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Real-world outcomes of sacituzumab govitecan in patients with pretreated triple-negative breast cancer and brain metastases: data from a central European cohort

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Background

- Patients with metastatic triple-negative breast cancer (mTNBC) and brain metastases (BM) constitute a subgroup with poor prognosis and limited treatment options [1].
- In the pivotal ASCENT trial, sacituzumab govitecan (SG) demonstrated clinical benefit in pretreated patients with mTNBC [2].
- An exploratory subgroup analysis of ASCENT trial included 61 patients with radiologically stable BM (32 in the SG arm), showing a modest improvement in progression-free survival (PFS) with SG versus chemotherapy (2.8 vs. 1.6 months), but no overall survival (OS) advantage (6.8 vs. 7.5 months) [3].

Aim

- The purpose of this study was to evaluate the effectiveness and safety of SG in a real-world cohort of patients with active or treated BM.

Materials and Methods

- This retrospective multicenter study included female patients with mTNBC and radiologically confirmed BM who initiated SG between August 2021 and May 2025 across 13 oncology centers in the Czech Republic, Poland and Slovakia.
- Clinical data were extracted from patients' medical records.
- Adverse events (AEs) were assessed according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0.
- Radiologic responses were assessed using RECIST 1.1.
- Overall response rate (ORR), PFS, and OS were evaluated. Survival outcomes were estimated using the Kaplan-Meier method. Univariable Cox proportional hazards models were used to assess the association between BM burden and survival. Statistical analyses were performed in R (v4.3.3); $p < 0.05$ was set assignificant.

Abbreviations: BC, breast cancer; *BRCA1*/*BRCA2*, breast cancer gene 1 or 2; ECOG; Eastern Cooperative Oncology Group Performance Status; ER, estrogen receptor, HER2, human epidermal growth factor receptor 2; ICH, immunohistochemistry; PgR, progesterone receptor; *Only comorbidities that require active treatment and are clinically significant as per treating physician

Table 1. Patient characteristics.

Variable	Total (N = 29) (%)
Performance status	
ECOG 0	7 (24.1%)
ECOG 1	21 (72.4%)
ECOG ≥2	1 (3.4%)
Primary treatment intention at the time of cancer diagnosis	
Curative	24 (82.8%)
Palliative	5 (17.2%)
Histological subtype	
Invasive ductal	26 (89.7%)
Invasive lobular	1 (3.4%)
Metaplastic	1 (3.4%)
Secretory	1 (3.4%)
HER2 ICH	
0	15 (51.7%)
1+	8 (27.6%)
2+	2 (6.9%)
Unknown	4 (13.8%)
History of ER- or PgR-positive BC	
Yes	4 (13.8%)
No	25 (86.2%)
History of HER2 positive BC	
Yes	2 (6.9%)
No	27 (93.1%)
***BRCA1* or *BRCA2* mutation detected**	
Yes	7 (24.1%)
No	20 (69.0%)
Unknown	2 (6.9%)
Curative breast surgery in patient history	
Yes	24 (82.8%)
No	5 (17.2%)
Breast radiotherapy in patient history	
Yes	21 (72.4%)
No	8 (27.6%)
Comorbidities*	
Yes	13 (44.8%)
No	16 (55.2%)
Menopausal status	
Premenopausal	14 (48.3%)
Postmenopausal	15 (51.7%)

Results

- 29 patients with mTNBC and confirmed BM at SG initiation were included.
- The median age at SG initiation was 48.5 years (interquartile range [IQR] 42.1–58.0; range 29.8–69.6), with a mean of 50.4 years (standard deviation [SD] 10.4).
- The median number of prior palliative systemic therapy lines was 2 (range: 1-3) (Table 2).
- The median follow-up was 6.05 months (IQR: 3.66-11.06; range: 0.79-27.47).
- At the time of analysis, 22 patients had died and 26 had discontinued the treatment with SG.
- The median OS was 8.9 months. Estimated OS rates at 3, 6, 9, and 12 months were 85.2%, 60.3%, 42.3%, and 28.2%, respectively (Fig.2).
- Median PFS was 3.09 months, with 3-, 6-, 9-, and 12-month PFS rates of 53.6%, 31.4%, 22.5%, and 12.0%, respectively (Fig.2).
- ORR was observed in 8 of 26 evaluable patients (30.8%).
- SG administration required dose delays due to AEs in 15 patients (51.7%), and dose reductions in 11 (37.9%). Two cases (7.7%) of treatment discontinuation due to toxicity were reported. No unexpected new safety signals were observed.

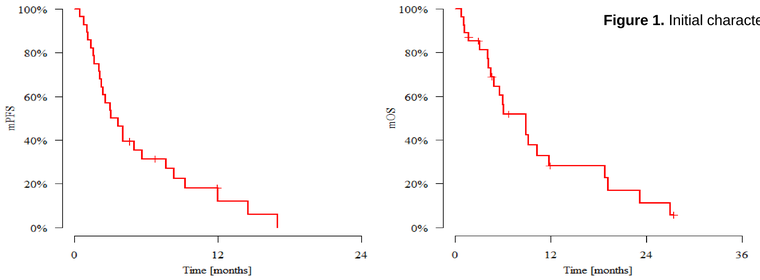


Figure 2. Kaplan–Meier curve for progression-free survival and overall survival in the study cohort.

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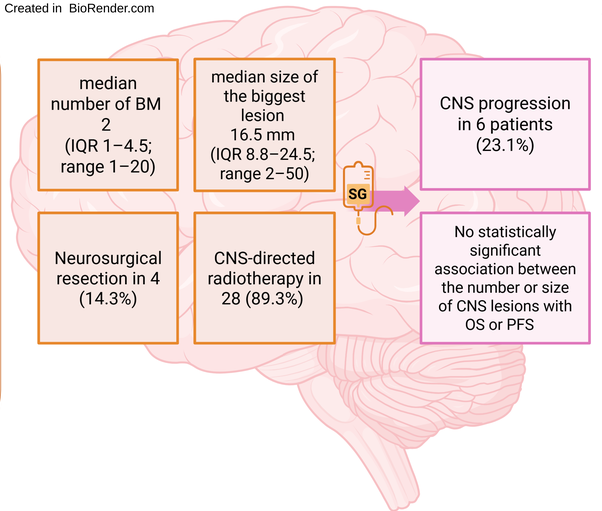


Figure 1. Initial characteristics and treatment of brain metastasis with outcomes following therapy with sacituzumab govitecan.

Table 2. Previous lines of treatment in palliative setting.

Treatment	N (%)
Platinum compounds	19 (63.3%)
Taxanes	15 (50.0%)
Anthracyclines	13 (43.3%)
Capecitabine	9 (30.0%)
Gemcitabine	8 (26.7%)
Pembrolizumab	6 (20.0%)
PARPi	5 (16.7%)
Vinorelbine	2 (6.7%)
Hormonal therapy	4 (13.3%)
Anti-HER2 therapy	1 (3.3%)
Others (including clinical trials)	4 (13.3%)

Abbreviations: HER2, human epidermal growth factor receptor 2; PARPi, poly(ADP-ribose) polymerase inhibitors.

Conclusions

- Median PFS and OS outcomes appeared comparable or numerically favorable to those reported in the ASCENT BM subgroup analysis.
- Neither the number nor size of BM lesions significantly impacted outcomes, suggesting SG may be effective irrespective of intracranial disease burden.
- SG demonstrated clinically meaningful activity and a manageable safety profile in this real-world cohort of patients with mTNBC and BM.

References

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