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Post-operative analgesic efficacy of transversus abdominis plane block as compared to local anaesthetic infiltration at the surgical site in lower abdominal surgeries: A randomized controlled trial

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***Abstract*---**We conducted the present study with an aim to compare the post-operative analgesic efficacy of transversus abdominis plane block (group-T) versus local anaesthetic infiltration (group-I) at the surgical site in lower abdominal surgeries. Our objectives were to assess the severity of pain (the analgesic efficacy of the two interventions) in both the study groups through the visual analogue scale (VAS) score for pain at the end of 2, 4, 6, 12, 18 and 24hrs, the time of first rescue analgesia in the form of injection tramadol 100mg i.m. required in each study groups to assess the duration of analgesia provided by each study technique. The patients were monitored and followed up to 24 hrs post-operative to assess our outcome parameters. In our study we allocated 50 patients into two study group with 25 patients in each study group. The study population in each of the study groups was similar in terms of the demographic profile such as age, height, weight and was also similar in terms of

their ASA status. The type and duration of the surgery they underwent were also comparable. Group “T” had significantly low VAS scores at the end of 2, 4, 6, 12, 18 and 24 hrs post-operatively. All the patients in group T were pain free up to 12 hrs post-operative (VAS score 0), whereas in group “I” all the patients were pain free only up to 2 hrs post-operative, from 2 to 6 hrs they had mild to moderate pain. The total tramadol consumption in first 24 hrs was also significantly less in group “T” than in group “I”. There was no side effects in group “T” but there was some side effects in the form of nausea in a few patients in group “I”. In conclusion, Tap block proved to be a better technique than surgical site infiltration with local anaesthetic in lower abdominal surgeries under general anaesthesia.

***Keywords*---**RCT, post-operative analgesia, transversus abdominis plane block, lower abdominal surgeries.

Introduction

Pain relief is provided by systemic medications such as opioids, non-steroidal anti-inflammatory drugs (NSAIDs), by administering local anaesthetic into the skin around the surgical wound, or by providing epidural or spinal analgesia. (1) Regional anaesthetic techniques and nerve blocks have been used for effective pain management in the perioperative period, either alone or in combination with systemic analgesics.(2) Its utility has been shown to reduce post operative complications, stress response, nausea, vomiting and other complications associated with use of opioids and to enhance recovery.

Transversus abdominis plane (TAP) block is a recently described easy and safe regional analgesic technique. (3–5) The technique was first introduced by Rafi in 2001 and was further developed by Mc. Donnell. (4,6) This technique involves instillation of local anaesthetic agent into a fascial plane between the internal oblique muscle and transversus abdomninis muscle, either by landmark technique, or under ultrasound guidance. Ultrasound guided block has been recently described as a technique that promises more accurate localization and drug deposition. (7–9) Pain experienced after abdominal surgery is mostly attributed to the incision made in the abdominal wall. TAP block anaesthetizes somatic supply of the anterior abdominal wall, which arises from the anterior rami of spinal nerves and runs along the plane between internal oblique muscle and transversus abdominis muscle. Local infiltration around the wound site has also been widely used, but its efficacy as a potent and useful adjunct in multimodal analgesia has been controversial. Little evidence is available from India on the efficacy and safety of this technique in Indian populations and the evidence is far from conclusive requiring further trials in the subject.

Therefore, with this background, the following study aimed to compare the analgesic efficacy of transversus abdominis plane block versus local anaesthetic infiltration on post operative pain assessed through the visual analogue scale (VAS) score. Our secondary objectives were to compare the time of first rescue

analgesia, the total analgesic consumption in first 24 hours and the adverse effects (eg: post-operative nausea vomiting, pruritus etc) between the two groups.

Methodology

Study design

This was a Prospective, randomized controlled trial conducted at MKCG Medical College hospital for a duration of 12 months between 2020-2021.

Study participants

We have included patients aged between 20 and 60 years scheduled for elective gynaecological surgery under general anesthesia. Those with known allergy to the study drugs, or those with ASA grade 3 and above and those who refused to participate were excluded from the trial.

Sample size

Based on a previous study, it was determined that a study with 22 patients per group would have an 80% power (alpha=0.05 and beta=0.2) for a 50% absolute reduction in the mean time for the first request for rescue analgesia. To minimize effect of any data loss, we elected to recruit 25 patients per group into the study, which made the total sample size to 50.

Ethical considerations

The study was conducted after approval of Institutional Ethical Committee, Scientific committee and written informed consent from each patient.

Randomization and blinded allocation

Patients were randomly allocated into two Groups. Patients who received TAP Block were placed in group T while those receiving local anaesthetic infiltration were placed in group I. Randomization was done using appropriate computer software and provided to the interventional anaesthesiologist using sealed envelopes on the day of surgery to ensure blinding.

Intervention

The primary intervention involved the performance of a routine General Anaesthesia. Any subsequent intervention to ensure patient safety and recovery from anaesthesia was performed using standard recommended protocols. Following a complete pre-anesthetic evaluation and preparation as per institutional procedures, the study medications were prepared identical in volume i.e. 0.5ml/kg body weight in non labeled syringes. Pre-operative aspiration prophylaxis was provided as per current standards. Patients were on Nil per oral for 6 hours for solid food and 2 hours for clear liquids. In the operating room, all monitors were attached, an intravenous cannula (18 G) was inserted in a peripheral forearm vein and patients were preloaded with balanced salt solution

at a dose of 10ml/kg. Conventional General anaesthesia was provided to both the group and injection diclofenac and injection paracetamol was also given to both the groups as per convention for intra-operative analgesia. At the end of the surgery and before reversal, the following interventions differed in the two groups:

- Group T received Ultrasound guided TAP Block (technique already discussed) with 0.25% Bupivacaine at a volume of 0.5ml/kg body weight.
- Group I received local infiltration of 0.25% Bupivacaine at a volume of 0.5 ml/kg body weight at the surgical incision site by the surgeon.

The patients of both the groups were reversed following the intervention according to standard protocols.

Outcome measures and data collection

Post-operatively, in the ward the following observations and recordings were made by an observer who did not know to which group an individual belonged and the results were noted for each individual.

1. VAS Scores at the end of 2, 4, 6, 12, 18, 24hrs in both the groups.
2. Time duration from the study technique to the first rescue analgesia in minutes in both the groups.
3. Total tramadol consumption in first 24 hrs in both the groups.

Side effects such as post-operative nausea-vomiting, pruritus, if any, in both the groups were also noted.

Statistical analysis

Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. Continuous variables are expressed as Mean ± Standard Deviation and compared across the 2 groups using Mann-Whitney U test. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

Results

There was no statistically significant difference between the two groups in terms of their physical and demographic characteristics as shown in table-1.

Table 1 : This table compares the mean age of the patients in both the groups

Variable		STUDY GROUP			
		Group T	Group I	p Value	Significance
AGE (mean , SD)		41.6 ± 9.75	40 ± 10.19	0.573	Not Significant
Age groups	18-20	1(4)	2(8)	0.960	Not

	21-30	3(12)	3(12)		Significant
	31-40	4(16)	5(20)		
	41-50	13(52)	12(48)		
	51-60	4(16)	3(12)		
Mean Height (in Cm)		157.19 ± 5.69	156.74 ± 5.11	0.773	Not Significant
Mean weight (in KG)		60.23 ± 8.53	59.48 ± 8.81	0.760	Not Significant
Mean BMI		24.27 ± 2.42	24.13 ± 2.73	0.849	Not Significant
ASA	I	15(60)	16(64)	0.771	Not Significant
	II	10(40)	9(36)		
Surgery performed	Ovarian cystectomy	5(20)	6(24)	0.591	Not Significant
	Ovarian mass laparotomy	1(4)	1(4)		
	TAH	2(8)	5(20)		
	TAH+BSO	17(68)	13(52)		
Mean duration of surgery		80.2 ± 14.4	78.6 ± 15.78	0.710	Not Significant
Mean volume of drugs used (in ml)		31.32 ± 7.68	29.49 ± 4.53	0.309	Not Significant

At every time interval or recording taken, none of the techniques had any effect on the heart rate (no significant deviation from baseline). While there was no significant difference in the systolic or diastolic BP before and after the procedure in both the groups up to 4 hrs post-operative but after 6 hrs group I had a significant rise in both systolic BP and diastolic BP, most likely due to pain. There was significant difference in the VAS scores between the two groups from 4hrs after surgery. At 24 hrs after surgery the difference was again insignificant probably due to rescue analgesia in both the groups as shown in figure-1 below.

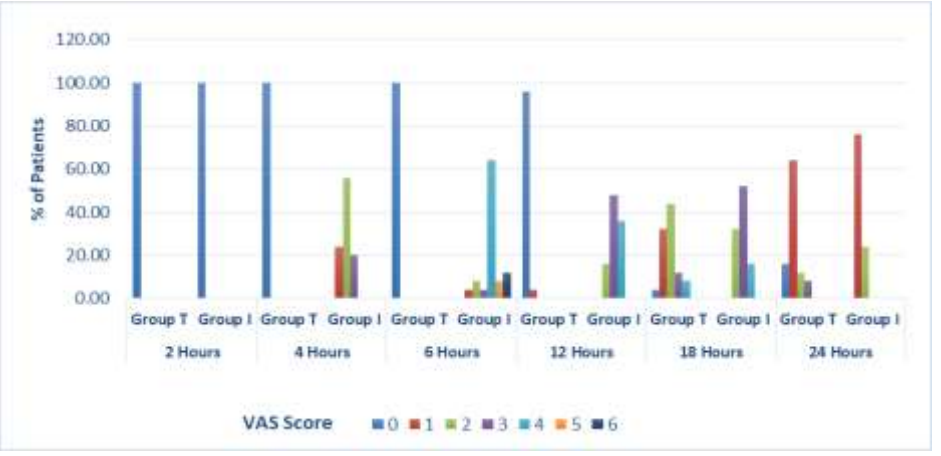

Figure 1.Percentage of population in each Vas score group in both the study group at various times interval

There was a statistically significant difference in the average time of first rescue analgesia between the two groups which was achieved at 26.76 (± 3.49) hours in group T as compared to 8.32 (± 2.69) in group I. The time for requirement of tramadol was significantly earlier in group T and the dosage of tramadol was also significantly higher as shown in table-2 below. No difference was seen in terms of side effects such as nausea between the two groups.

Table-2. Comparison of Analgesic requirement and side effects between the two groups

Variable		STUDY GROUP		Total	p Value	Significance
		Group T	Group I			
Total tramadol requirement in 1st 24 hrs	0	21(84)	0(0)	21(42)	<0.001	Significant
	100	4(16)	4(16)	8(16)		
	200	0(0)	9(36)	9(18)		
	300	0(0)	12(48)	12(24)		
Other side effects	Nausea	0(0)	3(12)	3(6)	0.235	Not Significant
	None	25(100)	22(88)	47(94)		
Total		25(100)	25(100)	50(100)		

Discussion

The aim of the study was to compare the efficacy and duration of action of the TAP Block versus surgical site infiltration with local anaesthetic for post-operative analgesia in patients undergoing lower abdominal surgeries under general anaesthesia. We have evaluated three outcome parameters in the two groups of patients, firstly the VAS scores at 2,4,6,12,18,24 hrs, the time of first rescue analgesia which was provided when the VAS scores were 4 and above, and lastly the total tramadol consumption in first 24 hrs. In our study only patients with ASA status of I and II were included, who uniformly distributed in both the study groups. Only four surgeries were selected in this trial namely open ovarian cystectomy, ovarian mass laparotomy, total abdominal hysterectomy (TAH) and TAH with bilateral salpingo-oophorectomy(BSO).

Among the three outcome parameters of our study, the principle outcome was assessing the post operative pain by visual analogue scale (VAS) score at 2, 4, 6, 12, 18 and 24 hrs post-operatively. We found that the mean VAS score at first 2 hrs were nil in both the groups implying the patients were pain free during the first 2 hrs in both the study groups. The mean VAS score in group T was still zero or very low at 4,6, and 12 hours post-operative, whereas in group I the mean vas score was 1.96±0.68, 4±1.15 and 3.2±0.71 at 4,6 and 12 hours post op. At 18 hrs post-operative mean VAS score in group T was 1.88±0.97 (without rescue analgesia) whereas in group I the mean VAS score was 2.84±0.69 (with rescue analgesia). The decrease in VAS score in group I from its previous reading was likely due to rescue analgesia provided in the form of injection tramadol 100mg i.m. At 24 hrs post-operative mean VAS score in group T was 2.12 ±0.78 (without rescue analgesia) whereas in group I the mean VAS score was 2.24±0.44 (with rescue analgesia). The decrease in VAS score in group I from its previous reading was likely due to rescue analgesia provided in the form of injection tramadol 100mg IM.

Our findings of VAS score corroborated with the findings of similar studies reported elsewhere where they found that TAP block was superior to either surgical site infiltration or placebo with normal saline in terms of duration and intensity of block and provided better post-operative analgesia. (10,11,11,12) Some other studies have found that TAP block was either equally or less effective than surgical site infiltration in similar kinds of surgeries. (13–15)

Our next outcome parameter was to compare the time of first rescue analgesia from the interventions in both the study group. We found that the mean time of first rescue analgesia in group "T" was 26.76 ± 3.49 hours whereas in group "I" it was 8.32 ± 2.69 hrs respectively. This finding of our study corroborated with similar study made by others. (10,16–18) Only a few studies made by Kim et.al etc showed there was no difference in the duration of analgesia with either of the procedures or even if the short term benefits was better with TAP block, but the over-all time duration of both the techniques were similar. (13–15)

Our next outcome parameter was the total tramadol required in first 24 hrs. Our study shows that in group "T" requirement for tramadol was significant lesser as compared to group "I" where all the patients required tramadol. This finding of our study corroborated with similar studies that found that TAP Block decreased the requirement of either tramadol or morphine which ever was used as rescue analgesic in first 24 hrs compared to either surgical site infiltration or placebo. (10,11,16,17)

Conclusion

In this study, we found that the intensity of sensory nerve blockade was far more with TAP block than with surgical site infiltration, which was evident from significantly low VAS scores in TAP block group. The duration of block was also significantly longer in TAP block group and the total supplemental analgesic requirement in the form of tramadol was much lower in the TAP block group than surgical site infiltration group with no other side effects. Thus we conclude that TAP block is a far better and superior technique for post-operative analgesia than surgical site local anaesthetic infiltration in lower abdominal surgeries under general anaesthesia.

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