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Omidubicel for Hematopoietic Cell Transplants: Considerations for Patients and Treatment Outcomes

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Abstract: For patients with hematologic malignancies requiring allogeneic stem cell transplantation, alternative donor sources are needed when lacking access to a matched related or unrelated donor. Umbilical cord blood (UCB) has been an important alternative allograft donor source for these patients; however, several limitations exist. Omidubicel is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from UCB. Omidubicel was approved in May 2023 by the United States Food and Drug Administration based on the results of a Phase III trial comparing it to UCB transplantation in patients with high-risk hematologic malignancies. Median time to neutrophil engraftment was faster with omidubicel compared to UCB transplantation (12 days vs 22 days; p<0.001). There was also a lower incidence of grade 2/3 bacterial or invasive fungal infections with omidubicel compared to UCB transplantation (37% vs 57%; p=0.027). From a safety perspective, omidubicel has a boxed warning due to the risk of life-threatening infusion reactions, graft-versus-host disease, graft failure, and engraftment syndrome. Omidubicel represents an important advancement in developing novel alternative allograft donor sources. This also has important implications in ensuring access to alternative donor sources for ethnic and minority populations.

Keywords: Omidubicel, hematopoietic cell transplant, hematology, cellular therapy

Introduction

Allogeneic stem cell transplantation remains an important and potentially curative therapeutic modality in the management of many hematologic malignancies. For patients who lack a matched related or unrelated donor, an alternative donor source will be needed.[1] The decision and selection of an alternative donor source can be dependent on many factors, including the experience and expertise of the transplant center, patient-specific factors, availability of the alternative donor source, and the distinct characteristics of the different allograft choices. Alternative allograft donor sources include haploidentical, mismatched unrelated, and umbilical cord blood (UCB) donors.

Graft-vs-host disease (GVHD) is a major complication and cause of morbidity and mortality following allogeneic stem cell transplantation, with a higher risk in alternative donor sources. However, according to the Center for International Blood and Marrow Transplant Research, haploidentical donors represent the second largest group surpassing matched related donors in recent years, making up 21% and 20% of allogeneic transplants, respectively in 2022.[2] This is largely due to the addition of post-transplant cyclophosphamide (PTCy) to the calcineurin inhibitor and antimetabolite backbone for GVHD prophylaxis, which has demonstrated low rates of acute and chronic GVHD.[3,4] It is now reported that 27% of all allogeneic recipients and 92% of haploidentical recipients received PTCy in 2022, compared to just 2% and 69% in 2012.[2] Despite the increased use of haploidentical donors, the use of mismatched unrelated donors has remained relatively stable over the past decade at approximately 10%, highlighting the need for ongoing advancements in strategies for alternative donor sourcing.

UCB has also been an important alternative allograft donor source for patients lacking a matched donor due to its multipotent potential and ability achieve reconstitution of hematopoiesis.[5] UCB is particularly helpful for patients of

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minority backgrounds who are less represented in stem cell registries. Due to the cellular immaturity of UCB, less stringent human leukocyte antigen (HLA) matching requirements are required, therefore increasing availability to minorities.[6] Additionally, due to the immaturity of UCB T cells, fewer cytokines, dendritic cells, and antigen presenting cells are activated leading to a lower risk of GVHD.[7] Rapid acquisition time due to more available donors enables shorter time to transplantation, which is another benefit of UCB. There are several disadvantages of UCB compared to other donor sources, including delayed time to neutrophil and platelet engraftment, higher risk of graft failure, and higher risk of infections.[6] There has been a noted higher risk of non-relapse mortality (NRM) than matched related donor and haploidentical transplants. With UCB transplants, there will also be no additional lymphocytes available in the event they are needed in the post-transplant setting.[8] Additionally, there can be increased acquisition costs with UCB, and adult patients may need more than one cord blood unit to attain enough cells for successful transplantation. For all the above reasons, there are limitations in access to UCB as it should only be performed at transplant centers with UCB transplantation experience. The inability to overcome some of the disadvantages described has resulted in a decreased utilization of UCB transplants that went from making up 11% of allogeneic transplants in 2012 to 4% in 2022.[2]

In May 2023, the US Food and Drug Administration (FDA) approved omidubicel for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for UCB transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.[9] Omidubicel represents a novel, alternative allograft donor source for patients needing to undergo allogeneic stem cell transplantation for a hematologic malignancy. Herein, we review the pharmacology, efficacy, and safety of omidubicel in the allogeneic stem cell transplant setting.

Omidubicel

Omidubicel is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy that is derived from umbilical cord blood. It is a patient-specific cellular therapy product.[9] Omidubicel consists of a CD133+ fraction that is expanded ex vivo and a CD133- fraction that is nonexpanded. Nicotinamide serves as the active agent in the culture systems and acts to inhibit cellular differentiation and enhances the functioning of the cultured progenitor cells. In the cell culture conditions, there are additional cytokines, including Flt-3 ligand, stem cell factor, thrombopoietin, and interleukin-6 added to the antibody-selected CD133+ cell fraction. These extra cytokines aid in increasing the number of stem cells and progenitor cells and enhancing the function and efficacy of cellular homing and engraftment.[10]

For the logistics of manufacturing process of omidubicel, the cord blood unit will be transported from the cord blood bank to a manufacturing facility in Kiryat Gat, Israel. The graft engineering process will begin with a unit of identified umbilical cord blood unit undergoing cell selection by utilization of immunomagnetic beads that will select CD133+ progenitor cells (Figure 1). These selected out cells will then be cultured with nicotinamide and additional cytokines for 21 days. The CD133- cells obtained via elution during this process are cryopreserved and saved for later as a T-cell source to prevent graft failure.

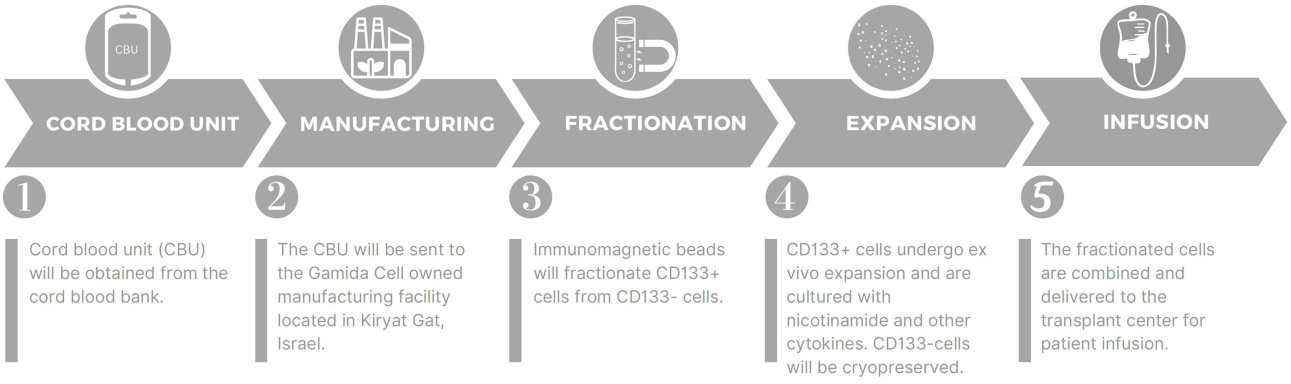

Figure 1 Overview of omibudicel manufacturing process.

Materials and Methods

We conducted an electronic search of medical literature using PubMed, spanning from inception of the database to March 1, 2024. We limited our search to English language articles. The search term "omidubicel" was used. We considered prospective clinical trials investigating the efficacy and safety of omidubicel in hematopoietic cell transplants and any investigations related to patient preferences, patient-reported outcomes, and impacts on health-related quality of life (HRQoL). The prescribing information for omidubicel was also reviewed.

Efficacy and Safety of Omidubicel in Hematopoietic Cell Transplants

Horwitz et al conducted a randomized, controlled phase III trial to compare the efficacy of omidubicel to standard umbilical cord blood transplantation.[11] Eligible patients included those between the ages of 12 and 65 years with a high-risk hematologic malignancy who were candidates for myeloablative allogeneic hematopoietic stem cell transplantation without a readily available matched donor, whether sibling or unrelated adult donor. Study subjects were randomized 1:1 and were stratified by age, institution, disease risk index, and intention to use either 1- or 2-unit umbilical cord blood grafts.

The primary endpoint of the study was the median time to neutrophil engraftment.[11] Secondary endpoints included platelet engraftment by day +42, incidence of grade 2/3 bacterial or invasive fungal infections up to day +100, days of out of hospital up to day +100, and days alive up to day +100. Additionally, exploratory endpoints included the incidence of acute and chronic GVHD, safety, NRM, relapse, overall survival, and disease-free survival.

A total of 125 patients were randomized to receive either omidubicel (n=62) or standard UCB (n=62).[11] The most common diagnoses included acute myeloid leukemia (n=60; 48%), acute lymphoblastic leukemia (n=41; 33%), and myelodysplastic syndrome (n=9; 7%). Patients received acute GVHD prophylaxis with a calcineurin inhibitor (tacrolimus or cyclophosphamide) and mycophenolate mofetil. Granulocyte-colony stimulating factor was given once daily starting on day +1 of transplant until the absolute neutrophil count exceeded 1000 cells/mm.[3] Median time to neutrophil engraftment was faster with omidubicel compared to the control arm (12 days vs 22 days; $p<0.001$). More patients receiving omidubicel compared to the control achieved platelet recovery by day +42 (55% vs 35%; p=0.028). A lower incidence of grade 2/3 bacterial or invasive fungal infections was observed in the omidubicel arm (37% vs 57%; p=0.027). Patients receiving omidubicel also spent more time out of the hospital through day +100 compared to the control arm (median, 61 vs 48 days; p=0.005). The incidence of grade 2–4 acute GVHD at day +100 was similar between both arms (56% vs 43%; p=0.18). The cumulative incidence of all chronic GVHD was similar between omidubicel and the control arm (35% vs 29%; p=0.57). NRM was decreased with omidubicel at 210 days (11% vs 24%; p=0.09) as well as treatment failure and mortality with omidubicel compared to the control arm with an adjusted hazard ratio of 0.79 (95% CI, 0.45–1.38; p=0.4) and 0.57 (95% CI, 0.3–1.1; p=0.09), respectively. While not reaching statistical significance, the data indicated a trend toward a higher incidence of relapse at 15 months with omidubicel (25% vs 17%; p=0.32).

Parikh et al conducted a phase I/II trial to evaluate if omidubicel would lead to improved engraftment in pediatric patients with sickle cell disease (SCD) undergoing myeloablative hematopoietic stem cell transplantation.[12] Eligible patients were 2 to 45 years old with severe SCD, no available matched related or unrelated donors, adequate organ function, Lansky or Karnofsky performance score ≥ 0, and a hemoglobin S (HbS) level of $< 45\%$. The primary end points were infusion toxicity and neutrophil engraftment. Secondary endpoints included platelet engraftment, acute and chronic GVHD, infections, adverse events, transplant-related mortality, event-free survival, and overall survival.

A total of 16 patients were included with two cohorts including 13 patients with a double cord transplantation (DC) and 3 patients with a single cord blood transplantation (SC).[12] Outcomes reported are for the DC cohort with descriptive outcomes discussed for the SC cohort. There were 8 patients (61.5%) in the DC group and 1 patient (33%) in the SC group that were receiving long-term transfusion therapy at baseline. Patients received myeloablative conditioning with one of the following: hydroxyurea, busulfan, cyclophosphamide, and antithymocyte globulin (n=3); hydroxyurea, fludarabine, busulfan and cyclophosphamide (n=12); or hydroxyurea, fludarabine, busulfan, cyclophosphamide, and antithymocyte globulin (n=1). GVHD prophylaxis was started on day −3 and continued with cyclosporine for at least 180 days and mycophenolate for at least 45 days. Three patients had a grade 3 event within 24 hours of infusion including a severe allergic reaction (n=1) and hypertension (n=2). Median time to neutrophil engraftment was 7 days

(range 6–20) and engraftment was sustained in 12 of 13 patients (92%). Platelet engraftment was reached at a median of 61 days (range 33–375). Ten patients (77%) experienced grade 2–4 acute GVHD and seven patients (54%) had chronic GVHD. Grade 2–3 infections occurred in 11 patients (85%). Additional adverse events included posterior reversible encephalopathy syndrome (n=2), acute subdural hemorrhage (n=1), and busulfan-induced seizures (n=1). One patient died of liver GVHD and one patient had secondary graft failure on day 13 and died after a second allogeneic transplant with a transplant-related mortality of 15% during the first year and one-year overall survival and event-free survival of 84.6% for both. All three patients in the SC cohort were alive at 1 year after transplant. This open-label single-arm study demonstrated rapid engraftment with omidubicel in SCD patients undergoing hematopoietic stem cell transplantation.

Linc et al conducted a pooled analysis of long-term outcomes from five prospective multicenter clinical trials.[13] The clinical trials included evaluated omidubicel transplantation in hematologic malignancies or sickle cell disease between January 2011 and April 2021. Patients who fully engrafted with an unmanipulated UCB were excluded. Outcomes assessed sought to confirm the safety, immune function, and graft durability of omidubicel transplantation. Additional endpoints included overall survival, disease-free survival, acute and chronic GVHD, and secondary malignancies.

A total of 105 patients from 26 transplantation centers were included. The majority of patients fully engrafted with omidubicel transplantation (n=97; 92%).[13] The most common disease types included acute myeloid leukemia (n=43; 41%), acute lymphoblastic leukemia (n=28; 27%), myelodysplastic syndrome (n=13; 12%), and SCD (n=8; 8%). All patients received GVHD prophylaxis with mycophenolate mofetil alone or in combination with either tacrolimus or cyclosporine. With up to 10 years of follow-up, omidubicel demonstrated durable hematopoiesis across white blood cells, hemoglobin, and platelets. Immune subsets including CD3, CD4, CD8, CD19, CD116, CD56, and CD123 were also evaluated and were within expected ranges with up to 8 years of follow-up. Secondary graft failure occurred in 5 patients (5%) with a median onset of 40 days (range 12–262). The estimated 3-year overall survival was 62.7% (95% CI, 52.1% to 71.6%) and 3-year disease-free survival was 56.4% (95% CI, 45.9% to 65.6%). The most common cause of death was disease relapse (n=16; 15%) with a 3-year cumulative incidence of 22.2% (95% CI, 14.5% to 31.1%). There were no deaths attributed to chronic GVHD with a 3-year cumulative incidence of 36.6% (95% CI, 26.0% to 46.2%), but there were six deaths (6%) attributed to acute GVHD. Two patients (2%) developed post-transplantation lymphoproliferative disease and one patient (1%) developed donor derived myelodysplastic syndrome. This pooled analysis provides long-term outcomes that support the safe, effective, and durable use of omidubicel transplantation.

Omidubicel use does not come without risk. There are several boxed warnings within the product labeling including infusion reactions, engraftment syndrome, graft failure, and GVHD.[9] Infusion reactions were observed in 47% of patients, with 15% experiencing a grade 3 or 4 reaction. Reactions may occur within minutes or be delayed with the worst symptoms occurring several hours after omidubicel infusion. Reactions may manifest as hypertension, mucosal inflammation, dysphagia, dyspnea, vomiting, and/or gastrointestinal toxicity. To prevent reactions, patients should be provided pre-medication with an antipyretic, histamine antagonist, and corticosteroid. Patients should be monitored throughout the infusion and the infusion should be stopped if a severe reaction occurs. Similar to infusion reactions, hypersensitivity reactions may also occur. These reactions are often more severe than infusion reactions and can result in bronchospasm, wheezing, angioedema, pruritus, hives, or angioedema. These reactions may be attributed to an allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material incorporated in the production of omidubicel.

Due to omidubicel's nature as a stem cell product, characteristic post-transplant complications of engraftment syndrome, graft failure, and GVHD may be observed.[9] The prevalence of engraftment syndrome with omidubicel has not been reported but it is a possible complication. Patients may experience a fever, rash, hypoxemia, weight gain, and pulmonary infiltrates around the time of engraftment. An experienced transplant clinician is vital to recognizing these symptoms and providing prompt treatment with corticosteroids to prevent progression to multiorgan failure or death. Graft failure, observed in 3% of clinical trial patients, may also be fatal if unrecognized. Defined as the inability to attain an absolute neutrophil count greater than 500 cells/mm^3 by day +42 after transplantation, patients' blood counts should be monitored closely. Most graft failure is due to rejection of the new stem cells. Finally, GVHD may be experienced by patients receiving omidubicel. Acute GVHD most commonly presents with a maculopapular rash, gastrointestinal symptoms, and/or elevated bilirubin. Despite receiving immunosuppressive medications to prevent GVHD, 58% of

patients studied reported grade II–IV acute GVHD and 17% grade III–IV acute GVHD. Chronic GVHD was observed in 35% of patients. Patients should be routinely monitored for signs and symptoms of GVHD after omidubicel and treated upon recognition. While very rare, patients receiving omidubicel may be at risk of acquiring malignancies of donor origin, serious infections transmitted from the donor, or rare genetic diseases from the donor. Donor UCB is screened for infectious diseases as well as sickle cell anemia and anemias due to other hemoglobin abnormalities, but given the donor is a newborn it is difficult to determine any pre-existing issues.

Other notable adverse effects of omidubicel should be considered after infusion. Grade I–III infections were common among patients studied in clinical trials including: viral infections (75%), bacterial infections (65%), and fungal infections (21%).[9] Frequently reported adverse effects included, pain (33%), mucosal inflammation (31%), hypertension (25%), hemorrhage (12%), gastrointestinal toxicity (19%), dysphagia (12%), renal impairment (12%), and respiratory failure (12%). Laboratory abnormalities were common, most notably: decreased magnesium (94%), increased magnesium (15%), increased liver function tests (aspartate aminotransferase and alanine aminotransferase each 56%), increased bilirubin levels (42%), increased alkaline phosphatase (42%), and increased creatinine (50%). Veno-occlusive disease/sinusoidal obstruction syndrome and thrombotic thrombocytopenic purpura/thrombotic microangiopathy were both rare adverse events, but proved fatal in 2% of patients.

Patient Selection and Impact on Health-Related Quality of Life

It is estimated that only 30% of patients will have a matched related donor.[1,14] The majority of patients with high-risk hematologic malignancies who require a hematopoietic stem cell transplant will therefore rely on the National Marrow Donor Program (NMDP) to provide additional donor sources. However, finding a match for an unrelated donor disproportionally impacts minority patients that are underrepresented in the NMDP, with Black or African American patients having the lowest probability.[15] UCB stem cells have a unique advantage with reduced matching stringency compared to other donor sources, expanding access to ethnic and racial minorities. These advantages come with the challenge of low cell doses leading to prolonged engraftment and increased risk of complications including infections, bleeding events, prolonged hospitalizations and early treatment-related morbidity and mortality.[16] There have been several expansion attempts to overcome these challenges over the last few decades, but the FDA approval of omidubicel as the first stem cell transplant product has the potential to address this unmet need. By expanding the number of stem cells, omidubicel is a more feasible UCB product, therefore increasing access of hematopoietic stem cell transplant to our minority patients. Inclusivity in transplantation goes beyond expanded access because it also addresses cultural sensitivity by facilitating a better understanding of the shortcomings of transplantation for patients with different ethnic backgrounds. Ultimately, the approval of omidubicel provides further opportunities for research as well as increased education that will improve clinical practices and foster a more inclusive future in transplantation for all ethnic and racial backgrounds.

In the phase III trial evaluating omidubicel compared to standard UCB transplant, an evaluation of patient reported outcomes and HRQoL was conducted.[11,17] Patients in the trial completed several patient-reported outcome measurement tools, including the Functional Assessment of Cancer Therapy-General (FACT-G), FACT-Bone Marrow Transplant subscale (FACT-BMT), and the EuroQol 5-Dimension 3-Level (EQ-5D-3L) index. A minimal clinically important difference (MCID) in scores was set for each scale; exceeding the MCID would be considered clinically significant. Assessments were completed at baseline, day +42, day +100, day +180, and day +365. Of the 125 patients randomized in the trial, 75 completed HRQoL assessments. Patients in both arms had similar baseline scores in all the HRQoL assessments. At day +42, there was an initial decline in the mean scores of all assessments, however there was no statistically significant difference in the decline between both arms.

There were significantly better FACT-G scores with omidubicel compared to standard UCB from days +42 to day +365 that exceeded the MCID.[17] The area-under-curve differences in the mean change in FACT-BMT scores through all assessments was significantly better, as indicated by exceeding the MCID, with omidubicel compared to standard UCB. Although there were demonstrated improvements in HRQoL with statistically significant improvements in FACT-G and FACT-BMT scores with omidubicel, there was no statistically significant difference in the mean change in the EQ-5D-3L index scores between both arms.

There was also a correlation between significant post-transplant clinical outcomes and HRQoL scores.[17] Patients experiencing neutrophil engraftment at day +42 had better FACT-G emotional well-being compared to those who did not. Development of grade 2–4 acute GVHD was associated with worse FACT-BMT scores and worse functional well-being. The total number of days in the hospital post-transplant through day +100 was associated with worse physical well-being, lower FACT-G scores, and lower FACT-BMT scores.

Conclusion

In conclusion, omidubicel is a novel cellular therapy product indicated for patients with hematologic malignancies who are planned for UCB transplantation following a myeloablative conditioning regimen. Along with haploidentical donors with PTCy for GVHD prophylaxis, this novel cellular therapy adds further to available alternative donor sources for patients without a matched related or unrelated donor. This has potentially strong implications for improving health disparities by expanding access to alternative donor sources for patients of ethnic minority populations.

Abbreviations

DC, double cord; DMSO, dimethyl sulfoxide; EQ-5D-3L, EuroQol 5-Dimension 3-Level; FACT, Functional Assessment of Cancer Therapy; FDA, Food and Drug Administration; GVHD, graft-versus-host disease; HbS, hemoglobin S; HLA, human leukocyte antigen; HRQoL, health-related quality of life; MCID, minimal clinically important difference; NMDP, National Marrow Donor Program; NRM, non-relapse mortality; PTCy, post-transplant cyclophosphamide; SC, single cord; SCD, sickle cell disease; UCB, umbilical cord blood; US, United States.

Disclosure

The authors report no conflicts of interest in this work.

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