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ELEVENTH ANNUAL MEETING

Sequential Allogeneic Stem Cell Transplantation (alloSCT) After Venetoclax (Ven)-Based Therapy for Relapsed or Refractory Acute Myeloid Leukemia (R/R AML) or Myelodysplastic Syndrome With Excess Blasts 2 (MDS-EB2)

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INTRODUCTION

It remains unclear whether complete remission (CR) is necessary to proceed to alloSCT for R/R AML or MDS-EB2, especially in the era of targeted therapy. Venetcolax is known to induce fast and deep remissions, while causing significant cytopenias.

AIM

To determine the safety and efficacy of sequential alloSCT during the aplasia period after Ven-based salvage therapy without documented CR for patients with R/R AML or MDS-EB2.

METHOD

- Observational, single-center, retrospective study (2019–2023).
- 15 R/R patients underwent sequential alloSCT after Ven-based salvage therapies.

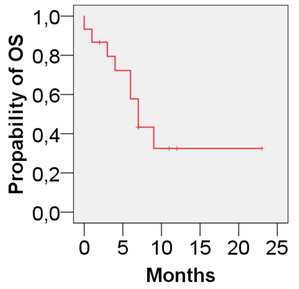
Characteristics	
Diagnosis, n/N (%)	
AML	11/15 (73.3)
MDS-EB2	4/15 (26.7)
Median age, years (range)	55 (34–72)
ECOG (range)	1 (0–2)
European LeukemiaNet 2022 risk group, n/N (%)	
Adverse	12/15 (80.0)
Favorable/intermediate	3/15 (20.0)
Median number of previous treatment lines, n (range)	1 (1–7)
Prior to sequential alloSCT patients received*:	
triplet ACTIVE	12/15 (80.0)
FLAMSA + Ven	1/15 (6.7)
FLAG-Ida + Ven	1/15 (6.7)
decitabine + Ven	1/15 (6.7)

Table 1. *Patients' characteristics.*
3 patients had prior Ven exposure;
1 patient had relapsed post alloSCT.

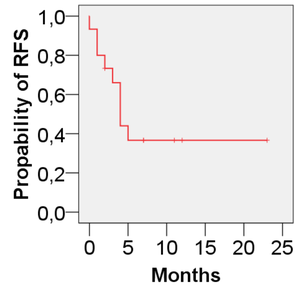
** **Triplet ACTIVE** - Ven, low-dose cytarabine, actinomycin D; **FLAMSA** - fludarabine, amsacrine, cytarabine; **FLAG-Ida** -fludarabine, high-dose cytarabine, idarubicin, granulocyte-colony stimulating factor.*

RESULTS

- After Ven-based cytoreduction, all patients (morphologic leukemia-free state, 13; stable disease, 2) proceeded to sequential conditioning (reduced-intensity, 13; myeloablative, 2) and alloSCT. One patient died of sepsis during conditioning and was excluded from further analysis.
- One month after alloSCT, 13/14 patients were in CR (n=7) or CR with incomplete count recovery (n=6); 1 patient relapsed.
- Measurable residual disease (MRD) negativity was confirmed in 6/14.
- Sixty-day mortality was 7%.
- At data cutoff, 6 patients were alive in CR (MRD–, n=3).



Scheme 1. *Median OS was 7.0 months (95 % CI: 5.2–8.8 months); 12-month OS was 32.5 %. .*



Scheme 2. *Median RFS was 4.0 months (95% CI: 2.8–5.2 months); 12-month RFS was 36.7 %.*

Adverse events	n/N (%)
sepsis	5/15 (33.3)
febrile neutropenia	5/15 (33.3)
pneumonia	2/15 (13.3)
invasive fungal infection	2/15 (13.3)

Table 2. *Adverse events of the treatment.*

CONCLUSIONS

Sequential allotransplantation after Ven-based therapies resulted in short-term remissions and modest OS in this real-life, high-risk R/R AML or MDS-EB2 group.

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