


CLINICAL INVESTIGATION

Duration of analgesia after supraclavicular brachial plexus block with intravenous dexamethasone with or without dexmedetomidine: a randomised, placebo-controlled, triple-blind trial

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Abstract

Background: Intravenous dexamethasone and dexmedetomidine are two adjuncts to local anaesthetics used independently to prolong analgesia after peripheral nerve block. This randomised, controlled, triple-blind trial tested the hypothesis that the combination of i.v. dexamethasone and dexmedetomidine would provide superior analgesia than i.v. dexamethasone alone as an adjunct in patients undergoing upper limb surgery with a supraclavicular brachial plexus block.

Methods: We randomised 100 participants to receive either dexamethasone 0.15 mg kg⁻¹ i.v. (Dexa group) or a combination of dexamethasone 0.15 mg kg⁻¹ and dexmedetomidine 1 µg kg⁻¹ i.v. (Dexa-Dexme group). The primary outcome was the duration of analgesia measured from the time of block procedure with a mix of mepivacaine 0.5% and ropivacaine 0.25% to first oral opioid intake. Secondary outcomes included duration of sensory and motor blocks, pain scores at rest and on movement, cumulative oral morphine consumption at 48 h, and incidence of hypotension episodes and bradycardia.

Results: The mean (SD) duration of analgesia was 621 (334) min in the Dexa group and 690 (544) min in the Dexa-Dexme group ($P=0.47$). Similarly, there were no significant differences in the secondary outcomes.

Conclusions: The combination of i.v. dexamethasone and dexmedetomidine does not provide superior analgesia than i.v. dexamethasone alone after supraclavicular brachial plexus block.

Clinical trial registration: NCT 05389852.

Keywords: adjuvant; brachial plexus block; local anaesthetic; peripheral nerve block; postoperative pain; regional anaesthesia

Editor's key points

- Dexamethasone and dexmedetomidine intravenously or perineurally are often used as adjuncts to local anaesthetics to prolong analgesia after peripheral nerve blocks. Although they are sometimes used together, it is not known whether the

combination is more effective than dexamethasone alone.

- This trial tested the hypothesis that the combination of i.v. dexamethasone and dexmedetomidine provides superior analgesia than i.v. dexamethasone alone in patients undergoing upper limb surgery with a supraclavicular brachial plexus block.

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- The combination of i.v. dexamethasone and dexmedetomidine did not provide superior analgesia compared with i.v. dexamethasone alone as an adjunct to supraclavicular brachial plexus block in patients undergoing upper limb surgery.

Dexamethasone and dexmedetomidine are two well-known adjuncts to local anaesthetics, widely used in clinical practice to prolong analgesia effectively after peripheral nerve block.^{1–3} These adjuncts can be administered either perineurally, or intravenously.^{3,4}

In the quest for constant improvement in postoperative analgesia, some authors have investigated the combination of i.v. dexamethasone and dexmedetomidine with an interscalene brachial plexus block for shoulder surgery, and reported a duration of analgesia of 66 h.⁵ However, a meta-analysis summarised the evidence and concluded that the combination likely provided a similar duration of analgesia as dexamethasone alone.⁶ However, only one of the nine trials included was at low risk of bias⁷; indeed, some included and subsequent trials were limited by methodological concerns such as inappropriate comparison between study groups (dexamethasone + midazolam infusion vs dexamethasone + dexmedetomidine infusion),⁸ administration of suboptimal doses of study drugs⁹ (dexamethasone 4 mg instead of 0.1–0.2 mg kg⁻¹ i.v. as recommended),³ perineural rather than i.v. administration^{10,11} or significant attrition rates.¹²

To further assess the potential initial promising analgesic synergy of these two adjuncts and to provide more robust evidence, we undertook this randomised, placebo-controlled, triple-blind trial. We tested the hypothesis that the combination of i.v. dexamethasone and dexmedetomidine would provide a longer duration of analgesia than i.v. dexamethasone alone in patients undergoing upper limb surgery with a supraclavicular brachial plexus block.

Methods

We followed the recommended process described in the Consolidated Standards of Reporting Trials (CONSORT) statement.¹³ This trial was approved by the Ethics Committee of the Canton of Vaud, Switzerland (protocol number: 2021-01654, approval date December 17, 2021) and prospectively registered on [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT05389852).

All patients aged 18 yr or older, American Society of Anaesthesiologists physical status 1–3, who were scheduled to undergo elbow, forearm or hand surgery between January 1, 2023 and January 1, 2024 were eligible to participate in this study. Exclusion criteria included contraindications to peripheral nerve block (e.g. coagulopathy, infection in the area), known allergy to any drug used in the study protocol, pregnancy, or chronic use of opioids. Written informed consent was provided by all participating patients.

After a standardised ultrasound-guided supraclavicular brachial plexus block, all participants received dexamethasone 0.15 mg kg⁻¹ i.v. Then, depending on the group allocation, participants received the study medication (placebo or dexmedetomidine i.v.) prepared by the pharmacy of Lausanne University Hospital, using a computer-generated randomisation sequence, with an identity number referring to the study medication. The study medication was prepared in

identical sterile perfusion bags of 100 ml, containing either 100 ml of normal saline or dexmedetomidine 1 µg ml⁻¹ in 100 ml of normal saline. The medication was transported to the study site in temperature-controlled containers. Participants, physicians, phase I and II recovery nurses, research assistants collecting the data, and the statistician were all kept blinded to group allocation.

Supraclavicular block

All ultrasound-guided blocks were conducted before surgery in a dedicated block procedure room by one of the investigators (SG) who is an experienced provider of ultrasound-guided peripheral nerve blocks. Briefly, participants were positioned supine in a semi-sitting position with the head turned 45 degrees to the nonoperative side, and with the ipsilateral arm placed adducted to the patient's side. Electrocardiogram, pulse oximetry, and blood pressure monitors were applied, and oxygen was provided. Peripheral i.v. access was established. Sublingual midazolam 1–3 mg was given before the block procedure, if needed.

The supraclavicular area was prepared with a solution of chlorhexidine 2% in isopropyl alcohol 70%. Under sterile conditions, a high-frequency linear array transducer (13–6 MHz, SonoSite S-Nerve; SonoSite, Inc., Bothell, WA, USA) was placed over the supraclavicular fossa, parallel to the clavicle to obtain a short-axis view of the divisions of the brachial plexus and the subclavian artery. A 23-G 70 mm insulated block needle (Temena UPC®, Felsberg-Gensungen, Germany) was inserted in-plane with the ultrasound beam, in a lateral-to-medial direction, until the needle tip was positioned at the junction of the first rib and the subclavian artery, in a location called the 'corner pocket'. Then mepivacaine 1%, 30 ml + ropivacaine 0.5%, 1:1 by volume, were injected slowly in 5 ml increments, with intermittent aspiration, and under constant ultrasound visualisation.

Surgical procedure

After completion of the block procedure, all participants received dexamethasone 0.15 mg kg⁻¹ i.v. Followed by a slow i.v. infusion of 1 ml kg⁻¹ of either placebo or dexmedetomidine 1 µg ml⁻¹ over 10 min. The doses of dexamethasone (0.15 mg kg⁻¹) and dexmedetomidine (1 µg kg⁻¹) were chosen according to the available evidence in the literature.^{3,14,15} In case of insufficient block, general anaesthesia was provided and the participant was included as per intention-to-treat protocol.

After application of routine monitors in the operating theatre and providing oxygen, sedation with propofol 1–3 mg kg⁻¹ h⁻¹ was provided on patient request. Episodes of bradycardia (symptomatic episode or heart rate <40 beats min⁻¹) and hypotension (symptomatic episode or mean arterial pressure <60 mm Hg) were treated with atropine (0.5 mg i.v.), ephedrine (boluses of 5 mg i.v.) or phenylephrine (boluses of 100 µg i.v.). After surgery, participants were transferred either to the ward or phase II recovery where they received a standardised postoperative analgesic regimen inclusive of oral paracetamol 1000 mg i.v. every 4 h and ibuprofen 400 mg i.v. every 8 h. Oral tramadol 50 mg or oxycodone 5 mg for ambulatory or hospitalised patients every 4 h was available as needed, following our institutional recommendations. Postoperative visits or phone calls were carried out at 4 h, 24 h, and 48 h, and 7 days after the intervention.

Outcomes

The primary outcome was duration of analgesia defined as the time from block procedure completion to first oral opioid intake. Secondary outcomes were duration of the sensory block (time from injection to first paraesthesia on the upper limb); duration of the motor block (time from injection to first movement [wrist flexion]); rest and dynamic pain score at 4 h, 24 h, and 48 h after surgery with a numeric rating scale (NRS) from 0 (no pain) to 10 (worst imaginable pain); cumulative oral opioid consumption at 24 h and 48 h after surgery (morphine equivalents); patient satisfaction with analgesia measured on a 4-level Likert scale at 7 postoperative days (very dissatisfied, dissatisfied, satisfied, very satisfied); incidence of any adverse event such as perioperative episodes of bradycardia or hypotension that required treatment; and incidence of infection, neuropathic pain, paraesthesia, and muscle weakness, measured at 7 postoperative days. After phase II recovery, participants were hospitalised overnight or discharged home. They were asked to document the time of analgesics intake, first paraesthesia of the arm, first movement of the arm, and pain scores at rest and on movement. At 24 h, 48 h, and 7 days after operation, all participants received a phone call by a research collaborator to record the abovementioned outcomes. Finally, participants were asked whether they would choose the same anaesthetic technique again, should they have another surgery. The trial was monitored by an independent person from the Clinical Trials Unit of Lausanne University Hospital, and all participants had 100% of their data verified for accuracy. We used the following scale for opioid conversion¹⁶: morphine 10 mg i.v.=oxycodone 30 mg p.o.=tramadol 100 mg p.o.

Statistical analysis

Based on previous data,¹⁷ the mean duration of analgesia after a supraclavicular brachial plexus block with the same local anaesthetic mixture was 381 (standard deviation [SD] 126) min. We hypothesised that the duration of analgesia would increase by 20% with dexmedetomidine i.v. added. To obtain a minimal power of 80% with an alpha of 5%, we calculated that 40 participants per group needed to be included. To correct for an anticipated drop-out and protocol violation rate of 20%, we planned to recruit a total of 100 participants (50 per group).

Data were analysed on an intention-to-treat basis. Categorical variables are presented as frequency and percentage, and continuous variables are summarised as mean and SD. Continuous data were compared between groups using Student's *t*-test. Categorical and dichotomous data were compared using Fisher's exact test. Kaplan–Meier curves were also established for durations of analgesia, sensory block, and motor block. Survival curves were compared between groups using the log-rank test. For analysis of longitudinal outcomes (pain score at rest, pain score on movement, patient satisfaction), mixed-effects linear models were used, including the group, the time and an interaction between group and time as fixed effects, and the participant as random effect. Significance was considered at $P < 0.05$ based on a two-tailed probability. Statistical analysis was performed using the Stata software (Stata version 18.0, StataCorp, College Station, TX, USA).

Results

Among the 100 participants recruited, one was excluded because of protocol violation. All participants had a successful

block except one who required general anaesthesia. Of note, six participants in the Dexa group and three in the Dexa-Dexme groups were hospitalised ($P=0.49$). Figure 1 describes the flow of participants during the trial, and Table 1 shows that participant characteristics were similar between groups.

The mean (SD) duration of analgesia, our primary outcome, was 621 (334) min in the Dexa group and 690 (544) min in the Dexa-Dexme group ($P=0.47$). Of note, five participants in each group (10%) did not take any oral opioid in the postoperative period ($P=1.00$). This outcome is represented as a Kaplan–Meier curve on Figure 2. Figure 3 displays the trajectory of the rest and dynamic pain scores during the course of the study, which were similar between groups. There were also no significant differences between groups for the other secondary outcomes such as durations of sensory and motor block, cumulative opioid consumption, and patient satisfaction (Table 2).

No participants developed hypotension or a bradycardia that required treatment. No participants developed infection, neuropathic pain, paraesthesia or muscle weakness in the upper limb at 7 postoperative days.

Discussion

Based on the data analysis of 99 participants included, this randomised, controlled, triple-blind trial shows that a combination of i.v. dexamethasone and dexmedetomidine does not provide superior analgesia compared with i.v. dexamethasone alone after a supraclavicular brachial plexus block for upper limb surgery. Durations of analgesia, sensory and motor block, pain scores, and oral opioid consumption were all similar between groups. There were no episodes of hypotension or bradycardia that required treatment. Such adverse effects occurring with dexmedetomidine have been well documented in the literature. For example, in a meta-analysis on 3019 patients comparing perineural dexamethasone with perineural dexmedetomidine there was an increased risk of hypotension with the latter (risk ratio 6.3, 95% confidence interval [CI] 1.5–27.5).² The difference in the incidence between the literature and our study stems probably from our definition, which specified that treatment was necessary.

Our trial confirmed our previous results on 122 patients undergoing rotator cuff repair with an interscalene brachial plexus block¹⁸ and those from Chassery and colleagues¹⁹ on 90 patients undergoing total knee arthroplasty under sciatic, femoral obturator, and lateral femoral cutaneous nerve blocks. The similar conclusion drawn from these three trials contrast with the findings reported by Kang and colleagues;⁵ after including 66 patients, these authors stated that adding dexmedetomidine i.v. to dexamethasone i.v. would increase the median duration of analgesia from 17 (interquartile range 15–36) h with dexamethasone i.v. alone to 66 (interquartile range 23–72) h, questioning the biological plausibility and validity of these results.⁵ We believe that our trial provides more robust evidence by eliminating some of the limitations present in the trials included in the abovementioned meta-analysis, such as inappropriate comparisons between study groups, administration of suboptimal doses of study drugs, perineural rather than i.v. routes of administration, and significant attrition rates.

The rationale for combining intermediate- and long-acting local anaesthetics (mepivacaine and ropivacaine) with i.v. adjuncts to prolong analgesia warrants comment. Our initial rationale for mixing ropivacaine and mepivacaine in a 1:1

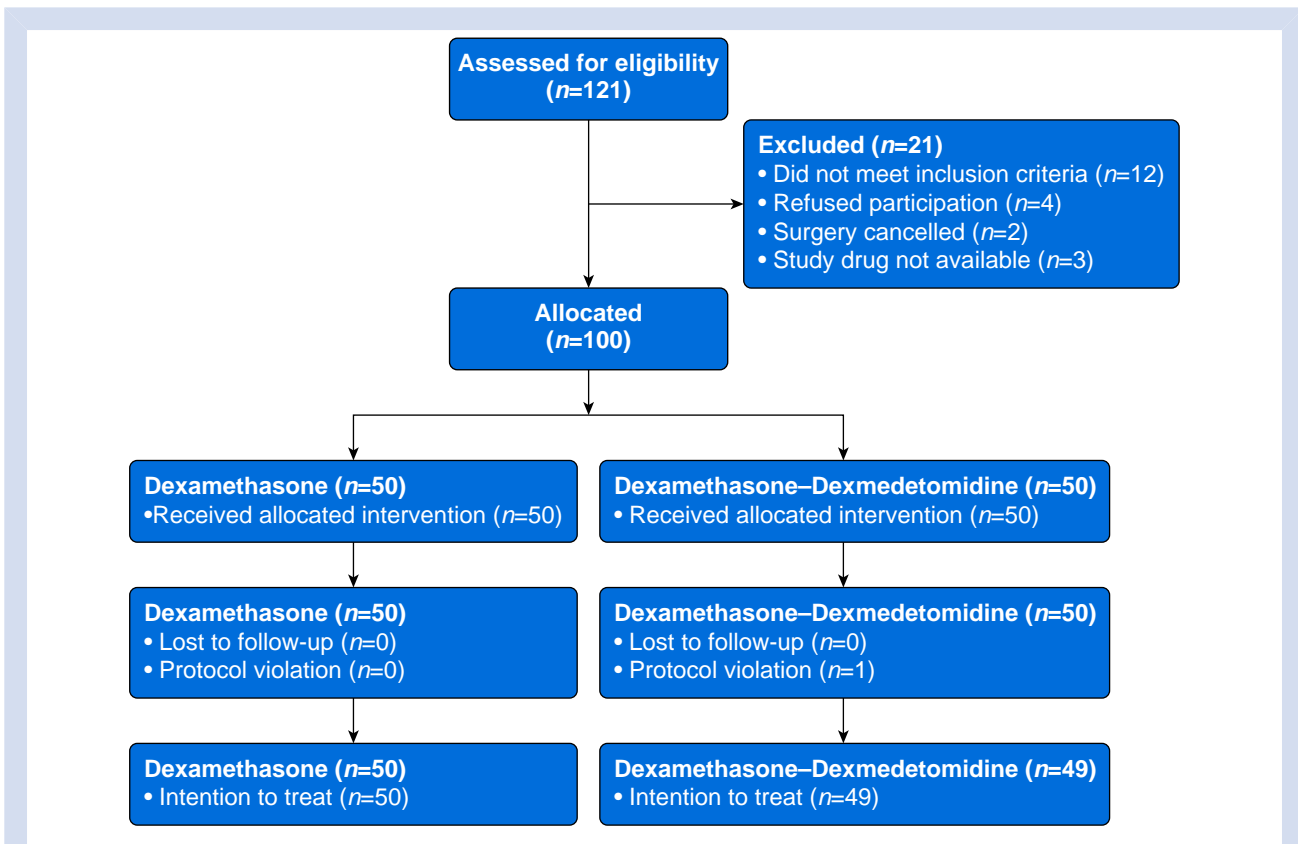


Fig 1. Flow of participants through the trial (CONSORT diagram). CONSORT, Consolidated Standards of Reporting Trials.

Table 1 Participant characteristics. Continuous data are presented as mean (standard deviation) and compared by Student's t-test; categorical data are presented as number of participants (%) and compared by using Fisher's exact tests.

	Dexamethasone group (n=50)	Dexamethasone-dexmedetomidine group (n=49)	Standardised mean difference	P-value
Sex			0.31	
Male; n (%)	18 (36)	25 (51)		0.16
Female; n (%)	32 (64)	24 (49)		
Age (yr)	50 (16)	53 (19)	0.19	0.36
Weight (kg)	73 (17)	73 (16)	-0.01	0.95
Height (cm)	168 (9)	170 (9)	0.25	0.22
Body mass index (kg m ⁻²)	26 (5)	25 (5)	-0.14	0.49
ASA physical status; n (%)				
1	13 (26)	15 (31)	0.31	0.32
2	33 (66)	26 (53)		
3	4 (8)	8 (16)		
Surgery location				0.36
Elbow	3 (6)	1 (2)	0.29	
Forearm	14 (28)	19 (39)		
Hand	33 (66)	29 (59)		
Duration of surgery (min)	47 (25)	55 (30)	0.31	0.13

volume ratio for supraclavicular blocks was two-fold: to achieve a more rapid onset of anaesthesia compared with ropivacaine alone, which is crucial in clinical settings with rapid surgical workflow, even if a dedicated block room is available; and to potentially reduce motor block duration, addressing patient discomfort or dissatisfaction commonly associated

with prolonged motor impairment. However, a recent meta-analysis has not confirmed these anticipated benefits.²⁰ Nevertheless, numerous studies have similarly used short- or intermediate-acting local anaesthetics combined with i.v. dexamethasone as an adjunct, underscoring the widespread acceptance and clinical validity of this approach.⁴

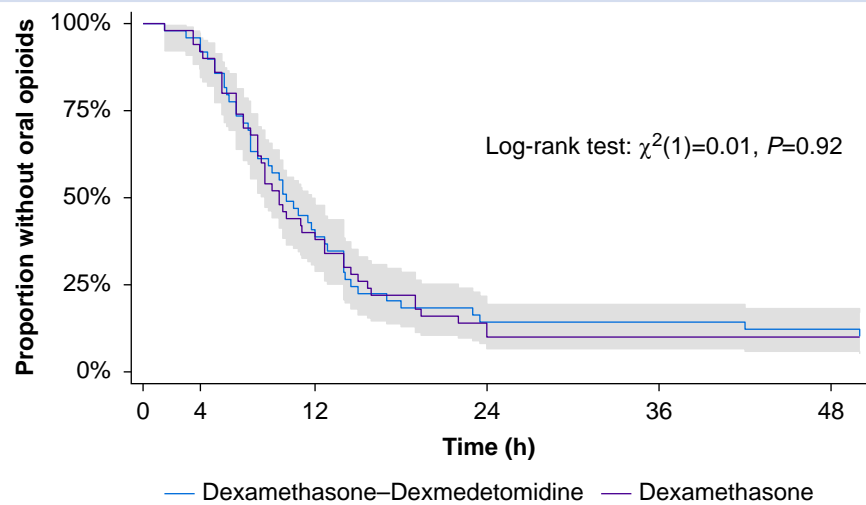


Fig 2. Kaplan–Meier curve of the effect of i.v. dexamethasone and the combination of i.v. dexamethasone and dexmedetomidine on duration of analgesia.

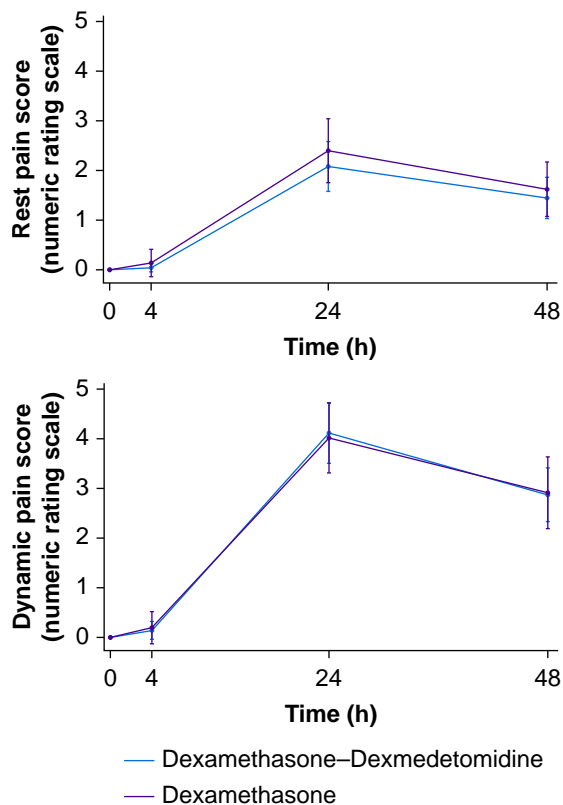


Fig 3. Rest and dynamic pain scores during the course of the study. Mean (95% confidence interval) is represented.

A few weaknesses of our study need to be mentioned. Firstly, we did not specifically specify on ClinicalTrials.gov that all patients received dexamethasone; however, we wrote that a history of hypersensitivity or intolerance to dexamethasone was an exclusion criteria. This item was specifically mentioned in the protocol submitted in the Ethics Committee. Secondly, the primary analysis was performed on a total of 89 patients, as 10 out of the 99 included patients did not need any oral opioid. We acknowledge that measuring time to first nonopioid analgesic request could have served as an alternative to our chosen primary outcome,²¹ time to first oral opioid intake, which is frequently used in similar studies. However, as nonopioid analgesics were administered at fixed intervals to all patients as part of a standardised multimodal analgesic regimen, consistent with current PROSPECT recommendations,^{22,23} time to first nonopioid analgesic request would not have provided clinically relevant information. Therefore, we retained time to first oral opioid intake as our primary outcome, as it better reflects clinically significant differences in postoperative analgesia. Thirdly, follow-up data were collected via telephone contact. Sole reliance on telephonic interaction might introduce recall bias, limit the objectivity of outcome assessment, and affect the consistency and completeness of data collection. Finally, while patients and care providers were all blinded to group allocation, we cannot exclude an unblinding effect from sedation, bradycardia or hypotension possibly occurring with dexmedetomidine.

In conclusion, the combination of i.v. dexamethasone and dexmedetomidine does not provide superior analgesia compared with i.v. dexamethasone alone after a supraclavicular brachial plexus block in patients undergoing upper limb surgery.

Table 2 Secondary outcomes. Continuous data are presented as mean (standard deviation) and compared by Student's t-test; categorical data are presented as number of participants (%) and compared by Fisher's exact test. NRS, numeric rating scale: 0 (no pain) to 10 (worst imaginable pain).

	Dexamethasone group (n=50)	Dexamethasone-dexmedetomidine group (n=49)	P-value
Duration of sensory block (min)	612 (278)	654 (232)	0.42
Duration of motor block (min)	627 (299)	660 (266)	0.56
Pain score at 4 h (NRS, 0–10)			
Rest	0.1 (1.0)	0.1 (0.3)	0.50
Dynamic	0.2 (1.2)	0.1 (0.7)	0.76
Pain score at 24 h (NRS, 0–10)			
Rest	2.4 (2.3)	2.1 (1.8)	0.45
Dynamic	4.0 (2.5)	4.1 (2.2)	0.83
Pain score at 48 h (NRS, 0–10)			
Rest	1.6 (2.0)	1.4 (1.5)	0.63
Dynamic	2.9 (2.6)	2.9 (1.9)	0.93
Cumulative opioid consumption (i.v. morphine equivalent)			
24 h	1 (3)	3 (5)	0.05
48 h	2 (6)	5 (9)	0.10
Patient satisfaction			1.00
Dissatisfied	1 (2)	0 (0)	
Neutral	0 (0)	1 (2)	
Satisfied	14 (28)	14 (29)	
Very satisfied	35 (70)	34 (69)	
Would you choose the same regional technique again?			1.00
No	1 (2)	1 (2)	
Yes	49 (98)	48 (98)	

Authors' contributions

Data interpretation: SG, EA
 Manuscript editing: SG, LB
 Patient recruitment: SG, AA, CC
 Block performance: SG
 Data collection: AA, CC
 Statistical analysis: JBR
 Study design, manuscript writing: EA
 Read and approved the final manuscript for submissions and agree to be responsible for its contents: all authors

Declarations of interest

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