Erector Spinae Plane Block Versus Transverse Abdominis Plane Block in Laparoscopic Hysterectomy

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Protocol: Version 4.0 4-23-19

1.0 Background

Each year, thousands of hysterectomies are performed for various indications including cancer, fibroids, endometriosis, and other conditions. Laparoscopic hysterectomy is often complicated by post-operative pain, making pain control challenging especially with the use of opioids. Improved pain control increases patient satisfaction and may lead to improved postoperative course.[1, 2] Our standard of practice at Indiana University Hospital is to perform Transverse Abdominis Plane (TAP) block using liposomal bupivacaine (LB) for these patients to help with postoperative analgesia. [3] Recent literature suggests that Erector Spinae Plane (ESP) block may be a safe and effective alternative for thoracic, extremity, and abdominal surgeries. [4] Currently there are numerous case reports supporting use of ESP block [5] but there are not prospective randomized controlled trials comparing these 2 blocks to date. . Our study aims to compare the efficacy of ESP block and TAP block in laparoscopic hysterectomy.

The ESP block, first described by Forero in 2016, provides regional anesthesia targeting in the range of the T2-L1 branches of thoracolumbar nerves.[6] The ultrasound is positioned in a parasagittal fashion, lateral to the spinous process, to visualize the transverse process. The needle is inserted cranial-to-caudal in plane traversing through the trapezius muscle, the rhomboid major muscle, and the erector spinae mucles, aiming to make contact with the transverse process, with the needle tip deep to the plane of the erector spinae muscle, which overlies the transverse process. Injection of saline confirms the correct location of the needle as determined by cranio-caudal spread of saline under the erector spinae muscle, "lifting" it off of the transverse process. Once the correct location is identified, the local anesthetic is injected.

We plan to use Exparel®, or a liposomal formulation of bupivacaine, as the analgesia for both arms of the study. Because Exparel® is in liposomal form, the lipid solubility allows bupivacaine to be released over an extended period of time. It is reported to provide long-lasting analgesia for up to 72 hours and may result in decreased opioid consumption and shortened hospital stays. [7] There is no current standard of practice for local anesthesia in ESP block. LB has good analgesia coverage for up to 72 hours postoperative when compared to normal saline and has been suggested to reduce postoperative opioid use as well. [8, 9]

2.0 Rational and Specific Aims

Both of the pain control modalities in this study have been used as postoperative analgesia in prior studies. The specific aim of this study is to compare the difference between the pain control methods in achieving the following:

1. Decreased opioid requirements
2. Improved postoperative pain scores
3. Decreased opioid side effects (Nausea, sedation, ileus, urinary retention, respiratory depression)

The primary endpoint of this study will be VAS pain score. The VAS scores will be taken with both rest and movement.

The secondary endpoint includes intravenous opioid consumption and opioid side effects (nausea, sedation, ileus, urinary retention, respiratory depression). The IV and PO opioid doses will be quantified at 1, 24, and 48 hours. We will also measure postoperative nausea and sedation scores at 1, 24 and 48 hours. We will also assess patient satisfaction postoperative at 24 and 48 hours. We will also measure time to first flatus, incidence of urinary retention, incidence of respiratory depression, ambulation activity, and hospital length of stay.

3.0 Inclusion/Exclusion

Inclusion criteria:

- Patients undergoing laparoscopic hysterectomy surgery at Indiana University Hospital
- ASA class 1, 2, 3 or 4
- Age 18 or older, female
- Desires Regional anesthesia for postoperative pain control

Exclusion criteria:

- Any contraindication for ESP or TAP block.
- History of substance abuse in the past 6 months.
- Patients on more than 30 mg morphine equivalents of opioids.
- Any physical, mental or medical conditions which in the opinion of the investigators, may confound quantifying postoperative pain resulting from surgery.
- Known allergy or other contraindications to the study medications (Acetaminophen, Gabapentin, Bupivacaine).
- Postoperative intubation.
- Any BMI greater than 40.0.

4.0 Enrollment/Randomization

All laparoscopic hysterectomy cases scheduled by OBGYN at IU Health University Hospital will be identified. Subjects will be contacted face-to-face prior to surgery. They will be informed about the study and all questions will be answered. All patients will undergo a standardized enhanced recovery perioperative care pathway designed and agreed upon by the perioperative team of anesthesiologists and surgeons.

A total of 80 subjects will be randomized by a computer program into two groups (40 in each group):

1. TAP block – placed by ultrasound using 266mg Exparel (20ml) and 60ml of 0.125% bupivacaine. 40ml on each side. 20ml injected for subcostal TAP and 20ml injected for posterior TAP.

2. ESP block – placed by ultrasound using 266mg Exparel (20ml) and 60ml of 0.125% bupivacaine. 40ml on each side. 20ml injected at T8 and 20ml injected at T12

Randomization will be performed using a block randomization of the 2 groups instead of a simple 2-group randomization to keep the study groups fairly balanced throughout enrollment. The primary investigator will inform the person doing the block as to what group the patients are randomized to. Both the patients and the research staff doing assessments will be blinded to the randomization.

5.0 Study procedures:

The TAP blocks will be placed intraoperatively after induction, while ESP blocks will be done preoperatively. All procedures will be done using sterile technique with masks, hats, and sterile gloves. All procedures will be placed under the supervision of the attending anesthesiologist on the acute pain service.

For the TAP block, the ultrasound probe is placed transverse to the abdominal wall, between the iliac crest and the costal margin. The needle is placed in the plane of the probe and advanced until it is between the internal oblique and the transversus abdominis muscles. Once in the plane, 2 mL of saline is injected to confirm needle position, then the local anesthetic solution is injected. [10]

For the ESP block, as mentioned previously, the ultrasound is positioned in a parasagittal fashion, 2-3 inches lateral to the spinous process. This approach visualizes the transverse process. The needle is inserted cranial-to-caudal to make contact with the shadow of the transverse process, with the needle tip deep to the fascial plane of the erector spinae muscle. Injection of saline confirms the location of the needle, and the anesthetic is injected.

All patients will receive PO acetaminophen and PO gabapentin the morning of surgery. Pt. will be placed on PRN oxycodone/acetaminophen (Percocet) postoperatively. PRN IV dilaudid may be given for severe breakthrough pain.

Opioid usage at 1, 24 and 48 hours after the block will be recorded by a member of the research team. Pain scores at rest and on movement will be measured by the investigator using Visual Analog Scale (VAS). Nausea will be measured using a categorical scoring system (none=0; mild=1; moderate=2; severe=3). Sedation scores will also be assessed by a member of the study team using a sedation scale (awake and alert=0; quietly awake=1; asleep but easily roused=2; deep sleep=3). All these parameters will be measured at 1, 24 and 48 hours after the blocks and patients will be encouraged to ambulate on postoperative day 1 under supervision. Their ambulation activity will be recorded.

6.0 Reporting of Adverse Events

Patients will be monitored by the primary team during the postoperative period, and any adverse events or unanticipated problems such as local anesthetic toxicity or any abdominal injury will be reported to the acute pain service and research team. All adverse events or unanticipated

problems that meet the criteria for prompt reporting will be reported to the IRB within 5 business days.

7.0 Study withdrawal/DC

The patient can withdraw from the study at any time by contacting the research team or acute pain anesthesia resident. In such an event, patient may still have access to all the IV and oral pain medications. Anesthesia acute pain team will continue to follow the patient for 24 hours. After 24 hours, the anesthesia acute pain team will sign off and all further pain management will be done by the primary team.

8.0 Statistical consideration

Primary outcome: VAS score at 24 and 48 hours

Primary Research Hypothesis: ESP block will provide lower postoperative pain scores compared to TAP block for laparoscopic hysterectomy as measured by VAS scores at 24 and 48 hours

Secondary outcomes: Narcotic usage after 1, 24 and 48 hours. Pain scores using VAS at rest and walking at 1, 24 and 48 hours. Nausea scores at 1, 24 and 48 hours. Sedation scores at 1, 24 and 48 hours. If the patient is discharged within 48 hours, every effort will be made to obtain data points. We will also assess patient satisfaction postoperative at 24 and 48 hours. We will also measure time to first flatus, incidence of urinary retention, incidence of respiratory depression, ambulation activity and hospital length of stay.

Secondary Research Hypotheses: ESP block will show improved patient satisfaction scores and decreased nausea and sedation scores compared to TAP block.

Statistical analysis will be performed using a standard statistical program (SAS or SPSS). All data will be summarized (means, standard deviations, standard errors, and ranges for continuous variables; frequencies and percentages for categorical variables) by group. Demographic data will be compared between the four groups using ANOVA or chi-square tests as appropriate. The primary outcome, VAS at 24 and 48 hours, will be compared between the groups using repeated measures ANOVA; the model will include fixed effects for group, time, and the group by time interaction and random effects to allow correlations between the two times and different variances for the two times. Pain and satisfaction scores and opioid usage over time will be analyzed using repeated measures ANOVA. Nausea and sedation scores will be compared between groups at each time point using Mantel-Haenszel chi-square tests for ordered categorical data. Time to first flatus will be compared using log-rank survival analysis; incidence of urinary retention, incidence of respiratory depression, and ambulation activity will be compared using chi-square tests; and hospital length of stay will be compared using Wilcoxon Rank Sum tests. Distributions of the continuous variables will be examined, and a transformation of the data (e.g. natural logarithm) or nonparametric tests will be used as necessary. A 5% significance level will

be used for all comparisons.

Based on prior studies, the coefficient of variation for the VAS score at 24 and 48 hours is estimated to be 0.70. With a sample size of 40 per group the study will have 90% power to detect a ratio of means of 1.6 for VAS score between any two groups, assuming two-sided tests each conducted at a 5% significance level.

9.0 Privacy

All study papers containing patient identifiers will be kept in each subjects confidential study file accessible to only the research team. All records will be kept in a locked room in a locked cabinet that only authorized staff enters. Collected data from each enrolled participant will be recorded on Redcap, which is a secure web-based data collection tool. Three years after completion of the study, all electronic information and paperwork containing patient identifiers will be deleted or shredded.

10.0 Follow-up/record retention

The study will start in middle of 2019 and will end when a sample size of 80 subjects is achieved. The estimated time frame to enroll 80 study subjects is 24 months. After 80 subjects have been enrolled, the study will be stopped and the data collected will be analyzed using statistical methods.

Three years after completion of the study, all study papers with patient identifiers will be shredded and only data without any patient identifiers will be retained by the research team for an indefinite time.

References:

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