Bispecific Antibodies Efficacious in Multiple Myeloma with Renal Impairment

Written by The Life Science Feed Editorial Team · Published 31 May 2026 · Edited by Mara Voss

Patients with relapsed/refractory multiple myeloma (RRMM) frequently present with renal impairment (RI), a complication that complicates treatment selection and prognosis. This often leads to their exclusion from pivotal clinical trials, leaving a data gap regarding optimal therapeutic strategies. A recent systematic review, presented at ASCO 2026, addresses this by evaluating the safety and efficacy of bispecific antibodies (BsAbs) in RRMM patients with RI, concluding that these agents maintain comparable outcomes to those with preserved renal function.1

KEY TAKEAWAYS

- The Pivot: Bispecific antibodies, previously under-evaluated in patients with renal impairment, are now supported for use in this high-risk population.
- The Data: Overall response rate (ORR), progression-free survival (PFS), and overall survival (OS) were comparable between patients with and without renal impairment.1
- The Action: Clinicians should consider bispecific antibodies as a viable treatment option for RRMM patients, irrespective of renal function status.

Renal impairment, defined as an estimated glomerular filtration rate less than 60 mL/min, with or without the need for dialysis, is a common and severe complication in patients with relapsed/refractory multiple myeloma.1 This condition can significantly impact patient prognosis, drug metabolism, and available treatment options.1 While bispecific antibodies have received approval for RRMM, their safety and efficacy in patients with RI have remained insufficiently characterized due to the exclusion of individuals with significant renal dysfunction from most clinical trials.1

Multiple myeloma (MM) is a plasma cell malignancy characterized by the proliferation of abnormal plasma cells in the bone marrow. It accounts for approximately 10% of all hematologic cancers. Renal impairment is a frequent comorbidity in MM patients, affecting 20-50% at diagnosis and up to 60% during the disease course. The mechanisms contributing to RI in MM are multifactorial, including cast nephropathy due to monoclonal light chains, hypercalcemia, amyloidosis, and drug-induced nephrotoxicity. The presence of RI significantly increases morbidity and mortality in MM patients, often necessitating dose adjustments or contraindicating certain therapeutic agents due to concerns about drug accumulation and increased toxicity. This creates a critical unmet need for effective and safe treatment options for this vulnerable patient population.

What the study did

A systematic review, conducted according to PRISMA guidelines, aimed to characterize the safety and efficacy of bispecific antibodies in RRMM patients with renal impairment.1 Researchers searched PubMed, Scopus, and ScienceDirect up to February 2, 2026, for clinical trials and retrospective real-world studies that reported data on BsAbs in RRMM patients with RI.1 Abstracts from major international scientific congresses over the preceding three years, including ASH, IMS, ASCO, EHA, and EMN, were also systematically screened.1

The search strategy employed specific keywords related to multiple myeloma, renal impairment, and bispecific antibodies to ensure comprehensive coverage of relevant literature. Inclusion criteria focused on studies reporting outcomes for adult patients with RRMM receiving bispecific antibody therapy, with a clear stratification or reporting of data for patients with varying degrees of renal function. Exclusion criteria included review articles, case reports, and studies not specifically addressing bispecific antibodies in RRMM or lacking data on renal impairment. Two independent reviewers screened titles and abstracts, followed by full-text review of potentially eligible articles, resolving discrepancies through consensus. Data extraction included study design, patient demographics, specific bispecific antibody used, renal function status at baseline, and reported efficacy and safety outcomes.

Bispecific antibodies are a class of immunotherapeutic agents designed to simultaneously bind to two different antigens. In the context of multiple myeloma, many bispecific antibodies target CD3 on T-cells and a myeloma-specific antigen, such as B-cell maturation antigen (BCMA) or GPRC5D, on myeloma cells. This dual binding brings T-cells into close proximity with myeloma cells, facilitating T-cell activation and subsequent lysis of the tumor cells. This mechanism of action is independent of renal function, suggesting that their efficacy might be preserved in patients with RI, unlike some conventional chemotherapies that rely heavily on renal excretion.

The review identified a total of 11 eligible studies, comprising 3 pivotal trials and 8 real-world cohorts, encompassing 1117 patients.1 The primary outcomes assessed included overall response rate (ORR), progression-free survival (PFS), and overall survival (OS).1 Safety profiles, specifically the incidence of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), infections, and hematologic toxicities, were also evaluated.1

Key Findings

The systematic review demonstrated that ORR, PFS, and OS were comparable between patients with and without renal impairment.1 The safety profile, including the incidence of CRS, ICANS, infections, and hematologic toxicities, was also comparable across renal subgroups.1 The only exception was thrombocytopenia, which showed a significantly increased incidence in patients with RI.1 Overall, bispecific antibodies demonstrated substantial efficacy and manageable safety in RRMM patients with renal dysfunction.1 The outcomes observed were similar to those in patients with preserved renal function.1 These findings support the use of bispecific antibodies in this high-risk population in both clinical practice and future clinical trials.1

Despite the comprehensive nature of this systematic review, certain limitations warrant consideration. The heterogeneity of the included studies, particularly the mix of pivotal trials and real-world cohorts, could introduce variability in patient populations, treatment protocols, and outcome reporting. The specific bispecific antibodies evaluated also varied across

studies, which might influence the generalizability of the findings to all bispecific agents. Furthermore, the definition and severity of renal impairment were not uniformly categorized across all studies, potentially affecting the precision of subgroup analyses. The relatively small number of patients with severe renal impairment or those requiring dialysis in some studies limits the statistical power for definitive conclusions in these specific subgroups. Future prospective studies with standardized definitions of renal impairment and larger cohorts of patients with advanced renal dysfunction are needed to further validate these findings and provide more granular insights into the optimal management of RRMM with RI.

CLINICAL IMPLICATIONS

The persistent exclusion of patients with renal impairment from pivotal trials has long been a clinical frustration, creating a void in evidence-based guidance for a vulnerable population. This systematic review provides a much-needed clarification, confirming that bispecific antibodies are not only efficacious but also manageable in terms of safety for patients with relapsed/refractory multiple myeloma and renal dysfunction. The comparable outcomes for ORR, PFS, and OS across renal subgroups should reassure clinicians, allowing for broader application of these agents without undue concern for diminished efficacy or exacerbated toxicity, save for a noted increase in thrombocytopenia.

For the pharmaceutical industry, this data offers a clear directive: future clinical trials for multiple myeloma therapies must actively include patients with varying degrees of renal impairment. The historical rationale for exclusion, often cited as concerns over drug metabolism and toxicity, appears less tenable for bispecific antibodies based on these findings. This inclusion will not only strengthen the generalizability of trial results but also accelerate the integration of new treatments into routine clinical practice for a significant proportion of the myeloma patient population.

Ultimately, this evidence empowers clinicians to offer a wider range of effective treatment options to patients who previously faced limited choices due to their renal status. It underscores the importance of real-world data and systematic reviews in bridging the gaps left by restrictive trial designs. While the increased incidence of thrombocytopenia in patients with RI warrants careful monitoring, the overall picture supports a more inclusive approach to bispecific antibody therapy, aligning treatment decisions more closely with the complex realities of multiple myeloma patient care.

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REFERENCES

1. 1. Ntanasis-Stathopoulos I, Manganas S, Filippatos C. The Role of Bispecific Antibodies in Relapsed/Refractory Multiple Myeloma With Renal Impairment: A Systematic Review. Am J Hematol. 2026;101(5):e200-e203. doi:10.1002/ajh.70312

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