The Role of Quadratus Lumborum Blocks Following Minimally Invasive Hysterectomy: A Blinded, Randomized Controlled Trial

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Protocol Title: The Role of Regional Blocks Following Minimally Invasive Hysterectomy: A blinded Randomized Controlled Trial

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Population: 76 female patients undergoing Minimally Invasive Hysterectomy

Number of sites: One site MHH-TMC

Study duration: 2 years

Subject duration: 6 weeks

General Information (PICO)
This is a single center double blind randomized controlled trial assessing the efficacy of the addition of anesthetic blocks in reducing systemic opiates use (PO and IV) and lowering pain scores when added to a standardized ERAS (Enhanced Recovery After Surgery) protocol bundle, in patients undergoing minimally invasive hysterectomy at MMH-TMC.
We seek to compare the efficacy of two interventions:

- Local anesthesia with sham QL block.
- Quadratus lumborum block (QL block) with sham local.

Both types of anesthetics options (local anesthetics and QL blocks) are used as usual care and depend on surgeon preference without strong evidence of efficacy.
Our main objective is to assess which intervention best improves the quality of recovery, reduces systemic opiates use (PO and IV) and lowers pain scores in patients undergoing minimally invasive hysterectomy at 24 hours.

Background Information

In 2017, the CDC reported 50,000 deaths related to Opioid overdose in the United States. Prescription opioids are involved in 40% of these deaths (1). Post-operative opioid prescriptions may contribute to this epidemic by increasing patients' risk of opioid dependency and overdose (2-7). Therefore, effective interventions are needed to address this problem, such as reducing opioid use intra-operatively and in the immediate postoperative period.

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Several adjuvant regional analgesic blocks have shown to effectively provide analgesia for surgery-associated pain following abdominal surgery (8).

However conflicting results have been found regarding their use in laparoscopy. Many clinical trials tested the TAP block (9-12) while others tested the QL block (13, 14). (15)

QL blocks have been proven to be effective in reducing morphine consumption after cesarean sections(16, 17), however this was not noted after laparoscopic colorectal surgery (18).

Conflicting results again have been demonstrated in a couple of RCTs after laparoscopic gynecologic surgery (19-25).

Results of an RCT including 120 patients undergoing cholecystectomy, demonstrated that TAP and QL blocks similarly reduced postoperative pain scores and analgesia consumption, with high patient satisfaction. However, subcostal TAP block could be considered preferable to QL block because it can be applied easily and in a shorter time (22).

The UT faculty at MHH usually offer QL blocks to patients presenting for minimally invasive hysterectomy while counseling about possible benefit in reducing pain during recovery. If a patient is not offered a QL blovk or declines, the surgeon will give local anesthetic at the port site.

While local anesthetic at the port site is given by the gynecologist, (QL) blocks are given by the regional anesthesia team. QL blocks are done under ultrasound guidance to improve efficacy and reduce complications.

Local anesthesia is given as per usual care: Each trocar site is infiltrated with 3 mL of the 0.25% marcaine in a diamond-shape pattern below and above the fascia.

The quadratus lumborum block (QL 2) is the newest modality, involves injection of local anesthesia in a fascial place formed partly by the posterior surface of the quadratus lumborum muscle.

It is described to cover many dermatomes (range from T4 to L1) with cephalad and posterior spread to provide both visceral and somatic analgesia likely due to paravertebral and possibly epidural spread and can last up to 24 hours (19-21). It is speculated that the use of QL block will reduce the use of systemic opiates within at least the first 24-36 hours.

Figure 1

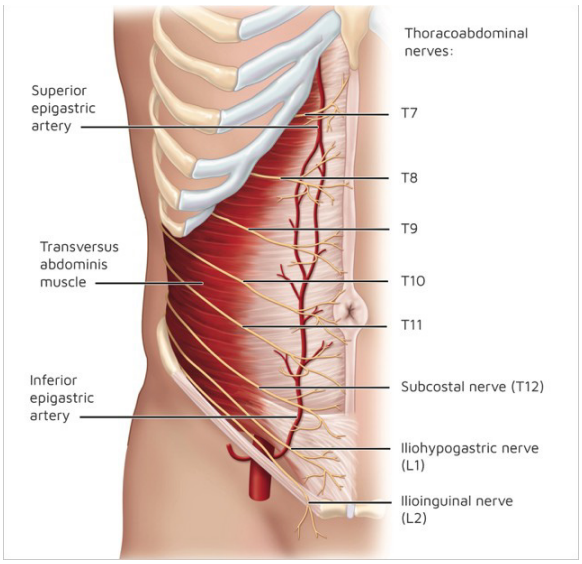
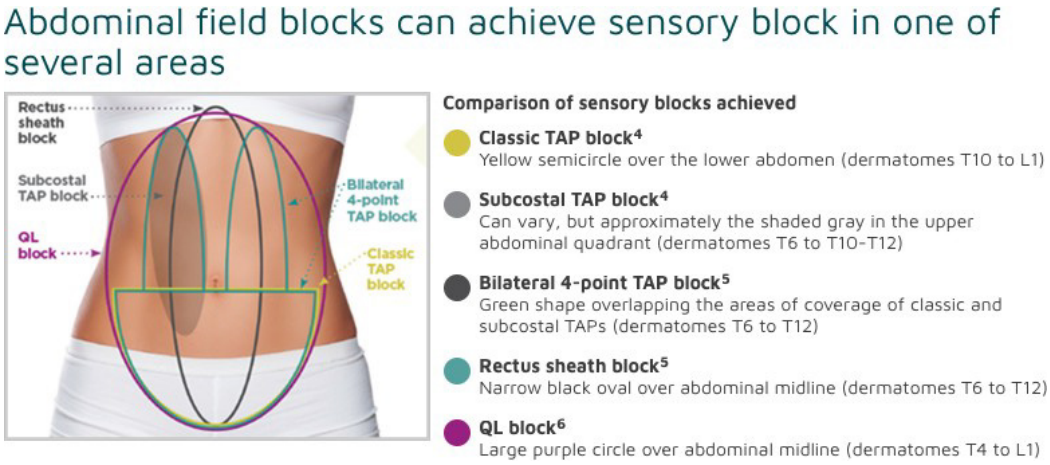


Figure 2



QL blocks however can take up operating room time, have to be performed by regional anesthesiologist and can add to the cost of the procedure. Evaluating the efficacy of these blocks in laparoscopy could change clinical practice in our institution.

Objectives

This study aims to compare quality of recovery as well as peri-operative systemic opiates use and pain scores in patients undergoing laparoscopic or robotic hysterectomy when local anesthetic versus Quadratus Lumborum nerve block (QL-2) is added to the standard pain management.

Primary Outcome measure:

For the primary outcome, we plan to Compare the Quality of Recovery (QOR-40) validated questionnaire scores between different arms

a. At 24 hours

The Quality of Recovery-40 (QoR-40) questionnaire measures the quality of recovery from anesthesia through five dimensions: physical comfort, physical independence, emotional state, psychological support, and pain. The validity, reliability, ease of use, responsiveness, and cross-cultural adaptation of QoR-40 have been previously confirmed and this questionnaire has been used successfully in several clinical trials. (27). (Appendix 1). This questionnaire takes 6.3 min to complete and will be filled by the research assistant.

Secondary Outcome measures:

1. *Compare* pain score (rest and dynamic as coughing or moving from lying down to sitting up) between the interventions at several time points: Patients will be instructed to use the visual analog scale (NRS), 0 corresponding to no pain at all and 10 corresponding to worst imaginable pain) at different time points,
    a. PACU immediately postoperatively
    b. At the time of first opiate administration,
    c. At the time of discharge (most patients are discharged the same day)
    d. On day 1 (24+/=4 hours),
    e. On day 14
    f. At 6 weeks
2. To collect these pain scores, the EHR will be used to extract the VAS scores documented by the RN while the patient is in the PACU and until the patient is discharged from the hospital.
3. A telephone call will be done at 24 hours (+/-4 hours) by the research assistant blinded to the procedure and the patient will be seen by the physician in the office at the 2 and 6 weeks mark as per usual care.
4. Compare time to administration of first pain medication in the hospital.
5. Estimate PONV scores (Worst score) before discharge across different interventions. Scale: (none, mild, moderate severe).
6. Compare the time needed to administer the intervention QL Block.
7. Compare opiate use in the postoperative period measured in oral morphine equivalent (OME)
    a. In the first 24 hours after the surgery (which is the duration of the block).
    b. 2 weeks post-surgery.
    c. 6 weeks post-surgery
8. We will use the oral morphine conversion table to convert any opiate use to OME for each patient (26).
9. Assess possible complications with each intervention (expected to be low).

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Study Population

- All female patients undergoing laparoscopic or robotic hysterectomy at MHH and will be recruited and consented for enrollment by the research team in the preoperative area.

Inclusion Criteria:

- English or Spanish speaking
- American Society of Anesthesiologists (ASA) physical status 1-3,
- Age greater than or equal to 18 years
- Planned laparoscopic or robotic hysterectomy

Exclusion Criteria:

- History of chronic pain requiring preoperative opioids, Known alcoholism disorder
- Congenital coagulopathy,
- Localized soft tissue infection,
- Use of anticoagulants,
- Dementia, inability or refusal to provide consent for the surgery
- Morbid obesity (BMI > 50), due to expected technical difficulty to achieve the block.

- Usual pain management will continue regardless of which arm of the study patients are in and measurements of pain scores, narcotic usage and abdominal numbness will be assessed in the post-operative period.

Study Design and Procedures

The study will be reported according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines (28).

All medications and procedures used in this study (0.25% bupivacaine, dexamethasone, acetaminophen, ibuprofen, QL blocks) are FDA approved and have been determined to be usual care in the coverage analysis.

1- Recruitment and consents:

Patients undergoing laparoscopic or robotic hysterectomy at MHH will be recruited and consented for enrollment and block randomized to one of 2 arms: Local anesthesia and QL block. The regional anesthesia nurse would consent the patients.
Spanish consents are available for Spanish speaking patients.
Patients will not be told if they will be receiving the drug or the control.

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Blinding is done by the nurse anesthetist preparing the medication, to assure anesthesiologist and research personnel are blinded to the drug used since each patient will receive the two modalities, with only one containing the active drug.

Three regional anesthesia nurses will be trained to obtain consents. They are the usual medical personel that currently mix and prepare the medication and they have been doing so for years. They will be drawing the active or the placebo drug in a sterile manner and give the syringes to the "regional" anesthesiologist and the scrub nurse, assuring safety of administration. We have discussed this procedure with DeAnn Kelly-Williams the Nurse in charge for the Gyn Surgical Services and she is argeable with the procedures (Email: Deanna.kelly-williams@memorialhermann,org)

The procedure is done after the patient is placed under general anesthesia assuring blinding for the patient as well as the research assistant who has no access to Care4. Regional anesthesiologist and surgeon are also blinded as they will be handed the medication sterile in a syringe in both cases.

2- Randomization:

It is done in preoperative unit at the time of obtaining consent via redcap set up by the statistician.

The Nurse anesthetist will then prepare the 20 mls syringes and label them (all drugs are visually identical to normal saline) according to the allocation specified by the randomization. See figure 3:

Figure 3:

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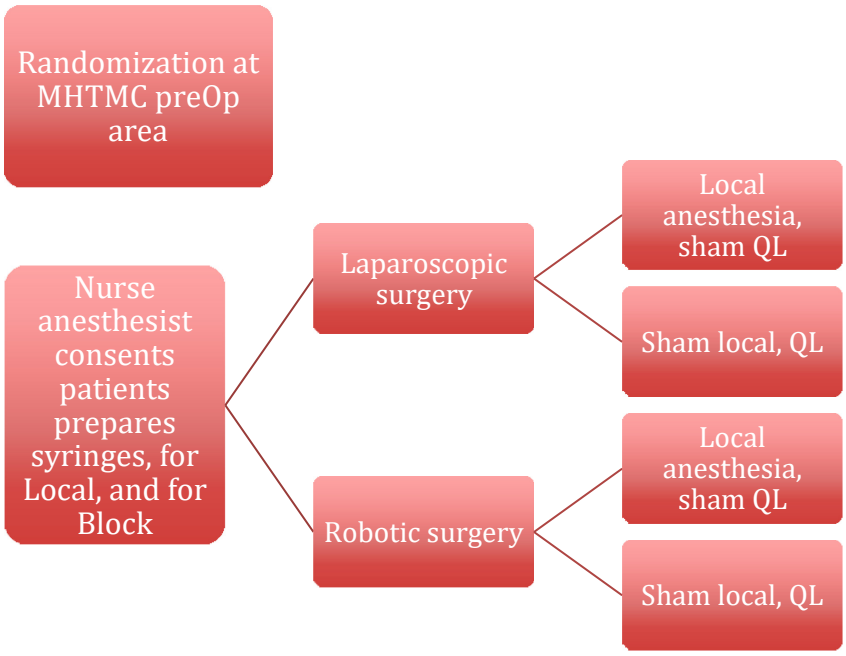

3- Intervention:

- **The intervention**: is performed by the gynecologist for the local anesthetic, and by the regional anesthesia team for the blocks (only attendings, fellows (under supervision) will be performing the block) under ultrasound guidance.

- As per **current** procedures, the nurse anesthetist will fill the syringes and give them to the regional anesthesiologist for the QL block and the scrub nurse for the local anesthetic.
- For the placebo QL block, the nurse will draw saline and for the study drug she will draw 19 mls of 0.25% bupivacaine and 4 mg of Decadron. Bupivacine and Decadron are mixed per the same procedure that is currently done, assuring patient safety.
- For the Local anesthetic and to blind the surgeon, the nurse anesthesist will draw the saline 20 mls for the placebo and the 20 mls of 0.25% bupivacaine for the actual local and give it to the scrub nurse via syringe into a sterile cup .

  Arm N1- local drug, Sham QL
  Arm N2- Sham local, QL drug

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	Study drug	Formulation in each syringe
Arm N1	Local	0.25% Bupivacine X 20 mls
	Sham QL	20 mls of normal saline
Arm N2	Sham Local	normal saline 20 mls
	QL	19 mls of the 0.25% bupivacaine + 1 mls (4 mg of Decadron), totaling 20 mls.

Doses of bupivacaine are calculated to stay below the 3mg/kg total dose, and diluted to provide the volume effect of the block (as per usual care).

Block procedures:

The nerve blocks will be placed after the patients are placed under general anesthesia, as is usual.

Skin is prepared twice with application of chlorhexidine 0.5% in ethanol 82%. The block procedure is performed under ultrasound guidance with a curvilinear transducer covered by a sterile transparent plastic sheath.

- The QL block will be administered on both the right and left sides. The transducer is placed transverse immediately cranial to the iliac crest and at the level of the posterior axillary line. The needle is then inserted inplane from the lateral edge of the transducer and advanced through the quadratus lumborum (QL) muscle until the needle tip penetrated the epimysium of the anterior part of the QL muscle. The anesthetic is injected after repeated negative aspiration tests for blood in the fascial interspace between the QL and psoas major (PM) muscles posterior to the transversalis fascia (30-32).

Successful injectate spread is confirmed by turning the transducer 90 degrees into the longitudinal sagittal plane to see separation of the muscle planes in each type of block.

Subjects are monitored with three-lead electrocardiogaphy, pulse oximetry, and noninvasive BP and have two IV lines.

The dermatomal segments of the QL block will be assessed using ice by staff after 1 h in the recovery area, and the rest of the study duration does not involve dermatomal assessment.

The standard ERAS protocol will followed in all patients:

Pre-Op

NON-Diabetics Carbohydrate load

Gatorade 8 oz 2 hours before procedure

Clear liquids up to 2 hours prior to surgery

Tylenol 1gm PO

Celecoxib 200mg PO

Gabapentin 300-600mg PO

Robaxin 750mg PO

Scopolamine unless contraindicated (Avoid in males with prostate issues)

Reglan-AVOID with bowel obstructions

Intra-Op

Standard Induction

- Reduction/elimination of narcotics beyond induction.

Decadron 4mg (in non diabetics)

Infusions

- Propofol (50-150 mcg/kg/min)
- +/- Dexmedetomidine (200mg/50ccNS) 0.25-0.5mg/kg IV bolus post-induction, then infusion at 0.1-0.3mg/kg/hr *Consideration: Start at 0.4mcg/kg/hr then decrease after 1 hour to 0.2mcg/kg/hr. During closing, decrease to 0 .1 mcg/kg/hr
- Ketamine 10mg/hr or 0.25mg/kg/hr. If not given per infusion, bolus patient with 50mg prior to incision and 1 hour prior to close. Consider 0.125mg/kg injections q30mins IVP if unable to start an infusion.
- +/- Inhalation agents (<0.5 MAC if used)
- Acetazolamide (TBD)
- Max Fentanyl 150 mcg (consider baseline HR and BP)

Intra-Op

Last hour of case

- Terminate Ketamine infusion
- Zofran 4mg

Closing (fascial)

- Propofol to 1mcg/kg/hr (bolus as needed)
- Dexmedetomidine Decrease to 0.1 mcg/kg/hr
- Pressure Support ventilation
- 60 % FiO2

Pointers

Goal directed fluid administration ~3-5cc/kg/hr of isotonic fluids (Avoid Normal Saline)

Minimal Use of invasive lines, NGTs, drains, foleys, and tubes

Glycemic control Blood sugar less than 200 (Glucose checks q hour)

Maintenance of core temperature >36 Optimal 37

Prevention/Control of nausea and vomiting

Lung protective ventilation. Decreased TVs; Increased PEEP (6-8ml/kg IBW PEEP 6-10)

Post-Op

- Acetaminophen 650mg by mouth every 4 hours-
- Celecoxib 200mg by mouth every 12 hours
- Gabapentin 300mg by mouth every 8 hour

- Tramadol 50-100mg by mouth every 6 hours as needed for breakthrough pain (pending phone call)

- If tramadol is ineffective at controlling breakthrough pain, the pain medication will be escalated to scheduled tramadol 100mg every 6 hours with oxycodone 5-10mg every 4 hours as needed for breakthrough pain dependent upon pain score.

Can consider Nucynta

Ondansetron 4mg IV every 6 hours scheduled

Promethazine 12.5mg IM every 6 hours as needed for nausea and/or vomiting

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All patients will receive the same post-operative pain medication regimen (this regimen is obtained via consensus from anesthesiologists and surgeons performing minimally invasive hysterectomy).

We will give the patients a Gabapentin, Tramadol prescription (50 mg X15 tablets as the only opiate) in addition to the Ibuprofen and Tylenol (See the ERAS protocol for details).

- Tylenol total 30 tab
- Ibuprofen 600 mg q6hr total 30 tab
- Gabapentin300 mg total 20 tab
  Tramadol 50 mg total 15 tab

5- Comparison:

The following variables will be recorded to compare the different interventions in the following timeline:

- In PACU: (Registered nurse, performs usual care) data is collected retrospectively by research staff
  - Collect pain score rest and dynamic using the Visual analog scale (VAS)
    - Immediately upon arrival
    - At the time of first opiate use
    - Worst pain score
    - At time of discharge
  - Postoperative nausea and vomiting (PONV) score (worst and at the time of discharge)
  - Time elapsed to first opiate use (in minutes)
  - Cumulative opiate use in OME in PACU
  - patient satisfaction will be measured on a Likert scale (5 points)
  - The incidence of postoperative adverse events such as nausea, vomiting, dizziness, headache, urinary retention, local anesthesia-induced side effects (paresthesia, hearing disturbance, visual disturbance, and dysarthria)
- At 24 hours (+/- 4 hours) telephone call by research assistant blinded to procedure
  - Filled Tramadol (Yes/no)
  - Cumulative opiate use in OME if any (How many Tramadol pills used).
  - QOR-40 (6.3 min validated questionnaire)
  - Dynamic pain score on VAS
  - Patient satisfaction will be measured on a Likert scale (5 points)
- Day 14: (clinic visit, usual care)
  - Filled Tramadol (Yes/no)
  - Cumulative opiate use in OME if any. (Via number of Tramadol pills left)
  - Dynamic pain score on VAS
  - Clinic visit on day 14 (per usual care)
  - Cumulative opiate use in OME if any (Check number of pills of Tramadol left. Versus need for refills).
  - Dynamic pain score on (VAS).
- 6 weeks clinic visit (per usual care)
  - Complications

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- Cumulative OME use if any
- Refill on pain meds, yes/no and which medications.

During the telephone encounters or the clinical visits, patients will be asked if they filled their prescription for Tramadol/narcotic and how many pills they have left). If the patient is not seen at the 2 weeks mark for any reason, a telephone call will be done to collect that information by the surgeon.

6- Expected duration of study and subject participation.

We currently perform at the minimum 5 hysterectomies per week and Memorial Hermann Hospital (Laparoscopic and Robotic) and expect to randomize half of the patients, to complete the study within up to 2 years after IRB approval.

Sample Size and Power

- Based on previous studies, the mean standard deviation of QOR-40 after gynecologic laparoscopy are 150-170 and 10-15, respectively.
- A clinically significant difference would be 10-15.
- A sample size of 31 patients per group is needed to detect the difference of 20 points in the global QOR-40 score, a SD 25, with a Type 1 error of 5% and a power of 90%.
- 76 patients will be included to allow for a dropout rate of approximately 18%. Lost to follow up is expected to be low.

For pain scores in the VAS: Meaningful clinical difference in VAS scores is 30%

Analysis Plan/Statistics

- For baseline patient characteristics, continuous variables will be reported as medians with 25th and 75th percentiles (interquartile range [IQR]), and categorical variables as counts and percentages.
- To compare across groups, Kruskal-Wallis tests will be performed for continuous variables and Chi-square tests for categorical variables.

- CONSORT diagram will be performed
- Intention to treat analysis will be performed
- All unadjusted outcomes will be reported descriptively (mean SD/ median IQR)
- For all outcomes, we will conduct intent-to-treat Bayesian analysis to calculate probabilities of intervention benefits and harms. We will use neutral priors and exclude large treatment effects. We will report posterior medians of group differences, their corresponding 95% credible intervals, and probability of treatment benefit.

Primary outcome as QOR will be analyzed with a negative binomial regression model to account for expected skewness. The model will include group (local, QL), and type of surgery as covariates. We will account for surgery type (Robotic versus laparoscopic hysterectomy) simply because of the difference in port placement and port size between both approaches.

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- We will report risk ratios and 95% confidence intervals comparing local to QL block. We will assess the normality of the data and robustness of the conclusion using the appropriate tests.
- As the pain scores are repeated over time, a linear mixed model analysis (patient as random intercept, patient-time as random slope, unstructured covariance) will be undertaken to identify any treatment differences across time.
- Arrival to PACU is defined as time 0.

All opioid or pain medications are registered in the subject's electronic file and are tallied to form the total postoperative opioid consumption.

FUNDINGS:

There is no funding for the study, this is PI initiated.
The cost will be that of the catheters for the blocks which will be donated to the anesthesiologist and no charges are incured to the patient or the hospital.
The anesthesia research team will waive billing for the QL procedure for the study patients. Local anesthesia is bundled with the surgery and does not constitute a separate charge. Local anesthesia is bundled with the surgery and does not constitute a separate charge. The placebo is just 20 mls of saline solution.

OVERSIGHT RESPONSIBILITIES

Oversight of the trial is provided by the Principal Investigator (PI), Dr. Randa Jalloul and Co-investigators Drs Nadia Hernandez and Sara Guzman *who will be actively involved in the conduct of the study.*

MONITORING PROCEDURES

Dr. Jalloul assures that informed consent is obtained prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan.

Study data are accessible at all times for the PI and co-investigators to review. Dr Jalloul and Dr Hernandez will review study conduct*:* accrual, drop-outs, protocol deviations on a quarterly basis. The PI, CO-PIs will review AEs individually real-time and in aggregate on a quarterly basis. They will also review serious adverse events (SAEs), including anesthetic allergy, local anesthetic toxicity, as well risk of infection in real-time. The PI ensures all protocol deviations, AEs, and SAEs are reported to the IRB according to the applicable regulatory requirements.

COLLECTION AND REPORTING OF SAEs AND AEs

For this study, the following standard AE definitions are used:

Adverse event: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a

medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

Serious Adverse Event: Any AE that results in any of the following outcomes:

- Death
- Life-threatening
- Event requiring inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity

AEs are graded according to the following scale:

Mild: An experience that is transient, & requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. This includes transient laboratory test alterations.

Moderate: An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. Includes laboratory test alterations indicating injury, but without long-term risk.

Severe: An experience that requires therapeutic intervention. The experience interrupts usual daily activities. If hospitalization (or prolongation of hospitalization) is required for treatment it becomes an SAE.

The study uses the following AE attribution scale

Not related: The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).

Possibly related: An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

Related: The AE is clearly related to the study procedures.

AEs are identified*:* during hospital admission when potential AEs are assessed through a review of the hospital chart on a daily basis and a physical examination of the subject. After discharge, AEs are assessed at time of study follow-up visits.

SAEs and specific procedure-associated AEs are reported to Dr Jalloul and Dr Hernandez within 24 hours. In addition, all AEs are reported according to the UT IRB, AE reporting guidelines.

PLAN FOR DATA MANAGEMENT

Compliance of regulatory documents and study data accuracy and completeness will be maintained through an internal study team quality assurance process.

Confidentiality throughout the trial is maintained by the use of Redcap.

Assessment of safety: Safety of the procedure will be ensured by following ASA guidelines for regional anesthesia, as well as using ultrasound for placement of the nerve blockade as is standard of care. We will also ensure that post-operative medications are not prescribed to patients who may have an allergy to one of the medications, as well as adjusting the doses prescribed to patients who may have renal or hepatic dysfunction. The study will not incur more than minimal risk for the intervention and the placebo group.

Ethics

- IRB approval will be sought for this study.
- Patients will undergo standard consent for regional anesthesia and for participation in this study.
- The study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement, the Helsinki Declaration, and monitored by the Good Clinical Practice Unit
- Will register the trial once the IRB is approved.

Data handling and record keeping

- Narcotic consumption, pain score patient data will be maintained in a secure file by the PI using Redcap to protect patient data.
- All nurses pre-operatively and post-operatively will be educated regarding the study and appropriate documentation of pain scores and medication requirements.

Publication Plan

- Plan to publish in the JMIG
- Results are not returned to subjects

Characteristic	N1	N2
Age		
Race		
Height		
Abdominal circumference		
Weight		
BMI		
Smoking		
Diabetes status		
Parity		
Hospital system		
Planned procedure		
Actual procedure		
Number of trocars used		
Largest trocar size (if single site used size of fascia incision)		
Largest trocar location		
Uterine size in grams		
Duration of surgery from cut to close		
Total anesthesia time		
Intraoperative complications		
Length of Hospital stay		

Incidence of adverse events	N1	N2
Nausea		
Vomiting		
Dizziness		
Headache		
Urinary retention		
Needle-insertion-site pain		
Hematoma		

Outcomes	N1	N2
Opiate use: yes/no		
Total number of Tramadol pills used, or other medications if any		
QOR-40 (6.3 min validated questionnaire)		
At 24 hours (+/- 4 hours): tel call by research nurse		
Cumulative Opiate use in (OME)		

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OME in PACU		
OME At 24 hours (20-28 hours): tel call by research nurse		
OME at Day 14, Clinic visit		
OME at 6 weeks clinic visit (per usual care)		
Pain scores at rest		
PACU arrival		
PACU At the time of first opiate use		
PACU Worst pain score		
PACU At time of discharge		
At 36 hours (28-44 hours): tel call by research nurse		
Day 14, Clinic visit		
6 weeks clinic visit (per usual care)		
Dynamic pain score		
PACU arrival		
PACU At the time of first opiate use		
PACU Worst pain score		
PACU At time of discharge		
At 36 hours (28-44 hours): tel call by research nurse		
Day 14, Clinic visit		
6 weeks clinic visit (per usual care)		
Time elapsed to first opiate use (in min)		

Duration of surgery, intraop opiates use and complications within 6 weeks, capturing unscheduled visits, ER visits etc..

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