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A prospective randomized controlled trial to identify the optimal postoperative pain management in shoulder arthroplasty: liposomal bupivacaine versus continuous interscalene catheter

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Background: Shoulder arthroplasty is the fastest growing joint replacement surgery in the United States, and optimal postoperative pain management is critical to optimize outcomes for these surgeries. Liposomal bupivacaine (LB) has gained popularity for its potential to provide extended postoperative pain relief with possibly fewer side effects. The goal of this study was to assess the impact of LB compared with continuous interscalene nerve block (CISB) in terms of postoperative pain control, outpatient pain scores, and patient-reported and functional outcomes after shoulder arthroplasty surgery.

Methods: A prospective randomized controlled clinical trial compared consecutive patients undergoing shoulder arthroplasty treated with CISB vs. LB with a single bolus interscalene block. The primary outcome measures included pain assessment up to 24 hours after surgery; in addition, all doses and times of narcotics administered during the inpatient stay were recorded. Patient-reported outcome measures for pain, satisfaction, and functional outcomes were recorded postoperatively.

Results: A total of 70 of 74 consecutive patients who underwent shoulder arthroplasty were included in the study. The LB group had equivalent narcotic use, pain scores, and time to first narcotic rescue compared with the CISB group within the first 24 hours ($P > .05$). The LB group had higher American Shoulder and Elbow Surgeons score and Penn Shoulder Score at final follow-up. There was an increased number of complications and cost for the CISB group.

Conclusion: This prospective randomized controlled trial demonstrated that LB provides excellent postoperative pain relief for shoulder arthroplasty patients. In addition, LB had fewer complications and lower cost, making it a promising addition to a multimodal pain regimen for shoulder arthroplasty.

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

The Institutional Review Board of Wayne State University approved this study: No. 014815MP2F.

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More than 90 million surgical procedures are performed every year in the United States, and according to several national surveys, approximately 80% of patients undergoing surgery report pain that is moderate, severe, or extreme in intensity during the first 2 weeks after the procedure.[3,8,36] The growth rates of shoulder arthroplasty are higher than the rates for total hip and knee procedures in the United States and were predicted to further increase by between 192% and 322% by 2015 based on 2008 numbers.[23] As this number of shoulder arthroplasties continues to grow, the significance of postoperative pain management becomes of primary importance.

Shoulder surgery has been identified as one of the most painful ambulatory surgeries, and inadequate perioperative pain management has been correlated with a wide range of poor outcomes, including increased readmissions, slower rehabilitation, delayed return to activities of daily living, increased cost, unnecessary burden of care on families, and progression to a persistent pain state.[25,31] Multimodal pain management for patients undergoing shoulder surgery typically consists of anti-inflammatory medications, opioids, and regional anesthesia. The addition of continuous interscalene block (CISB) has provided a number of advantages to postoperative pain control, including decreased pain, decreased opioid use and related side effects, reduced sleep disturbances, reduced time to discharge, improved time to mobilization, and overall satisfaction after shoulder surgery.[12,15,18,20,21] Despite this, CISB is also associated with limitations, such as technical problems with administration that could lead to inadequate pain control. CISB is also associated with risks, such as failure of nerve blockade, residual neurapraxia, displacement of the catheter postoperatively, systemic toxicity, and respiratory and neurologic complications.[6,18,27]

Liposomal bupivacaine (LB; Exparel, Pacira Pharmaceuticals, Inc., Parsippany, NJ, USA) has recently gained popularity for its potential to provide extended postoperative pain relief. Several studies have investigated its efficacy vs. regional anesthesia after hip and knee arthroplasty. The use of LB has demonstrated efficacy with decreased opioid consumption, early mobilization, lower hospital costs, and shorter length of stay for patients undergoing surgeries such as bunionectomy, open colectomy, umbilical hernia repair, breast augmentation, and total knee arthroplasty.[4,11,16,32]

Limited studies have evaluated the efficacy of LB for perioperative pain control in shoulder arthroplasty.[28] Hence, the objective of this study was to determine whether the use of an LB-based multimodal analgesic regimen provides better postoperative pain control and patient satisfaction, greater cost effectiveness, and lower risk profile compared with CISB.

Materials and methods

This prospective, randomized, controlled study included 70 consecutive shoulder arthroplasty patients from August 2015 through June 2016 during the period of 1 year. All patients undergoing primary shoulder arthroplasty were enrolled in the study if they met inclusion criteria (patients aged 18 years or older who met the criteria for standard of care of CISB per anesthesia guidelines issued by the American Society of Anesthesiologists). Exclusion criteria included contraindications to regional anesthesia, allergy to any component of multimodal analgesia, history of opioid use of >50 morphine milligram equivalents (MME) daily, significant peripheral neuropathy or neurologic disorder affecting the upper extremity, cognitive or psychiatric condition that might affect the patient's assessment or inability to provide informed consent, and pregnancy. Once patients were enrolled in the study, they were prospectively randomized into 1 of 2 pain management groups using a computer randomization program, Google Coin Flip. Preoperatively, all patients received standard analgesia consisting of 1000 mg of oral acetaminophen and 200 mg of celecoxib.

CISB group

Patients in the CISB group underwent catheter placement with ultrasound guidance by an experienced anesthesiologist. A 20-mL single bolus interscalene nerve block with 0.5% bupivacaine was administered, and then patients continued to receive 0.125% bupivacaine at a rate of 6 mL/hr postoperatively by ACTion Block Pain Pump (Ambu A/S, Ballerup, Denmark), allowing the maximum dose to be administered during 100 hours.

LB group

Patients in the LB group first received the 20-mL single bolus brachial plexus nerve block with 0.5% bupivacaine administered by the anesthesiologist using ultrasound guidance preoperatively. Intraoperatively, they received periarticular tissue infiltration with LB. The standard recommended 20-mL (266-mg) dose of LB was diluted to a total volume of 80 mL with 0.9% normal saline and administered by optimal recommended moving needle technique during the surgical procedure.[22] LB administration using the moving needle technique was done before prosthetic implantation in the area around the bone (48 mL); after prosthetic implantation into the capsule, deep musculature, and superficial musculature (16 mL); and in the subcutaneous layers and around the incision (16 mL). The technique has been validated and demonstrated success for total hip and knee replacements as well as for total shoulder arthroplasty.[2,26,28]

During surgery, all patients received general anesthesia with appropriate intraoperative doses of fentanyl or analogue equivalents. All surgeries were performed by 2 fellowship-trained shoulder surgeons (M.M. and V.J.S.) at the same facility. Standard surgical implants and techniques were used for all patients enrolled in the study. Postoperatively, patients were admitted to the orthopedic unit