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Treating the Underrepresented: Daratumumab in Combination with Cyclophospmaide, Bortezomib and Dexamethasone (Dara-CyBorD) in Newly Diagnosed Multiple Myeloma With Renal Failure

Amany Keruakous, MD[1,a]; Anvay Shah, MD[1]; Inemesit Akpan, MD[1]

[1] Georgia Cancer Center at Augusta University, Augusta, GA, USA

Corresponding author
[a] Amany Keruakous, MD, Georgia Cancer Center at Augusta University, Augusta, GA, USA
Email: amany.keruakous@gmail.com

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Abstract

Background

Acute renal impairment (RI) is a common presentation of newly diagnosed multiple myeloma (NDMM). Patients with RI have been largely excluded from pivotal trials. This study evaluated daratumumab plus CyBorD in NDMM with RI, with emphasis on the underrepresented African American (AA) population.

Methods

This prospective interventional trial enrolled NDMM patients with acute RI attributed to myeloma cast nephropathy at Augusta University beginning in October 2024. Patients received 4 cycles of Dara-CyBorD, followed by ASCT when eligible or 2 additional consolidation cycles, then 2 years of SQ daratumumab plus lenalidomide maintenance. Primary endpoints were renal response rate (RRR) and achieving VGPR or better after induction. The enrollment focus was on the African American (AA) patient population, an underrepresented group in myeloma trials despite

Results

As of June 23, 2026, 17 patients have been enrolled with a median age of 65 years; 64% were male; 82% (14 of 17) were AA. 82% of patients had ISS-III disease; 52.9% had high-risk cytogenetics (including 7 of 14 AA patients); and 28.6% had extramedullary disease (all were AA). Mean eGFR was 27.9 at diagnosis; 29.4% of study patients had impending dialysis dependence with eGFR of < 15; 80% of those were AA. At data-cutoff, 82% of study patients had completed induction therapy. The overall RRR for our ITT patients is 93.7%; 1 patient didn't respond and remained on dialysis. All responders maintained their renal response at data-cutoff. Median time to RR was 9 days. The overall response rate for our ITT patients, defined as PR or better, is 93.7%; 60% achieved VGPR or better, and 33% achieved CR or better; 1 patient was primary refractory. With a median follow-up of 11.4 months, the median PFS was not reached; only 3 of 15 responders had disease progression, one of them was due to non-compliance. PFS was 80%, and OS was 100% at the data-cutoff in this group of high-risk disease. The 3 patients who progressed on this regimen had either EMD and/or very high LDH > 400 at diagnosis and/or high cytogenetic risk (gain1q/tp53 mut); none of them underwent ASCT. At the time of data cutoff, 64.7% (11 of 17) of patients had an autologous stem cell transplant performed/planned; 41% completed ASCT with successful stem cell yield, a secondary endpoint. AEs deemed related to

daratumumab SQ included infections, injection site reaction, and anemia. Unrelated AEs included constipation, hyperglycemia, and peripheral neuropathy.

Conclusion

Adding Daratumumab SQ to CyBorD followed by ASCT, then Daratumumab SQ and Lenalidomide maintenance is a feasible and active therapy in high-risk NDMM with RI, to both reverse kidney failure and maintain kidney function; patients achieved a high overall myeloma response, with limited safety concerns.

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