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# Liposomal bupivacaine versus interscalene nerve block for pain control after shoulder arthroplasty: a prospective randomized trial

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**Hypothesis:** Our hypothesis was that in patients undergoing shoulder arthroplasty, a prospective randomized trial would find no significant differences in average daily pain scores of those treated with interscalene nerve block (INB) vs. local liposomal bupivacaine (LB).

**Methods:** Sixty patients undergoing primary shoulder arthroplasty were assessed for eligibility. Study arms included either intraoperative local infiltration of LB (20 mL bupivacaine/20 mL saline) or preoperative INB, with a primary outcome of postoperative average daily visual analog scale scores for 4 days. Secondary outcomes assessed included opioid consumption, length of stay, and complications. Randomization was by a computerized algorithm. Only the observer was blinded to the intervention.

**Results:** Three patients were excluded, all before randomization. A total of 57 patients were analyzed. Outcomes showed a significant increase in pain in the LB group between 0 and 8 hours postoperatively (mean [standard deviation] 5.3 [2.2] vs. 2.5 [3.0];  $P = .001$ ). A significant increase in intravenous morphine equivalents was found in the INB group at 13 to 16 hours (mean [standard deviation] 1.2 [0.9] vs. 0.6 [0.7];  $P = .01$ ). No significant differences were found in any variable after postoperative day 0 between the 2 groups.

**Conclusion:** An increase in early postoperative pain on the day of surgery was found with LB, whereas the INB group required more narcotics at the end of the day. After the day of surgery, there were no significant differences found in any variables. These findings suggest that LB provides similar overall pain relief as INB, with no increase in complications or length of stay and a decrease in narcotic requirements on the day of surgery.

**Level of evidence:** Level I; Randomized Controlled Trial; Treatment Study

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**Keywords:** Total shoulder arthroplasty; reverse total shoulder arthroplasty; pain control; liposomal bupivacaine; interscalene nerve block; local infiltration

The Institutional Review Board of Henry Ford Health System approved this study: No. 9001. The study is registered at [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT#02570022).

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Regional anesthesia with the use of peripheral nerve blocks has long been recognized as an effective analgesic technique to manage pain in patients undergoing shoulder arthroplasty.<sup>1,15,26</sup> Advantages of such techniques include decreased baseline pain levels, increased patient satisfaction,

reduced time to mobilization, and decreased hospital stay.<sup>1,11</sup> Interscalene nerve block (INB) is one of the most widely used regional techniques for shoulder arthroplasty, providing reliable coverage to the entire surgical field.<sup>22</sup> Whereas INB is effective at pain control, concerns remain about the safety of upper extremity nerve blocks relating to perioperative respiratory and neurologic complications.<sup>4,5,16,24,28,30</sup>

Local infiltration analgesia (LIA), as pioneered by Kerr and Kohan, is a technique that involves infiltration of the periarthicular tissues with a “moving needle” technique, often using an analgesic cocktail consisting of a combination of drugs such as ropivacaine, ketorolac, morphine, and epinephrine.<sup>12</sup> Several studies in the hip and knee arthroplasty literature have proven the efficacy of LIA.<sup>6,7,17,18,27</sup> Some studies even show a greater reduction in postoperative pain and an increase in mobilization in patients treated with LIA.<sup>2,7,13</sup> Although local infiltration has shown various benefits, the agents used in the analgesic cocktail have a short duration of action, after which patients can experience increased pain.<sup>25</sup>

With the advent of liposomal extended-release bupivacaine (Exparel; Pacira Pharmaceuticals, Inc, Parsippany, NJ, USA) to provide long-acting analgesic control, several studies have investigated its efficacy vs. regional anesthesia.<sup>2,23,27</sup> In total knee arthroplasty, liposomal bupivacaine (LB) has shown similar pain profiles and morphine consumption compared with femoral nerve block while allowing quicker mobilization of the patient.<sup>3,23</sup> LIA with LB appears to offer a cost-effective option for similar pain control without the deleterious side effects of regional anesthesia, including motor blockade and peripheral nerve injury, which has been cited to occur at a rate of 2.1% in INB.<sup>24</sup> However, there have been no previous studies evaluating the efficacy of LB in shoulder arthroplasty.

The purpose of our study was to perform a prospective randomized trial of INB vs. local LB for pain control in patients undergoing shoulder arthroplasty in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement 2010.<sup>21</sup> Our hypothesis was that in patients undergoing shoulder arthroplasty, treatment with LB would lead to no significant differences in average daily pain scores.

## Materials and methods

From October 2014 to June 2015, 60 patients surgically treated with a primary shoulder arthroplasty were assessed for study eligibility. Fifty-seven patients were consented for participation. Inclusion criteria included patients older than 18 years undergoing either primary anatomic or reverse total shoulder arthroplasty. Exclusion criteria included known allergies or intolerance to dexamethasone, ropivacaine, or bupivacaine; substantial alcohol or drug abuse; and pregnancy.

Patients who consented for inclusion in the study were compiled on a secure computer database. Subjects were then randomized to receive either LIA or single-injection INB using a computer-generated algorithm. One week before surgical intervention, the surgeon and anesthesiologist were notified by secure e-mail of the

patient’s group designation for the upcoming week by the project coordinator. The study did not require physician blinding as patient outcomes were self-recorded. Patients then underwent anatomic or reverse total shoulder arthroplasty by 1 of 3 fellowship-trained shoulder surgeons.

### INB group

One hour before surgical intervention, patients received an INB by a certified anesthesiologist fluent in the technique, with the guidance of ultrasound. No nerve stimulators were used during or after the procedure by the anesthesiologists. A single dose of 40 mL of 0.5% ropivacaine was injected into the nerve sheath of the brachial plexus with a 22-gauge needle of 80-mm length.

### LB group

Patients allocated to the LIA treatment group received local infiltration of 20 mL of LB (266 mg) mixed in 20 mL of sterile saline. This mixture was infiltrated locally using a standardized protocol at the completion of component implantation and before closure of the wound.

The injection protocol was as follows. A 60-mL syringe with a 1-inch, 18-gauge needle was used to administer the injection; 5 mL was injected into the periosteum; 10 mL was injected into the deltoid in 2-mL increments spread over the deltoid muscle anteriorly; 10 mL was injected into the pectoralis muscle, again in 2-mL increments; and the final 15 mL was injected evenly along the incision before wound closure.

After surgery, patients in both groups were admitted to the orthopedic floor. They were prescribed a standardized postoperative pain regimen consisting of 650 mg acetaminophen every 8 hours, oxycodone 5 mg every 4 hours as needed for pain levels <5, oxycodone 10 mg every 4 hours as needed for pain levels >5, and morphine 2 mg intravenously every 4 hours as needed for severe breakthrough pain.

### Data collection

Postoperatively, the patients’ pain levels and narcotic requirements were assessed initially every hour and then every 4 hours using a visual analog scale (VAS) and intravenous (IV) morphine equivalents. Results were logged for 4 days postoperatively including the day of surgery. Length of hospital stay was recorded, and patients discharged before postoperative day (POD) 3 were sent home with a pain diary binder to record pain and opioid consumption for the remaining days. After retrieval of patients’ pain diaries, a blinded observer recorded outcome measures. Before statistical analysis, opioid consumption between the control and study groups was converted to IV morphine equivalents. The 10-cm scale VAS score measurements were converted to a 0- to 10-point pain rating scale (Appendix S1).

### Statistical analysis

The primary end point of this project was an average daily pain difference on a VAS score of 13 mm between the INB and LB groups. This was based on previous data demonstrating that a difference of 13 mm on a VAS score represents, on average, the minimum change

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