Effect of Unilateral Ultrasound-Guided Subcostal Transversus Abdominis Plane Block in Patients Undergoing Laparoscopic Sleeve Gastrectomy
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Hypothesis: Laparoscopic sleeve gastrectomy patients who receive unilateral ultrasound-guided subcostal transversus abdominis plane (TAP) block will have decreased opioid consumption

Objectives

Primary Objective:

Compare amount of intravenous (IV) opioid consumption within 24-hour period amongst laparoscopic sleeve gastrectomy patients who receive the unilateral ultrasound-guided subcostal TAP block with bupivacaine to those who receive the block with only sterile saline.

Secondary Objectives:

a. Amount of intraoperative IV opioid consumption
b. Amount of post-operative IV opioid consumption
c. Severity of pain at rest using an 11-point numeric pain score Likert scale at 1, 6, 12 and 24-hour marks postoperatively
d. Time to breakthrough pain after surgery
e. Area of pain after surgery
f. Presence of postoperative nausea (yes/no) at 1, 6, 12 and 24-hour marks postoperatively
g. Time to ambulation after surgery
h. Analgesia satisfaction score at end of hospital stay
i. Hospital length of stay

Background

Over the last decade, there has been an increasing number of people undergoing bariatric surgeries, including laparoscopic sleeve gastrectomy. While these surgeries are performed laparoscopically, many patients still have considerable amounts of pain. The Enhanced Recovery After Surgery (ERAS) Society recommends a multimodal analgesic strategy for managing pain for laparoscopic sleeve gastrectomy patients so as to improve patient comfort, and minimize opioid consumption, thereby also reducing the complications associated with narcotic use, such as nausea, respiratory depression, and reduced bowel motility. However, there is currently no consensus as to the best pain management strategy for these patients. [1] Several different approaches to effective analgesic management for bariatric patients have been proposed. Studies comparing patient-controlled epidural to standard IV patient-controlled (PCA) opioid analgesia have been promising [2,3]. However, epidural placement in morbidly obese

individuals may be technically challenging. Furthermore, complications from epidural analgesia including hypotension, dural puncture, and spinal infection or injury can be catastrophic, limiting routine placement in patients undergoing bariatric surgery. Rectus sheath blocks have shown potential to reduce postoperative pain in patients undergoing upper abdominal surgeries, but no studies have evaluated its specific effects in laparoscopic bariatric surgery [4]. Local anesthetic infiltration into trocar sites have also been suggested, but so far has not been shown to reduce postoperative pain [5].

Recently, transversus abdominis plane (TAP) blocks has garnered attention due to the relative ease of placement and low risk for complications. [6] The goal of the TAP block is to deposit local anesthesia in the plane between the internal oblique and transversus abdominis muscles so as to anesthetize the anterior rami of the T7-L1 [7,8]. Studies have found that the classic TAP block, in which the needle enters at the lumbar triangle of Petit, provided analgesia only up to T10, making this block more suitable for lower abdominal surgeries [9,10], and less ideal for laparoscopic sleeve gastrectomy. Recent studies are now focusing on modified TAP blocks as a means to provide adequate perioperative analgesia for these patients [11,12]. Ibrahim et al. compared the effects of bilateral oblique subcostal TAP blocks, local anesthetic infiltration alone at port sites, and no block or infiltration; compared to the other two groups, patients receiving bilateral oblique subcostal TAP blocks had significantly lower pain scores postoperatively for patients undergoing laparoscopic sleeve gastrectomy surgeries [12]. Despite these positive results, oblique subcostal TAP blocks are harder to perform than the standard subcostal TAP block, requiring a longer ultrasound needle and larger volumes of local anesthetic [13]. Ari et al. also did not find any difference in pain scores between patients receiving bilateral subcostal TAP blocks to those receiving both bilateral subcostal and posterior TAP blocks [11].

Adequate perioperative analgesia is immensely important for bariatric patients, yet there is still no current consensus on optimal pain control. Regional anesthesia techniques are showing promising results. We propose that a unilateral subcostal TAP block, which is easy to perform with minimal risks to patients, may help in minimizing pain and nausea for patients undergoing laparoscopic sleeve gastrectomy.

Eligibility Criteria

Inclusion Criteria:

- Adults 18-80 years old
- Candidate for general anesthesia
- Undergoing laparoscopic sleeve gastrectomy
- Patients of participating surgeons

Exclusion Criteria:

- Prior bariatric surgery of any kind

- Previous abdominoplasty
- Allergy or intolerance to one of the study medications
- ASA $\geq$ 4
- Chronic opioid use (taking opioids for longer than 3 months or daily oral morphine equivalent of >5mg/day for one month)
- History of alcohol/drug abuse
- History of hepatic or renal insufficiency
- Patient refusal
- Patients who do not speak English

Other Aspects that Could Increase Subjects' Vulnerability
Patients undergoing surgical procedures often have anxiety with surgery. Anesthesiologists will treat this perioperatively with medications and reassurance.

Safeguards to Protect Subjects' Rights and Welfare
Perioperative anxiety will be treated by reassurance and medications as per standard of care. Regardless of participation in the study, patients will undergo their scheduled surgery. Patients will be provided contact information on the consent form in case of any rising concerns or suggestions. Researches will ensure that protected health information be kept safe and confidential.

Duration of Participation
Individual participation in this study will conclude following discharge from the hospital after laparoscopic gastrectomy surgery. Duration of participation will depend on the length of hospitalization. Typical duration of stay for this type of surgery is usually 1--3 days.

Procedures for Subjects to Request Withdrawal
Patients may withdraw from the study at any point in the investigation. Patients will be provided with contact information and must withdraw in writing. Should this decision be made prior to the procedure, the patient will undergo the surgery as per current standard of care; they will not be included in the experimental protocol. If they choose to withdraw following surgery, post-operative data collection will stop. Regardless of decision to withdraw from the study, subjects will receive current standard of care. Collected PHI will be destroyed at the time of withdrawal.

Procedures for Investigators to Withdraw Subjects
The patient will be informed if they need to be withdrawn from the study. Should this decision be made prior to the procedure, the patient will undergo the surgery as per current standard of care; they will not be included in the experimental protocol. If this is decided following surgery, post-operative data collection will stop. Regardless, subjects will receive current standard of care. Collected PHI will be destroyed at the time of withdrawal.

How Participants will be Identified

Patients scheduled for laparoscopic gastrectomy procedure with Dr. Scott Nguyen and Dr. Edwards Chin will be identified at at their preoperative surgical visit. The surgery team will discuss the study and provide written information/consent for the patient to review. Approximately 1 week prior to the surgery, a member of the research team will call the patient to discuss the study further and address any additional questions or concerns. They will also discuss the study in detail, confirm understanding, and review the consent form with the patient. If the patient agrees to the procedure, they will sign the consent on the day of surgery in the GP2 preoperative waiting area or in the GP3 holding area.

How Research will be Introduced to Participants
At the pre-operative surgical visit, eligible patients will be introduced to the research by the surgical team. Approximately 1 week prior to the surgery, a member of the research team will call the patient to discuss the study further and address any additional questions or concerns. They will also discuss the study in detail, confirm understanding, and review the consent form with the patient.

How Participants will be Screened
At the pre-operative surgical clinic visit, patients will be screened for eligibility based on stated inclusion and exclusion criteria. The patient will be screened again during the follow-up phone call made by a member of the research team approximately one week before the scheduled surgery.

Risk to Subjects
Complications for TAP blocks and its variants, including the subcostal TAP block, are rare. Incorrect needle advancement through the peritoneum may result in injuries to organs such as to the stomach or bowel perforation. Other complications include hematoma, infection and local anesthetic toxicity.

Description of Procedures Taken to Lessen the Probability or Magnitude of Risks
To minimize risk, ultrasound guidance will be used for all subcostal TAP blocks. Slow injection of local anesthetic with intermittent aspiration will help reduce the risk of inadvertent vascular injection of local anesthetic. Patients will be monitored in accordance to the standards of the American Society of Anesthesiologists during the entirety of the surgery. Following the surgery, they will be monitored in the post-anesthesia care unit.

Provisions for Research Related Harm/Injury
Patients will be provided with a phone number to call for any concerns related to surgery, anesthesia or the study. Should any complication requiring medical attention arise, patients will be instructed to return to the hospital. Subjects injured as a result of the this study will be treated, with the costs billed to them and/or their insurance company. Patients will not be compensated for research related injury.

Expected Direct Benefit to Subjects

Patients who receive a subcostal TAP block may experience less postoperative pain. This may possibly lead to lower opioid consumption, and thereby, result in fewer side effects related to opioid consumption.

Benefit to Society
Subcostal TAP blocks may be incorporated into an Enhanced Recovery after Surgery protocol for laparoscopic gastrectomies should this study show decreased opioid consumption and improved outcomes with this truncal nerve block.

Provisions to Protect the Privacy Interests of Subjects
De-identified data will be stored on secure, password-protected servers maintained by the Mount Sinai Information Technology department. Access to the data will only be available to Mount Sinai IT administrators and the study investigators. A one-way hash ID will be generated for each record once the de-identified data set is released for analysis. Only the study investigators with access to the full data set will be able to match the hash ID to the original record. All investigators must have completed the HIPAA training pertaining to PHI confidentiality.

Economic Impact on Subjects
There is no additional cost to subjects for participating in this study. There is no compensation for participants.

Description of Study Design
Patients who are eligible for this subject will be invited to participate. Written informed consent will be obtained from eligible volunteers for this study.

This study will be a double-blinded randomized control trial. Patients will be randomized into one of two groups. Patients in Group 1 will undergo general anesthesia with a post-induction, post-intubation, pre-procedural subcostal TAP block with 40 mL 0.25% bupivacaine on the ipsilateral side as the extraction site. Patients in Group 2 will undergo general anesthesia with a post-induction, post-intubation, pre-procedural subcostal TAP block with 40 mL sterile normal saline on the ipsilateral side as the extraction site. Investigators will be blinded to the randomization of these patients. Following performance of these blocks, patients will receive standard care for the surgery as well as during the postoperative recovery period. Data will be obtained from the EPIC electronic medical record, and from the anesthesia computer record. Patients will be asked postoperatively to assess items such as their nausea and pain scores. Patients will also be contacted by phone within 1-2 days of discharge to obtain analgesic satisfaction scores. This data will be collected on the Redcap server.

Description of Procedures being Performed
Group allocation and instructions on preparing the injectate solution for the subcostal TAP block will be included in a sealed envelope. On the day of the surgery, the group allocation will be

revealed to an anesthesiologist not involved with the research study. The anesthesiologist will prepare the solution to be used for the subcostal TAP block.

Standard ASA monitors will be applied to all patients. A preoperative intravenous line will be placed. Patients will undergo standard induction with IV propofol, fentanyl and rocuronium. All study patients will receive 1.5mcg/kg of IV fentanyl on induction. Following induction, a subcostal TAP block will be performed on the ipsilateral site as the extraction site. Patients will be positioned in the supine position. A linear ultrasound probe will be parallel to the lower margin of the rib cage. The rectus abdominis muscle, posterior rectus sheath, and transversus abdominis muscle are identified on the ultrasound. A block needle will be advanced using an in-plane approach from medial to lateral, targeting the fascial plane between the posterior rectus sheath and the transversus abdominis muscle. For group 1 patients, 40mL of 0.25% bupivacaine will be deposited in this fascial plane. For group 2 patients, 40mL of normal sterile saline will be used instead.

General anesthesia will be maintained with inhalational anesthetic gas. Boluses of fentanyl will be given to all patients for pain control as needed, regardless of which group they are assigned to. Patients will also receive muscle relaxants for surgical relaxation as needed. Standard intravenous antiemetics, 8mg ondansetron and 10mg dexamethasone, will be given at the end of the surgery prior to extubation, unless otherwise contraindicated. Surgeons will use local anesthetic to subcutaneously infiltrate the other port sites. Following extubation, patients will recover in the post-anesthesia care unit (PACU) and then to the general hospital floor. Patients will be given scheduled intravenous acetaminophen 1000 mg and ketorolac (30 mg), as well as PRN intravenous opioids, i.e. fentanyl, hydromorphone.

Description of the Source Records that Will be Used to Collect Data about Subjects
Data will be collected from computerized medical record charts including EPIC and Compurecords. Investigators will also ask subjects questions about items such as their pain, nausea, and satisfaction with analgesia care.

Description of Data that Will be Collected Including Long-Term Follow-Up
Data collected includes age, gender, BMI, ASA status, duration of surgery, total opioid use in PACU, total opioid consumption in 24 hours, severity of pain at rest on a Likert scale (0-10) and presence of postoperative nausea (yes/no) at 1 hour, 6 hours, 12 hours and 24 hours postoperatively, time to breakthrough pain after surgery, area of pain after surgery, time to ambulation after surgery, analgesia satisfaction score at time of discharge, and hospital length of stay.

Where and When Consent will be Obtained
Verbal consent will be obtained via telephone approximately 1-2 weeks prior to the surgery. Written consent will be obtained on the day of the surgery.

Waiting Period for Obtaining Consent

Patients will receive a written consent form to review at the time that their surgery is scheduled. Approximately 1-2 weeks prior to surgery, the patient will be contacted by an investigator to discuss the study in detail, answer all questions and confirm understanding. Subjects will provide verbal consent for the study via this telephone call. On the day of surgery, they will sign a written consent form.

Description of Health Information that will be Viewed, Recorded or Generated
The following data will be collected:

1. Amount of intraoperative IV opioid consumption
2. Amount of post-operative IV opioid consumption
3. Severity of pain at rest using an 11-point numeric pain score Likert scale at 1, 6, 12 and 24-hour marks postoperatively
4. Time to breakthrough pain after surgery
5. Area of pain after surgery
6. Presence of postoperative nausea (yes/no) at 1, 6, 12 and 24-hour marks postoperatively
7. Time to ambulation after surgery
8. Analgesia satisfaction score at time of discharge
9. Hospital length of stay

How PHI will be Protected from Improper Use or Disclosure
Only study investigators will have access to patient data. All research team members must have completed the institutional HIPAA certification. Extracted data will be stored on the Mount Sinai Redcap data server, which is stored in accordance to Mount Sinai research policies. A one-way hash ID will be generated for each record in order to de-identify the subjects. Only study investigators with access to the full data set will be able to match the hash ID to the original source. De-identified data will be given to a statistician employed by the Mount Sinai Department of Anesthesiology for analysis.

When and How PHI will be Destroyed
Following publication of this study, PHI will be destroyed. Digital encrypted files on the Mount Sinai network will be deleted permanently.

Description of PHI that will be Shared
Age, sex, BMI, ASA status will be shared. All other subject demographics such as name, MRN or date of birth will not be shared.

Justification for Sharing PHI
De-identified data will be given to a statistician employed by Mount Sinai Department of Anesthesiology for data analysis.

With Whom Directly PHI will be Shared

De-identified data will be given to a statistician employed by Mount Sinai Department of Anesthesiology for data analysis.

Location where Data will be Stored
Extracted data will be stored on the Mount Sinai Redcap data server, which is stored in accordance to Mount Sinai research policies.

Duration Data will be Stored
Data will be stored for the duration of the study until publication. Following publication, the data will be deleted permanently from the Mount Sinai network.

Steps that will be Taken to Secure the Data during Storage Use and Transmission
Encrypted and secured flash drives and Mount Sinai emails will be used for data transmission. All study data will be stored electronically in accordance to Mount Sinai Hospital policies.

Data analysis plan including any statistical procedures
Data analysis will be completed by a biostatistician employed by the Department of Anesthesiology.

Summary of Study Design

- Inclusion Criteria:
    - Adults 18-80 years old
    - Body mass index >27 and <45 kg/m^2
    - Candidate for general anesthesia
    - Undergoing laparoscopic sleeve gastrectomy
    - Patients of participating surgeons
- Exclusion Criteria:
    - Prior bariatric surgery of any kind
    - Previous abdominoplasty
    - Allergy or intolerance to one of the study medications
    - ASA ≥ 4
    - Chronic opioid use (taking opioids for longer than 3 months or daily oral morphine equivalent of >5mg/day for one month)
    - History of alcohol/drug abuse
    - History of hepatic or renal insufficiency
    - Patient refusal
    - Patients who do not speak English

- Eligible patients identified during surgery clinic → Phone call 1-2 weeks prior to surgery to discuss study, assess participation, and obtain verbal consent → Written consent obtained on day of surgery
- Group allocation information revealed to separate anesthesiologist on the day of surgery

- Intraoperative Management
    - Induction: propofol, rocuronium, lidocaine, 1.5mcg/kg fentanyl
    - Ipsilateral subcostal TAP block performed
    - Maintenance: sevoflurane, rocuronium as needed, fentanyl as needed
    - Prior to extubation: 8mg ondansetron and 10mg dexamethasone unless otherwise contraindicated
    - Surgeon will infiltrate other port sites with local anesthetic subcutaneously

- Following extubation, patients will receive opioids along with scheduled IV acetaminophen and ketorolac unless otherwise contraindicated

- Investigator or nurse will assess:
    - Pain at rest using 11-point numeric pain score Likert scale at 1, 6, 12 and 24-hour marks postoperatively
    - Presence of postoperative nausea (yes/no) at 1, 6, 12 and 24-hour marks postoperatively
    - Area of most pain after surgery (assessed on postoperative day 1)

    - Analgesia satisfaction score at time of discharge (assessed via telephone call within 1-2 days of discharge)
- Data from EPIC
    - Amount of post-operative IV opioid consumption
    - Time to breakthrough pain (time from surgery end to first requirement of IV opioid)
    - Time to ambulation after surgery
    - Hospital length of stay
- Data from Compurecord
    - Amount of intraoperative IV opioid consumption

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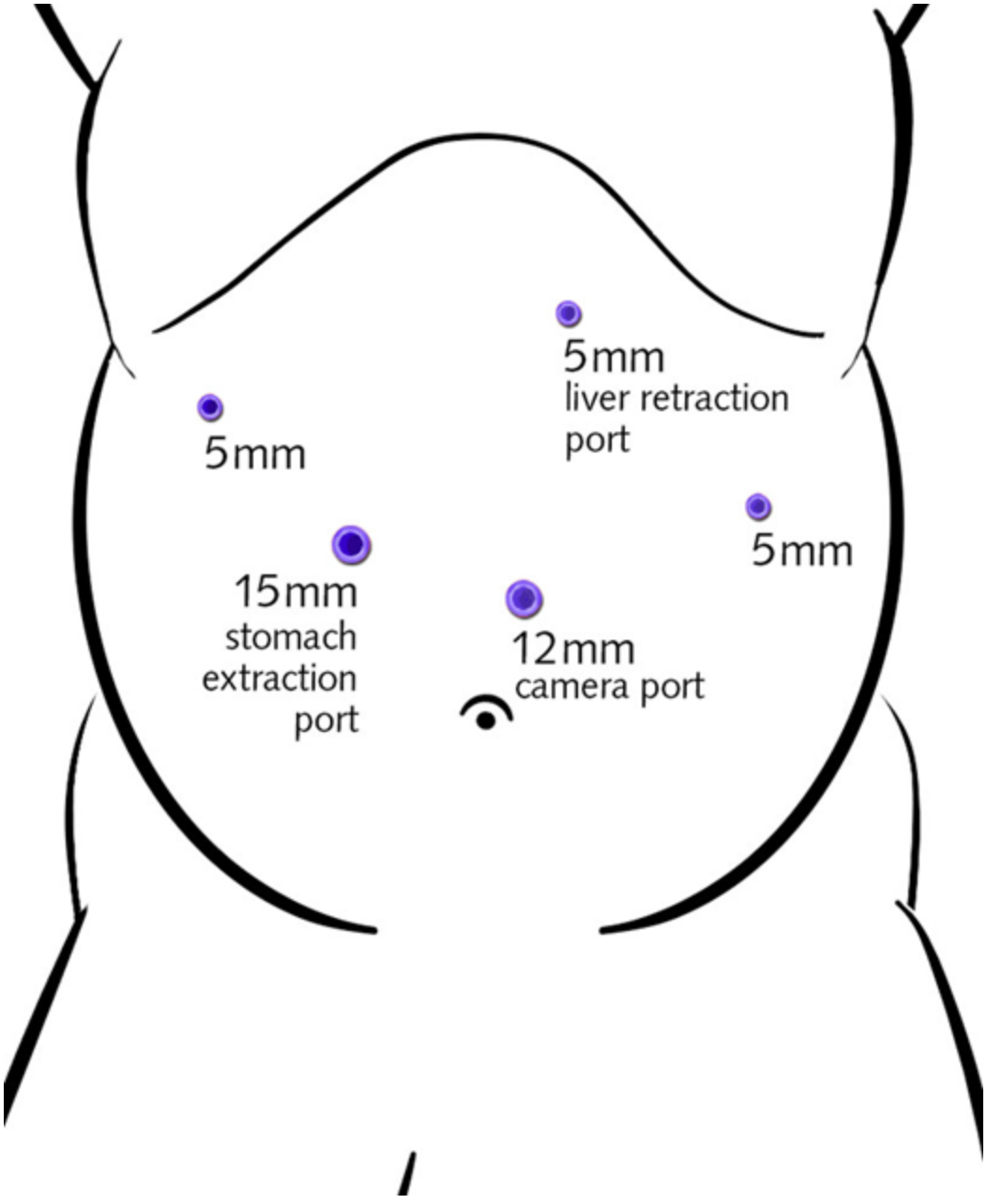
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