Original Article

Determination of the efficacy of ultrasound-guided bilateral transversus abdominis plane (US-TAP) block in laparoscopic total extraperitoneal (TEP) repair of unilateral hernia surgeries: A randomized controlled trial

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Abstract

Background and Aims: Bilateral ultrasound-guided transversus abdominis plane (US-TAP) block has been successfully used to provide analgesia for most lower abdominal procedures. Our aim was to determine the efficacy of US-TAP block with levobupivacaine in laparoscopic total extraperitoneal (TEP) repair of unilateral hernia surgeries under general anaesthesia (GA) as compared to no block.

Material and Methods: It is prospective randomised controlled study done in a tertiary care centre in South-East Asia. After obtaining Institute Ethics Committee approval and consent, 60 patients of ASA I-II aged between 18 to 80 years were randomized into two groups. After receiving GA, Group TAP - received bilateral US-TAP block with levobupivacaine 0.25% 0.3ml kg⁻¹ on either side whereas, the control group did not receive any block. The time taken to first request for rescue analgesic (T Rescue) by the patient and the Numeric Rating Scale (NRS) at that time point were noted and tramadol 50mg i.v. was administered, followed by 50mg i.m. PRN for 24 h from the time of extubation. The 24 h analgesic requirement was noted in mg kg⁻¹.

Results: Results were analysed using SPSS 16 and P < 0.05 was considered significant. T Rescue was significantly longer in the TAP Group (P = 0.02) with lower NRS at time points 24 h (P = 0.02) and 12 h (P = 0.004). Postoperative nausea and vomiting were significantly less in TAP Group (P < 0.001).

Conclusion: Bilateral US-TAP block provided better analgesia and side effect profile as compared to no block when administered in laparoscopic TEP repair of hernia surgeries.

Keywords: Laparoscopic unilateral inguinal hernia repair, levobupivacaine, ultrasound-guided transversus abdominis plane block.

Introduction

Laparoscopic total extraperitoneal inguinal hernioplasty (TEP) as compared to open repair is less painful, with shorter hospitalization and shorter duration to recovery, but it is not completely pain-free.^[1] Pain in TEP typically is in the lower

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abdomen associated with port access, tissue dissection, and gas insufflation, leading to increased patient discomfort, prolonged hospital stay, and chronic pain.^[2]

Transversus abdominis plane (TAP) block is a technique first described by Rafi and works by blocking the thoraco-lumbar nerves (T6-L1) which supply sensory fibers to the

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

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Material and Methods

After obtaining approval from the institutional ethics committee and registration with Clinical Trials Registry - India (CTRI/2017/04/008287) and informed consent, 60 ASA I-II patients between 18 and 80 years of age posted for elective laparoscopic TEP repair of unilateral inguinal hernia under general anesthesia (GA) in a tertiary care center in Southeast Asia between August 2017 and August 2018 were included in this randomized controlled trial. Patients with local anesthesia allergy, coagulation disorders, recurrent or bilateral hernia or those coming for emergency surgery, infection at block site, and those who refused to give consent were excluded from the study.

Patients were randomized into two groups by computer-generated randomization by another person who is not involved with the intervention or observations and groups were assigned by the same person using an opaque sealed-envelope technique.

Patients were premedicated with oral famotidine 20 mg and diazepam 5 mg the night prior and on the morning of surgery. After connecting standard monitors (noninvasive blood pressure monitor, pulse oximetry, electrocardiogram, and capnography) and intravenous access, as per institute protocols, endotracheal tube-controlled GA was induced with propofol 2 mg kg⁻¹ and muscle relaxation with vecuronium 1 mg kg⁻¹ and maintained on O2 and N2O 1:2 with isoflurane up to 1% and fentanyl 2 mcg kg⁻¹ i.v. administered at induction. After induction, using a strict aseptic technique, Group US-TAP were administered bilateral US-TAP blocks using a 23 G Quincke needle under direct visualization using a high-frequency linear probe 5-12 MHz (SonoSite M Turbo, SonoSite Inc., Bothell, WA, USA) with 0.25% levobupivacaine 0.3 mL kg⁻¹ on either side (up to a maximum of 2 mg kg^{-1}). The probe was placed horizontally just above the iliac crest at the mid-axillary line, and an in-plane method with medial to lateral insertion of needle was done, to place needle tip between the internal oblique and transversus abdominis muscle. The precise spread was confirmed by the separation of the layers by the drug. A single anaesthesiologist administered the blocks in all cases to prevent interindividual procedural variability. The control group (Group Control) did not receive any block. Increments of fentanyl 0.5 mcg kg⁻¹ i.v. were supplemented if further analgesia was required intraoperatively by monitoring for a 20% increase in heart rate or mean arterial pressure. The patients were extubated at the end of surgery after the reversal of muscle relaxation. The participants, as well as observers of postoperative findings, were blinded to the group allocation.

In post-anesthesia care unit (PACU), under standard monitoring conditions, the time taken to the first request for analgesic (from the time of extubation) T Rescue and numerical rating scale (NRS) (on an 11-point scale with 0 = no pain to 10 = worst possible pain) were noted at T Rescue, and tramadol 50 mg i.v. was administered if NRS >4.

NRS readings were also noted at rest, and also on movement (coughing) at 2, 4, 6, 12, and 24 h postoperatively. Postoperative observations were made by a blinded observer, who is unaware as to which group the patient belongs. Tramadol 50 mg i.m. was administered on a PRN basis for 24 h (from the time of extubation). Total tramadol usage in 24 h was noted down in mg kg⁻¹.

Postoperative nausea and vomiting (PONV) if any, was treated with ondansetron 0.1 mg kg^{-1} i.v. PRN.

The surgical procedure involved making a 10 mm sub umbilical transverse incision, anterior rectus incision, and rectus muscle retraction laterally to enter the preperitoneal space. A 10 mm laparoscopic port was inserted and preperitoneal space created in midline up to pubic symphysis using a telescope. Two 5 mm ports were inserted in the midline to create preperitoneal space on the side of the hernia. Sac dissected out from cord structures. Triangle of doom and the triangle of pain were defined. A prolene mesh was left in the preperitoneal space covering the myopectineal orifice. Mesh fixation was not done. CO2 decompression was done under vision so that the peritoneum abuts the mesh to keep in position. Port sites were closed in layers. A single surgeon with an assistant performed all the laparoscopic TEP repairs to prevent interindividual variability in tissue handling.

Primary objective of our study was duration of analgesia T Rescue, which is the time to first request for analgesia from the end-operative time point. Our secondary objective was quality of analgesia assessed by NRS at T Rescue time point as well as NRS at rest and on movement for 24 h postoperatively. The sample size was calculated to be n = 24 per group based on a pilot study done by us prior to our study on 10 patients for obtaining a meaningful clinical difference of 50% reduction in T Rescue (primary outcome) between groups, with a power of 80% and an alpha error of 0.05. To add for any data loss, the sample size was taken as 30 per group.

Statistical analysis was done by using statistical package for the social sciences (SPSS) 21.

Demographic data were analyzed using the Students' t-test or Fisher's exact test as appropriate. T Rescue, NRS at T Rescue, and 24-h analgesic requirement were analyzed by Mann-Whitney U-test. NRS comparison at various time intervals was done by t-test or Mann-Whitney U-test as appropriate. Categorical data analyzed by the Chi-square test or Fisher's exact test as appropriate. Data presented as mean \pm SD and median (interquartile range: IQR). P < 0.05 was considered as significant.

Results

All the 60 patients enrolled were randomized and went through the study process without any loss to follow-up and were analyzed [Figure 1]. None of the TEP procedures had a breach in the peritoneum with conversion to the transabdominal pre-peritoneal procedure (TAPP). Demographics were comparable among both the groups [Table 1]. T Rescue was significantly longer (P = 0.02) in Group US-TAP. There was no significant difference between the groups in terms of 24-h analgesic requirement and NRS at T Rescue [Table 2]. There was no difference between the two groups in terms of

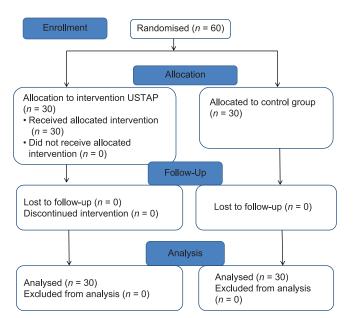


Figure 1: CONSORT Flow Diagram of Study

surgical duration, as well as intraoperative consumption of fentanyl. Patients with PONV were significantly less in the US-TAP Group (P < 0.001) [Table 3].

In Group US-TAP, significantly lower NRS was observed at time points 24 h (at rest) (P = 0.02) and 12 h (on movement) (P = 0.004) [Figure 2a and b & Table 4a and b].

	Group US-TAP (n=30) Mean±SD	Group Control (n=30) Mean±SD	Р
Age (years)	43.43±14.44	45.63±16.03	0.58
Gender M/F	28/2	26/4	0.67#
Weight (kg)	59.50 ± 8.59	64.03±11.49	0.09^
Height (cm)	171.55 ± 7.14	173.00 ± 8.50	0.48^

US-TAP - Ultrasound-guided transversus abdominis plane block (*P<0.05 significant). ^Student's unpaired t-test. *Fishers' exact test

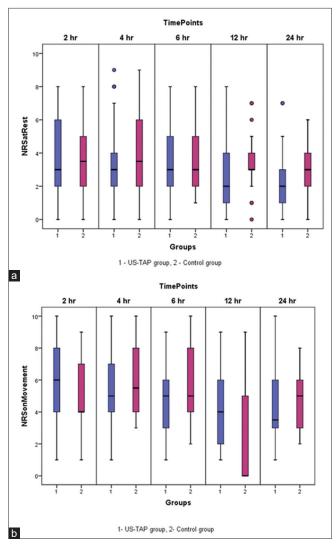


Figure 2: NRS (numerical rating scale 0 to 10) at rest (a) and on movement (b) comparison between ultrasound-guided transversus abdominis plane block (US-TAP and control) groups at various time points over first 24-h postoperatively (Mann-Whitney U test)

Discussion

Our study demonstrated the analgesic advantage of bilateral US-TAP in TEP surgeries by significantly prolonging the duration of pain-free period postoperatively (T Rescue), as well as lesser NRS scores at 24 h (at rest) and 12 h (on movement) postoperatively, thereby effectively catering to the day 0 pain which is predominantly seen in TEP procedures.^[11] Longer time to first request for analgesia in the US-TAP group similar to our study was found in other studies.^[12,13]

In their study on TAP block in laparoscopic inguinal hernia repair surgeries, Arora et al. have included both TAPP (transabdominal preperitoneal) as well as TEP repairs into a single group and compared them with port-site infiltration.^[12] Pain-related to TAPP procedure is a deep intra-abdominal pain and also shoulder pain as a consequence of pneumoperitoneum in contrast to TEP, which involves only preperitoneal insufflation, with no pneumoperitoneum.^[11] Pain in TEP may be limited to the lower abdomen alone, which is not the case with the TAPP procedure.^[5] Pain due to preperitoneal insufflation forms an important component of pain in TEP, apart from port site incisions and other tissue handling. Thus, we included only TEP procedures to maintain uniformity in procedure-related pain and also made sure that a single-surgeon with an assistant performed all the procedures, so that inter-individual variability in tissue handling is avoided.

We had planned to administer the US-TAP block before incision after induction, to confer a preemptive analgesic advantage to the patient. Although it was found to be effective in various studies, preincisional port site infiltration was avoided by us in our study, in contrast to other studies, so as to not have an overlapping analgesic effect of this intervention with that of US-TAP, and also, not to cross the safe limit of the analgesic dosage of levobupivacaine, while combining both.^[5,14,15]

Table 2: Primary Outcome Variables				
		Group control Median (IQR)	Р	
T Rescue (min)	235 (438)	175 (156)	*0.02@	
NRS T Rescue	7 (2)	7.5 (1)	0.10@	
Total analgesia (mg kg ⁻¹)	1.5 (1.2)	1.85 (0.9)	0.16@	
NRS - Numerical rating scale.	(*P<0.05 significant)	. @Mann-Whitnev U 1	Test	

In our findings, we found marginally increased total duration of surgery in the TAP group 100.67 \pm 37.53 minutes compared to the control group 84.17 \pm 28.8, but it was not significantly different between the groups similar to other studies.^[5,12]

We had given bilateral TAP blocks as a 0.3 mL kg⁻¹ volume of 0.25% levobupivacaine, rather than administer a fixed volume as done by few other authors, to be well within the toxic dose (maximum 2 mg kg⁻¹) as well as to individualize the dose as per their body weight.^[5,8,12,16] Levobupivacaine, an S(-) enantiomer of bupivacaine was chosen as it has a better safety profile than racemic bupivacaine or ropivacaine.^[17,18]

We chose to administer bilateral US-TAP blocks and not unilateral block, due to the pain related to midline ports, which are needed for TEP. Beyls *et al.*, in their study on ambulatory laparoscopic unilateral inguinal hernia repair, administered unilateral TAP block as against standard care without block and found that there was no difference in VAS score or opioid consumption in both groups in the early postoperative period.^[16]

Stebelski *et al.* studied the analgesic effect of TAP block by landmark method in laparoscopic inguinal hernia repair and, they found that there was no significant difference between TAP and control groups.^[13] This was probably due to the addition of adrenaline and clonidine as additives in both groups, insufficient power of the study and also due to the occurrence of pneumoperitoneum in several patients, the associated pain of which might not have been relieved by TAP block. We have not used any additive and used a more precise US-TAP method, which has become the standard of care of late.

The immediate postoperative difference in NRS was observed by Kim *et al.* unlike our study, and this may be due to usage of short-acting remifentanil intraoperatively and stoppage of infusion towards end of the surgery, whereas, we had used fentanyl intraoperatively, the effect of which would have lasted for some time into the early postoperative period till the T Rescue time point.^[5]

PONV was significantly higher in our control group (P < 0.001), as compared to other studies, which can be

Table 3: Intraoperative fentanyl requirement, duration of surgery and PONV			
	Group US-TAP Mean±SD	Group Control Mean±SD	Р
Fentanyl (total mcg)	120±40	130±33	0.22 [@]
Duration (min)	100.67 ± 37.53	84.17±28.80	0.06^
PONV (Numbers per group)	7	21	*<0.001\$

PONV - Postoperative nausea and vomiting (*P<0.05 significant). @Mann-Whitney U test. ^Student's unpaired t-test. \$Chi-square test

Table 4a: NRS at rest			
	Group 1 (Median (IQR)	Group 2 (Median (IQR)	P<0.05 significant*
2 H	3 (4)	3.5 (3)	.95 [@]
4 H	3 (3)	3.5 (4)	.36 [@]
6 H	3 (3)	3 (4)	.32 [@]
12 H	2 (3)	3 (1)	.06 [@]
24 H	2 (2)	3 (2)	.02 ^{@,*}
@Mann-V	Whitney U test		

Mann-Whitney U i

Table 4b: NRS on Movement			
	Group 1 (Median [IQR])	Group 2 (Median [IQR])	<i>P</i> <0.05 significant*
2 H	6 (4)	4 (3)	.18 [@]
4 H	5 (4)	5.5 (4)	.31@
6 H	5 (3)	5 (4)	.50 [@]
12 H	4 (4)	5 (2)	.004 ^{@,*}
24 H	3.5 (3)	5 (3)	.18@

@Mann-Whitney U test

explained by the higher 24-h analgesic usage postoperatively, though it was not found to be statistically significant.^[5]

Altiparmak et al. have shown that bilateral ultrasound-guided erector spinae plane block (US-ESP) provided better analgesia than bilateral subcostal oblique US-TAP in laparoscopic cholecystectomy.^[19] Future research might give insights into comparing the bilateral US-TAP with that of bilateral US-ESP in laparoscopic TEP surgeries as well.

In a recent study, quadratus lumborum block (QLB) was described to be a successful technique as a sole anaesthetic for TEP procedures as compared to GA, though they have added rectus abdominis sheath block to the QLB.[20] The comparison of OLB to US-TAP would probably give better insights into analgesia for TEP.^[20]

We had certain limitations in our study. Firstly, true blinding of patients could not have been possible due to some amount of decreased sensation in those who underwent US-TAP as compared to those who did not receive the block. We had not opted for bilateral 0.9% saline injection in the control group for blinding purposes, and instead, did not give any block at all. thereby preventing unnecessary invasive procedures in this group.

The observer in PACU was blinded to the group distribution but the intraoperative measurement - fentanyl requirement, by the anesthesiologist could not have been blinded, hence some amount of bias could not be ruled out.

Postoperatively, i.v. patient-controlled analgesia was not used as it was not available in that particular postoperative ward.

Continuous infusion through TAP catheters was not studied, as maintenance of continuous bilateral catheters would have been cumbersome, and this aspect was not part of the study. The pain on day 0 is maximum and hence continuing study beyond that period was not deemed necessary.^[11] We had certain long-term follow-up constraints at our setup, and hence, chronic pain outcome parameters could not be evaluated.

Finally, an objective assessment of the block was not done as the block was administered after the institution of GA. before skin incision.

Conclusion

Bilateral US-TAP in laparoscopic TEP surgeries provides a longer duration of analgesia with lesser PONV as compared to no block. NRS at 12 h (on movement) and 24 h (at rest) were found to be better in the US-TAP group, thereby providing better comfort to patients in the early postoperative period.

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Conflicts of interest

There are no conflicts of interest.

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