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ORIGINAL RESEARCH

Comparison of Ultrasound-Guided Caudal Epidural Blocks and Spinal Anesthesia for Anorectal Surgery: A Randomized Controlled Trial

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ABSTRACT

Introduction: The aim of this study is to observe the effect of spinal anesthesia (SA) and ultrasound-guided caudal epidural blocks (CEB) on perioperative satisfaction in patients undergoing anorectal surgery.

Methods: A group of 106 patients were randomly allocated to receive either SA (the SA group) or CEB (the CEB group), and 11 patients were excluded. Finally, 95 patients were left, with 48 in the SA group and 47 in the CEB group for data analysis. The primary endpoint was patient satisfaction with the quality of their anesthetic technique. The secondary outcome measures included postoperative pain at 2, 4, 8, 16, 24, and 48 h after surgery at rest, time to first analgesic request, analgesia requirements, incidence of phantom limb syndrome (PLS), time until return of bowel function, time to ambulation, incidence of postoperative nausea and vomiting (PONV), intraoperative mean arterial pressure (MAP) reduction > 20% from baseline, and surgeon satisfaction.

Results: A significantly lower proportion of patients in the SA group was highly satisfied with the quality of their anesthetic technique compared with the CEB group (20.8% versus 68.1%). NRS scores at rest were significantly lower at 4, 8, 16, and 24 h after surgery in the CEB group compared with the SA group. The time to first analgesic request was significantly earlier for patients in the SA group compared with patients in the CEB group. Analgesia requirements, the incidence of PLS, the incidence of PONV, and intraoperative MAP reduction > 20% from baseline were significantly decreased in the CEB group. There were no significant differences between the groups in time until return of bowel function, surgeon satisfaction, or time to ambulation.

Conclusions: Ultrasound-guided caudal epidural blocks have higher patient satisfaction compared with spinal anesthesia.

Trial Registration: This study was registered in the Chinese Clinical Trial Registry (ChiCTR 2000041026) on 06/12/2020.

Keywords: Spinal anesthesia; Caudal epidural blocks; Anorectal surgery; Phantom limb syndrome; Postoperative pain

Shibiao Chen and Aiping Wei contributed equally.

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Key Summary Points
Why carry out this study?
There have been few randomized controlled studies comparing spinal anesthesia (SA) with ultrasound-guided caudal epidural blocks (CEB) in patients undergoing anorectal surgery.
The aim of this study is to observe the effect of SA and ultrasound-guided CEB on perioperative satisfaction in patients undergoing anorectal surgery.
What was learned from the study?
This is the first randomized controlled study to identify that ultrasound-guided CEB in anorectal surgery increased patient satisfaction perioperatively.
Ultrasound-guided CEB is a novel, effective, and promising technique in anorectal surgery and should be used widely.

INTRODUCTION

Minor anorectal diseases occur with incidence of approximately 5% of the adult population [1]. Currently, most of these patients can be treated conservatively, and 10% of cases require surgical treatment [2]. Patients undergoing anorectal surgery require deep levels of anesthesia due to dissection and incision in the rich innervation of the region [2]. Anorectal surgery is usually performed under general anesthesia, local infiltration, spinal anesthesia (SA), or caudal epidural blocks (CEB), and each technique has its advantages and drawbacks [3, 4].

SA is the most widely used regional anesthetic technique for anorectal surgery and has the advantages of rapid onset and offset [2]. However, arterial hypotension as well as the extensive sensory and motor block provided by SA in patients undergoing anorectal surgery results in a longer hospital stay. Conversely, CEB can avoid arterial hypotension and extensive sensory and motor block and provide prolonged postoperative analgesia in patients undergoing anorectal surgery [5]. The use of CEB for anorectal surgery may offer some of these benefits and provide prolonged postoperative analgesia, avoiding the need for early systemic analgesics and their potential side effects. The success rate with the blind technique for caudal anesthesia is only 68–75% even in experienced hands due to abnormal sacral anatomy [6], and it is not as widely used in adults as in pediatric patients [7, 8]. However, several studies [9–11] have reported very high success rates (96.9–100%) with ultrasound-guided caudal epidural injection.

To our knowledge, no study has compared SA and ultrasound-guided CEB for anorectal surgery in a randomized controlled trial. The aim of this study is to observe the effect of SA and ultrasound-guided CEB on perioperative satisfaction in patients undergoing anorectal surgery.

METHODS

This study was approved by the ethics committee of First Affiliated Hospital of Nanchang University (approval no. 2021056), and written informed consent was obtained from all subjects participating in the trial. Then, it was registered in the Chinese Clinical Trial Registry (registration no. ChiCTR2000041026). Our study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Patients in the age group of 18–65 years undergoing anorectal surgery with American Society of Anesthesiologists physical status I–II were enrolled. Exclusion criteria was as follows: allergy to local anesthetics, psychiatric problems, bleeding disorders, systemic anticoagulation, peripheral neuropathy, infection at injection site, and diabetes (as diabetic patients often combine multiple systemic complications). The adult patients enrolled in our trial were randomly divided into two groups: the SA group receiving spinal anesthesia and the CEB

group receiving ultrasound-guided caudal epidural blocks.

Randomization and Blinding

Random allocation sequence was performed using a computer program for each patient to prevent bias in our study. The SA group received 1% ropivacaine 20 mg with 5% glucose 1 ml, while the CEB group received 0.5% ropivacaine 20 ml. The group allocation was kept in a sealed envelope by the first investigator. A selected nurse opened the group assignment envelope and prepared the local anesthetic. A third investigator performed spinal anesthesia or caudal epidural blocks according to the group allocation. Postoperative data collection was recorded by another researcher. The patients, surgeons, anesthesiologist, intensive care unit staff, nurses, and other investigators were not aware of the medication assignment. This was a double-blind randomized controlled study.

Surgery and Anesthesia

All patients did not receive any premedication. Electrocardiography, oxyhemoglobin saturation, noninvasive blood pressure, and heart rate were monitored continuously before the anesthesia and thereafter continuously throughout the study.

Enrolled patients underwent SA in the lateral position at the L3–4 level, which is usually preferred with a median approach. A subarachnoid block was completed with a 27-G spinal needle. After verification that the cerebrospinal fluid was freely flowing from the hub, 1% ropivacaine 20 mg with 5% glucose 1 ml was injected for approximately 15 s.

Patients were placed in prone position, and the lumbosacral area was prepared aseptically for injection. We performed CEB using a high-frequency linear ultrasound probe (Mindray, Shenzhen, China). The liner transducer was first placed transversely (axial) proximal to the anus at the midline and where the sacral bone was seen.

The transducer was moved cranially until the two sacral cornua, the base of the sacrum, the sacrococcygeal ligament, and the sacral hiatus appeared. The two sacral cornua and the base of the sacrum appeared as two hyperechoic structures. The sacral hiatus appeared in the hypoechoic region between the hyperechoic structures (Fig. 1). The probe was then turned longitudinally to obtain a sagittal view of the caudal space [12]. CEB was administered with 20 ml 0.5% ropivacaine by an in-plane approach.

No patients received additional local anesthesia intraoperatively, and patients requiring sedation during surgery were given dexmedetomidine. Patient-controlled analgesia (PCA) with intravenous sufentanil was used postoperatively, and 50 mg flurbiprofen axetil was injected i.v. as a supplementary analgesic according to patient demand. All surgeries in our trial were performed by the same group of surgeons.

Study Endpoints

The primary endpoint was patient satisfaction with the quality of their anesthetic technique, which was evaluated using a four-point Likert scale (1, not satisfied; 2, somewhat satisfied; 3, satisfied; 4, highly satisfied) 24 h after surgery, as previously described in the assessment of perioperative and anesthesia care [13]. Secondary outcome measures included postoperative pain at 2, 4, 8, 16, 24 and 48 h after surgery at rest, time to first analgesic request, analgesia requirements (sufentanil and flurbiprofen axetil consumption), incidence of phantom limb syndrome (PLS), time until return of bowel function, time to ambulation, incidence of postoperative nausea and vomiting (PONV), and reduction of intraoperative mean arterial pressure (MAP) $>$ 20% from baseline. At the end of the surgery, the surgeon rated his satisfaction with the operating conditions using a four-point Likert scale (1, not satisfied; 2, somewhat satisfied; 3, satisfied; 4, highly satisfied). During and after SA, patients frequently report a series of abnormal sensations that are manifested in abnormalities of limb motion, temperature, touch, shape, size, and position, and these conditions are called PLS [14]. Postoperative

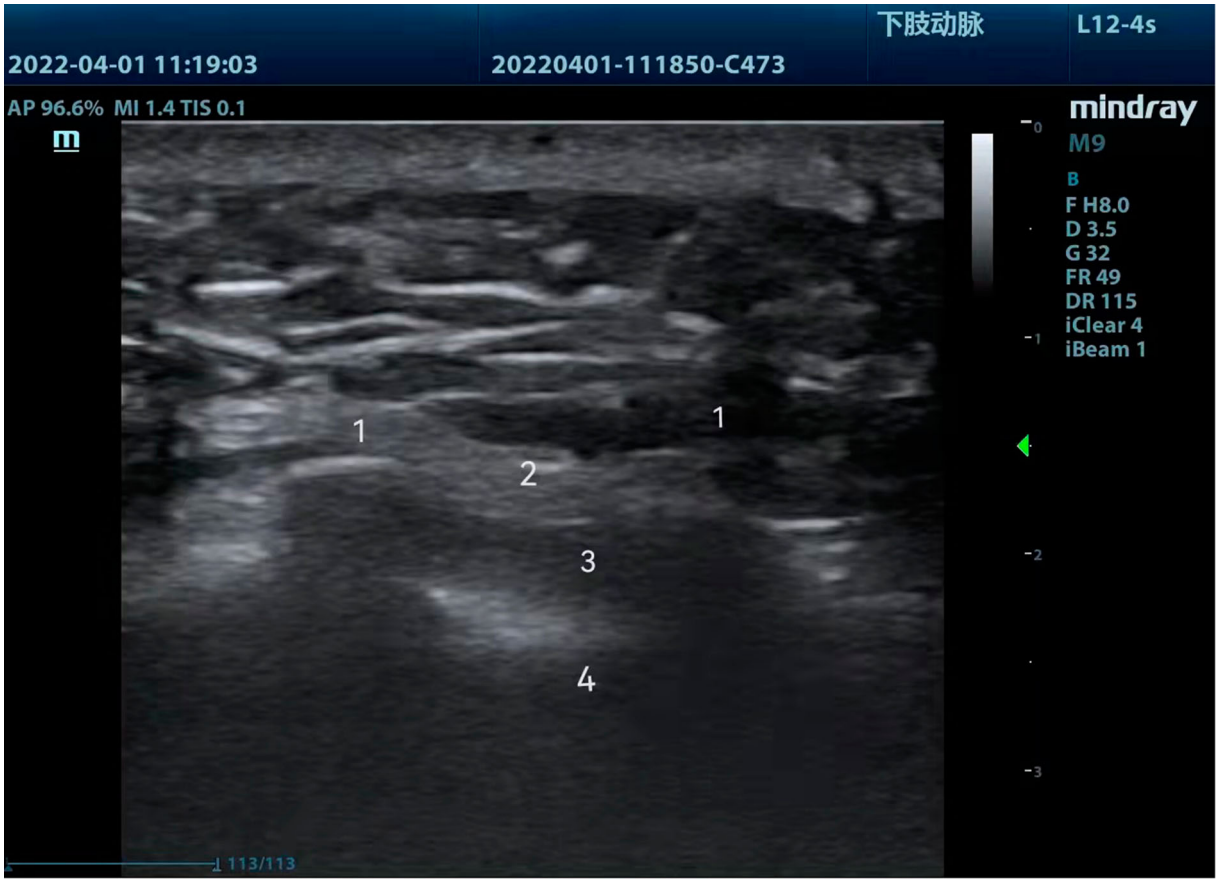

Fig. 1 Ultrasound image of caudal epidural blocks. 1, cornuae of sacrum; 2, sacrococcygeal ligament; 3, sacral canal; 4, base of sacrum, posterior surface

pain was measured using the numerical rating scale (NRS) score, which ranged from 0 (no pain) to 10 (worst severe pain). We carefully explained the PCA and NRS preoperatively to all patients in our study.

Statistical Analysis

A sample size calculation in this study was based on a pilot study ($n = 15$ adult patients per group), which compared patient satisfaction as a primary outcome (2.9 ± 1.8 versus 3.7 ± 0.5). So, 88 adult patients were needed to achieve a type I error of $\alpha = 0.05$, a type II error of $\beta = 0.1$, and a power of 90%, and the dropout rate was 20%. Finally, a minimum of 106 patients were needed in our study.

Statistical analysis was performed using SAS software (version 9.1.3, North Carolina, USA). The Student t test/Mann–Whitney U test were used to compare the two groups in case of continuous data. For discrete variables, we calculated percentages. To compare differences between groups in patient and surgeon satisfaction, we used the χ^2 test or Fisher's exact test. Pain after surgery and intraoperative mean arterial pressure were compared with repeated-measures (two-way) analysis of variance between SA group and CEB group. A probability value of less than 5% was considered significant.

RESULTS

Study Subjects

A total of 106 patients were randomized in the study. Six patients from the SA group and five

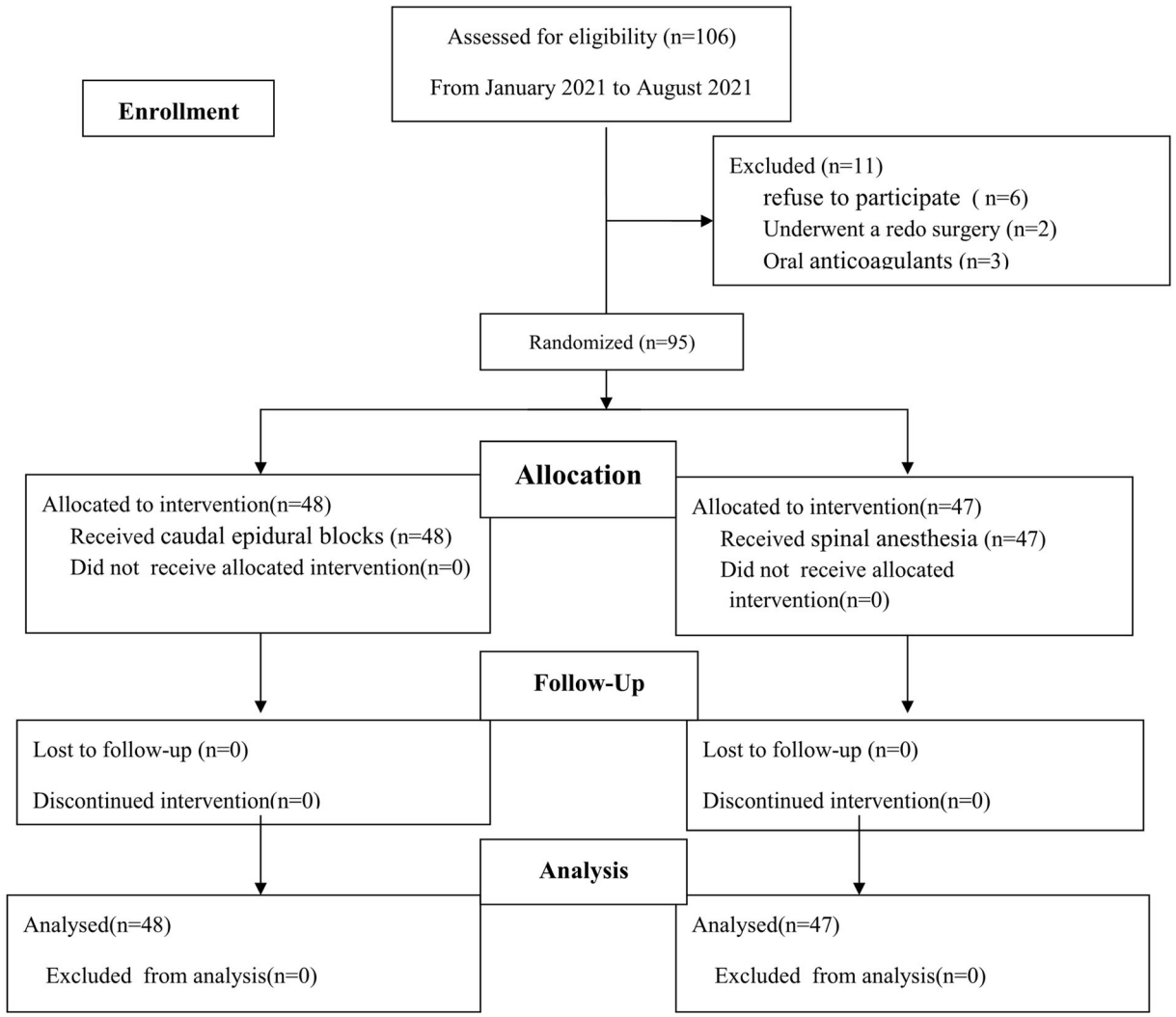

Fig. 2 Patient flow diagram

patients from the CEB group were excluded from the study for the following reasons: refuse to participate (six), redo surgery (two), and oral anticoagulants (three). Finally, 95 patients were left in our study, with 48 in the SA group and 47 in the CEB group for data analysis (Fig. 2). Patient demographics and type of procedure showed no statistically significant differences between SA group and CEB group (Table 1).

Clinical Outcomes

A significantly lower proportion of patients in the SA group was highly satisfied with the quality of their anesthetic technique compared with the CEB group (Table 2). NRS scores at rest were significantly lower at 4, 8, 16, and 24 h after surgery and showed no differences at 2 h and 48 h after surgery in the CEB group compared with the SA group (Fig. 3). The time to first analgesic request was significantly earlier for patients in the SA group than for patients in the CEB group. Analgesia requirements (sufentanil and flurbiprofen axetil consumption), incidence of PLS, incidence of PONV, and intraoperative MAP reduction $> 20\%$ from baseline were significantly lower in the CEB group than in the SA group (Table 2). There were no significant differences between the

Table 1 Patient demographics and surgical characteristics

	SA group ($n = 48$)	CEB group ($n = 47$)	*P* value
Age (years)	45.3 ± 20.5	47.4 ± 18.9	0.75
Height (cm)	165.4 ± 15.9	169.5 ± 16.2	0.69
Weight (kg)	59.7 ± 19.8	57.7 ± 20.3	0.47
Sex ratio (M/F)	22/26	20/27	0.53
ASA classification (I/II)	30/18	27/20	0.86
Duration of surgery (min)	47.6 ± 11.4	46.3 ± 10.7	0.64
Intraoperative bleeding volume (ml)	25.5 ± 5.5	26.5 ± 6.5	0.42
Intraoperative crystalloids (ml)	430 ± 100	400 ± 120	0.38
Anesthesia operation time (min)	10.5 ± 3.2	11.1 ± 2.3	0.36
Intraoperative dexmedetomidine dosage (μg/kg)	3.5 ± 1.4	3.3 ± 1.6	0.57
Main diagnosis			0.49
Hemorrhoids	30	28	
Anal fissure	12	14	
Anal fistula	6	5	

The SA group patients received spinal anesthesia; the CEB group received caudal epidural blocks
ASA American Society of Anesthesiologists

groups in time until return of bowel function, surgeon satisfaction, or time to ambulation (Table 2).

DISCUSSION

A randomized controlled trial demonstrated that the use of ultrasound-guided CEB in patients undergoing anorectal surgery increased patient satisfaction in terms of providing effective analgesia for 24 h after surgery and reducing analgesia requirements, incidence of PLS, incidence of PONV, and intraoperative MAP reduction > 20% from baseline compared with spinal anesthesia. CEB could also delay the time to first analgesic request.

The success rate of the blind technique for CEB is not high [15, 16]. This high failure rate could be attributed to the soft tissues over the bone and anatomic variations of the bony sacrum, which include narrowing of the sacral canal, displacement of the hiatus, and ossification of the sacrococcygeal membrane that can occur in adult patients [17]. However, some trials in various ethnic populations have found very high success rates (96.9–100%) of ultrasound-guided CEB [9, 11, 18]. Our study also found that ultrasound-guided CEB can safely be used in patients undergoing anorectal surgery, with a 100% success rate. Although the anatomical variation of the sacrum is relatively great among adults, the sacral hiatus can be easily identified on ultrasound imaging in different patients. Ultrasound-guided CEB would be a practical neuraxial anesthetic option for adult patients undergoing anorectal surgery. To our knowledge, there have been few randomized controlled studies to compare SA with ultrasound-guided CEB in patients undergoing anorectal surgery.

PLS induced by regional anesthesia can be distressing and unpleasant to patients, lengthen the time to recovery and resumption of normal activity, and increase the intensity of other postoperative symptoms and complications

Table 2 Intra- and postoperative clinical outcomes

	SA group ($n = 48$)	CEB group ($n = 47$)	*P* value
Time to first analgesic request (min)	259 ± 53	759 ± 65	< 0.01
Postoperative sufentanil consumption (μg)	67 ± 10	35 ± 12	< 0.01
Flurbiprofen axetil consumption (mg)	150 (100–200)	50 (0–100)	< 0.01
Incidence of phantom limb syndrome (%)	40 (83.3%)	2 (4.3%)	< 0.01
Incidence of PONV (%)	10 (20.8%)	5 (10.6%)	< 0.05
Patient satisfaction, *n* (%)			< 0.01
Highly satisfied	10 (20.8%)	32 (68.1%)	
Satisfied	37 (77.1%)	15 (31.9%)	
Somewhat satisfied	1 (2.1%)	0	
Not satisfied	0	0	
Reduction > 20% from baseline of MAP	12 (25.0%)	5 (10.6%)	< 0.05
Time until return of bowel function (h)	31.2 ± 4.3	29.1 ± 5.4	0.56
Time to ambulation (h)	15.7 ± 6.3	12.4 ± 7.2	0.87
Surgeon satisfaction, *n* (%)			0.37
Highly satisfied	35 (72.9%)	32 (68.1%)	
Satisfied	13 (27.1%)	15 (31.9%)	
Somewhat satisfied	0	0	
Not satisfied	0	0	

The SA group patients received spinal anesthesia; the CEB group received caudal epidural blocks
PONV postoperative nausea and vomiting, *PLS* phantom limb syndrome, *MAP* mean arterial pressure

[19]. Our results show that the incidence of PLS was significantly lower in the CEB group (4.3%) compared with the SA group (83.3%). Wang et al. [20] found that PLS increased the chance of experiencing postoperative fatigue, physical discomfort, and emotional upset. Therefore, this is also one of the reasons for the decline in patient satisfaction with spinal anesthesia.

Our results indicated that ultrasound-guided CEB could provide longer postoperative analgesia compared with the SA technique. In addition, CEB could reduce sufentanil and flurbiprofen axetil consumption postoperatively and delay the time to first analgesic request. The reduced incidence of PONV in the CEB group was probably caused by the use of a minimal amount of sufentanil and was associated with good analgesic effect of CEB in anorectal surgery. Moreover, extensive sensory and motor block as well as sympathetic block

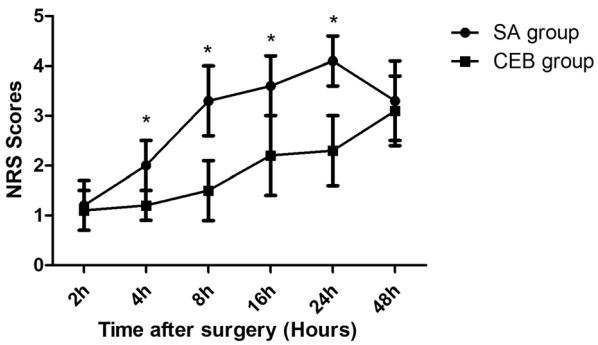

Fig. 3 Pain intensity at rest after surgery measured by NRS scores. *$P < 0.05$ considered statistically significant

provided by SA resulted in arterial hypotension in our study, whereas CEB is an anesthetic option with a reportedly low incidence of hypotension. Therefore, ultrasound-guided CEB in patients undergoing anorectal surgery could greatly increase patient satisfaction and would not reduce surgeon satisfaction. In future clinical work, we will apply ultrasound-guided CEB to more and more anorectal surgery, promote it at academic conferences, and discuss with relevant experts.

There are several limitations to this study. First, the volume and concentration of CEB used in our study was based on our clinical experience. In further trials, the optimum capacity and concentration of CEB in patients undergoing anorectal surgery should be evaluated. Second, pain scores from the NRS are very subjective. Third, patients undergoing anorectal surgery may suffer postoperative pain for weeks, but we did not observe the effect of CEB for a longer period of time.

CONCLUSIONS

This study showed that the use of ultrasound-guided CEB in anorectal surgery increased patient satisfaction by providing effective analgesia for 24 h after surgery, reducing analgesia requirements, decreasing incidence of phantom limb syndrome, incidence of PONV, and intraoperative MAP reduction > 20% from baseline, and delaying the time to first analgesic request.

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Author Contributions. Yang Zhang and Shibiao Chen were responsible for conceived, designed this study and collected the data. Yang Zhang and Aiping Wei were responsible for study execution and manuscript writing. Jia Min and Lei Li was responsible for data analysis. All authors have read and approved the final version of the manuscript.

Disclosures. Shibiao Chen, Aiping Wei, Jia Min, Lei Li, Yang Zhang have nothing to disclose.

Compliance with Ethics Guidelines. This study was approved by the ethics committee of First Affiliated Hospital of Nanchang University (approve number: 2021056) and written informed consent was obtained from all subjects participating in the trial. Then it was registered in the Chinese Clinical Trial Registry (registration number ChiCTR2000041026).Our study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Data Availability. The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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