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Toxicities of High-dose Chemotherapy Followed by Autologous Hematopoietic Stem Cell Transplantation: Relationship with Survival and Transplantation Outcomes in a Single-center Experience

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ABSTRACT

Aim: This study evaluated the toxicities associated with mobilization and conditioning regimens and examined the relationship of these toxicities to survival and transplant outcomes in patients with multiple myeloma (MM) and lymphoma undergoing high-dose chemotherapy followed by autologous hematopoietic stem cell transplantation.

Methods: We conducted a retrospective analysis of 58 patients treated at a single tertiary referral center in Türkiye. The median follow-up was 24 months. Toxicities were categorized by organ system and graded according to the Common Terminology Criteria for Adverse Events version 5.0.

Results: For the entire cohort, overall survival (OS) was 89.5% at one month, 75.7% at twelve months, and 70.2% at the last follow-up. In MM, the three month treatment response was strongly associated with OS; OS was 94.1 percent for patients in remission and 35.7 percent for those with refractory disease ($p<0.001$). Across toxicity categories, no statistically significant associations were observed with OS or disease-free survival (DFS). In MM, mucositis and anemia did not show a statistically significant association with shorter DFS, yet the observed trend may be clinically relevant.

Conclusion: In this single-center experience, regimen-related toxicities did not independently predict transplant outcomes or OS. Nevertheless, the direction and consistency of effects on mucositis and anemia in MM justify prospective confirmation. Multicenter studies with homogeneous patient populations are warranted to clarify the prognostic role of treatment-related toxicities and to refine supportive care strategies.

Keywords: Lymphoma, multiple myeloma, transplant, toxicity, mobilization, conditioning, chemotherapy

Introduction

For nearly 30 years, high-dose chemotherapy (HDT) followed by autologous hematopoietic stem cell transplantation (AHSCT) has been one of the most critical treatments for multiple myeloma (MM) and has been used for a similar duration to treat aggressive non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma (HL) [1]. This approach allows the administration of intensive cytotoxic therapy while enabling rapid hematopoietic recovery through reinfusion of autologous stem cells. Initial HDT/AHSCT has demonstrated efficacy and become the standard of care, especially for eligible patients with newly diagnosed MM. In recent years, the therapeutic landscape of MM has evolved considerably with the introduction of novel agents, including proteasome inhibitors, signaling lymphocytic activation molecule family member 7 inhibitors, histone deacetylase inhibitors, immunomodulatory drugs, and anti-cluster of differentiation 38 monoclonal antibodies. These agents have significantly improved response rates and survival outcomes in patients with MM. Despite these advances, HDT/AHSCT continues to play an important role in the management of eligible patients. Previous studies have demonstrated that HDT/AHSCT can provide clinical benefit for MM patients with both high risk and standard risk genetic profiles [2].

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Numerous complications can occur during HDT/AHSCT. These complications may involve multiple organ systems and may adversely affect quality of life, prolong hospitalization, contribute to long-term complications, and potentially influence transplantation outcomes. The type and severity of complications observed after hematopoietic stem cell transplantation may vary according to several patient and treatment-related factors. These include previous treatments, the disease status at the time of transplantation, existing comorbid conditions, and the intensity of the conditioning regimen. In addition, the duration of cytopenias and immunosuppression, as well as underlying or treatment-related organ dysfunction, may influence the occurrence and severity of post-transplant complications [3]. Although Many studies have examined the toxicities associated with chemotherapy protocols used in HDT/AHSCT, the relationship between these toxicities and transplant-related outcomes remains incompletely understood. In this study, we aimed to evaluate the toxicity profiles of HDT/AHSCT protocols and to investigate their potential association with survival and transplant outcomes in patients with lymphoma and MM. By jointly analyzing these factors, this study aims to improve understanding of how treatment-related toxicities may influence clinical outcomes.

Methods

Patients

We retrospectively analyzed the clinical and laboratory records of patients with NHL, HL, and MM who underwent HDT/AHSCT between March 2018 and November 2020 (n=58). All patients provided informed consent prior to HDT/AHSCT.

Study Design

This retrospective, single-center, non-interventional study was designed to evaluate the toxicity of mobilization and conditioning regimens, and their effects on transplantation outcomes and survival in patients with MM and lymphoma who underwent HDT/AHSCT at our centre. The median follow-up duration was 24 months. The study was approved by the Clinical Research Ethics Committee of İzmir Bozyaka Training and Research Hospital, University of Health Sciences Türkiye (approval no: 10, date: 21.10.2020). Patients with incomplete clinical records or insufficient follow-up data were excluded from the analysis. Cases with missing information regarding treatment-related toxicities were also excluded. In addition, patients who did not undergo autologous stem cell transplantation and those younger than 18 years were not included in the study.

Chemotherapy Regimens, Protocols, and Supportive Care

Chemotherapy regimens and protocols

Tables 1 and 2 summarize the mobilization and conditioning regimens used for patients with MM and lymphoma, respectively.

Supportive care

Patients were admitted to the bone marrow transplant unit in designated rooms equipped with high-efficiency particulate air filters to maintain a sterile environment. Blood transfusions were performed when hemoglobin levels dropped below 7 g/dL or platelet counts fell below 10×10^3/µL. All patients received fluconazole and acyclovir prophylaxis, beginning with the conditioning regimen.

Assessment of Toxicity

Mucositis was monitored daily and recorded in the patients' charts. Toxicities were assessed according to the Common Terminology Criteria for Adverse Events v5.0 criteria. Toxicities

Table 1. Multiple myeloma mobilization and conditioning regimens

	Regimen	n (%) =40
Mobilization	G-CSF alone	2 (5%)
	Cyclophosphamide + G-CSF	33 (82.5%)
	Cyclophosphamide + G-CSF + plerixafor	5 (12.5%)
Conditioning	Melphalan 200 mg	30 (75%)
	Melphalan 140 mg	9 (22.5%)
	No conditioning given	1 (2.5%)

G-CSF: Granulocyte colony-stimulating factor

Table 2. Lymphoma mobilization and conditioning regimens

	Regimen	n (%) =18
Mobilization	IVAC + G-CSF	1 (5.5%)
	Cyclophosphamide + G-CSF	2 (11.1%)
	R-ICE + G-CSF	1 (5.5%)
	R-ESHAP + G-CSF	7 (38.8%)
	Gemcitabine + G-CSF	1 (5.5%)
	R-IDARAM + G-CSF	2 (11.1%)
	Etoposide + G-CSF after R-IDARAM	1 (5.5%)
	Etoposide + G-CSF after cyclophosphamide + plerixafor	1 (5.5%)
	Etoposide + G-CSF	2 (11.1%)
Conditioning	BEAM	4 (22%)
	CBV	3 (16%)
	BuCYE	2 (11%)
	Mitoxantrone	1 (5%)
	Mitoxantrone + melphalan	4 (22%)
	TBC	4 (22%)

G-CSF: Granulocyte colony-stimulating factor, IVAC: Ifosfamide, etoposide, cytarabine, R-ICE: Rituximab, ifosfamide, carboplatin and etoposide, R-ESHAP: Rituximab, etoposide, methylprednisolone, cytarabine and cisplatin, R-IDARAM: Rituximab, cytarabine, idarubicin, methotrexate and dexamethasone, BEAM: Carmustine, etoposide, cytarabine and melphalan, CBV: Cyclophosphamide, carmustine and etoposide, BuCYE: Busulfan, cyclophosphamide and etoposide, TBC: Thiotepa, busulfan and cyclophosphamide

were graded on a five-level scale based on their severity and clinical impact. Grade 1 corresponds to mild or asymptomatic events that do not require specific medical intervention. Grade 2 represents moderate adverse events that may require minimal, local, or non-invasive interventions and limit age-appropriate instrumental activities of daily living. Grade 3 indicates severe or medically significant events that are not immediately life-threatening but may require hospitalization or prolong hospitalization, and may limit self-care activities of daily living. Grade 4 refers to life-threatening adverse events requiring urgent medical intervention. Grade 5 corresponds to death related to the adverse event [4].

Nine toxicity categories were evaluated: gastrointestinal, cardiac, pain, neurological, pulmonary, dermatological, hematological, renal, and neutropenic fever (infectious toxicity).

Neutropenic fever was defined as a single oral temperature of ≥38.3 °C or ≥38 °C lasting for at least one hour, accompanied by an absolute neutrophil count of <500 cells/μL [5].

Gastrointestinal toxicities were subcategorized into seven groups: nausea, vomiting, anorexia, mucositis, dyspepsia, diarrhea, and liver toxicity.

Hematological toxicities were classified into three groups: anemia, thrombocytopenia, and neutropenia.

Cardiac toxicities were classified into five categories: sinus tachycardia, new-onset atrial fibrillation, sinus bradycardia, acute coronary syndrome, and reduced ejection fraction.

Neurological toxicities were classified into three categories: epileptic seizures, cerebral ischemic injury, and posterior reversible encephalopathy syndrome.

Pulmonary toxicities were classified into three categories: respiratory distress, pulmonary edema, and pulmonary hemorrhage.

Renal toxicities were assessed based on the progression of creatinine levels.

Dermatological toxicities included rash, dry skin, and hair loss. These skin-related adverse events were assessed through clinical examination during follow-up visits and documented according to their severity and clinical significance.

Pain toxicities were evaluated based on patient-reported symptoms and their effect on daily functioning.

Overall survival (OS) and disease-free survival (DFS) analyses were performed for toxicities observed in a sufficient number of patients. The toxicities and number of patients in each group are listed in Table 3. When patients within the same toxicity group experienced multiple subgroup toxicities, the highest-grade toxicity was recorded.

Evaluation and Description of Clinical Response

Treatment response was evaluated in accordance with the 2016 International Myeloma Working Group uniform response criteria for MM and the International Working Group consensus response evaluation criteria for lymphoma [6,7]. Assessments included physical examinations, laboratory tests, and radiologic evaluations. Patients were evaluated for response at three months post-HDT/AHSCT and for final response.

Outcomes

The primary endpoints were DFS and OS. DFS was defined as the time from HDT/AHSCT to the detection of disease recurrence or progression. OS was defined as the time from HDT/AHSCT to death from any cause [8].

Statistical Analysis

For descriptive analysis, a database was created using SPSS 21.0 (IBM Corp., Armonk, NY, USA), with data presented as frequencies, percentages, means, standard deviations, and median values.

Toxicities induced by mobilization and conditioning regimens were categorized as Grades 1 and 2, Grades 3-5, or as present/absent. OS and DFS were analyzed using the Kaplan-Meier method. A p value of <0.05 was considered statistically significant.

Results

Patient Characteristics

A total of 58 patients diagnosed with lymphoma (n=18) or MM (n=40) were included in this study. The median age was 56.5

Table 3. Toxicity group, subgroups and number of patients

Toxicity	Mobilization number of events n		Conditioning number of events n	
	Grade 1 and 2	Grade 3-5	Grade 1 and 2	Grade 3-5
Cardiac	3	1	6	4
Hematological	4	51	0	57
Gastrointestinal	16	1	26	16
Neurological	2	1	0	1
Pulmonary	1	1	0	2
Renal	0	0	2	0
Neutropenic fever	0	1	0	17
Dermatological	0	0	4	0
Pain	8	2	1	0

years (range, 25-72 years). Patient clinical characteristics are summarized in Table 4.

Outcomes

OS was evaluated in all patients (n=58). The OS rates were 84.1% at 4 months, 75.7% at 12 months, 66.0% at 18 months, and 70.2% at the end of the follow-up period (Figure 1). The presence of comorbidities was not significantly associated with OS (70.4% vs. 70.0%, p=0.911).

DFS was analyzed in 53 evaluable patients (Figure 2). The DFS rates were 61.5%, 52.4%, and 46.2% at 1, 12, and 24 months, respectively. Five patients lacking response evaluations were excluded from the analysis.

Among patients with MM (n=40), 38.8% remained in remission, 7.5% were refractory, and 17.5% relapsed at 24 months. Survival analysis by sex revealed higher OS in males than in females (86.4% vs. 58.8%), reaching borderline statistical significance (p=0.053). In patients with MM, DFS was 65.7% at 1 month, 56.1% at 12 months, and 45.7% at the end of the study. No significant associations were observed between age and either DFS or OS in patients with MM. For patients with lymphoma, OS was 77.8% at 2 months, 53.5% at 14 months, and 61.1% at 24 months.

Among the 18 patients with lymphoma, seven (38.8%) died before the final response evaluation: three deaths were transplant-related; three were due to coronavirus disease-2019 (COVID-19) (one in remission and two refractory); and two resulted from sepsis. In the MM group, seven patients died:

Table 4 . Patient characteristics

Characteristic	n (%)
Sex	
Male	36 (62.1%)
Female	22 (37.9%)
Age	
<60 years	35 (60.3%)
≥60 years	23 (39.7%)
Diagnosis	
Hodgkin lymphoma	7 (12.1%)
Non-Hodgkin lymphoma	11 (19%)
Multiple myeloma	40 (68.9%)
Comorbidities	
Cardiac disease	10 (17.2%)
Diabetes mellitus	7 (12%)
Pulmonary disease	8 (13.7%)
Neurological disease	2 (3.4%)
Renal disease	4 (6.8%)
Acquired immunodeficiency syndrome	2 (3.4%)
No comorbidities	38 (65.5%)
Multiple Myeloma Subgroup (n=40)	
ISS Stage I	6 (15%)
ISS Stage II	18 (45%)
ISS Stage III	16 (40%)
IgA lambda	9 (22.5%)
IgA kappa	6 (15%)
IgG lambda	5 (12.5%)
IgG kappa	16 (40%)
Kappa light chain	2 (5%)
Lambda light chain	2 (5%)
High cytogenetic risk	4 (10%)
Standard cytogenetic risk	32 (80%)
Not evaluated	4 (10%)
Lymphoma Subgroup (n=18)	
Mixed cellularity Hodgkin lymphoma	4 (22.4%)
Lymphocyte depleted Hodgkin lymphoma	1 (5.6%)
Nodular sclerosis Hodgkin lymphoma	2 (11.2%)
Diffuse large B-cell lymphoma	8 (44.2%)
Follicular lymphoma	1 (5.6%)
Burkitt lymphoma	1 (5.6%)
Mantle cell lymphoma	1 (5.6%)

ISS: International staging system, IgA: Immunoglobulin A, IgG: Immunoglobulin G

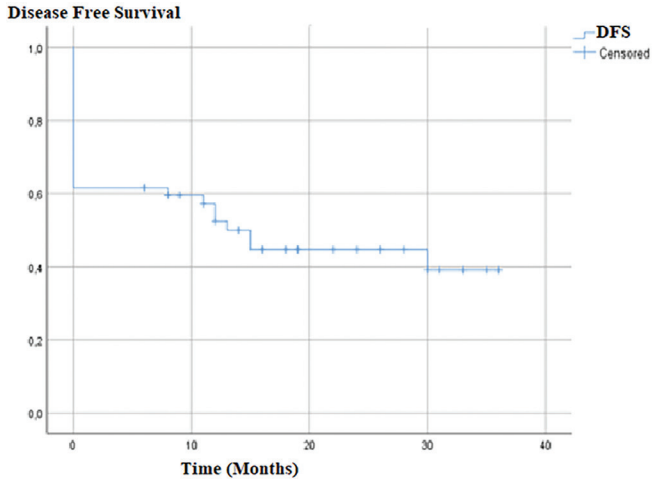

Figure 1. DFS was assessed in the all patient
DFS: Disease-free survival

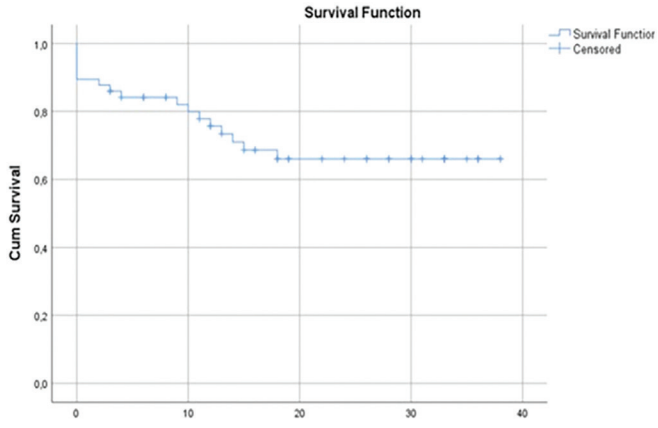

Figure 2. Evaluation of all patients for overall survival

six had treatment-refractory disease, and one experienced a relapse after a nine-month remission. The mean age at death was 58.1 years. Causes of death included sepsis (n=4), intracranial abscess (n=1), and rapidly progressive viral pneumonia (n=1); the cause of one death remained uncertain because the patient was followed at another center. At the last follow-up, seven patients with lymphoma (38.8%) were in remission, two (11.1%) were refractory, one (5.5%) had relapsed, and one (5.5%) was lost to follow-up.

A significant association was observed between treatment response at 3 months and OS (p=0.001). Patients who achieved remission had a markedly higher OS rate (94.1%) than those with refractory disease (35.7%).

Assessment of treatment-associated toxicities revealed no statistically significant associations with OS or DFS. Patients experiencing low-grade and high-grade gastrointestinal toxicity had similar survival outcomes: OS: 74.1% vs. 62.5% (p=0.260) and DFS: 36.8% vs. 57.1% in patients with MM (p=0.456). Likewise, cardiac toxicity was not significantly associated with OS (61.5% vs. 72.7%, p=0.101) or DFS (38.5% vs. 48.7%, p=0.177). Neutropenic fever had no significant effect on DFS (43.8% vs. 47.2; p=0.830).

Pain and dermatological toxicities were documented during follow-up; however, the available data were insufficient to permit statistical evaluation of their relationships with survival and transplantation outcomes. Therefore, these variables were not included in the final analysis.

Although these results were not statistically significant, several findings may have clinical relevance. Notably, among patients with MM, those with mucositis had a DFS nearly twofold lower than that of patients without mucositis (28.6% vs. 57.1%), a difference that approached statistical significance (p=0.056). This finding suggests that mucositis may adversely affect post-transplant management and that it warrants additional investigation in larger cohorts. A similar pattern was observed in MM patients with higher-grade anemia, who had lower DFS than those with low-grade anemia (35.7% vs. 52.6%, p=0.263), indicating a potentially unfavorable effect. Although the sample size was limited, necessitating cautious interpretation, these findings collectively underscore the toxicities that may substantially affect patient outcomes and warrant further investigation.

Detailed subgroup analyses of treatment-related toxicities are provided in Supplementary Table 1.

Discussion

Toxicities associated with mobilization and conditioning regimens in HDT/AHSCT have been extensively investigated [9]. Unlike several previous studies that evaluated mobilization or conditioning regimens separately, the present single-center analysis examined survival outcomes and treatment-related toxicities in patients with MM and lymphoma undergoing HDT/AHSCT, considering both treatment phases together. Our objective was to determine whether transplantation outcomes and survival were associated with treatment-related toxicities and to contextualize our real-world results within the current literature.

Among all patients, OS was 84.1% at 4 months, 75.7% at 12 months, and 66.0% at 18 months, with 70.2% alive at last follow-up (Figure 1). DFS was 61.5% at 1 month, 52.4% at 12 months, and 46.2% at 24 months (Figure 2). Early treatment response emerged as the strongest predictor: patients in remission at 3 months had markedly higher OS than those with refractory disease (94.1% vs 35.7%). This finding aligns with prior studies in MM demonstrating that depth of response after induction and early remission status are critical predictors of long-term survival [10].

HDT/AHSCT is a well established treatment modality in MM and is the standard of care in relapsed or refractory HL [11-13]. In NHL, the use of HDT/AHSCT remains histology-dependent, with heterogeneous outcomes reflecting differences in salvage regimens [13].

Although the heterogeneity of regimens in our lymphoma subgroup and limited sample size precluded direct comparisons, hematologic toxicities emerged as the most frequent adverse events, consistent with other real world series [14].

The COVID-19 pandemic markedly affected outcomes. Several patients failed to attend follow-up evaluations, and infections were directly responsible for mortality in both the remission and refractory groups. Similar findings have been documented by transplant programs worldwide, indicating that COVID-19 was associated with considerable disruptions and resulted in increased non-relapse mortality among hematopoietic cell transplant patients [15,16]. This may account for our slightly lower day-100 survival rate (89.5%) compared with the ~95-99% reported in previous MM and lymphoma transplantation cohorts [17-19].

No significant associations were observed between treatment-related toxicities (gastrointestinal toxicity, cardiac toxicity, and neutropenic fever) and survival outcomes. However, two observations in our cohort merit attention. MM patients with mucositis had a nearly twofold lower DFS than those without mucositis (28.6% vs. 57.1%), with the difference approaching statistical significance (p=0.056). Likewise, higher-grade anemia was associated with a numerically worse DFS (35.7% vs. 52.6%). These trends are biologically plausible and consistent with literature describing mucositis and cytopenia as notable complications of transplantation that warrant careful supportive care [20,21].

Fanning et al. [21] reported that severe mucositis in patients with lymphoma undergoing HDT/AHSCT was linked to poorer OS, highlighting its potential prognostic relevance. In our study, mucositis appeared to affect DFS in patients with MM, with DFS rates of 28.6% among patients who developed mucositis versus 57.1% among patients who did not develop mucositis. Taken together, these findings suggest that while mucositis is consistently a clinically relevant toxicity, its prognostic significance may vary depending on disease type and on whether OS or DFS is considered. Although our study is underpowered to confirm these associations, they may nevertheless have prognostic value and warrant validation in larger, multicenter cohorts.

Study Limitations

This study has some limitations that must be addressed. The relatively small and heterogeneous patient population reduced the statistical power of subgroup analyses and precluded regimen-level comparisons. The retrospective design and pandemic-related loss to follow-up further limited the evaluation of complete response. Nevertheless, this study contributes to the literature by systematically assessing mobilization and conditioning toxicities, emphasizing early remission status as a crucial prognostic factor, and identifies mucositis and anemia as toxicities that may affect long-term outcomes in patients with MM.

Conclusion

We evaluated HDT/AHSCT-related toxicities in patients with MM and lymphoma in relation to demographic characteristics and survival outcomes. Early response at three months was a strong predictor of OS, underscoring its value as a prognostic marker. Although no significant correlation was observed between specific toxicities and OS, toxicities such as anemia and mucositis were associated with reduced DFS in patients with MM. These findings highlight the importance of careful, supportive care and provide clinicians with practical guidance for early outcome assessment and management of treatment-related complications. Future multicenter studies are needed to confirm these associations and inform the development of more effective supportive care strategies.

Ethics

Ethics Committee Approval: The study was approved by the Clinical Research Ethics Committee of İzmir Bozyaka Training and Research Hospital, University of Health Sciences Türkiye (approval no: 10, date: 21.10.2020).

Informed Consent: This is a retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.S., F.G., Concept: M.S., F.G., Design: F.G., Data Collection or Processing: M.S., F.G., Analysis or Interpretation: M.S., Literature Search: M.S., Writing: M.S.

Conflict of Interest: No conflict of interest was declared by the authors.

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Supplementary Table 1: https://d2v96fxpocvxx.cloudfront.net/e6921826-40a4-4ec2-8c4c-3b8dc63111d7/content-images/8e25d99b-af37-4152-847c-5b09636d79de.pdf

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