A RETROSPECTIVE DATA COLLECTION STUDY TO EVALUATE THE FEASIBILITY AND SAFETY OF PERCUTANEOUS INTRODUCTION OF A NARROW PADDLE LEAD INTO THE EPIDURAL SPACE

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INTRODUCTION

Spinal cord stimulation leads can be implanted percutaneously through a Touhy needle or surgically after a laminectomy. The former involves the percutaneous insertion of a cylindrical-type lead into the epidural space. Paddle-type leads require a laminotomy or laminectomy for implantation into the epidural space.

Paddle-type leads offer several advantages over cylindrical-type leads. Despite these advantages, paddle leads require a more invasive surgery. The laminotomy/laminectomy procedure used to place paddle leads involves removal of part of the spinous process. This is undoubtedly more invasive and painful to the patient than cylindrical lead placement, which only requires insertion of a needle into the epidural space. Thus, the ideal situation for lead insertion would be percutaneous delivery of a paddle lead. A few physicians have attempted this procedure with reported success and few adverse events. The following study was designed to systematically evaluate the feasibility and safety of these attempts.

METHODS

This study was a retrospective, patient record review approved by the AZ-St Lucas (Ghent) Ethics Committee. Each patient signed informed consent and was screened according to the inclusion/exclusion criteria prior to the initiation of any study related data collection.

Data was collected retrospectively from the medical records of 40 patients previously implanted with a Lamitrode S-Series™ paddle lead (St. Jude Medical Neuromodulation Division, Plano, Tex) using a delivery device, which consisted of a 10 gauge stainless steel needle (percutaneous implantation) at 2 investigational sites.

Information collected included the following:

- Patient demographics
- Angle of insertion of the lead delivery device
- Delivery device advancement
- Lamitrode S-Series paddle lead advancement
- Adverse events

RESULTS

Patient Demographics

Age	
Mean ± SD	53.9 ± 11.3
Range	29-75
Gender	
Male: n (%)	16 (40%)
Female: n (%)	24 (60%)
Race	
Caucasian: n (%)	40 (100%)
Diagnosis	
FBSS: n (%)	29 (72.5%)
Radiculopathy: n (%)	11 (27.5%)

Table 1. Patient demographics. The majority of patients had a diagnosis of FBSS.

Delivery Device Advancement

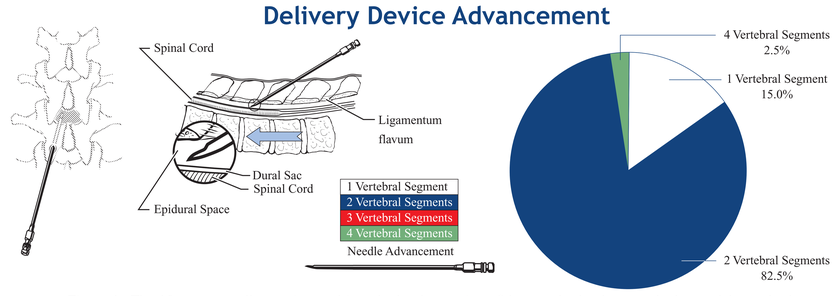

Figure 1. The 10-gauge needle was inserted into the lumbar region of the vertebral column and advanced 1 vertebral segment in 6 (15%) patients, 2 vertebral segments in 33 (82.5%) patients, and 4 vertebral segments in 1 (2.5%) patient.

Lamitrode S-Series Paddle Lead Advancement

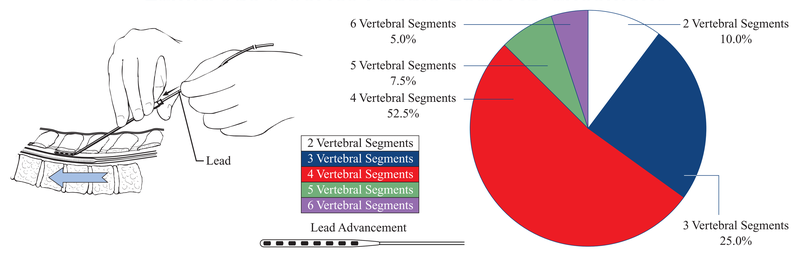

Figure 2. The Lamitrode S-Series paddle lead was inserted into the vertebral column through the needle and advanced 2 vertebral segments in 4 (10%) patients, 3 vertebral segments in 10 (25%) patients, 4 vertebral segments in 21 (52.5%) patients, 5 vertebral segments in 3 (7.5%) patients, and 6 vertebral segments in 2 (5%) patients.

Delivery Device Angle of Insertion

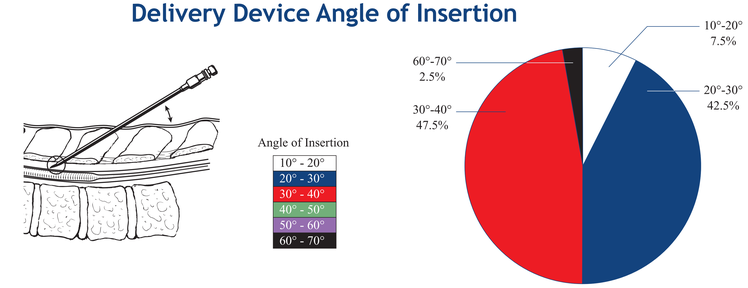

Figure 3. The 10-gauge needle was inserted into the lumbar region of the vertebral column at a 10°-20° angle in 3 (7.5%) patients, 20°-30° angle in 17 (42.5%) patients, 30°-40° angle in 19 (47.5%) patients, and 60°-70° angle in 1 (2.5%) patient.

Adverse Events

Type of Adverse Event	Number of Patients	Action Taken
Adverse events related to percutaneous implantation	**0**	**N/A**
SCS-related adverse events		
Undesirable change in stimulation	32	Reprogramming
Infection	4	Lead replaced or system explanted
Lead migration	5	Lead revised or replaced
New pain	7	Reprogramming or treatment
Other	6	Miscellaneous
TOTAL	**40**	

Table 2. There were no adverse events related to percutaneous implantation. The most common SCS-related adverse event was undesirable changes in stimulation, with 32 patients experiencing this event. Formation of new pain occurred in 7 patients, lead migration occurred in 5 patients, and infection occurred in 4 patients.

SUMMARY AND CONCLUSIONS

- Data was collected from a total of 40 patients.
- The lead delivery device was advanced 2 vertebral segments in 82.5% of patients.
- The Lamitrode S-Series paddle lead was advanced 4 vertebral segments in over 50% of patients.
- There were no adverse events related solely to percutaneous implantation of the Lamitrode S-Series paddle lead.
- Reported SCS-related adverse events included undesirable changes in stimulation (32 patients), new pain (7 patients), lead migration (5 patients), infection (4 patients), and other (6 patients).
- No adverse events related to locomotor ability and/or sensory function occurred.
- The goal of this study was to demonstrate the safety of percutaneous implantation and advancement of the Lamitrode S-series paddle lead. Our finding of no adverse events specifically related to this procedure achieved this goal.

This work was supported by St. Jude Medical Neuromodulation Division through a sponsored clinical research study.