

[OP167] REGENERATIVE SURGERY – A PRELIMINARY STUDY ON THE RESIDENT STEM CELLS IN THE TREATMENT OF “NON HEALING” LEG ULCERS

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Free Paper Session: Leg Ulcer 2

Aim: Stem cells were proposed as a new way to solve the chronic leg ulcers problems. Different types of stem cells have been proposed, but the share resident mesenchymal cells seems to be the most promising.

Method: 7 patients (3 males and 4 females, average age 68,7 yy) affected of “non healing” leg ulcers of different etiological order were selected. Exclusion criteria were ulcer infection and neoplastic origin. All patients underwent to anamnestic and clinic evaluation. An hystological study was performed in each lesion to evaluate the presence of malignancy.

A fragment of healthy skin was taken from each patient and subjected to cell separation using the device and subsequently applied to the lesion whose border was protected by zinc oxide. Lesions were subsequently checked in the subsequent five weeks evaluating wound areas, secretion and pain.

Results / Discussion: In each patient a rapid disappearance of pain in the hours following the application of the solution was observed. After two weeks changes in the characteristics of the lesions were present, both as decrease of exudation both as regrowth of the proliferative tissue. By the fifth week were observed healings of 4 injuries.

Conclusion: The experimental study demonstrates the effectiveness of the method, but it doesn't allow a statistically valid conclusions. The reduction of pain within a few hours after application and the morphological changes after few days, suggest the hypothesis that the use of resident stem cells may be a promising method.

[OP168] A COMPARISON OF PUNCH-GRAFTING AND STANDARD OF CARE FOR TREATMENT OF CHRONIC LEG AND FOOT ULCERS – A RETROSPECTIVE COHORT STUDY

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Free Paper Session: Leg Ulcer 2

Aim: Punch-grafting treatment is a treatment method where autologous dermal punch-biopsies are grafted to an ulcer. The aim was to assess the healing and adverse events rates of punch-grafting for the treatment of hard to heal foot and leg ulcers.

Method: The study was a single centre retrospective chart study. The punch-graft-group consisted of a consecutive series of all patients that had undergone punch-graft-treatment for one or several foot or leg ulcers at the Department of Dermatology during year's 2009-2013.

Results / Discussion: 92 patients with 119 ulcers with a mean duration of 28.8 months had undergone punch-grafting. The cases were 59.8% female with a mean age of 72.9 ± 11.7 years. 6.7% were foot ulcers and 93.3% leg ulcers. 42.9% were venous ulcers, 8.4% arterial ulcers, 26.1% mixed arterial/venous ulcers, and 22.7% had other aetiologies.

Complete healing had been reached for 16.8% at 3 months and 50.5% at 12 months with a mean healing time of 148 days. At both 3 and 12 months arterial ulcers had a higher healing rate than venous ulcers. Adverse events recorded consisted of 12 patients with ulcer infection, and one patient who got a hard to heal ulcer at the donor site.

Conclusion: This retrospective study indicates that punch-grafting treatment may be a beneficial treatment in chronic ulcers with long duration where standard treatment methods have failed. The method may support healing and has a low adverse events rate. The method should be further evaluated in randomized controlled trials.

[OP169] PHOTOACUSTIC TOMOGRAPHY FOR NON-INVASIVE DIAGNOSTIC IN PATIENTS WITH CHRONIC VENOUS LEG ULCERS TREATED WITH HEMOGLOBIN SPRAY - FIRST RESULTS OF A PROSPECTIVE CLINICAL STUDY

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Free Paper Session: Leg Ulcer 2

Aim: Improvement of oxygenation is getting increasing attention in modern wound care. Therefore the intention of this prospective clinical study (DRKS-ID: DRKS00005993) was to measure the potential increase of oxygenated hemoglobin in chronic venous leg ulcers after topical application of haemoglobin spray with photoacoustic tomography (PAT).

Method: Laser-light with different wavelengths is applied on the wound surfaces. The laser-light encounters hemoglobin, which can be oxygenated or desoxygenated. Hemoglobin is a chromophore, which is a strong absorber for laser-light. The absorbance depends on the status of oxygenisation. The environment is heating through the absorption of laser-light and is enlarging. Therefore a short laser impulse creates an ultrasound echo, which can be detected via an ultrasound detector. The resulting sound wave pattern is converted to a high resolution image. Thus, the concentration of oxygenated and desoxygenated hemoglobin in wounds is reliably imaged and quantifiable. We measured chronic venous leg ulcers via PAT before, 5 min., and 20 min. after application of hemoglobin spray.

Results: Between July and November 2014 altogether 20 patients with chronic venous leg ulcers were included. The median percentage of oxygenated hemoglobin in the wounds before application of hemoglobin spray was significantly lower compared to 20 min. after topical hemoglobin application (58.5% vs 75.5%, $p=0.047$).

Conclusion: PAT is a new and innovative option to measure differences in the amount of oxygenated hemoglobin in chronic wounds. Importantly, topical application of hemoglobin spray increases significantly the amount of oxygenated hemoglobin in chronic venous leg ulcers.

[OP170] IMPROVING OUTCOMES IN CHRONIC VENOUS LEG ULCERS WITH A TOPICAL HAEMOGLOBIN SPRAY, USING POST HOC ANALYSIS AND SIMULATION OF WOUND CLOSURE

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Free Paper Session: Leg Ulcer 2

Aim: To evaluate the effect of topical haemoglobin spray on treatment response and wound-closure rates in patients with chronic venous leg ulcers.

Method: A linear regression model was used to forecast healing outcomes over a twelve-month period. Simulated data was taken from normal distributions based on post-hoc analysis of a 72 patient study (36 standard care, 36 patients standard care plus topical haemoglobin spray). Using a simulated 25,000 “patients” from each arm the proportion of wound closure over time was projected.

Results: Simulation results predicted a 55% wound closure rate at 6 months in the haemoglobin arm, compared to 4% in the standard care arm. Over a 12-month simulation period a 43% overall reduction in wound burden was predicted. 85% of wounds were expected to heal in the haemoglobin spray arm by 12 months compared to 13% in the standard care arm.

Conclusion: Topical haemoglobin spray promises a considerably more effective treatment for chronic venous leg ulcers than standard care alone. Further research is required to validate these predictions and to identify achievable outcomes in other chronic wound types.

[OP171] TREATMENT WITH LL-37 IS SAFE AND EFFECTIVE IN ENHANCING HEALING OF HARD-TO-HEAL VENOUS LEG ULCERS: A RANDOMIZED, PLACEBO-CONTROLLED CLINICAL TRIAL

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Free Paper Session: Leg Ulcer 2

Venous leg ulcers (VLUs) are one of the most prevalent types of chronic wounds. The aims of this first-in-man clinical study were to show the safety of three different doses of the human synthetic peptide LL-37 in hard-to-heal VLU patients, and to obtain dose–response efficacy data on wound healing. This trial included 34 participants with VLUs and comprised a 3-week, open-label, run-in period on placebo, followed by a 4-week randomized double-blind treatment phase with twice weekly applications of LL-37 (0.5, 1.6, or 3.2 mg/mL) or placebo, and a 4-week observation (follow-up) period. The primary efficacy variable was the ulcer healing rate described by an exponential decay model. The healing rate constants for 0.5 and 1.6 mg/mL of LL-37 were approximately six- and threefold higher than for placebo ($p=0.003$ for 0.5 mg/mL and $p=0.088$ for 1.6 mg/mL). Furthermore, square-root transformed wound area data showed improved healing for the 0.5 and 1.6 mg/mL dose groups compared with pretreatment values ($p<0.001$ and $p=0.011$, respectively). Consistently, treatment with the two lower doses of LL-37 markedly decreased the mean ulcer area (68% for 0.5 mg/mL and 50% for 1.6 mg/mL groups). No difference in healing was observed between the groups receiving 3.2 mg/mL of LL-37 and placebo. There were no safety concerns regarding local or systemic adverse events.

Taken together, topical treatment with LL-37 for chronic leg ulcers was safe and well tolerated with the marked effect on healing predictors at the two lower doses warranting further investigations (EU Clinical Trials Register 2012-002100-41).