

484P: Real World Sacituzumab Govitecan (SG) use and outcomes in Advanced Triple Negative Breast Cancer (aTNBC) in Australia (TRACIE)

Vanessa Wong (1,2), Catherine Morton (1), Yoland Antill (3,4), Sally Baron-Hay (5), Frances Boyle (6), Kerry Cheong (7,8), Katharine Cuff (9), Rachel F Dear (10,11), Richard de Boer (12), Abhishek Joshi (13), Sanjeev Kumar (14,15), Louisa Lo (16), Louise Nott (17), Gaik Tin Quah (18), Iris Tung (19, 20), Michelle White (3,4), Shane White (21, 22), Belinda Yeo (22), Nicholas Zdenkowski (23), Sheau Wen Lok (1)

Personalised Oncology Division, Walter and Eliza Hall Institute of Medical Research, VIC ¹, Grampians Health, VIC ², Cabrini Health, VIC ³, Faculty of Medicine, Dentistry and Health Sciences, Monash University, Clayton, VIC ⁴, Australia, Genesis Care North Shore, NSW ⁵, Mater Hospital Sydney, NSW ⁶, Icon Cancer Centre Adelaide, SA ⁷, Faculty of Medicine, University of Adelaide, SA ⁸, Princess Alexandra Hospital, QLD ⁹, The Kinghorn Cancer Centre, St Vincent's Hospital, Sydney, NSW ¹⁰, Faculty of Medicine & Health, UNSW Sydney ¹¹, St Vincent's Private, VIC ¹², Townsville University Hospital, Townsville QLD ¹³, Chris O'Brien Lifehouse, NSW ¹⁴, Garvan Institute, NSW ¹⁵, St Charles Gairdner Hospital, WA ¹⁶, Icon Cancer Centre Hobart, TAS ¹⁷, Calvary Mater Newcastle, NSW ¹⁸, Eastern Health, VIC ¹⁹, Eastern Health Clinical School, Monash University, VIC ²⁰, Warringal Private Hospital, VIC ²¹, Austin Health, VIC ²², Hunter Valley Oncology, Gateshead, NSW ²³

Background

- SG use in Australia is approved for advanced TNBC (aTNBC) in second line (2L) treatment and beyond, with the ASCENT trial^{1,2} demonstrating improvement in both
 - Progression free survival (PFS): 4.8 vs 1.7 months (HR 0.41) and
 - Overall survival (OS): 11.8 vs 6.9 months (HR 0.51) when compared to chemotherapy
- Real world evidence on treatment patterns and outcomes is limited
- This study aims to collect data in Australian patients with aTNBC treated with SG, in order to examine patterns and survival outcomes

Methods

- TRACIE is a secondary data analysis of Australian aTNBC patients who received SG via the Expanded Access Program and/or Pharmaceutical Benefits Scheme
- Data were collected and analysed from 143 patients across 19 sites who commenced SG between Oct 2021 – Sept 2024
- Median follow up was 11.1 months

Results

- Median time from metastatic diagnosis to SG initiation was 15.1 months (1QR-3QR 7.8, 31.6)
- 88 (62%) had received ≥2 prior lines of therapy for metastatic disease
- 32 (22%) received immunotherapy in the metastatic setting prior to SG.
- 49 (35%) of patients received on treatment SG dose reductions
- At time of data cutoff (9 Mar 2026), 138 (97%) of patients had discontinued SG. Of these, 107 (77%) discontinued due to progressive disease, 10 (7%) due to toxicity, 1 (<1%) due to death and 21 (15%) due to unspecified reasons in the absence of toxicity
- There were no treatment related deaths

Table 1: Baseline clinicopathologic characteristics

	n=143
Mean Age (SD)	55.1 (±11.9)
Age ≥ 65 years	34 (24%)
Treatment location	
Metropolitan	110 (77%)
Regional	33 (23%)
SG via Access Program	28 (20%)
SG via Pharmaceutical Benefits Scheme	115 (80%)
ECOG	
0	80 (56%)
1	24 (17%)
2 +	6 (4%)
Unknown	33 (23%)
Germline testing	
BRCA 1/2 mutation	13 (9%)
Other pathogenic variant	8 (6%)
No pathogenic variant identified	98 (68%)
Not tested	24 (17%)
PD-L1 status	
PD-L1 negative	41 (29%)
PD-L1 positive	43 (30%)
Unknown/Not Done	59 (41%)
Relapsed disease	116 (81%)
De novo metastatic disease	27 (19%)
Site(s) of metastatic disease	
Nodal	94 (66%)
Bone	75 (52%)
Lung	60 (42%)
Liver	54 (38%)
Brain	25 (18%)

References
 1. Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. *N Engl J Med*. 2021;384(16):1529-1541. doi:10.1056/NEJMoa2028485
 2. Bardia A, Rugo HS, Tolaney SM, et al. Final Results From the Randomized Phase III ASCENT Clinical Trial in Metastatic Triple-Negative Breast Cancer and Association of Outcomes by Human Epidermal Growth Factor Receptor 2 and Trophoblast Cell Surface Antigen 2 Expression. *J Clin Oncol*. 2024;42(15):1738-1744. doi:10.1200/JCO.2023.01409



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Corresponding author: Dr Vanessa Wong, WEHI. Email: wong.v@wehi.edu.au
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Figure 1: Progression Free Survival of all SG treated patients

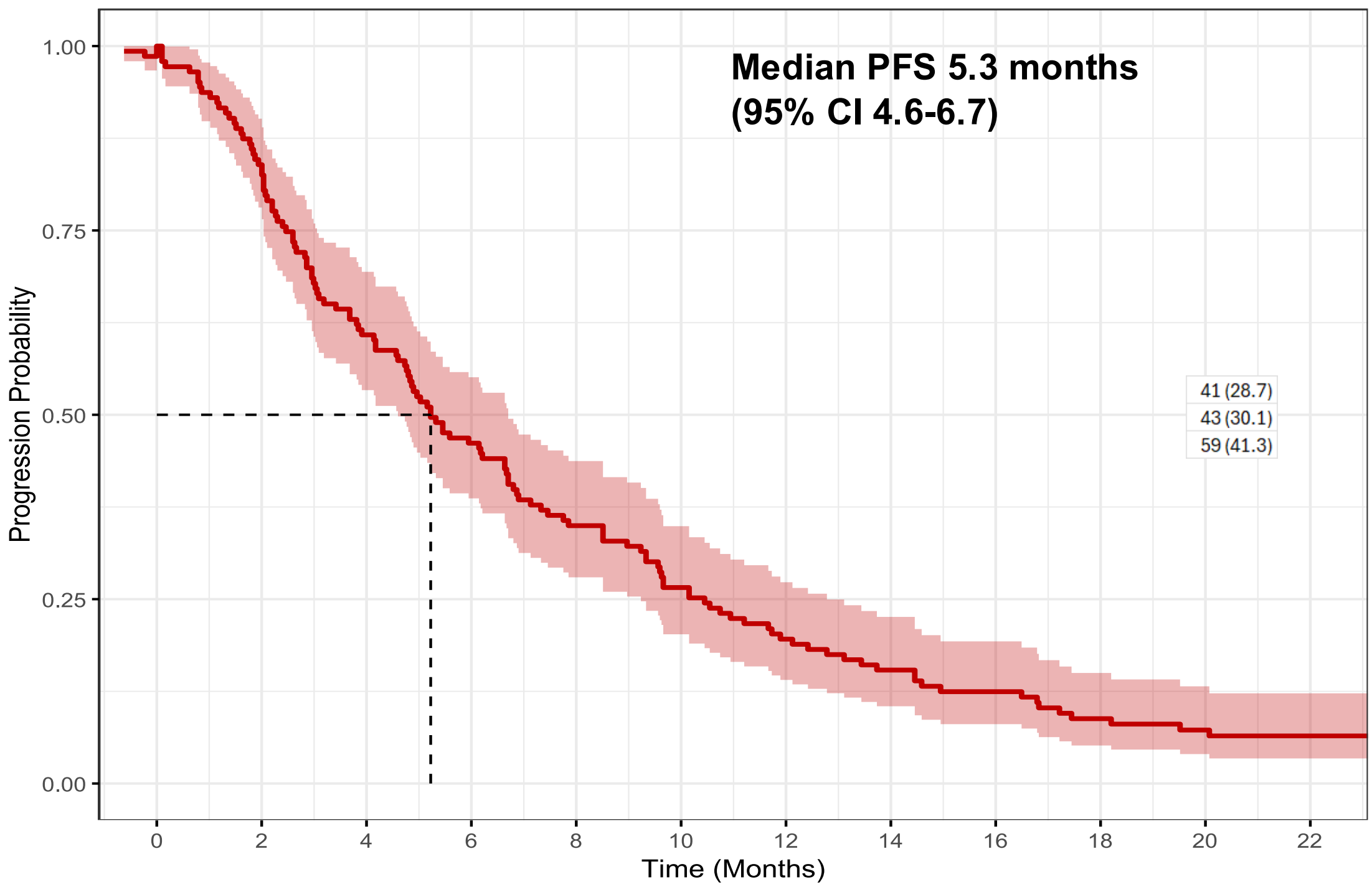


Figure 2: Overall Survival of all SG treated patients

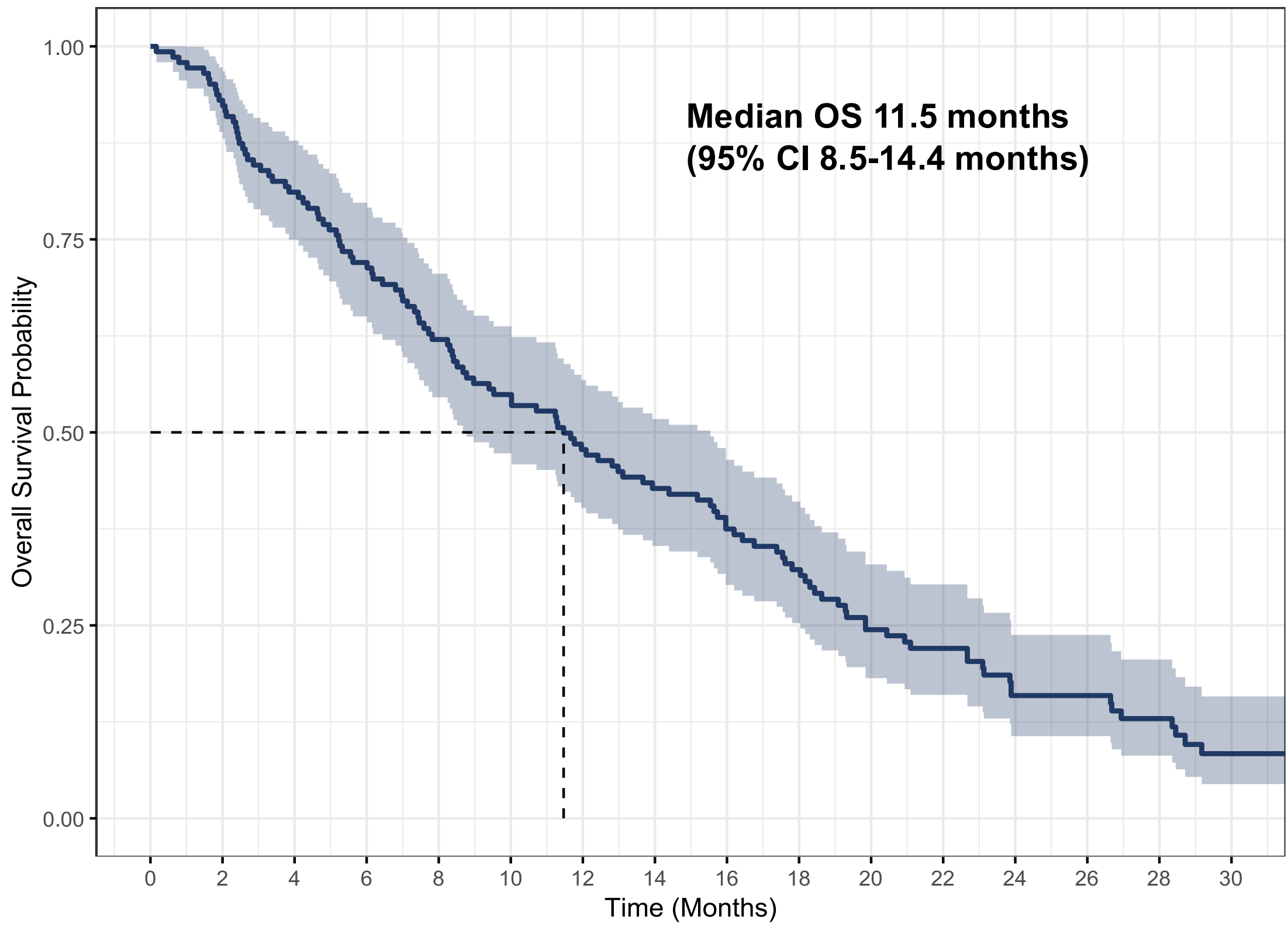


Figure 3: Survival of participants by SG line initiation*

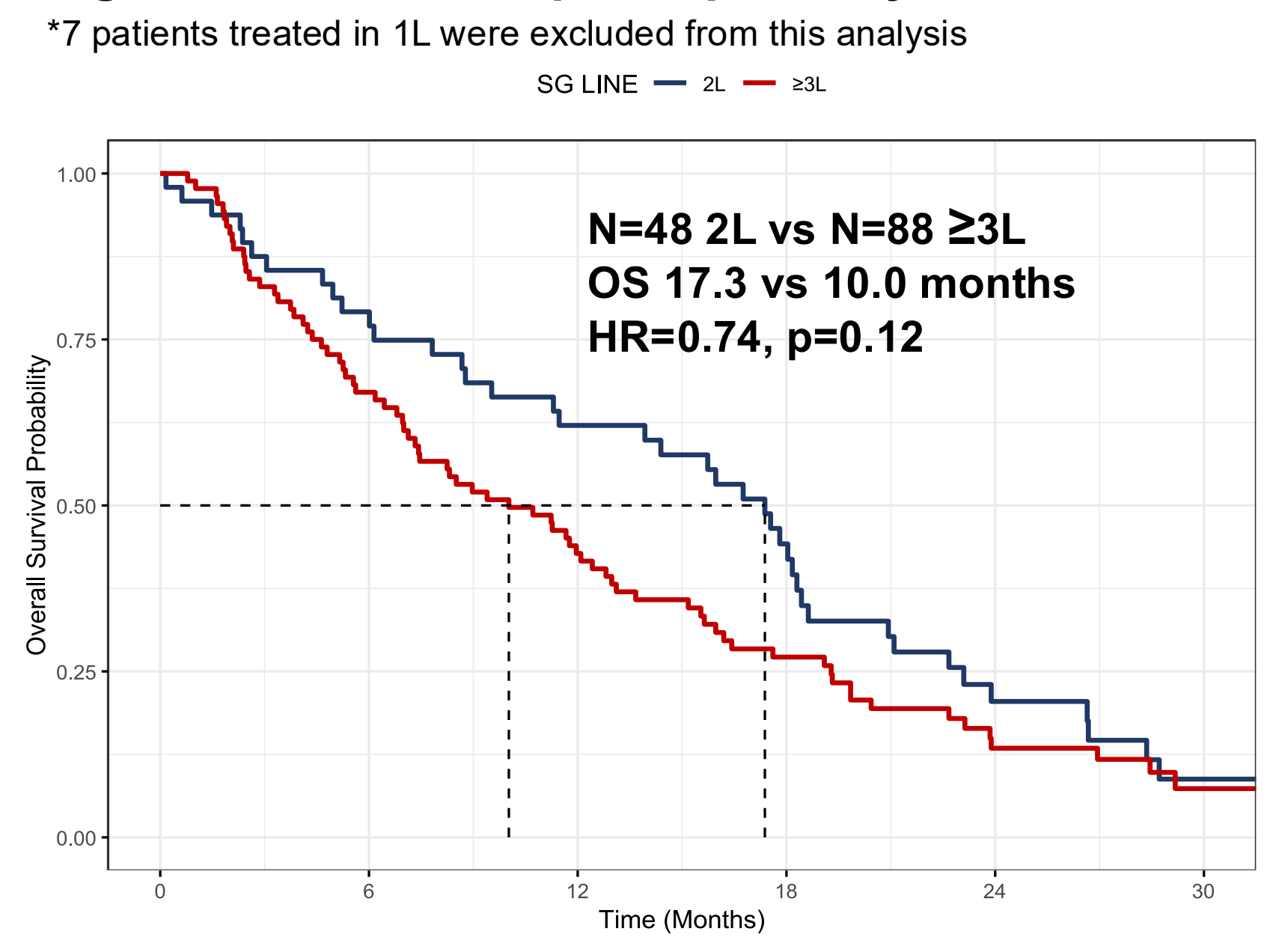


Figure 4: Survival of early vs late relapsers (defined as <12 vs ≥12 months from end of curative treatment to relapsed disease)

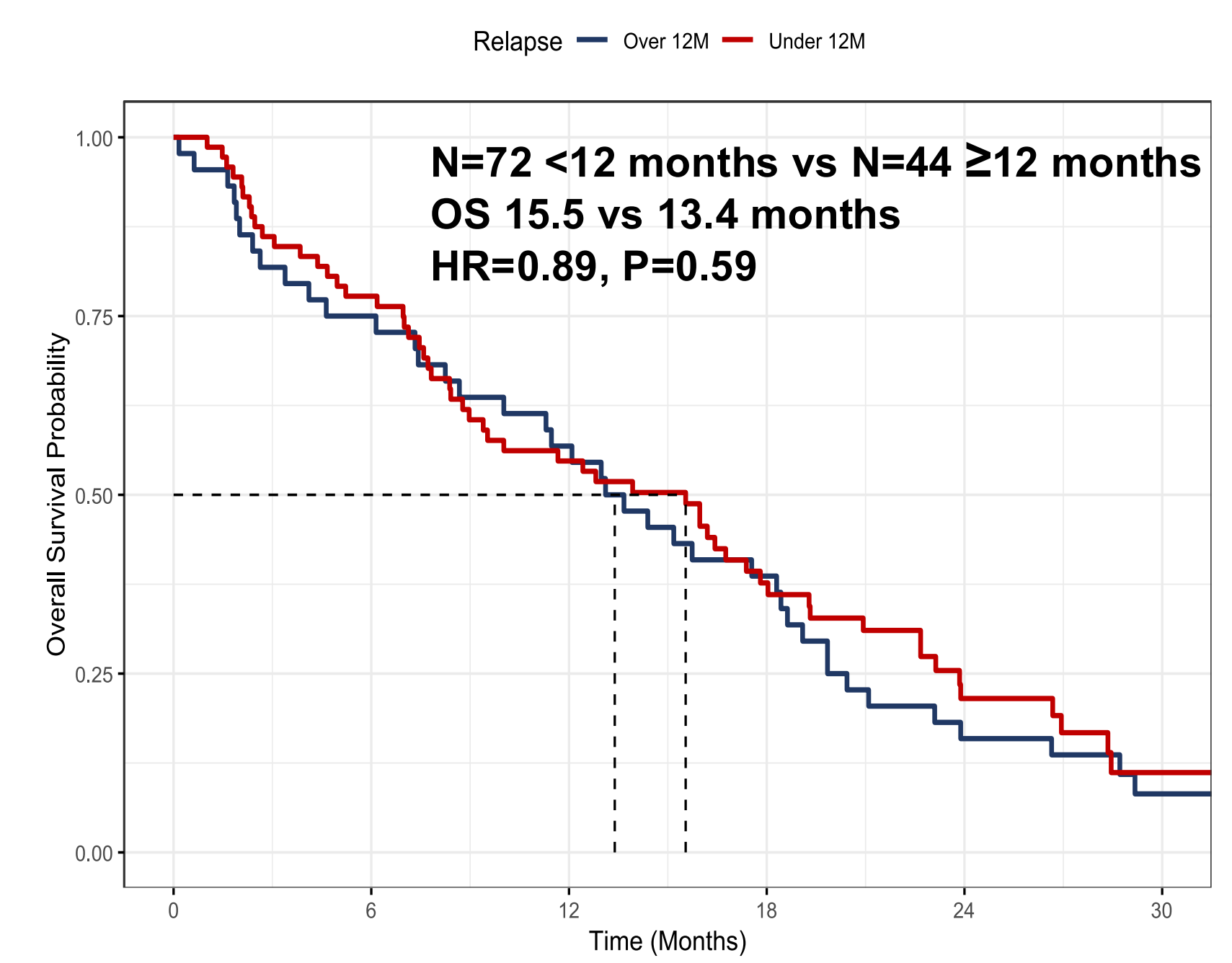


Figure 5: Survival in patients who received and did not receive SG dose reductions (DR)

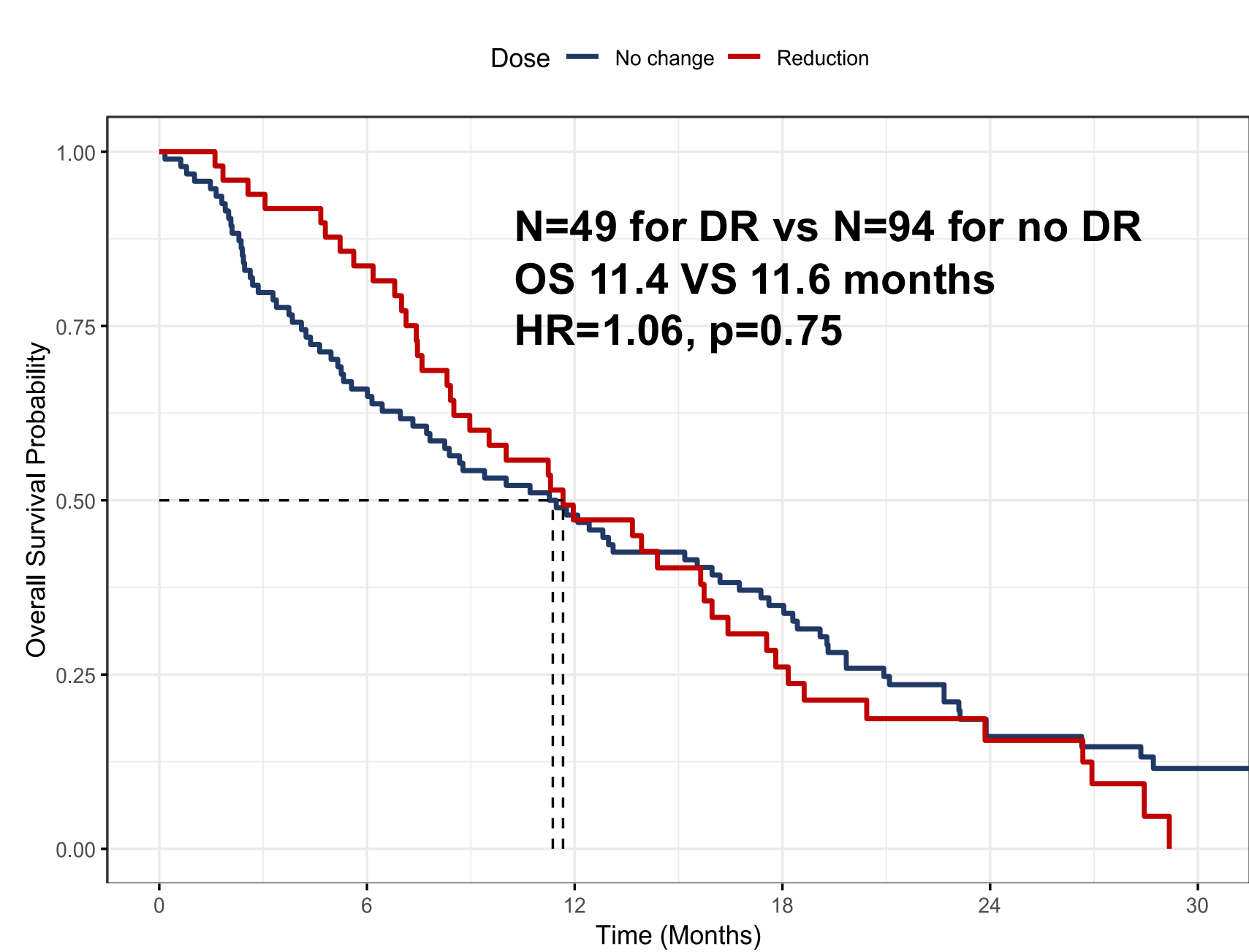
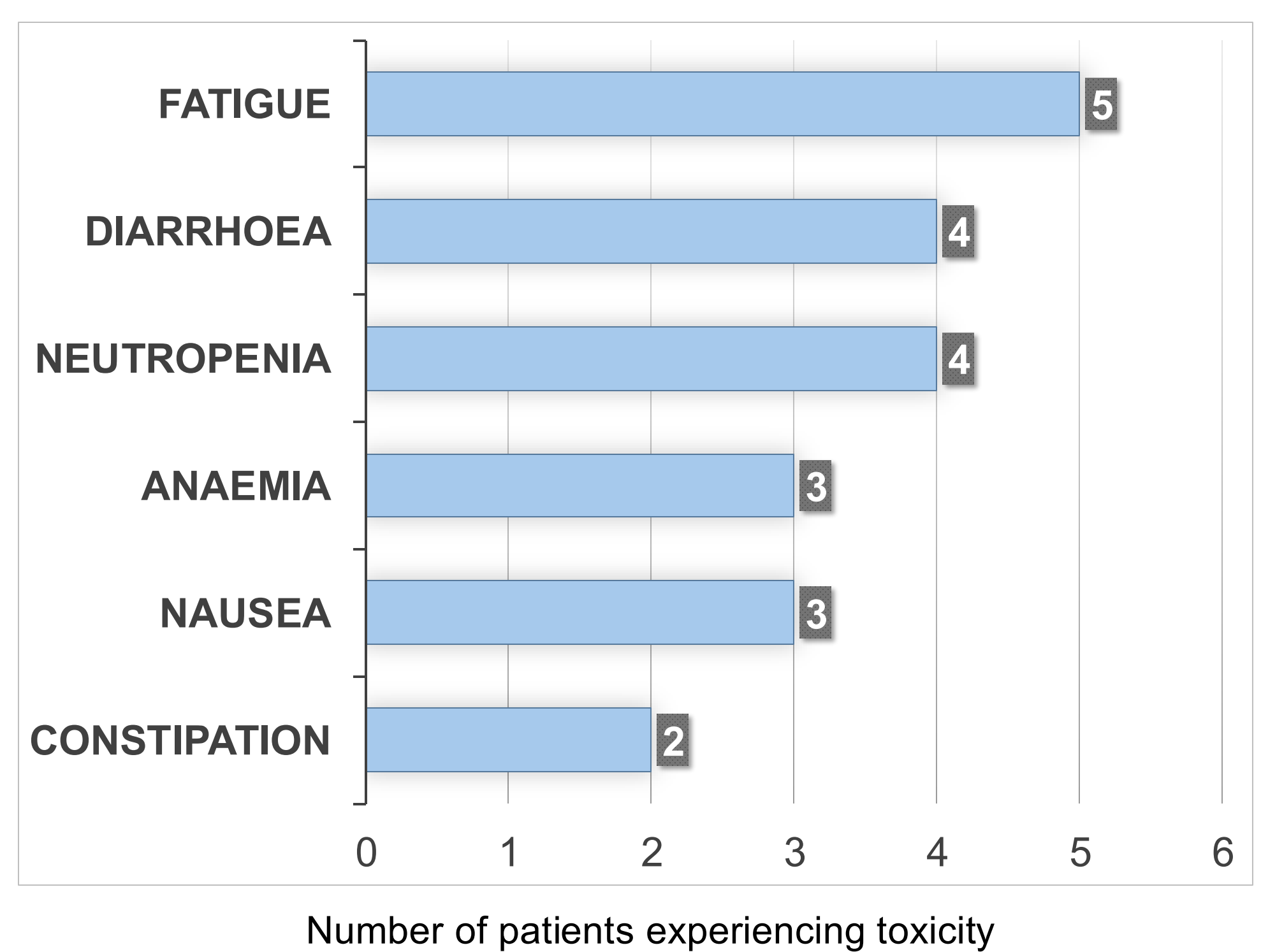


Table 2: SG Treatment patterns

	n=143
SG treatment line in metastatic setting	
1L	7 (4%)
2L	48 (34%)
3L	40 (28%)
4L and beyond	48 (34%)
Patients who commenced SG at full dose	128 (90%)
Patients who received dose reductions	49 (34%)
Reason for dose reduction	
Toxicity	34 (24%)
- Diarrhoea	16 (11%)
- Fatigue	10 (7%)
- Neutropenia	6 (4%)
Other (primarily clinician preference)	15 (10%)
Number of dose reductions per patient after starting treatment	
1	27 (19%)
2	15 (11%)
≥3	7 (5%)
G-CSF use	
Primary (within 14 days of starting SG)	39 (27%)
Secondary (post neutropenia)	17 (12%)

Figure 6. Most common toxicities leading to SG discontinuation



Conclusion

- Analysis of real-world data for Australian aTNBC patients treated with SG demonstrates survival outcomes consistent with the ASCENT trial, with a manageable safety profile and no unexpected toxicities.
- There was a trend toward greater benefit when SG was used in earlier line therapy.
- No adverse impact on overall survival was observed in patients who received SG dose reductions.