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A retrospective observational study of autologous peripheral blood stem-cell transplantation and long-term survival outcomes - An institutional experience

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Abstract

Autologous peripheral blood stem cell transplantation (PBSCT) has been employed in patients with various haematological and non-haematological malignancies. The present retrospective study aimed to examine the clinical efficacy and overall long-term survival outcomes of the patients who underwent autologous PBSCT. The clinical data of 49 patients with various haematological and non-haematological malignancies from the Department of Haematology of SMS Hospital from April 2015 to March 2021 were retrospectively analysed. The median age of our patients was 41.5 years. Among all indications, relapsed hodgkins lymphoma (10, 20.4%) and multiple myeloma (27, 55.1%) were reported to be high. The average engraftment was observed to be 11 days with no post-operative complications. The average follow-up period was 2.5 years with a mortality rate of 8.16% (4). Overall, a total of 43 (87.75%) patients showed a complete response with a relapse rate of 12.24% (6). In conclusion, autologous PBSCT can be an effective treatment option with good clinical efficacy, and long term survival outcomes. Our results are comparable to those of many national and international published reports. Overall, the results suggest that with improved management of conditioning-related toxicities and infections, it is possible to develop PBSCT programs in third-world countries and achieve outcomes comparable to those in the international data.

Keywords: autologous transplantation, peripheral blood stem-cell transplantation, conditioning regimen, retrospective observational study, survival outcomes

1. Introduction

Cancer is the leading cause of death worldwide with an estimated 19.3 million new cancer cases and 10 million cancer deaths in 2020 alone (1). Among all the cancers, hematological malignancies are a heterogeneous group of cancers that comprise diverse subgroups of neoplasms originated from uncontrolled growth of hematopoietic and lymphoid tissues (2,3). These biologically and clinically heterogeneous disorders account for 6.5% of all cancers around the world (2). They are commonly classified into four common subtypes: multiple myeloma (MM), non-Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL), and leukemia.

In patients with hematological malignancies and disorders, bone marrow failure is a common phenomenon. In such patients, myeloablation or myeloablative therapy is initiated using very high doses of chemotherapy/radiation therapy to kill the cancer cells as a potentially curative treatment for a variety of hematological diseases. Such high doses also lead to death of normal bone marrow stem cells. In such cases, hematopoietic stem cell transplantation is done to restore those destroyed cells using either autologous or allogeneic stem cells through one of the following methods: bone marrow transplant (BMT), peripheral blood stem cell transplant (PBSCT), and cord blood transplant (CBT). The goal of the engraftment is for the transplanted cells in the bone marrow to grow/make healthy blood cells over time.

Among all hematopoietic stem cell transplantation methods, PBSCT has been preferred over others for more than 25-30 years, since its first reported use in 1989 (4,5). The use of PBSCT as a source is preferred and supplanted over BMT due to its higher potency to restore hematopoietic and immune functions, stem cell harvesting technique without the need of general anesthesia, and the discomfort associated with multiple BM aspirations (4). Other major benefits include graft-versus-tumor effect, fewer febrile days, a lower incidence of infections, a lower requirement of antibiotics, a lower number of platelet and red cell transfusions, and lower intensive care requirements leading to reduced costs (4). In contrast, the treatment with PBSCT is highly toxic and risky due to its severe immunological complications such as acute/chronic graft versus host disease (GVHD) (6,7). The most common causes of post-transplant mortality are organ toxicity, infections (11%), GVHD (12%), and relapse of neoplastic

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disease (41%) (6,8).

In the present study, we report our experience of autologous peripheral blood stem-cell transplantation, its clinical efficacy, and long term survival outcomes in our patients.

2. Matherials and Methods

2.1. Patient screening and selection

In this single-centre observational study, the medical records of all the patients who underwent autologous stem cell transplant from April 2015 to March 2021 were retrospectively analysed. The age range for the consideration was ≤75 years with a suitable Eastern Cooperative Oncology Group (ECOG) performance status, and the lack of significant comorbidities or multiple organ dysfunctions. Patients with only particular cancers (table 1) were included, while other active cancer patients were deemed ineligible.. The present study data was also keen on multiple patient specific characteristics as mentioned in table 1 such as type of transplantation, diagnosis, status of the transplant, chemotherapy regimen, etc. All patients gave their written informed consent. This retrospective evaluation has been approved by the institutional ethics committee. The objectives of our study were to investigate overall survival (OS), and treatment-related death (TRD) after transplantation.

2.2. Data collection and analysis

The patient's information such as socio-demographic profile, clinical history, diagnosis, type of transplant underwent, status of transplant, chemotherapy given, and follow-up details were collected, classified, and categorised. Procured data was analysed descriptively. OS was calculated starting from the day of the first PBSCT (day 0) until death from any reason with censoring of patients alive at their last follow-up. TRD was determined as death other than progression or relapse before day +100 from the last PBSCT. The results were compiled and statistically analysed using SPSS 22 (SPSS Inc., Chicago, IL, USA).

3. Results

Table 1 shows the base-line characteristics of the 49 patients. Among the 49 patients, the youngest one was 5 years and the oldest was 67 years. Only patients undergoing their first transplant were considered for this present study and all of them underwent PBSCT using their own cryopreserved stem cells collected prior to conditioning. The most common diagnosis reported in our patients was multiple myeloma (27, 55%), relapsed (non-hodgkins and hodgkins lymphoma) (13, 26.53%), and multiple sclerosis (3, 6.1%). At the time of transplant, 67.34% of our patients were under remission. The average follow-up period post transplantation was 30 months. Among 49 patients, 4 patients were succumbed due to renal failure (2, 4%) and other GI infections (2, 4%). In the remaining, 43 patients have shown a complete response (87.75%) and 2 (4.4%) were under relapse. Overall, an average engraftment period for all the patients was reported to be 11 days.

Table 1. Baseline patient characteristics and transplant data of our autologous patients

Characteristics	Number of patients (n=49), %
Age (years ± SD)	41.5 (14.7)
Sex	
Men	36 (73.4)
Women	13 (26.6)
Chronological number of transplant - 1st transplant	49
Type of Transplant - Autologous	
Donor - Self - PBSCT	
Type - PB - Mobilized peripheral blood stem cells (all are cryopreserved stem cells)	
Diagnosis - conditioning regimen used	
Relapsed (non-hodgkins and hodgkins lymphoma) - BEAM	13 (26.53)
Relapsed non - hodgkins lymphoma - LACE	2 (4.08)
Neuroblastoma - CECy	1 (2.04)
Amyloidosis - Melphalan	1 (2.04)
Primary CNS Lymphoma - RCT	1 (2.04)
Relapsed seminoma testes - CECy	1 (2.04)
Multiple sclerosis - BEAM-ATG	3 (6.12)
Multiple myeloma - Melphalan	27 (55.1)
Day of engraftment (on average)	11
Status at transplant	
Remission	33 (67.34)
Non-Remission	16 (32.65)
Time (average days)	914
Status at LFU	
Alive	45 (91.83)
Dead	4 (8.16)
Cause of Death	
kidney failure	2 (4.08)
Infections	2 (4.08)
If Alive	
Complete response	43 (87.75)
Relapse	6 (12.24)

BEAM - Carmustine, etoposide, cytarabine, melphalan; BEAM ATG - Carmustine, etoposide, cytarabine, melphalan, anti-thymocyte globulin (ATG); CECy - Carboetocyclophasphamide; LACE - Lomustine, etoposide, cytarabine(Ara-C), cyclophosphamide; RCT – Rituximib, Carmustine, thiotepa; PBSCT - Peripheral blood stem cells transplantation; LFU – Last follow-up.

4. Discussion

The rationale of the present study was to compile and analyse the data to observe the survival outcomes our patients after autologous transplantation performed in the past decade at our centre. The four main indications were multiple sclerosis (MS), relapsed non-hodgkins lymphoma (NHL), relapsed hodgkins lymphoma (RHL), and multiple myeloma (MM). Over the past 20 years almost all the haematological malignancies are treated with PBSCT by largely replacing the bone marrow transplantation procedure for both autologous and allogeneic stem cell transplantation. Use of such mobilized PBSC were

proven to be highly efficient in terms of rapid restoration of the immune system, convenience of stem cell collection, fewer transfusions, shorter engraftment time, and a shorter hospital stay. In all of our patients, PBSCT were used.

Many studies have shown the preponderance of haematological and non-haematological malignancies in elders (60 years of age or older) compared to adolescents (0–19 years) and young adults (20–59 years) (9–11) However, some reports have made exceptions and have shown a higher frequency in adolescents and young adults (AYA, 0 – 39 years).(12,13) Our patients group median age was observed to be high in young adults as reported by previous studies (12,13). Many studies have confirmed the slight predominance of male over female patients.(2) In contrast, majority of our patients were male. Whereas with the current transplantations, almost all of autologous and a majority of allogeneic transplants are performed with mobilized peripheral blood stem cells due to their potential for tumor cell free collection and restoration of hematopoietic and immune functions more rapidly than BM (14,15,24,16–23). Before transplantation, conditioning regimens were given to all the patients with hematological indications using myeloablative conditioning chemotherapy using central lines by avoiding non-myeloablative or reduced intensity regimens and total body irradiation.

The preparative or conditioning regimen is a critical element that helps prepare patients for stem cell transplantation by killing any cancer cells that are in the body. As shown in table 1 and table 2, every indication has its own conditioning regimen for better outcomes. Most of our patients have four main indications and their conditioning protocols are presented in table 2.

Over the last three decades, BEAM and LACE have been the most widely used conditioning regimens before autologous stem cell transplantation for patients with NHL, relapsed NHL, and relapsed hodgkin lymphoma (HL).(2,3,11,13,25–30) In recent times, as a result of two major ground-breaking CORAL and PARMA trials, it has become a standard of care (SOC) in the treatment of chemotherapy-sensitive and relapsed NHL.(27,31,32) BEAM and LACE are generally very effective and well tolerated. In view of findings from previous studies, in our patients too we have adapted the BEAM and LACE protocols as SOC to treat HL, NHL, and relapsed NHL.(25,29,32–35)

Table 2. Disease indication conditioning regimens and their protocols

Conditioning regimens	Indications	Protocol
BEAM(25,29,33,34)	Relapsed hodgkins lymphoma and relapsed non-hodgkins lymphoma	Day-6: Carmustine (BCNU) (300mg/m^2) Days −5, −4, −3, −2: Etoposide (200mg/m^2) Cytarabine (Ara-c) (400mg/m^2) Day −1: Melphalan (140mg/m^2) Day 0: stem-cell transplant
BEAM-ATG(36–41)	Multiple sclerosis	Day -6: Carmustine (BCNU) (300mg/m2) Days −5, −4, −3, −2: Etoposide (200mg/m2) Cytarabine (Ara-c) (400mg/m2) Day −1: Melphalan (140mg/m2)] + peri-transplant ATG as an intermediate-intensity regimen. Day 0: stem-cell transplant
LACE(26,28,30,50–52)	Relapsed non - hodgkins lymphoma	Day -7: Lomustine (200mg/m^2) Day -7: Etoposide (1000mg/m^2) Day -6. -5: Cytarabine (Ara-C) (2000mg/m^2) Day -4, -3, -2: cyclophosphamide (1800mg/m^2) Day 0: stem-cell transplant
Melphalan (42,45,49,53–55)	Multiple myeloma	Day -1: Melphalan (200mg/m^2) or Melphalan (140mg/m^2) Day 0: stem-cell transplant

BEAM - Carmustine, etoposide, cytarabine, melphalan; BEAM ATG - Carmustine, etoposide, cytarabine, melphalan, anti-thymocyte globulin (ATG); CECy - Carboetocyclophasphamide; CM – Carbomelphalanetopocyte; LACE - Lomustine, etoposide, cytarabine(Ara-C), cyclophosphamide; RCT – Rituximib, Carmustine, thiotepa;

Recently, BEAM has been in the process of being replaced by a more economic and available fotemustine or bendamustine, etoposide, cytarabine, and melphalan (BeEAM) regimen. However, due to a lack of larger, prospective trials data on its risk-benefit ratio- instead of BeEAM, BEAM chemotherapy was used in our patients. In MS, we have used BEAM-ATG as conditional regimen due its high safety and efficacy profile. Its usage is also quite popular across Europe, North and South America. (36–41) Whereas in our MM patients, the current accepted standard conditioning regimen - high-dose melphalan (200 mg/m^2) was used (42). Previous trials attempting to replace this with oral and intravenous busulfan have failed, due to increased toxicity and a lack of superiority, respectively (42–44).

The average engraftment period after conditioning in our patients was observed to be 11 days and it was consistent and comparable with the reports published from multiple studies and other standard international data. On average, almost all

the studies have reported the median engraftment day of their patients as 13 days (± 4 days) (28,34,38,45–48). Overall survival of our autologous transplant patients was 91.83%. with a remission rate as high as 67.34% compared to the other studies where it was 30 - 65% (47,49). Complete remission means the disappearance of all signs of cancer, but it does not always mean that the cancer has been cured. A total of 87.75% of our patients have shown complete responses. On the other hand, transplant related mortality was reported in our patients, however, two patients were succumbed to kidney failure and infections due to non-transplant related complications. Such non-transplant mortalities due to various causes were reported to be up to 37% and they were 8% in our patient group (47).

In a developing and resource limiting settings like India, performing autologous PBSCT are complex due to various reasons such as a lack of expertise, knowledge, infrastructure, and high treatment related costs. However, reports from this study can assure the fellow clinicians and the patients about the positive outcomes and we encourage other centres to start performing such transplantations or refer eligible patients for this available important treatment option.

In conclusion, our results reinforced the evidence for encouraging autologous PBSCT for eligible patients. In our study with 49 patients treated with autologous PBSCT, the long-term overall survival and complete response were highly positive. Autologous PBSCT is now evolving as a highly efficacious and relatively safe therapeutic option for the treatment of patients with variable hematological and non-hematological malignancies. In autologous PBSCT, conditioning chemotherapy is of utmost importance and it plays a vital role in overall survival of the patient by avoiding various unnecessary post-operative and long-term complications. Even though the study is limited by its retrospective nature and some differences in cohort, the findings indicate that autologous PBSCT could serve as a best available treatment. Large prospective clinical trials and long-term registry data are required to ascertain its long-term safety, efficacy and to optimise the transplant techniques. It is of prime importance for scientists, healthcare organizations, haematological societies, and persons to organise such large prospective studies to demonstrate the effectiveness of Autologous PBSCT.

Conflict of interest

The authors declared no conflict of interest.

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Authors' contributions

Concept - M.K., J.Y.; Design - M.K., J.Y.; Data Collection or Processing - M.K., S.J., A.M., K.G., R.K., L.M., S.K., J.Y.; Analysis or Interpretation - M.K., J.Y.; Literature Search - M.K., J.Y.; Writing: M.K.

Ethical Statement

This study was approved by the Institutional Review Board and Ethics Committee of SMS Hospital, Jaipur as part of project in accordance with the 1964 Helsinki declaration and later amendments. As the study was retrospective, there was no study-specific consent. All patients granted verbal or written consent prior to and investigation or treatment.

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