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ORIGINAL ARTICLE

A randomized controlled trial of the effect of combined spinal-epidural analgesia on the success of external cephalic version for breech presentation

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ABSTRACT
Background: Improving the success of external cephalic version (ECV) for breech presentation may help avoid some cesarean deliveries. The results of randomized trials comparing the success of ECV with neuraxial analgesia compared to control are inconsistent. We hypothesized that combined spinal-epidural (CSE) analgesia would increase the success of ECV when compared with systemic opioid analgesia.
Methods: Parturients with singleton breech presentation (n = 96) were randomized to receive CSE analgesia with bupivacaine 2.5 mg and fentanyl 15 μg (CSE group) or intravenous fentanyl 50 μg (SYS group) before ECV attempt. The primary outcome was ECV success.
Results: The success rate of ECV was 47% with CSE and 31% in the SYS group ($P = 0.14$). Subsequent vaginal delivery was 36% for CSE and 25% for SYS ($P = 0.27$). Median [IQR] visual analog pain scores (0-100 mm scale) were lower with CSE (3 [0-12]) compared to SYS analgesia (36 [16 to 54]) ($P < 0.005$) and patient satisfaction (0-10 scale) was higher (CSE 10 [9 to 10] versus SYS 7 [4 to 9]) ($P < 0.005$). There were no differences in fetal heart rate patterns, but median time to return to fetal heart rate reactivity after analgesia was shorter with CSE (13 [IQR 9-21] min) compared to the SYS group (39 [IQR 23-51] min) ($P = 0.02$).
Conclusions: There was no difference in the rate of successful ECV or vaginal delivery with CSE compared to intravenous fentanyl analgesia. Pain scores were lower and satisfaction higher with CSE analgesia, and median time to fetal heart rate reactivity was shorter in the CSE group.

Keywords: Breech presentation; External cephalic version; Combined spinal-epidural analgesia

Introduction

Singleton breech presentation, which occurs in 3-4% of term pregnancies, has been associated with increased risk of injury to the neonate during attempted vaginal delivery.[1] The American College of Obstetricians and Gynecologists cautions against the routine practice of breech vaginal delivery and encourages the use of external cephalic version (ECV) to reposition the fetus to a vertex presentation in an effort to avoid cesarean delivery.[2] The mean success rate for ECV is 59% in published clinical trials and ranges from 35 to 100%.[3] Therapeutic measures aimed at increasing the success of ECV may help avoid cesarean deliveries.

Neuraxial anesthesia and analgesia have been shown to substantially reduce maternal pain during ECV, and several randomized controlled trials report an increase in the success of ECV with neuraxial anesthesia.[4–6] However, increased procedural success has not been universal,[7] and it is not clear what comprises the optimal analgesic technique in this setting.[8] Considerations in selecting an analgesic technique include fetal safety (risk of abruption and fetal heart rate (FHR) abnormalities), monitoring requirements and side effects. The purpose of this investigation was to determine if ECV was successful more frequently with combined spinal-epidural analgesia than with systemic opioid analgesia. We postulated that combined spinal-epidural (CSE) analgesia would increase the success rate of ECV for breech

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presentation and, subsequently, the incidence of vaginal delivery when compared with systemic opioid analgesia (SYS).

Methods

The study was approved by the Office for the Protection of Research Subjects at Northwestern University. After confirmation of breech position by ultrasound examination, patients scheduled for ECV between September 2002 and June 2006 were interviewed by an anesthesiologist and written informed consent for study participation was obtained. Eligible subjects were $\geqslant 36$ weeks of gestation with singleton pregnancies and willing to receive either CSE analgesia or systemic opioid analgesia for ECV. Patients with contraindications to neuraxial anesthesia or allergies to any study medication were excluded from participation. Group assignments were determined using a computer random number table and were sealed in sequentially numbered opaque envelopes that were opened after consent was obtained.

Peripheral intravenous access was established and all subjects received 500 mL of Ringer's lactate solution before initiation of analgesia. Subjects randomized to the CSE group were placed in the sitting position and low lumbar CSE analgesia was initiated using a needle-through-needle technique. Plain bupivacaine 2.5 mg plus fentanyl 15 μg was injected into the intrathecal space, followed by epidural administration of lidocaine 45 mg and epinephrine 15 μg. Ten minutes after the intrathecal dose, sensory level to cold was assessed. Subjects randomized to the SYS group received fentanyl 50 μg intravenously. Terbutaline 0.25 mg was administered intravenously to provide uterine relaxation in both groups.

Fetal breech position was reconfirmed by ultrasound. Continuous pulse oximetry and blood pressure measured every 2.5 min were recorded from the time of initiation of analgesia until the ECV procedure was complete, but for not less than 20 min. Fetal heart rate was monitored for 30 min before and 60 min after the procedure.

After hemodynamic stability was assured, obstetricians, not blinded to treatment group, attempted ECV. The procedure was terminated because of failure to reposition the infant, persistent severe fetal bradycardia, or patient intolerance according to the obstetrician's judgment. The primary outcome variable was successful ECV, defined as vertex presentation on ultrasound examination.

Before the procedure obstetricians were asked to estimate the expected difficulty of ECV using a four-point scale (very easy, easy, difficult, and very difficult). Following the procedure the obstetrician rated the degree of abdominal muscle relaxation (poor, fair, good, excellent), as well as overall difficulty of the procedure using the aforementioned scale. Maternal pain during the procedure (visual analog scale (VAS) 100-mm unmarked line) and overall satisfaction with the analgesic technique (verbal numeric scale 0 to 10) were recorded immediately after the ECV. Patients reported the incidence and severity of nausea (none, mild, moderate, severe) and the incidence of vomiting. Mode of delivery and reason for cesarean delivery were abstracted from the medical record after delivery.

A perinatologist blinded to group assignment evaluated (FHR) patterns beginning 30 min before until 60 min after ECV using National Institute of Child Health and Development guidelines.[9] Baseline FHR, degree of variability, number of accelerations, number and type of decelerations and time to reactivity were recorded. Time to reactivity was defined as time from initiation of analgesia to the development of two 15-beat accelerations (15 s duration) occurring within 20 min of each other.[10]

Statistical analysis

A sample size calculation determined that 94 subjects would be required to demonstrate a 30% difference in the success rate of ECV between groups ($\alpha = 0.05$, power = 87%) assuming an overall success rate of 50% (institutional data). Rates of successful version and vaginal delivery were compared between the two groups using Fisher's exact test. Demographic data (maternal age, height and weight, parity and gestational age) and outcome data (obstetrician prediction and assessment of ECV difficulty, assessment of abdominal muscle relaxation, duration of the procedure, incidence and severity of nausea, incidence of vomiting, patient pain and satisfaction with analgesic method) were compared between groups using the χ^2, Fisher's exact or the Mann-Whitney U test. We also compared prediction and assessment of ECV difficulty, assessment of abdominal muscle relaxation, and duration of the procedure in patients with successful vs. unsuccessful ECV. $P < 0.05$ was used to reject the null hypothesis.

Results

Three hundred and ninety-five subjects were assessed for eligibility during the study period (Fig. 1), 165 subjects were approached by study personnel and 96 patients gave informed consent and were enrolled in the study. Two hundred and thirty subjects were not approached by study personnel primarily at obstetrician request. One patient was excluded following randomization because she underwent emergency cesarean delivery for non-reassuring fetal status after group assignment but before analgesic intervention, leaving 95 subjects available for analysis (48 CSE, 47 SYS). Forty-seven obstetricians participated in the trial. The median number of ECV procedures per obstetrician was 1 and the interquartile range was 1 to 2. Pre-procedural group characteristics were similar, as was the obstetricians' predicted difficulty in successful ECV (Table 1).