

## A Double-Blind Randomized Controlled Trial for the Evaluation of Efficacy of Transversus abdominis Plane block after Caesarean Delivery

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### Abstract

**Background and Aim:** The transversus abdominis plane (TAP) block is a novel approach for blocking the abdominal wall neural afferents and providing effective postoperative analgesia in patients undergoing lower abdominal wall surgery. We aimed to evaluate its analgesic efficacy during the first 24 postoperative hours, in patients undergoing caesarean delivery through a Pfannenstiel incision. Also, to evaluate the requirement of additional analgesics in the postoperative period and to study the time required for ambulation.

**Methods:** It was a prospective Randomized Controlled, Double Blinded study done in 60 ASA I and II female patients undergoing caesarean delivery through a Pfannenstiel incision under a standard spinal anesthesia. These patients were randomly divided in two groups of 30 each. Group A (n =30) received a bilateral TAP block with 15ml of 0.25% bupivacaine on each side versus Group B (n =30) received TAP block with normal saline (placebo). Each patient was assessed postoperatively by a blinded investigator: in the post-anaesthesia care unit and at 15, 30, 45 minutes, 1, 2, 4, 6, 12, 18 and 24 hour after TAP blockade.

**Results:** The TAP block with bupivacaine compared with placebo reduced postoperative visual analogue scale pain scores and categorical pain scores. The mean time to first request for rescue analgesia diclofenac was longer 15.47 hours in patients who received a TAP block with bupivacaine, as compared with 3.17 hours in the control group. The requirement of an additional rescue analgesic drug paracetamol was significantly higher in control group as compared to the patients who received TAP blockade with bupivacaine. The comfort level of mother during first breast feeding was significantly better in patients who received TAP block with bupivacaine (group A) as compared to controls (group B). The mean ambulation time in patients who received TAP block with bupivacaine was significantly less (3.8 hours) as compared with control patients (5.43 hours).

**Conclusions:** The TAP block, as a component of a multimodal analgesic regimen, provided superior analgesia when compared with placebo block up to 24 postoperative hours after elective caesarean delivery and also facilitated early ambulation.

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### I. Introduction

Caesarean delivery has become most commonly performed surgical procedure worldwide, which induces moderate-to-severe pain for 24-48 hours post operatively and hence postoperative analgesia is needed so the mother can bond and look after her newborn. The provision of effective postoperative analgesia is of key importance to facilitate early ambulation, infant care, nursing and prevention of postoperative morbidity.<sup>1</sup>

McDonnell et al. showed that the transverses abdominis plane (TAP)block decreases morphine use following abdominal surgery, including caesarean delivery.<sup>2,3</sup> It is a regional anaesthetic technique that blocks the abdominal wall neural afferents by introducing local anaesthetic in the plane between the internal oblique and transverse abdominis muscles.<sup>2</sup> McDonnell et al. showed that landmark based TAP block can be used successfully to provide postoperative pain relief following caesarean delivery.<sup>3</sup> Using Ultrasonography for these nerve blocks one can have a real time image of the needle as it traverses to the neuro-facial plane and also visualise the spread of local anaesthetic which will improve the safety and guarantee more effectiveness.

The lateral abdominal wall comprises of three muscle layers, the external oblique, the internal oblique and the transverse abdominis, along with their fascial sheaths. The nerves supplying the anterior abdominal wall traverse through the neurofascial plane between the two muscles -internal oblique and the transverse abdominis. The lumbar triangle of Petit can be considered as an access point to this neurofascial plane. By introducing local anaesthetic into the transversusabdominis plane (TAP) via the triangle of Petit, results in blocking of the sensory nerves of anterior abdominal wall before they leave this plane and pierce the musculature.<sup>2</sup>

So, the TAP block can be hypothesised, as a part of a multimodal analgesic regimen, which would result in decreased opioid and non-steroidal anti-inflammatory drugs (NSAIDs) consumption and thus reduction in their subsequent adverse effects and improved analgesia. Thus leading to improved comfort level of patient during breast feeding and early ambulation in the first 24 hours after caesarean delivery. The purpose of this study is to test this hypothesis and observe side effects, following elective caesarean delivery via a Pfannenstiel abdominal wall incision.

Existing standards of pain relief are non-steroidal anti-inflammatory drugs (NSAIDs) like diclofenac and paracetamol. Non-steroidal anti-inflammatory drugs usually give inadequate pain relief and are frequently associated with adverse effects like gastrointestinal disturbances including abdominal pain, dyspepsia, heartburn, nausea, gastro intestinal ulcers (gastric, duodenal), bleeding, perforation and vomiting. Other side-effects include deranged renal functions, increased bleeding time, etc.

Although neuraxial techniques using long acting opioids administration (additive), produce effective analgesia, they are associated with frequent side effects like nausea, vomiting, pruritus, sedation, and respiratory depression, which reduce overall patient satisfaction.<sup>1</sup> Furthermore, there is risk of delayed maternal respiratory depression in case of hydrophilic opioids such as morphine requiring strict post-operative monitoring.<sup>4</sup> Therefore TAP block maybe a reasonable alternative.

## **II. Methods**

After obtaining approval from Ethics Committee, and written informed consent from the patient, we studied 72 ASA grade I-II patients of age group more than 18 years and weighing 30-90kg, posted for Caesarean deliveries via a Pfannenstiel incision. After excluding the dropout rate, 60 patients were included (30 in each group using convenient sampling size), in this double blind, randomized, controlled trial. Patients were excluded if there was a history of drug or drug component allergy, they were on any medical therapies considered to result in tolerance to opioids, any neurological deficit, or with any pre-existing medical condition complicating pregnancy like pregnancy induced hypertension.

Sixty females undergoing caesarean delivery were randomized to undergo TAP block with bupivacaine ( $n=30$ ) versus placebo ( $n=30$ ), in addition to standard postoperative analgesia comprising regular diclofenac (1 mg/kg to a maximum of 75mg) and paracetamol (15mg/kg to a maximum of 1gm). Patients were randomized and allotted to two groups by computer generated tables. Blinding was maintained as the person injecting the solution while giving TAP block was unaware of whether it is a placebo (normal saline) or bupivacaine as it was prepared by another person in operation theatre. As well as the person evaluating the VAS score did not know whether the subject had received Bupivacaine or Placebo (normal saline).

All patients received a standard spinal anesthesia consisting 0.5% hyperbaric bupivacaine (1.5cc) + 25 micrograms ( $\mu$ g) fentanyl (0.5cc). Prophylactic antiemetic drugs (IV Ondansetron 0.08 mg/kg, IV Ranitidine 1 mg/kg) were administered as premedication.

The TAP block was performed at the end of the surgery following all aseptic precautions using the following technique. A 22-gauge 1½" blunted needle attached with flexible tubing to a syringe filled with the study solution was used. A loss-of resistance technique was used to locate the TAP. This was possible because the fascial extensions of the abdominal wall muscles within the floor of the triangle of Petit create an easily appreciated increased resistance to needle advancement. With the patient in a supine position, the iliac crest was palpated from anterior to posterior until the latissimusdorsi muscle insertion was appreciated. The triangle of Petit was palpated between the anterior border of latissimus dorsi, the posterior border of the external oblique, and the iliac crest. The skin over the triangle of Petit was pierced with the needle held at right angles to the coronal plane. The needle was stabilized and advanced at right angles to the skin in a coronal plane until resistance was encountered. This first resistance indicated that the needle tip was traversing the fascial extension of the external oblique muscle. Further gentle advancement of the needle resulted in a loss of resistance, or "pop" sensation, as the needle entered the plane between the external and internal oblique fascial layers. Further gentle advancement resulted in the appreciation of a second increased resistance as the needle traversed the fascial extension of internal oblique. A second pop indicated entry into the transversus abdominis fascial plane. After careful aspiration to exclude vascular puncture, a test dose of 1ml was injected (The presence of substantial resistance to this injection indicates that the needle is not between fascial planes, indicating the need to reposition the needle). After a negative test dose, 15 ml of study solution (0.25% Bupivacaine - group A or 15 ml saline - group B) was injected through the needle, observing closely for the signs of toxicity. The TAP block was then performed on the opposite side using an identical technique. Patient was further observed for 15 minutes and shifted to post-anaesthesia care unit (PACU).

The presence and severity of pain was assessed systematically by an investigator blinded to group allocation. These assessments were performed at 15, 30, 45 minutes, 1, 2, 4, 6, 12, 18 and 24 hour after TAP blockade. All patients were asked to give scores for their pain at each time point. Pain severity was measured using both a Visual Analogue Scale (VAS, 10 cm unmarked line in which 0 cm = no pain and 10 cm = worst

pain imaginable) and a Categorical Pain Scoring system (none = 0; mild = 1; moderate = 2; severe = 3). Rescue analgesics (diclofenac, paracetamol) were offered to any patient who complained of pain (VAS Score >4). Comfort of mother during first breast feeding was noted.

The time of ambulation in both the groups was also assessed. Once the effect of spinal anaesthesia was receded and the vitals of the patients were stable with pain well controlled, the oxygen mask was removed. Movements from side to side were encouraged and gradually the sitting position was achieved. Deep breathing and leg movement were encouraged. While sitting, the patient was allowed time (10 minutes) to adjust and then was carefully helped to their feet. Next, the patient was encouraged to walk with assistance. Time to achieve this was noted. The study ended 24 hours after TAP blockade.

### **III. Statistical analysis**

After data collection, analysis is done with the help of SPSS Software version 15, Statistica 7 and Sigmaplot Version 11. Quantitative data is presented with the help of Mean, Standard Deviation, Median and IQR, comparison between study groups is done with the help of Unpaired T test or Mann-Whitney test as per results of Normality test. Qualitative data is presented with the help of Frequency and Percentage table, association among study group is assessed with the help of Chi-Square test. P value less than 0.05 is taken as significant level.

### **IV. Results**

Total 60 women undergoing caesarean delivery under spinal anaesthesia were included in this study. Group A received TAP block with Bupivacaine ( $n=30$ ) versus Group B received TAP block with placebo i.e. normal saline ( $n=30$ ), after surgery. Groups were comparable in terms of age, weight (table 1). In all patients, the triangle of Petit was located easily on palpation, the transversus abdominisneuro-fascial plane was localized after one to two attempts, and the block performed without complication.

Postoperative VAS pain scores and categorical pain scores were reduced after TAP block at all postoperative time points assessed (Fig.1,2). Patients undergoing TAP block with bupivacaine had a significantly longer time to first rescue analgesia request (Fig. 3). The mean time to first request for rescue analgesia diclofenac was  $3.17 (\pm 1.84)$  hours in the control group, compared with  $15.47 (\pm 3.79)$  hours in patients who received a TAP block with bupivacaine. The requirement of an additional rescue analgesic drug paracetamol was significantly higher in control group as compared to the patients who received TAP blockade with bupivacaine. Twenty seven percent patients from control group (group B) required additional rescue analgesic drug as compared to only 7% patients from bupivacaine group (group A).The comfort level of mother during first breast feeding was significantly better in patients who received TAP block with bupivacaine (group A) as compared to controls (group B) (data not shown). The mean ambulation time in patients who received TAP block with bupivacaine was  $3.80 (\pm 0.76)$  hours and in control patients  $5.43 (\pm 0.94)$  hours. The difference in the two groups was statistically significant (P value < 0.001). Thus the time to ambulation was significantly less in patients who received TAP block with bupivacaine.

### **V. Discussion**

Caesarean delivery is one of the commonly performed surgeries worldwide. The analgesic regimen should be safe, provide adequate analgesia, and be without side effects to the newborn. A multimodal analgesic regimen is most likely required to achieve these goals. However, the optimal components of this regimen continue to evolve. Single-shot neuraxial techniques which include long-acting opioids, or patient-controlled epidural opioid administration, although provide adequate analgesia, are associated with a frequent incidence of side effects, like nausea, vomiting, and pruritus, reducing patient satisfaction.<sup>1</sup> The risk of delayed maternal respiratory depression from spread of hydrophilic opioids such as morphine is always present.<sup>4</sup> Furthermore, it may not always be possible to provide neuraxial opioid analgesia due to presence of medical contraindications or certain other issues. Although intravenous patient controlled analgesia using morphine gives greater control to the patient, and thereby results in better satisfaction, the analgesia produced is often incomplete, and opioid-mediated side effects are problematic.<sup>1</sup> Systemically administered lipophilic opioids such as meperidine may appear in breast milk and produce transient neonatal adverse neurobehavioral effects. A regional technique such as a TAP block may form an effective technique to complement the multimodal regimen used for post-caesarean delivery analgesia.<sup>3</sup>

An important component of the pain complaint in patients after abdominal surgery is due to abdominal wall incision. So the TAP block, as part of a multimodal analgesic regimen, may result in improved analgesia during first 24 hours after caesarean delivery when it is compared with a placebo block. This study intended to test this hypothesis and observe side effects in patients undergoing elective caesarean delivery by a Pfannenstiel abdominal wall incision. Also to evaluate whether TAP block is useful in improving mother infant bonding and facilitating early ambulation.

Standard post-operative analgesia at our institution includes intravenous diclofenac and additional intravenous paracetamol to the patients who still complained breakthrough pain. Both the groups received standard analgesics in post-operative period so, in placebo group there was no deviation from standard protocol. Rescue analgesics were offered to the patients who complained VAS score > 4 and/or CPS score > 2.

Blind technique without ultrasound guidance was used in this trial, hence pre-emptive use of TAP block before start of surgery with pregnant uterus was avoided. Also fetal drug levels monitoring would not have been possible, hence post-surgery TAP block was used.

This randomized, double-blind, controlled trial showed that when standard multimodal analgesic regimen is combined with a TAP block using bupivacaine it provided superior analgesia when compared with placebo block up to 24 postoperative hours after caesarean delivery and also delayed request for supplemental rescue analgesia. TAP block improved maternal comfort during breast feeding thus facilitating maternal infant bonding and infant care. It also resulted in postoperative early ambulation after caesarean delivery. These results are consistent with the results of McDonnell JG et al who evaluated the analgesic efficacy of transversus abdominis plane block after caesarean delivery.<sup>3</sup> They found that TAP block using ropivacaine reduced postoperative visual analogue pain scale scores when compared with placebo. The findings are also congruent with those of a study conducted in 2009 by Belavy D et al. They evaluated the analgesic efficacy of the ultrasound guided TAP block in patients undergoing caesarean delivery.<sup>5</sup> Our findings also support those of a study conducted in 2012 by LalehEslamian et al, who found that bilateral TAP block with bupivacaine in parturients undergoing caesarean section with a Pfannenstiel incision under general anaesthesia can decrease postoperative pain. Rescue analgesia requirements were also delayed in the parturients who received the TAP block.<sup>6</sup>

We looked for complications like intravascular injection, local anaesthetic toxicity, hematoma, intra-peritoneal injection, bowel injury and transient femoral nerve palsy. As with any regional technique, careful aspiration helps avoid intravascular injections. This ‘blind’ TAP block technique, as described, is easy to perform and with few complications. We did not have any of these complications in either group.

The of limitations of our study that we did not use ultrasound to confirm needle position which would further reduce the risk of any complications. A further limitation is that we did not measure the success rate or the extent of abdominal wall sensory blockade after the block . This was done to preserve blinding of the assessor.

Further studies are warranted with other local anaesthetics, in varying concentrations, doses, with ultrasound-guided technique, using additives and in other surgeries, and also comparing pain on movement.

We conclude that TAP block is a promising technique in alleviating postoperative pain in gynecological surgeries via a lower abdominal incision especially when used as part of multi-modal analgesia regimen. It also shows that a single-shot TAP block can produce effective analgesia for up to 24 h. The reasons for the prolonged duration of analgesic effect after TAP blockade may relate to the fact that the TAP being poorly vascularized, drug may not be cleared fast. The procedural simplicity of this block, along with reliable level of analgesia, longer duration as well as good quality, with lesser rescue analgesics requirement and their side-effects makes the TAP block an attractive option for caesarean deliveries.

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**Table No. 1: Comparison of age and weight between two groups**

Study parameter	Group A (N=30)		Group B (N=30)		Unpaired T test	P value
	Mean	Std.Dev.	Mean	Std.Dev.		
Age (yr)	25.43	3.29	25.2	3.96	0.248	0.805
Weight (kg)	53.97	4.88	53.33	4.52	0.521	0.604

**Figure 1 :** Visual Analogue Score at various time intervals in Group A and Group B



**Figure 2 :** Categorical Pain Scores at various time intervals in Group A and Group B



**Figure 3:** Comparison of rescue analgesia ( diclofenac ) between groups

