J Shoulder Elbow Surg (2019) 28, 819–827

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Journal of Shoulder and Elbow Surgery

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Liposomal bupivacaine reduces opiate consumption after rotator cuff repair in a randomized controlled trial

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Background: Arthroscopic rotator cuff repair (ARCR) provides excellent clinical outcomes but is often associated with significant postoperative pain. The use of intraoperative anesthesia in conjunction with multimodal pharmacologic strategies is a widely accepted approach for managing surgical pain and reducing opiate use. The purpose of this study was to determine whether using a combined field and suprascapular nerve block with liposomal bupivacaine (LB) in addition to an interscalene block would provide greater pain relief and a reduction in opiate consumption compared with an interscalene block alone.
Methods: The study enrolled 50 patients with full-thickness rotator cuff tears undergoing primary ARCR surgery. Patients were randomized to receive intraoperative LB (n = 25) or not (n = 25) and given postoperative ''pain journals'' to document visual analog scale pain scores and to track their daily opioid consumption during the first 5 postoperative days.
Results: Patients in the LB group reported statistically and clinically lower pain scores during postoperative days 1 and 2 ($P < .0001$ and $P = .03$, respectively). In addition, patients in the LB group consumed significantly fewer narcotics than the control group during the 5-day period, demonstrating a 64% reduction in total narcotic consumption ($P = .002$).
Conclusion: The findings of this study suggest that the addition of LB to multimodal anesthetic protocols significantly reduces the acute perioperative pain experienced following rotator cuff repair and the number of narcotic pills consumed in the first 5 days after ARCR. Furthermore, the findings provide guidelines for postoperative narcotic prescribing to reduce the quantity of opiates prescribed.
Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Postoperative care; analgesia; opioid epidemic; pain management; rotator cuff repair; liposomal bupivacaine

Arthroscopic rotator cuff repair (ARCR) provides excellent clinical outcomes but is often associated with significant postoperative pain.[22] Welton et al[24] reported that physicians prescribe an average of 462.5 ± 196.9 oral morphine equivalents (OMEs), the equivalent of 61.7 ± 26.3 oxycodone 5-mg pills, to

This study was approved by the Greenwich Hospital Institutional Review Board (2016017).

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https://doi.org/10.1016/j.jse.2019.01.008

patients undergoing ARCR. The pain associated with ARCR often may last for an extended period, with most patients requesting at least 1 refill of their narcotic pain medication prescription within the first 2 months after surgery.[18,26]

As ARCR procedures become increasingly more common, with a 238% rise between 1995 and 2009, the narcotic prescriptions that accompany them also increase and may contribute to the rising opioid epidemic.[7,12] Prolonged (>2 months) postsurgical use of narcotic medications is directly associated with abuse and addiction.[9,16] Furthermore, the majority of non-prescribed opiate use originates from excess pills provided by friends or relatives from previous physician-provided prescriptions.[7] In a recent report on shoulder surgery, Kumar et al[10] reported an average of 32 unused pills per patient undergoing shoulder surgery. Identifying postoperative pain management methods that reduce the need for narcotic medication and accurately prescribing the appropriate number of pills required following ARCR procedures are imperative, yet no published data or guidelines exist to aid surgeons.

The use of intraoperative local and regional anesthesia or field blocks (in contrast to interscalene blocks [ISBs]), in conjunction with multimodal pharmacologic strategies, is a widely accepted approach for managing surgical pain and reducing opiate use.[11] The development of long-acting local anesthetics that are capable of providing significant pain relief for the first 48 to 72 postoperative hours may offer a viable tool to improve the efficacy of local and regional anesthesia by providing extended pain relief during the initial acute perioperative period. The purpose of this study was to determine whether using a combined field and suprascapular nerve block with liposomal bupivacaine (LB) in addition to an ISB would provide greater pain relief and a reduction in opiate consumption compared with an ISB alone. The hypothesis of this study was that using a field block with a long-acting local agent in addition to an ISB would provide greater pain relief and a reduction in opiate consumption compared with use of an ISB alone.

Materials and methods

This study was registered at clinicaltrials.gov and followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Fig. 1). A sample of 55 patients undergoing ARCR surgery performed at Orthopaedic & Neurosurgery Specialists (Greenwich, CT, USA) by the surgical authors (P.M.S. and S.R.M.) between February 2017 and March 2018 were enrolled in this parallel-group study. The sample size was determined via an a priori power analysis set at 0.8 assuming a minimal clinically important difference (MCID) of 1.4 (effect size) and a P value of .05. This required 20 patients in each group. To be included in the study, the patients had to meet the following inclusion criteria: at least 18 years of age; ARCR surgery for a full-thickness tear; willingness to fill out the ''pain journal''; ability to understand the informed-consent process and to document informed consent prior to completion of any study-related procedure; and ability to read, comprehend, and complete subject-reported outcome measures in English. Patients were excluded from the study if they met any of the following criteria: pregnant, documented history of drug or alcohol abuse, use of narcotic painkillers greater than 3 months prior to surgery, neurologic deficit or disability involving the surgical extremity, known allergy to amide anesthetics, known allergy or intolerance to hydrocodone or oxycodone, currently enrolled or planning to enroll in another clinical trial during this study that would affect the outcome of this study, and/or history of a cognitive or mental health status that would interfere with study participation. Subject sex, age, and concomitant procedures were all recorded. Patient eligibility assessments and patient recruitment were performed by the principal investigator (P.M.S.) or a trained, authorized site delegate.

Study participants were randomly alternately assigned to either the LB group or control group in a sequential fashion. After a coin flip, the first subject was deemed a control subject and the next was deemed an LB subject, alternating henceforth. All patients received 1000 mg of acetaminophen orally and 400 mg of gabapentin orally prior to surgery. The control group received an ISB (ultrasound guided with 20 mL of 0.5% bupivacaine and 4 mg of dexamethasone). The LB group received the same ISB and additional intraoperative injections of LB into the surgical site. Specifically, after surgical preparation and prior to the first incision, a solution consisting of 20 mL of LB diluted with an additional 40 mL of saline solution was injected into a triangular field block using a 22-gauge spinal needle. A 10-mL bolus injection was given in the suprascapular notch (which constitutes a suprascapular nerve block); then, 3.0-mL injections into the muscle (injecting as the needle was withdrawn) were spaced 1.5 cm apart and followed the perimeter of the triangle depicted in Figure 2. Study participants were blinded to all intraoperative interventions via the study randomization and informed-consent procedure and received no financial incentive for their participation.

Participants were provided with a pain journal to be filled out during the first 5 postoperative days (PODs) as a means to collect postoperative narcotic consumption data. The principal investigator or a trained, authorized site delegate explained to the patients how to correctly record their pain score and narcotic pill consumption every 8 hours, concurrently with the doses of Tylenol (Johnson & Johnson, New Brunswick, NJ, USA), using the provided visual analog scale (VAS). VAS responses were indicated by a dash along a 100-mm line ranging from 0 (no distress) to 10 (agonizing pain). Patients in both groups were provided with the same information regarding their postoperative pain management protocol and given the same education regarding postoperative pain expectations.

Following surgery, while the patient was in the postanesthesia care unit, VAS pain scores were recorded when the patient was fully alert; any pain medication administered in the postoperative unit was also recorded. Once discharged, the patient recorded his or her VAS pain score and narcotic pill consumption every 8 hours for the first 5 PODs. Patients received 1000 mg of Tylenol 3 times per day. All patients were given 25 oxycodone 5-mg tablets and were instructed to take them as needed. Patients were called on POD 1 to confirm adequate pain control and reminded to complete the pain journal. They were instructed to return the completed pain journal to their physician at their first postoperative visit on POD 7 to 10 to complete their involvement in the study.

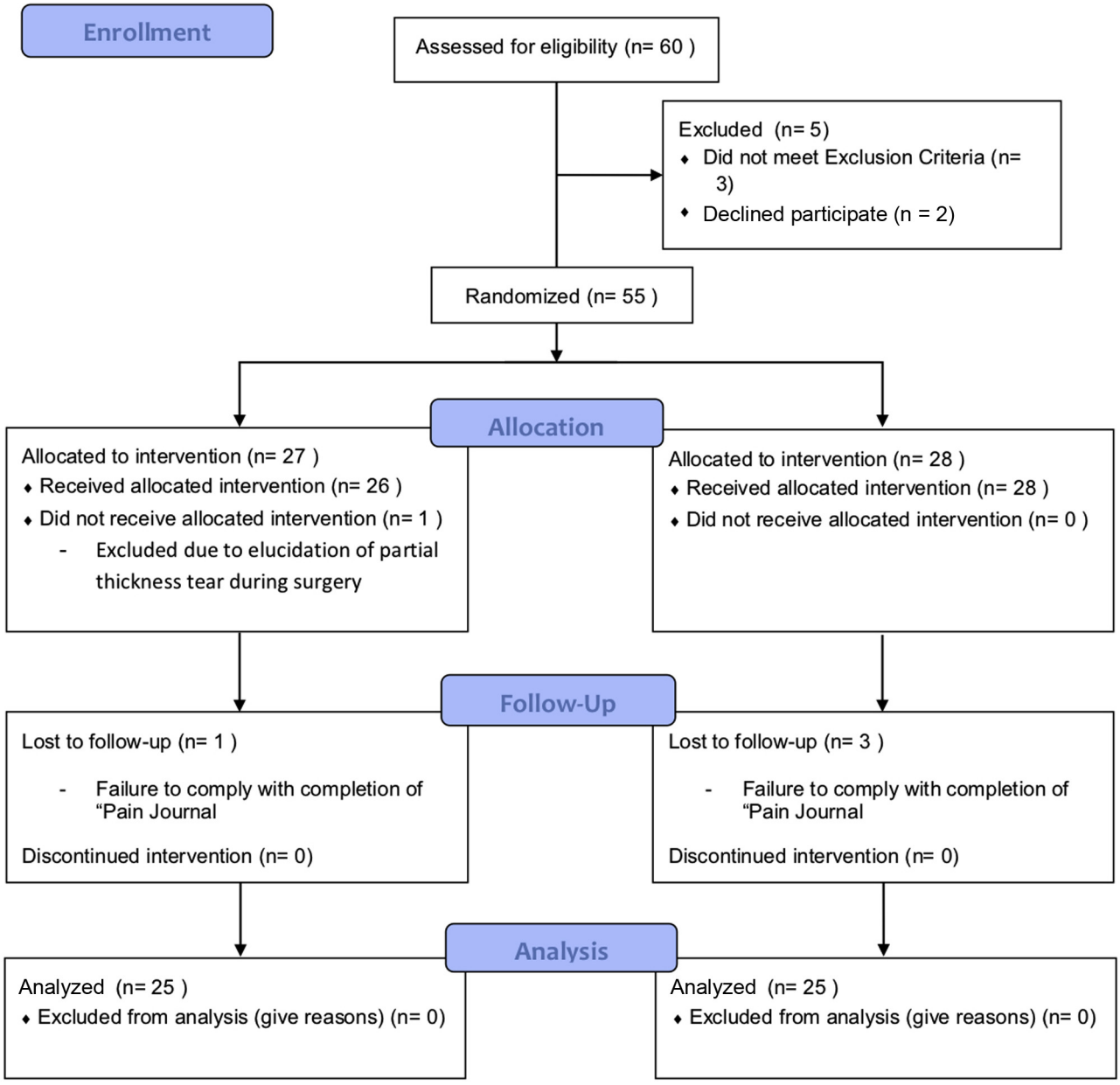

Figure 1 Flow diagram based on Consolidated Standards of Reporting Trials (*CONSORT*) guidelines.

Data from the journal were organized in an Excel spreadsheet (Microsoft, Redmond, WA, USA) for data analysis and evaluation. The quantity of narcotic pills consumed each day was converted to milligrams of morphine equivalents (OMEs) for data analysis. The data were evaluated through calculations of means, standard deviations, and an unpaired *t* test assuming unequal variances, in addition to time-trend analysis.

Results

Male patients comprised 52% of subjects in the LB group compared with 56% in the control group. The mean ages for the LB and control groups were 56.2 and 59 years, respectively. Biceps tenodesis in addition to ARCR was performed in 9 subjects in the LB group compared with 8 controls. One subject in the LB group underwent a clavicle resection compared with 2 controls. None of these differences were significant. Of the 55 patients, 50 completed the study: 25 in each group. One patient in the LB group was excluded because of a finding of partial-thickness tears on arthroscopic inspection. We excluded 1 patient in the LB group and 3 patients in the control group because of failure to comply with completing the pain journal. No subjects switched study groups, and no unintended harm or adverse effects were observed among the subjects in either group.

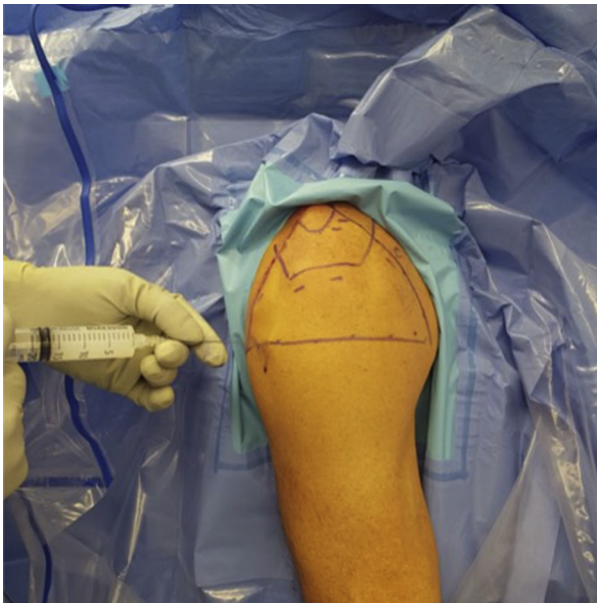

Figure 2 Intraoperative image of triangular field block. This lateral view depicts the triangular injection field for the intraoperative introduction of liposomal bupivacaine into the surgical site in a right shoulder during arthroscopic rotator cuff repair. After surgical preparation and prior to the first incision, a solution consisting of 20 mL of liposomal bupivacaine diluted with an additional 40 mL of saline solution was injected into a triangular field block using a 22-gauge spinal needle. A 10-mL bolus injection was given in the suprascapular notch; then, 3.0-mL injections into the muscle (injecting as the needle was withdrawn) were spaced 1.5 cm apart and followed the perimeter of the triangle.

The 3 VAS pain scores collected each day were averaged to obtain a daily score to account for daily and nocturnal fluctuations in pain (Table I). The LB group reported significantly lower pain scores than the control group on POD 1, with scores of 2.6 of 10 in the LB group and 5.8 of 10 in the control group ($P < .001$). These scores differ by 3.2, which is greater than the MCID of 1.4 for a numeric pain rating scale (NPRS)–VAS in rotator cuff disease.[19,20] The values reported on POD 2 of 3.6 of 10 in the LB group and 5.1 of 10 in the control group also exhibited a clinically and statistically significant difference ($P = .03$).

No statistically significant differences were noted between the NPRS-VAS pain scores of the 2 groups on POD 3 to POD 5 (Table I). Over the 5-day period, the control group reported a cumulative NPRS-VAS score of 19.7 of 50 whereas the LB group reported a cumulative score of 13.9 of 50 ($P = .02$).

The LB group consistently took statistically significantly lower quantities of OMEs than the control group for every measured POD, as shown in Table II. Over the 5-day period, the LB group consumed a total of 73.8 ± 51.9 OMEs, the equivalent of 9.8 ± 6.9 oxycodone 5-mg pills, whereas the control group consumed a total of 204.9 ± 131.1 OMEs, the equivalent of 27.3 ± 17.5 pills ($P = .002$). This was a 64% reduction in overall narcotic consumption by the LB group compared with the control group. The greatest absolute difference in OME consumption was seen on POD 1 to POD 3, whereas the greatest percentage difference in OME consumption was seen on PODs 0, 4, and 5. During the 5-day perioperative period, 7 patients (28%) from the control cohort requested and were granted refills of their prescriptions (25 tablets of oxycodone, 5 mg) whereas no patients from the LB cohort requested prescription refills ($P = .002$). By POD 3, 12 patients (48%) from the LB cohort had stopped consuming narcotic medication whereas only 1 patient (4%) from the control cohort had stopped ($P = .02$). By POD 4, these numbers rose to 18 patients (72%) in the LB group and 3 patients (12%) in the control group ($P = .003$). By POD 5, the number of patients from the LB group who had stopped consuming narcotic medications increased to 20 (80%) whereas the number of patients from the control group remained the same ($P < .001$).

Discussion

The findings of this study suggest that the addition of an LB field block to a standard bupivacaine ISB for rotator cuff repair significantly (statistically and clinically) reduces the

Table I Postoperative pain measured by NPRS-VAS in patients undergoing ARCR

	Average NPRS-VAS score						
	Postoperative day						Cumulative
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	
Control (n = 25)	0.5 ± 1.0	5.74 ± 1.6	5.13 ± 2.1	3.93 ± 2.0	2.74 ± 1.6	2.12 ± 1.6	19.66
Liposomal bupivacaine (n = 25)	0.5 ± 1.0	2.58 ± 1.6	3.63 ± 1.3	3.01 ± 1.31	2.59 ± 1.6	2.05 ± 1.5	13.86
P value	>.999	.001	.029	.148	.783	.898	.021
Difference in means	0	3.16	1.50	0.92	0.15	0.07	5.80

NPRS-VAS, numeric pain rating scale–visual analog scale; *ARCR*, arthroscopic rotator cuff repair.
The average daily and cumulative VAS pain scores recorded by patients undergoing ARCR surgery with or without liposomal bupivacaine are shown, in addition to the statistical *P* value calculated using a 2-tailed *t* test assuming unequal variances, as well as the difference between the 2 values on each postoperative day. Significant differences were noted on postoperative days 1 and 2 and in cumulative VAS scores.

Table II Postoperative narcotic consumption of patients undergoing ARCR

	Average narcotic use (OMEs)							
	Postoperative Day						Average	Cumulative
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5		
Control (n = 25)	15.5 ± 0.5	62.0 ± 33.8	57.0 ± 29.33	38.6 ± 32.7	28.5 ± 24.53	18.9 ± 18.0	34.1 ± 20.5	204.9 ± 123.2
Liposomal bupivacaine (n = 25)	4.0 ± 5.2	24.4 ± 19.0	28.3 ± 25.0	10.6 ± 11.2	7.0 ± 11.0	3.4 ± 5.9	12.3 ± 8.7	73.8 ± 51.9
P value	.001	.002	.006	.01	.009	.01	.003	.003
Difference in means	11.5	37.6	28.7	27.9	21.5	15.5	21.9	131.1
% difference in means*	−74.2	−60.7	−50.4	−72.5	−75.5	−81.9	−64	−64

ARCR, arthroscopic rotator cuff repair; *OME*, oral morphine equivalent.
The average daily and cumulative narcotic consumption recorded by patients undergoing ARCR surgery with or without liposomal bupivacaine is shown, in addition to the statistical *P* value calculated using a 2-tailed *t* test assuming unequal variances, as well as the absolute and percentage differences between the 2 values on each postoperative day.
* Percentage reduction in mean OME consumption in liposomal bupivacaine group compared with control group.

acute perioperative pain scores, number of narcotic pills consumed, and requirement for medication refills. The use of LB also led to a 64% reduction in overall narcotic consumption. These results suggest that LB, as part of a multimodal analgesic protocol, clinically and statistically improves pain management during the acute perioperative period following ARCR.

It is incumbent on the orthopedic community to identify postoperative pain management methods that reduce the need for narcotic medication following ARCR procedures as a means to mitigate the impact of orthopedic procedures on the opiate epidemic. At the time of this publication, there are no evidence-based published guidelines for opiate prescriptions with respect to shoulder surgery. In fact, Kumar et al[10] reported that orthopedic surgeons prescribe approximately 32 unused pills per shoulder surgery. On the basis of measured OME consumption in our study, it is recommended that patients undergoing ARCR surgery with LB and an ISB (Fig. 3) receive 25 oxycodone 5-mg pills and are appropriately educated on realistic perioperative pain expectations and appropriate use of narcotic medication. These recommendations contrast with recent reports of prescribing 62 ± 26 of the same pills for the same procedure and may eliminate pills that may be inappropriately diverted or misused.[18,24]

Statistically significant improvements in pain control were observed during PODs 1 and 2, recognizably the most painful PODs following shoulder surgery.[3] Patients in both groups exhibited minimal pain on POD 0, corresponding to the analgesic activity of the ISB. On POD 1, after the effects of the ISB had worn off, patients in the LB group reported NPRS-VAS pain scores that were 3.2 points lower than those in the control group, a value that is 2 times greater than the MCID for NPRS-VAS pain scores in rotator cuff disease. On POD 2, patients in the LB group reported NPRS-VAS pain scores that were 1.5 points lower than those in the control group, indicating that patients continued to feel significant analgesic benefits from LB 48 hours after surgery (Fig. 4). Recorded NPRS-VAS pain scores demonstrated equalization of pain between the 2 groups by POD 4, consistent with the duration of the medication. Even more important, despite the convergence of pain scores by POD 4, opiate consumption remained significantly lower in the LB group during PODs 4 and 5 (Figs. 5 and 6). This relationship shows that the reduction of initial pain in the LB group translated to less pain and a lower dependence on narcotics over the entire experience as the severity of pain perceived by the LB group never mirrored that of the control group.

Furthermore, none of the patients from the LB group requested prescription refills, whereas 7 patients (28%) from the control group requested and were given refills of their narcotic medications. In the LB group, 48% of patients were narcotic free by POD 3; 72%, by POD 4; and 80%, by POD 5. Conversely, only 1 patient (4%) from the control group had stopped consuming narcotic medication by POD 3 ($P = .02$), increasing to 3 patients (12%) by POD 4 ($P = .003$). These results suggest that optimizing pain management during the early stages of initial perioperative pain can significantly reduce the quantity of pain relievers required following the surgical event and shorten the period during which patients require narcotic pain medication. Reducing the duration of narcotic consumption and eliminating the need for prescription refills are significantly impactful in improving the current opioid crisis as refills and prolonged narcotic consumption may lead to opioid addiction and abuse. A recent study from the Centers for Disease Control and Prevention examined

Suggested Multimodal Anesthetic Protocol for Rotator Cuff Repair	acetaminophen 1000 mg PO(in holding area)
	gabapentin 400 mg PO (in holding area)
	0.5% bupivacaine 20 mL with dexamethasone 4 mg (ultrasound-guided interscalene block)
	liposomal bupivacaine 20 mL diluted with 40 mL normal saline (surgeon-administered triangular field block)
Suggested Postoperative Medications	oxycodone 5 mg PO q4 as needed (dispensed 25)
	acetaminophen 1000 mg PO q8 for 5 days
	gabapentin 300 mg PO QHS for 5 days

Figure 3 Recommended anesthetic protocol using liposomal bupivacaine for rotator cuff repair. The recommended multimodal anesthetic protocol to be used for rotator cuff repair for improved perioperative pain management and reduced reliance on narcotic medication is detailed. It includes 2 oral (*PO*) medications to be administered preoperatively, an ultrasound-guided interscalene block to be administered by the anesthesiologist, and the liposomal bupivacaine triangular field block to be administered by the surgeon. *Q4*, every 4 hours; *Q8*, every 8 hours; *QHS*, before bed.

risks of developing opiate dependence.[16] The authors demonstrated an increased risk of long-term opiate use after just 3 days of medication. As such, surgeons should strive to reduce the duration of opiate exposure after rotator cuff repair.[16]

The use of LB in providing postoperative pain relief via local infiltration has been previously studied in several randomized trials in total knee arthroplasty (TKA), total hip arthroplasty, and total shoulder arthroplasty (TSA) with both positive and equivocal results.[2,4,8,14,15,17,21,23,27] Bramlett et al[4] reported statistically significant benefits in cumulative pain scores at rest during POD 2 to POD 5 in TKA patients who received LB compared with those who received bupivacaine hydrochloride. Webb et al[23] reported significant reductions in narcotic consumption and length of hospital stay with the use of LB in TKA, whereas Snyder et al[17] reported significant reductions in pain levels and narcotic consumption on POD 1 to POD 2 in addition to significantly higher patient satisfaction with the use of LB in TKA. Jacob et al,[8] in contrast, only reported modest reductions in opioid use and the length of stay in both knee and hip arthroplasty patients. In shoulder arthroplasty patients, Sabesan et al[15] reported equivocal pain control during the first 24 hours in patients treated with LB compared with patients treated with an ISB,

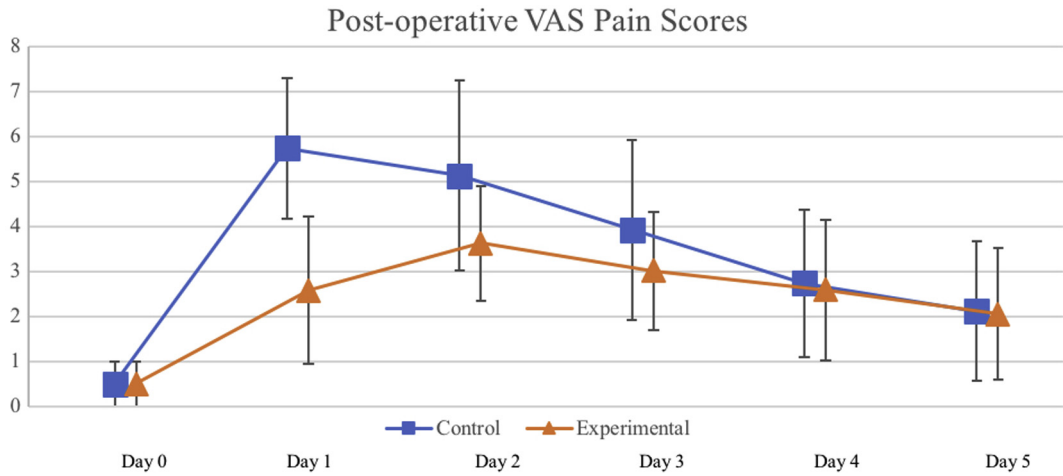

Figure 4 Postoperative pain measured by numeric pain rating scale–visual analog scale (*VAS*) for patients undergoing arthroscopic rotator cuff repair. The chart presents the average daily numeric pain rating scale–VAS pain scores, out of 10, recorded by patients undergoing arthroscopic rotator cuff repair surgery with (experimental) or without (control) liposomal bupivacaine, including standard deviations. Patients in the liposomal bupivacaine group had statistically and clinically lower pain scores. The convergence of the pain scores in the 2 groups on postoperative day 4 corresponds with the 48- to 72-hour duration of the analgesic effects of liposomal bupivacaine.

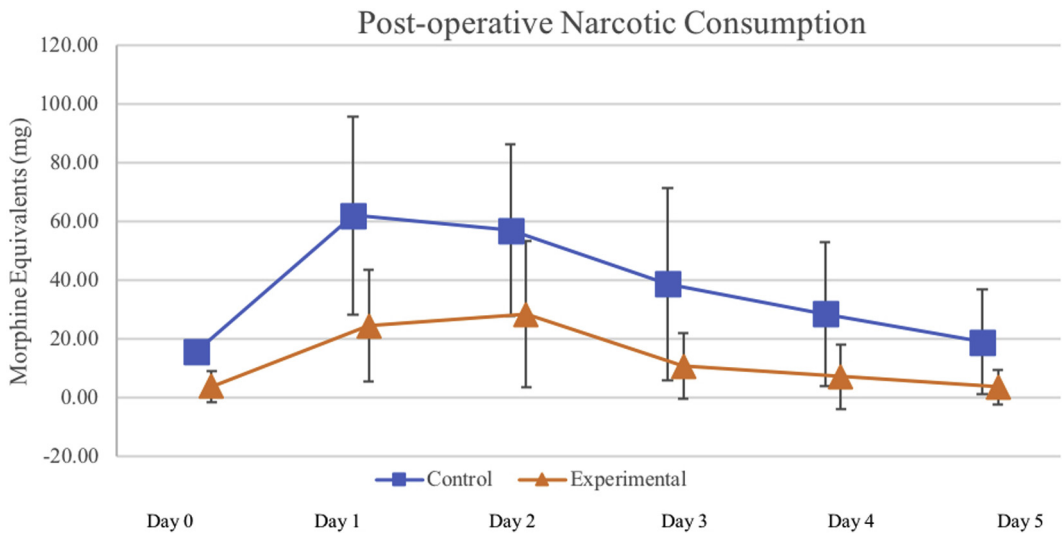

Figure 5 Postoperative narcotic consumption of patients undergoing arthroscopic rotator cuff repair. The chart presents the average daily narcotic consumption recorded by patients undergoing arthroscopic rotator cuff repair surgery with (experimental) or without (control) liposomal bupivacaine, including standard deviations.

with improvements in patient-reported outcomes, fewer complications, and potential cost savings with LB compared with an ISB. Yan et al[27] reported that LB had comparative effectiveness in reducing pain and the length of stay in TSA patients compared with an ISB. Routman et al[14] reported significantly reduced narcotic consumption and pain, as well as a shorter hospitalization, in TSA patients treated with LB compared with those treated with an ISB.

Namdari et al[13] recently reported no significant reduction in NPRS-VAS pain scores in LB patients while showing increased opiate consumption over a 24-hour postoperative period compared with controls. This study demonstrated lower opiate use at the 24-hour evaluation and at all following time points; no rebound pain was observed (Fig. 4). Namdari et al examined arthroplasty rather than arthroscopy, used a lower volume of anesthetic in the field block, and only evaluated a 24-hour window for opioid consumption, all of which may explain the conflicting results. Although their data demonstrate no clinical difference from additional LB administration, the improvements shown by our study coincide with the results of previous authors.[14]

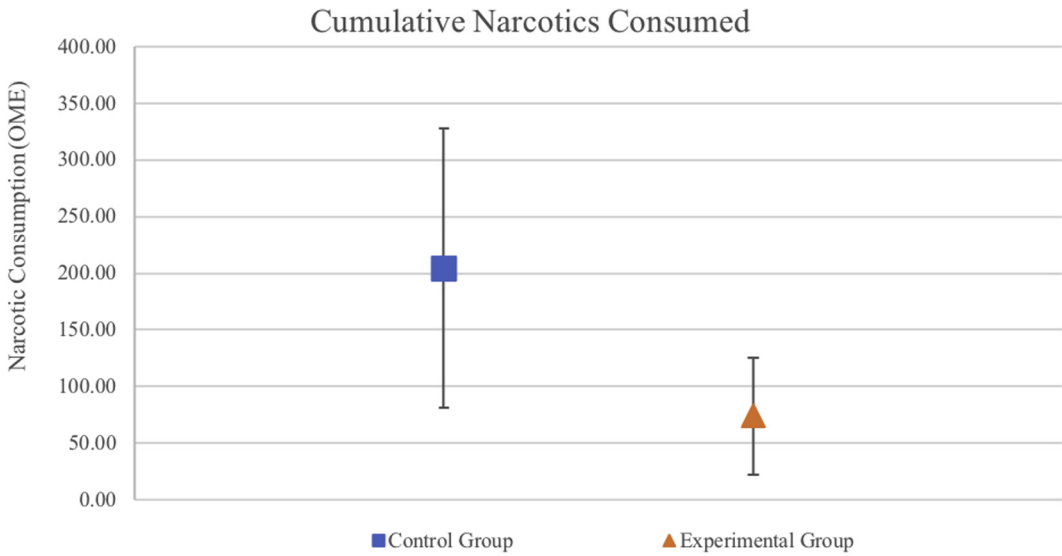

Figure 6 Cumulative postoperative narcotic consumption of patients undergoing arthroscopic rotator cuff repair. The chart presents the average cumulative narcotic consumption recorded by patients undergoing arthroscopic rotator cuff repair surgery with (experimental) or without (control) liposomal bupivacaine over the first 5 postoperative days, including standard deviations. There was a 64% reduction ($P = .002$) in total opiate consumption in the experimental group. *OME*, oral morphine equivalents.

The triangular field block technique used in this study is based on previously reported techniques, first described in 1941 by Wertheim and Rovenstine.[5,25] This technique anesthetizes the branches of the suprascapular nerve, which provides 70% of the sensory input to the glenohumeral joint and innervates the infraspinatus and supraspinatus muscles.[1,6] The posterior limb of the injection targets the sensory branches of the axillary nerve, and the anterior limb of the triangle targets the supraclavicular nerves. On this anatomic basis, this technique has been proposed to produce sufficient analgesia for shoulder surgery. Local regional anesthesia using a suprascapular nerve block alone has been suggested as an ISB alternative, with some evidence suggesting that the two are not different for postoperative analgesia.[24]

Study limitations

This study is not without its weaknesses. Preoperative education alone regarding the use of narcotic medication and expectations of postoperative pain has been shown to reduce patient need for postoperative narcotic pain medication; however, because the same education was provided to all participants, it can be expected that this would have the same impact on both groups.[18] This may be one reason both groups used less opiate medication compared with previous reports.

Patients may have inaccurately reported the quantity of pills consumed as pill counts were not conducted. Furthermore, it is possible that an internist or other outside source of narcotic medication was used to obtain additional pills. All subjects had a query performed on the state database to ensure this was not the case.

This study excluded patients with a history of narcotic dependence; thus, its findings may not apply to all patients as those with a history of preoperative opiate consumption are more likely to fill postoperative opioid prescriptions at 3 and 12 months after surgery.[26] Furthermore, it was a short-term study, focused solely on the initial perioperative period, and thus does not provide any indication as to the impact of this long-acting field block–based multimodal protocol on the healing of the repaired rotator cuff.

Conclusion

The use of an LB field block with a standard bupivacaine ISB in rotator cuff repair significantly (statistically and clinically) reduced the acute perioperative pain scores, as well as the number of narcotic pills consumed, and eliminated the requirement for medication refills. The use of LB led to a 64% reduction in overall narcotic consumption and to 69% of patients being narcotic free by POD 5. Furthermore, these findings led to guidelines for postoperative narcotic prescribing that greatly reduce the suggested quantity of narcotic pills provided to patients, which may help to mitigate the current opioid epidemic.

Disclaimer

Paul M. Sethi has received royalties and consulting fees from Arthrex and Pacira unrelated to the funding or sponsorship of this study. All the other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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