Argentinian Register of Biologics Treatments (BIOBADASAR) RESULTS

FRI-0560

V . Saurit 1, M. C. de La Vega 2,*, G. Citera 2, E. Catay 2, A. Quinteros 3, O. Rillo 2, Gi. Gomez 2, C. Gobbi 1, A. Capuccio 2, I. Exeni 1, A. Eimon 2, E. Mussano 1, A. Alvarez 2, D. Dubinsky 2, S. Magri 2, D. Pereira 2, R. Quintana 4, M. de la Sota 2, Gr. Gomez 2, S. Agüero 5, M. Larroude 2, A. Ortiz 4, E. Scheines 2, A. Bertoli 1, G. Seleme 3, M. Apaz 1, F. Risueño 2, C. Battagliotti 1, N. Garrone 3, J. Barreira 2, L. Martinez 2, G. Casado 2 and BIOBADASAR GROUP.
1Sociedad Argentina Reumatología, Córdoba, 2Sociedad Argentina Reumatología, Buenos Aires, 3Sociedad Argentina Reumatología, Tucumán, 4Sociedad Argentina Reumatología, Santa Fé, 5Sociedad Argentina Reumatología, Catamarca, Argentina.

Background

It´s known that LatinAmerican countries have different prevalence of infectious diseases and so it´s important to assess the incidence of adverse events using biologics to compare in the future with results from other registries.

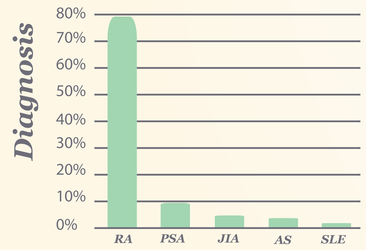
15 PANLAR-SER Iniciative
Argentina, Chile, Brazil, Uruguay, Paraguay, Peru Ecuador, Venezuela, Colombia, Honduras, Costa Rica, Mexico, Guatemala, El Salvador, Dominican Republic

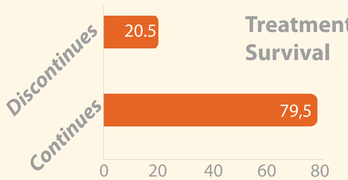
Objective:

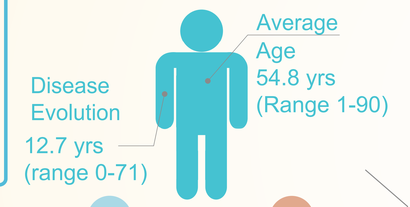
The objective of this paper is to communicate data from BIOBADASAR, Argentine Registry of Adverse Events (AE) caused by the use of biological agents in Rheumatology.

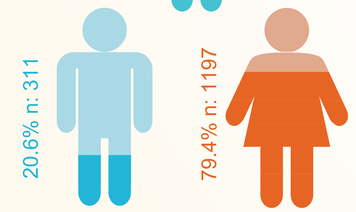
METHODS

All Patients with rheumatic diseases that requires biologic treatment and a control patient, not treated with biological agents, were included in the database from 31 sites participating along Argentine. Three data areas were studied: patient features, treatment assigned and adverse events(AE). The BIOBADASER database was given from the Spanish Society of Rheumatology for our use. Loading data began in August 2010 and closed for this analysis, in July 2012. The Infostat software was used to stadistic analysis. Incident rates, relative risk and person/year incidence for adverse events were calculated.





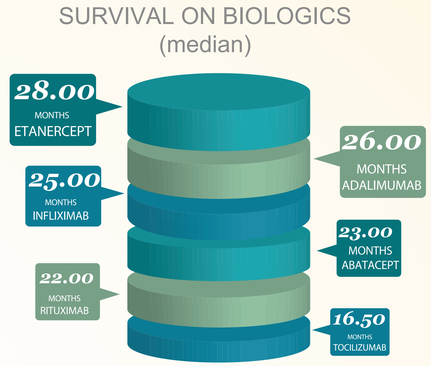


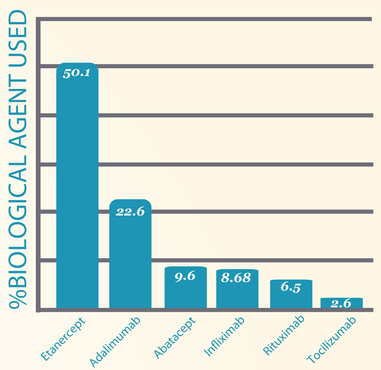


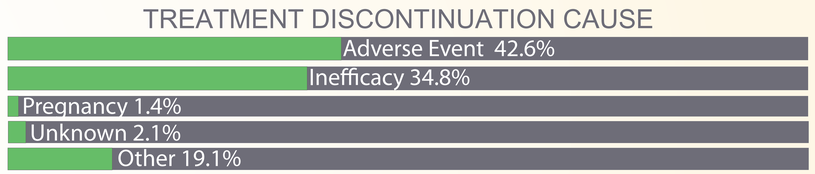
DEMOGRAPHIC DATA

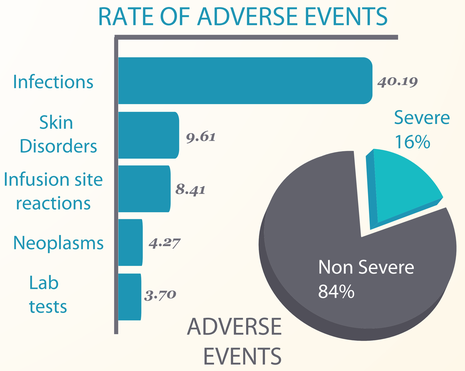
ADVERSE EVENTS. INCIDENCE AND RELATIVE RISK

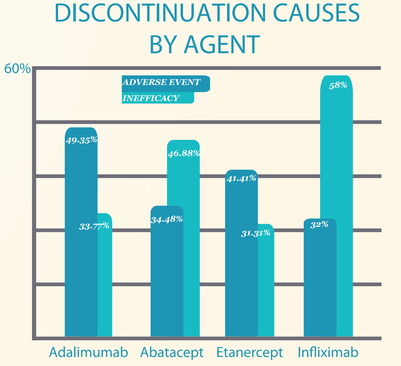
Event	Biologic	Control	RR-CI (IL;SL)-p-value
Serious Adverse Events	86 28/1000 P/yr	19 3/1000 P/yr	6,84 (4,17;11,21) P<0,05
Serious Infection	55 18/1000 P/yr	3 1/1000 P/yr	27,10 (8,67;88,47) P<0,05
Infection	236 78/1000 P/yr	55 12/1000 P/yr	5,49 (4.18;7,19) P<0,05
Pneumonia	40 13/1000 P/yr	2 0,44/1000 P/yr	30,22 (7,3;14,95) P<0,05
Herpes Zoster	14 5/1000 P/yr	4 1/1000 P/yr	5,29 (1,74;16,05) P<0,05
Cellulitis	11 4/1000 P/yr	3 1/1000 P/yr	5,54 (1.54;19,84) P<0,05
Tuberculosis	3 1/1000 P/yr	1 0,2/1000 P/yr	4,53 (0,47;43,56) P> 0,05
Chickenpox	1 33/1000 P/yr	1 0,22/1000 P/yr	1,51 (0,09;24,15) P>0,05
Neoplasms	22 7/1000 P/yr	10 2/1000 P/yr	3,32 (1.57;7,01) P<0,05











COMORBIDITY	TOTAL	CONTROL	CASES
Hypertension	24.9%	24.6%	25.5%
Osteoporosis	17.8%	15.4%	19.7%
Diabetes	5.8%	5.9%	5.7%

Conclusions: This is the BIOBADASAR report showing the reality of biological treatments in Argentina. The patients of LatinAmerican countries could show some differences with other countries using the same treatments due to differences in regional diseases, vaccination or tolerability to pathogen agents. This topics might be studied and reported in the near future.