EFFECTIVENESS OF BIOSIMILAR FILGRASTIM VS ORIGINAL GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) IN FEBRILE NEUTROPENIA PREVENTION IN BREAST CANCER PATIENTS RECEIVING DOCETAXEL/DOXORUBICIN/CYCLOPHOSPHAMIDE (TAC)

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Background

G-CSF biosimilars are an emerging class of biopharmaceutical agents that may become an interesting cost-saving alternative to cope with the increasing burden of cancer. Frequently, these drugs are supported by limited clinical data at the time of approval and it is necessary to add experience in daily clinical practice to demonstrate its equivalence.

Purpose

To compare the effectiveness of biosimilar filgrastim (Zarzio™) with original G-CSF (Granocyte™ and Neulasta™) in febrile neutropenia (FN) prevention in breast cancer patients receiving docetaxel/doxorubicin/cyclophosphamide (TAC) and to analyze treatment patterns of these drugs.

Methods

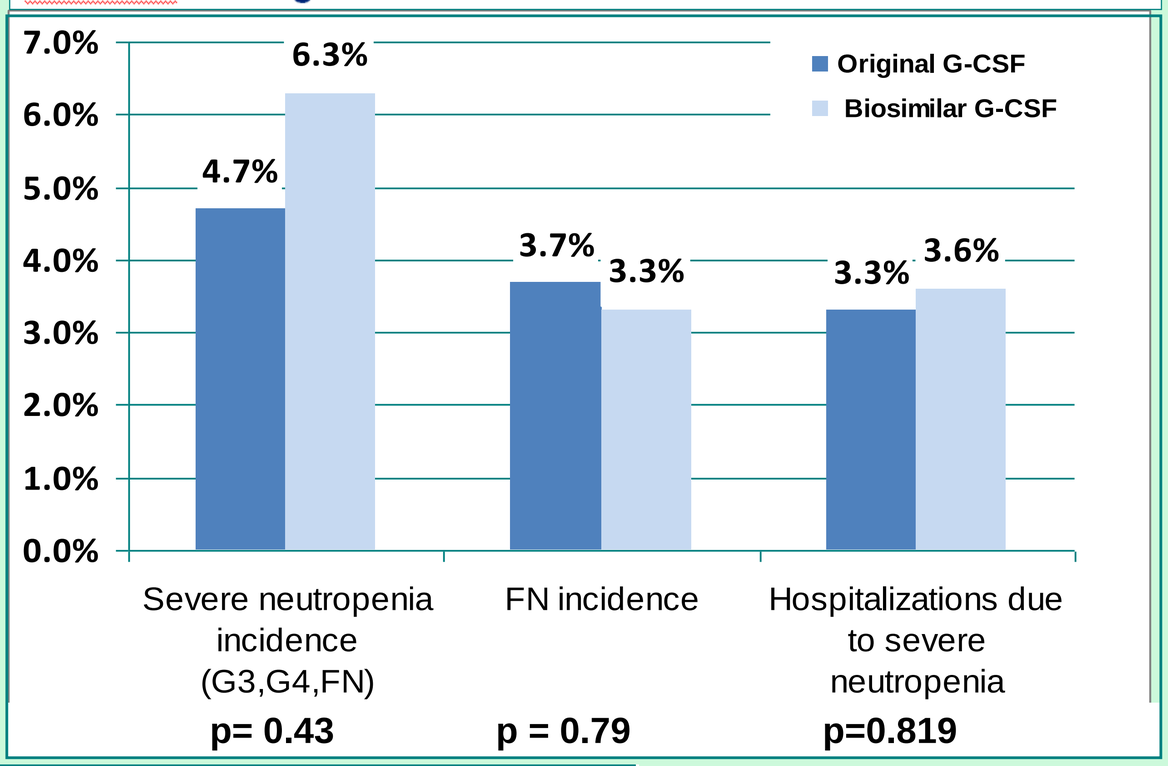
This is a comparative cohort study developed in a tertiary referral hospital with retrospective data collection (2012-2014). The analysis included patients with breast cancer that received FN primary prophylaxis during TAC treatment. Variables were extracted from electronic database (Pharmatools™) and medical center intranet. Effectiveness of G-CSF was evaluated by the FN incidence. Other parameters were: severe neutropenia (G3, G4 and FN) incidence and hospitalizations due to severe neutropenia. Data were analyzed using each cycle as unit of analysis. Variables were assessed using independent t-test and chi-square. All statistical analysis was performed using SPSS v.15.0, with a significance level of $p<0.05$.

Results

Patients demographic and clinical characteristics

Patient-level characteristics	Total (N=518)	Original (N=215)	Biosimilar (N=303)	p-value
Age, $\bar{x}$ (SD)	49.1 (8.8)	50.2 (9.5)	48.4(8.2)	0.019
Weight (kg), $\bar{x}$ (SD)	66.6 (11.5)	67.0 (11.3)	66.4 (11.6)	0.538
Female, %	98.8	100.0	98.0	0.354
Breast afected %				0.011
Left	50.8	54.0	48.5	
Right	46.1	45.6	46.5	
Bilateral	3.1	0.5	5.0	
Stage, %				<0.001
I	12.0	16.7	8.6	
IIA	45.0	53.5	38.9	
IIB	21.2	14.4	26.1	
III – IV	21.8	15.3	26.4	
Nº cycles TAC / patient (1-	5.3			

FN, severe neutropenia and hospitalizations due to FN incidence of biosimilar and original G-CSF



G-CSF pattern of use

	Original		Biosimilar	
	Pegfilgrastim (Neulasta™)	Lenograstim (Granocyte™)	Filgrastim (Zarzio™)	p-value
Total nº of cycles of TAC, n	180 (34.7)	35 (6.8)	303 (58.5)	
Dosage (µg/kg/day), $\bar{x}$ (SD)	*	5,7 (0.9)	4.9 (0.8)	<0.001
Duration G-CSF treatment				
Mode (min-max)	1 (1 – 1)	7 (3 – 10)	5 (2 – 10)	
$\bar{x}$ (SD)	¥	7.1 (1.9)	5.6 (1.4)	<0.001

*Fixed dose: 6 mg/cycle

¥Pegfilgrastim: one administration per cycle $\bar{x}$ = 1 (0.0)

Conclusions

No differences between original and biosimilar G-CSF effectiveness were detected. ZarzioTM was considered lower cost alternative and equally effective as their comparators to reduce FN incidence in breast cancer patients receiving TAC.

Conflict of interest: None **21th EAHP CONGRESS** **CP-169**