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Cryopreservation and Storage Patterns of Hematopoietic Progenitor Stem Cells for Multiple Myeloma

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Abstract

Autologous hematopoietic stem cell transplantation (HCT) has been a standard of care treatment for eligible patients with newly diagnosed multiple myeloma (MM). Guidelines generally recommend hematopoietic progenitor cell (HPC) harvest for two potential HCT. There is a paucity of data reporting use of such collections in the era of novel approved therapies. In this single-center retrospective study, our goal was to determine the HPC utilization rate and costs associated with leukocytapheresis, collection, storage, and disposal to guide future HPC collection planning.

We included 613 patients with MM who underwent HPC collection over a nine-year period. The patients were separated into four groups based on HPC utilization: 1) patients who never proceeded to HCT, or Harvest and Hold (14.8%), 2) patients who proceeded to one HCT with banked HPC remaining (76.8%), 3) patients who proceeded to one HCT without HPC remaining (5.1%), and 4) patients who proceeded to two HCTs (3.3%). After collection, 73.9% of patients underwent HCT within 30 days. Of patients with banked HPC, defined as not undergoing HCT

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CLB: Conceptualization, methodology, formal analysis, investigation, writing – review and editing.
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within 30 days of leukocytapheresis, the overall utilization rate was 14.9%. At 2- and 5-years post HPC collection, utilization rate was 10.4% and 11.5%, respectively.

In conclusion, our results suggest very low utilization of stored HPC, raising into question the current HPC collection targets. Given advances in MM therapy, as well as significant costs associated with harvest and storage, collection for unplanned future use warrants reconsideration. As a result of our analysis, our institution has reduced our HPC collection targets.

Keywords

peripheral blood stem cells; multiple myeloma; hematopoietic stem cell transplantation; cryopreservation; mobilization; storage

1.1 Introduction

Multiple myeloma (MM) accounts for approximately 10% of hematologic cancers and 1% of all cancers in general[1]. While generally considered an incurable malignancy, the treatment paradigm includes induction therapy for initial debulking. After induction treatment and improvement in myeloma tumor burden, eligible patients are considered for high dose chemotherapy consolidation with the goal of achieving a deeper and more durable response. This is then followed by a period of lower intensity maintenance treatment to balance duration of myeloma control with patient quality of life.

This use of high-dose chemotherapy followed by autologous hematopoietic stem cell transplantation (HCT) is the current standard consolidation treatment for eligible patients with newly diagnosed MM[2], with new data suggesting robust progression-free survival interval of 67.5 months[3]. Peripheral blood mobilized hematopoietic stem cells are the source of hematopoietic progenitor cells (HPC) for HCT[4,5]. Given the historical use of tandem and/or second HCT, many centers establish targets to collect and store enough HPC for two potential HCT during leukocytapheresis (hereafter referred to as apheresis)[6]. HPC collection is also increasingly used for storage purposes in the setting of no planned upfront HCT as a "Harvest and Hold" (H&H) strategy due to risk of future mobilization difficulty[7,8].

Recently, there has been development of many novel therapies for treatment of MM. The rapid approval of agents such as monoclonal antibodies against SLAMF7[9], CD38[10], and BCMA[11,12] directed therapies has coincided with a decreasing trend in the frequency of second HCT use over the past decade[6,13]. The incorporation of new therapies within the contemporary treatment landscape of MM, including new ways to mobilize[14,15], as well as development of minimal residual disease-guided decision trees[16,17] have pushed the role of early consolidation HCT into the spotlight.

The HPC mobilization, collection, and storage process is a necessary component of HCT planning that imposes significant financial impact[18]. Single center data has brought into question the utility of stored HPC grafts in patients with MM[6,19,20]. We aimed to evaluate the mobilization, collection, storage, and disposal patterns and costs of HPCs for treatment

of patients with MM at our cancer center. In this study, we looked at 613 patients with MM who underwent HPC collection over a 9-year period.

1.2 Materials and Methods

1.21 Patient Selection and Data Collection

We retrospectively reviewed Stem Cell Laboratory records for patients with MM who underwent autologous HPC collection at the University of Miami between August 2011 and February 2020. This study was approved by the University of Miami Institutional Review Board (20230471). In total, 613 patients were included. Data regarding HPC collection, harvest outcomes and disposal (if applicable) were collected. The final dataset analysis was performed after February 28, 2020, which was set as the follow-up date. Statistical analyses were performed using Microsoft Excel 365 (Microsoft Corporation 2023, Seattle WA, USA). Values are provided as median unless otherwise specified.

1.22 HPC Mobilization and Collection

HPC mobilization and collection in HCT-eligible patients included a standard regimen of filgrastim 10 mg/kg × 5 days and plerixafor (at discretion of the treating physician). Cells were collected utilizing the Cobe Spectra (Gambro BCT, Lakewood CO, USA) or the Spectra Optia (Gambro BCT, Lakewood CO, USA) using large volume apheresis. The minimum number of CD34+ cells considered sufficient for successful transplant was defined as greater than or equal to 2.0×10^6 cells/kg, with the general goal of 10×10^6 cells/kg.

1.23 HPC Cryopreservation, Storage, Infusion, and Disposal

Before cryopreservation, cell density was optimized to $200 – 250 \times10^6$ cells per ml. Volume per cryobag ranged between 30 ml and 70 ml as per manufacturer recommendation. Thus, the optimal cell concentration and recommended volume per cryobag ultimately determined how many cryobags would be stored for each collection. The final product included a final DMSO concentration of 5% and was stored in vapor-phase liquid nitrogen at a temperature of <−140°C after controlled-rate freezing. We observe no expiration for the life expectancy of cryopreserved cells based on on-going stability studies.

Stored HPCs were sufficient for at least one HCT (minimum 2×10^6 CD34/kg cells). The treating physician determined the necessity of HPC collection and transplant usage. Harvest and Hold collections were also carried out based on the intent of treating physician. The disposal of HPC products was performed when death of the recipient was confirmed, and all inventory was updated at that time.

1.24 HPC Storage Period and Cost Estimation

The following costs were estimated: the costs for the apheresis sessions that were necessary to collect the apheresis product, the cost to process the product including enumeration of the target cell population, and the costs to store the variable number of stem cell cryobags per patient. The cost for apheresis was estimated including the cost of apheresis catheter insertion, mobilization drug cost of filgrastim but without factoring in cost of plerixafor (not tracked).

The cost of mobilization and collection by apheresis is an integral component of HCT planning. At least one day of collection is required to acquire the minimum necessary 2×10^6 CD34/kg HPC. With each additional day of collection, increased utilization of apheresis and cryopreservation costs resulted in increased collection costs of about $7,678 per additional day based on CMS code 38206.

We considered a second apheresis day "additional" if the total CD34 cell count was > 10×10^6 CD34/kg. This signified intent to harvest HPC for two HCT.

The cost of the apheresis catheter was estimated to be $499 per patient and additional interventional radiology costs for ultrasound and fluoroscopy-guided vascular access were estimated to be $59 and $71 respectively. Moderate sedation for the procedure cost was $49. Therefore, the total cost for placement of the apheresis catheter was estimated to be $678 per patient.

The storage duration was determined separately for non-transplanted (H&H) patients, patients who received one transplant with remaining cryobags, and patients who received two transplants until the follow-up date, February 28, 2020, or date of disposal, whichever came first.

The cost of storage per group was calculated as the total cryobags collected multiplied by the total number of cryobag storage days (CBTD) multiplied by × $0.02 per cryobag/day. Storage costs of $0.02 per cryobag/day was derived from purchase of one storage dewar a year ($34,000) plus annual liquid nitrogen costs ($24,960; $60/tank, 8 tanks per week). Therefore, storage cost per day is estimated at $161.53 divided by approximately 8000 cryobags stored at any time.

1.3 Results

We identified 613 patients who underwent HCT for MM and separated them into four groups based on HPC utilization:

1. patients who never proceeded to HCT, or H&H,
2. patients who proceeded to one HCT with banked HPC cells remaining,
3. patients who proceeded to one HCT without HPC remaining, and
4. patients who proceeded to two HCTs.

HPC collection and storage characteristics are summarized in Table I. The number of apheresis days was two (range 1–5), and HPC collection was 9.68×10^6 CD34/kg per patient across all groups.

1.31 Time to Utilization

Within 30 days of HPC collection, 73.9% (453/613) of patients had their first HCT. The overall HPC usage rate of patients with banked HPC, defined as HPC collected and retained for at least 30 days following apheresis, was 14.9% (87/582). Banked HPC utilization rates were 10.4% and 11.5% two and five years after apheresis, respectively.

1.32 Collection and Transplantation

Ninety-one (91/613, 14.8%) patients underwent HPC collection but never underwent HCT, representing the H&H group. HPC harvest was 10.12×10^6 CD34/kg per patient in this group. Three patients collected fewer than 2×10^6 CD34 cells/kg and were thus ineligible for HCT, however are included in this series because their HPC were stored.

Most patients (471/613, 76.8%) underwent one HCT with remaining banked HPC. HPC harvest was 9.83×10^6 CD34/kg per patient.

Thirty-one patients (31/613, 14.8%) underwent one HCT and exhausted all collected HPC. These patients had no stored cells. In this group, the total collected and infused HPC dose was 3.65×10^6 CD34/kg.

Twenty patients (20/613, 3.3%) underwent two HCT. Of these, four proceeded to allogeneic HCT. Fourteen (14/613, 2.3%) of these patients underwent two melphalan based HCT. Two (2/20) had remaining HPC. The number of HPC collected at apheresis was 9.37×10^6 CD34/kg per patient. The interval from HPC collection to first HCT was 14 days, and from HPC collection to second HCT was 982 days. Three patients underwent planned tandem HCT within six months of the first HCT. There was a median of 7 cryobags (range 2–34) stored after first HCT, with a time elapsed from first to second HCT of 907 days (range 41–2098).

1.33 Storage

Across all groups, the median number of stored cryobags per patient was seven, calculated from the day of collection until 2/28/20 or the day of HPC disposal, whichever came first. The median number of days of storage from collection to follow-up date was 1198 days. Duration of cryobags stored is summarized in Figure I. Thirty-one percent of patients had cryobags stored for less than 1 year, 46% percent for 2–5 years, and 23% percent of cryobags have been stored for > 5 years. Notably, within the H&H group, 16 out of 91 (17.6%) patients died after H&H without HPC utilization.

1.34 Cell Disposal

Across storage groups, 10% (57/562) of HPCs were ultimately disposed from storage. The reasons for removal were death (93%; 53/57) or transfer to another treatment center (7%; 4/57). The median number of storage days for disposed products was 1359 days for 476 cryobags. Median time from date of death to disposal was 558 days (range 63–2176), driven largely by lag in notification to the Stem Cell Laboratory.

1.35 Cost Estimations

The cost estimations for HPC collection and storage are detailed in Table II. The cost of catheter placement for mobilization and collection by apheresis totaled $415,614 for all groups. Within the H&H group, given no planned HPC utilization, all apheresis costs and catheter are considered “additional” and totaled $1,059,564. Among the other groups, 70 additional apheresis days were identified to achieve the CD34 cell count of $> 10 \times 10^6$ CD34/kg, totaling extra costs of $537,460.

HPC storage in patients who underwent one HCT with no banked cells remaining is a standard of care cost and is negligible at $184. In the two HCT group, the cost of storage from apheresis to first HCT, and then first HCT to either second HCT or disposal of cells (907 days) was $3,172. The cost of storage in patients who had one HCT with remaining cells is $80,363, and in the H&H group is $24,184.

In our study, storage costs incurred for HPCs that have not been infused at data cut off is estimated at $104,547. The total cost of storage in cases where unused HPCs were ultimately disposed was $12,938 among all four groups.

1.4 Discussion

While numerous clinical trials have demonstrated the benefit of HCT in the consolidation as well as salvage setting[1,13,18,21–23], the evolving role of consolidation HCT is questioned with the approval of multiple novel[10–12] therapeutics and combination approvals[22] that improve disease control. The introduction of minimal residual disease-based consolidation is also casting question into the ubiquitous use of frontline HCT[16,17]. This study describes the mobilization, apheresis, storage, and disposal practices of HPC in MM patients undergoing HCT at our institution. Six-hundred and thirteen (613) patients underwent mobilization and apheresis, with a median length of storage from collection to follow-up being 1198 days. Ninety-one patients (14.3%) did not proceed to HCT. Among these 91 patients who underwent H&H, 17.6% died without use of their stored HPC.

Only 2.3% (14/613) of patients underwent two autologous HCT and overall utilization of stored HPCs was very low at 14.9%. Our results contribute to the growing body of literature suggesting that collected and stored HPCs have low rates of utilization. One study(16) of 75 MM patients reported 8% of collected HPCs were never used, and that 51.9% of stem cell units were still stored. Phipps, et al.[6] reported 81.6% of patients had residual HPCs stored after initial HCT, and only 15% underwent a second HCT over time. Chhabra, et al. found the cumulative incidence of stored HPC use for salvage HCT or HPC boost at 6 years was 13.9%[23] reflecting low utilization rates and excess financial impact. Kansagra, et al.[24] reported 51% (176/342) of patients collected for delayed HCT had never subsequently underwent planned HCT.

The potential costs associated with current HPC targets and storage are consistent with prior published data. Phipps et al[6] reported cost of $8971 for one additional day of collection which is similar to our cost of $7678. Similarly, our single-center experience is that 69% of patients had cryopreserved products beyond two years, compared to the 70% reported by Phipps study. A sizeable cost is attributed to harvest and hold practices, totaling $1,083,748. The use of additional apheresis days in one HCT with banked cells group to attain a HPC goal sufficient for two HCTs is calculated at $506,748.

Limitations of this study include the retrospective nature of the analysis. Data was collected from the Cellular Therapy Laboratory records and no data was abstracted from clinical charts. As a result, clinical correlations such as disease outcomes and reasons for not proceeding to first or second HCT were not available. Data regarding plerixafor usage

was also not available, and likely contributes to an underestimation of mobilization costs. In addition, calculations of costs were based on estimates using CMS codes (2022) and institutional cost inquiries that may be not broadly generalizable. However, the Stem Cell Laboratory data is advantageous given the high level of detail available in regard to CD34 collection and storage numbers. In addition, all records are reported even when patients may request transfer of HPC to other institutions.

At many centers, HPC collection goals continue to target sufficient stem cell infusion for two potential HCTs. However, this practice warrants reconsideration given novel effective therapies for MM, improved mobilization strategies, rare use of tandem HCT, and low utilization of stored HPCs. Mobilization failure, despite pre-treatment with modern regimens, is rare, occurring at a rate of 0–12%[25]. Even in heavily pretreated patients, HPC mobilization is feasible with advent of agents such as plerixafor, a selective and reversible antagonist of CXCR4, or chemotherapy[26,27]. The possibility of persistent cytopenias after immune effector cell therapy may provide alternative usage for stored HPCs[28], however this is a largely theoretical concept to date. Overall, this study highlights the low utilization and associated collection and storage costs of banked HPCs.

1.5 Conclusion

Autologous HCT remains an important therapy and standard treatment option for patients with MM. However, among patients with HPC product not used within 30-days of collection, the long-term utilization rate of banked HPCs is low at 14.9%. Novel drug approvals, more sensitive tumor detection methods, and increasingly effective mobilization strategies may reduce the necessity of upfront planning for delayed or second HCT. As such, routine mobilization, collection and storage of HPCs for delayed or two potential HCTs should be re-evaluated and operational rules for storage duration be considered. Upon identifying our low usage of banked HPCs, our center has implemented reduced HPC collection targets and stricter guidelines for H&H collection candidates.

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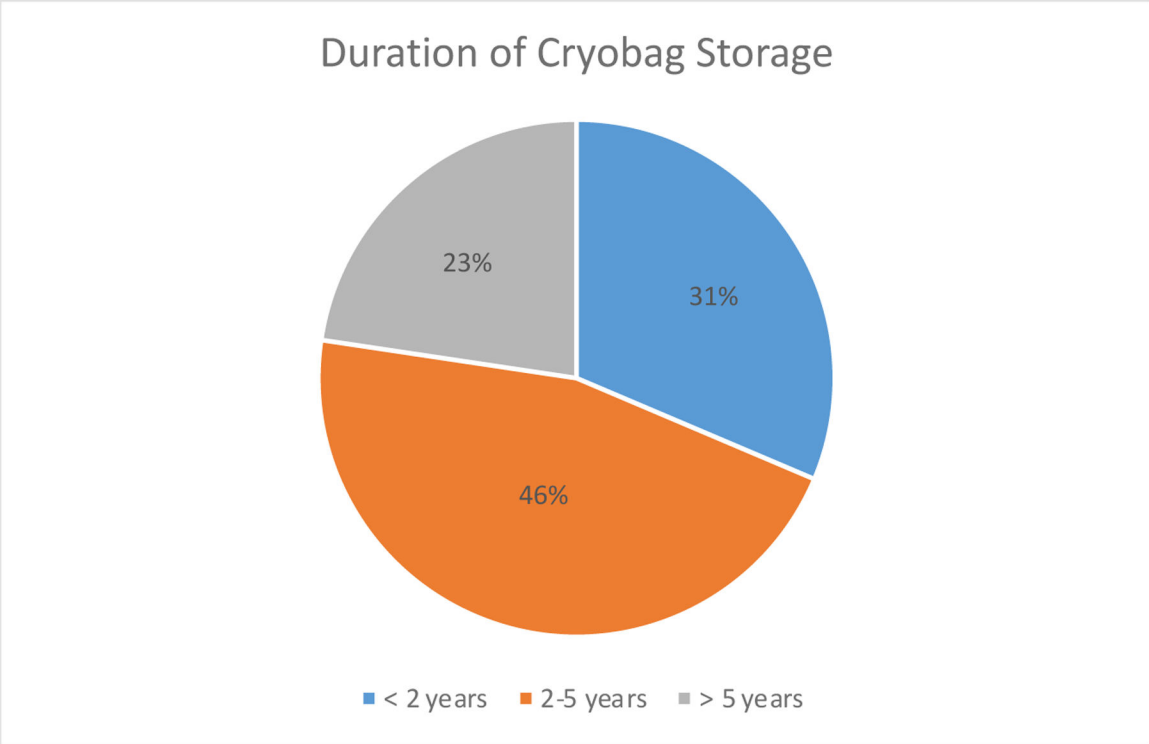

Figure I:

Patient Hematopoietic Progenitor Cell Storage Duration

Thirty-one percent of patients had cryobags stored for less than 2 years, while 69% of patients had cryobags stored for >= 2 years.

Table I.

Hematopoietic Progenitor Cell Collection and Storage.

	All Groups	No transplant	1 transplant with remaining cells	1 transplant without remaining cells	two transplants
Total Patients (n)	613	91	471	31	20
Collection days, M (range)	2 (1–5)	1 (1–5)	1 (1–6)	2 (1–3)	2 (1–3)
CD34 per patient (x10^6 cells/kg), M	9.68	10.12	9.83	3.65	9.31
Total Cryobags stored	4412	1121	3291	-	-
Cryobags per patient, M (range)	7 (2–34)	10 (3–34)	6 (1–26)	-	-
Storage Duration, days, M (range)	1198 (3–3133)	1019 (30–2657)	1093 (18–3133)	14 (4–226)	960 (48–2120)
Time from collection to first transplant, days, M (range)	16 (2–2456)	-	16 (2–2456)	14 (4–226)	14 (3–102)
Time from collection to second transplant, days, M (range)	960 (48–2120)	-	-	-	960 (48–2120)
Time between first and second transplants, days, M (range)	-	-	-	-	907

M=median. Storage duration calculated as median number of days from collection to follow up or disposal.

Table II.

Cost Estimations for Collection and Storage

	Total Apheresis Days	Additional Days of Apheresis to achieve HPC > 10 × 10^6 CD34/kg	Apheresis Catheter Costs (USD)	Additional Apheresis Costs (USD)*	Total Stored Cryobags	Total Cryobag × Total days stored (CBTD)	Storage Cost CBTD × 0.02 (USD)
One HCT without banked cells (n = 31)	62	0	$21,018	$0	402	9224	$185
One HCT with banked cells (n = 471)	749	66	$319,338	$506,748	3291	4018147	$80,363
Two HCT (n = 20)	36	4	$13,560	$30,712	148	158596	$3,172
Harvest and Hold (n=91)	138	-	$61,698	$1,059,564	1121	1019	$24,184
Total		70	$415,614	$1,597,024	4962	4186986	$107,904

HCT; hematopoietic stem cell transplant, USD; United States Dollar. CBTD; total cryobag × total days stored. An “Additional” day of apheresis is notated only if the final HPC harvest is > 10^6 CD34/kg, signifying intent to collect to 2 potential HCT. For the Harvest and Hold group, all apheresis days are considered “Additional”.