A retrospective study on the safety of trastuzumab biosimilar (Kanjinti®) following a single switch from the reference product in patients with HER2-positive breast cancer

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Introduction

Trastuzumab has improved the survival of patients with HER2-positive breast cancer.

However, due to economic cost to the healthcare system, a switch is being conducted to biosimilars.

Concern still remains regarding biosimilars, especially regarding its safety, thus, it is necessary for safety to be established in clinical practice to increase confidence and uptake.

Materials and methods

Analysis of medical records from a metropolitan specialist cancer centre was used to assess frequency of adverse events, toxicity and immunogenicity at two time-points Month 0 and 12 for eligible patients commencing or switching to ABP 980. Analysis was conducted between the arms and between the two timepoints.

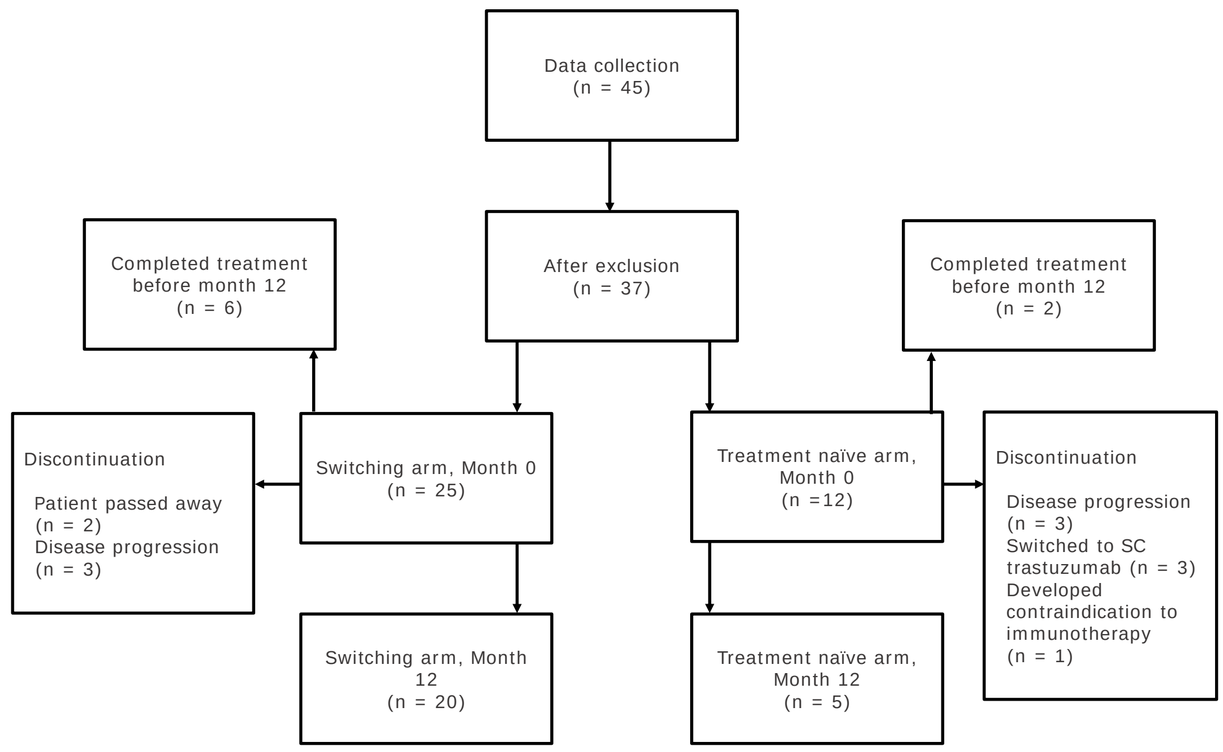

Figure 1. Diagram showing study arms

Table 1. Participant demographics

Characteristic	Biosimilar/biosimilar (n = 12)	TRZ/biosimilar (n = 25)	p-value
Age (years), median (IQR)[a]	54 (43 – 67)	59 (50 – 64)	.281
Gender, female n (%)	12(100.0)	25 (100.0)	-
Metastatic **'Yes',** n (%)[b]	7 (58.3)	24 (96.0)	.009
More than 1 tumour, n (%)[b]	7 (58.3)	23 (92.0)	.026
Missing	1 (8.3)	1 (4.0)	
ECOG Performance Status, median (IQR) [a]	2 (1 – 2)	1 (1 – 2)	.900
Stage of Treatment – Maintenance, n (%) [c]	7 (58.3)	24 (96.0)	.009
Treatment cycle, median (IQR)	-	30 (11 – 60)	-

[a.] *Mann-Whitney U test*
[b.] *Fisher's Exact test*
[c.] *Chi-squared test*

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

	Biosimilar/biosimilar (n = 5)			TRZ/biosimilar (n = 20)		
Adverse Events, n (%)	Month 0	Month 12	p-value	Month 0	Month 12	p-value
Number of events	2	0		10	6	
Patients experiencing any AE (Grade ≥ 3)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Arthralgia	1 (20.0)	0 (0.0)	1.00	1 (5.0)	0 (0.0)	1.00
				.367		
Asthenia	0 (0.0)	0 (0.0)		4 (20.0)	0 (0.0)	.625
				.549		
Constipation	0 (0.0)	0 (0.0)		0 (0.0)	1 (5.0)	1.00
					1.00	
Diarrhoea	0 (0.0)	0 (0.0)		1 (5.0)	0 (0.0)	1.00
				1.00		
Itch/Rash	0 (0.0)	0 (0.0)		1 (5.0)	3 (15.0)	.500
				1.00	1.00	
Nausea and Vomiting	1 (20.0)	0 (0.0)	1.00	1 (5.0)	2 (10.0)	1.00
				.367	1.00	
Peripheral Neuropathy	0 (0.0)	0 (0.0)		2 (10.0)	0 (0.0)	1.00 (switch m0 vs m12)
				1.00 (Bio m0 vs switch m0)		

Of 37 patients analysed, no patients experienced significant adverse events leading to discontinuation or death. The most common adverse event in Month 0 was asthenia (20%) and peripheral neuropathy (10%) in the switching arm. In contrast, itch or rash was the most common adverse event in Month 12 switching arm (15.0%) compared to no adverse events experienced in Month 12 biosimilar only arm. However, no statistically significant difference was observed between the arms.

Conclusions

This retrospective study evaluating the safety of biosimilar trastuzumab in clinical practice has provided preliminary results on the comparability of biosimilar use in treatment naïve patients and patients who are required to switch from the reference product.

While non-conclusive, results showed the switch-over did not significantly increase the incidence of adverse effects.

However, there is need for a larger study with long-term safety and efficacy data to provide conclusive evidence, thus increasing prescribing confidence of patients switching to biosimilar trastuzumab for HER2-positive breast cancer.

Literature cited

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Further information

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