

The optimal anesthesia method for external cephalic version (ECV): a randomized controlled trial

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Research article

Keywords: epidural anesthesia, combined spinal-epidural anesthesia, breech presentation, external cephalic version

Posted Date: August 12th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-52916/v1>

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Abstract

Background: The aim of the study is to investigate the success rate of ECV and relevant complications with intrathecal analgesia for singleton breech pregnancy.

Methods: Sixty pregnant women received obstetrical regular prenatal care were randomly divided into EA group(epidural anesthesia, n = 30), CSEA group(combined spinal-epidural anesthesia, n = 30), control group(no analgesia, n = 30). The primary outcome of our study was the success rate of ECV confirmed by ultrasound. Visual analogue scale,, the rate of cesarean section and relevant side effect were recorded.

Results: The success rate of spontaneous inversion to cephalic version was 76.7% in EA group, which was higher than that in CSEA group (53.3%) and control group (46.7%) (p = 0.058 and p = 0.017, respectively). The rate of cesarean section in EA group was 33.3%, which was also lower than that in CSEA group (53.3%) and control group (50.0%), however, the difference was not statistically significant between CSEA group and EA group(p = 0.19). The VAS scores in the EA group and the spinal group were respectively 1.87 ± 2.94 and 1.73 ± 2.71 , obviously better than that of the control group (6.84 ± 3.08) (p = 0.001 and p = 0.001).It was no significant difference between EA group and Control group (p = 0.118). The incidence of hypotension, nausea and vomiting, and fetal heart rate deceleration in CSEA group was significantly higher than that in control group (p = 0.000, p = 0.161, p = 0.129). The occurrence rate of spontaneous fetal heart rate deceleration in the EA, CSEA and control group were 6.7%, 20% and 6.7%, respectively, the differences were not statistically significant.

Conclusions: EA can be more effective to enhance the success rate of spontaneous inversion to cephalic version than CSEA, and CSEA is accompanied with more side effects. Meanwhile, EA or CSEA don't affect the rate of cesarean section of ECV for breech single pregnancy. (Registration number: ChiCTR1800017124)

Trial registration: Name of the registry: Comparison of epidural analgesia with dexmedetomidine or sufentanil combined with ropivacaine: an observational study of multi-center ; Trial registration number: ChiCTR1800017124; Date of registration: 07-13-2018; URL of trial registry record: <http://www.chictr.org.cn/edit.aspx?pid=29087&htm=4>

Background

The incidence of single breech pregnancy was 3–4% [1–3]. Due to increased risk of injury to the neonate during attempted vaginal delivery, 90% of full-term breech-presenting pregnancy women may have to choose cesarean section [4, 5]. ECV is encouraged to reposition the fetus to a vertex presentation to avoid cesarean delivery[6], which is also considered as a cost-effective breech treatment with few complications. The success rate of ECV ranges from 35%-100% based on previous relevant studies, however, 58% of women following an ECV attempt had a cephalic presentation at birth. Even if the benefits are remarkable, ECV is not universally acceptable to women. It has been reported that 9% of women decline ECV because of the pain and fear [7]. Pain increases the contraction of the mother's

abdominal muscles and involuntary abdominal tension, reducing the success rate of ECV [3, 8]. To improve this situation, neuraxial anaesthesia is an effective method to reduce the fear and the muscle contractility of the patients.

The common analgesic methods of EVC mainly include neuraxial anaesthesia and local anaesthesia. Many studies have suggested that neuraxial anaesthesia could improve the success rate of ECV [9, 10, 11] and even reattempt of ECV [12]. It was reported that the optional dose of spinal bupivacaine for ECV was 2.5 mg, However, it is still unknown which neuraxial technique is the optimal method for ECV. So we hypothesized that EA was more effective to enhance the success rate of spontaneous inversion to cephalic version compared to SA. In our study, we evaluated the effects of different intravertebral anesthesia techniques on ECV.

Methods

The patients who having a single breech pregnancy at 35–37 weeks of gestation were enrolled in our study. 90 women who received regular obstetric prenatal care were randomized into three groups: EA group (epidural anaesthesia), CSEA group (combined spinal- epidural anaesthesia) and control group (no analgesia). The procedures followed in this study were in accordance with the ethical standards set by the First Maternal and Child Health Hospital affiliated to Tongji University and approved by the committee(2018-038). The trial was registered at www.chictr.org.cn (Registration number: ChiCTR1800017124). Eligible women signed informed consent prior to receiving analgesia and ECV.

The inclusion criteria included ASA physical status I-II, singleton pregnancy, 35 to 36⁺⁶ weeks of gestation breech-presentation was confirmed by ultrasound, no fetal abnormality, no contraindication for vaginal delivery, or no contraindication to neuraxial anaesthesia. The patients companied with complicated multiple pregnancies, antepartum hemorrhage, placenta previa, premature rupture of membranes, previous caesarean section, obesity, severe pre-eclampsia, and other complicated indications for cesarean section were excluded.

ECV was administrated in a special delivery room, adjacent to the operating room, in the delivery suite with fetal monitoring equipment and ultrasound machines.

All women received a standard dose of tocolytic agent, nifedipine 20 mg orally, before the procedure. The heart rate, blood pressure and pulse oxygen saturation of pregnant women were continuously monitored after entering the room. ECV is stopped if the patient complains of cardiac discomfort or the fetal heart rate is not within a safe range.

All patients received 500 ml of Ringer's lactate solution before anaesthesia. With the patient placed in the left lateral position, epidural puncture was performed at L₂₋₃ interspace in the EA or CSEA group,

In the EA group, the epidural catheter was inserted into the head direction for 3–4 cm, and the test dose was 3 ml of 1.73% lidocaine carbonate. After no abnormal anesthesia levels were observed within 5

minutes, We intermittently gave 10 mL of the anesthetic. In CSEA group, after successful spinal-epidural puncture, bupivacaine hydrochloride was slowly injected into the subarachnoid space with 2.5 mg.

After the spinal anesthesia needle was removed, the epidural catheter was inserted 3 ~ 4 cm deep into the epidural space and 3 ml lidocaine carbonate (1.73%) was injected into the epidural space. The anesthesia level of the two groups was controlled below T6 level.

All procedures of ECV were performed by the senior obstetricians who had more than 5 year experience with the ECV. Ultrasonography examination to verify fetal orientation and placental position and fetal cardiotocographic monitoring (non-stress test, NST) were performed before ECV.

A detailed description of the external cephalic version protocol, timing and techniques has been previously reported [13]. Whether the ECV was achieved or not, cardiotocographic and ultrasonographic monitoring was performed again to ensure the safety of the fetus before the patient left the delivery room.

Visual analogue score (VAS) was recorded to represent the pain level of pregnant women (Pain scores range from 0 to 10, 0 indicates painless, and 10 indicates severe pain) The numbers of successful ECV, the proportion of occipital presentation in delivery, the way of delivery (the proportion of instrument midwifery and cesarean section), the adverse reactions of the fetus and the pregnant women were recorded.

Statistical analysis

The quantitative data were expressed as mean \pm standard deviation, When variance between groups showed homogeneity, we compared with different groups using t-test; enumeration data were expressed by a percentage, which were compared using chi-square test. Data should be entered in 2 columns, then descriptive statistics and crosstab were used. $P < 0.05$ indicates that the difference is statistically significant. All statistical tests were performed using a statistical package (Statistical Package for the Social Science for window version 17.0, SPASS Inc., Chicago IL).

Results

1. Flow diagram of study and demographic data

A total of 98 women meets inclusion criteria for this study, of these, are randomized and 90 women receive allocated intervention (Fig. 1, flow diagram of study). Seven women don't receive allocated intervention because of those patients suffering from some diseases including heart disease history ($n = 3$), scoliosis ($n = 2$) and fever ($n = 2$). Four patients declined to further participate to study.

2. Characteristics and delivery outcomes of primiparas

As shown in Table 1, there was no significant difference in the age, the body mass index (BMI), gestational weeks and neonatal weight($p > 0.05$).

Table 1
Characteristics and delivery outcomes of primiparas

	Control	EA	CSEA
Age (yr)	28.0 ± 3.1	27.7 ± 2.3	29.0 ± 1.4
BMI(Kg/m ²)	20.4 ± 1.7	20.5 ± 1.6	21.4 ± 1.3
Gestation (wk)	35.0 ± 1.9	35.0 ± 2.1	36.0 ± 2.7
Weight of neonates (g)	3350 ± 390	3350 ± 370	3340 ± 350
All data were presented mean ± SD. Statistically significant difference was analysed by t-test. $P > 0.05$			

3. VAS score, success rate in EVC and ratio of cesarean section

VAS score, success rate in EVC and ratio of cesarean section was shown in Table 2. The pain scores of the pregnant women in the EA group and the CSEA group were respectively 1.87 ± 2.94 and 1.73 ± 2.71 , obviously better than that of the control group (6.84 ± 3.08) ($p = 0.001$ and $p = 0.001$). There was no significant difference in pain score between EA group and CSEA group. The success rate of spontaneous inversion to cephalic version in EA group was 76.7%, which was higher than that in CSEA group (53.3%) and control group (46.7%) ($p = 0.058$ and $p = 0.017$, respectively). The rate of cesarean section in EA group was 33.3%, which was also lower than that in CSEA group (53.3%) and control group (50.0%). The difference was not statistically significant ($p = 0.19$ and $p = 0.118$).

Table 2
Success rate in ECV and ratio of cesarean section among three groups

	Control	EA	CSEA	P-value
Successful ECV	14(46.7%)	23(76.7%)	16(53.3%)	\$P = 0.017 *p = 0.606 #p = 0.058
VAS score	6.84 ± 3.08	1.87 ± 2.94	1.73 ± 2.71	\$p = 0.001 *p = 0.001
CS delivery rate	16(53.3%)	10(33.3%)	15(50.0%)	\$P = 0.118 *p = 0.796 #p = 0.19
\$EA group VS. Control group. * CSEA group VS. Control group. #CSEA group VS. EA group. All data were presented as n (%) or mean ± SD. Statistically significant difference was analysed by t-test or Fisher's exact test as appropriate.				

4. Complications and adverse reactions of parturients in three groups

Complications and adverse reactions of parturients in three groups were shown in Table 3. The incidence of hypotension, nausea and vomiting, and fetal heart rate deceleration in CSEA group was significantly higher than that in control group ($p = 0.000$, $p = 0.161$, $p = 0.129$). The rate of spontaneous fetal heart rate deceleration in the EA, CSEA and control group were 6.7%, 20% and 6.7%, respectively. The difference is not statistically significant. No placental abruption occurred in three groups during ECV. There was no significant difference in the incidence of premature delivery and umbilical cord around the neck among the three groups.

Table 3
Complications and adverse reactions of parturients among three groups (% ,n = 30)

	Control	EA	CSEA	P-value
Hypotension	2 (6.1)	4(11.6)	17 (57.3)	\$p = 0.389 *p = 0.000 #0.000
Nausea and vomiting	1(3.7)	2(5.4)	4(13.1)	\$p = 0.389 *p = 0.161 #0.389
Transient fetal bradycardia	2(6.7)	2(6.7)	6(20)	\$p = 1 *p = 0.129 #p = 0.129
Placenta abruption	0	0	0	-
Premature delivery	1(2.7)	1(2.9)	1(3.1)	-
Umbilical cord around neck	5(18.5)	5(16.3)	6(20.1)	-
\$ EA group VS. Control group. * CSEA group VS. Control group. # CSEA group VS. EA group. All data were presented as frequency (percentage). Statistically significant difference was analysed by chi-square test as appropriate.				

Discussion

In our study, the VAS scores of EA and CSEA group was significantly lower than the control group. So intravertebral anesthesia can relieve the pain of the mother, which was consistent with previous studies included pain and satisfaction[9, 11, 13]. Neuraxial analgesia induces motor nerve block, and improves abdominal muscular relaxation and relieve maternal anxiety. There has been controversy over which intravertebral technique provides the best conditions for ECV success. Previous studies have reported that spinal block has lower success rates for ECV comparing lumbar anesthesia or epidural block with non-anesthesia. However, these different success rates may be due to dose effects rather than technical effects [10, 14, 15].

In our study, referring to the routine methods of similar studies in other teams, we gave pregnant women full analgesia rather than deep anesthesia. EA and CSEA were showed the same level of block, and the degree of spinal nerve block in the thoracolumbar segment was more severe in EA. As we have known, the advantages of CSEA on perineal analgesia were significantly greater than those of EA. The study of Sullivan et al. [13] showed that the CSEA could not improve the success rate of the ECV, although VAS scores of parturients were significantly reduced and satisfaction degree increased, but there were also

increased occurrence rate of hypotension in CSEA group in our study. The results of our study also showed that EA could improve the success rate and decrease the occurrence rate of cesarean section. It is obvious that CSEA can not improve the success rate of transient ECV, which may be associated with the high incidence of hypotension.

Limitations

There are some limitations in our study. The sample size in this study is relatively small. In the future work, we will carry out relevant studies with large samples to further explore the CSEA risks and strategies in ECV treatment.

Conclusion

our study indicated that EA other than CSEA could improve the success rate of ECV, and EA or CSEA don't affect the rate of cesarean section of ECV treatment for breech single pregnancy.

Abbreviations

ECV
external cephalic version;

CSEA
combined spinal-epidural anesthesia;

BMI
body mass index;

Declarations

Availability of data and materials

The data will be accessible by contacting the corresponding author of this study.

Ethics approval and consent to participate

Ethical approval for the study was acquired from the Institutional Review

Board on the First Maternal and Child Health Hospital affiliated to Tongji University and approved by the committee(2018-038). The trial was registered at www.chictr.org.cn (Registration number: ChiCTR1800017124). Enrollment of the respondents was voluntary, and all patients gave written consent to participate in the study.

Consent for publication

Not applicable.

Competing interests

The authors have no conflicts of interest to declare

Funding

Shanghai Jiao Tong University School of Medicine, Innovation center of Translational Medicine Collaboration(No: TM201729); Youth talent fund and Perinatal Potential Subject of International Peace Maternity and Child Health Hospital, Shanghai Jiao Tong University School of Medicine.

Authors' contributions

Study design: H.L. and Z.Y. Data collection: H.L, X.W., W.Y., M.Q., and Y.W. Data analysis: Z.Y. and W.Z., Writing of manuscript: X.W and Y.Z. Review of manuscript: W.Z and Z.Y.

Acknowledgments

The authors would like to thank the nurses and midwives of the delivery room of the the First Maternal and Child Health Hospital affiliated to Tongji University for assisting in this study.

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Figures

CONSORT Flow Diagram

The optional anesthesia method for external cephalic version (ECV):

a randomized controlled trial

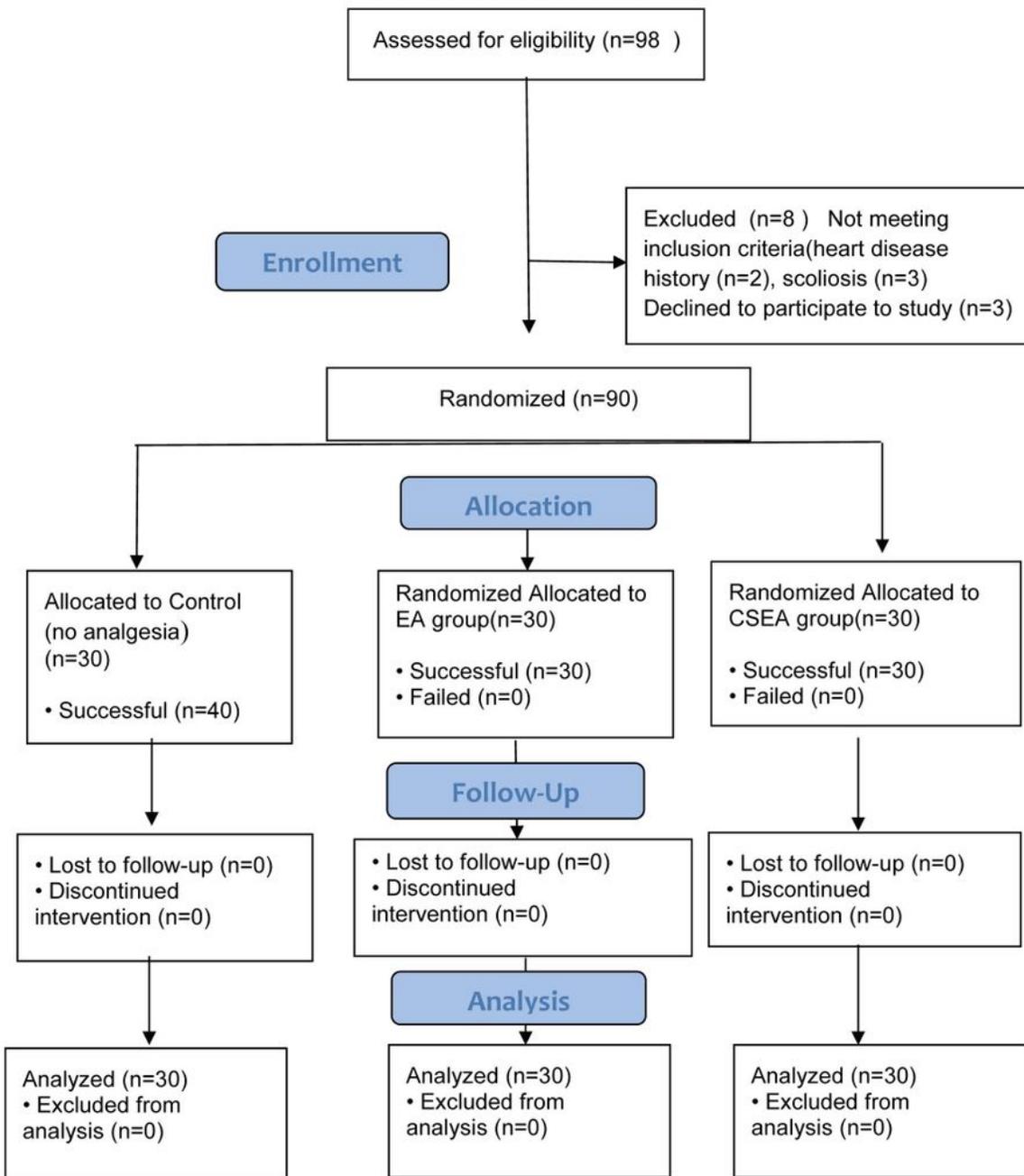


Figure 1

flow diagram of study