

Activity of decitabine combined with all-*trans* retinoic acid in oligoblastic acute myeloid leukemia: results from a randomized 2x2 phase II trial (DECIDER)

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Supplementary Table 1

Variable	ATRA	no ATRA	Total
Patients			
total (%)	22 (39.3)	34 (60.7)	56
VPA			
No	C: 9 (40.9)	A: 13 (38.2)	22 (39.3)
Yes	D: 13 (59.1)	B: 21 (61.8)	34 (60.7)
Sex			
female	5 (22.7)	8 (23.5)	13 (23.2)
male	17 (77.3)	26 (76.5)	43 (76.8)
Age, years			
Median (range)	75 (61-83)	73.5 (61-88)	75 (61-88)
< 75yrs	7 (31.8)	20 (58.8)	27 (48.2)
>= 75yrs	15 (68.2)	14 (41.2)	29 (51.8)
ECOG PS			
0	7 (31.8)	13 (38.2)	20 (35.7)
1	12 (54.6)	17 (50)	29 (51.8)
2-3	3 (13.6)	4 (11.8)	7 (12.5)
Comorbidity index *			
0	6 (27.3)	10 (29.4)	16 (28.6)
1-2	7 (31.8)	6 (17.7)	13 (23.2)
>= 3	9 (40.9)	18 (52.9)	27 (48.2)
Prior hematologic			
no	8 (36.4)	10 (29.4)	18 (32.1)
yes	14 (63.6)	24 (70.6)	38 (67.9)
Treatment related			
No	19 (86.4)	31 (91.2)	50 (89.3)
yes	3 (13.6)	3 (8.8)	6 (10.7)
Variable	ATRA	No ATRA	Total
WBC per μl **			
Median 1000/ μ L (range)	3.4 (0.5-52.6)	2.75 (0.8-43.2)	3.25 (0.5-52.6)
<5	14 (63.6)	23 (67.7)	37 (66.1)
5-29	6 (27.3)	10 (29.4)	16 (28.6)
>= 30	2 (9.1)	1 (2.9)	3 (5.4)
Platelet count per μl			
<50	7 (31.8)	19 (55.9)	26 (46.4)
>=50	15 (68.2)	15 (44.1)	30 (53.6)
Serum LDH, U/L			
<300	17 (77.3)	22 (64.7)	39 (69.6)
>=300	5 (22.7)	12 (35.3)	17 (30.4)
Hemoglobin, g/dL			
<8	6 (27.3)	5 (14.7)	11 (19.6)
>= 8	16 (72.7)	29 (85.3)	45 (80.4)
2010 European LeukemiaNet genetic risk classification			
Favorable	0 (0.0)	2 (5.9)	2 (3.6)
Intermediate I	10 (45.5)	12 (35.3)	22 (39.3)

Intermediate II	7 (31.8)	7 (20.6)	14 (25)
Adverse	3 (13.6)	11 (32.4)	14 (25)
Not available	2 (9.1)	2 (5.9)	4 (7.1)
BM Blasts %			
median (range)	24.3 (20-30)	24.8 (20-30)	24.6 (20-30)

Supplementary Table 2

Response	ATRA (n=22)	No ATRA (n=34)	Total (n=56)
CR	2 (9.1)	4 (11.8)	6 (10.7)
CRi	4 (18.2)	3 (8.8)	7 (12.5)
PR	1 (4.6)	0 (0.0)	1 (1.8)
ALE	4 (18.2)	6 (17.7)	10 (17.9)
SD	6 (27.3)	4 (11.8)	10 (17.9)
PD	5 (22.7)	17 (50)	22 (39.9)

Supplementary Table 1: Patients and disease characteristics treated with DEC + ATRA (+/- VPA)

vs. DEC - ATRA (+/- VPA). Abbreviations: DEC: decitabine, ATRA: all-*trans* retinoic acid, VPA: valproate, ECOG PS: Eastern Cooperative Oncology Group performance status, AML: acute myeloid leukemia, WBC: white blood cell count, LDH: serum lactate dehydrogenase.

*: According to the hematopoietic cell transplantation index (HCT-CI)

**: WBC at time of screening prior to cytoreduction as per protocol

Supplementary Table 2: Responses of patients treated with DEC + ATRA (+/- VPA) or DEC -

ATRA (+/- VPA). Abbreviations: ATRA: all-*trans* retinoic acid, CR: complete response, CRi: complete remission with incomplete hematologic recovery, PR: partial response, ALE: anti-leukemic effect, SD: stable disease.