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Tecovirimat for Monkeypox in the Central African Republic under Expanded Access

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TO THE EDITOR:

We report on the protocolized use of tecovirimat[1] under an Expanded Access Programme (EAP) for all patients treated for monkeypox virus (MPXV) disease in Mbaïki, Central African Republic (CAR) between December 2021 and February 2022.[2]

Fourteen patients – 71% female, median age 23 years (range 4–38), median time from symptom onset to treatment start 21 days (range 4–45) – gave their written informed consent to receive tecovirimat for monkeypox (Text S1). Data on clinical signs and symptoms were recorded daily throughout treatment and at follow-up visits (Table S2). Blood or lesions samples were taken at admission, throughout treatment, and at day 28 to assess viral presence of MPXV. Ethical approval was obtained from the University of Oxford and the University of Bangui before enrolment began.

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All 14 patients tested positive for MPXV on at least one admission sample, of whom 12 were positive on blood with a mean CT (cycle threshold) value of 32 (range 21–42) on a MPXV generic real-time PCR assay (G2R-G); 12 were also positive on MPXV Clade I-specific CL3 assay.

At admission and post-baseline, all 14 patients presented with muscle pain, headache, lymphadenopathy, and lesions characteristic of MPXV – 11/14 had >100 lesions (Table 1, Table S3). Active lesions were reported for 10 patients. The median time to no active lesions was five days (Figure S4). All patients completed the 14-day treatment course (600mg po bid in adults) and 13 completed the 28-day follow-up. MPXV was detected in at least one sample in 7/14 patients by Day 4, 1/10 by Day 8, 1/8 by Day 14, 1/2 by Day 21, and 1/1 by Day 28. By Day 14, 12/14 patients were discharged with no active lesions and of the remaining two, one was discharged on D21 with a negative PCR and one remained positive on D28. By the final study visit, 12/13 patients were PCR negative and recovered – nine with scarring. Two serious adverse events were reported: life-threatening anaemia during treatment in an HIV-positive patient and an unexplained death post-discharge; neither was considered to be related to the study treatment.

Data collected through this EAP increases our knowledge of the use of tecovirimat in a country endemic for Clade I MPXV, where 116 confirmed cases have been recorded between 2010 and September 2022, with 11 deaths (10.4%) (Table S5). This programme has also piloted a community outreach programme and sustainable community-based surveillance system and increased clinical research capacity in CAR.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Patients' baseline characteristics and outcomes

Demographic characteristics	
Male : female	4 : 10
Age (years): median (range)	23 (4 – 38)
Comorbidities	
Malaria: n/N (%) patients tested	11/13 (85%)
HIV: n/N (%) patients tested	1/3 (7%)
General characteristics	
Time (days) from symptom onset to treatment start: median (range)	21 (5–45)
Signs and symptoms: n/N (%) patients	
Fever (temperature >38·0 °C)	9/14 (64%)
Patients with lesions:	14/14 (100%)
Patients with new lesions	10/14 (71%)
Number of patients with >100 lesions	11/14 (79%)
Outcome: n/N (%) patients	
Completed full course of treatment	14/14 (100%)
PCR positive at day 4	7/14 (50%)
PCR positive at day 8	1/10 (10%)
PCR positive at day 14	1/8 (12%)
PCR positive at day 21	1/2 (50%)
PCR positive at final visit	1/13 (8%)
Time (days) to no new lesions: median (range)	5 (0–28)
Recovered without sequelae at D28	4/13 (31%)
Recovered with sequelae at D28	9/13 (69%)
Patients with at least one serious adverse event	2/14 (14%)