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Impact of prior treatment exposure and clinical-pathological factors on response and survival with Sacituzumab-govitecan in advanced breast cancer: a consecutive real-world series

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Data updated since abstract submission, with minor changes in patient numbers and events.

Background

- Sacituzumab-govitecan (SG) is an antibody–drug conjugate (ADC) approved for the treatment of advanced triple negative (TNBC) and estrogen receptor positive-HER2 negative (HR+/HER2-) breast cancer (BC).
- Real-world data on response determinants are limited.
- This study evaluated clinical-pathological factors associated with objective response rate (ORR), progression-free survival (PFS), and overall survival (OS) in a consecutive patient series treated in routine practice.

Methods

- **Study population:** Retrospective cohort of 79 consecutive female patients treated with SG at the Hospital Clinic of Barcelona between April 2022 and August 2025.
- **Collected variables:** Tumor subtype, TILs % and ECOG performance status were recorded at baseline. IHC phenotype shift was assessed in the metastatic setting. Disease burden was characterized by the number of metastatic sites and the presence of visceral metastases. Prior systemic therapies were documented for all patients. Ki-67 index was obtained from the pretreatment biopsy or the most recent metastatic biopsy available. No patient had received a previous ADC containing a TOP1 inhibitor payload.
- **Efficacy assessment:** Objective Response Rate (ORR) was evaluated radiologically according to RECIST v1.1 criteria.
- **Statistical analysis:** Associations between baseline variables and ORR were explored using univariate logistic regression. Survival outcomes were estimated through Kaplan–Meier curves. Prognostic impact of variables on survival was assessed using Cox proportional hazards models.

Results

- Clinical-pathological features are reported in **Table 1**. In the metastatic setting, 14 patients with an initial HR+/HER2- histotype switched subtype to triple-negative and just 1 from triple-negative to HR+/HER2- subtype **(Figure 1).**
- ORR in the overall population, stratified by IHC subtype (HR+/HER2- vs TNBC) and by the number of prior lines of chemotherapy (<3 vs ≥3), is shown in **Figure 2.**
- In logistic univariate regression, having received ≥3 chemotherapy lines, compared to <3, was associated with significantly lower odds of response (odds ratio [OR]=0.11, 95% CI: 0.01–0.59, p=0.04) in ORR **(Figure 3).**
- Median PFS and OS in the overall population, stratified by IHC subtype (HR+/HER2- vs TNBC), are shown in **Figure 4A-B.**
- Worse ECOG (HR=2.88; p<0.001), ≥3 prior chemotherapy lines (HR=1.88; p=0.04) were associated with shorter PFS; ; in contrast, prior endocrine therapy (HR=0.59; p=0.040) correlated with longer PFS **(Figure 5, 6A-B-C).**
- For OS, visceral disease (HR=3.44; p=0.026), ECOG ≥ 1 (HR=4.55; p<0.001) and presence of brain metastases (HR=2.7; p=0.010) were linked to worse survival, whereas HR+/HER2- subtype (HR=0.31; p=0.002) correlated with longer OS **(Figure 7A-B-C, 8).**

Results

Table 1. Patients baseline characheristics

Variable		n(%)
Median Age	-	57 (range 27-81)
IHC Tumor subtype	TNBC	44 (55.7%)
	HR+/HER2–	35 (44.3%)
Visceral metastases	Yes	69 (87.3%)
	No	10 (12.7%)
Histologic subtype	Ductal	63 (79.7%)
	Lobular	13 (16.5%)
	Others	3 (3.8%)
Brain metastases	Yes	11 (13.9%)
	No	68 (86.1%)
ECOG performance status	0	32 (40.5%)
	≥1	47 (59.5%)
Number of metastatic sites	≤3	34 (43%)
	>3	45 (57%)
Number of prior chemotherapy lines	<3	63 (80%)
	≥3	16 (20%)
Prior endocrine therapy in M+ setting	Yes	48 (61%)
	No	31 (39%)

Figure 1. River plot. Change of IHC subtype in metastatic setting

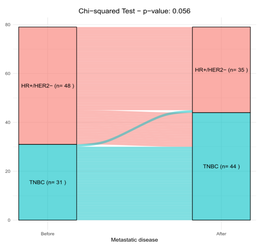


Figure 2. Objective Response Rate (ORR) in overall population, by IHC subtype and by number of prior chemotherapy lines.

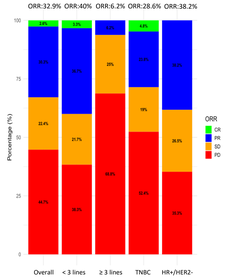


Figure 3. Univariate analysis of ORR and Clinical-pathological features

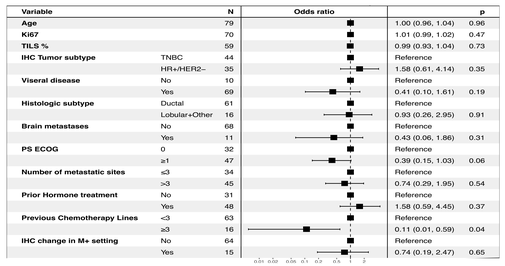


Figure 4. PFS (A) and OS (B) in HR+/HER2-, TNBC and overall population

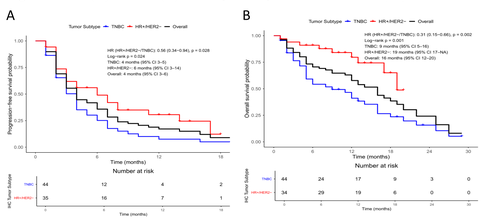


Figure 5. Univariate analysis of PFS and Clinical-pathological features

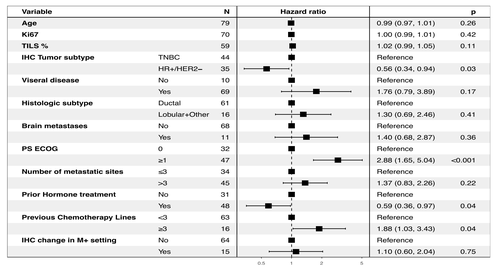


Figure 6. Association of PFS and Number of chemotherapy lines (A), PS ECOG (B) Prior endocrine therapy in M+ setting (C)

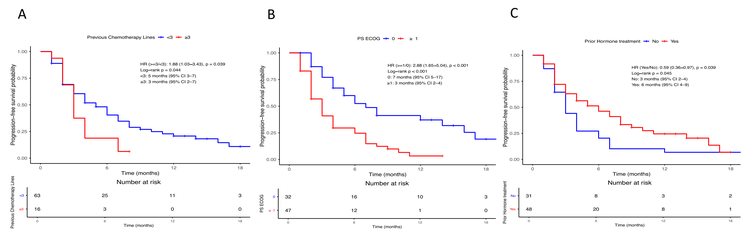


Figure 7. Association of OS and Presence of Visceral disease (A), PS ECOG (B), Presence of brain metastases (C)

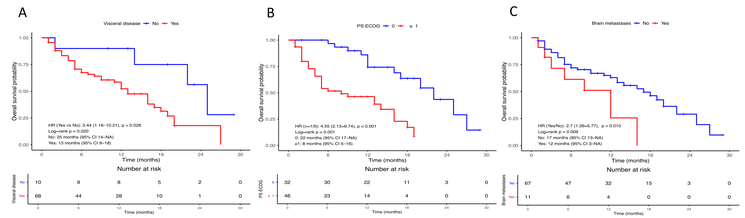
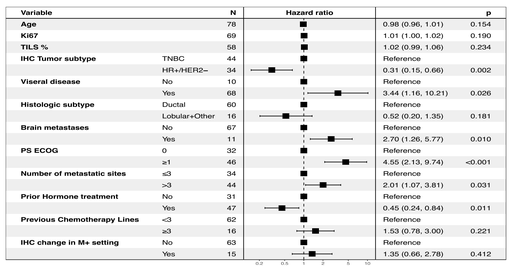


Figure 8. Univariate analysis of OS and Clinical-pathological features



SG demonstrated antitumor activity across both TNBC and HR+/HER2- breast cancer in this real-world cohort. Clinical benefits were greater in patients with limited prior treatment exposure and preserved ECOG status. These findings support the earlier use of SG.

The presenting author declares no conflicts of interest. Email: Carla.gullotta24@gmail.com