OP0142 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
Methods: Retrospective longitudinal multicenter observational study which included SSc-patients treated with rituximab upon the decision of their physician within the framework of EUSTAR. We interrogated the participating centres and EUSTAR database to determine epidemiological and clinical characteristics, the indication for initiating the treatment, and the following parameters at baseline and at the last visit under treatment: modified Rodnan Skin Score (mRSS), joint, lung and gastrointestinal involvements, treatment, laboratory tests and safety events.
Results: 248 patients were included: 70 (28%) men, mean age: 51±13 years, mean disease duration: 7±7 years; 150 (65%) had diffuse cutaneous-SSc, 54% were positive for anti-topoisomerase and 71% had lung fibrosis. Overlap disease was noticed in 62 patients (26%) 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 for lung with 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±6 and from 3±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 heart failure, 1 sepsis, 2 respiratory insufficiencies, 2 sudden deaths). 76 patients had infection, requiring hospitalisation in 20 patients.
Conclusions: In this study, skin, lung 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.
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OP0143 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 BMMSCs. 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 omponent, 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 (AT) grafting (G) 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-G or a sham procedure (SP). AT-G consisted of injection at the base of the finger with DU of 0.5–1 ml of AT after centrifugation of fat aspirate from abdominal adipose tissue. SP consisted of a false liposuction followed by the injection of 0.5–1 ml of 0.9% saline solution at the base of the affected finger. Weekly iloprost infusion (0.5–2 ng/Kg/min), and calcium-channel blockers (oral nifedipine 20 mg daily) were administered during the entire observation time to all of the patients enrolled in both arms of the study.
The primary end-point was to compare the cumulative prevalence of healed DUs in the two groups within the following 8 weeks. Secondary end points to be assessed were: (i) pain intensity modification (measured by VAS), and (ii) variation of the number of capillaries in the affected digits (recorded by nailfold videocapillaroscopy) in patients receiving AT-G compared to those who underwent SP.
Results: AT-G and SP were performed in 25 and 13 patients, respectively. The two groups were comparable for age, gender, disease duration and SSc subtypes.
DU healing was observed in 23/25 and 1/13 patients treated with AT-G and SP, respectively (p<0.0001). The 12 patients who received the unsuccessful SP underwent a rescue AT-G. Also in all of them DU healing was observed after 8 weeks of observation. It was noticeable that only in the patients treated with AT-G either a significant reduction of pain intensity or an increase of capillary numbers in the affected finger were recorded after both 4 and 8 weeks (p<0.0001 in all the comparisons).
Conclusions: This RCT strongly confirm previous preliminary and uncontrolled data indicating that AT-G may be a successful option for inducing improvement and healing in ischaemic SS-related fingertip DUs that are resistant to more traditional therapeutic approaches.
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