Early results from the effectiveness and safety evaluation of biosimilar rituximab and brand-rituximab in glomerular inflammatory disease

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Background and importance

Biosimilar drugs require to prove clinical efficacy comparable with the referring brand to get the authorization from medicine regulatory agencies. Nevertheless, the effectiveness and safety from **off-label** uses are not always proved.

Aim and Objectives

Evaluate the early **effectiveness** and **safety** of biosimilar-rituximab compared with the referring brand from an off-label use: **glomerular inflammatory disease**.

Materials and Methods

Observational and **retrospective** study

Patients with glomerular inflammatory disease

Age > 18-years-old

Rituximab (RTX) treatment for the first time

1g single-dose or 1g two-doses (days 0 and 15)

Groups:

- **Biosimilar-RTX:** 2018 treatment year
- **Brand-RTX:** 2019 treatment year

Results

	BIOSIMILAR-RITUXIMAB		BRAND-RITUXIMAB	
	Pre-RTX (-60 to 0 days)	**Post-RTX** (0 to +60 days)	**Pre-RTX** (-60 to 0 days)	**Post-RTX** (0 to +60 days)
Number of patients (n)	6		13	
Biodemographic data				
Age (years)[+]	59 (26 - 74)		58 (25 - 81)	
Sex (%, female)	50		30	
Analytical data				
Leucocytes (x10^9/L)[*]	6.52 ± 2.00	6.13 ± 1.94	9.80 ± 4.62	8.77 ± 3.78
Lymphocytes (x10^9/L)[*]	2.28 ± 1.10	1.30 ± 0.59	1.92 ± 1.13	1.67 ± 1.13
Creatinine (mg/dL)[*]	1.63 ± 1.04	1.16 ± 1.19	1.61 ± 0.85	1.56 ± 1.19
Proteinuria (g/24h)[*]	6.84 ± 3.36	3.29 ± 0.58	5.81 ± 4.55	3.36 ± 2.20

[+]Median (interquartile range); [*]Mean ± standard deviation

- After RTX administration **CD19+ lymphocytes** become negative in all patients with this analytical determination (5/5 for the biosimilar group; 6/6 for the brand group).

EFFICACY

	Patients
BIOSIMILAR-RITUXIMAB	
Total remission	2/6
Partial remission	1/6
No-response	3/6
BRAND-RITUXIMAB	
Total remission	1/13
Partial remission	5/13
No-response	7/13

SAFETY

	Patients
BIOSIMILAR-RITUXIMAB	
Good infusion tolerance	6/6
Infections	0/6
BRAND-RITUXIMAB	
Good infusion tolerance	11/13
Infections	4/13

Conclusions and Relevance

- ✓ Biosimilar-rituximab shows an **effectiveness and safety** profile **comparable** to brand-rituximab.
- ✓ The small sample limits the statistical power and suggests a **larger study to confirm** these results.