

# Multi-center phase II study with lenalidomide plus rituximab as initial treatment for mantle cell lymphoma: survival update and health-related quality-of-life analysis

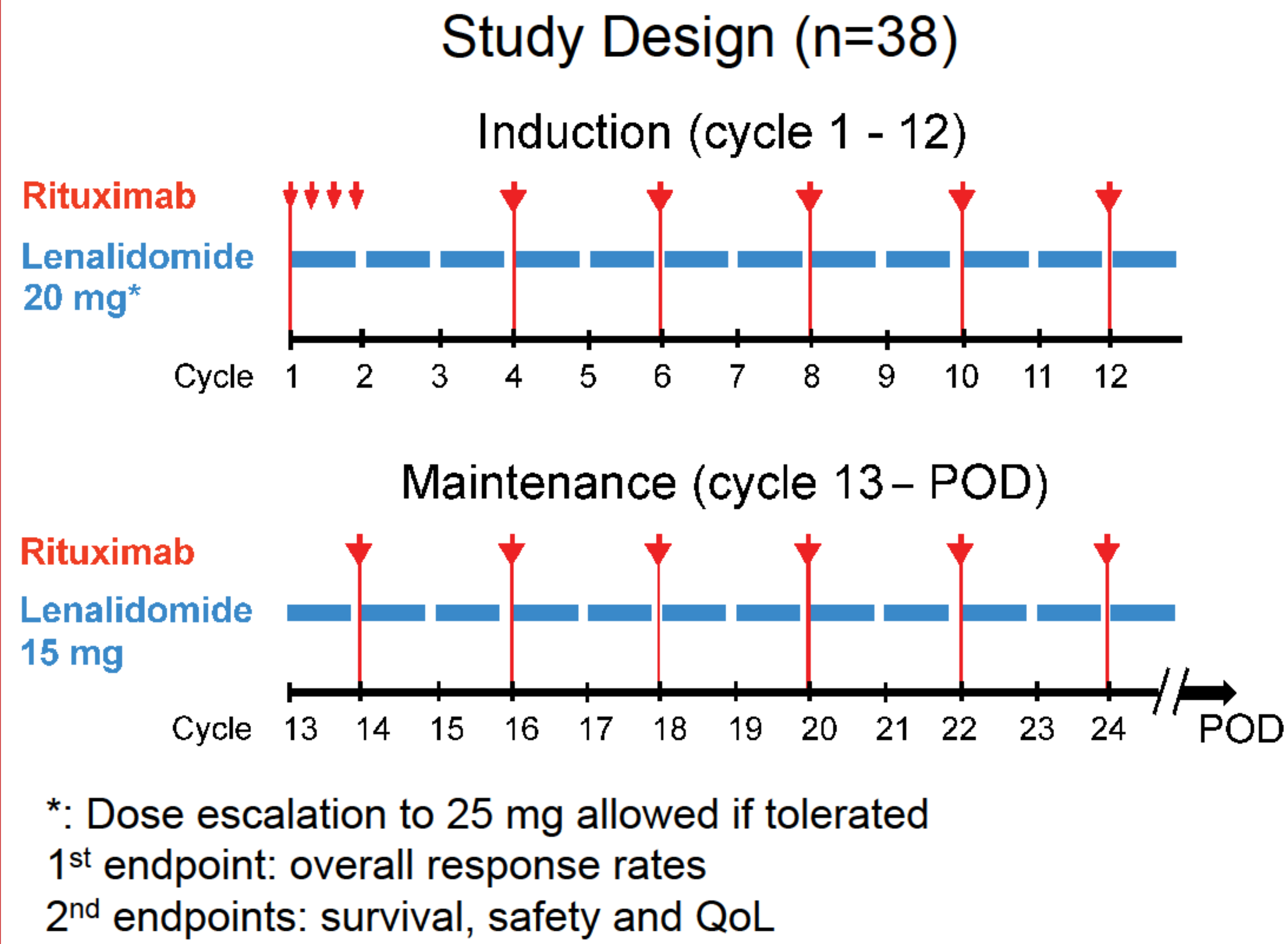
J. Ruan<sup>1</sup>, P. Martin<sup>1</sup>, B. Shah<sup>2</sup>, S. J. Schuster<sup>3</sup>, S. Smith<sup>4</sup>, P. Christos<sup>5</sup>, R. R. Furman<sup>1</sup>, A. Rodriguez<sup>1</sup>, J. Svoboda<sup>3</sup>, J. Lewis<sup>1</sup>, O. Katz<sup>1</sup>, M. Coleman<sup>1</sup>, J. P. Leonard<sup>1</sup>

<sup>1</sup> Hematology/Oncology, Weill Cornell Medical College, New York, United States, <sup>2</sup> Malignant Hematology, Moffitt Cancer Center, Tampa, United States, <sup>3</sup> Abramson Cancer Center, University of Pennsylvania, Philadelphia, United States, <sup>4</sup> Hematology/Oncology, The University of Chicago, Chicago, United States, <sup>5</sup> Biostatistics and Epidemiology, Weill Cornell Medical College, New York, United States.

## OBJECTIVES

- MCL remains incurable, and initial treatment is not standardized.
- The therapeutic goal is to extend survival and maintain quality of life whenever possible.
- We have reported the high efficacy associated with a frontline biologic doublet of Len plus R (ORR 84.2% with 52.6% CR, ASH2014).
- We now report the survival update and health-related quality-of-life (HRQoL) outcome analysis.
- ClinicalTrials.gov-NCT01472562

## METHODS



## HRQoL Analysis

- FACT-LYM questionnaires were obtained at baseline, every 3 months for 2 years, every 6 months thereafter.
- QoL exploratory analysis was performed in patients who have completed at least 24 months of therapy.
- The FACT-LYM total score and trial outcome index (TOI) score were correlated using paired t-test to clinical features, treatment, and response.

## RESULTS

Characteristic	No. of Patients	Percent
No. of Patients	38	100%
Sex		
Male	27	71%
Female	11	29%
Age, years		
Median	65	
Range	42-86	
MIPI risk category		
Low risk (score <5.7)	13	34%
Intermediate risk (5.7 ≤ score < 6.2)	13	34%
High risk (score ≥ 6.2)	12	32%
IPI risk category		
0-1	6	16%
2	18	47%
3	10	26%
4-5	4	11%

Response	ITT (n=38)	Evaluable (n=36)
Overall response	87%	92%
CR	61%	64%
PR	26%	28%
SD	3%	3%
PD	5%	6%
<b>Survival</b>		
Median PFS	Not reached	
2-year PFS	85% (95% CI = 67%, 94%)	
2-year OS	97% (95% CI = 79%, 99%)	
Median follow-up	30 months (range 11-43)	
Median time to PR	3 months (range 3-13)	
Median time to CR	11 months (range 3-22)	

Figure 1. Kaplan-Meier Survival Analysis

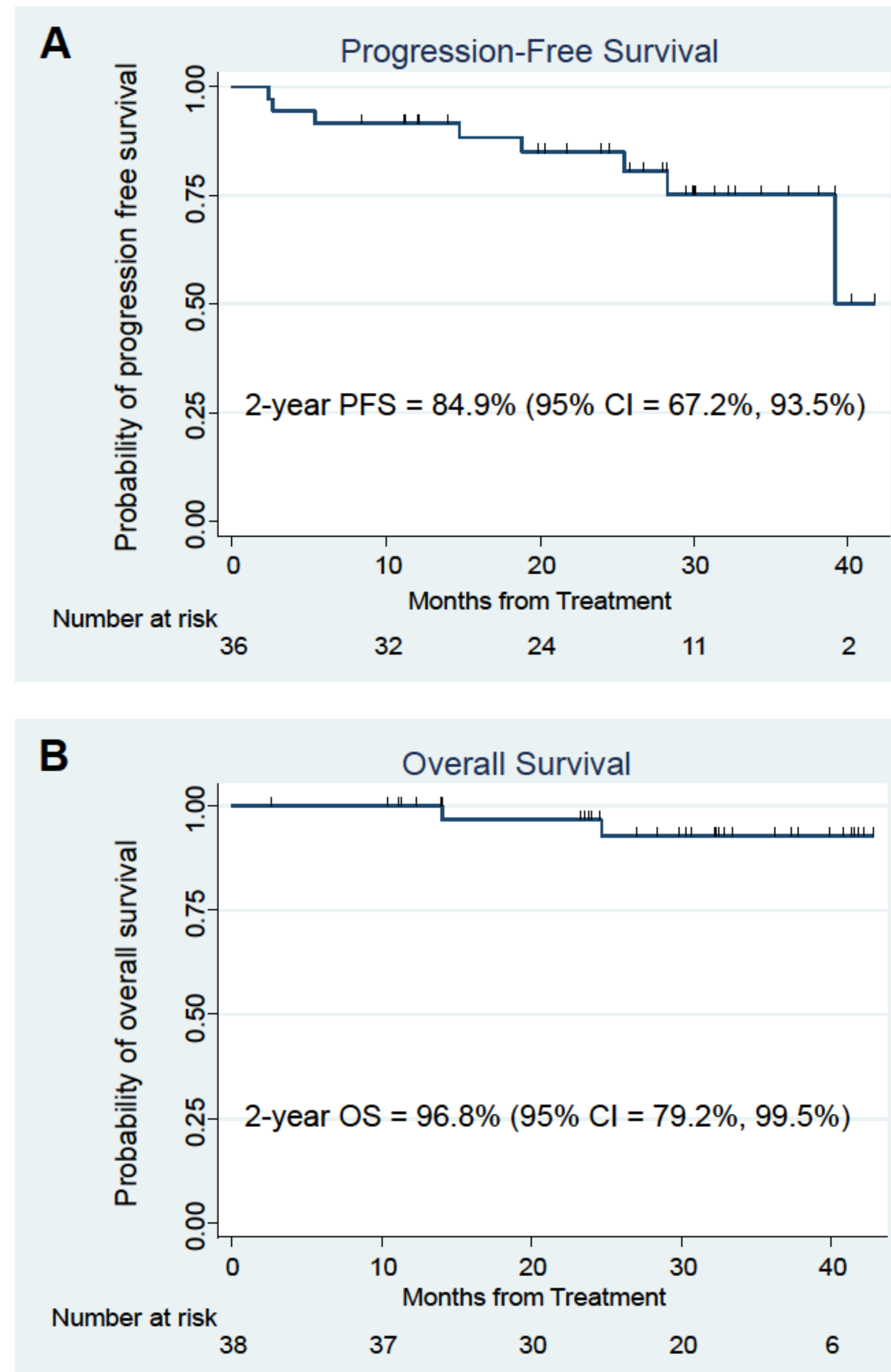
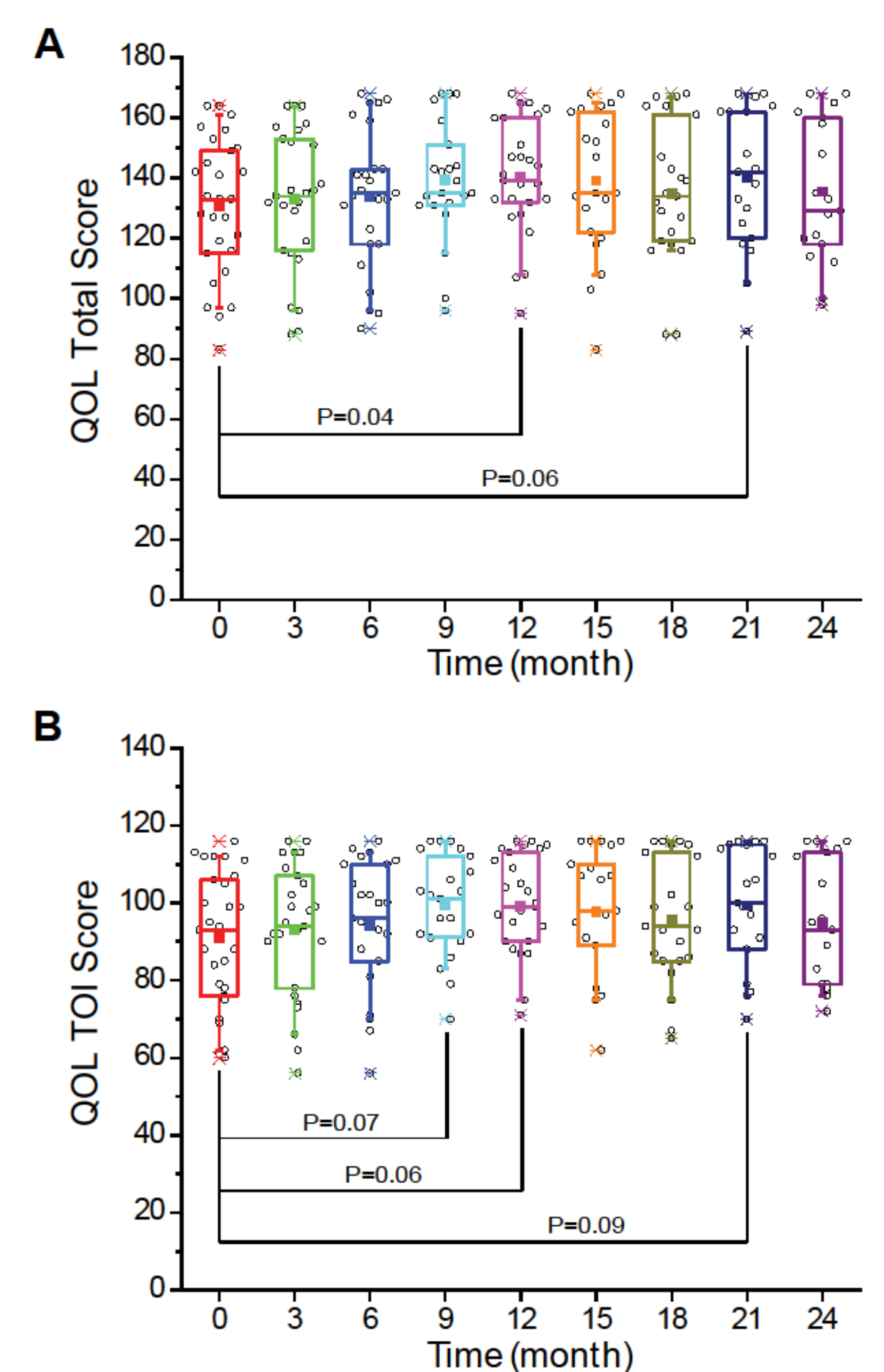


Figure 2. Exploratory Analysis of HRQoL



## CONCLUSIONS

- This study provides the first demonstration that a chemotherapy-free, combination biologic approach is active with durable responses as initial therapy for mantle cell lymphoma.
- High efficacy induction therapy with Lenalidomide and Rituximab generally improves HRQoL, while maintenance strategy with both agents appears feasible with preservation of HRQoL in the upfront setting.

## REFERENCES

1. Goy A, Sinha R, Williams ME, et al. Journal of Clinical Oncology 2013;31:3688-95
2. Wang M, Fayad L, Wagner-Bartak N, et al. The Lancet Oncology 2012;13:716-23
3. Kluin-Nelemans HC, Hoster E, Hermine O, et al. New England Journal of Medicine 2012;367:520-31
4. Smith SK, Zimmerman S, Williams CS, Zebrack BJ. Cancer 2009;115:3312-23

