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Allogeneic Hematopoietic Stem Cell Transplantation for Older Patients with Hematological Malignancies

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ABSTRACT

Allogeneic hematopoietic stem cell transplantation (allo-HCT) has been established as a curative treatment for hematological malignancies such as acute myeloid leukemia and myelodysplastic syndrome. Patients aged ≥ 70 years have traditionally been considered ineligible for this procedure, because of concerns over high transplant-related mortality rates and difficulties managing post-transplant complications. However, recent advances in supportive care, expanded donor availability, and the development of reduced-intensity conditioning (RIC) regimens have increased the availability of allo-HCT for older patients. Notably, the number of allo-HCT procedures performed in patients aged ≥ 70 has been steadily increasing in Japan and Western countries, reflecting a re-evaluation of transplant eligibility in older patients. When assessing transplant eligibility in older patients, it is crucial to consider not only disease risk stratification and treatment response, but also comprehensive evaluations of general health status, comorbidities, cognitive function, and social backgrounds. In particular, indexes such as the Hematopoietic Cell Transplantation-Comorbidity Index and Comprehensive Geriatric Assessment have proven useful for predicting patient prognoses and non-relapse mortality. Donor selection and the intensity of the conditioning regimen used can both significantly influence transplant outcomes. RIC or non-myeloablative regimens are generally recommended for patients aged ≥ 70 years. Human leukocyte antigen-matched related or younger unrelated donors are preferred, while haploidentical donors or cord blood may be considered when matched donors are unavailable, although evidence in older patients is limited. This review provides a comprehensive overview of the current status of and challenges related to allo-HCT in patients aged ≥ 70 years. Patient eligibility, conditioning strategies, donor selection, and transplant outcomes are discussed in detail, based on the latest available evidence.

Key words allogeneic hematopoietic stem cell transplantation; Geriatric Assessment; Hematopoietic Cell Transplantation-Comorbidity Index; older patients; reduced-intensity conditioning

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Abbreviations: allo-HCT, allogeneic hematopoietic stem cell transplantation; AML, acute myeloid leukemia; BMT, bone marrow transplantation; CBT, cord blood transplantation; CGA, comprehensive geriatric assessment; CIBMTR, Center for International Blood and Marrow Transplant Research; CR1, first complete remission; CT, conventional chemotherapy; EBMT, European Group for Blood and Marrow Transplantation; ECOG PS, Eastern Cooperative Oncology Group Performance Status; FB, fludarabine/busulfan; FM, fludarabine/melphalan; GVHD, graft-versus-host disease; HCT-CI, Hematopoietic Cell Transplantation-Comorbidity Index; HLA, human leukocyte antigen; HR, hazard ratio; IADL, instrumental activities of daily living; KPS, Karnofsky Performance Status; LFS, Leukemia-free survival; MAC, myeloablative; MRD, matched related donor; MSD, matched sibling donor; MUD, matched unrelated donor; NMA, non-myeloablative; NRM, non-relapse mortality; OS, overall survival; PFS, progression-free survival; PTCy, post-transplantation cyclophosphamide; RIC, reduced-intensity conditioning; RM, restricted mean; TRM, transplant-related mortality

Allogeneic hematopoietic stem cell transplantation (allo-HCT) has been established as a curative treatment for hematologic malignancies such as acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), which are often difficult to cure with standard chemotherapy. Recent advances in the prevention and management of complications such as graft-versus-host disease (GVHD) and infections have significantly reduced transplant-related mortality (TRM) in this patient demographic.[1–3] Furthermore, the development of reduced-intensity conditioning (RIC) regimens has facilitated the use of allo-HCT in older and medically vulnerable patients.

In Japan, the bone marrow bank was established in 1991. Initially, bone marrow transplantation was limited to patients aged < 50 years. However, since the 2000s, the number of patients in their 50s and 60s undergoing allo-HCT has been steadily increasing. Currently, > 50% of allo-HCT procedures are performed in patients aged ≥ 50 years, and the number of transplants in patients aged ≥ 70 years has also been rising (Fig. 1).[4] In the United States, the number and

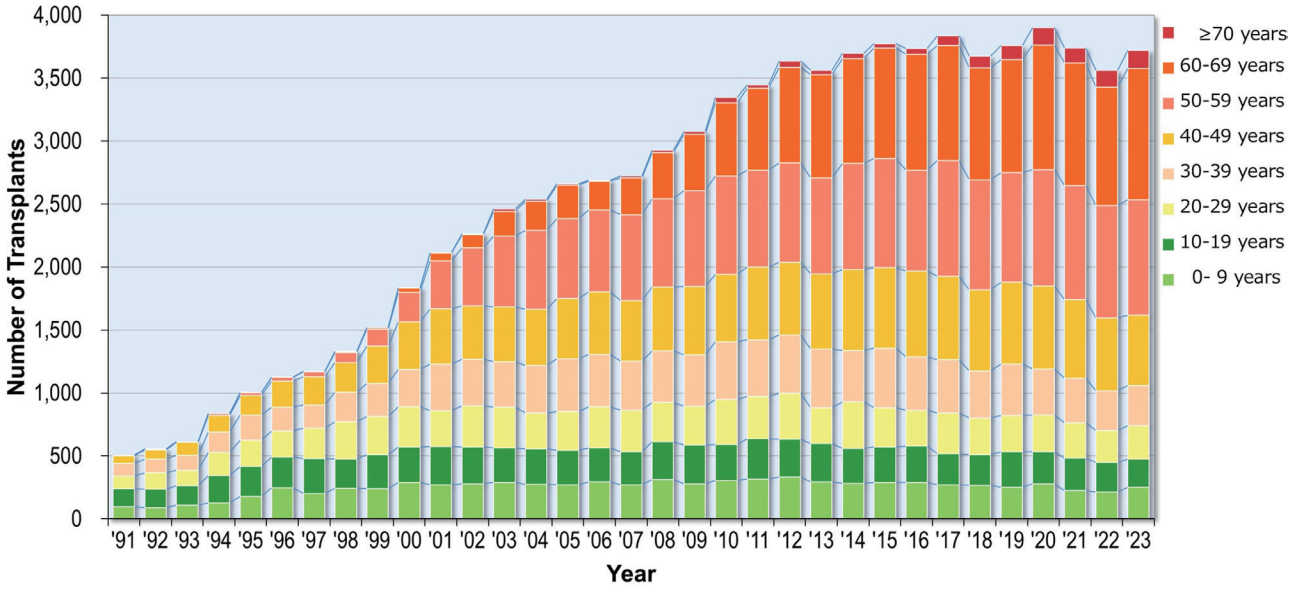

Fig. 1. Annual number of allogeneic hematopoietic stem cell transplantations by recipient age in Japan. [Hematopoietic Cell Transplantation in Japan 2024 Summary Slides provided by the Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT)].

proportion of allo-HCT performed in patients aged ≥ 70 years increased from 0.1% in 2000 to 3.85% in 2013.[5] Recent data from the Center for International Blood and Marrow Transplant Research (CIBMTR) indicate that patients aged 65–74 years accounted for 26% of all allo-HCT recipients in 2023, while those aged ≥ 75 years comprised 3%.[6] The European Group for Blood and Marrow Transplantation (EBMT) has also reported that the number of transplants performed in patients with MDS aged ≥ 70 years has been increasing: from 16 over 2000–2004, to 27 in 2005–2007, 89 over 2008–2010, and 181 in 2011–2013.[7] As these data illustrate, the use of allo-HCT in older patients continues to increase yearly. Historically, patients aged ≥ 70 years were rarely considered for allo-HCT, because of their higher TRM rate and concerns surrounding their ability to tolerate the procedure. However, with improved supportive care, better donor availability, and tailored conditioning strategies, this trend has been changing significantly in recent years. Nevertheless, certain challenges remain—including the management of comorbidities, frailty, and post-transplant complications in this age group.

This review aims to provide an overview of the current indications, conditioning approaches, donor selection, and outcomes of allo-HCT performed in older patients, highlighting the recent trends and challenges associated with expanding transplant eligibility to this growing demographic.

CHALLENGES IN OLDER PATIENTS

Patient age has long been recognized as an important factor when determining eligibility for allo-HCT, and transplant decisions have traditionally relied heavily on this variable. Although older patients with hematological malignancies are often characterized by comorbidities, physiological decline, cognitive impairment, and socioeconomic challenges,[8, 9] these factors vary considerably among individuals. Therefore, chronological age alone should not serve as the sole criterion for transplant eligibility, as a substantial proportion of patients in their 70s maintain preserved organ function and have few or no significant comorbidities. However, even without overt comorbidities, age-related functional decline affects multiple organs—including the liver, kidneys, heart, bone marrow, muscle, and central nervous system—and significantly alters the pharmacokinetics and pharmacodynamics of systemic anticancer agents.[10] This is particularly relevant for allo-HCT, which involves high-dose chemotherapy conditioning and prolonged administration of multiple drugs post-transplantation—including GVHD prophylaxis and antimicrobial agents—thus increasing the risk of drug-induced organ toxicity.

The median age at diagnosis for most hematological malignancies is > 60 years. This figure is ~68 years for AML, and ~77 years for MDS.[11, 12] Thus, the number of patients with such conditions who are considered eligible for allo-HCT is substantial. Although overall survival (OS) rates have improved with the introduction

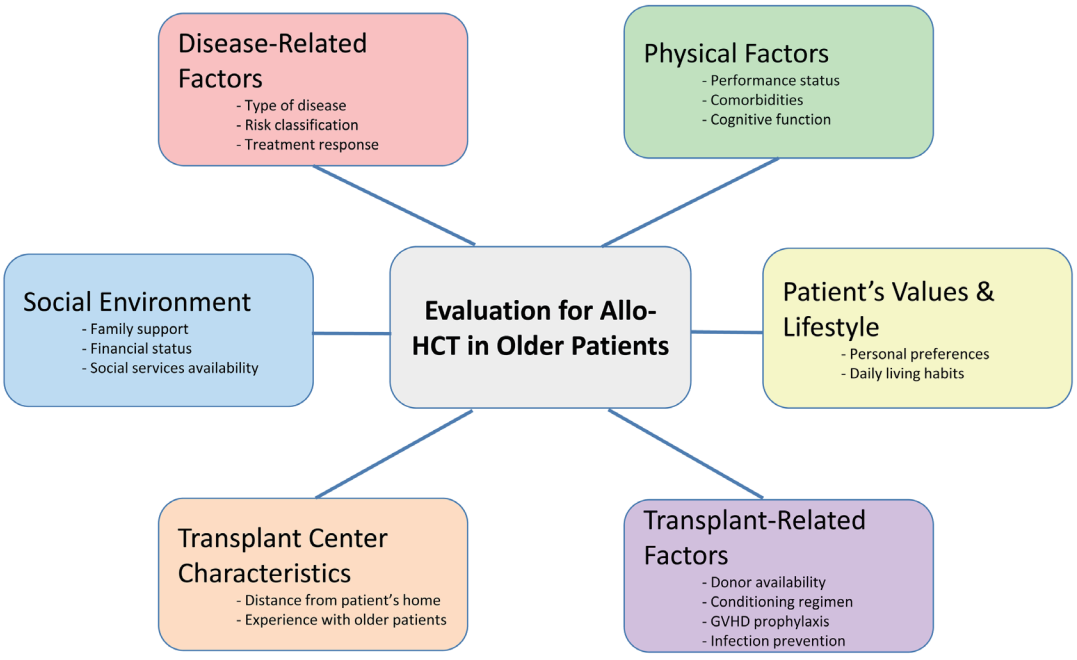

Fig. 2. Key factors to consider when determining indications for allogeneic hematopoietic stem cell transplantation in older patients.

of novel therapies such as venetoclax combined with azacitidine in older patients with AML,[8] curative treatment remains difficult to achieve for most. However, as low-intensity therapies such as venetoclax-based regimens become more widely adopted, the number of older patients who are eligible for allo-HCT is expected to increase further.[13, 14] Concurrently, recent advances in conditioning regimens and improved management of transplant-related complications have made it increasingly appropriate to reconsider transplant eligibility in older patients. In other words, there may be a subset of patients in their 70s who are more likely than was previously believed to benefit from allo-HCT and potentially achieve long-term remission or be fully cured through the procedure.

EVALUATION OF ELIGIBILITY FOR ALLO-HCT IN OLDER PATIENTS

A wide range of factors must be carefully evaluated when considering the indications for allo-HCT in older patients (Fig. 2). These include (i) disease-related factors (e.g., the type of disease, its risk classification, and treatment response); (ii) patient-related physical factors (e.g., performance status, comorbidities, and cognitive function); (iii) the patient's social environment (e.g., family support, financial status, and availability of social services); (iv) the patient's values and lifestyle; (v) the characteristics of the transplant center (e.g., its distance from the patient's home and level of experience with older transplant recipients); and (vi) transplant-related factors (e.g., the availability of a suitable donor, conditioning regimens, GVHD prophylaxis, and infection prevention strategies).[15]

This section focuses primarily on patient-related physical factors. Among these, the Eastern Cooperative Oncology Group Performance Status (ECOG PS) and Karnofsky Performance Status (KPS) are the most widely used, owing to their simplicity and clinical relevance. These performance scales are instrumental when assessing a patient's functional status, and are commonly deployed to evaluate the feasibility of chemotherapy or allo-HCT in patients with hematological malignancies.[16, 17] They have also been shown to be useful in older patients undergoing allo-HCT.[18] Notably, lower performance status scores have been associated with increased transplant-related morbidity and mortality, underscoring their prognostic significance in treatment planning.

The likelihood of comorbidities generally increases with age. Renal, cardiac, hepatic, and respiratory functions are often impaired in older individuals vs younger ones. The Hematopoietic Cell Transplantation-Comorbidity Index (HCT-CI), which quantifies organ dysfunction and comorbidity burden, is widely used to predict non-relapse mortality (NRM) and OS following transplantation.[19] For example, an HCT-CI score of 0 is

associated with a 2-year NRM of 14%, while scores of 1–2 and ≥ 3 are associated with rates of 21% and 41%, respectively. Sorror et al. also reported that the hazard ratio (HR) for NRM increases significantly with age, with an HR of 1.84 for patients aged ≥ 60 years vs those aged < 20 years ($P = 0.005$).[20] To better account for the impact of age, they incorporated age ≥ 40 years as an additional point in the HCT-CI, creating a composite comorbidity/age index that was shown to represent a reliable predictor of both NRM and OS. Although age itself is not a component of the original HCT-CI, older individuals are more likely to have comorbidities and organ dysfunction, thereby contributing to higher scores.

While ECOG PS/KPS and HCT-CI undoubtedly represent useful tools for assessing transplant eligibility in older patients, they may not fully capture the complexity of aging-related vulnerabilities. Consequently, comprehensive geriatric assessment (CGA) has been increasingly recognized as a valuable complement to traditional risk scores. CGA is a multidimensional and interdisciplinary process that evaluates functional status, cognition, emotional health, nutrition, social support, and comorbidities.[21] In a prospective single-center study of 148 patients aged ≥ 50 years who underwent allo-HCT, Huang et al. showed that impairments identified by CGA effectively predicted post-transplant outcomes.[22] Deficiencies in instrumental activities of daily living (IADL) were significantly associated with lower OS and progression-free survival (PFS). Medical Outcomes Study—Physical Health scores of < 85 were also independently linked to lower OS and PFS, higher NRM, and more severe non-hematological toxicities within 100 days post-transplantation.

One multi-institutional retrospective study of 330 allo-HCT recipients aged ≥ 50 years found that cognitive impairment, as measured by the Blessed Orientation Memory Concentration test prior to transplantation, was independently associated with higher 1-year NRM and lower OS.[23] In patients aged ≥ 60, cognitive impairment represented the only geriatric assessment metric predictive of NRM. A retrospective study of 457 patients aged ≥ 60 years undergoing first allo-HCT demonstrated that pre-transplant impairments in geriatric domains, particularly IADL, were linked to increased NRM and reduced OS.[24] Combining IADL impairment with indexes such as HCT-CI/age or disease risk index improved risk stratification. These findings highlight key geriatric vulnerabilities that can guide pre-transplant assessments and interventions to improve outcomes in older allo-HCT recipients.

Although CGA is important for assessing the suitability of allo-HCT in older patients, its comprehensive implementation in routine clinical practice is challenging because of the time required. Therefore, other simpler geriatric assessment tools—including the Geriatric-8, Vulnerable Elders Survey-13, and various frailty indexes—have also been explored for their prognostic value in transplantation settings.[25, 26] However, large-scale data are currently lacking, and further investigations are warranted to determine the extent to which these tools can be effectively utilized.

The integration of these assessments into the pre-transplant evaluation process may help refine patient selection, guide supportive care strategies, and improve outcomes in older patients undergoing allo-HCT.

TRANSPLANTATION METHODS

Conditioning regimens for allo-HCT have been classified as RIC, myeloablative (MAC), or non-myeloablative (NMA), according to the operational definitions of the National Marrow Donor Program/ CIBMTR, based on the doses used for chemotherapy and total body irradiation.[27, 28] Representative regimens of MAC, RIC, and NMA are shown in Table 1.[27–29] MAC regimens, which are typically used in younger patients, are associated with significant toxicity and have historically limited the use of allo-HCT in older patients or those with comorbidities. However, with the widespread adoption of RIC regimens, the indications for allo-HCT have been expanded to include older patients as well. Despite this progress, the optimal pre-transplantation strategies for older patients aged ≥ 70 years remain unclear. In a study reported by the CIBMTR on allo-HCT in patients aged ≥ 70 years, 88% received RIC/NMA regimens, and 10% received MAC regimens.[5] The use of MAC instead of RIC/NMA in patients with early or intermediate AML/MDS and chemosensitive non-Hodgkin lymphoma between 2008 and 2013 was found to represent a significant adverse prognostic factor for both TRM (HR, 2.06; $P = 0.001$) and OS (HR, 1.60; $P = 0.009$). In a separate study on allo-HCT for MDS reported by the EBMT, 17% of the patients received MAC, 66% received RIC, and 17% received NMA. However, conditioning intensity was not associated with differences in NRM or OS.[7]

Previously, we analyzed allo-HCT outcomes in patients ≥ 50 years using data from a Japanese registry.[30] The patients received either fludarabine/busulfan (FB2: busulfan 6.4 mg/kg; FB4: busulfan 12.8 mg/kg) or fludarabine/melphalan (FM140: melphalan 140 mg/m^2). Although NRM was significantly higher with FB4 and FM140 vs FB2, relapse rates were significantly lower, resulting in no significant differences in OS among the groups. This underscores a key clinical

Table 1. Representative regimens of MAC, RIC, and NIMA[27–29]

MAC*	RIC*	NMA
CY + TBI (CY: 120 mg/kg, TBI: 12 Gy)	FLU + MEL140 (FLU: 125 mg/m^2, MEL: 140 mg/m^2)	TBI (TBI: 2 Gy)
CA + CY + TBI (CA: 8 g/m^2, CY: 120 mg/kg, TBI: 12 Gy)	FLU + BU2 (FLU: 180 mg/m^2, ivBU: 6.4 mg/kg)	FLU + TBI (FLU: 90 mg/m^2, TBI: 2 Gy)
BU + CY (ivBU: 12.8 mg/kg, CY: 120 mg/kg)	FLU + CY (FLU: 125 mg/m^2, CY: 120 mg/kg)	
FLU + BU4 (FLU: 180 mg/m^2, ivBU: 12.8 mg/kg)	FLU + BU2 + MEL80 (FLU: 180 mg/m^2, ivBU: 6.4 mg/kg, MEL: 80 mg/m^2)	
FLU + BU4 + MEL80 (FLU: 180 mg/m^2, ivBU: 12.8 mg/kg, MEL: 80 mg/m^2)		

*TBI/TLI or ATG may also be used in combination. ATG, Anti-Thymocyte Globulin; BU, Busulfan; CA, Cytarabine; CY, Cyclophosphamide; FLU, Fludarabine; iv, intravenous; MAC, Myeloablative Conditioning; MEL, Melphalan; NMA, Non-Myeloablative Conditioning; RIC, Reduced-Intensity Conditioning; TBI, Total Body Irradiation; TLI, Total Lymphoid Irradiation.

dilemma: reducing the intensity of the conditioning regimen lowers TRM/NRM but increases the risk of relapse. Notably, this balance is expected to vary with age. Yanada et al. analyzed the impact of AML patient age on post-transplantation outcomes following allo-HCT with either MAC or RIC regimens.[31] Their findings demonstrated that age significantly affected both NRM and OS, and that this effect was modulated by the intensity of the conditioning regimen. The RIC regimen appeared to represent a suitable option for older patients, as it attenuated the adverse prognostic impact associated with advanced age. Shinohara et al. compared transplantation outcomes between younger (aged < 60 years) and older (aged ≥ 60 years) adult patients with hematological malignancies undergoing initial allo-HCT using the FB4 regimen—a reduced-toxicity conditioning regimen classified as a MAC.[32] The 3-year NRM was significantly higher in the older group vs the younger one (30.9% vs. 23.0%; $P < 0.01$). The 3-year cumulative incidence of relapse was comparable between the two groups, while the 3-year OS was significantly lower in the older group (39.9% vs. 48.5%; $P < 0.01$). Based on these findings, the investigators concluded that FB4 should be used with caution in older patients. City of Hope reported a retrospective study of allo-HCT using melphalan-based RIC in 53 patients aged ≥ 70 years with hematological malignancies.[33] The melphalan dose was either 100 mg/m^2 ($n = 6$) or 140 mg/m^2 ($n = 47$). The 2-year OS, PFS, and NRM rates were favorable, at 68.9%, 63.8%, and 17.0%, respectively.

Based on these results, RIC or NMA regimens are recommended for patients aged ≥ 70 years, to reduce non-TRM/NRM. However, further studies are warranted to determine the optimal RIC regimen for this population.

DONOR SELECTION

The optimal donor for allo-HCT is an human leukocyte antigen (HLA)-matched related donor (MRD).[34–36] However, in patients aged ≥ 70 years, the likelihood of identifying such a donor is lower vs younger patients. This is because potential sibling donors are also older and often ineligible because of age-related health conditions, even if they are HLA-compatible. Although the second most suitable donor is typically an HLA-matched unrelated donor (MUD), it is of particular clinical importance whether to select an older MRD or a younger MUD. The EBMT reported that, in patients aged ≥ 50 years with MDS, transplantation from MUDs aged < 30 years was associated with significantly higher 5-year OS vs that from MRDs or MUDs aged > 30 years (40% vs. 33% vs. 24%, respectively).[37] A retrospective cohort study conducted by the CIBMTR similarly evaluated patients with MDS who underwent allo-HCT from HLA-matched sibling donors (MSDs) aged ≥ 50 years vs MUDs aged ≤ 35 years.[38] Transplantation from younger MUDs was associated with lower relapse rates and improved disease-free survival, although a higher incidence of GVHD was noted—and thus should be considered during donor selection. In contrast, a large-scale study conducted by the Dana-Farber Cancer Institute analyzed 499 patients aged ≥ 60 years with AML or MDS and found no significant differences in 4-year PFS or OS between transplantation recipients from MRDs aged ≥ 50 years and MUDs aged ≤ 35 years.[39]

In the absence of available MSDs or MUDs, alternative donor sources such as HLA one-locus

mismatched unrelated donors, umbilical cord blood, or haploidentical donors may be considered. However, there is currently limited evidence in the literature regarding the optimal alternative donor source for older patients. Haploidentical transplantation has gained popularity in recent years. This is because of the widespread use of post-transplantation cyclophosphamide (PTCy), which has significantly improved outcomes by reducing GVHD and improving engraftment rates.[40–42] From a donor availability perspective, haploidentical donors are often more accessible for older patients, as parent–child relationships can serve as suitable alternatives when matched siblings or unrelated donors are unavailable. At Johns Hopkins, 271 patients aged 50–75 years with hematological malignancies underwent NMA haploidentical bone marrow transplantation (BMT) with PTCy. Six-month NRM rates were similar across the different age groups—8% (50s), 9% (60s), and 7% (70s)—with no significant differences in 3-year PFS or OS, indicating that age alone did not impact outcomes.[43] In a separate cohort of 93 patients aged ≥ 70 years (median age, 72 years), the 2-year OS and EFS rates were 53% and 43%, respectively. Although 6-month NRM was relatively low, at 14%, it increased to 27% at 2 years, suggesting a role for age-related factors in late mortality. Nonetheless, haploidentical BMT with PTCy appears to represent a feasible and relatively safe option for older patients.[44] In a retrospective EBMT study of patients with AML aged ≥ 60 years, the outcomes of non-T-cell-depleted haploidentical transplantation (65% with PTCy) were comparable to those of MUD transplantation, with no significant differences in relapse, NRM, GRFS, or OS.[45] These findings support the use of haploidentical donors as a viable alternative in older patients without matched donors.

Umbilical cord blood represents a viable alternative graft source, owing to its widespread availability and HLA compatibility. A large retrospective CIBMTR study conducted in patients aged ≥ 70 years identified cord blood as an adverse factor for OS vs MRDs.[5] Similarly, Konuma et al. used Japanese registry data to report higher transplant-related mortality and inferior OS with cord blood transplantation (CBT) vs MRD in patients aged ≥ 50 years, although GRFS outcomes were comparable.[46] Therefore, CBT remains a reasonable option in the absence of MRD or MUD availability.

Based on these findings, allo-HCT from an MRD or MUD is recommended in patients aged ≥ 70 years. When such donors are unavailable, haploidentical transplantation or CBT represent acceptable alternatives.

TRANSPLANTATION OUTCOMES AND PROGNOSES

(1) Allo-HCT in Patients Aged ≥ 70 Years

Data concerning allo-HCT in patients aged ≥ 70 years remain limited in the literature. Table 2 summarizes the key studies that have been conducted in this patient population thus far.[5, 7, 43, 44, 47, 48] The CIBMTR reported outcomes for 1,106 patients aged ≥ 70 years who underwent first allo-HCT in the United States in 2000–2013.[5] The median patient age was 72 years (range, 70–84), with AML (54%) and MDS (22%) representing the most common indications. Two-year OS improved significantly, from 26% over 2000–2007 to 39% over 2008–2013 ($P < 0.001$), and PFS improved from 22% to 32% ($P = 0.003$). In contrast, the 2-year TRM remained relatively stable (33–35%, $P = 0.54$). Adverse prognostic factors for OS in the 2008–2013 cohort included an HCT-CI score of ≥ 3, CBT, and myeloablative conditioning. A retrospective analysis by the EBMT evaluated outcomes in 313 patients aged ≥ 70 years who underwent allo-HCT for MDS or secondary AML in 2000–2013.[7] The median patient age was 72 years (range, 70–78). The 3-year OS and relapse-free survival rates were 34.3% and 29.3%, respectively. One-year NRM was 32.4%, and the 3-year cumulative relapse incidence was 28.3%. Poorer OS was associated with a KPS score of ≤ 80% and seropositivity for cytomegalovirus.

Based on these findings, allo-HCT should be considered in older patients with low HCT-CI scores (i.e., ≤ 2) and good performance status, as it offers the potential for long-term survival and even cure.

(2) Allo-HCT vs Chemotherapy

There is no consensus regarding whether allo-HCT or conventional chemotherapy (CT) should be used as consolidation therapies in older patients with AML. Table 3 summarizes key studies that compared allo-HCT with chemotherapy. One study compared outcomes in patients with AML aged 60–77 years who received allo-HCT ($n = 431$) to those of patients who were enrolled in a prospective National Clinical Trials Network study who received induction followed by CT consolidation ($n = 211$).[49] The allo-HCT group was younger (median age: 64.2 vs. 67.9 years, $P < 0.001$) but had a higher prevalence of adverse features (e.g., secondary AML, higher white blood cell, poor cytogenetics). OS was lower in the allo-HCT group during the first 9 months after first complete remission (CR1) was achieved (HR = 1.52, $P = 0.02$), but significantly higher thereafter (HR = 0.53, $P < 0.0001$). TRM was higher over the first 9 months post-HCT (HR = 2.8, $P = 0.0009$), while relapse risk after 9 months was lower (HR = 0.42,

Table 2. Allogeneic hematopoietic stem cell transplantation in older patients aged ≥ 70 years

Study	Number of patients	Median age, y (range)	KPS (%)	HCT-CI (%)	Disease (%)	Condition-ing (%)	Donor source (%)	TRM/NRM	OS
Muffly, et al.[5] (Retrospective)	1106	72 (70–84)	< 80% (9) ≥ 80% (82)	0 (22), 1–2 (21), ≥ 3 (38)	AML (54), MDS (22), NHL (10), etc.	MAC (10), RIC/NAM (88)	MUD (47), MRD (27), others	1-year TRM: 25% 2-year TRM: 33%	1-year OS: 50% 2-year OS: 36%
Heidenreich, et al.[7] (Retrospective)	313	71.6 (70–78)	40–80% (39) 90–100% (61)	–	MDS (71), sAML (29)	MAC (17), RIC (66), NMA (17)	Unrelated (75), Related (25),	1-year NRM: 32.4% 3-year NRM: 42.5%	1-year OS: 52.1% 3-year OS: 34.3%
Imus, et al.[44] (Retrospective)	93	72 (70–78)	70–80% (25), 90% (56), 100% (19)	0 (25), 1–2 (41), ≥ 3 (33)	AML (35), NHL (35), MDS (18)	NMA (100)	Haplo (100)	180-day NRM: 14% 2-year NRM: 27%	2-year OS: 53%
Devine, et al.[47] (Prospective)	114	65 (60–74)	–	–	AML in CR1 (100)	RIC (100)	MUD (52), MRD (48)	2-year NRM: 15%	2-year OS: 48%
Chalandon, et al.[48] (Retrospective)	316	63.8 (60–75.8)	–	0 (44.9), 1–2 (22.6), ≥ 3 (32.5)	ALL (100)	MAC (35.4), RIC (64.6)	MUD (44.9), MSD (26.3), Haplo (17.7)	3-year NRM: 23%	3-year OS: 46%
Kasamon, et al.[43] (Retrospective)	271	61 (50–75)	–	0 (25), 1–2 (34), ≥ 3 (41)	NHL (55), AML (24), MDS (18)	NMA (100)	Haplo (100)	180-day NRM: 6% 1-year NRM: 12%	1-year OS: 65% 3-year OS: 46%

AML, acute myeloid leukemia; CR1, first complete remission; Haplo, haploidentical donor; HCT-CI, Hematopoietic Cell Transplantation-Comorbidity Index; KPS, Karnofsky Performance Status; MAC, myeloablative conditioning; MDS, myelodysplastic syndrome; MRD, matched related donor; MSD, matched sibling donor; MUD, matched unrelated donor; NHL, non-Hodgkin lymphoma; NMA, non-myeloablative conditioning; NRM, non-relapse mortality; OS, overall survival; RIC, reduced-intensity conditioning; TRM, transplant-related mortality; y, years.

$P < 0.0001$).

The BMT CTN 1102 trial included 384 patients aged 50–75 years with high-risk de novo MDS (IPSS Int-2 or higher) who were eligible for allo-HCT.[50] Patients were assigned based on donor availability. Those with donors received reduced-intensity allo-HCT, while the rest received hypomethylating agents or best supportive care. The median patient age was 66.7 years. Donor types included both MUDs (69.2%) and MRDs (30.8%). The adjusted 3-year OS was 47.9% in the donor group vs 26.6% in the non-donor group ($P = 0.0001$), representing a 21.3% absolute difference. Leukemia-free survival (LFS) was also higher in the donor group (35.8% vs. 20.6%; $P = 0.003$). Although specific results for patients aged ≥ 70 years were not reported, a subgroup analysis of those aged > 65 years showed a significantly higher OS in the donor group. Notably, this survival benefit was not associated with reduced quality of life.[51] A parallel cost-effectiveness study concluded that allo-HCT represents a cost-effective option for patients aged > 65 years with high-risk MDS.[52]

Another randomized trial evaluated patients with AML aged 60–75 years in CR1, comparing consolidation with allo-HCT vs non-HCT therapy.[53] Of the 245 total patients enrolled, 125 were randomized following donor identification: 83 to the HCT group, and 42 to the non-HCT one. The primary endpoint, 5-year restricted mean (RM) LFS, was significantly longer in the HCT group (24.5 months vs. 15.6 months; $P = 0.022$), owing to a lower relapse rate (37.8% vs. 91.1%; $P < 0.0001$). However, 5-year RM OS was similar (HCT: 27.8 months vs. non-HCT: 28.6 months), and NRM was higher with HCT (33.4% vs. 0%). These findings indicate that, although allo-HCT improves disease control, it does not necessarily translate into longer OS in older patients with AML, highlighting the need to balance relapse risk against TRM.

Taken together, these results support the feasibility of allo-HCT in older patients with high-risk AML or MDS, provided they have adequate performance statuses and no major comorbidities and a suitable donor is available. Future studies, including randomized controlled trials that specifically target patients aged ≥ 70 years, as well as research focusing on quality of life and decision-making support, are warranted to further guide optimal treatment selection in this population.

FUTURE DIRECTIONS

Despite encouraging advances in allo-HCT for older patients, several challenges remain that warrant further

Table 3. Allo-HCT vs chemotherapy in older patients, including those aged ≥ 70 years

Study	Number of patients	Median age, y (range)	KPS (%)	Disease (%)	Conditioning (%)	Donor source (%)	TRM/NRM	OS
Ustun, et al.[49] (Retrospective)	Allo-HCT: 431	64.2	< 90% (36), ≥ 80% (64)	AML in CR1(100)	MAC (21), RIC/NAM (79)	MUD (41), MSD (25), CB (24%), MMUD (10)	5-year TRM: 32%	5-year OS: 28/6%
	CT: 211	67.9	< 90% (64), ≥ 80% (36)	AML in CR1(100)	–	–	5-year TRM: 23%	5-year OS: 13.8%
Nakamura, et al.[50] (Prospective)	Allo-HCT: 260 (Donor)	66.3 (50.1–75.3)	< 90% (45.0), 90–100% (55.0)	MDS (100)	RIC (100)	MUD (69.2), MRD (30.8)	1-year TRM: 15.5%	3-year OS: 47.9%
	Non-HCT: 124 (No-donor)	67.3 (50.7–75.1)	< 90% (58.3), 90–100% (41.7)	MDS (100)	–	–	–	3-year OS: 26.6%
Niederwieser, et al.[53] (Prospective)	Allo-HCT: 83	67.3 (IQR 64.7–70.4)	< 90% (45.0), 90–100% (55.0)	MDS (100)	NMA (100)	Unrelated (77.1), Related (22.9)	5-year NRM: 33.4%	5-year RM-OS: 27.8%
	Non-HCT: 42	66.4 (IQR 63.6–69.9)	< 90% (58.3), 90–100% (41.7)	MDS (100)	–	–	5-year NRM: 0% (5-year Relapse: 91.1%)	5-year RM-OS: 28.6%

Allo-HCT, allogeneic hematopoietic stem cell transplantation; AML, acute myeloid leukemia; CB, cord blood; CT, chemotherapy; KPS, Karnofsky Performance Status; MAC, myeloablative conditioning; MDS, myelodysplastic syndrome; MRD, matched related donor; MUD, matched unrelated donor; NMA, non-myeloablative conditioning; NRM, non-relapse mortality; OS, overall survival; RIC, reduced-intensity conditioning; RM-OS, restricted mean overall survival; TRM, transplant-related mortality; y, years.

investigation and innovation. Several specific focus areas have been identified as key to improving outcomes for this growing patient population (Fig. 3).

First, personalized conditioning regimens must be refined by incorporating not only chronological age, but also biological markers of aging, comorbidities, and functional assessments. For example, using tools such as the HCT-CI or biomarker-informed models may better predict tolerability. Second, the development of simplified and pragmatic geriatric screening tools such as gait speed or grip strength assessments can facilitate more widespread usage in routine practice and serve as valuable predictors of post-transplantation morbidity and mortality. Third, GVHD prophylaxis strategies tailored to older patients, such as PTCy-based regimens or $CD34^+$ selection, warrant optimization to balance immune suppression with infection risk and relapse prevention. Fourth, enhancing post-transplantation care through structured interventions (e.g., early physical rehabilitation, nutritional support, or cognitive screening) may promote quality of life and the recovery of independence, which are particularly critical for older recipients. Fifth, the incorporation of patient-reported outcomes into both clinical practice and research is crucial. Understanding trajectories concerning quality of life, functional status, and psychological well-being can better guide patient-centered care. Lastly, real-world data and prospective multicenter studies—particularly those involving older patients—are essential to validate findings from single-center trials and inform evidence-based clinical guidelines for this unique patient population. In this context, a comprehensive assessment of late

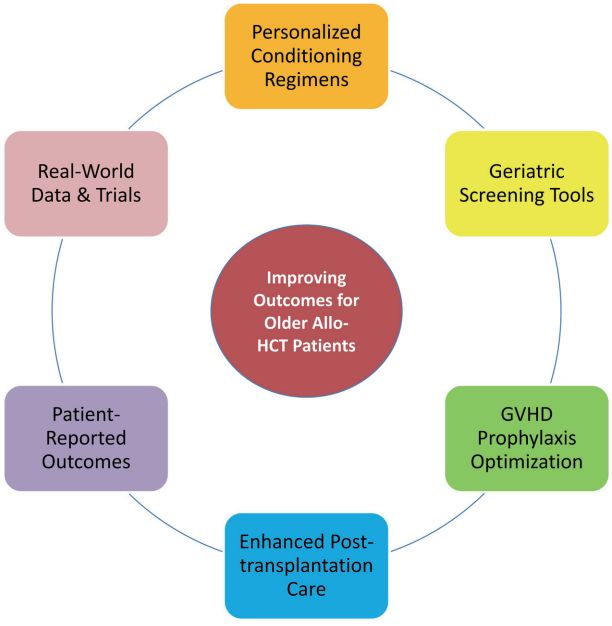

Fig. 3. Future directions regarding allogeneic hematopoietic stem cell transplantation in older patients.

complications—such as chronic GVHD, non-infectious pulmonary complications, cardiotoxicity, and secondary malignancies—is critical for estimating long-term quality of life after allo-HCT.

A multifaceted, age-conscious approach that integrates clinical, biological, functional, and psychosocial dimensions is crucial to the continued evolution of allo-HCT in older patients.

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