BIOSIMILARS IN THE REAL-WORLD: RESULTS FROM AN ACTIVE PHARMACOVIGILANCE PROGRAMME IN A PORTUGUESE ONCOLOGY HOSPITAL

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BACKGROUND

The use of biologics is essential in the management of several types of cancer. When patents of reference biologics expired, biosimilars emerged, widening the patient's access to biological therapy and providing cost savings to health care systems. The hospital pharmacist stands in a privileged position structuring post-marketing surveillance, implementing active pharmacovigilance programs to monitor the safety of these technologies.

OBJECTIVES

The aim of this study is to evaluate the safety profiles of two biosimilar medicines (rituximab and trastuzumab) in the treatment of cancer patients within a Portuguese oncology hospital using an intensive monitoring program.

METHODS

This hospital-based prospective observational study followed a cohort event monitoring approach focused on signalling suspected adverse drug reactions (ADRs). Patients undergoing treatment with rituximab biosimilar CT-P10 (Truxima®) or trastuzumab biosimilar CT-P6 (Herzuma®) were recruited over an 11-month and a 6-month period (from 1st November 2018 and 1st April 2019, respectively, until the 30th November 2019). A paper-based Adverse Drug Reaction (ADR) reporting form was developed for each biosimilar medicine and filled by clinicians. Clinical secretariats sent those reports through an electronic platform to the pharmacovigilance department for analysis of seriousness, expectedness and causality of suspected ADRs.

RESULTS

Ninety-four patients received biosimilar medicines (rituximab, n=35; trastuzumab, n=59). Of those, 4 patients (11.4%) experienced 16 ADRs with rituximab and 1 patient (1.7%) experienced 5 ADRs with trastuzumab. All case reports contained serious and expected ADRs that were at least probably related with biosimilar medicines under study. Based on the MedDRA PT coding, the most reported ADR for rituximab CT-P10 (Truxima®) was chest discomfort (n=4; 19.1%), followed by odynophagia (n=2;9.5%). Trastuzumab CT-P6 (Herzuma®) was associated with back pain, headache, pain in extremity, tachypnoea and tremor (each, n=1; 4.8%).

***FIGURE*: Study design and main results.**

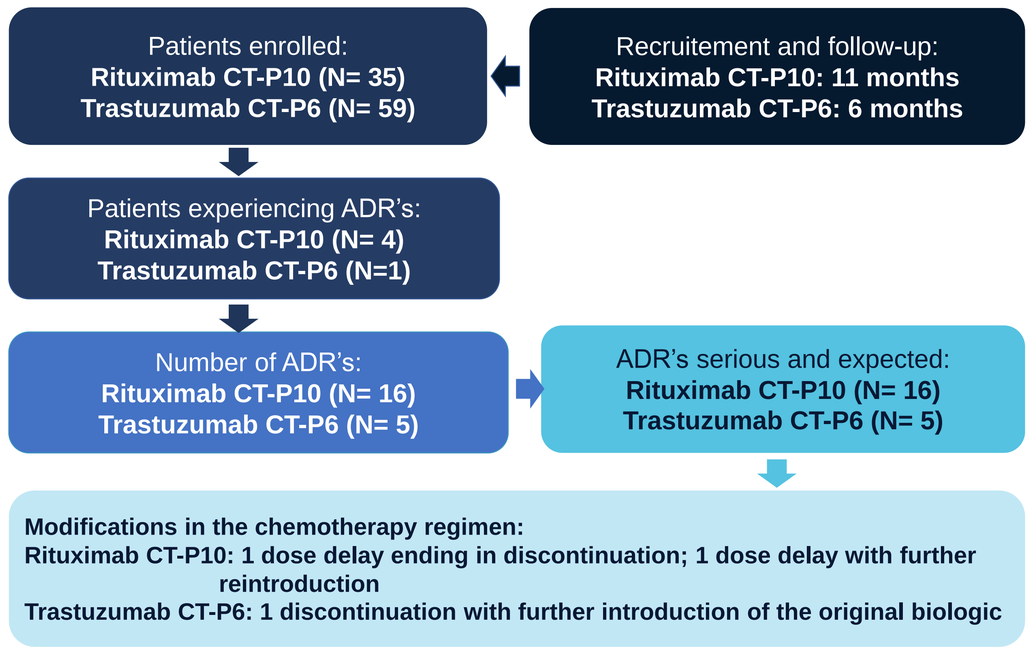

TABLE*: *Adverse drug reactions (ADRs) reported for each biosimilar medicine, according to the System Organ Class (SOC) and Preferred Term (PT) coding of MedDRA.

ADR (SOC / PT)	Rituximab CT-P10, n= (%)	Trastuzumab CT-P6, n= (%)
General disorders and administration site conditions	**6 (37.50%)**	**-**
Chest discomfort	4 (25.0%)	-
Malaise	1 (6.25%)	-
Pyrexia	1 (6.25%)	-
Gastrointestinal disorders	**3 (18.75%)**	**-**
Odynophagia	2 (12.5%)	-
Gastrointestinal pain	1 (6.25%)	-
Nervous system disorders	**1 (6.25%)**	**2 (40.00%)**
Headache	-	1 (20.00%)
Tremor	1 (6.25%)	1 (20.00%)
Musculoskeletal and connective tissue disorders	**-**	**2 (40.00%)**
Pain in extremity	-	1 (20.00%)
Back pain	-	1 (20.00%)
Respiratory, thoracic and mediastinal disorders	**1 (6.25%)**	**1 (20.00%)**
Dyspnoea	1 (6.25%)	-
Tachypnoea	-	1 (20.00%)
Skin and subcutaneous tissue disorders	**2 (12.50%)**	**-**
Erythema	1 (6.25%)	-
Hyperhidrosis	1 (6.25%)	-
Blood and lymphatic system disorders	**1 (6.25%)**	**-**
Febrile neutropenia	1 (6.25%)	-
Infections and infestations	**1 (6.25%)**	**-**
Infection	1 (6.25%)	-
Renal and urinary disorders	**1 (6.25%)**	**-**
Acute kidney injury	1 (6.25%)	-
Total	**16 (100%)**	**5 (100%)**

CONCLUSIONS

The results of this study suggest that in the real-world setting the biosimilar rituximab and biosimilar trastuzumab to treat cancer patients is associated with acceptable safety profiles. No new safety problems were identified. In addition, the results of this study show that to carrying out active pharmacovigilance programs in oncology pharmacy practice is feasible and that such activities contribute to better characterizing the safety profiles of medicines.

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