HEALTH OUTCOME COMPARISONS BETWEEN EPILEPSY PATIENTS WHO USE VERSUS DON'T USE CANNABINOID PRODUCTS

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INTRODUCTION

- Epilepsy is a class of serious neurologic disorders that is difficult to treat and rare forms may not respond to standard clinical interventions.
- Individuals with epilepsy are turning to or are considering use of various hemp and cannabis products for symptom relief.
- Outside of randomized clinical trials, minimal systematic data has been collected to assess health outcomes among patients with epilepsy who endorse use of medicinal cannabinoids.

STUDY AIMS

- Characterize basic demographics, health characteristics, and health care utilization among epilepsy patients enrolled in a large observational research registry (ORR) that includes cannabis users and controls.

METHODS

Observational Research Registry

- **Realm of Caring (RoC)**: Non-profit foundation that strives to improve understanding of the therapeutic use of cannabinoids through research and education. Currently maintains a large patient registry, members are invited to participate in observational studies.

Participants

- 397 adult patients or caregivers of adult or child epilepsy patients registered with the RoC and participated in a web-based observational research study.

Survey Assessments

- Locally-developed demographic, health, and cannabinoid use questions.
- Hospital Anxiety and Depression Scale (HADS).
- Pittsburgh Sleep Quality Index (PSQI) or Children's Sleep Habits Questionnaire (CSHQ).
- World Health Organization Quality of Life Questionnaire (WHOQOL).

Statistical Analyses

- Chi-Square or 2-tailed t-tests with level of significance set to p<.05.

RESULTS

Table I. Baseline Epilepsy Patient Demographic Characteristics

	Cannabinoid Users N=256	Controls N=141	p-value
Age, Mean (SD)	23.3 (16.5)	20.2 (15.8)	ns
Sex, N (%)			ns
Male	110 (43.0)	66 (46.8)	
Female	138 (53.9)	74 (52.5)	
Not Reported/Unknown	8 (3.1)	1 (0.7)	
Race/Ethnicity, N (%)			ns
Caucasian	177 (69.1)	108 (76.6)	
Non-Caucasian	63 (24.6)	30 (21.3)	
Not Reported/Unknown	16 (6.3)	3 (2.1)	
Education, N (%)			ns
High School	88 (34.4)	44 (31.2)	
No High School	137 (53.5)	89 (63.1)	
Not Reported/Unknown	31 (12.1)	8 (5.7)	

Note: ns=not significant.

RESULTS

Table II. Patient Health Characteristics and Healthcare Service Utilization in the Past Month

	BASELINE (N=397)			INITIATORS (N=23)		
	Cannabinoid Users	**Controls**	**p-value**	**Baseline**	**Follow-Up**	**p-value**
Quality of Life (WHOQOL)	3.5 (1.2)	3.4 (1.2)	ns	3.2 (1.3)	4.1 (0.9)	**p<.05**
Health Satisfaction (WHOQOL)	2.6 (1.2)	2.3 (1.1)	**p<.05**	2.1 (1.1)	3.0 (1.2)	**p<.05**
Child Sleep (CSHQ)*	28.7 (10.3)	33.0 (11.0)	**p<.01**	32.3 (10.2)	26.2 (11.3)	**p<.05**
Adult Sleep (PSQI)*	8.1 (4.0)	10.7 (3.8)	**p<.01**	13.2 (3.3)	9.2 (4.7)	**p<.05**
Anxiety (HADS)*	6.5 (4.7)	7.6 (5.2)	**p<.05**	7.9 (5.5)	5.8 (4.3)	**p<.05**
Depression (HADS)*	4.5 (4.3)	5.8 (4.9)	**p<.01**	7.1 (5.3)	2.9 (3.0)	**p<.01**
# Prescription Medications	3.3 (2.0)	3.6 (2.1)	ns	3.8 (2.2)	3.0 (1.9)	ns
# Over-the-Counter Medications	2.4 (1.4)	2.1 (1.4)	ns	2.7 (1.6)	2.0 (1.1)	p=.06
% With Outpatient Visits	66%	77%	**p<.05**	74%	65%	ns
% With Emergency Room Visits	29%	44%	**p<.05**	22%	9%	ns
% With Hospital Admissions	20%	35%	**p<.05**	17%	4%	ns
% With Sick Days (Work/School)	52%	62%	ns	70%	44%	ns

Note: ns=not significant. * denotes items where lower scores mean better outcomes

Table III. Epilepsy-Specific Outcomes Among New Cannabinoid Initiators

	Baseline Mean (SD)	Follow-Up Mean (SD)	p-value
Seizure Activity (Past Month)			
# of Seizures	42 (45)	17(7)	**p<.01**
Length of Seizures (sec)	207 (44)	136 (41)	p=.06
Outpatient/Hospital Visits (Past Month)			
Seizure-Related Outpatient Visits	3.3 (3.9)	1.1 (2.3)	**p<.05**
Seizure-Related ER Visits	0.8 (0.7)	0.1 (0.4)	**p<.01**
Seizure-Related Hospital Admissions	0.6 (1.1)	0.1 (0.3)	**p<.05**
5 of 23 Reported No Seizure Activity in Past Month			

Table V. Cannabinoid Products and Characteristics Among Users

	N = 256
Product Chemotype Most Often Used	
CBD dominant	68%
THC dominant	1%
CBD:THC balanced	1%
Other (THC-A, CBG, CBN)	<1%
Not Reported/Unknown	29%
CBD Product Dose Among Initiators (N=21)	Mean: 96mg/day Range: 16 – 425mg/day Mean: 2mg/kg Range: 0.3mg/kg – 8mg/kg
Physician Recommended Use	
No	31%
Yes	30%
Declined to Answer	39%
Use of Cannabinoids for Epilepsy Was	
First Line Treatment	6%
Second Line Treatment	13%
Adjunct to Other Treatment	44%
Last Resort Treatment	32%
Declined to Answer	5%

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Table IV. "*How has therapeutic use of cannabinoids helped?*" (N=256)

	Percent of Epilepsy Patients Spontaneously Reporting
Desirable Effects	
Reduced Seizure Frequency	56%
Reduced Seizure Duration	13%
Reduced Seizure Severity	18%
Improved Cognition	19%
Improved Mood	14%
Improved Anxiety	7%
Improved Sleep	10%
Reduced Other Medication Use	13%
Undesirable Effects	
Increased Seizure Frequency	5%
Interactions with Epilepsy Medications	2%
Gastrointestinal Disturbance	2%

CONCLUSIONS

- Epilepsy patients predominantly use CBD products, and initiate cannabinoid use after other treatment options fail.
- Across multiple domains, cannabinoid users reported better health compared with demographically similar controls who were not using cannabinoids.
- Among the subset who initiated cannabinoid use after baseline, health outcomes improved across most domains assessed.
- Though limited to self-report from a convenience sample, the data indicates positive health benefits of CBD use among individuals with epilepsy.

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DISCLOSURES

- Dr. Vandrey is a paid consultant to Zynerba Pharmaceuticals, Insys Therapeutics, and Battelle Memorial Institute. Dr. Bonn-Miller is an employee of Zynerba Pharmaceuticals and is a paid consultant to Tilray.