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Cannabis use preferences in women with myofascial pelvic pain: A cross-sectional study

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ARTICLE INFO	ABSTRACT			
<i>Keywords:</i> Myofascial pelvic pain Chronic pelvic pain Cannabis Vaginal suppository Vulvar cream	Objective: Myofascial tenderness is present in most chronic pelvic pain conditions and causes significant distress to patients. Treatment is challenging and often not curative. Cannabis is often used for self-management of chronic pelvic pain. However, we do not know which concentrations and routes of administration are most acceptable to users. We aimed to investigate patterns and willingness of cannabis product use among both habitual users and non-users with myofascial pelvic pain (MPP), to inform therapeutic development. Study design: We conducted a cross-sectional study of questionnaire responses from female patients with MPP from two tertiary pelvic pain centers. We aimed for a convenience sample of 100 responses with representation from both centers. Inclusion criteria were age over 18 with pelvic floor muscle tenderness on standard gyne- cologic examination. We collected information on demographics, pelvic pain history, cannabis use status, cannabis use preferences, validated opioid misuse risk assessment, and interest in using gynecologic cannabis products and used descriptive analyses. Results: 77/135 (57 %) questionnaire respondents were cannabis users and 58 (43 %) were non-users. Most users consume cannabis daily, (48.1 %) orally (66.2 %) or by smoking (60.7 %), and rated cannabis as effective at relieving pelvic pain. Lack of information and potential adverse effects were the most common reasons for unwill- ingness to use. Approximately 3 of 4 respondents were willing to try vaginal or vulvar application of cannabis products for pelvic pain. 			

1. Introduction

Pelvic pain is associated with impaired functioning in all facets of life from poor sleep, potential analgesic dependency, to medical and financial burdens [1,2]. Within pelvic pain, myofascial pelvic pain (MPP) is an important but commonly overlooked contributor [3]. MPP affects 22–94% of patients with chronic pelvic pain [4]. It is characterized by the presence of painful trigger points in pelvic floor musculature and connective tissue, and is typically associated with allodynia and hyperalgesia [3,5]. A validated, standardized technique for MPP examination now exists which will hopefully improve routine recognition and targeted treatment [6].

Treatment for MPP is difficult, often requiring a combination of synergistic therapies [2]. Current treatments include nonsteroidal anti-inflammatories, muscles relaxants, neuromodulators, and pelvic floor physical therapy [7]. Opioid analgesics and trigger point injections, with or without botulinum toxin, can also be used [8]. MPP is frequently refractory to common treatments because of the concurrent myofascial component, central sensitization, and chronic inflammation [9]. Novel therapies are greatly needed.

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Abbreviations: MPP, Myofascial pelvic pain; SOAPP, Screener and Opioid Assessment for Patients with Pain; CCS, Canadian Cannabis Survey; CBD, Cannabidiol; THC, Delta-9-tetrahydrocannabinol.

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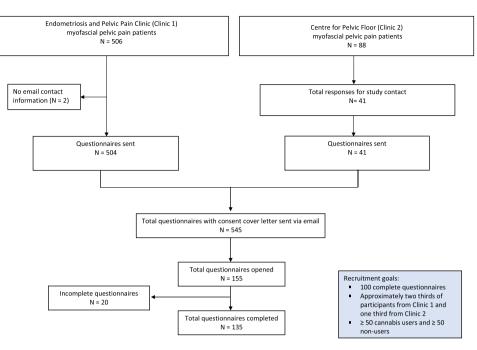


Fig. A. Recruitment and data collection flowchart.

Cannabis use is increasing and self-medicating is common for the treatment of pain [10]. Meta-analysis results show that smoked cannabis, oromucosal cannabis sprays and oral cannabinoids all significantly reduced chronic, non-cancer pain compared to placebo without increased risk of serious adverse events [11]. Legalization of cannabis in Canada in 2012 increased use by 8.2 % in patients with chronic pelvic pain, and we showed that one in five female patients use cannabis products for relief [12]. Over half of patients who have never used cannabis expressed willingness to use it for gynecological pain [13]. Although recent surveys show almost nine of ten women are willing to consider being in a clinical trial of medical cannabis to treat chronic pelvic pain, it is unclear which products should be used, at what concentration, and through which route [14]. We aimed to recruit cannabis users and non-users with MPP to determine details of current products used as well as willingness to use potential topical products such as vaginal inserts. The goal was to inform further research and development of new treatments for myofascial chronic pelvic pain.

2. Material and methods

Our descriptive cross-sectional study was approved by local institutional research ethics boards (#H20-01959). We wrote a detailed questionnaire in consultation with a pharmacology expert (AB) and a clinical psychologist (LB) (Appendix A). Cannabis users were defined as participants currently using cannabis for any medical or recreational reasons. Non-users were participants not currently using cannabis for any reason.

We recruited female patients with MPP from two tertiary pelvic pain centers. Inclusion criteria were patients over age 18 with recorded tenderness in at least one of the right or left levator ani or obturator internus muscles during gynecologic examination. We excluded patients not fluent in English. We used slightly different recruitment methods at each of the two sites. Clinic 1 had an existing registry (EPPIC; Clinicatrials.gov #NCT02911090) of pelvic pain patients [14]. Emails containing a cover letter explaining the research study and a private link for the questionnaire were sent to patients who had consented for research participation. Clinic 1 has a focus on MPP due to endometriosis. Clinic 2 did not have an existing registry. We identified patients with MPP using ICD codes on chart review and mailed invitation letters, then followed up with a phone call and collected email addresses from those interested in participating. Clinic 2 has a focus on MPP due to urogynecologic concerns.

From both centers, we aimed for a total convenience sample of 100 complete questionnaire responses. Given different patient volumes between the two recruitment sites (Clinic 1 higher volume), and different recruitment strategies (Clinic 1 more efficient with a registry), we aimed to recruit approximately two thirds of participants from Clinic 1 and one third from Clinic 2, as well as \geq 50 users and \geq 50 non-users. We stopped recruitment when we reached our a priori goals.

All participants completed demographic and Screener and Opioid Assessment for Patients with Pain (SOAPP) questionnaires [15]. Demographic questions included age, education, income, employment, ethnicity, cigarette smoking, alcohol use, and recreational drug use. Information collected on pelvic pain history included self-reported rating of pelvic pain severity, presence of superficial and deep dyspareunia, years since diagnosis of MPP, other pelvic pain diagnoses, and use of medications for pelvic pain. The SOAPP questionnaire assessed risk of opioid abuse. Participants were asked "yes" or "no" questions to determine their cannabis use status.

We asked cannabis users to provide the following: age of first use, reason for using, frequency of use, duration of use, methods of consumption (smoking, vaporizing, oral, skin application, other), types of cannabis products (dried flower/leaf, edibles, liquid, cannabis vape pens/cartridges, topical products, concentrates, other), quantity of products, origin of products (licensed/unlicensed storefront, online store, self-grown, dealer), and average cost spent per month on cannabis. Users were asked to rate the effectiveness of cannabis for relieving pelvic pain, decreasing use of other pain medications, and impact on mood, sleep, social life, physical health, physical mobility, mental health, home life, work or studies, and quality of life. Some questions were inspired by the Canadian Cannabis Survey [16].

We asked non-cannabis users if they had ever used cannabis in the past. If applicable, we asked what they previously used cannabis for, and reasons for stopping. We also asked non-users whether they would be willing to use cannabis for pelvic pain, and if yes, how (methods of consumption, types of products, origins of products, cost per month). All participants were asked how likely (very unlikely, unlikely, likely, very likely) they would be to use each of the following products for pelvic

Table 1

Patient characteristics.

Variable	All $(n = 105)$	Non-users	Users (n	Р
	135)	(n = 58)	= 77)	
Age				< 0.00
Mean (SD)	38.2	44.5	33.5	
	(11.6)	(11.6)	(9.2)	
Range	(20.0,	(24.0,	(20.0,	
	73.0)	73.0)	64.0)	
Education – College or higher,	100	46 (79.3)	54 (70.1)	0.22
n (%)	(74.1)			
Ethnicity – white, n (%)	118	48 (82.8)	70 (90.9)	0.15
Annual household income, n	(87.4)			0.040
(%)				
Unknown	17	12	5	
< \$20,000	13 (11.0)	1 (2.2)	12 (16.7)	
\$20,000-\$39,999	19 (16.1)	7 (15.2)	12 (16.7)	
\$40,000-\$59,999	14 (11.9)	3 (6.5)	11 (15.3)	
\$60,000-\$79,999	22 (18.6)	11 (23.9)	11 (15.3)	
\$80,000 or more	50 (42.4)	24 (52.2)	26 (36.1)	
Current employment status, n (%)				0.02
Unknown	3	2	1	
Employed full time	5 62 (47.0)	2 34 (60.7)	28 (36.8)	
Employed part time/Self-	37 (28.0)	12 (21.4)	28 (30.8) 25 (32.9)	
employed part time/sen-	37 (20.0)	14 (41.7)	20 (32.7)	
Unemployed/Student/	33 (25.0)	10 (17.9)	23 (30.3)	
Retired/Other			· · · ·	
Current smoker, n (%)	14 (10.4)	4 (6.9)	10 (13.0)	0.25
Currently drink alcohol, n (%)	67 (49.6)	31 (53.4)	36 (46.8)	0.44
Years since diagnosis for pelvic				0.04
pain/pelvic muscle spasm				
Unknown, n	5	3	2	
Median (IQR)	5.0 (2.0,	7.0 (4.0,	4.0 (2.0,	
	10.0)	10.0)	8.0)	
Range	(0.0,	(0.0, 46.0)	(0.0,	
	46.0)	(,	36.0)	
Other diagnoses, n (%)				
Endometriosis	97 (71.9)	33 (56.9)	64 (83.1)	0.00
Adenomyosis	15 (11.1)	8 (13.8)	7 (9.1)	0.38
Interstitial cystitis	12 (8.9)	5 (8.6)	7 (9.1)	0.92
Irritable bowel	36 (26.7)	8 (13.8)	28 (36.4)	0.003
Inflammatory bowel disease	8 (5.9)	3 (5.2)	5 (6.5)	1.00
Lower back injury	11 (8.1)	4 (6.9)	7 (9.1)	0.64
Hip injury	7 (5.2)	1 (1.7)	6 (7.8)	0.23
Other	21 (15.6)	10 (17.2)	11 (14.3)	0.63
Superficial dyspareunia, n (%)	21 (10.0)	10 (17.2)	11 (11.0)	0.00
Unknown	1	0	1	0.000
No	51 (38.1)	15 (25.9)	36 (47.4)	
Yes	67 (50.0)	31 (53.4)	36 (47.4)	
Not sexually active	16 (11.9)	12 (20.7)	4 (5.3)	
Deep dyspareunia, n (%)	10 (11.7)	12 (20.7)	т (3.3)	0.02
No	21 (15.6)	8 (13.8)	13 (16.9)	0.02
Yes	98 (72.6)	38 (65.5)	60 (77.9)	
Not sexually active	98 (72.0) 16 (11.9)	12 (20.7)	4 (5.2)	
Current prescription	10 (11.7)	14 (40.7)	т (3.4)	
medications for pain, n (%)				
Opioids	23 (17.0)	6 (10.3)	17 (22.1)	0.073
Anti-inflammatories	23 (17.0) 71 (52.6)	30 (51.7)	41 (53.2)	0.86
Muscle relaxants	71 (52.6) 19 (14.1)		41 (55.2) 11 (14.3)	
Neuroleptics		8 (13.8)		0.93
Neuroleptics Herbal medicine (not incl.	23 (17.0)	8 (13.8)	15 (19.5) 14 (18.2)	0.38
	18 (13.3)	4 (6.9)	14 (18.2)	0.05
cannabis)	17 (10 ()	0 (10 0)	0 (11 7)	0.71
Other	17 (12.6)	8 (13.8)	9 (11.7)	0.71
SOAPP total score $>$ 4, n (%)	46/132	15/57	31/75	0.07
SOAPP total score	(34.8)	(26.3)	(41.3)	0.00
SOAPP total score	3	1	2	0.00
Unknown, n Mean (SD)	3	1	2	
	3.2 (2.0)	2.6 (1.5)	3.6 (2.2)	
Range	(0.0,	(0.0, 6.0)	(0.0,	

pain if available: cannabis vaginal suppositories, vaginal creams, and external vulvar creams.

We carried out a descriptive analysis to evaluate the current use and acceptability of use of cannabis in female patients with MPP. We also compared demographics between cannabis users and non-users.

3. Results

We sent a total of 545 invitations and closed recruitment after receiving 135 complete questionnaire responses (Fig. A). 77 participants were cannabis users (57 %) and 58 were non-users (43 %). Differences in demographics, pelvic pain characteristics, and SOAPP scores between cannabis users and non-users are depicted in Table 1. The most common diagnosis associated with MPP in our cohort was endometriosis (71.9 %).

Among the 77 cannabis users, 61 (79.2%), 38 (49.4%), and 43 (55.8 %) reported using cannabis for pelvic pain, other medical reasons, and recreation respectively. Most users for pelvic pain (77%) started using cannabis because conventional treatments did not work, 63.9 % desired more natural treatment options, and 32.8 % were influenced by recommendations from others who had tried cannabis for pelvic pain. 48.1 % used cannabis daily, while 18.3 % reported using less than once a week. Most used products for pelvic pain were dried cannabis flowers/ leaves (68.9 %), edibles (60.7 %), and topicals (54.1 %). A small proportion of patients used CBD only or THC only products for pelvic pain (8.2 % and 1.6 % respectively). 86.9 % used products containing both CBD and THC. Evening (19:00-23:00) was the most common (82 %) time of day patients used cannabis for pelvic pain, however 31.1 % of patients reported using cannabis during the morning (06:00-10:00). Users reported spending an average of \$126.3 Canadian dollars on cannabis for pelvic pain per month (median \$80; range \$0-\$800). 52.5 % of participants had been using cannabis to treat pelvic pain for more than 2 years.

Participants rated effects of cannabis positively. On a scale of 0 (totally ineffective) – 10 (totally effective), 68.9 % of users rated the effectiveness of cannabis as 7 or higher at relieving pelvic pain. They also noted improvements in mood (75.4 %), sleep (91.8 %), physical health (62.3 %), physical mobility (70.5 %), mental health (77.0 %), home life (67.2 %), and quality of life (96.7 %). 73.8 % of users reported decreasing their use of other pain medications after starting to use cannabis for pelvic pain. About a third (31.1%) of users reported ever experiencing adverse effects from using cannabis for pain, most commonly unwanted feelings of being high (36.8 %), decreased attention span (36.8 %), dizziness (26.3 %), and anxiety (26.3 %).

Of the 58 non-cannabis users, 37 (63.8 %) would be willing to use cannabis for pelvic pain. For those not willing, the most common concerns were lack of information (47.6 %) and unwanted side effects (42.9 %). Six non-users (28.6 %) reported that they did not think cannabis use for pelvic pain was appropriate. 56.9 % of non-users had previously used cannabis for any reason but stopped mainly because of loss of interest (54.5 %), unwanted side effects (30.3 %) or inefficacy (18.2 %). Non-users willing to use cannabis for pelvic pain were most interested in consuming it orally (86.1 %), and were more willing to use edible, liquid, and topical cannabis products over dried flowers/ leaves and vaporizers. The average price per month non-users were willing to spend on cannabis for pelvic pain was \$83.10 Canadian dollars (median \$50, range \$0-\$300).

A large proportion of both cannabis users and non-users were willing to use gynecological cannabis products if available. Notably, 88.3 % of users and 72.9 % of non-users responded that they would be either likely or very likely to use a vaginal cannabis insert. 75.4 % of users and 75.6 % of non-users responded that they would be willing to use an internal vaginal cannabis cream. Finally, 82.9 % of users and 83.4 % of non-users responded that they would be willing to use an external vulvar cannabis cream (Fig. B).

4. Discussion

Our cross-sectional study provides a comprehensive description of cannabis use and willingness to use patterns in myofascial pelvic pain

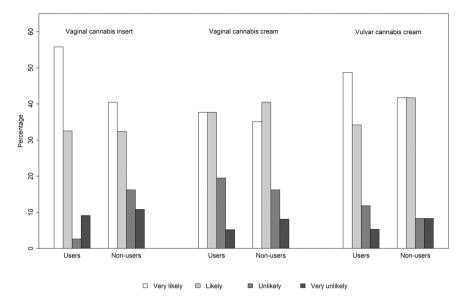


Fig. B. Willingness to use gynecological cannabis products if available.

patients for the broader research community. Most users turned to cannabis due to lack of effectiveness of conventional treatments, indicating a need for development of new therapeutic modalities.

Given that patients with MPP have great difficulty with vulvovaginal touching because of symptoms of vestibulodynia and vaginismus, it is particularly important to explore their willingness to use topical therapies. 50 % and 73 % of our participants noted pain at the superficial and deep vagina during penetration respectively. Although some demographic differences existed between users and non-users in our study, the majority of both considered vaginal and vulvar topical cannabis acceptable for use. One third of cannabis users in our study reported negative side-effects. The frequency of side-effects ranges up to 84 % in prior surveys [23]. Almost half of non-users in our study cited possible side-effects as detractors to use, and 30 % of non-users who had previously tried cannabis stopped due to unwanted side-effects. Cannabis products with topical application may have fewer side-effects but are not currently available in Canada. This highlights a potential pharmacologic therapy option deserving of further research for patients with MPP.

The Canadian Cannabis Survey (CCS) is administered annually by Health Canada and explores cannabis use behaviors in the general population. It asks about cannabis use for both medical and recreational purposes but does not go into details of the medical conditions. Cannabis users in our study were significantly younger than non-users (by approximately a decade). This is consistent with CCS results showing the highest reported prevalence of use among young adults [16]. Cannabis users compared to non-users in our study were less likely to be employed full time and had lower annual household incomes, however there were no differences in levels of education achieved. In the general population, the CCS found that Canadians with high school education or less had greatest proportions of cannabis use compared to those with higher levels of education [16]. It is possible that in patients with pain, a higher level of education may encourage exploration of unconventional therapies, such as cannabis [17–19,24].

The characteristics of cannabis use by our study participants are consistent with those of medical cannabis users, which tend to differ from purely recreational users in the amount consumed, THC content, and form of ingestion. We recently described patterns of cannabis use in a cohort of medical cannabis users at a dispensary in Vancouver, BC, where individuals would be subject to many of the same regulatory and environmental conditions as those in the present study [20]. In the dispensary study, medical users reported similar patterns of use, including amount consumed (most using 3.5–7 g per week), method of ingestion (70 % smoking), THC content (most using a THC:CBD mix)

and time of day (mostly 7–10 pm) [20]. These patterns of use are typical of medical cannabis users, where daily help is required and edibles provide a more sustained form of pain relief that can be supplemented by smoking/vaping for acutely; THC:CBD combinations offer the advantage of effective pain relief with reduced euphoric effects, while use in the evening minimizes impairment during days and can aid with sleep. Although oral consumption was the top choice of non-users willing to try cannabis, a larger proportion of non-users (77.8 %) were interested in trying cannabis via skin application compared to 27.3 % of users. This may reflect an openness of non-users to try novel or less conventional cannabis products.

It is unknown whether chronic use of cannabis for MPP might predispose some users to a Cannabis Use Disorder, which is associated with neurobiological changes [21]. There is evidence for CB1 upregulation in the reward pathway of those who use opioids, supporting the role of the endocannabinoid system in opioid abuse [22]. However, the potential for cannabis use in those with MPP to lead to opioid use has never been studied. Users in our study had a significantly higher SOAPP score than non-users, indicating a higher likelihood of addiction to opioids (mean 3.6 vs 2.6, p = 0.004). However, both users and non-users had a mean SOAPP score below the cut-off of 4 (which has a sensitivity of 0.86 and positive likelihood ratio of 2.59 for opioid addiction). Additionally, 73.8 % of cannabis users in our study indicated they were able to decrease their use of other pain medications. This is a higher proportion when compared to male and female participants who completed the medical portion of the CCS (57 % decreased) and may indicate better effects of cannabis on MPP when compared with other types of pain, or sex differences in outcomes [16]. This is a notable finding in the current climate of crisis with respect to opioids and their addictive effects.

Only one third of non-users had adequate pain management without cannabis and one half of them needed more information before attempting use. Legalization did not necessarily eradicate the stigma associated with cannabis use for pain. Educational initiatives on safety, tolerability and efficacy are needed in this context.

Strengths of our study include having a representative sample of patients with MPP from two pelvic pain clinics with various underlying conditions across ages, and well as including a non-cannabis user comparison group. Limitations of our study include possible participation bias from cannabis users in responding to our study; we addressed this to the best of our ability with a priori methodology to recruit at least 50 cannabis users and 50 non-cannabis users. As with most survey studies, our study also includes possible non-response bias as we are unable hear from non-responders. This is important to keep in mind when applying our results to the broader population of patients with MPP. Our study did not aim to establish prevalence but rather obtain a cross-sectional representation of details of use and willingness to use in a group of patients with MPP to inform further research. This was reflected in our recruitment goals. Moreover, willingness to disclose cannabis use remains low, with only 51 % of survey respondents more willing to publicly disclose in Canada post-legalization [16]. This causes inherent challenges for recruitment into cannabis use studies.

5. Conclusion

Many female patients are self-medicating with cannabis and ideally should be supported by rigorous pharmacological and clinical efficacy research. Our study provides detailed information about patient preferences with respect to cannabis products and informs further research into pharmacokinetics and the development of new therapeutic options which may be more acceptable and better tolerated. Finally, the potential for opioid use should be monitored in any future trial of cannabis in MPP.

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Declaration of conflicts of interest

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.eurox.2023.100192.

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