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Impact of low thoracic paravertebral block on intraoperative remifentanil consumption

Submission date 10/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/11/2025	**Overall study status** Ongoing	
Last Edited 18/11/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Multimodal analgesia is the preferred approach for pain management after surgery. It aims to minimize the side effects associated with opioid medication while optimizing recovery after surgery. Integrating regional anesthesia techniques such as blocks is a fundamental component of multimodal analgesia strategies.

The paravertebral block is a technique that provides pain relief on one side of the body. Local anesthetic are injected in the paravertebral space where the nerves emerge from the spine. The thoracic paravertebral block is widely used in cardiothoracic surgeries and breast surgeries, but is less for surgeries in the abdomen. Two blocks (one on each side) will cover the whole abdomen for optimal pain relief.

Analgesia for laparoscopic surgeries is often underrated since the approach is done through a minimally invasive technique. However, pain can be moderate to severe and can lead to longer lengths of stay in the hospital or even prevent the patient from being discharged on the same day of surgery. Bilateral low thoracic paravertebral blocks (T10-T12) can provide excellent analgesia for abdominal pain. The same blocks also have fewer side effects, such as postoperative nausea and vomiting (PONV) and thus might even allow the patient to leave the hospital sooner.

This study aims to demonstrate a reduction in remifentanil (a short-acting opioid used for general anesthesia) consumption in the group with paravertebral blocks. It is hypothesized that patients in the paravertebral block group will require less intraoperative remifentanil to maintain the pain monitoring device (NOL index) within the pre-established range. In the recovery room, lower pain scores and reduced opioid consumption are anticipated.

Who can participate?
Adult patients aged 18 years old to 80 years old undergoing a laparoscopic surgery in the abdomen.

What does the study involve?
This study involves comparing the use of the paravertebral block to a standard pain control

regimen for patients undergoing a laparoscopic surgery of the abdomen. Thirty participants will be included to receive 2 paravertebral blocks, one on each side of the spine at a low thoracic level, approximately at the middle of the back, more specifically at the level of the T10 vertebrae. The block will be performed before the surgery and also before the induction of general anesthesia.

The group with the standard regimen will be recruited through 2 other research projects that are currently including patients at our center. Using a control group through multiple research projects will help us conclude the project faster, to get faster results while using fewer research resources that are usually very limited.

The research team will compare many variables during surgery, such as blood pressure, cardiac frequency, and NOL values (a monitor that measures pain levels during anesthesia). The same vital signs values will be compared in the recovery room, as well as the need for pain medication in the recovery room and the amount of time participants will spend in the recovery room and in the day surgery unit before they are discharged home.

What are the possible benefits and risks of participating?
The research protocol, per se, other than the paravertebral block, carries no other extra risk for the participant.

The possible risks of participating in this study are the same as receiving general anesthesia, as well as the risks inherent in the block procedure. The risks of a paravertebral block include infection or bleeding at the site of the block, perforation of the lung envelope (pneumothorax 0.01% per level blocked), as well as a very low risk of allergy to the anesthetic used in the block. A vaso-vagal reaction could also happen as a result of the block, as with any other medical procedure.

Where is the study run from?
The study will be run in a tertiary university hospital center in Montreal, Quebec, Canada, Hopital Maisonneuve-Rosemont, CIUSSS de l'Est-de-l'Île-de-Montréal.

When is the study starting and how long is it expected to run for?
Jaunary 2026 to March 2027

Who is funding the study?
The Department of Anesthesiology of the CIUSSS de l'Est-de-l'Île-de-Montréal, Canada.

Who is the main contact?
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2. Mrs Nadia Godin (Research Nurse), ngodin.hmr@ssss.gouv.qc.ca

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Additional identifiers

Study information

Scientific Title
Impact of low thoracic paravertebral block on intraoperative remifentanil consumption in patients undergoing abdominal laparoscopic surgery: a prospective historical cohort trial

Study objectives
The primary objective of this study is to evaluate the impact of a low thoracic paravertebral block on intraoperative remifentanil administration, based on NOL-guided nociception management in patients undergoing abdominal surgery under general anesthesia.

The secondary objectives aim to evaluate the hemodynamic impact in patients receiving a low thoracic paravertebral block as well as pain scores, adverse effects, and the post-anesthesia care unit (PACU) length of stay.

More specifically, we aim to :
1. Compare the mean intraoperative blood pressure and heart rate
2. Compare intraoperative episodes of high blood pressure/low blood pressure and tachy or bradycardia
a) High blood pressure defined as + 20% of the patient's baseline
b) Low blood pressure defined as – 20% of the patient's baseline

c) Tachycardia over 100 bpm / bradycardia under 45 bpm
3. Compare requirements of rescue medications to maintain BP and HR within the limits previously described.
4. Compare intraoperative NOL index
5. Compare postoperative morphine equivalent consumption in the PACU
6. Compare pain scores using the visual analogue scale from arrival to discharge from PACU
7. Compare adverse events in PACU: hypotension, bradycardia, PONV
8. Compare length of stay in PACU
9. Compare time from end of surgery to extubation
10. Compare total propofol consumption throughout the surgery in mg.kg -1.h -1
11. Compare Quality of recovery (QoR) index 24h post-op
12. Compare pain scores using the numeric rating scale (NRS) 24h post-op

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/09/2025, Research Ethics Committee of the CIUSSS de l'Est-de-l'Île-de-Montréal (5415 boulevard de l'Assomption, Montreal, H2V 2Z2, Canada; +1 514-252-3400; cer.cemtl@ssss.gouv.qc.ca), ref: 2026-4115

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Historical

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Analgesia for patients undergoing extensive abdominal laparoscopic surgeries

Interventions
The study design is a prospective interventional trial compared to a historical cohort, conducted in a single center. The historical cohort will be constituted of patients recruited in the control groups of one study already underway in our center (ESMONOL) as well as another study that should start recruitment shortly (DEXREM).

Intervention: In the intervention group, an ultrasound-guided low thoracic paravertebral block will be performed at the lowest level that provides favorable ultrasound imaging between T10 and T12 before the procedure. A maximum dose of ropivacaine 0,5%, 20 mL per side will be used. For patients with an ideal body weight lower than 70 kg, a total dose of 3 mg/kg of ropivacaine 0,5% will be used and split in half for each side. Remifentanil will be started at the induction of the general anesthesia.

The patient will be in a sitting position. Canadian anesthesia society monitors will be installed and an IV started before the block. The most favorable levels between T10 and T12 will be identified with ultrasound prior to starting the block. Midazolam 1-2 mg IV and fentanyl 50-100 mcg will be administered prior to the block. The blocks will be administered following a sterile procedure and using the parasagittal paravertebral ultrasound-guided block technique. A Pajunk 80 mm needle will be used for the blocks. Saline aliquots of 0,5 to 1 mL will be used to confirm the position of the needle in the correct paravertebral plane.

Once the optimal needle position is confirmed, the total one sided dose of ropivacaine will be administered in 5 mL increments with aspiration between each 5 mL. The same procedure will be repeated on the other side. Following usual paravertebral block practice, presence of sliding lung will be confirmed with ultrasound at the completion of both blocks.

In the SOC group, no block will be performed. The remifentanil infusion will be started at the time of induction. A bolus of IV lidocaine will be given during induction of anesthesia.

Anesthesia induction: All patients will receive 1g PO acetaminophen with 10mL of water prior to entering the operating room. Standardized general anesthesia (GA) protocol will be administered in both groups following these procedures: propofol induction with target controlled infusion (TCI) pump used with the Schnider model set to an effect-site concentration of 4 +/- 0.5 µg.ml -1, remifentanil with TCI pump and Minto model set to an effect-site concentration of 3ng.ml -1, rocuronium 0.8 mg.kg -1 of total body weight (TBW), and dexamethasone 4 mg. A bolus of lidocaine (1mg/kg IBW) will be administered to the patients in the control group only. Videolaryngoscopy (McGrath) and tracheal intubation will be done when TOF < 2/4 and remifentanil/Propofol TCI effect-site concentration (Ce) have reached their target. Once intubated, remifentanil infusion will be reduced to a Ce of 1ng.ml -1 and propofol infusion will be adjusted by 0.3 µg.ml -1 steps every 2 minutes to maintain a BIS value between 40 and 60. A no-touch period of 3 minutes will be observed.
Patient’s installation will then resume. This induction is part of a standard anesthesia and does not involve any research protocol. It is standardized to homogenize our population.

Anesthesia maintenance during surgery:
Nociception management: The remifentanil target-controlled infusion will be set at 3 ng.ml-1 prior to the surgical incision, and will be adjusted according to the NOL index. If the NOL index is > 25 for more than 1 min, we will increase remifentanil TCI by 0.5 ng.ml-1. This rate will be decreased by steps of 0.25 ng.ml-1 if the NOL index is < 10 for more than 3 min. The minimal remifentanil TCI concentration allowed in the protocol will be 1 ng ml-1, to ensure a minimal antinociception drug administration in case of inaccuracy of NOL Index in either group. Furthermore, in the event of a TAM > 120% of its basal level, and despite a NOL Index between 10 and 25, remifentanil will be increased.

Only the intervention and anesthesia maintenance sections above differ from the usual management of patients under general anesthesia.

In both groups, IV hydromorphone 0.006 mg.kg-1 and ondansetron 4 mg will be administered once pneumoperitoneum is deflated and skin suture is started. Remifentanil infusion will be stopped and removed at the start of wound dressing.

Hemodynamic management: Baseline mean arterial blood pressure (MAP) will be defined as the average of three consecutive values taken 1 min apart and determined before the induction of general anesthesia. Intravenous (IV) infusion of norepinephrine will be adjusted to maintain +/- 20% of the baseline values of the pre-anesthesia MAP. Balanced crystalloids will be administered to patients at a rate of 3 ml.kg-1.h-1 (ABW) throughout the surgery. Intravenous fluid boluses will be administered at the discretion of the anesthesiologist in charge. Perioperative blood management will be done according to guidelines.

Depth of anesthesia management: : The maintenance of anesthesia will rely on propofol perfused with a TCI pump to maintain a BIS index of 40-60. Propofol will be discontinued at the end of the final skin suture, and participants will be extubated in the operating room and transferred to the post-anesthesia care unit (PACU).

Neuromuscular blockade management: The TOF ratio will be maintained at 0/4 with repeated boluses of 0.1 à 0,2 mg.kg -1 rocuronium. The patient’s neuromuscular blockade will be reversed by sugammadex 2 mg.kg -1 to 4 mg.kg -1 (TBW) according to TOF response, to obtain T4/T1 ratio > 0.9.

Patient management in PACU: Patients will be transferred to the PACU, and as soon as sufficient contact is obtained by the PACU nurses the pain level will be assessed. Pain level (NRS) as well as all the postoperative criteria will be assessed at arrival in PACU and until time of readiness for discharge. According to standard practice, the attendant nurse will administer doses of 0.2 to 0.3 mg of IV hydromorphone every 5 min to obtain a pain score < 4 on a NRS.

24h follow-up
The patient will be contacted 24 hours after the surgical procedure to assess the quality of recovery using the Quality of Recovery (QoR) index and to evaluate pain intensity using the Numerical Rating Scale (NRS).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. The intraoperative amount of remifentanil in mcg.kg-1.h-1, administered between the first surgical incision and its discontinuation at the wound dressing measured using data collected from patient medical records at one timepoint

Key secondary outcome(s)
1. Mean intraoperative blood pressure and heart rate measured using an anesthesia monitor during the intraoperative period
2. Intraoperative episodes of high blood pressure, low blood pressure, tachycardia, and bradycardia measured using an anesthesia monitor during the intraoperative
3. Requirements of rescue medications to maintain blood pressure and heart rate within the limits previously described measured using the anesthesia record during the intraoperative period
4. Intraoperative nociception level (NOL) index measured using a NOL monitor during the intraoperative period

5. Time from the end of surgery to extubation measured using the anesthesia record at one timepoint at the end of surgery
6. Total propofol consumption throughout the surgery in $mg \cdot kg^{-1} \cdot h^{-1}$ measured using the anesthesia record during the intraoperative period
7. Postoperative morphine equivalent consumption measured using the medication record at post-anesthesia care unit (PACU) stay
8. Pain scores measured using the Visual Analogue Scale (VAS) at PACU stay from arrival to discharge
9. Adverse events in PACU: hypotension, bradycardia, PONV measured using PACU records at PACU stay
10. Length of stay in PACU measured using the PACU record at PACU stay
11. Quality of Recovery (QoR) index measured using the QoR questionnaire at 24h post-op
12. Pain scores measured using the numeric rating scale (NRS) at 24h post-op
13. Hospital length of stay measured using the hospital record at discharge

Completion date
18/03/2027

Eligibility

Key inclusion criteria
1. Patient from 18 to 80 years old
2. ASA 1-3
3. Laparoscopic surgery (including general surgery, gynecology, urology), a small abdominal incision (less than 5 cm) will be tolerated.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patient refusal
2. Chronic use of opioids

3. Allergy to medication used in the trial
4. Pregnant or breastfeeding women
5. Contraindications to dexmedetomidine
6. Bradycardia, arrythmia or pacemaker, severe ventricular dysfunction

Date of first enrolment
10/01/2026

Date of final enrolment
10/01/2027

Locations

Countries of recruitment
Canada

Study participating centre
Hopital Maisonneuve-Rosemont, CIUSSS de l'Est de l'Île de Montréal
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Sponsor information

Organisation
Integrated University Health and Social Services Centre of East Montreal Island

Funder(s)

Funder type
Not defined

Funder Name
Centre Intégré Universitaire de Santé et de Services Sociaux de l'est-de-L'île-de-Montréal

Results and Publications

Individual participant data (IPD) sharing plan

Data will be stored on a password-protected computer, which has been assigned to the PI by the CIUSSS de l'Est-de-l'Île-de-Montréal. The PI will maintain primary responsibility for this computer and the data it contains. The CIUSSS de l'Est-de-l'Île-de-Montréal's Department of Anesthesia research nurse, Nadia Godin, will manage access to the data.

Paper copies (consent form) of patient information will be stored in a locked file cabinet in a locked office in the Department of Anesthesiology.

Data are confidential. Data will be assigned a unique study code (P1, P2, and so on up until PX), and the codes will be linked to the participant's identities. The link will be kept separately from the data so that no patient can be identified in the event of loss or theft. Patients consent to this use of anonymized data and storage.

Only the PI and the co-investigators will have access to all the data during the study and study analysis. All records relating to this clinical trial will be retained for a period of 7 years.

Every person involved in this study will receive appropriate training and abide by confidentiality guidelines to protect the subject's privacy.

All Health Information Protection Act rules and regulations will be strictly followed.

IPD sharing plan summary

Stored in non-publicly available repository