Quality of Recovery After Rotator Cuff Repair With Interscalene Liposomal Bupivacaine Versus Interscalene Nerve Catheter

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Background: Interscalene nerve catheters have been proven to be effective in managing pain after rotator cuff repair (RCR) surgery. Liposomal bupivacaine is a newer approved therapy for use around the interscalene brachial plexus, but its analgesic efficacy has limited supporting data in various patient populations.

Purpose/Hypothesis: The purpose of this study was to investigate the quality of recovery after arthroscopic RCR in patients who received either single-injection interscalene liposomal bupivacaine or an interscalene peripheral nerve catheter. It was hypothesized that interscalene peripheral nerve catheters would provide more reliable analgesia and improved patient satisfaction 48 hours after surgery.

Study Design: Cohort study; Level of evidence, 2.

Methods: Enrolled were 93 consecutive patients who underwent arthroscopic rotator cuff surgery at a single ambulatory surgery center between October 2020 and June 2021. Of these patients, 13 were lost to follow-up; thus, 80 patients were included in statistical analysis. One group of patients (n = 48) received a preoperative interscalene nerve block placed with 10 mL 0.5% bupivacaine and 10 mL 1.3% liposomal bupivacaine. The second group (n = 32) received a preoperative interscalene catheter with an initial bolus of 20 mL 0.25% bupivacaine and a 0.2% ropivacaine infusion by an elastomeric pump set at 10 mL/hr for 48 hours. The primary outcome was the difference between preoperative and 48-hour postoperative quality of recovery-15 (QoR-15) scores. Secondary outcomes included visual analog pain scores, opioid use, and patient satisfaction. Complications and adverse effects were also noted. The Kruskal-Wallis test was used to analyze means and standard deviations for continuous endpoints; Fisher exact test was used to analyze counts and proportions for categorical endpoints.

Results: The liposomal bupivacaine group had a mean reduction of 3.9 in their postoperative QoR-15 scores, and the catheter group had a mean reduction of 25.1 in their postoperative QoR-15 scores, indicating a significantly worse functional recovery period compared with liposomal bupivacaine within the first 48 hours ($P < .001$). Patients who received liposomal bupivacaine also had significantly lower pain scores on the second postoperative day, improved quality of sleep, and improved satisfaction with analgesia ($P < .05$ for all).

Conclusion: The use of interscalene liposomal bupivacaine demonstrated significantly improved quality of recovery when compared with interscalene nerve catheter after RCR.

Keywords: interscalene; liposomal bupivacaine; quality recovery; shoulder arthroscopy

Arthroscopic rotator cuff repair (RCR) often causes significant postoperative pain. Given an aging population, RCR is an increasingly common ambulatory procedure. Effective postoperative analgesia and return to quality of life are therefore of high importance. Interscalene peripheral nerve catheters have proven to be an effective method to reduce postoperative pain and decrease perioperative opioid use after RCR.[13] Liposomal bupivacaine was recently approved for use at the interscalene brachial plexus and has also been shown to be effective for major shoulder surgery,[3,8,13,14,16-18] although analgesic efficacy has limited supporting data.[19]

To recalibrate and standardize our processes for RCR, we realized there were 2 clinical camps who both believed in the quality of their technique. Both interscalene catheters and interscalene liposomal bupivacaine were currently in

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use at our institution for analgesia after shoulder arthroscopy and RCR. A recent meta-analysis has called into question the efficacy of liposomal bupivacaine for postoperative analgesia when compared with traditional methods,[1,2,4,10-12] but at the time of design of this quality improvement project, there were no prospective randomized studies published comparing interscalene catheters with interscalene liposomal bupivacaine with regard to the quality of recovery after RCR.

Previous studies have focused primarily on unidimensional outcomes of postoperative pain score or opioid consumption between techniques. Comparing regional anesthetic techniques by examining quality of recovery as a primary outcome is more holistic and patient-centered. The purpose of this article was to report the results of a quality improvement project that examined the quality of recovery with liposomal bupivacaine analgesia compared with the practice of placing interscalene peripheral nerve catheters. Our hypothesis was that interscalene peripheral nerve catheters would provide more reliable analgesia and improved patient satisfaction 48 hours after surgery.

METHODS

Project Design

A prospective, single-center, pragmatic quality improvement project was conducted that compared the quality of recovery after RCR with 2 commonly employed ultrasound-guided techniques: (1) interscalene single-shot liposomal bupivacaine (Exparel; Pacira Biosciences) and (2) interscalene block with bupivacaine and a peripheral nerve catheter. All patients underwent their procedures at a single ambulatory surgery center. The quality improvement project was deemed exempt by the institutional review board and was registered on ClinicalTrials.gov on September 25, 2020, before commencement of the quality improvement initiative (registration number NCT04571606).

Included were all patients older than 18 years who underwent arthroscopic RCR between October 9, 2020, and June 21, 2021, at our ambulatory surgery center. The operations were performed by 1 of 3 orthopaedic surgeons at our institution, all with more than 10 years of experience. The only exclusion criteria were a contraindication to regional anesthesia or inability to speak fluent English enabling accurate postoperative follow-up. Only 4 patients were excluded from the project, all for inability to speak fluent English for follow-up data collection. There were 97 consecutive patients initially identified. Follow-up including the postoperative quality of recovery-15 (QoR-15) was incomplete for 13 patients; thus, 80 patients underwent statistical analysis (Figure 1).

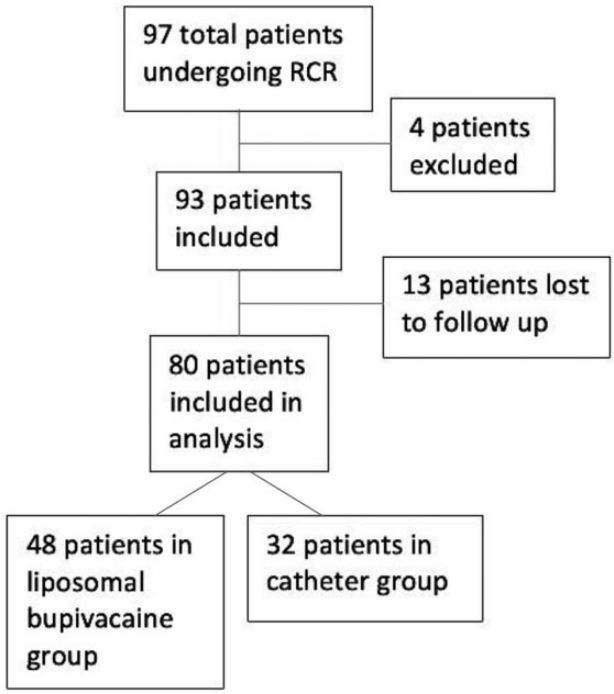

Figure 1. Flow diagram of patient enrollment. RCR, rotator cuff repair.

Patient Grouping

The study patients were divided into 2 groups. One group (n = 48) received a preoperative single-shot interscalene nerve block with 10 mL 0.5% bupivacaine and 10 mL 1.3% liposomal bupivacaine. The second group (n = 32) received a preoperative interscalene catheter with 20 mL 0.25% bupivacaine and a 0.2% ropivacaine infusion via an elastomeric pump (On-Q; Avanos Inc) started in the post-anesthesia care unit at 10 mL/h for 48 hours. Both groups were given an equal bolus dose of 50 mg bupivacaine in 20 mL block solution to create a comparable initial block in both groups. The 48-hour follow-up was designed to assess the long-acting analgesic effects of liposomal bupivacaine and peripheral nerve catheters without any lasting effect from the initial single-shot nerve block.[5] All attending anesthesiologists routinely provide care with single-shot and peripheral nerve catheter techniques.

The patients were not randomized, but the study groups were alternated weekly to standardize practice and reduce

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2 potential confounding factors: practice variation based on the attending anesthesiologist's regional technique preference and changes over time that could have led to unanticipated variation (eg, changes in nursing or surgical care) and confound the quality results. In addition, alternating groups weekly in this teaching center could reduce the impact of the evolving regional skills of our anesthesiology residents who rotate through the surgery center in month-long rotations.

All patients received preoperative oral multimodal analgesics consisting of 1000 mg acetaminophen, 400 mg celecoxib, and 100 mg pregabalin. General anesthesia with volatile anesthetic maintenance was standard, with intraoperative 25 to 250 μg fentanyl as needed. Six patients received intraoperative hydromorphone doses between 0.25 and 1 mg, and 10 patients received a single intraoperative 30-mg ketamine dose. All patients were discharged with 2 weeks of scheduled acetaminophen, 3 days of scheduled gabapentin, and up to 5 days of 5 mg oxycodone tablets as needed for breakthrough pain management.

Evaluation of Recovery

Postoperative quality of recovery was evaluated using the QoR-15 questionnaire.[7] The QoR-15 is a systematically reviewed and validated questionnaire shown to accurately assess postoperative quality of recovery irrespective of surgical procedure. The QoR-15 consists of a standardized set of 15 questions assessing a variety of postoperative milestones[15]; scores can range from 0 to 150. Patients completed the QoR-15 once preoperatively on the day of surgery and a second time 48 hours postoperatively. All follow-up calls were made by 1 of 4 project personnel (J.W.S., M.G., R.S., T.B.).

Outcome Measures

The primary outcome was the difference between preoperative and 48-hour postoperative QoR-15 scores. A smaller difference between the preoperative and the postoperative QoR-15 score or an improved postoperative QoR-15 indicates a higher quality of recovery. A larger reduction in the QoR-15 score indicates decreased quality of recovery. Subanalysis of the 5 functional domains of the QoR-15 questionnaire (pain, physical comfort, physical independence, psychological support, emotional state) was performed to identify any domain that was particularly different between the 2 groups.

Secondary outcome measures included postoperative pain scores (evaluated on an 11-point verbal numeric rating scale), opioid use (fentanyl and oxycodone), quality of sleep (assessed on an 11-point verbal numeric rating scale), and overall patient satisfaction (assessed on a 5-point scale). Complications and adverse effects of either nerve block technique were also screened during routine follow-up.

Statistical Analysis

Statistics were provided for various endpoints and their differences between the interscalene liposomal bupivacaine group and interscalene peripheral nerve catheter group. For continuous endpoints, means and standard deviations were calculated, and their differences were tested by the Kruskal-Wallis test. For categorical endpoints, counts and proportions were calculated, and their differences were tested by the Fisher exact test. P values less than .05 were treated as statistically significant. All analyses were conducted by the statistical package R (version 4.0.3, R foundation).

Based on published data in outpatient surgery, a mean value for QoR-15 is expected to be approximately 130 of 150,[5] and the published minimally significant difference in score is 8 points.[9] With a sigma of 12, a calculated sample size minimum of 36 per group would be required. Allowing for loss of data at follow-up and variations in group size, an estimated sample size of 90 patients was calculated.

RESULTS

The characteristics of the 80 study patients are shown in Table 1. There were no significant differences in preoperative data between the patients who received liposomal bupivacaine (n = 48) and those who received interscalene catheter (n = 32).

Results for the primary outcome are shown in Table 2 and Figure 2. The liposomal bupivacaine group had a mean reduction of 3.9 points in their QoR-15 score from preoperatively to 48 hours after surgery, demonstrating high quality of recovery, whereas patients who received bupivacaine block and peripheral nerve catheter had a mean QoR-15 score reduction of 25.1 points, indicating significantly worse quality of recovery ($P < .001$). This significant difference in QoR-15 scores did not vary over time between the 2 groups, as demonstrated in Figure 3.

There were several significant secondary outcomes between the groups (Table 3); however, no multiplicity adjustments were made, and these results should be regarded as exploratory. The interscalene catheter group reported significantly decreased quality of sleep during the first night after surgery ($P = .038$). The interscalene catheter group also reported significantly higher pain scores on postoperative day 2 ($P = .048$). Postoperative satisfaction with analgesia as assessed on a 5-point scale was significantly better in the liposomal bupivacaine group on postoperative days 1 ($P = .046$) and 2 ($P = .035$).

Subanalysis of the 5 domains within the QoR-15 questionnaire is reported in Table 4. Differences in preoperative and postoperative scores between groups were significantly improved across all 5 domains in the liposomal bupivacaine group.

DISCUSSION

The findings of this study demonstrate improved quality of recovery through 48 hours after rotator cuff surgery in patients with interscalene liposomal bupivacaine, as compared with an interscalene peripheral nerve catheter with a bupivacaine bolus followed by a continuous infusion of

TABLE 1
Patient Characteristics[a]

Characteristic	Total (N = 80)	Liposomal Bupivacaine (n = 48)	Interscalene Catheter (n = 32)	*P*
Age, y	58.5 ± 9.7	57.6 ± 9.9	59.9 ± 9.5	.298
ASA class	2.26 ± 0.61	2.33 ± 0.56	2.16 ± 0.67	.261
Sex				.411
Male	38 (47.5%)	21 (43.8%)	17 (53.1%)	
Female	42 (52.5%)	27 (56.2%)	15 (46.9%)	
Race or ethnic group				.529
White	54 (67.1%)	30 (62.5%)	24 (73.5%)	
Black	19 (24.4%)	13 (27.1%)	6 (20.6%)	
Asian	4 (4.9%)	2 (4.2%)	2 (5.9%)	
Pacific Islander	1 (1.2%)	1 (2.1%)	0 (0.0%)	
Other race	2 (2.4%)	2 (4.2%)	0 (0.0%)	
Body mass index	29.0 ± 4.8	28.8 ± 5.1	29.4 ± 4.5	.594
Preop opioid use	8 (10%)	3 (6.25%)	5 (15.6%)	.298
Preop pain score (0-10)				
At rest	3.23 ± 3.13	3.56 ± 3.4	2.78 ± 2.73	.392
With movement	6.48 ± 2.82	7.00 ± 2.67	5.81 ± 2.91	.080

[a]Data are presented as mean ± SD or n (%). ASA, American Society of Anesthesiologists; Preop, preoperative.

TABLE 2
Difference Between Preoperative and 48-Hour Postoperative QoR-15 Scores by Study Group[a]

QoR-15 score	Total (N = 80)	Liposomal Bupivacaine (n = 48)	Interscalene Catheter (n = 32)	*P*
Preoperative	124.6 ± 16.1	123.2 ± 17.6	126.7 ± 13.7	.529
48 hours postoperative	111.8 ± 22.3	119.4 ± 18.9	101.6 ± 22.5	**<.001**
$\Delta_{post\ -\ pre}$	-12.4 ± 22.3	-3.9 ± 20.0	-25.1 ± 19.4	**<.001**

[a]Data are presented as mean ± SD. Boldface *P* values indicate statistically significant difference between study groups ($P < .05$). pre, preoperative; post, postoperative; QoR-15, quality of recovery-15.

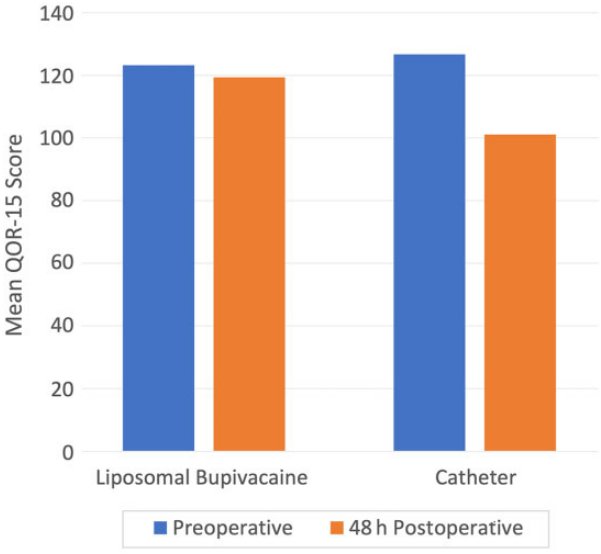

Figure 2. Mean preoperative and postoperative QoR-15 scores by study group. QoR-15, quality of recovery score-15.

0.2% ropivacaine via an elastomeric pump (mean difference in QoR-15, -3.9 vs -25.1; $P < .001$). The initial nerve blocks in both groups utilized a similar concentration and volume of local anesthetic so that the primary outcome will reflect the difference in analgesia provided by the liposomal bupivacaine as compared with the peripheral nerve catheter infusion.

A recently published meta-analysis of liposomal bupivacaine compared with bupivacaine for multiple applications revealed no clear benefit.[6] The meta-analysis used pain score as its primary outcome rather than the more patient centric and holistic assessment of quality of recovery as examined in this paper, and although the meta-analysis did include 3 studies on RCR, none of the 3 examined quality of recovery as an outcome. Despite no significant difference in postoperative opioid use, subanalysis of the QoR-15 questionnaire domains demonstrate improved scores across all domains in the liposomal bupivacaine group. The results reported here indicate that comparisons of liposomal bupivacaine with other therapies may be outcome dependent or procedure dependent and warrant further exploration based on specific surgeries and clinical settings.

Our initial hypothesis was that a single injection of interscalene liposomal bupivacaine would not provide meaningful analgesia for 48 hours after RCR and that the primary outcome would favor the peripheral nerve catheter technique. This project was not designed with the power to determine why patients with interscalene catheters reported more

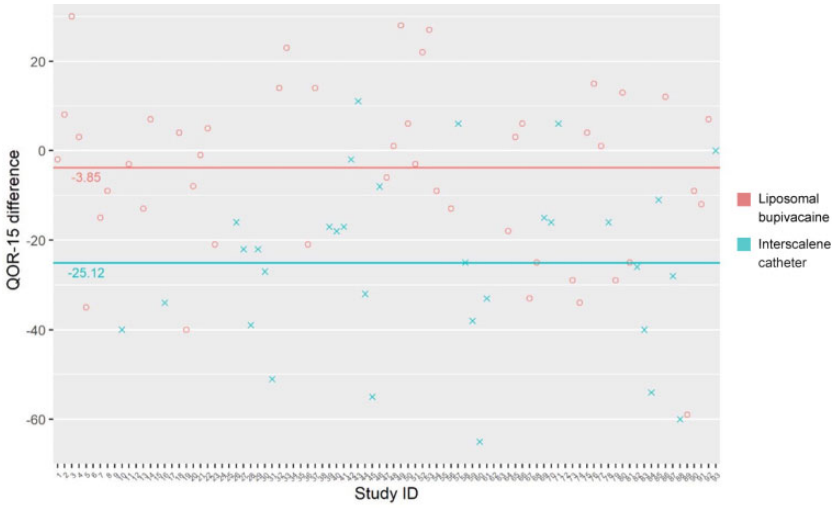

Figure 3. Difference between preoperative and postoperative QoR-15 scores over time. QoR-15, quality of recovery score-15.

TABLE 3
Difference Between Preoperative and Postoperative Pain, Opioid Use, and Satisfaction.[a]

Variable	Total (N=80)	Liposomal Bupivacaine (n = 48)	Interscalene Catheter (n = 32)	*P*
Pain score				
First PACU	3.22 ± 3.13	3.38 ± 3.31	3.03 ± 2.97	.702
Mean PACU	3.33 ± 2.95	3.34 ± 3.11	3.45 ± 2.78	.711
Mean POD1	3.67 ± 2.92	3.42 ± 2.99	4.03 ± 2.92	.34
Highest POD1	4.82 ± 3.48	4.41 ± 3.63	5.48 ± 3.3	.16
Lowest POD1	1.70 ± 2.24	1.53 ± 2.15	2.065 ± 2.41	.327
Mean POD2	4.22 ± 2.55	3.79 ± 2.71	4.94 ± 2.21	.105
Highest POD2	5.80 ± 2.97	5.28 ± 3.22	6.72 ± 2.41	**.048**
Lowest POD2	2.24 ± 2.06	2.02 ± 2.16	2.71 ± 1.85	.095
Fentanyl, μg				
Intraoperative	104.4 ± 44.7	101.7 ± 33.0	109.4 ± 58.5	.953
PACU	37.7 ± 78.5	33.2 ± 72.4	46.9 ± 89.1	.099
Intraoperative hydromorphone, mg	0.06 ± 0.22	0.05 ± 0.2	0.08 ± 0.25	.598
Oxycodone, mg				
Total PACU	2.2 ± 5.4	2.3 ± 6.3	2.2 ± 4.0	.396
POD1	11.2 ± 15.9	11.8 ± 17.6	10.4 ± 13.6	.863
POD2	13.2 ± 14.2	12.3 ± 14.0	14.5 ± 14.6	.401
Quality of sleep, POD1 (0-10)[b]	3.6 ± 3.6	3.0 ± 3.5	4.5 ± 3.5	**.038**
Satisfaction with analgesia (1-5)				
POD1	4.53 ± 0.82	4.67 ± 0.74	4.32 ± 0.91	**.046**
POD2	4.50 ± 0.83	4.62 ± 0.82	4.32 ± 0.83	**.035**
POD3	4.58 ± 0.80	4.60 ± 0.91	4.55 ± 0.59	.228

[a]Data are presented as mean ± SD. Boldface *P* values indicate statistically significant difference between study groups ($P < .05$). PACU, postanesthesia care unit; POD, postoperative day.
[b]0 = no interference by pain.

discomfort, but secondary catheter failure may have been a contributing factor. There may also be some difficult to quantify discomfort associated with having an indwelling nerve catheter at the base of the neck attached to a bulky ball of ropivacaine. Despite not knowing exactly why our patients with liposomal bupivacaine blocks felt better after RCR, this project has helped our department move away from placing interscalene catheters in this patient population.

Limitations

This study is not without limitations. One weakness of the study design is the lack of blinding and potential bias at data collection. The liposomal group had no pump or catheter visible. Placement of a sham catheter is not without risk and not feasible for a quality improvement project. The patients were not randomized; however, the data were

TABLE 4
Difference Between Preoperative and Postoperative QoR-15 Domain Scores[a]

QoR-15 Domain	Overall (n = 80)	Liposomal Bupivacaine (n = 48)	Interscalene Catheter (n = 32)	*P*
Pain	2.8 ± 6.9	4.8 ± 6.4	-0.2 ± 6.8	**.001**
Physical comfort	-4.5 ± 8.5	-1.7 ± 7.9	-8.8 ± 7.7	**<.001**
Physical independence	-6.5 ± 5.3	-5.4 ± 4.7	-8.3 ± 5.6	**.037**
Psychological support	-1.6 ± 3.9	-0.8 ± 2.5	-2.9 ± 5.1	**.001**
Emotional state	-2.4 ± 7.8	-0.8 ± 7.8	-4.9 ± 7.1	**.019**

[a]Data are reported as mean ± SD (postoperative - preoperative). Boldface *P* values indicate statistically significant difference between study groups ($P < .05$, Kruskal-Wallis rank-sum test). QoR-15, quality of recovery-15.

collected prospectively, and the groups were alternated on a weekly basis. The patients were scheduled ahead by the surgical team who were unaware of which group was scheduled for which week. There were patient-related variables that were not controlled including rotator cuff tear size and morphology. There were exceptions to the standardized analgesics given during the intraoperative anesthetic, but they were not significantly different between the 2 groups. The groups were uneven in size, but this does not preclude accurate statistical analysis. Although we used a validated test of recovery in the QOR-15, we only assessed 1 time point as our primary outcome. Strengths of this project include the prospective data collection, similar demographics including preoperative pain scores between groups, identical postoperative analgesic prescriptions, and the lack of restrictive exclusion criteria, which allow us to draw meaningful clinical conclusions about our specific patient population.

CONCLUSION

After analyzing data from this quality improvement project, patients at our institution have an improved quality of recovery after RCR with interscalene liposomal bupivacaine as opposed to an interscalene peripheral nerve catheter. Additional blinded prospective investigations are warranted to assess the quality of recovery provided by liposomal bupivacaine compared with peripheral nerve catheters on a procedure-specific basis.

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