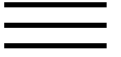


stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome.

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## Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome

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### Abstract

Patients with neuropathic pain secondary to failed back surgery syndrome (FBSS) typically experience persistent pain, disability, and reduced quality of life. We hypothesised that spinal cord stimulation (SCS) is an effective therapy in addition to conventional medical management (CMM) in this patient population. We randomised 100 FBSS patients with predominant leg pain of neuropathic radicular origin to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group) for at least 6 months. The primary outcome was the proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were improvement in back and leg pain, health-related quality

legs. Secondary outcomes were improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6 months, 24 SCS patients (48%) and 4 CMM patients (9%) ( $p \hat{=} 0.001$ ) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction ( $p \hat{=} 0.05$  for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications. In selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.



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## Keywords

Spinal cord stimulation; Neurostimulation; Neuropathic pain; Failed back surgery syndrome; Radicular pain; Randomised controlled study

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