Erector Spinae Plane Block With Liposomal Bupivacaine for Post Cesarean Delivery Analgesia: A Pilot Study

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Patients over the age of 18 years, American Society of Anesthesiologists (ASA) Physical Status Classification II or III scheduled to undergo elective cesarean delivery (CD) under spinal or combined spinal epidural anesthesia with a term pregnancy of 37 to 42 weeks will be approached to participate in the prospective open label component of the study. Exclusion criteria include: patients with greater than 3 prior CDs, a pre-pregnancy body mass index >40 kg/m^2, planned concurrent surgical procedure other than tubal ligation, receiving chronic opioid therapies, clinically significant event or condition uncovered during surgery (e.g. excessive bleeding, acute sepsis) that might render the patient medically unstable or complicate the patient's postsurgical course, and an allergy or contraindication to any component of the multimodal analgesic regimen.

All patients will receive the standard of care intraoperative and postoperative analgesic regimen used at Duke University Medical Center incorporating 100 mcg intrathecal morphine (ITM), intraoperative acetaminophen 1000 mg IV and ketorolac 15 mg IV, followed by a postoperative regimen of scheduled oral acetaminophen 975 mg every 6 hours, 15 mg IV ketorolac every 6 hours for 3 doses, followed by oral ibuprofen 600 mg every 6 hours. Intraoperatively, all patients will receive nausea and vomiting prophylaxis using metoclopramide 10 mg, ondansetron 4 mg and dexamethasone 8 mg. Oxycodone 5-10 mg will be used for rescue analgesia every 4 hours as needed in the postoperative period according to reported pain scores. Intravenous fentanyl or hydromorphone will be used for pain unrelieved with oral oxycodone or if the patient was unable to receive oxycodone. At the end of surgery, a bilateral erector spinae plane block (ESPB) will be performed at the T10 level under ultrasound guidance using 133 mg liposomal bupivacaine and 20 ml bupivacaine 0.25% per side.

Data will be collected at 2 h, 24 h, and 48 h after surgery by a member of the research team. We will collect information about pain scores (0-10 verbal rating scale, 0= no pain, 10= worst possible pain), need for rescue antiemetics or antipruritics, and need for rescue analgesia. At 24 h and 48 h we will collect the obstetric quality of recovery score and ask patients about their satisfaction with postoperative analgesia on a 0-10 scale (0=not satisfied, 10=totally satisfied). At 48 h, patients who had a repeat CD will be asked about how analgesia for this delivery compared with the prior CD (can't remember, worse, same, better, much better). Prospectively enrolled patients will be matched in a 1:4 ratio by age, race, history of prior CD, and insurance status with historical controls who received the same multimodal analgesic regimen but no truncal blocks identified through a review of electronic medical records (Epic Systems EMR, Verona, WI, USA).

The primary outcome of the study is postoperative oxycodone consumption 0-48 h after surgery. Secondary outcomes include: total postsurgical opioid consumption through 24 h, time to first postsurgical opioid rescue medication, area under the curve (AUC) of visual analog scale (VAS) pain intensity scores through 48 h (AUC0–48), need for treatment of PONV and pruritus, and proportion of opioid free patients (defined as patients not receiving any rescue opioids postoperatively).

A power analysis was conducted assuming a log-normal distribution of postoperative opioid consumption. With 30 recruited block patients matched 1:4 to historical controls (total sample size 150), we had 80% power to detect a reduction in opioid use of 36% (mean ratio

0.64) with an alpha of 0.05 in a log-linear regression model. Based on historical data this corresponds to a reduction of OME use from approximately 55 mg in the control group to 35 mg in the block group through 48 h post-surgery. This power analysis assumes a coefficient of variation 0.9, which is consistent with historical patients at Duke. The primary outcome of 48 h oxycodone consumption will be compared between groups using a log-linear regression model and the effect size reported as a geometric mean ratio. Secondary outcomes will be compared using chi-squared tests or log-linear regression, as appropriate.