

paracingular cortex ($p=0.06$), anterior ($p=0.1$) and posterior cingulate cortex ($p=0.07$). No myelination disorders were detected in the cerebellum.

Image:

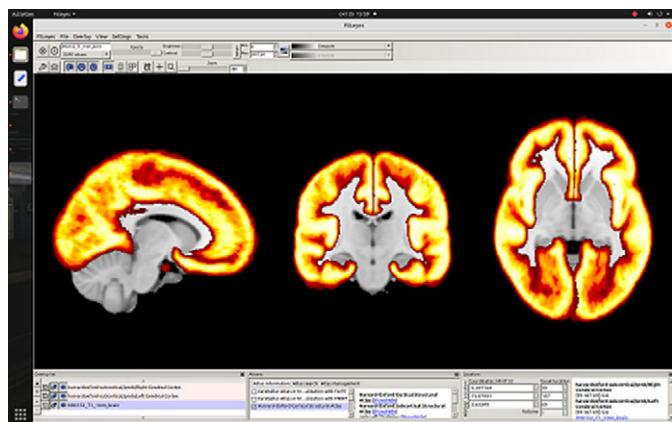


Image 2:

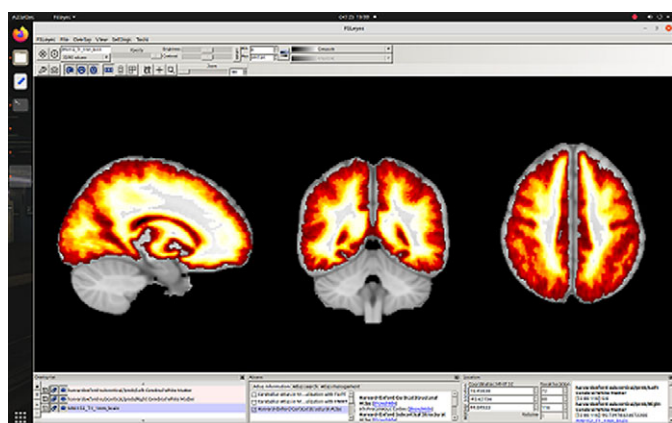


Image 3:



Conclusions: To our knowledge, the absence of cerebellar myelination disorders in patients at an early-stage schizophrenia is reported for the first time, while the observed decrease in cerebrum myelination in schizophrenia is consistent with the previous findings. The difference in myelination between cerebellum and cerebrum may help to characterize the dynamics of the pathological process and provide additional information for understanding the biological mechanisms of the development of schizophrenia. Grant RSF 20-15-00299 (partially).

Disclosure of Interest: None Declared

O0143

Is there a dose-response relationship between cannabis use and violence? A longitudinal study in individuals with severe mental disorders

M. Beaudoin^{1,2,3,*}, L. Dellazizzo^{1,2}, S. Giguere^{1,2}, J.-P. Guay^{2,4,5,6}, C.-E. Giguere², S. Potvin^{1,2} and A. Dumais^{1,2,4}

¹Psychiatry and addictology, University of Montreal; ²Research Center, Institut universitaire en sante mentale de Montreal; ³Faculty of Medicine, McGill University; ⁴Research Center, Institut national de psychiatrie légale Philippe-Pinel; ⁵Criminology School, University of Montreal and ⁶Centre international de criminologie comparée, Montreal, Canada

*Corresponding author.

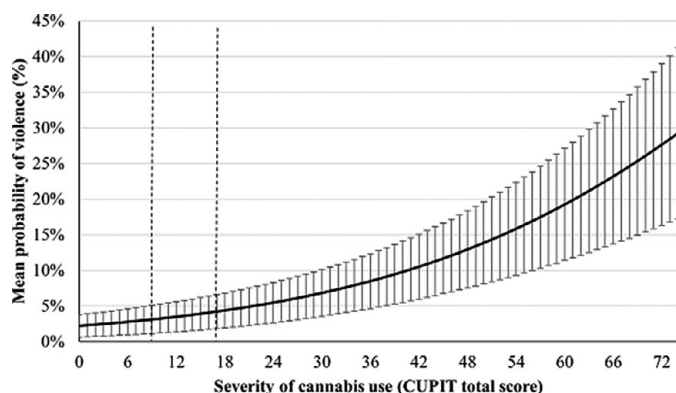
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Introduction: Recent longitudinal studies point towards the existence of a positive relationship between cannabis use and violence in people with severe mental disorders. However, the existence of a dose-response relationship between the frequency and/or the severity of cannabis use and violence has seldom been investigated.

Objectives: This study aimed to determine if a dose-response relationship between cannabis use and violence exists in a psychiatric population.

Methods: This observational study was conducted at the *Institut universitaire de santé mentale de Montréal* (Montréal, Canada). A total of 98 outpatients (81 males and 17 females, all over 18 years of age) with severe mental disorders were included in the analyses. Clinical evaluations were conducted every 3 months for a year. Substance use, violent behaviors, and potential covariables were assessed through self-reported assessments, urinary testing, as well as clinical, criminal, and police records. Using generalized estimating equations, the association between cannabis use frequency (non-users, occasional, regular, and frequent users, assessed using the Time-Line Follow-Back and confirmed with urinary testing) and violence was investigated, as well as the association between the severity of cannabis use (measured using the Cannabis Use Problems Identification Test – CUPIT) and violent behaviors.

Results: Cannabis use frequency and severity were significant predictors of violent behaviors. After adjustment for time, age, sex, ethnicity, psychiatric diagnoses, impulsivity and use of alcohol and stimulants, odds ratios were of 1.91 ($p < 0.001$) between each frequency profile, and 1.040 ($p < 0.001$) for each increase of one point of the severity of cannabis use score (0 to 79).

Image:

Conclusions: These findings have important implications for clinicians, demonstrating that cannabis use may have serious adverse consequences in a psychiatric population. Nevertheless, the mechanisms underlying this association remain unclear.

Disclosure of Interest: None Declared

O0144

Long-term efficacy and safety of paliperidone 6-month formulation: An open-label extension of a double-blind study in adult patients with schizophrenia

D. Najarian¹, I. Turkoz², S. Galderisi³, H. F. Lamaison⁴, P. Zalitacz⁵, S. Aravind² and U. Richarz^{6*}

¹Janssen Scientific Affairs, LLC; ²Janssen Research & Development, LLC, Titusville, NJ, United States; ³University of Campania "Luigi Vanvitelli", Naples, Italy; ⁴Department of Psychiatry, National University of La Plata (UNLP), Buenos Aires, Argentina; ⁵Head of Psychiatric Unit, Gorlice Specialist Hospital, Gorlice, Poland and ⁶Janssen Research & Development-Cilag, Gubelstrasse, Zug, Switzerland

*Corresponding author.

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Introduction: Paliperidone palmitate 6-month (PP6M), administered twice-yearly, demonstrated non-inferiority to paliperidone palmitate 3-month (PP3M) in preventing relapse in patients with

schizophrenia in a phase-3 randomized, double-blind (DB) global study.¹ We report results of a 2-year single-arm, open-label extension (OLE) of this study (NCT04072575).

Objectives: To assess long-term efficacy and safety of PP6M in patients with schizophrenia.

Methods: Patients who completed DB study without relapse were enrolled and followed up every 3 months for up to 2 years. Patients received 4 PP6M injections (700/1000 mg eq.) at baseline, 6-month, 12-month, and 18-month visits. Efficacy endpoints included relapse rate, Positive and Negative Syndrome Scale (PANSS) total score, Personal and Social Performance (PSP) score, and Clinical Global Impression-Severity (CGI-S) scale change from baseline. Safety was assessed by treatment-emergent adverse events (TEAEs), physical examinations and laboratory tests.

Results: Of 178 patients, 154 (86.5%) completed the study; mean age: 40.4 years; 70.8% were men. Mean duration of PP6M exposure was 682.1 days. Overall, 7/178 (3.9%) patients relapsed between 20 to 703 days after enrolment. Mean (SD) change from baseline to endpoint: PANSS total score, 0.7 (8.22); CGI-S, 0.0 (0.51); PSP Scale, 0.5 (7.47). Overall, 111/178 patients (62.4%) reported ≥ 1 TEAE; most common ($>10\%$) TEAEs were headache (13.5%) and blood prolactin increased (10.7%). Total, 7/24 patients withdrew due to TEAEs, and 8/178 (4.5%) patients experienced serious TEAEs; no deaths were reported.

Conclusions: Relapse rate with PP6M was very low ($<4\%$). Clinical improvements in PANSS, CGI-S, and PSP scales demonstrated in DB study were maintained during this 2-year OLE study and no new safety concerns were identified.

Reference: 1. D. Najarian et al. *Int J Neuropsychopharmacol.* 2022 Mar 17;25(3):238-251.

Disclosure of Interest: D. Najarian Shareolder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, I. Turkoz Shareolder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, S. Galderisi Consultant of: Janssen, Gedeon Richter-Recordati, Angelini, Speakers bureau of: Angelini, Gedeon Richter-Recordati, Janssen, Lundbeck, Sunovion, Recordati, H. Lamaison Grant / Research support from: Novartis, Eli Lilly, Lundbeck, Servier, AstraZeneca, Wyeth, Pfizer, Otsuka, Takeda, Sunovion, Roche, Janssen Pharmaceutical, Speakers bureau of: Servier, Abbot, Raymonds, Raffo, Temis Lostalo and Janssen Pharmaceutical, P. Zalitacz: None Declared, S. Aravind Shareolder of: Johnson & Johnson, Employee of: Advarra, Inc. USA, U. Richarz Shareolder of: Johnson & Johnson, Employee of: Janssen Research & Development-Cilag, Switzerland.