SUMMARY
A randomized controlled trial of the effectiveness of liposomal bupivacaine (Exparel) when compared to local injection of bupivacaine after thoracoscopy

Sponsor
MEDNAX Center for Research, Education and Quality
Inova Fairfax Hospital - Department of Surgery /Department of Anesthesiology

Study type - Prospective Randomized Controlled Trial

Single site - Patients will be recruited from the Cardiac Vascular and Thoracic Surgery Associates (CVTSA) practice. Operations, injections of Exparel, and pain pump administration will occur at Inova Fairfax Medical Center (IFMC). The final patient outcome at 30 days will occur in the CVTSA offices during follow-up. Data analysis will then be performed at IFMC.

Study enrollment goal - A total of 100 patients (50 per study arm) are expected to participate in this study.

Purpose
1. To establish a safe and effective role for liposomal bupivacaine (Exparel) in thoracoscopy.
2. To provide patients with a superior and longer lasting form of pain relief.
3. To improve patient satisfaction and decrease perioperative narcotic use.

Background
Video-Assisted Thoracic Surgery (VATS) has been shown to hasten patient recovery by attenuating the physiologic stress of surgery and decreasing post-operative pain. Despite this approach, incisions in the chest are proportionally more painful than in other parts of the body, and most patients require some form of narcotic pain medication.

Multiple strategies for post-operative pain control have been attempted in thoracic surgery with no obvious superiority of one versus another. Pain catheters have been increasingly used over the past decade in different surgical procedures in order to minimize incisional pain for the first 3 to 7 days after an operation.

For the past 5 years we have routinely used an axial subpleural tunneling technique that delivers local anesthetic to the intercostal space, without leakage elsewhere, creating a functional multi-level rib block. The published literature is equivocal as to the efficacy of such approaches following thoracic surgery with most recent series reporting no benefit in the use of these catheters. Despite our own positive subjective results, objective data is lacking and therefore we conducted our own randomized trial to assess the efficacy of these catheters to standard intraoperative injection of bupivacain. This study confirms that there is no difference in patient pain, satisfaction, or narcotic use.
Exparel is a formulation of liposomal bupivacaine that is reported to allow local anesthesia for up to 72 hours post injection. It is our aim to follow our prior study with a randomized trial to compare local infiltration of liposomal bupivacaine at the conclusion of each procedure with injections of standard .5% bupivacaine.

Study Population
Male and female patients will be considered for this study. Any patient over the age of 18 and having an isolated thoracoscopic procedure for a therapeutic or diagnostic purpose will be screened. No study exclusions will be based on the racial or ethnic considerations. This study will not include minors or other vulnerable populations.

Recruitment
Patients who fit the inclusion and exclusion criteria will be asked to participate in the study when seen prior to their operation either in the CVTSA offices or in the pre-anesthesia unit.

Inclusion Criteria
All patients over 18 years of age
- Isolated thoracoscopic procedure for therapeutic or diagnostic purposes

Exclusion Criteria
- Previous ipsilateral thoracic surgery
- Need for operative pleurectomy or pleurodesis
- Chronic use of pain medication (narcotics or NSAIDS), sedatives, or hypnotics
- Allergies to bupivacaine or other local anesthetics, narcotics, NSAIDs or acetaminophen
- Liver dysfunction (INR > 1.5, albumin < 2.8g/dl, bilirubin > 2mg/dl)
- Renal dysfunction (eGFR < 60ml/min/1.73m2)
- History of peptic ulcerative disease
- Sleep apnea in need of CPAP/Bipap
- Severe COPD requiring continuous oxygen supplementation
- Inability to consent
- Pregnancy

Outcome Measures
Primary outcomes
The primary outcome will be overall amounts of pain medications through postoperative day 7.

Secondary outcomes
Secondary outcomes include summed visual analog pain scores, patient satisfaction, analog pain scores at post-operative day 30, incidence of paresthesias, hospital length of stay (days), return to baseline activity, return to work, and overall hospital cost calculated as a factor value.
Follow-up
Data for the first 7 post-operative days will be recorded, beginning during the hospital stay and continuing at the patients' homes. The next and final day of subject participation is on post-operative day 30.

References


