every year were significantly associated with peripheral eosinophilia in SSc patients (OR 3.46 (95%CI 1.11-10.73) and 1.16 (95%CI 1.03-1.30), respectively), while Raynaud's phenomenon had a significantly negative correlation with peripheral eosinophilia in SSc (OR 0.27: 95%CI 0.09-0.84). Other parameters—such as SSc subset, severity of skin tightness, serology, cytokines (transforming growth factor- β , interleukin-5)—were not correlated with peripheral eosinophilia.

Conclusion: Peripheral eosinophilia of unknown cause can be detected 1 in 5 SSc patients. The factors associated with peripheral eosinophilia are longer disease duration and being male while vasculopathy has a negative association.

REFERENCES

- [1] Falanga V, Medsger TA. Frequency, levels, and significance of blood eosinophilia in systemic sclerosis, localized scleroderma, and eosinophilic fasciitis. *J Am Acad Dermatol*. 1987 Oct;17(4):648–56.
- [2] Giordano M, Ara M, Valentini G, Chianese U, Bencivenga T. Presence of eosinophilia in progressive systemic sclerosis and localized scleroderma. *Arch Dermatol Res*. 1981;271(4):411–7.
- [3] Tefferi A, Patnaik MM, Pardanani A. Eosinophilia: secondary, clonal and idiopathic. *Br J Haematol*. 2006 Jun;133(5):468–92.
- [4] Mejia R, Nutman TB. Evaluation and differential diagnosis of marked, persistent eosinophilia. *Semin Hematol*. 2012 Apr;49(2):149–59.
- [5] Kargili A, Bavbek N, Kaya A, Koşar A, Karaaslan Y. Eosinophilia in rheumatologic diseases: a prospective study of 1000 cases. *Rheumatol Int*. 2004 Nov;24(6):321–4.
- [6] Gustafsson R, Fredens K, Nettelbladt O, Hällgren R. Eosinophil activation in systemic sclerosis. *Arthritis Rheum*. 1991 Apr;34(4):414–22.

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SAT0300 ABSTRACT WITHDRAWN

SAT0301 THE USE OF 16 GRIPS TEST TO EVALUATE HAND IMPAIRMENT IN SYSTEMIC SCLEROSIS (SSC): PRELIMINARY TO CONSTRUCTION OF PERSONALIZED DEVICES

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Background: Systemic sclerosis (SSc) is a progressive connective tissue disease of unknown etiology characterized by autoimmune response and changes in the microvascular system. Although skin fibrosis represents the primary element of this disease, patients may present muscular and/or joint damage. Hand impairment is a major cause of morbidity and disability in about 90% of SSc patients. The ADL difficulties are similar to those of patients with rheumatoid arthritis but SSc patients use a low number of assistive device. In our center an interdisciplinary research unit composed of rheumatologists, rehabilitators, occupational therapists, and design engineers, with the directly involvement of the SSc patients within the design team, are developing a design method to prototype ergonomic assistive device personalized for hands.

Objectives: Evaluate through the 16 grip test which were the most difficult grips for SSc patients in order to understand what particular changes we need to focus on more rehabilitative attention. Determine what ADL can be linked to difficult grips to understand how to work on it. Give advice and design appropriate customized ergonomic aids.

Methods: 92 patients (79 females and 13 males) with SSc followed by our tertiary University based Rheumatologic Center have been specifically evaluated by Hand Rehabilitation Service. The average age of patients was 56y. The 16 grip test was used to evaluate patients. It includes 16 different pattern of grip divided into power grip and precision pinch - Moreover it tests basically two different grip and pinch modalities:

static prehension and dynamic prehension. The score for each grip goes from 0 to 4 (0=impossible, 1=realized with high difficulty, 2=medium difficulty, 3= low difficulty, 4=normal).

Results: 30 patients (32%) had no grip problem, 9 only on the left and 5 on the right hand; 4 patients presented grip difficulty in both hands with a reduction > 25%. 31 had difficulty in 2 or more grip pattern. The most interested grips are the monodigital and pluridigital pressure, the tip to tip pinch, the extension grip in both sexes; the teno-digital in males and the digito-palmar in females. Over 60% of the grips were normal; in particular in our patients only few deficiencies in the power and in the static prehension grips were reported. The most interested patterns of grips are in the group of precision handling related to the use of the fingertips; the extension grip to the difficulty in opening the first commissure. The problems of hand impairment are restricted to a subset of patients around 10-15%. From these results we can obtain useful data to construct our personalized devices for SSc hands.

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REFERENCES

- [1] A Co-Design Method for the Additive Manufacturing of Customised Assistive Devices for Hand Pathologies. F Gherardini, MT Mascia, V Bettelli, F Leali. *JIDPS Pre-press*, pp. 1-18, 2018

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SAT0302 SINGLE-PORT THORACOSCOPIC SYMPATHICOTOMY IS VERY EFFECTIVE FOR TREATMENT RESISTANT RAYNAUD'S PHENOMENON: A ONE MONTH FOLLOW-UP

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Background: In some patients, Raynaud's Phenomenon (RP) symptoms prove resistant to conventional vasodilatory treatment. Thoracic sympathectomy is shown to be effective as treatment of RP, but is associated with surgical burden. During this procedure, the sympathetic nerve traversing to the upper extremity is dissected, subsequently leading to vasodilatation. In our centre, single-port thoracoscopic sympathectomy (SPTS) has been developed, a minimally invasive technique, extensively limiting surgical burden. [1]

Objectives: To evaluate SPTS feasibility and efficacy after one month in patients with treatment resistant RP.

Methods: In this study RP patients were their own controls, as they received an unilaterally left sided sympathectomy. The effects of the SPTS was assessed at baseline and one month after the procedure. Perfusion of the hand was assessed using a cooling and recovery procedure, and laser speckle contrast analysis (LASCA) at room temperature of 23 degrees Celsius. The number and duration of RP attacks was reported over a two week period prior to reassessment by standard questionnaire.

Results: Eight patients were included in the study, 6 male/2 female, with a median (IQR) age of 45.2 (30.2–55.3) years, body mass index of 23.9 (23.4–26.8) kg/m², and RP duration of 7.0 (2.5–14.3) years. Five patients suffered from primary RP, and three patients had RP secondary to connective tissue disease (CTD) [mixed CTD (n=2) and limited cutaneous systemic sclerosis (n=1)]. All patients were very satisfied with the results and the number of attacks in the left hand decreased (p=0.018). After surgery an unilateral improvement in left hand perfusion was observed

during the cooling and recovery procedure ($p=0.008$, figure 1), and in the fingertips with LASCA ($p=0.023$). No serious adverse events occurred.

Figure 1. Mean number of fingers per hand with normal perfusion during a cooling and recovery procedure before and after left-sided SPTS

Conclusion: SPTS, a minimally invasive technique, appears to be feasible and effective in improving hand perfusion in patients with RP after one month. Although these results are promising, long-term efficacy needs to be established and therefore follow-up is on-going.

REFERENCE

- [1] Kuijpers M, Klinkenberg TJ, Bouma W, DeJongste MJ, Mariani MA. Single-port one-stage bilateral thoracoscopic sympathectomy for severe hyperhidrosis: prospective analysis of a standardized approach. *J Cardiothorac Surg* 2013;8:216-8090-8-216.

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SAT0303 DESIGN OF PHASE 3 STUDY OF LENABASUM FOR THE TREATMENT OF DERMATOMYOSITIS

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Background: To date, there has not been a Phase 3 study evaluating efficacy and safety of a new chemical entity solely in subjects with dermatomyositis (DM). There is no precedence for design of such a pivotal study, including selection of patients or efficacy outcomes.

Objectives: Develop a Phase 3 study design for testing efficacy and safety of lenabasum in DM that would be acceptable to experts and for registration purposes.

Methods: Lenabasum is a synthetic, non-immunosuppressive, selective cannabinoid receptor type 2 agonist that activates resolution of innate immune responses. Lenabasum had acceptable safety and tolerability and improved multiple physician-reported and patient-reported efficacy outcomes in a 16-week double-blinded, randomized, placebo-controlled Phase

2 trial in DM subjects with refractory, skin-predominant involvement, as well as in the open-label extension of that study. The Phase 3 trial design was based on Phase 2 data, input from a steering committee of experts in DM clinical trials, and recommendations made by regulatory authorities in the US, EU, Sweden, and Japan.

Results: A global, double-blind, randomized, interventional design was chosen to provide an unbiased assessment of the efficacy, safety and tolerability of lenabasum 20 mg bid and 5 mg bid compared to placebo in the treatment of DM. A 52-week treatment duration was selected to provide safety and efficacy data adequate to support chronic treatment. Subjects with DM were classified by Peter and Bohan criteria or the 2017 EULAR/ACR classification criteria for DM (both amyopathic DM and classic DM). Subjects will be required to have active disease, as assessed by an expert and based on a range of muscle, skin, and other disease manifestations. Subjects must be on stable doses of current DM treatments with any background immunosuppressive medications allowed except prednisone ≥ 20 mg per day or equivalent. This inclusivity allows testing of efficacy and safety of lenabasum in the setting of current treatment practice and reduces risk of disease flare early in the study. The primary efficacy outcome is change from baseline in 2016 ACR/EULAR Total Improvement Score (TIS) for DM and polymyositis. This composite outcome has six domains that broadly capture improvement in disease activity, is relevant to the range of manifestations in DM, and is applicable to the assessment of efficacy in the target patient population. Secondary efficacy outcomes were chosen to assess how the subject functions (Short Form – 36 physical functioning domain), major organ involvement (MMT-8, CDASI activity score, and a new Investigator Global Assessment scale of skin activity designed specifically for this study), and lung function (FVC). Change in oral corticosteroid dose also will be captured.

Conclusion: To our knowledge, this is the first Phase 3 study in DM with a new molecular entity. As such, agreement with experts and regulatory authorities on design represents a step forward in the development pathway of new treatments for DM.

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Corbus—design of clinical trial in DM

23 and me—ad hoc consulting

Admiryx—ad hoc consulting

Janssen—SAB for PSOLAR database

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SAT0304 RELATIONSHIP BETWEEN INTERLEUKIN-23 AND GASTROINTESTINAL INVOLVEMENT IN PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: Growing evidence suggests that T-cell proliferation and cytokine secretion play an important role in the pathogenesis of systemic sclerosis (SSc). Gut involvement is the leading cause of morbidity in patients with SSc. In this study we evaluated interleukin-23 (IL-23) protein expression profiles and investigated its association with gastrointestinal involvement in SSc patients.