

Tablet containing CBD shows promise in reducing post-operative pain

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An orally absorbed tablet containing cannabidiol (CBD) effectively reduces pain after shoulder surgery with no safety concerns, a new study finds.



Led by researchers in the Department of Orthopedic Surgery at NYU Langone Health, the study found that the tablet ORAVEXX safely managed <u>pain</u> after minimally invasive rotator cuff surgery, and did not produce side effects sometimes associated with CBD use, such as nausea, anxiety, and liver toxicity. The findings were presented at the American Academy of Orthopaedic Surgeon's (AAOS) 2022 Annual Meeting in Chicago.

"There is an urgent need for viable alternatives for pain management, and our study presents this form of CBD as a promising tool after arthroscopic rotator cuff repair," says lead investigator Michael J. Alaia, MD, associate professor in the Department of Orthopedic Surgery at NYU Langone Health. "It could be a new, inexpensive approach for delivering pain relief, and without the side effects of anti-inflammatory drugs like NSAIDs and addiction risks linked to opiates. Additionally, CBD has the benefit of pain relief without the psychotropic effects associated with THC or marijuana."

The multicenter Phase 1/2 clinical trial randomly sorted 99 participants across two study sites (NYU Langone Health and Baptist Health/Jacksonville Orthopaedic Institute) between the ages of 18 and 75 into a placebo group and a group receiving oral-absorbed CBD. Participants were prescribed a low dose of Percocet, instructed to wean off the narcotic as soon as possible, and to take the placebo/CBD three times a day for 14 days after the surgery.

On the first day after surgery, patients receiving CBD experienced on average 23 percent less pain as measured by the Visual Analog Scale (VAS) pain score compared to patients receiving the placebo, highlighting that in patients with moderate pain, CBD may render a significant benefit. On both the first and second days after surgery, patients receiving CBD reported 22 to 25 percent greater satisfaction with pain control compared to those receiving placebo. Further analysis



also showed that patients receiving 50 mg of CBD reported lower pain and higher satisfaction with pain control compared to patients receiving placebo. No major side effects were reported.

While the results are promising, Dr. Alaia cautioned consumers against seeking out commercialized CBD products. "Our study is examining a well-designed, carefully scrutinized product under an investigational new drug application sanctioned by the FDA. This is currently still experimental medicine and is not yet available for prescription," he added.

ORAVEXX, the buccally absorbed tablet used in this study, is designed and manufactured by Orcosa Inc., a life sciences company. It is a non-addictive, fast-absorbing CBD composition designed to treat pain.

Moving forward, NYU Langone Health has launched a second study looking at whether ORAVEXX can specifically treat <u>chronic pain</u> in patients with osteoarthritis. Multiple Phase 2 studies also are planned to evaluate the drug's efficacy for other acute and chronic <u>pain</u> <u>management</u> issues and assess the role of CBD on inflammation.

More information: Conference: www.aaos.org/annual/

Provided by NYU Langone Health

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