Ultrasonographic Salivary Glands Response To Rituximab In Primary Sjögren Syndrome Patients In the Tolerance and Efficacy Of Rituximab In Primary Sjogren Syndrome Study Is Not Associated With The Anatomopathology Changes

Abstract: #2881

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Description:

Background/Purpose: We conducted a multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy of Rituximab (RTX) in active pSS patients in France (TEARS study) and we evaluated, in a single centre (Brest, France), the echostructural and vascularisation changes in this population.

Methods:

The TEARS study included pSS patients with scores above 50 mm on at least two of four visual analog scales (VASs) evaluating dryness, pain, fatigue, and global disease. They were randomly assigned (1:1) to RTX (1 g at weeks 0 and 2) or placebo (PBO). Patient had recent-onset (<10 years) biologically active pSS and/or systemic pSS. 28 pSS patients had ultrasonographic examination and a salivary gland biopsy before the first infusion (placebo or RTX) and at 24 weeks follow up. Both parotid and submandibular glands were assessed. The echostructure of each gland was scored using a semi quantitative scoring (0 to 4) (figure 1). We also evaluated the size of each glands and the vascularisation using the resistive index of the transverse facial artery of the parotid glands before and after stimulation with lemon juice. Concerning the echostructural scoring of each gland, we considered an improvement if the score of the glands was improved by one point or more and the comparison between the RTX and placebo group were obtained using the Fisher's exact test. Difference of size (mm) and resistive index before and after treatment (RTX or PBO) were evaluated using the non parametric Wilcoxon test.

Results:

Parotid echostructural scoring was improved in 50% of pSS patients in the RTX group versus 7% in the placebo group (p=0.03). Table 1 shows the changes of grade before and after treatment in both RTX and PBO groups. The US submandibular scoring was also improved in 35% of pSS patients in the RTX group compared to 16% in the placebo but the difference was not statistically significant (p= 0.16). There were no changes concerning the size of each gland in RTX or placebo groups (figure 2). Regarding the modifications between week 0 and week 24 of lemon stimulation response, measured by resistive index variation before and after stimulation, the two groups were not different. 35 had a Chisholm

score evaluation before and after treatment, 16 a focus score evaluation and 28 an ultrasound evaluation. At least one parotid gland had an improvement in 2/14 in the P group versus 7/14 in the R group. At least one submandibular gland had an improvement in 1/14 in the PBO group versus 7/14 in the R group (p: 0.03). Focus score was lower after treatment in 3/10 in both PBO and R groups. Similarly, 3/18 had an improvement of their Chisholm score in the P group versus 2/17 in the R group (NS). The concordance between both submandibular and parotid glands US score and focus score was low (kappa<0.1).

Conclusion:

In our pSS population treated by RTX or PBO, ultrasound evaluation showed a more important improvement of the echostructure of the salivary glands in treated patients than in the placebo group. In contrast, RTX did not modify neither sizes of the salivary glands nor vascularisation inside the glands. Ultrasonographic improvement was not associated to anatomopathologic changes of the minor salivary gland labial biopsy.