



Outcomes of Allogeneic Stem Cell Transplant in Chronic Myeloid Leukemia - Blast Phase: A Single-center Experience from South India

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Abstract

The blast phase (BP) is challenging to treat and leads to inferior survival in chronic myeloid leukemia (CML). Allogeneic hematopoietic stem cell transplant (AlloSCT) is the only curative option for CML-BP. We are sharing our experience of AlloSCT in seven patients with CML-BP who underwent transplants during the period from January 2017 to December 2019. Three patients each had myeloid-BP, lymphoid-BP, and one patient had mixed phenotypic BP. Donors were matched siblings in four, mismatched siblings in one, and haploidentical in two. All patients received peripheral blood stem cell grafts. The median CD34+ dose was 7.6 (range: 6.6–8.9) $\times 10^6$ cells/kg. Neutrophil engraftment was observed at a median of 15 (10–20) days and platelet engraftment at 19 days (10–22). At a median follow-up of 24 months, the 2-year leukemia-free survival (LFS) and overall survival (OS) were 43% and 57%, respectively. Transplant-related, non-relapse mortality was observed in three patients. AlloSCT results in promising survival for carefully selected patients of CML-BP, especially with a matched sibling donor.

Keywords

- chronic myeloid leukemia blast phase
- allogeneic hematopoietic stem cell transplant
- survival

The blast phase (BP) remains a significant challenge in the treatment of chronic myeloid leukemia (CML). The World Health Organization (WHO) defines BP as peripheral blood or bone marrow blasts of $\geq 20\%$ or extramedullary proliferation of blasts.¹ BP can be initial presentation in less than 5% of CML patients.² In the era of tyrosine kinase inhibitors (TKI), 2 to 5% of patients progress to the advanced phase (accelerated phase or BP), compared with 10 to 50% in the pre-TKI era.^{3–5} The management of BP depends on the type of BP (myeloid or lymphoid) and previous treatment course. The goal of therapy for CML BP is to revert to the chronic phase with the use of newer TKIs (based on prior TKI use and the presence of resistant mutations) with or without chemotherapy (based

on the BP subtype), followed by allogeneic hematopoietic stem cell transplant (AlloSCT) preferably within a year of diagnosis.⁶ Currently, AlloSCT remains the best chance of cure for BP with 3-year survival ranging from 35 to 40%.^{7,8} Patients with BP treated with TKI alone without AlloSCT have poor outcomes with a 4-year survival of only 10%.⁹ Similar results were reported in an Indian study with a median survival of 12 months with imatinib alone.¹⁰ There is limited contemporary data of AlloSCT in CML BP from resource-limited settings. We hereby present our experience of AlloSCT in patients with CML BP from a growing transplant unit in a tertiary care cancer center.

The transplant program started at our institute in 2013. The first allogeneic transplant was done in 2014. A total of 48 cases of CML advanced phase were registered in the

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transplant clinic from 2015 to 2020. We have included all consecutive patients of CML-BP who underwent AlloSCT at our center in the given period. We collected data on the baseline patient and disease characteristics, pre-transplant response and donor type, peri-transplant features, post-transplant morbidity and mortality, post-transplant response, and survival from the medical records of the Department of Medical Oncology. Leukemia-free survival (LFS) was taken as the time from the AlloSCT to relapse or death due to any cause. Overall survival (OS) was defined as the time from AlloSCT to death due to any cause. Descriptive statistics were used to summarize baseline and peri-transplant data. The Kaplan–Meier method was used to estimate LFS and OS. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) software version 19.0 (SPSS Inc., Chicago, IL, USA). The institute ethics committee approved the study, and a waiver of consent was granted (approval number JIP/IEC/2016/30/979).

Between October 2017 to December 2019, seven CML-BP (WHO criteria) patients underwent AlloSCT at our center. The median age was 40 years (9–52), and the male-to-female ratio was 5:2. Overall, four patients had de novo BP; the subtype of BP was lymphoid in three, myeloid in three, and mixed phenotypic (B/myeloid) in one. No patient had a detectable mutation on imatinib resistance mutation analysis (IRMA). Dasatinib was the most commonly used TKI before AlloSCT in five patients, Imatinib was used in two. In five patients, chemotherapy (vincristine and steroids for lymphoid BP) or hypomethylating agent decitabine (for myeloid BP) was used along with TKI to achieve remission. All patients reverted to the chronic phase before AlloSCT, i.e., complete cytogenetic response (CCyR) in five; \geq major molecular response (MMR) in one; and complete hematologic response (CHR) in one. The median time from the diagnosis to AlloSCT was 6 months (range: 3–12 months). Pre-transplant disease features, donor characteristics, graft versus host disease (GVHD), veno-occlusive disease (VOD) prophylaxis, post-transplant course, and outcome for all patients are summarized in ►Table 1.

All patients received myeloablative conditioning (Flu-Bu in six and Cy-Bu in one, without any dose modifications), and stem cells were harvested from peripheral blood. Four patients received stem cells from a matched sibling donor (MSD), one had a mismatched sibling donor (MMSD, 9/10), and two from the haploidentical family donor. The median CD34+ dose was 7.6 (range: 6.6–8.9) $\times 10^6$ cells/kg. Neutrophil engraftment was observed at a median of 15 days (range: 10–20 days) and platelet engraftment at 19 days (range: 10–22 days). Peri-transplant toxicities in patients within the first 100 days included febrile neutropenia with septic shock in three, cytomegalovirus (CMV) reactivation in three, \geq grade 3 mucositis in two, veno-occlusive disease (VOD) in two, primary graft failure in one, and poor graft function in one patient. Day 100 transplant-related mortality (TRM) was observed in two patients: one had moderate VOD (d22), and the other had primary graft failure (d24). The final event was disseminated infections as the cause of death for both patients. One patient with poor graft function received

CD34+ stem cell boost on D + 102 but died because of grade 4 acute graft versus host disease GVHD on D + 174. Post-AlloSCT, all alive patients received dasatinib maintenance starting at a median of 50 days (range: 47–60 days) at a dose of 50 to 100 mg depending on blood counts and tolerance. Among alive patients ($n=4$), one patient had mild chronic graft versus host disease on long-term follow-up. Another developed dasatinib-related pleural effusion 18 months post-transplant, which resolved with supportive treatment and change of TKI to imatinib. One patient developed CNS relapse at 16 months post-transplant. She was not willing for intensive systemic therapy and second AlloSCT. Hence, dasatinib was continued, and CNS-directed therapy was given with triple intrathecal therapeutics (methotrexate, cytarabine, and hydrocortisone) followed by craniospinal radiotherapy. She had a response in the CNS disease and continues to be on dasatinib dosage with a complete cytogenetic response on the last follow-up. The other three patients are in MMR and are continuing maintenance TKI. On the last follow-up on April 30, 2021, and with a median follow-up of 24 months, the 2-year LFS and OS were 43% and 57%, respectively.

From our small series of AlloSCT in patients with CML BP, we report a promising 2-year LFS and OS of 43% and 57%, respectively, especially with MSD. In the pre-TKI era, CML accounted for $\sim 25\%$ of cases of allogeneic transplants worldwide. In contrast, in recent times, only 2% of AlloSCT in hematological malignancies are done for CML.¹¹ Present indications for AlloSCT in CML include advanced disease (BP or refractory/progressive AP) and intolerance or resistance to multiple TKIs.⁶

Though there has been a remarkable improvement in outcomes of CML with long-term survival of more than 90% with current therapy for newly diagnosed CML, outcomes for patients in the developing countries are far removed from that in the west.¹² Several challenges are encountered in the day-to-day management of patients with CML in resource-limited settings, including but not limited to higher disease burden, late presentation, poor treatment compliance, lack of resources and expertise, irregular follow-up, monitoring of response, limited accessibility, and affordability to second or higher generation TKIs.^{13,14} Thus, a higher proportion of patients present with or progress to advanced phase disease, thereby underscoring the need for AlloSCT in these patient subgroups. However, performing AlloSCT in these settings is even more challenging again due to the lack of centers with expertise and resources for transplant, socioeconomic constraints, the long waiting period for transplant, risk of disease progression, mortality during treatment of advanced disease, lack of general awareness for donor safety and transplant outcomes, and difficulties in donor availability.¹⁵ Our record of transplant clinic registration shows that only 7 (15%) had undergone a transplant in the 48 cases of CML advanced phase registered over the past 5 years.

Despite all the challenges, we have observed an encouraging 2-year survival of 57% in our small patient cohort of CML-BP transplanted in the second chronic phase. Our

Table 1 Pre-transplant features and post-transplant course for all patients (n = 7)

Patient	Date of AlloSCT	Age/Sex	Time from diagnosis to transplant (Months)	Pre-Transplant Response	Donor (type/sex)	EBMT Score	HCT- CI Score	Conditioning	GVHD Prophylaxis	Graft failure	VOD [†]	Post-transplant Response (D-100)	Acute GVHD	Chronic GVHD	Relapse	Survival status at LFU
P1	Oct 2017	47Y/M	4	CHR	MSD, male	4	1	Cy-Bu	CSA + MTX	no	yes	CCyR (D30)	No	NA	No	Died (d44)
P2	Jan 2018	9Y/M	6	CCyR	HID, male	3	0	Flu-Bu	PTCY + Tac + MMF	No*	No	DMR	Yes* (Grade 4)	No	No	Died (d174)
P3	Jan 2019	49Y/M	12	CCyR	MSD, male	4	0	Flu-Bu	CSA + MTX	No	No	MMR	Yes (Grade 2)	Yes (Mild)	No	Alive (d842)
P4	Feb 2019	40Y/F	4	CCyR	MSD, male	4	1	Flu-Bu	CSA + MTX	No	No	DMR	No	No	Yes CNS (d494)	Alive (d801)
P5	May 2019	52Y/M	3	CCyR	MSD, male	4	1	Flu-Bu	CSA + MTX	No	No	DMR	No	No	No	Alive (d716)
P6	June 2019	26Y/F	7	MMR	MMSD, male	4	1	Flu-Bu	PTCY + Tac + MMF	No	Yes	DMR	No	No	No	Alive (d672)
P7	July 2019	31Y/M	11	CCyR	HID, male	4	0	Flu-Bu	PTCY + Tac + MMF	Yes [#] (d24)	No	Unknown (D30)	No	NA	No	Died (d65)

Abbreviations: CCyR, complete cytogenetic response; CHR, complete hematological response; CNS, central nervous system; CSA, cyclosporine; Cy-Bu, cyclophosphamide 60 mg/kg on Day-7 to Day-6 and Busulphan 3.2 mg/kg/day D-5 to D-2; DMR, deep molecular response; EBMT, European Group for Blood and Marrow Transplantation; Flu-Bu, fludarabine 30 mg/m² Day-6 to Day-2 and Busulphan 3.2 mg/kg/day Day-6 to Day-3; GVHD, graft versus host disease; HCT-CI, hematopoietic cell transplantation-specific comorbidity index; HID, haploidentical donor; LFU, last follow-up; MMF, mycophenolate mofetil; MMR, major molecular response; MMSD, mismatched sibling donor; MSD, matched sibling donor; MTX, methotrexate; PTCY, posttransplant cyclophosphamide; Tac, tacrolimus; VOD, veno-occlusive disease.

*D84 had poor graft function, which was treated with stem cell (CD34) boost on d102–this was followed by acute grade 4 GVHD and death on d174.

[†]UDCA (ursodeoxycholic acid) was used for VOD prophylaxis in all until Day 100; patient 1 had moderate VOD (treated with diuretics and other supportive care, defibrotide was not available) followed by sepsis and death; patient 6 had mild VOD that resolved with supportive treatment (fluid restriction and diuretics).

For the two patients with acute GVHD and one with chronic GVHD, treatment was done with systemic corticosteroids (methylprednisolone in acute and prednisolone in chronic GVHD) in the first line.

[#]Patient had primary graft failure, died due to disseminated sepsis before a plan of second allogeneic transplant could be executed.

Table 2 Summary of studies evaluating allogeneic stem cell transplant outcomes in chronic myeloid leukemia advanced phase

Study	N	Indication for AlloSCT (n)	Phase before AlloSCT (n)	Donor (%)	TRM (y)	LFS (y)	OS (y)
CML-IV study 2010 ¹⁹	28	CML-Advanced phase (28)	CP2 (15) AP/BP (13)	Sibling (32%) Unrelated (68%)	18% (3)	Not available	59% (3)
CIBMTR 2012 ⁷	449	CML-advanced phase	CP2 (184) AP (185) BP (80)	MSD (27%) MRD (3%) MMRD/MUD (70%)	CP2: 39% (3) AP: 37% (3) BP: 54% (3)	CP2: 27% (3) AP: 37% (3) BP: 10% (3)	CP2: 36% (3) AP: 43% (3) BP: 14% (3)
Ma et al 2016 ²¹	90	CML-BP (90)	Not available	MSD (25%) HID (75%)	27% (3)	49% (3)	58% (3)
Swedish CML 2019 ¹⁶	118	CP (81) AP (11) BP (21) Unknown (5)	CP1 (56) ≥ CP2 (48) AP/BC (14)	MSD (27%) URD (72%) HID (1%)	CP: 11.6% (5) AP/BP: 23% (5)	CP1: 34% (5) CP2: 46% (5) AP/BP: 20% (5)	CP1: 96% (5) CP2: 70% (5) AP/BP: 37% (5)
EBMT data 2019 ⁸	170	CML-BP	CP2 (95) BP (75)	Related (46%) Unrelated (56%)	CP2: 20% (3) BP: 27% (3)	CP2: 34% (3) BP: 12% (3)	CP2: 51% (3) BP: 24% (3)
TMC abstract 2019 ¹⁷	40	CP (26) AP (8) BP (6)	Not available	MSD (83%) MUD (2%) HID (15%)	20% (5 y)	57% (5 y)	70% (5 y)
Neiderweiser et al., 2021 ¹⁸	147	BP (96) AP (51)	CP2 (70) AP (40) BP (37)	MSD (39.5%) MUD (24.5%) Unknown (36%)	28%	26% (15 y)	34% (15 y)
Current study	7	CML-BP (7)	CP2 (7)	MSD (57%) MMRD (14%) HID (29%)	43% (2 y)	43% (2 y)	57% (2 y)

Abbreviations: AlloSCT, Allogeneic stem cell transplant; AP, Accelerated phase; BP, Blast Phase; CIBMTR, Center for International Blood & Marrow Transplant Research; CML, Chronic Myeloid Leukemia; CP1, first chronic phase; CP2, second chronic phase; EBMT, European Society for Blood and Marrow Transplantation; HID, Haploidentical donor; LFS, Leukemia free survival; MMRD, Mismatched related donor; MSD, matched sibling donor; OS, Overall Survival; TMC, Tata Memorial Center; TRM, Transplant related mortality; URD, Unrelated donor.

survival outcomes are comparable to those reported in the literature for CML-BP post-transplant.^{7,8,16–19} The largest series of transplant outcomes in CML-BP in the literature reports 3-year survival of around 40% in the Center for International Blood & Marrow Transplant Research (CIBMTR) Registry and European Society for Blood and Marrow Transplantation (EBMT) Registry.^{7,8} Swedish CML population-based data for all phases of CML have reported 5-year survival of 70% post allogeneic transplant.¹⁶ There are sparse data of transplants in CML advanced phase from developing countries. In one recent report from India, for patients with TKI resistant and advanced phase CML ($n=40$; including six patients of CML-BP), 5-year OS was 70%.¹⁷ In the most recent report by Neiderweiser et al, donor age >36 years, BP at AlloSCT, and low CD34+ count were shown to be risk factors for inferior OS.¹⁸ **Table 2** summarizes the contemporary data on transplant outcomes in CML advanced phase. For patients with CML-BP, the data show definitively that AlloSCT represents the best chance of long-term remission or cure.

Some of the specific challenges we faced were:

- (a) Early TRM in three patients, from disseminated infection and sepsis with underlying VOD, graft failure, and severe acute GVHD,
- (b) poor graft function, and secondary graft failure for patients with haploidentical donor transplant.

Multidrug-resistant infection is a significant problem across all transplant centers in developing countries, contributing to early deaths and poorer outcomes.²⁰ Our study's adverse outcomes for the haploidentical transplant patients underscore the need for careful donor selection and reflect the initial learning curve. Studies reporting haploidentical transplant in CML advanced phase have shown that with improvement in post-transplant GVHD prophylaxis and supportive care, survival outcomes were similar to MSD in CML.²¹ We suggest that transplant outcomes can be improved for these high-risk patients with thorough counseling of patients and their family caregivers to allay their fear of risk to the donor and general transplant outcomes, proper patient and donor selection, persistent efforts at careful monitoring of pre- and post-transplant conditions, rigorous infection control measures in the transplant unit, and initial mentorship from a high-volume center for both nurses and physicians, if feasible.

The role of post-AlloSCT TKI maintenance in CML is not well-defined. Although it is adopted as a common practice, large studies investigating this approach are lacking. In a recently published report by the CIBMTR study group, only 23% of the patients in their cohort ($n=390$) received TKI maintenance.²² A landmark analysis from D + 100, demonstrated no benefit in 5-year clinical outcomes (LFS, OS, relapse, TRM, or cGVHD) in the “TKI maintenance group” when compared with the “no maintenance” group. However, the authors conclude that there were several limitations in their retrospective analysis and choice to initiate TKIs after AlloSCT should be an individualized decision, based on patient, disease, and transplantation-related factors, which

may benefit a subgroup of patients.²² Another retrospective study has shown that TKI maintenance (mostly with dasatinib) might reduce the risk of relapse and improve post AlloSCT survival outcomes in CML and Ph+ acute lymphoblastic leukemia.²³ Maintenance with dasatinib is generally followed in lymphoid BP for neuroprophylaxis as it is known to cross the blood–brain barrier. Presently, with five available TKIs targeting BCR-ABL1, there is no clear choice for optimal TKI following AlloSCT. In our series, all surviving patients received dasatinib maintenance until unacceptable toxicities or medullary relapse. It was feasible to deliver TKI maintenance with minimal toxicities in our setting. Regular monitoring of BCR-ABL transcript levels with a sensitive assay is imperative after AlloSCT to identify early signs of relapse. Other post-SCT strategies such as donor lymphocyte infusion, change in TKI, or use of investigational agents may improve outcomes.

Despite its limitations of retrospective small case series with short follow-up, our experience suggests that AlloSCT can result in promising survival for carefully selected patients of CML-BP, especially with a matched sibling donor. Nevertheless, efforts should be made to improve compliance to first-line treatment for CML in general and enhance transplant resources for eligible patients with advanced phase disease.

Ethics Approval

Institute Ethics Committee approval was taken before the commencement of the study.

Consent to Participate

Waiver of consent was granted for the retrospective data and analysis.

Author's Contributions

Study conceptualization and methodology: TN, AB, SK, BD, and PG. Data collection and analysis: TN, AB, NK, SD, DBT, and SK. Manuscript writing: TN, AB, SK, NK, DBT, and BD. Review and editing: SK, BD, SD, and PG. Final approval of manuscript: all authors.

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Conflict of Interest

None declared.

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