CYTOMEGALOVIRUS REACTIVATION AND TISSUE-INVASIVE CMV DISEASE ASSOCIATED WITH BISPECIFIC ANTIBODIES IN MULTIPLE MYELOMA: A FAERS PHARMACOVIGILANCE ANALYSIS

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INTRODUCTION

Bispecific antibodies targeting BCMA and GPRC5D have expanded treatment options for relapsed/refractory multiple myeloma, but their immune effects may predispose patients to opportunistic viral infections. **Cytomegalovirus (CMV) reactivation and tissue-invasive CMV disease** are increasingly recognized complications of T-cell–redirecting therapy, yet their postmarketing reporting patterns across individual bispecific antibodies remain incompletely characterized. Understanding these patterns may help inform CMV surveillance and supportive care strategies.

AIM

To characterize and compare **CMV reactivation and tissue-invasive CMV disease** reported with **elranatamab, teclistamab, and talquetamab** using the FDA Adverse Event Reporting System (FAERS).

METHOD

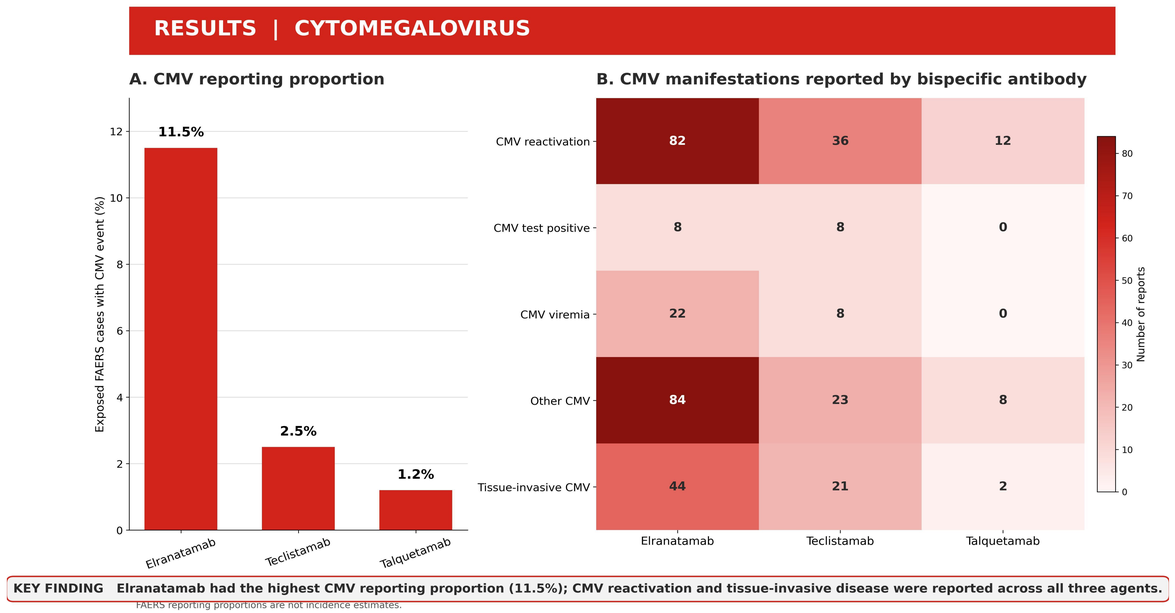
We performed a retrospective pharmacovigilance analysis of FAERS reports involving **elranatamab, teclistamab, and talquetamab**. Drug exposures were identified using standardized generic and product-name mappings, and CMV-related adverse events were identified using reported preferred terms.
CMV events included **CMV infection, CMV reactivation, CMV viremia, CMV test positivity, and tissue-invasive CMV disease**, including chorioretinitis, colitis/enterocolitis, gastroenteritis, hepatitis, encephalitis, and esophagitis. Duplicate reports were addressed at the case level, and CMV reporting proportions were calculated among exposed FAERS cases. CMV manifestations were compared descriptively across agents.
Because FAERS is a spontaneous reporting system, results represent **reporting patterns rather than incidence or causal risk**.

CONCLUSIONS

CMV reactivation and clinically significant **tissue-invasive CMV disease** were identified in postmarketing reports involving bispecific antibodies used for multiple myeloma. Elranatamab demonstrated the greatest CMV reporting burden, while CMV events were also observed with teclistamab and talquetamab.
These findings highlight CMV as an important opportunistic infection during T-cell–redirecting therapy and support further prospective investigation of **risk-adapted CMV surveillance, optimal monitoring intervals, and preventive strategies**. Differences between BCMA- and GPRC5D-directed therapies warrant additional study, while the limitations of spontaneous FAERS reporting preclude conclusions regarding incidence or causality.

RESULTS

MV-related events were reported with all three bispecific antibodies, with marked differences in reporting burden across agents. **Elranatamab demonstrated the highest CMV reporting proportion (11.5%), followed by teclistamab (2.5%) and talquetamab (1.2%). CMV reactivation was the most frequently reported specific manifestation**, with 82 reports associated with elranatamab, 36 with teclistamab, and 12 with talquetamab. CMV viremia and CMV test positivity were also reported.
Importantly, **tissue-invasive CMV disease was identified across all three agents**, with 44 reports for elranatamab, 21 for teclistamab, and 2 for talquetamab. Reported manifestations included **CMV chorioretinitis, colitis/enterocolitis, gastroenteritis, hepatitis, encephalitis, and esophagitis**.
Overall, CMV reporting was more prominent among the **BCMA-directed agents elranatamab and teclistamab** than with GPRC5D-directed talquetamab.



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