

General AML

## Phase II study on fludarabine, busulfan and cytarabine versus standard BuCy2 for patients with acute myeloid leukemia



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Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is a potentially beneficial treatment option for patients with acute myeloid leukemia (AML). However, the optimal conditioning regimen for allo-HSCT remained controversial. Wei-Ping Zhang and colleagues from Changhai Hospital, The Second Military Medical University, Shanghai, China, conducted a prospective, randomized, phase II study to compare the outcome of the fludarabine, busulfan, and cytarabine (FBA) conditioning regimen with classical busulfan and cyclophosphamide (BuCy2) regimen in younger adult patients with AML in complete remission (CR). The authors published their paper in *Bone Marrow Transplantation*.

A total of 111 patients with AML in CR1 or CR2 were randomly assigned 1:1 to receive either FBA (FBA cohort, n = 56; median age = 34 years [range, 16–58]) including Flu (30 mg/m<sup>2</sup>/day, day -10 to -6), Ara-C (1.5 g/m<sup>2</sup>/day, day -10 to -6), and Bu (0.8 mg/kg, day -5 to -3), or BuCy2 (BuCy2 cohort, n = 55; median age = 38 years [range, 20–56]) comprising Bu (0.8 mg/kg, day -8 to -5) and cyclophosphamide (60 mg/kg/day, day -4 to -3).

The primary endpoint of the study was treatment-related mortality (TRM) at 100 days post-transplantation

### Key findings:

- 100-day TRM was not significantly different between the FBA and BuCy2 arms: 1.79% vs 5.45%,  $P = 0.260$
- 3-year overall survival (OS) and event-free survival (EFS) were not statistically different in the FBA and BuCy2 cohorts: 68.37% (95% CI, 53.28–79.49) vs 65.76% (95% CI, 51.23–76.90),  $P = 0.369$  and 59.06% (95% CI, 44.70–70.86%) vs 61.96% (95% CI, 47.19–73.71%),  $P = 0.412$ , respectively
- 3-year cumulative incidence of relapse was similar in the FBA and BuCy2 groups: 15.22% (95% CI, 7.00–26.38) vs 18.93% (95% CI, 9.63–30.62),  $P = 0.541$
- 100-day cumulative incidence of grade II–IV acute graft-versus-host disease (aGvHD) in the FBA and BuCy2 cohorts: 8.93% vs 21.86%,  $P = 0.032$
- 100-day cumulative incidence of grade III–IV aGvHD: 1.79% vs 9.09%,  $P = 0.025$
- 3-year GvHD-free/relapse-free survival (GRFS) in the FBA and the BuCy2 cohorts: 31.20% vs 14.96%,  $P = 0.004$
- Non-hematological toxic effects that occurred from the beginning of conditioning to 30 days after transplantation:
  - Incidence of diarrhea of all grades in the FBA and BuCy2 arms: 28.57% vs 65.45%,  $P < 0.001$
  - Incidence of grades 2–4 oral mucositis in the FBA and BuCy2 groups: 51.79% vs 70.91%,  $P = 0.039$

The authors concluded by stating that the FBA regimen showed similar TRM, relapse rate, OS and EFS as the BuCy2 regimen with “with lower incidences of aGVHD and mucosal complications in the early stage of allo-HSCT.” They further added that this data needs to be further validated in larger, prospective trials.

## References

1. [Zhang W.P. et al.](#) Preconditioning with fludarabine, busulfan and cytarabine versus standard BuCy2 for patients with acute myeloid leukemia: a prospective, randomized phase II study. [Bone Marrow Transplant](#). 2018 Oct 19. DOI: [10.1038/s41409-018-0356-5](#). [Epub ahead of print].

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