

Neurostimulator for the treatment of injuries in critical limb ischemia in patients technically inoperable

E. Ricci¹, F.Moffa, R. Cassino, E. Tonini, S. Ferrero, M. Gonella, P.Amione

¹UOA Difficult Wounds Casa di Cura San Luca, Pecetto Torinese (Turin), Italy

Introduction. Wound treatment in patients with arterial occlusive disease (AOD) still remains one of the most difficult intervention. AOD treatments are well coded and aimed at achieving revascularisation, the crucial point for tissue repairing. Sometimes, patients are technically inoperable and delaying amputation is the only result, if pain is well controlled. In these cases vasoactive drugs are used, first of all prostaglandins, the last ditch before amputation. Another alternative could be Hyperbaric Oxygen Therapy, not definitive and requiring repeated cycles. Nevertheless, in some patients neither revascularisation nor prostaglandins therapy could be performed.

Aim. The primary end point was to reduce the amputation rate with neurostimulator treatment (FREMS, Lorenz Biotech). Secondary clinical success was to improve clinical symptoms measured by Visual Analogic Scale (VAS).

Methods. A total of 166 patients (87 women; mean age 80.0 ± 12.2 years) with an injury caused by AOD, technically inoperable and with problems with the administration of prostaglandins were analyzed. Patients with neuropathy were excluded. Fifty-nine (35%) patients were treated with FREMS for 10 consecutive two-daily sessions within two weeks. The others were analyzed as control group.

Results. In a one-month period, the amputation rate was reduced from 52.34% to 30.51% (controls vs FREMS, $p=0.0187$). The reduction was mostly in minor amputation rate (13.07% less).

In FREMS group, vascularisation of the wound bed was increased after the first application and repair process was reactivated at the end of the treatment. The clinical improvement in wound healing corresponded to pain control that was achieved 48 hours after the first FREMS application. VAS was reduced from 7.1 ± 2.9 to 2.9 ± 2.0 ($p < 0,0001$) at the end of FREMS treatment.

Conclusions. FREMS treatment is safe and effective for patients with injuries in critical limb ischemia, technically inoperable and with problems with the administration of prostaglandins.