Medical or Research Professionals/Clinicians

Topic area: Clinical topics by disease

Topic: 15. Rheumatoid arthritis - non biologic treatment

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THE USE OF EULAR REMISSION AND RESPONSE CRITERIA AND DIVERSE DISEASE ACTIVITY MEASURES DEMONSTRATE THAT THE TREATMENT OF RHEUMATOID ARTHRITIS WITH STAPH PROTEIN A LEADS TO SUSTAINED CLINICAL RESPONSES

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My abstract has been or will be presented at a scientific meeting during a 12 months period prior to EULAR 2017: No

Is the first author applying for a travel bursary and/or an award for undergraduate medical students?: No

Background: Staph Protein A (SpA) is currently being investigated (PRTX-100, Protalex Inc.) as a treatment for Rheumatoid Arthritis[1] (RA) and immune mediated thrombocytopenic purpura[2]. The mode of action of SpA in the treatment of autoimmune disease is unknown, but macrophage suppression and B cell depletion[3] have been considered, amongst several other possibilities.

Objectives: To determine the duration of clinical responses following the treatment of RA with SpA.

Methods: The results of a single center open label trial in which SpA was given to patients with active RA has been previously reported[1]. Following completion of that protocol, the eleven patients were followed as standard of care in a private rheumatology clinic using a treat to target (T2T) strategy which consists of clinical reassessments on an every two to four month basis. In addition to conventional disease activity measures (DAMs), a multi biomarker disease activity test (Vectra, Crescendo Inc.) was obtained. Vectra DA is a validated measure of disease activity in patients with RA. The Vectra DA algorithm uses the concentrations of the 12 biomarkers to calculate an MBDA score between 1 and 100.

Ultrasound power Doppler joint counts (UPD) were also obtained, utilizing a truncated methodology in which three sites at the dorsal wrist and three dorsal metacarpal sites were analyzed bilaterally for a total of twelve sites studied These UPDs were read at the time of the patient's visit, for use in T2T decision making, but were stored digitally and subsequently reread in duplicate in a blinded fashion a year after completion of the PRTX-105 protocol. Each joint site was subjectively scored from 0 (normal) to 3 (severe) with a possible total score of 0 -36.

Intra-observer reliability was determined by two-way random intra-class correlations (ICC).

Eular 2011 response and remission criteria were determined.

Results: Eleven patients entered the PRTX-105 protocol and had a final assessment one month after their last SpA treatment. One patient was lost to follow up at that time, and two patients had new therapies added. Eight patients were followed after completion of the PRTX-105 protocol in a T2T strategy with no change in their therapy.

Intra-observer UPD score reproducibility was high (ICC = 0.874).

Image/graph:

	N	Eular Remission	DAS Mild^	DAS Mod^	DAS Severe^	Good!	Mod!	None!	UPD*	Vectra*
Day 1	11	NA	0	4	7	NA	NA	NA	7.9 +/-2.7	42.9 +/-12
Day 49	11	0	5	5	1	7	2	2	6.5 +/-3.7	44.5 +/-12
Post TX 1 Month	11	3	4	2	2	9	0	2	6.3 +/-3.2	40.5 +/-8
Post TX 3 Month	8	4	3	1	0	7	0	1	6.6 +/-2.2	34.3 +/-13
Post TX 6 Month	7	3	2	1	1	5	0	2	5.8 +/-1.9	
Post TX 12 Month	4	1	1	2	0	4	0	0		

*for the 8 patients reaching Post TX 3 Month ^DAS28CRP Mild < 3.2 Mod >=3.2-5.1 Severe > 5.1 !Eular Response Criteria

Conclusions: Diverse DAMs demonstrate that the treatment of RA with SpA can lead to sustained clinical responses lasting from several months to one year.

Such sustained clinical responses in RA following exposure to treatment is not seen with any current therapy for RA with the exception of B cell depletion with rituximab.

References:

1. Wiesenhutter, C. Treatment of Rheumatoid Arthritis Patients with Parenteral Staphylococcal Protein A (PRTX-100): An Open-Label Single-Site Extension Trial. Ann Rheum Dis 2016;75:1019 doi:10.1136/annrheumdis-2016-eular.2540

2. Bussel, J.B. et al Safety and Efficacy of PRTX-100, a Highly Purified Form of Staphylococcal Protein A, in Patients with Immune Thrombocytopenia (ITP) Blood 2016 128:4929

3. Silverman, G.J et al On the mechanism of staphylococcal protein A immunomodulation. Transfusion 2005; 45:274–280. |
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Disclosure of Interest: None declared