ORIGINAL RESEARCH

Effect of adding dexmedetomidine to levobupivacaine in bilateral transversus abdominis plane block for post-operative analgesia after caesarean delivery

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ABSTRACT

Background and Aims: TAP block is a simple and effective regional anaesthesia technique with a very low complication rate. Dexmedetomidine, an alpha 2 adrenergic agonist, is known to prolong the action of local anaesthetics in peripheral nerve blocks. We aimed to study the effect of Dexmedetomidine as an adjuvant to Levobupivacaine in TAP block after CS. **Material and Methods:** A randomized double-blinded study was done on 50 patients scheduled for CS. Group A patients (n=25) received 20ml of 0.25% Levobupivacaine bilaterally and Group B patients (n=25) received 19.5 ml of 0.25% Levobupivacaine + 50µg of Dexmedetomidine (total 20ml bilaterally) for TAP block. Patients were monitored 24 hours for postoperative analgesia, vital parameters and drug-related adverse effects. Rescue analgesia was provided with 100mg of Tramadol. Time for the first requirement of rescue analgesia and the total analgesic requirement was noted. **Result:** The two groups were comparable in terms of age, weight, and ASA grade 1 and 2. The mean time for the first requirement of rescue analgesia was significantly longer in Group B {test group,10.43 ± 2.65 hours} as compared to Group A {control group, 8.12 ± 2.49 hours}; (p<0.05). The total dose of Tramadol requirement was lesser in Group B as compared to Group A. Patients of both groups were vitally stable and did not have any drug-related side effects (p>0.05). **Conclusion:** The addition of Dexmedetomidine to Levobupivacaine increases the duration of analgesia and decreases the requirement of the total amount of rescue analgesia.

Key words: Levobupivacaine, TAP block, dexmedetomidine

INTRODUCTION:

BACKGROUND

Caesarean Section is inevitably accompanied by considerable postoperative pain which is not addressed adequately. Additional analgesia in obstetric patients is crucial as mothers have to breastfeed and care for their new-borns. These duties can be compromised if analgesia is not satisfactory. Ideal post-CS analgesia with systemic opioids, NSAIDs and/ or regional analgesia as a part of multimodal analgesia is an essential component of ERAS (Enhanced Recovery after Surgery) protocols as these have been shown to decrease postoperative complications and hasten recovery. However, Opioids are associated with significant side effects like nausea, vomiting, pruritus, urinary retention & respiratory depression. Thus, it is important to explore long-lasting non-opioid techniques.

Transversus Abdominis Plane block is an evolving regional anaesthesia technique, a non-dermatomal

somatic field block in which local anaesthetic solution is injected between Internal oblique & Transversus abdominis muscles from the side of the abdomen to block ventral branches of T7- L1 spinal nerves, thus preventing pain signals from the abdominal wall to reach the brain.

TAP block with Bupivacaine provides effective analgesia for only 4-5 hours which limits its use. Levobupivacaine, a newer local anaesthetic agent, s-isomer 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. Studies have also shown that Levobupivacaine provided more prolonged anaesthesia for 7-8 hours & significantly decreased the incidence of postoperative rescue analgesia. Many adjuvants to local anaesthetics have proved to prolong the duration of analgesia.

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. Therefore, this study is designed to assess the postoperative analgesic efficacy of Levobupivacaine alone (Control/Group A) and Levobupivacaine with added Dexmedetomidine (Test/Group B) in landmark-guided TAP block for 50 females undergoing Caesarean delivery.

GOAL/AIM:

To formulate better regional analgesia options into the protocol, adopt safer drugs like Levobupivacaine for routine use, promote the use of adjuvants with LA and follow a multimodal approach for pain relief.

PRIMARY OBJECTIVE:

To evaluate the analgesic duration of Dexmedetomidine when added to Levobupivacaine in Transversus Abdominis Plane block for postoperative pain management following CS.

SECONDARY OBJECTIVE:

To check the safety of newer local anaesthetic drug Levobupivacaine.

METHODOLOGY

STUDY DESIGN: *Prospective Randomized Control, double-blinded comparative study.

STUDY SETTING: * Gynaecology Operation theatre in a tertiary care centre.

STUDY PERIOD: *6-7 months after CTRI approval.

STUDY POPULATION: *50 female patients of ASA grade 1 or 2, aged 18-40 years, scheduled for elective Caesarean Section.

SAMPLE SIZE: Sample size is calculated after comparison with similar studies , using Open Epi software, Version 2 taking VAS at 24 hours of a previous study.

Variables are taken into consideration to calculate the sample size

Pain score (VAS) at 24 hours	Group A (Levobupivacaine)	Group B (Levobupivacaine with Dexmedetomidine)	Mean Difference
Mean	3.63	2.13	1.5
Standard deviation	2.07	1.48	
Variance	4.2849	2.1904	

At Power 80% and Confidence Interval 95%, the calculated sample size was 46, taking in consideration the drop outs and statistical errors it was adjusted to 50 [Group A (n=25) and Group B (n=25)] with a 10% non-response rate.

Patients are randomly allocated to receive either of the study drugs using Rando Software.

INCLUSION CRITERIA

- Age 18-40 years.
- ASA physical status 1 or 2.
- Scheduled for CS.
- Those patients who can understand and rate their pain on a VAS scale (0-10) and provide written & audiovisual consent.
- Patient who stays in hospital for at least 48 hours.

EXCLUSION CRITERIA

- Patient's refusal
- Emergency surgery
- History of Anaphylaxis or Allergy to Local anaesthetics
- History of Bleeding Disorders
- History of Drug abuse
- Infection at the site of TAP block or Spinal Anesthesia
- Inability to provide informed consent

INTERVENTION: After approval from Institutional Ethics Committee (Dr NDDFMSR/IEC/02/2021) and CTRI registration (CTRI/2021/05/033465), informed written and audiovisual consent is taken. A pre-anaesthetic assessment, routine Blood and Urine investigations, ECG & Physician's clearance for Surgery is obtained. CS is performed under Spinal anaesthesia with 2ml of Inj. 0.5% Bupivacaine (heavy)

using a 27G spinal needle. Immediately after skin closure, Transversus Abdominis Plane block is given bilaterally with either 100mg (40ml of 0.25%) Levobupivacaine - Group A or 100 mg Levobupivacaine + 50 microgram Dexmedetomidine - Group B. Baseline vital parameters & pain score are noted by the Investigator. Similarly, after 2, 6, 12 & 24 hours also, vital parameters are noted & patient is asked to rate her pain on the VAS scale by 3 trained anaesthesia assistants. A 24 hours assessment of the patient is done by the Investigator before she leaves the hospital.

STUDY PROCEDURE

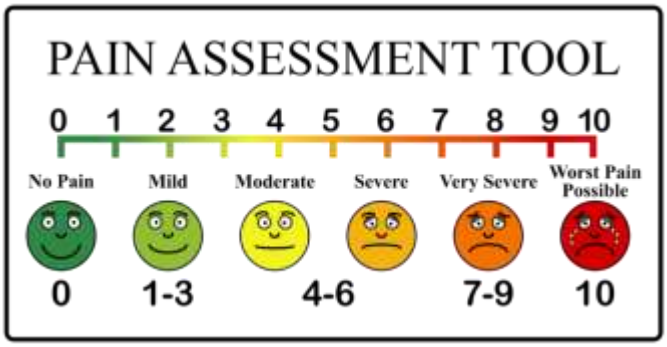
TAP block, though intervention, is our routine practice. It is given with Landmark guided/ Blind technique involving needle insertion at the triangle of Petit. This area is bound by latissimus dorsi muscle posteriorly, the external oblique muscle anteriorly, and the iliac crest inferiorly (base of the triangle). We prefer to use the midpoint of the costal margin and iliac crest in the midaxillary line as the point of needle insertion; this point is approximately 5 cm above & lateral to the anterior superior iliac spine. A 21G 1.5inches long blunted BD needle is inserted perpendicular to all planes, looking for two clicks/ pops (loss of resistance). The first pop indicates penetration of the fascia of the External oblique and entry into the plane between External and Internal oblique muscles; the second pop signifies penetration of the fascia of the internal oblique muscle and entry into the TAP plane between the Internal oblique and Transversus Abdominis muscles. Preparation/filling of the drug (19.5 ml of 0.25% levobupivacaine + 0.5ml NS for each side in group A patients and 19.5ml of 0.25% Levobupivacaine + 0.5ml Dexmedetomidine for each side in group B patients) done by one trained Anesthesia Assistant. A total of 40ml (4 syringes of 10ml each) drug is given to each patient (either 100mg Levobupivacaine alone or 100mg Levobupivacaine + 50µg Dexmedetomidine according to her allotted group). Patients are selected using randomization and double-blinding technique (either Levobupivacaine alone -Group A or Levobupivacaine in combination with Dexmedetomidine-Group B) immediately following Caesarean Section and a TAP block is given. Rescue analgesia with 100mg Tramadol is given to the patient if her VAS score is ≥ 5 or on the patient's demand irrespective of the VAS score. 4mg of Inj. Ondansetron used as antiemetic prophylaxis.

FOLLOW-UP

Postoperatively,

- Time for the requirement of 1st rescue analgesia.
- Number of patients requiring analgesia in the first 24 hours.
- Number of patients having nausea, vomiting, hypotension, somnolence, or pruritus.

DATA COLLECTION TOOL: Visual Analogue Scale-VAS is a validated, subjective measure for pain. Scores are recorded by making a handwritten mark on a 10 cm line that represents a continuum between "no pain" to "worst possible pain". A VAS scale of ≥5 or patient's demand irrespective of the VAS score will be considered significant for Rescue analgesia.



ETHICAL CONSIDERATIONS: Informed written and audio-visual consent is taken from the patient after explanation of the study.

STATISTICAL ANALYSIS: Categorical data were described in fractions or percentages and analyzed using the Chi-square test depending on sample size. Continuous data were described as mean or median and analyzed using unpaired *t*-test. A two-sided *p* value of < 0.05 was considered significant.

Table 1: Comparison of Demographic and Clinical Characteristics between Group A and Group B

Characteristics	Group A	Group B	*p*-value
Age, years (SD)	26.72(5.19)	26.64(4.10)	0.95
Weight, kg (SD)	85.68(8.67)	88(8.08)	0.33
ASA grade I (%)	22 (88)	18 (72)	0.15
ASA grade II (%)	3 (12)	7 (28)	

*p value <0.05, significant

The above table1 shows the demographic and clinical characteristics between (control) Group A and (test) Group B. In all, 50 patients (25 in each group) were enrolled and completed the study. None of the patients in either group reported pain for approximately 6 hours after the surgery. The two groups were comparable in terms of age, weight, and ASA grade I and II. The mean time for the requirement of rescue analgesia was significantly higher in Group B (test group) (10.43 ± 2.65 hours) when compared with Group A (control group) (8.12 ± 2.49 hours; $p<0.05$). The total amount of analgesia required by patients of (control) Group A is more as compared to patients of (test) Group B ($p<0.05$).

Table 2: Baseline Vital Parameters and Routine Investigations

	Group A	Group B	p-value
Hb	10.98(0.92)	10.87(0.89)	0.66
RBS	95.92(15.75)	100.92(21.80)	0.36
Urea(mg/dl)	17.84(3.56)	16.6(5.52)	0.35
Creatinine	0.93(0.18)	0.94(0.18)	0.77
Temp (◦C)	36.95(0.08)	36.80(0.32)	0.02*
Pulse (per min)	82.64(1.46)	89.68(12.5)	0.03*
Diastolic B.P (mmHg)	78.84(9.91)	80.24(8.21)	0.57
Systolic B.P. (mmHg)	127.96(13.37)	125.64(15.60)	0.58
Resp. Rate (per min)	15.24(1.23)	14.92(0.99)	0.31
SpO2 (%)	99.44(1.17)	99.24(0.72)	0.33
MPG I (%)	19(79)	20(80)	0.73
MPG II (%)	6(24)	5(20)	

Table 2 shows the baseline vital and general examination of the study patients. The baseline data of patients of the two groups were comparable in terms of HB, RBS, Urea(mg/dl), Creatinine, Temperature (◦C), Pulse (per min), Diastolic Blood pressure (mmHg), Systolic Blood pressure (mmHg), Resp. rate (per min), SpO2 (%), MPG I (%), MPG II (%). No significant difference was found between baseline characteristics of patients of both groups ($p>0.05$).

Table 3: VAS Score Comparison between group A and group B

	at 6 hours	at 12 hours	at 24 hours
Group A (Control)			
The number of patients who requested rescue analgesia	7(28)	19(76)	18(72)
Pain score (VAS) n (%)			
0	0	0	0
2	3(12)	0	0
3	15(60)	6(24)	6 (24)
4	3(12)	12(48)	14(56)
5	4(16)	7(28)	5 (16)
Pain score (VAS) mean (SD)	3.32 (0.9)	4.04(0.73)	3.96 (0.67)
Group B (Test)			
The number of patients who requested rescue analgesia	5(20)	21(84)	4(16)
Pain score (VAS) n (%)			
0	18(72)	0	0
2	2(8)	2(8)	2(8)
3	0	2 (8)	19(76)
4	4(16)	16(64)	4(16)
5	1(4)	5(20)	0
Pain score (VAS) mean (SD)	1(1.73)	3.96(0.78)	3.08(0.49)
Mean time for the requirement of rescue analgesia in hours (SD)	8.12(2.49)	10.43(2.65)	0.00*

Table 3 shows that 28%, 76% & 72% participants of group A and 20%, 84% & 16% participants of group B requested for rescue analgesia at postoperative 6, 12, 24 hours respectively. Around 88%, 100% & 100% participants of group A and 20%, 92% & 92% participants of group B were noted with VAS score ≥3 at postoperative 6, 12, 24 hours respectively. The mean VAS score of participants of group A was 3.32, 4.04, 3.96 and group B was 1, 3.96, 3.08 at postoperative 6, 12, and 24 hours respectively.

DISCUSSION:

TAP block can be applied as a part of a multimodal technique of analgesia after caesarean delivery which provides a better analgesic effect by combining various drugs with different duration and onset of actions with a reduction of the side effects of individual drugs [1].

The present study found that the two groups were comparable in terms of age, weight, and ASA grades I and II but it was statistically not significant (p>0.05). The present study found that the mean time for the requirement of rescue analgesia was statistically significantly higher among the participants of the Levobupivacaine with Dexmedetomidine group (10.43 hours) compared to participants of the Levobupivacaine group (8.12 hours) (p<0.05). The total amount of analgesia required was less in Group B as compared to that of Group A. Present study found that the two groups were comparable in terms of Hb (gm/dl), RBS (gm/dl), Urea (mg/dl), Creatinine (mg/dl), Diastolic B.P (mmHg), Systolic B.P. (mmHg), Resp. Rate (per min), SpO2 (%), MPG I (%) & MPG II (%) but it was statistically not significant (p>0.05). The two groups were comparable in terms of temperature (◦C) and pulse (per min) and it was statistically significant (p<0.05).

The present study found that the VAS score was higher among the participants of the Levobupivacaine (Control) group compared to participants of Levobupivacaine with the Dexmedetomidine (Test) group. This suggests improvement in the quality of analgesia with the addition of dexmedetomidine.

Abdelaal W *et al*., [2]. 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 [2].

In a similar study Singh R *et al*., [3]. 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[3].

A study done by Siddiqui MR *et al*., [4] observed 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[4].

Almarakbi WA *et al*., [5]. Reported that adding dexmedetomidine to bupivacaine in a TAP block reduced morphine consumption and improved VAS scores after abdominal hysterectomy[5].

Zhang Y *et al*., [6]. Reported that 100µg Dexmedetomidine prolonged the sensory and motor duration of axillary brachial block in combination with ropivacaine. Also, Esmaoglu A *et al*., [7]. Reported that 80µg dexmedetomidine prolonged the sensory duration of axillary brachial block in combination with levobupivacaine[6].

A study done by Srivastava U *et al*., [8], Cansiz KH *et al*., [9] and Abdel Raouf HS *et al*., [10] observed that pain scores were lower and the time of demand for the first analgesia was significantly longer in study groups (TAP block with Dexmedetomidine) compared with control (no drug) groups[8-10].

Biswas *et al*., [11] 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*., [12] showed that adding Dexmedetomidine to Levobupivacaine in paravertebral block increases the duration of analgesia after Cholecystectomy than using Levobupivacaine alone.

CONCLUSION:

TAP block prolongs the duration of analgesia significantly after Cesarean section postoperatively. Additives like Dexmedetomidine are better for improving the duration of analgesia further facilitating patient's satisfaction.

CONFLICTS OF INTEREST: None.

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