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³Compassionate use – Medicines in special situations. AEMPS

Background and Importance

- In July 2022 and August 2024, WHO declared MPOX outbreaks as public health emergencies. In September 2025, cases remain uncontrolled in central-eastern Africa, and therapeutic options are almost non-existent.
- Tecovirimat, active against *Orthopoxvirus*, inhibits p37 protein, preventing viral envelope formation. In our country, it is only available via special import authorization.

Aim and Objectives

- To evaluate tecovirimat's safety and efficacy through clinical data and patient feedback from MPOX cases treated at our centre.

Materials and Methods

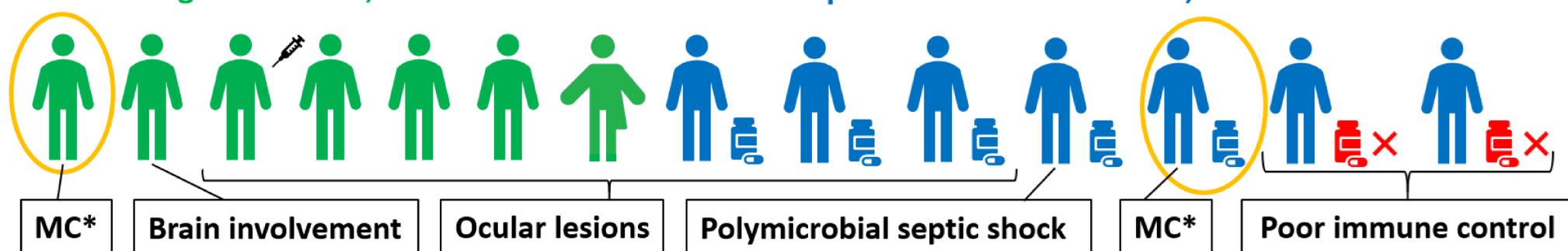
- We analysed clinical and demographic data from patients treated between June 2022 and September 2025 at a tertiary hospital. Satisfaction was assessed using TSQM 1.4 (Treatment Satisfaction Questionnaire for Medication). All participants gave informed consent; protocol was approved by the ethics committee.

Results

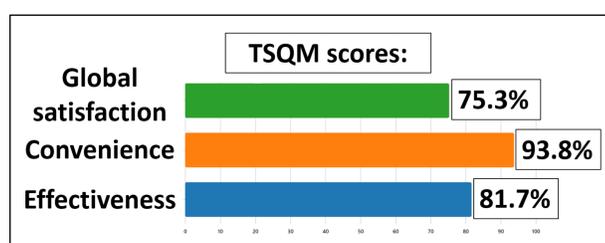
- 14 patients (median age 36 y.o.) were treated with tecovirimat, 7 of them (50%) were HIV-positive.
- It was always prescribed in severe cases: ocular lesions, poor immune control, polymicrobial septic shock, brain involvement. One in each group **did not respond** to symptomatic treatment, both with mucocutaneous (MC*) manifestations. Only one had been previously vaccinated.

HIV-negative: 6 men, 1 trans woman

HIV-positive: 5 well controlled, 2 not controlled



- Posology: 600 mg/12 h 14 days – 8 (57.1%), others:
 - 5 days: early recovery (already vaccinated) – 1
 - 7 days: adverse event – 1
 - 28 days: ocular lesions and dosing error – 2
 - 5 x 14-day cycles: ocular lesions – 2



Viral load (cp/mL)	CD4 count (cells/μL)
1.300.000	158
49.800	166

- Six patients (42.9%) reported mild adverse effects (stomach ache, nausea, diarrhea); one (7.1%) developed probable¹ toxic hepatitis (RUCAM² score = 6), requiring treatment discontinuation.

Conclusion and Relevance

- Tecovirimat was generally safe and well tolerated, though close monitoring is advised. Vaccination may help prevent complications. Further research is needed to confirm efficacy and explore new treatments.

References:

¹Ruiz-Cabrera D et al, EIMC 2025 online, DOI: [10.1016/j.eimc.2025.503030](https://doi.org/10.1016/j.eimc.2025.503030); ²Danan G et al, Int J Mol Sci. 2015, PMID: 26712744; PMCID: PMC4730261

