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Original Article

Comparison of Intrathecal Nalbuphine with Different Doses of Bupivacaine in Infraumbilical Surgeries

Joginder Pal Attri[1], Manjit Singh[2], Brij Mohan[2], Rohit Kumar[3]

[1]Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [2]Associate Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [3]Junior Resident, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India

Abstract

Background: Subarachnoid block (SAB) is a widely used regional anesthetic technique for infraumbilical surgeries.

Aims: The study was conducted to compare intrathecal nalbuphine with different doses of bupivacaine in infraumbilical surgeries with respect to hemodynamic changes, side effects, onset and duration of sensory as well as motor blockade, and duration of analgesia.

Materials and Methods: After obtaining Institutional Ethics Committee approval, a prospective study was conducted on 90 patients belonging to American society of Anesthesiology Grades I and II, aged 18–60 years and scheduled for infraumbilical surgeries using SAB. Three Groups A, B, and C each with 30 patients were given 0.8 mg nalbuphine along with 10, 12.5, and 15 mg of hyperbaric bupivacaine, respectively.

Statistical Analysis: Chi-square and unpaired "t" test and following results were observed.

Results: Mean onset of sensory block until T10 dermatome was 2.59 ± 0.43, 2.49 ± 0.30, and 2.44–0.33 min while its total duration was 102.23 ± 5.81, 110.10.83 ± 83, and 136.33 ± 6.15 min in Groups A, B, and C. Maximum motor blockade was achieved in 7.55 ± 0.57, 7.41 ± 0.51, and 7.30 ± 0.62 min and mean duration of motor block was 145.27 ± 11.80, 155.00 ± 11.58, and 188.00 ± 10.27 min in Groups A, B, and C. Mean time of total duration of the analgesia in Groups A, B, and C was 240.83 ± 36.34, 413.77 ± 68.60, and 719.90 ± 99.93 min. Patients in Group C had hypotension at 8th and 10th min intraoperatively while other parameters and side effects were non-significant.

Conclusion: About 0.8 mg of nalbuphine when combined with 12.5 mg of hyperbaric bupivacaine had optimum duration of analgesia and sensory block with lesser hemodynamic alterations and side effects.

Key words: Bupivacaine, Intrathecal, Nalbuphine

INTRODUCTION

Pain as described by International Association for the study of pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage."[1] Surgical pain may occur either due to direct tissue injury such as dissection, cutting, incision or inflammation of tissue, or associated nerve injury. The nociceptive pain is caused by stimulation of sensory nerve fibers.[2] The American Board of Anesthesiology lists "relief and prevention of pain during surgical, obstetric, therapeutic, and diagnostic procedures" as one of the essential components of the specialty. The maximum surgical stress response occurs during the post-operative period and it affects almost every part of the body systems. Previously general anesthesia was the only anesthetic modality available for all types of surgeries irrespective of site and duration of surgery. It has its several disadvantages like multiple drug usage with their adverse effect on the body, loss of consciousness, and longer

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Corresponding Author: Dr. Manjit Singh, Department of Anaesthesia, Government Medical College, Amritsar – 143001, Punjab, India. Phone: +91-9501025275. E-mail: jpattri12@yahoo.co.in

duration of hospital stay.[3,4] Regional anesthesia came out as a boon to anesthesia with fewer side effects, less drug usage, better patient compliance, maintenance of consciousness, spontaneous respiration, and better post-operative period with good analgesia. The drawbacks of spinal anesthesia are its shorter duration of action with limited post-operative analgesia when it is performed only with local anesthetics. This problem can be nullified by adding various adjuvants such as opioids, alpha 2-adrenoreceptor agonist, epinephrine, and ketamine to local anesthetics. Intrathecal opioids are most commonly used adjuvants. They improve the quality of neuraxial anesthesia in terms of decreased post-operative pain, prolonged sensory and motor blockade, and maximum post-operative analgesia.[5] Nalbuphine is a semi-synthetic opioid with κ agonistic and μ antagonistic action. It belongs to phenanthrene series. Its analgesic actions are due to agonistic activity at opioid kappa ("κ") receptors. Its affinity to κ receptors leads to analgesia, sedation, and cardiovascular stability with minimal respiratory depression.[6,7] The present study was done to compare intrathecal nalbuphine with different doses of hyperbaric bupivacaine in infraumbilical surgeries with respect to hemodynamic changes, side effects, onset and duration of sensory as well as motor blockade, and duration of analgesia.

MATERIALS AND METHODS

This randomized controlled prospective study was done on 90 patients belonging to American Society of Anesthesiology (ASA) Grades I and II, aged 18–60 years of either sex and posted for infraumbilical surgeries, using subarachnoid block (SAB) after obtaining informed and written consent from patients themselves and approval from the Institutional Ethics committee, Government Medical College, Amritsar. The patients were randomly divided into three Groups A, B, and C each having 30 patients and were given 0.8 mg intrathecal nalbuphine along with 10, 12.5, and 15 mg of hyperbaric bupivacaine and 1.2, 0.7, and 0.2 ml of 0.9% normal saline, respectively. A statistician was consulted to calculate the sample size taking account of the duration of analgesia, sensory and motor block, hemodynamic stability, and side effects. Power of study was >85%. All the patients were kept fasting for 6 h before surgery. In the operation theatre, an intravenous line was secured on one arm of the patient with a 20 G intravenous cannula, and pre-loading was started with Ringer's lactate at 10 ml per kg body weight. Monitors such as automated noninvasive blood pressure, pulse oximetry, and electrocardiography (ECG) were attached. Injection midazolam 0.03 mg/kg intravenously was given to all the patients before turning to the left lateral/right lateral decubitus or sitting position for the application of spinal block. Under all aseptic conditions, the back of the patient was painted with povidone-iodine solution, the area was draped with sterile towels, L_{3-4} intervertebral space was identified, and a skin wheal was raised by 26 gauze needle with 2% xylocaine. Quincke spinal needle No. 23 was introduced into subarachnoid space using a midline approach. After aspiration of cerebrospinal fluid, the patient was given one of the study drugs intrathecally according to the random number chart. After injecting the drug, spinal needle was taken out and the patients were immediately put in supine position and O_2 was given 5 L/min of through an oxygen inhalational mask. The same anesthesiologists performing the SAB recorded the intraoperative data and follow the patient postoperatively until discharged from post-anesthesia care unit.

Assessment

In our study, sensory and motor blockade was checked every 2 min for first 15 min by pinprick method using 27 G hypodermic needle and modified Bromage scale, respectively. The time of onset of the sensory block was taken as the time interval from injection of local anesthetic intrathecally to loss of pinprick sensation up to T10 dermatome while the duration of sensory block was taken as time to two segment regression from maximum sensory level. Bromage scale three was taken as time to complete motor block. Surgery was allowed to proceed only when full surgical anesthesia had developed. Sensory and motor blockade was not checked once the surgery was started, only pulse rate, heart rate, respiratory rate, non-invasive systolic and diastolic blood pressure, SpO_2, and ECG were monitored, thereafter. In the post-operative period, sensory and motor blockade was checked half hourly for next 3 h, every hourly for next 9 h and then, every 3 hourly until 24 h. Bradycardia (which was defined as heart rate <60 bpm) was treated with intravenously injection atropine sulfate 0.3 mg. Hypotension (defined as fall in systolic blood pressure <20% less than baseline value) was treated with intravenous ephedrine as per required and additional ringer's lactate solution. Continuous monitoring of pulse rate, heart rate, respiratory rate, non-invasive systolic and diastolic blood pressure, SpO_2, and ECG was done for hemodynamic response perioperatively. After SAB, the readings were recorded at 2 min for the first 10 min, then every 5 min up to 30 min, every 15 min up to 120 min, half-hourly up to 180 min and thereafter hourly until the 12 h of surgery in all three groups. Pain assessment was done using visual linear analog scale (VAS)[8] and sedation was analyzed using Ramsay sedation scale.[9] The VAS interpretations were explained 1 day before the operation to all patients taken for study to determine the quality of analgesia in the post-operative period. This was carried out with 0–10 cm line. The first end mark "0" means "no pain" and the end marked "10" means "severe pain." The patients were asked to mark

Table 1: Demographic profile

Parameters	Group A	Group B	Group C	A/B	B/C	A/C
Age	35.70±11.86	36.37±12.28	34.06±11.70	>0.05	>0.05	>0.05
Height (cm)	168.2±7.80	169.10±6.15	167.67±5.94	>0.05	>0.05	>0.05
Weight (kg)	70.7±5.01	69.00±5.55	69.80±5.26	>0.05	>0.05	>0.05
Duration of surgery (minute)	62.74±7.11	63.67±6.91	64.17±7.08	>0.05	>0.05	>0.05

P value non-significant (0.0.05)

Table 2: Variable

Parameters	Group A	Group B	Group C	*P* value
Onset of sensory block (min)	2.59	2.49	2.44	0.25 (NS)
Onset of motor block (min)	7.55	7.41	7.30	0.16 (NS)
Duration of sensory block (minute)	102.23	119.23	136.33	0.03 (S)
Duration of motor block (min)	145.27	155.00	188.50	0.01 (S)
Total duration of analgesia (min)	240.83	417.77	719.90	0.02 (S)
Mean number of rescue analgesia	3.2	2.63	1.93	0.01 (S)

the severity of the pain experienced. Rescue analgesia was given when VAS score >3. The time from administration of SAB to demand of first rescue analgesia (VAS >3) was defined as total duration of analgesia. Injection diclofenac 75 mg was used as rescue analgesia.

Statistical Analysis

The data of our study were statistically analyzed using IBM SPSS 21 (Armonk, NY: IBM Corp.) software and were expressed as mean, standard deviation, number, and percentages. The non-parametric patient characteristics were analyzed using "Chi-square tests," and the intergroup comparison of the parametric data was done using the unpaired "*t*"-test. "*P*" value was calculated to evaluate the levels of significance. $P > 0.05$ was considered non-significant and $P < 0.05$ was considered as significant at 5% significance level while $P < 0.01$ was considered highly significant at 1% significance level and by taking α error 0.05 > 90% power was achieved.

OBSERVATION AND RESULTS

The groups were comparable with respect to age, weight, height, ASA grade, and duration of surgery as shown in Table 1.

The onset of sensory and motor blockade was non-significant among the groups. Significantly prolonged duration of sensory, motor, and effective analgesia was noted in Group C followed by B and A. Furthermore, the requirement of rescue analgesia was least in Group C as compared to other two groups as shown in Table 2.

VAS Score during Post-operative Period

In Group A, VAS started increasing after 3 h and the first dose of rescue analgesia was given at 4th h postoperatively, the second and third dose of rescue analgesia was given at 10th and 21st h postoperatively. In Group B, VAS started increasing at 5 h and patient demanded first dose of rescue analgesia at 7th h postoperatively, second and third dose of rescue analgesia was given at 15th and 24th h postoperatively. In Group C, VAS started increasing at 10 h and patient was given the first dose of rescue analgesia 12th h, the second dose of rescue analgesia was given at 23rd h postoperatively as shown in the Chart 1.

Heart Rate during Pre-operative, Intra-operative, and Post-operative Period

Preoperatively, the groups were comparable to each other with respect to heart rate. There is a slight fall in heart rate compared to baseline after SAB in all three group patients. The mean heart rates were comparable in all the groups intraoperatively as well as postoperatively. The fall in heart rate was seen in two patients in Group C, one patient in Group B, and in 0 patient in Group A; intraoperatively. The patients in all three groups showed rise in heart rate postoperatively when VAS score was >3 as shown in Chart 2.

Blood Pressure during Pre-operative, Intra-operative, and Post-operative Period

The mean systolic and diastolic blood pressure in the three groups was non-significant during most of the intra-operative and post-operative period. There is a slight fall in blood pressure compared to baseline after SAB in all three group patients. A significant fall in blood pressure was noted at 8th and 10th min after SAB in Group C patients as compared to Groups B and A. Similar to heart rate, there is an increase in blood pressure postoperatively when VAS >3 as shown in Charts 3 and 4.

Side Effects and Complications

A total of 3 (10.00%) patients in Group C and 1 (3.33%) patient in the Group B developed hypotension. 2 (6.67%) patients in Group C, 1 (3.33%) patient in Group B showed bradycardia. None of the patients in Group A had hypotension or bradycardia. Other side effects and complications were comparable among the groups.

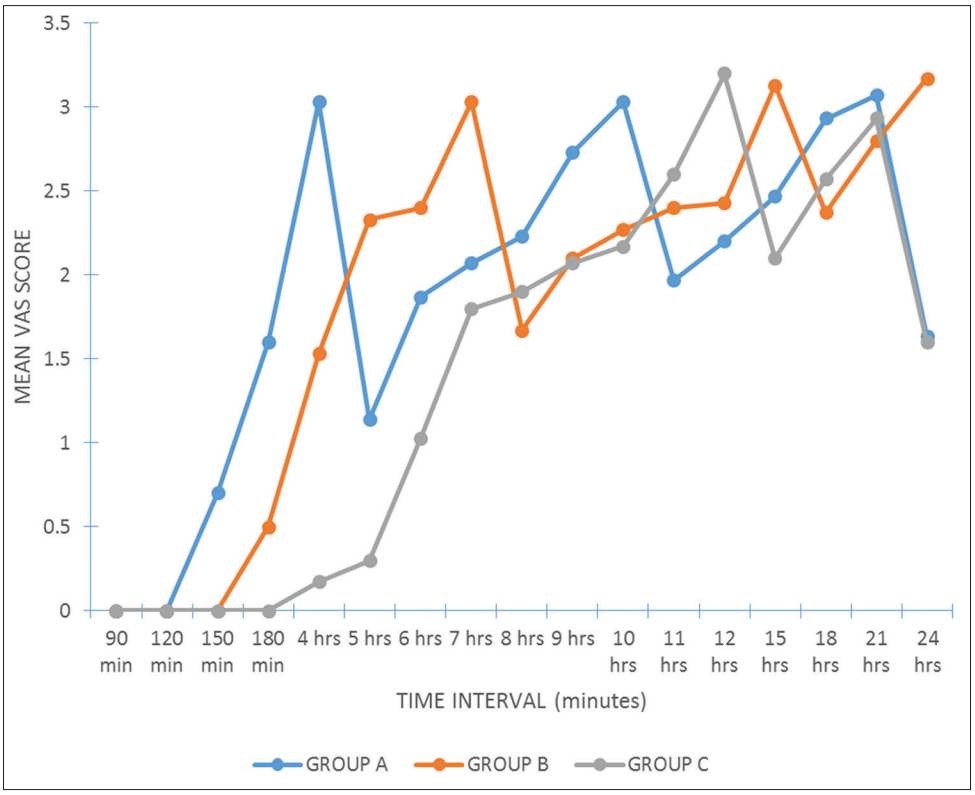

Chart 1: VAS score

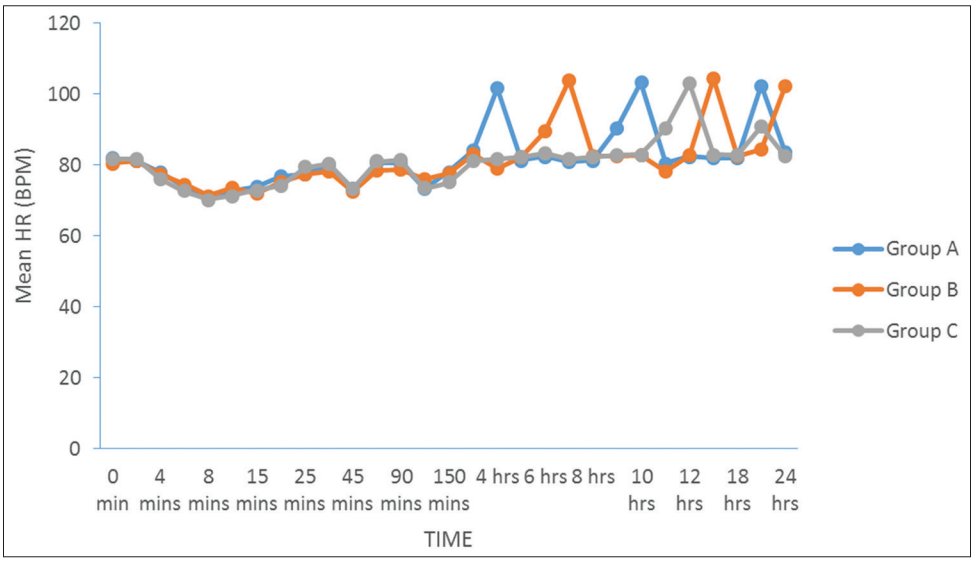

Chart 2: Changes in heart rate

DISCUSSION

Effective pain control is of paramount importance to facilitate rehabilitation and promote early function recovery after various surgeries. For infraumbilical surgeries, spinal anesthesia is the preferred technique over other techniques. It provides reliable surgical anesthesia, good muscle relaxation, and analgesia also. Shorter duration of block and post-operative analgesia is drawbacks of this technique. To overcome these problems, many intrathecal adjuvants have been used for, for example, opioids, alpha agonists, dexmedetomidine, and other drugs such as dexamethasone and neostigmine ketamine.

In our study, the mean onset time (up to T10 dermatome) of sensory block was 2.59 ± 0.43 min, 2.49 ± 0.30 min, and 2.44 ± 0.33 min and maximum sensory level (up to T6 dermatome) was achieved in 6.63 ± 1.00 min, 6.40 ±

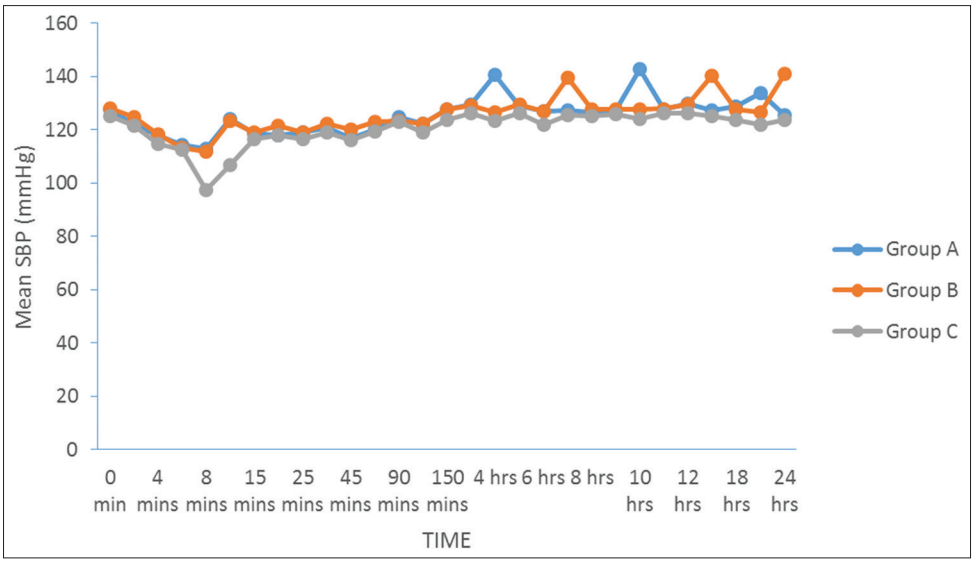

Chart 3: Systolic blood pressure

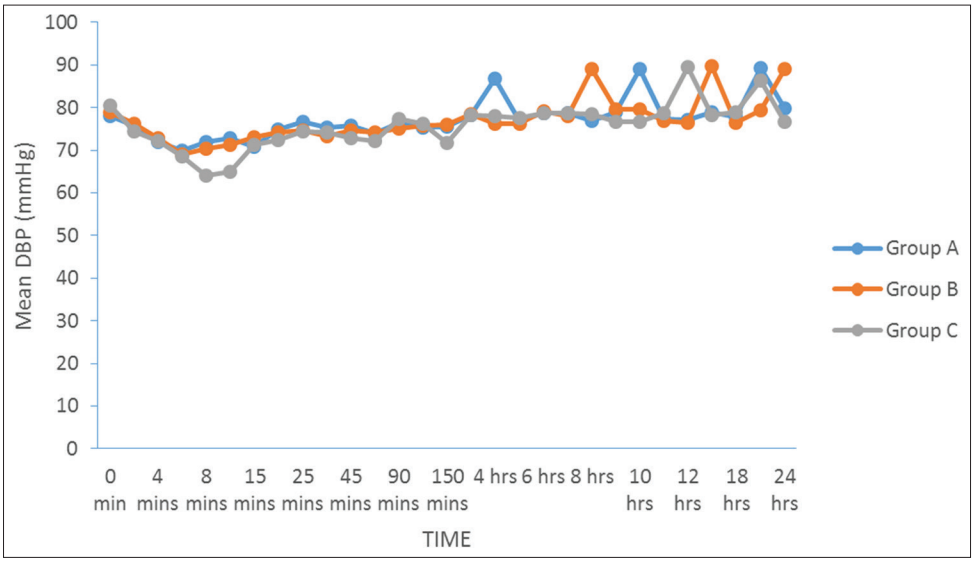

Chart 4: Diastolic blood pressure

0.62 min, and 6.30 ± 0.84 min in Groups A, B, and C, respectively. The mean duration of sensory block (defined by two segment regression) was 102.23 ± 5.81 min, 110.10.83 ± 83 min, and 136.33 ± 6.15 min in Groups A, B, and C, respectively. The onset time and maximum sensory level achieved was non-significant while the duration of sensory block was significant among the groups with Group C having maximum sensory block followed by B and A.

The time taken to achieve maximum motor block (Bromage score 3) was 7.55 ± 0.57 min, 7.41 ± 0.51 min, and 7.30 ± 0.62 min while the mean duration of motor block was 145.27 ± 11.80 min, 155.00 ± 11.58 min, and 188.00 ± 10.27 min in Group A, B, and C, respectively. Group C patients had more intense motor blockade at the end of surgery. Furthermore, the duration of motor block was statistically longer in Group C as compared to Groups B and A.

The mean total duration of analgesia was 240.83 ± 36.34 min, 413.77 ± 68.60 min, and 719.90 ± 99.93 min in Groups A, B, and C, respectively. The result was significant with Group C patients having longest duration of analgesia followed by Group B. Group A have shortest duration of analgesia.

The time of the first request for analgesia in Groups A, B, and C was 4th h, 7th h, and 12th h postoperatively, respectively. This difference was significant with more requirement of rescue analgesia in Group A as compared to Groups B and C.

The mean systolic and diastolic blood pressure was non-significant between the groups during most of intra-operative and post-operative period. Group C patients showed a significant fall in systolic and diastolic blood pressure at 8th–10th min intraoperatively.

The finding of our study is similar to the study done by Sharan *et al.* who compared intrathecal fentanyl with different doses of bupivacaine on lower limb surgeries. They found out that onsets of sensory block were non-significant among the groups. T4 was maximum sensory level achieved in all the three groups. The intensity and duration of motor blockade were prolonged with an increase in the dose of bupivacaine. Furthermore, the time of request of the rescue analgesia and duration of effective analgesia was longest in group given more bupivacaine but at the cost of more hypotension.[10]

Sendil *et al.* studied the effect of three different doses of bupivacaine along with fentanyl during spinal anesthesia for transurethral resection of prostate surgery. They concluded that addition of fentanyl with higher dose of bupivacaine resulted in prolonged motor blockade as compared to lower doses. The onset and level of sensory and motor block were similar in all the three groups. The time to two segment sensory regression, complete sensory regression, and post-operative analgesia was longest with increased dose of bupivacaine with significant hypotension.[11]

Gupta *et al.* conducted a study using intrathecal nalbuphine and bupivacaine and intrathecal bupivacaine alone in lower limb surgery. It was seen that addition of nalbuphine improved intraoperatively analgesia without causing any undue side effects and complications, analogous to our study.[12]

CONCLUSION

Our study concluded that 0.8 mg of nalbuphine when combined with 12.5 mg of hyperbaric bupivacaine (Group B) had optimum duration of analgesia and sensory block with lesser hemodynamic alterations and side effects. The higher dose of bupivacaine, that is, 15 mg of hyperbaric bupivacaine with 0.8 mg nalbuphine (Group C) was associated with more incidence of hypotension and more intense and prolonged motor blockade after surgery, thus, delaying the recovery from spinal anesthesia and late ambulation. The lower dose of bupivacaine, that is, 10 mg of hyperbaric bupivacaine with 0.8 mg of nalbuphine (Group A) was associated with shorter duration of effective analgesia and sensory block, and thus, there is more requirement of rescue analgesia in this group.

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