Minimum Effective Concentration of Ropivacaine For Ultrasound-Guided Adductor Canal + IPACK Block In Total Knee Arthroplasty

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Research Article

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Abstract

Background: This study aimed to investigate the minimum effective concentration ($MEC_{90,}$ defined as effective in 90% of patients) of ropivacaine during the combined procedure of adductor canal block (ACB) and infiltration between the popliteal artery and capsule of the posterior knee (IPACK) block for patients undergoing total knee arthroplasty.

Methods: This double-blind, randomized dose-finding trial was based on a biased coin up-and-down sequential design, where the concentration of ropivacaine administered to a given patient depended on the previous patient's response. Before surgery, the first patient received 20 ml of 0.2% ropivacaine for ACB and again for IPACK. If the block failed, the next subject received a 0.025% higher ropivacaine concentration; otherwise, the next subject received either a 0.025% smaller dose (probability of 0.11) or the same dose (probability of 0.89). Block success was defined as the patient did not suffer significant pain and did not receive rescue analgesia within 6 hours after surgery. MEC_{90} was estimated by isotonic regression, and the 95% confidence interval (CI) was calculated by bootstrapping.

Results: Based on analysis of 52 patients, the MEC_{90} was 0.247% (95% CI 0.227–0.271%), MEC_{95} was 0.260% (95% CI 0.244–0.282%) and MEC_{99} was 0.272% (95% CI 0.260–0.291%). In contrast, four of nine trials in a recent systematic review reported ropivacaine concentrations below 0.247%.

Conclusions: Our small trial suggests that 0.247% ropivacaine in 20 ml respectively can provide successful ACB + IPACK block in 90% of patients. However, given that many published trials have used lower concentrations, our findings should be verified in larger studies.

Trial registration: This study was registered with the Chinese Clinical Trial Registry (http://www.chictr.org.cn/index.aspx). The clinical trial registration number was ChiCTR2100048757 (Date of registration: July 16, 2021).

Background

Total knee arthroplasty is one of the most common surgical procedures for patients with end-stage knee degenerative diseases [1], but it is associated with moderate to severe postoperative pain in more than 60% of patients [2, 3]. Inadequate pain management can delay recovery and reduce patient satisfaction [4, 5]. Multimodal pain protocols and regional anesthesia have substantially mitigated pain after total knee arthroplasty and shortened the associated hospitalization [6, 7]. For example, peripheral nerve block is a widely used technique of multimodal pain protocol [8, 9], and extensive studies have explored the analgesic efficacy of combining adductor canal block (ACB) and infiltration between the popliteal artery and capsule of the posterior knee (IPACK) block in order to block only sensory nerves [10–16]. In fact, ACB + IPACK block is recommended by some researchers for postoperative analgesia in enhanced recovery protocols after total knee arthroplasty [1, 10, 17, 18].

The optimal concentration of ropivacaine for ACB + IPACK block is unclear. Previous studies have reported concentrations from 0.2–0.5% [10, 15, 16, 19, 20, 21]. Since the dose should be optimized to minimize risk of systemic toxicity [22], we conducted a double-blind, randomized dose-finding trial in order to determine the minimum effective concentration (MEC_{90}, defined as effective in 90% of patients) of ropivacaine for ACB + IPACK block in patients undergoing total knee arthroplasty.

Methods

This study was approved by the Clinical Trials and Biomedical Ethics Committee of Sichuan University West China Hospital, and written informed consent was obtained from all subjects.

Patient recruitment

To be enrolled in this study, patients had to older than 18 years, diagnosed with osteoarthritis, and scheduled for primary unilateral total knee arthroplasty under general anesthesia. Patients also had to have an American Society of Anesthesiologists functional status of I–III, as well as normal quadriceps strength.

Patients were excluded if they presented with any of the following: knee flexion deformity ≥ 30°, varus-valgus deformity ≥ 30°, known allergies to the drugs used in this study, history of open knee surgery or knee infection, drug addiction, or neuromuscular disorder. Patients were also excluded if they were unable to communicate verbally.

Study design

This trial was a double-blind, randomized study to estimate MEC_{90} for ultrasound-guided, single-injection ACB + IPACK block in patients undergoing total knee arthroplasty. Drug concentration was assigned using a biased coin up-and-down sequential design, where the concentration of local anesthetic administered to a given patient depended on the previous patient's response. The first patient to be recruited received 20 ml 0.2% ropivacaine (AstraZeneca, London, England) for ACB and 20 ml 0.2% ropivacaine for IPACK. If the block was successful in the first patient, the next patient was randomized to receive either the same ropivacaine dose (at a probability of 0.89) or a 0.025% lower dose (at a probability of 0.11). If, however, the block failed in the first patient, the next patient received a 0.025% higher concentration. The maximum concentration was set at 0.5%. If the block failed in a patient who received this maximum concentration, the next patient did not receive a higher concentration. The assessment criteria for block success were shown in the outcome section.

The sequential allocation of biased coin up-and-down sequential design was carried out using a computer-generated list of random numbers prepared by a statistician with Microsoft Excel (Redmond, WA, USA). Investigator 1 accessed the list and prepared the corresponding syringes of ropivacaine in the central pharmacy, adding epinephrine (CrandpharmaCo.Ltd., Wuhan, China) (2.0 μg/mL) to all

ropivacaine formulations. Then Investigator 1 carried the syringes to the operating room. In this way, the patient, anesthesiologist, surgeon, and postoperative caregiver were blinded to concentration allocation.

Analgesic procedures

One anesthesiologist performed all ACB and IPACK procedures in the operating room for all patients 30 minutes before general anesthesia. After subcutaneous infiltration with 1 ml of 2% lidocaine, ACB and IPACK block were performed with the patient in the supine position. For ACB (Figure 1), a high-frequency linear-array ultrasonic transducer (Anesus ME7, Mindray, Shenzhen, China) was used to scan the middle of the thigh, halfway between the inguinal crease and patella, in order to identify the adductor canal, superficial femoral artery, sartorius, adductor longus, and adductor magnus. The site of injection was chosen as the anterolateral hyperechoic structure of the artery (saphenous nerve and nerve to vastus medialis). Once the site was located, a 21-gauge, 100-mm needle (Pajunk, Geisingen, Germany) was introduced in-plane in a lateral to medial direction. Correct needle placement was confirmed using 3 ml of isotonic saline, then 20 ml of ropivacaine was injected.

IPACK was performed using the same ultrasonic transducer mentioned above (Figure 2). The anesthesiologist identified the popliteal artery at the popliteal crease and moved cephalad just beyond the femoral condyles, to where the condyles merged with the shaft of the femur. The tibial and peroneal nerves superficial to the popliteal artery were located, and when the space between the femur and popliteal artery was located, the needle was inserted in-plane in a medial to lateral direction. The tip was positioned at the middle of the femur, near the lateral border near the periosteum. Then 5–10 ml of ropivacaine was injected to ensure adequate spread to the lateral end of the femur. As the needle was withdrawn, the rest of the ropivacaine was injected along the femur, such that 5 ml infiltrated incrementally into the area between the artery and femur, ending at the medial end of the femur. Altogether 20 ml of ropivacaine was injected during IPACK.

Surgery and concomitant medication

On the day before surgery, celecoxib (200 mg) was administered twice as a preemptive analgesic. Patients were instructed to fast for eight hours before surgery and to drink 100 ml of a clear, pure carbohydrate liquid two hours before surgery. All surgeries were conducted under general anesthesia. After pure oxygen inhalation, the following anesthetics were administered intravenously: Midazolam, 2 mg/kg; Propofol, 2 mg/kg; Sufentanil, 0.3 μg/kg; and Cis-atracurium, 0.2 mg/kg. Patients were then intubated and given an inhaled anesthetic (Sevoflurane, 1-1.5 MAC). Flurbiprofen (50 mg) was administered 20 min before the end of the surgery to prevent postoperative pain, along with Tropisetron (5 mg) to prevent postoperative nausea and vomiting. After regaining consciousness, patients were sent to the post-anesthesia care unit, where Investigator 2 (postoperative caregiver) administered an opioid add-on to the multimodal pain treatment whenever the pain score at rest exceeded 3, in accordance with routine procedures at our hospital. The patients whose pain score exceeded 3 simultaneously received intravenous Sufentanil (5 μg).

After awakening from anesthesia, patients were sent to the bed ward, and an ice compress was applied around the incision. Patients did not receive any oral analgesics

within 6 hours after surgery. If the patient was unable to tolerate the pain, a further 5 mg of morphine hydrochloride as rescue analgesia was injected subcutaneously.

Outcome assessment

The primary outcome was whether the block was successful. Block success was defined as the patient did not suffer significant pain and did not receive rescue analgesia within 6 hours after surgery. The assessments were performed by Investigator 2 (postoperative caregiver), who was blinded to concentration allocation. Pain at rest was assessed in the post-anesthesia care unit, at 2 h, 4 h, and 6 h after surgery. If the pain score at rest exceeded 3 in a numerical rating scale from 0 to 10 [23] at any time point, the patient was recorded as experiencing block failure. Pain during motion was assessed at 2 h, 4 h, and 6 h after surgery. If the pain score during motion exceeded 5 at any time point, the patient was recorded as experiencing block failure. In addition, if the patient received rescue analgesia (received Sufentanil in the post-anesthesia care unit or morphine hydrochloride in the bed ward) within 6 h after surgery, the patient was recorded as experiencing block failure.

Any adverse events that occurred during surgery or postoperative recovery in hospital were recorded.

Statistical analysis

Based on previous studies [24, 25], we estimated that we would need to observe at least 45 successful ACB + IPACK blocks in order to estimate MEC_{90}. Thus, we decided to recruit patients until we had achieved this.

Data were analyzed statistically using R statistical software (R Foundation for Statistical Computing, Vienna, Austria). MEC_{90} was calculated using isotonic regression, and the 95% confidence interval (CI) was derived by bootstrapping [26, 27]. Similar procedures were used to estimate the minimum effective concentrations to produce a successful block in 95% or 99% of patients (MEC_{95}, MEC_{99}) [28]. We used the dose estimator μ3, defined as the interpolated dose whose probability of effect was estimated to be 0.9.

Results

A total of 52 patients completed the study, the characteristics of included patients are shown in Table 1. The sequence of biased coin up-and-down sequential design is displayed in Figure 3. The MEC_{90} was 0.247% (95% CI 0.227–0.271%); MEC_{95}, 0.260% (95% CI 0.244–0.282%); and MEC_{99}, 0.272% (95% CI 0.260–0.291%).

Table 1
Patient characteristics

Characteristic	Value
Age (years)	66.2±7.8
Sex	
Male	18 (34.6%)
Female	34 (65.4%)
Weight (kg)	67.9±11.8
Height (cm)	162.1±8.0
Body mass index (kg/m^2)	25.7±3.5
Block side (right/left)	
Right	30 (57.7%)
Left	22 (42.3%)
ASA status (I/II/III)	
I	0 (0%)
II	36 (69.2%)
III	16 (30.8%)
Values are n (%), or mean±SD.	
ASA, American Society of Anesthesiologists	

Response rates at each ropivacaine concentration are shown in Table 2. During the nerve block, no events of vascular puncture were observed; after nerve block, none of the patients suffered nausea, vomiting or dyspnea before general anesthesia. After surgery, none of the patients suffered diminished quadricep strength, residual paresthesia, or residual neural deficits. None of the patients showed signs of local anesthetic intoxication during the trial.

Table 2
Observed response rates

Assigned concentration	Total blocks	Successful blocks	Observed response rates
0.200%	2	1	50.0%
0.225%	16	12	75.0%
0.250%	25	23	92.0%
0.275%	9	9	100.0%
Values are n or percentage			

Discussion

The analgesic efficacy of ACB + IPACK block remains controversial: some studies indicate that it can significantly improve analgesic and functional outcomes following total knee arthroplasty [10, 17, 29, 30], while other studies have reported that it is not superior to ACB alone [12, 31]. This discrepancy may reflect the use of different doses of local anesthetic, highlighting the need for the present dose-finding study. To our knowledge, we provide the first estimate of MEC_{90} for ropivacaine in ACB + IPACK block. We calculated a MEC_{90} of 0.247% (95% CI 0.227–0.271%). No adverse effects were observed during the study, suggesting that this MEC_{90} is safe.

Ropivacaine is a long-acting amide local anesthetic which produces less suppression of motor fibers and has a significantly higher threshold for cardiovascular and central nervous system toxicity than bupivacaine [32, 33]. We chose 0.2% as the initial concentration in the present trial because previous studies using ropivacaine for ACB + IPACK block have used concentrations from 0.2–0.5% [10, 15, 16, 19, 20, 21]. Based on the drug instructions of ropivacaine (AstraZeneca, London, England), the action time for peripheral nerve block is about 6 hours. Therefore, we chose postoperative 6 hours as the endpoint of this study. We added epinephrine to our ropivacaine formulations because epinephrine modulates the sympathetic nervous system, which can increase analgesic potency and duration [34].

We opted to estimate the MEC_{90} because the classic parameter of median effective dose (ED_{50}) offers little clinical relevance [35]. To estimate MEC_{90}, we applied a biased coin up-and-down sequential design, which can directly determine higher quantiles (ED_{90} and ED_{95}) than the classical Dixon and Massy approach to estimate ED_{50}. In addition, the biased coin up-and-down sequential design has the advantage of allocating concentrations in a sequential, interactive way, such that patients are randomized to doses more likely to be effective without causing toxicity [24, 36].

Our MEC_{90} estimate for ropivacaine, 0.247%, is higher than the concentration of ropivacaine reported in four of nine trials in a recent systematic review of analgesic procedures in ACB + IPACK block [21]. The variation in concentrations in these trials may help explain divergent results about efficacy. To obtain

more reliable results, it may be worthwhile to express ropivacaine doses in terms of the MEC_{90} that we determined here. In this way, our MEC_{90} may help guide future clinical and investigational work aimed at optimizing ACB, IPACK and promoting an opioid-sparing multimodal pain management for total knee arthroplasty.

Nevertheless, our results should be interpreted with caution in light of several points. First, the success rate can vary depending on the investigators' definition of block success, caution should be exercised when comparing different studies. Second, the study is of relatively small size, and all procedures were done by one anesthesiologist, and one surgeon, potentially limiting generalizability of the study. Third, we did not administer local anesthetic by periarticular infiltration, which may make it difficult to apply our results to situations where such infiltration analgesia is given [21]. Fourth, we estimated MEC_{90} for the case of a single injection of ropivacaine during ACB and then again during IPACK, so our results may not generalize to the case of continuous administration [31]. Fifth, we did not assess the effects of volume on MEC_{90}, injecting always the same total volume of 40 ml based on previous studies [10, 29, 31]. Other volumes of local anesthetic have been reported for ACB and IPACK block [13, 37, 38], so it is unclear whether our results can generalize to other volumes. Future work should address these limitations, as well as verify and extend our findings for a range of multimodal pain regimens.

Conclusions

Under the conditions of the present study, our biased coin up-and-down sequential design-based trial provides evidence that ultrasound-guided single injection of 0.247% ropivacaine in 20 ml respectively (containing 2.0 μg/mL of epinephrine) can provide successful ACB + IPACK block in 90% of patients undergoing total knee arthroplasty. However, given that many published trials have used lower concentrations, our findings should be verified in larger studies.

Abbreviations

ACB: adductor canal block; CI: confidence interval; ED_{50}: median effective dose; IPACK: infiltration between the popliteal artery and capsule of the posterior knee; MEC_{90}: minimum effective concentration (defined as effective in 90% of patients).

Declarations

Ethics approval and consent to participate

This study was approved by the Clinical Trials and Biomedical Ethics Committee of Sichuan University West China Hospital. Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Q.W and J.H were responsible for manuscript writing. L.C was responsible for data collection. A.B was responsible for data analysis and manuscript writing. J.Y and P.K were responsible for the study design and correspondence. All authors read and approved the final manuscript.

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Figures

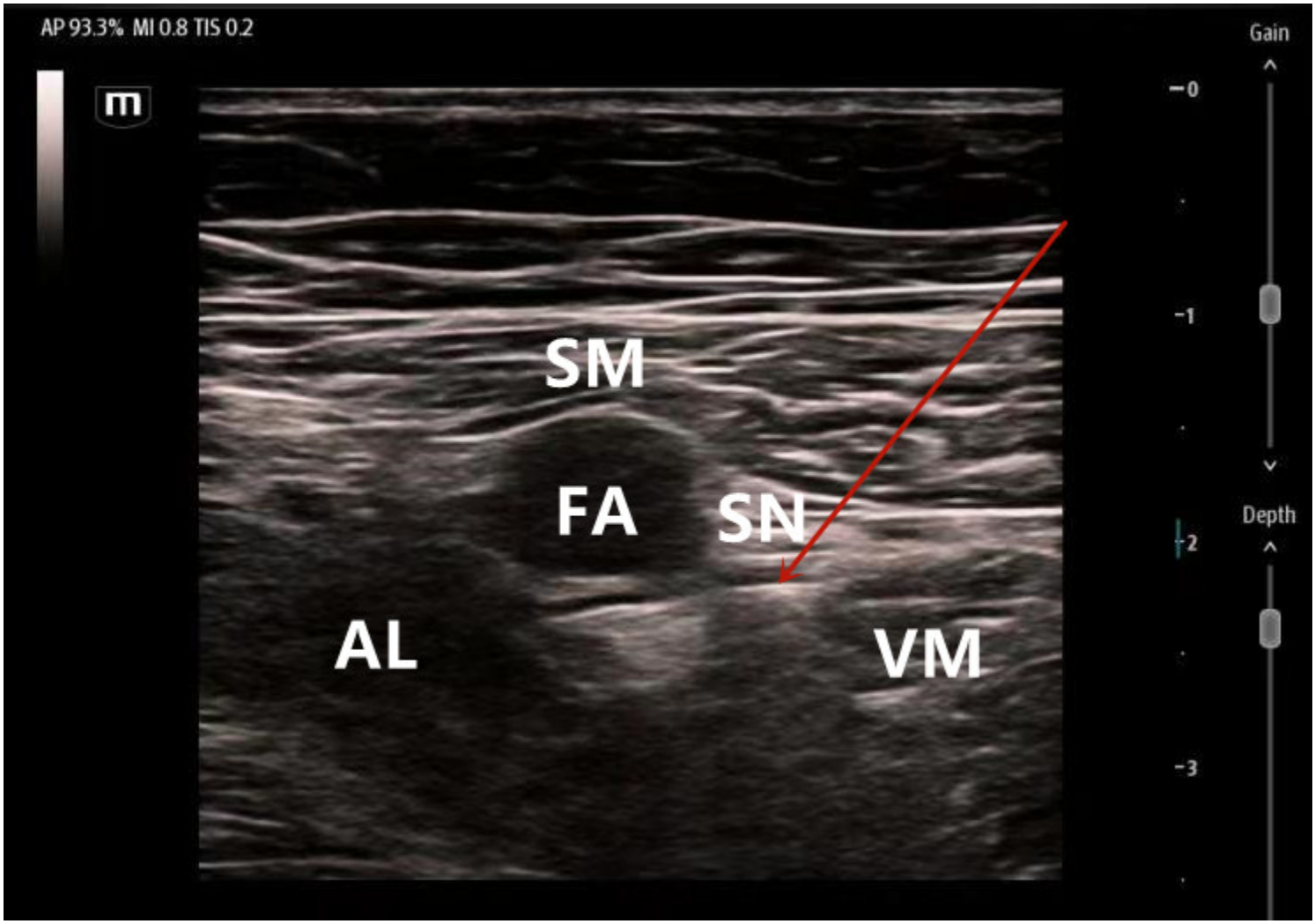

Figure 1

Ultrasound-guided adductor canal block. AL, adductor longus; FA, femoral artery; SM, sartorius muscle; SN, saphenous nerve; VM, vastus medialis; line, needle insertion point

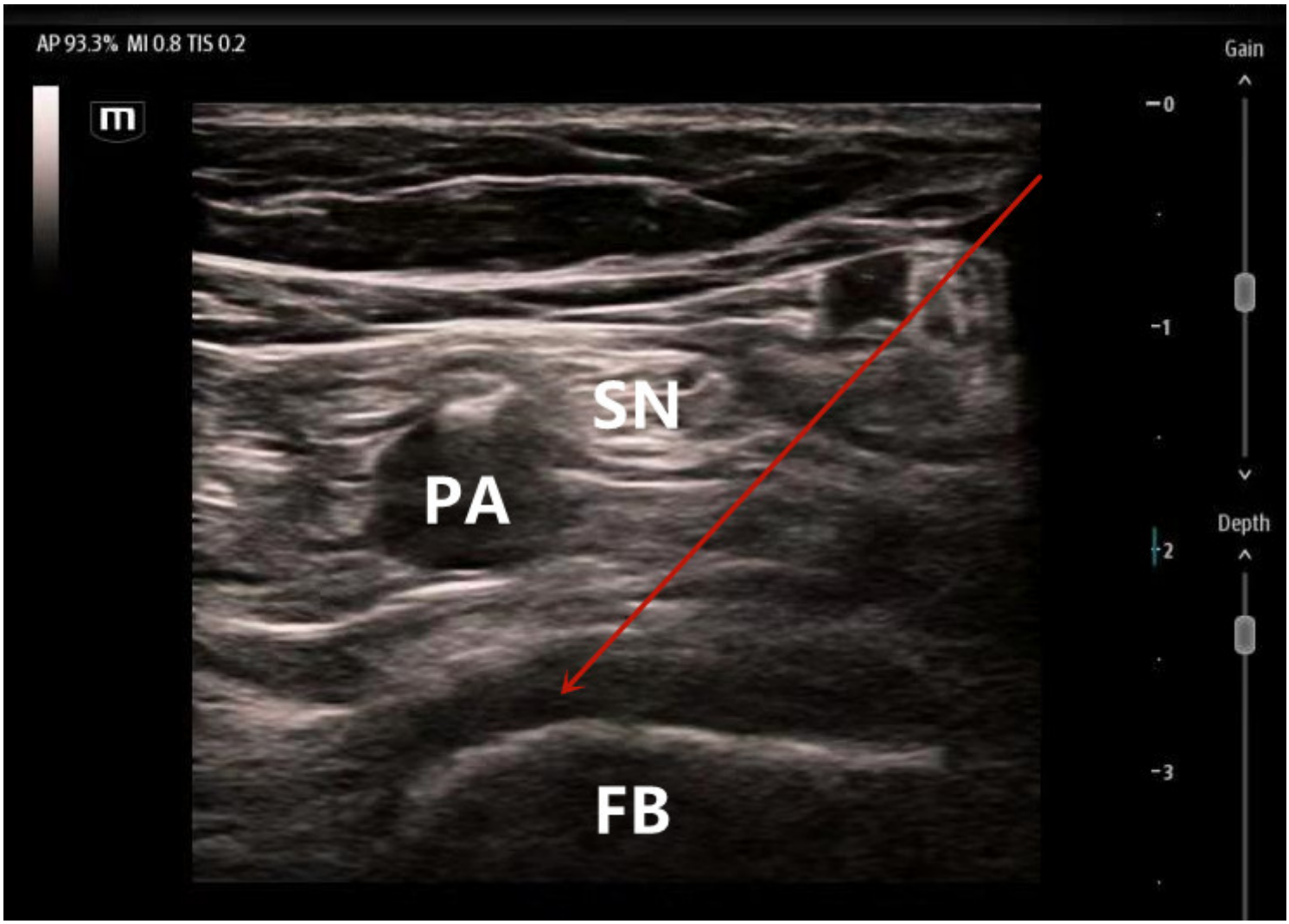

Figure 2

Ultrasound-guided infiltration between the popliteal artery and capsule of the posterior knee block. FB, femoral bone; PA, popliteal artery; SN, saphenous nerve; line, needle insertion point

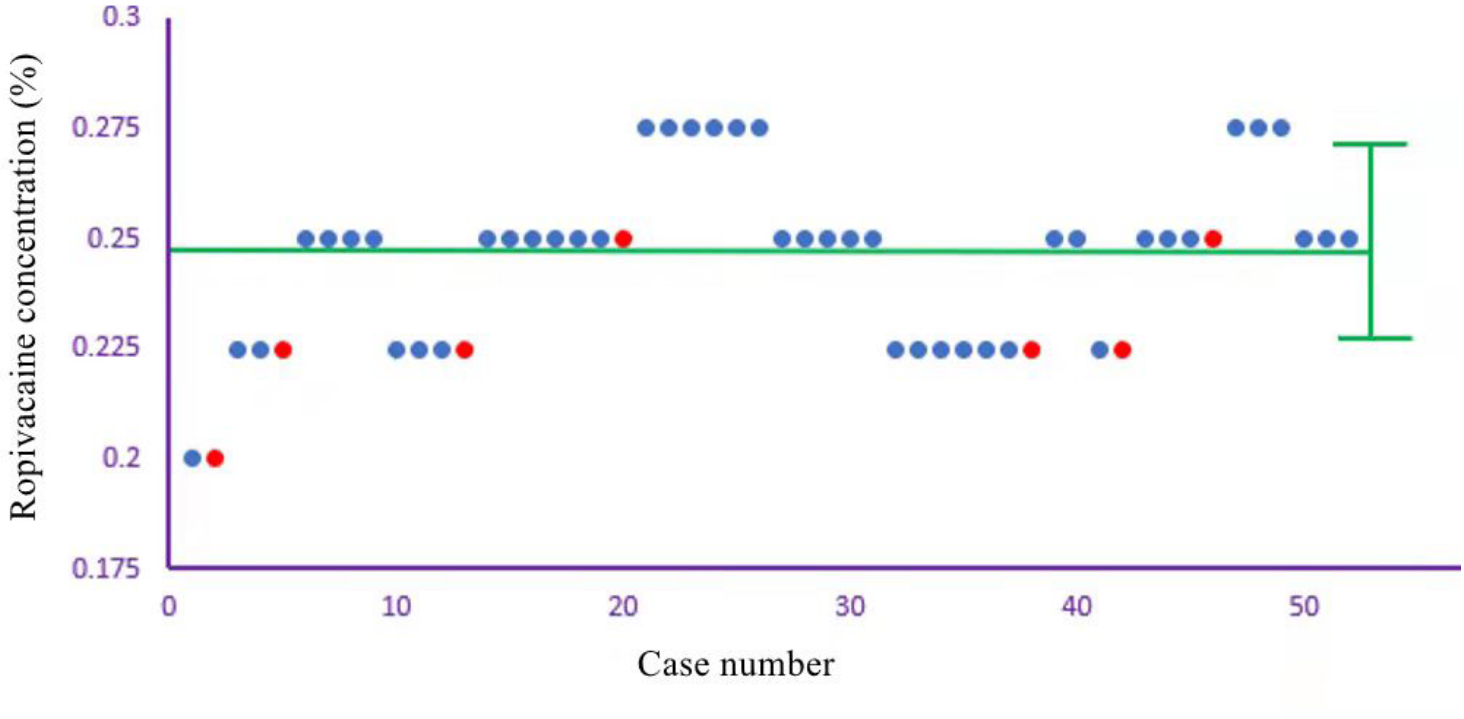

Figure 3

Graph of successful ( ) and failed ( ) blocks with different ropivacaine concentrations. The horizontal line is the calculated minimum effective concentration of ropivacaine providing successful ACB + IPACK block in 90% of patients (MEC_{90}); error bars represent 95% confidence interval.