RITUXIMAB IN SYSTEMIC SCLEROSIS: SAFETY AND EFFICACY DATA FROM THE EUSTAR NETWORK

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Background: Few small-sized observational studies have suggested that rituximab might be a promising treatment in systemic sclerosis (SSc).

Objectives: To evaluate the outcomes of SSc-patients receiving in routine care rituximab. Infections and other severe adverse events were frequently reported. A comparative study including control patients from EUSTAR centres is ongoing.

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REGIONAL GRAFTING OF AUTOLOGOUS ADIPOSE TISSUE IS EFFECTIVE IN INDUCING PROMPT HEALING OF INDOLENT DIGITAL ULCERS IN PATIENTS WITH SYSTEMIC SCLEROSIS: RESULTS OF A MONOCENTRIC RANDOMISED CONTROLLED STUDY

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Background: Adipose-derived stromal/stem cells (ADSCs) are believed to be pluripotent cells with characteristics similar to BMSCs. Preliminary attempts of cell therapy with ADSCs have been carried out with the purpose of inducing ulcer healing in peripheral vascular impairment that can be observed in animal models and human conditions. In a recent pilot open study from our group it has been demonstrated that lipofilling with autologous adipose tissue-derived cell fractions, which are known to contain both ADSCs and a stromal/vascular cell component, was effective in inducing a prompt healing of long lasting digital ulcers (DU) localised in the fingertips of a small number of patients with Systemic Sclerosis (SSc). The DU healing was accompanied by the rapid disappearance of local ischaemic pain and evidence of a partial restoration of capillary bed in the involved digits when assessed by nailfold videocapillaroscopy (NVC).

Objectives: A randomised controlled trial (RCT) was performed to confirm preliminary uncontrolled data indicating that regional adipose tissue derived AT/G (grafting) is effective in inducing DU healing in patients with SSc.

Methods: Patients with SSc fulfilling the 2013 ACR/EULAR classification criteria and suffering from a DUs lasting for at least 6 weeks prior to enrolment time and showing no tendency to heal, were randomised to be blindly treated with AT or a sham procedure (SP). AT-G consisted of injection at the base of the finger with 0.9% saline solution at the base of the affected finger. Weekly iloprost infusion was noticed in 62 patients (60%) including 23 with rheumatoid arthritis. The indication for the treatment was lung involvement (56%) followed by articular (42%) and skin involvements (30%). At baseline, 175 patients were treated with steroids and 132 with DMARDs. Mean follow-up was 2.4±1.9 years.

In the whole sample, mRSS decreased from 15±11 to 10±8 (p<0.01). For SSc-patients treated with lung for baseline FVC <70%, FVC improved from 56±9% to 59±12%; p=0.02. In patients with articular involvement (n=83), tender joint and swollen joint counts decreased from 9±7 to 4±8 and from 5±5 to 1±3, respectively (p<0.01). In the whole population, 45 patients could stop steroids and mean dose decreased from 10 mg to 7 mg in the other. During the follow-up, 78 (31%) patients had side effects including 35 (14%) with severe side effects leading to discontinuation of the treatment in 10%. Six deaths were recorded (1 IRIS, 1 sepsis, 1 sudden deaths). 76 patients had infection, requiring hospitalisation in 20 patients.

Conclusions: In this study, local and joint involvement appeared to improve under rituximab. Infections and other severe adverse events were frequently reported. A comparative study including control patients from EUSTAR centres is ongoing.