Multimodal Nonopioid Pain Protocol Provides Better or Equivalent Pain Control Compared to Opioid Analgesia Following Arthroscopic Rotator Cuff Surgery: A Prospective Randomized Controlled Trial

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Purpose: To evaluate the efficacy of a multimodal nonopioid analgesic protocol in controlling postoperative pain compared to opioids following a primary arthroscopic rotator cuff repair. Methods: Seventy consecutive patients undergoing a primary rotator cuff repair were assessed for eligibility. An observer-blinded prospective randomized controlled trial was designed in accordance with the Consolidated Standards of Reporting Trials 2010 (CONSORT) statement. The two arms of the study included a multimodal nonopioid pain regimen for the experimental group, and a standard of care narcotics for the control group. The primary outcome was visual analog scale (VAS) pain scores for the first 10 postoperative days. Secondary outcomes included PROMIS-PI (Patient-Reported Outcomes Measurement Information System-Pain Interference) scale, patient satisfaction, and adverse drug events. Results: Thirty patients declined to participate or were excluded, and 40 patients were included in the final analysis. A total of 23 patients were in the traditional group, and 17 patients were in the nonopioid group. Control patients on opioid pain management reported a significantly higher VAS pain score on postoperative day 1 (opioid: 5.7 ± 2 , nonopioid: 3.7 ± 2.2 ; P = .011) and postoperative day 4 (opioid: 4.4 ± 2.7 , nonopioid: 2.4 ± 2.7 2.2; P = .023). No significant difference was seen on any other postoperative day. When mixed measured models were used to control for confounding factors, the nonopioid group demonstrated significantly lower VAS and PROMIS-PI scores (P < .01) at every time point. Patients in the traditional analgesia group reported significantly more days with constipation (P = .003) and days with upset stomach (P = .020) than those in the nonopioid group. **Concussion:** The present study found that a multimodal nonopioid pain protocol provided equivalent or better pain control compared to traditional opioid analgesics in patients undergoing primary arthroscopic rotator cuff repair. Minimal side effects were noted with some improvement in the multimodal nonopioid pain cohort. All patients reported satisfaction with their pain management. Level of Evidence: Level I, prospective randomized controlled trial.

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Introduction

Postoperative pain management is an essential responsibility of the orthopaedic surgeon. Physicians have historically managed acute postoperative pain with the use of opioids; however, opioid misuse and overprescription has been plaguing Americans.¹ In 2017, the National Institutes of Health declared an opioid epidemic.² Short-term exposure to narcotics postoperatively creates the risk for long-term misuse, abuse, and addiction in patients.³ In fact, previous studies have demonstrated that musculoskeletal conditions are one of the leading issues associated with the initial prescription of narcotics, inciting the addictive chain.⁴ In order to curtail the risk of narcotic abuse perioperatively, studies have characterized patient risk factors for prolonged postoperative opioid use.^{5,6} Further studies have sought



Fig 1. CONSORT 2010 flow diagram.

to assess the efficacy of nonopioid analgesics in the postoperative period.^{7,8} It is imperative that orthopaedic surgeons work to minimize the use of narcotics in the management of postoperative pain.

Studies have demonstrated that 30% of patients over the age of 60 experience rotator cuff tears, with that number rising to 62% over the age of 80.9 As the average age of Americans increases, the incidence of arthroscopic rotator cuff repair (RCR) in the United States is expected to experience a concomitant increase. Previous literature has sought to evaluate pain control following an arthroscopic RCR.^{7,10} In a cohort study, Moutzouros et al. used a nonopioid multimodal pain regimen consisting of an nonsteroidal antiinflammatory drug (NSAID), acetaminophen, diazepam, and gabapentin following common orthopedic sports procedures and found that a multimodal pain regimen can provide effective pain control with a limited side effect profile.⁷ Magasaki et al. evaluated pain control following shoulder surgery and found that patients administered NSAIDs in combination with an intravenous patient-controlled analgesia (IV PCA) had

significantly lower opioid consumption postoperative compare to patients who received the IV PCA alone. These studies have demonstrated the value of multimodal analgesic regimens in diminishing the postoperative opioid burden; however, to date, no study has eliminated the use of narcotics after rotator cuff repair.

The purpose of this randomized controlled trial was to evaluate the efficacy of a multimodal nonopioid analgesic protocol in controlling postoperative pain compared to opioids following a primary arthroscopic rotator cuff repair. The authors hypothesized that our nonopioid analgesic regimen would provide improved pain control with no significant difference in patientreported adverse drug event between groups.

Methods

This study was a prospective observer-blinded randomized controlled trial with 2-week follow-up and was developed in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement (Fig 1).¹¹ This investigation received institutional review board approval at our institution (IRB no. 12316)

Table 1. Multi	modal Nonc	pioid Pain	Regimen
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Postoperative Days 1-5					
Morning	Noon	Afternoon	Evening		
 Ketorolac, 10 mg Gabapentin*, 300 mg Methocarbamol, 750 mg Acetaminophen, 1000 mg 	 Ketorolac, 10 mg Gabapentin, 300 mg Methocarbamol, 750 mg Acetaminophen, 1,000 mg 	 Ketorolac, 10 mg Gabapentin, 300 mg Methocarbamol, 750 mg Acetaminophen, 1,000 mg 	- Ketorolac, 10 mg - Methocarbamol, 750 mg		
	Postoperativ	e Days 6-14			
Morning	Afternoon		Evening		
 Meloxicam, 7.5 mg Methocarbamol, 750 mg Acetaminophen, 1,000 mg 	Meloxicam, 7.5 mgMethocarbamol, 750 mgAcetaminophen, 1,000 mg		Methocarbamol 750 mgAcetaminophen 1,000 mg		

Preoperative by mouth (PO) Regimen: PO celecoxib, 400 mg; acetaminophen, 975 mg; gabapentin, 300 mg; tramadol, 50 mg; dexamethasone, 8 mg iv. Intraoperative Local Infiltration Analgesia: 150 mg (30 mL) ropivacaine, 30 mg (1 mL) of ketorolac, and 1 mg (1 mL) of epinephrine *Gabapentin weaning began on postoperative day 6 in the following manner: 300 mg in the morning and 300 mg in the evening on days 6-7,

400 mg in the morning on days 8-9, and discontinuation on day 10.

and was registered at ClinicalTrials.gov (NCT03818919). A hypothesis was formulated prior to trial initiation. Between August 2019 and December 2020, 70 consecutive patients who presented to two fellowship-trained sports surgeons and were scheduled to undergo a primary arthroscopic rotator cuff repair were screened for inclusion. Inclusion criteria required patients to be between the ages of 18 and 75 and scheduled for a primary arthroscopic RCR. Exclusion criteria included being non-English speaking, history of ipsilateral surgery in the previous year, undergoing revision surgery, use of blood thinner medication, history of peptic ulcer disease, history of substance abuse, and intolerance or allergies to study medication.

Following the surgical consult, patients consented to participate in the study. Using an adaptive randomization software (MD Anderson Cancer Center, Houston, TX) with a 1:1 allocation, patients were randomized into the opioid or nonopioid cohort. A secure computer database was used to store all deidentified patient data. One week prior to the date of surgery, the project coordinator used a secure e-mail to inform the surgical staff of the patient's group designation. Because of the fact that all outcomes would be self-reported by the patient, it was not necessary for the treating physician to be blinded. The research coordinator was not involved in patient care and performed patient enrollment and data collection.

Intervention

All patients indeterminate of treatment group received the following medication preoperatively: celecoxib 400 mg, acetaminophen 975 mg, tramadol 50 mg, gabapentin 300 mg, and 8 mg dexamethasone intravenously. Arthroscopic RCR was performed under preoperative block. Intraoperatively, all patients received a local infiltration of 30 mg (1 mL) ketorolac, 1 mg (1 mL) epinephrine, and 150 mg (30 mL) of .5% ropivacaine. Using a 20-mL syringe and 22-gauge needle, local infiltrate was administered in 2-mL increments in the subcutaneous tissue around the portal sites.

Patients who randomized into the control group were prescribed 40 pills of 5 mg oxycodone. Patients were instructed to take 1-2 pills every 4-6 hours as needed (PRN) and told not to supplement their analgesia with ibuprofen or acetaminophen.

Patients in the nonopioid group received a multimodal nonopioid analgesic regimen previously described in the literature.⁷ The protocol was developed to target various postoperative pain generators. Gabapentin was used to target neuropathic pain. Methocarbamol was selected because of its excellent control of muscle spasms and cramps. Acetaminophen and NSAIDs (ketorolac and meloxicam) were used to target the pain cascade and the inflammatory process. Medication dosage and frequency are listed in Table 1.

Prior to discharge patients were instructed to call the on-call physician regarding uncontrolled pain or adverse drug events postoperatively. Patients were provided an educational pamphlet describing the effects of narcotics, providing ways to manage pain, and treatment goals after surgery. All patients were discharged home the same day of surgery.

Outcomes

The data collection was performed by blinded observers. Preoperatively, patients completed the Patient-Reported Outcomes Measurement and Information System Pain Interference Short Form (PROMIS PI-SF) questionnaire. Postoperatively, a mobile messagingbased outcomes collection software (Mosio, Inc, Seattle, WA) was used to collect patient-reported outcomes. Patients' responses were submitted as numerical response via text message. This process allowed for the timely collection of data. Surveys were distributed to patients 3 times daily for 10 postoperative days.

Patient-reported pain scores were collected using a 11-point visual analog scale 3 times a day; in the morning (9 AM), afternoon (1 PM), and evening (7 PM). Questions regarding adverse drug effects and the number of opioids consumed in the last 24-hour period (if applicable) were distributed each evening. Responses regarding the amount of opioid consumption daily was converted to morphine milligram equivalents (MME). During the first postoperative clinic visit (Postoperative days 7-10), patients completed the PROMIS-PI SF questionnaires.

Information regarding the patients' demographic data (age, body mass index [BMI], race), anxiety/depression status, workers compensation, and previous opioid use was extracted from the electronic medical record.

Statistical Analysis

A power analysis was performed prior to the initiation of this investigation. Following a primary arthroscopic rotator cuff repair, previous literature has indicated that the minimal clinically significant difference (MCID) in VAS pain scores is 2.4 mm on a 10-mm scale.¹² Additionally, a previous case series demonstrated that the standard of deviation among VAS pain scores in patients following an arthroscopic rotator cuff repair was 2.3 mm on a 10-point scale.⁷ With a power of 80% (β level = .80, α level = .05), effect size of 2.4 mm, and standard deviation of 2.3 mm; the minimum number of patients was 16 per cohort (n = 32) to evaluate the primary outcome.

Continuous variables are reported as means and standard deviations, while frequency counts and percentages are displayed for categorical variables. Comparisons between the two pain control groups (traditional and nonopioid) are performed using chisquare tests, while Fisher's exact test is used when expected cell counts are <5. For continuous variables, two-group comparisons are performed using independent 2-sample *t*-tests if the variable is normally distributed and using Wilcoxon rank sum tests if the variable is non-normally distributed.

Pearson correlation coefficients and their corresponding *P* values are provided to show the correlation between select variables for the traditional pain control group, the nonopioid pain control group, and all patients.

Repeated-measures analyses of variance were performed using mixed models and included the effects of time, pain control group, and the interaction between time and pain control group as applicable. If needed, significant interaction effects were analyzed with post hoc comparisons using a Tukey-Kramer *P* value correction. Predicted means of the outcome variables resulting from the models were plotted. Statistical significance is set at P < .05 for group comparisons and main effect testing. Significance is set at P < .10 for interaction testing. All analyses are performed using SAS 9.4 (SAS Institute, Inc., Cary, NC).

Results

Demographics

Seventy consecutive patients with the primary diagnosis of rotator cuff tear were assessed for participation in the study. Thirty patients either declined to participate or were excluded from the study. A total of 40 patients were included in the final analysis, and participants were randomized into 2 groups. Twenty-three patients were randomized to receive traditional opioid analgesia, and 17 were randomized to receive nonopioid analgesia. A total of 23 patients in the opioid group and 17 patients in the nonopioid group were included in the final analysis. All participants had an average age of 55.1 \pm 8.0 years old and an average BMI of 30.8 ± 5.8 . Twenty-five (56.8%) participants identified as male, and 19 (43.1%) identified as female. Table 2 summarizes all demographic characteristics, preoperative block type, tear size, number of tendons

Table 2. Demographic Characteristics of Patients on Cohort

	Traditional	Nonopioid	
	(n = 23)	(n = 17)	P Value
Age (years)	55.9 ± 7.2	53.7 ± 9.1	.382
Sex			
Male	13 (56.5%)	9 (52.9%)	.680
Female	10 (43.5%)	8 (47.1%)	
BMI (kg/m ²)	29.9 ± 5.5	32.2 ± 6.3	.218
Race			
White	14 (60.9%)	7 (41.2%)	.238
AA	7 (30.4%)	8 (47.1%)	
Other	2 (8.7%)	2 (11.8%)	
Preoperative Block			
Supraclavicular	5 (21.7%)	3 (17.6%)	.758
Interscalene	18 (78.3%)	14 (82.4%)	
Tear Size			
Less than 1 cm	4 (14.8%)	1 (5.8%)	.777
1-3 cm	16 (69.6%)	11 (64.7%)	
3-5 cm	2 (8.7%)	5 (29.4%)	
Greater than 5 cm	1 (4.3%)	0 (0%)	
Tendons involved	$1.4 \pm .8$	$1.7 \pm .4$.194
Concomitant Procedures			
None	2 (8.7%)	0 (0%)	.479
Biceps tenotomy	2 (8.7%)	2 (11.8%)	
Biceps tenodesis	3 (48.3%)	4 (23.5%)	
DCE	2 (8.7%)	1 (5.9%)	
SAD	14 (60.9%)	10 (58.8%)	
Anchors (mean \pm SD)	2.6 ± 1.1	$2.7\pm.8$.770

Bold values denote statistical significance (P < .05).

AA, African American; BMI, body mass index; DCE, distal clavicle excision; SAD, subacromial decompression.



Fig 2. Average daily visual analog scale (VAS) pain score of patients of traditional and nonopioid pain regimen. *Values denote statistical significance (P < .05).

involved and codominant procedures between the two cohorts. There were no workers compensation claims.

Traditional Versus Nonopioid Analgesia

Patients in the traditional pain control group reported a significantly higher VAS pain score on postoperative day 1 (opioid: 5.7 ± 2 , nonopioid: 3.7 ± 2.2 ; P = .011, Fig 2) and postoperative day 4 (opioid: 4.4 ± 2.7 , nonopioid: 2.4 ± 2.2 ; P = .023). No significant difference was seen on any other postoperative day. There were no significant differences in PROMIS PI-SF scores between both groups preoperatively (opioid: 64.4 ± 4.2 , nonopioid: 62.9 ± 4.3 ; P = .0291) and postoperatively (opioid: 60.0 ± 9.3 , nonopioid: 59.3 ± 8.5 ; P = .805). Following a repeated-measure, mixed-model analysis to assess covariates, the mean VAS score was significantly greater in the traditional group than in the nonopioid group across all postoperative days (P < .01) (Fig 3). Mixed-measures models also demonstrated that there was no significant difference in postoperative PROMIS-PI scores between cohorts (P = .49) (Fig 4). In the traditional pain control group, the highest opioid consumption, as reported on postoperative day 1-3 (POD 1: 3.7 \pm 1.3 pills, 28.3 \pm 9.1 MME; POD 2: 3.4 \pm 2.4 pills, 26.3 \pm 17.7 MME; and POD 3: 2.8 ± 1.8 pills, 21.2 ± 13.3 MME) and lowest on postoperative days 8-10 (POD8: 1.1 ± 1.4 pills, 8.3 ± 10.9 MME; POD 9: $.8 \pm 1.2$, 5.4 ± 8.8 MME; and POD 10: 1.2 ± 1.7 , 6.7 ± 9.9 MME) (Fig 5).

When evaluating all patients as a whole, patient demographics (age, gender, BMI, and ethnicity) and

concomitant procedures did not have a statistically significant relationship with postoperative VAS scores or MME (P > .05).

Adverse Events

There was no significant difference in the number of days patients reported any adverse events (opioid: 4.1 ± 3.5 days, nonopioid: 2.2 \pm 3.4 days; P = .08). The most commonly reported side effects for patients in both groups were drowsiness (opioid: 2.7 \pm 3.3 days, nonopioid: 1.9 \pm 3.3 days) and constipation (opioid: 2.2 \pm 2.9 days, nonopioid: $.2 \pm .6$ days). Patients in the traditional analgesia group reported significantly greater average number of days with constipation (opioid: 2.2 \pm 2.9, nonopioid: .2 \pm .6; P = .003) and days with upset stomach (opioid: 1.3 \pm 2.5, nonopioid: $.0 \pm .0$; P = .020) than those in the nonopioid group. Additionally, there was no significant difference for nausea (P = .06), diarrhea (P = .46), drowsiness (P = .33), or dizziness (P = .68) between cohorts. Table 3 summarizes side effects for both cohorts. All (100%) patients in the nonopioid protocol reported they were satisfied with their pain management. There were no reported complications with the nonopioid protocol, and no patients required emergency opioid analgesia.

Discussion

The current study found that the multimodal nonopioid analgesic protocol provided at least equivalent postoperative pain management with a similar or lesser



Fig 3. Mean hourly pain data controlling for age, graft, body mass index, sex, smoking, and depression comparing daily pain levels between the two groups. The mean visual analog scale (VAS) score is significantly greater in the traditional group than in the nonopioid group (P < .01).

side effect profile compared to traditional opioid analgesia. In conjunction with national efforts to reduce opioid addiction and consumption, the results suggest a multimodal nonopioid pain protocol may be an effective alternative for postoperative pain management following arthroscopic RCR. Reports of postoperative pain protocols successfully eliminating opioids have been promising but limited in the literature. Previous studies have suggested a potential benefit to postoperative nonopioid pain management, including alternatives such as NSAIDs, gabapentin, cryotherapy, local anesthesia injections,





Predicted Mean MME

Fig 5. Predicted mean MME for opioid group when controlling for age, sex, body mass index, smoking, and depression. Morphine equivalent usage was found to decrease as time from surgery increased (specifically, from sequential day to day). Time was found to be a significant factor (P < .0001). MME, morphine milligram equivalents.

and nerve blocks.¹³ A randomized control trial by Syed et al. demonstrated opioid-related preoperative education alone significantly reduced opioid consumption at 6 weeks (P = .02) and 3 months (P = .01) after arthroscopic RCR.^{14,15} In a randomized control trial investigating the addition of liposomal bupivacaine injection to multimodal anesthetic protocols in primary RCR, Sethi et al. found a significant reduction in postoperative pain in days 1 (P < .001) and 2 (P = .03) and the number of opioids used in the first 5 days after arthroscopic RCR (P = .003) compared to the control group.¹⁶ In a prospective study of 36 patients investigating the use of ketorolac, zolpidem, and acetaminophen as an alternative to opioids following RCR, Theosmy et al. found that 67% of patients successfully completed opioid-free arthroscopic RCR.¹⁷ They also found that patients who did not take opioids postoperatively demonstrated higher satisfaction with their

Table 3. Average Number of Days Side Effects Were Reported in the Traditional and Nonopioid Pain Protocol

	Traditional $(n = 23)$	Nonopioid $(n = 17)$	P Value
Total constipated days	2.2 ± 2.9	.2 ± .6	.003
Total nausea days	1.0 ± 1.6	.1 ±.3	.066
Total diarrhea days	$.1 \pm .2$	$.0 \pm .0$.457
Total upset stomach days	1.3 ± 2.5	$0.\pm .0$.020
Total drowsiness days	2.7 ± 3.3	1.9 ± 3.3	.327
Total dizziness days	$.4\pm1.0$	$.2$ \pm $.4$.681

Values are expressed as mean days \pm SD. Bold values denote statistical significance (P < .05).

pain management. Finally, in a case series by Moutzouros et al. of 141 patients (27 RCR) using an identical nonopioid pain protocol to the current study, they found that 45% of all patients did not require any breakthrough opioids, and the average VAS pain score at 1 week postoperatively was 3.9 ± 2.8 following RCR.⁷ In accordance with previous literature, the present study demonstrates that equivalent pain control postoperative as reported by VAS pain scores. Additionally, patients in the nonopioid group reported a statistically significant decrease in VAS scores when controlling for confounding variables. All patients in the present study reported 100% satisfaction with their respective pain control regimens, highlighting that postoperative pain control and patient satisfaction can be achieved while minimizing the risk of opioid addition postoperatively.

When deciding on a postoperative pain regiment, it is essential to consider how to best maximize therapeutic benefit while minimizing adverse events and side effects for patients. Opioids have a broad side effect profile. commonly. including most drowsiness. gastrointestinal issues, such as constipation and nausea, and vomiting.¹⁸ In a survey of 500 patients assessing their perception of treatment with opioids, respondents reported nausea (78%) and constipation (64%) as the most common causes for discontinuing opioids.¹⁹ In a prior case series using a nonopioid analgesia protocol, Moutzouros et al. found that 53.6% of patients reported no adverse effects of their pain regimen, with the most commonly reported side effects in both groups being constipation (opioid: 1.9 ± 2.9 ; nonopioid: $.9 \pm$ 2.0) and drowsiness (opioid: 2.5 \pm 3.6; nonopioid: 1.0 \pm 1.6).⁷ The current study demonstrated that the multimodal analgesia cohort had significantly fewer total constipated days and upset stomach days than the traditional opioid analgesia cohort, suggesting improved gastrointestinal side effect experiences for patients with no compromise on pain control. The current study also demonstrated a nonsignificant decrease in total nausea days (1.0 in the opioid cohort vs.1 in the nonopioid cohort). Opioid medications are a well-known source of sedation and drowsiness in patients.²⁰ Dizziness or drowsiness may also be caused by methocarbamol and gabapentin; however a randomized controlled trial investigating gabapentin use following shoulder arthroscopy demonstrated that the use of gabapentin had no significant differences in somnolence-dizziness and nausea-vomiting and increased patient satisfaction.²¹⁻²³ While the multimodal pain control regimen may present concerns regarding the use of NSAIDs and tendon to bone healing, a meta-analysis by Duchman et al. demonstrated that there is not sufficient evidence in the literature supporting the avoidance of NSAIDs following acute injury or surgical repair of the tendonbone interface; however, this is an area that warrants further investigation.²⁴

Previous literature has assessed pain control and MME levels and its correlation with demographic characteristics and concomitant procedures. In a retrospective analysis investigating chronic opioid use following surgery, Sun et al. found that preoperative history of drug or alcohol abuse, depression, benzodiazepine use, or antidepressant use were associated with chronic opioid consumption postoperatively.25 Additionally, Sun et al. also found that men were associated with chronic opioid use following surgery. In a cohort study examining factors that predicted the severity of postoperative pain after RCR surgery Rizvi et al. found that tendon tear size was inversely related with pain severity ($R^2 = .85$). Additionally, they demonstrated that other factors associated with postoperative pain frequency included work-related injury status (P <.001), younger age (P = .001), and female sex (P = .04). The current study revealed no correlation between gender, concomitant procedures, and VAS scores, and no association with tendon tear size. Since pain perception and tolerance may be influenced by a wide range of factors, this area warrants further investigation to provide the most effective pain management for patients.

Limitations

This study is not without limitations. Because of the study design, double blinding was not possible, since patients were informed of their postoperative treatment. Consequently, this made bias in patientreported pain scores possible. Furthermore, we were unable to measure patient compliance with medication, which may have further influenced pain scores as patients could opt to not take their medication. Additionally, this study was only powered to assess the primary outcome of VAS scores postoperatively. The sample size was not large enough to perform a comprehensive subgroup analysis for all demographic characteristics and concomitant procedures. A high number of patients declined to participate because of the predetermined preferences for postoperative analgesia. These patients did not want to risk randomization and not receiving their desired pain regimen. Although this may have impacted the study group, it is important to note that it was not possible to blind patients to their medication, particularly when evaluating side effect profile of each regimen. Finally, it was not possible to evaluate the total pain reduction possible with the nonopioid pain regimen, as it would be unethical to withhold pain medication from patients following surgery.

Conclusion

The present study found that a multimodal nonopioid pain protocol provided equivalent or better pain control compared to traditional opioid analgesics in patients undergoing primary arthroscopic rotator cuff repair. Minimal side effects were noted with some improvement in the multimodal nonopioid pain cohort, and all patients reported satisfaction with their pain management.

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