

Potential signal of necrotising soft tissue infections including necrotising fasciitis with vincristine

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Introduction

Vincristine is an antitumour medication given to the patient as part of polychemotherapy. Necrotising soft tissue infections (NSTIs) are serious life-threatening medical conditions starting in the dermis and epidermis, which then damage the deeper layers of adipose tissue, fascia, or muscle. NSTIs progress rapidly with severe morbidity and have fatality rates of 25%–35%, even with appropriate therapy. Vincristine-associated NSTIs was identified as a potential signal of disproportionate reporting on both the Egyptian and global level.

Objectives

To assess a potential signal of NSTIs in patients taking vincristine, focusing on causality and possible risk factors.

Methods

Vincristine-associated NSTIs were analysed during the signal detection and causality assessment workshop at Uppsala Monitoring Centre in May 2023. Data analysis, based on case reports from participants' country-specific data, was performed in VigiBase, the WHO global database of individual case safety reports. Reports were retrieved up to April 2023. In addition, the literature was screened for related information on vincristine-associated NSTIs.

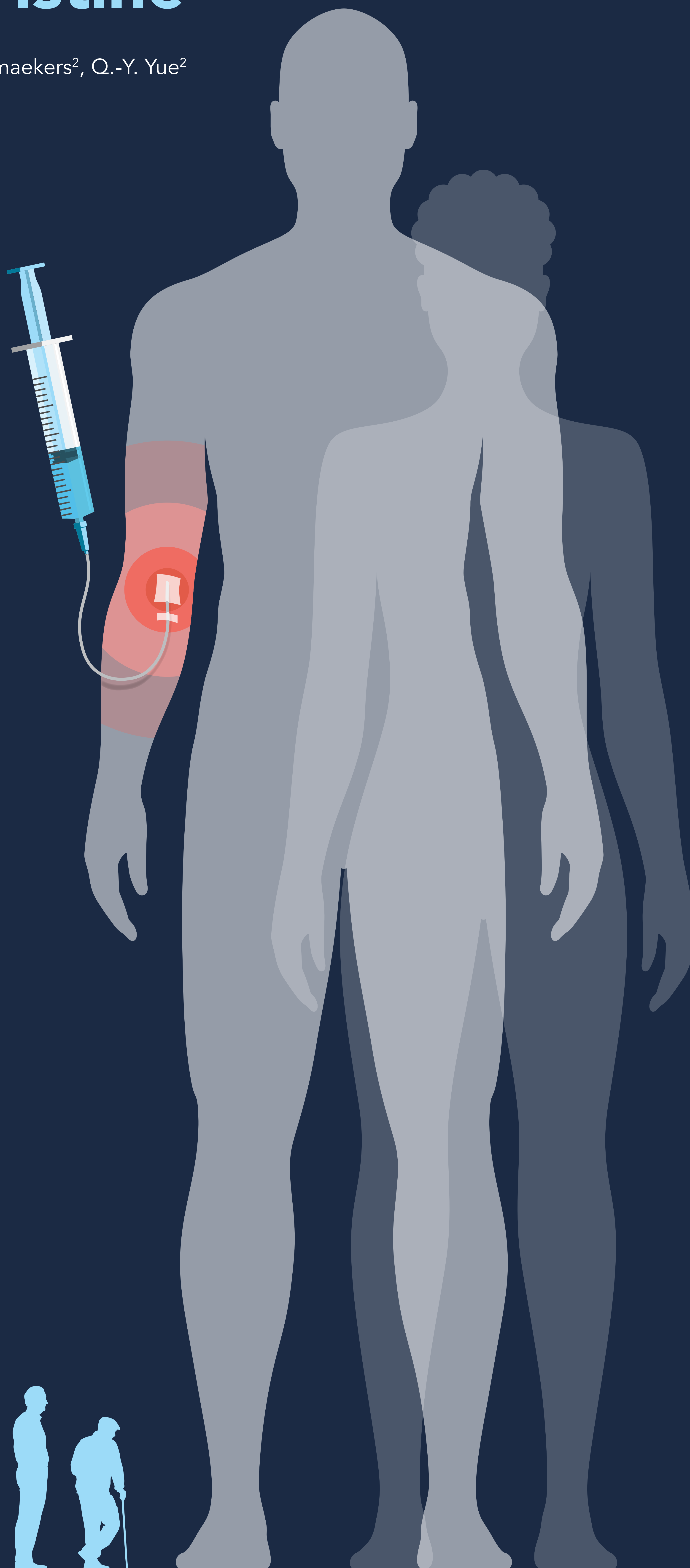
Results

VigiBase contained 48 cases of vincristine-associated NSTIs including necrotising fasciitis. The information component (IC_{025}) value was 3.1 indicating statistically disproportionate reporting. The reports came from nine countries, with an age range of 2 to 82 years (median 21.5). The time from vincristine administration to event onset (TTO) was reported in a single case as 15 days. Dechallenge information is not supportive as the medical condition is irreversible.

Eight cases were published in scientific literature. Five of these cases representing the Egyptian national dataset came from a retrospective study published in an Egyptian medical journal identifying the NSTI to be related to cannula site insertion¹. Two other cases of necrotising fasciitis mentioned the causality to be related to extravasation during vincristine administration². One additional case had necrotising fasciitis at the site of a bonemarrow biopsy that was diagnosed 30 days after the procedure. The causality and slow disease progression were considered to be related to the immunocompromised state of the patient³.

Conclusions

The weighted available evidence identified from local and global cases suggest a potential signal for NSTIs and necrotising fasciitis with the use of vincristine. Although there is a need for a more thorough review of safety data considering the seriousness of the condition to confirm the risk and potential risk factors, such as extravasation and an immunocompromised state, healthcare professionals should be aware of the potential risk in patients taking vincristine.



References/
further sources
of information

1. Sallam K, Mostafa M, Shalaby L, Yasser Medany, Aly, Sayed A, et al. Delayed Debridement for Necrotizing Soft Tissue Infections: Experience with Immunocompromised Pediatric Cancer Patients. *Al-Azhar Med. J. (Surgery)*. 2021 Jan; 50 (1): 207-20
2. Trelles Garcia V, Weir C, Bustamante-Soliz D, Kumi D. Catastrophic Complications of Chemotherapy Extravasation. *Chest*. 2021 Oct;160 (4): Supplement a768
3. Hammond AM, Satcher KG, Bender NR, Schoch JJ, Motaparthi K. Necrotizing Escherichia Coli Skin and Soft Tissue Infection with Malakoplakia-Like Features Mimicking Pyoderma Gangrenosum. *Jaad Case Reports*. 2021 Jun; 12: 1–4

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