Impact of Overall Survival on the Use of Prophylactic Granulocyte Colony-Stimulating Factor With Sacituzumab Govitecan-hziy in the Treatment of Triple-Negative Metastatic Breast Cancer Patients

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Introduction

Treatment options for metastatic triple-negative breast cancer (mTNBC) are limited, but antibody-drug conjugates (ADCs) such as sacituzumab govitecan (SG) have shown improved survival outcomes compared to single-agent chemotherapies.

However, individuals undergoing this treatment are at an increased risk of neutropenia. Furthermore, updates to the package insert recommend primary prophylaxis with granulocyte-colony stimulating factor (G-CSF) for at-risk patients (pts).

This study evaluated the impact of prophylactic G-CSF use on time to treatment discontinuation (TTD) and real-world overall survival (rwOS) among individuals with mTNBC who received SG.

Methods and Materials

Patient Criteria

- >18 years of age at diagnosis
- 2+ years of documented visits
- mTNBC diagnosis
- Initiated SG between 4/22/2020 and 4/9/2025

Data Collection

- 615 pts evaluated from the deidentified Integra PrecisionQ database

- Prophylactic G-CSF was defined as any G-CSF use within 8 days following initiation of SG.
- Pts were excluded from the analysis if there was documentation of neutropenia (neutrophil count <1500/μL), discontinuation of SG, death, or censoring within 8 days of SG initiation.
- Gray's test was performed to assess cumulative incidence of neutropenia, adjusted for the competing risk of death, and 4-month estimates are reported.

Patients were assessed overall and by prophylactic G-CSF use by:

Race **ECOG** **Age at SG**

Table 1. Demographic and Clinical Characteristics Stratified by Prophylactic G-CSF Use

Characteristic	Overall N=615	No n=468	Yes n=147	*P* value
Median Age (Q1, Q3) at Index Start, yr	60 (53, 69)	60 (52, 70)	60 (53, 68)	>0.9[a]
Race, n (%)				0.83[b]
Black	89 (14%)	66 (14%)	23 (16%)	
White	413 (67%)	314 (67%)	99 (67%)	
Other	113 (18%)	88 (19%)	25 (17%)	
ECOG PS at Index Start, n (%)				0.33[b]
0	177 (29%)	133 (28%)	44 (30%)	
1	253 (41%)	198 (42%)	55 (37%)	
2+	82 (13%)	65 (14%)	17 (12%)	
Unknown	103 (17%)	72 (15%)	31 (21%)	

[a]Wilcoxon rank sum test. [b]Pearson's Chi-squared test.
ECOG PS, Eastern Cooperative Oncology Group performance status; G-CSF, granulocyte colony stimulating factor; Q, quartile

Table 2. Time-Stratified Multivariable Cox Proportional Hazards Model (0-4 months/4+ months) With Expanded Coefficients[a]

Characteristic	HR	95% CI	*P* value
Prophylactic GCSF Use * Time Period			
Yes * time period=0-4 months	—	—	—
No * time period=0-4 months	2.37	1.22, 4.59	0.011
Yes * time period=4+ months	—	—	—
No * time period=4+ months	1.02	0.79, 1.30	>0.9

[a]Adjusted for age at index start, race, and ECOG PS.
ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio

Figure 1. Cumulative Incidence of Neutropenia by Prophylactic G-CSF Use

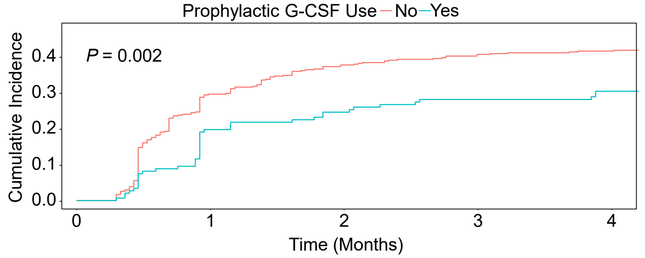


Figure 2. Time to Discontinuation by Prophylactic G-CSF Use

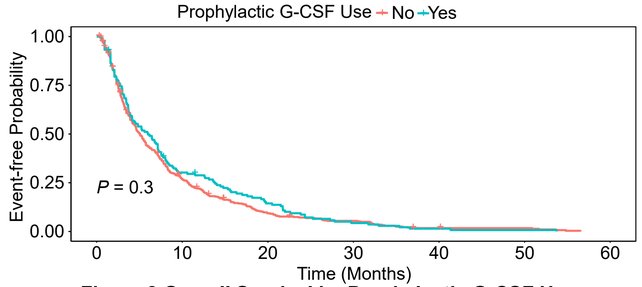
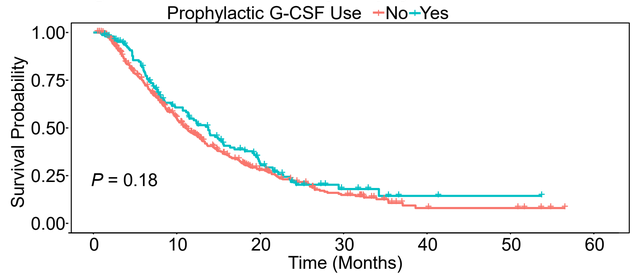


Figure 3.Overall Survival by Prophylactic G-CSF Use



Results

- Table 1 shows the baseline demographic and clinical characteristics. Most pts (67%) were identified as White, 41% had an ECOG performance status of 1, and 88% did not receive prophylactic G-CSF. The median age at SG initiation was 60 years (interquartile range: 53, 69).
- Age, race, and ECOG performance status did not significantly differ by prophylactic G-CSF use.
- At 4 months, cumulative incidence of neutropenia was significantly higher among pts who did not receive prophylactic G-CSF (42% vs. 30%, Gray's test *P*=0.002) (Figure 1).
- Median TTD and rwOS did not significantly differ by prophylactic G-CSF use (Figure 2 and Figure 3).
- From 0-4 months, pts who did not receive prophylactic G-CSF were >2 times more likely to die compared to those who received prophylactic G-CSF within 8 days of SG initiation (HR: 2.37; 95% CI: 1.22-4.59; *P*=0.011). This impact was attenuated after 4 months (HR: 1.02; 0.79-1.50; *P*=0.4), indicating a time-varying effect of prophylactic G-CSF use on rwOS after SG initiation (Table 2).
- There was no significant difference observed in TTD in either time-interval.

Conclusion

Prophylactic use of G-CSF had a significant initial impact on rwOS among pts with mTNBC receiving SG. While prophylactic use of G-CSF did not confer a significant survival benefit after 4 months, the upfront effect warrants clinical consideration and integration into early treatment practices. These findings also indicate the need for further research assessing the impact of continued G-CSF use on overall survival.

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