TITLE: Ultrasound guided posterior quadratus lumborum block for improved postoperative analgesia in minimally invasive gynecologic surgery

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INTRODUCTION

The overall decrease in morbidity associated with advances in minimally invasive surgery has transformed the concept of postoperative management, with lower complication rates, earlier mobilization, rapid postoperative recovery, and earlier discharge from the hospital. However, at times, laparoscopic surgery is associated with higher postoperative pain than traditional laparotomy in the immediate postoperative period; often requiring significantly higher doses of pain medication within the first 4 hours after surgery. In general, laparoscopic procedures could be associated with longer operative times; however, minimally invasive surgeons are presented with the most challenging patients- often morbidly obese, prior history of several surgical procedures in the abdomen and pelvis, and/or adhesive disease. Overall operative time is increased, including time under general anesthesia and amount of surgical dissection, which makes control of postoperative pain all the more problematic.

BACKGROUND AND SIGNIFICANCE

The challenge to achieve adequate analgesia has led to the development of directed, multi-modal protocols specific to management of post-laparoscopy pain in effort to decrease the amount of additional administration of narcotic medication. While several non-opioid regiments have been found to be effective, opioid medications still play a significant role in early postoperative analgesia. Given the adverse side effects of narcotic medications, regional blocks utilizing local anesthetic agents and has been shown to improve overall pain control in this time period.

Truncal abdominal nerve blocks are useful for pain control in abdominal and pelvic surgeries. More recently, the utilization of the quadratus lumborum (QL) block has effectively alleviated somatic and visceral pain in the upper and lower abdomen. The QL block provides analgesia spanning from the T4 to L1 dermatomal levels in the thoracolumbar plane to provide a broad sensory level analgesic effect. The approach involves injecting local anesthetic under ultrasound guidance into the plane posterior to the quadratus lumborum muscle and middle layer of thoracolumbar fascia.

Given the utility of the QL block in controlling somatic pain, this study aims to determine whether the QL block is an effective analgesic adjunct in the control of postoperative pain period, specifically with regards to patients undergoing laparoscopic gynecologic surgery.

STUDY OBJECTIVES

this study aims to determine whether the posterior QL blocks is an effective analgesic adjunct in the control of postoperative pain period, specifically with regards to patients undergoing laparoscopic gynecologic surgery.

HYPOTHESIS

The patients receiving QL blocks will have lower post-operative pain scores and will need less oral supplemental pain killers.

Subjects:

Women aged 18 to 65 presenting for scheduled laparoscopic or robotic total or supracervical hysterectomy for benign indication.

Eligibility Criteria:

Patient will be eligible for recruitment if between the ages of 18 to 65 scheduled to undergo laparoscopic or robotic total or supracervical hysterectomy for benign indications. Only surgery for benign pathology will be considered to enrollment. No Malignancy cases will be included.

Exclusion criteria:

1. History of adverse reaction or allergy to Bupivacaine or liposomal bupivacaine

2. Medical contraindication to placement of QL block.

3. Suspicion of possible reproductive cancer with contraindication of morcellation of uterine tissue.

4. Significant medical condition or laboratory result that in the opinion of the Investigator indicate an increased vulnerability to study subject which exposes the subject to an unreasonable risk as a result of participating.

5. Any clinically significant condition uncovered during the surgery, such as excessive bleeding or decompensation, that might render the subject medically unstable to continue the study or complicate the subject's intraoperative or postoperative course.

6. Pregnant patients

7. Less than 40Kg weight.

Design:

Prospective Cohort observational study. All patients that meet criteria for participation in this study will be screened: patients scheduled to undergo a laparoscopic hysterectomy for benign conditions by attending physicians in the division of Minimally Invasive Gynecologic Surgery. Based on surgeon's preference, and patient's consent, the patient is offered a QL block or not. Our aim is to follow the patient's pain scores post op and amount of oral pain medication used whether they received QL block or not. If the patient received the QL block then they will be considered part of the study arm. If the patient did not receive the QL block then they will be considered part of the control arm.

The QL block is best thought of as a volume or compartment block in that volumetric spread of LA along the fascial plane is associated with efficacy in blocking the thoracolumbar nerves between T7-L1. It can be reasonably assumed that this compartment is the same across patients and is not affected by the amount of subcutaneous or central fat present in the obese patient.

If a block is to be performed, the QL block will be performed using a 21G x 100mm Stimuplex needle under ultrasound guidance using a curvilinear probe. Subjects will be positioned in the semi-lateral position to facilitate access into the plane posterior to the quadratus lumborum muscle and middle layer of thoracolumbar fascia. The QL block will be administered via an in-plane approach and local anesthetic will be injected between the quadratus lumborum muscle and the middle layer of the thoracolumbar. The QL block will be in the operating room after induction prior to starting the scheduled surgical procedure. If the block is performed, it will include 20ml of 0.25% bupivacaine and 5ml of liposomal bupivacaine (Exparel) per side. The block will be done bilaterally therefore **a total** of 40ml of 0.25% bupivacaine and 10ml of liposomal bupivacaine (Exparel) will be administered.
Patients will be pre-medicated with Midazolam. Routine monitoring will be performed including electro-cardiography, non-invasive blood pressure monitoring, heart rate oxygen saturation and end-tidal carbon dioxide and capnograph will be performed. General anesthesia will be induced with Propofol 1-2 mg/kg and analgesia will be provided with Fentanyl 2 mcg/kg. General anesthesia will be maintained using the Sevoflurane titrated to effect as determined by the anesthesia team caring for the patient Rocuronium will be administered during the duration of the case to provide muscle relaxation for the duration of the procedure, with an induction dose of 0.6 mg/kg and titrated to 1-2 twitches assessed by continuous twitch monitor. Reversal of neuromuscular blockade will be achieved using 0.06 mg/kg of Neostigmine and 0.012mg/kg of Glycopyrrolate or 2mg/kg of sugamadex.

Possible allergic type reactions of receiving bupivacaine include urticaria, pruritis, erythema, angioedema, tachycardia, sneezing, nausea, vomiting, dizziness, and syncope. Overdosage or rapid absorption lead to systemic toxicity manifestation that need immediate counter measures related to the central nervous system and cardiovascular system. There is also risk of nerve injury given the location of the regional block. Routine precaution is taken by the surgical and anesthesia team to avoid overdosing. Any reactions or overdosing will be managed accordingly. The study will not alter the subjection to possible adverse reaction as this is an observational study.

Data Collection Procedures:

As this is an observational (prospective cohort) study, there will be no randomization or blinding done. We will be observing the patient's post op pain scores and amount of pain medication used

Postoperatively, patients will be transferred to the PACU for monitoring.
The amount, timing and type of additional pain medications necessary at 1 and 3 hours after surgery will be recorded. Pain levels will be documented at the same 1- and 3-hours intervals, and scored utilizing a 1-10 Numeric Rating Scale (NRS). The NRS is a verbal assessment, asking patients to quantify their pain on 1- 10 scale. It has previously been shown in studies to be a simple, valid alternative to the visual analog scale (VAS).

Study subjects will receive a telephone call 24 hours after surgery and asked about how much additional medication they have taken for pain control, as well as their pain level utilizing the same 1-10 NRS assessment.

Our primary outcome is difference in pain scores at 3 hours. Our secondary outcome is difference in pain scores, at 1 hour, 24 hours, difference in additional medication taken orally for pain control, and adverse effects if any.

Sociodemographic and clinical data of study subjects will also be obtained, including age, body mass index, history of abdominal and pelvic surgeries, history of pelvic adhesive diseases such as endometriosis, duration of surgery, and duration of stay postoperatively in PACU.

Data Analysis: the mean difference between pain scores at 1 hour, 3 hour, and 24 hour, and the difference in the amount of oral pain medication used will be assessed as below.

Expected Outcomes: Our study aims to show that patients receiving a preoperative QL block will have lower post-operative pain scores and will need less oral pain medication

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