

Archives of Hematology and Blood Transfusion

Research Article

Outcomes of Reduced-Intensity Conditioning Regimens in Elderly Patients with Myelodysplastic Syndrome

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Received: 30 September 2025; Accepted: 24 December 2025; Published: 28 March 2026.

Citation of this article: Olejnik I, Gregor A, Chudy V (2026) Outcomes of Reduced-Intensity Conditioning Regimens in Elderly Patients with Myelodysplastic Syndrome. Arch Hematol Blood Transfus, 8(1): 01-06. DOI: [10.5281/zenodo.22818831](https://doi.org/10.5281/zenodo.22818831)

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Abstract

Background: Allogeneic transplantation is the only curative therapy for myelodysplastic syndrome, but myeloablative conditioning has been considered too toxic for the older, comorbid patients in whom the disease most often arises.

Objective: To synthesize evidence on reduced-intensity conditioning (RIC) transplantation in elderly myelodysplastic syndrome, including comorbidity-based selection and outcomes versus hypomethylating agents.

Methods: Narrative synthesis of randomized trials, biologic-assignment studies and comorbidity-index cohorts addressing RIC transplantation, the HCT-specific comorbidity index (HCT-CI), and transplant-versus-hypomethylating comparisons.

Findings: RICMAC showed RIC and myeloablative conditioning produce indistinguishable 10-year survival (54.0% vs 44.4%). Two biologic-assignment trials found transplantation improves overall survival over hypomethylating therapy (48% vs 27%; 37% vs 15%), including in TP53-mutated disease (23% vs 11%). HCT-CI scores of 0, 1-2 and 3+ stratify 2-year non-relapse mortality at 14%, 21% and 41%.

Conclusions: Age alone is a poor basis for excluding older MDS patients from RIC transplantation; comorbidity- and genomic-risk-adjusted selection now allows transplantation with a favorable risk-benefit balance into the eighth decade of life.

Keywords: myelodysplastic syndrome; reduced-intensity conditioning; allogeneic transplantation; comorbidity index; hypomethylating agents

1. Introduction

Myelodysplastic syndrome is, in most series, a disease of the seventh and eighth decades of life, and allogeneic hematopoietic cell transplantation remains the only therapy with curative intent. For decades that fact was largely theoretical for older patients, because myeloablative conditioning carried non-relapse mortality that made the procedure unattractive once a patient passed roughly 55 years of age. Reduced-intensity and nonmyeloablative conditioning regimens were developed to change that calculus, trading some direct antileukemic effect of high-dose chemoradiotherapy for a graft-versus-leukemia effect sustained by the donor immune system, extending transplantation to patients who would otherwise have received only hypomethylating agents or supportive care. A nonmyeloablative approach using fludarabine with low-dose total body irradiation produced durable engraftment and graft-versus-tumor responses in early feasibility work, and subsequent series in acute myeloid leukemia extended median recipient age well past 60 while keeping day-100 non-relapse mortality in the single digits [1].

The question this literature has had to answer is not whether RIC transplantation is feasible in older adults with MDS — established for close to two decades — but whether it outperforms hypomethylating-agent therapy, and for which patients the toxicity trade-off is favorable. The evidence base now includes two prospective biologic-assignment trials, a randomized comparison of conditioning intensity, a validated comorbidity index, and consistent registry data extending transplantation into the eighth decade. This review synthesizes that evidence, organized around patient selection, comparative efficacy against non-transplant therapy, and the toxicity trade-offs that define RIC transplantation in this population.

2. Rationale for reduced-intensity conditioning in older adults with MDS

The rationale for RIC rests on comparative data showing

that conditioning intensity, once the marrow is made receptive to donor engraftment and comorbidity burden is accounted for, contributes less to long-term survival in MDS than in more proliferative acute leukemias. The EBMT RICMAC trial randomized adults with MDS (and MDS-derived AML with less than 20% blasts) between reduced-intensity busulfan-fludarabine and standard myeloablative busulfan-cyclophosphamide; at 10-year follow-up the arms were statistically indistinguishable: overall survival 54.0% after RIC versus 44.4% after myeloablative conditioning ($p=0.15$), relapse-free survival 43.9% versus 44.2% ($p=0.78$), relapse incidence 25.7% versus 25.2% ($p=0.66$), and non-relapse mortality 30.3% versus 30.5% ($p=0.50$) [2]. The original report of that trial additionally showed patients with low-risk cytogenetics did significantly better with the reduced-intensity arm on survival and non-relapse mortality, arguing for tailoring intensity to disease biology rather than defaulting to maximal conditioning [3]. A larger randomized comparison across AML and MDS, BMT CTN 0901, was stopped early after an interim analysis favored myeloablative conditioning on relapse, but overall survival did not differ significantly between arms, and the trial excluded patients unfit for myeloablative conditioning — the population for whom the RIC-versus-no-transplant question is actually being asked [4].

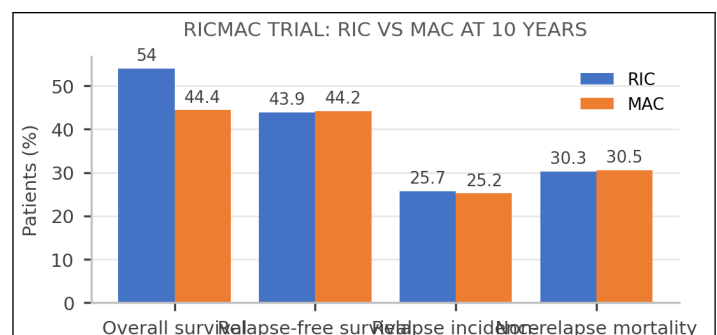


Figure 1: Ten-year RICMAC outcomes: RIC matches myeloablative conditioning (MAC) on overall survival (54.0% vs 44.4%), relapse-free survival (43.9% vs 44.2%), relapse (25.7% vs 25.2%) and non-relapse mortality (30.3% vs 30.5%) [2].

Age-stratified registry analysis reinforces that message. In

a CIBMTR analysis of RIC transplantation for AML in first remission or MDS, three-year overall survival, relapse, and treatment-related mortality did not differ significantly across age deciles from 40 through 70 once comorbidity and disease risk were accounted for, indicating chronological age is a weak discriminator once the regimen has been de-intensified [5]. Earlier feasibility work reached similar conclusions: a nonmyeloablative fludarabine/low-dose-TBI platform produced day-100 non-relapse mortality below 10% and long-term disease control at a median age in the low 60s with substantial comorbidity, establishing the procedure itself, not age, as the limiting factor [1,6]. CALGB 100103, restricted to AML patients in first remission who were 60 or older, showed a structured RIC platform could be delivered across a cooperative-group network with acceptable toxicity at a median age exceeding 65 [7]. A single-center comparison of nonmyeloablative and myeloablative transplantation in patients over 50 found comparable survival despite the nonmyeloablative group being older and more comorbid at baseline, evidence that de-intensified conditioning absorbed, rather than merely deferred, that risk [8].

3. Comorbidity-adjusted patient selection: HCT-CI and beyond

If conditioning intensity has been de-emphasized, patient selection has correspondingly gained weight, and the hematopoietic cell transplantation-specific comorbidity index (HCT-CI) is the instrument that operationalized it. In the original derivation and validation cohort of 1,055 recipients, patients with an HCT-CI score of 0 had two-year non-relapse mortality of 14%, rising to 21% for a score of 1-2 and 41% for a score of 3 or higher, with corresponding two-year survival of 71%, 60%, and 34% respectively, and the index outperformed the Charlson comorbidity index and Karnofsky performance score in multivariable comparison [9]. Applied to a combined Fred Hutchinson/MD Anderson cohort of AML patients in first remission, the same graded relationship held: non-relapse mortality and overall survival tracked the comorbidity

score independently of conditioning intensity and cytogenetic risk [10]. Because chronological age and comorbidity burden are correlated but not interchangeable, Sorror and colleagues subsequently proposed a combined comorbidity-age index, in which each decade of age beyond 40 contributes points alongside the standard comorbidity items; in the validation cohort this composite stratified four-year non-relapse mortality and overall survival more finely than either variable alone [11].

Table 1: Two-year non-relapse mortality (NRM) and overall survival (OS) by HCT-CI score in the original derivation cohort [9].		
HCT-CI score	2-year NRM	2-year OS
0	14%	71%
1-2	21%	60%
3 or higher	41%	34%

Disease-specific risk has to be layered onto comorbidity risk rather than substituted for it. The revised International Prognostic Scoring System (IPSS-R), derived from 7,012 untreated MDS patients, refined cytogenetic risk into five groups and improved discrimination of overall survival and AML evolution compared with the original 1997 IPSS, which used only three cytogenetic categories [12,13]. A molecular update, IPSS-M, incorporated somatic mutation data from more than 2,700 patients and reclassified nearly half of patients relative to IPSS-R, with the largest movement in patients carrying TP53 multi-hit genotypes or SF3B1 mutations — with direct implications for whether a comorbidity-eligible older patient falls into a risk category that justifies transplant-related toxicity [14]. Registry work applying HCT-CI and cytogenetic risk jointly to older MDS recipients of RIC transplantation found both to be independent predictors of survival, identifying a subset of older, higher-comorbidity, adverse-cytogenetics patients for whom transplant-related mortality approached or exceeded the risk of untreated disease [15]. Eligibility should be adjudicated on a comorbidity-and-genomic risk score rather than a birthdate, and decision-analytic

models built on this logic conclude that early transplantation, rather than delayed transplantation at progression, maximizes life expectancy for higher-risk MDS regardless of age within the ranges studied [16,17]. Dose-targeting, rather than simple dose reduction, offers a related route: pharmacokinetically targeted busulfan with cyclophosphamide reduced regimen-related toxicity relative to fixed-dose busulfan, underscoring that "reduced intensity" is individualized intensity rather than one fixed regimen [18].

4. Randomized and registry evidence for transplant versus hypomethylating therapy

The comparison that matters most to an older patient is not RIC versus myeloablative conditioning but RIC transplantation versus a hypomethylating agent, and until recently that comparison had never been tested prospectively. Two biologic-assignment trials — in which patients with a suitable donor were assigned to transplant and those without one continued on medical therapy, removing the selection bias inherent in comparing only patients who agreed to transplant — closed that gap. BMT CTN 1102 enrolled patients aged 50-75 years with intermediate-2 or high-risk MDS by IPSS; at three years, overall survival was 48% in the donor/transplant group versus 27% in the no-donor group, a difference of 21 percentage points, with a multivariable hazard ratio for death of 0.43 favoring transplantation [19]. The advantage was not confined to favorable molecular profiles: a companion genetic analysis of the same cohort found transplantation improved overall survival across high-risk genetic subgroups, including TP53-mutated MDS, where three-year overall survival was 23% with transplantation versus 11% without it, a hazard ratio of 0.26 [19]. A structurally similar French biologic-assignment trial through GFM and SFGM-TC randomized higher-risk MDS patients up to age 70 by donor availability and likewise found benefit favoring transplantation, with four-year overall survival of 37% in patients who proceeded to transplant against 15% in those treated with

hypomethylating therapy or supportive care alone [20].

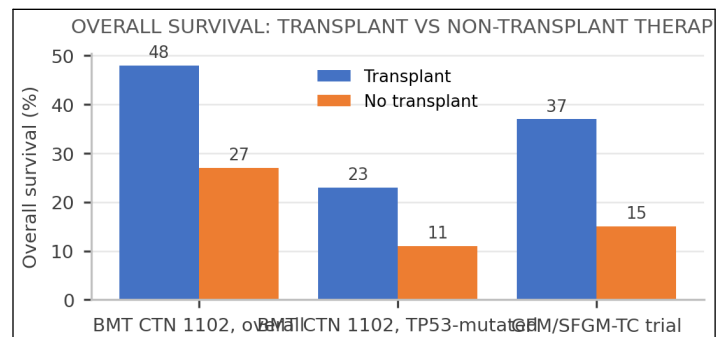


Figure 2: Overall survival, transplant vs non-transplant therapy: 48% vs 27% in BMT CTN 1102 overall, 23% vs 11% in its TP53-mutated subgroup, and 37% vs 15% in the GFM/SFGM-TC trial [19,20].

These trials converge with two decades of decision-analytic literature reaching the same conclusion by different methods. A Markov decision-analysis model incorporating age, comorbidity, and IPSS risk concluded that RIC transplantation conferred a life-expectancy advantage specifically in higher-risk disease, while the advantage reversed for lower-risk MDS, for whom the up-front mortality risk of transplantation outweighed the deferred risk of progression [17]. An earlier decision analysis using the original Fred Hutchinson experience reached the same qualitative conclusion, showing the risk-stratified benefit is not an artifact of newer, gentler conditioning alone but has held across conditioning eras once disease risk is properly stratified [16]. Registry analyses of azacitidine outcomes in higher-risk MDS have shown a median overall survival benefit over conventional care, establishing hypomethylating therapy as a genuine comparator rather than a placebo arm [21].

5. Non-relapse mortality, relapse, and GVHD trade-offs in RIC transplantation

The survival benefit of transplantation is purchased with a specific toxicity profile, and quantifying it is what allows comorbidity-based selection to function. Across the randomized RICMAC comparison, RIC and myeloablative conditioning produced statistically indistinguishable ten-year non-relapse mortality (30.3% versus 30.5%) and relapse incidence (25.7% versus 25.2%), meaning

de-intensifying conditioning did not simply trade transplant-related death for later relapse death, as earlier nonrandomized comparisons had suggested [2]. GVHD remains the dominant chronic toxicity of the RIC platform: with modern regimens incorporating limited-dose antithymocyte globulin, grade III-IV acute GVHD is generally held below 10%, while extensive chronic GVHD still affects roughly 10-30% of long-term survivors and remains the principal driver of late morbidity even when transplant-related mortality is low. In the CALGB 100103 experience, RIC transplantation in AML patients 60 and older produced a favorable non-relapse mortality and disease-free survival profile without excess severe acute GVHD attributable to advanced age [7].

Table 2: Overall survival (OS), non-relapse mortality (NRM) and relapse by conditioning platform and age, including cohorts extending to age 70 and older [2,1].			
Cohort	3-year OS	NRM	Relapse
RICMAC, RIC arm, all ages	54.0%	30.3% (10-yr)	25.7% (10-yr)
RICMAC, MAC arm, all ages	44.4%	30.5% (10-yr)	25.2% (10-yr)
EBMT registry, age >=70	34%	32% (1-yr)	21%
FluCy/TBI-2Gy, age >=70	69%	16%	18%

Extending the age boundary sharpens this trade-off. In an EBMT registry analysis of 313 patients aged 70 or older transplanted for MDS or secondary AML, three-year overall survival was 34%, one-year non-relapse mortality was 32%, and relapse incidence was 21%, worse on the mortality axis than the younger RICMAC cohort, though relapse control was preserved. By contrast, a more selectively conditioned cohort using fludarabine/cyclophosphamide with 2-Gy total body irradiation in patients 70 and older achieved three-year overall survival of 69%, non-relapse mortality of 16%, relapse incidence of 18%, and grade III-IV acute GVHD of only 6%, showing how much outcome variance at advanced age reflects regimen and patient selection rather

than age itself. Renal function is an underappreciated modifier: an estimated glomerular filtration rate below 60 mL/min roughly doubles non-relapse mortality across conditioning intensities, arguing for incorporating renal function alongside comorbidity indices [9,11].

6. Extending eligibility further with age

The upper age boundary for RIC transplantation in MDS has moved steadily over the past fifteen years, tracking improvements in supportive care and comorbidity-based rather than age-based selection. CIBMTR trend analyses documented a sharp rise in transplants performed in patients 70 and older, increasing more than tenfold between the early 2000s and early 2010s, with outcomes in the most recent era approaching those historically reported a full decade younger, attributable to careful comorbidity screening and regimens purpose-built for frailty [22]. A Medicare Coverage with Evidence Development study comparing outcomes across age bands to beyond 65 found survival differences by age decile were modest once transplantation occurred, in contrast to the much larger gap between transplanted and non-transplanted patients within any given band, reinforcing that whether to transplant carries more prognostic weight than how old is too old [23]. Measurable-residual-disease-guided strategies extend this logic post-transplant: preemptive intervention triggered by molecular relapse monitoring reduces overt relapse after transplantation and hypomethylating-agent therapy, preserving survival gained from transplantation in the population least able to tolerate further intensive therapy [24].

Taken together, these extensions describe a field in which age has been substantially displaced as the primary gatekeeper to transplantation, replaced by a composite assessment of comorbidity, cytogenetic and molecular risk, renal function, and donor availability. The open question is less whether RIC transplantation can be delivered safely into the eighth decade of life — the data

above suggest it usually can, in appropriately selected patients — than how consistently that selection process is applied outside the referral centers that generated the evidence.

7. Conclusion

The literature on RIC transplantation in older adults with myelodysplastic syndrome has moved from feasibility to comparative efficacy over roughly two decades. Randomized data show de-intensifying conditioning does not sacrifice relapse control or survival relative to myeloablative regimens [2,3], comorbidity-based tools identify which older patients can tolerate the procedure with an accuracy chronological age alone cannot match [9,11], and two independent biologic-assignment trials now provide randomized-grade evidence that transplantation, when a donor is available, produces a substantial absolute survival benefit over hypomethylating-agent therapy in higher-risk disease, including molecularly adverse subgroups [19,20]. The residual toxicity of RIC transplantation — non-relapse mortality of roughly 15-30% and chronic GVHD in a similar proportion of survivors — is real and age-sensitive, but cohorts extending into the eighth decade show that with careful comorbidity, renal, and genomic risk stratification the procedure remains net favorable well beyond the age thresholds once considered absolute contraindications. An older patient with higher-risk MDS and an available donor should not be excluded from transplant evaluation on age alone; exclusion, when warranted, should follow from a comorbidity and disease-risk assessment the current evidence base now allows clinicians to make with considerably more confidence than a decade ago.

8. References

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