

BiobadaBrasil: Brazilian Biologic Registry

In this volume, the article *Brazilian Biologic Registry: BiobadaBrasil implementation process and preliminary*, the authors described the implementation of the registry “Monitoring the Brazilian Registry of Biological Therapies in Rheumatic Diseases – BiobadaBrasil” promoted by the Brazilian Society of Rheumatology (BSR), and presented data from the first ten months of the study providing this registry available to all rheumatologists and the Brazilian Society.

The registry implementation was a proposal from the “First Forum of New Resources Rheumatology”, held in Sao Paulo in July 2007, to create a national database of biological agents. Afterwards, a contract was signed with the BSR, PANLAR and Spanish Society of Rheumatology (SSR) in order to participate in BIOBADAMERICA in November of that year. This action was the result of the vision of President of SBR (2006-08), Fernando Neubarth, that participate in a registry already consolidated as BIOBADASER and rely on its support and advice would facilitate the implementation and consolidation of the Brazilian registry. Using a simple online platform makes this registry accessible to all study centers with internet access and all rheumatologists interested in participating.

The implementation process is described in the article, with a training phase, the BiobadaBrasil I, with the system and documents adaptation from Spanish to Portuguese, staff training, and gradual implementation. In April 2009, it was officially presented in the “XX Brazilian Conference Rheumatology” in Natal, and rheumatologists were invited to participate. Throughout this period, the study was presented and discussed in all SBR events and its disclosure was made at the company website and magazine. The President of BSR (2008-10), Ieda Laurindo, actively supported the study, encouraged and guided the implementation team, and was the main responsible for implementing the study in 23 centers and including 1,037 patients until February 2010.

The need for a study to evaluate the safety and effectiveness of treatment with biological agents in our country is well justified because in spite of the genetic diversity of our population, existence of endemic diseases, and continental dimensions we have no data available on pharmacovigilance. Several Brazilian centers have participated in clinical trials to assess the clinical efficacy and safety of these drugs, but their results reflect the ideal treatment for patients without comorbidities, in the special conditions of the trials, and accompanied by a limited time. Using a prospective observational study with patients treated with the difficulties of real life allows results to be generalized, complementing data from clinical trials and comparing with data obtained from registries of other countries.

The preliminary results of BiobadaBrasil included:

- The growth of the study, reaching 23 centers and 1,037 patients, demonstrating the interest of Brazilian rheumatologists. On 31/01/2011 we had 32 active centers and 1,785 patients enrolled;
- Interruption of treatment with biological treatment in 22.2%, mainly due to lack of efficacy (50%), with only 30% of relevant adverse events, data similar to those observed in other records;
- Infection was the main adverse event, especially in groups with biological; three cases of pulmonary tuberculosis despite of the screening for latent TB in all patients using biological. This incidence is higher than expected in our country;
- Higher survival in patients with AS treated with biological compared to RA patients, as well as in other records.

The study maintenance is demonstrated by the establishment of the *BiobadaBrasil Comission* in the 2010-12 Board of SBR by President Gerald C. Pinheiro, defining the committee with the following goals:

- Improving the study's "quality control", represented by the tutoring system, to keep as "active centers" only those who regularly update the data and have not pending;
- Extend the study to other states with interested centers within existing resources and encourage participation of private centers;
- Publishing general information about the registration and encouraging the publication of data centers in society events and BJR.

Our participation in BIOBADAMÉRICA must continue sharing data with Biobadamex, Mexican registry that included two thousand patients, and Biobadasar, Argentina registry, which is starting, supporting studies in other Latin American countries and continue with the support of BIOBADASER.

Our main goal is the rheumatic patient using biological agent, and acquire reliable data on the effectiveness and safety

of these treatments. We do not know how many Brazilians are using these drugs but we know that it is increasing. By data from MS-DATASUS, we know that the number of monthly treatments of RA and JIA with anti-TNF increased from almost 600 in January 2007 to more than 11,000 in February 2010, and about 16,000 in November 2010, including As and psoriatic arthritis.

The main product of BiobadaBrasil can be witnessed but can not be measured: it is the improvement of quality in rheumatic patient care using biological agents. We need to methodically record the disease activity and possible adverse events due to therapy, in order to treat the patient with more security and efficacy, justifying to the Brazilian society the significant resources that are driving to these Brazilian patients.

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