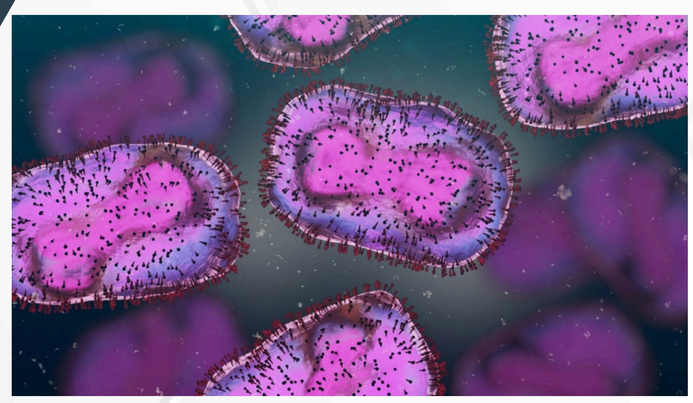
PHARMACOVIGILANCE OF THE ANTI-MPOX VACCINE : CLINICAL EXPERIENCE IN A HOSPITAL SETTING

MARIO D'AURIA, ILARIA BARBATO, FRANCESCA MUSELLA, MARIA PISTUCCI, ROSSANA ELIANA D'APICE, MICAELA SPATARELLA

"AZIENDA OSPEDALIERA SPECIALISTICA DEI COLLI"
Monaldi - Cotugno - C.T.O.



AIM AND OBJECTIVES

This study aimed to review reports collected between August 2022 and April 2025 and to compare them with national trends

BACKGROUND AND IMPORTANCE

Mpox is a zoonotic viral infection caused by the monkeypox virus, a member of the Poxviridae family. In humans, it is characterized by fever, rash, and varying degrees of asthenia. While zoonotic transmission is predominant, human-to-human spread may also occur through close contact with symptomatic cases. To limit viral spread, and in accordance with Italian Ministerial Circular 35365 (August 5, 2022), vaccination was made freely available to selected groups, including laboratory staff and individuals engaging in high-risk sexual behaviors. The vaccine is based on an attenuated virus obtained after more than 500 passages in chicken embryo fibroblast (CEF) cells. In our hospital vaccination center, its administration was accompanied by dedicated pharmacovigilance monitoring

MATERIAL AND METHODS

We extracted the total number of patients treated and the doses administered from the institutional vaccination platform for the period between August 16, 2022, and April 15, 2025. Concurrently, adverse reactions (ADRs) reported in the pharmacovigilance network were analyzed and classified by severity and System Organ Class (SOC)

RESULTS

Over the study period, 561 vaccine doses were administered. A total of 325 patients were treated, with a mean age of 42 years. Of these, 95% received two doses, while the remaining 5% received only one, thus not completing the vaccination schedule. In the same time frame, 2.6% of the 561 administered doses resulted in an adverse reaction report. All ADRs were non-serious and were classified as systemic disorders (60%), skin disorders (25%), and musculoskeletal disorders (15%). Notably, one case of psoriasis flare-up was observed in a 50-year-old man, occurring 14 days after the first dose. The classification of events according to SOC indicates that our findings are consistent with trends observed at the national level

CONCLUSION AND RELEVANCE

Our center contributed significantly to national monitoring, generating 35.7% of the adverse reaction reports recorded in Italy and subsequently included in the National Pharmacovigilance Network. The pharmacovigilance activity we conduct aims to systematically improve understanding of the tolerability of the Mpox vaccine and to investigate in detail its risk–benefit profile