Journal of Carcinogenesis
Covering Genesis to Therapeutics

Journal of Carcinogenesis, ISSN: 1477-3163
2025; Vol 24: Issue 4, https://carcinogenesis.com/

Autologous Stem Cell Transplant in Adult Hematological Malignancies- Experience from a Centre in South India

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ABSTRACT

Introduction: Autologous stem cell transplantation (ASCT) is a standard of care for consolidation therapy in younger multiple myeloma (defined variably as age < 65–75 years) and relapsed/refractory lymphoma patients. Several nonrandomized, randomized and population-based studies and meta-analyses have proposed that ASCT is related to improved response rates and EFS (event-free survival) compared with conventional chemotherapy treatment.

Aims & Objectives: To study demographics, type of hematological malignancy and to assess complications and outcomes of ASCT in adult hematological malignancies.

Materials & Methods: This is a retrospective observational study conducted in 70 patients diagnosed with various hematological malignancies, who underwent transplant at our institute from September 2022 to June 2025. Demographics, type of malignancy, complications and outcomes post-transplant were analyzed in this study. The patients were followed up for disease relapse and other complications.

Result: Median age has been 42.5+/-16.9 years (range 16-65 yrs). Most common type of malignancy was multiple myeloma (54.2%), followed by relapsed Hodgkin lymphoma (24.2%). A mean of 6.4 million/kg Stem cells were infused (range 2.2 to 16.8). The median time for neutrophil engraftment was 10+/-1.4 days, and for platelet engraftment was 12+/-1.6 days. Most common complication observed during transplant was diarrhea. The transplant-related mortality (TRM) was 1.4%. The estimated DFS was 985.215 days (95% CI with lower limit 907.548 and upper limit 1062.882 days) and estimated OS was 1014.863 days (95% CI with lower limit 946.846 and upper limit 1082.880days).

Conclusion: ASCT is a low-risk procedure and should be offered as a consolidation therapy in all eligible patients in developing countries. It remains a cornerstone in treatment of multiple myeloma and relapse/refractory lymphomas, offering significant improvement in DFS and OS

Keywords: *Autologous Stem Cell Transplant, Multiple Myeloma, Lymphoma, Transplant Related Mortality.*

How to Cite: Smitha C Saldanha, Gopishetty Raghu, Manjunath S Hiremani, Suresh Babu MC, Lokesh K.N, Rudresha A.H, L K Rajeev, Giri G V, (2025) Autologous Stem Cell Transplant in Adult Hematological Malignancies- Experience from a Centre in South India, *Journal of Carcinogenesis*, *Vol.24, No.4*, 323-328.

1. INTRODUCTION

ASCT (Autologous stem cell transplantation) is a treatment modality for consolidation in several myeloma and relapsed/refractory lymphoma. It is utilized as a bridge to the marrow failure which.

develops throughout high-dose chemotherapy (HDC) given for treating hematological malignancies. It has become a standard of care for patients having myeloma, lymphoma, as well as certain malignancies of childhood. "EBMT (European Bone Marrow Transplant)" annual activity survey for 2023 stated 57.1% rate of ASCT, of which Plasma cell disorders contributed 58.2% and lymphomas 32.2%.[1] Peripheral blood serves as a source in 99 percent of all autologous transplant procedures. 2024 data from CIBMTR (Center for International Blood and Bone Marrow Transplant Research) presented that 10,092 autologous transplants have been performed, of which multiple myeloma as well as lymphomas have been prevalent indications.

A systematic literature search has been conducted from February 2017 to August 2024 in patients with Malignant lymphoma.[2] In the experimental arm, HDC was given followed by ASCT, while control group received only standard chemotherapy. Outcome indicators have been "PFS (progression-free survival)", "complete remission rate" ("CR (complete response)" + "PR (partial response)"), and "OS (overall survival)". Findings from fifteen studies consisting of 896 subjects in experimental group, along with 1229 subjects in control group, odds ratio (OR) was 2.23, with 95 percent "CI (confidence interval)" [1.54, 3.22], Z= 4.25; P< 0.0001, indicating that groups varied in OS as well as PFS rates. Also, PFS rate was 2.70, with 95 percent CI of 1.86 to 3.92, Z=4.25; P<0.0001, as well as OS rate 2.23, concluding that patients with malignant lymphoma receiving chemotherapy had improved OS and PFS rates with ASCT treatment. Two systematic reviews evaluated the efficiency of HDC with single ASCT v/s conventional chemotherapy in patients with myeloma.[3] Pooled findings indicate that difference in survival among HDC + stem cell rescue and chemotherapy treatment is statistically insignificant (HR, 0.92; 95 percent CI, 0.74 to 1.13; p= 40). HDC + stem cell rescue was linked to a statistically significant enhancement in PFS outcome (HR, 0.75; 95 percent CI, 0.59 to 0.96; p=.02).

A new BMT unit was started in our institute in JUNE 2022, both Autologous and allogenic HSCT are being carried out for various hematological malignancies. In our study we analyzed data of autologous transplants in adult population from SEPTEMBER 2022 to JUNE 2025.

MATERIALS AND METHODS

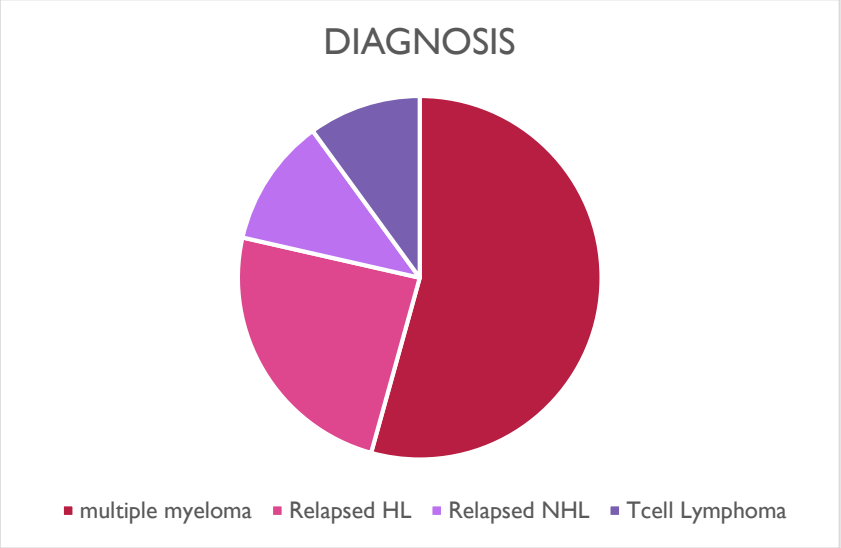
We retrospectively analyzed data from every patient who received ASCT from September 2022 to June 2025. These included patients with HL, NHL, T-cell lymphomas and multiple myeloma. Our institute is a tertiary care, government hospital with 757 beds dedicated to cancer patients. The new transplant unit was established in 2022 with 10 bedded facility and an exclusive ICU. Patients are referred to for bone marrow transplant from all over country. The patients are initially evaluated in outpatient department. The patients, along with their families, are informed about procedure, potential risks, as well as advantages. The pretransplant evaluation included the hemogram with peripheral smear, liver and kidney function tests, infectious disease profile (i.e., HIV antibody, hepatitis C antibody, hepatitis B surface antigen), blood group typing, coagulation profile, pulmonary function tests, ECG, echocardiography, and dental evaluation and the required specialist references are taken for fitness. A guided central line or "PICC (peripherally inserted central catheter)" line has been inserted in every patient. All patients have been admitted to individual rooms, as well as reverse barrier nursing has been practiced. Written informed consent has been given by patients for transplantation, blood product transfusions, as well as chemotherapy. Mobilized "PBSCs (peripheral blood stem cells)" have been harvested from every patient. For mobilization, patients received "granulocyte colony-stimulating factor (G-CSF)" 10μg/kg/day subcutaneously for 4-6days. On 5-7days, stem cells were collected. Chemotherapy, along with G-CSF was used in some patients for mobilization. The patients have been given high-dose melphalan (200mg per m^2) for multiple myeloma.[4] For patients with lymphomas BEAM protocol was used etoposide (200mg per m^2), cytarabine (ara-C; 200mg per m^2), carmustine (BCNU; 300mg per m^2), as well as melphalan (140mg per m^2).[5] Patients have been admitted to individual rooms with HEPA (high-efficiency particulate air) filter. Standard antibiotic prophylaxis with ciprofloxacin (500mg twice daily), fluconazole (200mg once), and acyclovir (400mg twice daily) has been started in every patient on day −5. Every patient has been provided with neutropenic diet. Autologous stem cells have been reinfused on 0th day by central venous catheter or PICC line, which was preceded by intravenous pheniramine maleate (50mg). G-CSF, 5μg per kg, has been started on day +1. Every patient received irradiated and leuco-depleted blood products only. Patients were monitored for complications and managed according to the standard guidelines for any complications. Engraftment has been described as attainment of absolute neutrophil count of $\geq 0.5\times10^9$ / L for 3 consecutive days, as well as platelet engraftment, which has been described as a count $\geq 20 \times 10^9$ / L liter and transfusion independence. Post-transplant patients after discharge were followed monthly for at least 1 year, followed by every 3 months thereafter. Lymphoma patients have been assessed for response at 12 weeks after transplant at the outpatient clinic with PET-CT reassessment and subsequent follow-up clinical examinations. In multiple myeloma patients' response has been evaluated as well as monitored utilizing myeloma biochemistry panel at 12 weeks and then started on maintenance therapy. DFS has been described as from date of transplant until disease relapse/progression. OS has been described as from date of transplant until death or date of last follow-up patient visit. OS curve has been plotted as per Kaplan and Meier. Statistical analysis has been conducted utilizing SPSS version 23.

RESULTS

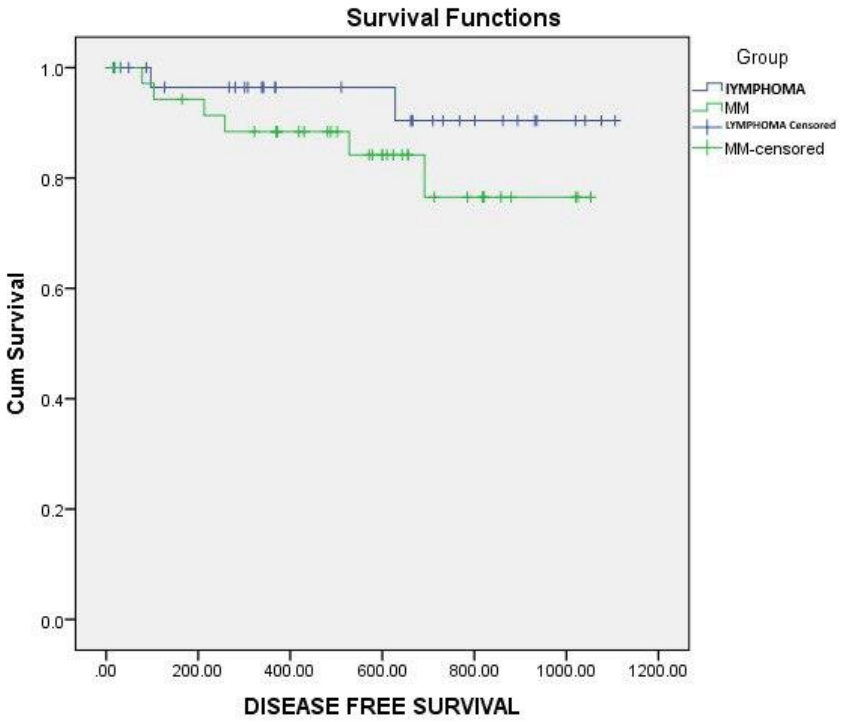
During study period, total 76 adult Stem cell transplants have been conducted at our institute, of which 70 have been autologous. Among autologous stem cell transplants, Multiple myeloma constituted 54.2%(n=38), followed by

Relapsed/Refractory Hodgkin lymphoma 24.2%(n=17). Median age was 42.5+/-16.9 yrs (range 16-65 yrs). G-CSF and plerixafor were used for chemo-mobilization in 95.7% patients, and in the rest, chemo-mobilization was used(one plasma cell leukemia- cyclophosphamide was used, in two lymphoma patients, ICE- Ifosfamide+ Carboplatin+ Etoposide) protocol was used. A mean of 6.4 million/kg Stem cells were infused (range 2.2 to 16.8) for each patient. The median time for neutrophil engraftment was 10+/-1.4 days, and for platelet engraftment was 12+/-1.6 days. The median hospital stay was 18.5 days (range 14 to 40 days). Most common complication encountered was diarrhea seen in 32% patients. Documented infection (culture positive) was seen in 22.8% patients. The mean number of Single donor platelets transfused was 4.5 units, and the mean number of Packed RBC transfused was 0.7 units. The TRM (transplant-related mortality) in the study group was 1.4%(n=1), and the cause was sepsis. The relapse rate was 8.5%(n=6). Presently, 88.5%(n=62) of patients are under follow-up, of which multiple myeloma patients are 51.6%(n=32) and are on maintenance therapy, and lymphoma patients are 48.3%(n=30). The estimated DFS was 985.215 days (95% CI with lower limit 907.548 and upper limit 1062.882 days) and estimated OS was 1014.863 days (95% CI with lower limit 946.846 and upper limit 1082.880days).

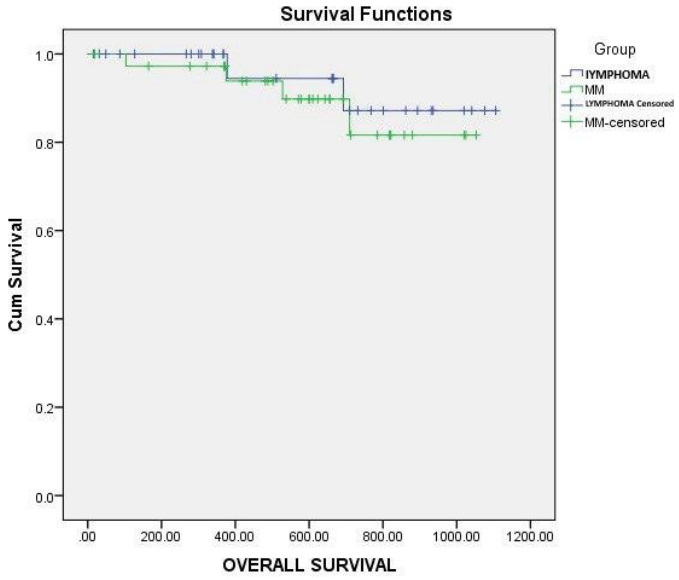
TOTAL (n=70)	
Males	58.5%(n=41)
Females	41.4%(n=29)
Median age	42.5+/-16.9 yrs
Disease type Multiple Myeloma Relapsed HL Relapsed NHL T cell Lymphomas	 54.2%(n=38) 24.2%(n=17) 11.4%(n=8) 10%(n=7)



STEM CELL MOBILIZATION G CSF+ PLERIXAFOR CHEMO-MOBILIZATION	 95.7% (n=67) 4.3% (n=3)
Apheresis sessions	1 (71.4%) >1 (28.5%)
Stem cell infused	Mean - 6.4 million/kg
Neutrophil engraftment	10+/-1.4 days
Platelet engraftment	12+/- 1.6 days
Complications Diarrhea Documented infection TRM	 32% 22.8% 1.4% (n=1)
Post ASCT Follow up Relapsed	 88.5% (n=62) 8.5% (n=6)



	Mean[a]			
			95 % CI	
Group	Estimate	Std. Error	Lower Bound	Upper Bound
LYMPHOMA	1041.156	44.240	954.446	1127.867
MM	900.129	56.398	789.589	1010.669
Overall	985.215	39.626	907.548	1062.882



Group	Mean[a]			
	Estimate	Std. Error	95 % CI	
			Lower Bound	Upper Bound
LYMPHOMA	1035.551	47.371	942.705	1128.398
MM	954.485	45.821	864.675	1044.294
Overall	1014.863	34.702	946.846	1082.880

DISCUSSION

As per Indian Society for Blood and Marrow Transplantation Registry (ISBMT), as of December 30, 2022, there were 114 transplant centers in India, and 26,843 transplants have been performed between 1983 and 2022. Indications for HCT have been increasing over last few decades, and mortality rates are decreasing. Current research aimed to analyze data on frequency, complications, as well as OS after ASCT performed at our institute. The two common indications were multiple myeloma and relapsed Hodgkin lymphoma, according to frequency reported from CIBMTR, EBMT, and ISBMT. Median ± SD age was 42.5+/-16.9 years. With respect to multiple myeloma, various studies have been reported in India. According to Malhotra et al., median OS & PFS for the 6.5-year study period were 76.7 & 55.8 percent, respectively.[6] According to Kumar et al., an estimated OS at 10 & 15 yrs of 40.4 & 17.7 percent, respectively, along with day +100 TRM 5.2 percent.[7] Kulkarni et al have reported 5-yr OS & PFS of 61.6 & 37.2 percent, respectively, along with TRM 2.86 percent.[8] In our study, median DFS was 30 months(900.129days) and the TRM was 2.7% in accordance with the published studies. With respect to lymphoma, in a research by Kumar et al, in an identical cohort of patients treated with ASCT, estimated 5-yr OS & EFS for patients having RR-HL & NHL have been 54.34 & 34.3 percent, respectively, along with TRM 7 percent.[9] In our research median DFS was 34.7 months(1041.156 days) and TRM was 0. In comparison with the aforementioned studies, our institute had a very low TRM. In an era of targeted therapy and immunotherapy for Multiple myeloma and Lymphoma, ASCT still holds a key role in improving DFS and OS, especially in developing countries like India, with most of the population below the poverty line who can't afford such costly targeted treatment.

CONCLUSION

Autologous stem cell transplant is a curative and low-risk treatment option for Multiple myeloma and relapsed/refractory lymphomas. Infection and relapse post-transplant are still the major obstacles to successful outcomes post-transplant.

ETHICS

Study has been performed according to principles outlined in Declaration of Helsinki. As this has been a retrospective observational study, separate ethics committee clearance was not required as per our institutional protocol. Patient anonymity and confidentiality were strictly maintained throughout the study.

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