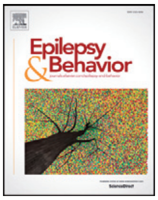
Epilepsy & Behavior 70 (2017) 364–369

Contents lists available at ScienceDirect

Epilepsy & Behavior

journal homepage: www.elsevier.com/locate/yebeh



Social correlates of health status, quality of life, and mood states in patients treated with cannabidiol for epilepsy

Magdalena Szaflarski [a,*], Barbara Hansen [a], E. Martina Bebin [b], Jerzy P. Szaflarski [b]

[a] Department of Sociology, University of Alabama at Birmingham, HHB 460H, 1720 2nd Ave South, Birmingham, AL 35294-1152, USA
[b] UAB Epilepsy Center, Department of Neurology, University of Alabama at Birmingham, 312 Civitan International Research Center (CIRC 312), 1720 2nd Avenue South, Birmingham, AL 35294-0021, USA

ARTICLE INFO

Article history:
Accepted 12 December 2016
Available online 21 February 2017

Keywords:
Cannabidiol
Epilepsy
Social determinants of health
Health disparity
Patient-centered outcomes
Quality of life

ABSTRACT

Social characteristics, such as socioeconomic status and race/ethnicity, play a role in the treatment and outcomes of patients with epilepsy (PWE), but little is known about how these factors affect patients receiving cannabidiol (CBD) to treat seizures. This exploratory study examined the sociodemographic profile of patients treated with CBD ($n = 80$) and associations between social factors and patient-centered outcomes – overall health status, Quality of Life in Epilepsy-89 (QOLIE-89), and Profile of Mood States (POMS) – in this population. Associations were examined using Pearson correlations and multiple ordinary-least-squares regression ($\alpha = 0.1$). The sample was predominantly white (96%) and non-Hispanic/Latino (96%); 76% of patients had family incomes of $40,000+/year. Some patients/families reported experiencing food scarcity (13%), not being able to make ends meet (6%), or not being able to afford antiepileptic medications (8%). The patients' health ratings declined with age and income ($p \le 0.014$), and there was a statistically significant interaction ($p < 0.055$) between these variables: for example, a higher-income 10-year-old had a predicted health rating of 3 ("very good"), followed by a higher-income 40-year-old with a rating of 2 ("good"), a low-income 10-year-old with a rating of 1 ("fair"), and a low-income 40-year-old with a rating of 0 ("poor"). This is the first study reporting the social profile of patients taking pharmaceutical grade CBD for the treatment of epilepsy. The results suggest that despite free access to this treatment some patients may not be accessing CBD because of their socioeconomic situation or race/ethnicity. Larger, diverse samples and longitudinal data are needed to more accurately model social factors and patient-centered outcomes in PWE receiving CBD.

This article is part of a Special Issue entitled "Cannabinoids and Epilepsy".

1. Introduction

How individuals fare in sickness and in health depends on their social position. Social characteristics, such as socioeconomic status (SES) and race/ethnicity, play an important role in the treatment and outcomes of patients with epilepsy (PWE) [1], but little is known about how these factors affect patients receiving cannabidiol (CBD) therapy to treat seizures. This exploratory study examined the sociodemographic profile of patients being treated with CBD oil and the association between social factors and patient-centered outcomes – overall health status, Quality of Life in Epilepsy-89 (QOLIE-89) [2], and Profile of Mood States (POMS) [3] – in this population. This paper also provides an introductory conceptual framework for future investigations of social factors and patient-centered outcomes in cannabis-based therapies to treat epilepsy and other disorders.

1.1. CBD treatment for epilepsy in Alabama

In 2016, Carly Chandler of Birmingham, Alabama was 5 years old and had CDKL5, a rare neurological disorder that has no cure or treatment [4]. For most of her life, Carly has experienced 200–300 seizures a day lasting up to 20–30 min; she has not been able to talk or walk. In 2014, Dustin Chandler, Carly's father, approached the Alabama state legislature about legalizing CBD oil for treatment of seizures. Despite initial resistance, he went "door-to-door" showing the lawmakers videos of his convulsing child, and ultimately convinced them of the importance of compassionate access to CBD as a treatment for epilepsy. In April of 2014, Alabama passed legislation titled Carly's Law, which authorized the use of CBD oil as part of a clinical study conducted at the University of Alabama at Birmingham.

Carly is now one of the participants in the study, which is testing the safety and tolerability of the oil for patients with treatment-resistant seizures. She currently has only 3–4 seizures per day, often very short in duration, and she has several days at a time without any seizures. Her cognitive ability has reportedly improved, and she has taken her

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* Corresponding author.
E-mail addresses: szaflam@uab.edu (M. Szaflarski), barbarap@uab.edu (B. Hansen), ebebin@uabmc.edu (E.M. Bebin), szaflaj@uab.edu (J.P. Szaflarski).

http://dx.doi.org/10.1016/j.yebeh.2016.12.033
1525-5050/

first steps. Dustin Chandler hopes that the oil can help treat other people: "[T]his was just the beginning to allow more people to get help. It was never about my daughter (…) if it didn't help her, if it could help one other child or adult, it made it all worth it" (p. 95) [4]. Although Dustin Chandler called for expanding access to CBD oil, and the UAB study does not charge patients for the drug, it is unclear if access to this treatment is open to individuals of any social standing. As we explain below, there are disparities in epilepsy and epilepsy treatment by SES and other social characteristics, which may prevent some PWE from taking advantage of this treatment.

1.2. Social determinants of health

The key social factors that affect health are referred to as social determinants of health (SDH), which are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems (e.g., social norms, economic and health systems) that shape the conditions of daily life [5]. Social determinants of health also interact with biological factors in shaping individual and population-level outcomes and are the main driver of health inequalities [6,7]. Individual-level SDH most often studied include SES, race/ethnicity, age, and gender.

Socioeconomic status refers to a person's social position and life chances based on educational attainment, income, and occupational status. Socioeconomic status of children and youth is typically assessed by using parental or family SES. The SES-health link is well established: the higher the SES, the higher the health status of an individual or group. Most evidence points to the causal mechanism in which SES affects health, but a reverse process has also been demonstrated – with poor health or illness state leading to lower SES and fewer economic resources. Research shows that socioeconomic deprivation increases the incidence and prevalence of epilepsy, that PWE have lower education, household income, and health status compared with the healthy population, and that finding employment is difficult for PWE [8,9]. Other research has shown associations between poor medication adherence and lower SES and insufficient insurance among PWE [8,9]. Housing, school/employment situation, and nutrition are examples of material factors potentially mediating the relationship between SDH, care, and outcomes in epilepsy [1]. Financial and material assets provide people with stability and allow them to reside in places characterized by higher standards of living and better access to and quality of health care. These conditions, in turn, are conducive to better outcomes [9,10].

Racial and ethnic disparities in health are also prevalent. African American PWE have higher rates of hospitalizations and ER visits, lower rates of surgery, and more deaths after surgery than their white counterparts [8,11–13]. In a recent national study, white and privately insured patients were found to be more likely to have surgery than their respective minority and publicly-insured counterparts [14]. Because whites are more likely than minority patients to have private insurance, access and financial considerations are potential barriers to advanced epilepsy treatments for minority and low-SES PWE.

Age and gender are both demographic and social variables. Epilepsy tends to affect the young and the older groups, and males have higher rates of epilepsy than females. However, membership in a specific age and gender group is also associated with a social position characterized by a certain level of SES and material and other resources, which, in turn, determine health status and quality of life. For example, resources tend to shrink in older ages, and women have on average lower SES and access to resources than men.

1.3. Patient-centered outcomes

Outcomes researchers have concluded that patients are often the best source of information regarding their condition [15]. Medical technology allows assessments of physical, physiological or biochemical data of the patient, but these data are limited and cannot provide the complete picture of the patient's condition or treatment. Some information can be obtained only directly from the patient [16]. Patient-centered outcomes research (PCOR) has become a gold standard as a strategy to assess success of medical treatments. The goal of PCOR is to emphasize research that examines choices and clinical outcomes that are meaningful to patients. This research takes into account patients' views, values, and preferences.

Patient-reported outcomes (PROs) are any reports of the status of a patient's health condition (his/her feelings, function, well-being, symptoms, or life satisfaction) that come directly from the patient, without interpretation of the patient's response by a clinician or anyone else [17]. Sometimes a self-report is provided by a proxy respondent (e.g., parent reporting for a child) [18]. For example, patients or proxies might be asked to assess their general health, ability to complete various activities, mood, level of fatigue, and pain. Health-related quality of life (HRQOL) assessments are especially valuable. In contrast to a symptom assessment which is unidimensional, HRQOL represents the patient's general perception of the effect of illness and treatment on various aspects of life such as physical, psychological, and social well-being. While the primary objective of treatment is to have a direct effect on symptoms, HRQOL is often described as an indirect outcome of disease state or treatment. Patient-reported outcomes provide unique information about impact of disease on the patient, help to empower patients/families, allow the determination of efficacy of treatment, and create a rapport between the patient/family and clinician, all of which contribute to useful interpretation of clinical outcomes and treatment decision making [16,19].

1.4. Study aims and hypotheses

Because of limited current knowledge, this study aimed to describe the sociodemographic profile of PWE receiving CBD in a clinical research program and to examine the association between social factors and several patient-centered outcomes – overall health status, quality of life, and mood states – in this population. Considering the general health inequalities and disparities in epilepsy, we hypothesized that patients taking CBD for the treatment of epilepsy would be predominantly white, non-Hispanic, and high-SES, and experience few financial strains. We further hypothesized that age would be negatively associated with socioeconomic measures and outcomes (i.e., older ages would be associated with lower socioeconomic resources/higher financial strains and worse health outcomes). We also expected that patient outcomes would be associated with patient/family incomes and levels of financial constraints. That is, higher income levels would be associated with higher overall health status and quality of life and fewer mood problems. Conversely, financial difficulties would be associated with lower overall health status and quality of life and greater mood problems. We also hypothesized potential interactions between age, gender, and socioeconomic measures, with higher ages and female patients having, compared to younger and male patients, lower socioeconomic resources and thus worse outcomes.

2. Material and methods

2.1. Data

Baseline social and outcomes data were collected from patients with treatment-resistant epilepsy enrolled in the University of Alabama at Birmingham CBD Program between 4/1/2015 and 3/30/2016 using standardized questionnaires. All patients with treatment-resistant epilepsy were referred to the study by their neurologist by submitting information packets containing treatment histories, laboratory testing results, medication lists, a report of video-electroencephalogram (VEEG) confirming the diagnosis of epilepsy, and a seizure calendar documenting at least 4 seizures per month averaged over the preceding 3 months. Complete packets were reviewed by a committee for approval. Neurologists submitting incomplete packets were notified of the missing