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Comparison of post-operative analgesic efficacy between transversus abdominis plane block and local wound infiltration in caesarean section using bupivacaine and clonidine

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Abstract
Background and Aims: Pain is the commonest complaint in post-operative period. Multimodal methods are employed to alleviate pain which helps in early ambulation and recovery. Here two regional anaesthesia techniques, Transversus Abdominis Plane (TAP) block and local infiltration anaesthesia are compared for post-operative analgesic efficacy.
Methods: One hundred and ten patients undergoing Lower Segment Caesarean Section (LSCS) under Spinal Anaesthesia (SA) were randomly allocated into two groups of fifty five each, to receive either TAP block at the end of the procedure by nerve stimulator technique (Group T) or to receive Local Infiltration Anaesthesia [LIA] (Group L). Inj Bupivacaine 0.25% 40 ml with inj. Clonidine 1 µg/kg was used in both technique. Visual Analogue Scale (VAS) score was assessed at regular intervals. Duration of analgesia and requirements of tramadol in 24 hours was recorded and compared.
Results: The duration of rescue analgesia for group T was 307.17±76.39 mins and for group L it was 147±53.88 mins. (*P)* value was found to be 0.0001, indicating it to be significant. Total requirement of Tramadol in 24 hours in group T was 96.67±31.98 mg whereas, group L had 235±43.85 mg with significant *P* value of 0.0001.
Conclusion: TAP block with bupivacaine and clonidine was found to have significantly longer duration of analgesic effect with decreased requirement of tramadol in 24 hours when compared to local infiltration anaesthesia along with better patient satisfaction.

Keywords: Transversus abdominal plane block, local infiltration anaesthesia, post-operative analgesia, clonidine

Introduction
Pain is the commonest symptom observed postoperatively and adequate post-operative analgesia is important. An ideal post-caesarean analgesic regimen must be economical, simple to implement and placental transfer of drug must be minimal, with no adverse effects on the new-born.
Multimodal therapy for postoperative analgesia benefits obstetric patients. There are several methods to treat post-operative pain and to improve patient's condition which includes systemic drugs such as non-steroidal anti-inflammatory drugs, acetaminophen, opioids, ketamine and gabapentin and local anaesthetic technique targeting peripheral nerves [1]. Although single-shot neuraxial analgesic technique using long-acting opioids, or patient-controlled epidural opioid administration, produce effective analgesia, they are associated with side effects, like nausea, vomiting, and pruritus, which reduces overall patient satisfaction. These side effects can be reduced or eliminated by regional anaesthesia with local anaesthetics. Blockade of the neural afferent supply of the abdominal wall, such as abdominal field blocks, ilioinguinal, and iliohypogastric nerve blocks provide significant postoperative analgesia in patients undergoing caesarean section [2].
The TAP block is performed bilaterally, within the ilio-lumbar triangle of Petit, bounded inferiorly by the iliac crest, posteriorly by the latissimus dorsi, and anteriorly by the External Oblique (EO) muscle [3]. The blunt technique uses a double-loss of resistance as the needle is advanced through the EO and Internal Oblique (IO) fascia layers. The aim is to place the tip

of the needle between the IO and the Transversus Abdominis (TA) muscles. In LIA, local anaesthetics (LA) are infiltrated in all layers of the surgical incision under direct visualisation in a controlled and meticulous manner, with the help of 22 gauge, 1.5 inch needle. The needle is inserted approximately 0.5 to 1 cm into the tissue plane (e.g., peritoneal, musculofascial or subdermal planes), and LA solution is injected while slowly withdrawing the needle, which should reduce the risk of intravascular injection Two major endpoints to assess the efficacy of LA wound infiltration are the decrease of opioids use and pain score relief [4].

Bupivacaine is an amide-type, long-acting local anaesthetic. Bupivacaine in concentration of 0.25%-0.5%, maximum allowable dosage of 175-225 mg is used in TAP block and LIA [5]. Clonidine is a frequently used adjuvant to LA. The analgesic properties of clonidine when administered intrathecal or epidural have been demonstrated; they seem to be attributable to its α2 agonist properties. The benefit of adding clonidine to LAs for peripheral nerve blocks is less clear, although it is widely believed that clonidine improves quality and duration of LA block [6]. Clonidine is used in the dose of 1 µg/kg [7]. To 3 µg/kg [7] in TAP block and LIA.

This randomised double-blind study was designed to compare post-operative analgesic efficacy between transversus abdominis plane block and local wound infiltration in caesarean section using bupivicaine and clonidine.

Methods

After obtaining Ethical Committee approval and written informed consent from patients, 110 women aged 18-35 years, weighing 50-100 kg, height ≥ 150 cms, belonging to the American Society of Anaesthesiologists (ASA) Physical status I or II posted for LSCS under SA were included in the study. Patient refusal for the study, known history of allergy to the study drugs, ASA III and IV patients, Body Mass Index (BMI) more than 30 kg/sqm, patients presenting with cord prolapse, hand prolapse and uterine rupture were excluded from the study. They were randomly divided into two groups of 55 each, Group T and Group L, using computer-generated random list. Group T received TAP Block with 40 ml of 0.25% Bupivicaine given on both sides with 1 µg/kg clonidine in divided doses and Group L received 40 ml of 0.25% Bupivacaine and 1 µg/kg clonidine.

Systemic examination along with investigations were undertaken prior to the day of surgery. Procedure regarding SA, TAP block, LIA technique, post- operative follow up and VAS score was explained during the pre-anaesthetic evaluation. All the patients were advised to take pre-medication with oral ranitidine 150 mg on the previous night of surgery. Patients were kept nil orally for at least 8 hours.

In the operating room, 18 G iv cannula was secured and patients were preloaded with lactated ringer's solution at 15 ml/kg. Basal vitals like heart rate, blood pressure, and saturation were recorded using Electrocardiography, Non-invasive blood pressure and pulse oximeter.

Spinal anaesthesia was performed in both the groups. Patient's vitals like heart rate, blood pressure, saturation were monitored continuously throughout the surgery and complications like hypotension and bradycardia, were treated accordingly using inj mephentermine and inj atropine respectively. For post-operative analgesia 2 techniques were employed. Group T received TAP block at the end of procedure by nerve stimulator technique. Inj. Bupivacaine 0.25% 20ml with inj. Clonidine 1µg/kg was given at each side. Group L received local infiltration anaesthesia which includes injecting drug at multiple layers of the abdomen. Inj. Bupivacaine 0.25% with inj. Clonidine 1µg/kg [40 ml] as divided into 3parts. 10ml of the solution was injected in the paracolic gutter on each side, 10 ml was injected into the rectus by the operating surgeon, remaining 10ml was given subcutaneously after the wound closure. Patients were shifted to Post Anaesthesia Care Unit for further management.

Patients who underwent the above techniques were followed up for 24 hours, and pain was assessed using VAS score at 0, 2, 4, 6, 8, 12, 24 hrs. Scores were recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain." The patient-acceptable symptom state for pain has been shown to be 2.0 to 3.0 cm on a 10-cm VAS. Patients with VAS score greater than 4 (Break through pain) received tramadol and the time at which the drug was given was noted. The time from the placement of block to the time at which first dose of tramadol given was considered as duration of analgesia. Total consumption of tramadol in first 24 hrs was noted and recorded. Patients were assessed for vitals heart rate, blood pressure and oxygen saturation post operatively at 0, 2, 4, 6, 8, 12, and 24 hr and any hemodynamic abnormality were treated. Adverse effects related to procedure or drugs were noted and recorded. The sample size was calculated from the previous study done by Das N *et al.* [9]. The mean difference between the two groups of first demand of analgesia was 0.4 and standard deviation was 0.748. Considering the results obtained in their study, the above value was used to calculate sample size. Taking an alpha error of 5% and statistical power of 80%; the sample size was determined to be fifty five in each group. Data was analysed using SPSS software. Intergroup comparison of demographic data, duration of analgesia, post-operative heart rate, blood pressure and mean arterial pressure was carried out by Student's t test. The comparison of duration of post-operative analgesia in two study groups was done by Chi-Square test.

Results

110 patients, who were included, successfully completed the study. Both groups were comparable with respect to age, weight and duration of surgery [Table 1].

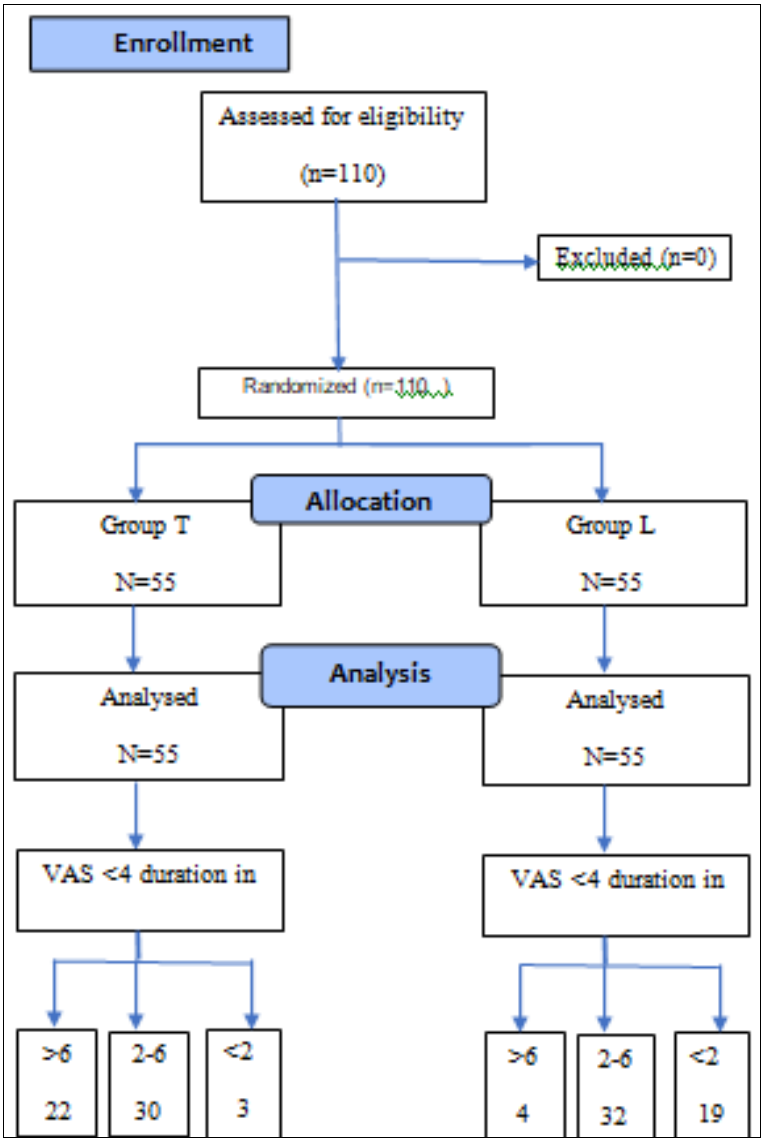

Fig 1: Consort diagram of the study

Table 1: Showing the frequencies of age group, mean and standard deviation of weight and duration of surgery among the two group

	Group L (%) N=55	Group T (%) N=55	Total (%)	P -Value
Age group (Years)				
≤ 20	9 (16.36)	8(14.54)	17 (15.45)	0.0650
21-25	30 (54.54)	29 (52.72)	59 (53.63	
≥ 26y	16 (29.09)	18 (32.72)	34 (30.90	
Weight	62.43±6.91*	61.80±5.38		0.6934
Duration of surgery	67.2±6.35	67.27±6.64		0.336

* Mean ± Standard Duration

In group L 16.36% were aged <=20 years, 54.54% aged between 21-25, and 29.09% aged >=26 years. In group T 14.54% were aged <=20 years, 52.72% were aged 21-25, and 32.72% aged >=26 years of age. The two groups were similar with respect to age, Weight, Duration of surgery, the differences were statistically insignificant (*P* value > 0.05), so that the difference proved in other variables has least possibility of occurring by chance [Table 1].

Table 2: Comparison of Group L and Group T with postoperative mean VAS scores at different time points by independent t test

Treatment Times	Group L (Mean ± SD)	Group T (Mean ± SD)	P value
0 hrs	1.27±0.45	1.10±0.30	0.0984
2 hrs	2.13±1.11	1.50±0.62	0.0085*
4 hrs	4.77±1.17	2.43±1.10	< 0.001*
6 hrs	5.10±0.80	3.90±1.34	< 0.001*
8 hrs	5.43±0.77	5.50±0.97	0.7701
12 hrs	5.17±0.99	5.47±0.25	0.2566
24 hrs	4.73±0.94	5.03±0.66	0.1610

**p*<0.05 clinically significant

Post-operative analgesia was analysed using VAS score at different intervals for 24 hours [Table 2]. There was significant lower VAS score values between 2-6 hours in group T when compared to group L with a *P* value of <0.05. There was no significant difference noted at 8, 12 and 24 hour. Mean VAS score values were found highest at 8 hour in both the groups, 5.43±0.77 in group L and 5.50±0.97 in group T. But VAS score of >4 was seen earlier in group L with mean of 4.77±1.17 at 4 hour.

Table 3: Mean and Standard Deviation of first demand of analgesic (Mins), Total dose of Tramadol among the groups by independent t test

Variable	Group L (Mean ± SD)	Group T (Mean ± SD)	*P*-value
First demand of analgesia(Mins)	147.33±53.88	307.17±76.39	< 0.001*
Total dose of Tramadol(mg)	235.00±43.85	96.67±31.98	< 0.001*

*p<0.05 clinically significant

Inj tramadol 50mg I.M. was the rescue analgesic used in our study. Compared with Group L, Group T was found to have longer duration of rescue analgesia and was statistically significant with a *P* value of 0.0001 [Table 3].

Total requirement of tramadol in 24 hours was noted in both groups. Mean of total dose of tramadol (mg) required in group L was higher compared to Group T and was statistically significant with *P* value of 0.0001 [Table 3].

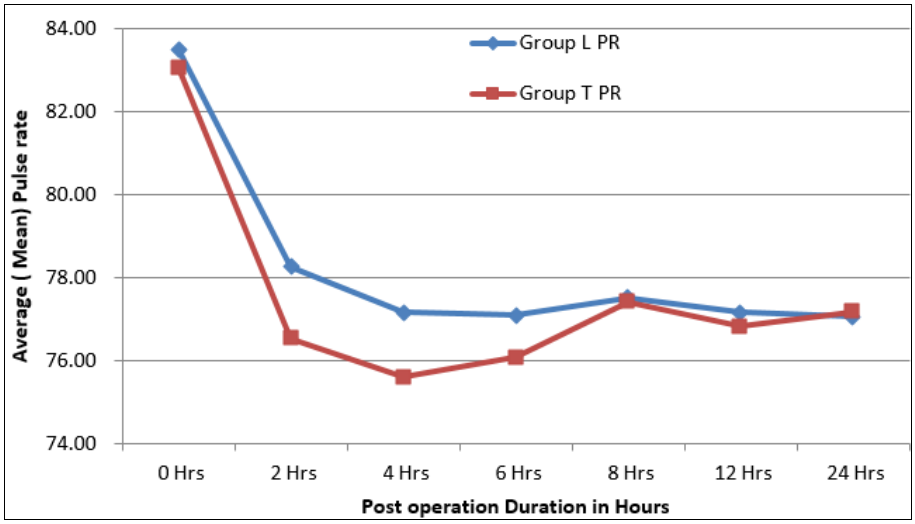

Fig 2: Comparison of Group L and Group T with postoperative mean pulse rate at different time points

Post-operative pulse rate was monitored for 24 hours. The mean pulse rate was > 75 at all points. There was no significant difference between the two groups and therefore both the groups were comparable with respect to pulse rate. There was no bradycardia observed in both the groups [Fig. 2].

Discussion

This present randomised double-blind study showed that TAP block was superior when compared to LIA with respect to duration of postoperative analgesia, lower VAS scores, decreased rescue analgesic consumption and better patient satisfaction. There were no complications associated with both the techniques.

TAP block is a regional anaesthesia technique commonly used for postoperative analgesia following lower abdomen surgeries. It reduces analgesic consumption, early ambulation, and thereby early discharge.

LSCS under SA provides an excellent opportunity to perform TAP block. Injection in the postoperative period avoids operating room time delays, and by that time the neonate has already been delivered and is not placed at risk. So we performed TAP block at the end of surgery.

Hemodynamic parameters were recorded intraoperatively and postoperatively for 24 hours. Postoperative VAS score, duration of analgesia, time of first rescue analgesia given, total dose of rescue analgesic required and side effects were noted.

We found that in our study Group T had significantly lower pain scores than Group L in the first 6 hours. Later the VAS scores were comparable in both the groups for first 24 hours.

The reason being TAP block acts by blocking the anterior primary rami of T7-T12 spinal nerves that pass between IO and TA and then perforate rectus abdominis and end as the anterior cutaneous branches, which innervate the anterior abdomen [10]. In LIA, only peripheral nerves at the site of incised tissue planes are blocked.

Our findings were similar to that of study conducted by Das N *et al.* [9] where the VAS scores were significantly lower in TAP block and time to rescue analgesia was longer in TAP block group when compared to that of LIA group.

Atim *et al.* [11] in their prospective research which was similar to our study evaluated the effect of TAP block with bupivacaine, infiltration of skin and subcutaneous tissue of the wound in patients undergoing hysterectomy. They found that lesser pain scores in TAP block group at 6 hour and 24 hour and suggested that TAP block was more effective than infiltration at surgical site in postoperative pain management.

Another study conducted by Mir TA *et al.* in 2016 to evaluate efficacy of bupivacaine and bupivacaine plus clonidine in TAP block for postoperative analgesia showed that addition of clonidine as adjuvant to local anaesthetic increased the duration of block and hence increased time of first rescue analgesic [12].

Hence we found that patients who received clonidine as an adjuvant to bupivacaine for TAP block had longer time for first rescue analgesia than patients who received the same drug in LIA.

Although intravenous clonidine causes sedation, association is less when used in peripheral block; McCartney *et al.* reviewed 27 studies and reported that only 5 studies showed sedation where clonidine was used as additive [13].

We selected Tramadol for rescue analgesia as several studies have confirmed the analgesic effects of single-dose intramuscular tramadol 50-100 mg can provide effective postoperative analgesia comparable to that obtained with morphine, pentazocine and ketorolac [14].

Our study demonstrated that end operative TAP block reduced VAS score significantly in the study group during first six hours when compared to group which received LIA. Similar results were obtained in a meta-analysis consisting 9 Randomised Controlled Trials conducted by Guo Q *et al.* in 2015 [15]. Morphine was used as rescue analgesic in their study. TAP block significantly reduced 24-hour overall morphine consumption by 3.85 mg (P = 0.04) compared with wound infiltration. They concluded that TAP block provides superior analgesia compared with wound infiltration in the setting of a multimodal analgesic regimen.

Conclusion

It can be concluded that the TAP block is an effective postoperative analgesic procedure for post caesarean section patients.

Conflicts of interest

There are no conflicts of interest.

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