

Safety and Efficacy of Medical Cannabis in Fibromyalgia

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Introduction

Fibromyalgia is a common chronic pain syndrome that is characterised by a diverse symptom burden that can be **difficult to treat**, resulting in a significant impact on patients' quality of life (QoL).

The efficacy of **existing pharmacological interventions is limited**. In the case of opioids, clinicians face the challenge of balancing the need for symptom relief with a high risk of dependency and serious adverse events.

This retrospective-prospective study reports findings on the **efficacy and safety of medical cannabis** treatment in patients with **treatment-refractory fibromyalgia** and its impact on their use of other medications, including opioids, benzodiazepines and other analgesics.

Aim of the study

To investigate the characteristics, safety, and effectiveness of medical cannabis therapy for patients with fibromyalgia.

Methods and materials

A retrospective observational analysis of a prospective data registry of **367 fibromyalgia patients treated with medical cannabis**, which collected patient-reported outcomes at one- and six-month follow-ups.

The study cohort was **patients diagnosed with primary or secondary fibromyalgia and who showed no improvement after a year of treatment** with other regimens. Patient characteristics were representative of the population most affected by fibromyalgia.

The treatment intervention with medical cannabis included CBD- and THC-rich strains delivered as drops, edible flowers, capsules or inflorescence.

Throughout the study, patients gradually titrated the dose from a low initial amount until reaching a subjective therapeutic effect.

Primary and secondary outcomes

The primary outcome was treatment response at six months, defined as:

- A moderate to significant improvement in their condition;
- Which was reported by patients using an 8-point Likert scale (1 – severe deterioration to 8 – significant improvement);
- And without cessation of treatment or serious side effects

Secondary outcomes assessed pain intensity as measured by an 11-point numeric rating scale (NRS) and QoL as measured by a 5-point Likert scale.

Results

This study achieved the primary outcome, with 81.1% of patients (n = 194/239) achieving treatment response with medical cannabis at six months (figure 1).

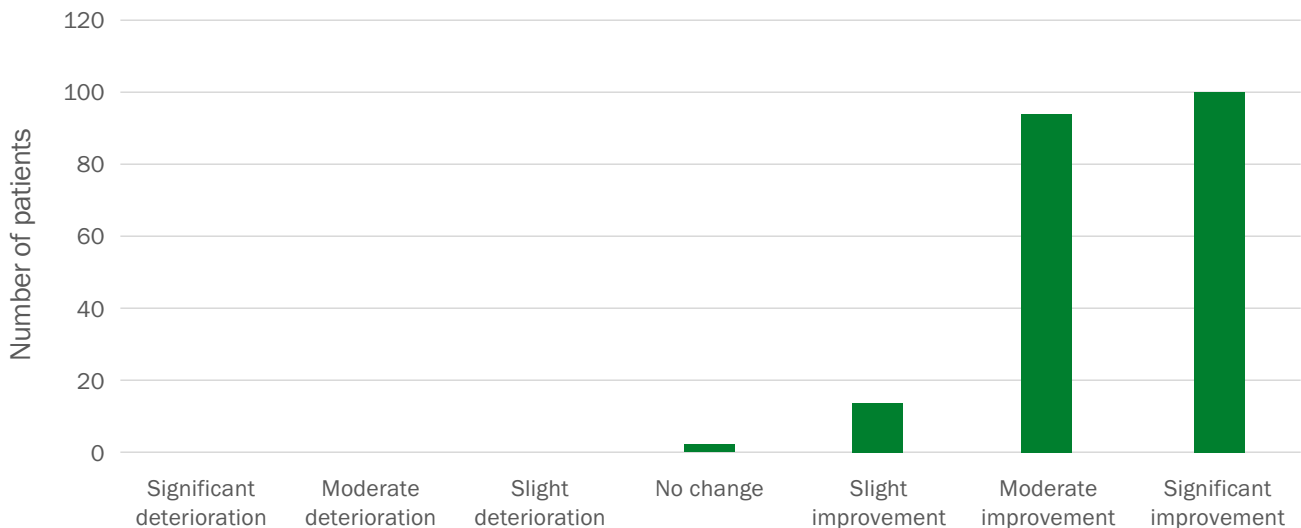


Figure 1 Perception of the general effect of cannabis on the patient's condition after six months of treatment.

For all fibromyalgia symptoms, a significant proportion of patients saw improvement or symptom disappearance after six months of treatment with medical cannabis vs. baseline ($p < 0.005$), including 86.6% of patients who reported improvement or disappearance of sleeping problems.

Secondary outcomes were achieved for pain intensity and QoL

- At baseline, 52.5% of patients reported high pain levels (8-10 on the NRS scale), which reduced to 7.9% of patients at six months (193 vs 19)
- Overall median pain intensity reduced from 9.0 at baseline to 5.0 at six months ($p < 0.001$)
- Patients reporting good or very good QoL increased from 2.7% at baseline to 61.9% at six months (10 vs 148; $p < 0.001$)

Secondary treatment outcomes were maintained when stratified for primary vs secondary fibromyalgia.

A significant portion of patients stopped or reduced their use of opioids, benzodiazepines and other analgesics, including pregabalin, gabapentin and amitriptyline, compared to baseline after six months of treatment with medical cannabis ($p < 0.001$).

Adverse events

At the six-month follow-up, patients reported minor adverse events at relatively low rates, which included dizziness (7.9%), dry mouth (6.7%) and vomiting and nausea (5.4%), and reported tolerance to adverse events within days of treatment. At the six-month follow-up, only 7.6% of patients ceased treatment with medical cannabis, suggesting that side effects were tolerable.

The safety analysis included patients who ceased cannabis treatment before six months.

Discussion

This observational study with a large study cohort and six-month follow-up suggests that medical cannabis may be a safe and effective treatment for patients with treatment-refractory fibromyalgia when titrated gradually.

A large proportion of patients achieved treatment response at six months, and treatment with medical cannabis significantly improved symptoms, quality of life and pain intensity at six months compared to baseline.

Additionally, medical cannabis may be a reasonable therapeutic alternative to opioids and shows promise for reducing reliance on traditional analgesics and benzodiazepines for fibromyalgia symptoms.

References

Sagy, I., Bar-Lev Schleider, L., Abu-Shakra, M., & Novack, V., 2019. Safety and efficacy of medicalcannabis in fibromyalgia. *Journal of clinical medicine*, 8(6), pp.807-819.



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