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ORIGINAL RESEARCH

Effect of Epidural Catheter Design on Analgesic Efficacy During Programmed Intermittent Epidural Boluses: A Randomized Double-Blinded Controlled Trial

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Purpose: To compare analgesic outcomes between single- and multi-orifice epidural catheters at a 360-mL/h delivery rate during programmed intermittent epidural bolus.

Patients and Methods: In this prospective randomized double-blinded controlled trial, 102 healthy nulliparous parturients requesting labor analgesia at the Shanghai First Maternity and Infant Hospital were enrolled from July to September 2023. Participants were given either single- or multi-orifice catheters for epidural analgesia (0.1% ropivacaine with 0.3 μg/mL of sufentanil; 10 mL every 45 min at 360 mL/h). The primary outcome was ropivacaine consumption per hour, calculated as the total amount of ropivacaine administered divided by the duration of labor analgesia (mg/h).

Results: Median ropivacaine consumption per hour was not significantly different: 12.6 mg/h [11.6–13.2 mg/h] for single-orifice vs 12.8 mg/h [12.3–13.3 mg/h] for multi-orifice catheters (difference 29%; 95% confidence interval [CI], –10.2 to 68.2%; P=0.241). No significant differences were found in patient-controlled epidural analgesia boluses requested and delivered, time to first bolus request, or the number of clinician-administered boluses. However, adequate analgesia at 20 min was higher with single-orifice catheters (84.0% vs 63.5%, difference 22.5%; 95% CI: 9.2% to 35.1%, P=0.019). Median times to adequate analgesia were 8 min [4–16] vs 15 min [9.5–22.5] for single- and multi-orifice catheters (P=0.002). Pain scores differed only at 6 and 18 min. There were no differences in the incidence of motor or unilateral block, side effects, maternal satisfaction, or catheter-related complications between the two groups.

Conclusion: Single-orifice catheters did not enhance analgesia quality during labor maintenance under a 360-mL/h programmed intermittent epidural bolus delivery rate but were linked to more rapid analgesic onset than multi-orifice catheters.

Keywords: labor analgesia, programmed intermittent epidural bolus, neuraxial anesthesia, labor

Introduction

Since programmed intermittent epidural bolus (PIEB) was introduced to maintain labor analgesia in 2006,[1] it has been shown to provide a preferable analgesic effect with reduced consumption of local anesthetics, less motor block, fewer patient-controlled epidural analgesia (PCEA) boluses, and a lower incidence of instrumental vaginal deliveries. Additionally, PIEB improves maternal satisfaction compared to continuous epidural infusion (CEI) methods.[2,3] Although many studies have explored variations in PIEB regimens (drug concentration, bolus dose, interval, bolus

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delivery rate) to optimize labor analgesia,[4–6] less attention has been given to the specific design features of epidural catheters associated with this technique.[7]

The effectiveness of epidural analgesia depends on several factors, including catheter design. Historically, the number of orifices in an epidural catheter has been linked to analgesic outcomes. Multi-orifice catheters have been reported to provide better analgesic efficacy than single-orifice catheters, given that the presence of multiple orifices can enhance drug distribution within the epidural space.[8–11] However, these studies were conducted using conventional continuous infusion or manual bolus techniques. Our in vitro study[12] revealed significant differences in flow and drug distribution between single- and multi-orifice catheters under varying rates of programmed intermittent bolus administration. Theoretically, anesthetic distribution within the epidural space is essential for adequate labor analgesia, especially when coverage of the lumbar epidural space (low thoracic and sacral dermatome coverage) is required. In a subsequent clinical trial,[13] we found that single-orifice catheters outperformed multi-orifice catheters in terms of faster analgesic onset, lower local anesthetic consumption, and reduced PCEA use at a PIEB delivery rate of 480 mL/h. However, whether this effect persists at a commonly used rate of 360 mL/h remains unclear.

This prospective, randomized, double-blind, controlled trial aimed to compare the analgesic outcomes of single-orifice and multi-orifice catheters at a 360-mL/h delivery rate during PIEB. We hypothesized that single-orifice catheters would improve labor analgesia and reduce ropivacaine consumption.

Materials and Methods

Study Population

This prospective, randomized, double-blind study was approved by the Institutional Ethics Committee of Shanghai First Maternity and Infant Hospital (Ethics No: KS23161; March 20, 2023). This trial adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines and was registered with the Chinese Clinical Trial Registry (No: ChiCTR2300072694; principal investigator: Weijia Du; date of registration: June 21, 2023; Chairperson of the ethics committee: Ye Lou) before patient enrolment.

The inclusion criteria were as follows: healthy, term, nulliparous women, aged 20 to 40 years, with an American Society of Anesthesiologists physical status II; singleton pregnancies with vertex presentation; active labor with progressive cervical dilation; requesting epidural analgesia with cervical dilation between 2 and 5 cm; and a numerical rating scale (NRS) pain score >5 (NRS: 0 = no pain and 10 = worst pain imaginable). Exclusion criteria included a body mass index >40 kg/m, history of drug abuse, use of pharmacological analgesics within 4 h before the epidural request, contraindications to epidural anesthesia, conditions increasing the risk of caesarean delivery (ie, placenta previa, history of uterine anomalies or surgery), and fetal abnormalities. Eligible participants were given verbal and written information, and all provided written informed consent. Participants were excluded from further studies if delivery occurred within 1 h of epidural catheterization.

Randomization and Concealment of Group Assignments

Participants were randomly assigned in a 1:1 ratio using fixed blocks of four, without stratification factors, generated by one of the investigators using SAS 9.4 (SAS Institute, Cary, NC). They were allocated to receive either a single-orifice epidural catheter (Group A) or a multi-orifice catheter (Group B). To ensure allocation concealment, staff not involved in the study placed group assignments in opaque, sealed envelopes. The anesthesiologist responsible for catheter placement based on group assignment was not included in the study. All other study personnel, including the nurse conducting cervical examinations and pain assessment at the request for labor analgesia, the research nurse performing the follow-ups, and the participants, were blinded to group allocation.

Epidural kits labelled for Group A contained a 19-G, single-orifice, open-end, wire-reinforced, polyurethane, and flexible catheter, whereas kits for Group B contained a 19-G, four-lateral-hole, wire-reinforced, polyurethane, and flexible catheter (Arrow International, Westmeath, Ireland). All components of the epidural kits were identical except for the epidural catheter. The two types of catheters were manufactured by the same company, with different hole layouts being the only difference.

Treatment Protocol

Epidural Catheter Placement

Standard maternal and fetal monitoring was performed, including baseline maternal heart rate and non-invasive arterial blood pressure (BP) measurements. An intravenous catheter was inserted, and 500 mL of lactated Ringer's solution was infused over 15 min during the epidural procedure. The attending anesthesiologist placed all catheters. Analgesia was initiated with the parturient in the right lateral decubitus position, targeting the L2–L3 interspace using pre-procedural spinal ultrasound assessment. After identifying the epidural space via the loss-of-resistance technique, a single- or multi-orifice epidural catheter was advanced 4 cm into the epidural space, with the needle bevel-oriented cephalad, and secured. The parturients were then placed in a supine position with left uterine displacement. After confirming negative aspiration for blood and cerebrospinal fluid, a 3-mL test dose of 1.5% lidocaine with 15 μg of epinephrine was administered. Parturients with a positive test dose were withdrawn from the analysis. These cases were managed according to standard clinical practice: the epidural catheter was either repositioned or replaced, and alternative analgesia was provided as needed. Complications such as intravascular or intrathecal placement, paresthesia, or difficulty threading the catheter were recorded.

Initiation of Labor Analgesia

Epidural analgesia was initiated with a loading bolus of 12 mL of 0.1% ropivacaine mixed with sufentanil (0.3 μg/mL). This was administered 3 min after administering the test dose, delivered in 6-mL increments every 2 min. Adequate analgesia was defined as an NRS score ≤ 2 during two consecutive uterine contractions with no request for additional analgesia, confirmed by tocodynamometer tracings.

Maintenance of Labor Analgesia

After adequate analgesia was established, an epidural pump (Apon ZZB-IV; Jiangsu Apon Medical Technology, Jiangsu, China) was initiated to deliver PIEBs of 10 mL every 45 min, the first bolus was administered 45 min after the loading bolus. Additionally, all parturients had access to PCEA, which allowed 8-mL boluses with a 10-min lockout interval between PCEA or PIEB/PCEA boluses. The solution used for PIEB and PCEA was 0.1% ropivacaine with sufentanil (0.3 μg/mL). The injectate rate was set at 360 mL/h, with a 40-mL hourly maximum volume.

Pain scores were recorded using NRS, and sensory blockade (assessed via cold stimulation) and motor strength were assessed every 2 min during the first 20 min, and subsequently at 30 min, 60 min, and then at 60-min intervals until delivery. Motor strength was measured using the modified Bromage score: 0= No impairment; 1= Inability to raise the extended leg but preserved knee and foot movement; 2= Inability to raise the extended leg or flex the knees, with retained foot movement; 3= Complete block (no movement at ankles, feet, or knees). Motor blockade was defined as a modified Bromage score ≥ 1. The sensory blockade level to cold was assessed bilaterally along the mid-clavicular line, from the caudal to the cephalad. The upper sensory block level was recorded as the highest dermatome, where the parturient no longer felt normal sensations compared to the forehead or cheek. Dermatomal levels in the lower extremities were tested at the inguinal crease at the midclavicular line (L1), anteromedial thigh (L2), medial femoral condyle above the knee (L3), medial malleolus (L4), dorsum web between the great and second toes (L5), lateral calcaneus (S1), and midpoint of the popliteal fossa (S2). The study continued for 6 h post-initial dose or until full cervical dilation, whichever occurred first.

Standard care at the institution included non-invasive BP monitoring every 2 min during the first 20 min, then at 30- and 60-min intervals until delivery, along with continuous maternal heart rate, pulse oximetry, and fetal heart rate monitoring. Maternal hypotension episodes (systolic BP <90 mmHg or <80% of baseline) and fetal bradycardia (<110 bpm for >10 min) were recorded and treated properly. The parturient was excluded from the analysis if delivery occurred within 1 h of epidural catheterization. Data on analgesic usage were extracted from the investigator's history of pump use after delivery.

Inadequate Analgesia

In the event of an NRS score >3 or a maternal request for additional medication 20 min after the loading bolus, the parturient was instructed to self-administer the PCEA bolus. If the pain persisted after two PCEA boluses within 20 min,

a provider bolus of 5 mL of 0.2% ropivacaine was administered manually. If necessary, an additional 5 mL was administered after a 10-min interval. If adequate analgesia was still not achieved, the epidural catheter was replaced, and the parturient was withdrawn from the analysis.

Outcomes

The primary outcome was ropivacaine consumption per hour, calculated as the total amount of ropivacaine administered (via pump and provider-administered boluses) divided by the duration of labor analgesia (mg/h). The duration of labor analgesia was defined as the time from pump initiation to delivery. Secondary outcomes included the percentage of parturients with adequate analgesia 20 min after the initial epidural bolus, time to achieve adequate analgesia, PCEA boluses requested and delivered, time to first PCEA bolus request, and the number of clinician-administered boluses. Other analgesic characteristics such as the frequency of motor block and unilateral blockade were also collected.

Additional data collected included demographic information, obstetric variables, maternal satisfaction (assessed 24 h after delivery using a 5-point rating scale: 5 = excellent, 4 = very good, 3 = good, 2 = fair, 1 = poor), and the incidence of side effects such as pruritus, vomiting, postpartum headache, hypotension, and fetal bradycardia.

Statistical Analysis

The primary outcome was ropivacaine consumption per hour. Data from a previous study[13] involving 182 parturients indicated that the mean (standard deviation) ropivacaine used per hour was 14.45 mg (1.87 mg) with a single-orifice catheter and 15.49 mg (2.10 mg) with a multi-orifice catheter. A sample size of 59 participants per group provided 80% power to detect this difference at $\alpha = 0.05$ using a two-sided *t*-test. To account for 5% dropouts and catheter failures, we aimed to enroll 124 participants. Sample size calculations were performed using PASS software (NCSS, Kaysville, UT).

Data from this randomized controlled trial were analyzed on an intention-to-treat basis using SPSS (version 24.0; IBM, Armonk, NY). The normality of continuous data was tested using the Shapiro–Wilk test. Normally distributed data are presented as mean ± standard deviation and analyzed among groups using the *t*-test. Skewed data are presented as median [interquartile range] and compared using the Mann–Whitney *U*-test. Categorical variables are reported as frequencies (percentages) and were compared using the chi-squared (χ^2) test. Standardized differences and 95% confidence intervals (CIs) were calculated for interval data using Hedge's g and for ordinal and dichotomous data using Cliff's delta, calculated via the "effsize" function in R software (version 4.1.2; R Foundation for Statistical Computing, Vienna, Austria) through R Studio (version 2023.06.1+524; RStudio, Boston, MA).

To assess the within-subject variability in VAS scores between groups, a mixed-effects model with repeated measures was used, incorporating group, time, and their interaction as fixed effects, with a random intercept and group-specific residual variances. This was compared to a restricted model with equal residual variances. Maximum likelihood estimation was used to determine covariance parameters. The least squares mean for VAS scores was also estimated using mixed effects with repeated measures. Statistical analyses for the mixed-effects model were conducted using SAS (version 9.4; SAS Institute). $P<0.05$ was considered statistically significant.

Results

This study was conducted at Shanghai First Maternity and Infant Hospital between July 2023 and September 2023. The participant flow is outlined in Figure 1. A total of 102 participants were included in the final analysis (50 in the single-orifice catheter group and 52 in the multi-orifice catheter group). Maternal demographics and baseline characteristics were well-balanced between the two groups (Table 1).

The primary and secondary outcomes are summarized in Table 2. The median (interquartile range) ropivacaine consumption per hour showed no significant difference between the groups: 12.6 mg/h [11.6–13.2 mg/h] for the single-orifice catheter group and 12.8 mg/h [12.3–13.3 mg/h] for the multi-orifice catheter group (difference 29%; 95% CI, –10.2 to 68.2%; P=0.241, Figure 2). There were also no significant differences in the median time to the first PCEA bolus, the percentage of parturients who required PCEA, or the number of PCEA boluses administered between the two groups. However, a higher percentage of parturients achieved adequate analgesia 20 min after the loading bolus with the single-orifice catheter compared to the multi-orifice catheter (84.0% vs 63.5%, difference 22.5%; 95% CI, 9.2% to 35.1%,

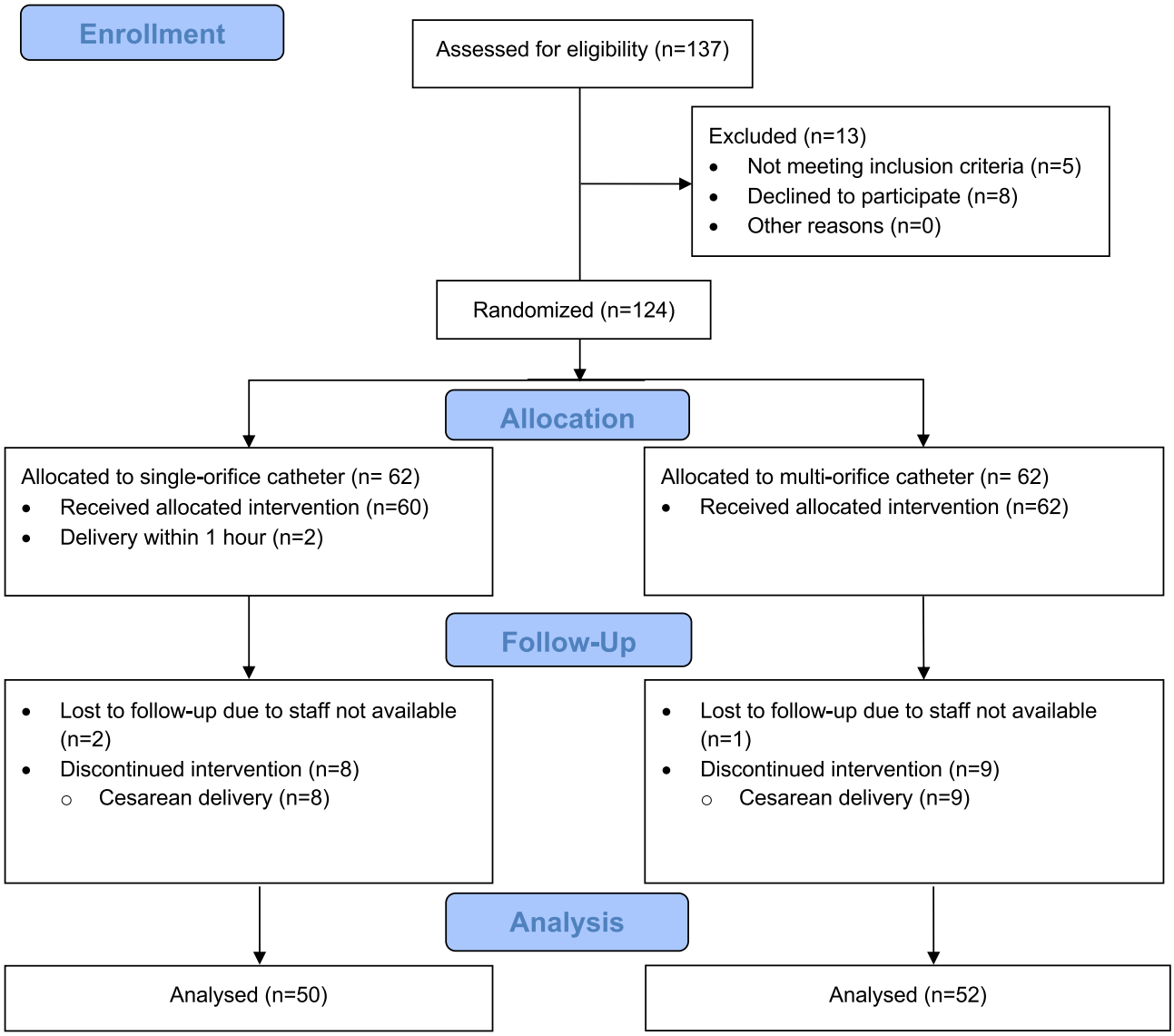

Figure 1 Flow chart showing study participant recruitment.

P=0.019). The median time to adequate analgesia was significantly shorter for the single-orifice catheter group at 8 min [4–16] compared to 15 min [9.5–22.5] for the multi-orifice catheter group (*P*=0.002). Pain scores were similar between the groups, except at 6 and 18 min (Table 3). None of the parturients in either group experienced motor or unilateral block. Maternal satisfaction scores were comparable between the groups, and there were no significant differences in side effects or catheter-related complications.

The obstetric and neonatal outcomes were also well-balanced between the two groups (Table 4).

Discussion

In this randomized, double-blind, controlled study, no significant difference was found in hourly ropivacaine consumption between single- and multi-orifice wire-reinforced flexible catheters during the maintenance of labor analgesia with a PIEB at a delivery rate of 360 mL/h. Additionally, PCEA boluses requested and delivered, time to first PCEA bolus request, and the number of clinician-administered boluses were similar across both groups, suggesting that catheter design did not affect the quality of analgesia during labor maintenance. However, a higher percentage of parturients with

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Table 1 Baseline Characteristics

	Single-Orifice Group	Multi-Orifice Group	P Value	Standardized Difference (95% CI of the Difference)
Mean age (SD) in years	30.7 (2.2)	29.6 (2.3)	0.325	−1.12 (−2.23 to −0.02)
Median height (IQR) in cm	164 (160–166)	160 (158–162)	0.385	−0.660 (−1.060 to −0.259)
Mean weight (SD) in cm	70.4 (6.2)	69.0 (7.8)	0.21	−1.47 (−1.82 to 1.88)
Mean body mass index (SD) in kg/m^2	26.4 (3.2)	26.8 (2.8)	0.518	0.38 (−0.79 to 1.56)
Mean gestational age (SD) in weeks	39.3 (1.1)	39.4 (1.1)	0.759	0.07 (−0.36 to 0.50)
Management of labor, n (%)			0.066	−0.169 (0.342 to 0.015)
Induction of labor	20 (40.0%)	12 (23.1%)		
Spontaneous rupture of membranes	30 (60.0%)	40 (76.9%)		
Median systolic blood pressure (IQR) in mmHg	119.5 (113.0–129.5)	119.0 (113.0–125.0)	0.752	−0.064 (−0.456 to 0.328)
Mean diastolic blood pressure (SD) in mmHg	73.2 (8.1)	72.8 (8.3)	0.771	−0.475 (−3.704 to 2.753)
Median heart rate (IQR) in beats/min	83 (76–90)	80 (71–89)	0.247	−0.172 (−0.565 to 0.221)
Median cervical dilation (IQR) at the time of epidural placement in cm	2 (2–2)	2 (2–2)	0.486	0.173 (−0.218 to 0.563)

Notes: P value compares single-orifice versus multi-orifice group. *t*-test used to compare means, Mann–Whitney *U*-test used to compare median, $\chi 2$ test used to compare percentages. Standardized differences reported as Hedge's g for interval data and Cliff's delta for dichotomous data.

Table 2 Analgesic Outcomes

	Single-Orifice Group	Multi-Orifice Group	P value	Standardized Difference (95% CI of the Difference)
Primary outcome				
Median ropivacaine consumption (IQR) in mg/h	12.6 (11.6–13.2)	12.8 (12.3–13.3)	0.241	0.290 (−0.102 to 0.682)
Secondary outcomes				
Analgesic success[a]	42 (84.0)	33 (63.5)	0.019	0.225 (0.092 to 0.351)
Median time to analgesic success (IQR) in min	8 (4–16)	15 (9.5–22.5)	0.002	0.467 (0.038 to 0.895)
Median total ropivacaine consumption (IQR) in mg	75.0 (57.5–98.5)	80.0 (56.1–100.0)	0.419	0.204 (−0.187 to 0.595)
Median time to first PCEA request (IQR) in min	218.0 (75.0–302.0)	95.0 (70.5–381.5)	0.596	0.135 (−0.818 to 1.088)
Median delivered PCEA bolus (IQR)	0.5 (0.0–1.0)	1.0 (0.5–1.0)	0.295	0.421 (−0.515 to 1.358)
Median requested PCEA bolus (IQR)	1.0 (1.0–2.3)	1.0 (1.0–3.0)	0.749	0.223 (−0.706 to 1.152)
Requests for PCEA, n (%)	10 (20.0)	9 (17.6)	0.762	−0.024 (−0.177 to 0.131)
Median requests for clinician-administered bolus, n (%)	5 (10.0)	4 (7.7)	0.950	0.023 (−0.089 to 0.135)
Adverse effects, n (%)				
Fever[b]	14 (28.0)	16 (30.8)	0.759	−0.028 (−0.205 to 0.151)
Nausea	2 (4.0)	2 (3.8)	1.000	0.002 (−0.075 to 0.078)
Vomiting	2 (4.0)	0	0.238	0.040 (−0.016 to 0.095)
Pruritus	1 (2.0)	2 (3.8)	1.000	−0.018 (−0.085 to 0.048)
Headache	2 (4.0)	1 (1.9)	0.614	0.021 (−0.047 to 0.088)
Maternal satisfaction	5 (5–5)	5 (5–5)	0.682	−0.820 (−0.474 to 0.310)
Catheter-related complications, n (%)				
Difficult insertion	0 (0)	0 (0)	-	-
Paresthesia	0 (0)	0 (0)	-	-
Intravascular cannulation	0 (0)	0 (0)	-	-
Intrathecal placement	0 (0)	0 (0)	-	-
Difficult catheter removal	0 (0)	0 (0)	-	-

Note: P value compares single-orifice versus multi-orifice group. *t*-test used to compare means, Mann–Whitney *U*-test used to compare median, $\chi 2$ test used to compare percentages. Standardized differences reported as Hedge's g for interval data and Cliff's delta for dichotomous data. [a]Analgesic success is defined as the incidence of NRS<=2 20 min after the loading bolus was given to initiate labor epidural analgesia. [b]Fever is defined as a temperature of ≥38°C.
Abbreviations: PCEA, patient-controlled epidural analgesia; IQR, interquartile range; CI, confidence interval.

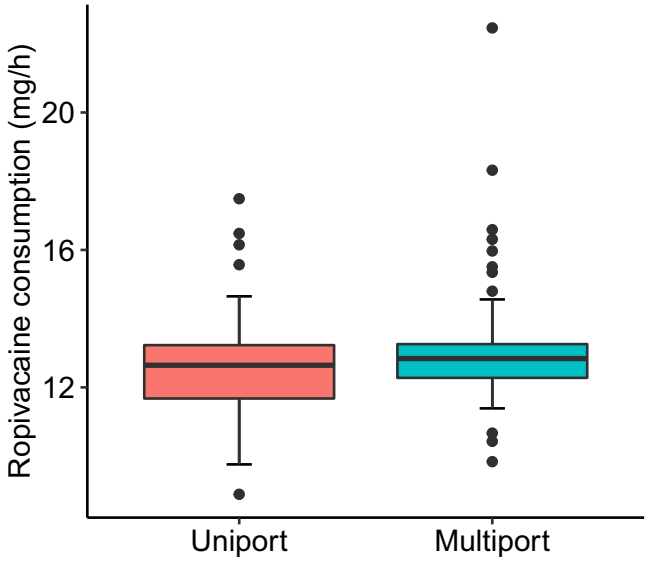

Figure 2 Kaplan-Meier curves for time to achieving NRS ≤ 3 following initial bolus dosing with single-orifice or multi-orifice catheters. Survival probability indicates probability of subjects surviving with NRS ≤ 3 at given time.

NRS score ≤2 within 20 min of the loading bolus was observed in the single-orifice catheter group compared to the multi-orifice group.

Several factors, such as patient position, the volume and concentration of the local anesthetic, the injection site, and epidural space compliance, can influence drug distribution in the epidural space. The limited available data make it difficult to determine whether the number and position of the catheter orifices impact analgesic outcomes and potential side effects. It has been suggested that multi-orifice catheters might allow for preferential efflux through single or multiple orifices depending on the rate and pressure of delivery.[14] This could lead to greater lateral drug spread, improved

Table 3 Comparison of NRS Pain Scores at Each Time-Point. Values are Median (IQR [Range])

Time	Single-Orifice Group	Estimate (95% CI)	Multi-Orifice Group	Estimate (95% CI)	P Value
0 min	9 (8–10 [5–10])	8.680 (8.156–9.204)	9 (8–10 [5–10])	8.596(8.082–9.110)	0.919
2 min	7 (4–8 [0–10])	5.916 (5.310–6.523)	7 (6–8 [3–10])	6.786 (6.177–7.394)	0.346
4 min	5 (3–7 [0–9])	4.774 (4.183–5.364)	6 (5–7 [0–9])	5.396 (4.760–6.032)	0.230
6 min	3(1–6 [0–8])	3.294 (2.675–3.913)	5.0 (3.5–6.5 [2–9])	4.890 (4.275–5.505)	0.013
8 min	3 (1–5 [0–8])	3.163 (2.515–3.811)	5 (3–5 [0–9])	4.191 (3.605–4.778)	0.202
10 min	3.5 (1.0–5.0 [0–7])	2.588 (1.924–3.253)	3.5 (2.0–5.0 [0–8])	3.595 (2.892–4.298)	0.421
12 min	3 (0–4 [0–6])	2.267 (1.627–2.907)	3 (2–4 [0–7])	3.043 (2.440–3.646)	0.189
14 min	2.0 (0.5–3.5 [0–8])	2.279 (1.631–2.926)	3 (2–4 [0–8])	2.837 (2.208–3.465)	0.178
16 min	1 (0–3 [0–8])	1.583 (0.950–2.216)	2.5 (1.0–3.0 [0–8])	2.503 (1.859–3.147)	0.124
18 min	1 (0–2 [0–8])	1.686 (1.030–2.342)	2 (1–3 [0–8])	2.257 (1.628–2.886)	0.038
20 min	1.5 (0–3 [0–7])	1.563 (0.944–2.183)	2 (1–3 [0–5])	1.803 (1.188–2.418)	0.695
30 min	1 (0–2 [0–5])	1.220 (0.680–1.760)	2 (0–3 [0–7])	1.808 (1.278–2.337)	0.088
1 h	0 (0–2 [0–5])	1.020 (0.480–1.560)	1 (0–3 [0–5])	1.454 (0.922–1.986)	0.073
2 h	1 (0–3 [0–10])	1.791 (1.245–2.337)	1.5 (0–3 [0–6])	1.785 (1.246–2.323)	0.470
3 h	0 (0–2 [0–8])	1.417 (0.857–1.977)	1 (0–2 [0–5])	1.487 (0.942–2.032)	0.416
4 h	1 (0–3 [0–8])	1.861 (1.27–2.451)	1 (0–2 [0–4])	1.389 (0.817–1.961)	0.632
5 h	1 (0–3 [0–8])	2.182 (1.526–2.838)	1 (0–2 [0–7])	1.768 (1.139–2.397)	0.785
6 h	1 (0–5 [0–8])	2.553 (1.711–3.396)	1 (0–2 [0–7])	1.854 (1.151–2.557)	0.764
Cervix full dilation	1 (0–3 [0–6])	1.480 (0.956–2.004)	1.5 (0–3 [0–10])	1.769(1.255–2.283)	0.473

Abbreviations: NRS, numerical rating scale; Estimate, least squares mean from a mixed-effect model for repeated measurements; 95% CI, confidence interval.

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Table 4 Obstetric and Neonatal Outcomes

	Single-Orifice Group	Multi-Orifice Group	P Value	Standardized Difference (95% CI of the Difference)
Neonatal outcomes				
Median Apgar score (IQR) at 1 min	9.0 (9.0–9.3)	9.0 (9.0–9.0)	0.801	−0.042 (−0.432 to 0.348)
Median Apgar score (IQR) at 5 min	10 (9–10)	10 (9–10)	0.076	−0.366 (−0.759 to 0.027)
Mean (SD) in gram	3277.80 (350.00)	3338.65 (381.57)	0.403	−0.165 (−0.555 to 0.226)
Delivery mode				
Forceps, n (%)	6 (12.0)	4 (7.7)	0.521	0.043 (−0.075 to 0.160)
Episiotomy, n (%)	13 (26.0)	12 (23.1)	0.732	0.029 (−0.140 to 0.197)
Median oxytocin usage for labor, n (%)	32 (64.0)	27 (51.9)	0.217	0.121 (−0.074 to 0.307)
Median duration of first stage of labor (IQR) in min	496.0 (412.5–716.3)	607.5 (423.8–705.0)	0.202	0.222 (−0.169 to 0.613)
Median duration of second stage of labor (IQR) in min	38.0 (26.5–51.0)	33.0 (24.0–47.0)	0.152	−0.175 (−0.566 to 0.216)
Median duration of labor (IQR) in min	581.0 (456.3–755.0)	652.5 (470.0–760.0)	0.258	0.178 (−0.213 to 0.568)

Notes: P value compares single-orifice versus multi-orifice group. *t*-test used to compare means, Mann–Whitney *U*-test used to compare median, $\chi 2$ test used to compare percentages. Standardized differences reported as Hedge's g for interval data and Cliff's delta for dichotomous data.

injectate distribution,[9] and better analgesic outcomes. However, under PIEB administration, flow dynamics at the catheter orifice may differ. In an in vitro study,[12] we found that multi-orifice catheters offered no advantage over single-orifice catheters in drug spread when programmed injections were delivered at a rate above 360 mL/h. When combined with high-rate epidural injection, the open-ended design of single-orifice catheters may facilitate more efficient passage into the epidural space, leading to more extensive medication distribution. This has been linked to improved clinical outcomes under PIEB, such as improved analgesia and lower bupivacaine consumption.[1–15] Our subsequent clinical findings supported this hypothesis,[13] showing that single-orifice catheters resulted in a more rapid analgesic onset, reduced ropivacaine consumption, and better pain control at full cervical dilation compared to multi-orifice catheters at a PIEB delivery rate of 480 mL/h. However, in the present study with a programmed bolus rate of 360 mL/h, we did not observe any clinical benefits during the maintenance of labor analgesia. This could be attributed to the lower injection pressure at this delivery rate, which might be insufficient to produce a "jet effect" necessary for optimal drug dispersion through the open end of the epidural catheter. Bolus delivery rates are programmable and have varied significantly in previous studies. In vitro studies[12–14,16] have demonstrated that an increasing delivery rate is associated with a higher delivery pressure at the catheter orifice. Multi-orifice catheters can generate higher pressures with higher delivery rates, sometimes triggering occlusion alarms.[12–17] Therefore, single-orifice catheters may be preferable to multi-orifice catheters when considering the use of high-rate (>360 mL/h) PIEB administration for the maintenance of labor analgesia.

This is the second randomized controlled trial investigating the analgesic efficacy of two different epidural catheters under a PIEB regimen. In this study, single-orifice catheters were associated with a higher percentage of parturients achieving adequate analgesia after the initial manual rapid bolus. They attained adequate analgesia almost in half the time as the multi-orifice catheters. A similar association was observed in our previous study,[13] where an initial bolus was administered using a pump at a rate of 480 mL/h. These findings may hold clinical significance, suggesting that single-orifice catheters provide "transient" benefits regarding the faster analgesic onset when compared with multi-orifice catheters. Further studies are needed to explore the outcomes of these two catheter types in various clinical scenarios requiring manual epidural top-ups, such as epidural anesthesia for caesarean delivery, conversion from labor analgesia to anesthesia, and the management of breakthrough pain during labor.

We observed no differences between the two groups in the incidence of difficult catheter insertion, paresthesia, intravascular cannulation, intrathecal placement, or challenging catheter removal. The materials used in manufacturing epidural catheters can influence clinical performance, including intravascular cannulation, paresthesia, and ease of catheter removal and placement.[7] Early studies suggested that single-orifice catheters were associated with difficult placement[11] and inadequate blocks.[8–10] However, advancements in materials and the development of flexible inner wire coils in recent decades have significantly reduced the incidence of catheter-related complications and improved the quality of labor analgesia. Spiegel et al[18] conducted a prospective, randomized, controlled trial and found no statistically

significant differences in analgesic outcomes or complications between single-orifice, wire-reinforced polyurethane catheters and multi-orifice, wire-reinforced nylon catheters. The authors posited that the flexibility provided by the wire coil could mitigate the potential risks associated with single-orifice designs.

The strength of our study is its randomized, double-blind design, which effectively minimized the bias and influence of known and unknown confounders. However, this study had some limitations. First, the study subjects were restricted to nulliparous parturients to obtain longer durations of labor analgesia. As a result, these findings may not be applicable to multiparous parturients with short labor durations. Second, the initiation of labor analgesia was achieved via conventional epidural analgesia in the current study, and the results may differ if using combined spinal-epidural or dural puncture epidural techniques. Both techniques are hypothesized to enhance drug transfer from the epidural to the intrathecal space, thereby hastening block onset and analgesic efficacy.[19] Finally, the catheters used were from a single manufacturer. In terms of catheter design, including the number and position of orifices, there is a wide range of variability in the characteristics between single- and multi-orifice catheters from various brands, which could influence the distribution of epidural medication and catheter-related complications. Therefore, the results of the current study cannot be generalized to other brands of epidural catheters.

Conclusion

In conclusion, our study found no significant differences in analgesic quality between catheter designs during the maintenance of labor analgesia, as measured by hourly ropivacaine consumption and PCEA requests at a delivery rate of 360 mL/h under PIEB. However, the single-orifice catheter was associated with a more rapid analgesic onset after the loading bolus, suggesting that single-orifice catheters may be preferable for PIEB at higher delivery rates (>360 mL/h) compared to multi-orifice catheters.

Data Sharing Statement

- Intent to Share: We intend to share individual deidentified participant data collected during this clinical trial.
- Specific Data to be Shared: This will include the raw deidentified dataset, the study protocol, the statistical analysis plan, and the informed consent form.
- Access Method: The data will be made accessible to researchers who provide a methodologically sound proposal. Requests should be directed to the corresponding author, Weijia Du, at Email: duweijia10317@fckyy.org.cn.
- Timeline: The data will become available 6 months after article publication and will remain accessible for a period of 5 years.

Declaration of Helsinki Compliance

This study was performed in line with the principles of the Declaration of Helsinki.

Disclosure

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