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Clinical Characteristics and Quality of Life in Adults Initiating Medical Marijuana Treatment

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Medical marijuana · Health-related quality of life · Clinical characteristics

Abstract
Introduction: Despite the rising availability and use of medical marijuana (MM) in the USA, little is known about the demographics, clinical characteristics, or quality of life of MM patients. This study describes the demographic characteristics and health-related quality of life (HRQoL) of MM patients who are initiating treatment in Pennsylvania. ***Methods:*** Two-hundred adults naive to MM and referred for any of the 23 state-approved qualifying conditions were recruited at three MM dispensaries in Pennsylvania between September 2020 and March 2021. All participants consented to the study; completed semi-structured interviews that included demographic questionnaires, the Short Form-36 (SF-36), and Generalized Anxiety Disorder-7 (GAD-7); provided height and weight measurements; and allowed access their dispensary medical records. ***Results:*** Participants had a mean age of 48.5 ± 15.6 years, predominantly identified as female (67.5%), and were most commonly referred for chronic pain (63.5%) and/or anxiety (58.5%). Additionally, 46.0% were living with obesity as determined by BMI. Relative to a normative sample, participants reported diminished HRQoL in several domains, most notably in role limitations due to physical health ($M = 46.0 \pm 42.0$), role limitations due to emotional problems ($M = 52.5 \pm 42.3$), energy and fatigue ($M = 39.8 \pm 20.2$), and pain ($M = 49.4 \pm 26.0$). ***Discussion/Conclusion:*** Patients initiating MM treatment experienced low HRQoL in multiple domains. Future studies could evaluate the relationship between HRQoL and patients' decisions to pursue MM treatment, as well as changes in HRQoL with MM use over time.

Introduction

Medical marijuana (MM) is currently legal in 36 US states and 4 territories [1] and is swiftly gaining traction as a therapeutic option for a range of health concerns [1]. Federally, MM continues to be classified as a Schedule I controlled substance [2], limiting the feasibility of conducting randomized controlled trials involving MM.

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Table 1. Characteristics of adults presenting for MM treatment at three Pennsylvania dispensaries (*N* = 200)

Demographic variable	Frequency	%	*M*	SD
Age, years			48.55	15.60
Monthly income, USD			2,650.10	2,386.80
Weight, pounds			189.81	50.21
Height, inches			66.39	3.88
BMI, kg/m^2			30.18	7.15
Underweight	1	0.50		
Healthy weight	44	22.00		
Overweight	63	31.50		
Obese	92	46.00		
Biological sex				
Male	65	32.50		
Female	135	67.50		
Race				
White	189	94.50		
Black	6	3.00		
Asian	2	1.00		
American Indian	0	0		
Alaska Native	0	0		
Hawaiian/Pacific Islander	0	0		
Mixed	2	1.00		
Other	1	0.50		
Ethnicity				
Hispanic or Latinx	5	2.50		
Non-Hispanic or Latinx	195	97.50		
Education				
Some high school	6	3.00		
High school diploma or equivalent (GED)	50	25.00		
Some college	33	16.50		
Trade/technical/vocational training	12	6.00		
Associate's degree	21	10.50		
Bachelor's degree	53	26.50		
Master's degree	21	10.50		
Doctorate	4	2.00		
Marital status*				
Single (never married)	49	24.50		
Married	114	57.00		
Domestic partnership	2	1.00		
Separated	4	2.00		
Divorced	22	11.50		
Widowed	7	3.50		
Living situation				
With partner and children	68	34.00		
With partner alone	62	31.00		
With children alone	7	3.50		
With parents	11	5.50		
With family	18	9.00		
With friends	8	4.00		
Alone	25	12.50		
Controlled environment	1	0.50		
Employment status (past 3 years)				
Full-time (40 h/week)	101	50.50		
Part-time (regular hours)	15	7.50		
Part-time (irregular hours)	11	5.50		
Student	12	6.00		
Retired/disability	50	25.00		
Unemployed	11	5.50		

* Marital status unknown for 2 participants.

Without data from large, randomized clinical trials of MM for the treatment of qualifying conditions (which vary by state), there is little clarity regarding safety, efficacy, or appropriate dosing of MM for these conditions [3, 4]. A review of MM clinical trials found the strongest evidence to support its efficacy for the treatment of chronic pain, neuropathic pain, and spasticity associated with multiple sclerosis [5]. Currently, there is a paucity of randomized, controlled trials supporting the efficacy of MM for the treatment of post-traumatic stress disorder and anxiety disorders [6, 7].

Despite the burgeoning availability and use of MM, relatively little is known about the characteristics, health-related quality of life (HRQoL), and psychosocial functioning of MM patients. Studies of patients in Florida [8] and California [9] reported chronic pain, anxiety, stress, and insomnia to be the most common complaints or conditions prompting referrals for MM. Among chronic pain patients in Ohio considering MM, 67.6% wanted to reduce their use of opioid medications, and 93.6% were amenable to following physician recommendations regarding the use of opioids and MM concurrently [10]. Additionally, a study of patients seeking MM cards in Michigan found lower self-perceptions of general health in this population compared to adult respondents in a statewide Behavioral Risk Factor Survey [11].

In 2016, Pennsylvania became the 24th US state to legalize MM, and the product is now available in a variety of forms including pills, oil, tincture, and dry leaf for the treatment of 23 medical conditions (Table 1) [12]. The current observational study sought to describe the demographic and clinical characteristics, including HRQoL, of patients initiating MM treatment for any of these approved conditions at three dispensaries in central Pennsylvania.

Materials and Methods

Inclusion/Exclusion Criteria

Patients were eligible to participate if they were 18 years of age or older, prescribed MM for any approved medical condition, and had not previously initiated MM treatment (i.e., this was their first MM treatment episode). Patients who presented with cognitive impairment that precluded informed consent, reported heavy recreational marijuana use, or were not English speaking were excluded from the study.

Procedure

Participants were recruited between September 2020 and March 2021 at three dispensary locations in central Pennsylvania. Interested patients were introduced to research staff utilizing a "warm handoff" from the dispensary pharmacist. Pharmacist consultations were conducted via phone, and patients who expressed interest in the study were transferred to the on-site research staff. Interested patients that met the eligibility criteria were invited for a brief in-person meeting at the dispensary to complete the informed consent process and select assessments (i.e., cognitive assessments, height, and weight). The remaining baseline study measures were administered via phone within 1 week of the completion of informed consent. Participants who completed the baseline assessment were remunerated 25 USD and offered a discount on their MM purchases. In total, the baseline in-person and phone appointments took approximately 60–90 min to complete. Of the 245 patients approached for study participation, 200 provided consent and were enrolled (81.63%). The most common reasons for declining to participate were not having time to complete study activities and preferring to begin use of MM before the scheduled date for the baseline assessment.

Table 2. Frequencies of MM referral reason and pharmacist medication recommendation ($N = 200$)*

Condition	Total	%
Chronic pain	127	63.50
Anxiety	117	58.50
PTSD	16	8.00
Neuropathies	11	5.50
Cancer	12	6.00
IBS	12	6.00
Damage to nervous tissue	6	3.00
Multiple sclerosis	5	2.50
Glaucoma	3	1.50
Crohn's disease	2	1.00
Parkinson's disease	2	1.00
Dyskinetic disorder	1	0.50
Sickle cell anemia	1	0.50
Autism	1	0.50
ALS	1	0.50

* Participants may be referred for more than one condition. PTSD, post-traumatic stress disorder.

Measures

All survey and anthropometric measures were administered at baseline for the current study.

Montreal Cognitive Assessment

The Montreal Cognitive Assessment (MoCA-B) screens for cognitive impairment in six domains: visual perception, executive functioning, language, attention, memory, and orientation [13]. The maximum score on the MoCA-B is 30 with lower scores indicating greater impairment and a cutoff of 26 considered normal cognitive functioning.

36-Item Short-Form Health Survey

The 36-Item Short-Form Health Survey (SF-36) is a structured clinical interview assessing general health in terms of overall functioning and well-being [14]. The SF-36 measures HRQoL in eight domains: physical functioning (limitations in performing daily ac-

Table 3. Means and standard deviations for the SF-36 composite scales in the MM patients (*N* = 200) and MOS participants (*N* = 2,471) [18, 19]

	MM patients (*N* = 200)		MOS study patients [19] (*N* = 2,471)	
	M	SD	*M*	SD
Physical functioning	69.67	27.99	70.61	27.42
Role limitations due to physical health	46.00	42.05	52.97	40.78
Role limitations due to emotional problems	52.50	42.33	65.78	40.71
Energy/fatigue	39.80	20.16	52.15	22.39
Emotional well-being	63.32	19.48	70.38	21.97
Social functioning	64.06	28.02	78.77	25.43
Pain	49.45	26.00	70.77	25.46
General health	54.74	24.78	56.99	21.11

tivities due to physical health), role limitations due to physical challenges (difficulties performing normal roles at work, school, or home due to physical challenges), emotional well-being (general mental health), role limitations due to emotional challenges (difficulties performing normal roles at work, school, or home due to emotional challenges), social functioning (ability to socialize given physical and/or mental health challenges), energy/fatigue (general vitality), pain (current levels of bodily pain), and general health (current perceptions of overall health). Lower scores indicate lower functioning in each domain.

The SF-36 is normed using data from adults in the Medical Outcomes Study (MOS, Table 3). We felt comparison of our participants' scores on HRQoL to MOS norms appropriately given that the MOS study recruited patients with a high prevalence of chronic health conditions and were seen in family medicine, general internal medicine, cardiology, or psychiatry/psychology in health centers from four US census regions.

Problem Severity Rating

Participants reported the current severity of their primary referring condition on a scale ranging from 1 to 10, with 10 being the most severe.

Generalized Anxiety Disorder-7 Item Scale

The Generalized Anxiety Disorder-7 Item Scale (GAD-7) [15] is a seven-item scale assessing symptoms of anxiety and their impact on functioning in the past 2 weeks using a Likert-type scale. Scores of 0, 1, 2, and 3 are assigned to four response categories, indicating the frequency with which the participant experienced symptoms. Scores on each question are then added together for a total score between 0 and 21. Scores of 0–4, 5–9, 10–14, and 15–21 represent minimal, mild, moderate, and severe levels of anxiety, respectively.

Anthropometric Measures

Research staff collected participants' heights (in) and weights (lbs.) (SECA 813; SECA Corp., Chino, CA, USA) with no shoes and light clothing. BMI (kg/m^2) was calculated using these measurements.

Demographic and Medical Information

Participants reported their biological sex at birth, identified gender, age, marital status, race/ethnicity, education, socioeconomic status, medical diagnoses, and the medical reason for their marijuana recommendation. Information from participants' dispensary records, including referring condition, route of administration and MM products' prescribed dose, and the frequency of MM use, was also recorded.

Statistical Analyses

Descriptive statistics (e.g., means, standard deviations, and percentages) were calculated to characterize the sample in terms of demographic and clinical characteristics, functional status, and HRQoL at treatment initiation.

Results

Demographic and Clinical Characteristics

Participants (*N* = 200) had a mean age of 48.5 ± 15.6 years, and the majority were female (67.5%), married (57.0%), and White (94.5%) with an average monthly income of 2,650.1 ± 2,386.8 USD (Md = 2,000 USD). Participants' mean BMI was 30.18 ± 7.15 kg/m^2, and 46.0% were living with obesity (Table 1). More than three-quarters of the sample (78%) reported no significant history of recreational marijuana use. The most common methods of administration for MM were tincture (47%), topical (32.5%), and hybrid cartridge (31%). Additionally, 27% of participants endorsed currently using any prescribed psychotropic medication.

The most common reasons for MM referral were to treat chronic pain (63.5%), anxiety (58.5%), and/or posttraumatic stress disorder (8.0%) (Table 2). Overall, participants endorsed moderate referral condition severity ratings (6.78 ± 2.01).

HRQoL

Participants (N = 200) reported low levels of HRQoL in multiple domains relative to normative data, most notably in role limitations due to physical health (46.0 ± 42.0), role limitations due to emotional problems (52.5 ± 42.3), energy and fatigue (39.8 ± 20.2), and pain (49.5 ± 26.0, Table 3). Participants presenting with only chronic pain reported a mean pain score of 40.2 ± 20.7. Furthermore, participants also reported diminished HRQoL as measured by the physical and mental composite scores from the SF-36 (38.66 ± 19.95; 31.91 ± 20.96, respectively). SF-36 scores for the current sample of MM patients, as well as patients with chronic conditions from the MOS, are in Table 3 [12].

Cognition

Participants' (N = 197) mean MoCA score was 25.83 ± 3.57. Mean scores for the MoCA-B domains were as follows: executive functioning = 4.27, naming = 2.93, attention = 5.29, language = 2.38, abstraction = 1.67, delayed recall = 3.47, and orientation = 5.88.

Anxiety

Participants (N = 200) reported mean GAD-7 scores of 7.57 ± 5.50, indicating mild levels of anxiety. Average GAD-7 scores in participants who presented with anxiety as a referring condition were 9.53 ± 5.14, indicating mild to moderate levels of anxiety.

Discussion/Conclusion

This study is among the first to describe the biopsychosocial profiles of patients presenting for MM treatment. Several findings are noteworthy. First, the most common referral conditions of participants in the sample were chronic pain and anxiety, which is consistent with findings from previous studies in this area [8, 9]. Collectively, our findings suggest that patients with chronic pain or anxiety may pursue alternative therapies for symptom relief beyond prescription medications or psychotherapy. It is possible that the addictive potential of certain prescription medications for these particular disorders (e.g., benzodiazepines, opioids), the limited but growing evidence base supporting the efficacy of MM for these conditions [5, 16, 17], and/or lack of symptom relief or resolution from other types of treatment may contribute to the decision to pursue MM in individuals living with chronic pain or anxiety. Alternatively, physicians may be more willing to recommend MM for chronic pain and anxiety compared to other qualifying conditions. This trend could also be an artifact of the higher prevalence of these conditions when compared to many of the other qualifying conditions in Pennsylvania. Future studies including qualitative interviews with patients who have these conditions and/or their referring health care providers could offer more clarity regarding decision-making related to initiating MM. Finally, in our study, we utilized the SF-36 [14] to assess pain, which asks respondents to both rate the severity of their pain over the past 4 weeks, as well as how pain has interfered with their normal activities. While this SF-36 scale is well-validated and widely used, future studies should consider utilizing more comprehensive pain measurements to obtain a better understanding of pain levels and its impact on functioning in MM patients.

In our study, 67.5% of participants in the current study identified as female. This high rate of female study participation may be due to a number of factors. Prior research suggests that females are more likely to be diagnosed with chronic pain and anxiety disorders than males, and more are likely to use MM [18–20]. In addition, females are more likely to utilize other complementary and alternative medicines than males [21] and are less likely to report satisfactory pain relief from commonly prescribed pain medications [22].

It is important to note that 46.0% of this predominantly White sample lived with obesity, which is approximately 7% higher than obesity rates reported in White adults in the general US population (39.8%) [23]. The high rate of chronic pain patients in our sample, who may experience limited mobility [24], may have contributed to these elevated rates. Patients with chronic pain had significantly higher rates of obesity (p = 0.038) when compared to the rest of the sample. Nonetheless, changes in body weight may be an important clinical factor to monitor as MM treatment progresses, particularly in patients presenting with obesity.

MM patients reported diminished HRQoL in several areas when compared to patients with chronic health conditions in the MOS [12] and others [25]. Specifically, participants reported mean HRQoL pain scores that were 30% lower (indicating reduced functioning due to pain), and energy/fatigue scores that were 24% lower than the MOS sample. They also reported notable limitations in physical and emotional functioning, even relative to those observed in another study of MM patients [25]. Given the perceived improvements in anxiety associated with marijuana for some users [26], future studies are needed to understand the impact of MM treatment on HRQoL over time. Finally, it is possible that the diminished HRQoL observed in this

study may be attributed to the COVID-19 pandemic. In all, these findings emphasize the need to further understand the factors influencing baseline characteristics in patients referred for MM.

Most participants' cognitive functioning, as measured by the MoCA, was within a normal range. The MoCA was utilized previously as a screening tool for global cognitive functioning impairment in patients with cancer using MM compared to nonusers [27], and no significant differences were found over the first 3 months of MM use. However, cognitive impairment can be associated with several of the qualifying conditions for MM (e.g., amyotrophic lateral sclerosis, epilepsy, Huntington's disease) or alternatively can develop as a side effect of the traditional treatment of them (e.g., «chemo brain»). Therefore, screening for cognitive impairment prior to MM initiation could help to identify patients that may require additional support to adhere to their recommended MM regimen and, in turn, maximize the potential benefits of this therapeutic approach.

The current study had several strengths. First, well-validated measures examined patient characteristics and assessed functioning. Additionally, the high percentage of eligible individuals recruited (81.63%) and large sample size support the generalizability of our findings. The study also had several limitations. This study was observational, did not employ an experimental design, and did not examine changes in functioning over time. Although it is likely that most patients engaging in MM treatment expect their health-related functioning, including limitations related to pain, to improve, it is plausible that the potential adverse effects of regular use could also negatively impact various domains of quality of life. Longitudinal studies that incorporate rigorous experimental designs would help to better clarify potential positive or negative changes in functioning associated with MM use. Despite these limitations, the current study furthers understanding of the biopsychosocial profiles of individuals initiating MM treatment in Pennsylvania.

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Statement of Ethics

This study protocol was reviewed and approved by the Institutional Review Board at the Philadelphia College of Osteopathic Medicine and given the approval number H17-060. Written informed consent was obtained from all participants to participate in the study.

Conflict of Interest Statement

The authors have no conflicts of interest to disclose.

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Author Contributions

Michelle R. Lent, PhD, Karen L. Dugosh, PhD, and David S. Festinger, PhD, conceived and carried out the study. Paulina Syracuse, MS, managed the data and conducted analyses. Lydia S. Buonomano, Thomas R. McCalmont, Matthew M. Mitnick, and Michelle R. Lent, PhD, conducted the literature review. Lydia S. Buonomano, Thomas R. McCalmont, Matthew M. Mitnick, and Michelle R. Lent, PhD, drafted the initial manuscript. All the authors were involved in writing the paper, and five of the six manuscript authors approved the final version of this manuscript; however, one author, David S. Festinger, PhD, passed away prior to this submission. His significant contributions to this study and to the initial manuscript drafts warrant inclusion as an author.

Data Availability Statement

At this time, all data, study materials, and analysis code for this study are not publicly available because data collection is ongoing. All study data will be made publicly available when the study concludes via Dryad at https://doi.org/10.5061/dryad.n8pk0p2xq. This study was not preregistered. There has been no prior dissemination of the data nor the narrative interpretations found in this manuscript.

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