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Management of Hypersensitivity in Oncology Practice: Risk Stratification, Phenotypic Markers, and Desensitization Protocols

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Abstract

Background

Hypersensitivity reactions (HSRs) to antineoplastic agents frequently complicate optimal cancer care. This study evaluated the clinical characteristics of patients experiencing Grade ≥ 2 HSRs and compared the efficacy and safety of a simplified single-bag (1-bag) desensitization protocol with the standard three-bag (3-bag) protocol.

Methods

We analyzed 84 independent episodes in 69 patients followed in an oncology center under oncologist supervision who developed NCI CTCAE v5.0 Grade ≥ 2 reactions between January 2024 and January 2026. For patient safety, we adopted a strict single-attempt policy, immediately stopping desensitization upon any breakthrough reaction. Patients with anaphylactic shock were excluded.

Results

The predominant agents were taxanes (66.7%) and platinums (28.6%). Taxane reactions occurred significantly earlier (cycle 1.55 vs. 3.46, $p < 0.001$) and more acutely after infusion onset (9.45 vs. 38.83 minutes, $p < 0.001$) compared to platinums. The 1-bag protocol achieved an 82.8% (24/29) success rate, comparable to the 85.7% (24/28) success rate of the 3-bag protocol ($p = 0.993$). Pathogenic germline mutations in homologous recombination repair (HRR) genes were identified in 31.0% of breast cancer patients with HSRs. Overall treatment continuation success was 75.0%.

Conclusions

Although not yet standard practice, the single-bag protocol offers comparable clinical success to the three-bag regimen while reducing operational complexity. Distinct temporal differences between taxanes and platinums, along with HRR mutation status, serve as valuable parameters for risk stratification. However, these procedures should ideally be performed under the guidance of an allergy specialist in a multidisciplinary setting whenever possible.

Introduction

Hypersensitivity reactions (HSRs) to antineoplastic agents are a major clinical challenge affecting the continuity of oncological treatment [1,2]. These reactions range from mild cutaneous manifestations to life-threatening anaphylaxis [3]. These reactions involve heterogeneous immunological mechanisms, ranging from IgE-mediated type I hypersensitivity (commonly seen with platinum agents) to non-IgE-

mediated pathways such as complement activation-related pseudoallergy (CARPA), which is frequently observed with taxanes [4–6].

For moderate to severe reactions (Common Terminology Criteria for Adverse Events [CTCAE] v5.0 Grade 2 and above), standard premedication or simply slowing the infusion rate is generally insufficient; this often forces the patient to switch to less effective second-line therapies [2,7]. Rapid drug desensitization (RDD) is the primary strategy that ensures patient access to optimal therapy by inducing a temporary immune tolerance [5,8]. Historically, 12-step, three-bag (3-bag) protocols have been considered the gold standard, but their complex preparation processes increase the risk of operational errors and pharmacy workload in busy oncology clinics [8–10].

Recent meta-analyses and real-world studies suggest that "one-bag" (1-bag) protocols, where the drug concentration remains constant, have a safety and efficacy profile similar to traditional multi-bag methods [11–13]. Especially in resource-constrained centers, these simplified regimens stand out as a rational alternative to traditional protocols by improving operational efficiency and minimizing preparation errors [11,14]. However, there is still a need for real-world cohort analyses that directly compare the success rates and reaction phenotypes of these two different protocols.

This study aimed to compare the clinical success and safety of single-bag versus three-bag desensitization protocols in patients with Grade ≥ 2 HSRs and to evaluate temporal and phenotypic differences between taxane- and platinum-induced reactions.

Materials and Methods

Study Design and Data Collection

This retrospective, single-center study was conducted by reviewing the data of patients who developed HSRs while receiving antineoplastic agents or targeted therapies between January 1, 2024, and January 1, 2026. The study included patients who experienced an index reaction of National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v5.0 Grade 2 or higher, and for whom continuing first-line treatment was considered medically mandatory. Patients with severe anaphylactoid reactions or anaphylactic shock did not undergo the desensitization process.

Since the focus was on reaction characteristics and management success rather than survival outcomes, analyses were performed at the episode level, treating each reaction and procedure as an independent event. These 84 episodes represent independent hypersensitivity events occurring in the same or different treatment lines. A “single attempt” policy was implemented as a stopping criterion specifically for breakthrough reactions occurring during the desensitization process.

The study data were obtained from the records of the “Infusion-Related Reaction Notification Form,” which is standardly completed in real-time for every patient who develops a reaction during chemotherapy infusion at our center. This form includes baseline patient characteristics, the treatment

cycle during which the reaction occurred, the time elapsed since the start of the infusion (in minutes), observed clinical symptoms, the severity of the reaction, and any emergency medical interventions performed. Additionally, patients who were found to have developed recurrence or metastasis during the evaluated treatment period were excluded from the study due to potential changes in their primary treatment goals and protocols. Ethical approval for the study was obtained from the Tekirdağ Namık Kemal University Non-Interventional Clinical Research Ethics Committee.

Clinical Management and Desensitization Protocols

After the index reaction, the choice between single-bag and three-bag desensitization was made at the treating clinician's discretion. All patients received standard premedication comprising systemic corticosteroids and H1 and H2 receptor antagonists prior to desensitization. For the three-bag (3-bag) desensitization strategy, the standard 12-step protocol described by Castells et al. was followed; the culprit agent was prepared in three separate dilution bags (1/100, 1/10, and 1/1 concentrations) and infused in steps with rate increments every 15 minutes. In the single-bag (1-bag) slow infusion protocol, where the drug concentration remains constant and immune tolerance is induced solely through precise rate escalations, the target dose was prepared in a single, undiluted bag. In this method, the infusion was initiated at a rate of 2 mL/h for the first 15 minutes using high-precision pumps, then increased to 20 mL/h, 40 mL/h, and 80 mL/h in subsequent 15-minute intervals, respectively, and finally maintained at 120 mL/h until the infusion was completed. If a breakthrough reaction occurred during desensitization, the infusion was stopped; for patients who stabilized after symptom management, the procedure was resumed either at the same rate or one step below the rate at which the reaction occurred.

Clinical Safety and Stopping Policy

Although continuing the protocol with modifications for breakthrough reactions during desensitization is suggested by some high-volume centers in the literature [11, 15], a "single attempt" policy was adopted in our study to standardize patient safety in a general oncology ward setting without an on-site allergist. In cases where a reaction of any grade developed during the desensitization process, the procedure was immediately terminated, and a second desensitization attempt with the same agent was not performed. Patients lacking a suitable alternative treatment were referred to an allergy specialist and excluded from the study.

Statistical Analysis

Statistical analyses of the data were performed using IBM SPSS Statistics (v27.0) software. Categorical variables were expressed as frequencies (n) and percentages (%), and intergroup comparisons were performed using the Pearson Chi-square or Fisher's Exact test. Continuous variables were presented as mean ± standard deviation (SD), and differences between the taxane and platinum groups were evaluated using Generalized Estimating Equations (GEE) models to account for the within-patient

correlation (clustering) of recurrent episodes. A p-value of < 0.05 was considered statistically significant for all analyses.

Results

Patient Characteristics and Baseline Clinical Data

A total of 84 independent hypersensitivity reaction (HSR) episodes, which developed during chemotherapy infusion in 69 patients meeting the study criteria, were included in the episode-level analysis. Of the evaluated episodes, 86.9% (n = 73) were observed in female patients, and the mean age of the overall cohort was 52.45 ± 13.15 years (range, 20–78 years). The most frequent primary oncological diagnosis was breast cancer (n = 58, 69.0%), followed by gastrointestinal tract tumors (n = 15, 17.9%), lung cancer (n = 6, 7.1%), and gynecologic malignancies (n = 3, 3.6%). The baseline demographic and clinical history data of the included patients are summarized in Table 1.

When evaluating genetic predispositions, pathogenic germline mutations in the homologous recombination repair (HRR) pathway were detected in 31.0% (n = 18) of the cases comprising the breast cancer subgroup (BRCA1/2 in 14 patients, CHEK2 in 2 patients, and PALB2 in 2 patients). Upon examining the medical history factors that could affect the patients' anaphylaxis risk profile, a known history of atopy or allergy was present in 16.7% (n = 14) of the cases. Additionally, 44.0% (n = 37) were recorded as using angiotensin-converting enzyme inhibitors or beta-blockers (ACEI/BB), which are antihypertensive agents that can increase the refractoriness of the reaction and complicate hemodynamic management (Table 1).

Table 1
Baseline Characteristics of the Study Cohort

Characteristic	Overall Cohort (N = 84)
Age (years), mean ± SD (range)	52.45 ± 13.15 (20–78)
Sex, n (%)	
Female	73 (86.9)
Male	11 (13.1)
Primary Diagnosis, n (%)	
Breast	58 (69.0)
Gastrointestinal	15 (17.9)
Lung	6 (7.1)
Gynecologic	3 (3.6)
Other	2 (2.4)
Clinical History & Risk Factors, n (%)	
Pathogenic Germline Mutation*	18 (31.0% of breast cancer patients)
History of Atopy	14 (16.7)
ACE Inhibitor or Beta-Blocker Use	37 (44.0)
Disease Stage & Treatment Intent, n (%)	
Stage II / III / IV	31 (36.9) / 32 (38.1) / 21 (25.0)
Neoadjuvant / Adjuvant / Metastatic	36 (42.9) / 25 (29.8) / 23 (27.4)
Causative Agent, n (%)	
Taxanes (Docetaxel / Paclitaxel)	56 (66.7)
Platinums (Carboplatin / Oxaliplatin)	24 (28.6)
Others (Etoposide / Epirubicin / Irinotecan)	4 (4.8)
CTCAE v5.0 Grade, n (%)	
Grade 2 / 3 / 4	71 (84.5) / 11 (13.1) / 2 (2.4)
Predominant Symptom Phenotype, n (%)	
Cardiopulmonary Predominance (Hypotension, Dyspnea)	63 (75.0)
Autonomic Predominance (Hypertension, Flushing)	14 (16.7)
Cutaneous Predominant (Urticaria, Maculopapular Rash)	6 (7.1)

SD, Standard deviation. CTCAE, Common Terminology Criteria for Adverse Events. *Comprises 14 BRCA1/2, 2 CHEK2, and 2 PALB2 pathogenic germline variants.

Clinical Phenotypes and Temporal Dynamics of Reactions

Taxanes (docetaxel/paclitaxel) caused 66.7% (n = 56) of the reactions, platinums (carboplatin/oxaliplatin) 28.6% (n = 24), and other agents (etoposide, epirubicin, irinotecan) 4.8% (n = 4). When reaction severity was evaluated according to NCI CTCAE v5.0 criteria, the vast majority of episodes (84.5%, n = 71) were classified as Grade 2, whereas Grade 3 and 4 reactions requiring medical urgency were observed in 13 episodes (15.5%).

In phenotyping based on predominant clinical symptomatology, a cardiopulmonary/IgE-like phenotype, primarily characterized by hypotension, dyspnea, and bronchospasm, was observed in 75.0% (n = 63) of the episodes. In 16.7% (n = 14) of the cases, an autonomic instability (non-IgE/CARPA) phenotype characterized by hypertension, severe back pain, and flushing—which is particularly specific to taxanes—was detected.

Taxane and platinum reactions differed significantly in timing (Table 2). Compared to the platinum group, taxane reactions occurred at significantly earlier cycles (mean cycle 1.55 ± 0.74 vs. 3.46 ± 1.96, $p < 0.001$) and in a shorter time following the onset of infusion (mean 9.45 ± 11.66 vs. 38.83 ± 31.25 minutes, $p < 0.001$) (Table 2).

Table 2
Comparison of Taxane- and Platinum-Induced Hypersensitivity Reactions

Variable	**Taxanes (n = 56)**	**Platinums (n = 24)**	**p-Value**
Age (years), mean ± SD	49.89 ± 11.90	59.00 ± 12.29	0.003
Sex (Female / Male), n	54 / 2	17 / 7	0.001
Treatment Intent, n (%)			
Neoadjuvant	30 (53.6)	4 (16.7)	0.004
Adjuvant	16 (28.6)	9 (37.5)	
Metastatic / Palliative	10 (17.8)	11 (45.8)	
Reaction Timing			
Cycle of Onset, mean ± SD	1.55 ± 0.74	3.46 ± 1.96	< 0.001
Time to Onset (minutes), mean ± SD	9.45 ± 11.66	38.83 ± 31.25	< 0.001

SD, Standard deviation. Continuous variables (cycle of onset and time to onset) were compared using Generalized Estimating Equations (GEE) to account for within-patient correlation across multiple episodes. Categorical variables were analyzed using the chi-square or Fisher's exact test, as appropriate.

Comparative Success of Single-Bag and Three-Bag Protocols

Among the episodes where symptoms were controlled following the index reaction and the decision was made to continue first-line treatment, a single-bag (1-bag) desensitization protocol was applied in 29 (34.5%) episodes, and a standard three-bag (3-bag) protocol was applied in 28 (33.3%). In line with our clinic's safety-first "single attempt" policy, the procedure was immediately terminated in cases where a breakthrough reaction developed during desensitization. In the remaining cases (n = 27), patients were either switched to an alternative agent or their treatment was discontinued.

In the protocol-based success analysis, the procedure was successfully completed by reaching the target cumulative dose in 24 (82.8%) of the 29 episodes managed with the 1-bag protocol, and similarly in 24 (85.7%) of the 28 episodes managed with the standard 3-bag protocol (Table 3). No statistically significant difference was detected between the two desensitization protocols in terms of clinical success (completion) rates ($p = 0.993$). In the context of risk stratification, an analysis of the platinum subgroup—which carries the highest risk of anaphylaxis—revealed that the 1-bag application had an 83.3% (5/6) success rate, which was statistically similar to the 75.0% (6/8) success rate of the standard 3-bag protocol ($p = 0.248$).

An analysis of 13 episodes where a strategy of switching to an alternative taxane was implemented instead of desensitization following a taxane reaction showed that cross-reactivity developed during the infusion of the second agent in 4 (30.8%) of these cases. As a result of all these management strategies (RDD and agent switching), the safe maintenance of antineoplastic therapy was successfully achieved in a total of 75.0% (n = 63/84) of the episodes in the overall cohort.

Table 3
Post-Reaction Management Strategies, Desensitization Protocols, and Clinical Outcomes

Outcome Parameter	n	%
Post-Reaction Management Strategy		
Single-Bag Protocol	29	34.5
Three-Bag Desensitization Protocol	28	33.3
Switch to Alternative Regimen	20	23.8
Permanent Discontinuation	7	8.3
Treatment Completion (Attainment of Target Dose)		
Yes	63	75.0
No	21	25.0
Reasons for Treatment Non-Completion (n = 21)		
Breakthrough Reaction	15	71.4
Patient Refusal	3	14.3
Disease Progression	2	9.5
Other	1	4.8
Protocol-Specific Completion Rates		
Single-Bag Protocol (n = 29)	24	82.8
Three-Bag Desensitization Protocol (n = 28)	24	85.7
Protocol Efficacy by Drug Subgroup		
Taxanes — Single-Bag (n = 22) / Three-Bag (n = 18)	18 / 16	81.8% / 88.9%
Platinums — Single-Bag (n = 6) / Three-Bag (n = 8)	5 / 6	83.3% / 75.0%

‡ Treatment completion was defined as successful administration of the intended cumulative target dose without permanent discontinuation. § Intergroup comparisons for protocol efficacy were performed using a Binary Logistic Generalized Estimating Equations (GEE) model to account for within-patient correlation.

Discussion

The management of HSRs to antineoplastic agents remains a major challenge in maintaining treatment continuity [1,2]. Our analysis demonstrated that a simplified single-bag (1-bag) protocol achieved clinical

efficacy comparable to the standard three-bag (3-bag) regimen (82.8% vs. 85.7%; p = 0.993), consistent with recent studies evaluating the safety and efficacy of 1-bag approaches [11,15]. However, as protocol assignment was at clinician discretion rather than randomized, our findings should be considered hypothesis-generating. Larger prospective non-inferiority studies are needed to validate these findings.

High-volume centers have reported success rates above 90% by continuing desensitization after breakthrough reactions [5,8,9,16]. Our lower success rate most likely reflects our strict single-attempt safety policy in a general oncology setting without on-site allergist support. In the absence of continuous allergist support, breakthrough reactions resulted in immediate protocol termination without re-challenge, and patients with anaphylactic shock were excluded from desensitization. As also reported by Rasmussen et al. (2025), this cautious approach may represent a feasible strategy for resource-limited oncology centers [13,14]. In addition, because no universally accepted standard currently exists for 1-bag protocols, future optimization studies evaluating alternative infusion rate escalations are warranted.

Our findings also support distinct temporal and phenotypic differences between taxane- and platinum-related HSRs ($p < 0.001$). Taxane reactions occurred rapidly after infusion initiation (mean 9.45 minutes), potentially reflecting previously described complement-mediated mechanisms, whereas platinum reactions developed after repeated exposure (mean 3.46 cycles), consistent with classical sensitization patterns [6,7,10]. In settings without access to skin testing, these temporal characteristics may help guide clinical risk stratification [15]. Additionally, we observed a 31.0% pathogenic germline mutation rate among breast cancer patients who developed HSRs. Although HRR mutations have mainly been associated with platinum hypersensitivity [17], our observations suggest that HRR-mutated patients may also experience taxane-related reactions. This potential association should be investigated further in larger studies.

Limitations

The main limitations of this study include its retrospective design, single-center setting, and the lack of routine skin testing. In addition, the absence of serum tryptase measurements and advanced immunologic assessments prevented definitive mechanistic characterization of the observed reaction phenotypes. The analyses were conducted at the episode level, meaning that some patients contributed more than one reaction episode. Although the potential within-patient correlation was addressed using Generalized Estimating Equations (GEE), the retrospective nature of the study limits causal interpretation of the findings. Ideally, patients with HSRs should be evaluated by an allergist and managed using individualized strategies supported by immunologic testing whenever available. Nevertheless, in oncology centers without continuous allergist access, the presented protocols may provide a feasible clinical alternative.

Conclusions

Although 1-bag protocols are not currently incorporated as standard approaches in guidelines for antineoplastic agent-related HSRs, our findings suggest that they may achieve completion rates comparable to conventional three-bag regimens while reducing preparation complexity. We also observed that HRR mutations identified in the breast cancer subgroup were present in patients with both platinum- and taxane-related reactions, suggesting a possible role for genetic markers in future personalized HSR management strategies. However, patients presenting with severe life-threatening reactions such as anaphylactic shock may not be appropriate candidates for desensitization. Whenever possible, desensitization should be carried out in a multidisciplinary setting with allergist involvement.

Declarations

The requirement for informed consent was waived by the institutional ethics committee due to the retrospective nature of the study.

Conflict of Interest

The authors declare no conflict of interest.

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Author Contribution

Conception and design: Ö.F.Elçiçek, E.Çavdar. Administrative support: Ö.F.Elçiçek, E.S.Seber, Collection and assembly of data: All authors, Data analysis and interpretation: Ö.F.Elçiçek, E.Çavdar. Manuscript writing: Ö.F.Elçiçek, Final approval of manuscript: All authors, Accountable for all aspects of the work: All authors

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