

(9,158 vs 188,815 DNA copies/mL, $p=0.038$, Mann-Whitney test) with a similar trend also for blood (6,307 vs 9,440 DNA copies/mL; $p=0.070$). Patients who failed to respond to cidofovir were treated with ganciclovir \pm foscavir; however, three patients died, two because of CMV-related interstitial pneumonia, and one because of thrombotic thrombocytopenic purpura. Cidofovir treatment was well tolerated, and neither renal nor hematopoietic toxicity was observed.

In a recent report from the *Infectious Disease Working Party of the EBMT*,⁷ cidofovir was shown to be effective in both primary and secondary pre-emptive therapy. In that study, 10/20 patients with CMV disease responded to cidofovir, as did 25/38 (66%) who had failed to respond to or relapsed after pre-emptive therapy with other agents; furthermore, 62% of patients receiving CDV as primary pre-emptive therapy responded. Cidofovir has also been employed as pre-emptive therapy in a pilot study in 4 patients⁸ and in 10 patients after dose-reduced conditioning.⁹ Our data are in line with results from the above studies, having obtained a 57% response; we also observed that response to cidofovir was influenced by viral load at diagnosis, and that after only two doses a complete virus clearance was obtained in half of responders. No renal toxicity developed, unlike in the retrospective EBMT analysis (25.6% of cases, being persistent in 57.1%); however, in this series, most patients had received previously, or concomitantly with cidofovir, other antiviral agents; indeed the frequency of renal toxicity decreased from 35% to 29% to 12% in patients who received cidofovir for CMV disease, or for secondary or primary pre-emptive therapy, respectively.

In conclusion, the results of this prospective study indicate that cidofovir may be safely and effectively used as a first choice pre-emptive treatment in HSCT recipients, especially in those with a low CMV load according to a PCR assay. Most importantly, early administration of cidofovir as the only antiviral agent is not complicated by renal toxicity. Cidofovir may be delivered in an outpatient setting, being better accepted by the patient and also more cost-effective.

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Key words: cidofovir, CMV, hematopoietic stem cell transplantation, PCR, pre-emptive therapy.

Acknowledgments: supported in part by Fondi MURST ex 60%.

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Manuscript processing

This manuscript was peer-reviewed by two external referees and by Professor Jordi Sierra, Deputy Editor. The final decision to accept this paper for publication was taken jointly by Professor Sierra and the Editors. Manuscript received December 27, 2001; accepted February 19, 2002.

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Acute myeloid leukemia in the elderly: evaluation of overall survival in 69 consecutive patients

The aim of this study was to evaluate the impact of an intensive induction treatment on overall survival in elderly patients (age ≥ 66 years) with acute myeloid leukemia (AML) observed in our institution. Although complete remission was achieved in 58% of treated patients, the median overall survival was equally poor for treated ($n=26$) and untreated ($n=40$) patients (5 and 2 months, respectively), raising the question about the usefulness of an aggressive treatment in elderly patients with non-M3 AML.

haematologica 2002; 87:447-448

(http://www.haematologica.ws/2002_04/447.htm)

Acute myeloid leukemia in elderly patients is associated with a poor overall survival (OS), regardless of treatment. Possible explanations for this include the frequent evolution from an underlying myelodysplastic syndrome (MDS), a high frequency of unfavourable cytogenetic abnormalities, a poor performance status (PS) and/or the presence of associated diseases contraindicating intensive induction regimens.¹ In addition, when complete remission (CR) can be achieved, leukemia relapse occurs after a short time in the majority of cases.²

Between February 1986 and December 1995, 69 consecutive AML patients aged ≥ 66 years (median age 72, range 66-92 years; males 39, females 30) were observed in our institution. According to FAB classification the number in each group was M0 5, M1 5, M2 15, M3 3, M4 16, M5 8, M6 2, M7 2. Thirteen cases could be confidently considered as secondary AML (evolution of MDS).

Only 26 patients (38%; 12 males, 14 females, median age 68 years, range 66-74; M0 4, M1 5, M2 6, M4 7, M5 3, M7 1) in good PS ($> 70\%$) and without evidence of secondary leukemia were treated with aggressive chemotherapy, consisting of 3 courses of induction therapy followed by monthly maintenance chemother-

Table 1. Treatment schedule.

Remission induction therapy	
Courses 1 and 3	Course 2
ADM 35 mg/m ² 30 min. i.v. infusion days 1-2	ADM 50 mg/m ² 1 h i.v. infusion day 1
Ara-C 100 mg/m ² q 12 h 2 hours i.v. infusion days 1-7	VCR 1.3 mg/m ² i.v. day 2
6-TG 100 mg/m ² q 12 h orally days 1-7	Ara-C 500 mg/m ² q 12 h 2 hours i.v. infusion days 3-8
Maintenance treatment*	
Course A	Course B
ADM 25 mg/m ² i.v. day 1	VCR 1 mg/m ² i.v. day 1
Ara-C 100 mg/m ² i.m. bid. days 1-5	VP16 100 mg/m ² i.v. days 1-3
6-TG 100 mg/m ² q 12 h orally	Ara-C 100 mg/m ² i.m. bid. days 1-5

ADM: doxorubicin; 6-TG: thioguanine; VCR: vincristine; Ara-C: cytosine arabinoside; VP16: epipodophyllotoxin. *Maintenance treatment consisted of 12 monthly courses, alternating course A and B.

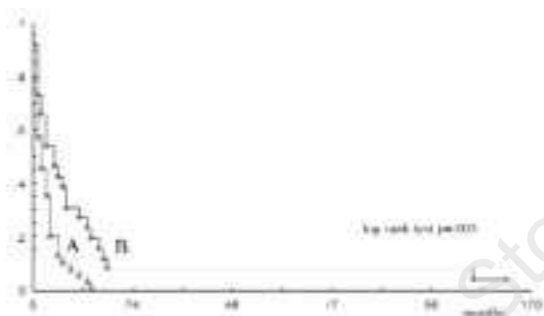


Figure 1. Survival in 40 untreated patients (line A) and in 26 treated patients (line B).

apy for 1 year (Table 1).

The 3 FAB M3 patients (aged 66, 74, and 75 years) received all-trans retinoid acid alone in 1 case and associated with chemotherapy in 2 cases.

The remaining 40 patients (58%; 25 males, 15 females, median age 74 years, range 66-92 years) with organ dysfunction, poor PS (< 60%) or leukemic transformation of MDS (13/40) were excluded from aggressive treatment and received only supportive care (transfusions and/or hydroxyurea).

Among the 26 chemotherapy-treated non-M3 patients, 15 (58%) achieved a CR, 7 (27%) failed to obtain a CR and 4 were not evaluable due to early death. Seven died of treatment-related toxicity (27%; 3/7 while in CR). Eight out of the 12 patients who achieved a CR started maintenance therapy but only 2/8 patients could complete the planned treatment, whereas 6/8 relapsed during maintenance therapy. The median OS was 5 months (range 0-114 months), with 2 long survivors (the first

patient, with FAB M4 AML and normal karyotype, relapsed after 104 months and the second patient, with FAB M5 AML and trisomy 8, is still in continuous CR after 114 months). On the other hand, the median OS of patients receiving only supportive care was 2 months. Figure 1 reports the survival curves of the two groups of patients. In spite of the statistically significant difference ($p = .003$), the outcome was equally poor for both groups, the intensive treatment being of benefit in terms of OS only for 2/26 cases (7.7%) and in terms of potential cure only for 1/2.⁶ All 3 M3 patients are in continuous CR (after 72, 77 and 84 months), further supporting the concept that M3 AML treated with all-trans retinoid acid-containing regimens is associated with good prognostic perspectives even in the elderly.

In conclusion, in agreement with previous reports, our data do not provide any evidence in favor of intensive treatment for non-M3 AML in the elderly^{3,4} and raise the question of whether an aggressive treatment, although of some benefit for a minority of cases, should ever be applied to this setting of patients. In our opinion, curative treatment should only be considered in elderly patients selected among those with good PS and *de novo* AML. Clearly, prospective trials are needed to clarify this point.⁵

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Manuscript processing

This manuscript was peer-reviewed by two external referees and by Professor Elihu Estey, who acted as an Associate Editor. The final decision to accept this paper for publication was taken jointly by Professor Estey and the Editors. Manuscript received January 15, 2002; accepted March 4, 2002.

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