



COMPARATIVE STUDY OF TWO COMBINATIONS OF ROPIVACAINE AND FENTANYL FOR POSTOPERATIVE PAIN RELIEF AFTER UMBILICAL AND LOWER ABDOMINAL SURGERIES

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ABSTRACT

Objectives: Ropivacaine has been used, either alone or with local anesthetics, for epidural analgesia. This study was undertaken to compare quality and safety of two combinations of epidural ropivacaine with fentanyl for providing postoperative analgesia for 48 hours after umbilical and lower abdominal surgeries.

Methodology: In a prospective randomized, controlled study, 70 patients age group between 20-60 years, of either gender, scheduled for routine umbilical and lower abdominal surgeries were randomly distributed into two groups of 35 patients each. Postoperatively, two combinations of ropivacaine and fentanyl [group 1 ropivacaine .2% and fentanyl 4 µg and group 2 ropivacaine .1% and fentanyl 2 µg] for postoperative pain relief, diluted in 10 ml of normal saline was injected in the epidural space (between L₂-L₃ space) through the catheter and then repeated 6 hourly. Pain intensity score, onset of analgesia, number of top-ups required and overall patient satisfaction score were recorded.

Results: Mean onset of analgesia was 10.31 ± 1.5 min with group 1 as against 11.23 ± 1.2 min with group 2. Pain Intensity (PPI) score ≤ 1 was observed in 68.21% observations belonging to group 1 and in 60% observations belonging to group 2. Twenty five patients (71.4%) from group 1 and 30 patients (85.7%) from group 2 required rescue analgesia. The patient's feedback on pain relief was graded as very good or good by 78.5% of the patients in Group-1 and 69% patients in Group-2.

Conclusion: Though both drug combinations are equally safe, **group 1 concentration** is faster acting, more potent and efficient analgesic than group 2 when used for postoperative pain relief in umbilical and lower abdominal surgeries. However motor power was better preserved in group 2

KEYWORDS : epidural; Postoperative analgesia; Fentanyl; Ropivacaine, Motor Block

INTRODUCTION

Postoperative pain and hypoxemia are common complications following umbilical and lower abdominal surgeries. Inadequately treated pain results in an increased incidence of pulmonary complications and morbidity. An ideal analgesic regimen should provide pain relief with minimal side effects and should allow early return of normal function. Regional analgesia provides superior quality of pain relief after surgery and avoids many of the side effects of conventional narcotic analgesics. Epidural blockade using lipophilic opioids has advantages of better postoperative pain relief, minimal central nervous system depression, minimal somatic and visceral pain and abolition of the reflex muscle spasm.

Ropivacaine is a long-acting, enantiomerically pure amide local anaesthetic with a high pK_a and low lipid solubility which blocks nerve fibres involved in pain transmission (Aδ and C fibres) to a greater degree than those controlling motor function (Aβ fibres). The drug is less cardiotoxic than equal concentrations of racemic bupivacaine.

Extensive clinical data have shown that epidural ropivacaine 0.2% is effective for the initiation and maintenance of labour analgesia, and provides pain relief after abdominal or orthopaedic surgery especially when given in conjunction with opioids (coadministration with opioids may also allow for lower concentrations of ropivacaine to be used). The drug had efficacy generally similar to that of the same dose of bupivacaine with regard to pain relief but caused less motor blockade at low concentrations.[1]

Fentanyl have been used either alone or in combination with bupivacaine or ropivacaine for epidural analgesia. There are studies that directly compare these widely used drugs for postoperative pain relief via epidural approach in umbilical and lower abdominal surgeries. This study was undertaken to compare the clinical efficacy and safety of two combinations of ropivacaine

and fentanyl [group 1 ropivacaine .2% and fentanyl 4 µg and group 2 ropivacaine .1% and fentanyl 2 µg] for postoperative pain relief. The primary outcome measure compared was quality of analgesia expressed as Present Pain Intensity (PPI) score.⁷

METHODOLOGY

A prospective double-blind, randomized, study design with two parallel groups was used. After prior approval from Institutional Ethics Committee, this study was conducted at Bundelkhand Medical College, Sagar during a period of 2 years [January 2015 – December 2016] on 70 patients, aged group between 20-60 years, of either gender, scheduled for routine umbilical and lower abdominal surgeries. Informed written consent was obtained from all patients. Exclusion criteria were severe systemic disorders including diabetes mellitus, hypertension, heart disease; addiction to narcotic drugs; chronic alcoholism; psychiatric disorders; allergy to study drugs and known contraindications to epidural anaesthesia. Patients were randomly distributed into two groups of 35 patients each and randomization was concealed.

Group-1 (n=35): In this group, each patient received ropivacaine .2% and fentanyl 4 µg diluted in 10 ml normal saline via epidural catheter. This was considered as control group.

Group-2 (n=35): In this group, each patient was given 2 ropivacaine .1% and fentanyl 2µg diluted in 10 ml normal saline via epidural catheter. This was considered as study group.

Method of Randomization was Blocked randomization. Thirty five blocks of two each with treatment allocation of 1:1 for Group-1 and Group-2 were created with the help of computer software. Coded envelopes (total 35) were used and each envelope was used for two patients leading to random assignment of one subject to one group. For sample size calculation a pilot study was done on 20 patients (each group containing 10 patients). Present Pain Intensity (PPI) score was recorded at 6 hourly intervals for 48 hours. PPI score ≤ 1

was observed in 34(42.5%) observations in Group-1 as against 69(86.25%) observations from Group-2, out of total 80 observations made in each group. Sample size was calculated to detect effect size of 43.75% between two groups accepting alpha error 0.05 and β error 0.90 was 28.

In the operating room pre-operative parameters (pulse rate, blood pressure, respiratory rate and oxygen saturation) were noted. Patients were placed in sitting position and under aseptic precautions; a 18G epidural needle was inserted through the paramedian approach at a suitable space between L₂-L₃ depending on the level of surgical incision. Epidural space was identified by 'loss of resistance' technique and a disposable epidural catheter was inserted cephaloid 2-3 cm into the epidural space and secured with an adhesive. Its position was confirmed by a test dose of 2 ml lignocaine 2% with adrenaline and a possibility of subarachnoid or intravascular injection was excluded. After a negative test dose, patients were placed in the supine position and general anesthesia was induced with thiopentone (4-6 mg/kg) followed by succinyl choline (1.5 mg/kg) injected intravenously. Orotracheal intubation was done with a cuffed endotracheal tube of appropriate size and anesthesia was maintained with oxygen and nitrous oxide supplemented with halothane. Intraoperative analgesia was maintained with intravenous fentanyl 100 micrograms at the start and then if required. Muscle relaxation was provided with vecuronium. At the end of surgical procedure, patient was extubated after reversal of neuromuscular block with glycopyrrolate. 0.01 mg/kg and neostigmine 0.05 mg/kg. Physiological parameters e.g. pulse rate, blood pressure, respiratory rate and oxygen saturation, were recorded every 5 min during intraoperative period and before shifting to postoperative ward.

In the postoperative ward a bolus of either ropivacaine .2% with fentanyl 4µg or ropivacaine .1% with fentanyl 2µg diluted in 10 ml of saline was injected in the epidural space through the catheter when the patient complained of pain. The bolus was repeated 6 hourly. Both the patient and anesthesiologist were blinded to the study solutions. Syringes were prepared and coded just before injection by a third person. The observer was also blinded. Analgesia with epidural catheter was provided for two days postoperatively, then the catheter was removed and analgesia was maintained with conventional methods. Pulse rate, blood pressure and respiratory rate were recorded along with present pain intensity (PPI) score every 6 hours. The degree of pain was assessed by using the Present Pain Intensity (PPI) scale; 0=no pain; 1=mild pain; 2=discomfort; 3=distress; 4=horrible pain and 5=excruciating pain. Highest PPI score during the period of six hours between two top-ups was noted. Thus, there were 8 observations of PPI for each patient and total number of observations was 280 for each group. Percentage of different PPI scores out of total number of observations was used for comparison of two groups.

During this interval if any patient had PPI >3; 'rescue top-ups' were given in Group-1 and Group-2 respectively and number of such 'rescue analgesia top up' doses were noted. Catheter was removed after 48 hours. Any side effect e.g. nausea, vomiting, backache, sedation or drowsiness, hypotension, sign of excessive block or numbness / weakness in limbs was noted.

On 3th postoperative day each patient was interviewed regarding feedback on overall pain relief during the first 2 postoperative days as very good, good, fair or poor. This scale was used to compare both groups as secondary outcome measure regarding quality of analgesia.

OBSERVATION TABLES

TABLE 1: PATIENT CHARACTERISTICS

| Characteristics | Group-1 (n = 35) Mean ± SD | Group-2 (n = 35) Mean ± SD | P value |
|-----------------|-------------------------------|-------------------------------|---------|
| Age (in years) | 33.57 ± 10.27 | 35.86 ± 13.17 | > 0.05 |
| Height (in cm) | 161.29 ± 5.26 | 159.14 ± 6.86 | > 0.05 |

| | | | |
|-----------------|--------------|--------------|--------|
| Weight (in Kgs) | 63.83 ± 6.82 | 62.57 ± 5.91 | > 0.05 |
| Gender | 29 (82.86) | 29 (82.86) | > 0.05 |
| | 6 (17.14) | 8 (22.86) | |

Group-1 = Epidural Ropivacaine .2% + fentanyl 4 µg in 10 ml normal saline

Group-2 = Epidural Ropivacaine .1% + fentanyl 2 µg in 10 ml normal saline

TABLE 2: TYPES OF SURGICAL PROCEDURES PERFORMED

| Type of Surgery | Group-1 (n = 35) | Group-2 (n = 35) | P value |
|------------------------------|------------------|------------------|---------|
| Inguinal Hernias | 14 | 10 | > 0.05 |
| Anorectal Surgery | 11 | 17 | |
| Perforation peritonitis | 3 | 3 | |
| Vaginal Hystrectomies | 5 | 2 | |
| Hydatid cyst removal | 1 | 1 | |
| Excision of Tuboovarian mass | 1 | 1 | |
| Abdominal Hystrectomy | 0 | 1 | |
| Total | 35 | 35 | |

TABLE 3: QUALITY OF ANALGESIA

| Quality of analgesia | Group-1 (n = 35) | Group-2 (n = 35) | p Value |
|--|------------------|------------------|---------|
| Onset of analgesia in min (Mean ± SD) | 10.31 ± 1.5 | 14.23 ± 1.2 | < 0.05 |
| Rescue analgesia (Number of top-ups required)* | 0 | 5 | > 0.05 |
| | 1 | 2 | |
| | 2 | 15 | |
| | 3 | 8 | |
| | 4 | 0 | |
| | Total | 35 | |
| Overall satisfaction regarding analgesia* | Very Good | 5 | > 0.05 |
| | Good | 19 | |
| | Fair | 10 | |
| | Poor | 1 | |
| | Total | 35 | |
| PPI Score ≤ 1 [n(%)] | 219 | | < 0.05 |
| PPI Score 0 [n(%)] | 49(17.5) | 11 (3.93) | < 0.05 |
| Total Number of observations | 280 | 280 | |

* Number of patients

TABLE 4: INCIDENCE OF SIDE EFFECTS. DATA GIVEN AS N(%)

| Side effect | Group-1 (n = 35) | Group-2 (n = 35) |
|-----------------------------|------------------|------------------|
| Hypotension | 5(14.29) | 8(22.86) |
| Pruritus | 4(11.43) | 5(14.29) |
| Nausea and vomiting | 3(8.57) | 5(14.29) |
| Respiratory depression | 2(5.71) | 3(8.57) |
| Sedation | 2(5.71) | 0 |
| Gastrointestinal discomfort | 0 | 1(2.86%) |
| Total | 16(45.71) | 22(62.86%) |

Twenty five patients out of 35 from group 1 required rescue analgesia as against 30 patients from group 2. Out of them 8 patients needed 3 top-ups, 15 patients needed 2 top-ups and 2 needed one top-up. Out of 30 patients from group 2, 2 patients needed 4 top-ups, 6 patients needed 3 top-ups 17 needed 2 top-ups and 5 needed one top-up. This difference was not significant.

Overall feedback was graded as very good or good by 78.5% patients in Group-1 and 69% patients in Group-2. Only one patient from Group-1 and 4 from Group-2 graded analgesia as poor. Mild hypotension was seen in 5 patients from Group-1 and 8 patients in Group-2, which was easily corrected with crystalloid infusions. Two patients from Group-1 and 3 patients from Group-2 had transient fall in oxygen saturation that responded to an increase in FiO₂. No significant difference was observed between the two groups. Table

4 shows the incidence of side effects in both the groups.

RESULTS

Both groups were comparable in respect of demographic characteristics as shown in Table I. Groups were also comparable in type and duration of surgery (Table 2). Various surgical procedures performed included hernias, TURP'S, TURBT, etc. Table 3 compares the quality of analgesia among the groups. Group 1 was found to be faster in action as compared to group 2. Mean onset of analgesia was 10.31 ± 1.5 min with group 1 as against 11.23 ± 1.2 with second group (p value < 0.05). Quality of analgesia was also better with group 1 reflected by the fact that Present Pain Intensity (PPI) score was zero (means no pain at all) in only 11 observations out of 280 (3.93%) belonging to second group as against 49 (17.5%) observations belonging to group 1. PPI Score 1 (meaning slight pain) was observed in 129 (46.07%) observations belonging to second group as against in 219 (78.21%) observations belonging to first group. PPI score 3 and 4 was found in 105 and 35 observations respectively belonging to group 2 as against in 49 and 12 observations respectively belonging to group 1.

Statistical analysis: Statistical analysis was done using Stata 11 software. Demographic characteristics, hemodynamic parameters, onset of analgesia, quality of analgesia, level of sedation and side effects were compared between two groups and data was analyzed statistically. For continuous variables descriptive statistics (mean and standard deviations) were computed. Comparison of means in Group-S and Group-F was done using unpaired t-test. For categorical data chi-square test was applied. $P < 0.05$ was considered significant.

DISCUSSION

Lumbar epidural administration of 20 to 30ml ropivacaine 0.5% provided anaesthesia of a similar quality to that achieved with bupivacaine 0.5% in women undergoing caesarean section, but the duration of motor blockade was shorter with ropivacaine. For lumbar epidural anaesthesia for lower limb or genitourinary surgery, comparative data suggest that higher concentrations of ropivacaine (0.75 or 1.0%) may be needed to provide the same sensory and motor blockade as bupivacaine 0.5 and 0.75%. In patients about to undergo upper limb surgery, 30 to 40ml ropivacaine 0.5% produced brachial plexus anaesthesia broadly similar to that achieved with equivalent volumes of bupivacaine 0.5%, although the time to onset of sensory block tended to be faster and the duration of motor block shorter with ropivacaine.[1] Extensive clinical data have demonstrated that epidural 0.2% ropivacaine is nearly identical to 0.2% bupivacaine with regard to onset, quality and duration of sensory blockade for initiation and maintenance of labour analgesia. Ropivacaine also provides effective pain relief after abdominal or orthopaedic surgery, especially when given in conjunction with opioids or other adjuvants. Nevertheless, epidurally administered ropivacaine causes significantly less motor blockade at low concentrations. Whether the greater degree of blockade of nerve fibres involved in pain transmission ($A\delta$ - and C-fibres) than of those controlling motor function ($A\alpha$ - and $A\beta$ -fibres) is due to a lower relative potency compared with bupivacaine or whether other physicochemical properties or stereoselectivity are involved, is still a matter of intense debate.

Recommended epidural doses for postoperative or labour pain are 20–40mg as bolus with 20–30mg as top-up dose, with an interval of ≥ 30 minutes. Alternatively, 0.2% ropivacaine can be given as continuous epidural infusion at a rate of 6–14 mL/h (lumbar route). Preoperative or postoperative subcutaneous wound infiltration, during cholecystectomy or inguinal hernia repair, with ropivacaine 100–175mg has been shown to be more effective than placebo and as effective as bupivacaine in reducing wound pain, whereby the vasoconstrictive potency of ropivacaine may be involved. Similar results were found in peripheral blockades on upper and lower limbs. Ropivacaine shows an identical efficacy and

potency to that of bupivacaine, with similar analgesic duration over hours using single shot or continuous catheter techniques. In summary, ropivacaine, a newer long-acting local anaesthetic, has an efficacy generally similar to that of the same dose of bupivacaine with regard to postoperative pain relief, but causes less motor blockade and stronger vasoconstriction at low concentrations.[2]

Epidural infusion of 0.2% ropivacaine is recommended for labor analgesia, but lower concentrations may be effective. The objective of this study was to compare 0.1% ropivacaine with 0.2% ropivacaine and to examine the effect of addition of fentanyl. In a randomized double-blind study, 58 nulliparous laboring parturients had epidural analgesia established with 0.2% ropivacaine and were then randomized to receive one of the following epidural infusions at 10 mL/h: 0.2% ropivacaine (group R2, $n = 19$), 0.1% ropivacaine (group R1, $n = 19$), or 0.1% ropivacaine with 2 $[\mu\text{g/mL}]$ fentanyl (group RF, $n = 20$). Supplementary analgesia was provided on request with 5-mL boluses of 0.2% ropivacaine. The authors concluded that epidural infusion of 0.1% ropivacaine alone at 10 mL/h provided adequate analgesia in the first stage of labor, and that the addition of 2 $[\mu\text{g/mL}]$ fentanyl to that concentration improved analgesia to a quality similar to 0.2% ropivacaine alone.[3]

The aim was to determine qualitative and quantitative aspects of caudal block, haemodynamic effects, and post-operative pain relief of ropivacaine 0.25% versus ropivacaine 0.25% with clonidine for lower abdominal surgeries in paediatric patients. The caudal block was administered with ropivacaine 0.25% (Group I) and ropivacaine 0.25% and clonidine 2 $\mu\text{g/kg}$ (Group II) after induction with general anaesthesia. Haemodynamic parameters were observed before, during and after the surgical procedure. Post-operative analgesic duration, total dose of rescue analgesia, pain scores and any side effects were looked for and recorded. All the results were tabulated and analysed statistically. The dose requirement for post-operative pain relief was also significantly lesser in Group II. The incidences of side effects were almost comparable and non-significant. A caudal block with 0.25% of isobaric ropivacaine combined with 2 $\mu\text{g/kg}$ of clonidine provides efficient analgesia intra-operatively and prolonged duration of analgesia post-operatively.[4]

Neuraxial adjuvants augment the action of local anesthetics. The aim is to determine the qualitative and quantitative aspects of epidural block of ropivacaine 0.75% versus ropivacaine 0.75% with clonidine for elective cesarean section. A randomized double-blind study was conducted among 51 healthy parturients, scheduled for elective cesarean section. Epidural block was administered with 20 ml of ropivacaine 0.75% (group R) and ropivacaine 0.75% and clonidine 75 μg (group RC) and anesthetic level was achieved minimum until T6–T7 dermatome. Onset time of analgesia, sensory and motor block levels, maternal heart rate and blood pressure, neonatal Apgar scores, postoperative analgesic dose and adverse events were recorded. Onset of analgesia was much shorter in RC group along with prolonged duration of analgesia. The incidence of bradycardia and hypotension was more in RC group as compared to R group which was statistically significant. The dose requirement for postoperative pain relief was significantly lesser in RC group. The addition of 75 μg clonidine to isobaric epidural ropivacaine results in longer, complete and effective analgesia with similar block properties and helped to reduce the effective dose of ropivacaine when compared with plain ropivacaine for cesarean delivery.[5]

Postoperative pain has been an important limiting factor for ambulatory laparoscopic cholecystectomy. Gupta A et al anesthetized 40 ASA physical status I–II patients using propofol for the induction and sevoflurane in oxygen and air for the maintenance of anaesthesia. At the end of the anaesthesia, the patients were randomized into one of two groups: Group P (Placebo) and Group R (0.5% Ropivacaine). Twenty milliliters of normal saline or ropivacaine, respectively, were injected intraperitoneally at the end of surgery via a catheter placed in the bed of the gall bladder. Postoperatively, intermittent injections (10

mL) of the study solution were given when required for pain. Ketobemidone 1–2 mg was given IV as rescue medication. Pain was assessed using a visual analogue scale. During the first 4 postoperative h, patients in Group R had lower scores for deep pain and during coughing compared with Group P ($P < 0.05$). No differences were found in the postoperative consumption of ketobemidone. Median times to recovery at home were similar between the groups. By the seventh day, 93% of the patients had returned to normal activities of daily living. They concluded that the early postoperative pain after ambulatory laparoscopic cholecystectomy could be relieved using intermittent injections of ropivacaine 0.5% into the bed of the gall bladder.[6]

Iijima T et al tried to find out the optimal concentration of ropivacaine in combination with fentanyl for patient-controlled epidural analgesia focusing on preservation of bowel function, analgesia, and motor function. Three hundred-twelve women scheduled to undergo gynecologic lower abdominal surgery, were randomly allocated to receive ropivacaine 0.05, 0.075, or 0.1% in combination with fentanyl 4 $\mu\text{g}/\text{mL}$ and droperidol 25 $\mu\text{g}/\text{mL}$. Bowel function was evaluated by the first passage of flatus and feces. Pain was assessed with a visual analog scale, and motor function was examined by modified Bromage scale. Data were collected in the evening on the day of surgery, in the morning and in the evening on the first postoperative day, and in the morning on the second postoperative day. Gastrointestinal motility was not different among the three groups. All three solutions produced equivalent analgesia and no motor blockade. They concluded that ropivacaine 0.05% is sufficient to preserve gastrointestinal motility, and provides excellent postoperative pain relief without motor blockade.[7]

In the current study Hofmann-Kiefer K et al compared ropivacaine and bupivacaine in a PCEA system (combined with sufentanil) taking this potency ratio into account but administering drug doses providing sufficient analgesia for all stages of labour. In a prospective, double-blinded study 114 parturients were randomised to receive either ropivacaine 2 mg/mL with sufentanil 0.75 $\mu\text{g}/\text{mL}$ or bupivacaine 1.25 mg/mL with sufentanil 0.75 $\mu\text{g}/\text{mL}$. After epidural catheter placement, PCEA was available with boluses of 4 mL, a lock-out time of 20 min and no basal infusion rate. They evaluated pain intensity during contractions, sensory and motor function, duration of labour, mode of delivery and neonatal outcome. Consumption of local anaesthetic and opioid drugs and PCEA system variables were recorded. Mean total consumption as well as mean hourly drug consumption was significantly increased in the ropivacaine–sufentanil group. No differences in analgesic quality, sensory or motor blocking potencies or neonatal outcome variables between groups were detected. Frequency of instrumental deliveries was significantly increased in the ropivacaine–sufentanil group. The results support the findings of previously published studies postulating ropivacaine to be 40–50% less potent for labour epidural analgesia compared to bupivacaine.[8]

The perioperative period is stressful, with many pathophysiologic alterations rendering patients vulnerable to several potential adverse events. In the last few years, it increasingly has been recognized that postoperative pain can contribute not only to human suffering but to postoperative morbidity. As postoperative pain has received more attention, it has become clear that improving pain relief alone, although of value from a humanitarian viewpoint, has not had marked impact on perioperative morbidity or mortality. Major improvements in surgical outcomes require careful integration of surgical, anesthetic, and pain management interventions into coordinated programs of perioperative care and rehabilitation.[9]

Buvanendran A et al studied the role of adjuvants for post operative pain relief. Adjuvants are compounds which by themselves have undesirable side-effects or low potency but in combination with opioids allow a reduction of narcotic dosing for postoperative pain

control. Adjuvants are needed for postoperative pain management due to side-effects of opioid analgesics, which hinder recovery, especially in the increasingly utilized ambulatory surgical procedures. NMDA antagonists have psychomimetic side-effects at high doses, but at moderate doses do not cause stereotypic behavior but allow reduction in opioid dose to obtain better pain control. Alpha-2 adrenergic agonists cause sedation, hypotension and bradycardia at moderate doses, but at low doses can be opioid sparing especially in spinal administration. Gabapentin-like compounds have low potency against acute pain, but in combination with opioids allow a reduction in opioid dose with improved analgesia. Corticosteroids may have only a limited role as adjuvants while acetylcholine esterase inhibitors may have too many side-effects. Newer adjuvants will be needed to reduce opioid dose and concomitant side-effects, even more as same day surgeries become more routine.[10]

CONCLUSION

Ropivacaine is a well tolerated regional anaesthetic with an efficacy broadly similar to that of bupivacaine. However, it may be a preferred option because of its reduced CNS and cardiotoxic potential and its lower propensity for motor blockade. In our study, no difference was observed between groups regarding patient satisfaction. All patients were hemodynamically stable. The incidence of side effects was remarkably minimal and both groups had comparable in this regard. Despite a significantly better safety profile of the pure S(–)-isomer of ropivacaine, the increased cost of ropivacaine may presently limit its clinical utility in postoperative pain therapy.

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