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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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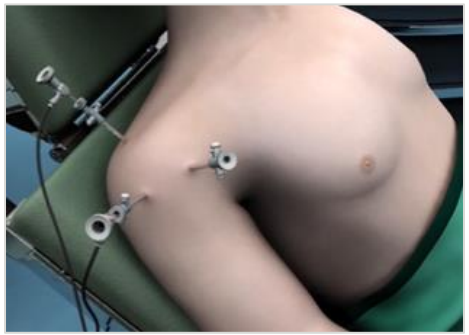
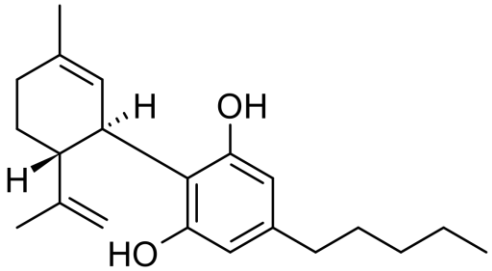
Disclosures

- Kevin M. Kaplan: Arthrex, Team 1 LLC, and Orcosa, Inc.
- Michael J. Alaia: Bodycad, DePuy Synthes, Arthrex, Gotham Surgical Solutions & Devices, Orcosa, Inc.
- Laith M. Jazrawi: Arthrex, Mitek, Smith & Nephew, and Wolters Kluwer Health
- Guillem Gonzalez-Lomas: Arthrex

Background

- Cannabidiol (CBD) has recently demonstrated a positive impact on patient pain and satisfaction immediately after arthroscopic rotator cuff repair (ARCR)
- Despite increasing popularity of non-prescription CBD for pain treatment, there are limited high-quality studies investigating therapeutic effects and safety long-term
- Does the addition of CBD to a postoperative regimen cause any changes in clinical outcomes?





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Purpose

To evaluate 1-year functional outcomes among patients who previously underwent ARCR and received buccally absorbed cannabidiol or an identical placebo in early post-operative pain management.

Hypothesis

There will be no significant differences in pain or shoulder function between those who received CBD vs placebo at 1-year follow-up.

Methods

- Inclusion:
  - All opioid-naive patients ages 18-75 years undergoing ARCR who previously completed an FDA-sanctioned, multi-center, placebo-controlled, randomized, double-blinded trial evaluating the analgesic effects of CBD in immediate postoperative period
- Exclusion:
  - Marijuana users, preop opiates, abnormal coag history/VTE, stroke/ACS history 3 months preop, renal/liver failure, on medications with significant interaction with CYP pathway
- Randomization
  - Experimental group: 25-mg CBD TID if <80kg and 50-mg of CBD TID if >80kg for 14 days
  - Control group: Identical placebo

Methods – Outcomes

- Patient-reported 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) score
  - Satisfaction (VAS)
- Statistical analyses
  - Mann-Whitney U test
  - Fischer’s exact test
  - One-way ANOVA with Tukey's post-hoc testing (25-mg, 50-mg, placebo)

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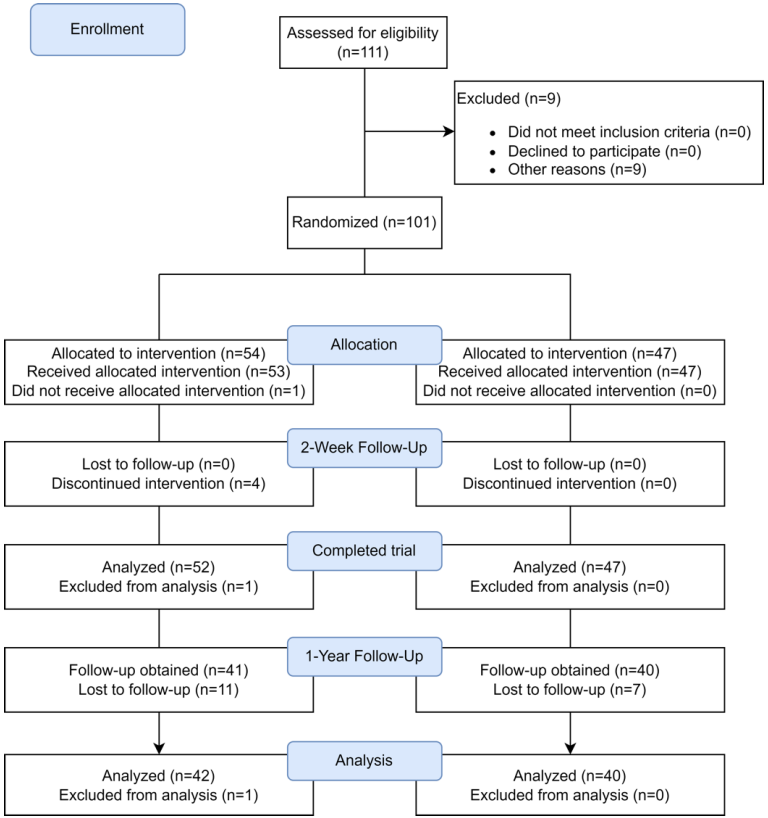
Methods – CONSORT Flow Diagram



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Results – Demographics and Operative Characteristics

VARIABLE	CBD	PLACEBO	*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

Results – Patient-Reported 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 (Y/N)	42 (100)	39 (97.5)	0.488
Would be willing to repeat (Y/N)	40 (95.2)	39 (97.5)	0.616

**Secondary procedures: Three patients, one in the CBD group (2.4%) and two in the placebo group (5.0%), underwent arthroscopic revision following the index ARCR ($p = 0.611$)

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Results – Subgroup Analysis by Dose

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 (Y/N)	16 (100)	26 (100)	39 (97.5)	0.603
Would be willing to repeat (Y/N)	16 (100)	24 (92.3)	39 (97.5)	0.150

*Patients <80-kg received 25-mg TID and those >80-kg received the 50-mg dose.

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Limitations

- Patients were no longer blinded regarding which treatment group they were assigned in original study by the time of latest follow-up
  - They were not reminded of their allocation during follow-up unless specifically requested
- Patient-reported outcome scores were not collected preoperatively, so it was not possible to calculate the pre- to postoperative improvement
  - 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
- Multiple orthopedic surgeons
  - However surgical technique was largely similar, and the postoperative protocol was uniform across patients in the study

Conclusion

- Peri-operative use of CBD for pain control among patients undergoing ARCR *does not* result in any significant differences in patient-reported pain, satisfaction, or functional outcomes at least 1-year postoperatively compared to a placebo control
- CBD can be considered in a postoperative multimodal pain management regimen without detrimental effects on outcome.

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