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Ambulatory Continuous Interscalene Nerve Blocks Decrease the Time to Discharge Readiness after Total Shoulder Arthroplasty

A Randomized, Triple-masked, Placebo-controlled Study

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Background: **A continuous interscalene nerve block (CISB) may be used to provide analgesia after shoulder arthroplasty. Therefore, inpatient stays may be shortened if CISB (1) provides adequate analgesia without intravenous opioids and (2) improves shoulder mobilization. This study investigated the relationship between ambulatory CISB and the time to reach three discharge criteria after shoulder arthroplasty.**

Methods: **Preoperatively, patients received a CISB. All patients received a perineural 0.2% ropivacaine infusion from surgery until 06:00 the following morning, at which time they were randomly assigned either to continue perineural ropivacaine or to switch to normal saline. The primary endpoint was the time from the end of surgery until three discharge criteria were attained (adequate analgesia, independence from intravenous analgesics, and tolerance to 50% of shoulder motion targets). Patients were discharged home as early as the afternoon after surgery with their CISB using a portable infusion pump.**

Results: **Patients receiving perineural ropivacaine (n = 16) attained all three discharge criteria in a median (10th–90th percentiles) of 21 (16–41) h, compared with 51 (37–90) h for those receiving perineural normal saline (n = 13, $P < 0.001$). Unlike patients receiving perineural ropivacaine, patients receiving perineural normal saline often required intravenous morphine, but still experienced a higher degree of pain and tolerated less external rotation.**

Conclusions: **An ambulatory CISB considerably decreases the time until readiness for discharge after shoulder arthroplasty, primarily by providing potent analgesia that permits greater passive shoulder movement and the avoidance of intravenous opioids. Additional research is required to define the appropriate subset of patients and assess the incidence of complications associated with earlier discharge.**

NEARLY 85,000 shoulder arthroplasty procedures are performed in the United States each year.[1] The number of replacements has quadrupled over the past 20 yr and is expected to continue to increase as the population ages.[1] Although these procedures improve patients' long-term quality of life, they usually result in severe pain in the immediate postoperative period.[2] This pain is greatly exacerbated with shoulder movement that is central to postoperative rehabilitation and, possibly, necessary for maximizing the ultimate surgical outcome.[2–4] The current analgesic standard of care after total shoulder arthroplasty (TSA) in the United States includes a multimodal regimen of oral analgesics combined with intravenous opioids, the latter requiring a hospital stay. A single-injection interscalene nerve block is often added. However, using this analgesic regimen, practitioners are left with the perplexing choice: require a multiple-day hospital stay to provide superior analgesia and improve tolerance to shoulder motion, or allow earlier home discharge with potentially inadequate analgesia and subadequate shoulder mobility.[5]

A continuous interscalene nerve block (CISB)—also called perineural local anesthetic infusion—offers an alternative analgesic option. This technique involves the percutaneous insertion of a catheter directly adjacent to the brachial plexus. The catheter is then infused with local anesthetic resulting in potent, site-specific analgesia free of significant side effects.[6,7] Compared with intravenous opioids, CISB provides superior analgesia in hospitalized patients after major shoulder surgery.[8,9] Furthermore, unlike traditional intravenous opioid adminis-

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tration, perineural infusion may be continued at home using a portable infusion pump after discharge.[10] Consequently, ambulatory CISB offers the potential of decreasing the hospitalization duration while simultaneously improving analgesia after TSA and other major hospital-based shoulder procedures.

Therefore, the primary objective of this randomized, triple-masked (patients, investigators, and statisticians), placebo-controlled study was to determine whether, compared with usual and customary analgesia, ambulatory CISB would shorten the time until three specific, predefined readiness-for-discharge criteria were met after TSA. Failure to meet one or more of these criterion account for the majority of hospitalization days at our institution and include (1) adequate analgesia, (2) independence from intravenous opioids, and (3) the ability to tolerate passive shoulder motion during physical therapy. Secondary endpoints included maximum passive shoulder elevation and external rotation, average and worst resting and dynamic pain scores, oral and intravenous opioid requirements, sleep disturbances, and patient satisfaction.

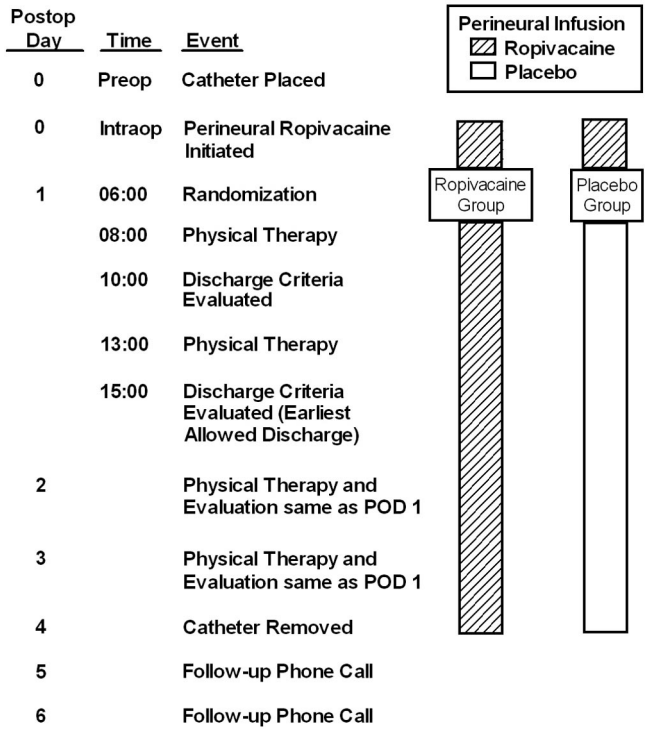

Fig. 1. Study design overview. POD = postoperative day.

Materials and Methods

Enrollment

After institutional review board (University of Florida, Gainesville, Florida) approval, we prospectively enrolled adult patients (aged ≥ 18 yr) scheduled to undergo unilateral TSA who desired a continuous interscalene nerve block for postoperative analgesia. Patients were required (1) to be able to understand the possible local anesthetic–related complications, study protocol, and care of the catheter and infusion pump system; and (2) to have a caretaker who would remain with them at home during the local anesthetic infusion. Exclusion criteria included any contraindication to interscalene nerve block, baseline room-air oxygen saturation less than 96%, a history of opioid dependence or current chronic analgesic therapy, allergy to study medications, known hepatic or renal insufficiency/disease, peripheral neuropathy, morbid obesity (body mass index > 40 kg/m^2), or comorbidity that resulted in moderate or severe functional limitation.

Preoperative Management

After written, informed consent was obtained, an interscalene catheter (StimuCath; Arrow International, Reading, PA) was placed in each patient by one of the investigators (B.M.I.) using a technique described previously.[11] Forty milliliters mepivacaine, 1.5%, with epinephrine, 100 μg, was injected *via* the catheter with gentle aspiration every 3 ml. After 20 min, the interscalene nerve block was evaluated and considered successful with inability to abduct the shoulder and a decrease in perceived sensation to cold of the skin over the deltoid muscle. Patients with a successful nerve block were retained in the study, and 10 ml ropivacaine, 0.5%, with epinephrine, 25 μg, was injected *via* the catheter (fig. 1).

Intraoperative Management

For the surgical procedure, patients received a standardized general anesthetic using sevoflurane, nitrous oxide, and oxygen for a Bispectral Index of 40–60. A perineural 0.2% ropivacaine infusion was initiated with a basal rate of 8 ml/h, a patient-controlled bolus dose of 3 ml, and a lockout time of 60 min. Intravenous hetastarch, 15 ml/kg, was administered before emergence. Fentanyl (25-μg increments) was administered for hemodynamic stability until emergence, at which time morphine sulfate was titrated for a respiratory rate of 14.

Postoperative Management

Patients were taken from the recovery room to the General Clinical Research Center (fig. 1). For the duration of the study, all patients received the current usual and customary analgesics provided at the University of Florida after TSA. This included the perineural ropivacaine infusion initiated in the operating room and continued until the morning after surgery, as well as 1 week of scheduled oral acetaminophen (975 mg every 6 h) and celecoxib (100 mg every 12 h). For breakthrough pain, patients were instructed to depress the bolus button on

Table 1. Protocol for Rescue Analgesic Administration

NRS	Analgesic	Route	Dose	Administration
Postanesthesia care unit (recovery room)				
1–2	Oxycodone	Oral	5 mg	If patient desired
3–4	Oxycodone	Oral	10 mg	Every 30 min
5–6	Morphine	IV	2 mg	Every 10 min
7–10	Morphine	IV	4 mg	Every 10 min
General Clinical Research Center				
< 4	Oxycodone	Oral	5 mg	If patient desired
4–7	Oxycodone	Oral	10 mg	Once
> 7	Morphine	IV	2–4 mg	Every 10 min until NRS < 4
Pain reassessed after 30 min				
< 4	Oxycodone	Oral	5 mg	If patient desired
4–10	Morphine	IV	2–4 mg	Every 10 min until NRS < 4

IV = intravenous; NRS = numeric rating pain scale (0–10, 0 = no pain and 10 = worst imaginable pain).

their infusion pump. Rescue opioid and route of administration were determined by pain severity using a numeric rating scale of 0–10, 0 equal to no pain and 10 equal to the worst possible pain imaginable (table 1).[12]

Randomization

Treatment group allocation occurred after confirmation of a successful initial surgical block preoperatively. Patients with a successful interscalene nerve block were randomized to one of two groups—0.2% ropivacaine or normal saline (placebo)—using a computer-generated table (Proc Plan, SAS 8.0; Cary, NC). Investigational pharmacists prepared the study solution. Investigators, patients, and all clinical staff were unaware of treatment group assignments.

Intervention

At 06:00 on postoperative day (POD) 1, patients' hospital-based infusion pumps filled with ropivacaine were replaced with portable infusion pumps (CADD-Legacy; Smiths Medical, St. Paul, MN) filled with 600 ml of study solution (7 ml/h basal, 3 ml bolus, 60 min lockout time).

Pain scores were recorded every 4 h (excluding periods of sleep) and when patients requested analgesics. Patients underwent physical therapy at 08:00 and 13:00 each day beginning the morning after surgery, and thereafter until discharge (fig. 1).

Primary Endpoint

Two hours after twice-daily physical therapy sessions, each of the three discharge criteria were evaluated separately and scored as either fulfilled or unfulfilled (evaluated at 10:00 and 15:00). The primary endpoint was the time from surgical stop until all three of the criteria were fulfilled—without a reversion to unfulfilled status. For example, if a patient met all three criteria the morning of POD 1, subsequently met only two criteria later that afternoon, and again met all three criteria the following morning, the primary endpoint would be the number of hours from surgical stop until 10:00 on POD 2.

Surgical stop was defined as the time at which the surgical dressing application was completed. The three specific readiness-for-discharge criteria included adequate analgesia, independence from intravenous opioids, and the ability to tolerate shoulder movement. Adequate analgesia was scored as fulfilled with a pain score of less than 4 on the numeric rating scale (NRS, 0–10, 0 = no pain and 10 = worst imaginable pain). Independence from intravenous opioids was scored as fulfilled if no intravenous morphine was administered in the previous 12 h. Shoulder movement was scored as fulfilled if patients could tolerate 50% of the range-of-motion goals for both elevation and external rotation.

Maximum tolerated shoulder elevation and external rotation were determined during each physical therapy session. For the first 2–6 weeks after TSA, patients undergo passive elevation and external rotation up to surgeon-defined maximums—or "targets"—to avoid damaging the subscapularis repair.[2,3] These targets were defined intraoperatively by one of the investigators (T.W.W.) with the repaired subscapularis muscle under direct vision to determine the maximum motion possible without suture line damage. Consequently, the defined targets for elevation or external rotation were individualized for each patient. To measure elevation, the patient's arm against the side of the body defined 0°, and elevation increased as the arm was raised (without elbow flexion) in the sagittal plane (fig. 2A).[2,3] For external rotation, the measurement was performed with the elbow at the patient's side and the forearm at a 90° angle with the upper arm (fig. 2B). The patient's hand directly in front of the elbow defined 0°, and external rotation increased with lateral hand motion.[2,3] During range-of-motion measurement, patients were instructed to tell the therapist when to stop as determined by comfort level, and to always stop before a pain score of 8 on the numeric rating scale. For purposes of analysis, the per-

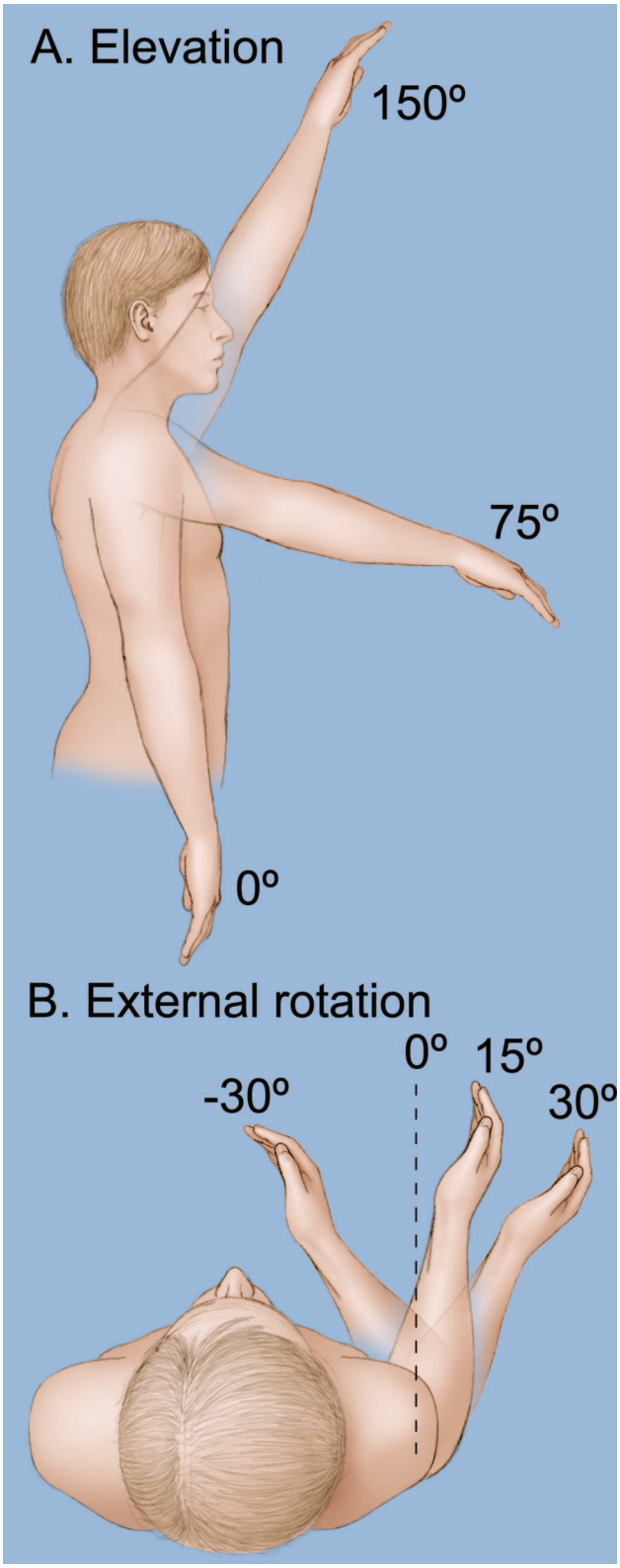

Fig. 2. Method for measuring the degrees of passive shoulder elevation and external rotation. (*A*) For elevation, the patient's arm against the side of the body defined 0°, and elevation increased as the arm was raised in the sagittal plane (without elbow flexion). (*B*) For external rotation, the measurement was performed with the elbow at the patient's side and the forearm at a 90° angle with the upper arm. The patient's hand directly in front of the elbow defined 0°, and external rotation increased with lateral hand motion.

centage of the target attained by each patient for both elevation and external rotation was calculated. For example, if the surgeon-defined elevation target was 150° and the maximum elevation achieved was 75°, the variable used for comparison would be 50%. If shoulder movement was prohibited during the first postoperative week (as with reverse TSA procedures),[13,14] only the two remaining discharge criteria were evaluated.

Home Discharge

Patients were discharged home with their portable infusion pump and perineural catheter *in situ*, but not before 15:00 on POD 1. This protocol provided a 9-h washout period for those patients randomized to placebo and therefore switched to perineural normal saline at 06:00 on POD 1 (fig. 1). Patients and their caretakers were provided with verbal and written catheter/pump instructions; the telephone and pager numbers of an investigator available at all times; a copy of the institutional review board–approved consent form; a stamped, self-addressed, padded envelope for infusion pump return; and prescriptions for their outpatient oral medications that did not differ from the oral analgesics provided in the hospital. Patients were telephoned on the afternoon of PODs 1–6 for data collection and infusion oversight (*e.g.*, appearance of the catheter site/dressing).

On the evening of POD 2, patients or their caretakers reprogrammed their infusion pumps for a basal rate of 5 ml/h with physician instructions provided by telephone. On the evening of POD 4, patients' caretakers removed the catheters at home, again with physician instructions by telephone. The presence of a metallic catheter tip confirmed complete removal. Patients were asked to rate their satisfaction with postoperative analgesia on a scale of 0–10, where 0 was equal to very unsatisfied and 10 was equal to very satisfied. Patients disposed of the catheter and any residual infusate, and the pump was returned to the investigators in the supplied envelope *via* the postal service.

Statistical Analysis

The study was powered for the primary question, time to reach the three discharge criteria. Based on a pilot study,[15] the planning distribution for the ropivacaine (placebo) group was 6 h: 71% (29%); 30 h: 14% (29%); 45 h: 14% (14%); and 54 h: 0% (29%). To ensure 80% power at $P = 0.05$ (two-sided) for the Wilcoxon rank sum test, we planned for 15 patients randomly assigned to each group.[16]

Secondary endpoints were also analyzed with the two-sided Wilcoxon test. The Wilcoxon test is distribution free and, even in the face of potential missing data, is a completely valid test of the null hypothesis that the ropivacaine and placebo target populations are equivalent. $P < 0.05$ was considered significant. With respect

Table 2. Population Data, Perineural Catheter Details, and Surgical Information

	Ropivacaine Group (n = 16)	Placebo Group (n = 13)*
Age, yr	67 (56–74)	68 (62–76)
Sex, F/M	9/7	9/4
Height, cm	172 (160–180)	173 (155–183)
Weight, kg	85 (66–105)	82 (64–95)
Body mass index, kg/m^2	28 (23–34)	28 (23–33)
Underlying etiology, DJD/RA	14/2	11/2
Minimum current *via* needle, mA	0.40 (20–50)	0.30 (27–40)
Minimum current *via* catheter, mA	0.34 (15–40)	0.20 (10–45)
Procedure		
Primary TSA	9	8
Primary reverse TSA	5	3
Revision TSA	2	2
Intraoperative fentanyl, μg	100 (0–250)	100 (0–350)
Intraoperative morphine, mg	2.5 (0.0–7.0)	3.0 (0.0–10.0)
Surgery duration, min	177 (144–201)	180 (155–231)

Values are reported as median (10th–90th percentiles).

* The institutional review board determined one patient in the placebo group to be ineligible for enrollment and required exclusion of all collected data. Therefore, this table includes data for only 13 of 14 patients randomized to the placebo group.

DJD = degenerative joint disease; RA = rheumatoid arthritis; TSA = total shoulder arthroplasty.

to secondary endpoints, statistically significant results require confirmation in a subsequent investigation.

Results

Enrollment commenced in January 2005 and concluded in February 2006. Thirty-two patients enrolled, and all but one (97%) had a perineural catheter placed per protocol (table 2). An additional subject retained shoulder abduction 20 min after receiving a local anesthetic bolus *via* the catheter and therefore was not randomized per protocol (this patient subsequently developed a complete motor and sensory block in the expected distribution and profound analgesia during the postoperative infusion). Of the remaining 30 subjects, 16 were randomly assigned to additional 0.2% ropivacaine (ropivacaine group), and 14 were randomized to be switched to normal saline (placebo group) at 06:00 on POD 1.

Primary Endpoint

Patients in the ropivacaine group receiving perineural ropivacaine through POD 4 attained all three discharge criteria in a median (10th–90th percentiles) of 21 (16–41) h, compared with 51 (37–90) h for patients in the placebo group receiving perineural ropivacaine only through the first postoperative night ($P < 0.001$; fig. 3).

Post Hoc *Analysis*

Although the specific time of day of actual home discharge was not recorded, the POD and period (morning/afternoon) were noted. Converting the available data into approximate hours from surgical stop, patients in the ropivacaine group were discharged home in a median (10th–90th percentiles) of 28 (28–47) h, compared with 52 (42–95) h for patients in the placebo group ($P < 0.001$).

Secondary Endpoints

Regarding pain scores, there were no statistically significant differences between the treatment groups on POD 0—while all patients received perineural ropivacaine—or on PODs 5–6 after catheter removal (figs. 4A–D). However, on PODs 1–4, patients in the placebo group receiving perineural normal saline reported higher pain scores than patients in the ropivacaine

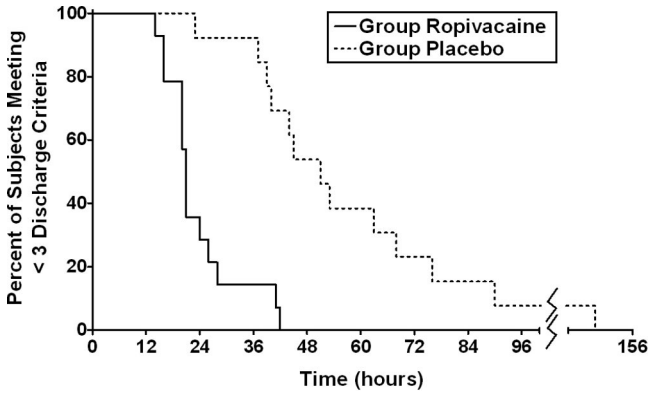

Fig. 3. Effect of interscalene perineural ropivacaine infusion on the time to reach three discharge criteria (adequate analgesia, independence from intravenous opioids, and the ability to tolerate at least 50% of passive shoulder motion targets during physical therapy) after total shoulder arthroplasty. Data are expressed in a Kaplan-Meier plot for patients randomly assigned to the ropivacaine group (perineural ropivacaine from surgery through postoperative day 4) or the placebo group (perineural ropivacaine from surgery through 06:00 postoperative day 1 followed by perineural normal saline through postoperative day 4).

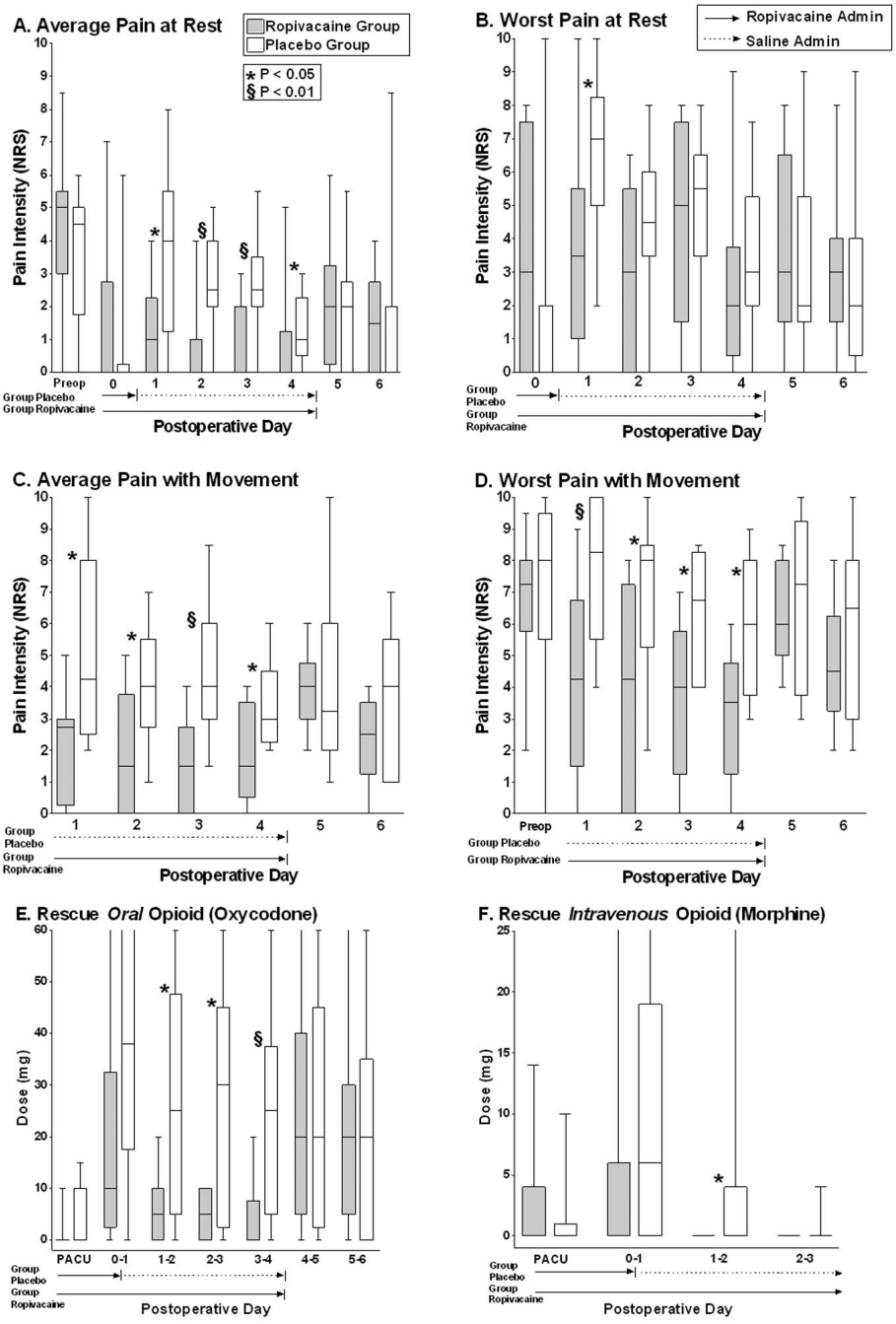

Fig. 4. Effects of interscalene perineural ropivacaine infusion on postoperative pain (*A–D*) and opioid requirements (*E, F*) after total shoulder arthroplasty. Pain severity is indicated using a numeric rating scale (NRS) of 0–10, 0 equal to no pain and 10 equal to the worst possible pain imaginable. Data are expressed as median (*horizontal bar*) with 25th–75th (*box*) and 10th–90th (*whiskers*) percentiles for patients randomly assigned to the ropivacaine group (perineural ropivacaine from surgery through postoperative day [POD] 4) or the placebo group (perineural ropivacaine from surgery through 06:00 POD 1 followed by perineural normal saline through POD 4). For tightly clustered data (*e.g.*, *A*, PODs 0 and 2–4; and *F*, postanesthesia care unit [PACU] and PODs 0–1, ropivacaine group), the median is 0.0 and approximated the 10th and 25th percentile values.

group. Patients in the placebo group often required high doses of oral opioids or intravenous morphine on PODs 1–2, whereas patients in the ropivacaine group did not (figs. 4E and F). Furthermore, even while using intravenous morphine, subjects in the placebo group experienced a greater degree of pain during physical therapy (figs. 4C and D) and tolerated less external rotation (fig. 5). Before catheter removal, no patients in the ropivacaine group reported pain limiting their shoulder range of motion, compared with 40–78% in the placebo group ($P < 0.001$, $P = 0.011$, and $P = 0.087$ for PODs 2, 3, and 4, respectively). After catheter removal, 40–80% of each group reported pain limiting their shoulder range of motion ($P = 0.14$ and 0.66 for PODs 5 and 6, respectively). Both groups experienced similar incidences of difficulty sleeping and awakenings because of pain. Satisfaction with postoperative analgesia was 10.0 (9.0–10.0) in the ropivacaine group and 7.5 (7.0–10.0) in the placebo group ($P = 0.002$).

Protocol Violations and Adverse Events

Two subjects in the ropivacaine group requested study withdrawal on POD 1, and subsequent data were excluded from analysis, as mandated by US ethical guidelines.[17] An additional subject from the placebo group completed data collection, but the institutional review board subsequently

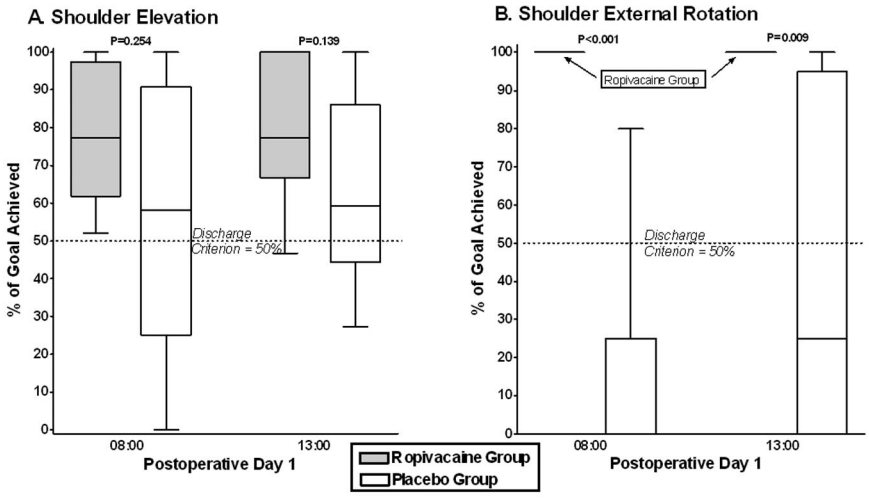

Fig. 5. Effects of interscalene perineural ropivacaine infusion on passive shoulder elevation (A) and external rotation (B) the day after total shoulder arthroplasty. Range of motion is analyzed as the percentage of the surgeon-defined target the patient achieved. Data are expressed as median (*horizontal bar*) with 25th–75th (*box*) and 10th–90th (*whiskers*) percentiles for patients randomly assigned to the ropivacaine group (perineural ropivacaine from surgery through postoperative day 4) or the placebo group (perineural ropivacaine from surgery through 06:00 postoperative day 1 followed by perineural normal saline through postoperative day 4). For tightly clustered data (*e.g.*, *B*, 08:00 and 13:00, ropivacaine group), the median approximated the 10th, 25th, 75th, and 90th percentile values because all subjects achieved 100% of their target angle.

determined him to be ineligible for enrollment and required exclusion of all collected data.|||| One patient in the placebo group dropped her infusion pump on POD 3 with a subsequent pump failure and continuous alarm, resulting in early catheter removal. An infusion pump of another patient in the placebo group produced a "high pressure" alarm on POD 3 that could not be resolved, also resulting in early catheter removal. A patient in the placebo group experienced a seizure on POD 2, resulting in catheter removal to allow magnetic resonance imaging (seizure subsequently determined to be due to hyponatremia of unknown etiology). For purposes of analysis, these subjects were retained in their respective treatment groups per the intention-to-treat principle.[18]

Discussion

This investigation provides evidence that an ambulatory CISB decreases the time until readiness for discharge after TSA, primarily by providing potent analgesia that permits greater passive shoulder movement and the avoidance of intravenous opioids (fig. 3). A previous study demonstrated that outpatient TSA—discharge directly from the recovery room—is possible using CISB.[15] However, that investigation did not include a control group, and therefore did not document or quantify the magnitude of effect CISB has on discharge readiness, pain scores, opioid requirements, sleep disturbances, or patient satisfaction. Although the current investigation does provide a comparison group, practitioners should be cognizant of how our specific protocol may influence the applicability of the results to their practices.

Study Design Implications

The design of the current study may result in an *under*-estimation of CISB's effect on the time until discharge readiness. First, all subjects received a preoperative interscalene nerve block and subsequent CISB with 0.2% ropivacaine through the morning of POD 1, at which time patients in the placebo group were switched to perineural normal saline (fig. 1). This protocol provided all patients with the current analgesic standard of care of our institution. However, the result is that patients in the placebo group received interscalene analgesia for a longer duration than even single-injection interscalene blocks with bupivacaine provide.[19] Patients undergoing TSA without a single-injection or continuous peripheral nerve block, as is common in many US institutions, may theoretically require even longer to reach discharge readiness than the placebo group of this study.

Second, the initial evaluation of the primary endpoint—attainment of the three noted discharge criteria—did not occur until 10:00 the morning after surgery (fig. 1). This design enabled all patients to undergo their first physical therapy session (providing range-of-motion data) before evaluation of discharge readiness. Therefore, even if a patient had attained all three required discharge criteria before the morning of POD 1, the time of discharge readiness would still be recorded as 10:00 the morning after surgery because this was the earliest that shoulder range-of-motion data were available. Hospital logistics dictated the study protocol: Occasionally a patient is discharged from the recovery room in the evening hours when physical therapists are unavailable. Considering that most patients in this study reported a complete absence of pain in the recovery room—as in a previous investigation of CISB after TSA in which all patients attained more than 50% of their required range of motion in the recovery room—there is a high

|||| This patient presented for surgery on his own accord and was enrolled by investigators after verbal and written informed consent. At the time of surgery, he wore a removable electronic monitoring device around his ankle placed by the judicial system. Subsequently, the University of Florida Assistant General Counsel concluded that, in her opinion, "individuals wearing ankle monitors are prisoners for purposes of human subject research." As this investigation was not approved for enrollment of prisoners, the institutional review board concluded that all collected data for this subject must be excluded from analysis to adhere to current ethical guidelines.[17]

probability that the patients in the current study were similarly ready for discharge earlier than the morning after surgery.[15] Therefore, it is possible—even probable—that the current study design greatly underestimated CISB's effect on the time until discharge readiness for the ropivacaine group.

Conversely, the current study design may have overestimated CISB's effect on the time until discharge readiness. Although it is widely accepted that physical therapy involving shoulder motion is critical in maximizing TSA outcomes, prospectively collected data examining the association of early postoperative and ultimate joint range of motion are unavailable.[3,4] The result is a lack of consensus regarding the optimal timing of therapy initiation or optimal range of motion targets.[2–4,20,21] For cases in which shoulder motion is not required—or minimal range of motion is considered acceptable—before home discharge, then the results of the current study overestimate the effect of CISB on discharge readiness after TSA. The criteria used in the current study—attaining 50% of the surgeon's range-of-motion goals for both passive elevation and external rotation—were based on published recommendations from TSA investigators as well as our current institutional practice but are somewhat subjective given the lack of outcome data available after TSA.[2–4] Similarly, if a higher degree of pain is considered acceptable compared with the current study's protocol (table 1), patients without a CISB may reach discharge readiness sooner than our results suggest. In addition, all patients initially received perineural local anesthetic, and this may have influenced subsequent perceptions of subjects switched to placebo the morning after surgery (a methodologic bias).

Last, the study design most likely artificially increased the time until actual home discharge for a majority of the ropivacaine group. Although eight subjects met all three discharge criteria the morning of POD 1, the earliest allowable home discharge was not until later that afternoon. This protocol was necessary to allow an adequate washout period before discharge evaluation for patients switched to placebo infusions the morning of POD 1.

Shoulder Range of Motion

Our findings regarding the effect of CISB on shoulder external rotation—but not elevation—are similar to a published retrospective case–control study.[22] Given the previously demonstrated analgesic quality of CISB,[6,7] the increased range of motion is not unexpected. However, the *degree* of differences is compelling, and this new data may be placed in perspective with a comparison to the published data after total knee arthroplasty.[23–25] The day after knee surgery, patients with a continuous femoral nerve block in one study achieved a median (25th–75th percentiles) of 40° (34°–40°) of knee flexion, compared with 30° (10°–40°) in patients using intravenous opioids ($P < 0.05$).[24] When converted into percentages of their 40° flexion target, patients with a continuous femoral nerve block and intravenous opioids alone achieved 100% and 75% flexion, respectively, on POD 1. This 25% point difference was noted to be a significant achievement.[26]

By comparison, on POD 1 after TSA, the current investigation found CISB associated with an improvement of 100 (morning) and 75 (afternoon) percentage points for external rotation the day after surgery ($P < 0.001$ and $P = 0.009$, respectively). Because the majority of patients in the ropivacaine group were discharged home on POD 1, it remains unknown whether the benefits associated with CISB the day after surgery continued in the postoperative period. It is notable that in the previously cited study of knee arthroplasty, while the difference in knee flexion between treatment groups decreased after the continuous femoral catheter was removed at 72 h, it still persisted 7 days postoperatively (median 90° [70°–95°] *vs.* 80° [65°–90°]; $P < 0.05$), although the difference was no longer statistically significant at 4 weeks.[24] This persistent benefit after perineural catheter removal suggests—or at least raises the possibility—that the benefits in shoulder mobility associated with CISB in the current study may outlast the perineural infusion itself.

Regarding shoulder elevation, a trend existed toward improvement with perineural ropivacaine the morning ($P = 0.254$) and afternoon ($P = 0.139$) after surgery (fig. 5). However, there was not a statistically significant difference between treatment groups, unlike in a previously published retrospective case–control study.[22] It remains unknown whether this disparity is the result of inadequate power of the current study or bias inherent in all retrospective case–control investigations.

Sleep Disturbances

A previously published investigation reported that outpatients receiving a ropivacaine CISB experienced few sleep disturbances compared with patients receiving a placebo infusion.[7] In contrast, the current study found no statistically significant difference in sleep disturbances between the two treatment groups. We hypothesize that this disparity is the result of the hospitalized patients receiving placebo in the current study having access to intravenous opioids, in contrast to the outpatients in the previous study. Because intravenous opioids are more potent than their oral counterparts, the patients receiving placebo in the current study were probably better able to achieve analgesic parity with patients receiving perineural ropivacaine, and therefore the differences in sleep between the two groups were closer than in the earlier study.

Patient Safety

Although this investigation suggests that the hospitalization duration after TSA may be decreased with CISB, it does not define the appropriate subset of patients and incidence of complications associated with early discharge. We excluded patients with any comorbidity that resulted in mod-

erate or severe functional limitation or a baseline room-air oxygen saturation of less than 96% because interscalene perineural infusion causes frequent ipsilateral diaphragm paralysis[27] (although the effect on overall pulmonary function may be minimal for relatively healthy patients).[28] Caution is warranted because pulmonary complications have been associated with interscalene perineural infusion in hospitalized[29,30] and ambulatory[31] patients. It is not our intention to suggest that inclusion of patients with cardiopulmonary disease is an unsafe practice. Rather, we prefer cautious application of this technique until additional investigation of hospitalized, medically supervised patients documents its safety.[32]

In the current study, there were no medical complications attributable to providing perineural infusion at home after TSA. However, the small number of patients does not permit us to draw definite conclusions about its relative safety.[33] The technical complication of infusion pump failure occurred in two patients on POD 3, although both were receiving perineural saline at that time. Should a catheter dislocation or pump malfunction occur earlier during ambulatory perineural local anesthetic infusion, patients are at high risk of experiencing severe surgical pain unresponsive to oral opioids and requiring hospital readmission. It is for this reason that we required caretakers who could return patients to the hospital, if necessary. Related to this issue, patients with heart disease resulting in a moderate or severe functional limitation were excluded from participation out of concern that acute, severe pain could trigger an adverse cardiac event.

In conclusion, the results of this investigation suggest that for a subset of patients without major comorbidities, an ambulatory CISB considerably decreases the time until readiness for discharge after TSA, primarily by providing potent analgesia that permits greater passive shoulder movement and the avoidance of intravenous opioids. Additional research is required to define the appropriate subset of patients and assess the incidence of complications associated with earlier discharge.

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