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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.

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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 ≥ 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 μ g was injected into the intrathecal space, followed by epidural administration of lidocaine 45 mg and epinephrine 15 μ g. Ten minutes after the intrathecal dose, sensory level to cold was assessed. Subjects randomized to the SYS group received fentanyl 50 μ g 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).

The overall rate of ECV success was 39% and the rate of vaginal delivery was 31%. The success rate was 47% for the CSE group and 31% for the SYS group ($P = 0.14$); the difference in rate was 16% (95% CI -3 to 24). Subsequent vaginal delivery was 36% for CSE and 25% for SYS ($P = 0.27$); the difference in rate was 11% (95% CI -1 to 24). No study subject had a vaginal breech delivery. Pain scores were lower with CSE analgesia than with SYS analgesia, and patient satisfaction with the analgesic method was greater following CSE technique (Fig. 2). Obstetrician predicted difficulty in successful ECV did not correlate with the subject reported pain during the procedure ($\rho = 0.07$, $P = 0.50$); however, abdominal relaxation was judged to be better in the group that received CSE analgesia (Table 2) and was inversely correlated with the subject-reported procedural pain ($\rho = -0.58$, $P < 0.005$).

Thirty subjects in the CSE group and none in the SYS group received ephedrine to maintain blood pressure within 20% of baseline ($P < 0.005$). The incidence (SYS 6.3% vs. CSE 25%; $P = 0.01$) and severity of nausea were lower in the SYS group, but the incidence of

Table 1 Demographic characteristics and obstetrician predictions

	CSE (n = 47)	SYS (n = 48)
Age (years)	32 [27-35]	33 [30-36]
Nulliparous (%)	63	62
Gestational age (weeks)	37 [37-38]	37 [37-38]
Height (cm)	163 [160-168]	165 [160-170]
Weight (kg)	79 [70-87]	77 [73-86]
Obstetrician predicted difficulty of version		
Very difficult	1	3
Difficult	36	34
Easy	10	11
Very easy	0	0

Data are median [interquartile range] or n; There was no significance difference between the groups. CSE: Combined spinal-epidural; SYS: systematic analgesia.

vomiting was similar (CSE 0%, SYS 2.1%; $P = 0.32$) (Table 2).

There were no differences in pre-procedural or post-procedural baseline FHR, degree of variability, baseline

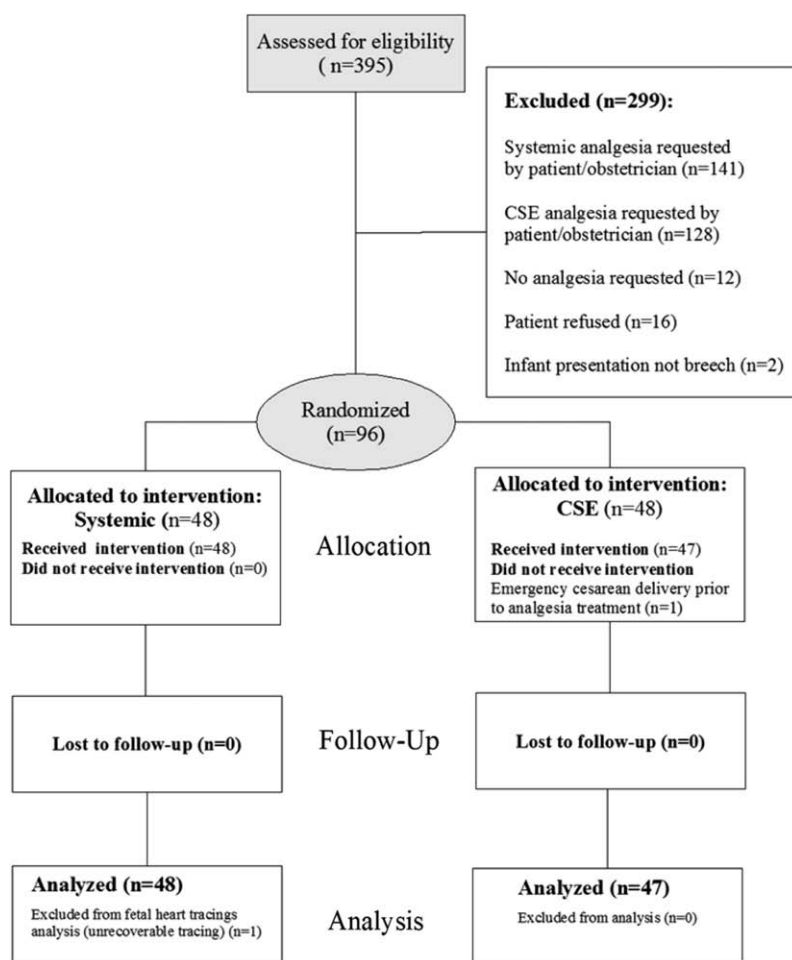


Fig. 1 Flow diagram of subject participation. CSE: combined spinal-epidural analgesia; Systemic: systemic analgesia.

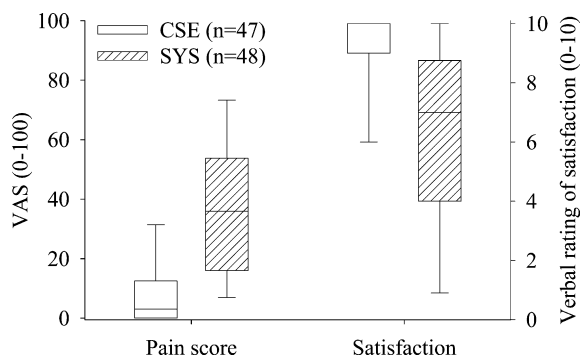


Fig. 2 Visual analog scale (VAS) pain scores (0-100 mm) and verbal rating scale scores of satisfaction (0-10) during external cephalic version. CSE: combined spinal-epidural; SYS: systemic analgesia. [†] $P < 0.05$ between groups.

number of accelerations and number and type of decelerations between the CSE and SYS groups (Table 3). Median time to reactivity was 13 [IQR 9 to 21] min in the CSE group versus 39 [IQR 23 to 51] min in the SYS group ($P = 0.02$). Reactivity was re-established before the ECV attempt in 35 of the 47 CSE compared to two of the 47 SYS group subjects ($P < 0.001$). The frequencies of decelerations (10.8% vs. 16.4%, $P = 0.45$) and persistent decelerations (5.4% vs. 16.4%, $P = 0.12$) following the procedure were not significantly different in subjects with successful compared to non-successful ECV. One patient in each group underwent cesarean delivery immediately following ECV for non-reassuring fetal status. A knot was found in one umbilical cord (CSE) and no pathology was identified in the second case (SYS).

The duration of the ECV attempt was shorter in successful compared to unsuccessful ECV. Ease of the ECV and degree of abdominal relaxation, as assessed by the

obstetrician, were greater in subjects who had successful versus unsuccessful ECV (Table 4).

Discussion

The main finding of this study was that CSE analgesia did not increase the success rate of ECV for breech presentation or the rate of subsequent vaginal delivery compared to systemic opioid analgesia. We selected CSE analgesia for this clinical trial because we sought to determine if an increase in ECV success could be achieved with a sub-anesthetic neuroblockade, in other words neuraxial *analgesia*. It has been postulated that procedural success may be associated with more forceful transabdominal manipulation, but that this may increase the incidence of placental abruption, FHR abnormalities and need for emergency cesarean delivery, and that neuraxial analgesia/anesthesia may allow the obstetrician to apply more force and thus increase the risk of adverse outcome.¹¹

ECV has been reported to be safe, but there are limited data on the safety of using neuraxial anesthesia or analgesia for ECV.³ A potential benefit of neuraxial analgesia is the ability to convert to neuraxial anesthesia for emergency cesarean delivery, although the need for this appears to be quite low.³ The results of this investigation are reassuring, but the low incidence of adverse events combined with a small sample size make conclusions about safety uncertain. Analysis of FHR pattern in all patients demonstrated no deleterious effect of CSE analgesia compared to systemic opioid analgesia. Patients in the CSE group also had a more rapid return of a reactive FHR tracing with 74% of the FHR tracings reassuring by the time the procedure was started; hence, CSE may provide more immediate

Table 2 Outcome and obstetrician post-procedure assessments

	CSE (n = 47)	SYS (n = 48)	P
Analgesia initiation to version initiation interval (min)	20 [16-25]	7 [4-7]	<0.01
Duration of version (min)	5 [3-10]	5 [3-8]	0.92
Obstetrician assessment of version difficulty [‡]			0.25
Very difficult	21	19	
Difficult	13	16	
Easy	6	10	
Very easy	7	2	
Obstetrician assessment of abdominal relaxation			<0.01
Poor	2	6	
Fair	4	18	
Good	16	21	
Excellent	25	3	
Nausea			0.02
None	35	45	
Mild	11	3	
Moderate	1	0	

Data are median [interquartile range] or n.

[‡] Obstetrician assessment not available for one case.

Table 3 Fetal heart rate tracing changes following external cephalic version

	CSE (n = 47)	SYS (n = 47) [‡]	P
Variability (n)			0.13
Absent	0	1	
Minimal (1-5 beats/min)	3	0	
Moderate (6-12 beats/min)	44	46	
Decelerations (n)	6	7	0.84
[Decrease FHR >15 beats/min for 15-120 s]			
Persistent decelerations (n)	7	5	0.76
[decrease FHR >15 beats/min for 2-10 min]			
Time to reactivity (min) [†]	13 [9-21]	39 [23-51]	0.02

Data are median [interquartile range] or n.

[‡] Unable to recover one tracing; [†] Time from initiation of analgesia to the development of two 15-beat accelerations [of 15 s duration] occurring within 20 min of each other.

Table 4 Outcomes and obstetrician post-procedure assessments in successful compared with unsuccessful external cephalic versions

	Successful ECV (n = 37)	Unsuccessful ECV (n = 58)	P
Duration of version (min)	2 [1-5]	7 [4-10]	<0.01
Obstetrician assessment of version difficulty*			<0.01
Very easy	9	0	
Easy	14	2	
Difficult	11	18	
Very difficult	3	37	
Obstetrician assessment of abdominal relaxation*			<0.01
Poor	2	6	
Fair	4	17	
Good	12	25	
Excellent	19	9	

Data are median [interquartile range] or n.

*Obstetrician assessment unavailable following one case.

reassurance of fetal well-being during and following ECV.

In the absence of improved procedural success and no difference in the rate of vaginal delivery, neuraxial analgesia may be justified purely on the basis of patient experience, despite the greater requirement to treat hypotension and increased incidence of nausea. Subjects in the CSE group reported lower pain scores and higher satisfaction with this method of analgesia. Pain during ECV without analgesia, although brief, has been reported to be moderate in intensity.¹² Our results agree with a previous study demonstrating lower pain scores in subjects with successful ECV,¹² although no correlation was found between predicted difficulty and pain in the current investigation. Therefore making a recommendation for or against an analgesic intervention based on predicted difficulty cannot be justified.

Other randomized controlled trials examining the impact of neuraxial anesthesia/analgesia on ECV have had conflicting results.⁴⁻⁷ Meta-analyses of neuraxial anes-

thesia techniques versus control suggest a favorable relationship for both epidural and spinal techniques and ECV success, but have not evaluated if this relationship is dose-dependent among the included trials.^{8,11} The three published randomized controlled trials of neuraxial blockade using techniques that resulted in surgical *anesthesia* (epidural 2% lidocaine with or without fentanyl 100 µg,^{4,5} intrathecal bupivacaine 7.5 mg⁶) reported increased ECV success with neuraxial anesthesia compared to control or no analgesia. In contrast, the current study and one other randomized trial in which neuraxial *analgesia* was compared to no analgesia failed to demonstrate an increase in procedural success.⁷ The results of this study combined with the aforementioned studies suggest that there may be a dose-dependent relationship between neuraxial analgesia/anesthesia and success of ECV. A meta-analysis of data from these trials demonstrates a favorable effect when the studies using neuraxial *anesthesia* are combined, but not when the studies using *analgesia* are combined (Fig 3). Whether

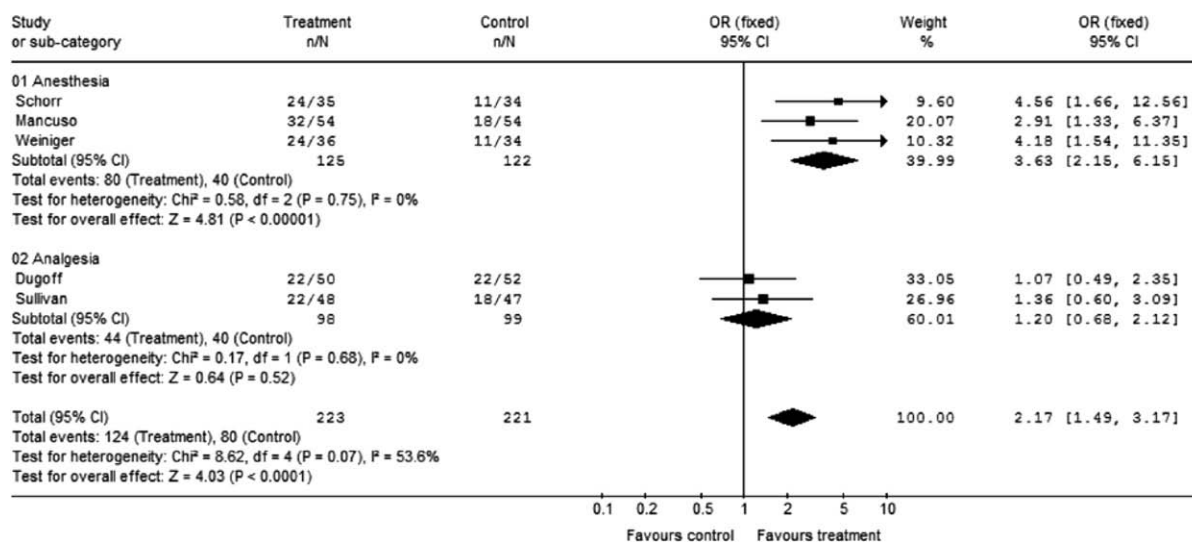


Fig. 3 Meta-analysis of randomized controlled trials comparing neuraxial anesthesia versus analgesia for success of external cephalic version. Neuraxial treatment interventions were as follows: Schorr⁴: epidural lidocaine 2% to achieve T6 anesthesia; Mancuso⁵: epidural 2% lidocaine with epinephrine 1:200 000, 13 mL; Weinger⁶: intrathecal bupivacaine 7.5 mg; Dugoff⁷: intrathecal sufentanil 10 µg plus bupivacaine 2.5 mg; Present study: intrathecal fentanyl 15 µg plus bupivacaine 2.5 mg. The meta-analysis was performed using Review Manager (RevMan) [Computer program]. Version 4.2 for Windows. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2003.

differences in neuraxial techniques influence the success of ECV bears further study.

There are several limitations to the study. Our study was underpowered (power = 0.37) to detect the 16% difference in the rate of successful cephalic version between groups that we actually observed. A sample of 290 subjects would be necessary to detect this difference. The overall ECV success rate of 39% was lower than the 50% rate that we used in our sample size calculation. This success rate was also lower than the institutional success rate of non-study participants during the study period (47%). The reason for differences in success rates is unclear and may reflect exclusion of patients with transverse lie in the study, or a bias against enrolling subjects with a greater likelihood of ECV success, such as multiparous patients. The large number of eligible subjects that were not approached for inclusion primarily at the request of the obstetrician may reflect this selection bias. An additional limitation of this study was that neither anesthesiologists and obstetricians, nor patients were blinded to group assignment.

Conclusion

Combined spinal-epidural analgesia did not increase the success rate of ECV, or increase the incidence of subsequent vaginal delivery, compared to systemic opioid analgesia. However, pain scores were lower and patient satisfaction was higher with CSE analgesia. No differences in fetal heart rate pattern were detected between

groups, but time to reactivity was shorter in the CSE group.

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