Cannabidiol for Postoperative Pain Control after Arthroscopic Rotator Cuff Repair Demonstrates No Functional Deficits: 1-Year Follow Up of a Randomized Controlled Trial

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INTRODUCTION:
Cannabidiol (CBD) recently has been shown to positively impact patient pain and satisfaction immediately after arthroscopic rotator cuff repair (ARCR). However, it is unclear if addition of CBD to a postoperative regimen will cause any changes in clinical outcomes. The purpose of this study is to evaluate 1-year functional outcomes among patients who previously underwent ARCR and received buccally absorbed cannabidiol or an identical placebo in early postoperative pain management.
METHODS:
Eligible patients had previously completed participation in an FDA-sanctioned, multi-center, placebo-controlled, randomized, double-blinded trial that evaluated the analgesic effects of CBD in the immediate postoperative period following ARCR. The experimental group received 25-mg of CBD TID if <80-kg and 50-mg of CBD TID if >80-kg for 14 days, with the control group receiving an identical placebo. We assessed the following outcomes at minimum 1-year follow up: Visual Analogue Scale (VAS) for pain, American Shoulder and Elbow Surgeons (ASES) score, Single Assessment Numeric Evaluation (SANE), and satisfaction. Continuous and categorical variables were compared with the Mann-Whitney U test and Fisher's exact test, respectively. Subgroup analysis comparing patients receiving 50-mg of CBD versus 25-mg of CBD versus placebo medication was conducted using one-way ANOVA for continuous variables. Post hoc Tukey testing was performed to compare all possible pairs of subgroup means to determine whether significant intergroup differences existed.
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 placebo groups with respect to age, sex, BMI, rate of concomitant procedures, or number of anchors used intraoperatively. VAS pain (0.8 vs. 1.2, p=0.384), ASES (93.0 vs. 91.1, p=0.714), and SANE score (87.6 vs. 90.1, p=0.236) did not significantly differ between CBD and placebo groups at 1-year follow up. A total of 98.8% of patients stated that surgery had met their expectations. Upon subgroup analysis, there were no significant differences in patient-reported outcomes between patients who received the 25-mg dose, 50-mg dose, or placebo (p>0.05).
DISCUSSION AND CONCLUSION:
Perioperative use of CBD for pain control among patients undergoing ARCR does not result in any significant deficits in patient-reported pain, satisfaction, or functional outcomes at least 1-year postoperatively compared to a placebo control. These findings suggest that CBD can be considered in a postoperative multimodal pain management regimen without detrimental effects on outcome.

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

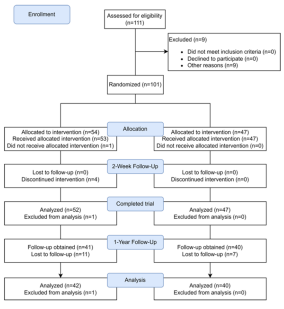

TABLE 1
Patient Demographics & Operative Characteristics*

Variable	CBD (n=42)	Placebo (n=40)	p
Age at surgery (years)	58.4 ± 9.5	57.5 ± 10.6	0.591
Sex (female)	15 (35.7)	14 (35.0)	0.946
Body mass index	28.9 ± 4.8	28.1 ± 7.6	0.659
Biceps tenodesis	7 (16.7)	11 (27.5)	0.236
Subacromial decompression	19 (45.2)	11 (27.5)	0.096
Both biceps tenodesis and subacromial decompression	10 (23.8)	16 (40.0)	0.115
No. of anchors used	3.3 ± 1.6	3.2 ± 1.4	0.660

*Data are shown as mean ± SD or n (%). Abbreviations: CBD cannabidiol.

TABLE 2
Clinical Outcomes*

Variable	CBD (n=42)	Placebo (n=40)	p
VAS Pain	0.8 ± 1.6	1.2 ± 1.8	0.384
ASES	93.0 ± 13.9	91.1 ± 15.0	0.714
Activities of daily living, subscore	45.7 ± 7.4	46.2 ± 5.7	0.764
Achieved PASS	34 (81.0)	31 (77.5)	0.788
SANE	87.6 ± 12.2	90.1 ± 13.1	0.236
Satisfaction	97.4 ± 5.2	95.4 ± 9.9	0.408
Surgery met expectations	42 (100)	39 (97.5)	0.488
Would be willing to repeat	40 (95.2)	39 (97.5)	0.616

*Data are shown as mean ± SD or n (%). Abbreviations: *CBD* cannabidiol, *MME* morphine milligram equivalents, *VAS* visual analogue scale, *ASES* American Shoulder and Elbow Surgeons Shoulder Score, *PASS* patient acceptable symptom state, *SANE* single assessment numeric evaluation

TABLE 3
Subgroup Analysis of Clinical Outcomes*

Variable	CBD 25-mg (n=16)	CBD 50-mg (n=26)	Placebo (n=40)	p
VAS Pain	0.7 ± 1.4	0.9 ± 1.8	1.2 ± 1.8	0.632
ASES	93.4 ± 11.2	92.1 ± 15.8	91.1 ± 15.0	0.747
Activities of daily living, subscore	46.6 ± 5.3	45.2 ± 8.6	46.2 ± 5.7	0.753
Achieved PASS	13 (83.3)	21 (80.8)	31 (77.5)	0.928
SANE	87.3 ± 13.1	87.8 ± 11.9	90.1 ± 13.1	0.664
Satisfaction	97.6 ± 4.4	97.2 ± 5.7	95.4 ± 9.9	0.578
Surgery met expectations	16 (100)	26 (100)	39 (97.5)	0.603
Would be willing to repeat	16 (100)	24 (92.3)	39 (97.5)	0.150

*Data are shown as mean ± SD or n (%). Abbreviations: *CBD* cannabidiol, *MME* morphine milligram equivalents, *VAS* visual analogue scale, *ASES* American Shoulder and Elbow Surgeons Shoulder Score, *PASS* patient acceptable symptom state, *SANE* single assessment numeric evaluation