

# Postoperative pain relief and functional outcomes after pre-emptive ultrasound-guided caudal analgesia in patients undergoing spinal laminectomy under general anaesthesia: Comparison between bupivacaine versus bupivacaine with morphine

## Address for correspondence:

Dr. Parul Jindal,  
Department of Anaesthesiology  
and Pain Management,  
HIMS, SRHU, Dehradun,  
Uttarakhand, India.  
E-mail: paruljindal@srhu.edu.in

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**Medha Bhardwaj, Parul Jindal, Aastha Srivastava, Brijesh Tiwari<sup>1</sup>**

Departments of Anaesthesiology and Pain Management and <sup>1</sup>Neurosurgery, HIMS, SRHU, Dehradun, Uttarakhand, India

## ABSTRACT

**Background and Aims:** Prevention of the start of the neural cascade may result in long-term advantages by the elimination of hypersensitivity produced by noxious stimulus. This study was designed to evaluate postoperative pain and long-term functional outcomes after pre-emptive ultrasound (US)-guided caudal analgesia in patients undergoing spinal laminectomy.

**Methods:** A total of 90 consecutive patients, aged 20 to 60 years, of either sex, scheduled for elective spinal laminectomy under general anaesthesia were randomly allocated to two groups. Group M (n = 45) received 3 mg morphine + 0.25% bupivacaine (25 ml), whereas group B (n = 45) was administered 0.25% bupivacaine (25 ml) in caudal block. The primary outcome was to observe postoperative static and dynamic pain using the Verbal Numerical Rating Score (VNRS) for 24 h. The secondary outcome was to record functional outcomes using two questionnaires—Oswestry Disability Index (ODI) and Rolland Morris Disability Questionnaire (RMDQ) during the preoperative period, at 1 month and 3 months postoperatively.

**Results:** The static and dynamic VNRS scores were significantly less in group M ( $P < 0.05$ ). There was a statistically significant clinical improvement in RMDQ and ODI scores at all-time intervals between both groups ( $P < 0.05$ ). A four-point difference in ODI during subsequent months represents a true change and the results of our study showed an outstanding improvement of 9-11 points at 1 and 3 months from the baseline. **Conclusion:** The use of caudal block with the US guidance in adults undergoing spine surgeries can bring new horizons in improving pain relief and long-term functional outcomes.

**Key words:** Laminectomy, morphine, ultrasonography

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## INTRODUCTION

Postoperative pain following lumbar laminectomy may be multifactorial. It may be due to the activation of various pain mechanisms like neuropathic, inflammatory and nociceptive.<sup>[1]</sup> Nociceptors and mechanoreceptors, with innervations via posterior rami of spinal nerves, cause severe pain owing to the extensive cross-connections of the nerves and may lead to referred pain, which remains persistent as chronic pain in patients.<sup>[2]</sup>

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In patients with chronic backache who undergo laminectomy, pain is more localised resulting in elevated pain scores. The number of vertebrae operated on peripheral as well as central sensitisation further increases the pain. Effective postoperative pain control improves radiculopathy and morbidity which in turn improves the overall functional outcome.<sup>[3]</sup> Multimodal analgesia and pre-emptive analgesia are recommended for enhanced recovery.

Administering adjuvants with local anaesthetics in the caudal block may act in synergism by improving pain relief along with decreasing the side effects.<sup>[4]</sup>

Ultrasound (US)-guided blocks reduce the dependency on anatomic references, help in the precise placement of drugs around the nerves and follow the real-time spread. The blocks are more effective, require fewer anaesthetic drugs and are safer.<sup>[5]</sup>

We hypothesised that pre-emptive caudal analgesia under US guidance with bupivacaine compared to bupivacaine with morphine can decrease both immediate pain and improve long-term functional outcomes. The primary outcome was to observe postoperative static and dynamic pain using the Verbal Numerical Rating Score (VNRS) for 24 h. The secondary outcome was to record long-term functional outcomes.

## METHODS

This experimental, randomised study was conducted after obtaining Institutional Ethics Committee approval (SRHU/Reg/Int/2019-85) and informed written consent from the participants in a tertiary care teaching hospital. The clinical research was done following the ethical principles for medical research involving human subjects by Helsinki's declaration of December 2013.

A total of 90 patients of either sex belonging to the American Society of Anesthesiologists physical status grade I or II were studied over 12 months (March 1, 2019 to February 29, 2020). Patients with a history of chronic low back pain persistent for 6 months despite alternative therapies and radiological findings of a prolapsed unilevel disc without ligamentary hypertrophy posted for lumbosacral spine surgery (a single-level lumbar discectomy at L3-L4, L4-L5 and L5-S1) for degenerative disease not requiring fusion or instrumentation under general anaesthesia were included in the study.

Patients who did not give consent, patients with body mass index greater than 35 kg/m<sup>2</sup>, contraindication to regional anaesthesia, allergy to any drug used under the protocol, history of previous spine surgery, patients on anticoagulation therapy, long-term intake of steroids and opioid intake preoperatively were excluded from the study. Patients with loss of follow-up were excluded from the analysis.

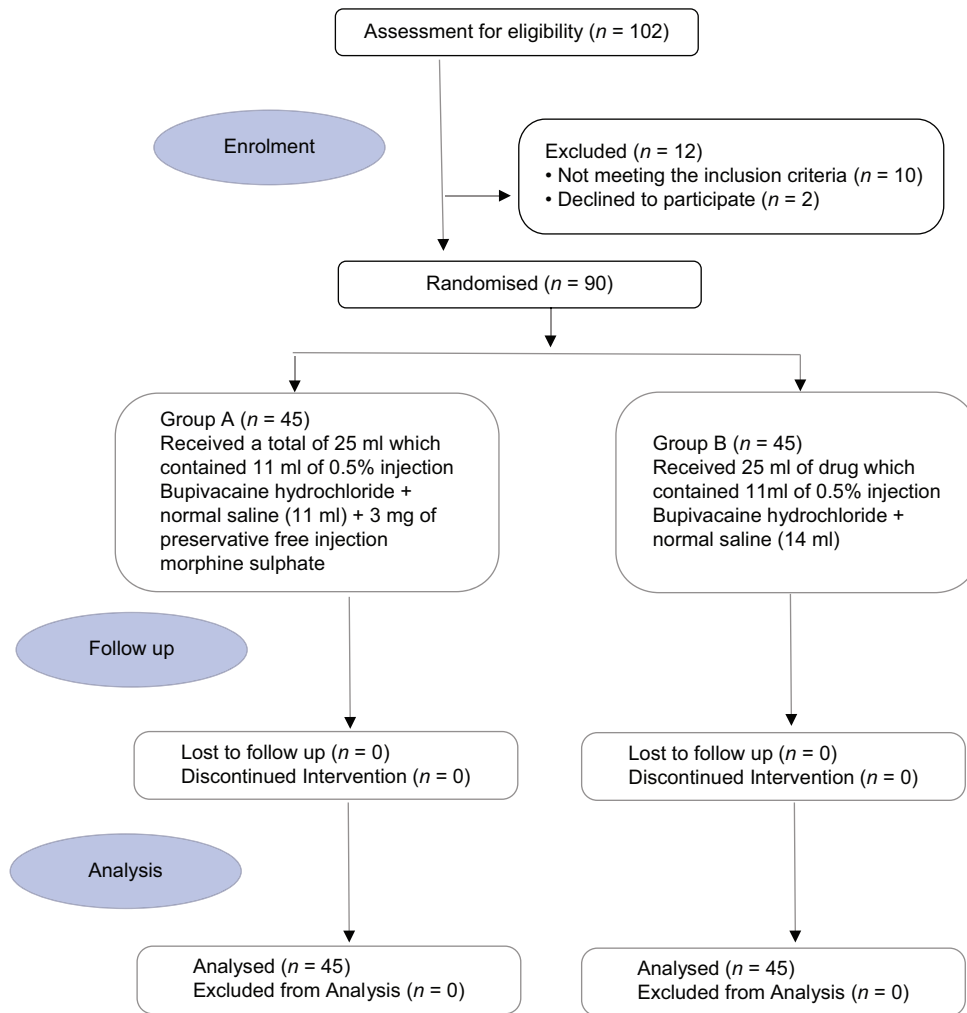
The patients were divided into two groups by a computer-generated table of random numbers [Figure 1].

Group M (n = 45) patients received 11 ml of 0.5% bupivacaine hydrochloride (Anawin 0.5%, Neon laboratories, Mumbai, India) + normal saline (11 ml) + 3 mg (1 mg/mL) of preservative-free morphine sulphate (Morpoy 10, Troikaa pharmaceuticals, Gujarat, India), totally 25 ml was administered.

Group B (n = 45) patients received 25 ml of drug containing 11 ml of 0.5% bupivacaine hydrochloride (Anawin 0.5%, Neon laboratories, Mumbai, India) + normal saline (14 ml).

Preoperatively, all patients were accustomed to the use of the VNRS, Oswestry Disability Index (ODI) modified English version questionnaire<sup>[6]</sup> and Rolland Morris Disability Questionnaire (RMDQ),<sup>[7]</sup> and baseline scores were recorded by the anaesthesia consultant who was not included in the study further.

VNRS is a verbal self-reporting pain assessment instrument with a 0 to 10 numeric rating scale, where 0 is no pain and 10 is the worst pain imaginable. The ODI consists of 10 items on the degree of severity to which back (or leg) pain has affected the daily routine. The 10 sections cover pain and the daily function including pain intensity, personal hygiene, lifting, walking, sitting, standing, sleeping, sexual activity, social activity and travelling. Each item is rated on a 6-point scale (0 to 5); higher score means a higher level of disability related to lower back pain. The RMDQ is a 24-item patient-reported outcome measure that enquires about pain-related disability resulting from low back pain. Items are scored 0 if left blank or 1 if endorsed, for a total RMDQ score ranging from 0 to 24; higher scores represent higher levels of pain-related disability. The threshold for important change has been estimated to be approximately 5 RMDQ points. This study used the English version and the translated Hindi version of the RMDQ which was available online.<sup>[8]</sup>



**Figure 1:** Consolidated Standards of Reporting Trials (CONSORT) diagram depicting the flow of study patients

Premedication was with tablet ranitidine 150 mg and tablet metoclopramide 10 mg on the previous night and also repeated on the day of surgery with small water sips. Standard protocol for nil per oral status was followed. In the operation theatre, the intravenous line using an 18-G cannula was established and standard monitors were attached to measure parameters such as heart rate (HR), electrocardiograph (ECG), systolic, diastolic and mean arterial pressure (SBP, DBP and MAP), peripheral oxygen saturation (SpO<sub>2</sub>), temperature, respiratory gases and capnography using Drager Vista 120 monitor model MS26680-04 at an interval of 10 min till the end of surgery.

Induction was done by intravenous fentanyl 2 µg/kg, propofol 1.5 to 2.5 mg/kg and vecuronium 0.1 mg/kg and the patient was mask ventilated for 3 min with oxygen (50%), air (50%) and sevoflurane. After achieving adequate relaxation, endotracheal intubation was secured by direct laryngoscopy with Macintosh

blade #3 or #4 and endotracheal tube 8.5 mm for men and 7.5 mm for women. The correct position of the tracheal tube was confirmed by capnography. The patients were ventilated using 50% oxygen, 50% air and sevoflurane keeping minimum alveolar concentration between 1 and 1.5. Maintenance was done with an injection of vecuronium 0.1 mg/kg and inhalational anaesthetic agents. The study drugs were prepared by the anaesthesia technician who had no further involvement. After giving the prone position, the caudal block was performed by the senior anaesthesiologist (with experience in performing more than 50 US-guided caudal blocks). He was blinded to the contents of the syringes and not included further in the study.

Under US guidance, a transverse image of the sacral hiatus and dorsal sacrococcygeal ligament lying between the two sacral cornua was obtained, and then the transducer was rotated by 90° to examine the sacral

hiatus in the longitudinal view.<sup>[9]</sup> A 22-gauge Quincke spinal needle was placed at around 45° angle and advanced further till the dorsal sacrococcygeal ligament and a hyperechoic band-like structure were approached using the in-plane method. The advancement of the needle was stopped once the sacrococcygeal ligament was penetrated. After confirming the negative aspiration of cerebrospinal fluid and blood, the drugs were injected and the needle positioning and drug dispersion into the epidural space were noted. To verify accurate placement, the whoosh test was performed. Any swelling over the sacral area that may occur due to drug extravasation into soft tissue was ruled out by carefully inspecting and palpating the area.

Intraoperatively, dose adjustment of sevoflurane concentration and intraoperative consumption of fentanyl were determined and recorded based on haemodynamics and other clinical signs. Inadequate analgesia was defined as an increase in HR and mean arterial pressure MAP >20% from the baseline and treated by administering intravenous fentanyl at an incremental dose of 25 µg. If there was a decrease in MAP >20% from the baseline, a 10 to 15 ml kg<sup>-1</sup> saline bolus was administered followed by a 6-mg injection of mephentermine. If HR was reduced to 45 beats per min, then intravenous atropine 0.5 mg was given. About 15 min before the skin closure, intravenous paracetamol 1 g and ondansetron 0.15 mg kg<sup>-1</sup> were administered to all the patients.

After the completion of the surgery, the patients were turned to a supine position and residual muscle paralysis was antagonised using an injection of neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg kg<sup>-1</sup>, and the patient was extubated.

In the postoperative period, VNRS for the static (when patients were not moving and thus were limited to bed) and dynamic pain (when they were made to log roll in bed 6 h post-surgery) was recorded at 0, 2, 4, 6, 8, 10, 12, 14, 16, 20 and 24 h by the nursing staff.

Rescue analgesia was given when the VNRS was >3 using intravenous diclofenac 75 mg (maximum dose 2 mg/kg/day) and if there was no response after 30 min, intravenous tramadol 2 mg/kg (maximum dose 5 mg/kg/day) was administered. Time of mobilisation was noted. Haemodynamic monitoring was done every 15 min for initial 4 h and then half-hourly for 24 h.

Side effects like nausea, vomiting, pruritus and any respiratory difficulty were noted and treated

accordingly. About 10 mg metoclopramide was given intravenously to treat nausea and intravenous ondansetron 4 mg was given for vomiting. The itching was treated with intravenous pheniramine maleate (45.5mg/2ml). Respiratory depression, defined as a respiratory rate lower than 12 breaths per minute, was managed with oxygen via a face mask at 5 l/min along with breath encouragement.

The patients were followed telephonically and were also asked to visit the neurosurgery department at 1 and 3 months. RMDQ and ODI scores at that time were noted by the anaesthesia resident.

The sample size was determined based on the efficacy of two groups (B and M) in the ratio of complete response (defined as postoperative pain relief). We chose a 40% baseline ratio of complete response after reviewing the literature.<sup>[1]</sup> Thus, we arrived at a sample size of 42 patients in each group, with 80% power at an alpha of 0.05 to detect a 30% difference between the two groups in the ratio of complete response. Factoring in a dropout rate of approximately 5%, we calculated that 45 patients would be required in each group. Statistical Package for Social Sciences System version 22 and Microsoft Office Excel 2010 was used for statistical testing. Mean ± standard deviation was used to denote continuous normally distributed variables, whereas categorical data were presented in the form of absolute numbers with percentages. Comparison between groups of normally distributed continuous variables was done with Student's *t*-test. Nominal categorical data were compared using the Chi-square test between the groups. Mann-Whitney U test was used to compare skewed continuous variables.

## RESULTS

None of the patients had a significant sonographic anomaly impeding the caudal approach, thus all the blocks were administered in the first attempt itself.

There was no significant difference in the demographic profile and operative details [Table 1]. The differences in haemodynamic parameters were found to be statistically insignificant at various time intervals. None of the patients had severe pain in group M in 24 h which reflects a very good control of postoperative pain [Table 2]. It was observed that in group B, a total of 27 (60%) took the first dose of rescue analgesia within the first 6 hours of the postoperative period. After 3 months, chronic postoperative pain

**Table 1: Demographic profile and operative details of the patients**

Parameter	Group B (n=45)	Group M (n=45)	P
Age (in years) mean±SD	42.06±10.14	42.80±9.24	0.72
Gender (Male:Female)	29:16	23:22	0.20
Height (in cm) mean±SD	165.80±7.43	164.66±7.34	0.47
Weight (in kg) mean±SD	62.28±8.65	61.33±8.12	0.59
ASA grade (I:II)	38:7	41:4	0.33
Comorbid conditions			
DM (%)	1 (2.22%)	0 (0%)	0.85
HTN (%)	3 (6.67%)	2 (4.44%)	
DM+HTN (%)	2 (4.44%)	1 (2.22%)	
Osteoarthritis (%)	1 (2.22%)	1 (2.2%)	
Site of surgery, L2-L3:L3-L4:L4-L5:L5-S1	3:6:23:13	0:4:25:16	0.28
Duration of surgery (in min) mean±SD	95.33±21.25	98.66±22.39	0.47
Fentanyl consumption intraoperatively (µg) mean±SD	131.44±29.45	119±22.75*	0.027
Time of rescue Analgesic			
Mean±SD	6.86±5.25	15.92±6.57*	<0.0001
0 - 6 hours	27 (60%)	8 (17.77)*	<0.0001
7 - 12 hours	14 (31.11)	10 (22.22)*	<0.0001
> 12 hours	4 (8.88)	27 (60%)*	<0.0001

Student's *t*-test, Chi-Square Test \*Significant difference  $P < 0.05$ . SD: Standard Deviation, ASA: American Society of Anesthesiologists physical status, DM: Diabetes Mellitus, HTN: Hypertension

**Table 2: Comparison of verbal numerical rating score (VNRS) static and dynamic at different time intervals in Group B and Group M**

VNRS Static	Group B (n=45)		Group M (n=45)		P	VNRS Dynamic	Group B (n=45)		Group M (n=45)		P
	Mean	SD	Mean	SD			Mean	SD	Mean	SD	
0 h	1.11	1.36	0.17	0.57	0.00*	-	-	-	-	-	-
2 h	0.89	1.07	0.15	0.47	0.00*	-	-	-	-	-	-
4 h	1.87	1.96	0.31	1.04	0.00*	-	-	-	-	-	-
6 h	1.71	2.09	0.71	1.29	0.008*	6 hrs	1.35	0.77	1.04	0.60	0.04*
8 h	1.80	2.15	1.11	1.49	0.08	8 hrs	1.80	1.23	1.35	0.83	0.05
10 h	0.96	1.22	1.15	1.15	0.43	10 hrs	2.53	1.91	1.20	0.62	0.00*
12 h	2.71	2.80	1.64	1.76	0.03*	12 hrs	1.91	1.79	1.67	1.11	0.44
16 h	2.44	2.62	2.15	2.11	0.56	16 hrs	1.68	1.62	1.64	0.91	0.87
20 h	1.67	1.65	2.15	2.26	0.24	20 hrs	1.60	1.14	1.58	0.72	0.91
24 h	1.53	1.42	2.00	2.06	0.22	24 hrs	1.80	0.92	1.75	1.00	0.83

Student's *t*-test, \*Significant difference  $P < 0.05$ . (VNRS: Verbal Numerical Rating Score); SD: Standard deviation

of moderate-intensity (VRNS 4-6) was observed in one (2.12%) and five (10.68%) patients in Group M and Group B, respectively, which was statistically significant ( $P = 0.00$ ). The pain was relieved after taking rest and analgesics [Table 2].

Nausea was observed in 2 (4.44%) patients in both groups. In group M, one (2.2%) and four (8.89%) subjects complained of pruritus and constipation respectively. The patient's compliance was found to be excellent as documented by nursing charts and the patient's proforma, filled by an unbiased anaesthetist, who was not included while evaluating the data. Thereafter, telephonic interviews at regular intervals were done by the same anaesthesiologist. Based on analysis of the serial questionnaires present in RMDQ, a clinical improvement over time could be assessed. There was a significant improvement

( $P$  value  $< 0.001$ ) in RMDQ and ODI scores seen at one and three months when compared with the baseline score and between groups. All the 10 sections in ODI showed a highly significant improvement in both the groups ( $P$ -value  $< 0.001$ ), except for section 8 which was an optional section and hence adequate data was not available for comparison [Tables 3 and 4].

## DISCUSSION

Eighty percent of the patients suffering from chronic backache undergo discectomy for pain relief, yet 86% of these patients experience moderate to severe postoperative pain.<sup>[10]</sup> Inadequate pain management after spine surgery can lead to patient dissatisfaction and delayed functional recovery, whereas optimal postoperative pain management leads to early ambulation, reduced length of hospital stay and better long-term functional outcomes.<sup>[10]</sup>



The prone positioning, adopted for posterior lumbosacral spine surgeries, provides an ideal position to enter the caudal epidural space. Standard landmark technique of giving caudal may lead to several complications like dural puncture, infection, injection in the intraosseous space and haemorrhage,<sup>[11]</sup> which can be considerably reduced with US guidance.<sup>[12]</sup>

Acute postoperative pain can be overcome by pharmacological methods like nonsteroidal anti-inflammatory drugs, N-methyl-D-aspartate receptor antagonists, opioids and antiepileptics like gamma-aminobutyric acid analogues. Local anaesthetics can be administered in neuraxial and peripheral blocks and local infiltration of the wounds.<sup>[13]</sup>

Bupivacaine was selected in this study as it has a prolonged duration of action of 4 to 8 h. The onset of sensory effect of 0.75% ropivacaine is four-segment in 15 to 20 min, whereas bupivacaine in a concentration of 0.5% spreads in 10 to 25 min.<sup>[11]</sup> The sensory effect regresses in 120 to 210 min every two segments with ropivacaine and 180 to 270 min every two segments with bupivacaine.<sup>[14]</sup>

Several adjuvants such as clonidine, neostigmine, ketamine, opioids, ephedrine, dexmedetomidine and magnesium prolong the duration of caudal analgesia.<sup>[15]</sup>

The analgesic effect of morphine given as an adjuvant can be attributed to its local action on opioid receptors in

the spinal cord. It is rapidly transferred from the epidural space to peripheral circulation and reaches a maximum concentration in plasma within 10 min after the caudal block. The half-life of plasma is approximately 2 h, and its elimination is by conjugation with glucuronic acid, forming a potent metabolite, morphine-6-glucuronide. This metabolite produces similar pain relief, dysphoria and sedation with less respiratory depression than morphine and morphine-3-glucuronide, which lacks significant activity.<sup>[16]</sup>

In accordance with a study by Hussien E *et al.*,<sup>[17]</sup> we observed that a single caudal epidural injection of morphine is a safe, simple and effective technique that provides a prolonged duration of postoperative analgesia in lumbar laminectomy surgeries. There are fewer analgesic requirements and early ambulation without the occurrence of any haemodynamic changes or increased incidence of adverse effects.

In our study, the time of ambulation was delayed as compared to the other studies. As per our institutional protocol, patients are ambulated on or after the second day depending upon the pain. A substantial improvement in RMDQ scores in an order of 9-11 points at all follow-up intervals was seen in our study. According to Stratford *et al.*,<sup>[18]</sup> a true change is represented by a four-point difference. The advantage of the ODI score is that it distinguishes an improvement score from a non-improvement score. Only a change of >10 points has a clinical significance.<sup>[16]</sup>

The study has some limitations. First, it is based on the data from a single centre. Second, the RMDQ and ODI questionnaire does not consider factors like the job of the patient, age, or state of mind. Further studies are needed to establish the efficacy and safety of pre-emptive caudal block over other techniques like local infiltration, epidural catheter insertion and newer blocks like quadratus lumborum block.

### CONCLUSION

Adding morphine to bupivacaine using pre-emptive US-guided caudal block translates into better control

**Table 3: Comparison of long-term functional outcomes over months between Group B and Group M**

	Group B		Group M		P
	Mean	SD	Mean	SD	
Rolland Morris Disability Questionnaire (RMDQ)					
0-1 month	49.31	17.43	66.95	15.33	0.000*
0-3 month	56.71	15.88	75.86	14.46	0.000*
1-3 month	13.58	15.40	26.13	22.24	0.003*
Oswestry Disability Index (ODI)					
0-1 month	49.26	10.50	48.91	11.41	0.881
0-3 month	26.08	9.28	17.11	10.69	0.000*
1-3 month	23.33	9.76	14.91	10.33	0.000*
	0.000*		0.000*		

\*Significant difference P<0.05 (SD: Standard deviation)

**Table 4: Comparison of Oswestry Disability Index Scores at different time intervals between the two groups**

Disability %	Group B			Group M		
	0 month n (%)	1 month n (%)	3 months n (%)	0 month n (%)	1 month n (%)	3 months n (%)
0%-20%, minimal	0	15 (33.33%)	22 (48.88%)	0	35 (77.77%)	36 (80%)
21%-40%, moderate	9 (20%)	27 (60%)	21 (46.66%)	13 (28.88%)	8 (17.77%)	8 (17.77%)
41%-60%, severe	31 (68%)	3 (6.66%)	2 (4.44%)	25 (55.55%)	2 (4.44%)	0
61%-80%, crippled	5 (11.11%)	0	0	7 (15.55%)	0	1 (2.22%)

of postoperative pain relief with good haemodynamic stability and improved long-term functional outcomes.

#### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

#### Conflicts of interest

There are no conflicts of interest.

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