Randomized Controlled Trial Comparing Mixed Liposomal Bupivacaine to Continuous Catheter for Interscalene Nerve Block During Shoulder Arthroplasty

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INTRODUCTION

- Continuous-interscalene catheters can prolong analgesia beyond 24h but are resource intensive, while analgesic efficacy of liposomal bupivacaine for single-injection interscalene blocks remains unclear.
- With a goal of delivering value-based care, understanding the "value" (outcome/cost) of regional anesthetic techniques is paramount to improving clinical pathways. This investigation examined *analgesic* efficacy, *quality* of recovery, and treatment *costs*.
- The authors hypothesized that continuous-interscalene catheter would provide superior analgesia at 24h after surgery but at a greater cost compared to mixed liposomal bupivacaine single-injection interscalene block.

METHODS

- Single-center, parallel, unblinded, superiority, randomized controlled trial evaluating 88 adult patients undergoing elective, unilateral, primary shoulder arthroplasty (anatomic or reverse) between December 2021 and March 2023.
- IRB approved and registered at ClinicalTrials.gov
- The mixed liposomal bupivacaine-interscalene group received 10mL (133mg) of liposomal bupivacaine mixed with 5mL of 0.5% standard bupivacaine HCl
- The continuous-interscalene group received a 15-20mL bolus of 0.5% bupivacaine-HCl premixed with epinephrine followed by a continuous infusion of 0.2% bupivacaine-HCl fixed at 8 mL/h for estimated 69 hours via an elastomeric ambulatory nerve catheter system.

OUTCOMES

- **Primary Outcome:** pain intensity score at rest (NRS 0 to 10) 24 h after surgery
- **Secondary Outcomes:** obtained through postoperative day 3 - pain scores, opioid consumption, complications, quality of recovery-15 assessment, and time-driven activity-based cost analysis.

RESULTS

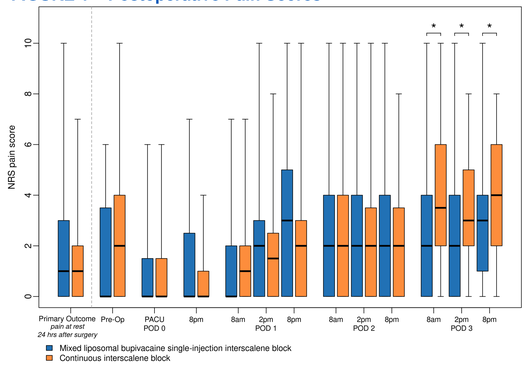
- 5 excluded; 83 patients for intention-to-treat analysis
- 100% telephone compliance, 100% sensory blockade
- No difference in baseline characteristics

DISCUSSION

- Unique to the present study was the assessment of three points of comparison: *analgesia, quality, and cost*. This integrative approach enables better determination of comparative value thereby bringing a broader informative perspective to clinicians.
- *Analgesia* - Reliability of elastomeric pumps and secondary block failure can impact analgesic outcomes in catheter-based techniques.
- Quality – QoR-15 is a validated, reliable, and feasible scoring system evaluating five dimensions of health: psychological support, comfort, emotions, physical independence, and pain.
- Cost - TDABC enables accurate cost analyses through estimating the individual unit cost of resource inputs as well as the time and quantity of resources required to perform an activity

RESULTS - TABLES AND FIGURES

FIGURE 1 – Postoperative Pain Scores



The box plot displays the median (bold line), box edges are the 25th and 75th percentiles, and the whiskers extend to the extremes (min/max) of the data. * Indicates statistical significance; POD 3: 8 am P=.0269, 2 PM P=.0093, 8 PM P=.0132

Table 1 – Opioid Consumption*

Phase of Care (OME mg)	Continuous Catheter (N=44)	Mixed liposomal bupivacaine (N=39)	P-value
Pre-Op & Intra-Op	45.0 (30.0, 63.8)	45.0 (30.0, 52.5)	0.1504
PACU	0.0 (0.0, 0.0)	0.0 (0.0, 15.0)	0.3411
Post-PACU to end of POD 0	0.0 (0.0, 0.0)	0.0 (0.0, 7.5)	0.0016
POD 1	0.0 (0.0, 7.5)	7.5 (0.0, 15.0)	0.0008
POD 2	0.0 (0.0, 7.5)	7.5 (0.0, 22.5)	0.0130
POD 3	7.5 (0.0, 15.0)	0.0 (0.0, 12.5)	0.0734
Cumulative - POD 0 to POD 3	15.0 (7.5, 38.8)	30.0 (7.5, 64.0)	0.0825

* Data are presented as median (25th, 75th); doses of each opioid-containing medication were converted to equivalent milligram doses of oral morphine.

Table 2 – Max Pain and Area Under Curve*

	Continuous Catheter (N=44)	Mixed liposomal bupivacaine (N=39)	P-value
Maximum Pain Score			
POD 0	1.0 (0.0, 2.1)	2.0 (0.0, 4.0)	0.0815
POD 1	2.0 (0.5, 4.0)	4.0 (1.0, 6.0)	0.0849
POD 2	2.0 (0.5, 5.0)	4.0 (1.0, 5.0)	0.4165
POD 3	5.0 (3.0, 7.0)	3.0 (1.0, 5.0)	0.0044
Overall (POD 0 to POD 3)	6.0 (4.0, 7.0)	5.0 (3.0, 7.0)	0.2522
AUC Pain Score (PACU through POD 3)	157.3 (93.0, 235.5)	158.4 (45.1, 291.0)	0.816

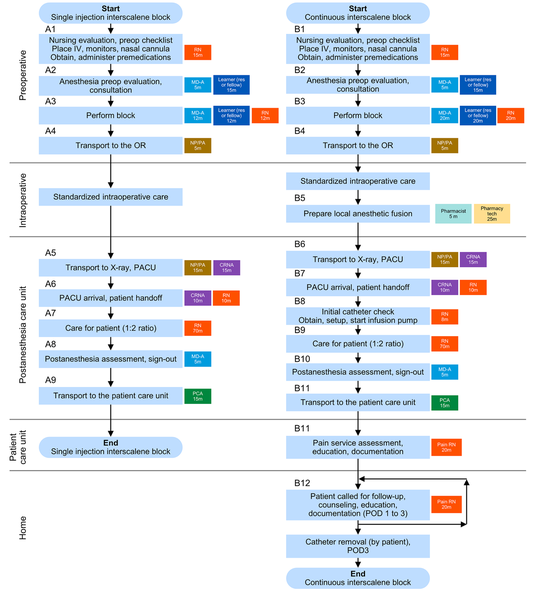
* Data are presented as median (25th, 75th); Area under curve (AUC) captures the pain over the duration of the measurement period

Table 3 – Hospital Outcomes*

	Continuous Catheter (N=44)	Mixed liposomal bupivacaine (N=39)	P-value
Hospital Stay (days)	0.5 (0.0, 1.0)	0.0 (0.0, 1.0)	0.4441
Duration of Surgery (min)	63.5 (59.0, 74.5)	63.0 (57.0, 76.0)	0.2869
Quality of Recovery-15			
POD 1	124.0 (111.0, 132.5)	126.0 (113.0, 133.0)	0.6712
POD 2	125.0 (114.0, 136.5)	132.0 (114.0, 138.0)	0.1709
POD 3	124.5 (114.5, 135.5)	132.0 (118.0, 142.0)	0.0555
Adverse Events			
Catheter-related AE**	7 (15.9%)	0 (0.0%)	
Dyspnea	6 (13.6%)	6 (15.4%)	>0.999

* Data are presented as median (25th, 75th); **5 leaking catheters, 1 accidental dislodgement, 1 reported as non-functioning.

Figure 2 –Time-Driven Activity-Based Cost Analysis



Detailed process map was created for each pathway. Compared to single injection liposomal bupivacaine-interscalene block, the total cost (labor and material) was 1.4 times greater to provide analgesia via continuous-interscalene block.

CONCLUSION

Considering *analgesia*, *quality*, and *cost* collectively, liposomal bupivacaine single-injection interscalene block appears to be an acceptable analgesic alternative and may offer improved "value" compared to an ambulatory continuous-interscalene block through POD 3 within our practice model.

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