

Table of Cytarabine Based Consolidation Protocols for Elderly Patients with AML

Reference	Study format	Consolidation option 1	Consolidation Option 2	Survival	PFS
[1]	Age > 60 Prospective Phase 2	ARA-C 1g/m ² bd (D1,3 and 5) x 4 cycles (n=47)	<i>No comparison arm</i>	Median OS 10.6 months	Median DFS 15.5 months
[4]	Age > 65 Prospective RCT	DNR 45mg/m ² D1-3 ARA-C 100mg/m ² D1-7 x 2 cycles Followed by ARA-C 1.5g/m ² daily (D1-4) x 4 cycles (n=141)	DNR 30mg/m ² D1-3 ARA-C 75mg/m ² D1-7 x 2 cycles Followed by ARA-C 1g/m ² daily (D1-3) x 4 cycles (n=156)	5 year median OS 24 vs. 39 months (p<0.001)	Median PFS 23 vs. 35 months (p<0.001)
[5]	Age > 65 Prospective RCT	<i>“Ambulatory”</i> : DNR 45mg/m ² D1 (or IDA 9mg/m ² D1) With subcut ARA-C 60mg/m ² bd D1-5 (n=81)	<i>“Intensive”</i> : DNR 45mg/m ² D1-4 or IDA 9mg/m ² D1-4 With infusion ARA-C 200mg/m ² D1-7 (n=68)	2 year OS 56% vs. 37% In favour of ambulatory consolidation	2 year DFS 28% vs. 17% In favour of ambulatory consolidation
[6]	Age 61-80 Prospective RCT	<i>Intravenous</i> IDA 8mg/m ² D1, 3,5 (IV) Etop 100mg/m ² D1-3 (IV) ARA-C infusion 100mg/m ² D1-5 (IV) (n=166)	<i>Oral</i> : IDA 20mg/m ² D1, 3,5 Etop 100mg/m ² bd D1-3 ARA-C 50mg/m ² subcut BD D1-5 (n=165)	Median OS 15.7 months (Oral) vs. 17.8 months (IV) (p=0.19)	Median DFS 9 months (oral) vs. 10.4 months (IV) (p=0.15)
[2]	Age > 60 subgroup Prospective RCT	ARA-C infusion 100mg/m ² D1-5	ARA-C infusion 400mg/m ² D1-5	Median DFS was 12 months (equal between groups)	OS at 4 years was 9% (equal between groups)
[7]	Age > 60 CBF AML only	ARA-C subcutaneous + oral MTX and 6MP	IV bolus ARA-C doses higher than 500mg/m ² for “at least 2 days” (n=48)	No difference in survival between	LFS 26 months (IV ARA-C) vs. 14 months (subcutaneous ARA-C)

NB: ARA-C: Cytarabine, DNR: Daunorubicin, IDA: Idarubicin, Etop: Etoposide, MTX: Methotrexate, 6MP: 6 Mercaptopurine, DFS: Disease free survival, LFS: leukemia free survival