Primary G-CSF Prophylaxis in Sacituzumab Govitecan-Treated mTNBC: Real-World Evidence from a Multinational Cohort

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BACKGROUND

Sacituzumab govitecan (SG) has emerged as a key agent in the treatment of metastatic triple-negative breast cancer (mTNBC), with use increasingly shifting toward earlier treatment lines. Consequently, the number of patients exposed to SG will continue to grow. Although recent updates to the SG summary of product characteristics list G-CSF primary prophylaxis as an option, the need for its routine use in all patients remains uncertain. We aimed to evaluate the impact of G-CSF primary prophylaxis on clinical outcomes and treatment-related toxicities in a multinational real-world cohort of patients with mTNBC treated with SG.

MATERIALS/METHODS

Baseline characteristics were balanced with respect to prior systemic treatment for early-stage disease, the number of previous treatment lines in the metastatic setting, comorbidities, metastatic sites, and prior episodes of febrile neutropenia (FN). However, ECOG performance status (PS) of 0 was more frequent in the prophylaxis group (50% vs. 37.1%, p=0.034). Efficacy endpoints included PFS and OS analyzed using the Kaplan-Meier method. Adverse events (AEs) were assessed according to CTCAE criteria. All analyses were conducted using Stata Statistical Software version 19.0.

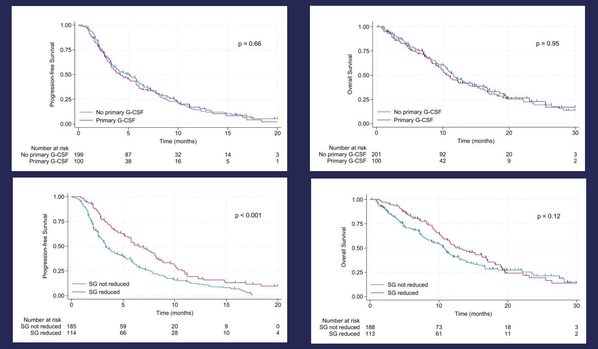
RESULTS

G-CSF primary prophylaxis was not associated withimproved clinical outcomes. Median PFS was 4.2 months in the primary prophylaxis group versus 5.1 months in the no-primary prophylaxis group (p=0.20),with 6-month PFS rates of 38.5% vs. 42.1%, respectively. Median OS was 10.9 vs. 11.6 months (p=0.95), and 12-month OS rates were 44.9% vs. 47.1%, respectively. There were no statistically significant differences in the rates of all-grade toxicities between groups. G≥3 neutropenia occurred less frequently in patients receiving G-CSF primary prophylaxis (33.0% vs. 50.7%, p=0.005), but this was not accompanied by a reduction in FN rates (4.0% vs. 4.4%, p=1.00). Rates of other all grade AEs—including anemia, diarrhea, nausea, vomiting, and alopecia—were similar between groups. Dose reductions due to toxicity occurred in 36.0% of the prophylaxis group and 38.4% of the non-prophylaxis group (p=0.71). Among those who did not receive G-CSF primary prophylaxis, 74.4% eventually required secondary G-CSF support. Ultimately, only 17.2% of patients were treated with SG without any G-CSF support. Notably, SG dose reductions due to toxicity were not associated with inferior outcomes. In contrast, patients who required dosereduction had significantly longer PFS (median 6.6 vs. 3.3 months, p<0.001) and numerically longer OS (median 13.0 vs. 10.7 months, p=0.12) compared to those without dose modification.

Table 1. Baseline characteristics and toxicity profile of patients with G-CSF primary prophylaxis (G-CSF primary prophylaxis group) and without primary prophylaxis with G-CSF (No primary prophylaxis group).

Characteristics	G-CSF primary prophylaxis group (n=100)	No primary prophylaxis group (n=203)	p
Systemic treatment in EBC	74 [74%]	163 [80.3%]	0.24
Additional comorbidities	43 [43%]	95 [46.8%]	0.54
ECOG 0	50 [50%]	75 [37.1%]	0.034
ECOG 1/2/3	50 [50%]	127 [62.9%]	0.034
Lung metastatses	50 [50%]	111 [54.7%]	0.46
Liver metastases	34 [34%]	65 [32.0%]	0.80
CNS metastases	10 [10%]	19 [9.4%]	0.84
Bone metastases	37 [37%]	85 [41.9%]	0.46
One line of previous systemic treatment line in MBC	48 [48%]	111 [54.7%]	0.33
More than 1 line of previous systemic treatment in MBC	52 [52%]	92 [45.3%]	0.33
Previous febrile neutropenia before SG initiation	4 [4%]	13 [6.4%]	0.60
SG dose reduction due to AEs	36 [36%]	78 [38.4%]	0.71
Febrile neutropenia during SG	4	9 [4.4%]	1.00
Neutropenia	62	147 [72.4%]	0.09
Neutropenia G3-4	33 [33%]	103 [50.7%]	0.005
Diarrhea	19 [19%]	40 [19.7%]	1.0
Thrombocytopenia	9	21 [10.4%]	0.84
Anemia	35	85 [41.9%]	0.26
Vomiting	11	21 [10.4%]	0.85
Nause	24	48 [23.7%]	1.00
Fatigue	41	75 [37.0%]	0.45
Alopecia	53	91 [44.8%]	0.13

Figure 1. Kaplan-Meier curves for PFS and OS according to G-CSF primary prophylaxis status and according to SG dose reduction.



CONCLUSIONS

In this large real-world cohort, primary G-CSF prophylaxis was not associated with improved survival or reduced FN, though it significantly reduced the incidence of grade ≥3 neutropenia. Given that the majority of patients ultimately received G-CSF as secondary prophylaxis, and considering the relatively short treatment duration in later lines, primary G-CSF prophylaxis remains a valid option inthis setting. Consistent with prior reports, SG dose reductions due to adverse events were not associated with worse survival.

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