BJA

British Journal of Anaesthesia 114 (6): 944–50 (2015)

doi: 10.1093/bja/aev107
Obstetrics

OBSTETRICS

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]

Accepted: March 18, 2015

Editor's key points

- There is no consensus on best anaesthetic technique for external cephalic version (ECV).
- In this study, success at ECV was higher using spinal anaesthesia compared with remifentanil infusion or no intervention.
- Pain was also reduced in the remifentanil group but success at ECV was no different to the no intervention group.
- The effect of spinal anaesthesia in ECV may relate to relaxation of the abdominal musculature.

Pain felt during ECV triggers abdominal guarding, which is an important factor limiting successful version.[3 8] 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 counselling, 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.