

Background

- Recent reports focused on the outcomes after discontinuation or completion of ICI therapy¹⁻².
- However, existing findings are largely derived from retrospective studies with heterogeneous populations, discontinuation reasons, and imaging intervals.
- Therefore, we aimed to elucidate outcomes after discontinuation or completion of pembrolizumab in randomized phase III trial.

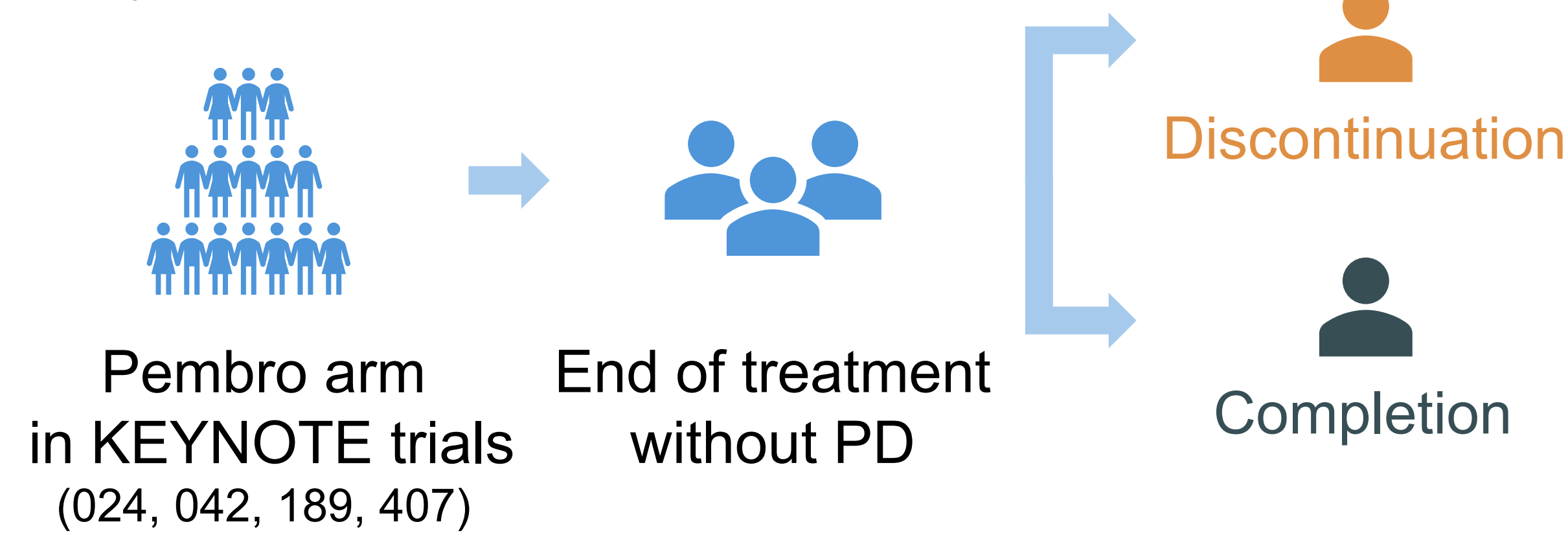
1) Nagai T, et al. Thorac Cancer. 2025
2) Pecci F, et al. Clin Cancer Res. 2025

Methods

Design & Setting

- Exploratory post-hoc analysis of 4 phase III trials (KEYNOTE-024, -042, -189, and -407 trials)

Target population



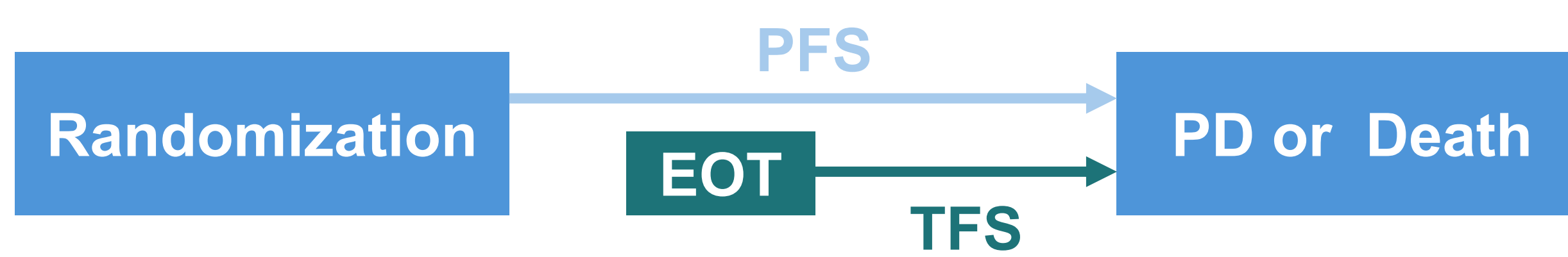
Outcomes

- ✓ Treatment-free survival (TFS)
- ✓ Overall survival from end of treatment (OS from EOT)

EOT: End of treatment

Definition of TFS

The time from the date of the last dose of treatment to progression or death without subsequent therapy



Analysis

- The patient data was supplied by Merck & Co., Inc.
- All analyses were performed using statistical analysis software R version 4.4.0 on the Vivli platform.

This presentation is based on research using data from Merck & Co., Inc., Rahway, NJ, USA. that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.

Results

Figure 1: Patients' flow

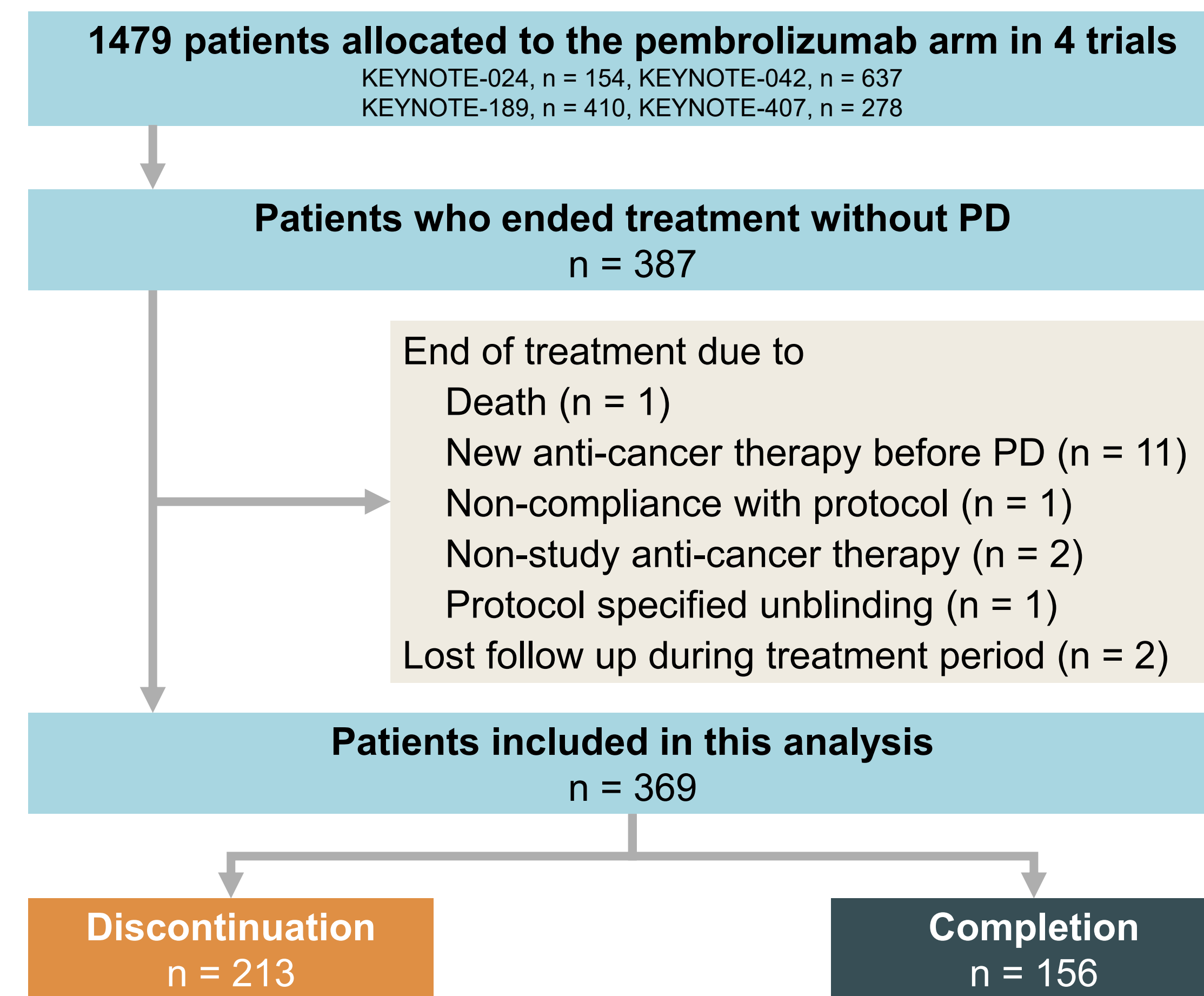


Table 1: Patients characteristics

Characteristic	Discontinuation n = 213	Completion n = 156
Age, median(IQR)	67 (60, 71)	62 (56, 68)
Sex, n(%)		
Male	150 (70%)	107 (69%)
Female	63 (30%)	49 (31%)
Smoking, n(%)		
Never	26 (12%)	15 (10%)
Former/Current	187 (88%)	141 (90%)
Histology, n(%)		
Squamous	65 (31%)	51 (33%)
Non-squamous	142 (67%)	105 (67%)
Brain metastasis, n(%)		
No	191 (90%)	134 (86%)
Yes	22 (10%)	22 (14%)
PD-L1 TPS, n(%)		
≥50%	105 (49%)	96 (62%)
1-49%	61 (29%)	48 (31%)
<1%	42 (20%)	10 (6.4%)
Treatment, n(%)		
Pembro mono	77 (36%)	100 (64%)
Pembro+Chemo	136 (64%)	56 (36%)
Response, n(%)		
CR/PR	140 (65%)	139 (89%)
SD	69 (32%)	17 (11%)
Discontinuation, n(%)		
AE	172 (81%)	-
Others*	41 (19%)	-
Treatment duration, median	6 months	24 months

*physician's decision (n=17), patient withdrawal (n=21), CR (n=3)

Figure 2: Treatment-free survival (TFS)

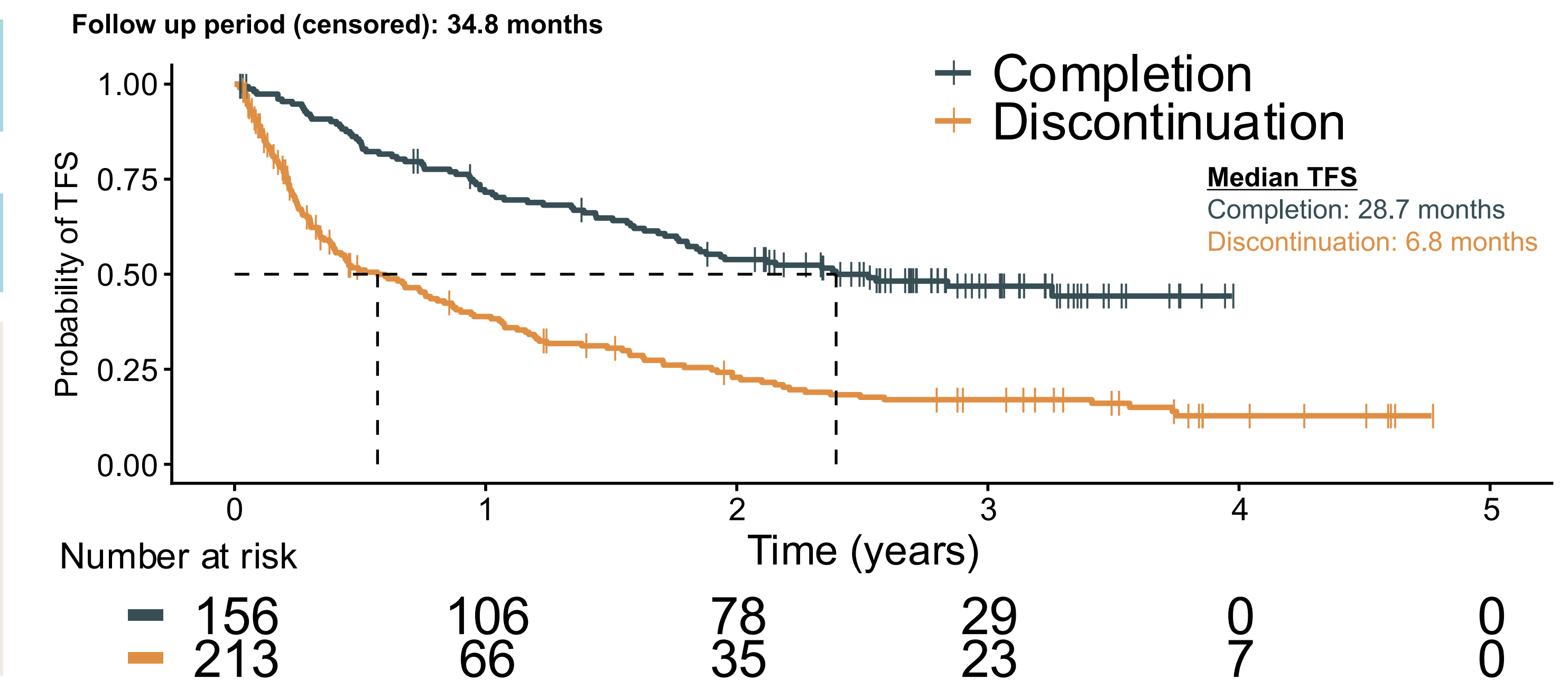


Figure 3: TFS by response

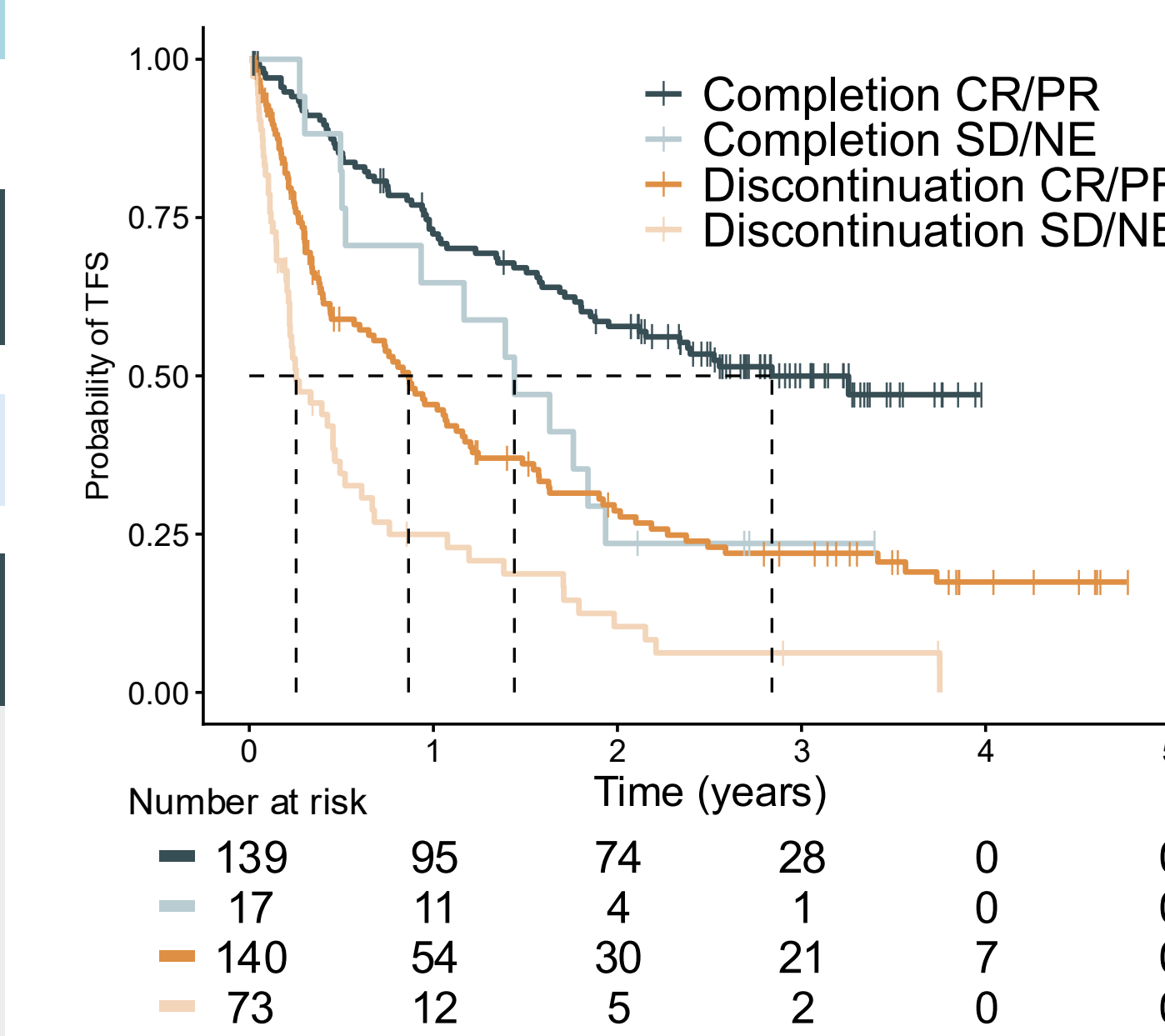


Figure 4: OS from EOT

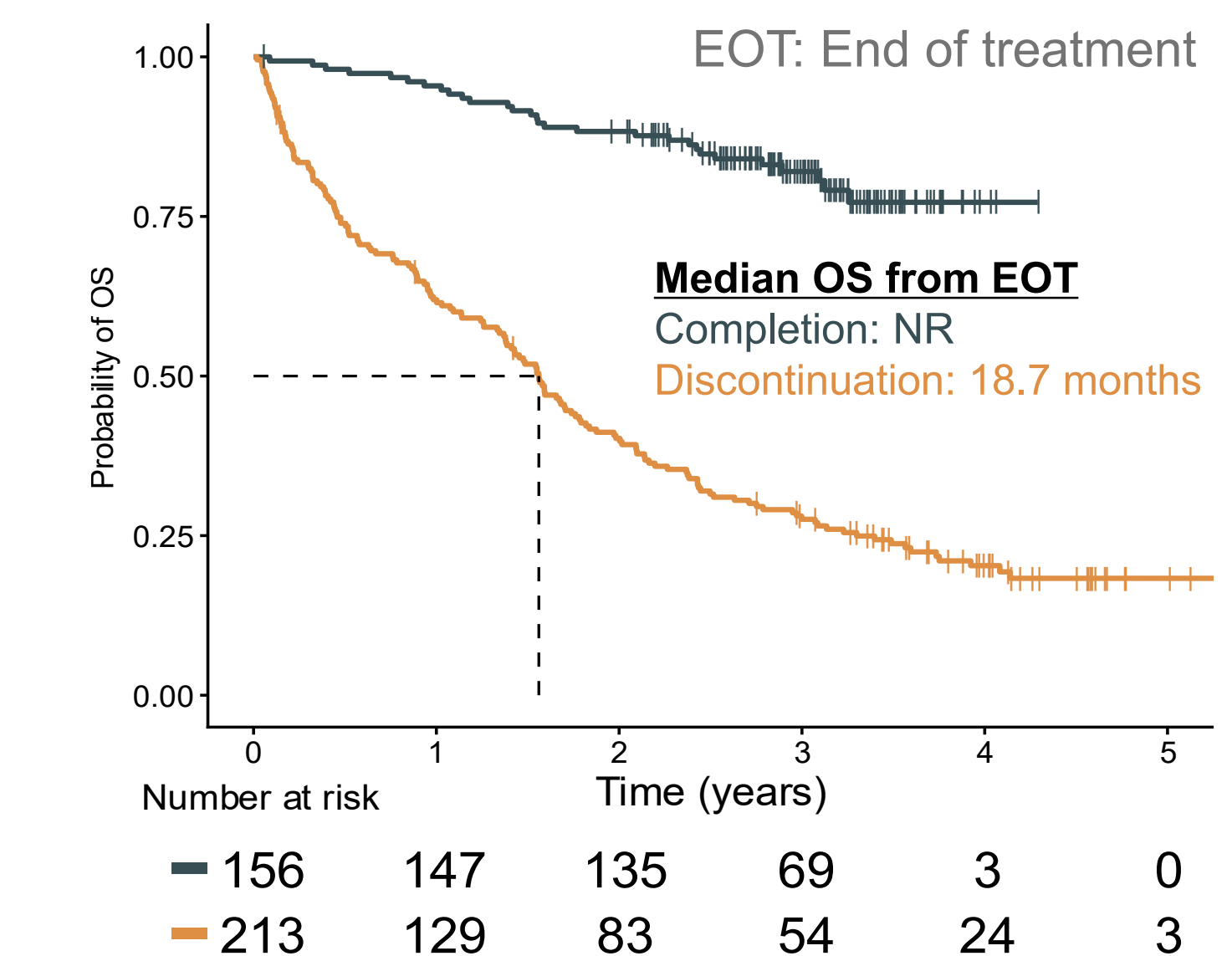
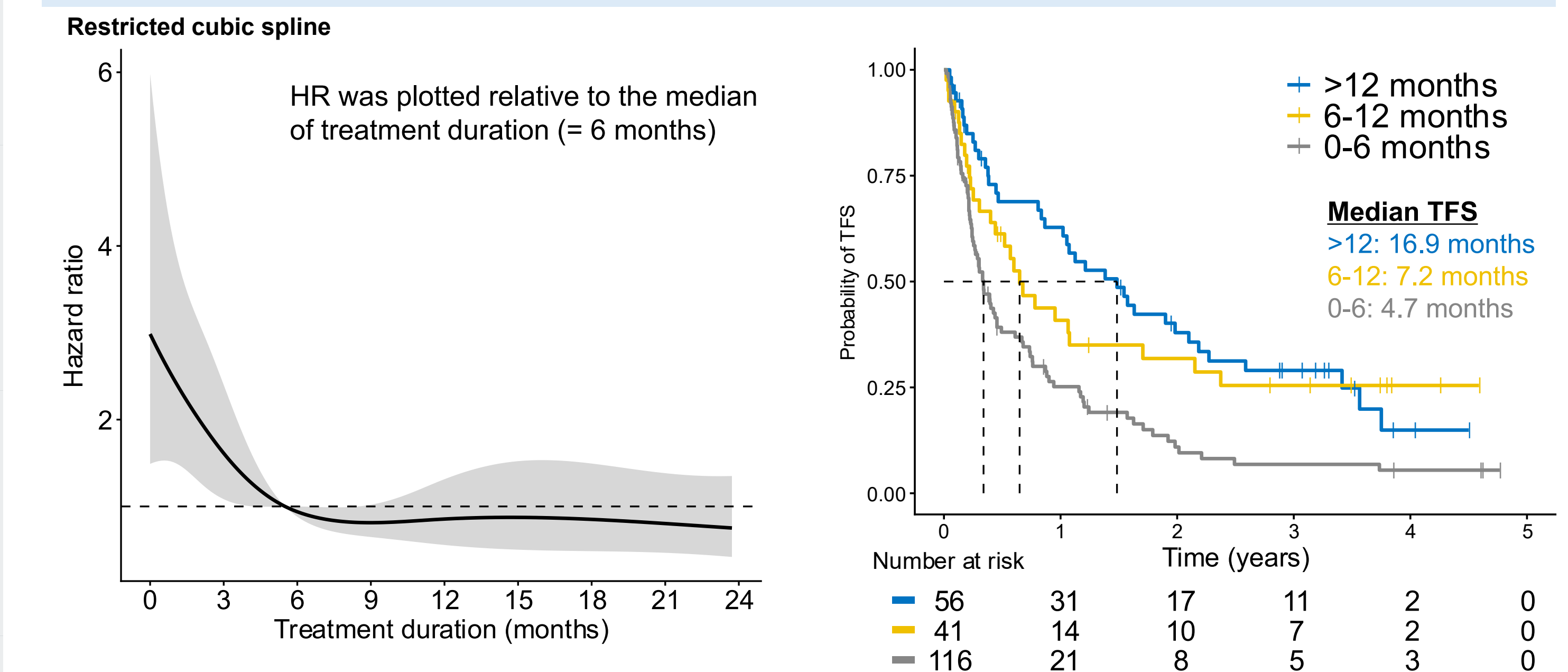


Figure 5: Association between treatment duration and TFS in the discontinuation group



Conclusion

- Even in the discontinuation group, approximately 20% of patients showed long-term TFS.
- The association between treatment duration and TFS may weaken beyond a threshold.