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LETTER

# Expanding on Abraxane Safety: Temporal Insights and Future Directions for Adverse Event Analysis [Letter]

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## Dear editor

I read with great interest the article by Zhao et al titled "Unveiling the Hidden Risks: An Update Decade-Long Analysis of Abraxane-Related Adverse Events from the FAERS Database".[1] The authors should be commended for their comprehensive analysis of Abraxane-related adverse events (AEs) using the FDA Adverse Event Reporting System (FAERS) database. This study provides valuable insights into the safety profile of this widely used nanoparticle albumin-bound paclitaxel formulation, which has shown significant clinical benefits in various cancer types.[2]

However, I would like to draw attention to several inconsistencies and areas for improvement in the manuscript. Firstly, the title mentions a "decade-long" analysis, yet the methods section states that data were collected from January 2004 through December 2023, spanning nearly two decades. This discrepancy should be addressed. Secondly, there appears to be redundancy in results, with Tables 1, 2, and 3 seemingly duplicating the information presented in Figures 2, 3, and 4, respectively. Streamlining this information could enhance the article's clarity. Lastly, while the flow diagram in Figure 1 indicates an analysis of the "onset time of events", this aspect is not thoroughly explored in the results or discussion sections.

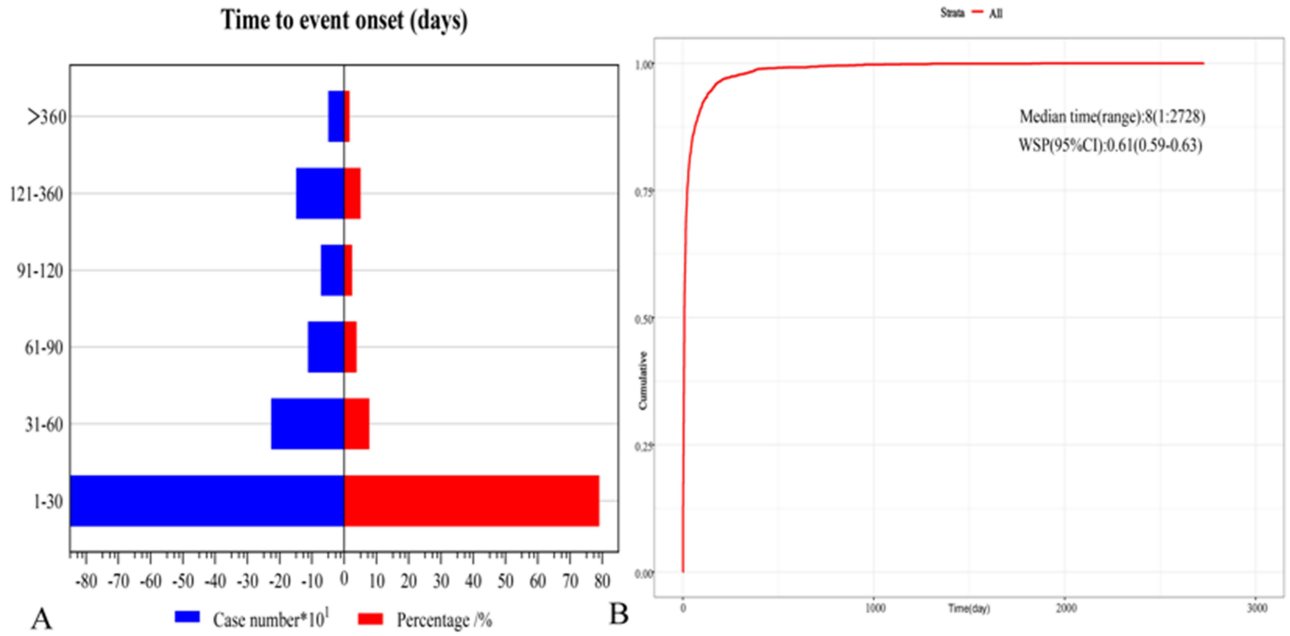


**Figure 1** Temporal Analysis of Adverse Events Associated with Abraxane Distribution and Cumulative Incidence from FAERS Database. (**A**) Bidirectional bar chart illustrating the induction time of treatment-related adverse events. (**B**) Cumulative incidence time chart showing the accumulation of treatment-related adverse events over time.

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I would suggest incorporating additional subgroup analyses. For instance, examining signal differences between genders could reveal important sex-specific safety considerations, as highlighted in recent pharmacovigilance studies.[3] Furthermore, stratifying results by administration route might uncover route-specific AE patterns, which could inform clinical decision-making.[4] Lastly, an age-stratified analysis could illuminate how Abraxane's safety profile varies across different age groups, which is particularly important given the aging population of cancer patients.[5]

To address the lack of temporal analysis in the original study, I have conducted a supplementary investigation using the FAERS database to examine the onset time of adverse events related to Abraxane. This analysis, which created time-to-event graph similar to Figure 1 in the article, provides additional insights into the temporal distribution of Abraxane-related adverse events.This analysis provides additional insights into the temporal distribution of Abraxane-related adverse events. The results reveal that the median time to event onset was 8 days (range: 1–2728 days), with a Weibull shape parameter (WSP) of 0.61 (95% CI: 0.59–0.63). This WSP value below 1 suggests a decreasing hazard rate over time, indicating that the risk of experiencing an AE is highest immediately after treatment initiation and decreases thereafter. This finding aligns with recent literature on the temporal patterns of chemotherapy-related adverse events, particularly for taxane-based regimens like Abraxane.[6]

In conclusion, while this study significantly contributes to our understanding of Abraxane-related AEs, addressing these points could further enhance its impact. The additional temporal analysis I have provided offers valuable insights into the risk profile of Abraxane over time, which could inform clinical decision-making and patient monitoring strategies. The suggested subgroup analyses would provide a more nuanced understanding of Abraxane's safety profile across diverse patient populations.

## Data Sharing Statement

This data can be accessed through the FDA's FAERS Public Dashboard at https://fis.fda.gov/extensions/FPD-QDE-FAERS/FPD-QDE-FAERS.html.

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## Author Contributions

Fangcai Yang: Conceptualization, writing - original draft, literature review. Wukun Ge: Conceptualization, writing - review & editing, supervision. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors declare no conflict of interest in this communication.

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