The Italian Experience with octopolar perc-paddle leads

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Introduction

Low back and leg pain (LBLP) is a rather common pathology and it's often treated with SCS. LBLP remains a difficult medical challenge, particularly for patients with post-laminectomy syndrome. The aim of this study is to evaluate the efficacy of Spinal Cord Stimulation (SCS) using octopolar perc-paddle leads (S-Series, St. Jude Medical) introduced percutaneously with St. Jude Medical’s Epiducer Lead Delivery System in patients suffering from Low Back and Leg Pain (LBLP). We performed a retrospective review of patients implanted from 2009-2012 in Italy.

Materials and Methods

Seventy-six patients from eight Italian Pain Centers were initially enrolled in the study. All patients were suffering from Low Back and Leg Pain (LBLP). Sixty-one patients were suffering from failed back surgery syndrome, fifteen patients had stenosis of the spinal canal. Ages ranged from 29 to 80 years (mean age 62), with 23 female and 53 male patients. The mean onset of painful symptoms was 3 years 3 months. Fifty-seven patients (15F 42M) had previously been subjected to one or more surgeries. Patients have been assessed before and after surgery using SF-36 questionnaire and Numerical Rating Scale (NRS). The patients' follow up varies from 12 to 30 months. Patients underwent the placement of one octopolar S-Series™ lead introduced through an Epiducer lead delivery system (St. Jude Medical), under intravenous light sedation with local anesthesia. The procedure was performed with patients in a prone position under fluoroscopic guidance. After a successful trial period (10 to 30 days), each patient underwent placement of a permanent system. Octopolar S-Series was positioned at the level of the dorsal columns after having adequately covered (more than 80%) with paresthesias the painful area. Twenty-five patients were studied up to 12 months, twenty-eight patients were studied up to 24 months and eighteen patients were studied up to 30 months. Any problematic issues linked to this method have been taken into consideration.

Results

Five patients did not have an adequate improvement during the trial (pain relief less than 50%), and the percutaneous paddle lead was removed. We had no problem in removing the percutaneous paddle lead. Leads were implanted with the tip at T8 (43 patients) and at T7 (28 patients). Seventy-one patients, sixty suffering from FBSS and eleven from spinal stenosis (20F 51M) reported significant improvement in pain symptoms and a good paresthesia coverage of the affected regions. In five patients, we had to reposition the paddle that was flipped. We had no cases of infection, or unusual postoperative pain. One dural puncture occurred, but resolved uneventfully. We had no patients with migration of the paddles. All treated patients did not need to add another lead in the epidural space or subcutaneously. Pain reduction according to the NRS ranged from 55% to 63%. All patients had significant improvement in all items of the SF-36. On average 66% of patients stopped taking pain medications, 31% of patients reduced the dosage of pain medications. For the
definitive implant forty two conventional IPGs and twenty nine rechargeable IPG were used. The positioning of the paddle was not more painful than a conventional procedure. No patient was lost in the follow up. The percutaneous placement of a paddle lead allows to avoid the laminectomy, maintaining the characteristics of stimulation of a paddle and increasing the number of specialists that can perform this technique.

**Conclusion**

Our experience using octopolar perc-paddle leads (S-Series) introduced through the St. Jude Medical’s Epiducer lead delivery system suggests that the percutaneous paddle placement is safe, effective, and apparently allows a better recruitment of the lumbar region and satisfaction of patients treated (when compared to standard percutaneous leads). Implanting physicians should be experienced and have undergone an appropriate training.

**REFERENCES**


