Efficacy of Sacituzumab Govitecan Among Metastatic Triple-Negative Breast Cancer Patients in Real-World Settings: A Systematic Review and Meta-analysis

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INTRODUCTION

- Metastatic triple-negative breast cancer (mTNBC) is an aggressive disease with limited treatment options and poor outcomes, driven by its aggressive biology and lack of targetable molecular pathways. [1]
- Sacituzumab govitecan (SG) is a Trop-2–directed antibody–drug conjugate consisting of an anti-Trop-2 antibody linked to the topoisomerase I inhibitor SN-38. [2]
- In the phase III ASCENT trial (**NCT02574455**), SG significantly improved progression-free survival, overall survival, and objective response rate compared with single-agent chemotherapy in heavily pretreated mTNBC. [2]
- Despite available chemotherapeutic options, patients with mTNBC frequently experience rapid disease progression and short survival, highlighting a substantial unmet medical need in later lines of treatment. [1]
- Clinical benefits of SG in ASCENT were observed across key patient subgroups, including those with prior exposure to multiple systemic therapies and those with visceral metastases. [1,2]
- SG demonstrated a manageable and well-characterized safety profile in the ASCENT trial, supporting its clinical use in a population with limited therapeutic alternatives. [2]
- Given the aggressive nature of mTNBC, limited later-line treatment options, and the restricted generalizability inherent to randomized trials, evaluation of SG in real-world settings is necessary to understand its clinical impact in everyday practice.

OBJECTIVES

This study aimed to evaluate the pooled efficacy of sacituzumab govitecan (SG) in patients with metastatic triple-negative breast cancer (mTNBC) in real-world settings.

METHODS

- **Data source:**
  - PubMed, Medline, EMBASE, and DOAJ
  - Supplementary open search on Google Scholar and Google.
- **Search Period:** Inception till December 2025.
- **Data extraction:** Conducted by three reviewers independently.
- **Model:** Random-effect model
- **Outcomes:** Overall response rate (ORR), complete response rate (CRR), overall survival (OS) and progression-free survival (PFS).
- **Risk of bias assessment:** ROBINS-I tool.

RESULTS

- Seventeen studies reporting efficacy of SG in real-world settings were included.
- The sample size of the included studies ranged from 33 to 381 participants.
- The median age of the participants in the included studies was 55 (range: 48 - 61) years.
- This meta-analysis observed an ORR of 33.25% (95% CI: 30.27% - 36.52%, I^2 = 0%, p-value = 0.69).
- The CRR observed was 2.06% (95% CI: 1.09% - 3.91%, I^2 = 0%, p-value = 0.93).

Fig 1: Overall response rate in real-world mTNBC

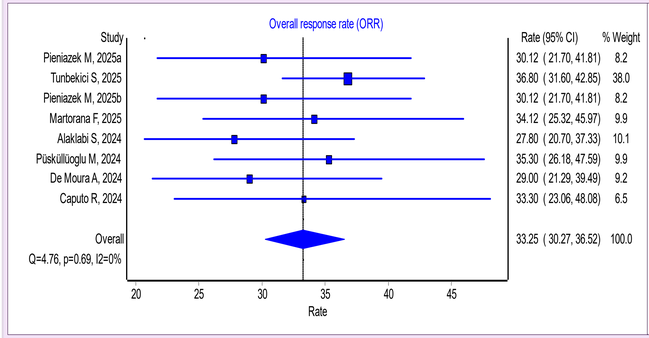


Fig 2: Complete response rate in real-world mTNBC

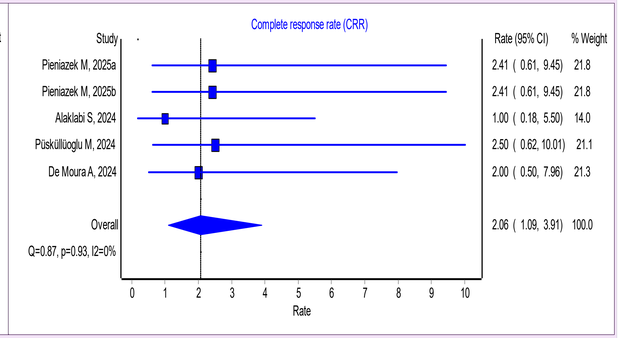


Fig 3: Overall survival in real-world mTNBC

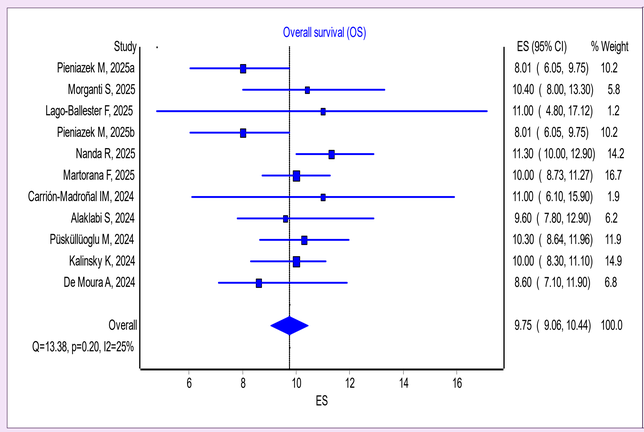
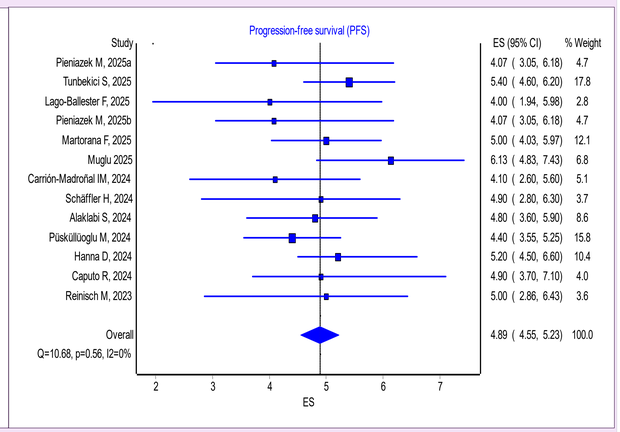
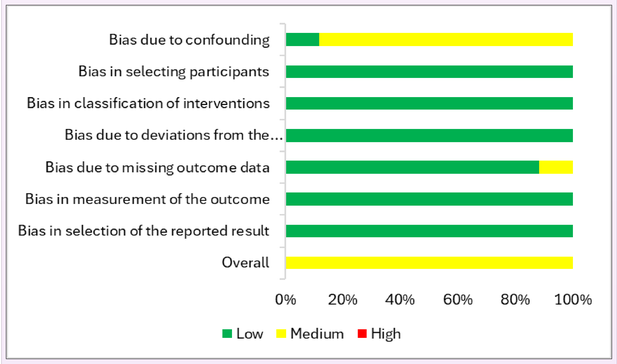


Fig 4: Progression-free survival in real-world mTNBC



- The median OS observed was 9.75 months (95% CI: 9.06 - 10.44, I^2 = 25%, p-value = 0.20).
- The median PFS observed was 4.89 months (95% CI: 4.55 - 5.23, I^2 = 0%, p-value = 0.56).
- The overall risk of bias was moderate in all the included studies.

Fig 5: Risk of bias assessment



DISCUSSION AND CONCLUSION

- This meta-analysis demonstrates that sacituzumab govitecan delivers consistent real-world efficacy in mTNBC:
  - Median PFS: RWE 4.89 months vs ASCENT 4.8 months
  - Median OS: RWE 9.75 months vs ASCENT 11.8 months
  - ORR: RWE 33.25% vs ASCENT 31%
- Low statistical heterogeneity was observed across outcomes, indicating consistent real-world effectiveness of SG; the modest heterogeneity in OS likely reflects variation in follow-up duration and baseline prognostic characteristics inherent to real-world populations.
- These findings support the generalizability of clinical-trial benefits to routine practice, reinforcing SG as an effective option for heavily pretreated mTNBC patients.

KEY TAKEAWAY

Pooled real-world evidence indicates that sacituzumab govitecan maintains clinically meaningful benefit in pretreated mTNBC, with **ORR, PFS, and OS outcomes broadly comparable to ASCENT**, reinforcing the external validity of trial efficacy in routine practice.

REFERENCES

[1] Carey LA, et al. Sacituzumab govitecan as second-line treatment for metastatic triple-negative breast cancer—phase 3 ASCENT study subanalysis. NPJ Breast Cancer. 2022 Jun 9;8(1):72.

[2] Bardia A, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. New England journal of medicine. 2021 Apr 22;384(16):1529-41.