A prospective comparison of continues catheter Paravertebral block vs continues catheter Erector spinal block in patients undergoing Robotic assistant Thoracic surgery

Trial Number: 0349-24-SOR

Version 2.0

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1. Scientific Background

In the last decade the quantity of Robotic thoraccoscopic surgery is dramatically rises those type of surgery are performed in a specially designed robotic surgery suite consisting of a **surgeon console** with hand and foot controls and a 3-D HD viewer, a **movable patient cart** with robotic arms, and a **vision cart** that displays three-dimensional magnified color images. [1,2]

Robotic surgery is a major advance for thoracic surgeons who must operate in a small area bounded by the rib cage. The da Vinci® Xi surgical robot operates through small incisions. The only tissue cut is the skin since deeper tissues are spread apart gently. The da Vinci® robot rotates around a pivot point near the patient's ribs. [1,2,3]

Thoracic Surgical procedures requiring an incision into the pleural cavity are some of the most painful procedures postoperatively and, if not managed appropriately, can lead to chronic pain. [3]

Sever pain continues to be a significant problem for many patients after major thoracic surgery. In addition to improving patient satisfaction and decreasing pain scores, enhanced perioperative pain control can improve clinical outcomes [4]. Thoracic epidural analgesia (TEA) remains a critical tool for anesthesiologists to use in acute pain management. TEA is particularly effective for reducing pain after thoracic and upper abdominal surgery and likely permits major surgical procedures to be performed on patients with moderate to severe comorbid diseases, who several years ago may have been determined to be too great a risk for surgery [4,5,6].

But TEA is not without consequences, the negative hemodynamic side effect, complication due to dural puncture or direct needle spinal cord trauma, bilateral thoracic analgesia, epidural hematoma and act..., taking it all together there is no best technic for analgesia in one sided thoracic surgery.

In the last decade, peripheral nerve blockade has dramatically improved perioperative analgesia for patients undergoing thoracic surgery. The best know and described block are Thoracic paravertebral block (TPVB) and Erector Spinae Plane block (ESP)

that gives comparison analgesic effect in multiple clinical trials, but for now there is not known best thoracic peripheral nerve block for ROBOTIC assisted surgery[4,5,7].

Because thoracic robotic assisted surgeries are time consuming and performed over hours of invasive manipulation, one- punch technic are less common and cannot give adequate analgesia duration for anesthetic plane analgesia and post operation analgesia.

A common practice to extend the analgesia for few days is to place a thin catheter in PVS/ESP blocks to continuously inject local anesthetic (LA) with or without adjuvants to that spaces, the end result is excellent analgesia extending for days to week, this practice is well described and common [6].

Uptodate in Soroka Medical Center we perform PVS/ESP blocks in thoracic surgeries in regular basis, there is no preferred block and the choice is only by the Anesthesia provider preference. So the purpose of this trial is to compare both technique and reveal the best effective technique for this type of surgery.

2. Objectives

The overall goal of this work is to find the preferred continues catheter- based thoracic block for patients who undergoing major ROBOTIC assisted thoracic surgery (Lobectomy, multiple segmental resection and thoracotomy). Specifically, this project aims to complete the following:

1. To compare analgesic efficiency of continuous TPVB vs ESP block in patients undergoing major robotic thoracoscopic operation

2. To assess failure rate, time to catheter placement and patient satisfaction of each block group

3. To compare complication rate of each block

3. Methodology

3.1. *Research design*

This study is designed as a prospective comparative cohort study.

3.2. *Research participants*

We will recruit adult patients undergoing major robotic thoracic procedures, such as Lobectomy, multiple segmental resection and thoracotomy. The recruitment period is planned for approximately 1 year. The follow-up period will be from admission until hospital discharge.

3.3. *Sampling criteria*

The criteria for inclusion are:

- Age ≥18 years
- All patients undergo major robotic thoracic surgery

The criteria for exclusion are:

- Patients who refuse to participate in the study.
- Patients who are unable to give an informed consent.
- Patients with local inflammation at the puncture site
- Patients with known allergy to local anesthetisc
- Pregnancy

4. Definitions

a) Video assisted thoracoscopic surgeries (VATS)

Video-assisted thoracic surgery (VATS) is a type of minimally invasive thoracic surgery that can remove parts of the diseased lung and lymph nodes. In video-assisted thoracoscopic surgery (VATS), a small tube called a thoracoscope is inserted through a small cut (incision) between the ribs. At the end of the tube is a small camera. This lets the surgeon see the entire chest cavity without having to open up the chest or spread the ribs. The surgeon then removes lung tissue with specially designed instruments inserted through one or two additional small incisions. The VATS technique can be

used for other types of chest procedures involving the lungs, esophagus, thymus, pleural or pericardium besides lung cancer surgery.

b) Ultrasound for peripheral nerve blocks

Ultrasound imaging is increasingly used to guide peripheral nerve blocks. Ultrasound guidance allows real-time visualization of nerves, surrounding structures, and the needle-tip to maximize block success and minimize complications. Unlike other imaging modalities (ie, magnetic resonance imaging and computed tomography), ultrasound equipment is portable and carries no risk of ionizing radiation.

Ultrasound machines — For use in the operating room, a variety of portable handheld or cart-mounted ultrasound machines are available. Ultrasound machines include a pulse generator, transducer(s), a receiver that amplifies signals returning to the transducer, a display or monitor that shows the image, and computerized memory that stores images. Most ultrasound machines include options for compound imaging and color-flow Doppler, and allow manual or automatic adjustment of frequency, gain, focus, and depth of scanning.

Needles — The block needle-tip should be visualized throughout the nerve block procedure to avoid inadvertent tissue damage or vascular puncture and inaccurate injection of local anesthetic (LA). Metal block needles are hyperechoic and appear white on the ultrasound image; they can be difficult to visualize in bright adipose tissue. Larger needles (ie, 17 gauge Touhy) are easier to visualize and to direct and are therefore useful for deeper blocks, when the angle of insertion is steep.

5. Methods

5.1 Paravertebral block (PVB)

Thoracic paravertebral block (TPVB) is the technique of injecting local anesthetic adjacent to the thoracic vertebra close to where the spinal nerves emerge from the intervertebral foramina. This results in ipsilateral somatic and sympathetic nerve blockade in multiple contiguous thoracic dermatomes above and below the site of injection [5,6].

It is effective in treating acute and chronic pain of unilateral origin from the chest and abdomen. Bilateral use of TPVB has also been described.

Our understanding of the safety and efficacy of TPVB has improved significantly in the last two decades, prompting its use in children and neonates and for surgical anesthesia [6,7].

The TPVB is used to provide anesthesia and analgesia for breast surgery, surgery that requires coverage of the axilla (eg, creation of dialysis access, axillary lymph node dissection), or for thoraco-abdominal surgery as an alternative to thoracic epidural.

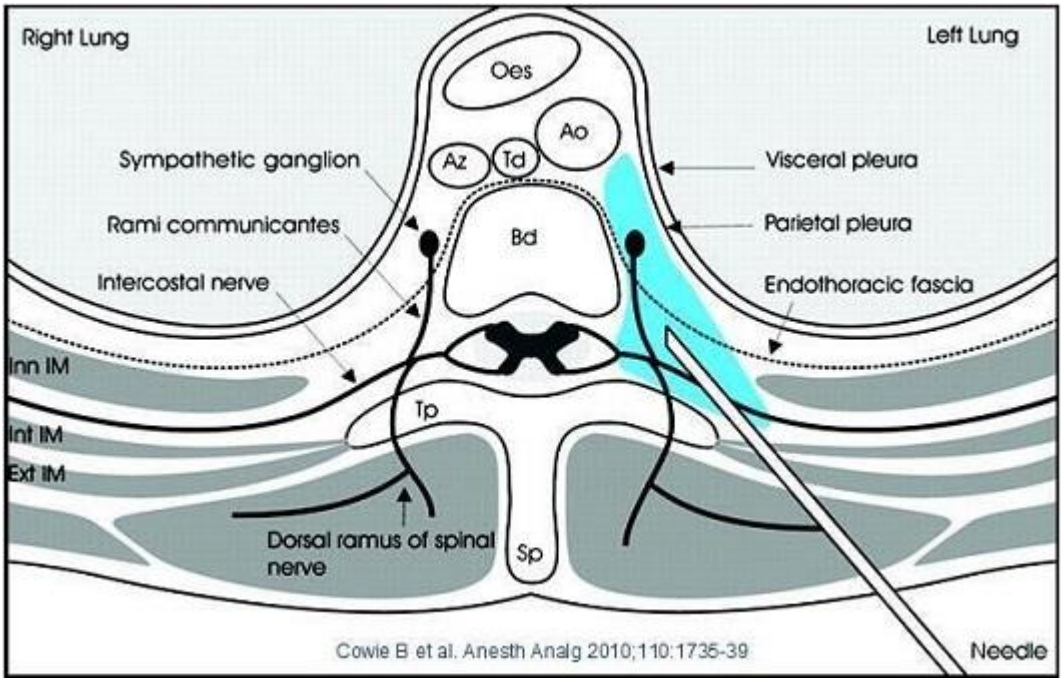
The selected level for the block should be as close to the location for the dermatome for the incision or injury as possible. Three to five contiguous intercostal nerves may need to be blocked to provide complete coverage for one dermatome, due to the interconnections between spinal nerves and overlap in innervation of dermatomes. This can be accomplished with blocks at multiple levels, or with a larger volume single-injection [6,7,8].

In studies that have used radiocontrast to evaluate the extent of spread after paravertebral injection, the ultimate extent of sensory block is usually slightly greater than the spread of contrast, perhaps due to diffusion on LA after initial injection.

Paravertebral block is a technique where local anaesthetic is injected into the space adjacent to the vertebrae to block the spinal nerves as they emerge from the

intervertebral foramen. Here the spinal nerves are devoid of covering fascia making them sensitive to the action of local anaesthetics. The block is of high quality and sufficient to provide analgesia for major surgery at various sites [7]. A single site injection can provide blocks of 4-6 dermatomes.Thoracic paravertebral block confers several advantages over epidural block: comparable pain relief with reduced side effects,

better pulmonary function and fewer pulmonary complications [7,8,9].



5.2 Potential complications

Potential complications associated with PVB peripheral nerve block on chest area are Pneumothorax, intravascular injection and Local Anesthetic Toxicity. Percent of complications documented in previous literature are very small and varying about 1-2 % of all block [7].

Pneumothorax is relevant considering following thoracoscopy and drainage. Block will be performed only experienced providers. Block after induction of anesthesia and positioning in order to minimize patients unpleasant sensation [6,7,9].

Dural puncture–related complications such as intrathecal injection, spinal anesthesia, and postural headache appear to be exclusive to the medial approach to the

TPVS and are probably related to the closer proximity of the needle to the dural cuff and intervertebral foramen. Transient ipsilateral or bilateral Horner syndrome can also develop [7,8].

5.3 The Erector Spinae Plane Block

In recent years a new conceptual type of regional anesthesia has emerged: the Erector Spinae Plane Block (ESP block). Originally it was described in 2016 in a case report regarding analgesia intervention for thoracic neuropathic pain. Since then, there has been growing interest and research adding experience about the ESP block for pain control after thoracic and abdominal surgery and also traumatic injury of chest and abdomen. Current literature is limited to approximately 60 publications, the majority of which is case reports and case series [7,8].

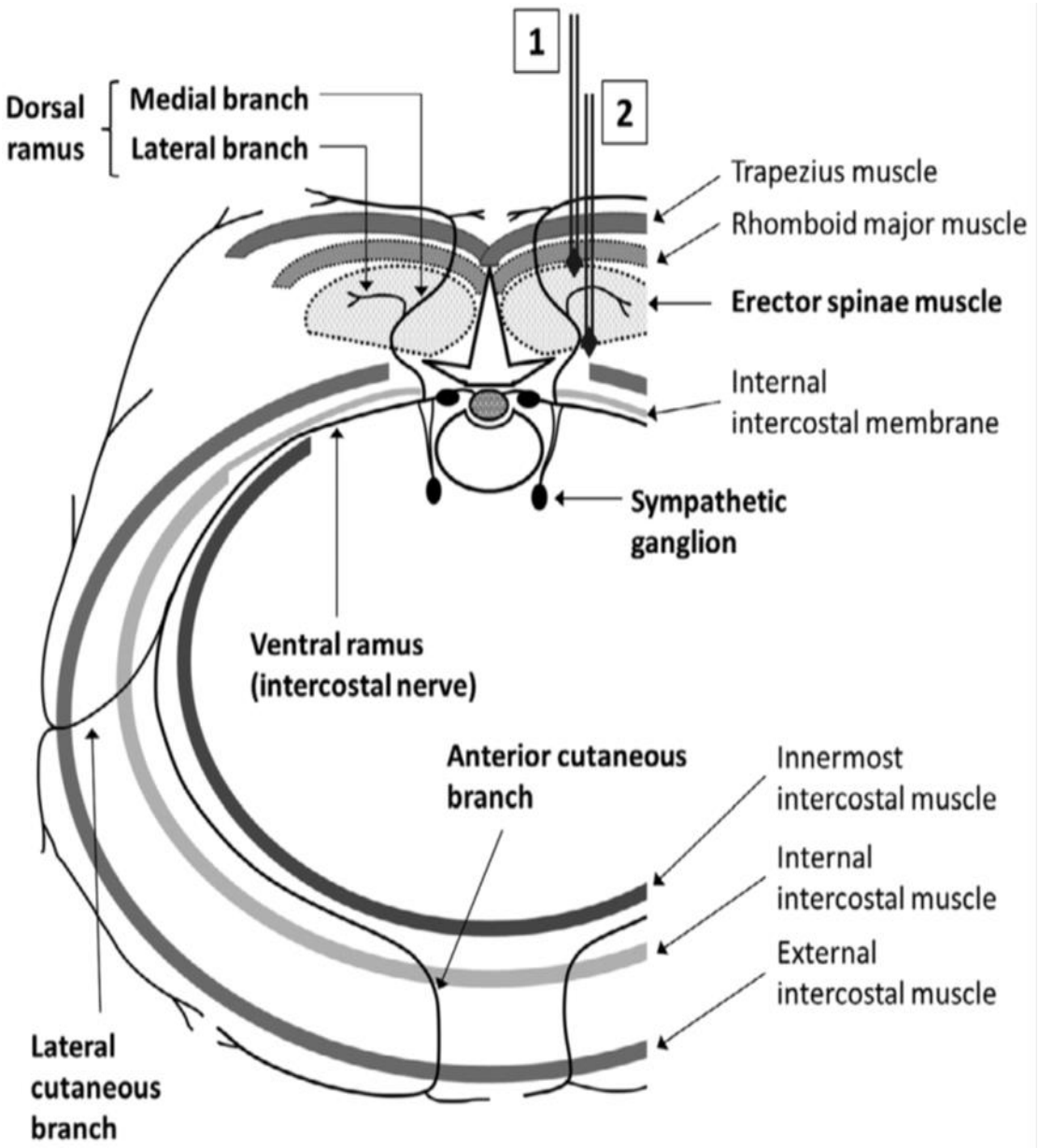
Thereby we started performing ESP block for postoperative pain control in thoracic and abdominal surgery, with very satisfactory results so far. The block appears to be sufficient for postoperative pain control and the complications are yet to be seen. The results of our previous study show that ESP block is superior to pectoralis and serratus blocks—also used in thoracic surgery—in regard for a larger area of analgesia, easier injection, and longer duration. Also, it offers better safety profile than neuraxial analgesia or the thoracic paravertebral block [7].

The current literature suggests that ESP block is an excellent adjuvant to multi-modal analgesia not just for thoracic, but for abdominal surgery as well.

It is an ultrasound guided interfacial block, achieved by injecting the local anesthetic solution between the transverse process and the erector spinae muscles (iliocostalis, longissimus, and spinalis). It can be performed either as a single shot or as a continuous catheter technique. The local anesthetic spreads in a caudal and cephalic direction while crossing the internal intercostal membrane and blocking dorsal and ventral rami of the spinal nerves. Anatomical and radiological investigations in fresh cadavers have indicated the probability of such mechanism of action [7,9].

The ESP block produces an extensive multidermatomal block, both somatic and sympathetic. A great advantage of the ESP block appears to be the provision of both somatic and visceral analgesia [7].

The Erector Spinae Plane Block holds promise as a simple and safe technique for thoracic and abdominal analgesia in both chronic neuropathic pain as well as acute postsurgical or posttraumatic pain.



1 - Injection above the erector muscle results in less segmental spread.

2 - The correct injection site i.e. below the erector spinae muscle.

Comparison of both techniques:

In thoracic surgery, both the Erector Spinae Plane (ESP) block and the Thoracic Paravertebral Block (TPVB) are utilized for analgesia.

Erector Spinae Plane (ESP) Block:

Advantages:

•Technical Simplicity: The ESP block is generally easier to perform due to its superficial anatomical location, making it more accessible, especially for practitioners less experienced with deeper blocks.

•Safety Profile: There's a reduced risk of complications such as pneumothorax because the injection site is farther from the pleura and major vascular structures.

•Analgesic Efficacy: Studies suggest that ESP blocks provide effective analgesia for thoracic surgeries, with benefits comparable to TPVB when a similar number of injections are administered.

Disadvantages:

•Potentially Limited Analgesic Coverage: While effective, the ESP block may not provide as extensive analgesic coverage as TPVB in some cases, potentially necessitating additional analgesic measures.

•Limited Long-Term Data: As a relatively newer technique, long-term efficacy and safety data are less comprehensive compared to TPVB.

Thoracic Paravertebral Block (TPVB):

Advantages:

•Established Efficacy: TPVB has a long-standing history of providing reliable analgesia for thoracic surgeries, with well-documented outcomes.

•Comprehensive Analgesia: It offers effective unilateral analgesia, which can be advantageous for procedures involving one side of the thorax.

Disadvantages:

•Technical Complexity: TPVB requires a higher degree of technical skill due to the proximity to the pleura and neurovascular structures, increasing the risk of complications.

•Risk of Complications: There's a higher potential for adverse events such as pneumothorax, vascular puncture, and hypotension.

In summary, both ESP and TPVB are effective for analgesia in thoracic surgery. The choice between them should be guided by patient-specific factors, surgical requirements, and the clinician's expertise with each technique.

5.3 Drug Description:

Ropivacaine is an amide-type local anesthetic most commonly used for local or regional anesthesia during surgery and for short-term management of acute pain**.**

Mechanism of Action

Local anesthetics prevent generation/conduction of nerve impulses by reducing sodium permeability & increasing action potential threshold.

Pharmacokinetics

Duration: 3-15 hr.; dose and route dependent; the greater the degree of vasodilation produced by the local anesthetic, the faster the rate of absorption & shorter the duration of action, Onset of action: 3-15 min.

This drug most common used for Regional anesthesia because his safety profile compere to Bupivacaine and accessibility of formulation (100ml – 0.2% solution).

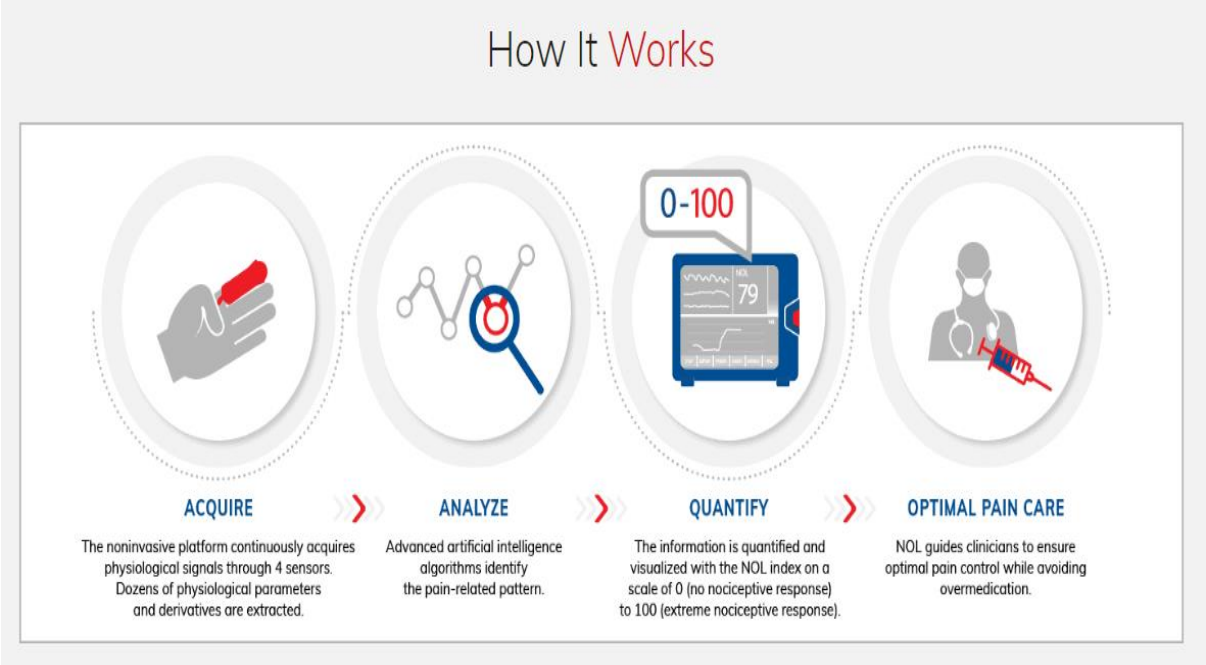
The usual dose for PVB/ESP block range between 15-20 ml 0.2% in bolus, and when used for continues infusion 5-6ml/hr. depend of body weight. [7,8].

In our trail we will use intermittent bolus of **15ml-0.2% Ropivacaine (30mg)** with interval of 6 hours between infusions (overall 4 boluses per 24hr) as accepted in acute pain protocol of Soroka Medical Center.

Intraoperative pain perception:

One of the main difficult problem that anesthesia provider face in the intraoperative setting is pain management in unconsciousness patient, because lack of patients subjective pain level interpretation, the anesthesia provider will manage pain mostly on objective data like heart rare, blood pressure and physiological respond to surgical stimulation, this can result in opioid over- or under dose with it side effect profile. We will use new FDA approved artificial intelligent device - NOL (Nociception Level) that helps in pain interpretation in anesthetized patient [20].

NOL is based on a proprietary, patented artificial intelligence technology that quantifies the individual physiological response to pain in real-time, continuously and noninvasively. Activation of the sympathetic nervous system, as a result of multiple stimuli and inputs, leads to a constellation of nociception-related physiological responses, with complex inter-associations and different response profiles. Recognizing the complex nature of this process, the Nociception Level (NOL) index was developed as a multiparameter composite of autonomic signals [20].



6. Study protocol

- Patient's recruitment and informed consent will be obtained at the pre-operational examination that performed 24hr before surgery.
- Study investigators will explain the goals of the study and the study protocol, possible complications, adverse effects and will obtain informed consent.
- Patients who are involved in the study will be divided into 2 groups randomly for this purpose we will use **randomization.com website**, that randomly assigned patients into 2 groups, each group will include **30** patients (overall 60 patients).
- Patients who are involved in the study will be divided randomly into 2 groups: **group I** will include all the patients that undergoing continues paravertebral block, **group II** will include the patients that undergoing continues ESP block.
- Hand hygiene and personal protective equipment (PPE) will be performed (washing hands, use of alcohol-based washing soap and running water, mask, scrub cap, sterile gown, and gloves). We will cover the ultrasound probe with a sterile cover.

NOTE: All invasive manipulations will be performed in sterile conditions.

- The patient will be placed in a supine position, be given 100 percent oxygen for preoxygenation, and connected to the monitoring machine (ECG, pulse oximetry, non-invasive blood pressure).
- General anesthesia: The anesthesia will be delivered by using a standard technique for thoracic patients: midazolam 0.5-1 mg/kg, fentanyl 10-100 mcg/kg, rocuronium 1.2mg /kg, anesthesia will be maintained with isoflurane 2 MAC.
- After intubation and verification of tube position, the patient turns to lateral position .

NOTE: Ultrasonography will be performed by using ultrasound Sonosite V (USA) with a linear probe (8-13 MHz).

- We use ultrasound guided technique for identification of Paravertebral and ESP spaces as gold standard for our technique in combination with loss of resistance technique for PVB.

- A 22-gauge Sonoflex needle (Pajunk,Germany) will be utilized for paravertebral at discharge.block in in-plane technique.

- Verification of needle insertion will be performed by ultrasound, the catheter will be inserted with needle-through-catheter technic, and the correct position will be identified by US again, the catheter will be left in place for 5-7 days based on patient overall status (VAS Score, ambulation, complication, home discharge readiness) and all the patients will get intra- and postoperative analgesia with continuous injection through block catheter in the surgical department.
- After verification the correct position we inject local anesthetics (ROPIVACAINE 0.2%-20 ml) without adjuvants in both groups.
- During the operation vital signs, hemodynamics respond we be monitored, in addition to that we will monitor pain scales with NOL (Nociception Level) technology that objectively quantify a patient's physiological pain response in score of 0 to 100, when 100 is maximal pain nociceptive respond and 0 is no pain.

- At the end of surgery, the patient will be awake, full consciousness, extubated and transferred to the postoperative care room, the vital sings and pain level will be continuously monitored.

- During the postoperative period stay the pain level of each patient will be assessed by of Visual Analog Score of pain (VAS: 0-10, 0= no pain, 10 = worst pain with picture of face) interviewing the patient every 60 minutes from the patient's admission from operation room and thereafter every 1 – 4 -8 -12 -24 -48 - 72 hours,
- For a more accurate assessment of pain, we also will check the level of pain before surgery.
- "Research" will be written on all patient's sheets.
- A postoperative pain is routinely will be managed by 5-10 mg of intravenous morphine to achieve a VAS scale of none or mild pain (the dose we be recorded) . We will also continue to record events of postoperative nausea and vomiting (PONV) within 24 hours after procedure. Recording of urinary retention, constipation, opioid requirements, itching will be done.

7. Schedule of events

Testing	Pre-surgery clinic	Surgical department (pre-op)	Operation department	Surgical department (post-op)
IRB Authorization				
Inclusion/Exclusion Criteria	X			
Demographics and Medical History	X	X		
Pre-hospitalization medications	X	X		
Clinical Assessment & Physical Exam	X	X		
General anesthesia			X	
Ultrasound Block			X	
Estimations of postoperative period				X
Pain assessment				X

8. Baseline procedure

8.1. *In the surgery department:*

After enrollment of subjects according to the inclusion and exclusion criteria the following will be done:

- Explanation and obtaining patient informed consent for participation in the study.
- Clinical assessment and physical examination.

Recording of basic parameters, such as heart rate, body temperature, oxygen saturation and blood pressure , check the level of pain before surgery.

8.2. *At the operating room*

- Lines insertion, Double–lumen tube intubation, and any complications will be recorded and precisely documented.
- Regional block will be done under ultrasound guidance and recorded in every case.

8.3. *Postoperative PACU and surgical department*

- Close observation for appearance of pain and immediately treatment
- Recordings of each parameter of hemodynamic state, new complications during hospitalization in cardiothoracic department and PACU

8.4. *After discharge:*

- Recording of all patients' complications that occurred during the follow-up period.
- Length of hospitalization

9. Data collection

For data collection the following programs, such as MetaVision® Clinical Information System (iMDsoft®, Israel), Chameleon Computerized Systems with the aim of retrieving demographic and clinical data during hospital stay will be used.

9.1 The following variables will be collected:

1. Dates: Duration of operation, Duration of hospital stay
2. Demographics: Age, gender, weight ,diagnosis, type of operation, comorbidities
3. Cardiovascular and respiratory system vital signs :BP , HR ,SatO2 , RR
4 .Recording of VAS (visual analog score of pain), Postoperative nausea and vomiting (PONV) events, post operation respiratory complication (desaturation events, reintubation,) urinary output, drainage timing and secretions
5. Complications' records

10. Outcomes

10.1. ***The primary outcomes are:***

1. Comparison Visual Analog Score and patient satisfaction between two groups.

2. Total morphine in the PACU and opioid consumption (equivalent to morphine dose in mg) until home discharge.

3. Side effect profile in every group.

10.2. ***Secondary outcomes:***

- Interventional complications
- Non-interventional complications
- Intraoperative time consumption until catheter placement (block done).
- Length of hospital stay

11. Statistical analysis

Study Power and Sample Size

Sample size was calculated based on primary outcome. The sample size calculation is based on a study by Turhan et al. [21], which compared the VAS pain score between paravertebral block and ESP block in thoracoscopic surgeries. In the study, VAS at the first postoperative hour was 3±1.3 and 4±1.4 in groups paravertebral block and ESP block, respectively. Based on this data, and with a power of 80% and alpha of 5%, the required sample size is 58 (29 patients in each group).

The sample size calculation was conducted using WinPepi software, version 11.65.

Statistical Analysis

Descriptive statistics

Each variable will be presented by the most suitable central and dispersion measures. Dichotomous and nominal variables (e.g, gender, comorbidities) will be presented by mode (%). Numerical (continuous) variables (e.g, age, BMI) will be described by mean±SD. Numerical (count) variables (e.g, number of hospitalization days) will be described by median and inter-quartile range (IQR). If needed, further graphical representation will be included.

Univariate analysis

Initially, we aim to conduct a comparative analysis of two patient groups, namely those with a paravertebral block and those with ESP block, with the purpose of delineating the characteristics of each group. This analysis will be conducted using appropriate statistical methods: Chi-square test for nominal variables, T-test for continuous variables with a normal distribution and Mann-Whitney test for count variables or continuous variables without a normal distribution.

Following the study's primary objectives, we will proceed to investigate the difference in VAS score and opioid consumption between the two study groups. Given the assumption of non-normal distribution of these variables, this comparison will first be conducted through univariate analysis, utilizing Mann-Whitney test, with subsequent analysis conducted using multivariate techniques, as outlined in detail below.

Multivariable analysis

Multivariate analysis will be conducted using Ordinal regression to examine the primary outcome – VAS, categorized into three levels of severity: mild, moderate, and severe pain. The analysis will include variables that were found statistically significant in the univariate analysis, as well as variables that are considered clinically important. Additional analyses will be conducted using logistic regression and linear regression for nominal (e.g, Interventional complications) or continuous (e.g., total opioid consumption) dependent variables, respectively. Variables that were associated with the dependent variables in the univariate analysis ($p<0.1$) will be considered potential confounders and their association with the main independent variables will be assessed. Those variables that exhibit a significant association with the dependent and independent variables will be further examined and adjusted for in the multivariate analysis. Additionally, possible interactions among the independent variables will be tested. We will also assess for collinearity between the independent variables using Pearson/Spearman correlation, and only variables with an R-value less than 0.7 will be considered for regression. Finally, several models will be created, and appropriate model fit tests will be used to assess their quality, ultimately selecting the most suitable model.

All statistical analyses will be conducted using SPSS Statistics V. 25, and a two-sided test significance level of 0.05 will be used for the entire study.

Table 1: Characteristics of the study population

Variable	Patients with paravertebral block (N=30)	Patients with ESP block (N=30)	p-value	Univariable test
Age, Mean±SD				T- test
Gender, N (%)				Chi-Square
BMI, Mean±SD				T- test
Comorbidities				
Diabetes mellitus, N (%)				Chi-Square

Peripheral vascular disease, N (%)				Chi-Square
Clinical outcomes				
VAS, Median (IQR)				Mann-Whitney
Total opioid consumption, Mean±SD				Mann-Whitney

Table 2: Co-linearity estimation between independent variables

	Age	Gender	BMI	Diabetes mellitus
Age	1			
Gender		1		
BMI			1	
Diabetes mellitus				1

Variable	Adj OR	95% CI	P-value	Model quality			
				-2LL	Omnibus test	Hosmer and Lemeshow test	AUC
Age							
Gender							
BMI							
Diabetes mellitus							
Block type							

Table 3: Model of ordinal regression

11. Participating Investigators

Unit	Investigator	Contact info
Soroka Medical Center Anesthesia and Intensive Care Unit	Alexander Smirnov	0503901110
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Soroka Medical Center Thoracic surgical Department	Yeal Rafaeli	0506264887
Soroka Medical Center Anesthesia and Intensive Care Unit	Michael Semyonov	08-6400262 0508260283
Soroka Medical Center Anesthesia and Intensive Care Unit	Avia Ashur	052-4897134

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21. Thoracic Paravertebral Block Achieves Better Pain Control than Erector Spinae Plane Block and Intercostal Nerve Block in Thoracoscopic Surgery: A Randomized Study : Özlem TURHANa,*; MD, Nükhet SİVRİKOZa; MD, Zerrin SUNGURa; MD Prof, Salih