World Academy of Science, Engineering and Technology
International Journal of Pharmacological and Pharmaceutical Sciences
Vol:15, No:05, 2021

A Patient-Centered Approach to Clinical Trial Development: Real-World Evidence from a Canadian Medical Cannabis Clinic

Authors : Lucile Rapin, Cynthia El Hage, Rihab Gamaoun, Maria-Fernanda Arboleda, Erin Prosk

Abstract : Introduction: Sante Cannabis (SC), a Canadian group of clinics dedicated to medical cannabis, based in Montreal and in the province of Quebec, has served more than 8000 patients seeking cannabis-based treatment over the past five years. As randomized clinical trials with natural medical cannabis are scarce, real-world evidence offers the opportunity to fill research gaps between scientific evidence and clinical practice. Data on the use of medical cannabis products from SC patients were prospectively collected, leading to a large real-world database on the use of medical cannabis. The aim of this study was to report information on the profiles of both patients and prescribed medical cannabis products at SC clinics, and to assess the safety of medical cannabis among Canadian patients. Methods: This is an observational retrospective study of 1342 adult patients who were authorized with medical cannabis products between October 2017 and September 2019. Information regarding demographic characteristics, therapeutic indications for medical cannabis use, patterns in dosing and dosage form of medical cannabis and adverse effects over one-year follow-up (initial and 4 follow-up (FUP) visits) were collected. Results: 59% of SC patients were female, with a mean age of 56.7 (SD= 15.6, range= (19-97)). Cannabis products were authorized mainly for patients with a diagnosis of chronic pain (68.8% of patients), cancer (6.7%), neurological disorders (5.6%), and mood disorders (5.4 %). At initial visit, a large majority (70%) of patients were authorized exclusively medical cannabis products, 27% were authorized a combination of pharmaceutical cannabinoids and medical cannabis and 3% were prescribed only pharmaceutical cannabinoids. This pattern was recurrent over the one-year follow-up. Overall, oil was the preferred formulation (average over visits 72.5%) followed by a combination of oil and dry (average 19%), other routes of administration accounted for less than 4%. Patients were predominantly prescribed products with a balanced THC:CBD ratio (59%-75% across visits). 28% of patients reported at least one adverse effect (AE) at the 3-month follow-up visit and 12% at the six-month FUP visit. 84.8% of total AEs were mild and transient. No serious AE was reported. Overall, the most common side effects reported were dizziness (11.95% of total AEs), drowsiness (11.4%), dry mouth (5.5%), nausea (4.8%), headaches (4.6%), cough (4.4%), anxiety (4.1%) and euphoria (3.5%). Other adverse effects accounted for less than 3% of total AE. Conclusion: Our results confirm that the primary area of clinical use for medical cannabis is in pain management. Patients in this cohort are largely utilizing plant-based cannabis oil products with a balanced ratio of THC:CBD. Reported adverse effects were mild and included dizziness and drowsiness. This real-world data confirms the tolerable safety profile of medical cannabis and suggests medical indications not yet validated in controlled clinical trials. Such data offers an important opportunity for the investigation of the long-term effects of cannabinoid exposure in real-life conditions. Real-world evidence can be used to direct clinical trial research efforts on specific indications and dosing patterns for product development.

Keywords : medical cannabis, safety, real-world data, Canada
Conference Title : ICCDDPTD 2021 : International Conference on Clinical Drug Development Process and Trial Design
Conference Location : Montreal, Canada
Conference Dates : May 24-25, 2021