AUTOIMMUNE BULLOUS DISEASES

# REAL WORLD EVIDENCE: RITUXIMAB EFFICACY AND SAFETY IN THE TREATMENT OF PATIENTS WITH MODERATE TO SEVERE PEMPHIGUS VULGARIS AND FOLIASCEOUS.

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Introduction: Rituximab received FDA approval in June 2018 –not yet in Europe- for the treatment of patients with moderate to severe pemphigus vulgaris.

Objective: To study the efficacy and safety of rituximab treatment in 26 patients with pemphigus that were resistant or had contraindication to classic immunosuppressive treatments (prednisone, azathioprine, cyclosporine, MMF, IVIg).

Materials and Methods: A total of 26 patients (10 men, 16 women), age mean 47,5 ( 21-74) years old, disease mean duration 97,5 (3 – 192) months were included: 20 with pemphigus vulgaris and 6 pemphigus foliasceous. Rituximab's efficacy was evaluated according disease control, retention of remission, disease severity, previous treatments. Adverse reactions were studied.

Results: From the 26 patients, 23 completed the first course: 2 discontinued during the first course due to adverse reactions and one died septic due to immunosuppression and Castleman disease caused by previous treatments. All of the 23 patients (100%) responded with complete remission after the first course of treatment and based on clinical judgement or disease severity 5 /23 due to relapse (21,7%) (6 months to 5 years after the first course) and 7 /23 (30,5%) as a prophylactic course received additional course (6-10 months later), whereas 11/ 23 (47,8%) received no additional course. No major adverse events were noticed.

Conclusions:Rituximab is very effective in the treatment of pemphigus and remarkably superior to classic immunosuppressive treatment in terms of both efficacy and safety , as larger periods of remission are achieved and lower doses of corticosteroids and immunosuppressants are needed.