



# Three versus five lumbar paravertebral injections for inguinal hernia repair in the elderly: a randomized double-blind clinical trial

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## Abstract

**Purpose** The objective of the study was to compare three nerve stimulator-guided paravertebral injections versus five injections for elderly patients undergoing inguinal hernia repair in terms of the amount of intraoperative fentanyl and propofol consumption and conversion to general anesthesia. The secondary objective was postoperative pain.

**Methods** A prospective, randomized, double-blind clinical trial was performed. 200 elderly patients undergoing unilateral herniorrhaphy were randomized into two groups. Group III received three PVB injections from T<sub>12</sub> to L<sub>2</sub> and placebo at T<sub>11</sub> and L<sub>3</sub>. Group V received five PVB injections from T<sub>11</sub> to L<sub>3</sub>.

**Results** The mean intraoperative fentanyl and propofol consumption were significantly lower in group V ( $4.9 \pm 7.2 \mu\text{g}$  versus  $20.0 \pm 12.9 \mu\text{g}$  and  $5.7 \pm 11.6 \text{ mg}$  versus  $34.6 \pm 22.9 \text{ mg}$ , respectively,  $p$  value  $< 0.0001$ ). Five patients (5.0%) in group III had failed block and were converted to general anesthesia ( $p$  value = 0.024). Group V had significantly lower pain scores compared to group III during the first three postoperative days ( $p$  value  $< 0.0001$ ).

**Conclusion** The five PVB injection technique is more suitable as a sole anesthetic technique for elderly patients undergoing herniorrhaphy, since it required less intraoperative supplemental analgesia and provided lower postoperative pain scores compared to the three PVB injection technique.

**Trial registration** Clinicaltrials.gov identifier: NCT02537860.

**Keywords** Nerve block · Postoperative pain · Geriatric anesthesia

## Introduction

Adult inguinal hernia repair is one of the most common surgical interventions that may be performed using general, regional or local anesthesia [1–3]. Although the most effective anesthetic technique for inguinal herniorrhaphy is still a controversial issue [2], paravertebral block (PVB) has shown remarkable postoperative analgesia, short hospital

stay and less postoperative nausea and vomiting (PONV) compared to general anesthesia (GA), spinal anesthesia (SA) and ilioinguinal nerve block [4–7]. Elderly patients present usually with a higher risk for developing cardiopulmonary complications and mental disturbances following GA or SA [8–11]. Thus, elderly patients may benefit from the PVB anesthetic technique.

Despite the reported satisfactory results for PVB and the continuous efforts to improve the outcomes, there is no standardized PVB for inguinal hernia repair in terms of technique and number of injections (ranging from one to five) [12–16]. These differences have led to various perioperative anesthetic success rates manifested by the need of local anesthetic infiltration and supplemental inhaled and/or IV sedation or even conversion to GA [2, 12, 15, 17]. Hence, two, three or four anesthetic injections did not provide complete surgical block and could not be used as a sole anesthetic method [12]. However, literature provided two recommendations that may improve the accuracy and efficacy of PVB. First, performing multiple injections at all

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relevant dermatomes may increase the likelihood of obtaining complete surgical blockade. Second, performing PVB under the guidance of nerve stimulator or ultrasound may eliminate the possible complications and increase the success rate [4, 7, 18, 19].

Based on this background, the study hypothesis was that five PVB injections could be used as a sole anesthetic technique. A prospective double-blind clinical trial was conducted to compare three nerve stimulator-guided PVB injections versus five injections for elderly patients undergoing herniorrhaphy. The primary objective was to compare the amount of intraoperative fentanyl and propofol consumption and conversion to general anesthesia. The secondary objective was postoperative pain.

## Methods

### Patients' selection and intervention

The clinical trial was registered in Clinicaltrials.gov (identifier: NCT02537860).

After approval of the Institutional Review Board, written informed consent was obtained from 200 patients aged above 65 years with ASA II, III or IV admitted to undergo elective unilateral inguinal hernia repair during the period from September 2015 and December 2017. Patients were randomized by computer-generated numbers and the sealed envelope technique was used to divide the patients into two groups. Group III (100 patients) received three PVB injections from T<sub>12</sub> to L<sub>2</sub> and placebo at T<sub>11</sub> and L<sub>3</sub>. Group V (100 patients) received five PVB injections between T<sub>11</sub> and L<sub>3</sub>. The anesthetist, surgeon, patient and data collector were all blind to the patients' assigned group. Exclusion criteria consisted of bilateral inguinal hernia, huge inguinoscrotal hernia, incarcerated hernia, known history of allergic reactions to local anesthesia, bleeding disorders, neurological disorders, infection at site of injection, emergency cases and pre-existing or obvious spinal diseases of the lower back as determined by physical examination.

ECG leads, pulse oximetry and non-invasive oscillometric arterial pressure were attached. Patients received intravenous premedication of 50 µg fentanyl before receiving PVB. Unilateral PVBs were performed while the patient was in the lateral decubitus position with the side to be operated on the upper position. Sites of injection were marked 2.5–3 cm lateral to the midline of the vertebral column.

### Paravertebral block technique

Following aseptic preparation of the skin, the injection sites were infiltrated with 0.1 ml of lidocaine 1% each using an 8 mm, 30 G needle (BD Micro-Fine Plus, Becton Dickinson

and company). PVB injections were done using a 100 mm 22 G nerve stimulator needle (Stimuplex, B. Braun, Melsungen, Germany). The injections began at L<sub>3</sub> and proceeded upward, reaching T<sub>11</sub>. The needle was introduced perpendicularly to the skin at the site of the injection point using the following nerve stimulator settings: 5 mA, 9V and 2 Hz. The stimulating needle was gently manipulated into a position to allow a muscular response (muscle contraction detected by eyesight or palpation) with a stimulating current of 0.4–0.8 mA.

To preserve the double blindness of this clinical trial, two syringes were used for both groups. The first syringe labeled (A) was filled with 15 ml of solution and used to inject 5 ml at each of the levels: T<sub>12</sub>, L<sub>1</sub> and L<sub>2</sub>. For group V, syringe (A) contained 9 ml bupivacaine (45 mg) in addition to 6 ml saline, while for group III the syringe (A) contained 15 ml bupivacaine (75 mg). The second syringe labeled (B) was filled with 10 ml and used to inject 5 ml of the solution at each of the levels T<sub>11</sub> and L<sub>3</sub>. For group V, syringe (B) contained 6 ml bupivacaine (30 mg) and 4 ml saline, whereas for group III the syringe (B) contained 10 ml saline (placebo) (Fig. 1). This ensures that the two groups received equal anesthetic dose of 75 mg bupivacaine (bupivacaine hydrochloride 5 mg/ml).

To allow for adequate blinding, the solution used for injection (saline or local anesthetic mixture) was prepared by an independent nurse outside the operating room and the randomization code was not broken before the end of the study.

While performing the block and after puncturing the skin with the nerve needle, the contraction of the dorsal paraspinal muscle occurred. When the nerve needle was inserted

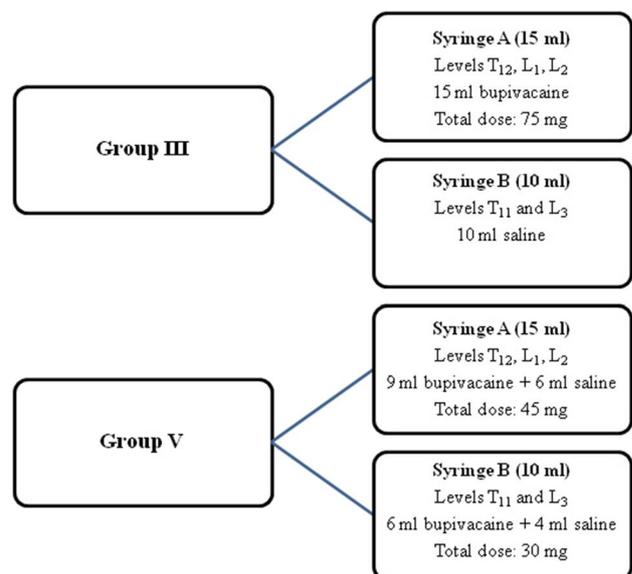


Fig. 1 Preparation of syringes used in the study

deeper, the abdominal muscles contracted. Then, the needle tip was adjusted to receive the maximum contraction while lowering the stimulating current. Block onset was determined by cold test.

Patients who felt pain during the surgery were given IV fentanyl (50–100 µg) and followed, if needed, by propofol (0.4–0.5 mg/kg) while keeping the patient responsive to verbal stimulation. If the latter was not sufficient, the patient was converted to GA since PVB was considered to be failed block.

## Data collection

Demographic and preoperative variables including gender, age, height, weight, body mass index (BMI) and ASA physical status were collected. Time to perform the block, onset time and intraoperative hemodynamic monitoring (MAP and HR) were noted during the entire surgery and recorded pre-precision, at skin incision, at traction of the inguinal hernia sac and upon wound closure. Supplemental intraoperative sedation (fentanyl and propofol) was also recorded. In addition, surgery duration, time to first diet, drinking, flatus, defecation, urination and walking as well as incidence of PONV, numbness and motor weakness were noted. Motor weakness was assessed by the Medical Research Council Manual Muscle Testing that has a scale from 0 to 5 with 0 indicating no muscle contraction and 5 indicating active movement against gravity and full resistance. Patients' satisfaction was also assessed and was based on their comfort and activity during the procedure, intra- and postoperatively. Patient's comfort was determined by the following criteria: feeling of pain, PONV and negative or bad memory of the procedural experience. The patient's activity was based on the ability to sit, walk and move. Patients rate these issues on a scale of one to three ranging from satisfied, partially satisfied and unsatisfied. Surgeon's satisfaction was based on the overall intra- and postoperative status of the patient. It was measured based on the following: (1) intraoperative discomfort manifested by patients' movement or feeling of pain, (2) self-transportation from the surgical table to stretcher and (3) postoperative pain reported by the patient.

Postoperative pain was assessed at predetermined time intervals during the first 5 postoperative days (0 h, 6 h, 12 h and day 1 till day 5) using the Verbal Numeric Rating Scale (VNRS) (where 0 means no pain and 10 corresponds to the worst possible pain). Patients were discharged on the same day once they had urinated and demonstrated the ability to tolerate oral diet. Data were collected during the hospital stay by residents blind to the patient's group. Patients were informed how to record their pain scores and were contacted by the same resident during the follow-up period by daily telephone calls.

## Statistical analysis

Data were reported as mean ( $\pm$  SD) or number of patients (%). Chi square test and *t* test (two-tailed) were used to assess any significant difference between the two groups. Two-way ANOVA with repeated measures was performed to determine if there was a significant effect on pain with respect to the two groups. Post hoc paired comparison was done to determine the time points at which the difference exists. *P* values  $< 0.05$  were considered statistically significant. Based on previously published study, a sample size of 100 patients in each group was sufficient to detect a 20% decrease in intraoperative propofol consumption (primary outcome) with 5% significance level and 90% power [12].

## Results

Two-hundred patients were enrolled in this study, 100 patients in group III and 100 patients in group V (Fig. 2). The two groups were similar with respect to demographic data (Table 1). Time needed to perform the block and onset time were similar in the two groups (Table 2). 90% of patients in group V did not require intraoperative sedation in comparison to 52% of patients in group III. Intraoperative fentanyl and propofol consumption was significantly lower in group V at skin incision and sac traction (*p* value  $< 0.0001$ ) (Table 2). Hemodynamics (MAP and HR) on incision and traction were significantly lower in group V (Table 2). There were no differences in hemodynamics at wound closure (Table 2). Five patients in group III had failed block according to the criteria presented in the methods and were converted to GA.

Regarding postoperative data, the two groups were comparable concerning time to first diet, flatus, defecation and urination (Table 2). Time to first walking was significantly longer in group V compared to group III (143.1 versus 134.3 min, *p* value = 0.003). Incidence of PONV, numbness and motor weakness in the lower extremity were comparable between the two groups. Seven patients had numbness in the thigh for 2–3 h, but they were able to walk (5 versus 2 patients for group V and III, respectively). Levels of patients' and surgeons' satisfaction were significantly higher in group V compared to group III (*p* value  $< 0.0001$ ) (Table 2).

Group V had significantly lower pain scores compared to group III during the first three postoperative days (*p* value  $< 0.0001$ ) (Fig. 3).

## Discussion

The results of the clinical trial showed that five PVB injections provided significantly better intraoperative anesthesia when compared with three PVB injections in terms of the

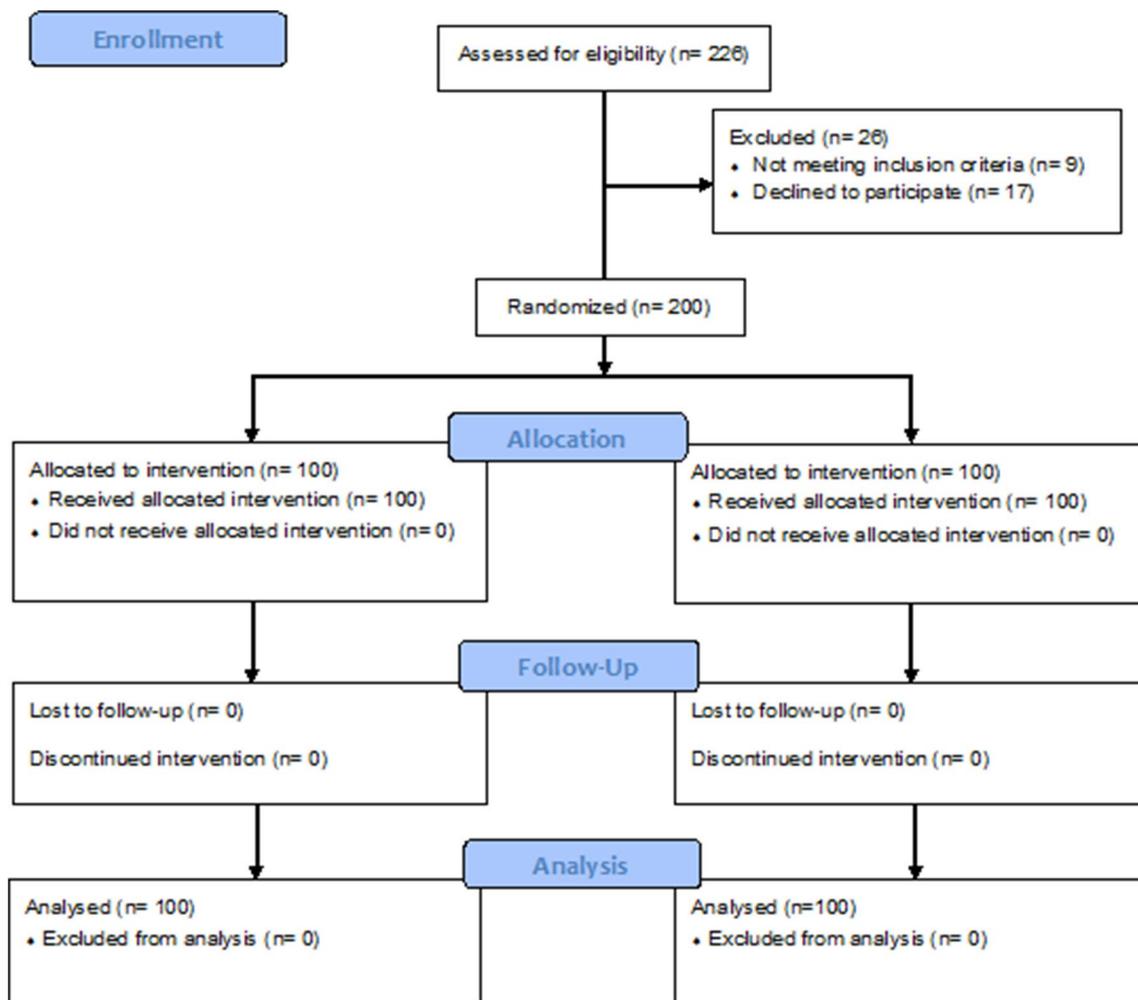


Fig. 2 Flowchart illustrating the selection of patients

need for intraoperative sedation and analgesics. Most of the patients (90%) in the five PVB injection group did not need any kind of sedation or analgesics during the operation compared to 52% of the patients in the three PVB group. Despite the results obtained in this study that 10 patients in the five injections group needed slight sedation, these results reflect that the use of five injections may be promising for elderly patients, since this could decrease morbidity and mortality compared to GA or SA while maintaining intraoperative hemodynamic stability [20]. However, there are three different aspects to the merit discussing: first, the use of PVB as a sole anesthetic technique; second, the need to increase the number of injections from three to five; and third, the possibility of incomplete block as observed in some patients.

First, elderly patients are at higher risk of delayed psychomotor and mental functions after the use of anesthetic drugs [18, 19]. GA and SA might be associated with complications and are contraindicated for patients with certain medical conditions [8, 21, 22]. Several studies have revealed that

local anesthetic infiltration for hernia repair is more safe and effective than general or regional anesthesia [23]. Nevertheless, it is usually accompanied by sedation [24].

Second, the number of injections used in previous studies ranged from one to five and the levels were in the range of T<sub>10</sub> till L<sub>2</sub> [7, 12, 15, 17, 25]. Ozkan et al. mentioned that for a successful hernia repair surgery, the ilioinguinal, iliohypogastric and genitofemoral nerves must be blocked. This could be achieved by performing injections at two levels. However, patients in their study required intraoperative sedation, similar to the results obtained in group III in this study [12]. Thus, two or three injections were insufficient to obtain solid surgical block without the need for sedation or analgesics in most patients. On the contrary, in the five injections group in this study, 90% of the patients did not need intraoperative sedation or analgesics. We performed, for patients in group V, injections in the thoracic region (T<sub>11</sub> and T<sub>12</sub>) as well as in the lumbar region to ensure complete blockade of the surgical area, since the lumbar paravertebral

**Table 1** Demographic and preoperative data

	Group V	Group III	<i>P</i> value
Number of patients	100	100	–
Gender			
Female	5 (5.0%)	4 (4.0%)	0.733
Male	95 (95.0%)	96 (96.0%)	
Age (years)	68.1 (5.0)	68.4 (4.9)	0.651
Height (cm)	168.1 (5.3)	169.4 (6.6)	0.115
Weight (kg)	71.5 (10.4)	71.37 (12.1)	0.930
Body mass index (kg/m <sup>2</sup> )	24.5 (3.7)	25.2 (3.0)	0.11
< 25	49 (49.0%)	44 (44.0%)	0.163
25–30	39 (39.0%)	50 (50.0%)	
≥ 30	12 (12.0%)	6 (6.0%)	
ASA physical status			
ASA II	51 (51.0%)	60 (60.0%)	0.436
ASA III	35 (35.0%)	28 (28.0%)	
ASA IV	14 (14.0%)	12 (12.0%)	

Data are presented as number of patients (%) or mean (SD) as appropriate

area is different and separate from the thoracic paravertebral region [1, 25–27]. Hence, increasing the number of injections may increase the likelihood that the required segments are anesthetized.

Third, most of the published PVB studies for hernia repair were accompanied by intraoperative sedation, knowing that they had used different number and level of injections [7, 12, 13, 15]. Using sedation with PVB might not be considered an acceptable alternative for some anesthesiologists [2]. Sedation has been associated with undesirable side effects such as postoperative delirium, respiratory depression, nausea and vomiting [28, 29]. Also, the risk of respiratory depression that could be caused by opioids increases significantly in the elderly [29]. This risk increases when combining opioid premedication with intraoperative fentanyl and neuromuscular blockers [30].

Despite the success of five injections, there is still a need for intraoperative sedation in few patients, although it was significantly lower in group V. This could be due to misplacing the needle while performing the injections which prevents the anesthetic solution from reaching the appropriate location. Another factor that may contribute to the need of sedation in few patients could be the anatomical variation of the lumbar plexus. Several studies have demonstrated that there is variability in the emergence, distribution and presence of the ilioinguinal and iliohypogastric nerves [31, 32]. This anatomical variation could lead to maldistribution of the local anesthesia, resulting in incomplete surgical block [33–35]. A combination of nerve stimulator and ultrasound-guided PVB may be applied to verify the position of the needle in the near proximity of the nerve and the distribution of the local anesthesia, and consequently reduce or eliminate the need for sedation or analgesics during the operation.

Similar to other studies, none of the patients had urinary retention, dural or epidural puncture [7, 12]. The results of the present study showed that increasing the number of injections may not increase the risk factors, since none was reported in this study.

The study had some limitations. First, the study did not show evidence of spread of local anesthetics or anatomical presentation to demonstrate the mechanism of the difference between three and five injections. Second, the superiority of five PVB injections compared to four injections is still unknown. Further studies are needed to compare four versus five PVB injections associated with ultrasound-guided technique.

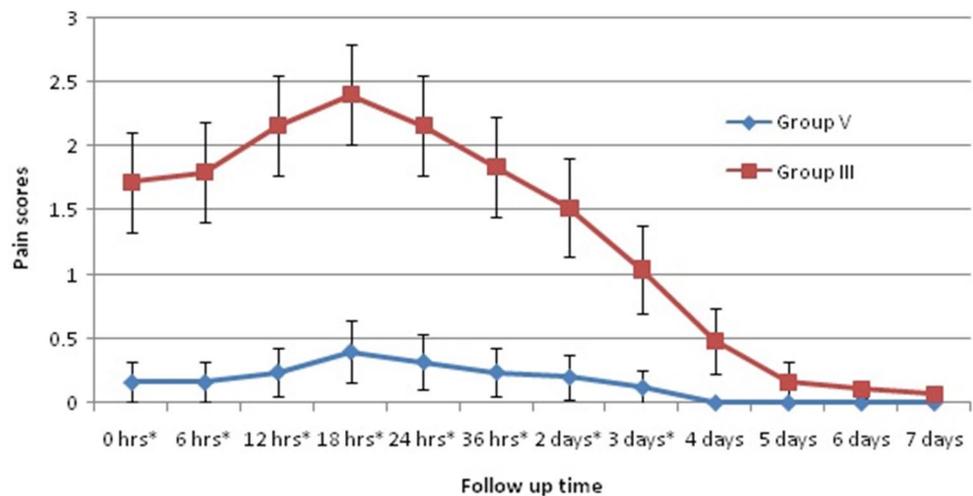
In conclusion, the present double-blind clinical trial showed that PVB performed at five segments would anesthetize the inguinal area with less need for intraoperative sedation while maintaining hemodynamic stability. This would be beneficial for elderly patients.

**Table 2** Pre-, intra- and postoperative characteristics

	Group V	Group III	P value
Time needed to perform block (min)	8.9 (0.8)	8.9 (0.7)	0.854
Block onset time (min)	15.2 (1.5)	15.1 (1.6)	0.549
At skin incision			
Fentanyl (µg)	0.3 (2.5)	4.5 (9.6)	<0.0001
Propofol (mg)	0.4 (2.8)	11.6 (9.9)	<0.0001
At sack traction			
Fentanyl (µg)	0.8 (4.3)	9.0 (13.1)	<0.0001
Propofol (mg)	4.1 (8.3)	9.3 (11.6)	<0.0001
Upon wound closure			
Fentanyl (µg)	3.9 (9.4)	6.3 (11.4)	0.114
Propofol (mg)	1.2 (4.6)	13.7 (14.6)	<0.0001
At skin incision hemodynamics			
MAP (mmHg)	96.1 (11.6)	102.0 (11.0)	<0.0001
HR (beats/min)	68.7 (8.9)	74.3 (7.9)	<0.0001
At sac traction hemodynamics			
MAP (mmHg)	96.6 (11.5)	102.5 (10.9)	<0.0001
HR (beats/min)	69.1 (8.8)	74.7 (8.0)	<0.0001
Upon wound closure hemodynamics			
MAP (mmHg)	99.2 (12.2)	102.2 (10.1)	0.059
HR (beats/min)	68.1 (8.7)	69.9 (7.5)	0.121
Fentanyl consumption (µg)	4.9 (7.2)	20.0 (12.9)	<0.0001
Propofol consumption (mg)	5.7 (11.6)	34.6 (22.9)	<0.0001
Failed block (converted to GA)	0 (0.0%)	5 (5.0%)	0.024
Surgery duration (min)	91.3 (22.9)	87.4 (21.2)	0.214
Time to first (min)			
Diet	345.8 (202.8)	392.00 (262.2)	0.262
Drinking	71.7 (57.1)	89.90 (48.2)	0.016
Flatus	57.4 (47.3)	57.38 (42.4)	0.994
Defecation	1028.6 (850.3)	1194.06 (885.4)	0.179
Urination	65.9 (53.5)	71.13 (49.1)	0.474
Walking	143.1 (19.7)	134.26 (21.8)	0.003
PONV	8 (8.0%)	12 (12.0%)	0.346
Numbness in the thigh	5 (5.0%)	2 (2.0%)	0.248
Motor weakness	5 (5.0%)	1 (1.0%)	0.097
Surgeon satisfaction			
Satisfied	99 (99.0%)	67 (67.0%)	<0.0001
Partially satisfied	1 (1.0%)	26 (26.0%)	
Unsatisfied	0 (0.0%)	7 (7.0%)	
Patient satisfaction			
Satisfied	89 (89.0%)	40 (40.0%)	<0.0001
Partially satisfied	9 (9.0%)	35 (35.0%)	
Unsatisfied	2 (2.0%)	25 (25.0%)	

Data are presented as number of patients (%) or mean (SD) as appropriate

**Fig. 3** Mean pain scores for the two groups. \*Post hoc paired significant difference  $p$  value  $<0.0001$ . Bars indicate 95% CI



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