THE CBD CRAZE: MAKING A CASE FOR OBSERVATIONAL CLINICAL DATA TO ASSESS MEDICAL CANNABIS TREATMENT EFFECTIVENESS

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INTRODUCTION

Cannabidiol (CBD) has quickly become the primary cannabinoid of interest and has had a huge increase in attraction following recent regulatory changes

- CBD is non-intoxicating, anticonvulsant, anxiolytic.[1]

- CBD has a favourable safety profile[2]

- Touted as a panacea for a wide range of health problems [3]

- Marketed as a dietary and 'wellness' product

Validation of the therapeutic expectations of CBD products lags behind and does not represent clinical settings where THC products is often required

- Limited results from randomized controlled trials [3]

- Lack of trust in product quality

- No clinical guidelines and dosages

Real-world evidence (RWE) may provide critical information for patients and healthcare professionals

STUDY OBJECTIVE

Investigate the difference in treatment effectiveness between CBD-rich treatments and THC:CBD treatments over 6 months

METHODS

SAMPLE: Adult patients without an history of psychotic disorders and available baseline data
DESIGN: Data collected between July 2017 and July 2019
MEASURES:

- Edmonton Symptom Assessment Scale (ESAS-r): symptom burden from 0 to 10

- Brief Pain Inventory-short form (BPI-sf): pain severity and pain interference with daily life from 0 (no pain) to 10 (worst pain)

- EuroQol Quality of Life measure (EQ-5D-5L): patients self-rated health on a VAS from 0 "the worst health" to 100 "the best health "

TIME POINTS: Baseline (BL); 3-month follow-up (FUP1); 6-month follow-up (FUP2)

GROUPS: CBD-rich (CBD) group ; THC:CBD group at baseline.

ANALYSES: One-way between-groups analyses of variance (ANOVA) for Mean score comparison

RESULTS

Groups	BPI Severity		BPI Interference		ESAS Pain		ESAS Tiredness		ESAS Drowsiness		ESAS Nausea		ESAS Lack of Appetite		ESAS Shortness of breath		ESAS Depression		ESAS Anxiety		ESAS Wellbeing		EQ5D Overall Health	
	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD	CBD-Rich	THC:CBD
Baseline	5.60	5.46	5.22	5.23	5.23	5.27	5.61	5.78	3.05	2.98	0.99	1.40	2.12	2.59	2.14	2.11	3.23	3.23	3.75	3.93	5.56	5.09	55.89	53.73
FUP1	4.95	4.76	4.21	4.15	4.43	4.37	4.90	4.91	2.60	2.48	0.91	1.29	1.76	2.19	1.65	1.61	2.47	2.74	3.05	3.44	4.53	4.39	59.77	61.15
FUP2	4.81	4.59	4.26	4.17	4.54	4.29	4.85	4.18	2.41	1.75	1.05	1.07	1.80	2.07	1.92	1.63	2.65	2.88	2.84	3.23	4.48	3.95	61.09	63.52

Table 1. Mean scores of outcomes measures across visits

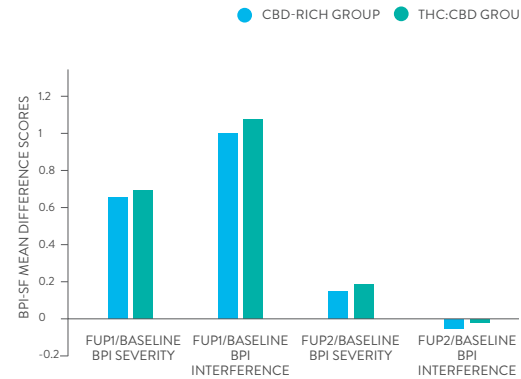|	CBD-Rich	THC:CBD
N patients (complete effectiveness data)		
BL	541	380
FUP1	339	158
FUP2	113	52
Age		
Min	18	20
Max	96	88
Mean	61.09	52.91
Std Dev	17.05	14.97
Gender (%)		
Female	68%	60%
Male	32%	40%
Primary Diagnosis (%)		
Pain	66.40%	56.80%
Neurological disorder	7.80%	7.10%
Cancer	7.40%	10.50%
Mood disorders	6.90%	11.30%
Inflammatory disease	5.50%	0.30%
Other	2.70%	3.90%
Gastrointestinal disorder	1.80%	1.30%
Headaches	1.00%	1.30%
Missing data	0.30%	6.60%
Cardiovascular disorder	0.10%	0.00%
Auto-immune disorder	0.10%	0.80%

Table 2. Demographics
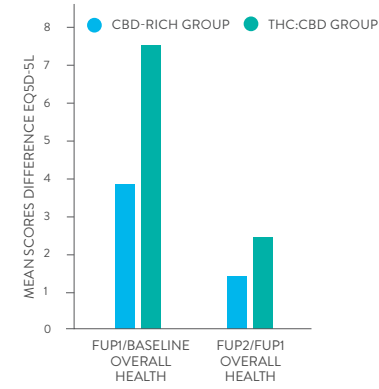

Figure 1. BPI-SF mean scores differences
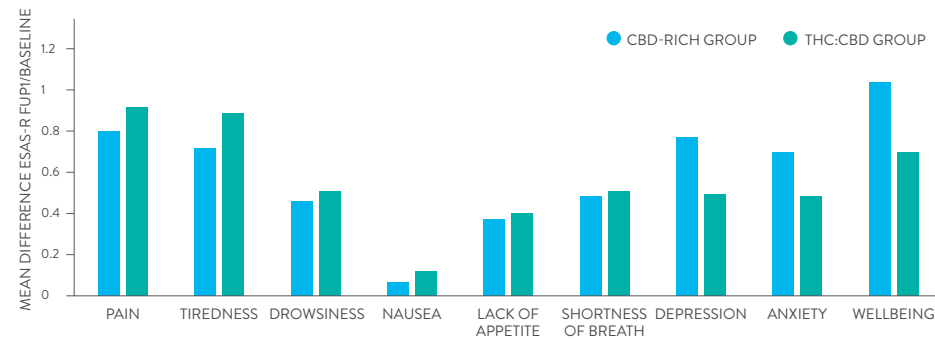

Figure 2. EQ5D-5L mean scores differences

Figure 3. ESAS-r mean scores differences

- Statistically significant (p <0.05) improvement between baseline and FUP1 for both groups on:

1. **BPI-SF:** Pain severity and Pain interference (Figure 1)
2. **EQ5D-5L:** Overall health (Figure 2)
3. **ESAS-r:** Pain, Tiredness , Wellbeing (Figure 3)

- **THC:CBD group** showed a larger improvement for: BPI-SF Pain severity and interference (Figure 1), ESAS-r pain, tiredness, drowsiness, nausea, lack of appetite, shortness of breath (Figure 3)

- **CBD-rich group** showed stronger improvement for depression, anxiety and wellbeing (ESAS-r) (Figure 3)

- Small not statistically significant differences between FUP1 and FUP2

DISCUSSION/CONCLUSION

- Results indicate the necessity of both CBD and THC-based treatments to improve treatment effectiveness across a diverse patient population

- Deeper investigation is required to validate the findings and control for potential biases (e.g. potential misclassification biases and selection biases)

- Continued prohibition of cannabinoid-based or specifically THC-based products within CBD-only medical cannabis frameworks limits research opportunities

- Canada serves as a regulatory model and an opportunity for real-word data collection in controlled clinical settings

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2. Chesney, Edward, Dominic Oliver, Alastair Green, Simina Sovi, Jack Wilson, Amir Englund, Tom P. Freeman, and Philip McGuire. "Adverse Effects of Cannabidiol: A Systematic Review and Meta-Analysis of Randomized Clinical Trials." Neuropsychopharmacology (2020/04/08 2020). https://doi.org/10.1038/s41386-020-0667-2. https://doi.org/10.1038/s41386-020-0667-2
3. Larsen C, Shahinas J. Dosage, efficacy and safety of cannabidiol administration in adults: a systematic review of human trials. Journal of Clinical Medicine Research. 2020;12(3):129.