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Original Research

Autologous Hematopoietic Stem Cell Transplant in Patients with Multiple Myeloma and Relapsed and Refractory Hodgkin Lymphoma

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ABSTRACT

Background: For individuals with multiple myeloma (MM) and Hodgkin's lymphoma relapsed or recurrent cases (R/R-HL) who fulfil transplantation criteria and are chemo-sensitive to salvage therapy, autologous haematopoietic stem cell transplantation (HSCT) is one of the conventional therapeutic choices. HSCT has shown to be a safe and effective therapy when used in inpatient settings, but it may also be used in outpatient settings.

Methodology: The study involves retrospective data collection of patients who underwent auto-HSCT in a cottage ward, a less intensive area with good air quality and confirmed diagnosis of MM and HL.

Results: Six patients received auto HSCT in the cottage ward, a less intensive area with good air quality,2 R/R-HL and 4 MM at our institution. The patients subjected to HSCT had a median age of 57.5 years for MM and 26 years for HL, respectively. The MM patients were presented at the time of admission with features such as stage II and stage III, 50% each, extensive bone involvement in 100%, and normal cytogenetics in 50% of the patients. The HL patients, at the time of admission were in Stage III according to the Ann Arbor classification with neither B-symptoms nor bulky disease. A 100-day survival rate of 100% was achieved in patients who underwent Auto-HSCT in the cottage ward, a less intensive area with good air quality.

Conclusion: Patients with MM and HL with standard risk can benefit from auto HSCT in a cottage ward, a less intensive area with good air quality, which is safe, effective, economical and feasible. Furthermore, HSCT in a cottage ward, a less intensive area with good air quality, can result in better patient compliance and satisfaction, swifter recovery and better outcomes.

Keywords: Multiple myeloma; Hodgkin lymphoma; Autologous hematopoietic stem cell transplantation; Non-cryopreservation; Outpatient transplantation

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INTRODUCTION

Multiple myeloma (MM) is characterized by the malignancy of the plasma cells with uncontrolled proliferation of monoclonal immunoglobulins in the bone marrow. These proliferating plasma clone cells result in extensive skeletal destruction leading to osteopenia, osteolytic lesions and secondary-end organ damage [1-6].Unlike other malignancies leading to bone metastasis, the lytic bone lesions in MM do not result in new bone formation, and hence, it is one of the primary reasons for disease morbidity and mortality [7].The other disease-related complications reported are hypercalcemia, acute renal injury, anemia and increased risk of infections [8,9]. MM management strategies mainly focus on the inhibition of proliferating plasma cells, thereby preventing complications and improving the overall survival (OS) rate [10]. The recommended first-line treatment for newly diagnosed standard-risk MM cases involves a three-drug regimen,

namely VRd (bortezomib, lenalidomide, and dexamethasone), while in patients with high-risk, quadruple therapy with daratumumab in addition to VRd improves the response, and progression-free survival (PFS) [4,7,11].There has been a huge transition in the treatment of MM after the advent of high-dose chemotherapy with autologous hematopoietic stem cell transplantation (HSCT). Discovery of novel drugs like monoclonal antibodies, proteosome inhibitors and immunomodulatory agents used for the management of newly diagnosed and relapsed MM cases ensure OS rate as well as improved disease response [12,13]. Even though the discovery of several new drugs is in the pipeline, MM remains an incurable disease to date. Therefore, it is important to identify (new drug targets with different mechanisms of action to attain a better response rate and tolerability compared to the existing treatment for MM and 2) the drug resistance mechanisms hindering the action of existing MM treatments to improve the patient's quality of life [12,13].

Hodgkin's lymphoma (HL) is a malignancy of B-cell lymphocytes where the Hodgkin and Reed–Sternberg (HRS) cells are mixed with a heterogeneous population of non-neoplastic inflammatory cells [14]. The features of HL include asymptomatic lymphadenopathy and other constitutional symptoms such as fever, night sweats, and unexplained weight loss within 6 months, namely B-symptoms [15]. HL constitutes 10%-30 % of all lymphomas, and it primarily affects young individuals[16-18]. The initial treatment approaches mainly depend on the histopathology, anatomical staging, and prognostic features of the disease. Imaging techniques are also clinically useful in finding suitable sites for biopsy and evaluating organ involvement in HL [17]. Due to the high sensitivity and specificity, positron emission tomography (PET)response-adapted chemotherapy is employed in the early phases of HL with a better OS and PFS [19,20]. For patients with advanced classical HL, ABVD regimen (doxorubicin, bleomycin, vinblastine, dacarbazine) serves as the initial choice of therapy. For selected patients, BV+AVD (brentuximabvedotin, doxorubicin, vinblastine, and dacarbazine) or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine and prednisone) is used as the alternative treatment choice [21-23]. However, 10-30% of the HL patients attain complete remission after the initial treatment, while 10-15% of patients have refractory disease (R/R-HL) [16, 24-27].Autologous HSCT is performed in R/R-HL following salvage therapy, which shows improved OS and PFSrate. Recently, several new regimens have been practised as salvage therapy such as ICE (ifosfamide, carboplatin, etoposide), ESHAP (methylprednisolone, cisplatin, etoposide, cytarabine), DHAP (dexamethasone, cytarabine, cisplatin), BV + checkpoint inhibitors, BV + bendamustine (BVB), BV + ICE and BV + dexamethasone + HD cytarabine + cisplatin [14,28-38]. Out of all the regimens, the use of DICEP and GDP regimen is found to be well tolerated with better tolerability, less toxicity and adequate mobilization potential when used as salvage therapy before high-dose chemotherapy and auto-HSCT in R/R-HL [40-42]. Hematological malignancies often need hospitalization, which leads to an increased risk of infections and direct medical costs. Although autologous HSCT is more common among in-patients, it can be performed effectively in outpatient settings also [43].

MATERIALS AND METHODS

A retrospective study was conducted for 6 months in the study setting in which all the patients with MM and HL who had undergone autologous HSCT during the study period were included in the study. The study was conducted at the SMS Medical College, Jaipur, India, and subsequently got ethical approval from the same institute. The medical records and patient clinical and laboratory data were retrieved for the study. Before transplantation, the primary disease is controlled by an induction chemotherapeutic regimen, and mobilization of stem cells is achieved using cyclophosphamide or related agents. The mobilized stem cells are collected by the process called apheresis, and it is initiated when the CD34+ cells count in the peripheral blood attains a target of 3.0 to 4.0 × 10^6 CD34+ cells/kg in a single autologous HSCT. After transplantation, appropriate antibiotics are administered for prophylaxis and filgrastim from day 5 of post-HSCT until the day of neutrophil engraftment. SPSS version 22 was used for statistical analysis, and the Kaplan-Meier technique was used to determine the risk variables related to transplantation as well as the survival rate following HSCT at day 100.

RESULTS

Six autologous HSCTs in the cottage ward, a less intensive area with good air quality, were carried out at the study center during the study period—two with R/R-HL and four with MM. Single autologous grafts were performed on all 4 cases of MM and 2 cases of R/R-HL. There were four males and two females among the six patients who received autologous HSCTs, and the median age at HSCT was 57.5 years for MM patients and 26 years for HL patients. Upon achieving disease control with appropriate induction therapy, the four MM patients were given autologous, non-cryopreserved hematopoietic stem cells.

According to the RISS, 50% of the MM patients belonged to stage II and III respectively at the presentation of the disease. Extensive bone involvement was present in all the patients characterized by multiple lytic lesions. Regarding cytogenetics, 50% of the MM patients possessed normal features and the data for the rest of the patients were not available (Table 1-3).Of note on the initial line of management in MM, all the patients (n=4) received VRd regimen (bortezomib, lenalidomide, and dexamethasone), out of which one patient received two lines of therapy with carfilzomib, pomalidomide and dexamethasonein addition to VRd prior to autologous HSCT (Table 4). Response to the treatment in patients before autologous HSCT showed achievement of complete response (CR) in all the patients (n=4, 100%). Regarding the early complications in MM patients, only 1 patient (25%) experienced grade 1 mucositis

following autologous HSCT (Table 5). For neutrophils and platelets, the median days to engraftment were 12.5 and 13.3 days, respectively. In the first 100 days following auto HSCT in cottage ward a less intensive area with good air quality, none of the two MM cases required hospitalization.

HSCT was performed on 2 patients (100%) with HL, with a median age of 26.The patients (n=2; 100%)presented at the time of admission were in stage III according to the Ann Arbor classification system. The histological subtype analysis revealed the 2 patients (100%) had nodular sclerosis, a feature of classical HL. Moreover, the patients (100%) had stage III disease at presentation; neither of the cases reported B-symptoms nor bulky disease (Table 6). Regarding the salvage line of treatment given to R/R-HL patients, the 2 cases received the double line of chemotherapy with ICE-DHAP and GDP-ICE. The stem cell mobilization was achieved in study participants using the BEAM regimen prior to autologous HSCT.A patient (50%) developed grade 2 mucositis and febrile neutropenia after HSCT(Table 7-9). After HSCT, neutrophils and platelets engrafted after an average of 12 days and 13.5 days, respectively, in patients with HL. All patients receiving auto HSCT in the cottage ward, a less intensive area with good air quality, had a 100% survival rate at day 100.

Table 1. Staging of MM patients who received outpatient autologous HSCT

Staging of the disease	Number	Percentage
Stage I	0	0
Stage II	2	50
Stage III	2	50
Unknown	0	0

Table 2. Bone involvement in MM patients who received outpatient autologous HSCT

Extent of bone involvement	Number	Percentage
Localized or single lytic lesions	0	0
Multiple lytic lesions	4	100
Pathological fractures requiring surgery	0	0

Table 3. Cytogenetic abnormalities in MM patients who received outpatient autologous HSCT

Cytogenetic abnormality	Number	Percentage
Normal	2	50
17p deletion	0	0
Translocation14 (t4:14,t6:14, t14:16, t14:20)	0	0
Trisomies of chromosome	0	0
Monosomies of chromosome	0	0
Unknown	2	50

Table 4. Initial line of chemotherapy given to MM patients who received outpatient autologous HSCT

Regimen/Protocol	Number	Percentage
VRd	4	100
KRd	1	25
VRd: bortezomib, lenalidomide, dexamethasone; KRd: carfilzomib, lenalidomide, dexamethasone.		

Table 5. Complications observed in MM patients subjected to outpatient autologous HSCT

Complication	Number	Percentage
Febrile neutropenia(FN)	0	0
Mucositis *Grade I*	1	25
Other	0	0

Table 6. Characteristics of HL patients who have undergone outpatient autologous HSCT

Characteristics	Details
Median age	26 years
Gender	Male (100%)
Classical HL type	Nodular sclerosis (100%)
Stage of diagnosis	Stage III (100%)
B-symptoms	Absent
Bulky disease	Absent

Table 7. The line of salvage therapy given for HL patients subjected to outpatient autologous HSCT

Line of therapy	Specific regimen	Number	Percentage
Single line	0		
Multiple line *double line*	2 ICE DHAP GDP ICE	2	100

Table 8. Stem cell mobilization regimen given for HL patients who are given outpatient autologous HSCT

Regimen	Number	Percentage
BEAM	2	100
BEAM: BCNU, etoposide, cytarabine, melphalan		

Table 9. Complications observed in HL patients subjected to outpatient autologous HSCT

Complication	Number	Percentage
Febrile neutropenia (FN)	1	50
Mucositis Grade II	1	50
Other	0	0

DISCUSSION

Autologous HSCT is widely used in hematological malignancies especially in MM and HL as a prominent treatment strategy [44,45]. The inclusion criteria for patients subjected to autologous HSCT is based on certain factors such as age, immune status, renal impairment and the presence or absence of comorbid conditions [10,46-48]. Cryopreservation is an important process for stem cell sample collection prior to HSCT using dimethyl sulfoxide as the cryopreservative agent. This method necessitates the hospitalization of patients and results in increased risk of infection and associated complications [3,48,49]. There is literature evidence which shows the use of non-cryopreserved sample for autologous HSCT since it is safer, more cost-effective and is considered efficacious as cryopreservation [45, 48-54].Autologous HSCT without cryopreservation is advantageous as it is simple to perform even in outpatient clinical settings [3,48,55]. We used non-cryopreserved stem cells for autologous HSCT in 6 patients (100%), measuring survival at day 100 post-HSCT.

Even with the advent of new medication therapies, autologous HSCT is still regarded as the gold standard of therapy for individuals with MM. [2,10,48,55,56]. Intravenous high dose melphalan (200mg/m^2) is used as the standard conditioning agent in MM patients who are undergoing autologous HSCT. However, a reduced dose of 140mg/m2 is employed in clinical practice due to the increased risk of toxicity [5,10,48,55,57]. In our study, MM patients who meet transplant eligibility requirements are given large doses of melphalan as a conditioning agent before autologous HSCT, considering their creatinine clearance. The stem cell mobilization is usually achieved by filgrastim and plerixaforto improve the mobilization potential. When the stem cells reach a count of a minimum of 2.5 x 10^6 /kg body weight in the peripheral sample, the stem cell collection is carried out using the apheresis procedure to enable a successful autologous HSCT [3,45,56].

R/R-HL has become a clinical concern in which one-third of the patients require salvage therapy despite using effective chemotherapeutic regimens in the first line [58]. As a result, salvage treatment, high-dose chemotherapy, and autologous HSCT have become the standard of care for patients with R/R-HL [16,17,24-26,59]. The literature indicates that, over a 5-year analysis period, high-dose chemotherapy followed by autologous HSCT improves the OS and PFS rate by 55% to 63% and 44% to 51.3%, respectively [60,61]. The long-term outcomes in 5 years of OS have grown to 92% and a PFS of 73.4% in R/R-HL patients with the use of salvage treatment with immune checkpoint inhibitors and BV regimens [20,62,63].

BEAM therapy is the standard conditioning agent used over 6 days of therapy in HL patients [59,64]. BEAM regimen is considered safe in out-patient settings also since it is safe and economical, with decreased risk of infections and associated complications, and it improves the overall quality of patient life [59,64]. There are other alternatives to BEAM therapy, such as mini-BEAM, the addition of radioimmunotherapy to the BEAM regimen, TEAM (thiotepa, etoposide, cytarabine, melphalan) regimen, and BEC (BCNU, etoposide, cyclophosphamide) [65-71]. Literature evidence suggests that using high-dose melphalan alone can be considered as a standard conditioning agent due to the simplicity of its administration in the outpatient setting [72-75].

Allogeneic HSCT is the only possible management strategy for patients with R/R-HL but do have chemosensitivity after autologous HSCT [26]. The use of high dose BEAM in in-patient settings over 6 days is considered as one of the standard regimens for patients with HL prior to autologous HSCT [59,64]. The high dose BEAM can be employed in outpatient settings since it is safe, economical, reduced hospitalization, complications and associated costs [59,75].

To date, autologous HSCTs are confined to in-patient settings due to safety concerns and recent studies are focusing on conducting autologous HSCTs in the outpatient setting. The speedy recovery, early improvement in supportive care, safety and economic considerations makes autologous HSCT more acceptable and feasible among the patients and healthcare professionals [76,77]. With a multidisciplinary approach and an effective hospital policy implementation, autologous HSCT in cottage ward a less intensive area with good air quality can be considered as an effective treatment strategy for MM and HL patients who fall into the inclusion criteria for transplantation.

The eligibility criteria of the patients for outpatient autologous HSCT mainly depends on the availability of the supportive care, good performance status, low risk medical comorbidity profile, preference of patient and the treating physician, convenience and compliance of patient to the treatment [78-82]. While patients>65 years of age, poor performance status, staying far away from the hospital settings, high risk MM or lymphoma cases and those who are having advanced comorbid conditions are considered ineligible for the outpatient HSCT [77,83-85]. The same inclusion and exclusion criteria were used in our study to choose the MM and HL patients for outpatient autologous HSCT.

The subjected to HSCT are indicated for admission in the hospital in case of complications such as febrile neutropenia, severe mucositis, poor oral intake, declining status of the patient and presence of serious infections or advanced comorbid conditions [77,84,86-90]. The risk factors predictive of hospitalization include the poor performance status of the patient, advanced age, female sex, albumin level and intensive treatment with regimens like BEAM chemotherapy [77]. All the patients (n=6; 100%) who have undergone autologous HSCT in cottage ward a less intensive area with good air quality did not require hospitalization in the first 100 days of post-HSCT. In both the MM and HL patients, grade I and II mucositis and febrile neutropenia were present but did not necessitate hospitalization.

Neutrophil engraftment usually takes 9–14 median days in outpatient autologous HSCT and platelet engraftment typically takes 12–19 median days [89]. The median duration of neutrophil and platelet engraftment in MM patients who underwent autologous HSCT was 12.5 days and 13.3 days, respectively, while the median days of engraftment for neutrophils and platelets in patients with HL were 13.5 days and 12 days, respectively. We achieved a 100% CR rate in both MM and HL patients after 100 days of post-HSCT.

The merits of autologous HSCT in cottage ward a less intensive area with good air quality in cottage ward a less intensive area with good air quality include considerable cost reduction, high patient satisfaction and compliance, limited resource utilization, and better tolerability in eligible patient population. This will result in a considerable reduction in the direct hospitalization costs in patients and save the hospital beds and facilities for unforeseen demands compared with routine in the HSCT unit [80,83,84, 91-94].

The maintenance therapy plays a vital role in improving the OS and PFS rate in MM patients after autologous HSCT [95]. Maintenance treatment with lenalidomide has been demonstrated to raise the OS and PFS and give a profound and durable response in patients with recently diagnosed MM [96-99]. Bortezomib can be considered as an alternative if the patient does not tolerate or is unresponsive to lenalidomide, renal impairment or having high risk cytogenetics (say, 17p deletion) [100.101,102]. In our study, one patient out of 4 MM cases (25%) received continuous therapy with VRd regimen followed by KRd and reported CR100 days after autologous HSCT.

CONCLUSION

The patients in our study group presented with MM and HL at a very young age compared to studies conducted in other countries. All the patients were presented with standard-risk and hence it was convenient to conduct the study in an auto HSCT in cottage ward a less intensive area with good air quality setting. There are specific inclusion and exclusion criteria to be considered for patients subjected to autologous HSCT in cottage ward a less intensive area with good air quality. The patients require regular monitoring, continuous supportive care and appropriate infection prophylaxis and management. Autologous HSCT in cottage ward a less intensive area with good air quality is safe, convenient, economical and patient-friendly making it widely acceptable among patients and the healthcare providers. This enables the exclusion of patients of standard risk of autologous HSCT from unnecessary hospitalization and overutilization of healthcare resources. One of the main requirements of HSCT in outpatient settings is non-cryopreservation of the stem cells and conditioning therapy with a high-dose chemotherapeutic agent. Autologous HSCT may be efficiently carried out in a cottage ward, a less intensive area with good air quality settings in MM and HL cases who are chemosensitive to salvage treatment, and it results in an overall improvement in patient's quality of life equivalent to in-patient settings.

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