OHDSI Save Our Sisyphus Challenge
7th March 2023

Population Estimation: **Comparative safety**:

Amongst people with psoriasis, does exposure to Risankizumab increase the risk of venous thromboembolism while on treatment relative to other biologic therapies?

Zenas Yiu
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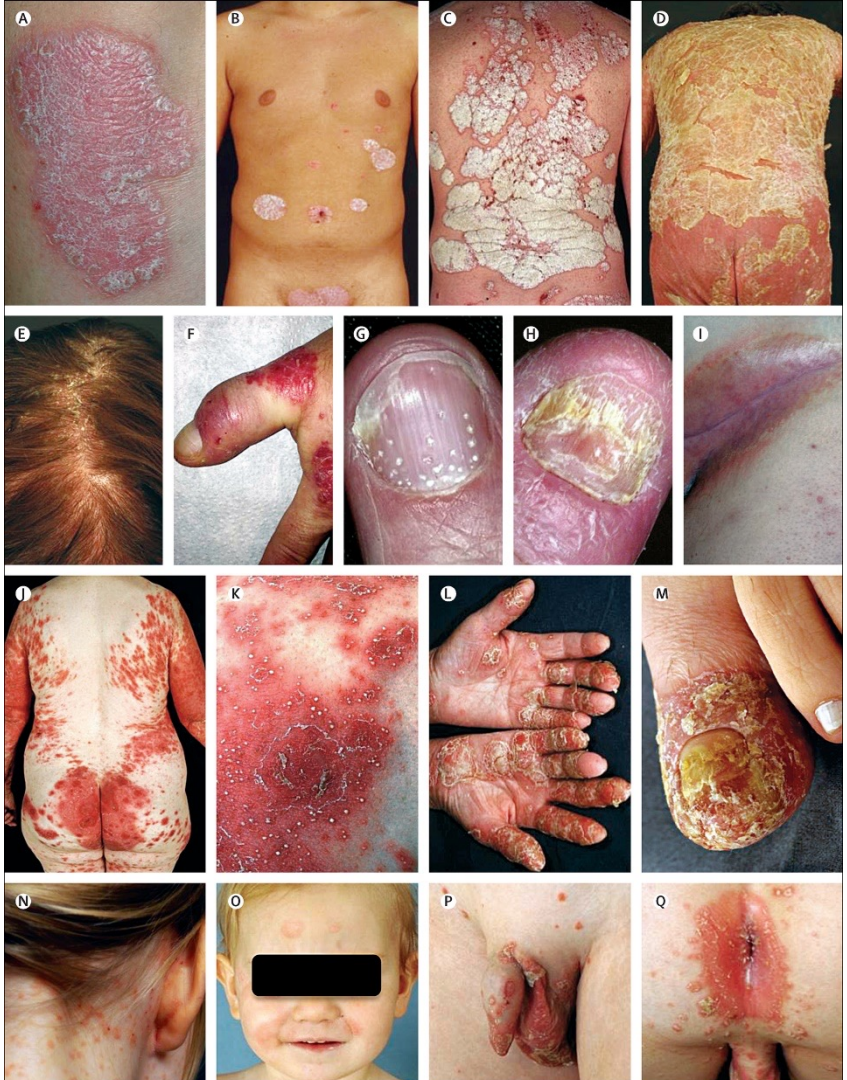
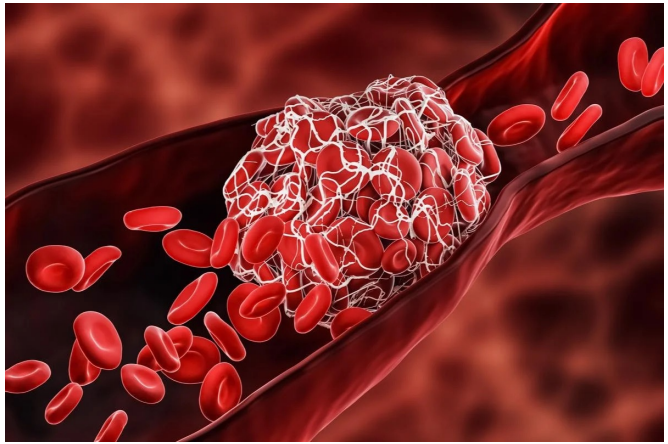
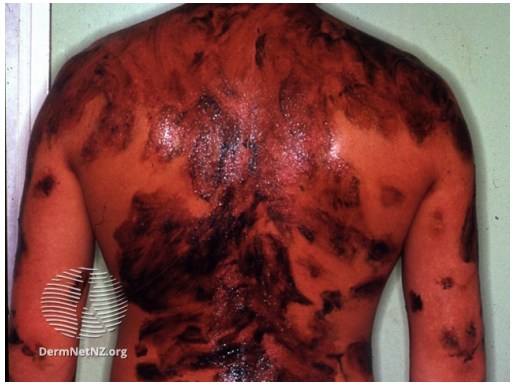
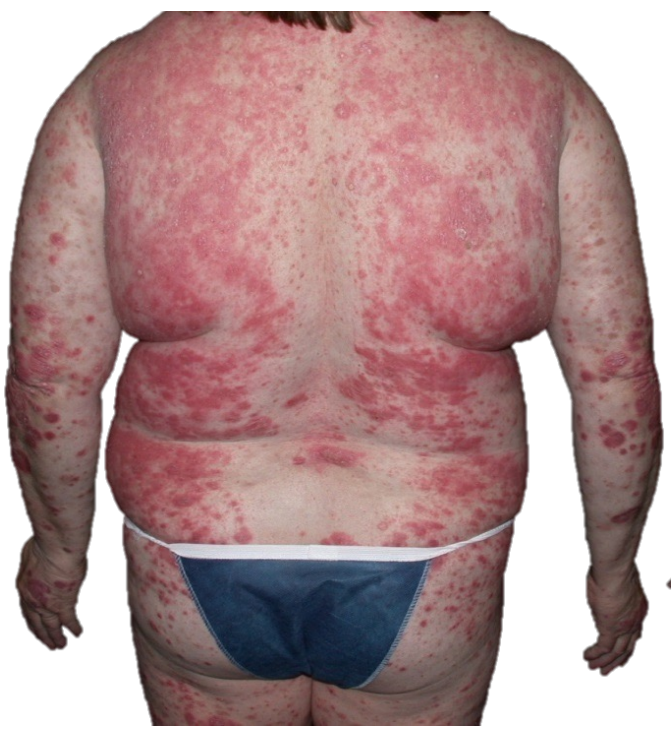




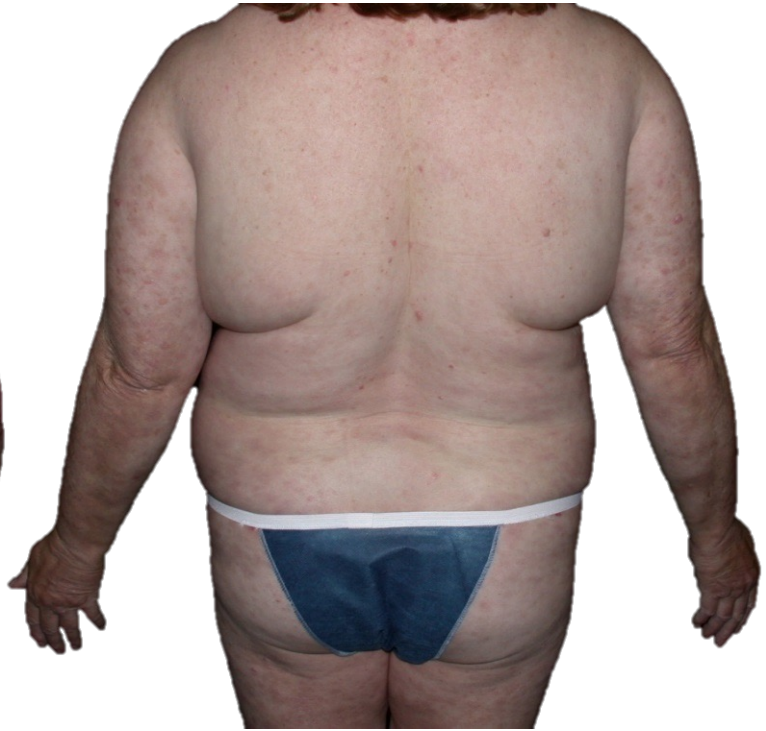
Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. Lancet. 2021 Apr 3;397(10281):1301-1315.



Photograph courtesy of DermNetNZ



Pre-biologic treatment



Post-biologic treatment

Topicals

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Classical / conventionals treatments, Phototherapy

↓

Biologic / novel small molecule treatments

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Tumor-necrosis factor (TNF) inhibitors

Interleukin(IL)-12/23 inhibitor

IL-17 inhibitors

IL-23 inhibitors

Risankizumab

Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis

Authors' conclusions

Our review shows that, compared to placebo, the biologics infliximab, bimekizumab, ixekizumab, and risankizumab were the most effective treatments for achieving PASI 90 in people with moderate-to-severe psoriasis on the basis of high-certainty evidence.

We found no significant difference in the assessed interventions and placebo in terms of SAEs, and the safety evidence for most interventions was low to moderate quality.

BJCP British Journal of Clinical Pharmacology

ORIGINAL ARTICLE

Potential cerebrovascular accident signal for risankizumab: A disproportionality analysis of the FDA Adverse Event Reporting System (FAERS)

Richard H. Woods

First published: 02 November 2022 | https://doi.org/10.1111/bcp.15581

Methods

A retrospective disproportionality analysis was conducted utilizing postmarketing adverse event reports submitted to the US Food and Drug Administration Adverse Event Reporting System (FAERS) through the fourth quarter of 2021.

Risankizumab was associated with significantly disproportionate CVA reporting compared to all other drugs in FAERS (ROR 2.48; 95% CI 2.14–2.88) as well as 11 alternative plaque psoriasis therapeutics across five pharmacologic classes

Increased reporting of cerebrovascular accidents with use of risankizumab observed in the FDA Adverse Events Reporting System (FAERS)

Alexander Egeberg[1,2] and Jacob P. Thyssen[1]

due to this initial observation, future real-world studies now risk suffering from confounding by indication, as dermatologists are now going to be less likely to prescribe risankizumab in patients with a particularly high cardiovascular risk profile out of fear of inducing a CVA.

while these initial data should raise a "red flag" for clinicians, there is a need for prospective long-term multinational observational studies to fully understand if there really is a safety issue.

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OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS