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615.ACUTE MYELOID LEUKEMIAS: COMMERCIALLY AVAILABLE THERAPIES, EXCLUDING TRANSPLANTATION AND CELLULAR IMMUNOTHERAPIES

Three-Day Decitabine Combined with Venetoclax in Patients with Newly Diagnosed or Relapsed/Refractory AML

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INTRODUCTION

Venetolax (VEN) combined with azacytidine (AZA), decitabine (DEC), and low-dose cytarabine has been the first-line therapy for newly diagnosed (ND) AML patients who are elderly or unfit for intensive chemotherapy. Previous reports shown that ten-day DEC with VEN (DEC 10-VEN) was an effective therapy for newly diagnosed elderly patients. Though higher remission rate in ND AML compared five-day DEC with VEN, DEC 10-VEN induced prolonged myelosuppression. Therefore, optimizing the combination of DEC with VEN is still being explored.

In this study, we retrospectively collected and analyzed the clinical data of three-day DEC combined with VEN (DEC 3-VEN) (**Tianjin-Handan regimen**) in twelve patients with ND or relapsed/refractory (R/R) AML who were elder or ineligible for intensive chemotherapy to evaluate the efficacy and safety of the regimen.

METHODS

Retrospectively collected and analyzed the clinical data of twelve ND or R/R AML patients treated with three-day DEC combined with VEN as induction therapy between July 2022 and June 2023 at 4 hospitals in china.

The induction regimen consisted of oral Ven (100mg Day 1; 200mg Day 2; 400mg Day 3-9 or 3-14), intravenous DEC (20mg/m²/q8h, days 4-6), sorafenib were administered (600mg days 8-14) in relapsed/refractory patients with FLT3/ITD. The primary objective was composite complete response rate (CR + CRi) and the secondary objectives was safety.

RESULTS

Until June 2023, twelve patients with *de novo* or relapsed/refractory AML were treated with three-day DEC combined with VEN as induction therapy. The median age of the twelve patinets was 67 years (range, 32-76), with 58.3% (7/12) male. Seven (58.3%) patients were ND AML, and five patients (41.7%) were R/R AML. The clinical data and treatment information of the patients are shown in table 1.

The composite complete response rate (CR + CRi) after one cycle of induction was 100% (CR 10/12, CRi 2/12). For patients who achieved CR or CRi, MRD negative rate was 77.8% (7/9) by flow cytometry. None of patients died during the induction therapy.The median time to recovery of the absolute white blood count (WBC) to $\geq 1.0 \times 10^9$/L and the platelet count to $\geq 20 \times 10^9$/L after induction was 13 (range: 7-25) and 15 days (range: 0-27), respectively.

CONCLUSION:

DEC 3-VEN is a highly effective and safe induction therapy for ND and R/R AML patients who are elderly or unfit for intensive chemotherapy. Further study with more patients will be updated.

Keywords: Venetoclax; decitabine; AML; induction treatment.

Disclosures No relevant conflicts of interest to declare.

Table 1. Clinical characteristics, treatment and outcome of the 12 AML patients

No	Sex	Age (y)	Disease State	WBC (10^9/L)	BM blast cell (%)	ELN (2022)	Mutation (NGS)	Treatment	Ven Days	Response	MRD (by flow cytometry)
1	M	37	relapsed	8.0	7.5%	unkown	unkown	Ven+DEC	9	CR	0.34
2	M	60	relapsed	5.0	8.0%	intermediate	IDH2, DNMT3A, PTPN11, ETV6	Ven+DEC	9	CR	neg
3	F	32	newly diagnosed	3.11	58.5%	Favorable	FLT3/TKD, NF1, NPM1, IDH1, NRAS	Ven+DEC	9	CR	neg
4	M	69	refractory	168.17	21.0%	intermediate	IDH2, NRAS, KNAS	Ven+DEC	14	CR	not tested
5	F	76	newly diagnosed	206.37	59.5%	Favorable	FLT3/TKD, NPM1, DNMT3A, JAK3	Ven+DEC	14	CR	not tested
6	M	71	newly diagnosed	109.38	81.0%	Adverse	FLT3/ITD, c-kit, WT1	Ven+DEC	14	CR	neg
7	F	66	newly diagnosed	14.39	76.0%	intermediate	TET2, NRAS, PHF6, WT1	Ven+DEC	9	CRi	not tested
8	F	67	relapsed	1.89	33.0%	unkown	unkown	Ven+DEC	9	CR	0.62
9	M	72	newly diagnosed	31.0	65.0%	Adverse	RUNX1, FLT3/ITD, TET2	Ven+DEC	9	CR	neg
10	F	71	newly diagnosed	123.79	73.0%	Favorable	NPM1, DNMT3A, IDH2 N-RAS	Ven+DEC	9	CR	neg
11	M	73	newly diagnosed	26.57	52.0%	Adverse	ASXL1, SRSF2, TET2, STAG2, DDX3X	Ven+DEC	14	CRi	neg
12	M	67	refractory	1.14	81.5%	intermediate	FLT3/ITD, DNMT3A	Ven+DEC+ sorafenib	14	CR	neg

Figure 1

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