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Review Article

Outcomes of Reduced-Intensity Conditioning Allogeneic Stem Cell Transplantation in Elderly Patients with Acute Myeloid Leukemia

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Summary

Acute myeloid leukaemia is a disease of people in their late sixties and seventies, and transplantation is the only reliably curative option. Reduced-intensity conditioning was developed to make that option available to them. The registry data suggest chronological age is the wrong thing to be selecting on.

Objectives: To review the published evidence on reduced-intensity conditioning allogeneic transplantation in older adults with acute myeloid leukaemia: how outcomes compare with chemotherapy and with myeloablative conditioning, whether age itself predicts outcome once intensity is reduced, and what should be selected on instead.

Material and Methods: Narrative review of randomised trials, registry analyses, comparative cohorts and consensus documents indexed in PubMed and the major haematology and transplantation journals. Studies were eligible if they reported outcomes after reduced-intensity conditioning transplantation in a defined acute myeloid leukaemia population, compared conditioning intensities, or examined the effect of age or comorbidity on transplant outcome. No new patient data were generated and no patients were recruited; every estimate quoted is one published by the original investigators.

Results: Comparing 94 patients aged 60 to 70 transplanted in first remission against 96 treated with chemotherapy on cooperative group protocols, transplantation reduced three-year relapse from 81 to 32 per cent ($p < 0.001$) and improved leukaemia-free survival from 15 to 32 per cent ($p = 0.001$), at the cost of raising non-relapse mortality from 4 to 36 per cent ($p < 0.001$); overall survival favoured transplantation at 37 against 25 per cent but did not reach significance ($p = 0.08$). In the randomised comparison of conditioning intensity, four-year survival was 65 per cent with myeloablative and 49 per cent with reduced-intensity conditioning (HR 1.54, 95% CI 1.07-2.20), but the median age was 55. Among 757 patients receiving reduced-intensity conditioning, three-year survival was 47.8, 45.2, 37.9 and 36.6 per cent across age bands from 50 to 65 and above, with no significant difference ($p = 0.24$), and non-relapse mortality was similarly flat.

Conclusion: Once conditioning intensity is reduced, chronological age adds little to outcome prediction across the range from 50 to over 65. The randomised evidence favouring myeloablative conditioning comes from a population whose median age was 55 and does not settle the question for older patients.

Abbreviations: AML – Acute Myeloid Leukaemia, MDS – Myelodysplastic Syndrome, allo-HCT – Allogeneic Haematopoietic Cell Transplantation, RIC – Reduced-Intensity Conditioning, MAC – Myeloablative Conditioning, NMA – Non-Myeloablative, NRM – Non-Relapse Mortality, TRM – Treatment-Related Mortality, LFS – Leukaemia-Free Survival, GVHD – Graft-Versus-Host Disease, HCT-CI – HCT Comorbidity Index, CR1 – First Complete Remission, PBSC – Peripheral Blood Stem Cells.

Keywords: *Acute Myeloid Leukaemia; Allogeneic Transplantation; Reduced-Intensity Conditioning; Elderly; Non-Relapse Mortality*

Introduction

Acute myeloid leukaemia is predominantly a disease of older adults, with a median age at diagnosis around 68 years and five-year survival in that age group that remains poor [1,2]. Allogeneic transplantation is the only reliably curative treatment for intermediate and adverse-risk disease, and for most of the history of the procedure it was not offered to the patients who most commonly have the illness [3,4].

The reason was non-relapse mortality. Myeloablative conditioning delivers a strong antileukaemic effect at a toxicity cost that older or comorbid patients frequently could not survive [5,6]. Reduced-intensity and non-myeloablative regimens were developed to shift that balance, relying more on the graft-versus-leukaemia effect and less on the conditioning itself [7,8,9].

The strategy worked in the sense that transplant volumes in older patients rose substantially over two decades [4,10]. Whether it works in the sense that matters, producing better survival than the alternatives, is a separate question, and it divides into two: how transplantation compares with chemotherapy in this age group, and whether reduced intensity is the right choice for those who are transplanted [11,12].

This review sets out what the comparative data show, examines whether age itself predicts outcome once intensity is reduced, and considers what selection criterion the evidence actually supports.

Material and Methods

Search strategy: PubMed and the archives of the major haematology and transplantation journals were searched for studies of reduced-intensity transplantation in older patients with acute myeloid leukaemia. Search terms combined acute myeloid leukaemia and elderly or older with allogeneic transplantation, reduced-intensity conditioning, non-myeloablative, non-relapse mortality, comorbidity index and graft-versus-leukaemia. Reference lists of retrieved trials and registry reports were screened by hand.

Eligibility: Studies were included if they reported outcomes after reduced-intensity conditioning transplantation in a defined acute myeloid leukaemia or myelodysplastic syndrome population, compared conditioning intensities or compared transplantation with chemotherapy, or examined the contribution of age or comorbidity. Studies including myelodysplastic syndrome alongside acute myeloid leukaemia are identified as such.

Data extraction and handling: Design, cohort size, age range, conditioning regimen, disease status at transplant and reported outcome estimates were extracted as published. Age range and median age are reported alongside every figure, because the central question in this field is whether findings from cohorts with a median age in the mid-fifties transfer to patients over 65. No pooling or re-analysis was performed and no patient-level data were obtained. Figures 1 to 4 and Tables 1 to 3 reproduce published values only. This is a narrative synthesis and was not registered as a systematic review.

Results

Transplant against chemotherapy in the sixties: The most direct comparison matched 94 patients aged 60 to 70 with acute myeloid leukaemia in first remission who received reduced-intensity

transplantation, reported to an international registry, against 96 treated with induction and post-remission chemotherapy on cooperative group protocols. All had been in remission at least four months [11].

Transplantation reduced three-year relapse from 81 to 32 per cent ($p < 0.001$) and improved leukaemia-free survival from 15 to 32 per cent ($p = 0.001$). It raised non-relapse mortality from 4 to 36 per cent ($p < 0.001$). Overall survival was longer after transplantation at 37 against 25 per cent, but the difference did not reach significance ($p = 0.08$) (Figure 1) [11].

Those four numbers contain the entire problem. The antileukaemic effect is large and unambiguous, more than halving relapse. The toxicity cost is equally large, and the two very nearly cancel. The investigators concluded that strategies reducing non-relapse mortality would be where meaningful improvement in overall survival lies [11].

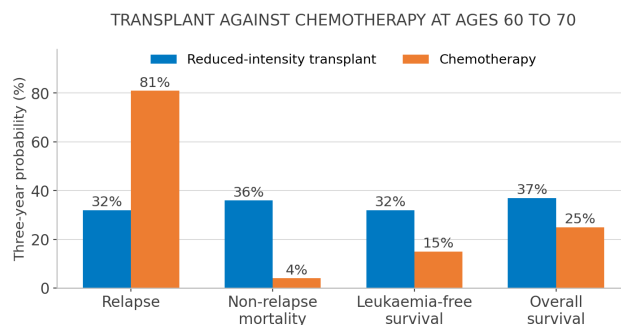


Figure 1: Reduced-intensity transplantation against chemotherapy in patients aged 60 to 70 in first remission [11]

What the randomised comparison of intensity shows:

Conditioning intensity was tested directly in a randomised trial enrolling patients aged 18 to 65 with fewer than 5 per cent marrow blasts, assigned to myeloablative ($n = 135$) or reduced-intensity conditioning ($n = 137$) before transplantation from a matched donor [12]. Accrual stopped early at 272 of a planned 356 because of a marked imbalance in relapse rates.

At 18 months, myeloablative conditioning gave longer relapse-free survival with no significant difference in overall survival [12]. With longer follow-up the survival difference emerged: four-year overall survival was 65 per cent with myeloablative and 49 per cent with reduced-intensity conditioning, and the hazard ratio for death with reduced intensity was 1.54 (95% CI 1.07-2.20, $p = 0.02$) (Figure 2) [13].

The critical detail is the population. Median age was 55 and the upper limit was 65, so the trial that most clearly favours myeloablative conditioning barely includes the patients this review is about [12,13]. Two other randomised comparisons were similarly stopped before completion and were underpowered for their primary endpoints [13].

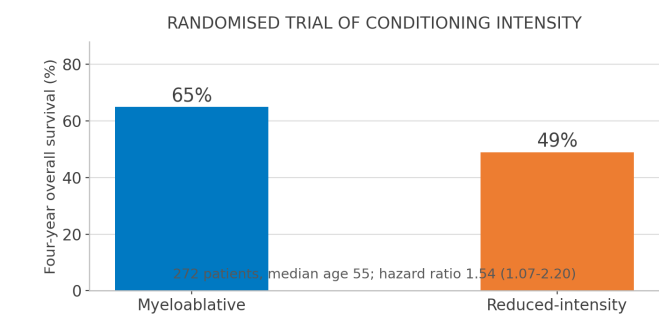


Figure 2: Four-year overall survival by conditioning intensity in the randomised comparison [12,13]

Study	n	Population	Principal reported finding
Aoudjhane et al. 2005 [14]	—	Over 50	RIC and MAC compared in sibling transplants
McClune et al. 2010 [15]	1,080	Over 40	Age not a dominant prognostic factor after RIC
Farag et al. 2011 [11]	190	60-70	Relapse 32% against 81%; NRM 36% against 4%
Sengsayadeth 2015 [9]	Review	Adults in CR	EBMT review of RIC in complete remission
Aoki et al. 2016 [16]	757	Over 50	Survival flat across age bands, p = 0.24
Scott et al. 2017 [12]	272	Median age 55	MAC longer relapse-free survival; stopped early

Table 1: Principal studies reviewed, with population and the finding as reported by the original investigators

Age stops predicting once intensity is reduced: A nationwide retrospective study examined 757 patients over 50 who received reduced-intensity conditioning, divided into four age bands: 89 aged 50 to 54, 249 aged 55 to 59, 301 aged 60 to 64 and 118 aged 65 or above. Three-year overall survival was 47.8, 45.2, 37.9 and 36.6 per cent respectively, with no significant difference across bands (p = 0.24) (Figure 3) [16].

Non-relapse mortality followed the same pattern, at 24.0, 22.8, 29.2 and 27.6 per cent, with the highest figure in the 60 to 64 band rather than in the oldest group (Figure 4) [16]. Analysis of 1,080 patients over 40 reported to an international registry reached compatible conclusions, finding that age was not the dominant determinant of long-term outcome after reduced-intensity conditioning [15].

The pattern extends beyond 70. Comparing 713 patients aged 70 or above against 16,161 aged 50 to 69, the incidences of acute and chronic graft-versus-host disease and of relapse were similar between age groups on multivariable analysis, despite the older group carrying more secondary disease, more active disease at transplant and lower performance status [17].

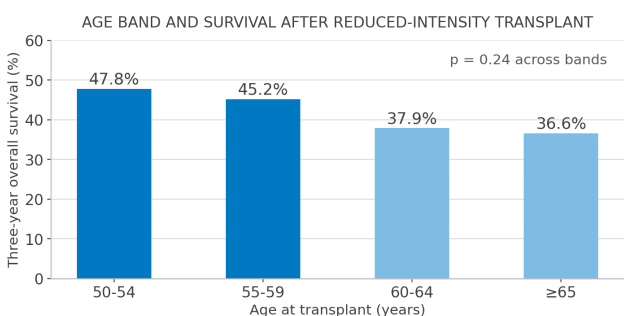


Figure 3: Three-year overall survival by age band after reduced-intensity conditioning [16]

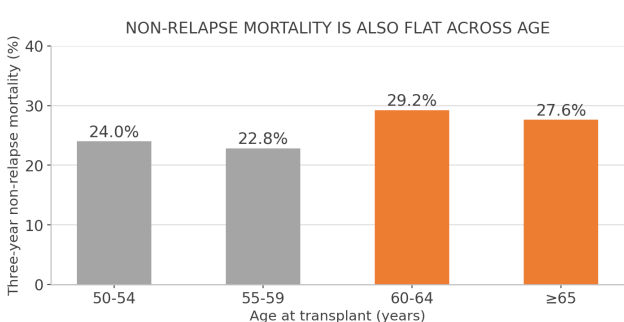


Figure 4: Three-year non-relapse mortality across the same age bands [16]

What does predict outcome: If age does not, comorbidity does. The haematopoietic cell transplantation comorbidity index was developed specifically to quantify pre-transplant organ dysfunction and predict non-relapse mortality, and it performs better than age for that purpose [18]. Scoring systems combining recipient age above 60 with a comorbidity index of 2 or more and graft source have been proposed to identify patients in whom reduced intensity meaningfully lowers non-relapse mortality [19].

Disease status is the other major determinant. Remission status at transplant, and measurable residual disease within remission, both predict post-transplant outcome [20,21], and residual disease-negative remission before conditioning is associated with better survival than remission alone [22]. Conditioning intensity interacts with peritransplant residual disease dynamics, which is one mechanism by which the intensity question and the disease burden question are connected [23].

Graft characteristics contribute independently. Peripheral blood stem cells were associated with superior overall survival (HR 0.67, p = 0.002) and leukaemia-free survival (HR 0.71, p = 0.008) against bone marrow in patients aged 65 and above [10], and post-remission consolidation before transplantation has been examined as a further modifiable variable [24].

Variable	Predicts outcome?	Evidence
Chronological age	Weakly or not at all	Survival flat 50 to over 65, p = 0.24 [15,16,17]
Comorbidity index	Yes	Developed to predict non-relapse mortality [18,19]
Residual disease at transplant	Yes	Predicts relapse and survival after HCT [20,21,22]
Conditioning intensity	Yes, in younger patients	MAC better at median age 55; unresolved above 65 [12,13]
Graft source	Yes	Peripheral blood superior to marrow, HR 0.67 [10]

Table 2: What predicts outcome after reduced-intensity transplantation, and what does not

The graft-versus-leukaemia effect does the work: The rationale for reducing intensity rests on the assumption that the allograft itself, rather than the conditioning, provides the durable antileukaemic effect. That was demonstrated directly in patients receiving reduced-intensity conditioning, where responses occurred in a pattern attributable to donor immunity rather than to the preparative regimen [8]. If the assumption holds, lowering intensity should cost relapse control only modestly.

The randomised data suggest the cost is real but bounded. Relapse was higher with reduced intensity, which is what stopped accrual early, yet the survival difference took four years to emerge and the trial had been designed around an 18-month endpoint [12,13]. In myelodysplastic syndrome the comparison has been made separately with broadly similar conclusions [19].

Reducing non-relapse mortality is the lever: If the value of transplantation in this age group hinges on non-relapse mortality, then the modifiable parts of it deserve attention. Graft source is one, with peripheral blood stem cells outperforming marrow in the oldest cohort [10]. Donor selection is another, and the availability of haploidentical and mismatched unrelated donors has widened access without the outcome penalty once expected [4,17].

Disease burden at transplant is the third and probably the largest. Residual disease-negative remission before conditioning predicts better survival than remission alone [22], and the interaction between conditioning intensity and peritransplant residual disease dynamics suggests that deeper remission may partly substitute for the intensity that older patients cannot tolerate [23,25]. Post-remission consolidation before transplant has been examined with that logic in mind [24].

The sequence implied is different from current practice. Rather than choosing conditioning intensity on age and then accepting whatever disease burden the patient arrives with, the evidence points toward maximising depth of remission first and then selecting

intensity on comorbidity [18,22,23]. Neither step requires anything unavailable.

Decision point	Current basis	What the evidence supports
Whether to transplant	Often age-anchored	Comorbidity index and disease risk [18,19]
Conditioning intensity	Age and fitness	Comorbidity; randomised data only to age 65 [12,13]
Timing relative to remission	Availability of donor	Depth of remission by residual disease [20,22]
Graft source	Centre preference	Peripheral blood over marrow above 65 [10]

Table 3: Transplant decisions in older patients and the basis the evidence supports for each

Discussion

The evidence supports a clear conclusion about selection and an unresolved one about conditioning. On selection, chronological age performs poorly. Three-year survival differed by eleven percentage points across a fifteen-year age span and the difference was not significant [16], and the same pattern holds in a larger registry cohort [15] and above age 70 [17]. Comorbidity, disease status and residual disease all predict better [18,20,21].

On conditioning intensity the answer depends on which population is being asked about. The randomised trial found four-year survival of 65 against 49 per cent favouring myeloablative conditioning, which is a large difference [13]. Its median age was 55 and its ceiling 65, so it describes patients at the younger end of what this review covers, and it cannot be extrapolated to a 72-year-old without assuming exactly the thing the age data call into question.

Why the survival comparison so nearly cancels

Transplantation in the sixties cut relapse from 81 to 32 per cent and raised non-relapse mortality from 4 to 36 per cent [11]. Those two effects are of similar magnitude in opposite directions, which is why overall survival differed by twelve points and missed significance. The clinical implication is that the value of transplantation in this age group is highly sensitive to the non-relapse mortality a given centre achieves.

That reframes the decision. Rather than asking whether an older patient should be transplanted in the abstract, the question is whether their individual non-relapse mortality risk, estimated from comorbidity and performance status, is low enough that the relapse reduction survives the toxicity [18,19]. For a fit 68-year-old with adverse-risk disease the arithmetic favours transplantation; for a comorbid 62-year-old it may not.

Study limitations

The limitations belong to the underlying literature. The comparison of transplantation against chemotherapy is a registry-to-trial comparison rather than a randomised one, and transplant recipients were younger and reached remission later, so selection effects operate in both directions [11]. The randomised trial of conditioning intensity stopped early and was underpowered for the endpoints on which it is now cited [12,13]. Age-band analyses are retrospective, and patients selected for transplant at 70 are not comparable to unselected 70-year-olds with the disease [15,16,17]. Conditioning regimens grouped as reduced-intensity differ substantially in actual intensity, and the boundary with non-myeloablative regimens is not standardised across registries [7,9,10]. And supportive care, graft-versus-host disease prophylaxis and donor selection all changed materially across the periods these cohorts span [4,24].

Two gaps deserve naming. No randomised comparison of conditioning intensity has been conducted specifically in patients above 65, which is the population in whom the question is most pressing [12,13]. And no study reviewed here reports outcomes stratified simultaneously by comorbidity index and conditioning intensity, which is what would allow the two decisions to be made together rather than sequentially [18,19].

Conclusion

Reduced-intensity conditioning has made transplantation available to older adults with acute myeloid leukaemia, and in the sixties it more than halves relapse, from 81 to 32 per cent, while raising non-relapse mortality from 4 to 36 per cent, so overall survival improves by twelve points without reaching significance. Across age bands from 50 to over 65, three-year survival and non-relapse mortality are both essentially flat, and the pattern persists above 70. The randomised trial favouring myeloablative conditioning, at four-year survival of 65 against 49 per cent, enrolled patients of median age 55 and does not answer the question for older ones. What the evidence supports is selecting on comorbidity, disease status and residual disease rather than on the year of birth.

The unanswered question is narrow and testable. A randomised comparison of conditioning intensity restricted to patients above 65, stratified by comorbidity index, would settle whether the myeloablative advantage seen at median age 55 persists or reverses in the population that actually has this disease [12,13,18]. Until that exists, intensity is being chosen for older patients by extrapolation from younger ones.

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Conflict of Interest

The authors declare no competing interests.

Ethics Statement

This article reviews previously published studies only. No new patient data were collected and no participants were recruited, so ethical approval was not required.

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