MOSAIC Clade 2b Mpox cohort study: Clinical Characterisation and Outcomes

737

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BACKGROUND

Over 80,000 cases of clade 2b Monkeypox (Mpox) were reported in 2022 outside traditionally endemic African countries. The transmission and features of clade 2b Mpox differ from clade 1, requiring systematic clinical characterization.

METHODS

- MOSAIC a cohort collecting clinical and virological outcomes of patients with laboratory-confirmed Mpox in 10 European countries started in May 2022 (EUCTR: 2022-501132-42-00),
- Administration of tecovirimat was at the discretion of the patient's treating clinician under routine care and subject to drug availability. Results are presented separately for tecovirimat and non-tecovirimat treated patients.

Primary outcome: Time to lesion resolution from the date of positive test result (or the date of treatment onset, if treatment initiated and was delayed) through Day 14 (D14) without any serious complications. Results obtained through Kaplan-Meier estimates.

Secondary outcomes:

- Virologic status at D14
- Clinical status at D28 using a four-point scale: all lesions resolved and no serious complications; active lesions and no serious complications; hospitalized due to a serious Mpox complication; death.

We selected non-tecovirimat patients with oropharyngeal or anal swabs or plasma samples available at D1 and D14.
qPCR was performed using a G2R target of MPXV (Ct value >40 was considered as negative).

Table 1: Baseline characteristics and primary outcome

Variable, n/total (%)	Tecovirimat N = 21	No tecovirimat N = 101
Time from onset to enrolment, median [IQR] (days)	7 [3 - 10]	6 [4 – 9]
HIV/AIDS [on ARV]	5/21 (24%) [4/5 (80%)]	33/101 (33%) [30/33 (91%)]
Smallpox vaccine PEP/PREP	1 / 21 (4.8%)	16 / 95 (16.8%)
Outpatient	11 / 21 (52%)	81 / 89 (91%)
Baseline infectious complications	10 / 19 (53%)	11 / 86 (13%)
Lymphadenopathy	17 / 20 (85%)	44 / 84 (52%)
>25 active skin and mucosal lesions	10 / 20 (50%)	8 / 77 (10%)
Genital/peri-genital lesions	14 / 19 (74%)	36 / 78 (46%)
Anal/peri-anal/rectal lesions	9 / 20 (45%)	29 / 82 (35%)
Kaplan-Meier estimate of lesion resolution by D14	39% [95%CI: 11-58]	58% [95%CI: 45-68]

Lesions and symptoms resolved within 28 days in most uncomplicated cases with supportive treatment without hospitalisation

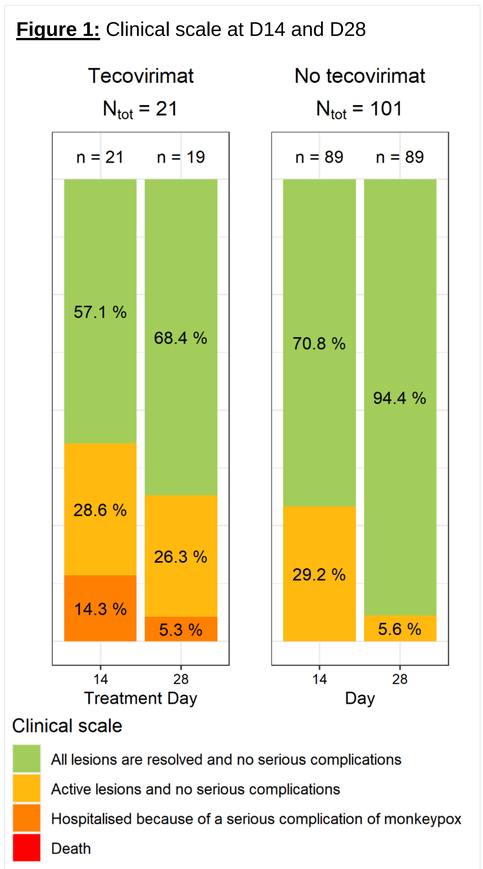
Some patients still have positive samples at D14 (even in plasma) although they no longer have active lesions

Observational studies contribute crucial information to characterise disease and inform practice in infectious disease outbreaks

RESULTS

- We report on the first 122 cases enrolled by November 15th 2022 (94 recruited in France, 24 in Switzerland and 4 in the UK), 98% males, median [IQR] age 35 [29, 44], of whom 21 received tecovirimat.
- Patients presented ~1 week after symptom onset (Table 1).
- A third of patients treated with tecovirimat had still active lesions or complications at D28 (Figure 1).

Figure 1: Clinical scale at D14 and D28



Virology

- 55 patients have virologic data available at D1 and D14.
- At baseline, median [range] qPCR Ct values were 34 [24, 40], 37 [32, 40], and 21 [17, 40] for oropharyngeal, plasma and anal samples, respectively.
- At D14, some samples were still positive (Figure 2)
  - 3/52 (6%) oropharyngeal: 2 lesions resolved + 1 active lesion, and no serious complications
  - 4/51 (8%) plasma: 3 lesions resolved + 1 active lesion, and no serious complications
  - 3/10 (30%) anal: lesions were resolved without serious complications in all patients (Figure 2).

CONCLUSIONS

- Lesions and symptoms resolved within 28 days in most uncomplicated cases with supportive treatment without hospitalisation.
- Some patients still have positive samples at D14 (even in plasma) although they no longer have active lesions.
- Tecovirimat treatment was more likely to be given to patients who presented with complications at baseline and those admitted to hospital. A lower proportion of these patients had all lesions resolved and no serious complications at D28.
- The study is not designed to assess the effect of tecovirimat treatment which is given according to local guidelines and availability, favouring more severe patients.
- While randomised controlled trials are needed to assess the effect of tecovirimat or other Mpox-specific treatments, observational studies contribute crucial information to characterise disease and inform practice in infectious disease outbreaks.

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Figure 2: Spaghettis plots of Ct values at Day 1 and Day 14