a complete update on ECV related risks. Furthermore we explored the hypothesis that complications occur more often after a successful ECV.

Because it is still questionable whether ECV before 36 weeks is effective, and at present a large randomised clinical trial is underway that assesses the effectiveness of ECV at 34 weeks compared to ECV at 37 weeks, we excluded studies that report on ECV before 36 weeks. Studies that used anaesthesia were also excluded, since this is not common practice anymore.

Materials and Methods

Sources

We performed an electronic search to identify all studies that report on complications of an ECV attempt. We searched the current Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), MEDLINE (1953-2007) and EMBASE (1980-2007). The search strategy incorporated the keywords “Version, fetal”, “External cephalic version” and “ECV”. No time or language restrictions were applied. Reference lists of review articles and eligible primary studies were checked to identify cited articles not captured by electronic searches. Reference manager 11.0 was used to manage the results of all searches.
Study selection

Studies were selected in a two-stage process. Two reviewers (KG, MK) scrutinized titles and abstracts of all references possibly reporting ECV complications and whether the outcome of the ECV attempt was reported. Of all studies that were selected, full manuscripts were obtained. Final in- and exclusion decisions were made after independent and duplicate examination of the full manuscripts of selected references by two reviewers (MK, KG). Studies were included if they reported on healthy pregnant women with a singleton breech pregnancy. A good fetal condition had to be performed in advance by performing cardiotocography, and evident fetal anomalies or pathology such as growth retardation seen in ultrasound examination were excluded. Studies providing unclear or insufficient data were also excluded. For each included article, data on clinical and methodological study characteristics were extracted independently by two reviewers on piloted data extraction forms. Any disagreements were solved by consensus and, if necessary, by a third reviewer (BWM).

All included manuscripts were assessed by two reviewers for study quality. For this review the following characteristics were extracted: study design (cohort/randomised controlled trial/case-control/other), consecutive patient recruitment (yes or no), prospective data collection (yes or no), in- and exclusion criteria, use of tocolytics, number of clinicians and experience of clinicians performing ECV.

Pooled risks were calculated by performing proportion meta-analysis. To assess whether there is a relationship between an ECV complication and the outcome of the ECV attempt, we constructed a two-by-two table cross-classifying complications against the outcome of the ECV attempt. From the two-by-two tables odds ratios (OR) and 95% confidence intervals (CI) were calculated. Data were plotted in forest plots. The $I^2$-test was used to assess homogeneity, using an $I^2$-value of 50% as a threshold. $I^2$ represents the percentage of the total variation across studies due to heterogeneity. It takes values from 0% to 100%, with a value of 0% indicating no observed heterogeneity. When homogeneity could not be rejected we used a fixed effect model to calculate a common odds ratio and 95% CI. When homogeneity was rejected we used a random effect model. Firstly, all complications were pooled together cross-classifying all complications against the outcome of the ECV attempt. Secondly we performed a subgroup analysis in which each separate complication was cross-classified against the outcome of the ECV attempt. We considered placental abruption and fetal death as serious complications. We categorised fetal death as ECV-attributable, unrelated to ECV and unexplained. We considered stillbirth to be ECV-attributable when it was diagnosed within 48 hours after ECV. Statistical analyses were performed using StatsDirect (StatsDirect Ltd., Cheshire, UK) and RevMan 4.2.
Results

Figure 1 summarises the process of literature identification and selection. The search detected 574 studies of which 147 were retrieved for complete assessment. The full report of two studies was unobtainable. Of the 145 retrieved articles, there were 23 studies that did not report on complications. In 20 studies some form of anaesthesia was used and in 16 studies ECV was performed before 36 weeks gestation. One article was excluded because no ultrasound was performed before the version and one article was excluded for not performing a cardiotocography before the ECV.

Figure 1 Study selection process.

Thus, there remained 84 studies reporting on complications after 12,955 ECV procedures (ranging from 11 to 1,353 versions per study). Data collection was prospective in 47 studies (57%). Sampling of patients was consecutive in 45 studies (55%). Fifty-seven studies were designed as cohort studies (70%), 15 (18%) as randomised controlled trials and 10 (12%) as case control studies. Furthermore, 70 (85%) studies used tocolysis. The ECV success rate ranged from 16% to 100% (pooled success rate 58%; 95% CI 56 to 57) with statistical significant heterogeneity ($I^2 = 94\%$). The results for complications
after ECV also showed statistical heterogeneity ($I^2 = 92\%$) and the pooled result using the random effects model showed the complication rate to be 6.1% (95% CI 4.7 to 7.8).

Subgroup analysis with good quality studies did not improve the homogeneity much. In 49 cases complications led to an emergency caesarean delivery, leading to a pooled risk of 0.35% (95% CI 0.26 to 0.47) with no statistically significant heterogeneity ($I^2 = 31\%$).

The serious complications stillbirth and placental abruption occurred in 23 cases, with a pooled risk of 0.24% (95% CI 0.17 to 0.34) with no statistical significant heterogeneity ($I^2 = 0\%$). ECV complications were not related to ECV outcome (OR 1.2, 95% CI 0.93 to 1.7) (Figure 2) (Table 1).

**Figure 2** Forest plot of odds ratios from individual studies reporting on all ECV related complications in relation to the ECV outcome.

ECV = external cephalic version; OR = odds ratio; CI = confidence interval

Fetal death occurred in 12 of the 12,955 cases (pooled risk 0.19%, 95% CI 0.12 to 0.27) with no statistically significant heterogeneity ($I^2 = 0\%$). Only two deaths were ECV-attributable$^{78,91}$, two were unrelated to ECV in time$^{16,60}$ and seven were unexplained$^{32,36,39,59,73,81}$. The unexplained cases of stillbirth were diagnosed at 10 to 31 days after the version. Eight studies, reporting on 1,215 ECV attempts, reported on stillbirth in relation to ECV outcome$^{36,59,60,73,78,81,83,91}$.

The occurrence of stillbirth was

72
more frequent after a successful ECV although the difference was not statistically significant (pooled OR 1.8, 95% CI 0.65 to 4.9)) (Figure 3). Homogeneity between the studies could not be rejected ($I^2 = 0\%$).

Placental abruption occurred in 11 cases, all but one resulting in a caesarean delivery, with a pooled risk of 0.18% (95% CI 0.12 to 0.26) ($I^2 = 0\%$). In four cases the abruption occurred during or immediately after the ECV, in two cases it occurred within 24 hours after the ECV, in three cases the placenta detached more than 24 hours after the ECV, whereas in two cases information on the exact moment of abruption was not available. In six cases the 5-minute Apgar score was eight or higher, whereas in five cases the Apgar score was not reported. In one case the fetus died due to complete placental abruption, despite an

Table 1 Reported complications and their relationship with ECV outcome.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Nr reported (%)</th>
<th>Nr of studies reporting on relation with ECV outcome</th>
<th>Pooled OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirth</td>
<td>12 (0.09)</td>
<td>8</td>
<td>1.8 (0.65 to 4.9))</td>
</tr>
<tr>
<td>Placental abruption</td>
<td>11 (0.08)</td>
<td>6</td>
<td>1.1 (0.32 to 3.5)</td>
</tr>
<tr>
<td>Cord prolapse</td>
<td>8 (0.06)</td>
<td>3</td>
<td>1.1 (0.19 to 6.2)</td>
</tr>
<tr>
<td>Abnormal cardiotocography</td>
<td>766 (6.1)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Foetal bradycardia</td>
<td>517 (4.0)</td>
<td>10</td>
<td>1.3 (0.94 to 1.9)</td>
</tr>
<tr>
<td>Foetal tachycardia</td>
<td>21 (0.16)</td>
<td>2</td>
<td>1.2 (0.29 to 5.1)</td>
</tr>
<tr>
<td>Leading to CS</td>
<td>29 (0.22)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Vaginal bleeding</td>
<td>40 (0.3)</td>
<td>4</td>
<td>0.33 (0.14 to 0.82)*</td>
</tr>
<tr>
<td>Fetomaternal transfusion</td>
<td>25 (0.9)</td>
<td>2</td>
<td>1.2 (0.18 to 7.4)</td>
</tr>
<tr>
<td>Ruptured membranes</td>
<td>23 (0.2)</td>
<td>3</td>
<td>0.33 (0.07 to 1.6)</td>
</tr>
</tbody>
</table>

$nr =$ number; ECV = external cephalic version; OR = odds ratio; CI = confidence interval; * = significant OR

Figure 3 Forest plot of odds ratios from individual studies reporting on stillbirth as a result of an ECV in relation to the ECV outcome.

ECV = external cephalic version; OR = odds ratio; CI = confidence interval

73
emergency caesarean delivery. Six studies, reporting on 1,000 ECV attempts, reported on placental abruption in relation to the outcome of ECV. A successful ECV attempt was not related to the occurrence of placental abruption (pooled OR 1.1, 95% CI 0.32 to 3.5) (Figure 4). Homogeneity between the studies could not be rejected (I² = 0%).

Cord prolapse was reported in eight cases of which six resulted in a caesarean delivery. The pooled risk for cord prolapse was 0.18% (95% CI 0.11 to 0.26), with no statistical significant heterogeneity (I² = 0%). Three studies, reporting on 714 ECV attempts, reported on the relation of cord prolapse with ECV outcome. The pooled OR was 1.1 (95% CI 0.19 to 6.2). Homogeneity among the studies could not be rejected (I² = 0%).

Transient abnormal cardiotocography patterns were reported in 796 cases (pooled risk of 4.7 (95% CI 3.5 to 6.2) with a statistical significant heterogeneity (I² = 92%). There were 517 bradycardias, four non-reactive non-stress tests, 21 fetal tachycardias, and in 254 cases the abnormality was not specified. There were 29 (0.21 %, 95% CI 0.14 to 0.29) pathological cardiotocographies leading to an emergency caesarean delivery. The fetal outcome was good in all these cases. Nine studies, reporting on 2,819 ECV attempts, reported on fetal bradycardia in relation to ECV outcome. There was no relation to ECV outcome, with a pooled OR of 1.3 (95% CI 0.94 to 1.9). Homogeneity of the studies was rejected (I² = 70%). Two studies reported on fetal distress in relation to ECV outcome, which showed no relationship with a pooled OR of 0.51 (95% CI 0.02 to 13). Homogeneity among the studies could not be rejected (I² = 53%). Two studies reported on fetal tachycardia in relation to ECV outcome. Fetal tachycardia was not related to ECV outcome (pooled OR 1.2, 95% CI 0.29 to 5.1). Homogeneity among the studies could not be rejected (I² = 0%).

**Figure 4** Forest plot of odds ratios from individual studies reporting on placental abruption as a result of an ECV in relation to the ECV outcome.

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Successful ECV n/N</th>
<th>Failed ECV n/N</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Köppel 1986</td>
<td>1/39</td>
<td>0/58</td>
<td>7.39 [4.56, 11.48]</td>
<td>100</td>
<td>1.05 [0.32, 3.47]</td>
<td>1986</td>
</tr>
<tr>
<td>Shalev 1992</td>
<td>1/40</td>
<td>0/15</td>
<td>13.16 [4.56, 39.84]</td>
<td>100</td>
<td>1.05 [0.32, 3.47]</td>
<td>1992</td>
</tr>
<tr>
<td>Lau 1997</td>
<td>1/169</td>
<td>0/74</td>
<td>13.06 [4.56, 39.84]</td>
<td>100</td>
<td>1.05 [0.32, 3.47]</td>
<td>1997</td>
</tr>
<tr>
<td>El Sayed 2004</td>
<td>1/36</td>
<td>1/23</td>
<td>34.99 [10.94, 114.48]</td>
<td>100</td>
<td>1.05 [0.32, 3.47]</td>
<td>2004</td>
</tr>
<tr>
<td>Leung 2006</td>
<td>1/192</td>
<td>0/97</td>
<td>12.50 [3.87, 41.48]</td>
<td>100</td>
<td>1.05 [0.32, 3.47]</td>
<td>2006</td>
</tr>
</tbody>
</table>

Total (95% CI) 586                   473  100.00 1.05 [0.32, 3.47] 2006

Test for heterogeneity: CH² = 2.96, df = 5 (P = 0.86), I² = 0%
Test for overall effect: Z = 0.08 (P = 0.94)

ECV = external cephalic version; OR = odds ratio; CI = confidence interval
Version related vaginal bleeding occurred in 40 cases (pooled risk 0.34%, 95% CI 0.25 to 0.45). In seven cases the bleeding occurred within 24 hours after the version. For 12 women a caesarean delivery was necessary because of the bleeding and four of those women had a placental abruption. Four studies, reporting on 1,173 ECV attempts, reported on vaginal bleeding and ECV outcome\(^{20,49,61}\). Vaginal bleeding occurred less frequent in patients with a successful ECV attempt (pooled OR 0.33, 95% CI 0.14 to 0.82). Homogeneity among the studies could not be rejected (\(I^2 = 0\%\)).

In 17 studies, reporting on 2,778 ECV attempts, a Kleihauer-Betke test was performed for detecting fetomaternal transfusion. Fetomaternal haemorrhage was found in 25 patients (0.9% of tested patients). Two studies, reporting on 256 ECV attempts, reported on ECV outcome\(^{78,92}\). Fetomaternal haemorrhage was not related to ECV outcome (pooled OR 1.2, 95% CI 0.18 to 7.4). Homogeneity between the studies could not be rejected (\(I^2 = 0\%\)).

Version related rupture of the membranes was reported in 23 (pooled risk 0.22%, 95% CI 0.15 to 0.31) cases. In 16 cases the membranes ruptured within 24 hours after the version and in five cases in the next 24 hours after the version. In two cases the moment of rupture was not reported. In four cases a caesarean delivery was performed and one woman delivered vaginally after successful ECV. Three studies, reporting on 145 ECV attempts, reported on ruptured membranes in relation to ECV outcome\(^{21,44,60}\). A successful ECV attempt was not related to the occurrence of ruptured membranes (pooled OR of 0.33, 95% CI 0.07 to 1.6). Homogeneity among the studies could not be rejected (\(I^2 = 0\%\)).

**Discussion**

Our systematic review has identified a wide range of studies reporting on ECV related complications. It is the most complete review on the subject thus far. This review confirms ECV is a safe procedure providing it is performed in a setting where a caesarean delivery can be performed. We did not find a significant relationship between fetal position after ECV and ECV related complications (OR 1.2, 95% CI 0.93 to 1.7).

This study has several important strengths. We conducted this review with a comprehensive search strategy; we used a prospective protocol, and made a concerted effort to find all the evidence. We scrutinized the selected studies for their quality. Methodological issues that may overestimate accuracy such as case control design, retrospective design and non-consecutive studies were present in less than 50% of the studies. For each complication related to ECV outcome, except for fetal bradycardia, homogeneity could not be rejected.
This study also has several limitations. First of all, this review is, like other reviews on the subject, limited by reporting bias. This is demonstrated by the observed heterogeneity for the overall complication rate. However, the complication rate in this review is comparable to that of the largest cohort study on complications after ECV, reporting on 805 consecutive ECV attempts. Therefore, we assume the true complication rate will not differ much from the rate we reported. We had the hypothesis that complications would occur more often after a successful ECV. Although there were more complications observed after successful ECV, this difference was not significant. Given the fact that more than half of the included studies reporting on complications do not report on the fetal position after ECV, it is possible that there still is a relationship of complications with ECV outcome. However, considering the low overall complication rate, the clinical importance of this knowledge is questionable.

There is also an issue of what should be reported as complications. Firstly, several studies report on nuchal cord as a complication of ECV. However, according to a large population-based study, nuchal cord is not associated with adverse perinatal outcome. Thus, we would not consider nuchal cord as a complication of ECV and consequently did not report on it. Secondly, there is a large heterogeneity between studies reporting on cardiotocographic abnormalities. As the cardiotocogram is a diagnostic test with a very low sensitivity and specificity, we would only consider cardiotocographic changes leading to a caesarean delivery as a complication of ECV.

We defined ECV-attributable death as fetal death diagnosed within 48 hours after ECV. This was an arbitrary choice, because it doesn’t seem likely that a fetal death more than 48 hours after the ECV is related to the procedure itself. As a result, only two of the 12 reported deaths were ECV attributable, resulting in a fetal death rate of 1 per 5,000 ECV attempts. One death occurred after a successful ECV and one after failed ECV. Placental abruption occurred in 1 per 1,200 cases. This incidence is three times higher than the incidence in a general population. It seems that, although abruption is still a rare complication, the placenta is affected by the manipulation from the outside.

In conclusion, the main clinical implication of this review is that ECV is a safe procedure, with a risk of fetal death in 1 per 5,000 ECV attempts. Therefore, all women eligible for ECV should be offered an ECV attempt and fetal assessment should take place before and after the ECV attempt. Considering the risk of an emergency caesarean delivery in 1 per 286 versions, ECV should only be attempted in settings in which caesarean delivery services are readily available. Future studies concerning ECV should report on both complications and fetal position after ECV.
References