A retrospective study on the safety of rituximab biosimilar (Riximyo®) following a single switch from the reference product in patients with Non-Hodgkin's Lymphoma

Hala Musa, Nina Song, Michael Soriano, Dr Jennifer Ong
Chris O'Brien Lifehouse, Camperdown, Australia
Sydney Pharmacy School, University of Sydney, Australia

Introduction

Rituximab is an essential medication used to treat a number of different conditions including Non-Hodgkin's Lymphoma.

However, high cost of rituximab causes economic burden to the healthcare system, thus use of biosimilars is crucial. While evidence is proven in phase 3 trials, evidence in clinical practice is essential to increase confidence in practical use.

Materials and methods

Analysis of medical records from a metropolitan specialist cancer centre was used to assess and compare the frequency of adverse events, toxicity and immunogenicity at month 0 for eligible patients commencing or switching to GP2013.

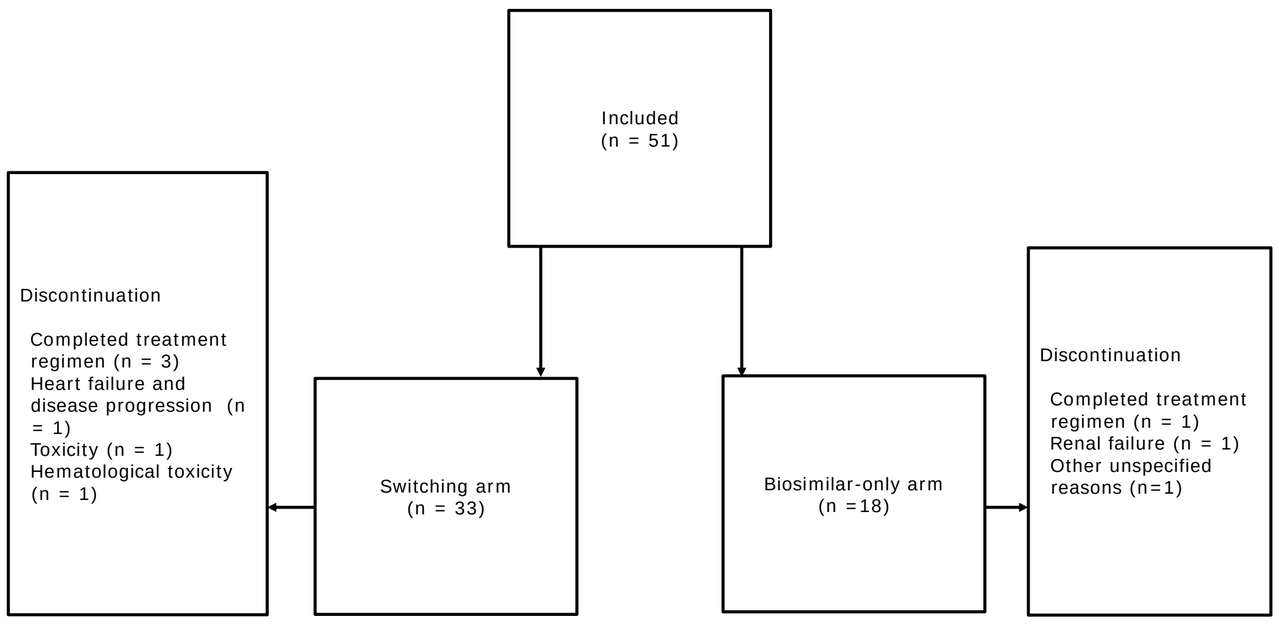

Figure 1. Diagram showing study arms

Table 1. Participant demographics

Subgroup	GP2013/GP2013 (n = 18)	R/GP2013 (n = 33)	p-value
Age (years), median (IQR)[a]	74 (52 – 79)	69 (59 – 76)	.615
Gender, male, n (%)[b]	10 (56)	20 (61)	.772
Pathological type, n (%)[c]			.803
CLL	0 (0.0)	2 (6.1)	
DLBCL	6 (33.3)	9 (27.3)	
Follicular lymphoma	1 (5.6)	4 (12.1)	
Hodgkin's lymphoma	1 (5.6)	0 (0.0)	
MALT lymphoma	0 (0.0)	2 (6.1)	
Marginal zone lymphoma	0 (0.0)	1 (3.0)	
Waldenström's macroglobulinemia	1 (5.6)	2 (6.1)	
Uncertain subtypes of B cell lymphoma	9 (50.0)	13 (39.4)	
ECOG Performance Status, median (IQR)[a]	1.0 (1.0 – 2.0)	1.5 (1.0 – 2.0)	.424
Cycle no. of first administration of biosimilar (cycle), median (IQR)[a]	1.0 (1.0 – 1.0)	3.0 (2.0 – 4.0)	.001
Treatment naïve, n (%)[b]	13 (72)	27 (82)	.634

CLL: Chronic lymphocytic leukaemia, DLBCL: Diffuse large B cell lymphoma, ECOG: Eastern Cooperative Oncology Group

[a] *Mann-Whitney U test*

[b] *Chi-squared test*

[c] *Fisher's Exact test*

Table 2. Summary adverse events at Month 0 of the biosimiliar switch vs Month 12

TEAEs, n (%)	GP2013/GP2013 (n = 18)	R/GP2013 (n = 33)	p-value[a]
Anaemia, Grade 2	1 (5.6)	2 (6.1)	1.00
Arthralgia	0 (0.0)	1 (3.0)	1.00
Cardiac failure	0 (0.0)	2 (6.1)	.534
Constipation, Grade 1	1 (5.6)	4 (12.1)	.645
Cough	0 (0.0)	1 (3.0)	1.00
Infection/infestation	0 (0.0)	2 (6.1)	.534
Nausea and vomiting	3 (16.7)	10 (30.3)	.336
Grade 1	2 (11.1)	8 (24.2)	
Grade 2	1 (5.6)	0 (0.0)	
Unknown	0 (0.0)	2 (6.1)	
Neutropenia	0 (0.0)	1 (3.0)	1.00
Pulmonary nephropathy	0 (0.0)	1 (3.0)	1.00

[a] *Fisher's Exact test*

Of 51 patients analysed, no patients experienced significant adverse events leading to discontinuation or death. The most common adverse event was nausea and vomiting for both biosimilar only (16.7%) and switching arms (30.3%), followed by constipation (biosimilar only, 5.6%; switching arm, 12.1%). There was no significant difference in the incidence of any adverse events observed between the switching/biosimilar only arms.

Conclusions

This retrospective study suggests that the safety of rituximab biosimilar GP2013 in switching patients is comparable to that in patients who received the biosimilar only throughout the entire treatment.

Results showed that there was no significant difference in the incidence of adverse events, however, a larger study should be undertaken to produce conclusive evidence.

Studies such as this would also benefit from the collection of immunogenicity data, thus an observational study to record such data may be beneficial to further increase confidence in switching to biosimilars in patients treated for NHL.

Literature cited

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Further information

Hala Musa
Email: hala.musa@lh.org.au