A Real-World Multicenter Study in China: Efficacy and Safety of Sacituzumab Govitecan in Heavily Pretreated HER2-Negative Metastatic Breast Cancer Patients and Brain Metastases

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Background

Sacituzumab govitecan (SG) is approved in China for metastatic triple-negative breast cancer (mTNBC) and hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) metastatic breast cancer (mBC)[1-4].
However, real-world evidence, particularly in brain metastases patients, remains limited.
This study evaluated the real-world efficacy and safety of SG in a Chinese cohort with heavily pretreated HER2-negative mBC, including those with brain metastases.

Methods

Retrospective data were collected on HER2− MBC patients who received SG treatment between June 2023 and October 2024, and completed at least one imaging assessment. Outcomes included real-world progression-free survival (rwPFS), objective response rate (ORR), disease control rate (DCR), real-world overall survival (rwOS), and safety.

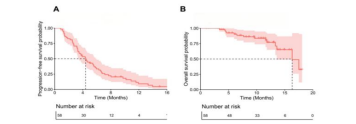
Results

A total of 58 HER2-negative metastatic breast cancer patients treated with SG were included, with a median age of 52.9 years. The median number of prior lines of therapy in the metastatic setting was 3 (range: 1-10). (Table 1)
At a median follow-up of 11.0 months, the overall population showed an ORR of 34.5%, a DCR of 81.0%, a median rwPFS of 4.41 months, a median rwOS of 16.32 months.(Figure 1)
In mTNBC patients, the ORR was 34.8%, DCR was 79.1%, median rwPFS was 4.97 months, and median rwOS was 16.32 months.
In HR+/HER2− mBC patients who received a median of 2 lines of prior endocrine therapy and 2 lines of chemotherapy, the ORR was 33.33%, DCR was 86.6%, median rwPFS was 4.41 months, and median rwOS was not reached.

Table 1. Baseline clinical characteristics for all patients.

Characteristic	All (n = 58)
Female, n (%)	58 (100)
Median age (range), y	52.9 (30-77)
ECOG PS, n (%)	
0	33 (56.90)
1	20 (34.48)
2	5 (8.62)
Molecular classification, n (%)	
mTNBC	43 (74.14)
HR+/HER2-mBC	15 (25.86)
Metastatic sites, n (%)	
Lung Metastases	24 (41.38)
Liver Metastases	32 (55.17)
Brain Metastases	12 (20.69)
Bone Metastases	31 (53.45)
Median time from initial metastatic diagnosis to enrollment (range), mo	16.3 (0-167.7)
Median prior anticancer regimens in the metastatic setting, n (range)[a]	3(1-10)
Number of prior anticancer regimens for metastatic disease[a], n (%)	
1	18 (31.03)
≥2	40 (68.97)
Treatment Regimen, n (%)	
SG alone	48 (82.76)
SG combination	10 (17.24)

Figure 1. Kaplan-Meier analysis of rwPFS(A) and rwOS(B) for all 58 patients.



(A).Real-World Progression-Free Survival (B).Real-World Overall Survival

	Median rwPFS	Median rwOS
mo	4.41	16.32
95% CI	3.45-5.95	13.59-Not reach

Among 12 patients with baseline brain metastases (11 TNBC, 1 HR+/HER2−BC), the ORR was 25%(Figure 2), DCR was 91.6%, median rwPFS was 5.43 months, and median rwOS was 17.50 months. The central nervous system objective response rate (CNS-ORR) was 41.6%, and the median rwCNS-PFS was 14.9 months(Figure 3).
Notably, 2 patients received concomitant radiotherapy achieving CNS-PR and CNS-CR respectively.

Figure 2. Waterfall plot of tumor burden for sum of target lesion diameters (per RESIST 1.1 criteria)—best relative change from baseline.

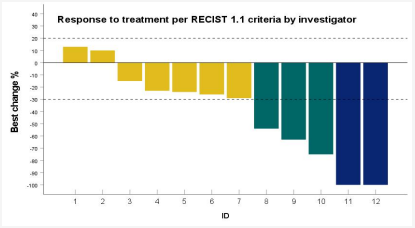
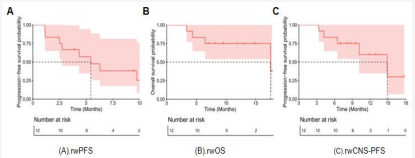


Figure 3. Kaplan-Meier analysis of rwPFS(A), rwOS(B) and CrwNS-PFS(C) for patients with Brain Metastases.



(A).rwPFS (B).rwOS (C).rwCNS-PFS

	Median rwPFS	Median rwOS	Median rwCNS-PFS
mo	5.43	17.5	14.87
95% CI	2.73-NR	17.5-NR	10.16-NR

The safety profile of SG in this study was manageable, lower incidences of neutropenia and diarrhea were observed (Table 2). In this study, G-CSF prophylaxis was indicated based on AEs or pre-existing risk factors for neutropenia or febrile neutropenia. Nine patients (15.5%) received polyethylene glycol G-CSF as primary prophylaxis, and none of them experienced grade 3 or higher neutropenia.

Table 2. Treatment-related Adverse Events

Adverse event, n (%)	Any grade	Grade ≥ 3
Neutropenia	30(51.72%)	9(15.52%)
Febrile Neutropenia	1(1.72%)	1(1.72%)
Anemia	25(43.1%)	4(6.9%)
Thrombocytopenia	1(1.72%)	1(1.72%)
Diarrhea	13(22.41%)	4(6.9%)
Nausea	21(36.21%)	0(0%)
Vomiting	15(25.86%)	0(0%)
Anorexia	16(27.59%)	0(0%)
Constipation	7(12.07%)	1(1.72%)
Fatigue	20(34.48%)	1(1.72%)
Alopecia	7(12.07%)	0(0%)
AST Elevation	20(34.48%)	1(1.72%)
ALT Elevation	20(34.48%)	0(0%)
Pneumonitis	1(1.72%)	0(0%)

Conclusions

- SG demonstrates robust clinically meaningful efficacy and a manageable safety profile in heavily pretreated patients with HER2-negative metastatic breast cancer (mBC).
- Notably, it confers particular benefit in patients with brain metastases—thereby offering a novel therapeutic option for this underserved population with limited treatment alternatives.
- Use of prophylactic G-CSF is advised as appropriate.
- Future studies should explore SG plus local therapies for brain metastases and standardized G-CSF prophylaxis to optimize outcomes.

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Disclosure Information

No conflicts of interest to declare

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