



The combination of gemtuzumab ozogamicin and azacitidine in the treatment of relapsed and refractory AML

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Context:

Treatment of patients with relapsed and refractory AML who are not candidates for intensive treatment is an actual problem.

Objective:

Assess the efficacy of gemtuzumab ozogamicin (GO) in combination with azacitidine; assess factors impacting remission, and assess and compare tolerability and safety.

Design:

A retrospective study was conducted, which included patients who were not candidates for intensive treatment (advanced age, low somatic status, relapse after high-dose chemotherapy, and refractoriness to high-dose chemotherapy). Patients received treatment at our center from 2017 to 2021.

Patients or Other Participants:

The study included 17 patients (8 women, 9 men), median age of 49 years (24–83 years), 53% (9/17) with refractory and 47% (8/17) with relapsed AML. According to the ELN classification, 17.6 % (3/17) were assigned to the favorable-risk group, 23.5 % (4/17) to the intermediate-risk group, and 58.9 % (10/17) to the adverse-risk group. The median expression of CD33 was 94.8 % (25.6%–100%). The median previous lines of therapy was 2 (range: 1–3). All patients received therapy with a combination of GO and azacitidine.

Results:

- Overall response rate — 68.75 % (11/16);
- Refractory — 31.25 % of patients (5/16);
- Early mortality rate was 5.8% (1/17) (Fig.1);
- Overall response rate was not associated with CD33 expression ($p > 0.05$),
- age ($p > 0.05$), prognostic risk group ($p > 0.05$), or number of previous lines
- ($p > 0.05$).

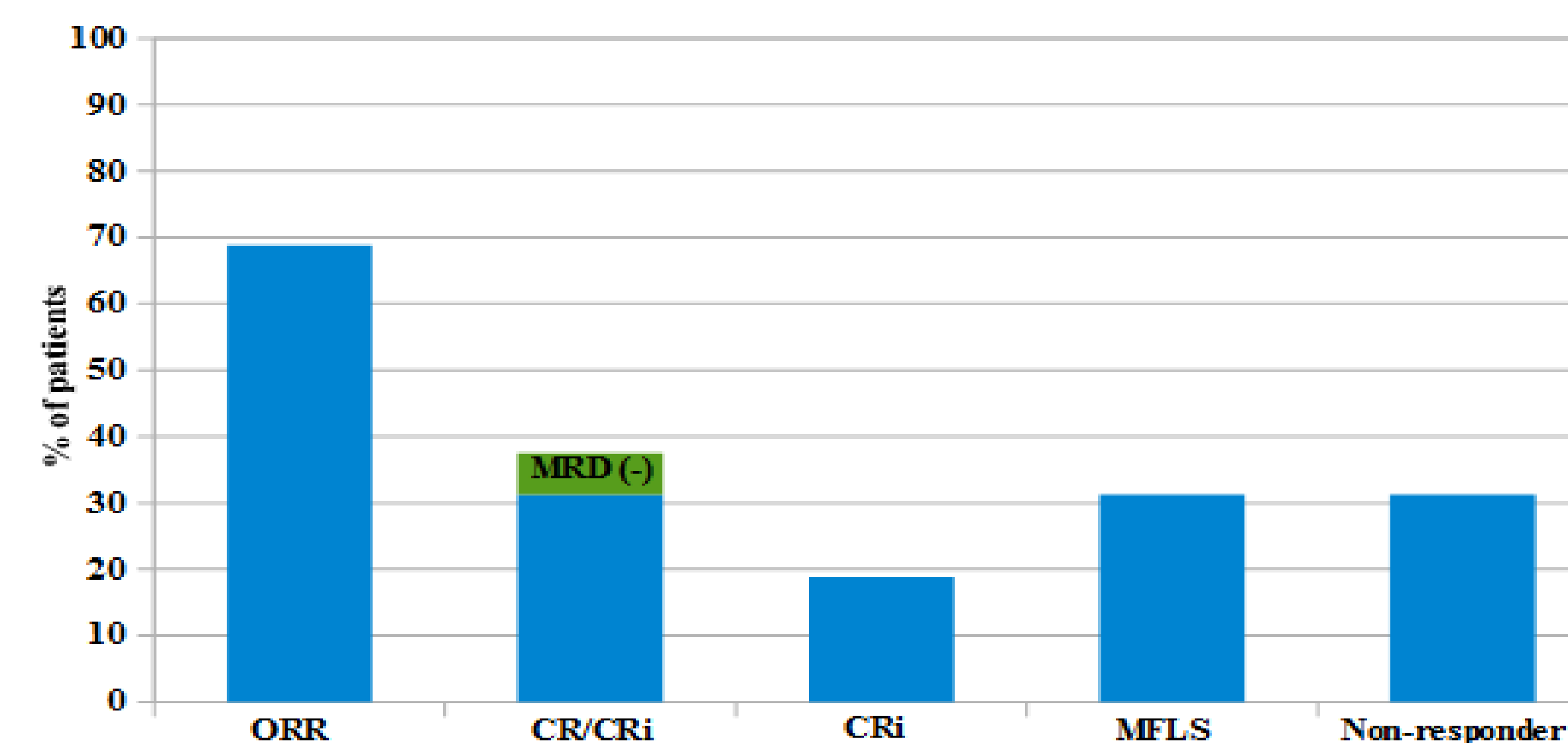


Fig. 1. The results of therapy

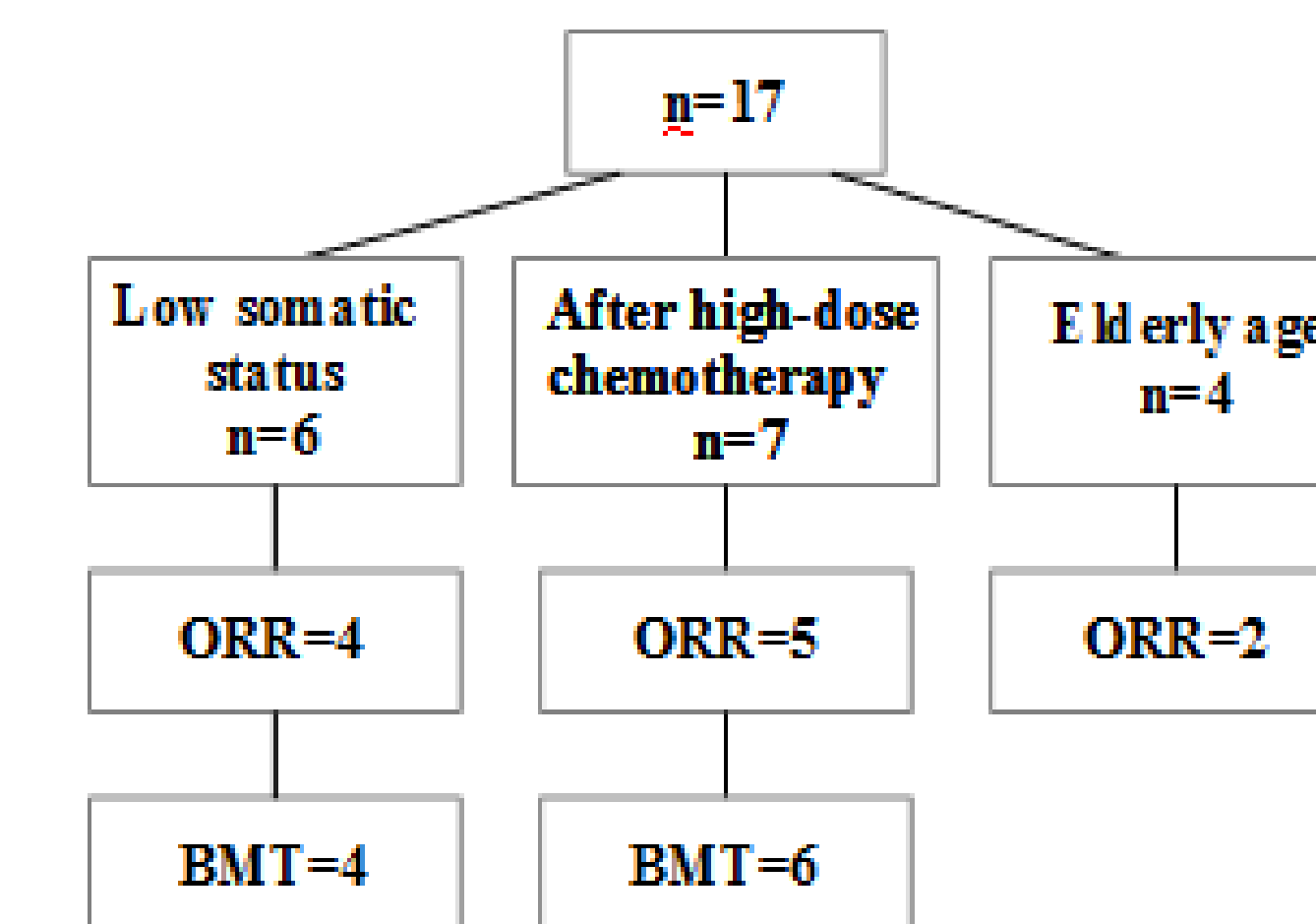


Fig. 2. The BMT in our group

- In the AML relapse group, the response rate did not depend on the number of relapses ($p > 0.05$).
- Of the 13 patients under 65 years, 10 patients (76.9%) achieved overall response, with a suitable somatic status according to ECOG (1 point) and infectious complications resolved, allowing them to perform allogeneic BMT (Fig.2).
- The median of grade 4 neutropenia was 21.8 days (10–29 days), grade 4 thrombocytopenia was 19.5 days (11–38 days).
- The rate of infusion-related complications $\geq$ grade 3 was 5.9% (1/17).
- No cases of VOD were reported.

Conclusions:

The combination of GO and azacitidine has been shown to be an effective and tolerable therapy for patients with relapsed and refractory AML who are not candidates for intensive treatment. This combination showed potential for use as a bridge to allogeneic BMT therapy after improving somatic status.