Matrix Protection Therapy in Vascular Disease: First Clinical Pilot Study of RGTA®

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Abstract

Background: Among patients who have non-healing leg ulcers due to critical limb ischaemia and who cannot undergo vascular surgery, 25% die and 50% require amputation within 1 year. No satisfactory solution is available for treating these patients. A device for topical application of engineered biodegradable nanopolymers mimicking heparan sulphates, known as RGTAs®, has produced promising results in preclinical models of chronic wounds .

Methods: We studied 14 chronic lower-extremity ulcers in 12 patients (median age, 71) with transcutaneous partial pressure of oxygen ($TcPO_2$) <30 mmHg and ankle brachial pressure index (ABPI) <0.5. At baseline, mean ulcer duration was 7 months and mean ulcer surface area was 14.15 cm^2. The RGTA device was used twice a week for one month and at all patients requests for another month and for some patient until ulcer healing or for 3 months. The percentage ulcer size decrease at 4 weeks versus baseline was the primary endpoint.

Findings: No adverse events were recorded. Ulcer size reduction at 4 weeks (primary outcome) was 35% ranging from 12-100%,(p<0.001) , increasing to 53% (p<0.001) at 8 weeks as 5 ulcers healed. RGTA was prolonged for 10 patients for a third months and 7 (50%) ulcers were completely healed. Follow up for 9 patients indicated that 8 were alive at 12 months, 6 at 2 years. Closed ulcers remained closed, none healed ulcers remained as such but one that eventually closed and no patient was amputated as a consequence of the none healed RGTA treated ulcer.

Interpretation: RGTA® therapy induced significant ulcer healing after 4 weeks in patients with severe ischemia for whom no other treatment options were available.

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