Rectus Sheath Block with liposomal bupivacaine for postoperative analgesia following gynecologic oncology surgery: a pilot study

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Study Title:

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Thoracic epidural catheters provide superior perioperative analgesia compared with parenteral opioids, and are associated with reduced postoperative pulmonary complications, and reduced risk for and duration of postoperative ileus.[1] Despite the benefits of thoracic epidural analgesia (TEA), it can be associated with complications, some of which can be serious. In a single center review of 10 years use of TEA involving 3126 patients, 3 major complications were identified: 2 subarachnoid blocks and 1 epidural abscess which led to permanent sequela. Numerous other complications were noted: hypotension, pruritus, accidental catheter removal, insertion site inflammation, motor weakness, catheter disconnection, catheter occlusion, post-dural puncture headache, and catheter fragment retention, which led to a 7.4% early discontinuation rate of TEA.[2] Similarly, in a retrospective study of 7430 patients receiving postoperative TEA, 7 serious adverse events were identified amounting to an incidence of 0.1% for serious adverse events and 0.014% for long term neurological adverse outcomes.[3] Rectus sheath block (RSB) is increasingly being used for laparotomies involving a midline vertical incision. In a randomized controlled trial, Gupta reported comparable opioid consumption between rectus sheath catheters (RSCs) and TEA with comparable pain scores.[4] In an observational study including all patients undergoing elective open colorectal resection and receiving either TEA or RSCs, Tudor found no difference in postoperative pain scores or length of stay but time to mobilization was shorter with RSCs compared with TEA.[5] In a meta-analysis, Claxton concluded that RSCs provide similar analgesia to TEA, with a favorable side effect profile reducing the risk of hypotension and time to mobilization.[6] Single shot block with liposomal bupivacaine would avoid issues associated with RSCs but has not been studied. At our institution, we have an established ERAS protocol that incorporates the use of TEA for patients undergoing laparotomy for gynecologic malignancy. The epidural catheter is typically left place for about 24 hours, and the patients are then transitioned to oral analgesia, which does not provide the same quality of analgesia. We hypothesize that the use of RSB with liposomal bupivacaine in the context of our ERAS protocol, would provide non-inferior analgesia to that provided with TEA.

Primary Objective:

Assess analgesic efficacy of Rectus Sheath Block (RSB) with liposomal bupivacaine in women undergoing laparotomy for gynecologic malignancy and receiving a postoperative multimodal analgesic regimen as part of our enhanced recovery after surgery (ERAS) protocol as assessed by the dose of rescue postoperative opioids needed compared to a historical control group of women receiving postoperative analgesia using thoracic epidural analgesia.

Primary Endpoint:

Postoperative opioid consumption 0- 72 h after surgery

Secondary Endpoints:

1. Total postsurgical opioid consumption at 0-24 and 24-48 hours
2. Intraoperative hypotension and need for intraoperative vasopressors
3. Postoperative hypotension
4. Need for rescue antiemetics and antipruritics
5. Area under the curve (AUC) of visual analog scale (VAS) pain intensity scores through 72 hours (AUC0–48)
6. Maximum pain scores reported.
7. Pain scores prior to administration of rescue analgesia.
8. Time to mobilization
9. Time to urinary catheter removal
10. Duration of PACU stay
11. Duration of hospital stay

Exploratory Endpoints:

1. Postoperative hypotension.
2. Need to pause or discontinue epidural infusion because of hypotension.
3. Inadvertent dural puncture.
4. Postural puncture headache.
5. Time needed for epidural placement and RSB placement
6. Time of discontinuing epidural analgesia

Hypothesis:

RSB with liposomal bupivacaine will be noninferior in terms of postoperative opioid consumption compared to a historical cohort of patients receiving postoperative analgesia using thoracic epidural analgesia

Design:

This will be a case control study with a prospective and a retrospective component. Women undergoing laparotomy for gynecologic malignancy as part of our ERAS protocol will be approached to participate in the prospective open label component of the study. Those women will receive the usual intraoperative and postoperative ERAS analgesic regimen used at Duke University typically incorporating intraoperative opioids (typically fentanyl and hydromorphone), intraoperative IV acetaminophen 1000 mg and IV ketorolac 15 mg. A bilateral RSB will be performed under ultrasound guidance after induction of anesthesia using 133 mg liposomal bupivacaine and 20 ml bupivacaine 0.25% per side.

Cases will be matched in a 1:2 ratio by age, race, insurance status and duration of surgery with historical controls who received postoperative analgesia using thoracic epidural analgesia.

Inclusion Criteria:

Patients ≥18 years presenting for a laparotomy for Gynecologic malignancy with ASA Classification II or III.

Exclusion Criteria:

BMI >50 kg/m2, chronic pain or chronic opioid therapy, or allergy or contraindication to any component of the multimodal analgesic regimen.

Statistical analysis plan:

30 patients prospectively enrolled will be matched 1:2 to 60 historical controls on the basis of age, race, insurance status and duration of surgery. Up to 40 patients will be consented to reach the goal of 30 prospective patients. Patient characteristics will be reported as median and interquartile range for numeric variables and count and percentage for categorical variables. The primary outcome, 72-hour postoperative opioid use, will be compared between patients receiving rectus sheath block and patients receiving standard of care using a log-linear regression model. The effect of block will be reported as a geometric mean ratio (GMR) with associated 95% confidence interval. A non-inferiority analysis will be conducted using a non-inferiority margin of 20%. Rectus sheath block will be considered non-inferior to standard of care if the upper bound of the 95% confidence interval for the GMR is less than 1.2. Categorical secondary outcomes will be compared using chi-square or Fisher exact tests, as appropriate. Continuous secondary outcomes will be compared using t-sets or Wilcoxon rank sum tests, as appropriate. A p-value less than 0.05 will be considered statistically significant and all statistical analysis will be carried out using R (version 4.1.2) or SAS (version 9.4).

A power analysis was conducted assuming a log-normal distribution of 72-hour postoperative opioid dose based on historical data. For a non-inferiority margin of 20%, 30 recruited block patients matched 1:2 to historical controls (total sample size 90) provides 80% power to detect non-inferiority assuming a mean ratio 0.7 in the block group relative to historical controls. This analysis assumes a threshold for statistical significance of $\alpha = 0.05$ and a coefficient of variation of 1.1, which is consistent with historical patients at Duke.

References:

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