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COMPARISON OF POSTOPERATIVE ANALGESIC EFFECT OF TRANSVERSUS ABDOMINIS PLANE BLOCK VERSUS DIRECT WOUND INFILTRATION FOR LOWER SEGMENT CAESAREAN SECTION - A PROSPECTIVE, RANDOMIZED DOUBLE BLIND CONTROLLED STUDY.

Anaesthesiology

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ABSTRACT

Background: TAP block has gained popularity to provide postoperative analgesia after abdominal surgery like in patients undergoing caesarean section who need to be comfortable and alert in order to take care of their babies, for which they must be pain free in post-operative period. The aim of present study is to compare the analgesic efficacy of TAP block with direct wound infiltration specifically in LSCS patients in reducing patient pain postoperatively, as well as to decrease the analgesic requirement.

Material and method: The study population consisted of 60 patients posted for elective caesarean section. They were blindly divided into two groups of 30 patients each. Group TAP received 30ml 0.25% Bupivacaine in Transverses abdominis plane (TAP) block for postoperative analgesia and group WI received 30ml 0.25% Bupivacaine as infiltration at incision site for postoperative analgesia. Patients were observed for numeric pain score (NPS), analgesic requirements, total analgesic consumption and adverse effects if any.

Results: The NPS values of Group WI at 2, 4, 6, 10, 12, 18 and 24th hours were found to be statistically significantly higher than those of Group TAP. ($p<0.0001$). Time for first rescue analgesic was statistically significantly higher in Group TAP ($p<0.0001$) and total amount of analgesic consumed were statistically significantly higher in Group WI ($p<0.0001$).

Conclusion: TAP block is a better postoperative analgesic procedure for post caesarean section patients in comparison to local infiltration.

KEYWORDS

Postoperative pain relief, TAP block, Local site infiltration.

INTRODUCTION:

Lower segment caesarean section is common procedure done in all over the world. Postoperative pain after the procedure is very unpleasant, dissatisfied feeling for the patient. It causes increased morbidity, functional disability and quality of life impairment resulting in the delay of patients' recovery and ability to return to daily functional activities.[1] Early recovery is especially important for a patient who is expected to take care of her newborn shortly after an operative procedure.[2]

Various pharmacological agents have been described in literature for postoperative pain relief through multimodal approach. epidural and caudal analgesia have been considered the gold-standard techniques after abdominal surgery for adults & children respectively. With passing years, new methods of regional anaesthesia have been gained a widespread use recently.

For lower abdominal surgeries, epidural analgesia has been the gold standard technique for providing postoperative analgesia, but contraindication for the same would warrant need for other equally good analgesic technique.

Rafi A N (2001)[3] first described the transversus abdominis plane block in 2001 which has been become the suitable option for analgesia in lower abdominal surgeries.

A blind landmark guided "double pop" technique or ultrasound-guided needle tracking through the external oblique and internal oblique (IO) muscles have been practiced for the TAP block. It works by blocking the thoracolumbar nerves (T6–L1), ilioinguinal and iliohypogastric nerve which supply sensory fibers to the anterior abdominal wall.[4,5]

Local anaesthetic infiltration is also widely performed convenient postoperative analgesia technique. The aim of local infiltration is to anesthetize nerve endings in a finite area of tissue by the injection of local anesthetics nearby. The uses of local infiltration anesthesia include subcutaneous infiltration for IV placement, superficial/shave biopsy, suturing, submucosal infiltration for dental procedures, laceration repair, wound infiltration for postoperative pain control at the incision site, intraarticular injections for postoperative pain control, arthritic joint pain control, infiltrative nerve blocks such as ankle block, scalp block, digital block.

TAP block and incision site infiltration technique have opioid sparing analgesic effect.[6] These techniques also helpful in preventing opioid related side effects like nausea, vomiting and respiratory depression.

Primary aim and objective of our study was to do comparison of analgesic efficacy between transversus abdominis plane (TAP) block and wound site infiltration (WI) in postoperative caesarean section using 0.25% bupivacaine.

In our study secondary objective was to see the time to administer first dose of rescue analgesic and total amount of analgesic consumed with patient satisfaction. We also noted haemodynamic parameters and side effects, if any.

MATERIALAND METHOD:

A prospective, double blind randomized controlled clinical study was performed at Jhalawar Medical College and Associated Hospitals, Jhalawar (Rajasthan) during June to December 2020 in the Department of Anaesthesiology after obtaining approval from Jhalawar institutional ethical committee and written informed consent from each patient.

Sample size was calculated with the assumption of a possibility of at least of 35% difference between the two groups. Therefore 30 patients were included in each group namely, the TAP group and the WI group, in order to obtain an alpha error of 5% and statistical power of 80%.

A total of 60 ASA Grade II pregnant patients, over 18year of age, who had completed 36weeks period of pregnancy and posted for elective caesarean section done by transverse incision were included in the study. ASA III and IV Patients, history of hypersensitivity or allergy to the study drugs, patient refusal, BMI more than 30kg/sqm, patient with any chronic systemic disease, patient posted for emergency LSCS were excluded from the study. All patients who qualified as per the selection criteria were explained in their vernacular language regarding surgical procedure, anaesthesia procedure & drugs to be used.

Patients were randomly allocated to two groups. The randomization was done by sealed envelope method. A total of 60 envelope (30 per group) were made, each envelope mentioning a computer generated random number which was allocated to a particular study group. After

completion of surgery at the time of intervention (TAP block/ WI), an anaesthetist different from principal investigator were asked to open the envelope and prepared the study drug to be given to patient according to group allocated.

Group TAP: Received TAP block with Bupivacaine 0.25% 30ml (15+15ml on each side)

Group WI: Received wound site infiltration with Bupivacaine 0.25% 30ml (15+15ml on each side)

Preoperative assessment was done for all patients day before surgery in elective LSCS cases.

Patients were received in operation theatre, identified and NBM status was confirmed.

All vital parameters were recorded like Heart rate, Systolic and Diastolic blood pressure, SpO2, ECG.

An intravenous access was established by 18G IV cannula and Ringer lactate solution was infused (20ml/kg) over 15 to 20 minutes for intravenous hydration to all patients. All patients were given Inj. Ranitidine 50mg and Inj. Metoclopramide 10mg 10 minutes before surgery as aspiration prophylaxis.

With the patient in sitting position, the L3-L4 inter-vertebral space was identified and infiltrated with 1ml of 2% lidocaine. After taking full aseptic precautions, lumbar puncture was performed at L3-L4 interspace through midline approach using a disposable 25G Quincke's spinal needle. 2ml of hyperbaric bupivacaine was then injected in the subarachnoid space after free flow of CSF and patient was made supine and 15^{0} wedges was placed under her right hip. Surgical incision was allowed once sensory dermatomal level of T4 was achieved.

Mean arterial pressure (MAP) and heart rate (HR) were recorded at every 5 min during whole operative procedure. Any fall in MAP of more than 20% of baseline was considered as hypotension and treated with intravenous fluid bolus followed by Inj. Mephentermine 6mg IV if required. Inj. Atropine was given IV (0.6 mg) if HR becomes less than 60 beats per minutes.

Intraoperative and postoperative complications, if any, noted.

In Group TAP, after the surgical procedure was accomplished, sterile skin cleaning was performed with patients lying supine and bilateral TAP block was given by landmark guided technique using Tuohy's needle along the mid axillary line one cm. above the highest point of iliac crest and 30 mL (15 mL+15 mL, bilaterally) bupivacaine of 0.25% concentration was administered over the transversus abdominis muscle after feeling of two pop up of external oblique and internal oblique respectively. All local anaesthetics were prepared by the same co-investigator and same co-investigator assisted during the whole TAP block procedure.

In Group WI after the completion of the surgical procedure, in total 30 mL (15 ml for each wound site) bupivacaine of 0.25% concentration was used for subcutaneous wound site infiltration of the patients.

Post- operative pain was evaluated by numeric pain score (NPS), on a scale of 1-10. Patients were asked to provide the number, with 10 being most severe pain they have ever had and 0 being no sensation of pain. In group WI, NPS after wound site infiltration and in group TAP, NPS after TAP block was considered as NPS 0 (Zero).

Patients were evaluated for pain at the 2^{nd}, 4^{th}, 6^{th}, 10^{th}, 12^{th}, 18^{th}, 24^{th} hr and at first mobilization (NPSfm) by a co-investigator, who was blinded to the used method. He asked for their pain score and recorded them as NPS2, NPS4, NPS6, NPSfm/ NPS 8, NPS 10, NPS12, NPS18 and NPS24 respectively. All patients were routinely mobilised, 8 hrs after the end of the operation. If the patient suffered from pain (NPS>5) at any hour, 50mg tramadol was given intravenously along with Inj. Ondansetron.

Time for first rescue analgesia and total amount of analgesic consumption were noted with vitals monitoring. Patient satisfaction was determined by asking verbally to provide a number between 0-10 (0-not satisfied, 10-fully satisfied) and the number was recorded. Patient satisfaction evaluation was performed 24 hours after the block. Recording of NPS, analgesic requirement and patient satisfaction score was done by an independent anaesthesiologist not involved in the study. Data were represented as mean ±SD. Categorical data were represented as number of patients. Physical characteristics, heart rate, mean arterial pressure, onset and duration of sensory block, onset and duration of motor block, first analgesic demand (duration of analgesia) were compared using the unpaired t-test.

Although systolic blood pressure, diastolic blood pressure and mean arterial pressure were monitored during intra and postoperative period but only mean arterial pressure was considered for statistical evaluation. Categorical data was compared using chi-square test. Adverse effects profile was compared using Fischer's exact test. P value <0.05 was considered to be significant. Data was entered into Microsoft excel sheet and was analysed using SPSS 21 version software.

RESULTS:

Demographic characteristics were comparable in both the study groups. (Table1)

Table 1: Demographic characteristics

Characteristics	Group TAP (n=30)	Group WI (n=30)	P value
Age (years)	24.3±3.2	23±3.7	0.242
Height (cm)	155.4±7.7	151.7±6.2	0.102
BMI (kg/m2)	24.0±1.6	24±2.3	1.000
Duration of surgery (min)	42.7±2.7	42.4±2.7	0.727

Pre-operative and intra-operative hemodynamic parameters e.g. heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, SpO2 were comparable in both the study groups during entire surgical procedure. (P Value>0.05) (Table 2)

Table 2: Haemodynamic parameters

TIME	HEART RATE			MAP		
	Group TAP	Group LSI	P value	Group TAP	Group LSI	P value
Pre-operative	86.8±13.2	85.4±13.6	0.24	92.8±10.6	88.0±10.11	0.11
O min	83.9±12.3	87.4±14.4	0.25	89.5±11.1	88.7±11.1	0.17
5min	84.5±13.0	86.7±14.1	0.186	90.2±11.5	90.0±8.9	0.12
10min	85.8±10.4	89.5±15.2	0.97	93.03±12.4	90.2±8.6	0.54
15min	86.8±10.4	87.4±14.1	0.59	94.03±11.5	90.2±8.7	0.57
20min	87.2±10.0	84.9±12.8	0.61	90.6±8.83	90.77±10.1	0.42
25min	86.9±10.6	85.4±10.7	0.22	90.4±9.0	91.37±9.49	0.51
30min	86.2±11.1	83.8±11.3	0.278	90.7±9.02	91.56±10.9	0.11
35min	85.7±10.9	84.0±11.0	0.342	90.4±8.86	90.9±9.6	0.28
40min	85.5±10.3	84.5±11.5	0.175	87.1±11.2	91.03±8.9	0.89

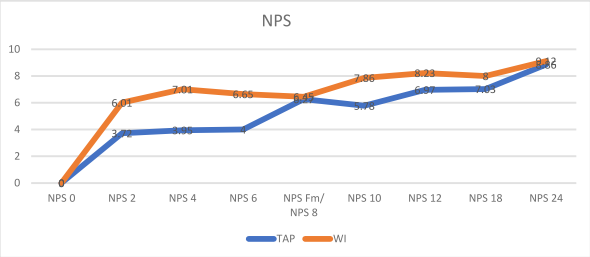
At the time of giving TAP block / wound site infiltration with local anaesthetic patients were under the effect of spinal anaesthesia. All studied TAP block were successful, if patient complained of pain at incision site just after the effect of spinal anaesthesia, it considered as failed TAP block and excluded from the study.

NPS at the time of giving TAP block or surgical site infiltration was 0. Analysis showed that there were significant difference in numeric pain scores at 2^{nd}, 4^{th}, 6^{th}, 10^{th}, 12^{th}, 18^{th} and 24^{th} hours between two groups. However, there was no significant difference in NPS scores at the time of first mobilization at 8^{th} hour (NPSFm) (Table- 3) (Figure- 1)

Table-3: Numerical pain score

Time (Hour)	Group TAP (Mean±SD)	Group WI (Mean±SD)	P Value
NPS 0	0.00±0.00	0.00±0.00	
NPS 2	3.72±1.07	6.01±1.04	<0.0001
NPS 4	3.95±1.16	7.01±1.15	<0.0001
NPS 6	4.0±0.69	6.65±0.72	<0.001
NPS Fm/ NPS 8	6.27±0.60	6.45±0.50	0.211
NPS 10	5.78±0.43	7.86±1.06	<0.0001
NPS 12	6.97±0.401	8.23±0.60	<0.0001
NPS 18	7.03±1.12	8.00±0.98	<0.001
NPS 24	8.86±0.42	9.12±0.50	<0.001

Figure-1



There is a significant difference between the two groups for first rescue analgesics and total amount of analgesic consumed.

Patient satisfaction score was evaluated at the end of 24 hours. Patients were asked to give a score between 1 and 10 depending on level of satisfaction achieved in pain relief and were evaluated using unpaired t- test. Level of satisfaction was more in TAP block group, but the difference was not significant (p>0.05) (Table- 4)

Table-4

Parameters	Group TAP	Group WI	P value
First demand of analgesic (in hr.) (Duration of analgesia)	9.5±1.0	2.8±1.5	<0.0001
Total amount of tramadol consumed in 24 hr. (mg)	150±30.8	312±38.5	<0.0001
Patient satisfaction score	7.84±1.03	7.56±0.67	0.314

Table-5 Number of patients requiring supplement of analgesic

Time (Hr.)	Group TAP	Group WI
0	0	0
2	2	25
4	6	26
6	10	26
8 (First mobilisation)	12	14
10	25	28
12	28	30
18	30	30
24	30	30

DISCUSSION:

Effective post-operative pain control is an essential component of the care of the surgical patient. Inadequate pain control may result in increased morbidity and mortality. Regarding a special postoperative condition like in postoperative caesarean section, during the planning of postoperative analgesic regimen, along with the mother, we need to consider the breast feed dependent new born also. It may result in respiratory, dietary intake and ambulation impairment which consequently leads to complications.[7] Another concern in these patients is that as they breast feed the new born, opioids must be avoided in these patients due to secretion in breast milk.

The advantage of wound site infiltration over the TAP block is that it requires no technical expertise and specialized equipment like ultrasound and can be performed by the operating surgeon himself. The advantage of TAP block for postoperative pain relief in patients undergoing LSCS, abdominal surgeries, laparoscopic cholecystectomy, and appendicectomy has been described in the literature.[4] Most studies compared TAP block with placebo or other pharmacological agents. However, limited literature is available comparing TAP block with local infiltration at the surgical wound site. So keeping these things in mind, we compared the TAP block and wound site infiltration using 0.25% bupivacaine in post caesarean pain relief.

We found that NPS in both the groups at the time of intervention was 0 and level of sensory block was at the level of T6 at the end of surgery and before application of TAP block or wound site infiltration. It was because of the fact that at the time of intervention patients were under the effect of spinal anaesthesia. We found in our study that 25 patients (n=30) in group WI needed supplemental analgesia in the form of Inj. Tramadol at the 2nd hour whereas in the group TAP only 2 patients required rescue analgesia. (Table-5) This difference in NPS 2 was statistically highly significant between these two groups (p<0.0001). We noted that NPS at 4th, 6th, 10th, 12th, 18th, and 24th hour were lower in group TAP compared to group WI. This difference between both the groups was statistically highly significant (p<0.001), proving more analgesic efficacy of TAP block in comparison to WI.

Our finding was supported by the study done by **Ayodogmus MT et al(2014)**[8] where they compared TAP block and local infiltration anaesthetic (LIA) using 0.25% levobupivacaine and found that USG-guided TAP block was superior to infiltration anaesthesia for the postoperative pain management of patients who have had caesarean section under spinal anaesthesia, and it provides longer-lasting and more efficient analgesia than infiltration anaesthesia.

There was no significant difference in first mobilisation NPS (NPSfm/ NPS 8) between both the groups. In our study, only 12 patients out of 30 in group TAP, experienced NPS >5 and in group WI 14 patients out of 30 experienced NPS >5 (p=0.211)(Table-5). This finding was similar to the study done by **Ayodogmus MT et al (2014)**[8] ; **Chandon M et al (2014)**[9] and **Das N et al(2018)**[10] where they compared the US guided TAP block with the continuous wound infusion in post caesarean section patients ; and did not find any statistically significant difference in terms of NPS between the two group after first mobilisation. (p>0.05)

In our study, in group WI, 26 patients (n=30) showed NPS >5 within 2-3 hours of the wound site infiltration whereas in group TAP, 25 patients (n=30) sustained their analgesic effects up to 8 hours after that they showed NPS >5 and were treated by parental rescue analgesia (Table-5). It was statistically highly significant(p<0.0001).

Sivapurapu V et al (2013)[11] compared bilateral TAP block with Local infiltration anaesthesia (LIA) using 0.25% bupivacaine and noted the time for first request of analgesia as well as visual analogue scale at that time (VAS T- rescue). They used morphine 0.1mg/kg IV as rescue analgesic. TAP proved its superiority over LIA in their study (p=0.001) as well.

In our study, cumulative total tramadol consumption was found lower in group TAP compared to group WI (p<0.0001), which is similar to the result obtained in a study by **Tan TT et al (2012)**[12] where they found TAP block group used significantly less analgesic than those who did not receive any block (p<0.001).

In a study by **Das N et al (2018)**[10] also found that total tramadol consumption was found lower in group TAP compared to group LIA (p<0.001)

Because during mobilisation, pain mainly arises from visceral component which is not under the effect of TAP or wound site infiltration. Hence during the mobilisation, both the groups demonstrated similar NPS score.

Patient satisfaction score and adverse effects profile was not significant in both the study groups. Which is supported by **Ayodogmus MT et al (2014)**[8] and **Das N et al (2018)**[10] where they also did not find any difference between the two procedures in terms of patient satisfaction score.

CONCLUSION:

In our Prospective double blind comparative study between transversus abdominis plane block and direct wound infiltration, from these observations and analysis we inferred that the TAP block is more effective postoperative analgesic procedure for post caesarean section patients in comparison to direct wound infiltration in terms of better analgesia, prolonging the duration for first rescue analgesia and total decreased analgesic consumption.

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