



# Clinical Effectiveness and Safety of Reference and Biosimilar G-CSF as Primary Prophylaxis in DLBCL

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## Aim

To compare real-world G-CSF outcomes as primary prophylaxis in DLBCL.

## Conclusions

- This comparative analysis revealed no statistically significant differences in **febrile neutropenia** or **infection** incidence between biosimilar and reference G-CSF products.
- No patients experienced AE-associated treatment discontinuation or death, regardless of G-CSF type (reference/biosimilar).
- These findings support using biosimilar G-CSF as a safe and effective alternative to the reference product.

## Background

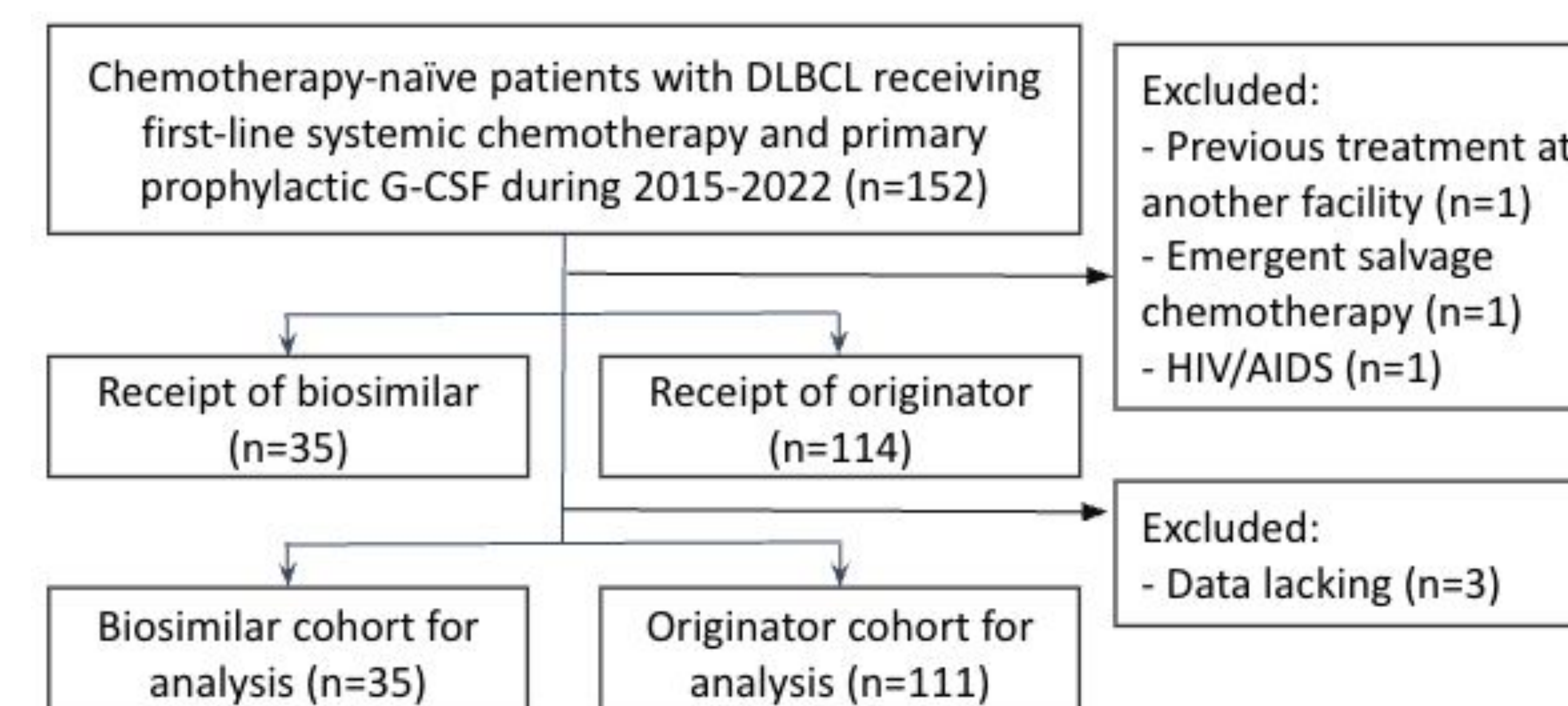
- Meta-analysis of clinical differences between reference and biosimilar G-CSF showed no significance in Western countries.
- Limited RWE exists on comparative G-CSF use in Asia.

## Study design

- A single-center retrospective cohort study was conducted in Taiwan (2015-2022).
- Patients with DLBCL receiving first-line chemotherapy and primary prophylactic G-CSF were eligible.
- Manual chart review assessed: febrile neutropenia, infection, AEs leading to treatment discontinuation or death.
- IPTW was used to minimize baseline imbalances, weighted and unweighted results were compared. Logistic regression was performed.

## Results

- This study included 146 patients (mean age, 65 years; 58% female), biosimilar product was used in 24% of patients.



Baseline characteristics (IPTW-weighted)

Variable	Overall	Biosimilar	Originator	SMD
Sex				
Female	42.86	31.05	48.30	-0.080
Male	57.14	68.95	51.70	0.080
Age, years, mean (SD)	64.29 (12.94)	63.31 (14.58)	64.74 (12.19)	-0.008
B symptoms				
Absent	77.14	87.38	72.42	0.048
Present	22.86	12.62	27.58	-0.048
ECOG PS				
0-1	85.71	88.64	84.37	0.180
≥2	14.29	11.36	15.63	-0.180
Ann Arbor stage				
1	20.00	22.55	18.82	-0.011
2	22.86	18.61	24.82	0.077
3	22.86	20.57	23.91	-0.012
4	34.29	38.28	32.45	-0.053
Body weight, kg, mean (SD)	66.97 (14.02)	71.85 (17.34)	64.71 (11.66)	0.015
LDH, units/L, median (IQR)	218 (187-299)	206 (185-222)	248 (188-317)	-0.122
Pretreatment ANC, cells/μL, mean (SD)	4657.71 (2318.06)	4655.82 (1835.10)	4658.59 (2519.15)	-0.166

Multivariable logistic regression for febrile neutropenia

Variable	Short- and long-acting G-CSF		Short-acting G-CSF	
	Original OR (95% CI)	Weighted OR (95% CI)	Original OR (95% CI)	Weighted OR (95% CI)
Biosimilar vs. originator	0.31 (0.06-1.61)	0.18 (0.04-0.91)*	0.23 (0.02-2.14)	0.16 (0.02-1.14)
Age (years)	1.06 (1.00-1.12)*	1.06 (1.02-1.10)*	1.06 (0.99-1.13)	1.06 (1.00-1.11)*
B symptoms	4.39 (1.47-13.10)*	4.18 (1.33-13.15)*	4.90 (1.37-17.56)*	4.14 (1.12-15.37)*
ECOG PS (≥2 vs. 0-1)			3.94 (1.06-14.66)*	3.48 (0.93-12.98)
Ann Arbor stage (ref: stage 1)				
2			9.40 (1.28-69.26)*	8.90 (1.48-53.62)*
4	3.75 (1.31-10.73)*	4.14 (1.44-11.90)*	15.60 (2.54-95.91)*	16.18 (3.30-79.39)*
Overall significance	<0.001	<0.001	<0.001	<0.001

Multivariable logistic regression for infection

Variable	Short- and long-acting G-CSF		Short-acting G-CSF	
	Original OR (95% CI)	Weighted OR (95% CI)	Original OR (95% CI)	Weighted OR (95% CI)
Biosimilar vs. originator	0.79 (0.23, 2.77)	0.60 (0.18, 2.01)	0.24 (0.03, 2.00)	0.16 (0.02, 1.23)
B symptoms	4.05 (1.55, 10.55)*	3.96 (1.48, 10.60)*	4.15 (1.48, 11.67)*	4.32 (1.53, 12.22)*
ECOG PS (≥2 vs. 0-1)	3.16 (1.17, 8.59)*	3.12 (1.13, 8.64)*	2.91 (1.02, 8.36)*	3.02 (1.10, 8.28)*
Ann Arbor stage 4 (vs. 1)	2.49 (0.98, 6.31)	2.92 (1.13, 7.50)*	2.61 (0.95, 7.17)	3.05 (1.11, 8.38)*
Overall significance	<0.001	0.001	<0.001	<0.001

\*Statistically significant with p < 0.05

- There was no significant difference between biosimilar and reference G-CSF in the incidence of febrile neutropenia (aOR 0.31, 95% CI: 0.06-1.61) or infection (aOR 0.79, 95% CI: 0.23-2.77).
- No patients experienced an AE leading to treatment discontinuation or death.

## Abbreviations

AE, adverse event; ANC, absolute neutrophil count; aOR, adjusted odds ratio; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; G-CSF, granulocyte colony-stimulating factor; IPTW, inverse probability of treatment weighting; LDH, lactate dehydrogenase; RWE, real-world evidence; SMD, standardized mean differences; SD, standard deviation

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