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## TO STUDY THE COMPARISON OF ANALGESIC EFFICACY OF PLAIN BUPIVACAINE WITH BUPIVACAINE AND CLONIDINE IN ULTRASOUND GUIDED TRANSVERSUS ABDOMINIS PLANE BLOCK

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### ABSTRACT

This prospective randomized double blinded case control study was done to evaluate the post-operative analgesic efficacy of bupivacaine alone or in combination with clonidine in ultrasound guided TAP block at Sree Lakshmi Narayana Institute of Medical Sciences, Pondicherry, after obtaining Hospital Ethical Committee approval and informed consent from all the patients. 60 patients who underwent lower segment cesarean section under subarachnoid block were enrolled in this study. They were divided into two groups of 30 each. Both groups received standard dose of 10mg 0.5% Bupivacaine in subarachnoid block. After the surgery when block level receded to T10 sensory level, ultrasound guided TAP block was performed bilaterally using posterior approach. The ultrasound was used to identify the correct position of needle and also the spread of local anaesthetic solution in the neurofascial plane between internal oblique and transversus abdominis muscle. Group BC received 20ml of 0.25% Bupivacaine with clonidine 0.5microgram/kg and Group B received 20ml of 0.25% Bupivacaine on either side. The hemodynamic parameters like pulse rate, blood pressure, respiratory rate, oxygen saturation and sedation score by means of Ramsay score was monitored after the performance of block. The analgesic efficacy was monitored by means of VAS score. The duration of analgesia was calculated from the time of performance of TAP block until the VAS score of 4 was obtained. The primary end point of study was when VAS score  $\geq 4$  was obtained. The average duration of analgesia was 516 minutes in bupivacaine and clonidine group compared to 277 minutes in plain bupivacaine group and this duration of analgesia was statistically significant in bupivacaine with clonidine group when compared to bupivacaine group. The sedation score of 3 was obtained in about 86.7% of the patients in bupivacaine and clonidine group compared to only 10% of patients in plain bupivacaine group. Thus the sedation score was significantly higher in bupivacaine with clonidine group but it was an arousable sleep. The incidence of complications like post operative nausea, vomiting hypotension and bradycardia was similar in both groups, and it was not statistically significant. Thus the addition of clonidine to bupivacaine extended the duration of analgesia without any significant side effects in ultrasound guided Transversus abdominis Plane Block.

**Key words:** Analgesia, Duration, Neurofascial plane, Monitoring.

### INTRODUCTION

Lower segment caesarean section is a common surgical procedure associated with postoperative pain and discomfort.

Pain free post operative period is necessary to give better infant care, breast feeding and early ambulation of these patients. The post operative analgesia should be

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safe with minimal adverse effects for both mother and the child. It can be provided with multimodal analgesic approach.

Most often postoperative pain is treated with systemic or neuraxial opioids. Despite the effective analgesia produced by neuraxial analgesic technique, it is associated with side effects like vomiting, nausea, and pruritus which decrease the satisfaction of the patient. These opioid side effects can be decreased or omitted by regional anaesthesia with local anaesthetics. Adequate post operative pain relief can be achieved by blocking the nerves which supply the anterior abdominal wall like ilioinguinal, iliohypogastric nerves and field block of the abdomen. But the abdominal wall blockade becomes difficult in patients planned for caesarean section due to the lack of clearly defined anatomical landmarks. This resulted in the development of new technique for post operative pain relief.

The incision put over the abdominal wall is the most common reason for significant pain in the post operative period. The abdominal wall is supplied by nerves which course between internal oblique and transversus abdominis muscles. These nerves can be blocked by injecting local anaesthetic drugs in the transversus abdominal plane in the region of triangle of Petit. Here the nerves are blocked before they enter the musculature of the anterior abdominal wall.

Success of regional anaesthesia depends on injecting the right drug, in right dose, in right place. So the success of TAP block depends on injection of local anaesthetic drugs between transversus abdominis and internal oblique muscles, where the neuro-fascial plane lies.

The adjuvant drugs used with local anesthetics reduced the dose requirement of each agent with enhanced analgesic efficacy and decreased incidence of adverse reactions. Injection of Alfa 2 adrenergic agonistic drugs has been suggested for enhancing the quality of nerve block. Clonidine has selective agonistic activity in  $\alpha_2$  adrenergic receptors with some agonist activity towards  $\alpha_1$  receptors. The onset time, block efficacy and post operative analgesic duration is increased with the usage of clonidine with local anaesthetic agents

Thus analgesic efficacy of bupivacaine and addition of clonidine with bupivacaine and using an ultrasonography in performing Transversus abdominis plane (TAP) block bilaterally for providing postoperative analgesia in caesarean section is evaluated in this study.

## MATERIALS AND METHODS

Present study was carried in the Radio Diagnosis Department, Sree Lakshmi Narayana Institute of Medical Sciences, Pondicherry Hospital Ethics Committee approval was obtained with proper explanation and written informed patient consent obtained. The study was conducted in 60 female patients of age group 18-35 years with ASA I and II

patients undergoing caesarean section by pfannenstiell incision, in a prospective, randomized, double-blinded, controlled trial. In the preoperative waiting room detailed history and physical examination was done. Baseline data like (pulse rate, blood pressure, respiratory rate), and basic investigations were collected.

Both groups were explained about the procedures (Both SAB and TAP Block) and postoperative follow up pattern. The VAS was explained as 0-10 cm scale reading and patient was asked to tell the number. Patients were divided randomly to receive TAP block either with 0.25% bupivacaine 20ml per side (n=30) or TAP block with 0.25% bupivacaine + clonidine 0.5mic.gm/kg (n=30).The investigator, patients and postoperative care physicians were blinded to group assigned.

Common to both groups are 18G IV Cannula was secured and preloading done with 1000ml of crystalloid. Under asepsis, in lateral position subarachnoid block given with 0.5% Bupivacaine 10mg using 23G Quincke's spinal needle to all the patients in both groups. Patient monitored intra-operatively and after the surgical procedure was over patients sensory level was assessed, once when the sensory level reached to T10, TAP was performed. Under asepsis TAP Block was performed bilaterally. An ultrasound guided posterior TAP block technique was used to locate the Transversus abdominis plane. Patient was positioned in supine, syringe containing local anaesthetic were prepared with asepsis. Syringes either contain bupivacaine 0.25% 40ml or bupivacaine 0.25% with clonidine 0.5mic.g/kg 40ml. Investigators were blinded to the injected solution. An high frequency (10-15Hz) Ultrasound probe was placed in mid way between costal margin and iliac crest along the mid axillary line. The satisfactory image was aimed to visualize the subcutaneous fat, and all three anterior abdominal wall muscles parallelly with peritoneum and intra peritoneal cavity. An 18G tuohy needle inserted anterior to the probe of the ultrasound probe. With continuous monitoring of needle, to lie in the fascial plane between transversus abdominis muscle and internal oblique muscle, a small volume of drug is injected to confirm the correct plane and needle tip, then 20 ml of prepared solution was injected in both left and right side. Injection was said to be successful when an echo luescent lens-shape (bi convex) area come in to view between the two muscles. After observing closely for signs of toxicity patients were shifted to post operative ward.

Total duration of analgesia: The presence and severity of pain assessment was done with visual analogue scale (VAS score 0 : no pain and 10 : worst pain) in 1, 2, 3, 4, 5, 6, 7,8,10,12, , and 24 hours by an investigator blinded to group assigned. Sedation was monitored using 6 point Ramsay sedation score, 1. Anxious or agitated and restless, 2. Oriented, calm, co-operative 3. Responsive to comment, 4. Brisk response to glabellar tap or loude sound, 5. Sluggesh response to glabellar tap or loude sound, 6. Unresponsive. Vitals parameters pulse rate, Blood pressure changes, respiratory rate changes, SpO<sub>2</sub>, symptoms and signs of local anaesthetic toxicity and complications were recorded up to VAS score reached to  $\geq 4$  in immediate postoperative period after TAP block. The primary end point of study is when the VAS score

reached  $\geq 4$ . Rescue analgesia: Inj. Tramadol 100mg i.m. was used as first rescue analgesia either on demand or when the VAS score was  $\geq 4$ . Data Analysis: In this study the analgesic efficacy of bupivacaine and adjuvant clonidine in ultrasound guided Transversus abdominis plane block in caesarean section for postoperative pain relief is evaluated. The observation and results were analyzed. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Results were considered statistically significant when “p” value was  $\leq 0.05$ . In order to ascertain the significance of demographic features, Kruskal Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate’s chi square test

for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Postoperative VAS pain scores were significantly reduced in Bupivacaine and clonidine group in all the time intervals when compared to Plain bupivacaine group. Even after 8hrs the mean VAS score was between 4 to 5 in Group BC. And the rescue analgesia was given when the VAS score reached  $\geq 4$ .

The duration of analgesia was significantly increased in bupivacaine and clonidine (BC) group and the "p value is 0.0001. 86.7% in the bupivacaine and clonidine group had sedation score of 3 while only 10% in the plain bupivacaine group had score of 3. This is statistically significant with a 'p' value of 0.0001.

**Table.No. 1: Characteristics of the study population. The data are mean (SD) or numbers of patients.**

	Group BC	Group B	P-values
Age	26.6 years (19-35 years)	26.4 years (19-35 years)	0.7668
ASA I/II	23/7	22/8	>0.05
BMI	28.3(5.6)	27.0 (6.3)	0.4492
Pulse rate (beats/min)	82.0(9.6)	81.7(9.4)	0.935
Systolic BP(mmHg)	117.2 (13.4)	119.2 (12.5)	0.4552
Diastolic BP (mmHg)	71.9 (8.3)	73.0 (8.7)	0.6481
SPO2	98.5 (0.7)	98.5 (0.7)	0.8418
Duration of surgery (min)	47.5 (8.5)	45.8 (8.4)	0.3509
Time to T <sub>10</sub> (minutes)	67.0 (9.1)	67.5 (8.5)	0.7645

**Table 2: Changes in VAS score.**

VAS at	VAS in				'p'	Significance
	Group BC		Group B			
	Mean	SD	Mean	SD		
30 minutes	0	-	0	-	-	-
1 hour	0	-	0	-	-	-
2 hours	0	-	0	-	-	-
3 hours	0	-	0	-	-	-
4 hours	0	-	0.33	0.8	0.0207	Significant
5 hours	0	-	3.33	0.76	0.0001	Significant
6 hours	0.7	1.29	4.6	0.56	0.0001	Significant
7 hours	3.27	0.69	-	-	-	-
8 hours	4.4	0.56	-	-	-	-
10 hours	4.5	0.51	-	-	-	-

**Table 3: Duration of Analgesia.**

Group	Duration of Analgesia ( in minutes)		
	Range	Mean	SD
Group BC	375 – 570	516.7	39.4
Group B	240-330	277.3	24.5
'p'	0.0001 Significant		

**Table 4: Ramsay sedation score.**

Sedation score	Group BC		Group B	
	No	%	No	%
2	4	13.3	27	90
3	26	86.7	3	10
'p'	0.0001 Significant			

## DISCUSSION

Pain after caesarean section is often severe. Effective pain relief has shown to reduce stress postoperatively and fasten recovery, early mobilisation, improve infant nursing care and reduces morbidity post operatively from caesarean section. It is well known that, local anaesthetics used in various techniques reduces pain and requirements of post operative analgesic which can improve the quality of postoperative recovery. The efficacy of TAP block by using local anaesthetics are proved in many studies.

In order to increase the duration of block clonidine has been used as an adjuvant to local anaesthetics in different regional techniques. It has been proved that clonidine in doses up to 0.15mg improves the quality and duration of local anaesthetic nerve blocks with minimal side effects. So clonidine as an adjuvant in TAP block is expected to prolong the duration of block thereby achieving a good postoperative analgesia. So this randomized, double-blinded, case-control study was done to evaluate the post-operative analgesic efficacy of bupivacaine alone or in combination with clonidine in ultrasound guided TAP block. Caesarean section under regional anaesthesia 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 at the end of surgery TAP block was performed. The best thing while performing the procedure is patients does not feel pain, because the TAP block was performed in the area already anaesthetised by subarachnoid block. In this study the local anaesthetics were deposited in the correct plane with ultrasound guidance.

In this study 20 ml of 0.25% bupivacaine or 0.25% bupivacaine with clonidine 0.5 mic/ kg on each side for ultrasound guided TAP block was used which is comparable to study conducted by Jumana M Baaj et al, where the duration of analgesia and efficacy of TAP block was studied for lower segment caesarean section. Tramadol is selected for rescue analgesia, as several studies have confirmed the analgesic effects of single-dose intramuscular tramadol 50–100mg can provide effective analgesia in post operative patients. Ultrasound guided bilateral TAP block has been shown to provide adequate analgesia to the skin and anterior abdominal wall musculature in patients undergoing caesarean section. All patients in both groups breathed deeply, coughed freely, moved without limitation and showed good satisfaction. The bupivacaine with clonidine group showed increased duration of analgesia, with mild sedation.

### Duration of Post Operative Analgesia

In this study results had demonstrated that post operative ultrasound guided TAP block reduced VAS score in the both groups. In group B (0.25% bupivacaine alone) the VAS score was almost zero in the first 4 hours while in

Group BC the VAS score was zero for about 6 hours, which itself explains the effectiveness of TAP block. In this study the mean time to reach VAS score of  $\geq 4$  was 516 minutes in bupivacaine with clonidine 0.5 mic/ kg (BC) group, when compared with 277 minutes in the 0.25% bupivacaine (B) the difference of 239 minutes with p value less than 0.05 was very significant statistically as shown in table. 9. This is in accordance to study conducted by Susmita chakraborty et al, where the addition of clonidine to bupivacaine in peripheral nerve block extended the duration of post operative analgesia. The reason for extended analgesic duration after TAP blockade may be due to the relatively poor vascularisation and slowed drug clearance from transversus abdominis plane, and may be due to avoidance of central sensitization by giving TAP block post operatively. The prolonged action of clonidine may be produced by membrane hyperpolarisation due to opening the potassium channels which increases the sodium channel blocking property of local anaesthetic. When added to local anaesthetic it enhance the quality and reduces the time of onset of block.

### Sedation

The mean sedation score of 3 was obtained in 86.7% of patients in bupivacaine with clonidine group compared to 10% of patients in bupivacaine group. Thus the sedation score was more in bupivacaine with clonidine group than plain bupivacaine group. Clonidine along with bupivacaine for prolonging analgesic duration also had significant sedative effect but arousable sleep. Thus TAP block as a component of multimodal analgesia has significantly increased the total postoperative analgesia, and those who received clonidine in addition to bupivacaine had prolonged duration of analgesia with adequate sedation without any complications. This is in accordance to study conducted by Casti A et al, where the addition of clonidine in peripheral nerve block extended the duration of analgesia with adequate sedation.

### Hemodynamic Stability

Hemodynamic stability in terms of changes in pulse rate, oxygen saturation and blood pressure were compared in both groups and there were no significant difference between them. This is in accordance to study conducted by Popping DM et al and Cucchiario G et al where the hemodynamic stability was comparable in both groups.

### Complications

In this study the incidence of post operative nausea and vomiting was very much reduced in both groups. This is similar to study conducted by Jumana M Baaj et al, where they reported reduced incidence post operative nausea and vomiting. Complications like peritoneal and visceral punctures related to TAP block were not encountered in this study, Carey M, Farooq M. in

2008 reported a case of Liver injury while performing Transversus Abdominis Plane Block.

Thorough familiarity with anatomy, safe monitoring and injection technique, knowledge of local anaesthetic pharmacology and toxicity would prevent the possibility of complications and the technique TAP block is simplified by proper knowledge and correct technique of ultrasound. These precautions will prevent major complications with TAP block. By using the ultrasonography real time needle position can be confirmed and is a promising approach that should further decrease the risk of visceral injury complication.

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## CONCLUSION

Ultrasound guided Transversus abdominis plane (TAP) block as a technique for providing postoperative analgesia is highly effective after caesarean sections. The addition of clonidine to bupivacaine in TAP block extended the duration of analgesia with minimal sedation when compared to plain bupivacaine without significant changes in hemodynamic parameters or complications. Ultrasound guided TAP block was easier to perform and provides reliable and effective analgesia.

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