Use of medical cannabis by patients with fibromyalgia in Canada after cannabis legalisation: a cross-sectional study

M.-A. Fitzcharles[1,2], E. Rampakakis[3], J. Sampalis[3,4], Y. Shir[2], M. Cohen[1], M. Starr[1], W. Häuser[5,6]

[1]*Division of Rheumatology, McGill University Health Centre, Montreal;*
[2]*Alan Edwards Pain Management Unit, McGill University Health Centre, Montreal;*
[3]*JSS Medical Research, St-Laurent;*
[4]*Jewish General Hospital, McGill University, Montreal, Canada;*
[5]*Department Internal Medicine I, Klinikum Saarbrücken, Germany;*
[6]*Department of Psychosomatic Medicine and Psychotherapy, Technische Universität München, Germany.*

Mary-Ann Fitzcharles, MB, ChB
Emmanouil Rampakakis, PhD
John Sampalis, PhD
Yoram Shir, MD
Martin Cohen, MD
Michael Starr, MD
Winfried Häuser, MD

Please address correspondence to:
Mary-Ann Fitzcharles,
Division of Rheumatology and
Alan Edwards Pain Management Unit,
McGill University Health Centre,
Montreal General Hospital,
1650 Cedar Avenue,
Montreal, QC H3G 1A4, Canada.
E-mail:
mary-ann.fitzcharles@muhc.mcgill.ca

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ABSTRACT

Objective. *Medications have only small to moderate effects on symptoms in fibromyalgia (FM). Cannabinoids, including medical cannabis (MC) may have potential to fill this gap. Since recreational legalisation of cannabis in Canada, patients have easier access and may be self-medicating with cannabis. We have examined the prevalence and characteristics of MC use in FM patients.*

Methods. *During a two-month period (June-August 2019), consecutive attending rheumatology patients participated in an onsite survey comprising 2 questionnaires: 1) demographic and disease information completed by the rheumatologist, 2) patient anonymous questionnaire of health status, cannabis use (recreational and/or medicinal) and characteristics of use.*

Results. *In a cohort of 1000 rheumatology attendees, 117 (11.7%) were diagnosed with FM. Ever use of MC was reported by 28 (23.9%; 95%CI: 16.5%-32.7%) FM patients compared to 98 (11.1%; 95%CI: 9.1%-13.4%) non-FM patients. Among FM ever users, 17 (61%) patients continued use of MC. FM ever users vs. FM non-users tended to be younger, 53 vs. 58 years (p=0.072), were more likely unemployed or disabled 39% vs. 17% (p=0.019) and used more medication types (p=0.013) but did not differ in symptom severity parameters. Cigarette smoking and recreational cannabis were more common in ever users. Global symptom relief on a VAS (1-10) was 7.0±2.3.*

Conclusion. *FM patients have commonly used MC, with more than half continuing use. Reported symptom relief was substantial. Cigarette smoking and recreational cannabis use may play a facilitatory role in MC use in FM. Adjunctive MC may be a treatment consideration for some FM patients.*

Introduction

Fibromyalgia (FM) is a prevalent condition affecting up to 4% of the general population as a unique condition, but also occurs as a comorbid condition in rheumatic diseases (1, 2). Characterised by chronic widespread pain and associated symptoms of sleep disturbance, fatigue, cognitive dysfunction and various somatic and psychological symptoms, FM is associated with suffering and reduced life quality (3). Treatments for FM seldom provide appreciable symptom relief. Various guidelines recommend non-pharmacologic treatments as a first step, but eventually most patients look to medications as a treatment option (4, 5). Medications in turn provide only a modest effect on pain for most patients, but seldom any substantial effect on other key symptoms of FM such as fatigue, sleep problems and anxiety (6). As cannabis may have an effect on multiple systems there is a hope for a more diverse effect. It is for this reason that patients may seek to self-medicate with over the counter or complementary treatments. Medical cannabis (MC) either prescribed or self-administered may be a treatment option that is explored by FM patients.

Available as a therapeutic treatment in Canada since 2001, patients may access MC via a physician document that is transmitted to a Health Canada regulated grower of cannabis. There is no pharmacy oversight of MC access. This "medical document" contains limited patient demographic information, without need to identify a diagnosis, but stating the daily amount of cannabis and the duration of use that can be up to 1 year and the cannabis product is shipped to the patient directly. There is no reimbursement of MC by provincial insurers, but some limited reimbursement by some private insurers and the

Canadian Veterans Administration is available.

In a survey of 1000 unselected rheumatology patients in Montreal in 2014, we identified that 4.3% of all patients had ever tried cannabis for medical reasons, with just over half continuing use (7). In October 2018, recreational cannabis was legalised in Canada and has been accessible in most provinces to persons over the age of 18 years, being able to be bought on-line or in store. The legal medical route has remained unchanged. In a follow up survey conducted in the same setting in the Spring of 2019 we identified that 12.6% of all attendees had ever used medical cannabis, triple the rate observed 5 years previously (8).

The objective of this current study was to examine the prevalence and characteristics of MC use by FM patients, either as a primary diagnosis or associated with an underlying primary rheumatic disease since cannabis recreational legalisation in Canada. We anticipated that recreational legalisation would be associated with a higher rate of use of MC in this patient group.

Methods

This is a sub-analysis of patients with a diagnosis of FM who participated in a previously described survey study of 1000 consecutively attending rheumatology patients (8). The study comprised two questionnaires completed at the time of the clinic visit, one physician completed with demographic and disease related information, and the other patient completed with information about cannabis use.

The anonymous patient completed questionnaire comprised the following: current pain in past 7 days, 10 cm VAS (0: no pain; 10: most severe pain); patient global assessment (PtGA) of health status, 10 cm VAS (0: very well; 10 very poorly); ever and current recreational cannabis use; ever and current MC use; if ever used at any time, the number of times, <10 times, or ≥10 times. If MC was discontinued, reason for discontinuation was recorded as not effective, side effects, cost, or other reasons. If MC had never been used, patients reported whether they would consider future use, and whether use had been suggested: family/friend, medical person, media or other.

Information about cannabis use for all users (medical or recreational, or both) included the following: 1) method of use as smoked, vaporised, oil/capsules, edibles, topical application or other; 2) daily amount in grams/day or ml/day; concentration of Δ^9-tetrahydrocannabinol (THC) and cannabidiol (CBD); 3) access via medical prescription, a store (legal recreational, illegal medical dispensary, illegal recreational outlet), internet, a friend, the street or other. Symptoms treated were identified as relief of pain, fatigue, poor sleep, anxiety or other symptom relief. Side effects included drowsiness, feeling high, fatigue, lack of energy, lack of motivation or other. The benefit of MC was assessed by the question "how much does cannabis help you with your symptoms?", 10cm VAS (0: not at all; 10: very much).

The study received ethics approval from the Institutional Review Board Services (IRB Services), Ontario, Canada, an independent research ethics board, and all participants provided written informed consent.

Statistical analysis

Descriptive statistics, including the mean and standard deviation for continuous variables and frequency distributions for categorical variables, were produced for all variables. Ninety-five percent confidence intervals (95% CI) around the point estimate of the prevalence of cannabis use were calculated based on the binomial exact method. In addition to the overall results, stratified analysis by ever use of MC was conducted. Between-group comparisons were conducted with the independent-samples t-test for continuous variables and the Fisher's exact test for categorical variables using a significance level set *a priori* of $p<0.05$. All analyses were conducted using SPSS Version 24.0 (IBM Corp. Armonk, NY).

Results

During a two-month period, mid-June to mid-August 2019, there were 1000 rheumatology attendees (73% female; mean age 64±14 yrs.), with 117 (11.7%) diagnosed with FM according to the clinician diagnosis. Ever use of MC was reported by 28 (24%) of the 117 FM patients (95% CI: 16.5%-32.7%), with 17 (60.7%) continuing use. For the 883 patients with a rheumatic condition other than FM, ever use of medical cannabis was 11.1% (95% CI: 9.1%-13.4%) with 5.4% continuing use.

Demographic, disease-related and treatment information for the FM patients (91.5% female; mean age 57±12 years) is shown in Table I. FM was a unique diagnosis for 35 (30%), and 82 (70%) were diagnosed with FM comorbid with an underlying primary rheumatic disease. The most commonly associated rheumatic conditions were osteoarthritis of small and/or large joints and/or spine in 50 (43%), and inflammatory arthritis in 35 (30%). Within the inflammatory arthritis FM comorbid group, 13 had inflammatory spondyloarthritis and 6 had ever used MC.

FM ever users *versus* FM non-users tended to be younger, 53.4 *vs*. 58.2 yrs. (p=0.072), were more likely unemployed or disabled 39.3% *vs*. 16.9% (p=0.019), and used more medication types in general, but not specifically medications used for symptom control such as opioids, tranquillisers, gabapentinoids or antidepressants (Table I). Medication adjustments related to MC use was not recorded. Symptom severity parameters did not differ between groups. Four (14.3%) ever users had obtained MC entirely via the legal medical route. Ever users were more likely to be past and current cigarette smokers, and both previous and current recreational cannabis consumers. The benefits of MC according to how much MC helped with symptoms was assessed as 7.0±2.3 on a 10cm VAS (0: not at all; 10: very much). Demographic, symptom characteristics, cigarette smoking, and methods of cannabis use did not differ between those with a unique diagnosis of FM comparted with those with comorbid FM (results not shown).

The most common reason for discontinuing MC was due to lack of effect for all 11 patients discontinuing MC (39.3% of ever users) while 4 also reported side effects. No patient discon-

Table I. Demographic and disease-related information. All FM patients.

			All patients (n=117)	Never medical cannabis users (n=89)	Ever medical cannabis users (n=28)	*p*-value
Demo-graphics	Age, years, mean (SD)		57.1 (12.2)	58.2 (11.7)	53.4 (13.5)	*0.072*
	Female gender, n (%)		107 (91.5)	79 (88.8%)	28 (100.0%)	0.115
	Employment					
	Full-time, n (%)		39 (33.3%)	30 (33.7%)	9 (32.1%)	0.109
	Part-time, n (%)		9 (7.7%)	6 (6.7%)	3 (10.7%)	
	Unemployed, n (%)		2 (1.7%)	1 (1.1%)	1 (3.6%)	
	Disabled, n (%)		24 (20.5%)	14 (15.7%)	10 (35.7%)	
	Student, n (%)		1 (0.9%)	1 (1.1%)	0 (0.0%)	
	Retired, n (%)		42 (35.9%)	37 (41.6%)	5 (17.9%)	
	Employment: unemployed/disabled, n (%)		26 (22.2%)	15 (16.9%)	11 (39.3%)	**0.019**
Rheumatic diseases	Inflammatory arthritis†, n (%)		35 (29.9%)	25 (28.1%)	10 (35.7%)	0.482
	Rheumatoid arthritis		12 (10.3%)	10 (11.2%)	2 (7.1%)	0.728
	Psoriatic arthritis		6 (5.1%)	5 (5.6%)	1 (3.6%)	>0.999
	Ankylosing spondylitis		13 (11.1%)	7 (7.9%)	6 (21.4%)	*0.078*
	PMR		3 (2.6%)	2 (2.2%)	1 (3.6%)	0.563
	SLE		1 (0.9%)	1 (1.1%)	0 (0.0%)	>0.999
	Other		1 (0.9%)	0 (0.0%)	1 (3.6%)	0.239
	Osteoarthritis§, n (%)		50 (42.7%)	44 (49.4%)	6 (21.4%)	**0.009**
	Small joints, n (%)		23 (19.7%)	23 (25.8%)	0 (0.0%)	**0.002**
	Large joints, n (%)		22 (18.8%)	19 (21.3%)	3 (10.7%)	0.274
	Spine, n (%)		30 (25.6%)	26 (29.2%)	4 (14.3%)	0.141
	Tendonitis/bursitis, n (%)		11 (9.4%)	9 (10.1%)	2 (7.1%)	>0.999
	Other rheumatic condition, n (%)		10 (8.5%)	5 (5.6%)	5 (17.9%)	*0.058*
Comorbid conditions	Cardiovascular, n (%)		30 (25.6%)	22 (24.7%)	8 (28.6%)	0.804
	Pulmonary, n (%)		4 (3.4%)	4 (4.5%)	0 (0.0%)	0.571
	Gastrointestinal, n (%)		31 (26.5%)	24 (27.0%)	7 (25.0%)	>0.999
	Neurological, n (%)		8 (6.8%)	7 (7.9%)	1 (3.6%)	0.678
	Endocrine, n (%)		44 (37.6%)	37 (41.6%)	7 (25.0%)	0.125
	Mood disorder, n (%)		33 (28.2%)	27 (30.3%)	6 (21.4%)	0.472
	Other psychiatric disorder, n (%)		5 (4.3%)	2 (2.2%)	3 (10.7%)	*0.088*
	Other comorbid condition, n (%)		3 (2.6%)	3 (3.4%)	0 (0.0%)	>0.999
Medications for rheumatic diseases	Number of medication types for rheumatic disease, mean (SD)		1.7 (1.3)	1.6 (1.1)	2.3 (1.6)	**0.013**
	Non-steroidal anti-inflammatory drug use, n (%)		40 (34.2%)	29 (32.6%)	11 (39.3%)	0.648
	Disease-modifying anti-rheumatic drug use, n (%)		15 (12.8%)	13 (14.6%)	2 (7.1%)	0.517
	Biologic use, n (%)		14 (12.0%)	7 (7.9%)	7 (25.0%)	**0.039**
	Opioids use, n (%)		19 (16.2%)	14 (15.7%)	5 (17.9%)	0.774
	Tranquiliser use, n (%)		12 (10.3%)	8 (9.0%)	4 (14.3%)	0.478
	Antiepileptic use, n (%)		34 (29.1%)	25 (28.1%)	9 (32.1%)	0.812
	Antidepressant use, n (%)		41 (35.0%)	32 (36.0%)	9 (32.1%)	0.822
	Steroid use, n (%)		4 (3.4%)	3 (3.4%)	1 (3.6%)	>0.999
	Cannabis pharmaceutical		5 (4.3%)	1 (1.1%)	4 (14.3%)	**0.011**
	Cannabis herbal		9 (7.7%)	0 (0.0%)	9 (32.1%)	NA
Disease assessment	Physician Global Assessment (PGA) (0-10), mean (SD)		3.5 (1.9)	3.4 (1.9)	3.7 (1.9)	0.402
	Patient Global Assessment (PtGA) (0-10), mean (SD)		5.5 (2.5)	5.5 (2.6)	5.5 (2.2)	0.945
	Pain, VAS cm, mean (SD)		6.5 (2.2)	6.5 (2.2)	6.6 (2.2)	0.806
Cigarette use	Non-smoker	n (%)	76 (65.0%)	64 (71.9%)	12 (42.9%)	**0.002**
	Past smoke	n (%)	16 (13.7%)	7 (7.9%)	9 (32.1%)	
	Current smoker	n (%)	25 (21.4%)	18 (20.2%)	7 (25.0%)	
Cannabis use	Recreational	Ever use, n (%)	44 (37.6%)	28 (31.5%)	16 (57.1%)	**0.024**
		Current use, n (%)	7 (6.0%)	2 (2.3%)	5 (17.9%)	**0.009**
	Medical	Ever used >10 times, n (%)	22 (19.5%)	NA	22 (78.6%)	NA
		Current medical use, n (%)	16 (13.7%)	NA	16 (57.1%)	NA
		If never used, consider medical use, n (%)	NA	45 (50.6%)	NA	NA
	Current cannabis use (any reason)§§	Current use, n (%)	19 (16.2%)	2 (2.2%)	17 (60.7%)	**<0.001**
		Method of herbal cannabis use††				
		Smoke, n (%)	9 (47.4%)§§	1 (50.0%)‡	8 (47.1%)‡‡	>0.999
		Vaporise, n (%)	8 (42.1%)§§	1 (50.0%)‡	7 (41.2%)‡‡	>0.999
		Oil/capsules, n (%)	7 (36.8%)§§	0 (0.0%)‡	7 (41.2%)‡‡	0.509
		Edible, n (%)	4 (21.1%)§§	0 (0.0%)‡	4 (23.5%)‡‡	>0.999
		Rub, n (%)	0 (0.0%)§§	0 (0.0%)‡	0 (0.0%)‡‡	N/A
	Current herbal cannabis use (medical reasons)	Relief of symptoms, mean (0-10) (SD)¥	7.0 (2.3)	NA	7.0 (2.3)	NA

NA: not applicable.
Significant ($p<0.05$) *p*-values indicated in bold. Missing category is not included in the comparison.
†Patients may have had more than one type of inflammatory arthritis.
§Patients may have had more than one type of osteoarthritis.
††Patients may have used more than one method of herbal cannabis.
§§Proportions are based on the number of patients currently using herbal cannabis for any reason (all patients: n=19; current recreational herbal cannabis users: n=2; current medical herbal cannabis users: n=17).
‡Proportions are based on the number of patients in the '*Never medical cannabis users*' group currently using herbal cannabis for recreational purposes (n=2).
‡‡Proportions are based on the number of patients in the '*Ever medical cannabis users*' group currently using herbal cannabis for any reason (All patients n=17).
¥Among patients using herbal cannabis for medical reasons. Minimum (0) represents 'no relief' and maximum (10) represents 'maximum relief".

tinued MC due to cost. Of the 17 current users, 6 had disclosed use of MC to their physician. Four of the 17 current users were also prescribed a pharmaceutical cannabinoid, but without the physician knowledge of MC use. Two of the current users obtained MC entirely via the legal medical route. The most common method of administration was by inhalation for 13 (6 smoking, 7 vaping) and 6 used ingested oils. Five patients administered cannabis both by inhalation and orally. When cannabis was inhaled, patients reported 0.5 to 2 grams per day mostly, but with one patient using up to 6 grams a day. No patient could accurately identify the amount or concentrations of THC or CBD in the preparations used, although 3 reported using mostly CBD products. Narrative report of symptom relief was as follows: pain relief in 12, sleep aid in 10, and relief of anxiety and fatigue in 7 each.

Discussion

This cross-sectional study of MC use by FM patients in Canada provides a snapshot of use by patients attending a rheumatology clinic following recreational legalisation. We have observed that almost one quarter of FM patients, including those with comorbid rheumatic conditions, had tried MC as a therapeutic intervention, with more than half of those reporting continued use. For those who continued use, MC was rated to be substantially effective. Reasons for discontinuation of MC were mostly due to lack of effect, with only a few discontinuing due to both lack of effect and side effects. FM patients who had tried MC were younger than non-users, more likely unemployed or disabled, and were using more medication categories to treat their rheumatic condition, but not medications for symptom relief such as analgesics, antidepressants or non-steroidal anti-inflammatory medications. Similar to findings of others, cigarette smoking as well as previous recreational cannabis use was more common for users.

Patients with FM, either as a unique condition, or in association with some other rheumatic disease had double the use of MC compared to non-FM rheumatology patients, with continued use reported by over 60%. A similar retention of about two thirds was reported for MC prescriptions in an Italian rheumatology clinic (9). Discontinuation of MC in FM patients is however less commonly reported when patients have been followed in designated cannabis clinics or in studies that were sponsored by a cannabis provider (10, 11). The observed high rate of trial of MC emphasises the unmet need for adequate symptom relief for these patients, even with concurrent use of a range of symptom focussed medications (2). There was also no difference in use of symptom focused medications for MC users compared to non-users, although we do not have information about medication adjustments that might have been related to MC use. In line with the findings of others, FM patients who continued to use MC reported considerable relief in general, with relief of pain and help with sleep identified as the symptoms most treated (9-11). Similar report of symptom relief was noted for use of CBD products in an internet survey in the United States (12).

Cigarette smoking, and recreational cannabis use was commonly reported by those who had ever used MC as well as those continuing to use MC, suggesting that inhalation habits may play a facilitatory role in MC use. Even with strong medical recommendation against inhalation of MC, this method was the most common method of administration, as has previously been reported (10, 13, 14). Furthermore, almost one third of current MC users reported that they also used cannabis recreationally, suggesting that for some there may not be a clear distinction between recreational and medicinal use of cannabis.

The lack of disclosure of MC use observed for over half (56%) of current users in this study is concerning. Furthermore, pharmaceutical cannabinoid in the form of nabilone had been prescribed concomitantly with MC without physician knowledge of MC use. It is noteworthy that not a single patient currently using MC could accurately identify the molecular content or amount of product being used. This can be understood as only 2 of the current users had obtained cannabis via the legal medical route, whereas cannabis used therapeutically was almost entirely accessed via the recreational route, either legal or illegal. Legal cannabis, both recreational and medical is costly with prices in the order of $6.00 -$8.00 Canadian per gram. This could partly explain the prevalent access to cannabis via the non-medical and often illegal route with competitive pricing for the black-market products. Interestingly, no patient cited cost as a reason for discontinuation of medical cannabis, which was one reason for discontinuation in the study of Boehnke et al which was conducted in the United States (12). Physicians should be aware that patients who currently self-administer cannabis do not view this product in the same context as other medicinal products, with defined dosage and scheduling.

A better understanding of the therapeutic potential for MC was identified as one of ten top research priorities in a study with input from clinicians and patients (15). Unfortunately, the evidence-based literature addressing use of MC in chronic pain in general and in FM in particular remains limited. Recreational legalisation has therefore provided a mechanism by which patients may have easier access to cannabis and may self-administer without medical oversight.

Our study has several strengths. The diagnosis of FM was identified by the treating rheumatologist, and this analysis included patients with both unique FM as well as FM comorbid with some other rheumatic disease. In the setting of recreational legalisation, patients may have been more willing to report use of cannabis without fear of any possible legal repercussions. Limitations include a single centre study, small number of patients with FM, and self-report of cannabis use at a single time point. We also had limited information about MC use in those who had discontinued use.

MC was commonly tried by FM patients, was mostly self-administered and use was often not disclosed to the treating rheumatologist. This prevalent use was likely influenced by increased availability of cannabis in Canada as a result of recreational legalisation.

Cannabis was seldom accessed via the legal medical route and patients were not knowledgeable of the amount or molecular content of the cannabis product that they were consuming. With report of considerable benefit, adjunctive medical cannabis may be a treatment consideration for patients with chronic widespread pain, either as a unique diagnosis of FM or comorbid with some rheumatic disease. The health care community should strongly advocate that patients understand that when cannabis is used as a therapy, it should be managed in the same way as any other prescribed medication with full disclosure and medical oversight.

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