



P1. 271: Sintilimab plus platinum doublet chemotherapy (chemo) vs Osimertinib as first-line therapy in EGFR-Mutant non-small cell lung cancer (NSCLC) with high PD-L1 expression: a phase II trial

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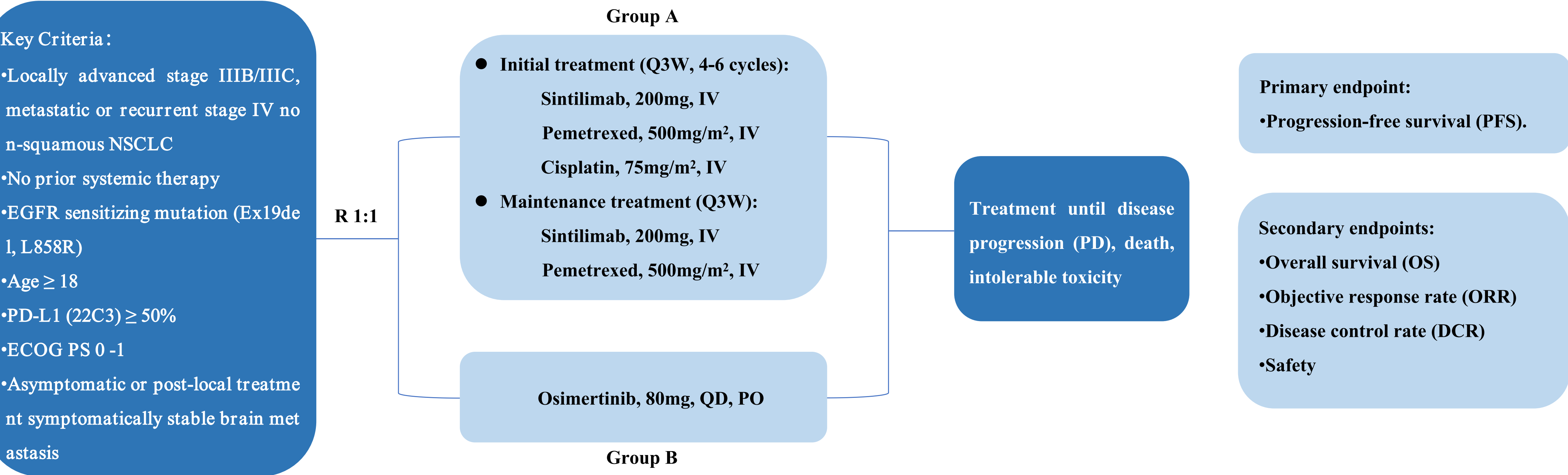
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INTRODUCTION

Tyrosine kinase inhibitors (TKIs) remain standard care for EGFR-mutated advanced NSCLC, yet patients (pts) with PD-L1 T PS $\geq 50\%$ show poor outcomes (progression free survival (PFS) 1-2 months). PD-1/PD-L1 inhibitors combined with chemo have shown efficacy in TKI-progressed populations. We investigate sintilimab plus chemo vs osimertinib as first-line therapy in EGFR-mutant NSCLC with PD-L1 $\geq 50\%$.

METHODS

This single-center, randomized, prospective phase II trial enrolled advanced NSCLC pts with both PD-L1 $\geq 50\%$ and EGFR-sensitive mutations (ChiCTR2400093087).



CONCLUSION

Sintilimab plus chemo as first-line therapy may improve PFS over osimertinib in advanced EGFR-mutant NSCLC with high PD-L1. Further investigation is warranted.

REFERENCES & ACKNOWLEDGEMENTS

REFERENCES

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RESULTS

- Between May 6, 2023 and January 15, 2026, a total of 40 pts were enrolled (Group A: 20, Group B: 20).
- PD occurred in 4 pts in group A and 12 pts in group B. Group A showed longer median PFS compared to group B (9.5 mo vs 5.0 mo, $p = 0.02$). Median OS was not reached in either group.
- ORR and DCR both favored group A (ORR: 55.0% vs 35.0%, $p = 0.20$; DCR: 100.0% vs 75.0%, $p = 0.06$).
- No grade ≥ 3 treatment-related/ immune-related adverse events.

Table 1. The baseline characteristics

	Group A (n = 20)	Group B (n = 20)
Age (age)	61.7 $\pm$ 9.2	62.8 $\pm$ 10.5
Smoking history(n%)	6 (30.0%)	4 (20.0%)
Gender (n%)		
Male	8 (40.0%)	6 (30.0%)
Tumor staging (n%)		
IIIC	1 (5.0%)	2 (10.0%)
IV	19 (95.0%)	18 (90.0%)
Baseline metastasis (%)		
Brain metastasis	3 (15.0%)	5 (25.0%)
Liver metastasis	2 (10.0%)	0 (0.0%)
Merging brain and liver metastasis	1 (5.0%)	2 (10.0%)
other metastasis	12 (60.0%)	11 (55.0%)
EGFR mutation (n%)		
21 L858R	7 (35.0%)	5 (25.0%)
Exon 19 deletion	12 (60.0%)	14 (70.0%)
EGFR concurrent alterations (n%)		
TP53	7 (35.0%)	7 (35.0%)

Table 2.Summary of clinical activities

	Group A (n = 20)	Group B (n = 20)
mPFS (95% CI), months	9.5 (9, NE)	5.0 (3, NE)
mOS (95% CI), months	NE	NE
ORR (%)	55.0	35.0
DCR (%)	100.0	75.0

Figure 1. Kaplan-Meier curves of PFS

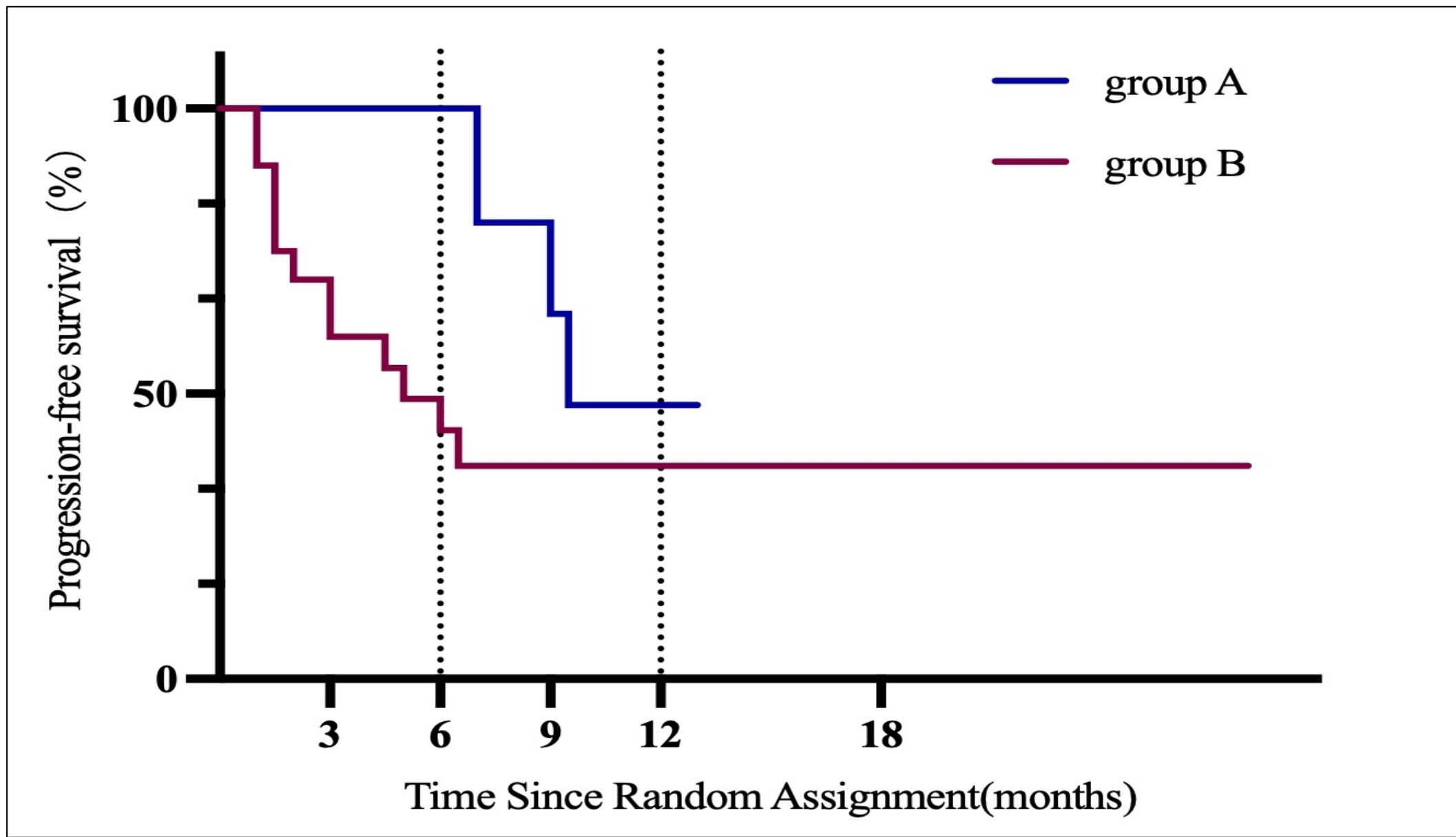


Figure 2. Kaplan-Meier curves of OS

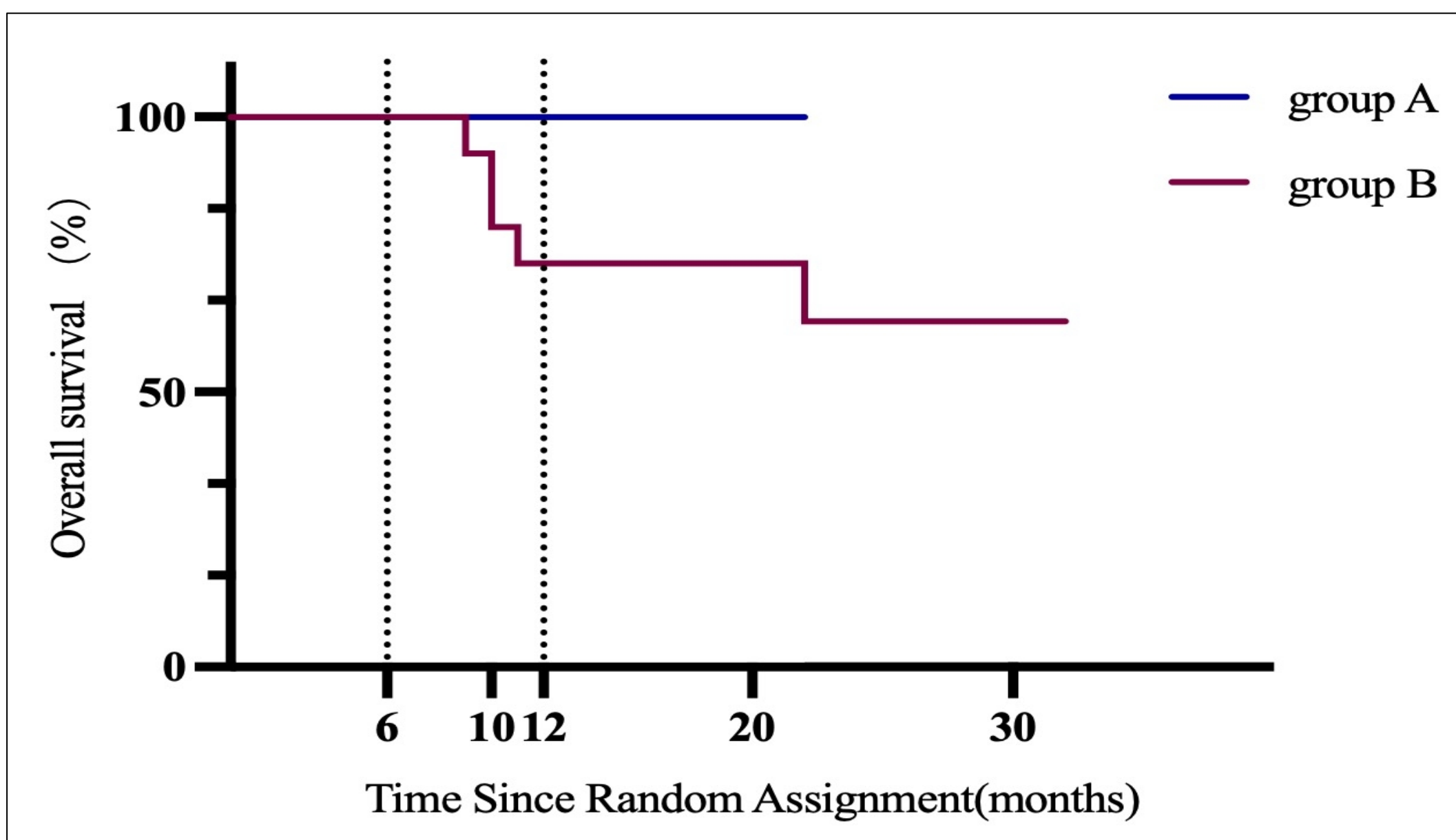


Figure 3. Waterfall plot of best-overall response

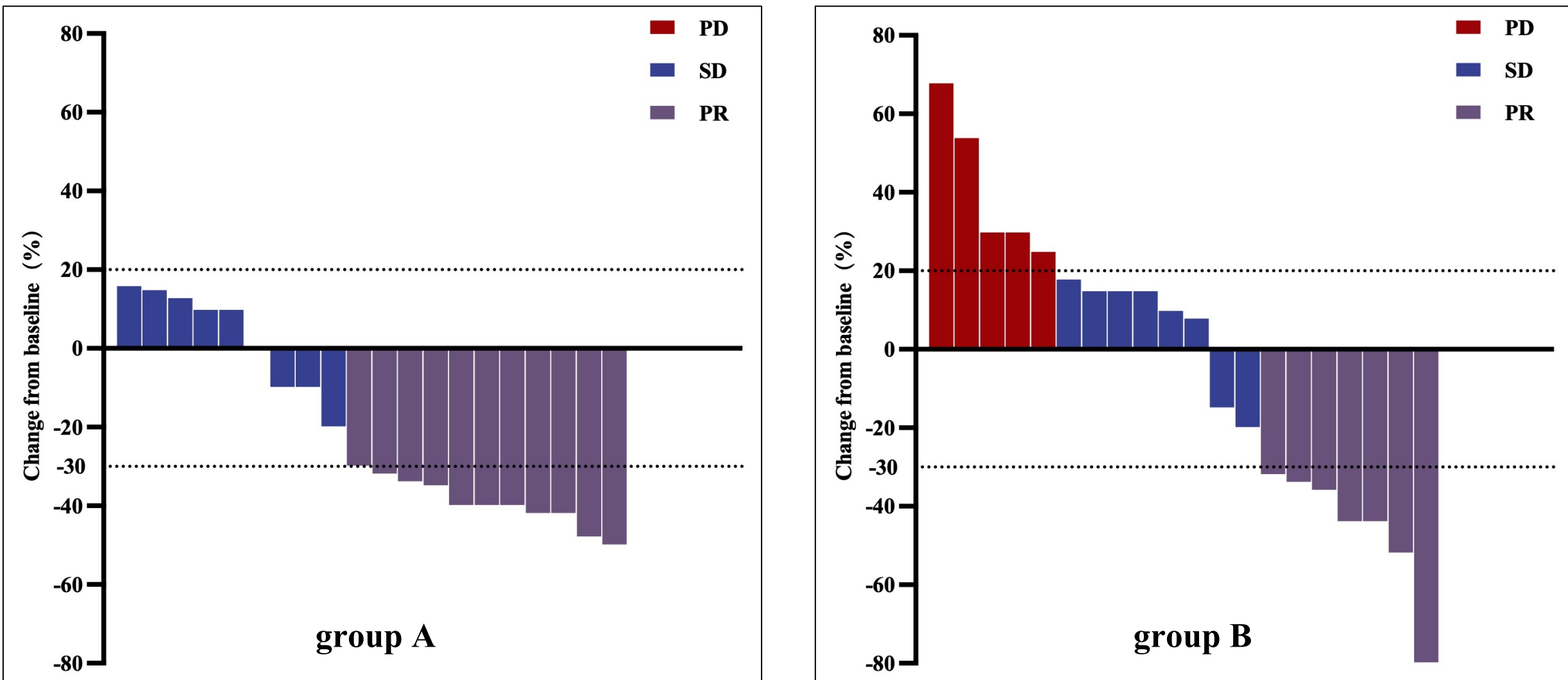


Table 3. Summary of best-overall response

	Group A (n = 20)	Group B (n = 20)
Complete response (n%)	0 (0.0%)	0 (0.0%)
Partial response (n%)	11 (55.0%)	7 (35.0%)
Stable disease (n%)	9 (45.0%)	8 (40.0%)
Progressive disease (n%)	0 (0.0%)	5 (25.0%)