

**A Randomised, Prospective, Comparative Study to Evaluate the Efficacy of Transversus Abdominis Plane Block and Intravenous Paracetamol for Post-Operative Analgesia after Laparoscopic Surgeries**

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**Abstract**

**Background:** Laparoscopic surgeries have revolutionized the concept of Early Recovery after Surgery (ERAS) and emphasis is being laid on minimising perioperative stress by effective analgesia regimen.

**Aim:** To study the efficacy of Transversus Abdominis Plane (TAP) Block compared to Intravenous (I/V)

Paracetamol for postoperative analgesia in patients undergoing laparoscopic surgeries.

**Materials and Methods:** This study was conducted in a tertiary care centre from 2018-2020. 70 patients of ASA 1, 2 status undergoing laparoscopic surgeries were randomized to receive either TAP Block with 15 ml of 0.25% bupivacaine on each side (Group T) or I/V Paracetamol 1 gram (Group P) at the end of surgery with primary outcome being analysis of Visual

Analogue scale (VAS) scores and need for rescue analgesia (diclofenac 75 mg) for first 24 hours. The vital trends and side effects with the study drugs were also observed during the study.

**Results:** VAS Scores were significantly higher in the group P and so was the need for rescue analgesia in the first 24 hours postoperatively ( $p < 0.05$ ). The mean heart rates, and systolic blood pressures were significantly higher till 8 hours in group P as compared to group T while being comparable at 12 and 24 hours postoperatively. Diastolic blood pressures and SpO<sub>2</sub> levels were comparable at all intervals ( $p > 0.05$ ).

**Conclusion:** TAP Block is a promising intervention for postoperative analgesia offering longer duration of pain free period as compared to intravenous paracetamol, thus reducing the need for rescue analgesia and promoting early recovery after surgery.

**Keywords:** TAP Block, Analgesia, Paracetamol, VAS Score, Diclofenac

### **Introduction**

Laparoscopic surgeries closer to diaphragm are shown to cause more postoperative pain and discomfort than maneuvers at a lower site in the abdomen. This is mainly due to CO<sub>2</sub> insufflation leading to stretching and inflammation of the superficial abdominal muscles.<sup>1</sup> The goals of effective pain management are to improve the perioperative outcome by facilitating rapid recovery and return to full function, allow early discharge from hospital and prevent post-operative morbidity. However, achieving postoperative pain relief after laparoscopic surgery is significantly challenging because of poor pain control with pharmacotherapy as well as simultaneously occurring side effects.

The transversus abdominis plane (TAP) block is a peripheral nerve block that provides pain relief to the

parietal peritoneum, skin and muscles of the anterior abdominal wall.<sup>2</sup> The present study aims at comparing the efficacy of TAP Block to intravenous paracetamol (PCM) infusion for postoperative analgesia in laparoscopic surgeries. The primary outcome was to critically compare the VAS scores postoperatively for first 24 hours along with requirement of rescue analgesia in the form of diclofenac 75mg. The hemodynamic parameters like heart rate, systolic blood pressures and SPO<sub>2</sub> levels were also monitored for 24 hours postoperatively. Any side effects occurring during the study were also noted.

### **Material and Methods**

This prospective randomized and comparative clinical trial, was conducted over a period of three years starting from year 2018 in the Department of Anaesthesiology at a tertiary care centre in India after obtaining Institutional Ethical Committee approval and written informed consent from all 70 patients. The patients were randomly divided into two equal groups of 35 each. Randomisation was achieved using sealed envelopes assigning the patients to either group. ASA status 1, 2 patients who were posted for elective laparoscopic surgery between the age group of 18-60 years were included in the study after taking written, informed consent while patients with ASA status 3 or more, having contraindication to TAP block like distorted anatomy at the injection site or allergy to local anesthetic were excluded from the study. If for any reason laparoscopic surgery was converted into open case, the patient was withdrawn from the data analysis. Group T was given TAP Block using 15 ml of 0.25% Bupivacaine on each side and Group P was given 1 gram of I/V Paracetamol after completion of surgery. After allocation and pre-anesthetic check-up, routine biochemical investigations were done (complete blood

count, urine routine and microscopy and ECG). All patients were advised to maintain a fasting status of 8 hours. In the operation theatre, all the basic monitors were attached (electrocardiography, pulse oximetry and noninvasive arterial blood pressure). Patients were premedicated with Inj glycopyrrolate 0.005mg/kg, Inj midazolam 0.05mg/kg, and Inj fentanyl 2 microgram/kg. Induction was achieved with Inj propofol 2-2.5mg/kg. Thereafter, neuromuscular blockade was achieved with I/V succinylcholine 2 mg/kg and the endotracheal tube was inserted under direct laryngoscopic vision. The patient was maintained on Intermittent Positive Pressure Ventilation (IPPV), oxygen, N<sub>2</sub>O, Isoflurane and injection Atracurium (Loading dose-0.5mg/kg; Maintenance dose-0.12mg/kg) whenever required.

After the closure of surgical port sites, Group T was given TAP Block with 23 Gauge Quincke's needle in the mid-axillary line midway between the subcostal margin and anterior superior iliac spine by landmark "two-pop" technique. The drug formulation used was 0.25% bupivacaine 15 ml each on either side.

Group P was given Intravenous PCM 1 gram after closure of surgical port sites.

Anti-emetic in the form of inj. ondansetron 0.1mg/kg was administered thereafter, and residual neuromuscular blockade antagonised with I/V neostigmine 0.05mg/kg and I/V glycopyrrolate 0.01mg/kg. 100 % oxygen was provided and then the patient was extubated after being fully awake and responsive to commands. All patients were then observed in the post anaesthesia care unit (PACU) for 1 hour after which they were shifted to the ward where the follow-up continued for 24 hours.

All patients were assessed for VAS scores at 30 minutes, 2 hours, 6 hours, 8 hours, 12 hours and 24

hours respectively. The percentage of patients demanding rescue analgesia at the preconceived time intervals and the total cumulative dose of rescue analgesia used for 24 hours was also noted down as a part of the study. The haemodynamic parameters like heart rate, systolic and diastolic blood pressures and SpO<sub>2</sub> were monitored for 24 hours post-surgery. Any side-effects during the study were also observed.

#### Results and discussion:

The statistical analysis was achieved using mean  $\pm$  standard deviation (S.D.) for continuous variables and proportions/ percentage for categorical data. SPSS (statistical package for social science) version 20 was used for data analysis. The mean VAS scores, rescue analgesia doses and vitals including mean heart rates, blood pressures and SpO<sub>2</sub> were compared in both the groups using Student-T test while for categorical variables like frequency of rescue analgesia demanded in first 24 hours as well as side-effect profile, Chi-square test was applied for intergroup comparison where a p-value < 0.05 was considered as statistically significant.

Out of 70 patients, 37 were female and 33 were male with equivalent distribution of baseline characteristic variables like age, BMI and ASA status in both the groups. Out of all the laparoscopic procedures 28% were cholecystectomies, followed by appendisectomies, common bile duct explorations, hernia mesh repairs, etc.

#### VAS Scores

Mean VAS scores in our study were found to be significantly higher in Group P at 30 minutes, 2 hours, 6 hours, 8 hours (p value- 0.000, 0.000, 0.022, 0.001 respectively)) but comparable at 12 hours and 24 hours post-operatively with Group T (p value- 0.174, 1.000 respectively). (Figure 1) This implies that TAP block

provided superior quality of analgesia during the first 24 hours after laparoscopic surgeries as compared to intravenous paracetamol. Numerous studies have presented the same results on TAP block analgesia when compared with local site infiltration as by Rajanbabu A et al<sup>3</sup> where 24 hours pain scores were lesser in TAP block group. However, in a study by Karnik PP et al<sup>4</sup>, TAP block was able to provide superior quality of pain relief for only 2 hours post-operatively as compared to port-site infiltration. This difference in results can be explained by the fact that TAP block carries a volume-based effect and higher doses (1-2 ml/kg) can result in extension of local anaesthetic to paravertebral space resulting in visceral analgesia as compared to smaller doses (0.4 ml/kg) which have only somatic analgesia as used in this study.

Similarly, other studies performed by single-injection technique<sup>5</sup> or dose –based comparisons<sup>6</sup> also elicited early post-operative pain relief by TAP block, reiterating that bilateral injections and higher dosages could be employed to prolong the duration of analgesia.

### **Rescue Analgesia**

We used TAP block as a part of multimodal approach, in an attempt to reduce the total NSAIDs consumption and their associated side effects. The frequency of demand for rescue analgesia in our study was significantly higher at all time periods of observation in first 24 hours i.e. 30 minutes, 2 hours, 6 hours, 8 hours, 12 hours and 24 hours after the surgery (p values- 0.039, 0.000, 0.000, 0.003, 0.05, 0.000 respectively ) in group P as compared to group T. (Fig-2). 54% of the patients among Group P required rescue analgesia at 2hrs and 8 hours of the procedure whereas Group T did not report the need of rescue analgesia upto 8 hours. Among Group T only 20% patients demanded rescue

analgesia at 8 hours after the surgery thus proving the effectiveness of the TAP Block. Thus, TAP block not only provided qualitatively enhanced analgesia as compared to intravenous paracetamol but also reduced the percentage of patients requiring rescue NSAID namely diclofenac for upto 24 hours post-operatively.

Also, the cumulative mean doses of diclofenac used in first 24 hours was also significantly higher in group P (124.29 mg) compared to group T (17.14mg) at all time intervals ( p values- 0.040, 0.000, 0.000, 0.003, 0.050, 0.000 respectively).(Fig-3) These findings suggest that TAP blocks can play a significant role in acute post-operative pain management after laparoscopic surgeries by reducing the requirement of strong analgesics like diclofenac as well as opioids for breakthrough pain.

Our results are in agreement to another clinical trial on post-operative tramadol requirements after TAP block versus standard analgesic regimen where the former reduced cumulative tramadol consumption to (24.27± 47.54 mg) as compared to standard regimen (270.2±81.9 mg).<sup>7</sup> However, in certain laparoscopic procedures like nephrectomies<sup>8</sup> and colorectal surgeries<sup>9</sup>, there is extensive tissue manipulation and neuroendocrine stress which could not be catered by TAP block alone in its mid-axillary approach with <1ml/kg volumes. Thus, studies refuting our results have showed similar opioid consumptions after TAP block as compared to other modes of analgesia citing that surgeries demanding predominantly visceral pain-relief were a major factor resulting in decreased efficacy of TAP block.

### **Haemodynamic Parameters**

It was very important to follow-up the vital trends of all the patients as a marker of patient satisfaction post-operatively. Any undue stress, first and foremost causality being pain, could lead to derangements in

haemodynamics namely heart rates, systolic and diastolic blood pressures as well as SpO<sub>2</sub>. The mean heart rates were found to be higher in Group P at 30 min, 2 hours, 6 hours and 8 hours but remained comparable at 12 and 24 hours (p values- 0.003, 0.006, 0.001, 0.001, 0.229, 0.309 respectively). (Fig-4) Similarly, mean systolic blood pressures after 30 minutes, 2 hours, 6 hours and 8 hours of surgery were found to be higher in Group P than Group T with significant p values (p=0.011, p=0.00, p=0.003, p=0.003) and were found comparable in the two groups at all other intervals during the observation (p>0.05) (Fig-4). However, the mean diastolic blood pressures and SpO<sub>2</sub> levels during the inter-group comparison were non-significant (p>0.05). This establishes that TAP block was able to reduce post-operative pain and stress upto 8 hours post-operatively leading to stable vitals as compared to intravenous paracetamol. After 8 hours, the magnitude of difference was, however, non-significant on comparison.

In studies conducted by Al-Sadek WM et al<sup>10</sup> and El Fawy DM et al<sup>11</sup>, haemodynamic variables were found to be comparable between TAP blocks versus standard analgesics or caudal respectively. The alterations in haemodynamic parameters after surgery can be caused by multiple factors apart from pain, thus, evaluation of clinically significant patient satisfaction as well as ruling out of other confounding factors is must before correlation of post-operative pain and haemodynamics. No adverse reactions were noted in any of the groups, thus suggesting that TAP blocks are a safe neuraxial technique for preventive analgesia after laparoscopic surgeries. The safety profile of TAP block has been time tested by numerous other trials and found to be excellent.<sup>12,13</sup>

There are several advantages and shortcomings associated with our study. We included local anesthetic drug bupivacaine and intravenous paracetamol as they are readily available drugs and cost effective, making our study more relevant for resource constrained settings. As laparoscopic surgeries are mostly of short duration and evoke lesser stress response, comparison of TAP block was conducted in a more rational perspective with NSAIDs like PCM and diclofenac resulting in opioid sparing postoperative analgesia for the whole patient population. No study has been by far conducted between the Transversus Abdominis Plane Block and paracetamol for laparoscopic surgeries making our study unique in all aspects. The major disadvantage of our study was the nonavailability of portable ultrasound because of which we opted for landmark guided block which perhaps might have affected the efficiency of block performance. Our study included only ASA 1 and ASA 2 patients for the block whereas studies should be conducted on ASA 3 and 4 candidates wherein high doses of opioids and NSAIDs post-operatively is considered detrimental for patient outcome. No adjuvant was used along with bupivacaine for TAP block in our study when it could have lead to further prolongation of pain-free period after surgery. Also, the follow-up could be done upto 48 hours as in many other studies.<sup>14,15</sup>

### Conclusion

From the present study it can be concluded that the TAP Block is a cost effective, efficient and safe modality of analgesia which reduces post-operative pain and need for rescue analgesia in the form of opioids and non-steroid anti-inflammatory drugs, thus contributing to the additive benefits of laproscopic procedures in contrast to the open surgeries in today's era. It is found to provide a better quality of analgesia

as compared to intravenous paracetamol, without any side effects. Catering to different laparoscopic surgeries with emphasis on ERAS requires individualistic approach towards formulating analgesia plan, and TAP block has found a place in all multimodal analgesia regimens as a “technique that complements all”.

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