P-0696 – APPLICATION OF COLLAGEN MATERIAL IN THE TREATMENT OF DIABETIC FOOT SYNDROME (multicenter study results)

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Background

Despite the use of different treatment options, the average healing time of ulcers in patients with diabetes mellitus (DM) is long. In the case of ulcers localization on the fingers and on the front part of the foot healing time is about 150 days, with the localization in the middle part of the foot is about 190 days, in the heel region is about 235-240 days. The foregoing demonstrates the need for refinement of existing treatment protocols and development of new efficient materials for local treatment of diabetic foot ulcers (DFU).

Aim

To assess the effectiveness of the collagen material (Collost/Salvecoll) application in patients with DFU.

Method

The multicenter randomized prospective study in patients with DFU was conducted. 71 patients with diabetic foot syndrome of varying severity were included, patients aged 30-80 years (mean age 58.96 ± 8.11 years; median 60 years) including 34 (47.9%) women and 37 (52.1%). The study was conducting on the bases of 5 clinical centers in Moscow, Moscow Region St.-Petersburg, Kazan. Patients were randomized into two homogeneous groups. The level of tissue defects: 50 patients (70.4%) - Wagner II, 21 patients (29.6%) - Wagner III. The duration of ulcer ranged from 6 weeks to 2 years, the average duration was 8.4 ± 9.1 months (Me: 6 months). Patients of comparison group received standard therapy, 36 patients (main group) additionally applied the collagen material Collost / Salvecoll

Results

Application of the collagen biomaterial Collost/Salvecoll led to more rapid and effective healing of the ulcer; the wound area decreased mainly due to a more rapid regression of wound area; the treatment success increased by 1.7 times. The significant improvement result of the wound healing in the main group was the most pronounced and ahead of the comparison group dynamics of the wound area regression. In the Collagen group the wound area regressed from 13.5 cm² (Me) at the 1st visit to 10.6 cm² (Me) at the 2nd visit (by 1.27 times), to 6.3 cm² (Me) at the 3rd visit (by 2.14 times) and to 2.1 cm² (Me) at the 4th visit (by 6.43 times). In the comparison group the wound area regressed from 12.6 cm² (Me) at the 1st visit to 12.5 cm² (Me) on the 2nd visit (by 1.01 times), and 10.0 cm² (Me) at the 3rd visit (by 1.26 times) and up to 7.0 cm² (Me) at the 4th visit (by 1.80 times). A statistically significant difference between the groups was registered on the 4th visit, in which wound area in the comparison group was by 3.33 times more than in Collagen group ($p < 0.05$).

Additional use of the collagen biomaterial led to increase in the incidence of complete epithelialization from 8.6% to 22.2% despite the reduction in the incidence of unsuccessful treatment from 34.3% to 8.3%. Correlation analysis showed that a favorable outcome reflected in the good or complete healing of wounds/ulcers was linked with the original small size of the defect, Wagner II without the expressed signs of infection and ischemia, as well as with the use of collagen material. The outcome was associated with initial low level of red blood cells, segmented neutrophils, protein, and also with a high content of lymphocytes. The outcome was worsened in proportion to the stage and extent of injury, recurrence of DFU, underwent amputations.