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Randomized, Prospective, Controlled Clinical Trial of Pulsed Electromagnetic Field

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Background Context

Pulsed electromagnetic field stimulation (PEMF) has been demonstrated to improve lumbar fusion rates. There are no published studies regarding the use of PEMF as an adjunct to cervical fusion.

Purpose

To determine the safety and efficacy of PEMF as an adjunct to cervical spine fusion.

Study Design/Setting

Randomized, prospective, controlled, multicenter clinical trial.

Patient Sample

Patients with symptomatic radiculopathy and correlating radiographic evidence of cervical nerve root compression were candidates for entry into the study. All patients were either smokers (at least one pack/day) or required multi-level surgery and underwent anterior cervical discectomy and Smith-Robinson fusion using allograft bone and anterior cervical plating (single plating system). Three-hundred-twenty-three patients were enrolled in the study; 160 in the non-PEMF (control) group and 163 in the PEMF group. Both groups were comparable with regard to gender, age, race and risk factors. Equal numbers were lost to follow-up in both groups.

Outcome Measures

Outcome measures included a focused neurological exam, a visual analogue scale for pain, the Oswestry Neck Disability Index (NDI) for function, and radiographs for fusion assessment. Radiographs were read blindly by two independent orthopedic spine surgeons as well as an independent radiologist and rated as fused or not fused based upon radiolucency, bony bridging, and motion on flexion-extension views.

Methods

Patients were randomized to receive pulsed electromagnetic field stimulation (PEMF) or not (non-PEMF). They were assessed preoperatively and at 1, 2, 3, 6, and 12 months postoperatively and annually thereafter until the last patient enrolled had reached 12 months follow-up. All patients were followed for adverse events to assess safety.

Results

Of the 240 patients available for evaluation at 6 months, the fusion rate was 83.6% (102/122) in the PEMF group and 68.6% (81/118) in the non-PEMF group ($p=0.0065$). At 12 months, fusion rates were 92.8% in the PEMF group and 86.7% in the control group ($p=0.1129$). Both groups showed a significant decrease in pain and NDI at 6 and 12 months. The incidence of adverse events was comparable in both groups.

Conclusions

This is a report of the results of a multi-center, prospective, randomized, controlled clinical trial of PEMF as an adjunct to anterior cervical fusion. In this at-risk patient population (smokers, multi-level fusion), the use of PEMF produced a significant increase in the fusion rate at 6 months postoperatively. At 12 months postoperatively, however, the fusion rates were not significantly different. Clinical outcome parameters improved in both groups to a significant degree. There were no differences in adverse events.