

PRONOSTIC VALUE OF POST-TREATMENT RESIDUAL TUMOR BURDEN ASSESSED BY FLOW CYTOMETRY IN WALDENSTRÖM'S MACROGLOBULINEMIA

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Background & Aims: Evaluation of therapeutic response in Waldenström's macroglobulinemia (WM) still relies largely on serum IgM quantification, which has important limitations in accurately reflecting residual disease burden. Although measurable residual disease (MRD) is an established prognostic factor in several hematologic malignancies, its clinical value in WM remains insufficiently characterized.

We aimed to evaluate the prognostic significance of post-treatment bone marrow residual tumor burden assessed by multiparametric flow cytometry (MFC) in patients with WM.

Methods: We analyzed 102 patients with WM (median age, 68 years [IQR, 61–75]; male-to-female ratio, 7:3) treated between 1995 and 2023 with chemoimmunotherapy (78%) or BTK inhibitors (21%). Median follow-up was 7 years (IQR, 4–12). Bone marrow residual tumor burden was assessed by MFC in samples collected between one month and one year after treatment completion.

Results: The overall response rate was 81%, while 15% of patients had stable disease and 4% experienced disease progression. The median percentage of clonal B lymphocytes (BL) in bone marrow decreased from 11.7% (IQR, 4.8–30.4%) before treatment to 0.2% (IQR, 0–1.3%) after treatment ($p < 0.0001$). Greater reductions in clonal B-cell burden were associated with deeper clinical responses (median pre/post-treatment clonal B-cell ratio: 26.9, 22.9, 5.1, 1.8, and 0.1 for complete response, partial response, minor response, stable disease, and progressive disease, respectively; $p = 0.006$).

Among patients with post-treatment MFC data ($n = 88$), those with undetectable residual clonal BL (MRD-negative, limit of detection 10^{-4}) had significantly longer duration of response (DR; $p = 0.007$) and progression-free survival (PFS; $p = 0.014$) compared to those who were MRD-positive (Figure 1). Six-year PFS was 61.4% in MRD-negative patients versus 32.4% in MRD-positive patients ($p = 0.014$).

Importantly, combining conventional response assessment with flow cytometry improved prognostic stratification. Among patients achieving an objective response, those with undetectable residual clonal BL had significantly longer PFS ($p = 0.0007$), DR ($p < 0.0001$) and

disease-specific survival ($p = 0.047$) than responding patients with detectable residual tumor burden (Figure 2).

Conclusions: Post-treatment residual tumor burden assessed by flow cytometry is strongly associated with survival outcomes and duration of response in WM. These findings suggest that incorporating residual disease evaluation may improve current response assessment criteria and support prospective studies using standardized treatment approaches to validate its clinical utility.

Figure 1. Survival outcomes according to post-treatment MRD status. Progression-free survival (A) and response duration (B) in patients with Waldenström's macroglobulinemia, stratified by post-treatment measurable residual disease (MRD) status of clonal B lymphocytes assessed by multiparametric flow cytometry.

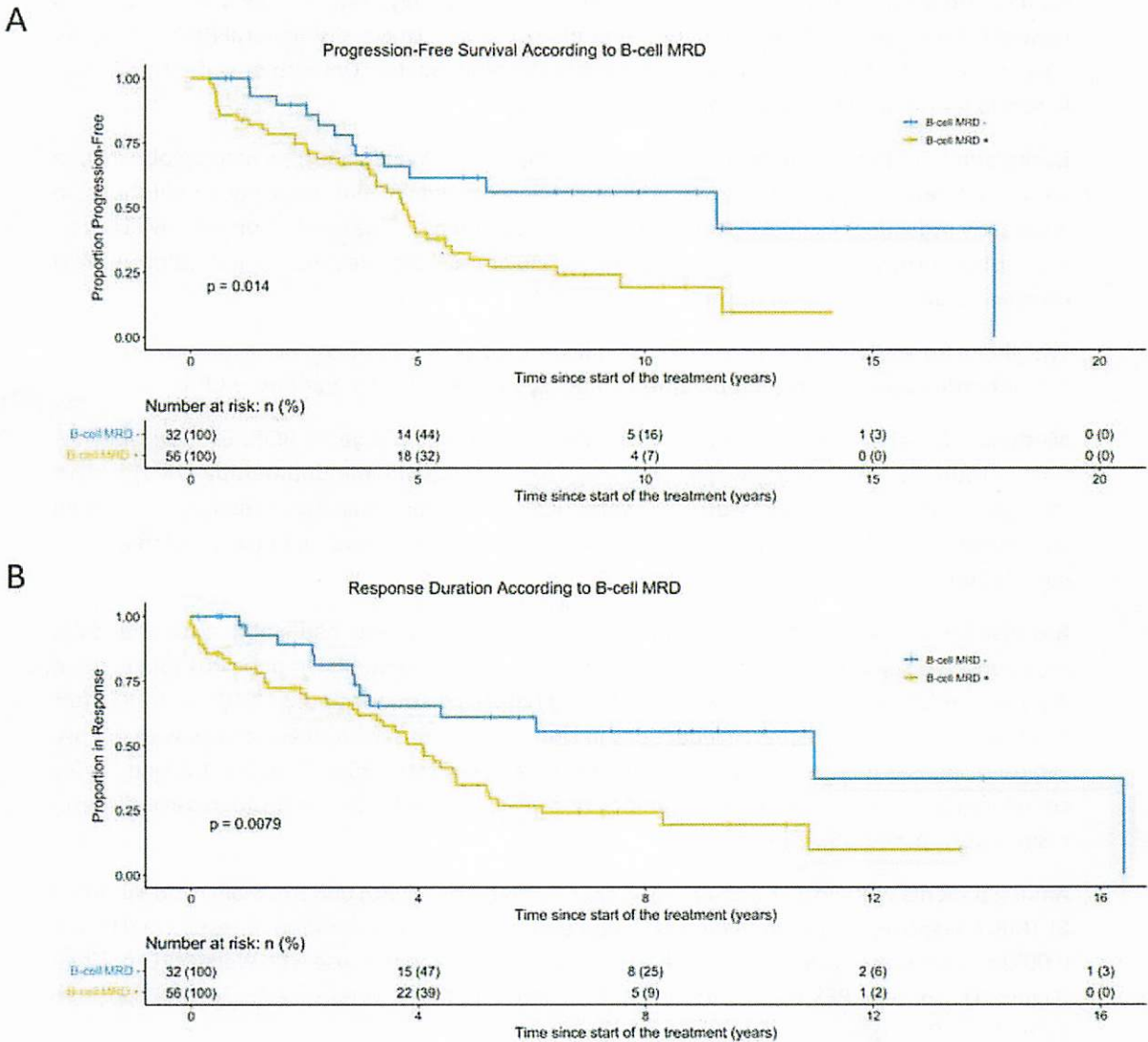
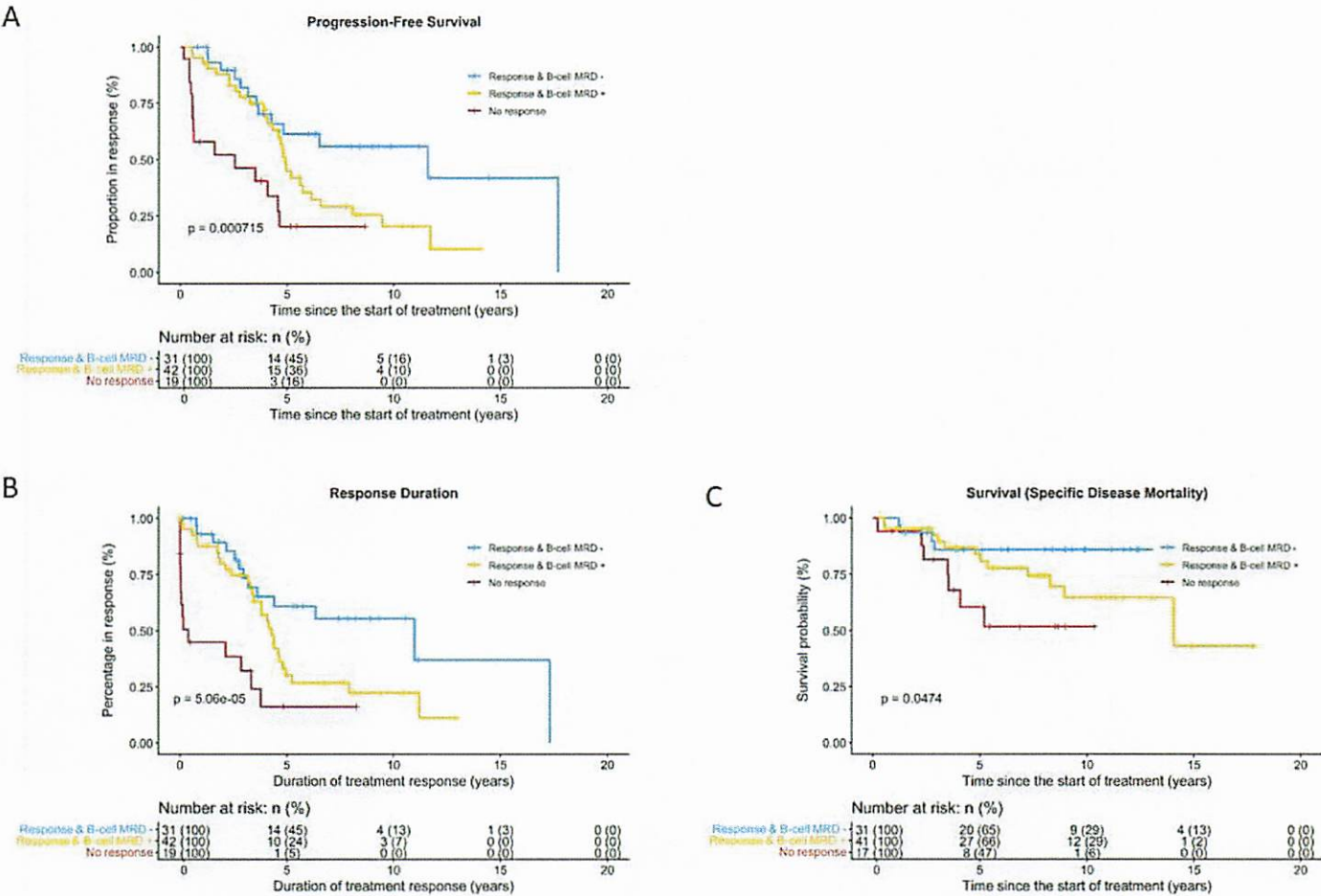


Figure 2. Prognostic impact of post-treatment MRD status integrated with clinical response. Progression-free survival (A), duration of response (B), and disease-specific survival (C) according to the post-treatment MRD status of clonal B lymphocytes and the response to treatment.



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