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# A double-blinded randomized controlled trial to evaluate the efficacy of ultrasound-guided transversus abdominis plane block after laparoscopic ventral hernia repair

Nikhil Mandya Nagakumar, Aditi Sachdeva, Vishal Lakhotia, Rushil Jain, Vikas Panwar, Sourav Panda

## Abstract

**BACKGROUND:** Laparoscopic ventral hernia repair (LVHR) is a widely recognized procedure for treating ventral hernias, yet managing postoperative pain remains difficult. To enhance pain control following LVHR, we conducted a prospective evaluation of the effectiveness of ultrasound-guided transversus abdominis plane (TAP) block.

**PATIENTS AND METHODS:** Our study was a prospective double-blinded randomized controlled trial conducted from March 2021 to June 2022 which included 52 subjects, randomized into two groups (Groups T and P) of 26 each, by computer-generated simple randomization. After taking written informed consent, an ultrasound bilateral TAP block was given to both the groups in which Group T received the drug (0.375% of levobupivacaine 40 mL), and Group P was a placebo (received 0.9% normal saline). Visual Analog Scale (VAS) for pain, the need for rescue analgesia, the time to ambulation within 24 h, and the length of postoperative stay were used to assess the primary outcomes of the study.

**RESULTS:** The mean age was 56.5 years (SD = 8.814) in Group T and 53.57 years (SD = 9.161) in Group P. The average duration of surgery was 77.5 min for Group T and 75.96 min for Group P. Postoperative stay averaged 26.76 h (SD = 7.941) in Group T and 31 h (SD = 12.109) in Group P. It was observed that there was a statistically significant difference in VAS, the requirement for rescue analgesia, and ambulation between the two groups at 2, 6, and 12 h. However, no significant difference was observed at 24 h or in the averaged postoperative stay.

**CONCLUSION:** LVHR with mesh is a proven technique, but controlling postoperative pain remains a difficulty. An ultrasound-guided TAP block with a long-lasting local anesthetic, such as bupivacaine, can markedly lessen early postoperative pain and decrease the reliance on narcotics after LVHR.

**TRIAL REGISTRATION:** Clinical trial registry information: Clinical trial registry name: CTRI. Trial number: CTRI/2020/09/007897 (Registered on 04/09/2020) trial registered prospectively.

## Keywords:

Early ambulation, laparoscopic ventral hernia repair, postoperative pain control, rescue analgesia, transversus abdominis plane block, Visual Analog Score

Department of General Surgery and Robotics, Max Super Speciality Hospital, Saket, New Delhi, Delhi, India

## Address for correspondence:

Dr. Nikhil Mandya Nagakumar,  
Department of General Surgery and Robotics, Max Super Speciality Hospital, Saket, New Delhi 110017, Delhi, India.  
E-mail: nikhil.m.n.779@gmail.com

## Introduction

The term ventral hernia is defined as the protrusion of abdominal contents through a weakness or defect of the anterior

abdominal wall. Abdominal hernias include epigastric, umbilical, spigelian, and incisional hernias.<sup>[1,2]</sup> Primary ventral hernias are classified as medial or lateral. Medial primary ventral hernia includes epigastric and

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umbilical hernia. Incisional hernias can be medial or lateral, depending on the incisions used in previous surgeries. Most of the time, midline incision is used in laparotomies; hence, midline incisional hernias are more common.<sup>[3-5]</sup> Primary lateral ventral hernias include spigelian and lumbar hernias. A spigelian hernia occurs along the linea semilunaris, just lateral to the rectus sheath.<sup>[6]</sup>

There is increasing use of the laparoscopic ventral hernia repair (LVHR) technique nowadays for ventral hernia repair due to less duration of hospital stay, lesser surgical site infection rates, and low recurrence rates compared with open repair.<sup>[7]</sup> However, no significant benefit is observed in postoperative as compared to the open approach. The most common complaint following LVHR is severe pain, which increases the duration of hospital stay. It has been described that fixing the mesh to the anterior abdominal wall using sutures and tacks is the main cause of postoperative pain.<sup>[8]</sup>

To enhance pain control following LVHR, we propose conducting this study to assess the effectiveness of the transversus abdominis plane (TAP) block for managing postoperative pain after the procedure.

In 2001, a technique known as TAP block was introduced in which a local anesthetic solution is injected into the space between the internal oblique and transversus abdominis muscles where nerves supplying the anterior abdominal wall innervates, that is, thoracolumbar nerves, which originate from the T6 to L1 spinal roots, hence provide analgesia to the region.<sup>[9]</sup>

## Materials and Methods

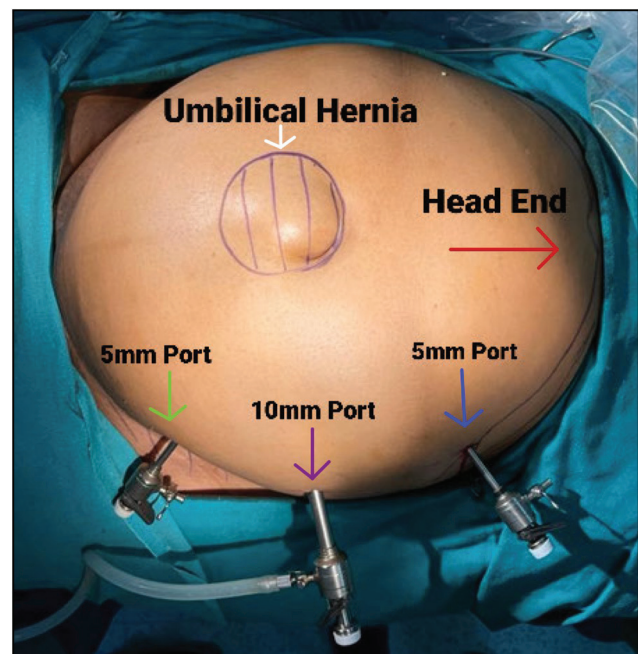
This was a prospective double-blinded randomized controlled trial (RCT) comparing the efficacy of ultrasound-guided bilateral TAP block after LVHR. The study was carried out in the Department of General Surgery and Robotics, Max Super Speciality Hospital, Saket, New Delhi, from March 2021 to June 2022.

Before the study, the approval of the Institute Review Board (IRB)/Institutional Ethical Committee was obtained. Written informed consent was obtained from each participant. Before the informed consent form, the entire study along with its implications was explained to all the subjects in their native language. Study participants and the researcher were blinded to the intervention. This study's primary objective was to reduce postoperative pain after LVHR as measured by the Visual Analog Scale (VAS) till 24h postoperatively. All individuals who were 18 years or older, undergoing LVHR for ventral abdominal hernias were included in the study. Patients who denied/did not consent to enroll in the study, patients not fit for general anesthesia/

laparoscopic surgery, history of allergy to local anesthetic, conversion to open surgery, patients on antiplatelet, anticoagulant or on regular use of opioids, paracetamol, or tramadol for a chronic medical condition, and difficulty in comprehending VAS were excluded from the study.

The study included 52 subjects who were randomly divided into Group T and Group P, with 26 subjects in each group, according to a computer computer-generated simple randomization schedule. A bilateral TAP block was given to both groups intraoperatively, but Group T received the drug (0.375% of levobupivacaine 40mL), and Group P received 0.9% normal saline as placebo. The sample size calculation has been performed based on the difference in VAS score in Group 1 and Group 2 at 2h. According to Jain *et al.* 2019, these are reported as an average of 4.56 and 3.56, respectively, with an SD of  $\sigma_1 = 0.87$  and  $\sigma_2 = 1.15$ . To detect a difference of at least 0.8 in mean VAS score with a power of 80% and significance level of 5%, the sample size required is 26 in each group.

All the patients who are included in the study underwent laparoscopic intraperitoneal onlay meshplasty. Port positions were used such that a 5mm optical trocar was placed in the left subcostal location, lateral to the midclavicular line (Palmer's point), a 10mm camera port in the lumbar region, and a 5mm working port in the iliac region [Figure 1]. After adhesiolysis and reduction of hernial content, a primary defect was closed by using



**Figure 1:** Depicting port placement in laparoscopic ventral hernia repair. The red arrow indicates the head end of the patient; the blue arrow indicates 5mm the working port in the left subcostal region; the purple arrow indicates 10mm camera port in the left lumbar region; the green arrow indicates 5mm working port in the left iliac region

0-polydioxanone sutures with a transcutaneous suture passing device. Mesh was placed to cover the defect fixed to the parietal wall using a combination of transfascial sutures and tacks.

After completion of the surgery, with aseptic preparation of the skin and the probe, an ultrasound-guided TAP block was given bilaterally to all the subjects [Figure 2]. The linear high-frequency probe (6–13 MHz) was used and placed below the xiphoid process and carefully moved posterolaterally for optimal identification of the transversus abdominis fascial plane. The block was given by in-plane technique using a invisible needle. About 0.375% of levobupivacaine 20 mL or 20 mL of 0.9% normal saline was injected slowly after repeated negative aspirations of blood. The spread of the drug was observed in real time. This step was repeated on the other side also.

VAS for pain was noted at 2h, then at the end of 6, 12, and 24h after completion of surgery. All the patients were given paracetamol 1 g intravenously every 8h and ondansetron 4mg intravenously for nausea and vomiting. No side effects due to any drugs used were noted. Intravenous tramadol 25mg was given as a rescue analgesic in some patients, where the VAS score was more than four in both groups. The VAS is a 10-point scale (for patient self-reporting of pain, a score of 1 is no pain, and 10 means worst imaginable pain).

The primary outcome of the study was measured by the VAS score for pain, the requirement of rescue analgesia, time for ambulation in the postoperative period till 24h (at

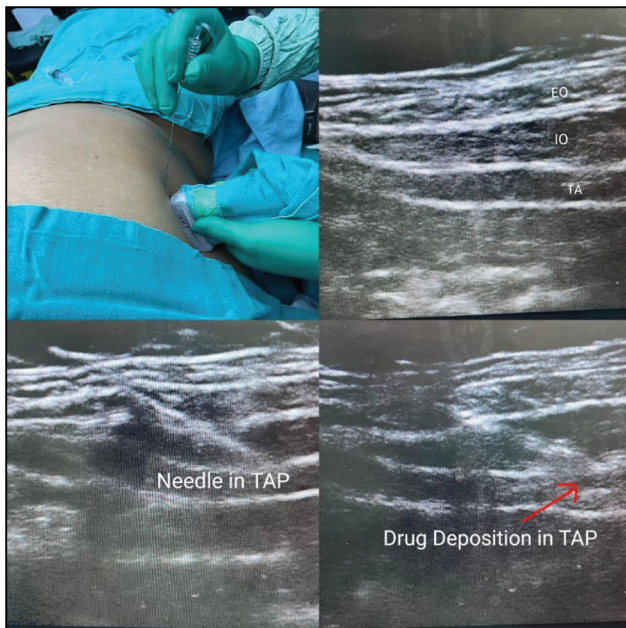
2, 6, 12, and 24h), and duration of postoperative stay. The secondary outcome of the study was measured by observing block-related or drug-related adverse effects such as nausea, vomiting, sedation, dizziness, reduced respiratory functional capacity, and occurrence of any major concurrent medical event requiring special diagnostic or therapeutic interventions.

## Results

Our study is a hospital-based, prospective double-blinded RCT evaluating the effectiveness of TAP block for managing postoperative pain after LVHR.

The calculated sample size of the study was 52. The study population was divided into Group T (receiving TAP block) and Group P (placebo). The findings of our study are as follows:

- The mean age was 56.5 years in Group T with an SD of 8.814 and 53.57 years in Group P with an SD of 9.161. In Group T, the total number of female patients was 14, and the total number of males was 12 in number whereas in Group P, the total number of female patients was 17, and the total number of male patients was nine in number.
- The mean BMI of Group T was 27.48 with an SD of 1.147, and Group P was 27.42 with SD of 1.286.
- Out of 52 subjects, 19 (36.53%) had an incisional hernia, 20 (38.46%) had an umbilical hernia, 11 (21.1%) had a paraumbilical hernia, and 2 (3.8%) had an epigastric hernia.
- The average duration of surgery in Group T was 77.5 min, and Group P was 75.96 min.
- Postoperative stay averaged 26.76h (SD = 7.941) in Group T and 31 h (SD = 12.109) in Group P.
- In this study, no statistically significant difference/association was found in age, gender, BMI, size of the hernia, size of the mesh, number of tacks used, and duration of surgery between Group T and Group P [Table 1].
- A significant difference was found in VAS, need for rescue analgesia, and ambulation between the two groups at 2, 6, and 12h but no significant difference at 24h [Table 2].



**Figure 2:** Depicting ultrasonography-guided transversus abdominis plane block. EO: external oblique; IO: internal oblique; TA: transversus abdominis; TAP: transversus abdominis plane

**Table 1: Baseline characteristics**

Characteristics	Group T	Group P	P value
Age, mean (SD), years	56.5 (8.81)	53.57 (9.16)	0.247
Female sex, No. (%)	14 (53.8)	17 (65.4)	0.026
Height, mean (SD), cm	165.30 (6.5)	167.53 (8.20)	0.283
Weight, mean (SD), kg	75.19 (6.53)	77.11 (7.88)	0.343
Size of the hernia, median, cm <sup>2</sup>	4.0	4.2	0.65
Size of the mesh, median, cm <sup>2</sup>	176.7	150	0.60
Number of tacks used, median	30.7	32.5	0.52
Duration of surgery, median, min	77.5	75.96	0.574

SD = standard deviation, Group T = receiving TAP block, Group P = placebo

**Table 2: Study outcome measures**

Outcome measures	Group T	Group P	P value
1) Postoperative pain on VAS of 1 to 10, mean (SD)			
At 2 h	4.62 (0.9)	5.96 (1.18)	<0.001*
At 6 h	4.03 (1.07)	5.46 (1.02)	<0.001*
At 12 h	3.42 (0.94)	4.88 (1.10)	<0.001*
At 24 h	2.34 (0.93)	3.92 (1.12)	0.475
2) Number of patients requiring rescue analgesia (% within the group)			
At 2 h	23 (88.5)	12 (46.2)	<0.001*
At 6 h	22 (84.6)	8 (30.8)	<0.001*
At 12 h	20 (76.9)	2 (7.7)	<0.001*
At 24 h	6 (23.1)	1 (3.8)	0.099
3) Number of patients ambulated (% within the group)			
At 2 h	0	0	0
At 6 h	5 (19.2)	14 (53.8)	0.01*
At 12 h	14 (53.8)	24 (92.3)	0.002*
At 24 h	24 (92.3)	26 (100)	0.490
4) Duration of postoperative stay (SD), Hours	26.76 (7.94)	31 (12.10)	0.144

VAS = visual analog score, SD = standard deviation, Group T = receiving TAP block, Group P = placebo

\* $P < 0.05$  is statistically significant

- No significant difference was observed in the averaged postoperative stay. Patients in both groups were discharged early when compared to other LVHR studies using intravenous analgesia for pain management.<sup>[10,11]</sup>
- No complications/adverse effects of surgery and TAP block were observed in our study.
- The major limitation of this study is that the pain was evaluated only until 24h postoperatively. So, it was not possible to analyze subsequent pain control after discharge.

## Discussion

LVHR was described by LeBlanc, as an advanced and better method as compared to open ventral hernia repair but the only drawback being the postoperative pain which was found similar to that of the open method. The most common complaint following LVHR is severe pain, which increases the duration of hospital stay.<sup>[8]</sup>

To enhance pain control following LVHR, this study was carried out among patients with ventral hernia who underwent laparoscopic intraperitoneal onlay mesh repair (IPOM), and the effectiveness of TAP block for managing postoperative pain after the procedure was assessed. After the study, it was analyzed that TAP block can be used for better pain management after LVHR. The outcomes were measured in terms of VAS, need for rescue analgesia, early ambulation, and average postoperative hospital stay.

We have included 52 cases which were divided into Group T (TAP block) and Group P (placebo), with 26 in each group. The mean age was 56.5 years in Group T and 53.5 years in Group P. In our study out of 52 patients, 31 were females and 21 were males. In a study by Jaykar *et al.*,<sup>[12]</sup> it was found that females

have a higher incidence of ventral hernia than males, which is in accordance with this study. A few reasons for this female prevalence include multiparity, anterior abdominal wall stretching, reduced abdominal wall muscle tone, and substitution of collagen with elastic fibers.

## Visual Analog Score

In our research, the VAS in Group T was notably lower than those in Group P, with this difference lasting up to 24h. A significant statistical difference ( $P$  value  $< 0.001$ ) was observed at 2, 6, and 12h, but there was no significant difference at 24h.

Jain *et al.* reported that TAP block in LVHR resulted in decreased VAS compared with intravenous systemic analgesia.<sup>[13]</sup>

## Rescue analgesia

In this study, Group T, which received the TAP block, needed less rescue analgesia as compared to Group P. A statistically significant difference was observed at 2, 6, and 12h, but no significant difference was found at 24h.

Previous research supports these findings, indicating that patients who receive a TAP block during abdominal surgeries typically require less additional analgesia compared with those who do not receive the block.<sup>[14,15]</sup>

## Ambulation

In our study, there was a significant difference in ambulation time post-surgery. Ambulation time was less in Group T patients ( $P$  value = 0.002) at 6 and 12h but no difference at 24h ( $P$  value = 0.490) when compared to Group P, which is in accordance with the results reported by Said *et al.*<sup>[16]</sup>

### Duration of postoperative stay in hospital

All our patients got discharged within 48 h, but Group T patients got discharged earlier compared with Group P. The average postoperative stay for Group T was 26.76 h (1.1 days), and Group P was 31 h (1.29 days). However, there was no significant difference ( $P$  value = 0.144 in the average postoperative stay) among both groups.

Many LVHR studies using TAP block for postoperative pain control have reported similar duration of postoperative stay. Jain *et al.* observed that the average postoperative stay in patients receiving TAP block after LVHR was 22.6 h (0.94 days).<sup>[13]</sup>

There have been numerous LVHR studies using conventional intravenous systemic analgesia for postoperative pain control that have reported a longer duration of postoperative stay. Roth *et al.* observed that the average postoperative stay in LVHR is 2.9 days in their prospective study laparoscopic incisional/ventral herniorrhaphy: a five-year experience.<sup>[10]</sup> Chowbey *et al.* in their retrospective study of LVHR on 202 patients observed that the mean duration of postoperative stay was 1.8 days.<sup>[11]</sup>

LVHR is a popular technique nowadays for the repair of ventral hernias but due to severe postoperative pain as shown by various studies, it is still not considered the standard approach.<sup>[8]</sup> In our study, Group T patients, that is, patients receiving TAP block were found to have less pain based on VAS, required less rescue analgesia, and ambulated early during an early postoperative period (2, 6, and 12 h). However, no significant difference was observed at 24 h in comparison with the patients receiving placebo, that is, Group P. There was no significant difference between the two groups in the average postoperative stay.

There are numerous studies that have shown better postoperative pain management using TAP block after LVHR and have similar results to our study.

Jain *et al.* observed that ultrasound-guided TAP block resulted in lesser VAS and need for rescue analgesia, patients ambulated early, and decreased average postoperative hospital stay in comparison with traditional methods of giving intravenous analgesia in LVHR.<sup>[13]</sup>

A prospective RCT was conducted by Sinha *et al.*, in which a laparoscopic guided TAP block using bupivacaine 0.25% was compared with saline for managing postoperative pain in patients undergoing LVHR. They showed that the TAP block with bupivacaine reduced postoperative pain and decreased the use of opioid analgesics over a 24 h period.<sup>[17]</sup>

There are many studies showing good postoperative pain relief after TAP block given by either laparoscopic or ultrasound-guided techniques for ventral hernia surgeries.<sup>[18-20]</sup>

There have been some studies that have reported liver laceration and colon injury due to TAP block and local anesthetic toxicity,<sup>[18,21]</sup> but no such adverse events were observed in our study.

There are a few limitations to our study. Pain after LVHR can persist for up to three months.<sup>[22,23]</sup> In our study, pain was evaluated only until 24 h postoperatively. So, it was not possible to assess subsequent pain after discharge. Most of the study population belongs to high socioeconomic status, hence results cannot be generalized.

### Conclusion

LVHR is an advanced procedure for treating ventral hernias, but postoperative pain remains a challenge. Our study clearly showed that the ultrasound-guided TAP block with long-acting local anesthetic (bupivacaine) significantly decreases early postoperative pain and opioid analgesics use following LVHR as evidenced by less VAS, decreased need for rescue analgesia, and early ambulation.

### Author contributions

Nikhil M Nagakumar: Conceptualization, Methodology, Investigation, Data Curation, Visualization, Writing – Original Draft. Vishal Lakhota: Software, Data Curation, Project administration. Aditi Sachdeva: Formal analysis, Investigation, Data Curation. Sourav Panda: Software, Formal analysis, Resources. Rushil Jain: Supervision, Project administration, Writing – Review and Editing. Vikas Panwar: Supervision, Project administration, Writing – Review and Editing.

### Ethical policy and institutional review board statement

Before the study, the approval of the Institute Review Board (IRB)/Institutional Ethical Committee was obtained. IRB board name: Institutional Ethics Committee, Devki Devi Foundation. Approval number: BHR/TS/MSSH/DDF/SKT-2/IEC/ GS/21-09 The date of approval: September 3, 2021.

### Declaration of patient consent

Written informed consent was obtained from each participant. Prior to the informed consent form, the entire study along with its implications were explained to all the subjects in their native language.

### Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

### Acknowledgments

Not applicable.

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