Randomized trial of anaesthetic interventions in external cephalic version for breech presentation

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Abstract

Background: Successful external cephalic version (ECV) for breech presenting fetus reduces the need for Caesarean section (CS). We aimed to compare the success rate of ECV with either spinal anaesthesia (SA) or i.v. analgesia using remifentanil.

Methods: In a double-phased, stratified randomized blinded controlled study we compared the success rates of ECV, performed under spinal anaesthesia (SA), i.v. analgesia (IVA) using remifentanil or no anaesthetic interventions. In phase I, 189 patients were stratified by parity before randomization to ECV, performed by blinded operators, under SA using either hyperbaric bupivacaine 9 mg with fentanyl 15 µg, i.v. remifentanil infusion 0.1 µg kg min⁻¹, or Control (no anaesthetic intervention). Operators performing ECV were blinded to the treatment allocation. In phase 2, patients in the Control group in whom the initial ECV failed were further randomized to receive either SA (n=9) or IVA (n=9) for a re-attempt. The primary outcome was the incidence of successful ECV.

Results: The success rate in Phase 1 was greatest using SA [52/63 (83%)], compared with IVA [40/63 (64%)] and Control [40/63 (64%)], (P=0.027). Median [IQR] pain scores on a visual analogue scale (range 0–100), were 0 [0–0] with SA, 35 [0–60] with IVA and 50 [30–75] in the Control group (P<0.001). Median [IQR] VAS sedation scores were highest with IVA [75 (50–80)], followed by SA, [0 (0–50)] and Control [0 (0–0)]. In phase 2, 7/9 (78%) of ECV re-attempts were successful with SA, whereas all re-attempts using IVA failed (P=0.0007). The incidence of fetal bradycardia necessitating emergency CS within 30 min, was similar among groups; 1.6% (1/63) in the SA and IVA groups and 3.2% (2/63) in the Control group.

Conclusions: SA increased the success rate and reduced pain for both primary and re-attempts of ECV, whereas IVA using remifentanil infusion only reduced the pain. There was no significant increase in the incidence of fetal bradycardia or emergency CS, with ECV performed under anaesthetic interventions. Relaxation of the abdominal muscles from SA appears to underlie the improved outcomes for ECV.

Key words: anesthesia regional; anesthesia, spinal; breech presentation; external cephalic version; obstetrics; remifentanil, analgesia, obstetric; term birth

Although the Term Breech Trial showed that planned Caesarean section (CS) confers a lower fetal risk than vaginal delivery,¹ ² CS is associated with increased maternal morbidity, pain, expenditure and a higher likelihood of requiring further subsequent CS.³ ⁴ Successful external cephalic version (ECV) eliminates the need for planned CS.⁵–⁷

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Pain felt during ECV triggers abdominal guarding, which is an important factor limiting successful version.3,9 Although the success rates for ECV can be improved by neuraxial anaesthesia,3,9 the underlying mechanism by which it works, specifically whether it is analgesia or relaxation of abdominal muscles from the neuraxial anaesthesia, is unclear.10,11 This is important because analgesia can be provided less invasively and more economically using i.v. infusion of remifentanil, whereas neuraxial anaesthesia provides relaxation of the abdominal muscles in addition to analgesia. Moreover, how these anaesthetic interventions should be deployed is unclear, whether for all primary attempts of ECV, or only for re-attempts of failed ECV.12

Our aim in Phase I of this prospective randomized blinded study was to evaluate the relative effectiveness of spinal anaesthesia (SA) or i.v. analgesia using remifentanil (IVA), on the success rates of primary attempts of ECV by comparison with a Control group that received no anaesthetic interventions. The routine practice in our unit previously was to use no anaesthetic interventions.

In Phase 2, patients in the Control group who had unsuccessful ECV in phase 1 were recruited for ECV to be re-attempted under a randomized allocation of anaesthetic interventions. Our primary objective measure was the success rate of ECV, and secondary objectives were comparisons of pain, sedation and the adverse effects from ECV.

Methods

Study design

This randomized blinded controlled study was conducted at The Prince of Wales Hospital, Shatin, Hong Kong SAR, China and received approval from our institutional Clinical Research Ethics Committee. The trial was registered with the Chinese Clinical Trial registry (www.chictr.org) ref: ChiCTR-TRC-12002644.

One hundred and eighty-nine ASA physical status I-II, term parturients, with breech-presenting fetus, were recruited after giving written informed consent. Patients were unpremedicated, but instructed to fast for at least 6 h before ECV, in case of a need for emergency surgery. A comprehensive ultrasound scan was performed to determine the suitability for ECV by one of the investigators, before recruitment. During recruitment and counseling, the modes of anaesthetic interventions were discussed, and written informed consent obtained. Patients randomized to SA group were offered the option to proceed to CS should ECV fail. Those who chose this option were given the same intrathecal dose of local anaesthetics, via a combined spinal-epidural (CSE) technique. We excluded patients with contraindications to ECV including patients with known uterine scar or anomaly, unexplained third-trimester bleeding, obstetric or medical conditions complicating pregnancy, compromised fetus, nuchal cord, fetal anomaly, pre-labour ruptured membranes and established labour.

ECV was performed in a specially equipped room, adjacent to the operating room, in the delivery suite with full anaesthetic and fetal monitoring facilities and an ultrasound machine. With the patient lying supine with left tilt on an operating table, standard monitoring comprising of non-invasive BP cycled at 1-min intervals, electrocardiography, pulse oximetry and cardiotocography (CTG) was applied and a wide bore i.v. cannula was inserted in the forearm under local anaesthesia. For the purpose of blinding, identical i.v. fluid infusion sets were used to infuse Hartmann’s solution, 500 ml, at a very slow rate to maintain venous patency.

The study was conducted in two phases. In phase 1, all patients were randomized to receive one of the two anaesthetic interventions or Control. In phase 2, patients in the Control group with whom ECV failed, were recruited to have a re-attempt of ECV under one of the two anaesthetic interventions. In each phase, patients were separately stratified according to parity (nulliparous or multiparous) before randomization, by drawing of sequentially numbered opaque sealed envelopes, that were prepared by random shuffling of the intervention codes.

Phase 1

Anaesthetic interventions

Spinal anaesthesia (SA) group. SA was established with patients in the left lateral position using 1.8 ml hyperbaric bupivacaine 0.5% (9 mg), plus fentanyl 15 μg injected at the L2/3 or L3/4 interspace using a 25G Whitacre needle. A CSE technique using the same intrathecal dosage, was used in patients who had requested in advance to have CS if ECV were unsuccessful. We selected this intrathecal dosage based on our experience, to satisfy the important requirements for this study which were: (1) to provide a dense motor block for complete abdominal muscle relaxation, (2) to provide adequate anaesthesia should an immediate CS be needed for fetal compromise and, (3) the patient must be fully recovered from anaesthesia in time for day care discharge.

No i.v. fluid preload was given and BP was maintained with a titrated phenylephrine infusion according to an established protocol.13 14 The onset of sensory anaesthesia was assessed by testing the sensory loss to ice and pinprick and motor block tested by the modified Bromage score at 2.5 min intervals.15

Once the block had reached the T7 dermatome as tested by pinprick, the patient was considered ready and was prepared for ECV. After ECV, patients were observed initially in the recovery area, and then discharged to the ward after stable observations and signs of recovery from SA. Patients were discharged home on the same day, upon fulfilment of an outpatient anaesthesia discharge criteria, after assessment by an obstetrician and an anaesthesiologist.

I.V. Remifentanil group (IVA). Patients in this group were given an i.v. infusion of remifentanil 0.1 μg kg⁻¹ min⁻¹. This infusion regimen was based from our experience in providing remifentanil infusion for analgesia, to parturients for short procedures. To facilitate blinding, and synchronize timing of ECV, the infusion was commenced after a delay of 15 min to account for the delay anticipated with patients in the SA Group. ECV was performed 10 min after the remifentanil infusion was started. Similarly, these patients were discharged home upon fulfilment of outpatient anaesthesia discharge criteria, and after assessment by an obstetrician and an anaesthesiologist.
Control group. Patients in this group received no anaesthetic intervention. ECV was delayed for approximately 20 min, which was the estimated delay anticipated in the other groups.

Blinding for anaesthetic interventions. To facilitate blinding, patients were draped below the shoulders to expose only the abdomen for ECV, and were instructed to remain quiet and motionless as much as possible during the procedure. To test the effectiveness of blinding, obstetricians were asked to guess the group allocation after ECV.

External cephalic version. A detailed description of the external cephalic version protocol, timing and techniques has been previously reported. Before commencing ECV, hexoprenaline 10 μg was given for tocolysis. To minimize adverse effects, this was injected intravenously slowly over 6 min, in three equally divided doses, spaced at 2 min intervals. A pool of five operators, who were all accredited obstetric specialists, experienced in performing ECV took part in this study. Each ECV procedure was performed with two operators and the choice of turning direction was randomized to receive either i.v. remifentanil or SA.

Assessment of pain and sedation. Upon completion of the study, patients were instructed to indicate to an assessor the degree of pain and sedation, on a visual analogue scale ruler (0 mm=none, 100 mm=most extreme).

Phase 2
Patients in the Control group who had unsuccessful ECV were counselled and consented to enroll to Phase 2 of this study, immediately after the end of Phase 1. After stratification, patients were randomized to receive either i.v. remifentanil or SA.

Outcomes
The primary outcome was the rate of successful ECV. Secondary outcomes were pain and sedation scores, and incidence of adverse effects from ECV, such as fetal heart rate abnormality, evidence of placental abruption or umbilical entanglements, necessitating emergency Caesarean section.

Statistical analysis
From our database, we estimated that a sample size of 63 subjects in each study group would be required to detect a 50% difference in success rate with an alpha error of 0.05 and a power of 80%, assuming a baseline success rate of 55% in patients who received no interventions.

Data were tested for equality of variance using Levene’s test, and the normal probability plot was used to test normality assumption. Based on the findings, statistical comparisons between groups were performed using analysis of variance (ANOVA) or the Kruskall-Wallis test with post-hoc comparisons using the Tamhane and Bonferroni procedures. The \( \chi^2 \) test for trend was used for comparison of equality of proportion. Results were analysed using SPSS 13.0 for windows (SPSS Inc., Chicago, IL, USA), and presented as mean and standard deviation or median and 25–75% interquartile range where appropriate. \( P<0.05 \) was considered significant.

Results

Phase 1
This study was conducted between April 2004 and March 2010 and a total of 189 patients, (nulliparous, \( n=108 \) and multiparous, \( n=81 \)) were recruited (Fig. 1). Maternal characteristics amongst groups were similar (Table 1). The overall rate for successful ECV was 70% (132/189), of whom 79% (104/132) had vaginal delivery (Table 2). The rates of successful ECV with SA, 83% (52/63) was significantly higher than both IVA 64% (40/63), and Control 64% (40/63) \( (\chi^2=7.23, P=0.027) \), mean difference (95% CI) 19% (3.5–33.5%). The vaginal delivery rates for patients who had successful ECV were 77% (40/52), 80% (32/40) and 80% (32/40) for SA, IVA and Control groups respectively. Pain scores, [median (IQR)] were lowest with SA [0 (0–0)], followed by IVA [35 (0–60)] and Control [50 (30–75)], \( P<0.001 \). Sedation scores, [median (IQR)] were highest with IVA [70 (50–80)], followed by SA, [0 (0–50)] and Control [0 (0–0)].

Phase 2
Eighteen patients who had unsuccessful ECV from the Control group were recruited and randomized to receive either SA (\( n=9 \)) or IVA (\( n=9 \)) for a repeated attempt of ECV. Patient characteristic data of these patients were similar, with seven nulliparous and two multiparous patients in each group. ECV was successful in seven patients (78%) with SA, whereas all attempts were unsuccessful with IVA \( (\chi^2=11.45, P=0.0007) \) (Table 2). All failures in the SA group were ECV attempted on nulliparous patients. Figure 1 summarizes the outcome for the complete study.

Emergency CS after ECV
Two patients in the Control group and one each in the SA and IVA groups required immediate CS, within 30 min of ECV, as a result of fetal bradycardia. A further eight patients (one from the Control group, two from the SA group and five from the IVA group) required CS within 24 h of ECV, as a result of non-reassuring CTG (Table 3). All babies were delivered healthy, with Apgar scores \( >7 \) at 5 min. Three patients who were randomized to receive SA, asked for CS to be performed immediately after failed ECV, with delivery of healthy babies and uneventful surgery. Three patients in the IVA group requested for further ECV attempts under SA, in which ECV were all successful.

Adverse effects from anaesthetic interventions
All patients recovered fully from the anaesthetic interventions. There were no complications from SA, such as hypotension during the procedure or post-dural puncture headache. No desaturation, pruritus or nausea and vomiting were recorded from patients who had IVA.

Effectiveness of binding
The obstetricians were able to correctly guess the mode of interventions in 51% (32/63) of the SA, 24% (15/63) of the IVA and 71% (45/63) of the Control groups in phase 1. In phase 2, the modes of interventions were correctly guessed in 78% (7/9) of the SA group, and 56% (5/9) of the IVA group. The presence or absence of...
abdominal guarding was the most cited reasons for correctly or incorrectly guessing whether a patient received SA or not. This was also the most cited reason for making the incorrect guesses for patients in the IVA group.

Discussion

We found an increase in the rate of successful ECV and a reduction in pain when SA was used for both primary and re-attempts of ECV. Although patients in the IVA group had less pain than the Control group, the success rate was not greater. The incidence of fetal bradycardia and non-reassuring CTG under anaesthetic interventions, were similar to the Control group after ECV. All babies were healthy at birth and there were no maternal complications from any anaesthetic intervention. Together, the findings in this study support the use of SA for both primary attempts, and for re-attempts of failed ECV, underlying the importance of abdominal muscle relaxation for successful ECV.
Pain during the ECV is an important factor which limits the success rate. Patients react involuntarily to pain with a tense guarded abdomen making ECV more difficult. Greater force would then be required for the procedure, thus risking fetal injury.\textsuperscript{11,18,19} Previously, it was assumed that SA increased the success rate for ECV by reducing pain from the procedure. However, another possible mechanism by which SA may have facilitated ECV was by relaxation of the abdominal muscles and eliminating abdominal guarding. In a notable study, Birnbach and colleagues\textsuperscript{10} used only 10 µg of intrathecal sufentanil for spinal anaesthesia, which presumably would have provided predominantly analgesia with very little abdominal muscle relaxation. Yet their data showed a markedly increased ECV success rate, from 33 to 80%, implying that analgesia alone may be effective. This was the basis for evaluating the use of remifentanil infusion in our study.

However, our findings in the IVA group showed that although pain scores were reduced, the rate of successful ECV was the same as in the Control group. Moreover, all ECV re-attempts using IVA in Phase 2 failed despite a reduction of pain scores, compared with the pain scores during the first attempts in Phase 1 when the patients received no analgesia.

The success rate in the control groups of our study were 64%, compared with Birnbach’s study of 33%. These marked differences in successful ECV rates could possibly be accounted for by differences in the pain threshold of the two populations. The likelihood of developing abdominal guarding during ECV would be much higher in a population with a lower pain threshold, and this could account for the lower success rate in Birnbach’s Control group, which received no analgesia. In such a population, the benefit when analgesia was provided using intrathecal sufentanil could be greater.

A number of publications have reported that the use of neuraxial anaesthesia improves the rate of successful ECV.\textsuperscript{3,9–11,20–25} However, there were marked variations in study designs, and application of spinal or epidural anaesthesia for primary attempts and for re-attempts of failed ECV. Recent systematic reviews concluded that neuraxial anaesthesia improved the success rate of ECV, particularly when a higher anaesthetic dosage was used.\textsuperscript{26–28} This supports the findings in our study, as it implied that abdominal muscle relaxation is important for successful ECV. In another study, for re-attempts of failed ECV under SA using identical dosage, we reported that both the forces exerted and the duration for the procedure was reduced, as a consequence of abdominal muscle relaxation.\textsuperscript{11}

Although the rate of successful ECV is increased by the additional use of neuraxial anaesthesia, a Cochrane review surprisingly found no improvement in the incidence of cephalic vaginal birth.\textsuperscript{12} This observation may have arisen as a result of the lower incidence of normal vaginal birth and a higher incidence operative delivery, even after successful ECV.\textsuperscript{29} Thus the impact of using SA for facilitating ECV on the incidence of cephalic vaginal birth is smaller.
From our review of published studies comparing the use of neuraxial anaesthesia against control, we noted marked variations in the reported success rates for ECV in their control groups ranging from 32–58%.1 3 9 10 20 25 Remarkably when neuraxial anaesthesia was used, the success rates of ECV in all these studies consistently increased to the order of ~80%. Although this could be attributable to many factors such as variations in skills, techniques or use of tocolytic agents,1 3 9 the implication from this observation is that SA would be more beneficial and cost-effective for use in maternity units where ECV success rate is low. These are the units which will see a greater marginal increase in their ECV success rates, to the order of ~80% if SA is used.

The strength of our study was that all ECV attempts and re-attempts were performed by the same few experienced operators, who were blinded to the interventions. This addressed the variations in results and inconsistencies arising from variations in operator skills, or baseline control rates as reported in other publications. Under our controlled study conditions, we have demonstrated that the additional use of SA increased the success rate substantially for both primary and re-attempts by the same operators.

The incidence of fetal bradycardia and the need for emergency CS was similar among groups, however it should be noted that this study is underpowered to detect such differences. As we have previously reported, an analysis of ECV performed over a period of almost two decades in our unit did not show any increased risk of intrapartum death.20 In this study, the use of a higher dosage of spinal anaesthetics, and performing ECV in the vicinity of an operating theatre provided us with an option to proceed immediately to CS in case of an emergency.

One of the challenges in performing such a study, as highlighted in the Cochrane review, is to provide adequate blinding and prevent operator bias. In this study, we were rigorous in attempting to blind the operators as to which anaesthetic intervention the patient had received. However, blinding was only partially effective as the obstetricians were 51 and 24% accurate in guessing the correct mode of interventions, for SA and IVA respectively. Having a soft abdomen with an absence of abdominal guarding was the most cited reason for correctly guessing the SA group, indicating that we could only blind the appearance but not the condition for ECV. Conversely, having a soft abdomen and an absence of abdominal guarding was also the most cited reason for making the incorrect guesses in the IVA group, implying some degree of effectiveness of remifentanil in providing analgesia and preventing abdominal guarding. However, the effectiveness of remifentanil in this respect did not translate into an increase in the number of successful ECV for this study.

The number of elective CS performed annually has increased both directly and indirectly as a consequence of the recommendations from the Term Breech Trial.3 Therefore any manoeuvres that can improve the success rate of ECV, and hence reduce the need for CS would be beneficial. In this study we have found that SA substantially increased the success rate and reduced the pain experienced during ECV.

Authors’ contributions
K.S. K. contributed to the study design, data collection, analysis and interpretation of data and drafting of the manuscript. S.W. Y. L. contributed to the study coordination, data collection and analysis and drafting of the manuscript. W.D. N.K. contributed to the study design and critical revision of manuscript. L.W. L. contributed to patient recruitment, data collection and interpretation. T.K. L. contributed to the study design. F.F. N. contributed to patient recruitment and data collection. T.Y. L. contributed to the study design, data collection, analysis of data and critical revision of manuscript. All of the authors read and approved the final manuscript.

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Declaration of interest
None declared.

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