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## Evaluation of the real-world effectiveness of adding cannabis leaf extract in seed oil to ultrasound gel for pain relief with ultrasound treatment of musculoskeletal pain

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### Abstract

**Objective:** To understand the real-world effectiveness of *Cannabis sativa* leaf extract in seed oil (Oreka+) when added to ultrasound gel for relieving musculoskeletal pain with ultrasound therapy.

**Methodology:** Twenty adult patients with musculoskeletal pain in lower back or shoulder-neck region for minimum of 1 month and maximum of 6 months, underwent ultrasound treatment with application of either ultrasound gel with added Oreka+ oil (1% *Cannabis sativa* leaf extract in cannabis seed oil, with added menthol and cinnamon camphor oil) as test group or ultrasound gel alone as control group, for 10 days. The study was randomized and patient blind in design.

**Results:** The average Numeric Pain Rating Scale (NPRS) reduction in test and control group at 10 days was 36.8% and 36.3% respectively. The average Functional Pain Scale (FPS) reduction in test and control group at 10 days was 67.8% and 50% respectively. The average daily NSAID requirement reduced by 66.6% and 50% in the test and control group respectively, while the overall NSAID usage over 10 days reduced by 75% and 70% in the test and control group respectively. No adverse events were seen in either group.

**Conclusion:** Addition of a topical preparation of cannabis leaf extract in cannabis oil to ultrasound gel during the sessions of ultrasound therapy for pain can have beneficial effects in reducing pain intensity, improving activities of daily living, and reduction of NSAID use.

**Keywords:** Cannabis, leaf extract, CBD, topical, ultrasound, pain

### Introduction

Musculoskeletal pain is a common health problem that can reduce quality of life significantly. It is usually treated by anti-inflammatory and analgesic pain relief agents like paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), opioids and gabapentinoids. However, long-term or recurrent use is not practical due to adverse effects and poor tolerability. Physical therapy (Physiotherapy) techniques are also useful modes of pain management as they act directly on the site, and do not have systemic side effects. Ultrasound is one such technique commonly used<sup>[1]</sup>.

Topical medication is a good option for pain management as it is effective, and better tolerated. Cannabinoids are lipophilic compounds derived from the leaf extract of the *Cannabis sativa* plant and include mainly Cannabidiol (CBD) as well as others like Cannabinol (CBN), Cannabigerol (CBG) and more than 100 other cannabinoids<sup>[2]</sup>. *Cannabis sativa* leaf extract also contains substances called terpenes that potentiate the effect of cannabinoids and have anti-inflammatory and antioxidant properties. The leaf extract (unlike bud and flower) is low in tetrahydrocannabinol (THC), known for psychoactive or narcotic effects.

Cannabinoids act via different receptors (like CB1, CB2, TRPV and GPR) at multiple levels of pain transmission that include desensitization of peripheral nociceptive receptors, inhibition of the release of neurotransmitters and neuropeptides from presynaptic nerve endings, modulation of postsynaptic neuron excitability, inhibition of ascending nociceptive pain transmission, activation of descending inhibitory pain pathways, reduction of neural inflammation, and reduction in emotional and cognitive manifestations of pain<sup>[3,4]</sup>.

Phytocannabinoids also modulate our body's endocannabinoid system (ECS), by inhibiting the enzymatic degradation of endogenous cannabinoids [5]. Cannabis seed oil serves as an effective vehicle for delivering cannabinoids by increasing the penetration of cannabinoids from the leaf extract, and providing local anti-inflammatory and antioxidant action through omega-3 (Alpha-linolenic acid) fatty acids and other antioxidants it contains [6,7].

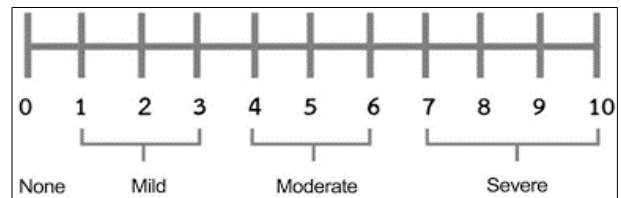
Cannabis leaf extract containing cannabinoids formulated in seed oil are available for topical application and pain relief, in many countries including India (Oreka +™). In this study, we have evaluated for the first time the benefit of combining topical cannabinoid therapy with physical ultrasound therapy. The objective is to understand the real-world effectiveness of *Cannabis sativa* leaf extract in seed oil (Oreka+) when added to ultrasound gel for relieving musculoskeletal pain with ultrasound therapy.

**Methodology**

Twenty patients with musculoskeletal pain were included in this study. The patients were adults aged 40-60 years male or female, and had pain of the lower back or shoulder-neck region for minimum of 1 month and maximum of 6 months. After giving their consent, they underwent ultrasound treatment with 1 MHz continuous ultrasound applied for a duration of 7 minutes over the pain site, daily for 10 days. A standard hydroxy cellulose based aqueous ultrasound gel was applied in all patients. In 10 patients selected randomly (Test group), 4-5 drops of Oreka+ oil (1% *Cannabis sativa*

leaf extract in cannabis seed oil, with added menthol and cinnamon camphor oil) was mixed with the ultrasound gel, while the other 10 patients in whom only ultrasound was used, served as control. The study was single (Patient) blind in design.

The evaluation was done at baseline before starting ultrasound treatment, and on day 10 after the treatment course was completed. The primary effectiveness parameters were decrease in Numeric Pain Rating Scale (NPRS) and Functional Pain Scale (FPS) from baseline to day 10. (Figure 1a-b) [8, 9]. Patients who had an FPS of >7 (8-10) at baseline which included those with intense, severe or immobilizing pain completely restricting sleep and all Activities of Daily Living (ADL), were excluded. The secondary effectiveness parameter was decrease in the requirement of daily NSAID medication for pain, assessed by recording the daily number of NSAID tablet intake at baseline compared to average daily intake over the last 3 days of ultrasound treatment. Any adverse effects like skin irritation, redness/rash, burning, itching, etc. if observed in any patient on application, was to be recorded.



**Fig 1:** Pain Scales: (A) NPRS – Numerical Pain Rating Scale

Descriptor	Definition
No Pain (0)	No pain
Minimal (1)	Hardly noticeable/no impact on ADL's/sleep not affected and able to use passive distraction for comfort. Mild range order
Mild (2)	Noticeable when not distracted/no impact on ADL's/sleep only slightly affected and able to use both passive and active distraction for comfort. Mild range order
Uncomfortable (3)	Pain is present but can complete all ADL's/sleep is slightly affected and passive distraction only gives marginal relief. Mild range order
Moderate (4)	Constantly aware of pain but can complete ADLs with modification/sleep marginally affected at times/passive distraction is of no use, but active distraction gives some relief. Moderate range order
Distracting (5)	Aware of pain/able to complete some ADL's but limited by pain/sleep is affected and active distractions are only slightly useful. Moderate range order
Distressing (6)	Pain is present/unable to complete most ADLs limited by pain/sleep is difficult and active distraction is only marginal. Moderate range order
Unmanageable (7)	Pain interferes with normal ADL's/nothing seems to help/sleep is very difficult/active distractions are very difficult to concentrate on. Severe range order

ADL: Activities of Daily Living

**Fig 1:** Pain Scales: (B) FPS - Functional Pain Scale

**Results**

The number of patients with low-back pain and neck-shoulder pain included were 10 each in the age-group 40-60 years. On randomization, there were 6 and 4 patients of neck-shoulder pain, and 4 and 6 patients of low-back pain in

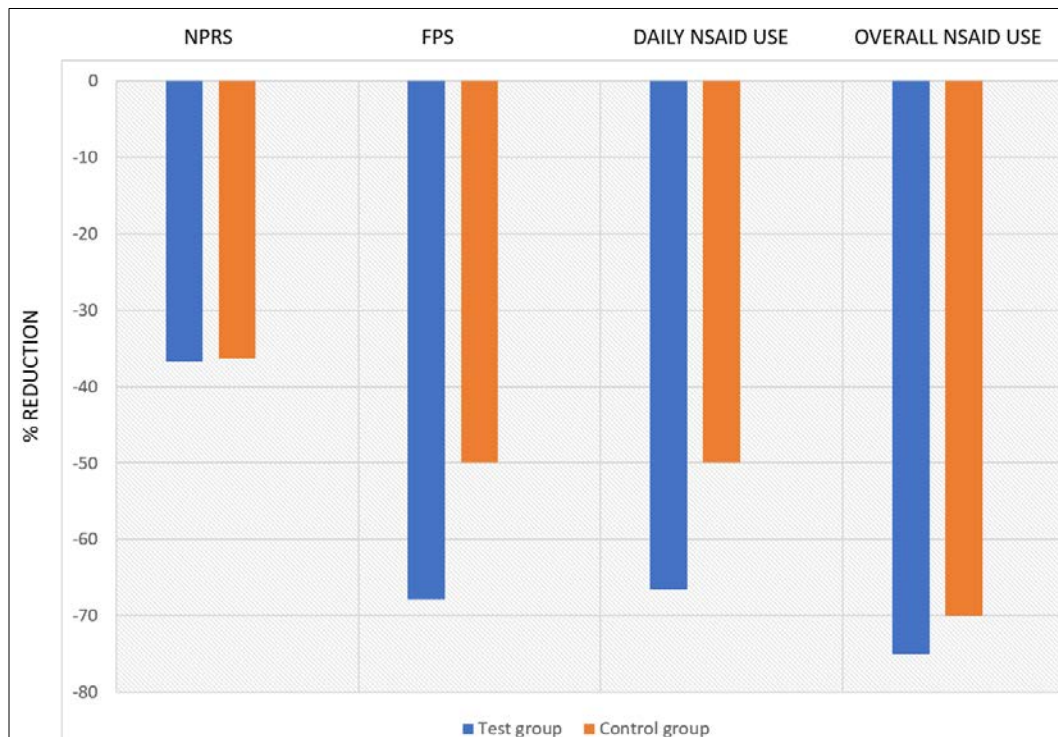
test and control group respectively. The average age in test and control group was 47.1 (40% female) and 49.7 (60% female) years respectively.

The results are summarized in figure 2. The average NPRS at baseline was 5.7 in the test group that reduced to 3.6 on

day 10 (-2.1 = 36.8% reduction). The average NPRS at baseline was 6.6 in the control group that reduced to 4.2 on day 10 (-2.4 = 36.3% reduction). The average FPS at baseline was 2.8 in the test group that reduced to 0.9 on day 10 (-1.9 = 67.8% reduction). The average FPS at baseline was 4.4 in the control group that reduced to 2.2 on day 10 (-

2.2 = 50% reduction). The average daily NSAID requirement reduced from 6 to 2 (66.6%), and 6 to 3 (50%) in the test and control group respectively. The overall NSAID usage over 10 days reduced by 75% and 70% in the test and control group respectively.

No adverse events were seen in either group.



**Fig 2:** Reduction in Pain scores and NSAID usage

NPRS-Numerical Pain Rating Scale; FPS-Functional Pain Scale; NSAID-Non-steroidal anti-inflammatory drug. Test Group-Ultrasound gel + Topical Cannabis leaf extract in seed oil; Control Group-Ultrasound gel only.

### Discussion

Ultrasound therapy is used in the management of musculoskeletal pain in sites like neck-shoulder, upper and lower back. It is one of the most commonly used electro-physical treatment in clinical practice for the management of musculoskeletal conditions by physiotherapists, osteopaths, chiropractors, and sports therapists. Ultrasound therapy acts by delivering energy to deep tissue sites through ultrasonic waves, to produce increases in tissue temperature or non-thermal physiologic changes. This helps in reduction of pain transmission. Clinical studies have found it to be an effective alternative treatment to reduce the intensity of pain in subjects with non-specific chronic musculoskeletal pain like back pain, etc. [10]

In this study there was no difference between test and control groups in patients' subjective perception of only pain as a parameter. But an important point here is also that due to randomization, the baseline NPRS pain scores were higher in control group than the test group. If baseline pain is high before pain relief is initiated, an effective treatment will be able to cause a larger change in pain intensity, and the power of a study to detect a large difference is high, compared with a study where the baseline pain intensity is low when even a very effective treatment will cause only a small change in pain intensity [11]. Therefore, considering a higher baseline pain score in control group, equal reductions

in pain rating in test and control pain groups draws a favourable conclusion towards the test group.

In spite of a higher baseline FPS score in control group, the reduction in FPS has been significantly higher in the test group. This suggests that adding topical cannabinoids to ultrasound therapy helps not only to reduce pain intensity, but can have clinical benefits in improving activities of daily living (ADL) and quality of life (QoL), by reducing pain transmission, providing anti-inflammatory and lubricating action to reduce stiffness, and also reducing psychological impact of chronic pain. The daily and overall use of NSAID medicines was also decreased more by adding topical cannabinoids to ultrasound pain treatment.

The study showed no adverse effects indicating a good treatment tolerability for cannabis leaf extract in seed oil, as well as its compatibility with ultrasound gel and treatment. The study also further suggests the additional self-application of cannabis leaf extract in seed oil by patients 1-2 times at home daily after the sonography session, to reduce need for rescue NSAID medications, and further improve mobility and pain relief, to enhance ADL and QoL. Topical cannabis preparations are gaining attention globally. The Arthritis Foundation's survey in 2600 patients living with arthritis for over 10 years showed that CBD topical formulations are used by more than half the arthritis population surveyed, and the majority of the population reported relief from pain and symptoms of arthritis [12]. Other studies have also shown improvement in chronic musculoskeletal pain, inflammation and mobility with topical cannabinoid preparations [13-15].



**Conclusion**

This study suggests co-therapy of topical cannabinoid therapy with ultrasound physical therapy can be a novel approach in pain management. Addition of a topical preparation of cannabis leaf extract in cannabis oil to ultrasound gel during the sessions of ultrasound therapy for pain can have beneficial effects in reducing pain intensity, improving activities of daily living, and reduction of NSAID use. Cannabis extract is gaining focus globally as a medically effective option in pain management, and more such and larger clinical studies can add further insights and value in this therapy space.

**Conflict of Interest**

Not available

**Financial Support**

Not available

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