JACIE Autologous Transplant Outcomes Report

2024-2025 Annual Report - Rolling Cohort Analysis

HSCT Program Quality Indicators

2026-01-27

Executive Summary

Reporting Period and Methodology

Reporting Period: Calendar Years 2024 and 2025

Methodology: Cumulative Rolling Cohort Analysis following JACIE Italian guidelines

> **❗ Cumulative Rolling Cohort Methodology**
>
> This report uses **cumulative rolling cohort analysis** as specified by JACIE Italy. For each timepoint, we calculate outcomes for patients who reached that milestone during the specified reporting period.
>
> **Key principle**: Patients are selected based on when they **reached** each milestone (100 days or 365 days post-transplant), not just when they were transplanted.
>
> **Cohort Selection:**
>
> - **100-day outcome**: Patients whose 100-day milestone fell within the reporting period
> - **365-day outcome**: Patients whose 365-day milestone fell within the reporting period
>
> This ensures adequate follow-up time for each patient included in the analysis.

Key Findings Summary

2025 Autologous Transplant Outcomes

Table 1: Table 1: 2025 Autologous Transplant Outcomes - Rolling Cohort Analysis

Endpoint	Timepoint	Cohort Size	Events	Rate
Overall Survival				
Overall Survival (OS)	100 days	49	1	98%
Overall Survival (OS)	365 days	32	2	93.8%
Treatment-Related Mortality				
Treatment-Related Mortality (TRM)	100 days	49	1	2%
Treatment-Related Mortality (TRM)	365 days	32	1	3.1%

> 💡 2025 Outcomes Highlights
>
> **Overall Survival:**
>
> - **100-day OS**: 98% (48/49 patients alive)
> - **365-day OS**: 93.8% (30/32 patients alive)
>
> **Treatment-Related Mortality:**
>
> - **100-day TRM**: 2% (1/49 patients)
> - **365-day TRM**: 3.1% (1/32 patients)

Detailed Results

1. Cohort Description

1.1 Patient Population

Table 2: Table 2: Patient Population Overview

Category	N
Total patients in database	69
Lost to follow-up	1
Evaluable patients	**68**
2024 transplants	32
2025 transplants	36

> ⚠️ **Lost to Follow-up**
>
> **1 patient** was lost to follow-up and excluded from the analysis:
>
> | Patient | Diagnosis | HSCT Date |
> |---|---|---|
> | Rapuano Giuseppe | LNH | 2024-07-08 |

1.2 Age at Transplant

Table 4: Table 3: Age at Transplant

Statistic	Value
Mean (SD)	58.3 years (SD: 10.6)
Median	62.1 years
Range	18.0 - 71.7 years

1.3 Follow-up Duration
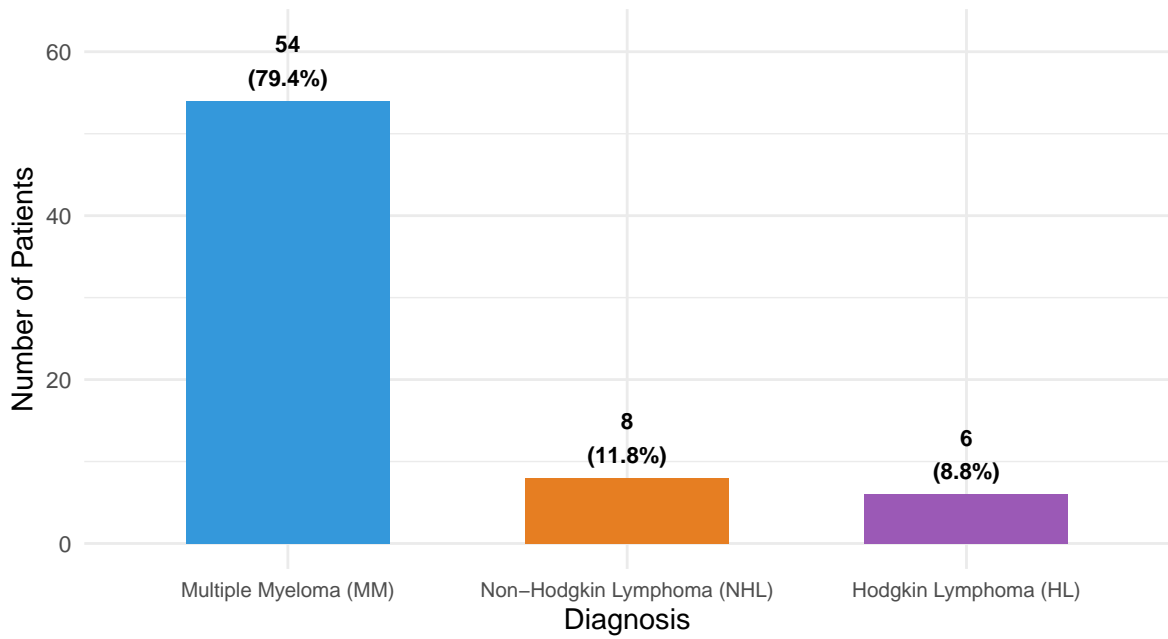
Table 5: Table 4: Follow-up Duration

Statistic	Days	Months
Mean	349.6 days	11.5 months
Median	350 days	11.5 months
Range	9 - 723 days	0.3 - 23.8 months

1.4 Diagnosis Distribution

Table 6: Table 5: Diagnosis Distribution

Diagnosis	N	Percentage
Multiple Myeloma (MM)	54	79.4%
Non-Hodgkin Lymphoma (NHL)	8	11.8%
Hodgkin Lymphoma (HL)	6	8.8%

Figure 1: Diagnosis Distribution

Autologous Transplant Cohort 2024–2025

1.5 Transplant Year Distribution

Table 7: Table 6: Transplant Year Distribution

Year	N	Percentage
2024	32	47.1%
2025	36	52.9%

2. Overall Survival (OS)

2.1 OS - 2025 Analysis

Table 8: Table 7: Overall Survival - 2025 Rolling Cohort

Timepoint	Cohort Size	Deaths	Alive (n)	OS Rate	Mortality Rate

Timepoint					
100 days	49	1	48	98%	2%
365 days	32	2	30	93.8%	6.2%

2.2 OS - 2024 Analysis

Table 9: Table 8: Overall Survival - 2024 Rolling Cohort

Timepoint	Cohort Size	Deaths	Alive (n)	OS Rate	Mortality Rate
100 days	12	0	12	100%	0%
365 days	0	NA	NA	N/A*	N/A*

> **i** Note on 2024 365-Day Analysis
>
> *N/A: No patients transplanted in 2024 had reached their 365-day milestone within the 2024 reporting period (milestone dates: Jan 1, 2023 - Dec 31, 2024). These patients are captured in the 2025 rolling cohort analysis.

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3. Treatment-Related Mortality (TRM)

3.1 TRM - 2025 Analysis

Table 10: Table 9: Treatment-Related Mortality - 2025 Rolling Cohort

Timepoint	Cohort Size	TRM Deaths	TRM Rate	n/N (%)
100 days	49	1	2%	1/49 (2%)
365 days	32	1	3.1%	1/32 (3.1%)

3.2 TRM - 2024 Analysis

Table 11: Table 10: Treatment-Related Mortality - 2024 Rolling Cohort

Timepoint	Cohort Size	TRM Deaths	TRM Rate	n/N (%)
100 days	12	0	0%	0/12 (0%)
365 days	0	NA	N/A*	N/A*

3.3 Death Details

Table 12: Table 11: Details of Deceased Patients

Patient	Diagnosis	HSCT Date	Days to Death	TRM
De Lazzari Adriano	Multiple Myeloma (MM)	July 03, 2024	364	No
Mares Henoch Sigisfredo	Multiple Myeloma (MM)	December 02, 2024	9	Yes

> **!** Death Summary
>
> **Total deaths:** 2
> **Death classification:**
>
> - TRM deaths: 1
> - Non-TRM deaths (NRM): 1
>
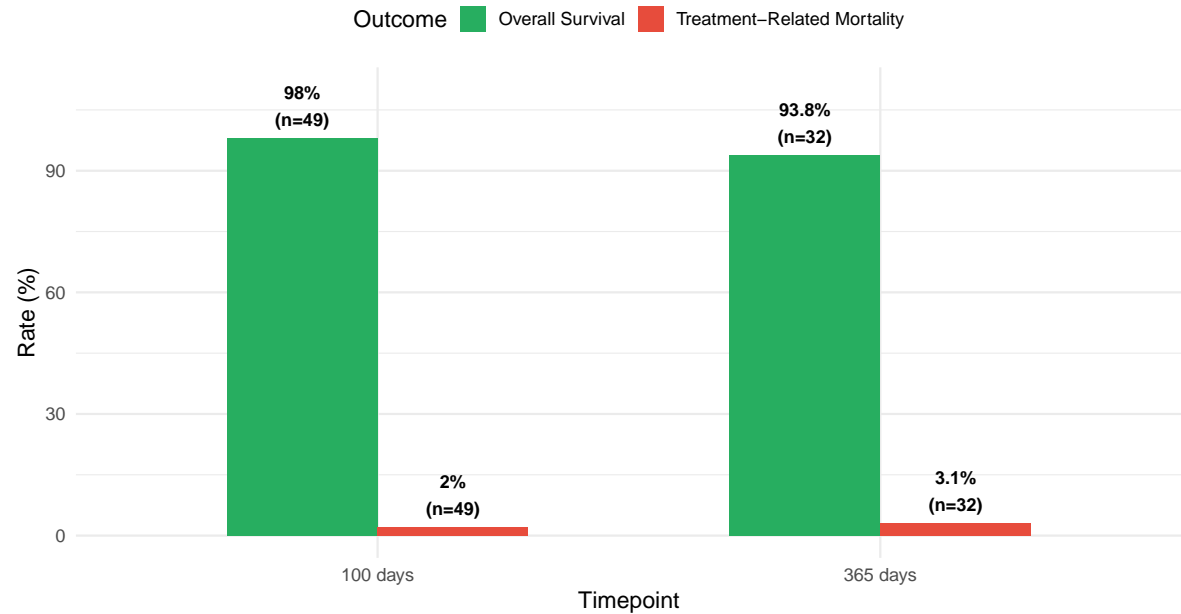> **Individual patient details:**
>
> - **De Lazzari Adriano**: Day 364 death (NRM)
> - **Mares Henoch Sigisfredo**: Day 9 death (TRM)

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4. JACIE Comparison: 2024 vs 2025

Table 13: Table 12: JACIE Comparison - 2024 vs 2025 Autologous Transplant Outcomes

Year	Endpoint	Timepoint	Cohort Size	Events	Rate
2024					
2024	OS	100 days	12	0	100%
2024	OS	365 days	0	NA	N/A*
2024	TRM	100 days	12	0	0%
2024	TRM	365 days	0	NA	N/A*
2025					
2025	OS	100 days	49	1	98%
2025	OS	365 days	32	2	93.8%
2025	TRM	100 days	49	1	2%
2025	TRM	365 days	32	1	3.1%

Figure 2: 2025 Autologous Transplant Outcomes

Overall Survival and TRM at 100 and 365 Days (Rolling Cohort Analysis)

Methodology

Cumulative Rolling Cohort Breakdown

The following table shows the detailed breakdown of each rolling cohort used in the analysis, including the number of patients selected and the time periods used for selection.

Table 14: Table 13: Cumulative Rolling Cohort Breakdown - Patients and Time Periods

Year	Timepoint	Milestone Date Range	HSCT Date Range	Patients Selected	Dea
2024 Analysis					
2024	100 days	Jul 1, 2023 - Sep 30, 2024	Mar 23, 2023 - Jun 22, 2024	12	
2024	365 days	Jan 1, 2023 - Dec 31, 2024	Jan 1, 2022 - Dec 31, 2023	0	
2025 Analysis					
2025	100 days	Jul 1, 2024 - Sep 30, 2025	Mar 23, 2024 - Jun 22, 2025	49	
2025	365 days	Jan 1, 2024 - Dec 31, 2025	Jan 1, 2023 - Dec 31, 2024	32	

> **ℹ Understanding the Cohort Selection**
>
> **How patients are selected:**
>
> - For **100-day analysis**: Patients whose 100-day post-HSCT milestone (HSCT date + 100 days) falls within the milestone date range
> - For **365-day analysis**: Patients whose 365-day post-HSCT milestone (HSCT date + 365 days) falls within the milestone date range
>
> **Example for 2025 100-day cohort:**
>
> - Milestone period: Jul 1, 2024 - Sep 30, 2025
> - This includes patients transplanted approximately Mar 23, 2024 - Jun 22, 2025
> - **49 patients** met these criteria
>
> **Note:** The 2024 365-day cohort has 0 patients because no patients transplanted in the required period (2022-2023) had their 365-day milestone fall within the 2024 reporting window.

Rolling Cohort Selection Criteria

Table 15: Table 14: Rolling Cohort Selection Methodology

Timepoint	Milestone Period (2025)	Milestone Period (2024)	Explanation
100 days	Jul 1, 2024 - Sep 30, 2025	Jul 1, 2023 - Sep 30, 2024	Patients whose 100-day post-HSCT
365 days	Jan 1, 2024 - Dec 31, 2025	Jan 1, 2023 - Dec 31, 2024	Patients whose 365-day post-HSCT

Key Definitions

Overall Survival (OS): Percentage of patients alive at the specified timepoint. Calculated as:

$$OS = \frac{\text{Patients Alive at Timepoint}}{\text{Total Patients in Cohort}} \times 100\%$$

Treatment-Related Mortality (TRM): Deaths directly attributed to the transplant procedure and its complications (not disease progression). Calculated as:

$$TRM = \frac{\text{TRM Deaths at Timepoint}}{\text{Total Patients in Cohort}} \times 100\%$$

Conclusions

Key Findings

2025 Autologous Transplant Program Performance

1. **Overall Survival**

   - 100-day OS: **98%** (48/49 patients)
   - 365-day OS: **93.8%** (30/32 patients)

2. **Treatment-Related Mortality**

   - 100-day TRM: **2%** (1 events)
   - 365-day TRM: **3.1%** (1 events)

3. **Cohort Characteristics**

   - Total evaluable patients: **68**
   - Mean age: **58.3 years**
   - Mean follow-up: **349.6 days** (11.5 months)
   - Primary indication: **Multiple Myeloma** (79.4%)

4. **Data Quality Note**

   - 1 patient (Rapuano Giuseppe) was lost to follow-up and excluded from analysis

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Report generated January 27, 2026 using cumulative rolling cohort methodology per JACIE Italian guidelines

OS = Overall Survival; TRM = Treatment-Related Mortality