Discontinuation Causes of Biological Therapies: Over a Five-Year Period. BIOBADASAR

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Background/Purpose

To analyze discontinuation causes of biologic therapies (bDMARDs) in patients who are registered in **BIOBADASAR** database (Argentinian Registry for Adverse Events with Biologic Treatments in Rheumatology.)

The importance of this register is to show local data because it could be different from other countries.

Methods

Database included patients with rheumatic diseases (diagnosis according to accepted criteria), type and duration of treatments and clinical information of adverse events.

A control group was incorporated for comparison, consisting of patients not treated with bDMARDs but similar demographic features.

Values are expressed as mean ± standard deviation, median (ranges), and frequencies (percentages), as appropriate. Student's t-test and the chi-squared test were applied. Fisher's exact test was used where necessary. Multivariate cause-specific regression models were used to measure the association with discontinuation. Values of p < 0.05 were considered to be statistically significant.

DEMOGRAPHIC DATA

BIOBADASAR

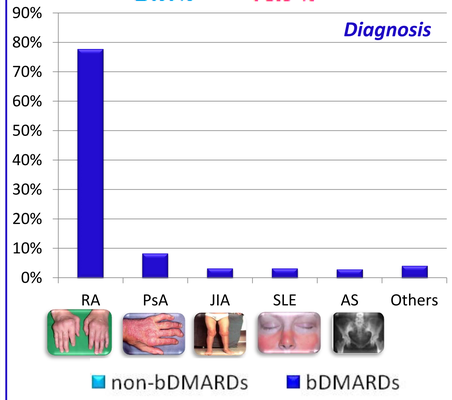
August 2010 to January 2016

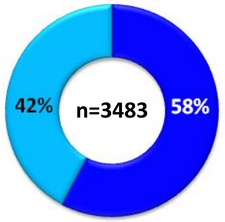
n =3483

Mean age **56.1 ± 15.7** yrs

n= 735 21.1%

n=2748 78.9 %

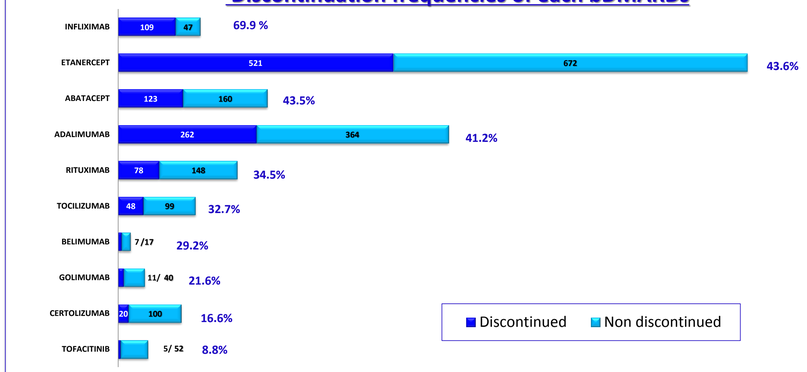




Results

Different ***bDMARDs*** were used in **2011(57.7%) patients** for a total of **2883 treatments cycles** (1.43/patients) . Of these, **1184 (41 %)** were discontinued.

Discontinuation frequencies of each bDMARDs



Main reasons for bDMARDs discontinuation

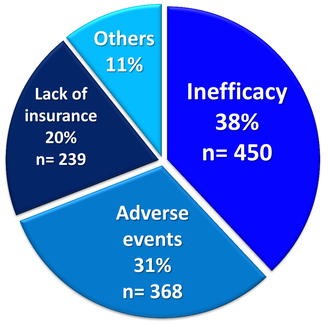


Table 1. Reasons for discontinuation of biologics therapies in BIOBADASAR

	Abatacept	Adalimumab	Belimumab	Certolizumab	Etanercept	Golimumab	Infliximab	Rituximab	Tocilizumab	Tofacitinib
Inefficacy, n (%)	53(43.1)	106(40.5)	3(42.9)	8 (40)	192(36.9)	4(36.4)	*55(50.5)**	16(20.5)	13(27.1)	0(0)
Adverse event, n (%)	32(26)	86(32.8)	1(14.3	8 (40)	152(29.2)	5(45.5)	34(31.2)	28(35.9)	18(37.5)	*4 (80)**
Lack of cover, n (%)	29(23.6)	44(16.8)	0(0)	2(10)	121(23.2)	1(9.1)	*9(8.3) **	19(24.4)	14(29.2)	0(0)
Lost of follow-up, n (%)	7(5.7)	18(6.9)	0(0)	0(0)	33(6.3)	0(0)	7(6.4)	6(7.7)	0(0)	0(0)
Pregnancy, n (%)	0(0)	3(1.2)	1(14.3)	2(10)	10(1.9)	0(0)	0(0)	1(1.3)	0(0)	1 (20)
Remission, n (%)	1(0.8)	2(0.8)	2(28.6)*	0(0)	5(1)	0(0)	3(2.8)	5(6.4)	2(4.2)	0(0)
Unknown, n (%)	1(0.8)	3(1.2)	0(0))	0(0	8(1.5)	1(9.1)	1(0.9)	3(3.9)	1(2.1)	0(0)

** p values <0.05*

Table 2. Predictors associated with discontinuation of biologics therapies. Logistic regression model

	OR (95% CI)	p
Use of infliximab	**2.17** (1.53-3.08)	*<0.001*
Corticosteroids concomitant use	**1.72** (1.44-2.04)	*<0.001*
Older age	**1.01** (1.01-1.02)	*<0.01*

	OR (95% CI)	p
Tofacitinib	**0.14** (0.04-0.48)	*<0.01*
Certolizumab	**0.21** ((0.11-0.39)	*<0.01*
Golimumab	**0.34** (0.15-0.8)	*<0.01*

CONCLUSIONS: The main reason for bDMARDs discontinuation was inefficacy. Discontinuation was significantly associated with infliximab therapy, corticosteroid use and older age.

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