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Unveiling the Hidden Risks: An Update Decade-Long Analysis of Abraxane-Related Adverse Events from the FAERS Database

Yue-Chen Zhao[1,2], Xin Li[3], Chao-Qun Wang[4], Yan Jiao[5], Yan-Nan Shen[2], Tie-Jun Wang[1,2,*], Chao-He Zhang[6,*]

[1]Department of Radiation Oncology, The Second Hospital of Jilin University, Changchun, Jilin, People's Republic of China; [2]NHC Key Laboratory of Radiobiology, School of Public Health, Jilin University, Changchun, Jilin, People's Republic of China; [3]Department of Radiology, The Second Hospital of Jilin University, Changchun, Jilin, People's Republic of China; [4]Department of Gynaecology, Aviation General Hospital, Beijing, People's Republic of China; [5]Department of Hepatobiliary and Pancreatic Surgery, General Surgery Center, First Hospital of Jilin University, Changchun, People's Republic of China; [6]Department of Hematology and Oncology, The Second Hospital of Jilin University, Changchun, Jilin, People's Republic of China

*These authors contributed equally to this work

Correspondence: Tie-Jun Wang, Department of Radiation Oncology, The Second Hospital of Jilin University, NO. 218 Ziqiang Street, Changchun, 130041, People's Republic of China, Email tjwang@jlu.edu.cn; Chao-He Zhang, Department of Hematology and Oncology, The Second Hospital of Jilin University, NO. 218 Ziqiang Street, Changchun, 130041, People's Republic of China, Email zhangchaohe@jlu.edu.cn

Purpose: Abraxane (nanoparticle albumin-bound paclitaxel) is a chemotherapeutic employed commonly for the management of various cancers including breast cancer, non-small cell lung cancer, and pancreatic adenocarcinoma. Although it has clinically beneficial properties, Abraxane is accompanied by multiple adverse events (AEs) that require close observation. This study aims to evaluate the AE profile of Abraxane using recently available data from January 2004 through December 2023 in the FDA Adverse Event Reporting System (FAERS).

Patients and Methods: The data for Abraxane-related AEs were obtained from the FAERS database. The dataset consisted of patient demographic characteristics as well as information on the types and outcomes of AEs reported. Reporting odds ratios (ROR) as well as proportional reporting ratio (PRR), considering the used definition of anti-cancer agent and AEs, were calculated to investigate any association with Abraxane.

Results: A total of 10,310 reports associated with Abraxane AEs were identified. Blood and lymphatic system disorders were the most frequent (ROR 6.44), followed by hepatobiliary (ROR 3.16), infections (ROR 1.45), and gastrointestinal disorders (ROR 1.42). Serious outcomes included hospitalization in 36.35% and death in 29.76% of cases. The top adverse reactions matched known profiles, including peripheral sensory neuropathy (ROR: 49.48). The analysis also found new adverse reactions, such as scleroderma-like reactions (ROR: 95.4) and vascular pseudoaneurysm ruptures (ROR: 87.71).

Conclusion: Our results re-emphasize the importance of a robust Post Marketing Surveillance system and suggest this FAERS database based analysis provides an updated, independent information on Abraxane related AEs to enrich its safety profile. A process of continuous vigilance and additional investigations on specific areas that may have some undesired events are imperative to increase our knowledge on how Abraxane should be handled in terms of its safety.

Keywords: Abraxane, FAERS database, adverse events, signal detection, pharmacovigilance

Introduction

In recent years, with the rapid development of nanomedicine, several nanomedicine-based drugs have been approved for clinical use, significantly advancing the field of oncology by enhancing drug delivery and reducing side effects.[1,2] Nanomedicine represents a breakthrough in cancer therapy by overcoming traditional limitations, such as poor solubility and rapid systemic clearance, through the use of nanoscale carriers. These carriers improve drug solubility, bioavailability, and enable targeted delivery, allowing therapeutic agents encapsulated within

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nanoparticles to penetrate tumor tissues more effectively while minimizing systemic toxicity.[3–5] Among these, Abraxane (nanoparticle albumin-bound paclitaxel) stands out as a highly effective chemotherapeutic agent that has been utilized for the treatment of several cancers, including breast cancer, non-small cell lung cancer, and pancreatic carcinoma.[6–8]

Abraxane was developed to overcome the limitations of solvent-based paclitaxel (Taxol®) by linking paclitaxel to albumin nanoparticles, allowing for more efficient drug delivery to tumor sites. This formulation eliminates the need for toxic solvents like Cremophor EL, which are known to cause severe hypersensitivity reactions, thus reducing solvent-related adverse events (AEs).[9] The albumin nanoparticle design offers improved drug solubility and stability, enabling higher concentrations of paclitaxel to be delivered directly to tumors. By utilizing albumin as a natural carrier, Abraxane leverages the body's own pathways to facilitate transcytosis across endothelial cells, promoting efficient drug accumulation within the tumor microenvironment.[10] This mechanism enhances the penetration of paclitaxel into tumor tissues while minimizing systemic side effects. Additionally, the use of albumin helps transport the drug across cellular barriers, further increasing its therapeutic efficacy. By avoiding solvent carriers, Abraxane reduces the need for premedication with corticosteroids or antihistamines, which simplifies treatment protocols and improves patient compliance. Overall, this innovative nanoparticle formulation allows for enhanced drug delivery while minimizing the adverse effects associated with traditional paclitaxel therapies.[11,12]

While there are beneficial aspects to the drug, it is not void of side effects like every other medication. Several AEs such as hematological toxicities, neuropathy, and gastrointestinal disorders have been reported in previous studies on their use.[13–15] As the clinical use of Abraxane continues to grow, pharmacovigilance efforts are crucial to monitor its safety profile, enabling early recognition of potential risks and guiding further investigations if new safety concerns arise. The US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) is an important pharmacovigilance resource to identify potential safety concerns with a large number of spontaneous reports reporting drug-related AEs in real-world clinical settings.[16]

The aim of this study is to present a new analysis of the adverse event profile through data from FAERS reporting period January 2004-December 2023, with focus on Abraxane AEs. This analysis provides additional details on the incidence and character of reported AEs associated with Abraxane, further supporting heightened awareness of this emerging safety issue to help guide patient care. Given the increasing use of Abraxane across multiple cancer types, maintaining a comprehensive and up-to-date safety profile is essential to understand both known and emerging risks, ensuring its safe integration into modern oncology treatment regimens. Comprehensive data analysis should provide critical information on the risk-benefit profile of the drug to aid healthcare professionals in making more informed choices about how and when it can be safely used as part of oncology treatment.

Materials and Methods

Data Source

The data in the present study were extracted from FAERS (an AE and medication error [ME] reports database), which received AEs and MEs reported by healthcare professionals, manufacturers, and patients. This publicly accessible database comprises various datasets, including patient demographics, drug specifics, and coded information on AEs, offering valuable insights for pharmacovigilance activities across different populations.

Data Extraction

Reports involving Abraxane as the primary suspect (PS) drug were identified with this specific PS code. The study was conducted from January 2004-December 2023. Duplicates were systematically removed following FDA guidelines, which prioritize the most recent entry when duplicates share identical case IDs. This approach ensured that only the most accurate and updated reports were included. The extracted data included patient demographics, drug details, adverse event descriptions, and outcomes received with reporting sources (Figure 1).

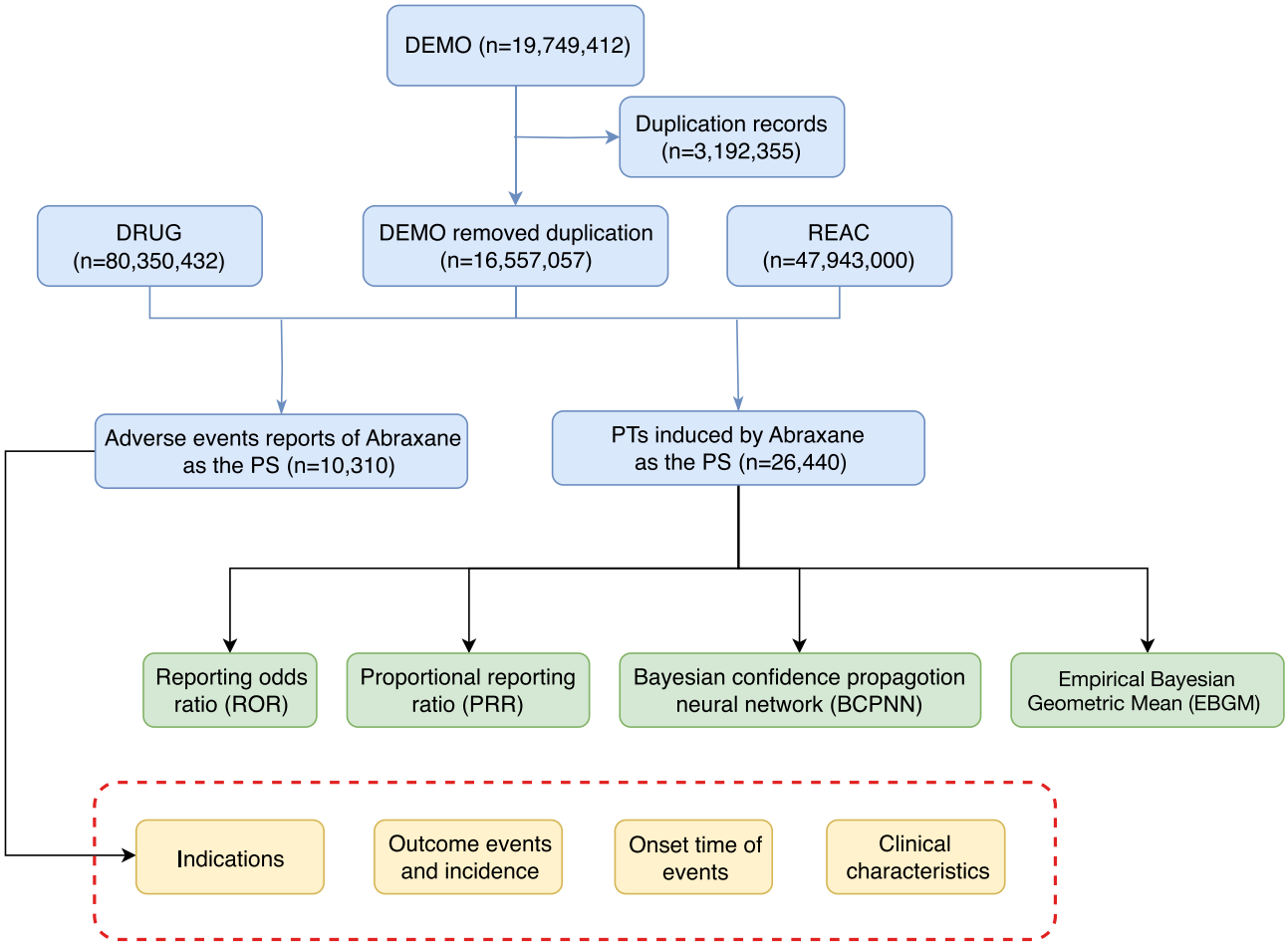

Figure 1 Flow diagram of selecting Abraxane-related adverse events (AEs) from the FAERS database. The diagram outlines the process of data extraction and analysis, starting from the initial dataset of 19,749,412 records. After removing 3,192,355 duplicate records, the dataset included 16,557,057 unique demographic records (DEMO). Further filtering for drug records (DRUG) and adverse reactions (REAC) related to Abraxane resulted in 10,310 reports of Abraxane-induced AEs. The flowchart also highlights the different statistical methods used to assess the association between Abraxane and various AEs, including the reporting odds ratio (ROR), proportional reporting ratio (PRR), Bayesian confidence propagation neural network (BCPNN), and Empirical Bayesian Geometric Mean (EBGM). The diagram summarizes the clinical characteristics, onset time of events, and incidence of the reported AEs.

Statistical Analysis

Measures of association with Abraxane for specific AEs were calculated in the form of reporting odds ratio (ROR) and proportional reporting ratios (PRR). To strengthen signal detection, we integrated multiple analytical approaches: ROR, PRR, Bayesian Confidence Propagation Neural Network (BCPNN), and Empirical Bayesian Geometric Mean (EBGM). These diverse algorithms helped in cross-verifying signals, offering a comprehensive understanding of Abraxane-associated risks compared to other drugs in the FAERS database.

The ROR served as the principal indicator of association, with values above 1 pointing to a stronger connection between Abraxane and the specific AE compared to other drugs. PRR values exceeding 2, along with significant chi-square results, were deemed robust signals. Bayesian methods, such as BCPNN and EBGM, were utilized to manage the detection of rare AEs by accounting for variability and reducing the likelihood of false positives.

Data Presentation

Table formations were used to summarize the frequency and strength of association between Abraxane and a particular AE in terms of System Organ Class (SOC) levels for results from our analysis. The tables reported the following information: number of case reports, RORs, PRRs, and 95% CI.

Inclusion and Exclusion Criteria

This analysis focused on reports where Abraxane was the PS drug. By doing this one is fairly certain that the AEs being reported are likely due to Abraxane. Reports that lacked crucial demographic data or were associated with unapproved uses were omitted to reduce potential biases. Only records where Abraxane was the PS in reported AEs were retained, ensuring that the analysis specifically targeted Abraxane-related effects.

Results

Basic Characteristics of Adverse Reactions

A total of 10,310 reports of Abraxane-related AEs were identified in the FAERS database from January 2004 to December 2023 (Table 1). The majority of these reports involved female patients at 48.45%, while male patients accounted for 41.80%. Nearly half of the AEs occurred in individuals aged 60 or older, representing 49.75% of cases. Intravenous drip was the most common route of administration used in 65.21% of instances, indicating it is the primary method for delivering the drug.

Table 1 Basic Characteristics of Adverse Reactions Related to Abraxane from the FAERS Database

Variable	Total
Gender	
Female	4995 (48.45)
Male	4310 (41.80)
Unknown	1005 (9.75)
Age	
<18	14 (0.14)
18~25	10 (0.10)
25~60	2434 (23.61)
≥60	5129 (49.75)
Unknown	2723 (26.41)
Weight	67.00 (56.00,79.70)
Reporter	
Physician	3985 (38.65)
Other health-professional	3649 (35.39)
Pharmacist	1547 (15.00)
Consumer	955 (9.26)
Unknown	154 (1.49)
Registered Nurse	18 (0.17)
Lawyer	2 (0.02)
Reported countries	
United States	4050 (42.39)
Japan	1240 (12.98)
Germany	886 (9.27)
Canada	695 (7.27)
Spain	373 (3.90)
China	333 (3.49)
Route	
Intravenous drip	6723 (65.21)
Other	2556 (24.79)
Intravenous	913 (8.86)
Parenteral	47 (0.46)

(*Continued*)

Table 1 (Continued).

Variable	Total
Subcutaneous	41 (0.40)
Oral	18 (0.17)
Intraperitoneal	12 (0.12)
Outcomes	
Hospitalization	4554 (36.35)
Death	3729 (29.76)
Other serious	3237 (25.84)
Life threatening	773 (6.17)
Disability	222 (1.77)
Required intervention to Prevent Permanent Impairment/Damage	10 (0.08)
Congenital anomaly	4 (0.03)

The outcomes of these AEs were widely variable. Hospitalization was a commonly reported serious outcome, occurring in 36.35% of cases, suggesting many AEs linked to Abraxane were severe enough to warrant admission. Death was reported in 29.76% of cases, underscoring the life-threatening potential of some AEs. Other serious outcomes included potentially lethal conditions at 6.17%, disabilities at 1.77%, and birth defects at 0.03%. These conclusions highlight the critical nature of some AEs associated with Abraxane and the importance of vigilant patient oversight (Figure 2).

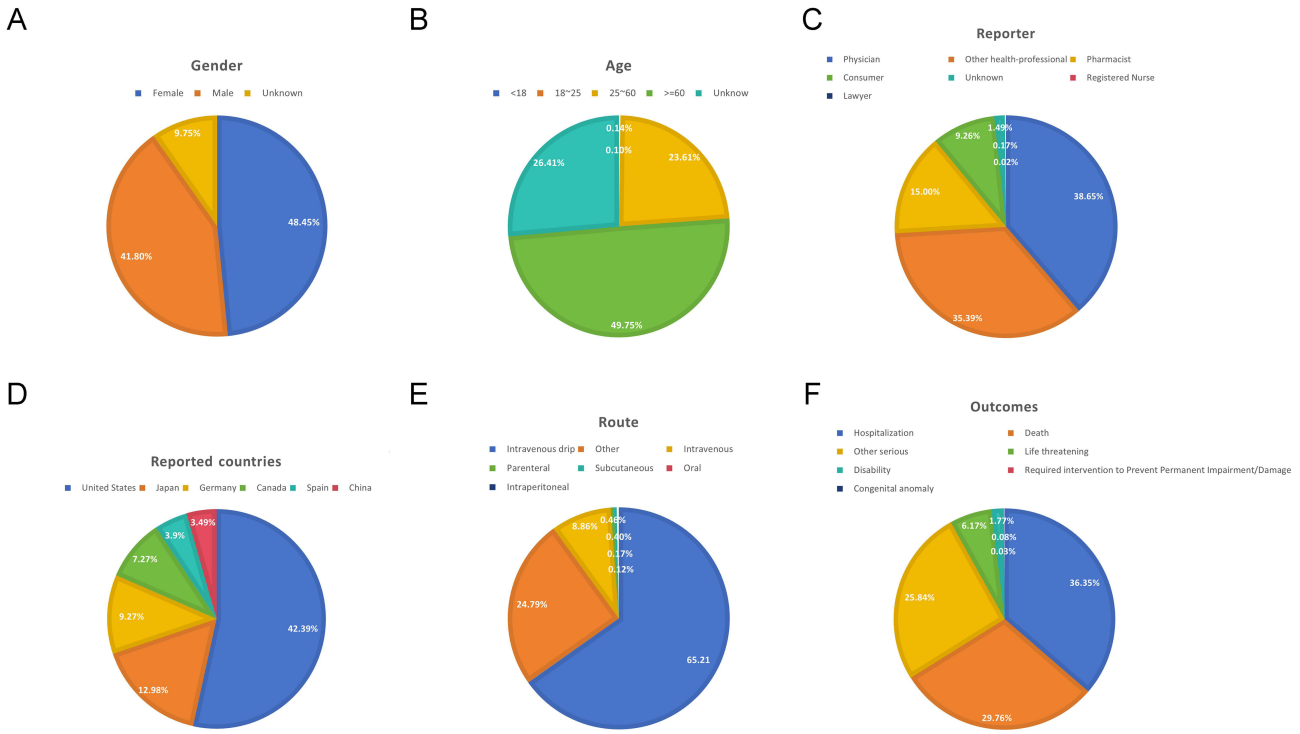

Figure 2 Basic characteristics of adverse reactions related to Abraxane from the FAERS database. (**A**) Gender distribution of reported cases, showing proportions of female, male, and unknown genders. (**B**) Age groups of patients, categorized as <18, 18–25, 25–60, ≥60, and unknown age. (**C**) Reporter types, indicating the proportion of cases reported by physicians, other health professionals, pharmacists, consumers, registered nurses, and lawyers. (**D**) Countries where adverse reactions were reported, highlighting the distribution across the United States, Japan, Germany, Canada, Spain, and China. (**E**) Routes of administration, displaying the frequency of different administration methods, including intravenous drip, intravenous, parenteral, subcutaneous, oral, and intraperitoneal. (**F**) Outcomes of adverse reactions, showing the breakdown of serious outcomes such as hospitalization, death, other serious events, life-threatening conditions, disability, and required interventions to prevent permanent impairment/damage.

AEs by System Organ Class

AEs tied to Abraxane were categorized by SOC to provide a comprehensive overview of their distribution and prevalence (Table 2). Blood and lymphatic disorders were the most frequently reported category, with a notably strong relationship to Abraxane use indicated by a ROR of 6.44 (95% CI 6.19–6.70). This significant ROR implies those receiving Abraxane are much more likely to experience blood and lymphatic issues versus other medications.

Liver problems were another prominent category, with an ROR of 3.16 (95% CI 2.94–3.39), underscoring a remarkable risk of hepatic AEs in Abraxane-treated patients. Infections and infestations were also commonly documented, with an ROR of 1.45 (95% CI 1.38–1.51), signifying an elevated risk of contracting infections. Gastrointestinal disorders were regularly reported too, with an ROR of 1.42 (95% CI 1.37–1.47), proposing patients receiving Abraxane face a higher probability of gastrointestinal issues. Moreover, respiratory, thoracic, and mediastinal disorders were meaningfully correlated with Abraxane use, evidenced by an ROR of 1.27 (95% CI 1.20–1.33) (Figure 3).

Top 30 Clinical Adverse Reactions

The FAERS database analysis identified several adverse reactions associated with Abraxane that align with the prescribing information. Among these, peripheral sensory neuropathy was notably prevalent, with an ROR of 49.48 observed in 123 cases, indicating its frequent occurrence across all approved indications. The analysis also revealed adverse reactions not prominently mentioned in the prescribing information, including scleroderma-like reactions (ROR: 95.4), vascular pseudoaneurysm ruptured (ROR: 87.71), and cholangitis infective (ROR: 78.39). Other rare but notable conditions identified include biliary

Table 2 Adverse Reactions of Abraxane at the System Organ Class (SOC) Level in the FAERS Database

SOC	Case Reports	ROR (95% CI)	PRR (95% CI)	Chisq	IC (IC025)	EBGM (EBGM05)
Blood and lymphatic system disorders	2730	6.44 (6.19, 6.7)	5.88 (5.65, 6.12)	11,221.67	2.55 (2.5)	5.87 (5.67)
Hepatobiliary disorders	770	3.16 (2.94, 3.39)	3.09 (2.86, 3.34)	1099.63	1.63 (1.52)	3.09 (2.91)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1508	2.07 (1.96, 2.18)	2.01 (1.9, 2.13)	783.68	1 (0.93)	2.01 (1.92)
Metabolism and nutrition disorders	1094	1.88 (1.77, 1.99)	1.84 (1.73, 1.95)	429.8	0.88 (0.79)	1.84 (1.75)
Infections and infestations	2043	1.45 (1.38, 1.51)	1.41 (1.36, 1.47)	260.96	0.5 (0.43)	1.41 (1.36)
Gastrointestinal disorders	3236	1.42 (1.37, 1.47)	1.37 (1.32, 1.42)	354.08	0.45 (0.4)	1.37 (1.33)
Respiratory, thoracic and mediastinal disorders	1645	1.27 (1.2, 1.33)	1.25 (1.2, 1.3)	86.11	0.32 (0.25)	1.25 (1.2)
Investigations	2004	1.2 (1.14, 1.25)	1.18 (1.13, 1.23)	58.94	0.24 (0.17)	1.18 (1.14)
Endocrine disorders	77	1.11 (0.89, 1.39)	1.11 (0.89, 1.38)	0.84	0.15 (−0.17)	1.11 (0.92)
General disorders and administration site conditions	4768	0.99 (0.96, 1.02)	0.99 (0.97, 1.01)	0.6	−0.01 (−0.06)	0.99 (0.96)
Vascular disorders	590	0.98 (0.91, 1.07)	0.98 (0.91, 1.06)	0.19	−0.03 (−0.14)	0.98 (0.92)
Cardiac disorders	646	0.87 (0.81, 0.94)	0.87 (0.8, 0.94)	12.16	−0.19 (−0.31)	0.87 (0.82)
Renal and urinary disorders	437	0.85 (0.77, 0.93)	0.85 (0.77, 0.94)	11.75	−0.23 (−0.37)	0.85 (0.79)
Nervous system disorders	1739	0.72 (0.69, 0.76)	0.74 (0.71, 0.77)	175.89	−0.44 (−0.51)	0.74 (0.71)
Skin and subcutaneous tissue disorders	1070	0.71 (0.67, 0.76)	0.72 (0.68, 0.76)	120.69	−0.47 (−0.56)	0.72 (0.69)
Ear and labyrinth disorders	84	0.7 (0.57, 0.87)	0.7 (0.56, 0.87)	10.44	−0.5 (−0.81)	0.7 (0.59)
Eye disorders	315	0.57 (0.51, 0.63)	0.57 (0.51, 0.64)	103.67	−0.81 (−0.97)	0.57 (0.52)
Immune system disorders	149	0.48 (0.41, 0.57)	0.49 (0.42, 0.57)	81.22	−1.04 (−1.27)	0.49 (0.43)
Musculoskeletal and connective tissue disorders	604	0.4 (0.37, 0.43)	0.41 (0.38, 0.44)	540.24	−1.28 (−1.4)	0.41 (0.38)
Injury, poisoning and procedural complications	629	0.23 (0.21, 0.25)	0.25 (0.23, 0.27)	1555.5	−2 (−2.11)	0.25 (0.23)
Reproductive system and breast disorders	44	0.19 (0.14, 0.26)	0.19 (0.14, 0.25)	151.91	−2.39 (−2.81)	0.19 (0.15)
Psychiatric disorders	243	0.14 (0.13, 0.16)	0.15 (0.13, 0.17)	1217.53	−2.71 (−2.89)	0.15 (0.14)
Congenital, familial and genetic disorders	8	0.09 (0.05, 0.18)	0.09 (0.05, 0.18)	71.28	−3.43 (−4.37)	0.09 (0.05)
Pregnancy, puerperium and perinatal conditions	7	0.06 (0.03, 0.12)	0.06 (0.03, 0.13)	106.56	−4.09 (−5.09)	0.06 (0.03)

Abbreviations: SOC, System Organ Class; ROR, reporting odds ratio; PRR, proportional reporting ratio; Chisq, Chi-Square; IC, Information Component; EBGM, Empirical Bayesian Geometric Mean.

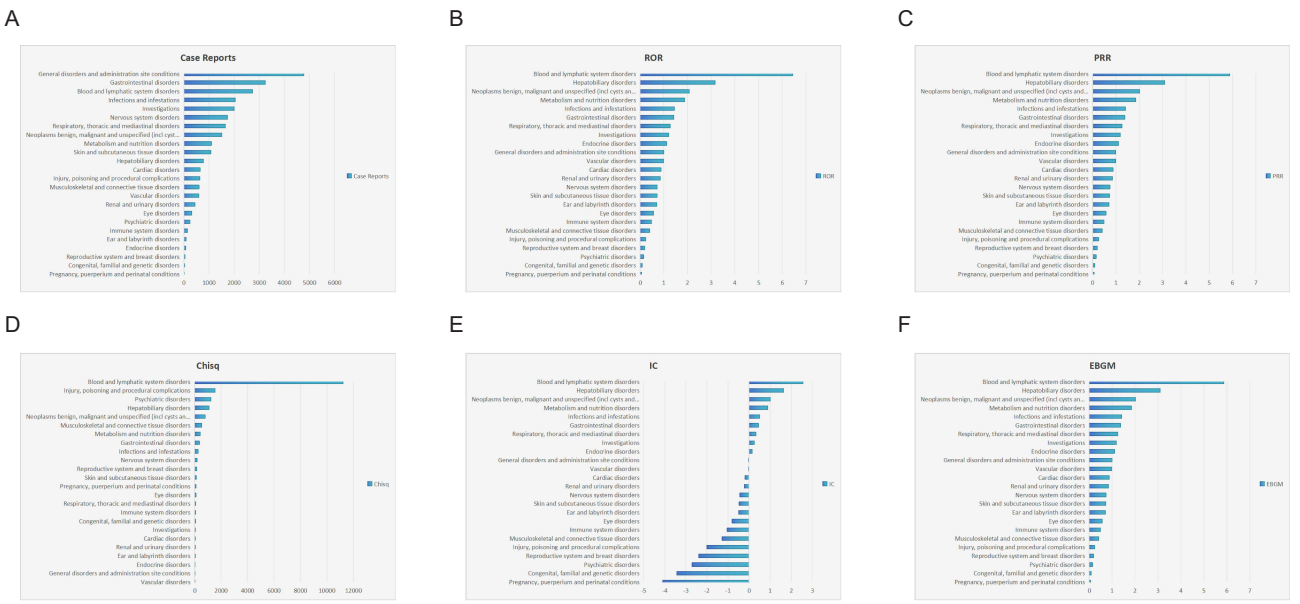

Figure 3 Adverse reactions of Abraxane at the System Organ Class (SOC) level in the FAERS database. (**A**) Case Reports, (**B**) ROR (Reporting Odds Ratio), (**C**) PRR (Proportional Reporting Ratio), (**D**) Chi-square (Chisq), (**E**) IC (Information Component), (**F**) EBGM (Empirical Bayesian Geometric Mean).

tract infection (ROR: 158.86), conjunctivalisation (ROR: 236.41), and pancreatic fistula (ROR: 85.5). Additionally, lymphatic disorders (ROR: 39.76) and pseudocirrhosis (ROR: 53.09) were observed, suggesting potential areas for further investigation. These findings highlight the importance of ongoing pharmacovigilance and underscore the need for continued research to better understand and manage these newly identified risks associated with Abraxane (Table 3 and Figure 4).

Discussion

The recent reanalysis of AEs tied to Abraxane (nanoparticle albumin-bound paclitaxel) using data from the FAERS database between January 2004 and December 2023 offers crucial insights into the safety profile of this medication. The results involving serious consequences especially worried us, notably the towering rates of hospitalization and death. Admission occupied the most frequent severe outcome at 36.35% of situations while death claimed 29.76% of cases. These discoveries underscore the possible threat posed by some AEs tied to Abraxane, underscoring the necessity for healthcare providers to closely track patients and promptly handle severe AEs. This high prevalence of grave outcomes aligns with data from other studies also reporting meaningful rates of hospitalization and mortality among Abraxane recipients.[17–19]

Comparing our results to past studies reveals notable resemblances and divergences. Wang et al also used the FAERS database and identified several adverse reactions associated with albumin-bound paclitaxel, including hematologic toxicities like neutropenia, thrombocytopenia, and lymphopenia, as well as hepatobiliary disorders such as liver failure and jaundice.[18] Consistent with Wang et al and earlier findings, our results highlight the common occurrence of peripheral sensory neuropathy and blood and lymphatic disorders, emphasizing the need for continuous monitoring and vigilant blood count management during treatment. Our updated analysis thus provides an expanded understanding of the safety profile of Abraxane, reinforcing the need for regular monitoring to mitigate these well-documented adverse reactions. However, Wang's study was based on data up to 2019, and since then, significant updates to the FAERS database have occurred. Our analysis, which includes data up to 2023, offers a more updated view of Abraxane's safety profile.

Our analysis also revealed several adverse reactions not explicitly mentioned in the Abraxane prescribing information, underscoring the need for enhanced pharmacovigilance as the drug continues to be widely used in oncology. Among the most notable findings, scleroderma-like reactions (ROR: 95.4) emerged as a significant concern. Although rare, these reactions may involve immune-mediated mechanisms, suggesting the need for heightened awareness among clinicians, especially for patients with autoimmune predispositions. Given the potential severity of these symptoms, early recognition and appropriate management are crucial to mitigate complications.

Table 3 Top 30 Clinical Adverse Reactions of Abraxane Ranked by ROR in the FAERS Database

SOC	PT	Case Reports	ROR (95% CI)	PRR (95% CI)	Chisq	IC (IC025)	EBGM (EBGM05)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma metastatic	205	159.86 (138.53, 184.49)	158.63 (138.29, 181.96)	29,527.94	7.19 (6.98)	145.94 (129.46)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung squamous cell carcinoma metastatic	3	100.69 (31.48, 322.07)	100.68 (31.68, 320.01)	280.49	6.58 (5.11)	95.44 (36.07)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma pancreas	40	64.65 (47.15, 88.64)	64.55 (47.17, 88.33)	2416.65	5.96 (5.51)	62.37 (47.89)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of head and neck	5	48.21 (19.83, 117.18)	48.2 (19.95, 116.44)	225.11	5.55 (4.38)	46.98 (22.34)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ductal adenocarcinoma of pancreas	6	45.32 (20.16, 101.89)	45.31 (20.29, 101.2)	253.63	5.47 (4.38)	44.23 (22.45)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Inflammatory carcinoma of the breast	3	41.19 (13.12, 129.38)	41.19 (13.22, 128.38)	115.02	5.33 (3.9)	40.3 (15.47)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-small cell lung cancer metastatic	13	38.96 (22.49, 67.5)	38.94 (22.49, 67.41)	470.47	5.25 (4.49)	38.14 (24.08)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic gastric cancer	6	36.37 (16.21, 81.62)	36.37 (16.28, 81.23)	202.31	5.16 (4.08)	35.67 (18.14)
Infections and infestations	Biliary tract infection	40	158.86 (114.97, 219.52)	158.62 (115.92, 217.05)	5761.02	7.19 (6.73)	145.94 (111.34)
Infections and infestations	Cholangitis infective	8	78.39 (38.62, 159.11)	78.37 (38.7, 158.7)	585.73	6.23 (5.27)	75.16 (41.57)
Infections and infestations	Pancreatic abscess	5	58.47 (24, 142.48)	58.46 (24.2, 141.22)	273.56	5.82 (4.65)	56.66 (26.89)
Infections and infestations	Enterocolitis infectious	22	48.72 (31.9, 74.42)	48.68 (31.63, 74.92)	1000.58	5.57 (4.97)	47.43 (33.28)
Infections and infestations	Biliary sepsis	9	40.29 (20.81, 78)	40.27 (20.68, 78.41)	337.19	5.3 (4.4)	39.42 (22.68)
Hepatobiliary disorders	Pseudocirrhosis	7	53.09 (25.04, 112.59)	53.08 (25.2, 111.79)	347.51	5.69 (4.67)	51.6 (27.51)
Hepatobiliary disorders	Cholangitis	126	50.12 (41.98, 59.85)	49.89 (41.82, 59.51)	5875.52	5.6 (5.35)	48.58 (41.88)
Hepatobiliary disorders	Bile duct stenosis	24	45.58 (30.4, 68.36)	45.54 (30.17, 68.73)	1019.97	5.47 (4.9)	44.45 (31.67)
Hepatobiliary disorders	Immune-mediated hepatitis	22	38.22 (25.05, 58.31)	38.19 (24.81, 58.78)	780.32	5.23 (4.63)	37.42 (26.28)
Hepatobiliary disorders	Haemobilia	7	36.89 (17.45, 77.97)	36.88 (17.51, 77.67)	239.46	5.18 (4.17)	36.16 (19.33)
Nervous system disorders	Peripheral sensory neuropathy	123	49.48 (41.35, 59.21)	49.25 (41.29, 58.75)	5661.08	5.58 (5.33)	47.97 (41.28)
Nervous system disorders	Cranial nerve paralysis	4	37.37 (13.88, 100.59)	37.37 (13.75, 101.54)	138.71	5.2 (3.91)	36.63 (16)
Nervous system disorders	Peripheral motor neuropathy	23	36.4 (24.09, 55.01)	36.37 (24.1, 54.89)	775.64	5.16 (4.57)	35.68 (25.25)
Gastrointestinal disorders	Pancreatic duct stenosis	4	94.16 (34.46, 257.28)	94.14 (34.65, 255.8)	350.42	6.48 (5.18)	89.54 (38.62)
Gastrointestinal disorders	Pancreatic fistula	5	85.5 (34.86, 209.68)	85.48 (34.7, 210.58)	398.68	6.35 (5.17)	81.68 (38.56)
Gastrointestinal disorders	Duodenal obstruction	7	51.37 (24.23, 108.9)	51.36 (24.39, 108.17)	336.13	5.64 (4.63)	49.97 (26.65)
Skin and subcutaneous tissue disorders	Nail toxicity	4	34.36 (12.78, 92.41)	34.36 (12.9, 91.55)	127.13	5.08 (3.8)	33.74 (14.74)
Musculoskeletal and connective tissue disorders	Scleroderma-like reaction	6	95.4 (41.98, 216.84)	95.38 (41.87, 217.25)	532.34	6.5 (5.4)	90.66 (45.61)

Injury, poisoning and procedural complications	Vascular pseudoaneurysm ruptured	6	87.71 (38.65, 199.02)	87.69 (38.5, 199.74)	490.48	6.39 (5.29)	83.69 (42.16)
General disorders and administration site conditions	Administration site reaction	5	33.69 (13.91, 81.61)	33.69 (13.95, 81.39)	155.68	5.05 (3.88)	33.09 (15.78)
Eye disorders	Conjunctivalisation	3	236.41 (70.98, 787.43)	236.38 (71.51, 781.36)	622.03	7.71 (6.19)	209.22 (76.45)
Blood and lymphatic system disorders	Lymphatic disorder	10	39.76 (21.24, 74.4)	39.74 (21.22, 74.41)	369.58	5.28 (4.42)	38.91 (23.03)

Abbreviations: SOC, System Organ Class; PT, Preferred term; ROR, reporting odds ratio; PRR, proportional reporting ratio; Chisq, Chi-Square; IC, Information Component; EBGM, Empirical Bayesian Geometric Mean.

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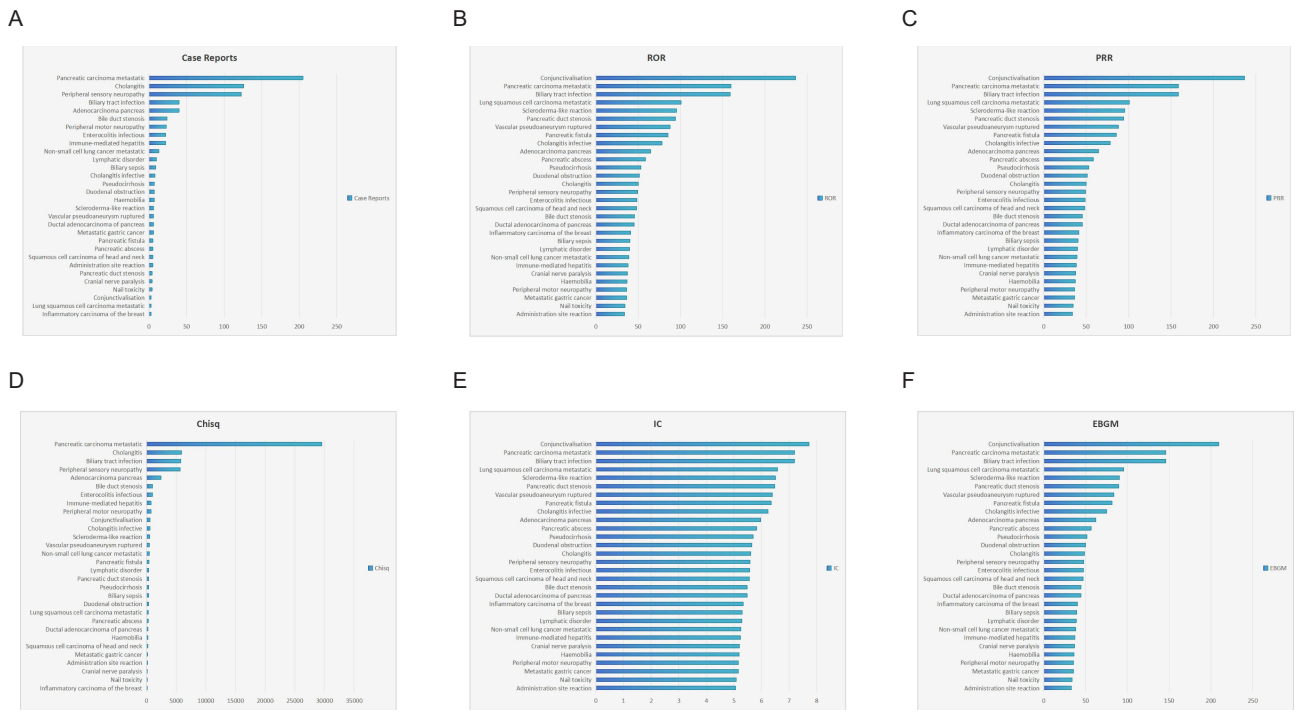

Figure 4 Top 30 clinical adverse reactions of Abraxane ranked by ROR in the FAERS database. (**A**) Case Reports, (**B**) ROR (Reporting Odds Ratio), (**C**) PRR (Proportional Reporting Ratio), (**D**) Chi-square (Chisq), (**E**) IC (Information Component), (**F**) EBGM (Empirical Bayesian Geometric Mean).

Another important finding was vascular pseudoaneurysm ruptures (ROR: 87.71), which highlighted possible effects on vascular integrity. This suggests the need for close monitoring, particularly in patients with pre-existing vascular conditions, to identify early signs of vascular compromise. Digestive system-related AEs, such as cholangitis infective (ROR: 78.39), biliary tract infection (ROR: 158.86), and pancreatic fistula (ROR: 85.5), were also observed, indicating a potential risk for hepatic or biliary complications. Regular assessment of hepatic and gastrointestinal health, especially in patients with a history of biliary disorders, is advisable to help manage these risks.[20,21]

Additionally, other rare conditions like conjunctivalisation (ROR: 236.41), lymphatic disorders (ROR: 39.76), and pseudocirrhosis (ROR: 53.09) highlight a broader spectrum of potential risks. While these AEs occurred less frequently, their identification points to the importance of continued monitoring and further research to better understand their association with Abraxane. Overall, these findings emphasize the need for vigilant pharmacovigilance to enhance the drug's safety profile and inform clinical practices.

Our findings reveal both strengths and limitations regarding Abraxane safety. Chiefly, the extensive FAERS data offers a comprehensive overview of real-world AEs. However, spontaneous reporting is prone to underreporting and overreporting biases. Furthermore, lacking clinical details like dosage, therapy duration, and patient comorbidities restricts definitive conclusions on specific adverse event risks. Future longitudinal studies should better elucidate the temporal relationship between Abraxane use and toxicity onset. Exploring biological pathways involved in Abraxane toxicities could provide insight for prevention or treatment. Enhanced pharmacovigilance, including active surveillance and real-world evidence research, is also critical to further characterize Abraxane's profile.

Conclusion

In conclusion, this updated Abraxane adverse event analysis from the FAERS database highlights significant associations with several serious AEs, including common adverse reactions and new, rare signals. These results underscore the importance of ongoing monitoring, promptly managing AEs, and additional studies to enhance Abraxane safety and efficacy in practice. By identifying and addressing safety concerns, healthcare providers can boost outcomes and ensure Abraxane's safe use in cancer treatment.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Informed Consent

The study was approved by the Medical Ethics Committee of the Second Hospital of Jilin University.

Author Contributions

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 report no conflicts of interest in this work.

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