

## High-frequency spinal cord stimulation in treatment of chronic limb-threatening ischemia (HEAL-SCS): short-term results of a randomized trial

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**Background.** Critical limb ischemia is defined as persistent ischemic pain attributed to a variety of severely compromised blood flow to affected extremities. The treatment of non-reconstructable critical limb ischemia is still challenging; the amputation rate was 9.3%, and mortality rate was 23.2% within 24 months. Spinal cord stimulation (SCS) has become an alternative clinical practice for the treatment of intractable pain of the extremities.

**Aim.** To determine whether high-frequency spinal cord stimulation (SCS) is better than low-frequency SCS for pain relief in chronic limb-threatening ischemia treatment.

**Methods.** Throughout enrollment 56 patients were examined, of whom 6 rejected to participate in the study. The participants were randomly allocated to high-frequency (HF) or low frequency (LF)-SCS groups of 25 patients each by an external statistician, using an online tool. The patients were examined by a neurosurgeon and a vascular surgeon to assess pain intensity by visual analog scale, quality of life by short-form-36 health survey (SF-36), and functional status by walking impairment questionnaire in 3 and 12 months. Tissue perfusion by transcutaneous oxygen tension measurement was also measured in 12 months.

**Results.** Intention-to-treat analysis demonstrated comparative advantage of HF-SCS over LF-SCS in 3 months with mean visual analog scale score 2.8 [95% CI, 2.4; 3.2] and 3.3 [95% CI, 3.0; 3.6] respectively ( $p = 0.031$ ). Clinical superiority of HF-SCS persisted at 12 months follow up ( $p < 0.001$ ). HF-SCS produces significantly greater pain relief by walking impairment questionnaire in 3 ( $p < 0.001$ ) and 12 months ( $p = 0.009$ ). Accordingly, general and mental health domains of SF-36 were significantly better in HF-SCS in 12 months. Despite a tendency toward better resting oxygen pressure in HF-SCS group, there was no intergroup difference by transcutaneous oxygen tension ( $p = 0.076$ ).

**Conclusion.** High-frequency spinal cord stimulation imposes better pain relief, life quality and functional activity in patients with chronic limb-threatening ischemia in short-term follow up.

**Keywords:** critical limb ischemia; intractable pain; spinal cord stimulation

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