



Therapeutic effects of different regimens for induction therapy in elderly patients more than 50 years old with newly diagnosed acute myeloid leukaemia

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Background: Acute myeloid leukaemia (AML) is a highly heterogeneous disease that commonly occurs in elderly cohorts. To date, there is still no standard induction therapy for elderly AML patients, and they experience low complete remission rates and short survival time.

Methods: We retrospectively analysed the clinical data of 86 AML patients aged ≥ 50 years admitted at the First Affiliated Hospital of Chongqing Medical University and the Second Affiliated Hospital of Chongqing Medical University. The patients were divided into three groups, idarubicin plus cytarabine (IA) group; decitabine, cytarabine, aclarubicin, and granulocyte stimulating factor (D-CAG) group; and daunorubicin plus cytarabine (DA) group. Patients' adverse reactions, complete remission (CR) rates, overall response (OR) rates, and long-term survival conditions were compared.

Results: The CR rates of the IA group, D-CAG group, and DA group were 47.4%, 54.3%, and 42.9%, respectively ($P=0.659$), and the OR rates were 52.6%, 71.4%, and 71.4%, respectively ($P=0.311$). The median survival time of the IA group was 12.47 months, while that of the D-CAG group was 28.6 months ($P=0.180$). All of the above results had no statistical difference. However, the D-CAG group had lower incidence of haematological adverse reactions, fever, and gastrointestinal response of grade II or above than the DA Group and IA group.

Conclusions: This study showed that IA regimen, D-CAG regimen and DA regimen have similar therapeutic effect on patients aged ≥ 50 years with newly diagnosed AML while D-CAG regimen shows fewer adverse reactions. Age and bone marrow blasts at initial diagnosis are risk factors for prognostic.

Keywords: Acute myeloid leukemia (AML); cytarabine; decitabine; elderly; induction therapy

Submitted Aug 24, 2018. Accepted for publication Dec 07, 2018.

doi: 10.21037/tcr.2018.12.21

View this article at: <http://dx.doi.org/10.21037/tcr.2018.12.21>

Introduction

Acute myeloid leukaemia (AML) is the most common malignancy of the blood and is highly heterogeneous. The incidence increases with age (1-3), and age is an

independent prognostic factor for AML (1,4-6). Despite the advances in the treatment of AML (7), elderly patients still experience poor prognosis due to poor performance status and comorbidities and are more likely to carry a

naturally drug-resistant gene. Elderly patients who achieve complete remission are faced with short survival time and high relapse rates. At present, there remains no standard induction therapy for elderly patients with AML, and they are suggested to participate in clinical trials. Many studies have shown that hypomethylating agents, such as decitabine, are an effective treatment option for elderly AML patients, especially in poor-risk cohorts (5,8). Several low-intensity decitabine-based chemotherapy regimens have emerged gradually. This study retrospectively analysed three commonly used regimens to provide evidence for clinical treatment.

Methods

Patients and inclusion criteria

A total of 86 newly diagnosed AML (non-M3) patients who were admitted between September 01, 2012 and June 30, 2017 in the First Affiliated Hospital of Chongqing Medical University and the Second Affiliated Hospital of Chongqing Medical University were included in this study. The inclusion criteria were follows: (I) patients aged ≥ 50 years; (II) patients who met the diagnostic criteria for AML, that is to say, those who had a bone marrow or peripheral blood blast cell count of $\geq 20\%$ (9); (III) patients who had an Eastern Cooperative Group performance status (ECOG PS) score of < 3 ; (IV) patients who did not develop severe complications in other organs.

Treatment

The patients were divided into three groups based on the treatment received. Among them, 19 were included in the IA group, 36 in the D-CAG group, and 31 in the DA group. The IA regimen was consists of a 3+7 course of idarubicin 10–20 mg/d given for 3 days (d1–d3) and cytarabine 100–150 mg/d given for 7 days (d1–d7). DA regimen was conducted by administering 35–60 mg/m² of daunorubicin, as a substitute for idarubicin on the basis of the IA regimen, for 3 days (d1–d3). D-CAG regimen was conducted by giving 25 mg/d of decitabine for 5 days, 30–40 mg/d of cytarabine for 4 days, 10 mg/d of aclarubicin for 7 days, and 300 μ g/d of G-CSF from day 1 until the WBC count increased to more than 20×10^9 /L. After remission, most patients in D-CAG group received one to three courses of D-CAG regimen for consolidation therapy, while patients in the IA and DA group receive

one or two courses of the same regimen followed by high dose cytarabine. Patients with residual disease after the first cycle of induction were allowed to receive a second induction cycle. 5 patients in IA group, 3 in D-CAG group, and 7 in DA group received hematopoietic stem cell transplantation (HSCT), of whom all but five were younger than 60 years old.

Supportive treatment

Patients with a haemoglobin level of ≤ 70 g/L were infused with red blood cells. By contrast, patients with a platelet count of $\leq 20 \times 10^9$ /L received platelet transfusion. In addition, antibiotics were used to prevent and treat infections.

Response criteria and adverse reactions criteria

The therapeutic efficacy was evaluated after one course of induction treatment. The treatment outcomes were divided into early death, complete remission (CR), partial remission (PR), and no remission (NR). The overall response (OR) rate was computed by adding the CR rate and PR rate. Early death was defined as death within 30 days from the first day of induction chemotherapy. Patients who achieved CR had a bone marrow blast of less than 5% and haemoglobin count of > 100 g/L (male) or 90 g/L (female), neutrophil count of $> 1.5 \times 10^9$ /L, and platelet count of $> 100 \times 10^9$ /L in the peripheral blood. Patients who achieved PR had a bone marrow blast of 5–20% or their clinical manifestation and peripheral blood count did not fully meet the criteria for CR. Patients were classified as NR when their bone marrow blasts, peripheral blood blasts, and clinical manifestations did not meet the criteria for CR. Adverse reactions were defined based on the World Health Organization's (WHO) chemotherapy side effects criteria.

Statistical analysis

All data were analysed using the Statistical Program for Social Sciences version 22.0. The measurement data were analysed using *t*-test and rank sum test, while enumeration data were analysed using chi-square test. The Kaplan-Meier method was used to perform survival analysis, log-rank test to compare the survival rates, and Cox regression model to identify the factors influencing survival. A P value of < 0.05 implied a significant difference.

Table 1 Patients basic feature of three groups

Group	IA (%)	D-CAG (%)	DA (%)	P1	P2	P3
Sex (male/female)	9/10	22/14	16/15	0.397	1.000	0.468
Age	59.37 [50–80]	63.36 [50–76]	57.55 [50–75]	0.036	0.548	0.001
WBC ($\times 10^9/L$)	28.10 (0.82–133.75)	10.24 (0.36–129.11)	49.72 (0.75–99.51)	0.002	0.834	0.006
BM blasts [%]	62.5 [20–93]	34 [20–93]	59.5 [20–97]	0.006	0.530	0.011
ECOG score						
0, 1	15/19 (78.9)	26/36 (72.2)	27/31 (87.1)	0.794	0.459	0.228
2	4/19 (21.1)	10/36 (27.8)	4/31 (12.9)	0.794	0.459	0.228
LDH						
Normal	6/17 (35.3)	12/33 (36.4)	5/28 (17.9)	1.000	0.284	0.154
>ULN	11/17 (64.7)	21/33 (63.6)	23/28 (82.1)	1.000	0.284	0.154
Cytogenetics						
Favorable risk	3 (16.7)	2 (6.3)	5 (20.8)	0.336	1.000	0.125
Intermediate risk	10 (55.6)	20 (62.5)	13 (54.2)	0.630	0.929	0.530
Adverse risk	5 (27.8)	10 (31.3)	6 (25.0)	0.797	0.839	0.608
Infection rate	3/19 (15.8)	6/36 (16.7)	3/31 (9.7)	1.000	0.661	0.488
Hemorrhage rate	1/19 (5.3)	4/32 (11.1)	2/29 (6.5)	0.649	1.000	0.678

P1, IA group vs. D-CAG group, P2, IA group vs. DA group, P3, DA group vs. D-CAG group. WBC, white blood cell; BM, bone marrow; LDH, lactic dehydrogenase; ULN, upper limit of normal. D-CAG, decitabine, cytarabine, aclarubicin, and granulocyte stimulating factor; WBC, white blood cell; LDH, lactate dehydrogenase; ULN, upper limit of normal.

Results

Therapeutic evaluation

The baseline characteristics of the three groups were compared (*Table 1*). There was no significant difference between the IA group and the DA group. Moreover, no significant difference was observed in the sex ratio, ECOG score, infection rates, and haemorrhage rates before chemotherapy of the three groups. However, the median age of the D-CAG group were higher than that of the IA group and DA group while the median bone marrow blasts and WBC count were lower.

All 86 patients completed one course of induction chemotherapy. However, the efficacy of this therapy was not evaluated in one patient from the D-CAG group and three from the DA group as the results of their bone marrow exam were not reviewed. There were 7 patients in IA group, 22 in D-CAG group, 6 in DA group received two courses of induction, the rest received just one course. The early death rates, CR rates, and OR rates of the three groups showed no significant difference (*Table 2*).

Adverse reactions

All patients developed grade IV haematological toxicities. The grade IV adverse reactions experienced by the patients and the appearing time of the lowest value of patients' WBC, platelet, and haemoglobin were compared among the three groups.

Furthermore, we compared the time required for the WBC values to recover to $\geq 1 \times 10^9/L$, for the platelet values to recover to $\geq 20 \times 10^9/L$, and for the haemoglobin values to recover to ≥ 60 g/L. Among them, the incidence of grade IV WBC toxicity in the D-CAG group was lower than that in the IA and DA group (*Table 3*).

Compared with the DA group, the lowest values of WBC and platelet were higher in D-CAG group and the recovery time of WBC and platelet was shorter. However, the time required for haemoglobin to recover to ≥ 60 g/L in the D-CAG group was longer than that in the DA group. Compared with the IA group, the lowest WBC count after

Table 2 Therapeutic effect of IA, D-CAG and DA group

Outcome	IA (%)	D-CAG (%)	DA (%)	P
Early death	2/19 (10.5)	2/35 (5.7)	0/27 (0)	0.209
CR	9/19 (47.4)	19/35 (54.3)	12/28 (42.9)	0.659
OR	10/19 (52.6)	25/35 (71.4)	20/28 (71.4)	0.311

D-CAG, decitabine, cytarabine, aclarubicin, and granulocyte stimulating factor; CR, complete remission; OR, overall response.

Table 3 Adverse reactions of three groups

Adverse reaction	IA (%)	D-CAG (%)	DA (%)	P1	P2	P3
Lowest value of WBC ($\times 10^9/L$)	0.35 (0–1.98)	0.86 (0.22–7.12)	0.36 (0.12–34)	0.011	0.624	0.000
Lowest value of platelet ($\times 10^9/L$)	5 [1–21]	9 [1–49]	3 [0–16]	0.110	0.047	0.000
Recovery time of WBC ¹ (day)	4 [0–22]	1 [0–51]	4 [0–24]	0.064	0.529	0.004
Recovery time of haemoglobin ² (day)	1 [0–10]	6 [1–18]	2 [0–7]	0.000	0.193	0.000
Recovery time of PLT ³ (day)	1 [0–5]	1 [0–19]	2 [1–14]	0.504	0.006	0.020
Grade IV WBC toxicity	16/18 (88.9)	20/36 (55.6)	29/31 (93.5)	0.016	0.618	0.001
Bleeding rates	10/19 (52.65)	10/36 (27.8)	19/31 (61.3)	0.710	0.551	0.006
Infection rates	12/19 (63.2)	23/36 (63.9)	22/31 (71.0)	0.957	0.566	0.538
Fever rates	16/19 (84.2)	21/36 (58.3)	24/31 (77.4)	0.052	0.560	0.097
Cardiac damage rates	7/19 (36.8)	9/36 (25.0)	6/31 (19.4)	1.000	0.629	0.437
Nausea and vomiting rates	7/19 (36.8)	9/36 (25.0)	6/31 (19.4)	0.358	0.171	0.580
Grade II–IV fever rates	15/19 (78.9)	17/36 (47.2)	24/31 (77.4)	0.043	1.000	0.014
Grade II–IV nausea and vomiting rates	5/19 (26.3)	2/36 (5.6)	3/31 (9.7)	0.041	0.232	0.656

¹, the time required for the WBC values to recover to $\geq 1 \times 10^9/L$, ², the time required for the platelet values to recover to $\geq 20 \times 10^9/L$, ³, the time required for the haemoglobin values to recover to ≥ 60 g/L. D-CAG, decitabine, cytarabine, aclarubicin, and granulocyte stimulating factor; WBC, white blood cell; PLT, platelet.

chemotherapy was higher in the D-CAG group but the time required for haemoglobin values to recover was longer. The IA group had similar hematologic adverse reactions with the DA group, except that the IA group had the lowest platelet value after chemotherapy and the time required for platelet values to recover was shorter in the IA group than that in the DA group (Table 3). No statistical difference was observed in other blood system adverse reactions of all three groups.

The primary non-haematological adverse reactions experienced by the patients were infection, fever, gastrointestinal symptoms, bleeding, and cardiac damage. Cardiac damage was primarily manifested by arrhythmia and acute cardiac insufficiency. The incidence of grade II–IV fever was lower in the D-CAG group than in the DA group and IA group. The D-CAG group had lower incidence of bleeding

than the DA group and had lower incidence of grade II–IV nausea and vomiting than the IA group (Table 3). There was no statistical difference in non-hematologic adverse reactions between the DA group and the IA group.

Survival follow-up

All patients were followed up until March 31, 2018. Two cases of early death occurred in both the IA group and the D-CAG group. Among them, one died of suicide and the other died of cerebral haemorrhage both in the two groups. There was no case of early death in the DA group. For the survival follow-up of the IA group and the D-CAG group, the median survival times were 12.47 months and 28.6 months, respectively ($P=0.18$) (Figure 1). Cox regression

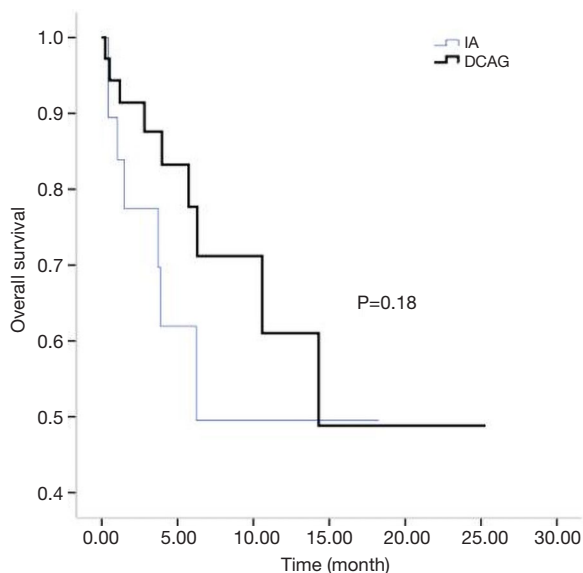


Figure 1 The overall survival (OS) of IA and D-CAG group. D-CAG, decitabine, cytarabine, aclarubicin, and granulocyte stimulating factor.

analysis showed that the age of ≥ 70 years and a bone marrow blasts of $\geq 70\%$ at initial diagnosis had a negative effect on long-term survival (Figure 2). However, the study showed that WBC count, LDH level, and ECOG score had no influence on the long-term survival.

Discussion

In the clinical treatment course of AML, most patients age 50–60 have bad situation and they can not tolerate intensive chemotherapy. And a few studies also choose ≥ 50 years old as the age limits (10,11).

In this study, the basic characteristics of patients in the IA and DA group were similar and comparable. Except that the IA group had a lower incidence of platelet toxicity while the time required for the haemoglobin values to recover to ≥ 60 g/L was longer than the DA group; there was no statistical difference between the two groups in terms of other haematological or non-haematological adverse reactions. In addition, there were no statistical difference in early death rates, CR rates, or OR rates between the two groups. It seems that the IA and DA regimens have similar therapeutic efficacy and adverse reactions to elderly AML patients. Hence, further studies should be conducted to explore the long-term effects of these regimens. A few studies pointed that the dose of daunorubicin remains

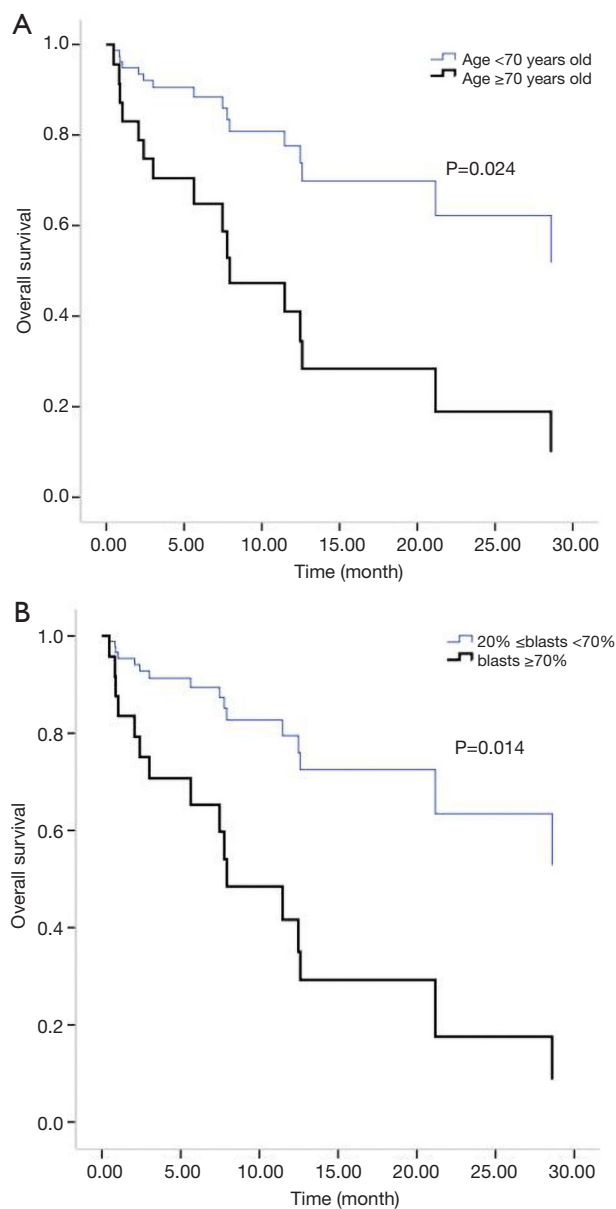


Figure 2 The overall survival of patients with different influence factors. (A) Age; (B) the percentage of bone marrow blasts.

controversial. However, for elderly fit patients, giving a 60 or 90 mg/m² dose may result in higher CR rates and longer survival time than giving a 45 mg/m² dose. However, compared with 60 mg/m² dose, administering a 90 mg/m² dose may not provide further benefits to the patients. On the contrary, it may cause more adverse reactions (12,13). The Chinese guidelines suggests that the standard dose is 40–60 mg/m² for elderly fit patients (14).

The semi-annual relapse rates of IA, D-CAG and DA group

were 37.5% (3/8), 13.3% (2/15) and 40% (4/10), respectively. Although the relapse rate was lower of D-CAG group, there was no statistical difference in three groups ($P=0.247$). The median OS time of the IA and D-CAG group were 12.47 months and 28.6 months, respectively, and no statistical difference was observed. However, as was shown in *Figure 1*, it seemed like there was a trend that patients of D-CAG group had a better long-term survival. Even so, the survival time was still too short for these patients. It was clear that age was an independent risk factor for AML patients. Our study also showed the same result. Moreover, age was included and listed separately by many prognostic models (6,15,16). Same as some other studies, we found high bone marrow blasts at initial diagnosis was a poor prognostic factor (17).

When we compared the baseline characteristics, we found that the median age of the D-CAG group was higher than that of the IA group and DA group while the median bone marrow blasts and WBC count were lower. Increasing the sample volume may eliminate these differences, and this is our future direction. As age was a generally accepted independent risk factor, it seemed that the D-CAG group had a worse physical condition than the IA and DA groups. Due to the limitations related to the fact that this is a retrospective study, it is possible that the physicians chose more sick patients for D-CAG regimen. In this condition, three group had similar CR rates. Moreover, the D-CAG group had lesser haematological and non-haematological adverse reactions than the IA and DA groups, especially in the haematological system. This finding indicated that the D-CAG regimen maybe a more effective treatment that can help achieve a complete remission with less adverse reaction. However, large sample studies are still needed. Our study showed that D-CAG group had less myelosuppression, decreasing the incidence of grade II–IV fever, which may be due to the use of G-CSF in the D-CAG regimen. Bob pointed that G-CSF can enhance the efficacy of a chemotherapy regimen by deriving leukemia cells into the cell cycle to increase the susceptibility of the cells to be killed by cytarabine (18). In fact, during our data collection, we found that the D-CAG regimen was used more frequently than the other two regimens gradually.

The CR rate was calculated after one course of induction treatment, which resulted in it being lower than usual. At present, increasing the CR rate of elderly AML patients remains a concern that needs to be addressed. Although the current treatment outcome is considered less desirable, receiving chemotherapy is a better option (3,19,20). As AML is a heterogeneous disease and there is no standard criteria in

choosing the best treatment, a comprehensive and systematic assessment of elderly patients before chemotherapy will have a significant effect on the patients' treatment outcome, and many prognostic models can be applied (6,15,16). Allogeneic hematopoietic stem cell transplantation remains the primary treatment for patients to achieve long-term remission; finding new target drugs may be beneficial to these patients. We do expect that the incorporation of newer therapies might change or impact these outcomes, such as the addition of FLT3 inhibitors, the use of Vyxeos (liposomal daunorubicin/cytarabine) for secondary AML in older patients, and venetoclax which has been studied in older AML patients with quite promising data.

Conclusions

Newly diagnosed AML patients aged ≥ 50 years are still faced with low complete remission rate and poor long-term survival conditions. Age and bone marrow blasts at initial diagnosis are risk factors for prognostic. The IA, D-CAG, and DA regimens as induction therapies can be well tolerated. D-CAG regimen can be a better treatment option as it only causes less adverse reactions and patients may have better long-term survival. Studies with larger sample size should be conducted. Hence, substantial efforts are needed to explore new drugs and treatments to benefit these patients.

Acknowledgments

Funding: This work was supported by the National Natural Science Foundation of China (no. 81772280).

Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/tcr.2018.12.21>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The written informed consent was waived due to the retrospective nature of the study. This study was approved by the ethics committee of Yongchuan Hospital of ChongQing Medical University.

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Cite this article as: Liu J, Zhong L, Yao J, Zhong P, Yuan Z, Liu D, Li L, Liu L, Zhao Y, Yao S, Chen M, Liu B. Therapeutic effects of different regimens for induction therapy in elderly patients more than 50 years old with newly diagnosed acute myeloid leukaemia. *Transl Cancer Res* 2018;7(6):1675-1681. doi: 10.21037/tcr.2018.12.21