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Original Research Article

A Randomized Controlled Assessment of Levobupivacaine and Levobupivacaine with Dexemedetomidine in Transeversus Abdominis Plane Block for Caesarean Delivery for Post-Operative Analgesia

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Abstract

Aim: The aim of the present study was to assess the TAP block with levobupivacane with or without dexmedetomidine was compared with control group for post-operative analgesia following cesarean delivery.

Methods: This was a double-blind randomized control trial conducted over a period of 1 year in ESIC Medical College and Hospital Bihta, Patna, Bihar, India. 120 consenting pregnant women scheduled for elective cesarean delivery under spinal anesthesia were enrolled in the study. The normal uncomplicated pregnancies (ASA 2) and age between 21 and 40 years with body mass index (BMI) 18.5 to 34.9 kg/m2 were considered as inclusion criteria.

Results: The time for first request for analgesia was significantly longer in Group LD when compared to Group L and control group, Group C had shortest period. There was significant difference between Group C versus Group L and Group LD ($P < 0.05$), however, there was no difference between Groups L and LD. The difference between Groups L and LD were significant ($P < 0.05$) at 12 h. There was no difference between the groups at 24 h. On enquiring about the VAS rating of postoperative analgesia satisfaction score in the first 24 h, Group C women gave a score of 6.08 ± 1.72 (mean ± SD), Group L women gave 7.74 ± 1.26 and Group LD women gave a score of 8.86 ± 0.64.

Conclusion: TAP block with levobupivacaine provides good immediate postoperative analgesia and addition of dexmedetomidine to levobupivacaine prolongs the duration of analgesia and improves quality with better patient satisfaction.

Keywords: Analgesia, cesarean delivery, dexmedetomidine, levobupivacaine, TAP block

Introduction

Caesarean section is often associated with severe pain, which may result in patient dissatisfaction, impaired patient rehabilitation and prolonged hospitalization. [1,2] Therefore, a well-planned analgesia regimen is required to ensure adequate maternal satisfaction, early initiation of breast feeding and early mobilization to prevent risk of thrombo-embolism as a result of immobility due to pain. Pain after caesarean section is mainly contributed to somatic component of pain (Abdominal wall incision) and less because of visceral pain (uterus). Thereby requiring a multimodal approach for postoperative pain management in the form of NSAIDS, opioids, local infiltration by LA and neuraxial blocks in the form of epidurals. [3]

Transversus abdominis plane block is used to provide analgesia to the anterior and lateral abdominal wall. A local anaesthetic solution (Bupivacaine) is injected into facial plane between the internal oblique and transversus abdominis muscle under ultrasound guidance. The procedural simplicity of this block, along with the reliable level of analgesia (T6-L1) and longer duration and quality of analgesia makes TAP block a good option for lower abdominal gynaecological surgeries, also been reported by American society of regional anaesthesia (ASRA). [4] The transversus abdominis plane (TAP) block is a peripheral nerve block that involves innervations of the anterolateral abdominal wall derived from T6-L1. [5] The block can be given either by anatomical landmark technique or by using

an ultrasound probe. In anatomical technique, the landmark is "lumbar triangle of Petit." The needle-entry site is cephalic to iliac crest in this triangle. The local anesthetic is deposited in a plane between internal oblique and transversus abdominis muscle. It provides adequate postoperative analgesia following various abdominal surgeries. [6-8]

TAP block with Bupivacaine provides effective analgesia for only 4-5 hours which limits its use. Levobupivacaine, a newer local anaesthetic agent, sisomer of racemic Bupivacaine, with a long duration of action, is equally potent, but less cardiotoxic and neurotoxic than its racemate, thus a safer alternative to Bupivacaine. Dexmedetomidine, a selective alpha 2 agonist with both sedative and analgesic properties, when added to Levobupivacaine, for TAP block can provide early onset of sensory analgesia, prolong the duration of postoperative analgesia for up to 10-12 hours, decrease postoperative opioid requirement, and give a better quality of recovery following caesarean delivery.

The aim of the present study was to assess the TAP block with levobupivacane with or without dexmedetomidine was compared with control group for post-operative analgesia following cesarean delivery.

Materials and Methods

This was a double-blind randomized control trial conducted over a period of 1 year in ESIC Medical College and Hospital, Bihta, Patna, Bihar, India. 120 consenting pregnant women scheduled for elective cesarean delivery under spinal anesthesia were enrolled in the study. The normal uncomplicated pregnancies (ASA 2) and age between 21 and 40 years with body mass index (BMI) 18.5 to 34.9 kg/m2 were considered as inclusion criteria.

Patients who didn't meet the above criteria or with chronic use of pain medications, alpha agonists/antagonists, history of tolerance to opiates were excluded from the study. In the preoperative assessment, written informed consent was obtained. All the cesarean delivery were performed under spinal anesthesia with 10 mg of 0.5% bupivacaine heavy with 25 mcg of fentanyl. At the end of the surgery, all women received per rectal diclofenac 100 mg, as per the standard protocol and were randomly assigned to one of the three groups by a computer generated randomization table.

• Group L: Received ultrasound (USG)-guided bilateral TAP block with 40 ml of 0.25% levobupivacaine (20 ml each side)

• Group LD: Received TAP as in Group L with addition

of dexmedetomidine 1µg/kg to levobupivacaine solution

• Group C: Control group, no TAP block.

Under aseptic precautions ultrasound scan of the abdominal wall was performed and transverses abdominis plane (TAP) was identified at the level of umbilicus in the midaxillary line using a high frequency (5–12 MHz) linear array USG probe. TAP block given using 10cm long Stimuplex needle with in plane approach and 20 ml of the drug administered. Procedure was repeated on the other side to complete bilateral TAP block.

In the postoperative period all the women were observed in the high dependency unit (HDU) for first 24 h and an investigator who was unaware of the group allocation noted the observations. The women were given an alerting bell whenever they felt for the need of supplemental analgesia. Intravenous paracetamol 1g was given as first rescue analgesia. If they needed further analgesics they were given tramadol 50 mg IV bolus. Patients were assessed at 1h, and every second hour, thereafter for the first 12h and 24 h for pain at rest and on movement using the visual analogue scale (VAS). We also looked at the number of women requesting analgesia in first 6 h, 12 h and 24 h period. Sedation score (Ramsay Sedation Score), side effects like–nausea, vomiting and pruritus (categorical scale) were also noted. At the end of 24 h patients were asked to rate their analgesic satisfaction using VAS.

Primary outcome measure was time for first request of analgesia. Secondary outcome measured are number of patients requested for analgesia in a particular time interval and the side effects like sedation, nausea and vomiting. We considered difference of 180 minutes between control group and block group for first call for rescue analgesia as clinically significant. Based on pilot study with nine patients in each limb, sample size was calculated with α of 5% and power of the study 80%, we required 28 patients in each group. Considering possible dropouts we included 30 patients in each group. The data were entered into the SPSS 15 SOFTWARE. Statistics were represented in terms of mean ± standard deviation (SD) for normal distribution and median with interquartile range for skewed data.

The Mann–Whitney U test and Kruskal–Wallis test were used for statistical analysis.

Results

Table 1: Time (in minutes) for first request for analgesia

	Group C	Group L	Group LD
Interquartile range	Q3=132	Q3=486.4	Q3=1112

The time for first request for analgesia was significantly longer in Group LD when compared to Group L and control group, Group C had shortest period.

Table 2: Number of patients requested for rescue analgesia

	First 6 hours	First 12 hours	In 24 hours
Group C (*n*=40)	38	40	40
Group L (*n*=40)	19	32	36
Group LD (*n*=40)	20	30	32
Pain score (VAS) at rest, at 6 hours, 12 hours and 24 hour timeline expressed as mean±SD			
Group C (*n*=30)	6.16±1.6	5.8±2.32	6.2±1.92
Group L (*n*=30)	3.7±2.36	3.6±1.93	3.60±2.08
Group LD (*n*=30)	2.96±1.72	2.34±1.46	2.14±1.46
Pain score (VAS) on movement, at 6 hours, 12 hours and 24 hour timeline expressed as mean±SD			
Group C (*n*=30)	6.62±1.8	6.4±2.6	6.34±1.96
Group L (*n*=30)	4.34±2.08	4.6±1.64	4.46±1.92
Group LD (*n*=30)	3.4±1.87	3.14±1.36	2.78±1.2

There was significant difference between Group C versus Group L and Group LD ($P < 0.05$), however, there was no difference between Groups L and LD. The difference between Groups L and LD were significant ($P < 0.05$) at 12 h. There was no difference between the groups at 24 h.

Table 3: Patient satisfaction score (mean±SD) at 24 hours

Group C	Group L	Group LD
6.08±1.72	7.74±1.26	8.86±0.64

On enquiring about the VAS rating of postoperative analgesia satisfaction score in the first 24 h, Group C women gave a score of 6.08 ± 1.72 (mean ± SD), Group L women gave 7.74 ± 1.26 and Group LD women gave a score of 8.86 ± 0.64.

Discussion

Cesarean delivery is often done under spinal anesthesia and postoperative analgesia is not addressed adequately. Additional analgesic plans like long-acting spinal or systemic opioids, regional analgesia or multimodal analgesia are crucial for overall well-being of the patient. However, systemic opioids are associated with side effects/adverse effects like nausea, vomiting, pruritus, sedation, urinary retention and respiratory depression. Thus, it is important to explore safer long-lasting alternative (non-opioid) techniques for postoperative analgesia. [9,10]

For abdominal surgeries, TAP blocks have been demonstrated to decrease the use of postoperative opioids and their side effects such as sedation and PONV, increase the time to first request for further analgesia, provide more effective pain relief, earlier mobilization and faster recovery. [11] Different local anaesthetics alone and addition of adjuvant to local anaesthesia may prolong the block's duration. A systematic review and meta-analysis of randomized controlled trials in 2015 by Zhang D and colleagues showed that addition of Dexamethasone to local anesthetics in ultrasound guided TAP block was a safe and effective strategy for postoperative analgesia in adult patients undergoing abdominal surgery. [12] The time for first request for analgesia was significantly longer in Group LD when compared to Group L and control group, Group C had shortest period. There was significant difference between Group C versus Group L and Group LD ($P < 0.05$), however, there was no difference between Groups L and LD. The difference between Groups L and LD were significant ($P < 0.05$) at 12 h. There was no difference between the groups at 24 h. Abdelaal W et al [13] Evaluated the effectiveness of the addition of dexmedetomidine to levobupivacaine in pre-emptive TAP block for postoperative pain management after abdominoplasty. In a total of 69 patients, they reported dexmedetomidine and levobupivacaine group had significantly lower pain scores as compared to the control group. In a similar study Singh R et al [14] used bupivacaine alone and clonidine with bupivacaine for TAP block following caesarean delivery in 100 women. They reported a longer duration of postoperative analgesia (17.8 ± 3.7 h vs 7.3 ± 1.2 h), lesser consumption of diclofenac and higher satisfaction score in patients who received TAP block with 1 mcg/kg of clonidine added to bupivacaine. However, they noted a higher incidence of sedation in the clonidine group.

In a randomized controlled trial McDonnell et al. studied 50 women undergoing elective cesarean delivery under spinal anesthesia, and evaluated the usefulness of transversus abdominis plane (TAP) block in providing analgesia over the first 48 h postoperatively. [6] The women were divided into two groups, one receiving TAP block with ropivacaine (1.5 mg/kg) and the other, placebo.

Additionally, postoperative analgesia in the form of patient-controlled intravenous morphine and acetaminophen and diclofenac was also given. The VAS scores, total morphine requirement and incidence of sedation, decreased in the first 48 h postoperatively in favour of TAP block with ropivacaine. On enquiring about the VAS rating of postoperative analgesia satisfaction score in the first 24 h, Group C women gave a score of 6.08 ± 1.72 (mean ± SD), Group L women gave 7.74 ± 1.26 and Group LD women gave a score of 8.86 ± 0.64.

Biswas et al [15] reported that Dexmedetomidine as an adjuvant to Levobupivacaine in supraclavicular brachial plexus block increased the duration of block thus facilitating surgery. A study by Sen et al [16] showed that adding Dexmedetomidine to Levobupivacaine in paravertebral block increases the duration of analgesia after Cholecystectomy than using Levobupivacaine alone. Siddiqui et al [17] performed a meta-analysis to evaluate the clinical effectiveness of TAP block. First request of morphine occured at an early stage in the non-TAP block group and TAP block group observed reduced pain up to 24 h postoperatively. They concluded that TAP block decreases opioids requirement postoperatively, increases the time to first request for further analgesia, provides effective pain relief and also has a good safety profile with fewer side effects which are associated with the opioids usage.

Conclusion

TAP block with levobupivacaine provides good immediate postoperative analgesia and addition of dexmedetomidine to levobupivacaine prolongs the duration of analgesia and improves quality with better patient satisfaction.

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