Long-term safety in breast cancer patients receiving Doxorubicin-Cyclophosphamide with secondary G-CSF prophylaxis: A single center prospective study

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Abstract Number: 1316

Introduction

- Granulocyte colony-stimulating factors (G-CSFs) reduce febrile neutropenia (FN) and maintain chemotherapy dose intensity, especially in high-risk or dose-dense regimens.[1-4]
- While primary prophylaxis is well-established, data on secondary prophylaxis in intermediate-risk regimens are limited. Studies suggest G-CSF may reduce hospitalizations and improve treatment delivery, but real-world, long-term safety data are lacking.[5,6]
- A possible signal between G-CSF use and secondary malignancies has been suggested.[7]
- **Objective:** To prospectively evaluate the long-term safety and outcomes of secondary G-CSF prophylaxis in breast cancer patients treated with q3-weekly Doxorubicin-Cyclophosphamide.

Methods

- Interim analysis of a prospectively maintained institutional database at the McGill University Health Centre between 2016 and 2025.
- Patients receiving dose-dense regimens or meeting criteria for primary prophylaxis were excluded.
- Secondary G-CSF (filgrastim or pegfilgrastim) was administered at the physician's discretion to prevent dose reductions or delays.
- Outcomes analyzed via multivariable logistic and Cox models, adjusted for prognostic factors.

Demographics

Table 1. Breast Cancer Patients Receiving Chemotherapy (n = 98)

Characteristic		No G-CSF (n=54)	G-CSF (n=44)	p-value
Age (years)	Mean ± SD	59.9 ± 11	61.8 ± 13.1	0.4
BMI	Mean ± SD	28.6 ± 7.1	29.1 ± 7.0	0.8
Histology	Invasive Ductal	49 (90.7%)	37 (84.1%)	0.2
	Invasive Lobar	1 (1.9%)	1 (2.3%)	
	Other*	4 (7.4%)	6 (13.6%)	
Tumor markers	ER positive	41 (75.9%)	32 (72.7%)	0.9
	HER2 positive	17 (31.5%)	10 (22.7%)	0.5
	Triple negative	8 (14.8%)	9 (20.2%)	0.6
Stage	I	10 (18.5%)	7 (15.9%)	0.9
	II	31 (57.4%)	24 (54.5%)	
	III	10 (18.5%)	9 (20.5%)	
	IV	3 (5.6%)	4 (9.1%)	

*includes invasive pleomorphic lobular carcinoma, invasive mammary carcinoma, and invasive micropapillary carcinoma.

Results

Table 2. Clinical Outcomes No G-CSF vs G-CSF use

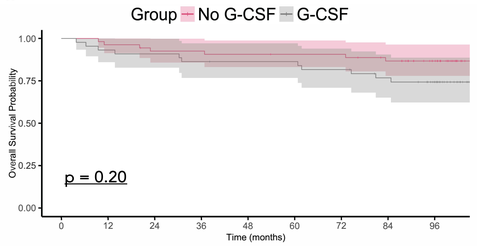
Outcome	Unadjusted OR	p-value	Adjusted OR	p-value
Metastatic rate	0.33 (0.07–1.18)	0.11	0.25 (0.04–1.09)	0.09
Mortality rate	2.24 (0.80–6.66)	0.13	2.09 (0.61–7.70)	0.25

Table 3. Follow-up Among Survivors

Group	N	Mean (SD) months	1-year FU (%)	2-year FU (%)	5-year FU (%)
No G-CSF	47	94.6 (14.2)	96.3	90.7	87.0
G-CSF	33	96.8 (12.7)	93.2	90.9	84.1

Results

Figure 1: Overall Survival by G-CSF Use



No difference in OS between G-CSF and non G-CSF users

Highlights

- 45% of patients received secondary G-CSF, most starting at cycle two.
- No significant difference was found in new metastases or overall survival between the groups.
- No excess mortality or secondary hematologic malignancies were observed; long-term follow-up exceeded 84% at 5 years.

Conclusion

- In this real-world cohort, secondary G-CSF prophylaxis during q3-weekly AC chemotherapy was not associated with significant differences in all-cause mortality between groups.
- No secondary hematological malignancies were observed.
- These results support the liberal use of secondary G-CSF in curative-intent regimens to prevent delays or reductions in dose intensity. Continued follow-up is warranted to confirm long-term safety.

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