CHRD 2024: Abstract Submission Form

Presenter Name
Manik Chhabra

Presenter Status
PhD Student

Role in the project
Design
Perform Experiments
Analyze Data
Write Abstract

Research Category
Clinical

Title
Real-world safety of Cannabidiol and its Clinical Drug Interactions in Children and Adolescents: Insights from Pharmacovigilance Study and Systematic Literature Review

Background
With the increasing use of Cannabidiol (CBD) for medical purposes, very little is known about its real-world safety and clinical drug interactions in children.

Objective
We aimed to study the real-world safety profile of CBD in children using open pharmacovigilance databases and systematically review evidence from the literature on CBD-related clinical drug interactions in children.

Methods
CBD-related spontaneous reports from the FDA Adverse Event Reporting System (FAERS) and EudraVigilance databases were analyzed to review suspected CBD-related AEs. We conducted a descriptive analysis of data from spontaneous reports, followed by a disproportionality analysis of FAERS data to generate signals using OpenVigil 2.1. MEDLINE, Embase, and Cochrane Library were searched to identify literature on CBD-related clinical drug interactions in children. Two reviewers independently performed the screening and data extraction.

Results
In total, 2,068 spontaneous reports (274 from FAERS, 104 from the regulated EudraVigilance CBD, and 1690 from the unregulated EudraVigilance CBD) were identified. Strong Signals were detected for seizures [PRR 19.767 (95% CI 18.035-21.665), 328 reports], sudden unexplained death in epilepsy [PRR 27.641 (95% CI 10.065-75.909), 4 reports], death [PRR 30.829 (26.03-36.514), 176 reports], and hospitalization [PRR 30.829 (26.03-36.514)]. Of the 19 included studies on CBD-related clinical drug interactions (546 children and adults), 68.4% (n=13/19) exclusively included children (267 children). A total of 14 CBD-related clinical drug interactions were reported in children. The most common was clobazam reported in 42% (n=8/19) of the studies, followed by valproic acid in 21% (n= 4/19), and mTOR inhibitors in 15.7% (3/19) of the studies. CBD interaction with topiramate and zonisamide was reported in 10.5% (n=2/19) of studies.

Conclusion
CBD has a complex pharmacological profile; it is reported to interact with multiple medications and increase the risk of adverse events; therefore, there is a need for cautious monitoring in children receiving CBD along with other medications. In addition, there is a need to generate long-term safety and drug interaction data on CBD use in children.

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No

Authors

Name	Email	Role	Profession
Manik Chhabra	chhabram@myumanitoba.ca	Presenter	PhD student
Myfanwy Graham	myfanwy.graham@newcastle.edu	Co Author	Graduate
Yaron Finkelstein	yaron.finkelstein@sickkids.ca	Co Author	Full Professor
Mê-Linh Lê	me-linh.le@umanitoba.ca	Co Author	Librarian
Lauren E Kelly	lauren.kelly@umanitoba.ca	Co Author	Associate Professor
Sieara Plebon-Huff	sieara.plebon-huff@hc-sc.gc.ca	Co Author	Health Canada