Efficacy of Cannabis Flos in Patients with Fibromyalgia: A Monocentric Observational Study

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Background/Purpose: Fibromyalgia (FM) is a syndrome characterized by chronic widespread pain, fatigue, sleep and affective disturbances. Treatment is based on the symptomatic relief of symptoms but only modest results are achieved. There are few evidences on the effectiveness of cannabinoids in the improvement of FM symptoms. A cannabinoid (Cannabis flos 19%), containing tetrahydrocannabinolic acid 19% and cannabidiolic acid <1% used as orally decoction, is available in Italy for treating chronic pain. The aim of the this study was to evaluate the efficacy of Cannabis flos 19% on pain, fatigue, sleep disturbances, anxiety and depression in FM patients.

Methods: · Fifteen patients affected by FM according to the ACR 2010 criteria and treated with Cannabis flos 19% (30 mg twice a day for the first month, 60 mg twice a day for the second month), have been evaluated at baseline and after 2 months of treatment with the following questionnaires: the Fibromyalgia Impact Questionnaire revised (FIQR), the Fibromyalgia Activity Score (FAS), the Functional Assessment of Chronic Illness Therapy (FACIT), the Pittsburgh Sleep Quality Index (PSQI), the Zung Self-Rating Anxiety Scale (ZS-RA) and the Zung Self-Rating Depression Scale (ZS-RD).

Results: Table 1 shows the demographic and clinical characteristics of the patients involved in study. 11/15 patients completed the 2-months follow up. After 2 months of treatment a statistical significant improvement in the terms of medians values of VAS pain (8.2±1 *vs* 6.2±2.4, p= 0,0273), FAS (7.8±1.7 *vs* 6.2±2.1, p= 0,0494), FACIT (13.5±7.4 *vs* 22.9±10.5, p= 0,0042), ZR-SA (66.2±14 *vs* 57.6±13.3, p= 0,0172) and ZS-RD (58±10.3 *vs* 48.7±11.5, p= 0,0491) has been found; while the median FIQ-R scores (74.4±17.2 *vs* 60.3±24.3, p= 0,0615) and sleep disturbances scores (PSQI, 11±2.8 *vs* 10.5±3.8, p= 0,5435) didn't change. Two patients (13%) stopped the treatment for inefficacy. Furthermore, although adverse events range from mild to moderate two patient stopped the treatment: one for the apparence of confusion and sweating and one for the mood deflection.
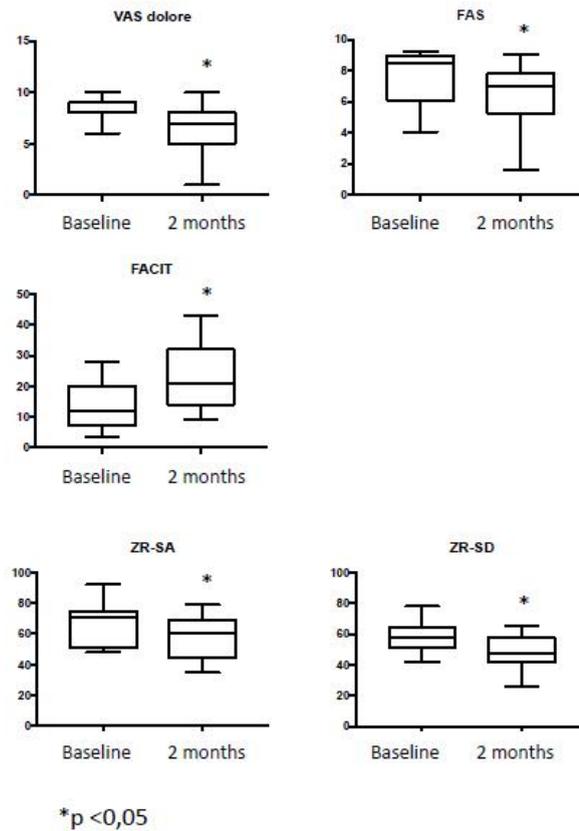
Conclusion: This study showed that Cannabis flos 19% is effective in improving pain, fatigue, anxiety and depression in FM patients.   Further studies are suggested in order to confirm this preliminary data on efficacy and safety of this therapy for treating FM patients.   **Table 1. Demographic and clinical characteristics of FM patients**

	FM patients (n=15)
Age, median (IQR)	53(50-54)
Female/Male	13/2
BMI, median (IQR)	26.6 (22-29)
No smokers, n(%)	4(27)
Ever smokers, n(%)	3(20)
Smokers, n(%)	8(53)
Disease duration (*months*), median (IQR)	180 (120-240)
Treatment, n (%)	
Pregabalin	2 (13)
Duloxetine	7 (47)
Amitriptyline	1 (7)
Tramadol	4(27)
Tapentadol	2 (13)
Others SNRIs	2(13)
Others opioids	3(20
Benzodiazepine	4(27)

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Figure 1. Significative improvement on VAS pain, FAS, FACIT, ZR-SA and ZR-SD

*p <0,05

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