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# Evaluation of Safety Profile of Rituximab + Lenalidomide Protocol in Frail Elderly Relapsed/Refractory Diffuse Large B-Cell Lymphoma Patients

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## INTRODUCTION

The standard treatment for frail elderly patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) has not been established. Chemotherapy-free regimens such as rituximab + lenalidomide (R2) have shown promising results with an acceptable toxicity profile.

## AIM

This study aimed to evaluate the safety and adverse effects of the R2 protocol in elderly DLBCL patients.

## METHOD

Five elderly patients with R/R DLBCL who were ineligible for autologous stem cell transplantation were included in the study. Patient characteristics, such as age, sex, Eastern Cooperative Oncology Group performance status (ECOG PS), and Cumulative Illness Rating Scale-Geriatric (CIRS-G) scores, were recorded. The R2 protocol consisted of rituximab 375 mg/m$^2$ on Day 1 and lenalidomide 5 to 20 mg on Days 1 to 21 for 6 cycles. Safety assessments included monitoring for cytopenias, infectious complications, and gastrointestinal or skin reactions. Response assessment was performed using positron emission tomography/computed tomography based on Lugano criteria.

## RESULTS

- The median follow-up after the first relapse was 14 months (range: 2-22 months).
- Response assessment could not be performed for two patients due to treatment discontinuation or patient unavailability.
- Three patients had stage 4B DLBCL, one had stage 2B, and one had stage 1B. Three patients had extranodal involvement.
- The median CIRS-G score was 15 points, and the ECOG PS was 2.
- Lenalidomide dose reduction was required for three patients due to grade 3 cytopenias.
- Two patients experienced community-acquired pneumonia, and one had a urinary tract infection, all managed as outpatients.
- One patient experienced gastrointestinal side effects.
- No thromboembolic events were reported.
- Two of five patients achieved a partial response (PR), while two patients were refractory to the R2 protocol. One patient experienced early relapse after a PR, and two patients died of progressive disease.

| case | Infection | Inpatient? | Thrombocytopenia (Grade) | Neutropenia (Grade) | TE | Skin | GIS | CIRS-G | ECOG | No. Of cycle | Response |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Yes | No | 1 | 4 | No | 0 | 0 | 14 | 2 | 6+4 | PR |
| 2 | Yes | No | 1 | 0 | No | 0 | 0 | 16 | 2 | 1 | ex |
| 3 | Yes | No | 2 | 2 | No | 0 | 0 | 15 | 2 | 6+5 | PR |
| 4 | No | No | 0 | 0 | No | 0 | 0 | 10 | 2 | 2 | n/a* |
| 5 | No | No | 2 | 3 | No | 0 | 2 | 17 | 2 | 6 | PR |

*Table 1: characterisstics of cases according to ECOG, adverse effects, number of cyycles and response assessment. TE: thromboembolia, GIS: gastrointestinal adverse effect, CIRS-G:* Cumulative Illness Rating Scale-Geriatric, ECOG: Eastern Cooperative Oncology Group performance status, PR: partial response, ex: exitus, n/a: not available,

## CONCLUSIONS

Managing R/R DLBCL in elderly patients is challenging due to clonal evolution and drug resistance. Frailty, polypharmacy, and increased side effects contribute to low response rates. The R2 protocol was well tolerated with manageable toxicity profiles and showed acceptable response rates in this study. In conclusion, the R2 combination appears to be a promising alternative regimen for elderly DLBCL patients.

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