


Research Article

Haematopoietic Stem Cell Transplantation in A Government Setup in India: New Directions in Indian Healthcare; Way To Go!

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Abstract

Introduction: Haematopoietic stem cell transplant (HSCT) is indicated for several haematological disorders as potentially curative treatment option. However, establishing a stem cell transplant unit demands infrastructure, multi-disciplinary services, medical supplies and skilled health care professionals. We established a transplant unit in a government hospital and provided a free of cost HSCT. We are sharing our experience of developing such unit, along with the outcomes of the first 35 HSCTs performed at our center.

Methods: It is a retrospective observational study that included patients with hematological disorders, both benign and malignant, who underwent autologous or allogeneic stem cell transplant between September 2021 and August 2023 at Employees' State Insurance Corporation and Medical College and Hospital, Faridabad, India.

Results: Of the 35 patients, 15 underwent autologous SCTs (Multiple Myeloma=12 and Classical Hodgkin Lymphoma= 3) and 20 underwent allogeneic SCT (Matched Related Donor (MRD)=9 and haploidentical donor=11). The median recipient age was 35 (range 13-67) years. The median time to neutrophil engraftment was 10(8-21) days, 13(10-14) days and 17(14- 19) days for autoSCTs, MRD and haploSCTs respectively. The median time to platelet engraftment was 12(11-27) days for autoSCTs, 15(12-17) days for MRD and 18(15-20) days for haploSCTs. Acute GVHD was seen in 5(25%) patients, whereas 2(10%) had chronic GVHD. The median follow-up duration was 248(15- 780) days. Overall survival (OS) and Progression free survival (PFS) for entire cohort was 248(15-780) days and 192(15-780) days respectively. Overall survival and PFS in in auto SCTs cohort was 224 (57-780) days, in MRD transplant group it was 511(94-687) days and 180 (94-687) days respectively whereas in haploSCTs it was 248 (15-519) days and 192 (15-519) days respectively. The OS rate at last follow-up for whole cohort was 91.43%. Precisely, OS for autoSCTs, MRD and haploSCTs was 100%, 88.89% and 81.82% respectively. The progression free survival rate at last follow-up for whole cohort was 77.14%. PFS for autoSCTs, MRD and haploSCTs was 100%,77.78% and 45.45 % respectively.

Conclusion: Our experience illustrates that the developing a SCT unit and performing HSCTs including haploSCTs is possible, even in resource limited settings. We strive to constantly improve our outcomes and provide this life saving modality of treatment to substantial number of patients.

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Introduction

Haematopoietic stem cell transplantation (HSCT) is a therapeutic procedure that has evidently shown the significant improvement in survival of the patients suffering from most, if not all, of the haematological disorders [1]. High risk haematological malignancies usually have tendency to relapse even after utilizing huge amount of money, time and efforts and hence, project as major financial burden on healthcare system. On the other hand, HSCT has its own complexities, as it is a highly skilled procedure. The cost involved in performing HSCT in private settings makes it less accessible for most of the Indian patients [2]. Building an allogeneic HSCT unit demands funding sources, infrastructure, equipment, medical supplies, and training of health care professionals. The existence of transplant unit is unimaginable without the availability of appropriately and efficiently functioning laboratory with facilities to perform human leukocyte antigen (HLA) typing, flow cytometry, cytogenetics, fluorescence in situ hybridization (FISH), and chimeric studies [3]. Additionally, blood bank with apheresis facility and well-maintained inventory is a pre-requisite to run a bone marrow transplant unit [4]. In addition, HSCT is not a one-time point procedure and the post-transplant follow-up involves the cost too.

According to a study conducted in United States of America, the median total healthcare cost at 100 days was USD289,283 for the myeloablative allogeneic transplant, USD253,467 for the nonmyeloablative/ reduced-intensity transplant, and USD140,792 for autologous transplant [5]. In a similar study from a private health care facility in India, the median cost of autologous transplant was USD 12,500 (range USD 10,331-39,367) and the median cost of allogeneic transplant was USD 17,914 (range USD 10,832-44,701) [6]. The comparison of the numbers between those cost estimates clearly illustrates that the stem cell transplant in India is much more affordable. Despite of that huge difference in cost, most of Indian patients cannot access transplant centers as most of them are private setups and the waiting lists in government hospitals are exhausting. In 2023, the average salary in India is 31,900 INR (Indian Rupee) per month or 383,000 INR per annum that is 387 USD per month, according to the exchange rates in June 2023 [7]. This fact clearly shows that establishing more and more transplant units in government hospitals and medical colleges can be a possible solution and a ray of hope for thousands of patients with blood disorders. On the similar principles of providing cost effective and easily accessible HSCTs to their country fellows, other low middle-income (LMIC) countries like Nepal, Pakistan and Bangladesh have successfully attempted to establish low cost transplant units [8,9].

Another un-compromised aspect of establishing a transplant unit is to curb the risk of infection with strict protocols, such as adherence of healthcare providers to meticulous infection prevention practices, including hand hygiene and the proper use of personal protective equipment. Moreover, educating patients and empowers them to actively participate in their safe transplant is equally important [10]. In developing regions of the world, poor environmental conditions and higher levels of antimicrobial resistance make it challenging and crucial to design a transplant unit with strict environmental controls. However, international guidelines do not advocate the compulsive use of high-efficiency particulate air filtration (HEPA) and positive-pressure in low risk transplants like autologous transplants and allogeneic transplants for thalassemia and sickle cell disease [11].

The key objective of this study is to share our experience of developing a bone marrow transplant unit (BMT) service in a government and teaching hospital in India. We present the outcomes of our first 35 HSCTs, including autologous and allogeneic, done at our center from September 2021 till August 2023.

Methods

All patients with hematological malignancies who underwent haematopoietic stem cell transplantation (autologous, matched related donor and haploidentical donor) between September 2021 and August 2023 at Employees' State Insurance Corporation and Medical College and Hospital, Faridabad, India were included in the present analysis. Allogeneic transplant (AlloSCT) indications were benign haematological disorder such as aplastic anemia and malignant disorders such as relapsed and/or refractory acute lymphoblastic leukemia or acute myeloid leukemia, high risk myelodysplastic syndrome, chronic myeloid leukemia either blast crisis in remission or refractory to at least two tyrosine kinase inhibitors. Multiple Myeloma and Classical Hodgkin Lymphoma were the indications for autologous stem cell transplantation. Written informed consent for HSCT was provided by patients and their relatives, after a detailed discussion of the risks and benefits involved in this procedure. All patients were treated in HEPA-filtered rooms in the 4 bedded BMT unit.

All transplant-eligible patients and donors underwent pre-transplant workup for both recipient and donor, that included an examination of the patient's performance status; organ function assessment, viral serology, screening for any underline infection. Donor-specific antibody screening was done for haploidentical transplant recipients. In case of presence of DSA in recipients, de-sensitization protocol was followed to make DSA negative before proceeding to haploidentical stem cell transplantation (haploSCT). Peripheral blood stem cell (PBSC) harvest was done in the

blood bank by trained apheresis team. Transplant program employed a primary transplant team which performed and monitored all peri-transplantation care and post-transplantation follow-up, supported by medical oncologists, residents and trained nursing staffs. The study was approved by the Institutional Review Board and hospital's Ethical committee.

The total cost was supported by the hospital which included the cost of chemotherapy, stem cell harvest, antibiotic usage, supportive care with blood, platelet transfusion and growth factors, the hospital stay charges and the investigation charges. There was no out-of-pocket expense by any patient.

Data collection

Data including age, sex, diagnosis, disease status at the time of transplant, conditioning regimen, engraftment details and transplant-related complications such as febrile neutropenia, Veno-occlusive disease(VOD), Haemorrhagic cystitis(HC), mucositis, transplant related mortality(TRM), graft versus host disease(GVHD)(both acute and chronic), peri-transplant and post-transplant infections, cytomegalovirus (CMV) reactivation, primary graft failure, relapse were collected retrospectively from the hospital information system.

Statistical analysis

Post-transplant outcomes including engraftment, non-relapsed mortality (NRM), relapse, progression-free survival, and overall survival were analyzed using SPSS version 29. Categorical variables were compared using the chi-square test, while continuous variables were compared using Student's t-test. Progression-free survival (PFS) was defined as survival without relapse or of hematological disease or death from any cause. NRM was defined as death from any cause and without evidence of relapse. We utilized the Kaplan-Meier method to calculate the probabilities of PFS and OS.

Results

Total 35 patients underwent HSCT between September 2021 and August 2023. Of 35 patients, 15(42.8%) patients underwent autologous transplantation (AutoSCT), 9(25.7%) received matched related donor transplantation (MRD) and 11(31.4%) received haploidentical donor transplantation(haploSCT). One patient had positive DSA and hence, required desensitization prior to haploSCT. 24(68.5%) patients were males and 11(31.4%) patients were females. The median age of recipients was 35(range 13-67) years. CMV status for all alloSCTs was donor reactive and recipient reactive. Patients who underwent autoSCT had multiple myeloma (MM){n=12(80%)} and classical hodgkin lymphoma (CHL){n=3(20%)}. In patients who underwent alloSCT transplant, had Acute myeloid leukemia {n=6(30%)}, B- Acute Lymphoblastic Leukemia {n=2(10%)}, Myelodysplastic syndrome {n=1(5%)},

Chronic myeloid leukemia {n= 2(10%)}and Aplastic anemia {n=9(45%)}. All MM patients received conditioning with high dose melphalan and all patients of CHL received conditioning with standard BEAM regimen. In MRD transplants, 3 (33.3%) patients received Fludarabine/Cyclophosphamide/AntiThymocyteGlobulin(Flu/Cy/ATG),6(66.6%) patients received Fludarabine/ Treosulfan/ ATG(Flu/Treo/ATG). In patients who underwent haploSCT 6(54.5%) received Thiotepa/Fludarabine/Cyclophosphamide/TBI200cGy (Thio/Flu/Cy/TBI) and 5(45.4%) received Flu/Cy/ATG/TBI400cGy. All MRD patients received GVHD prophylaxis with cyclosporine and methotrexate, whereas all HaploSCT patients received post-transplant cyclophosphamide (PTCy) as GVHD prophylaxis. 10(50 %) had male to male transplant, 4(20%) had male to female transplant, 5(25%) patients had female to male transplant and 1(5%) patient had female to female transplants. The number of patients with same blood group, major ABO incompatible, minor ABO incompatible and bidirectional mismatch transplants were 9(45%), 3(15 %), 4(20%) and 4(20%) respectively (Table 1).

Table 1: Patients' Characteristics.

Characteristics	Number of patients/N(%)/ {Median(range)}
Type of stem cell transplant	35
Autologous:	15
Multiple Myeloma	12
Hodgkin Lymphoma	03
Matched related donor	9
Haploidentical donor	11
Patient's age(years)	35(13-67) years
Patient's sex: Male	24
Female	11
Recipient/Donor Sex	
Male to male	10(50%)
Female to male	05(25%)
Male to Female	04(20%)
Female to Female	01(05%)
Recipient/Donor blood group	
Same	09(45%)
Major ABO mismatch	03(15%)
Minor ABO mismatch	04(20%)
Bidirectional mismatch	04(20%)
Disease indication in alloSCTs	
AML	06(30%)
B-ALL	02(10%)
CML	02(10%)
Aplastic anemia	09(45%)
MDS	01(05%)
Stem cell source	
PBSC	35(100%)
CD34 cell yield	9.1(3.4-23.6) million/kg of recipient body weight
CD34 cell dose	7.0(3.4-23.6) million/kg of recipient body weight
Conditioning Regimen	

MRD: Flu/Cy/ATG	03(33.3%)
Flu/Treo/ATG	06(66.6%)
Haplo: Flu/Cy/ATG/TBI400cGy	05(45.4%)
Thiotepa/Flu/Cy/ TBI200cGy	06(54.5%)
Engraftment	
Neutrophils: Auto	10(8-21) days
MRD	13(10-14) days
Haplo	17(14-19) days
Platelets: Auto	12(11-27) days
MRD	15(12-17) days
Haplo	18(15-20) days

Table 2: Transplant Outcomes.

Transplant complications	Number=N(%)/ {Median(range)}
Oral and/or abdominal mucositis	
Grade 1	06(17.1%)
Grade 2	14(40%)
Grade 3	15(42.8%)
Veno-occlusive disease	Nil
Hemorrhagic cystitis	Nil
Graft versus Host disease in alloSCTs	
Acute: MRD	02(10%)
Haplo	03(15%)
Chronic: MRD	01(05%)
Haplo	01(05%)
Documented Infections	
Bacterial	05(14.2%)
Fungal	01(2.8%)
Viral	-
CMV reactivations	20(100%)
Relapse	06(30%)
MRD	02(10%)
Haplo	04(20%)
Transplant related mortality	03(8.5%)
MRD	01(05%)
Haplo	02(10%)
Overall Survival	248(15-780) days
AutoSCT	224 (57-780) days
MRD	511(94-687) days
Haplo	248 (15-519) days
Progression Free Survival	192(15-780) days
AutoSCT	224 (57-780) days
MRD	180 (94-687) days
Haplo	192 (15-519) days

Engraftment and graft rejection

Median CD34 stem cell yield was 9.1(3.4-23.6) million/kg of recipient's body weight. Median CD34 stem cell dose was 7.0(3.4-23.6) million/kg of recipient's body weight. In autoSCTs, the whole stem cell product was infused, whereas for MRD and haploSCTs upper limit of infused dose was kept as 7 million cells/ kg of recipient's body weight. All patients who underwent autologous transplant engrafted. All patients who underwent alloSCT (except for two) achieved

engraftment. The median time to neutrophil engraftment for whole cohort was 13(8-21) days. The median time to neutrophil engraftment was 10(8-21) days, 13(10-14) days and 17(14- 19) days for autoSCTs, MRD and haploSCTs respectively. The median time to platelet engraftment for whole cohort was 15(11-27) days. The median time to platelet engraftment was 12(11-27) days for autoSCTs, 15(12-17) days for MRD and 18(15-20) days for haploSCTs. One (5 %) patient who underwent haploSCT had primary graft failure, whereas one (5 %) patient, who also underwent haploSCT, succumbed on day+15 post-transplant and hence engraftment could not be assessed. None of the patient had secondary graft failure.

Graft versus host disease

In alloSCT cohort, the cumulative incidence of grade II-IV acute graft versus host disease (aGVHD) was 5(25%). In MRD transplants, 2(10%) patients had aGVHD; whereas 3(15%) patients had aGVHD in haploSCTs. All patients had gastrointestinal (GUT) as the main organ involved. Out of these 5 patients, 2(40%) patients had steroid- refractory aGVHD (SR aGVHD). None of patients had TRM due to aGVHD.

Two (10%) patients had chronic graft versus host disease (cGVHD){MRD=1(5%) and haploSCT=1(5%)}. Skin and liver were main organs involved {skin=1, skin+Liver=1}. Out of these, 1(50 %) patient had steroid refractory cGVHD (SR cGVHD).

Other complications during and post-transplant (Table 2)

Oral and abdominal mucositis (Grade 2-3) was seen in all patients. 6(17.1%) patients had Grade 1, 14(40%) had grade 2 whereas 15(42.8%) patients had grade 3 mucositis. All were managed with supportive care. None of the patients who received alloSCTs, encountered VOD and HC during transplant. One patient who underwent MRD had liver hematoma due to thrombocytopenia, from which he could not be saved despite of adequate transfusion support.

Despite antimicrobial prophylaxis, we encountered infections. Thirty (85.7%) patients had febrile neutropenia during HSCTs. As a policy, anti-fungal prophylaxis was started from day+1 in cases who needed primary prophylaxis and from the start of conditioning regimen in patients who needed secondary prophylaxis, which was continued until immunosuppression was ongoing. Five (14.2%) patients had documented bacterial infections (Gram negative=4, Gram positive=1). Out of these patients, only one patient had pan-sensitive bacteria in blood culture whereas 3 patients had multi-drug resistant (MDR) bacteria. One patient who was infected with MDR bacteria had liver abscess as well. One (2.8%) patient had probable fungal pneumonia and required empirical antifungal therapy. Viral infections (other than

CMV) could not be documented as viral polymerase chain reaction (PCR) were not performed due to high cost and non-availability of the test.

CMV reactivation

All recipients and donors were seropositive for CMV before the transplant. CMV- PCR monitoring was done in alloSCTs only. In MRD transplants, monitoring was started from day +28 onwards weekly and in haploSCTs, it was started from day+14 onwards weekly. No CMV prophylaxis was administered. All patients who underwent MRD and haploSCTs had CMV reactivation. All of the CMV reactivation were treated pre-emptively with ganciclovir and valganciclovir. Foscarnet was never used in our cohort. There was no CMV disease and refractory CMV infection.

Outcomes: Relapses and Transplant related mortality

At last follow up, 33(94.2 %) patients were alive and 3 (8.5%) patients succumbed to transplant related complications. However, there was no TRM in autoSCT cohort. In MRD transplant group, TRM was seen in 1(05%) patient, whereas, in haploSCT group, TRM was observed in 2(10%) patients. Causes of TRM was sepsis, liver hematoma, relapse in these 3 cases.

Six (30%) patients who underwent alloSCTs relapsed. Out of which 2(10%) patients underwent MRD transplantation and 4(20%) patients received haploSCTs. Two of the relapsed patients had B-ALL, two patients had AML, and two patients had CML (both of which had molecular relapses). The median time of relapse post allograft was 142.5days (range 90-210 days). Among relapsed patients, 5 patients could be salvaged with chemotherapy and donor lymphocyte infusion (DLI) and were alive till last follow up (Table 2).

Survival

The median follow-up duration was 248(15- 780) days. Overall survival (OS) and Progression free survival (PFS) for entire cohort was 248(15-780) days and 192(15-780) days respectively. None of the patient had TRM and relapse in autoSCT cohort. OS and PFS in autoSCT cohort was 224 (57-780) days and 224(57-780 days), in MRD transplant group it was 511(94-687) days and 180 (94-687) days respectively whereas in haploSCTs it was 248(15-519) days and 192 (15-519) days respectively. The OS rate at last follow-up for whole cohort was 91.43% (Figure 1). Precisely, OS for autoSCTs, MRD and haploSCTs was 100%, 88.89% and 81.82% respectively (Figure 1a,1b,1c). The PFS rate at last follow up for whole cohort was 77.14% (Figure 2). PFS for autoSCT, MRD and haploSCT was 100%, 77.78% and 45.45% respectively (Figure 2a,2b,2c).

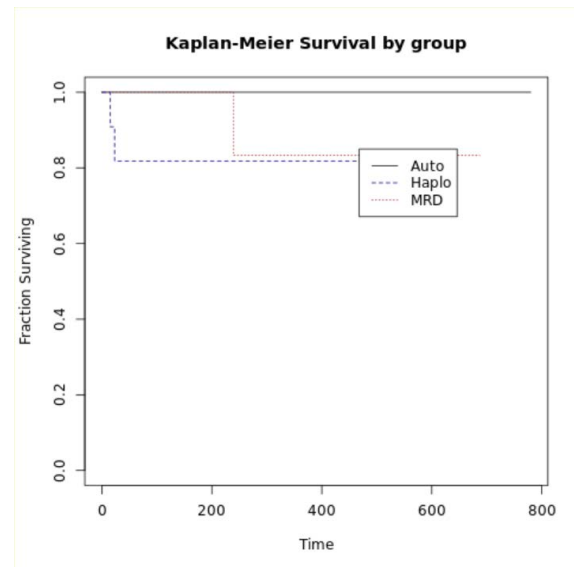


Figure 1: Overall Survival of whole cohort.

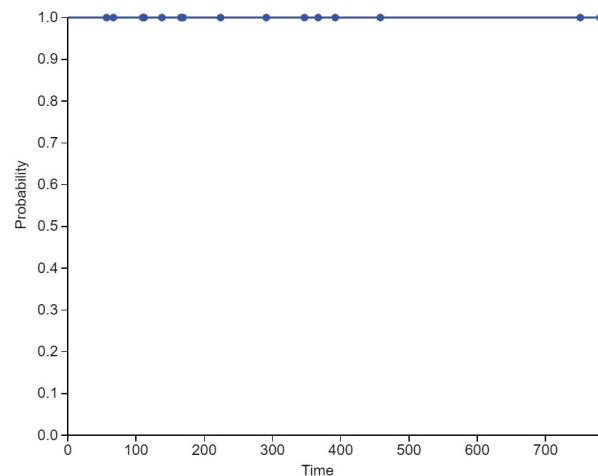


Figure 1a: Overall Survival of autologous stem cell transplantation patients.

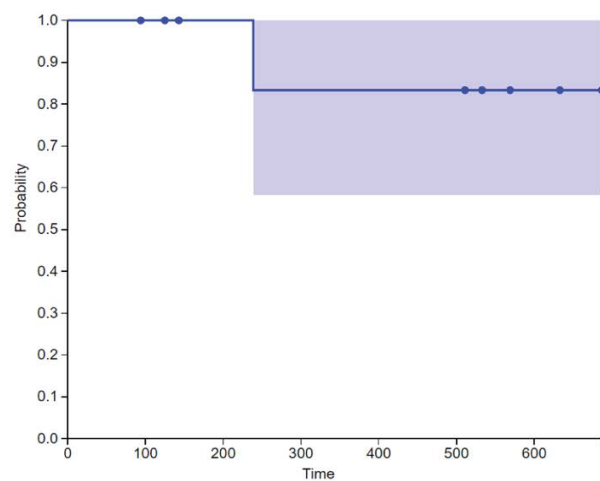


Figure 1b: Overall Survival of Matched Related Donor transplantation patients.

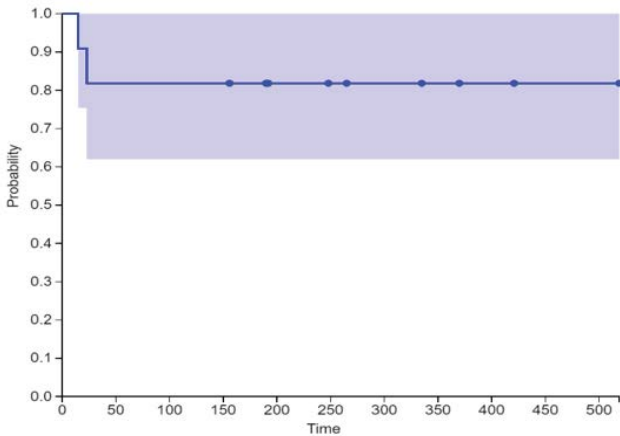


Figure 1c: Overall Survival of Haploidentical donor stem cell transplantation patients.

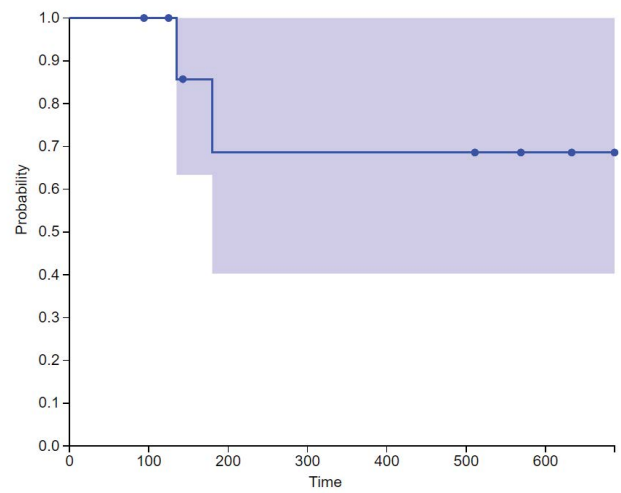


Figure 2b: Progression Free Survival of Matched related Donor transplantation patients.

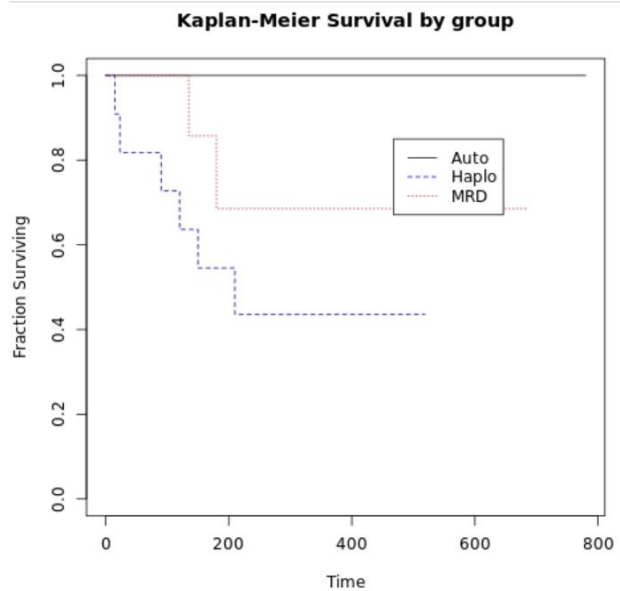


Figure 2: Progression free survival of whole cohort.

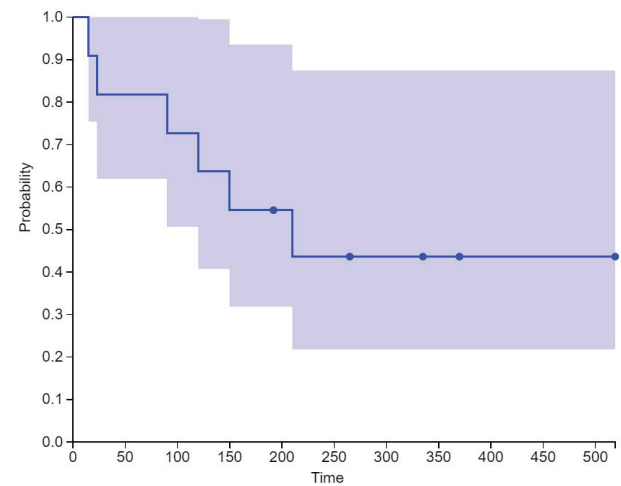


Figure 2c: Progression Free Survival of Haploidentical donor transplantation patients.

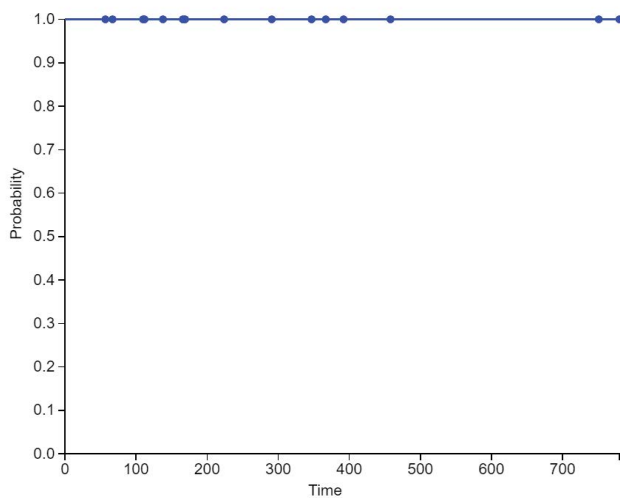


Figure 2a: Progression Free Survival of Autologous stem cell transplantation patients.

Discussion

It is a well-known fact that performing HSCT is an art and requires skilled healthcare workers. In addition to that, it cannot be denied that HSCTs require humongous financial support by funding agencies, social support from care givers and psychological support by family members. Hence, it is an essential step that multi-disciplinary aspects are aligned towards the common goal of patient's utmost care while developing a transplant unit in any center. Even if we were aware of these challenges, we were determined to establish a start-of art transplant center in a government hospital where patients could receive pre, peri and post-transplant care totally free of cost. There are many government funded institutions in India who are equipped with facilities and the medical staff who are eligible for performing transplants. According to a prospective study performed by PGIMER Chandigarh, the cost of autoSCT was INR 699,200 (USD10,282), out of which hospital paid only 34% of the cost [12]. It was

appropriately concluded in that study that the overall cost, out of the pocket expenditure (OOPE) & attendant cost contribute to a substantial financial burden on patient. Hence, absolute steps are needed to make HSCT an affordable and accessible procedure for general population of India. Keeping all the challenges in our mind, we established a transplant unit in a government hospital and we, hereby, aim to present the step by step approach of its development as well as our outcomes of initial 35 patients who have been benefitted with this effort.

ESIC Medical College and Hospital, Faridabad provides free-of-cost, state-of-the-art facilities to cancer patients. It serves the population of Haryana and surrounding area of National Capital Region (NCR), which is around 33 million in 2023. The idea of establishing such a unit was planted in June 2021 by discussion with Dean ESIC and the attempt was fruitful. A team was immediately formed and a visit to BMT center at Army hospital (Research and Referral) was undertaken. Various guidelines for setting up transplant unit, both National and International, were studied in detail and a task force was set up with the help of engineers and workers and very soon a one bedded BMT unit was formed. The first stem cell transplant was performed in September 2021 and eventually unit was expanded to 2 bed unit dedicated only for the HSCT which has now become a 4 bedded unit. Our BMT team includes 2 BMT physicians, a medical oncologist, haemato-pathologists, residents, nursing staffs and a BMT coordinator. We initiated the unit by facilitating the training of dedicated healthcare staff at a neighboring bone marrow transplant center and later with in-house training and workshops.

As infections are the most dreading complications during HSCTs and hence, our prime motive was to ensure the highest level of safety and infection control. Therefore, HEPA filter were attached to each room in the unit. Increasing antibiotic resistance and high prevalence of MDR in LMICs can wreak havoc even in low risk transplants. Hence, the proactive approach of nursing education about handling of central line, knowledge to patients' attendants and medical staff about hand hygiene, strict antibiotic stewardship and timely audits were the vital components of our working standard operating procedures (SOPs). We have established standard protocols of escalation and de-escalation of antibiotics depending on clinical status of the patient and blood culture sensitivity pattern. The rationale use of antibiotics were protocolized the directions and advisory from microbiologist and infectious disease department.

Imagining a successful transplant unit without having a good quality in-house laboratory is pointless. A ten-color state of the art flow cytometry laboratory was established within three months of employment of one of the senior most haemato-pathologist in the country. This was standardized in quick time and greatly aided the transplant program,

both academically and economically. We have a pathology laboratory which is fully equipped for testing bone marrow morphology, immunohistochemistry, flow cytometry for routine leukemia panels, minimal residual disease detection and CD34 enumeration. As molecular laboratory is under the process of getting standardization, high resolution HLA typing and DSA are being outsourced as of now. The molecular laboratory has been upgraded to conduct chimerism analysis using the DNA fragment analysis technique known as short tandem repeats (STR). In near future, performing in-house HLA typing with next generation sequencing (NGS) is in pipeline, along with development of state-of-the art PCR lab. In congruence with similar motif, employment of transplant immunologist has also been done.

Blood banking is an integral part of a properly functioning BMT unit. With the availability of technicians well-versed with platelet apheresis, we could do stem cell apheresis in-house. We utilize Spectra Optia and COM-TEC (Fresenius) apheresis system. We could also collect CD3 cells in-house through apheresis, if donor lymphocyte infusion (DLI) was indicated. Blood bank inventory is well supported by voluntary donors and we always encourage directed donation during actively ongoing transplantation. Facility to irradiate blood products are also available in our blood bank. Cryopreservation of stem cells in autoSCTs for lymphomas is usually outsourced. As Total Body Irradiation (TBI) is an essential part of many conditioning regimen, particularly in haploSCTs, nuclear medicine department has been developed to start TBI. We have been putting more efforts in optimizing haplo-identical transplants as they are more realistic in LMIC due to extra cost associated with procuring stem cell from unrelated donor registries.

There has always been a huge support and encouragement from hospital administration and hence, steps involved in the paper work involved in the whole process is extremely organized. Importantly, procurement of medicines related to specific conditioning regimens, including serotherapy like ATG was organized in a well-planned manner with great help from hospital administration. Post-transplant immunosuppression drugs (even the novel agents like ruxolitinib) in case patient developed GVHD were also arranged by administration without delay, as we all are aware that timely initiation of appropriate management of GVHD halts its progression. It involves a huge team work between transplant team and administrative staff and the common platform was provided through a common what's-app group where every problem is shared and solved. Multidisciplinary team meetings were held every week to discuss different perspectives of patient's condition. Along with patients, family members were also counselled on daily basis by treating physicians. In addition, regular psychological support through counselling was also provided during the tough phases of transplant.

We performed 35 HSCTs between September 2021 and August 2023, out of which 15 were autoSCTs, 9 were MRDs and 11 were haploSCTs. We achieved OS and PFS, at median follow up of 248(15-780) days, 91.43% and 77.14% respectively, with relapse rate of 30% in alloSCTs. We also encountered aGVHD and cGVHD in 25% and 10% patients respectively. Several attempts have been made in India earlier, with the similar motive to provide alloSCTs at minimal possible cost. Stalin et al has reported alloSCTs outcomes in transfusion dependent thalassemia patients started as low-cost transplant start-up and had shown thalassemia free survival (TFS) of 83% with OS of 93% with a median follow up of 17.5 months [13]. They also analyzed overall costs from admission up to one-year post-BMT which revealed a median cost of Rs 7,30,445 (USD11519). It is an encouraging data to support that low-cost transplants are possible even without large fancy units. There are several examples where non-profit organizations are performing transplants at a very low cost with comparable outcomes as reported in western world. Such non-profit organizations like Cure2Children and Sankalp India foundation had reported excellent outcomes in paediatric transplants for benign haematological disorders. They have performed 700 allogeneic BMTs over a 10-year period and have recently published their experience [14]. Similar attempts have been made outside India in other low-income countries. In Mexico, 75 (51%) patients and 71(49%) patients underwent autologous and alloSCTs, respectively with the help of non-governmental organization and according to the reported estimation of patient OOPE, the aid provided by NGO was around 88% and 72% respectively [15].

In literature there are not many reports by other LMIC countries where alloSCTs have been performed in government setups. Mahar UR et al performed 30 alloSCTs (MRD=24 and haploSCTs=6) in a government medical college in Lahore, Pakistan with OS rate at one year of 71.3% among all alloSCT patients, whereas the disease-free survival rate at one year of 63.7% [16]. Recently Nepal Civil Service Hospital, a government hospital in Kathmandu had reported their experience on establishing of BMT in their hospital by collaboration with the University of Illinois-Chicago. They performed 66 SCTs and the cost of transplantation was USD5200 for auto-SCT, USD 10,000 for MRD, and USD 13,300 for haploSCT. Among recipients of autoSCTs (n = 30), with a median follow-up of 1029 days, 87% were alive, and TRM was 10%. Among alloSCTs (n = 36), at a median follow-up of 204 days, 75% of them were alive, with TRM of 19%. The median OS in autoSCT was 1610 days and was not reached in alloSCT recipients [17]. In 2016, Bangladesh shared its experience of performing first autoSCT where Yeh AC et al had reported their outcomes of 21 autoSCTs done at Dhaka Medical College and Hospital with no TRMs and the longest disease-free survivor of 640 days till the time of reporting [18]. In Lebanon, Cheikh Jean El at al had attempted haploSCTs and had reported outcomes

of 17 haploSCTs (out of 99 alloSCTs performed) with TRM of 9% on day+100, 21% at 1 year and 24% at 2 years after transplantation. Relapse was 24% and 30% at 1-year and 2-years post-transplant respectively [19].

According to World Wide Network of Blood and Marrow Transplantation (WBMT), a cure without treatment sequelae is considered more valuable than a cure resulting continuing health disabilities [20]. Hence, we have focused our attention on providing quality care in terms of standard conditioning protocols, continued education of nursing staff and house-keeping staff regarding infection control policies, regular multidisciplinary team meeting on difficult cases and strict post-transplant follow-up by clinicians weekly to ensure the timely management of post-transplant complications. Conducting alloSCTs in LMIC comes with an in-built challenge of difficulty in establishing data base due to several logistic reasons, so it becomes difficult to report the outcomes to the world with authentic data [21]. In addition to working scientifically, we tried to be creative and systematically collected our data. Many of the challenges described here that limit the establishment of HSCT services are similar to those faced in other LMIC [22]. Therefore, the customized strategy applied for developing a HSCT center in ESIC could be used as a guiding-principles for other government hospitals and medical colleges without copying the western practice blindly. Participating and collaborating with multiple centers, is an important strategy to continuous self-evaluation and constant improvement.

We are aware of limitations of our study. As this study is retrospective with a small sample size and short median follow-up, the real-world impact of our data could be limited. However, as a responsibility to promote and encourage health care community to develop free of cost transplant centers within the country, we are sharing our outcomes and the hardships encountered in this journey. Initially, we faced resistance that slowly resolved by creating a culture for the change required through aligning the patients' needs and uniting people with ambitious goal to structure a team. Through the lessons learned throughout the whole process, it can work as a role model for other centers to develop cost-effective transplant units.

Conclusion

Our results illustrate that accomplishing good outcomes at a simplified and cost-conscious transplant unit is a realistic goal and long-term disease-free survival can be achieved if transplants are done timely and wisely. We also believe that patient selection solely on the basis of medical criteria, unbiased by financial background, employing simple and proven infection control measures, wise use of antibiotics, strong communication on patients' status among team members and effective post-transplant follow-up are critical components to the delivery of good outcomes. This

achievement has allowed us to provide this potential curative treatment to a substantial number of cancer patients. Our efforts might encourage other countries to dream about having their own transplant units and to learn and be skilled in this art of performing stem cell transplantation.

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