Case Report

Cervical Spinal Cord Stimulation with 5-Column Paddle Lead In Raynaud's Disease

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Objective: To report a case of Raynaud disease and its successful treatment with spinal cord stimulation utilizing the newly designed five-column Penta™ lead paddle. Specific electrode design, programming characteristics, and surgical technique are also discussed in this case.

Design: Case Report.

Setting: University pain management center.

Background: A 65-year-old man with Raynaud disease presented with neck and upper extremity pain. The patient also had herniation and spondylosis of the lumbar spine and intervertebral disc disease of the cervical spine. An examination revealed venous changes, chronic ulceration, and digit discoloration in upper and lower extremities.

Method: Conservative management and pharmacological treatment were ineffective. Sympathetic block produced significant but limited improvement. Treatment with spinal cord stimulation was tried after a successful 7-day trial.

Results: Initial stimulation of the cervical spine with two octapolar leads at the C2 level produced greater than 75% pain improvement. However, the patient lost coverage shortly after discharge due to lead migration which could not be regained with reprogramming. A revision with Penta™ lead paddles produced sustainable and significant paresthesia coverage.

Limitations: A case report.

Conclusion: We report the successful application of spinal cord stimulation utilizing a five-column paddle lead in an individual with severe refractory Raynaud disease.

Key words: Keywords: Spinal cord stimulation, Penta lead, five-column lead, electrode, paresthesia, Raynaud disease, cervical pain, programming.

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Spinal cord stimulation (SCS) was first introduced in 1967 and is now an accepted, US Food and Drug Administration approved treatment for neuropathic pain of the trunk and limbs. The most common indication for SCS implantation in the US is postlaminectomy syndrome (1-3). However, in Europe, spinal cord stimulation is frequently used to treat a variety of ischemic conditions, such as peripheral vascular disease and coronary occlusive disease (4). Although technically an off-label indication in the US, this practice is supported by many published studies, but its use in clinical settings remains limited (5-7).

While SCS has shown remarkable effectiveness for the treatment of radicular pain, results of long-term

maintenance of stimulation-induced paresthesias and pain relief in neck and back pain have been less consistent (8). Many strategies have been developed to address this issue (9-13). Recent research and development efforts resulted in the introduction of a novel design of surgical lead, which places 5 columns of electrodes from right to left across the epidural space. This allows for more sustainable and widespread paresthesia coverage and thus, theoretically decreases the need for surgical revisions secondary to misplacements and migrations of the lead.

Until now, little published literature exists describing the effectiveness of the 5-column Penta™ lead electrode (St. Jude Medical, Inc., Plano, TX) and its programming characteristics for chronic pain conditions (14). To the best of our knowledge, this is the first report on its application for the treatment of cervical and upper limb pain secondary to Raynaud disease.

Case Report

A 65-year-old-man was referred for evaluation and treatment of chronic back and neck pain. The patient had a chronic history of off-and-on low back and neck pain secondary to a herniated nucleus pulposus, spondylosis of the lumbar spine, and intervertebral disc disease of the cervical spine. He had exhausted routine conservative care, including heat and ice, physical therapy, home exercises, and over-the-counter nonsteroidal anti-inflammatory drugs.

On evaluation the patient reported primarily low back pain followed by neck pain. He denied any radiations but reported significant pain in his feet and legs as well as his hands and arms due to severe Raynaud disease. Pain was constant in his distal extremities, with increasing frequency and duration of flare-ups that caused pain more proximally.

Regarding his back and neck pain, on examination the patient had positive facet loading of his lumbar and cervical spine. Otherwise, the exam was unremarkable other than for venous changes of his lower extremity, chronic ulceration of his medial tibia, and discoloration of his digits in both upper and lower extremities.

The patient then underwent diagnostic medial branch blocks of his lumbar and cervical spine, followed by successful radiofrequency ablation, resulting in improvement of his lumbar and cervical pain.

On follow-up with his rheumatologist, due to continued progression of pain from his Raynaud disease, he was recommended to return to the pain clinic for further evaluation and possible treatment. For his symptoms, the patient had tried nonpharmacologic interventions, such as avoidance of environmental factors and modification of lifestyle, with limited efficacy. He was a nonsmoker and was on low-dose antiplatelet therapy. The patient also tried various medications, including calcium channel blockers and other vasodilators, but despite benefit, could not continue due to severe hypotension. Based on his history and examination, the available options were discussed. The patient underwent sympathetic blocks with a significant, but limited, duration of improvement. With the positive response, the options of sympathectomy and spinal cord stimulation (SCS) were offered and discussed. After reviewing the information, the patient elected to undergo an SCS trial for his lower extremity as well as for his back pain.

After clearance from the behavioral medicine department, the patient underwent a successful trial with greater than 90% relief of his lower extremity pain as well as low back coverage. He then subsequently underwent a successful permanent paddle lead implantation.

With the satisfaction of pain relief in his lower extremities and back, as healing of his ulcers, the patient elected to proceed with an SCS trial for his upper extremities and cervical pain.

The patient underwent a successful 7-day SCS trial. Two octapolar leads were placed at the C2 level (Fig. 1) with coverage of his cervical spine to all of his digits bilaterally. The patient noted greater than 75% improvement of his pain and elected to proceed with permanent SCS implantation. He subsequently underwent successful permanent paddle lead implantation (Fig. 2).

However, after discharge from the hospital, the patient returned for a follow-up 2 weeks later with complaints of coverage loss of his right hand, digits, and arm. He denied any trauma but stated that coverage was lost one evening several days prior. X-rays were obtained and showed the paddle lead to have shifted slightly to the left (Fig 3). Despite several attempts, the right upper extremity coverage could not be reobtained with reprogramming.

After significant discussion of the options and their pros and cons, including a percutaneous lead placement and revision with another paddle configuration lead, the patient elected for revision of the permanent paddle lead. As a result, he underwent removal of the octapolar paddle leads and had them replaced with the five-column Penta™ paddle lead at the C2 level (Fig. 4).

With the patient under general anesthesia, the

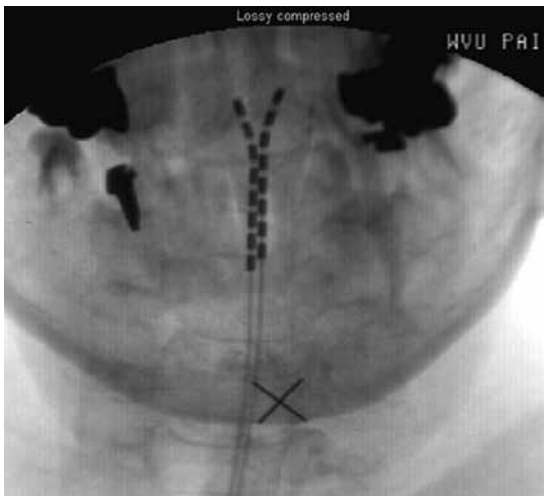

Fig. 1. *Percutaneous trial lead placement.*

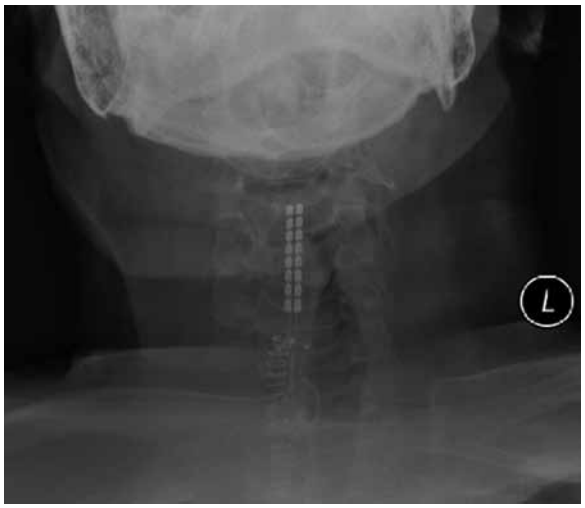

Fig. 2. *Permanent 2 octapolar lead placement, 12 hours postoperative.*

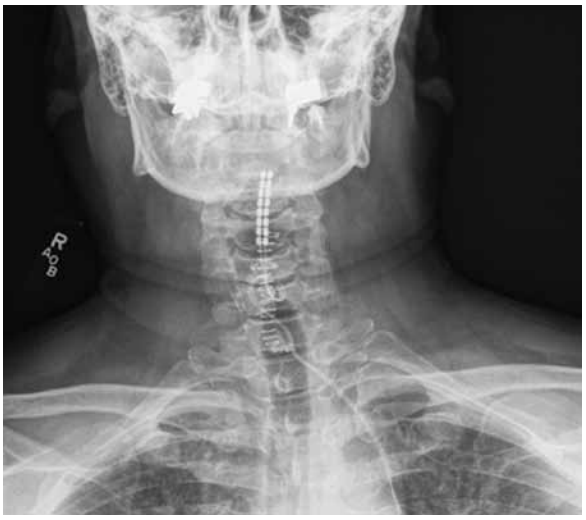

Fig. 3. *Octapolar lead position slightly shifted to the left, 2 weeks postoperative.*

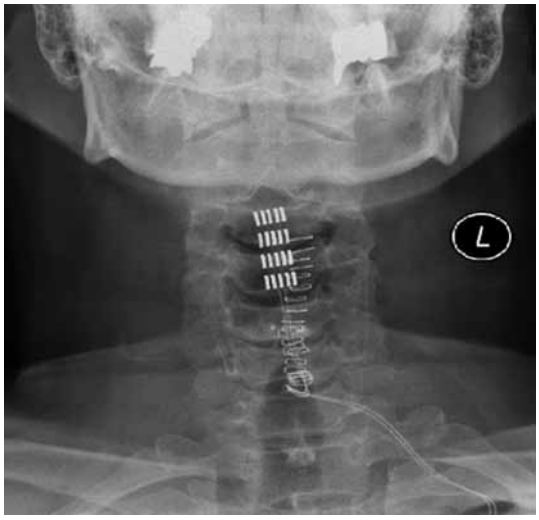

Fig. 4. *Permanent Penta™ lead revision placement, 12 hours postoperative.*

new lead was placed in an anterograde fashion using a wide laminotomy incision below C3. It was placed under fluoroscopic guidance and its position was confirmed to be midline, going slightly from left to right. Somatosensory evoked potentials with middle contacts were diminished bilaterally with stimulation, confirming good midline positioning of the lead.

Postoperative coverage and programming are shown in Fig. 5. Following surgery and on subsequent regular follow-ups over the next 9 months, the patient noted continued pain coverage of all of his digits, hand, arm, and cervical spine bilaterally.

Program 1
Continuous Mode
Magnet Mode: On/Off

Freq	PW	Polarities	Perc	Comfort	MaxTol
30	350	0000 000– 0+00 0000	6.40	10.60	14.80
30	362	000– 0+00 0000 0000	4.00	10.00	16.00

Program 2
Continuous Mode
Magnet Mode: On/Off

Freq	PW	Polarities	Perc	Comfort	MaxTol
68	350	0000 000– 0+00 0000	6.40	10.60	14.80
68	362	000– 0+00 0000 0000	4.00	10.00	16.00

Program 3
Continuous Mode
Magnet Mode: On/Off

Freq	PW	Polarities	Perc	Comfort	MaxTol
106	350	0000 000– 0+00 0000	6.40	10.60	14.80
106	362	000– 0+00 0000 0000	4.00	10.00	16.00

Program 4
Continuous Mode
Magnet Mode: On/Off

Freq	PW	Polarities	Perc	Comfort	MaxTol
120	350	0000 000– 0+00 0000	6.40	10.60	14.80
120	362	000– 0+00 0000 0000	4.00	10.00	16.00

Fig. 5. *Postoperative coverage and programming for permanent Penta™ lead placement.*

Discussion

To our knowledge, this is the first report on the application of the newly designed five-column Penta™ lead for the treatment of intractable cervical and upper limb pain secondary to Raynaud disease. First introduced in late 2009, these multicolumn leads are now gaining increasing popularity in clinical practice because of their ability to provide improved programmable capability and possible treatment outcome (14,15).

This novel lead is uniquely designed to provide significantly smaller contacts with an increased surface area which was achieved by a "microtexturing" technique, thus resulting in an increased electrical capacity for each contact (16). The electrodes in this design are far enough away to behave as independent anodes and cathodes, but near enough to allow for very discrete stimulation, thus producing large paresthesia coverage with just a single lead. In addition, the new design allows for correction of minor lead misplacements and migrations off of the anatomic midline during or after implantation and thus, functionality of the lead can theoretically be regained through programming without the need for surgical revision.

Lead migration usually occurs in the first 12 months

of implantation and varies between 8% (17) and 27% (18). It is the most common complication of SCS implantation, and can result in a change in the stimulation pattern and decreased analgesia. Lead migration may be attributed more to the anchoring technique rather than the actual lead design. Engineers are currently striving to identify a solution to lead migration through the development of consistent and verifiable anchoring technology. In the meantime, the development of transverse tripolar stimulation and five-column paddle lead configuration has allowed for mediolateral steering of the electric field to correct for inaccurate lead positioning and minor lead migrations (19).

A few previous reports have suggested the possibility of obtaining stimulation in the upper and lower extremities with neuroelectrodes placed in the cervical epidural space (20-22). In this case, however, we were initially focused on treating the patient's primary concern of low back and lower extremity pain. With the success of pain relief in these regions, the patient requested SCS for the neck and upper extremities. During the trial for cervical pain, we attempted 4-limb coverage with cervical lead placement, but did not obtain satisfactory stimulation of the individual digits. We eventually obtained coverage of the neck and upper extremities with the lead tip placed at the bottom of the C2 level but did not achieve 4-limb stimulation with such placement.

Not surprisingly, literature regarding the surgical procedure and technique in placement of the Penta™ paddle lead is still preliminary and limited (23). Based on our experience in this case, the laminotomy incision has to be slightly wider to accommodate proper placement of the lead, even extending up to the edges of the canal. However, with the lead being relatively short in length, it does not need to be pushed higher up, thus the risk of tip deviation to one side or the other is theoretically reduced. No other significant differences in lead placement or technique were noticed. In addition, with the Penta™ lead having comparable thickness to other lead designs, no greater technical difficulties or risks were encountered during placement.

Raynaud disease, as evidenced in this case, is typically characterized by an abrupt onset of digital pallor or cyanosis in response to cold exposure or stress. It is a vasospastic disorder affecting primarily the distal resistance vessels. Initially, the disease manifests itself as a burning sensation in the affected area accompanied by allodynia with vasomotor changes. Ultimately, as the ischemia worsens, this condition may progress to ulceration and amputation of the affected digits.

Initial treatment of Raynaud disease is usually conservative, advising patients to avoid provoking triggers such as cold, smoking, and vasoconstrictive medications. If that fails, pharmacological agents such as calcium channel antagonists and alpha-blockers may be tried, although their effects have been disappointing due to adverse effects and loss of long-term efficacy (24,25). Sympathectomy can be considered in patients with dystrophic changes leading to ulceration, although recurrence of symptoms is common (26-28). De Trafford et al reported the results of sympathectomies performed in 140 patients with Raynaud phenomenon. In this series, less than 20% had prolonged benefit, and 66% reported benefit lasting less than one year following the procedure (29).

For select patients who are refractory to these treatments, spinal cord stimulation may be considered as a viable alternative. A Cochrane review in 2005 regarding its use in critical ischemic vascular conditions concluded that SCS was associated with better pain relief than conservative treatment and fewer amputations (30). Although the exact mechanism of action of SCS on the microvascular system is still unknown, several theories have been postulated and demonstrated in animal studies. Such theories include modulation of the autonomic nervous system, activation of the descending inhibitory system, antidromic activation of sensory nerves (A-delta and C fibers) and the subsequent release of vasodilators, such as calcitonin gene-related peptide and nitric oxide, which are potent microvascular vasodilators (31-33). SCS is also associated with improvement in oxygen levels that may reduce the proliferation of fibroblasts, thus assisting in the reduction of endothelial and skin damage (34).

Conclusion

In this case, we report the successful application of SCS utilizing a 5-column paddle lead in an individual with severe refractory Raynaud disease. SCS should be considered as a viable alternative in select individuals who do not respond to otherwise conservative interventions. However, further studies are warranted to determine the long-term efficacy of SCS in ischemic vascular conditions, as well as the relative technical and theoretical advantages of new surgical leads in providing better pain relief and more steerable paresthesia, especially in the cervical region where lead misplacement and migration risks are theoretically more common.

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