Cannabidiol for Postoperative Pain Control After Arthroscopic Rotator Cuff Repair Demonstrates No Deficits in Patient-Reported Outcomes Versus Placebo

1-Year Follow-up of a Randomized Controlled Trial

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Background: Cannabidiol (CBD) has been shown recently to positively affect patient pain and satisfaction immediately after arthroscopic rotator cuff repair (ARCR). However, it is unclear whether the addition of CBD to a perioperative regimen could affect postoperative outcomes.

Purpose: To evaluate patient-reported outcomes among patients who underwent ARCR and received buccally absorbed CBD or an identical placebo for early postoperative pain management at 1-year follow-up.

Study Design: Randomized controlled trial; Level of evidence, 2.

Methods: Eligible patients had previously participated in a multicenter, placebo-controlled, randomized, double-blinded trial that evaluated the analgesic effects of CBD in the immediate postoperative period after ARCR. The experimental group received 25 mg of CBD 3 times/day if $<$80 kg and 50 mg of CBD 3 times/day if $>$80 kg for 14 days, with the control group receiving an identical placebo. The following outcomes were assessed at minimum 1-year follow-up: visual analog scale (VAS) for pain, American Shoulder and Elbow Surgeons (ASES) score, Single Assessment Numeric Evaluation (SANE), and patient satisfaction. The rates of achievement of the Patient Acceptable Symptom State (PASS) were compared based on ASES at latest follow-up. Continuous and categorical variables were compared with the Mann-Whitney *U* test and Fisher exact test, respectively.

Results: Follow-up was obtained from 83 of 99 patients (83.8%) who completed the original trial. There were no significant differences between the CBD and control groups with respect to age, sex, body mass index, rate of concomitant procedures, or number of anchors used intraoperatively. At 1-year follow-up, there were no significant differences between the CBD and control groups in VAS pain (0.8 vs 1.2, P = .38), ASES (93.0 vs 91.1, P = .71), SANE (87.6 vs 90.1, P = .24), or satisfaction (97.4 vs 95.4, P = .41). A majority of patients achieved the PASS (81.0% [CBD] vs 77.5% [control]; P = .79).

Conclusion: Perioperative use of CBD for pain control among patients undergoing ARCR did not result in any significant deficits in pain, satisfaction, or patient-reported outcomes at 1-year postoperatively compared with a placebo control group. These findings suggest that CBD can be considered in a postoperative multimodal pain management regimen without detrimental effects on outcome.

Registration: NCT04672252 (ClinicalTrials.gov identifier).

Keywords: cannabidiol; outcomes; randomized controlled trial; rotator cuff repair; satisfaction

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Rotator cuff tears are one of the most common causes of shoulder pain and disability, with full-thickness rotator cuff tears present in one-fourth of persons in their 60s and in half of those in their 80s.[38] Rates of arthroscopic rotator cuff repair (ARCR) have been increasing steadily, with estimates of nearly 460,000 procedures being performed annually in the United States.[15,47] In recent years, both medical and nonmedical overuse of opioids have been detrimental to public health, catalyzing an effort to diversify treatment algorithms for patients in pain.[20] Several prospective studies have investigated the feasibility of opioid-free postoperative protocols after ARCR as well as for other common sports orthopaedic procedures.[17,26,40]

The *Cannabis sativa* plant is a promising alternative for augmented pain control, with its derivative cannabinoids, namely cannabidiol (CBD), the subject of increased investigation. While there is growing evidence from in vitro and animal studies for CBD as a pain modulator,[2,9,14,16,25,44,48] there remains a lack of high-quality evidence in orthopaedics with respect to CBD.[23,28] A recent double-blinded, placebo-controlled randomized controlled trial demonstrated a significant reduction in acute postoperative pain after ARCR in patients who received buccally absorbed CBD.[1] Although there are currently no formulations of CBD for any pain-related indications that are approved by the United States Food and Drug Administration (FDA),[41] a survey study found 19% of all sports orthopaedic patients had utilized CBD at a single clinic from 2020 to 2021.[10] Despite the expanding popularity of nonprescription CBD as a synergistic pain treatment option among the public,[6,10] there are limited high quality studies that have investigated its potential therapeutic effects and long-term safety.

While a large body of research has been dedicated to investigating the effects of nonsteroidal anti-inflammatory drugs on musculoskeletal healing,[7,37] the mechanism of action of cannabinoids involves unique signaling pathways via endogenous cannabinoid type 1 and type 2 receptors found throughout the central nervous system and in immune cells, respectively.[4,30] Basic science research has found that CBD may enhance migration and differentiation of mesenchymal stems cells, which in turn could improve musculoskeletal healing via induction of osteoblastic differentiation.[34] Isolated tetrahydrocannabinol (THC) and CBD have also been found to stimulate expression of enzymes that catalyze lysine hydroxylation, an integral step in collagen crosslinking and stabilization.[19] In addition, CBD has been found to downregulate matrix metalloproteinases, which, if upregulated, may be detrimental to early tissue healing.[31] Whereas these studies suggest that the incorporation of CBD into multimodal pain management regimens would not negatively affect soft tissue healing, there is limited evidence with respect to postoperative outcomes among patients with perioperative exposure to CBD.

The purpose of this study was to evaluate patient-report outcomes among patients who previously underwent ARCR and received buccally absorbed CBD for postoperative pain management at minimum 1-year follow-up. The hypothesis was that there would be no significant differences in patient-reported outcomes between those who received CBD versus those who received a placebo.

METHODS

Study Design

This was an FDA-sanctioned (Investigational New Drug No. 147249), multicenter, placebo-controlled, randomized, prospective clinical trial. Institutional review board approval was obtained from both institutions involved in the study, and patient-informed consent was obtained before study enrollment. Patients were enrolled and treated from December 1, 2020, to December 31, 2021. All opioid-naïve patients, defined as no opioid use within 3 months before surgery, aged between 18 and 75 years undergoing ARCR (in addition to open subpectoral biceps tenodesis, subacromial decompression, both, or neither) were eligible for inclusion in the study. Exclusion criteria can be found in Table 1. In addition, all patients who entered the study were administered the Columbia Suicide Severity Rating Scale to ensure that no patient had previous or current suicidal ideation, in accordance with FDA recommendations for clinical trials involving drugs with central nervous system activity. Any patients with elevated liver enzyme levels in the preoperative period were also excluded. Urinalysis was performed on all patients to ensure that patients were opioid-naïve and not currently using marijuana. All participants were required to refrain from the use of THC or other cannabis-related products for the duration of the study. Those who were not able to comply were excluded from the final data analysis. Premenopausal female patients had to have been currently

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Ethical approval for this study was obtained from NYU Langone Health (reference No. i19-01293).

TABLE 1
Study Exclusion Criteria[a]

Patients were excluded from the study if they met any of the following criteria:
- Legally incompetent or mentally impaired (eg, minors, Alzheimer disease, dementia, etc)
- <18 years of age
- >75 years of age
- Any person considered a vulnerable subject: pregnant women or fetuses, children, cognitively impaired adults, prisoners
- History of cannabis abuse or dependence
- History of coagulation abnormalities and thromboembolic disease or current abnormal coagulation test values
- History of stroke or acute coronary syndromes within 3 months before surgery
- Abnormal coagulation profile
- Renal failure (serum creatinine >250 μmol/L [2.83 mg/dL]) or liver cirrhosis
- History of hypersensitivity to Percocet
- Having needed preoperative opioid management for any reason
- Having met the DSM-5 for major psychiatric illness, such as bipolar disorder
- Current or a history of suicidal ideation
- Breastfeeding females
- Clinically significant illness, including cardiovascular disorders
- Clinically significant laboratory abnormalities
- Abnormal LFTs
- Having a major neurological disorder (eg, dementia, Parkinson disease, cognitive impairment, epilepsy, history of traumatic brain/head injury, seizures)
- Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- Currently taking moderate or strong inhibitors of CYP3A4 and CYP2C19 concomitantly
- Currently taking strong CYP3A4 and CYP2C19 inducers concomitantly
- Currently taking substrates of UTG1A9, UTGB17, CYP2A1, CYP2B6, CYP2C8, CYP2C9, and CYP2C19 concomitantly

[a]DSM-5, Diagnostic and Statistical Manual of Mental Disorders, fifth edition; LFT, liver function test.

practicing 2 effective types of birth control, which are defined as those, alone or in combination, which result in a low failure rate (<1% per year) when used consistently and correctly.

Randomization and Study Intervention

Patients were randomized preoperatively by researchers who were not involved in the study using the validated web-based Research Randomizer (https://www.randomizer.org) to receive either CBD (CBD group) or an identically tasting and appearing placebo (control group).[42] Patients and the treating physicians were blinded to randomization. Patients were instructed to take 25 or 50 mg (patients >80 kg received 50 mg) of buccally absorbed CBD (Oravexx; Orcosa Pharmaceuticals) based on body weight, per the manufacturer's recommendation of 3 times a day for 14 days. Enrollees were educated on the proper administration of the medication before surgery. Patients were instructed to take a morning, afternoon, and evening dose, with an equal amount of elapsed time between each dose but were not given specific hour and minute times at which to take the doses. All patients received oxycodone/acetaminophen (Percocet, Endo Pharmaceuticals) 5 mg/325 mg tablets and were instructed to take them as needed, 1 to 2 tablets every 4 to 6 hours, and to wean themselves from narcotics as soon as possible. Patients were instructed to continue taking CBD or placebo throughout the entire 14-day follow-up period.

The study patients were provided with a medication log and instructed to indicate CBD use (yes or no) each time they took the medication during the 14-day period. These records were reviewed by 2 study coordinators (E.T.H. and K.D.V.) at the end of each patient's participation period to ensure compliance with the study protocol. A data safety monitoring board was created for the trial, and while no stopping rules were established, per the lead investigator's (M.J.A.) discretion, the trial was to be stopped if significant adverse effects were seen in the CBD group that threatened the safety of the patients or caused perioperative complications, including but not limited to severe nausea or vomiting, mental status changes, bleeding, or increases in the infection rate.

Surgical Technique and Postoperative Protocol

All procedures were performed by 1 of 5 fellowship-trained sports medicine orthopaedic surgeons (M.J.A., A.S.R., K.M.K., L.M.J. and G.G.-L.). Surgery was performed with the patient in either the beach-chair or lateral decubitus position, based on surgeon preference. Interscalene blocks were given preoperatively by the anesthesia team, who were also blinded to patient enrollment. Surgical time, number of anchors, and concomitant procedures were recorded. All patients undergoing biceps tenodesis underwent it in the form of open subpectoral biceps tenodesis to maintain homogeneity between groups.

All patients completed a standardized rehabilitation protocol designed for ARCR, with or without biceps tenodesis. Patients wore an abduction sling postoperatively for 4 to 6 weeks, at the discretion of the operating physician. Patients were allowed to perform simple elbow, wrist, and hand range of motion (ROM) exercises as soon as tolerated, as well as Codman or pendulum exercises as tolerated, after the first postoperative visit. By 4 weeks postoperatively, patients transitioned from passive to active-assisted ROM as tolerated. During this time, gentle active-assisted ROM exercises and gentle joint mobilization were progressed to active exercises with resistance, including shoulder flexion in an upright position as well as deltoid and biceps strengthening exercises. Patients who underwent biceps tenodesis did not begin biceps strengthening until week 8. During weeks 12 to 16, patients progressed to full active ROM and began internal and external rotation isometric exercises. Months 4 to 6 focused on advancing strength as tolerated with a progression of resisted exercises. A controlled return to sports was allowed after 6 months if approved.

TABLE 2
Patient and Surgical Characteristics by Study Group[a]

Variable	CBD (n = 42)	Control (n = 40)	*P*
Age at surgery, y	58.4 ± 9.5	57.5 ± 10.6	.59
Sex (female)	15 (35.7)	14 (35.0)	.95
BMI, kg/m^2	28.9 ± 4.8	28.1 ± 7.6	.66
Biceps tenodesis	7 (16.7)	11 (27.5)	.24
Subacromial decompression	19 (45.2)	11 (27.5)	.10
Both biceps tenodesis and subacromial decompression	10 (23.8)	16 (40.0)	.12
No. of anchors used	3.3 ± 1.6	3.2 ± 1.4	.66

[a]Data reported as mean ± SD or n (%). BMI, body mass index; CBD, cannabidiol.

Outcomes Measures

All patients who completed the original trial were eligible for 1-year postoperative follow-up. Outcome measures were assessed using a visual analog scale (VAS) for pain (0 = no pain, 100 = worst possible pain), VAS for satisfaction (0 = not satisfied at all, 100 = completely satisfied), the American Shoulder and Elbow Surgeons Shoulder Score (ASES), and the Single Assessment Numeric Evaluation (SANE) rating ("How would you rate your shoulder today as a percentage of normal [0% to 100% scale with 100% being normal]?"). The ASES activities of daily living (ASES-ADL) subscore was also calculated for each patient, with 50 being a perfect score. Lastly, patients were asked whether the surgery had met expectations ("Have the results of the surgery met your expectations?"), and whether they would be willing to repeat the surgery ("All things considered, would you be willing to undergo the surgery again?"). Achievement of the Patient Acceptable Symptom State (PASS) for the ASES after ARCR was defined as a score $\geq$86.7, as previously determined by Cvetanovich et al.[8] Other outcomes recorded included complications and revision surgeries within 1 year of the index procedure.

Statistical Analyses

An a priori power analysis was conducted based on the literature on postoperative pain control after shoulder arthroscopic surgery. Calculations were performed using VAS pain scores of 3.0 and 1.6 for the control and CBD groups, respectively, with a standard deviation of 2.0. To achieve 80% power to reject the null hypothesis of equal means when the population mean difference between the control and CBD groups is $\mu 1 - \mu 2 = 3.0 - 1.6 = 1.4$, with a standard deviation for both groups of 2.0 at a significance level (alpha) of 0.05 using a 2-sided, 2-sample equal variance *t* test, a sample size of 39 participants in each group was found to be required.[39]

Descriptive statistics were calculated for all continuous and categorical variables. Continuous variables were reported as the means with standard deviation, whereas categorical variables were reported as frequencies with percentages. Categorical variables were analyzed using the Fisher exact test. The Mann-Whitney *U* test was used to compare continuous variables, as these variables were found to be nonparametric. Subgroup analysis comparing patients receiving 50 mg of CBD versus 25 mg of CBD versus placebo was conducted using the Fisher exact test for categorical variables and 1-way ANOVA for continuous variables. Post-hoc Tukey test was performed to compare all possible pairs of subgroup means to determine whether significant intergroup differences existed. Comparisons with *P* values $<.05$ were considered statistically significant.

RESULTS

Of the 99 patients eligible for follow-up, 83 responses (83.8%) were collected. One patient in the control group was excluded from the 1-year analysis, as this patient underwent total shoulder arthroplasty at 9 months postoperatively (Figure 1). There were no significant differences between the CBD group (n = 42) and control group (n = 40) with respect to age at surgery, sex distribution, body mass index, the rate of concomitant procedures (biceps tenodesis or subacromial decompression), or the number of anchors used intraoperatively (Table 2). The mean follow-up was 14.7 ± 2.1 months, with no significant differences between groups (*P* = .93).

At minimum 1-year follow-up, VAS pain, ASES, SANE, and VAS satisfaction scores did not differ significantly between groups (Table 3). A majority of patients overall achieved the PASS (81.0% [CBD group] vs 77.5% [control group; *P* = .79). A large majority of patients affirmed that surgery had met their expectations (98.8%) and that they would be willing to repeat surgery (96.3%).

Subgroup Analysis

In the original trial, 23 patients had received the 25 mg dose and 29 patients had received the 50 mg dose, of whom follow-up was obtained from 16 and 26 patients, respectively. There were no significant differences in clinical outcomes among the patients who received 25 mg, 50 mg, or placebo (Table 4). A post-hoc Tukey test did not

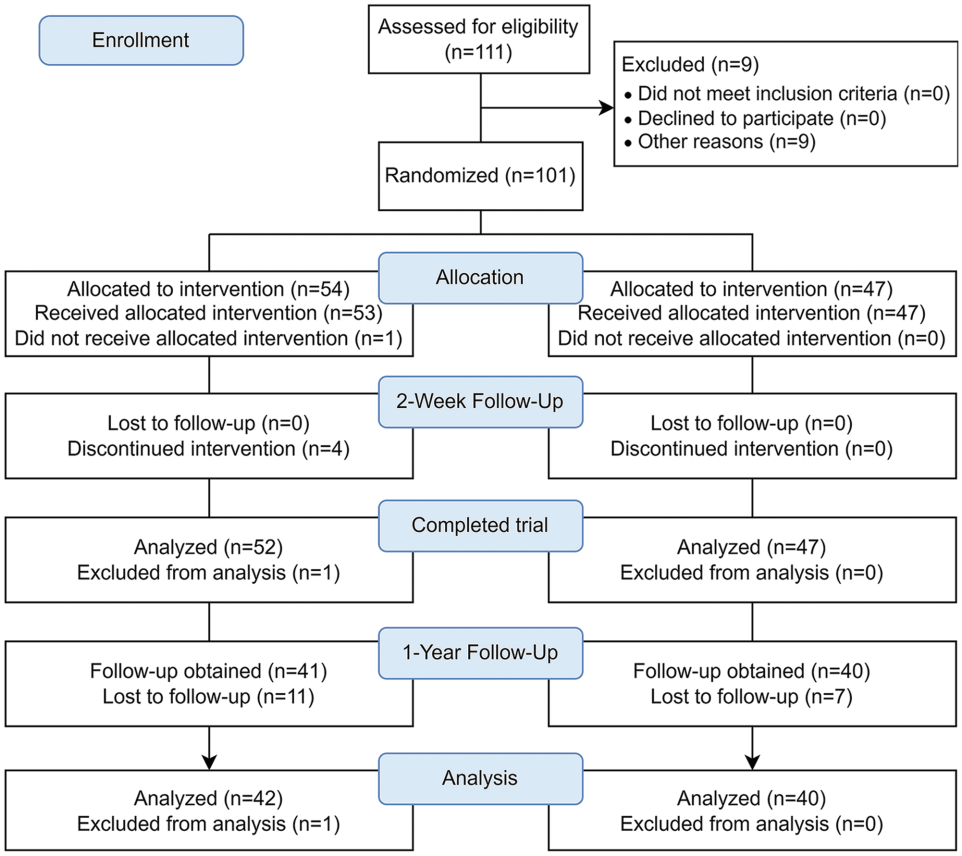

Figure 1. CONSORT flowchart of patient enrollment in the study. CONSORT, Consolidated Standards of Reporting Trials.

TABLE 3
Clinical Outcomes by Study Group[a]

Outcome	CBD (n = 42)	Control (n = 40)	*P*
VAS pain	0.8 ± 1.6	1.2 ± 1.8	.38
ASES	93.0 ± 13.9	91.1 ± 15.0	.71
Activities of daily living	45.7 ± 7.4	46.2 ± 5.7	.76
Achieved PASS	34 (81.0)	31 (77.5)	.79
SANE	87.6 ± 12.2	90.1 ± 13.1	.24
VAS satisfaction	97.4 ± 5.2	95.4 ± 9.9	.41
Surgery met expectations	42 (100)	39 (97.5)	.49
Willing to repeat	40 (95.2)	39 (97.5)	.62

[a]Data reported as mean ± SD or n (%). ASES, American Shoulder and Elbow Surgeons Shoulder Score; CBD, cannabidiol; PASS, Patient Acceptable Symptom State; SANE, single assessment numeric evaluation; VAS, visual analogue scale.

reveal any significant intergroup differences for VAS pain, ASES, SANE, or VAS satisfaction.

Complications

In all, 3 patients, 1 in the CBD group (2.4%) and 2 in the control group (5.0%), underwent a secondary procedure following the index ARCR, which was a nonsignificant difference (P = .61). The patient in the CBD group reinjured their arm 3 months postoperatively while walking their dog. This patient underwent revision ARCR 4 months after the index surgery, during which a single anchor was discovered to be partially dislodged and was replaced with a new implant. Of the 2 patients in the control group, the first patient underwent total shoulder arthroplasty 9 months postoperatively for constant and debilitating pain due to progression of glenohumeral osteoarthritis. The second patient was doing well until the patient tripped and fell 7 months postoperatively, dislocating the ipsilateral shoulder. This patient underwent arthroscopic repair of a full-thickness subscapularis tear and implantation of a subacromial balloon spacer as the supraspinatus tissue could not be re-repaired after this injury.

DISCUSSION

The most important finding of this study was that patients who utilized buccally absorbed CBD in a postoperative multimodal analgesic regimen after ARCR demonstrated no significant differences in clinical outcomes compared with a placebo control group at 1-year follow-up. The majority of patients in each group achieved the PASS, and patients were highly satisfied with their surgical

TABLE 4
Subgroup Analysis of Clinical Outcomes[a]

Outcome	25 mg CBD (n = 16)	50 mg CBD (n = 26)	Control (n = 40)	*P*
VAS pain	0.7 ± 1.4	0.9 ± 1.8	1.2 ± 1.8	.63
ASES	93.4 ± 11.2	92.1 ± 15.8	91.1 ± 15.0	.75
Activities of daily living	46.6 ± 5.3	45.2 ± 8.6	46.2 ± 5.7	.75
Achieved PASS	13 (83.3)	21 (80.8)	31 (77.5)	.93
SANE	87.3 ± 13.1	87.8 ± 11.9	90.1 ± 13.1	.66
VAS satisfaction	97.6 ± 4.4	97.2 ± 5.7	95.4 ± 9.9	.58
Surgery met expectations	16 (100)	26 (100)	39 (97.5)	.60
Willing to repeat	16 (100)	24 (92.3)	39 (97.5)	.15

[a]Data reported as mean ± SD or n (%). ASES, American Shoulder and Elbow Surgeons Shoulder Score; CBD, cannabidiol, PASS, Patient Acceptable Symptom State; SANE, single assessment numeric evaluation; VAS visual analogue scale.

outcomes. Furthermore, no significant differences were found upon subgroup analysis of outcomes based on the original 25- versus 50-mg dosing. Lastly, there was a low rate of revision procedures.

The results of this cohort align with previously reported rotator cuff repair outcomes. A previous study by Sallay and Reed[33] assessed normative ASES scores among 343 patients who presented to an outpatient orthopaedic clinic for conditions unrelated to the shoulder, and found the overall mean to be 92.2 ± 14.5, and found no significant differences between scores when stratified by decade of age. The scores reported by CBD and control groups were nearly identical to these normative values. It is also important to note that the total ASES score is calculated as the sum of a pain score and the ADL subscore, which are weighted equally and both scored out a maximum of 50.[45] The reported SANE scores in this cohort also did not differ significantly between groups and compared similarly with scores previously reported in the literature after ARCR.[3,5,35]

There are limited studies on the long-term safety profile of CBD in a healthy population.[1,13] Despite the growing enthusiasm for CBD among the public, it is important to discriminate between FDA-approved formulations and unregulated products, especially with respect to safety profile. Products labeled as CBD are publicly available in stores and in online marketplaces, and since these products are not subject to regulation, they may be contaminated with potentially harmful chemicals.[12] In addition, unregulated CBD products commonly have detectable levels of THC, with a recent study finding 52 of 80 samples to have detectable Δ9-THC; the maximum positive test had a THC concentration nearly 94-fold that of Epidiolex, with many being labeled as "THC-Free."[18] These studies underscore to need for increased regulation and quality of CBD, as unregulated formulations would not accurately reflect the effects of pharmaceutical grade CBD.

In other areas of orthopaedic surgery, clinical trials investigating CBD have demonstrated mixed results. Topical CBD was not found to significantly reduce pain, improve sleep quality, or decrease opioid consumption after total knee arthroplasty up to postoperative day 42, and had significantly greater VAS pain (69.9 vs 51.0, $P = .13$) at postoperative day 2 compared with placebo.[13] Another study found that oral administration of synthetic CBD tablet did not reduce VAS pain intensity in hand osteoarthritis and psoriatic arthritis significantly more than a placebo.[43] With respect to neuropathic pain, Xu et al[46] found a significant improvement in Neuropathic Pain Scale scores compared with placebo after 4 weeks of topical CBD application. It is important to note that the dosing and modes of administration of CBD were not uniform among the aforementioned trials, which could certainly affect the resulting efficacy.

There is also a lack of research examining the effect of cannabinoids on soft tissue healing mechanisms that would be involved in the successful healing of procedures such as ARCR. CBD exerts its pharmacological effects through the endocannabinoid system, primarily through endogenous cannabinoid type 1 (CB_1) and type 2 (CB_2) receptors. CB_1 receptors are distributed primarily throughout the central nervous system, particularly in regions of the midbrain and spinal cord that are responsible for pain perception.[30] CB_2 receptors occur mainly in immune cells, and are therefore believed to be responsible for regulation of inflammatory responses.[4,27,30] As CBD exhibits affinity to both of these receptors, it has the potential to enhance pain control and regulate healing responses.[22,25] Recently, Zhang and Bean[48] were able to isolate a specific mechanism by which CBD inhibits repetitive action potentials in nociceptive neurons in murine dorsal root ganglia. Another in vitro study found that cannabinoids enhanced the regenerative capacity of human and porcine adipose and bone-marrow-derived mesenchymal stem cells.[24] The mode of administration is an important consideration regarding cannabinoids, as previous studies have found that smoking increases the risk of failure after ARCR,[11,29] findings that could be relevant to inhaled forms of cannabis or CBD. In a recent animal model study investigating Achilles tendon-to-tendon repair, Stauch et al[36] compared biomechanical characteristics between a CBD group and control group and found no statistically significant differences in tendon strength, stiffness, or load to failure. While additional basic science research is necessary to elucidate the effect of CBD on soft tissue healing, the results of the current study provide

additional evidence that CBD does not detrimentally effect recovery after soft tissue procedures.

In orthopaedics, efforts are being made to reduce reliance on opioid pain medications through better medication stewardship and by investigating multimodal pain regimens. Regarding ARCR, several recent studies have aimed to investigate perioperative outcomes while eliminating opioids entirely. One prospective studies found that 67% of patients were able to complete opioid-free ARCR when undergoing multimodal pain regimen, including premedication, interscalene nerve block, intraoperative injection, and ketorolac, zolpidem, and acetaminophen at discharge.[40] A randomized controlled trial found that whereas a nonopioid group had significantly greater VAS pain on postoperative days 1 and 4 after ARCR, the nonopioid group actually demonstrated significantly lower VAS pain and pain intensity at every time point ($P < .01$) when accounting for confounding factors.[17] Moutzouros et al[26] found that 45% of patients were able to complete nonopioid postoperative protocols when enrolling patients undergoing a wide range of sports orthopaedics procedures, including anterior cruciate ligament reconstruction, ARCR, labral repair, and meniscectomy. With the addition of CBD to the pain management armamentarium, these previous findings could potentially be replicated and further ameliorated in future trials. When these results are viewed in combination with our previous findings of decreased pain and increased satisfaction in the immediate postoperative period, surgeons can be further reassured that the administration of CBD for this therapeutic application would not affect their surgical outcomes.

Limitations

Several factors must be considered when interpreting the results of this study. Foremost, patients were no longer blinded at the latest follow-up regarding which treatment group they had been allocated to in the original trial; however, they were not reminded of their allocation during follow-up unless specifically requested. There were 16 patients (16%) lost to follow-up, and their results could have influenced the distribution of the study results; however, demographics or operative characteristics did not differ significantly between these patients and those who were available for follow-up. It is possible that the high outcome scores of comparison groups may be due to a ceiling effect, which could potentially underrepresent differences between the CBD and control groups. In addition, patient-reported outcomes scores were not collected preoperatively, so it was not possible to calculate the pre- to postoperative improvement. Even so, the original trial randomization would have accounted for differences in baseline function, and the current study was adequately powered to determine differences in clinical outcomes at 1-year follow-up. The use of the PASS from a previously published value, as was performed in the current study, is a potential risk for selection bias.[21] Ideally, achievement of clinical thresholds should be derived utilizing prospectively collected data with anchor-based calculations. Last, it is important to note that this study was conducted with a 1-year minimum follow-up. Though a 2-year minimum is typically expected for the reporting of outcomes after surgical intervention, a recent systematic review and meta-analysis by Sahoo et al,[32] including 11 randomized controlled trials, found that patient-reported outcome measures after rotator cuff repair improved substantially from baseline to 1-year follow-up, but only small gains, which were less than the minimally clinically important difference, were observed from the 1- to 2-year mark. With respect to rotator cuff repair, a 2-year minimum for publishable patient-reported outcome measures may not be necessary to convey important results.[32]

CONCLUSION

Perioperative use of CBD for pain control among patients undergoing ARCR did not result in any significant deficits in pain, satisfaction, or patient-reported outcomes at 1 year postoperatively compared with a placebo control group. These findings suggest that CBD can be considered in a postoperative multimodal pain management regimen without detrimental effects on outcomes.

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