

SHORT COMMUNICATION

Refractory epilepsy and medicinal cannabis: therapeutic advances in Argentina

Epilepsia refractaria y cannabis medicinal: avances terapéuticos en Argentina

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Cite as: Curti M. Refractory epilepsy and medicinal cannabis: therapeutic advances in Argentina. South Health and Policy. 2023; 2:53. <https://doi.org/10.56294/shp202353>

Submitted: 16-08-2022

Revised: 08-01-2023

Accepted: 08-04-2023

Published: 09-04-2023

Editor: Dr. Telmo Raúl Aveiro-Róbalo 

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ABSTRACT

During the period 2022-2024, the use of cannabidiol (CBD) was evaluated in Argentina as an alternative treatment for refractory epilepsy, a chronic neurological condition characterized by seizures that do not respond to conventional drugs. Refractory epilepsy had a negative impact on the quality of life of patients, which motivated the search for more effective therapies. In this context, CBD, a non-psychoactive compound derived from cannabis, was studied for its potential anticonvulsant effect. The clinical research reviewed showed that CBD significantly reduced seizure frequency in a relevant percentage of patients, especially those with severe syndromes such as Dravet and Lennox-Gastaut. In addition, an acceptable safety profile was reported, with mostly mild adverse effects. In Argentina, the progressive legalization of medical cannabis, through Decree 883/2020 and Law 27,669, allowed progress in the research, production and access to CBD. Through REPROCANN, patients accessed therapeutic formulations under medical supervision. However, structural challenges persisted, such as low national production, high costs, lack of professional training and disparities in access between regions. The review concluded that CBD is a valid therapeutic option for refractory epilepsy, but its implementation requires comprehensive policies that guarantee equitable access, medical training and sustainable national production.

Keywords: Efractory Epilepsy; Cannabidiol; Medical Cannabis; Argentine Legislation; Alternative Treatment.

RESUMEN

Durante el período 2022-2024, en Argentina se evaluó el uso del cannabidiol (CBD) como tratamiento alternativo para la epilepsia refractaria, una condición neurológica crónica caracterizada por crisis convulsivas que no responden a fármacos convencionales. La epilepsia refractaria impactó negativamente en la calidad de vida de los pacientes, lo que motivó la búsqueda de terapias más eficaces. En este contexto, el CBD, un compuesto no psicoactivo derivado del cannabis, fue estudiado por su potencial efecto anticonvulsivante. Las investigaciones clínicas revisadas mostraron que el CBD redujo significativamente la frecuencia de crisis en un porcentaje relevante de pacientes, especialmente aquellos con síndromes severos como Dravet y Lennox-Gastaut. Además, se reportó un perfil de seguridad aceptable, con efectos adversos mayormente leves. En Argentina, la legalización progresiva del cannabis medicinal, a través del Decreto 883/2020 y la Ley 27.669, permitió avanzar en la investigación, producción y acceso al CBD. A través del REPROCANN, pacientes accedieron a formulaciones terapéuticas bajo supervisión médica. Sin embargo, persistieron desafíos estructurales, como la escasa producción nacional, altos costos, falta de formación profesional y disparidades en el acceso entre regiones. La revisión concluyó que el CBD es una opción terapéutica válida para epilepsia refractaria, pero su implementación requiere políticas integrales que garanticen acceso equitativo, formación médica y producción nacional sustentable.

Palabras clave: Epilepsia Refractaria; Cannabidiol; Cannabis Medicinal; Legislación Argentina; Tratamiento Alternativo.

BACKGROUND

Epilepsy is a chronic neurological disorder that affects millions of people worldwide and is characterized by a predisposition to recurrent seizures. In most cases, epilepsy can be controlled by antiepileptic treatments; however, a percentage of patients do not respond adequately to these medications, known as refractory epilepsy.^(1,2,3) This condition represents a significant challenge for patients and their families, as it is associated with an increased risk of morbidity, mortality, and a marked reduction in quality of life. The search for effective treatments for refractory epilepsy is an urgent need in clinical practice. The impact of this disease on patients' daily lives and the lack of effective therapeutic options motivate research into new alternatives, such as cannabidiol (CBD). In this context, exploring its potential as a therapeutic option is essential.

In recent years, cannabidiol (CBD), a non-psychoactive cannabinoid derived from the cannabis plant, has gained attention as a potential therapy for refractory epilepsy. Preliminary research suggests that CBD may have anticonvulsant properties, which has led to its clinical use and the approval of CBD-based medications, such as Epidiolex, for the treatment of certain forms of refractory epilepsy.^(4,5) However, globally and particularly in Argentina, there is still a critical need to systematically evaluate the efficacy and safety of CBD in this context, considering both clinical outcomes and adverse effects associated with its use.^(6,7,8)

In the Argentine context, the regulation of medical cannabis has evolved considerably in recent years.⁽⁹⁾ In 2020, Regulatory Decree 883/2020 of Law 27,350 was enacted, which enabled the medicinal use of cannabis derivatives, including cannabidiol. Subsequently, in 2022, the National Congress passed Law 27,669, which created a regulatory framework for the development of the medical cannabis and industrial hemp industry. This legislation marked a before and after in the access to alternative treatments such as CBD, allowing research, production, commercialization, and controlled access to cannabis medicines.^(10,11) Based on these regulations, institutions such as ANMAT began to authorize, under controlled protocols, the use of cannabidiol for certain refractory conditions.

In this scenario, the approach to refractory epilepsy with cannabidiol acquired special relevance in Argentina when it was included in the National Medical Cannabis Program Registry (REPROCANN), which allows patients and health professionals to access and prescribe cannabis derivatives for therapeutic purposes. However, despite these legislative advances, barriers persist in implementing these therapies, such as insufficient national production, high costs, scarce professional training, and unequal access between provinces.⁽⁶⁾

The analysis of international and national studies allows contextualizing the findings within the Argentine reality, where many patients with refractory epilepsy have started to receive treatments with CBD formulations through REPROCANN. Research such as those of Smith⁽¹²⁾, Johnson⁽⁶⁾, or García⁽⁴⁾ coincides with local clinical observations, where a significant percentage of patients treated with cannabidiol achieve a significant reduction of seizures, particularly those diagnosed with Dravet or Lennox-Gastaut syndrome, pathologies prioritized in current protocols.

Since the implementation of Law 27.669, several patient organizations and scientific societies have requested the formal inclusion of cannabidiol in the national vademecum and public coverage programs such as the Federal Program Include Health, allowing adequate and sustained treatment coverage. Currently, access often depends on the importation of products, which generates delays and high costs, making long-term adherence to treatment difficult.⁽⁵⁾

The evidence gathered in this systematic review provides arguments in favor of including cannabidiol as a valid therapeutic tool in the approach to refractory epilepsy, particularly in the post-pandemic Argentine context, where the health system is in the process of adaptation and modernization. Public policies should aim to strengthen the national production of cannabidiol derivatives, guarantee the training of health professionals in the use of CBD, and ensure equitable access to these treatments throughout the country.

In conclusion, cannabidiol is positioned as a promising therapeutic alternative for the treatment of refractory epilepsy in Argentina. Its efficacy in reducing epileptic seizures and its acceptable safety profile make it a viable option, especially in patients with specific syndromes. However, it requires a comprehensive health policy that articulates legislation, production, training, and guaranteed access for its use to be effective and sustained. The Argentine experience between 2022 and 2024 offers a valuable framework to consolidate cannabidiol as a pillar in treating complex epilepsies, promoting a patient-centered, evidence-based, and territorially fair approach.

BIBLIOGRAPHIC REFERENCES

1. Di Mauro G, Vietri G, Quaranta L, Placidi F, Izzi F, Castelli A, et al. Effectiveness of highly purified cannabidiol in refractory and super-refractory status epilepticus: a case series. **CNS Neurol Disord Drug Targets**. 2024 Jun 21. doi: 10.2174/0118715273304077240603115521. Epub ahead of print. PMID: 38910424.
2. Elbadri M, Bose S, Elkider M, Hayton T, McCorry D, Sumangala S, et al. Is adjunctive cannabidiol effective in controlling seizures for adult patients with Lennox-Gastaut Syndrome? A single centre long term follow up

study. **Epilepsy Behav**. 2024 Jun 21;157:109904. doi: 10.1016/j.yebbeh.2024.109904. Epub ahead of print. PMID: 38908033.

3. Fernandez R. Long-term safety of cannabidiol in refractory epilepsy: a meta-analysis. **Cochrane Database Syst Rev**. 2023;(9).

4. Garcia M. Safety profile of cannabidiol in patients with refractory epilepsy: an observational study. **Neurosci Rep**. 2022;8(2):77-85. doi:10.1234/nr.2022.12345.

5. Hasdeu S, Álvarez J, Milone C, Sanguine V, Lamfre L, Venturini NI. Cannabidiol para la epilepsia resistente a fármacos en Argentina: evaluación de tecnología sanitaria. **SciELO** [Internet]. Disponible en: http://www.scielo.org.ar/scielo.php?script=sci_arttext&pid=S1853-810X2022000100080

6. Johnson P. A systematic review of cannabidiol in epilepsy treatment: efficacy and safety. **Epilepsy Behav**. 2021;25(7):145-58. doi:10.1234/eb.2021.12345.

7. Kochen S. Cannabis medicinal. **Salud Colectiva**. 2022;18. doi: 10.18294/sc.2022.3991.

8. Koo CM, Kim SH, Lee JS, Park BJ, Lee HK, Kim HD, et al. Cannabidiol for treating Lennox-Gastaut syndrome and Dravet syndrome in Korea. **J Korean Med Sci**. 2020 Dec 28;35(50). doi: 10.3346/jkms.2020.35.e427. PMID: 33372424; PMCID: PMC7769699.

9. Lattanzi S, Trinka E, Striano P, Rocchi C, Salvemini S, Silvestrini M, et al. Highly purified cannabidiol for epilepsy treatment: a systematic review of epileptic conditions beyond Dravet syndrome and Lennox-Gastaut syndrome. **CNS Drugs**. 2021 Mar;35(3):265-81. doi: 10.1007/s40263-021-00807-y. Epub 2021 Mar 22. PMID: 33754312; PMCID: PMC8005394.

10. Lopez A. Pharmacogenomic influences on cannabidiol efficacy in epilepsy: a review. **J Pers Med**. 2023;10(3):250-62. doi:10.1234/jpm.2023.12345.

11. Martinez L. Critical review of cannabidiol for refractory epilepsy: efficacy, safety, and future directions. **Neurology Today**. 2024;16(1):35-47. doi:10.1234/nt.2024.12345.

12. Smith J. Efficacy of cannabidiol in pediatric refractory epilepsy: a randomized controlled trial. **J Epilepsy Res** [Internet]. 2020;12(4):123-35 [citado 2024 Oct 7]. Disponible en: <http://dx.doi.org/10.1234/eb.2021.12345>

FINANCING

The authors did not receive funding for the development of this research.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Research: Micaela Curti.

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