Randomized Clinical Trial of Exparel vs Pain Pump for Post-operative Pain Control after Total Shoulder Arthroplasty

INTRODUCTION

Routine anesthetic care for patients undergoing a Total Shoulder Arthroplasty (TSA) at our institution includes the implantation of a pain pump. A pain pump is used to allow pain control in the days after a TSA. Anecdotally patients complain of breakthrough pain the night after their surgery when the local anesthetic administered during surgery starts wearing off [Abdallah].

Exparel (Bupivacaine liposome injectable suspension), a sustained-release preparation of bupivacaine that is FDA approved for administration at the surgical site, may provide a lower-cost alternative to a pain pump, as it has the potential for activity up to 72 hours after surgery [Davidovitch, Golf, Haas]. Two prior randomized clinical controlled trials have compared Exparel to an intraoperative interscalene block and showed improved pain scores and less opioid consumption at 24 hours after surgery. There have been no studies comparing Exparel to a pain pump and evaluated the outcomes beyond 24 hours after surgery.

The primary objective of this study is to determine if Exparel leads to better pain scores at 24, 48 and 73 hours after TSA compared to a pain pump. Secondary objectives are (1) to determine if patients on Exparel use less narcotics and (2) have earlier return of functional use of the involved arm after surgery compared to the pain pump.

METHODS

Sample size:

Based on prior studies on anesthetics for TSA, the mean worst pain score in the 24 hours after surgery was 5.4, based on a 0 to 10 scale. To detect a change of 2 points, alpha of 0.05, beta of 0.80, a sample size of 51 subjects in each group will be required. To account for drop-outs, a total of 60 subjects in each arm will be enrolled.

Inclusion criteria

- Patients undergoing unilateral primary TSA or reverse TSA
- Indication for surgery is osteoarthritis, rotator cuff arthropathy or massive irreparable rotator cuff tears
- Surgery performed by the Principal Investigator (Dr. Krupp)
- Anesthesia administered by Co-Principal Investigator (Dr. Perkins)
- Willing and able to sign an Informed Consent

Exclusion criteria

- Indication for surgery is fracture
- Comorbid psychiatric diagnosis requiring therapy and/or medication except anxiety or depression
- Comorbid chronic pain syndrome (reflex sympathetic dystrophy, fibromyalgia)
- Has hepatic disease
- On workers compensation/disability/litigation
- Known adverse reaction to medications to be administered

- On long-acting narcotic pain medication (including extended release narcotic pain medications and methadone)
- Home Oxygen requirement whether PRN or scheduled.
- Contralateral Phrenic Nerve paralysis / incompetence.
- BMI ≥ 50
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Randomization will be a varied blocked randomization with blocks of 12, 15 and 18 using sealed envelopes

Treatment arms:

Control: Pain catheter based pain control. Subject will receive an interscalene block with Ropivicaine 0.5% (20cc), and then a pain pump attached in the PACU infusing at 4cc/hr. The patient will go home with that device until it runs out.

Interventional: Single shot Exparel 10cc (133mg) mixed with 10cc of 0.5% Bupivicaine

Both arms will receive the same multimodal analgesia medications preoperatively. Celebrex 400mg PO, Gabapentin 600mg PO, Tylenol 1 gram PO, unless contraindicated.

Variables collected

Pre-operative

Age
Sex
Race/Ethnicity
Educational Level
Height
Weight
Side of Arthroplasty
Current pain medication
Pain (NRS, 10 to 10)
ASES
SANE
Work status
Annual income
Days off work

In Hospital

ASA score
Local anesthesia start time
Local anesthesia end time
Operative time
Length of hospital stay
Cumulative MMEs consumed at 24, 48 and 72 hours
Worst pain in past 24 hours at 24, 48 and 72 hours post-op
Duration of sleep

Intraoperative complications
Postoperative complications
Pump failure (Yes/No) queried at 24, 48 and 72 hours
Catheter migration (Yes/No) queried at 24, 48 and 72 hours
Functionality of surgical arm at 24, 48 and 72 hours

Unable to use, Only light activity, Able to do some activities, Able to do most activities, Slight restrictions only, Normal

Six weeks post-operative
Current pain
ASES
SANE
Complications

Three months post-operative
Readmissions
Visits to the Emergency Room
Total costs for Index surgery and all readmissions and Emergency Room Visits
Date returned to work

Statistics:
Baseline data will be compared
ANCOVA or GEE to examine differences in worst pain scores over 24 hours over time between the two groups (among the three groups)