Video Abstract

Effects of Melatonin on Sleep Quality and Patient-Reported Outcomes After Arthroscopic Rotator Cuff Surgery

A Prospective Randomized Controlled Trial

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Background: Sleep disturbance is a significant symptom associated with both rotator cuff tears and arthroscopic rotator cuff repair. Melatonin has been shown to be safe and effective in managing multiple sleep disorders, including secondary sleep disorders, with relatively minor adverse effects and lack of addictive potential.

Purpose: To investigate the effects of oral melatonin on postoperative sleep quality after arthroscopic rotator cuff repair.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: This was a prospective randomized clinical trial evaluating patients undergoing arthroscopic rotator cuff repair. Exclusion criteria included history of alcohol abuse, current antidepressant or sedative use, revision rotator cuff repair, severe glenohumeral arthritis, and concurrent adhesive capsulitis. Patients were randomly assigned in a 1:1 ratio to 1 of 2 groups: 5-mg dose of melatonin 1 hour before bedtime or standard sleep hygiene (≥6 hours per night, avoiding caffeine and naps in the evening). Patients in the melatonin group took their assigned melatonin dose for 6 weeks beginning the day of surgery. Patient-reported outcome assessments, including the Pittsburgh Sleep Quality Index (PSQI), the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), and the Single Assessment Numeric Evaluation (SANE), and pain medication charts were collected preoperatively as well as at 2 weeks, 6 weeks, 3 months, 4 months, and 6 months postoperatively. Numeric variables were analyzed using paired and unpaired *t* tests, with significance set at $P < .05$.

Results: Eighty patients were included for final analysis (40 in the control group, 40 in the melatonin group). Patient characteristics such as age, sex, race, body mass index, and laterality did not differ significantly ($P \geq .05$). Preoperative ASES, SANE, and PSQI scores did not differ between groups ($P \geq .055$). PSQI scores were significantly lower (better quality sleep) in the melatonin group at the 6-week postoperative period ($P = .036$). There was a positive correlation between how patients rated the intensity of their pain and the PSQI at the 6-week postoperative period (0.566). The PSQI question regarding sleep quality was found to be significantly lower in the melatonin group at the 3-month, 4-month, and 6-month postoperative periods ($P = .015$, $P = .041$, and $P \leq .05$, respectively). SANE scores were significantly lower in the melatonin group ($P = .011$) at 6 weeks and then higher in the melatonin group ($P = .017$) at 6 months. ASES scores were significantly higher in the melatonin group at 4 and 6 months ($P = .022$ and $P = .020$, respectively). Lastly, patients who were randomized into the melatonin group were found to use significantly less narcotic medication at the 4-month postoperative period ($P = .046$).

Conclusion: Melatonin use after arthroscopic rotator cuff repair led to improved sleep quality (PSQI) in the early postoperative period as well as improved functional outcomes (ASES and SANE scores) and decreased narcotic use in the later postoperative period. Patients with significant sleep disturbances associated with rotator cuff repairs may benefit from the use of melatonin.

Registration: NCT04278677 (ClinicalTrials.gov identifier).

Keywords: arthroscopic rotator cuff repair; melatonin; sleep quality

Sleep disturbance is a significant symptom associated with both rotator cuff tear and arthroscopic rotator cuff repair (ARCR). In a previous study performed by Austin et al,[4] 89% of patients undergoing ARCR reported preoperative sleep disturbance. In that same study, 69% of patients

The American Journal of Sports Medicine
2024;52(12):3075–3083
DOI: 10.1177/03635465241272076

continued to experience abnormal sleep at 12 weeks postoperatively. Multiple studies have reported significant sleep impairment after other elective outpatient surgery.[28] Patients often report "decreased sleep time, increased numbers of awakening, lowered sleep quality, and frequent nightmares."[37] One study found that 23% of patients experience impaired sleep after elective procedures including orthopaedic procedures. The high rate of sleep impairment in elective surgery is especially concerning given that the study demonstrated that 2.9% of a control population in the community experienced sleep impairment.[27] Other studies have estimated that anywhere from 50 to 70 million Americans may have trouble with sleep.[1,26,29]

Although adequate sleep is important for the overall well-being and quality of life in all patients,[34] it is especially important for patients recovering from surgical procedures. There is evidence that sleep deprivation may lead to decreased skin barrier recovery, decreased growth hormone production, and increased stress, which can all decrease wound healing.[2,42] Additionally, sleep deprivation can lead to hyperalgesia and decreased efficacy of narcotics. Furthermore, postoperatively, patients often state that they take narcotics to help them sleep at night, although the orthopaedic community has been implementing multimodal pain management to combat this.[39] It is possible that sleep impairment may indirectly lead to increased narcotic consumption.[16,32] Therefore, it is important to investigate therapeutic interventions that may decrease the high rate of sleep impairment after ARCR.

Melatonin has been used safely as a sleep aid in adults for several years. It has been shown to be effective in managing multiple sleep disorders, including secondary sleep disorders, with relatively minor adverse effects and lack of addictive potential.[17,19,38] In a study examining the effects of melatonin on sleep efficiency after breast cancer surgery, melatonin was found to increase sleep efficiency and total sleep time.[22] Similar results were also found in patients who received melatonin after cardiac surgery.[13] Intriguingly, in a study examining the effects of melatonin after prostatectomy, preoperative oral melatonin decreased pain scores and tramadol consumption and enhanced sleep quality, sedation scores, and subjective analgesic efficacy during the postoperative period.[6] This further supports the notion that narcotic use may be decreased with the use of melatonin. A recent study conducted by Clarkson et al[10] found no change in sleep quality with melatonin after total joint arthroplasty; however, the group did not show postoperative pain scores after surgery, which could potentially affect the results. Considering the importance of sleep and the significant deterioration of sleep quality after rotator cuff repair (RCR), evaluation of melatonin for the reduction of sleep disturbance is warranted.

The primary purpose of this study was to investigate the effects of oral melatonin on postoperative sleep quality in patients undergoing primary ARCR. Additional aims were to evaluate the effect of melatonin on patient narcotic usage, pain, and shoulder function. We hypothesized that patients receiving melatonin would have better postoperative sleep quality compared with a control group of patients. We also hypothesized that patients receiving melatonin would consume fewer narcotics during their postoperative course.

METHODS

Study Design

After obtaining institutional review board approval (No. 19D.223) and registering the study on ClinicalTrials.gov (identifier: NCT04278677), we conducted a prospective randomized clinical trial. This study was performed at a multispecialty orthopaedic institution with a clinic and outpatient surgery center. Patients were enrolled by a research coordinator (H.D., A.P.) who recruited patients from 3 fellowship-trained sports medicine orthopaedic surgeons (F.P.T., M.D.P., B.S.T.) beginning April 1, 2020, and were followed until the last enrollee completed his or her final survey on December 20, 2023.

Participants

Patients undergoing ARCR between April 1, 2020, and April 6, 2023, who were eligible and able to complete postoperative surveys were enrolled. Patients were excluded if they had an irreparable cuff tear, severe glenohumeral arthritis, and/or adhesive capsulitis; were undergoing a revision RCR; had a history of narcotic dependence; were <18 years of age; were pregnant; or had an active workers' compensation claim. Patients who were taking melatonin for >1 week in the last 3 months; were taking antidepressants such as selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, tricyclic antidepressants, monoamine oxidase inhibitors, or vemurafenib; or had a history of alcohol abuse or heavy

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Submitted April 3, 2024; accepted July 8, 2024.

One or more of the authors has declared the following potential conflict of interest or source of funding: N.K.P. has received a grant from DJO and support for education from Smith & Nephew, Paladin Technology Solutions, Eclipse Technology Solutions, and Mid-Atlantic Surgical Systems. R.E.C. has received support for education from Arthrex and Liberty Surgical Inc and hospitality payments from Stryker Corporation. B.S.T. has received research support from DePuy, GID, and Pacira; has received consulting fees from Mitek, DePuy, Pacira, and Medical Device Business Services; and holds stock or stock options in Johnson & Johnson. F.P.T. has received royalties from Tigon Medical; consulting fees from Medical Device Business Services and DePuy Synthes; and hospitality payments from Smith & Nephew and MicroVention; and holds stock or stock options in Trice Medical. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

alcohol use (male: >14 drinks per week; female: >7 drinks per week) were also excluded from the study. Any medication that was not listed in the official exclusion criteria that is known to aid in sleep was elicited through conversation before enrollment. Medication surveys were also checked periodically during the postoperative period, and if new medications were seen that affected sleep, patients were contacted and asked if this medication was taken before enrollment.

Enrollment

Throughout the study period, patients who met eligibility criteria were approached during their preoperative visit by a trained research coordinator to obtain informed consent (H.D., A.P.). Surgeons were blinded to the study group designation. Patients were randomized to 2 groups in a 1:1 fashion using a computerized random number generator. Patients were assigned to either the control group (standard sleep hygiene, including being advised to get at least 6 hours of sleep per night and avoid caffeine or naps in the evening) or the melatonin group (received a 6-week supply of 5-mg doses of melatonin, instructed to take it 1 hour before bedtime beginning the day of surgery). The melatonin cohort was also given the standard sleep hygiene recommendations. Melatonin was provided free of cost by the institution where the study was performed. Patients were encouraged as well as given written instructions on how and when to take their nightly dose of melatonin. These instructions also contained information regarding which drugs to avoid (eg, alcohol) as well as known melatonin interactions with other drugs.

Operative Technique and Postoperative Protocol

Lateral decubitus positioning was used for all ARCRs. Repair technique and anchor numbers were determined by the surgeon (F.P.T., M.D.P., B.S.T.) and performed as necessary. Biceps tenodesis was not considered an exclusionary procedure. All procedures were performed with patients under general anesthesia, and patients received a liposomal bupivacaine interscalene nerve block, performed by a board-certified anesthesiologist. Standardized postoperative care provided to all patients included 5 mg oxycodone (Purdue Pharma) and 4 mg ondansetron (Novartis) for pain and nausea, respectively. Use of a cryotherapy cuff and nonsteroidal anti-inflammatory drugs was allowed. Our institution did not prescribe nonsteroidal anti-inflammatory drugs and recommended routine usage of 400 mg ibuprofen over the counter every 4 to 6 hours as needed without exceeding 2400 mg/day. All patients were treated with a uniform therapy program. Sling immobilization was carried out for 4 weeks after surgery, with passive range of motion allowed out of the sling during this initial phase. After 4 weeks, use of the sling was discontinued, and active-assisted range of motion was allowed with progression to active range of motion by 8 weeks. At 10 weeks after surgery, patients were started on a progressive strengthening program that continued until 4 months after surgery, at which time patients were transitioned to a home exercise program. Release to full activity was permitted at 6 months after surgery.

Surveys

Patients were asked to fill out the Pittsburgh Sleep Quality Index (PSQI) (Appendix A, available in the online version of this article), the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), and the Single Assessment Numeric Evaluation (SANE) (Appendix B, available online). Additionally, a pain medication chart (Appendix C, available online) was completed that detailed the medication name, dose, amount per day, and pain relief per dose on a scale of 0 to 100. Higher scores in ASES and SANE indicate better shoulder function; however, lower scores in PSQI surveys indicate better sleep quality. These surveys were administered preoperatively to assess baseline function and sleep quality. Postoperatively, surveys were administered at the 2-week, 6-week, 3-month, 4-month, and 6-month marks. Surveys were administered preoperatively in person during enrollment and via REDCap postoperatively.[23,24]

Statistical Analysis

Power analysis with PSQI being the primary endpoint demonstrated that a 2-sided test could generate approximately 80% power with a sample size of 60 (30 patients in each group). This power analysis was based on the minimal clinically important difference (MCID) for the PSQI. A previous study established the MCID of the PSQI for RCR to be an improvement of 4.4 from preoperatively at the 6-month postoperative follow-up.[35] The MCIDs for the ASES and SANE scores after ARCR were 11.1 and 16.9, respectively.[11] Statistical analysis was performed using pointwise t test, pairwise t test, and Mann-Whitney U test, with statistical significance set at $P < .05$. Statistical analyses were conducted using R software (Version 4.1.2).

RESULTS

A total of 102 participants were initially enrolled; however, 9 were unenrolled due to procedural changes that excluded them from the study, 8 were lost to follow-up, and 5 did not adhere to their protocol. Therefore, 80 patients were included in the final analysis (40 in the control group, 40 in the melatonin group) (Figure 1). Patient characteristics such as age, sex, race, body mass index, and laterality did not differ significantly between groups (Table 1).

Preoperative ASES, SANE, and PSQI scores did not significantly differ between groups ($P \geq .055$) (Table 2). In both groups, patient-reported outcome scores significantly improved from the preoperative to 6-month postoperative time points ($P < .001$; ASES: 45.8 to 83.6; SANE: 40.8 to 77.0). Postoperative SANE scores were found to be

TABLE 1
Patient Characteristics[a]

	Control (n = 40)	Melatonin (n = 40)	*P* Value	Total (N = 80)
Age, y	59.7 (7.04) [57.4-62.0]	62.3 (8.03) [59.7-64.8]	.131	61.0 (7.61) [59.3-62.7]
Sex			.621	
Male	30 (75.0) [58.8-87.3]	27 (67.5) [50.9-81.4]		57 (71.3) [60.0-80.8]
Female	10 (25.0) [12.7-41.2]	13 (32.5) [18.6-49.1]		23 (28.8) [19.2-40.0]
Race			.844	
Unknown	1 (2.5) [0.06-13.2]	1 (2.5) [0.06-13.2]		2 (2.5) [0.30-8.74]
White	34 (85.0) [70.2-94.3]	32 (80.0) [64.4-90.9]		66 (82.5) [72.4-90.1]
African American	3 (7.5) [1.57-20.4]	5 (12.5) [4.19-26.8]		8 (10.0) [4.42-18.8]
Asian	2 (5.0) [0-16.9]	1 (2.5) [0.06-13.2]		3 (3.8) [0.78-10.6]
Middle Eastern	0 (0) [0-8.81]	1 (2.5) [0.06-13.2]		1 (1.3) [0.03-6.77]
Not Hispanic	40 (100) [91.2-100]	40 (100) [91.2-100]		80 (100) [95.5-100]
BMI	28.9 (4.05) [27.6-30.2]	29.9 (4.60) [28.4-31.3]	.328	29.4 (4.33) [28.4-30.4]
Laterality			.364	
Right	21 (52.5) [36.1-68.5]	26 (65.0) [48.3-79.4]		47 (58.8) [47.2-69.6]
Left	19 (47.5) [31.5-63.9]	14 (35.0) [20.6-51.7]		33 (41.2) [30.4-52.8]

[a]Data are presented as mean (SD) [95% CI] or n (%) [95% CI]. BMI, body mass index.

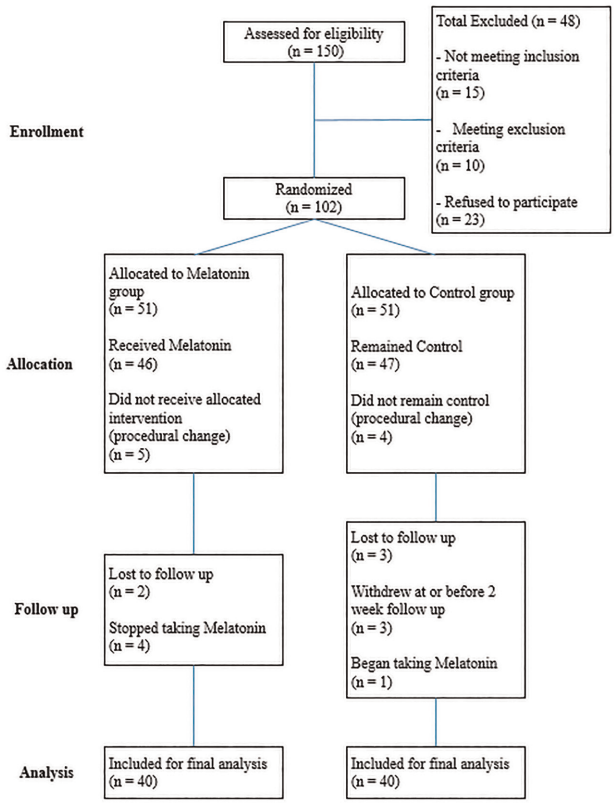

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

significantly lower in the melatonin group at 6 weeks (38.9 vs 51.6; $P = .011$) and higher at 6 months (81.0 vs 72.6; $P = .017$). ASES scores were found to be significantly higher in the melatonin group at 4 months (76.4 vs 69.6; $P = .022$) and 6 months (89.0 vs 77.7; $P = .020$) postoperatively. PSQI scores were only seen to be significantly lower (greater quality sleep) in the melatonin group at the 6-week postoperative period (6.59 vs 7.97; $P = .036$). Pairwise comparison of the melatonin and control groups is shown in Figure 2.

When correlating pain graded using the question "How intense is your pain on an average day? (0 if no pain, 100 is worst pain imaginable)" found in the ASES survey with the PSQI, we found a positive correlation at the 6-week postoperative period (0.566) (Table 3). This correlation implies the relationship that pain and sleep quality had with each other at 6 weeks postoperatively, while the preoperative and all other postoperative pain scores did not influence PSQI scores profoundly (correlation value, <0.500).

When looking at specific questions within the surveys administered, we found PSQI question 9, "During the past month, how would you rate your sleep quality overall?" to have a significantly higher score in the melatonin group at the 3-month, 4-month, and 6-month postoperative periods ($P = .015$, $P = .041$, and $P \leq .05$, respectively) (Table 4).

Lastly, patients in the melatonin group were found to use significantly less narcotic medication at the 4-month postoperative period ($P = .046$). No other time point was found to be statistically significant ($P \geq .05$) (Table 5).

Postoperative Complications

Three patients had a postoperative complication of adhesive capsulitis in the melatonin group, but this did not meet statistical significance compared with the control group ($P = .241$).

DISCUSSION

Patients who underwent ARCR in this study had improved ASES and SANE scores at the 6-month postoperative

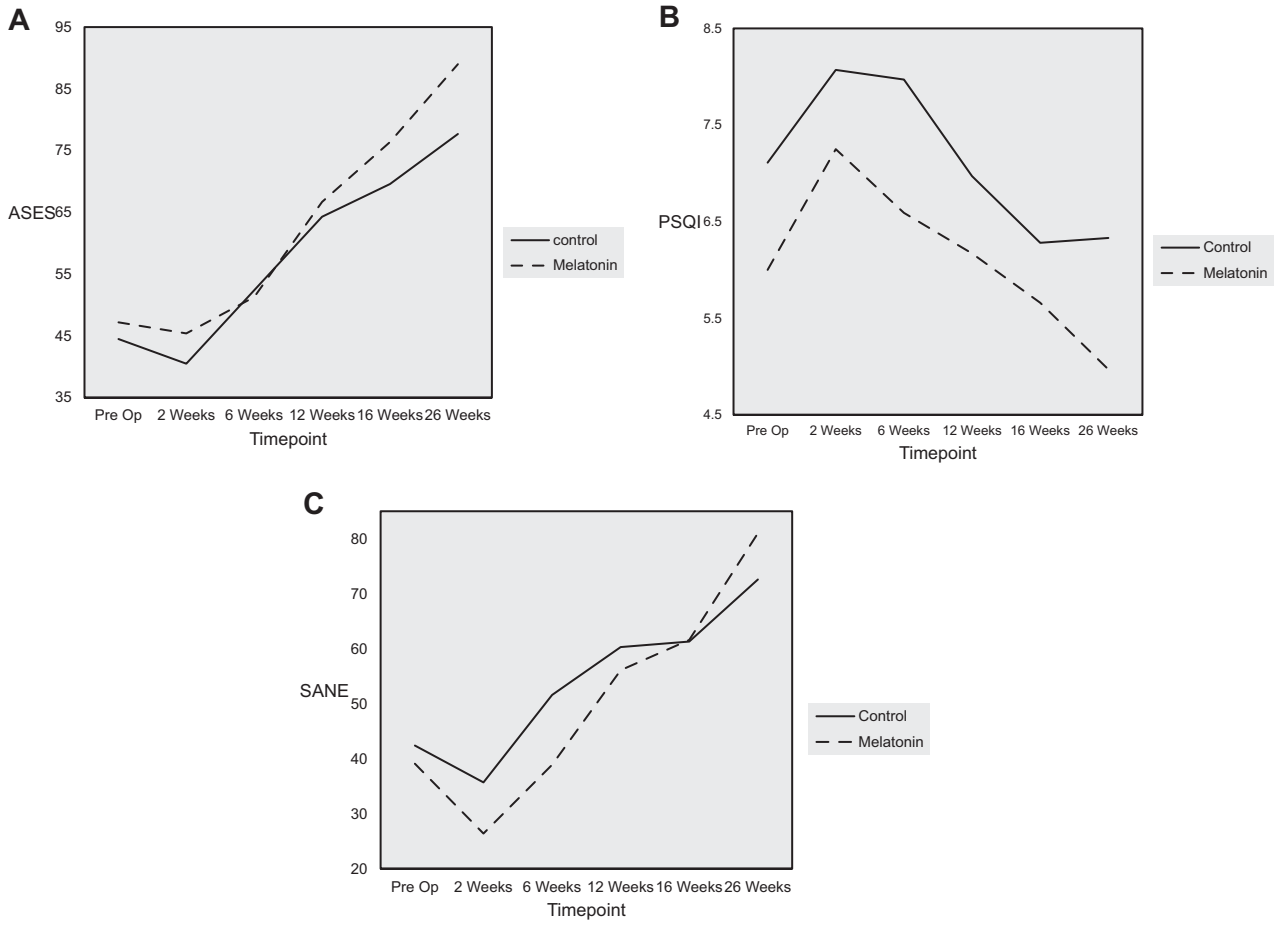

Figure 2. Postoperative pairwise comparison of the control group versus the melatonin group with regard to the (A) American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), (B) Pittsburgh Sleep Quality Index score (PSQI), and (C) Single Assessment Numeric Evaluation.

period compared with preoperative values. Narcotic use and sleep quality also improved in this time period throughout the whole cohort. The use of oral melatonin after ARCR resulted in improved sleep quality at 6 weeks according to PSQI scores, better patient-reported outcomes at 4 and 6 months according to ASES and SANE scores, and less narcotic use at 4 months when compared with patients who were not taking melatonin. Our initial hypotheses were supported by the data, as patients taking melatonin had greater postoperative sleep quality and used less narcotic medication at certain time points.

Historically, sleep disturbance is a frequent complaint seen in patients with rotator cuff tears and at times can be the reason patients decide to opt for operative management. There is strong evidence that after RCR, sleep disturbances improve dramatically as early as 3 months,[4] with most studies seeing significant improvement at 6 months and continuing into the 2-year postoperative period.[15,25,45] Initially, Austin et al[4] and Horneff et al[25] saw PSQI scores decrease at the first postoperative time point of 6 weeks. Our study found an increase, or worse sleep quality, at the first postoperative time point of 2 weeks. This was likely because of the initial inflammatory processes after surgery.[40] Horneff et al[25] found the greatest PSQI change from 6 weeks (11.3) to 12 weeks (8.3). Similarly, Austin et al[4] saw their largest difference within this postoperative period. Our study found significantly improved PSQI scores in the melatonin group at the 6-week postoperative period. This earlier improvement of sleep quality may possibly be attributed to the incorporation of melatonin, as the 2 aforementioned studies did not incorporate a medication in their methodology. In our study, patients had a mean preoperative PSQI of 6.54, which is consistent with scores seen in previous studies with a joint arthroplasty population,[9,10,31] but is lower in comparison with previous ARCR studies.[4,25] There can be a multitude of reasons for this, such as cuff tear size, where smaller tears are said to be more painful and increase PSQI scores.[20] We did not collect rotator cuff tear size in our study; however, 2 previous studies did not find a correlation with PSQI and size of cuff tear.[4,25]

Although a previous study showed that exogenous melatonin was not effective in improving sleep quality after total joint arthroplasty,[10] pain is a key factor when

TABLE 2
Pre- and Postoperative Scores[a]

	Control (n = 40)	Melatonin (n = 40)	*P* Value	Total (N = 80)
Preoperative scores				
SANE	42.4 (20.8) [35.7-49.1]	39.1 (20.4) [32.5-45.8]	.484	40.8 (20.5) [36.1-45.4]
ASES	44.5 (16.6) [39.1-49.9]	47.2 (16.2) [41.9-52.5]	.466	45.8 (16.4) [42.1-49.5]
PSQI	7.11 (2.56) [6.26-7.96]	6.00 (2.48) [5.20-6.80]	.055	6.54 (2.56) [5.95-7.13]
Intraoperative complication: no	40 (100) [91.2-100]	40 (100) [91.2-100]		80 (100) [95.5-100]
Postoperative complication			.241	
No	40 (100) [91.2-100]	37 (92.5) [79.6-98.4]		77 (96.3) [89.4-99.2]
Yes	0 (0) [0.00-8.81]	3 (7.5) [1.57-20.4]		3 (3.8) [0.78-10.6]
2-wk postoperative scores				
SANE	35.7 (27.0) [25.5-46.0]	26.4 (22.2) [18.9-33.9]	.198	30.6 (24.7) [24.5-36.7]
ASES	40.5 (16.8) [34.2-46.8]	45.4 (14.1) [40.6-50.1]	.215	43.2 (15.5) [39.4-47.0]
PSQI	8.07 (2.58) [7.07-9.07]	7.25 (2.79) [6.31-8.19]	.228	7.61 (2.71) [6.93-8.29]
6-wk postoperative scores				
SANE	51.6 (21.3) [44.3-58.9]	38.9 (19.5) [32.2-45.5]	**.011**	45.2 (21.2) [40.2-50.3]
ASES	52.4 (17.3) [46.4-58.3]	51.3 (15.2) [46.1-56.5]	.784	51.8 (16.2) [48.0-55.7]
PSQI	7.97 (2.64) [7.03-8.91]	6.59 (2.55) [5.67-7.51]	**.036**	7.29 (2.67) [6.63-7.95]
3-mo postoperative scores				
SANE	60.3 (20.7) [52.9-67.8]	56.1 (18.5) [49.9-62.4]	.286	58.1 (19.6) [53.4-62.9]
ASES	64.3 (17.3) [58.1-70.5]	66.7 (14.9) [61.7-71.8]	.535	65.6 (16.0) [61.7-69.5]
PSQI	6.97 (3.20) [5.77-8.16]	6.17 (2.39) [5.35-6.99]	.268	6.54 (2.80) [5.84-7.23]
4-mo postoperative scores				
SANE	61.3 (22.6) [52.9-69.8]	61.6 (23.3) [53.3-69.9]	.907	61.5 (22.8) [55.7-67.2]
ASES	69.6 (14.7) [64.1-75.1]	76.4 (18.5) [69.9-83.0]	**.022**	73.2 (17.0) [68.9-77.5]
PSQI	6.28 (2.81) [5.21-7.35]	5.66 (2.54) [4.74-6.57]	.372	5.95 (2.67) [5.27-6.63]
6-mo postoperative scores				
SANE	72.6 (20.0) [65.0-80.2]	81.0 (17.3) [74.8-87.2]	**.017**	77.0 (18.9) [72.2-81.9]
ASES	77.7 (18.1) [70.8-84.6]	89.0 (7.29) [86.4-91.7]	**.020**	83.6 (14.6) [79.9-87.4]
PSQI	6.33 (3.04) [5.13-7.54]	4.97 (2.35) [4.14-5.80]	.062	5.58 (2.75) [4.87-6.29]
Preoperative vs final postoperative *P* value				
SANE score	**<.001**	**<.001**		**<.001**
ASES score	**<.001**	**<.001**		**<.001**

[a]Data are presented as mean (SD) [95% CI] or n (%) [95% CI]. Bold *P* values indicate statistical significance. ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; PSQI, Pittsburgh Sleep Quality Index; SANE, Single Assessment Numeric Evaluation.

TABLE 3
Correlation Between Pain and PSQI[a]

Variable	Correlation Value	Relationship
Preoperative pain	0.338	None
2-wk postoperative pain	0.291	None
6-wk postoperative pain	0.566	Weakly positive
3-mo postoperative pain	0.229	None
4-mo postoperative pain	0.423	None
6-mo postoperative pain	0.391	None

[a]PSQI, Pittsburgh Sleep Quality Index.

assessing sleep. A recent study looking at patients who received total knee arthroplasty found no improvement in PSQI when patients were randomized to exogenous melatonin versus placebo while controlling for pain.[33] In our study, we gathered data regarding pain using the ASES survey. At the 6-week postoperative mark, even though there was no difference in ASES scores and therefore pain, PSQI scores were significantly improved in the melatonin group, again showing the efficacy of melatonin and sleep quality without pain as a confounding variable. Previous studies have demonstrated that after ARCR, sleep quality significantly improves.[4,25] These studies, which did not include any further intervention beyond surgery, found that at the 6-week postoperative period, PSQI scores were not significantly different from baseline scores.[4,25] In our study, however, we found that the melatonin cohort did see a significant improvement in PSQI scores when compared with the control group, enumerating the effect that melatonin can have in the postoperative period.

Furthermore, although there are no studies that have investigated the residual effects of melatonin after multiple weeks of administration, there is reason to postulate that melatonin has a long-lasting effect on sleep quality after administration when comparing sleep quality rating in both cohorts at the 3-, 4-, and 6-month postoperative periods. Austin et al[4] and Horneff et al[25] both found PSQI scores to be $\geq$5.5 without any intervention after

TABLE 4
Sleep Quality Rating[a]

	Control (n = 40)	Melatonin (n = 40)	Total Data (n = 80)	*P* Value
2 wk postoperatively				.985
Very good	1 (3.57) [0.09-18.3]	1 (2.78) [0.07-14.5]	2 (3.12) [0.38-10.8]	
Fairly good	10 (35.7) [18.6-55.9]	11 (30.6) [16.3-48.1]	21 (32.8) [21.6-45.7]	
Fairly bad	10 (35.7) [18.6-55.9]	13 (36.1) [20.8-53.8]	23 (35.9) [24.3-48.9]	
Very bad	7 (25.0) [10.7-44.9]	10 (27.8) [14.2-45.2]	17 (26.6) [16.3-39.1]	
6 wk postoperatively				.380
Very good	3 (9.09) [1.92-24.3]	2 (6.25) [0.77-20.8]	5 (7.69) [2.54-17.0]	
Fairly good	10 (30.3) [15.6-48.7]	16 (50.0) [31.9-68.1]	26 (40.0) [28.0-52.9]	
Fairly bad	12 (36.4) [20.4-54.9]	8 (25.0) [11.5-43.4]	20 (30.8) [19.9-43.4]	
Very bad	8 (24.2) [11.1-42.3]	5 (15.6) [5.28-32.8]	13 (20.0) [11.1-31.8]	
3 mo postoperatively				**.015**
Very good	6 (20.0) [7.71-38.6]	2 (5.71) [0.70-19.2]	8 (12.3) [5.47-22.8]	
Fairly good	7 (23.3) [9.93-42.3]	21 (60.0) [42.1-76.1]	28 (43.1) [30.8-56.0]	
Fairly bad	14 (46.7) [28.3-65.7]	9 (25.7) [12.5-43.3]	23 (35.4) [23.9-48.2]	
Very bad	3 (10.0) [2.11-26.5]	2 (5.71) [0.70-19.2]	5 (7.69) [2.54-17.0]	
4 mo postoperatively				**.041**
Very good	4 (13.8) [3.89-31.7]	5 (15.6) [5.28-32.8]	9 (14.8) [6.98-26.2]	
Fairly good	13 (44.8) [26.4-64.3]	19 (59.4) [40.6-76.3]	32 (52.5) [39.3-65.4]	
Fairly bad	12 (41.4) [23.5-61.1]	4 (12.5) [3.51-29.0]	16 (26.2) [15.8-39.1]	
Very bad	0 (0) [0.00-11.9]	3 (9.38) [1.98-25.0]	3 (4.92) [1.03-13.7]	
6 mo postoperatively				**.050**
Very good	5 (18.5) [6.30-38.1]	10 (31.3) [16.1-50.0]	15 (25.4) [15.0-38.4]	
Fairly good	8 (29.6) [13.8-50.2]	15 (46.9) [29.1-65.3]	23 (39.0) [26.5-52.6]	
Fairly bad	12 (44.4) [25.5-64.7]	4 (12.5) [3.51-29.0]	16 (27.1) [16.4-40.3]	
Very bad	2 (7.41) [0.91-24.3]	2 (6.25) [0.77-20.8]	4 (6.78) [1.88-16.5]	

[a]Data are presented as n (%) [95% CI]. Bold *P* values indicate statistical significance.

TABLE 5
Narcotic Use[a]

	Control (n = 40)	Melatonin (n = 40)	*P* Value	Total Data (n = 80)
Preoperatively	6 (15.4) [5.86-30.5]	4 (10.3) [2.87-24.2]	.735	10 (12.8) [6.32-22.3]
2 wk postoperatively	8 (27.6) [12.7-47.2]	10 (27.8) [14.2-45.2]	>.999	18 (27.7) [17.3-40.2]
6 wk postoperatively	6 (17.1) [6.56-33.6]	3 (8.57) [1.80-23.1]	.477	9 (12.9) [6.05-23.0]
3 mo postoperatively	4 (12.5) [3.51-29.0]	4 (11.1) [3.11-26.1]	>.999	8 (11.8) [5.22-21.9]
4 mo postoperatively	4 (13.3) [3.76-30.7]	0 (0.00) [0.00-10.6]	**.046**	4 (6.35) [1.76-15.5]
6 mo postoperatively	4 (13.8) [3.89-31.7]	1 (3.12) [0.08-16.2]	.182	5 (8.20) [2.72-18.1]

[a]Data are presented as n (%) [95% CI]. Bold *P* value indicates statistical significance.

ARCR at 24 months. This score, by definition, is still considered to indicate significant sleep disturbance.[36] Although not significant when compared with scores in our control group, PSQI scores were a mean of 4.97 at the 6-month postoperative period, which is close to the validated cutoff of 5 that meets criteria for sleep disturbance.[7]

The finding of improved shoulder function according to ASES and SANE surveys is an expected finding after ARCR, as both cohorts improved from their preoperative state. Previous studies have shown that arthroscopic repair leads to improved ASES and SANE scores.[21,43] Similarly, a recent study demonstrated the association between sleep dysfunction and patient-reported outcome measures in those with rotator cuff tears.[12] In the late postoperative period, melatonin users had greater SANE scores (6 months) and ASES scores (4 and 6 months), which may be because of the improvement in sleep that patients in this group experienced.

Melatonin has also been used as a preoperative additive in surgery and was found to be effective in decreasing postoperative pain.[3,30] Although there is increasing evidence that melatonin plays a role in pain regulation, the exact cellular mechanism by which this occurs has not been identified.[44] In our study, we found significantly less narcotic use in the melatonin cohort at 4 months postoperatively. Even though the experimental group was not using melatonin at this time point, the decreased narcotic use does implicate melatonin as a possible regulator of pain (perhaps

through a faster return to improved sleep). Narcotic use is known to affect the sleep cycle[14,41]; however, Glogovac et al[18] did not find narcotic use to be predictive of the PSQI score in a series of patients with RCR. This allows us to consider the greater sleep quality (question 9 on the PSQI, referenced in Table 4) found in the melatonin group at 4 months to not be related to their narcotic use. To our knowledge, our study is the first to demonstrate the potential analgesic properties of melatonin in a population with RCR. The exact mechanism by which this occurs is unclear.

The decision to prescribe melatonin postoperatively is complex. A previous study established the MCID of the PSQI for RCR to be an improvement of 4.4 from preoperatively at the 6-month postoperative follow-up.[35] Our study did not meet this established MCID, although we did see improvements in PSQI that ultimately fell below the "significant sleep disturbance" cutoff of 5. Therefore, we believe that physicians can consider the use of melatonin and counsel their patients on its possible but not absolute benefit when it comes to improving sleep quality. Patients may simply benefit from following standard sleep hygiene, as this is associated with earlier improvement in shoulder function.[45] Future research should involve the exploration of other medications and their effects on sleep quality. Although there is existing literature in the realm of joint arthroplasty,[5,8,10,33] no randomized trials besides ours have been conducted in a population with RCR.

Our study was not without limitations. This analysis did not include objective measures such as tear size on imaging that may play a role in the postoperative rehabilitation of patients in both groups. The randomization protocol used in our study should have helped to eliminate this as a potential confounder between groups. Second, our study was performed using the patient populations of 3 board-certified sports medicine orthopaedic surgeons. There may be subtle variations between each surgeon with regard to technique and postoperative rehabilitation, making generalization of findings difficult. Although this allows us to have greater patient variability, it can lead to additional confounders that may not have been balanced in the randomization process. Our study relied on patient self-reporting of melatonin use. This may have introduced recall bias into the study, which may have affected the number of patients who truly adhered to the melatonin regimen for 6 weeks. Patients in the melatonin cohort may have also been subject to bias because they were not blinded to their medication. This could have caused them to report improved sleep parameters as this medication is commonly utilized to improve sleep disturbance. Similarly, the pain medication surveys distributed to both groups had 1 specific question regarding the use of melatonin. This could have tipped patients off to the aims of the study or potential benefits of melatonin and may have affected their self-reporting of outcome scores.

CONCLUSION

Melatonin use after ARCR led to improved sleep quality (PSQI) in the early postoperative period as well as improved functional outcomes (ASES and SANE scores) and decreased narcotic use in the later postoperative period. Patients with significant sleep disturbances associated with RCRs may benefit from the use of melatonin.

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