



cGvHD

TCT Meeting 2019 | Azithromycin for the management of moderate to severe chronic graft-versus-host disease

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On 21 February 2019, [Dr. Mark Shamoun](#) from the [University of Michigan Medical Center](#), Ann Arbor, MI, USA, presented data from a retrospective, single-center study assessing relapse rates in a cohort of patients receiving azithromycin for moderate to severe chronic graft-versus-host disease (cGvHD) at the [2019 TCT Transplantation and Cellular Therapy Meetings of ASBMT and CIBMTR](#) in Houston, Texas, USA. The [US Food and Drug Administration \(FDA\) safety warning](#) in August 2018, raised concerns on the risk of relapse in patients receiving azithromycin as prophylaxis for bronchiolitis obliterans syndrome (BOS) following allogeneic hematopoietic cell transplant (allo-HCT).

Patients and methods:

- The allo-HCT database, at the University of Michigan, included n = 239 patients between 2010 and 2017
- Median age = 55 years (range, 4–72)
- Diagnosis: moderate-severe cGvHD
- Patients were divided into two groups:
 - Patients receiving an extended course of azithromycin (≥ 14 days) for cGvHD management (cohort 1, n = 86)
 - Patients who did not receive an extended course of azithromycin (cohort 2, n = 153): patients in this cohort either did not receive any azithromycin (n = 122) or had received an abbreviated (< 14 day) course (n = 31) of azithromycin post-allo-HCT

Key findings:

All data is given as cohort 1 vs cohort 2

- Patients exhibiting BOS: 100% vs < 5%
- Rates of cGvHD:
 - Moderate: 22% vs 49%
 - Severe: 78% vs 51%
- Median time to commencement of azithromycin post-allo-HCT (cohort 1): 15 months (range, 3–68)
- Median duration of azithromycin therapy (cohort 1): 26 months (range, 1–77)
- Two-year cumulative incidence of relapse: 2% (95% CI, 1–9) vs 16% (95% CI, 11–23), $P = 0.001$
- Two-year relapse rate: 4.0% (95% CI, 1.0–9.0) vs 17.0% (95% CI, 11.0–23.0), $P = 0.001$

- Relapse rates post allo-HCT: 7/86 (8.1%) patients vs 28/153 (18.3%) patients
- Median time to relapse: 876 days (range, 379–1303) vs 371 days (range, 98–1252)
- Two-year overall survival: 93% (95% CI, 88–99) vs 78% (95% CI, 72–85), $P = 0.003$

In summary, administration of azithromycin for the treatment of moderate to severe cGvHD was not associated with an increased risk of relapse in patients undergoing allo-HCT. Furthermore, Dr. Mark Shamoun concluded that azithromycin therapy for patients with cGvHD should not be contra-indicated, as this study has illustrated that azithromycin is safe for patients with BOS post-allo-HCT.

References

1. Shamoun M. et al. The effect of azithromycin on relapse in patients with moderate-severe chronic graft versus host disease (CGVHD). 2019 Feb 21; Oral Abstract #33: 2019 TCT Transplantation and Cellular Therapy Meetings of ASBMT and CIBMTR, Houston, Texas, USA.

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