



P2.380: First-Line Toripalimab in Combination with Platinum-Doublet Chemotherapy for Advanced B3 Thymoma and Thymic Carcinoma: An Open-Label Prospective Phase II Trial

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INTRODUCTION

Thymic epithelial tumors (TETs) are rare neoplasms that originate from the epithelial component of the thymus gland. A retrospective study indicates that the combination of immune checkpoint inhibitors with chemotherapy yields a better median PFS of 12.7 months and an ORR of 44.4%. Here we conducted a phase II, prospective trial to explore the safety and feasibility of toripalimab plus chemotherapy as first line treatment in advanced TCs.

METHODS

Design:

Patients with histologically diagnosis of Masaoka stage III or IV TCs will be enrolled. Eligible patients will receive toripalimab (240mg, d1, q3w) plus paclitaxel (175mg/m², d1, q3w) and carboplatin (AUC=5, d1, q3w) for 4-6 cycles and continued to receive toripalimab (240mg, d1, q4w) maintenance therapy until disease progression, intolerable toxicity, or withdrawal of consent. The primary endpoint is progression-free survival (PFS). Secondary endpoints are objective response rate (ORR), Disease control rate (DCR), duration of response (DoR), overall survival (OS) and safety.

DISCUSSION AND CONCLUSION

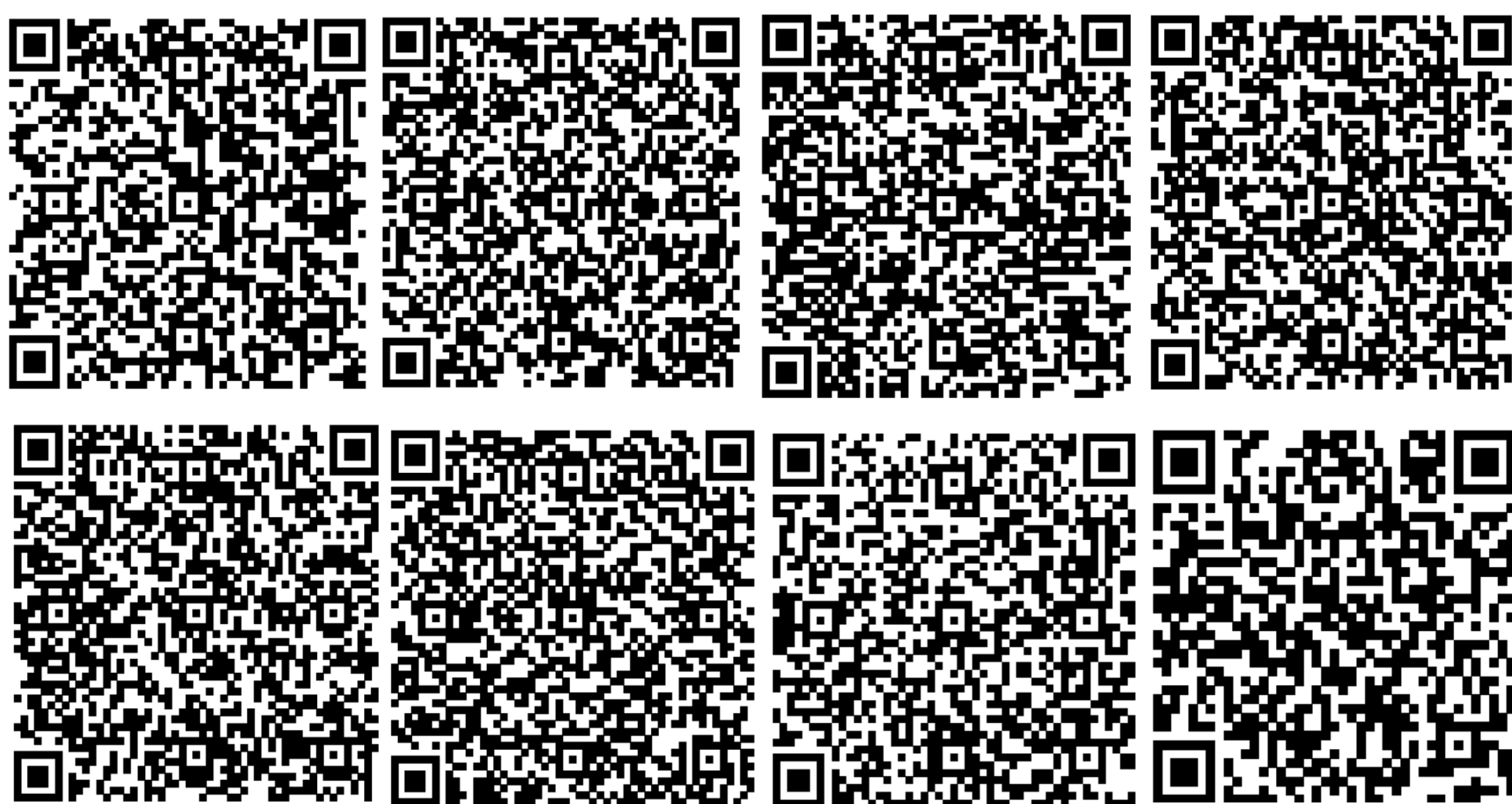
Actionable Take Away Message

- Toripalimab plus chemotherapy is effective and well tolerated as first line treatment for patients with advanced thymic carcinoma
- Specific characteristics of the TIME and genome might aid clinicians in identifying favorable patient subgroups

Future Direction for Research

- Sample size could be increased
- Precise identification of low irAE risk through biomarkers and genetic signatures is needed
- Multi-omics approaches could be adopted

REFERENCES & ACKNOWLEDGEMENTS



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RESULTS

From December, 2020 to September, 2024, 24 patients were enrolled. Median age was 55 years (range: 35–69) and 16 (66.7%) patients were male. The median follow-up was 22.1 months (range: 12.1–52.7 months). Nine (37.5%) patients achieved the best response of PR, and 15 (62.5%) showed the best SD response. The median tumor reduction was -18.8% (range: 0 to -81.8%) . The median PFS was 19.3 months (95% CI: 12.8–25.8) . The ORR was 37.5% (95% CI: 18.8%–59.4%), and DCR was 100% (95% CI: 85.8%–100%). The median DoR was 26.4 months (95% CI: 0–57.8). The median OS was not reached. Grade 3-4 TRAEs occurred in 12 patients (50.0%). Immune-related adverse events (irAEs) were identified in 11 (45.8%) patients, grade ≥3 irAE was reported in 1(4.2%) patient. Further analysis revealed specific infiltration pattern of CD8+ T cell, M1/M2 macrophage, CD56bright natural killer cell within the tumor immune microenvironment as well as the mutations in NF-κB pathway were associated with better clinical outcome.

Table 1. Patient characteristics

Characteristic	Eligible patients (n=24)
Age, No. (%)	
≥ 60	7 (29.2)
< 60	17 (70.8)
Median age, years (range)	53 (34-68)
Sex, No. (%)	
Male	16 (66.7)
Female	8 (33.3)
Histology, No. (%)	
B3 thymoma	2 (8.3)
Squamous carcinoma	22 (91.7)
Masaoka stage, No. (%)	
III	1 (4.2)
IV A	9 (37.5)
IV B	14 (58.3)
TNM staging (AJCC 9th edition), No. (%)	
III	1 (4.2)
IV A	7 (29.2)
IV B	16 (66.7)
Smoking history, No. (%)	
Yes	8 (33.3)
No	16 (66.7)
ECOG PS, No. (%)	
0	9 (37.5)
1	15 (62.5)
Tumor size, No. (%)	
≥ 50 mm	15 (62.5)
< 50 mm	9 (37.5)
Metastasis, No. (%)	
Pleura	14 (58.3)
Lung	4 (16.7)
Liver	3 (12.5)
Bone	1 (4.2)
Lymph node	10 (41.7)
Previous treatment, No. (%)	
Thymectomy	10 (41.7)
Neoadjuvant Chemotherapy	2 (8.3)
Adjuvant Chemotherapy	3 (12.5)
Thoracic Radiotherapy	4 (16.7)
None	14 (58.3)

Figure 1. Best Change From Baseline (%)

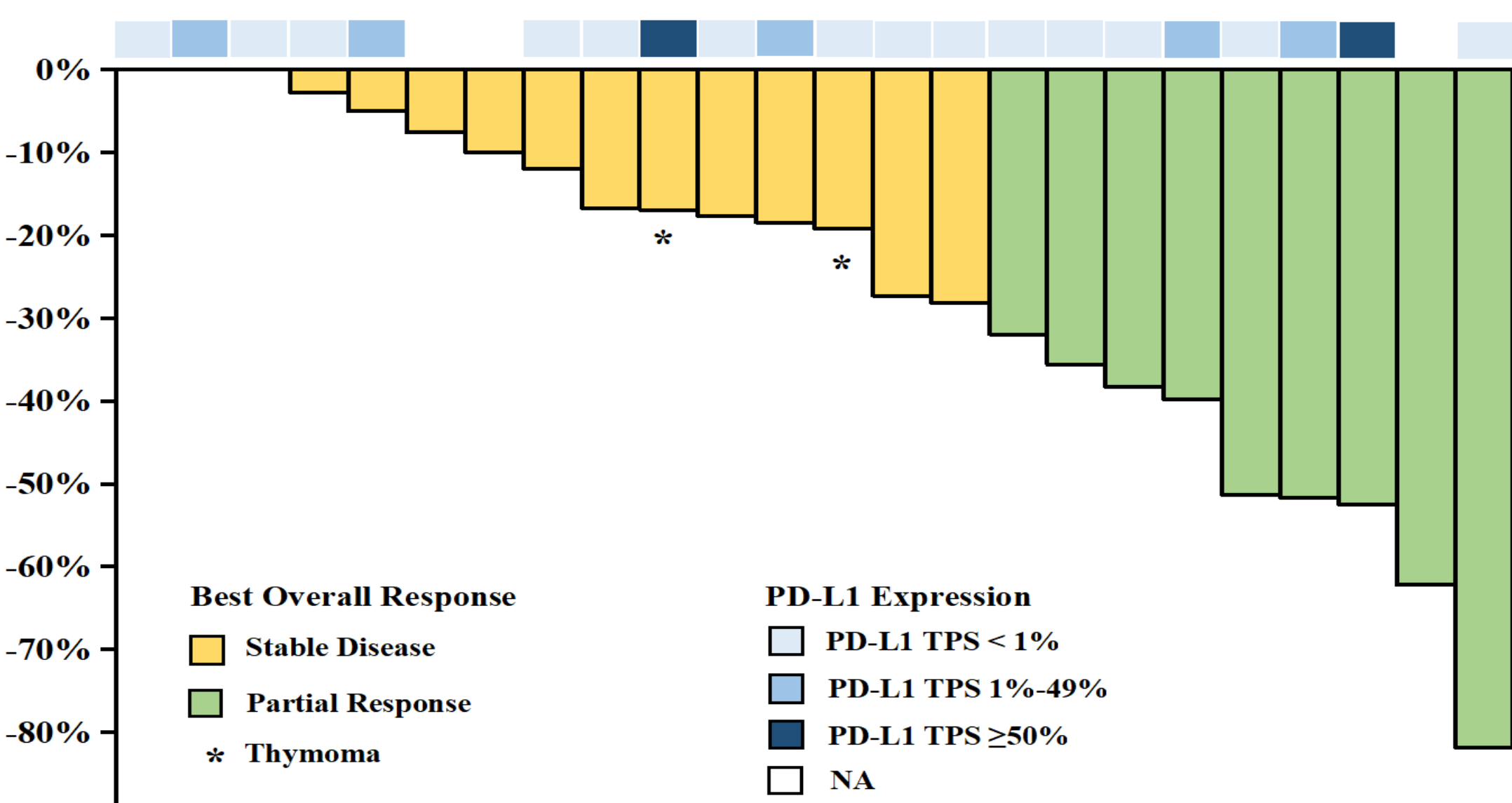


Figure 2. Progression-Free Survival

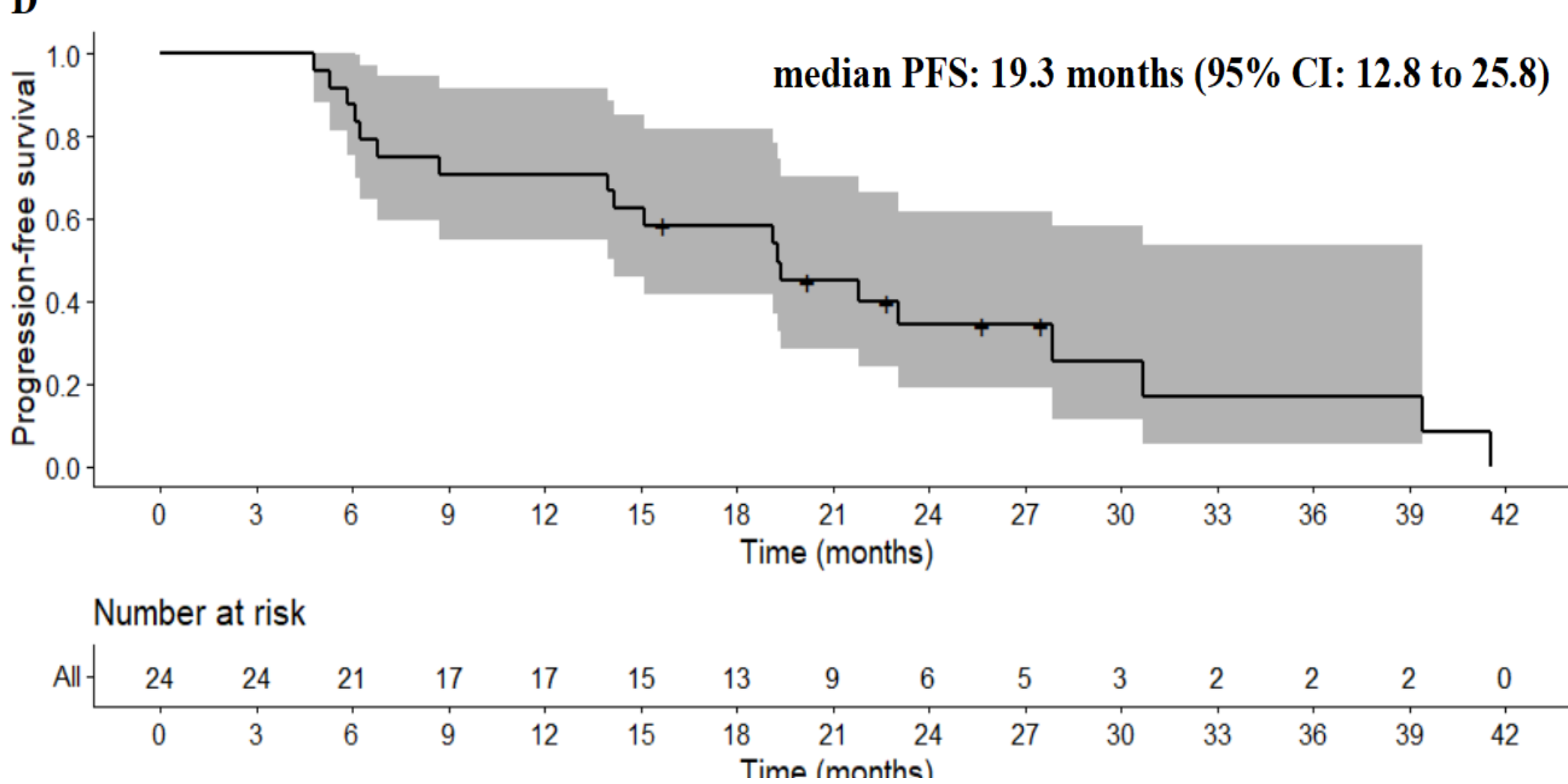


Table 2. Response to treatment

Response	
Best Response, No (%)	
Partial response	9 (37.5)
Stable disease	15 (62.5)
Progressive disease	0
Progression-free survival, months, median (95% CI)	19.3 (12.8 to 25.8)
Overall response rate, % (95% CI)	37.5 (18.8 to 59.4)
Disease control rate, % (95% CI)	100 (85.8 to 100)
Duration of response, months, median (95% CI)	26.4 (0 to 57.8)

Figure 1. Study design

