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Research Article

Ropivacaine 0.4% iontophoresis versus continuous catheter infusion after iliac crest bone grafting in lumbar spine surgery

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KEYWORDS

Iontophoresis;
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Spine surgery

Abstract *Background:* Iliac crest (IC) pain accompanies IC grafting in spine surgery. The study evaluates the effectiveness of ropivacaine 0.4% iliac crest iontophoresis as compared to infusion through an IC catheter.
Methods: Thirty patients, 10 in each group, undergoing lumbar spine surgery had an intraoperative epidural block performed and initiated with 20 ml ropivacaine, 0.5% (100 mg) at termination of surgery and after 6 h maintained for 48 h (t48) at 10 ml/h with ropivacaine, 0.2%. Thirty millilitres NaCl, 0.9% (Group I "placebo group" and Group II "ropivacaine iontophoresis group") or 30 ml ropivacaine, 0.4% (Group III "ropivacaine IC catheter group") was also administered via an intraoperatively placed IC catheter. At t0, and for 48 h, 5 ml/h ropivacaine, 0.4% was administered via the IC catheter in Group III. In Group II, 30 ml ropivacaine, 0.4% iontophoresis was done using iontocare iontophoresis device. At t0 and for 48 h, 5 ml 0.4% ropivacaine iontophoresis was done at iliac crest site every hour using the iontocare device in Group II. Any further pain was controlled using intravenous morphine 0.1% in 5 mg increments. Pain assessment scores at IC site and at surgical site were evaluated at rest and at motion every 8 h for 48 h and after 4 m. Unbound and total plasma ropivacaine, morphine consumption, and patient satisfaction were evaluated.

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Results: At IC site, significant lower pain scores were elucidated in Groups II and III as compared to Group I at rest and at motion in the initial 48 h and at motion after 4 m. Plasma unbound ropivacaine was higher significantly in Group III at t48 when compared with Group I. Morphine consumption was lower significantly in Groups II and III at 24 and at 48 h when compared with Group I.
Conclusions: Ropivacaine IC iontophoresis provides safe effective analgesia for the initial 48 h and after 4 m.

1. Introduction

Spine surgeries are considered procedures associated with postoperative considerable discomfort and pain [1]. Moreover, they frequently mandate grafting from iliac bone, with two agonizing patient foci of pain. Continuous local anesthetic application via epidural placed catheter is regarded a postoperative lumbar spine surgery pain control established modality [2,3]. Although the pain at the iliac donor graft site usually persists throughout the initial postoperative weeks, the pain in its site may not resolve and may represent a significant postoperative morbidity source [4]. Moreover, pain incidences were reported after harvesting iliac crest (IC) bone graft revealing 29%, 38%, and 19% at 3 months, 6 months, and 2 years, respectively [1,5]. Lidocaine iontophoresis, which is the percutaneous delivery of charged drugs using low level electrical current, was proved to be potentially effective, safe and with no systemic bioavailability [6].

Local morphine administration and wound bupivacaine infiltration were used to be performed for pain control in the donor site at the IC [7].

Although the pain mechanism in IC donor site is still unrevealed, some periosteal and muscular postulations arose in relation to abductors stripping from bony ilium. It was also observed that pain increases at 3 months during flexion of the thigh toward the thorax and pain of neuropathic origin was postulated to be due to superior cluneal, the lateral femoral cutaneous or ilioinguinal nerves injury [4].

Grafted bone from IC is also often undergone in anterior cervical fusion where donor IC site pain may frequently be more agonizing than the pain at the primary site of operation. As local anesthetic direct site infiltration after bone harvesting is one method used for pain relief, patients who were administered bupivacaine needed less morphine and reported lower average length of hospital stay. This clinically implies that local anesthetic usage for the relief of the pain at the donor site is an effective and safe modality [7].

The study aimed at evaluating the analgesic safety and efficacy of ropivacaine 0.4% iontophoresis as compared to infusion via an IC catheter for 48 h at the site of harvested bone graft in patients undergoing lumbar spine surgery. Additionally, the donor IC site pain was assessed at 4 months after surgery.

2. Methods

After obtaining local hospital ethics committee approval and written informed consents, 30 adult patients, scheduled to undergo elective lumbar spine surgery from a dorsal approach using IC bone grafts, were enrolled in this prospective, randomized, double-blind study. Patients (American Society of Anesthesiologists status I or II; age, 20–70 years; weight, 55–110 kg; height, 150–190 cm) were eligible for inclusion if they had no known sensitivity to local anesthetics or morphine, were not pregnant, did not have a pacemaker, did not receive ropivacaine before surgery for at least 7 days and did not receive any opioid or antiinflammatory nonsteroidal drug. Failure to place an epidural catheter intraoperatively was also regarded as an exclusion criterion for the study.

This model is a standardized surgery mandating a similar amount of iliac bone grafting and with both surgical locations receiving same pain relieving drug. Patients were handed a number between 1 and 30 by picking up a sealed envelope enclosing the number. Patients were divided into three groups with 10 patients in each group. Each patient's attributed number was given to a pharmacist, who was indulged in preparing the anesthetic pack (for bolus and for maintenance) of the specified concentration of the ropivacaine or the placebo, in accordance to the randomization special list. On the surgery day, patients' premedication with 0.2 mg/kg midazolam was orally given 90 min before induction of anesthesia. Induction of general anesthesia was initiated using propofol 1.5–2.5 mg/kg and maintained using propofol 4–12 mg/kg/h. 0.6 mg/kg rocuronium in addition to 0.2 mg fentanyl were administered to facilitate intubation of the trachea. Each patient was meticulously turned into the prone position and spine surgery was undergone. Via an oblique surgical incision from proximal–medial to distal–lateral perpendicular to the posterior IC, bone graft was harvested. After exposing adequate field, an osteotome was used to cut through the IC exposing the iliac bone marrow cavity. Before wound closure, a foam pad self-resorbing dressing was directly placed over the bone. Tuohy 18-gauge needle (Perifix® B. Braun Melsungen AG, Melsungen, Germany) was used for tunneling the skin lateral to the incision in order to allow placement of a 20-gauge catheter directly in contact with the dressing. Then this catheter was secured to skin via sutures and adhesive dressing after completing the surgery. A thin adhesive dressing, covering only the suture line, was also placed at IC graft site allowing iontophoresis to be performed at the IC site from all around the suture line. At the termination of the lumbar spine surgical intervention, a multiple-hole epidural catheter (B. Braun, Melsungen, Germany) was introduced by the orthopedician either under direct visualization (if epidural space was opened during the surgical procedure) or with the loss-of-resistance technique using an 18-gauge Tuohy needle. The catheter was tunneled inside the epidural space for 3 cm and secured with a surgical knot to the skin. The catheter was tested by aspiration and the administration of a test dose consisting of 3 ml of bupivacaine, 0.5% with epinephrine (1:200,000). Initiation of the epidural block with 20 ml of ropivacaine, 0.5% (i.e., 100 mg) was done in all studied patients. Starting at 6 h after the initial epidural block, continuous epidural analgesia, with 0.2% of ropivacaine at an infusion rate of 10 ml/h, was also administered to all patients.

Figure 1 Iontocare device.

In Group I "placebo group", 30 ml of NaCl, 0.9% was administered via the IC catheter at the end of surgery followed by a continuously infused solution of NaCl, 0.9% at an infusion rate of 5 ml/h, and corresponding to the t0 of the study and for 48 h. Thirty millilitres NaCl, 0.9% iontophoresis was done at IC site at the end of surgery followed by 5 ml NaCl, 0.9% iontophoresis, at t0 and every hour for 48 h.

In Group II "ropivacaine iontophoresis group", 30 ml of NaCl, 0.9% was administered via the IC catheter at the end of surgery followed by a continuously infused solution of NaCl, 0.9% at an infusion rate of 5 ml/h, at t0 of the study and for 48 h. Thirty millilitres ropivacaine, 0.4% iontophoresis was done at IC site at the end of surgery followed by 5 ml, 0.4% ropivacaine iontophoresis, at t0 and every hour for 48 h.

In Group III "ropivacaine IC catheter group", 30 ml of ropivacaine, 0.4% was administered via the IC catheter at the end of surgery followed by a continuously infused solution of 0.4% ropivacaine at an infusion rate of 5 ml/h, at t0 of the study and for 48 h. Thirty millilitres NaCl, 0.9% iontophoresis was done at IC site at the end of surgery followed by 5 ml NaCl, 0.9% iontophoresis, at t0 and every hour for 48 h.

Iontophoresis was done using iontocare (Luventas-Medical, Germany) iontophoresis device (Fig. 1) and a sterile sprayer after skin sterilization using sterillium (Bode Chemie, Hamburg). The sterilized device roller, representing anode, is rolled over the skin at IC site of the operated upon side holding the device, from its sides, representing cathode, in one hand while touching the patient abdomen with the other hand to close the circuit. The device is adjusted at 4 mA and the ion switch is turned to the "positive" ion side. The device is shown to be operating when a blue light is lit on the light-emitting diode (LED) of the device.

Patients were transferred after tracheal extubation to the Post Anesthesia Care Unit (PACU).

Any further pain was controlled using intravenous morphine 0.1% in 5 mg increments and reported in the patient record. All the patients were instructed to receive 25 mg oral rofecoxib in addition to 2 g oral paracetamol each day for pain management within the 3 postoperative weeks if pain persisted after discharge.

2.1. Data assessment

A nurse not enrolled in or aware of the study protocol was responsible for evaluating pain in the operated site at IC and the spine (from t0 and every 8 h till t48, i.e., end of study) using the visual analog scale (from 0 mm = no pain to 100 mm = worst pain imaginable) at state of rest and during state of motion. The state of motion was elicited with thigh flexing toward thorax and this test was regarded as adequate when the thigh of the patient was in direct contact with his abdomen. All attacks of nausea, vomiting, or pruritis were also reported. Amount of consumption of morphine was reported at t24 and at t48. Daily observation of the IC catheter and epidural catheter for any inflammatory signs or signs of infection was done. Patients were requested to rank their satisfaction starting from 0, i.e., absolutely dissatisfied till 10, i.e., absolutely satisfied on the day after termination of the study. Four months after surgery, all studied patients were observed separately by an anesthesiologist and a surgeon. This was both to evaluate the pain at state of rest and during state of motion at the operated sites at IC and the spine, via the visual analog scale (0–100 mm) by the anesthesiologist and to perform neurologic evaluation comprising numbness, paresthesias and dysesthesias for damage of the ilioinguinal, lateral femoral cutaneous and superior cluneal nerves by the surgeon.

2.2. Blood ropivacaine sampling

Blood concentrations of ropivacaine were reported at t0, at t24, as well as at t48. Ten millilitres blood samples were retrieved in heparinized test tubes for unbound and total plasma ropivacaine concentration determination. Centrifugation (at 3000 rpm for 10 min) for plasma separation was done at room temperature and within 60 min after collection. Plasma was stored at −20 °C till performing drug assay. Gas chromatography was used for plasma total ropivacaine concentration determination while the plasma unbound ropivacaine concentration was determined using liquid chromatography with mass spectrometric detection after sample ultrafiltration.

2.3. Statistical analysis

In accordance to prior studies, pain severity at state of rest in this operative context was unbearable in 20% of patients receiving morphine via a patient-controlled analgesia device in the initial 48 h postoperatively. A power analysis was indicative of a size of a sample of 10 patients per group to sufficiently have an 80% power at 95% significance level. Mean ± SD was used to present the data unless otherwise was stated. Parametric variables were analyzed via Analysis of Variance. Mann–Whitney *U*-test with Bonferroni correction for multiple comparisons was used to analyze the pain scores. Fisher exact test was used to analyze adverse effects. *P* value of less than 0.05 was regarded significant.

3. Results

All studied patients fulfilled the protocol of the study. All groups were considered comparable regarding age, height, sex, weight, and surgical procedure duration (Table 1). All epidural analgesia catheters were successfully instituted, with no technical or

disconnection problems throughout the study course. Significant lower pain scores were elicited at the IC donor site at state of rest and during the state of motion in the ropivacaine groups (Groups II and III) when compared with Group I evaluated every 8 h up till t48 (Table 2A and B). Reports at the 4 months revealed that pain at the IC donor site in the state of motion (aching pain type) was lower significantly in the Groups II and III in comparison to Group I. At the state of rest, pain scoring was comparable in all groups (Table 3). No achievable significant difference was elicited among the studied groups as regards pain in the spine surgical site at the state of rest or during the state of motion, either throughout the initial 48 h postoperatively (Table 4A) or after 4 months (Table 4B). In Group I, the morphine consumption was increased significantly in comparison to the ropivacaine studied groups (Groups II and III) at 24 as well as at 48 h (Table 5). The incidence of nausea and vomiting, which occurred in 7, 5, and 4 of the studied patients in Groups I, II, and III, respectively, revealed no statistically significant difference. Pruritis was reported in 6, 3, and 4 of the studied patients in Groups I, II, and III, respectively, reaching no significant difference as well. There were not any observed signs of infection or inflammation at the IC catheter point of skin puncture in any of the studied patients. Ropivacaine groups (Groups II and III) revealed significantly greater patient satisfaction as compared to Group I. Patient satisfaction (mean ± SD) was 4 ± 2, 7 ± 1, and 9 ± 1 in Group I, II, and III, respectively. The plasma total ropivacaine concentrations were comparable in the three studied groups of patients at all studied times (Table 6A). The unbound ropivacaine fraction was higher in the ropivacaine groups (Groups II and III) than Group I at t0 and t24, as well as at t48, but only at t48 was higher significantly in Group III in comparison to Group I (Table 6B). Four months postoperatively, there were no patients revealing any signs of neurologic injury of the ilioinguinal, the lateral cutaneous, or the superior cluneal nerves. Moreover, there were no patients revealing paresthesias or numbness.

Table 3 VAS at site of the iliac crest in state of rest as well as during the state of motion after 4 months in the three studied groups. Values are presented as mean ± SD.

	At state of rest	During state of motion
Group I	14 ± 6	36 ± 10
Group II	6 ± 5	12 ± 7*
Group III	4 ± 2	11 ± 8*

VAS = visual analog scale from 0 = no pain to 100 = worst pain imaginable.
* Significant difference between the studied group and Group I ($P < 0.05$).

4. Discussion

This study reveals that, as compared to placebo, the 0.4% ropivacaine IC iontophoresis group of patients achieves significantly better postoperative pain control at the IC donor site both at the state of rest as well as during the state of motion, achieves significantly lower consumption of morphine as well as significantly higher satisfaction of patients and without significantly higher total or unbound ropivacaine plasma concentration at any time. Furthermore, the advantageous impact on pain remained available during the state of motion 4 months postoperatively in those patients.

Table 1 Patient characteristics.

	Group I (n = 10)	Group II (n = 10)	Group III (n = 10)
Sex, male/female	8/2	7/3	6/4
Age, years (mean ± SD)	26 ± 3	29 ± 4	25 ± 4
Weight, kg (mean ± SD)	79 ± 5	85 ± 7	75 ± 11
Height, m (mean ± SD)	1.68 ± 8	1.65 ± 4	1.70 ± 5
Operated upon site, right/left	3/7	4/6	7/3
Surgery time, min (mean ± SD)	77 ± 29	84 ± 19	82 ± 31

Table 2 VAS at site of the iliac crest in state of rest (A) as well as during the state of motion (B) in the three studied patient groups postoperatively (=t0) and then every 8 h up till t48. Values are presented as mean ± SD.

	t0	t8	t16	t24	t32	t40	t48
A							
Group I	40 ± 20*	19 ± 12*	18 ± 11*	18 ± 13*	17 ± 12*	16 ± 11*	18 ± 12*
Group II	12 ± 8	7 ± 3	7 ± 5	4 ± 4	4 ± 1	6 ± 4	5 ± 4
Group III	9 ± 12	6 ± 5	7 ± 4	4 ± 3	3 ± 3	4 ± 3	4 ± 2
B							
Group I	58 ± 25*	32 ± 20*	29 ± 13*	30 ± 19*	30 ± 13*	29 ± 16*	26 ± 15*
Group II	12 ± 10	9 ± 6	9 ± 7	8 ± 4	7 ± 3	6 ± 5	7 ± 5
Group III	12 ± 8	8 ± 7	9 ± 4	7 ± 6	6 ± 4	6 ± 4	7 ± 4

VAS = visual analog scale from 0 = no pain to 100 = worst pain imaginable.
* Significant differences between the studied group and the other groups ($P < 0.05$).

Table 4 Postoperative pain at the spine operative site expressed as VAS in state of rest (*A*) as well as during the state of motion (*B*) in the three studied patient groups postoperatively (=t0) and then every 8 h up till t48. Values are presented as mean ± SD.

	t0	t8	t16	t24	t32	t40	t48	4 months
A								
Group I	1 ± 2	2 ± 3	3 ± 3	4 ± 3	3 ± 5	4 ± 3	5 ± 6	12 ± 5
Group II	1 ± 3	1 ± 2	2 ± 3	6 ± 5	4 ± 6	3 ± 4	3 ± 6	11 ± 4
Group III	2 ± 4	1 ± 2	4 ± 3	4 ± 1	4 ± 3	3 ± 5	4 ± 2	9 ± 3
B								
Group I	3 ± 5	5 ± 7	7 ± 10	7 ± 9	6 ± 4	7 ± 8	9 ± 11	20 ± 8
Group II	4 ± 4	2 ± 3	7 ± 7	7 ± 10	4 ± 1	8 ± 10	8 ± 5	16 ± 5
Group III	4 ± 6	4 ± 6	6 ± 8	11 ± 12	5 ± 4	7 ± 9	7 ± 10	17 ± 6

VAS = visual analog scale from 0 = no pain to 100 = worst pain imaginable.

Table 5 Mean postoperative consumption of morphine (in milligrams) in the three groups of studied patients at 24 h and at 48 h postoperatively. Values are presented as mean ± SD.

	At 24 h	At 48 h
Group I	28 ± 14*	47 ± 19*
Group II	12 ± 8	18 ± 12
Group III	13 ± 4	17 ± 10

* Significant differences between the studied group and the other groups ($P < 0.05$).

In the current study, ropivacaine was used because, in comparison to the other long lasting and amino acid local anesthetics, it carries the least neurotoxicity as well as the greatest safety margin [8]. The 0.4% concentration was the ropivacaine concentration used at the IC site via iontophoresis and through IC catheter as a preliminary conducted pilot study revealed good postoperative pain control at the IC donor site at this concentration.

To our knowledge, this study is amongst the first studies eliciting the efficacy of 0.4% ropivacaine iontophoresis at the iliac crest donor site in patients undergoing lumbar spine surgery with IC graft.

Functional complications encountered by adults who performed IC grafting entailed that 37.9% of those patients did report pain at 6 months in the postoperative period. Thereafter pain incidence was reduced, where 18.7% of the patients continued reporting pain after more than 2 postoperative years [1]. Schenk et al. proved that after major spine surgery, continuous epidural ropivacaine analgesia resulted in significantly superior analgesia and patient satisfaction than intravenous morphine analgesia [2].

Lidocaine iontophoresis was reported to be an effective noninvasive local anesthesia for laser surgery of superficial skin lesions [9]. It has also been proved effective in topical anesthesia in children and in adults [10].

It was shown by Knudsen et al. that the tolerated maximum dose for CNS symptoms was more in 9 out of 12 subjects after ropivacaine and after bupivacaine was more in 3 subjects [11]. It has been documented that correctly placed 'surgical' epidural catheters are effective means of good analgesia after posterior spinal surgery [12]. This is advantageous in this study for almost absolutely aborting the pain originating other than that arising from the IC donor site.

The beneficial outcomes of local anesthetics iontophoresis have been illustrated by variable clinical studies [9,10]. In a study by Cowan et al. [7] positive results were reported after repeated applications of 0.25% bupivacaine boluses for IC donor site pain. Gundes et al. [13] revealed that addition of morphine to bupivacaine achieved a better control of pain in comparison to bupivacaine solely. Efficacious control of pain in the acute phase had a favorable outcome on long-term dysesthesia and pain, which constitutes the main issues that patients complain of postbone grafting from iliac crest [13]. The advantageous impact of this management was still evident after 3 months.

The favorable outcome of less chronic pain at the donor location encountered in the current study and in another study [13] is suggestive of a chronic pain-relieving effect where a diminution in spinal cord hyperexcitability is produced by a quick decrease in afferent noxious input [14]. Nevertheless, this matter is under controversy [15]. Furthermore, as revealed by Kelly et al. [16] the changeable patient features relative to the operative noxious stimulus mandated individualization of the method chosen. Additionally, multimodal pain-relieving methods appear more efficient as compared to a sole-drug management [17].

In the present study, no patient got any clinical manifestations of pain of neuropathic nature, plus no sensory disorders were encountered. The advancement of the IC catheter in a swab on the periosteum appears suitable as the neurosensory pain fibers resides in high condensation in the periosteum, while fine nonmyelinated as well as myelinated fibers escort vessels to the inside of the bone [18,19].

In the ropivacaine groups of studied patients (Groups II and III), patients were given 0.4% ropivacaine at a rate of 5 ml/h at the iliac crest. The mean blood unbound ropivacaine concentrations in Group III given the 0.4% ropivacaine through IC catheter were 0.051, 0.061, and 0.090 mg/l at t0, t24, and t48, respectively, while in Group II given the 0.4% ropivacaine iontophoresis at IC site were 0.053, 0.059, and 0.039 mg/l at t0, t24, and t48, respectively. These blood levels stay well behind the levels reported by Knudsen et al. regarding early central nervous toxicity signs of 0.15 mg/l [11].

In the clinical study by Knudsen et al., a central nervous system threshold for toxicity was evident at a mean plasma free level of almost 0.6 mg/l for ropivacaine as well [11].

Table 6 Plasma total (*A*) and unbound (*B*) concentration of ropivacaine in the three groups of studied patients at 24 h and at 48 h postoperatively. Values are presented as mean ± SD.

	t0	t24	t48
A			
Group I	0.60 ± 0.3	1.2 ± 0.4	1.5 ± .07
Group II	0.81 ± 0.2	1.4 ± 0.8	1.8 ± 0.2
Group III	0.80 ± 0.5	1.6 ± 0.3	1.8 ± 0.7
B			
Group I	0.032 ± 0.035	0.028 ± 0.015	0.020 ± 0.012
Group II	0.053 ± 0.032	0.059 ± 0.021	0.039 ± 0.028
Group III	0.051 ± 0.048	0.061 ± 0.011	0.090 ± 0.110*

* Significant difference between the studied group and Group I ($P < 0.05$).

The unbound ropivacaine blood level reported in the current study at t48 in Group III being given ropivacaine 0.4% through IC catheter was the only blood level achieving significantly higher blood levels as compared to Group I "placebo group".

The occurrences of pruritis, nausea as well as vomiting were comparable in the three studied groups in spite of the lower consumption of morphine plus the better control of pain in the ropivacaine groups of patients. The major endpoint in the present investigation was the pain score, and thus, the investigation was presumably underpowered in unveiling a dissimilarity in-between the three studied groups as regards the side effects.

The current study reveals that 0.4% ropivacaine iontophoresis at the iliac crest harvest site can diminish the occurrence as well as the severity of initial acute and later chronic pain at the iliac crest donor site postlumbar spine surgery with IC graft. This was coupled with a reduced pain score in the early postoperative time, diminished consumption of morphine, higher level of satisfaction of patients, few side effects as well as a reduced pain score during state of motion four months postoperatively. Those favorable results were comparable to those elicited in patients given 0.4% ropivacaine through IC catheter but without a significantly higher unbound ropivacaine blood level as compared to control group 48 h postoperatively.

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