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Paddle-Lead Spinal-Cord Stimulation Surgeries for Chronic Neuropathic Pain: A Single Surgeon Case-Series Outcome Analysis in Indian Population

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Abstract

Background Spinal-cord stimulation (SCS) for relief of chronic neuropathic pain is well established.

Objective The inherent limitations with conventional percutaneous lead SCS are lead migration, positional variations in stimulation, as well as possible nonreplication of benefits after permanent SCS implantation, which were experienced during a positive trial period. To circumvent these limitations, we analyzed five consecutive cases of chronic intractable neuropathic pain who underwent direct SCS paddle lead placement during the trial period for pain relief. In addition, during the process of placing a permanent paddle lead, the impediment created by prior epidural scarring in such chronic patients can be obviated mechanically thereby increasing the efficacy of the procedure.

Material and Methods The demographic details, diagnosis, preoperative visual analogue scale score (VAS), and follow-up VAS were recorded. Surgical procedure consisted of a standard dorsal laminotomy followed by placement of permanent paddle leads.

Results All patients reported significant improvement in their VAS scores. Mean duration of follow-up was 23.6 months (9–35 months). Mean preoperative VAS was 9.4 and 1.4 at the last follow-up. No major complications were found.

Conclusion With careful patient selection and appropriate surgical strategy, it was possible to implant permanent paddle leads during SCS trial itself in our five patients thereby replicating and sustaining the trial period pain relief. We argue that this can be a new cost-effective and reliable technique for the placement of SCS leads achieving excellent and sustained pain relief.

Keywords

- spinal-cord stimulation
- failed back surgery syndrome
- permanent paddle leads
- chronic neuropathic pain

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Table 1 Demographics

Cases	Diagnosis	Age/sex	Preoperative status	Postoperative status	Last follow-up	VAS at last follow-up
1.	FBSS	78 y/F	VAS: 10	VAS: 0	32 mo	2
2.	FBSS	51 y/M	VAS: 7	VAS: 0	25 mo	0
3.	FBSS	81 y/F	VAS: 10	VAS: 1	17 mo	3
4.	FBSS	65 y/M	VAS: 10	VAS: 3	9 mo	2
5.	CRPS-1 cervicobrachial	40 y/M	VAS: 10	VAS: 2	35 mo	0

Abbreviations: CRPS, complex regional pain syndrome; F, female; FBSS, failed back surgery syndrome; M, male; VAS, visual analogue scale score; Y, years.

Key Message

Direct implantation of permanent paddle leads allows replication and sustainment of the trial period pain relief, as well as obviates the risks of lead migration and positional variation.

> "Each generation goes further than the generation preceding it because it stands on the shoulders of that generation. You will have opportunities beyond anything we've ever known" - Ronald Reagan

Introduction

Spinal-cord stimulation (SCS) for relief of chronic neuropathic pain is well established. They are used as a treatment modality for failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), and refractory radiculopathies.[1–9]

This treatment is usually a two-staged process, wherein patients first undergo a SCS trial with a goal of 50% pain reduction and improvement in quality of life, followed by permanent implantation of SCS lead and implantable pulse generator (IPG). SCS systems can be either a percutaneous system or a paddle lead system. Percutaneous leads are less invasive and are much more commonly used, whereas paddle leads tend to be more invasive and require surgical implantation via laminotomy or laminectomy. Both systems have their own advantages and disadvantages. Although laminotomy for paddle lead placement is a more invasive procedure compared to placement of percutaneous leads, they have significant advantages in terms of more durable pain coverage and extremely less tendency to migrate.[10–12]

The standard technique of placing SCS electrodes is to first place a trial lead system at the intended site; upon satisfactory pain relief during the postoperative trial period, patient undergoes a second surgical procedure to replace the trial leads with a permanent lead system. This technique carries the inherent risk of lead migration, positional variations, and the possibility of nonreplication of successful trial lead period results after implanting the permanent leads. We believe that it is fruitful to directly implant permanent paddle leads during the trial period itself, thereby replicating and sustaining the trial period pain relief as well as obviating the risks of lead migration and positional variation.

In addition, during the process of placing a permanent paddle lead, the impediment created by prior epidural scarring in such chronic patients can be obviated mechanically, thereby increasing the efficacy of the procedure.

In this article, we analyze five consecutive cases of chronic intractable neuropathic pain a single surgeon case series (►**Table 1**), operated by senior author (ADB), who underwent direct permanent paddle lead placement (placed during trial period) for pain relief.

Materials and Methods

This is a single-center, retrospective case series of five consecutive cases of chronic neuropathic pain who underwent direct permanent paddle lead placement (placed during trial period) for pain relief. The study was conducted in the Institute of Neurosciences, Medanta the Medicity, Gurgaon India, from September 2017 till August 2020. Institutional ethics committee permission was taken (IRB 1224/2021).

Clinical Presentation

Details of clinical presentation for each case are provided in tabular format in ►**Table 2**.

Therapeutic Intervention

All procedures were performed by the senior author (ADB).

Surgical Procedure for Cases 1, 2, 3, and 4

All patients underwent epidural SCS placement of paddle leads via a standard laminotomy at D10. Case #3 additionally underwent an adjacent stenotic level decompression of D11 and D12 via a posterior approach in the same sitting.

Patient was placed prone on a standard operating Allen's frame table under general anesthesia. The D10 spinous process was marked using fluoroscopy. Standard midline dorsal spine incision was made and fascia incised. A high-power operating microscope was used to facilitate a D10 laminotomy. The ligamentum flavum was carefully incised and the thecal sac was exposed. Epidural scar tissue was scraped and removed and epidural space created from D10 to D8 superiorly. After ensuring proper hemostasis, the paddle lead (Medtronic Sure Scan Restore Ultra 5-6-5; 16 Contact Paddle Lead) was passed from D10 to D8 and placed in a manner such that the leads are placed in the midline

Table 2 Clinical presentation of cases

Cases	Presentation	Diagnosis	Previous treatment	Implants	Others
1	Intractable chronic LBA for 13 years; VAS 10	FBSS	Oral analgesics, antidepressants, epidural injections	Transpedicular screws and rods from L4 to S1	No spinal canal compromise, no hardware malfunction
2	Intractable chronic LBA 3 years; VAS 7	FBSS	L5-S1 PIVD operated 22 years back, oral anlagesics, antidepressants, root blocks, RFA	Nil	Nil
3	Intractable chronic LBA 5 years; wheelchair bound; VAS 10	FBSS	Oral anlagesics, antidepressants	L1-S1 spinal instrumentation 5 years	Nil
4	Intractable chronic LBA 15 years; bilateral hip severe dysesthetic pain; VAS 10	FBSS	Oral anlagesics, antidepressants	D12 to L2 spinal instrumentation for L1 fracture 15 years back	Nil
5	RTA 12 years back followed by severe neuropathic pain bilateral upper limbs (left more than right) VAS was 10; his diagnosis was reconfirmed to be CRPS type 1	Cervicobrachial CRPS type I associated with myoclonic jerks	Oral analgesics, antidepressants and anticonvulsants. Regional nerve blocks and intravenous ketamine infusion	Nil	There was superimposition of severe myoclonic jerks (induced by the slightest of touch) involving both upper limbs

Abbreviations: CRPS, complex regional pain syndrome; FBSS, failed back surgery syndrome; LBA, low back ache; PIVD, prolapsed inter-vertebral disc; RTA, road traffic accident; VAS, visual analogue scale score.

(►**Fig. 1**) and opposite D8-D10 vertebral bodies. After ensuring proper lead position (►**Figs. 2**, **3**) using intraoperative fluoroscopy, the paddle lead was secured to fascia with a 2-0 Silk suture. The distal end of the lead was tunneled and passed subcutaneously toward a separate skin incision via an intervening extension wire over the flank.

Trial Period

A trial period of 5 to 7 days and diligent monitoring of response to the external stimulator parameters ensued in each case. If successful, patients underwent the second-stage procedure under a short duration anesthetic for the IPG placement over the flank.

Surgical Procedure for Case 5

Retrograde placement of high cervical (C1-C2) paddle-lead spinal cord stimulator (MEDTRONIC Inc, Minneapolis, Minnesota, United States).

After written and informed consent, surgery was performed in two stages, both under general anesthesia and in prone position.

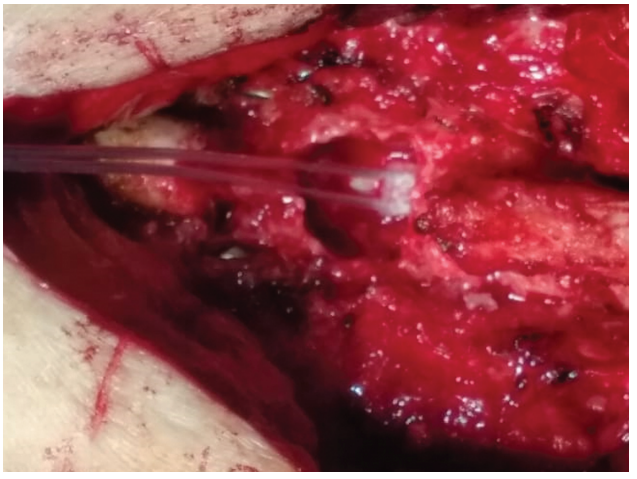

Fig. 1 Intraoperative photograph of epidural paddle lead placement from D10 to D8.

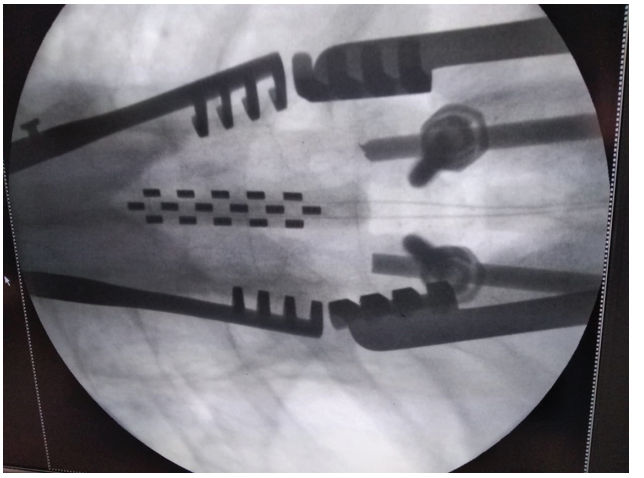

Fig. 2 Intraoperative fluoroscopic anteroposterior view image showing accurate placement of epidural paddle lead in patient Case 4. Implant position at D12 level placed many years back in 2004.

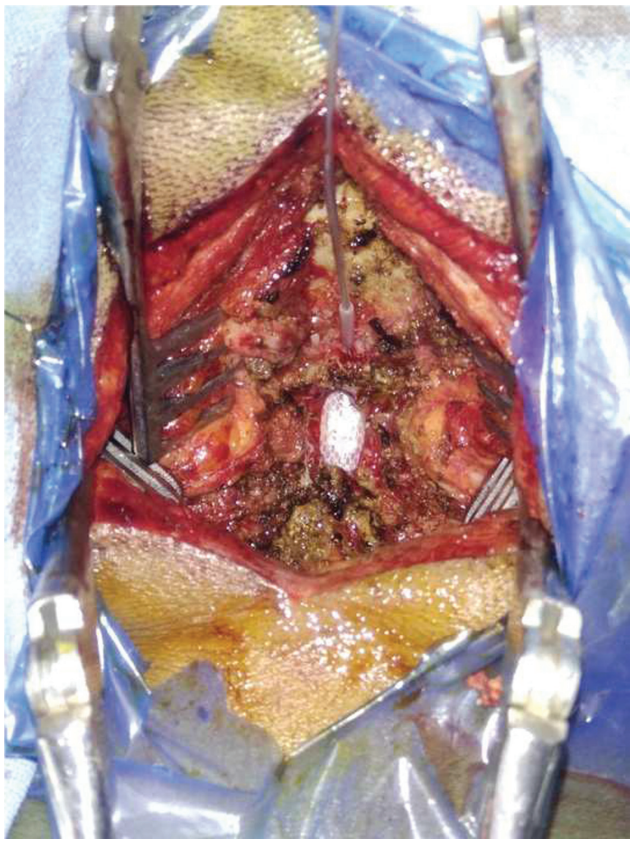

Fig. 3 Retrograde C1 to C2 paddle lead placement.

Stage 1: A midline incision was marked from the Inion to the C2 spinous process; the foramen magnum rim to C2 spinous process was then exposed in the usual manner following the midline avascular plane. The upper margin of C1 posterior arch was undercut with Kerrison's punch and with the help of Penfield dissector the sublaminar space of C1 and C2 vertebrae were dissected off. With fluoroscopic guidance, the paddle-lead was then passed from C1 (►**Fig. 4**) level with the tip lying at C4 level along posterior midline epidural space. The lead was then connected to an extension wire, which was tunneled to the shoulder area.

Stage 2: In the trial period, stimulation was carried out by an external pulse generator and on getting satisfactory response, second-stage surgery was done after 4 days,

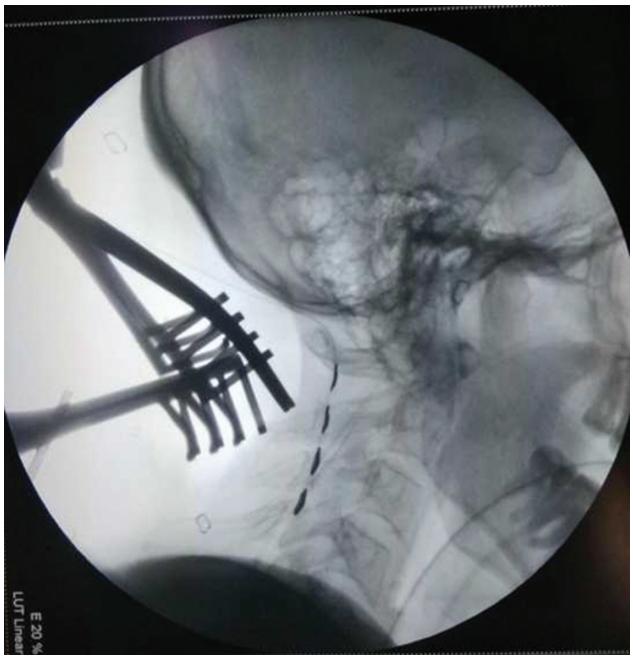

Fig. 4 Fluoroscopic positional confirmation of lead system.

when an IPG (MEDTRONIC Inc, Minneapolis, Minnesota, United States) was implanted in the posterior hip region and connected to the extension wire by subcutaneous tunnelling.

Outcomes

The calibration details for each patient, the postoperative VAS, and the VAS at last follow-up are detailed in tabular format in ►**Table 3**. A definite and sustained pain relief is seen in all patients.

Discussion

SCS for relief of chronic intractable neuropathic pain is well established since the 1960s.[13] Numerous studies and randomized controlled trials (RCTs)[2–4] provide strong evidence that SCS results in excellent pain control and remarkable improvement in the quality of life in patients with chronic neuropathic pain syndromes such as FBSS[12,14] as well as CRPS.[15,16] These studies have also compared conservative

Table 3 Outcomes

	Case 1	Case 2	Case 3	Case 5	Case 4 Standing	Case 4 Lying down
Row	0 −,4+ 5 −,10+ 11 −,15+	11 −,15+	0 −,4+ 5 −,10+ 11 −,15+	0 +,3−	3 +,4− 14 +,15−	2 +,4− 13 +,15−
Amplitude	1.5 V	2.2 V	1.5 V	0.3 V	1.65 V	2.25 V
PW	210 µs	210 µs	210 µs	300 µs	210 µs	210 µs
Rate	60 Hz	90 Hz	300 Hz	60 Hz	50 Hz	50 Hz
VAS	0/10	0/10	1/10	2/10	3/10	3/10
VAS at last follow-up	2/10	0/10	3/10	0/10	2/10	2/10

Abbreviations: PW, pulse width; VAS, visual analogue scale score.

medical management and/or repeat surgeries with SCS for the management of such pain and have demonstrated that SCS was by far superior in the management of such cohort of patients.

The prospective RCT by Kumar et al[2] had recruited 100 patients of FBSS into two arms: 52 patients in the SCS arm and 48 in the medical management arm. A statistically significant number of patients in the SCS arm (48 vs. 9%, $p < 0.001$) achieved more than 50% reduction in pain (the primary outcome) at 6 months. This benefit was sustained even at follow-up after 2 years, with the "intention to-treat analysis" revealing that a significant number of the SCS group (37 vs. 2%, $p = 0.003$) continued to have at least a 50% improvement in pain relief.[3]

The second RCT randomized 50 patients to an SCS arm or to a reoperation arm. This trial demonstrated that significantly more SCS patients (47 vs. 12%, $p < 0.01$) were able to achieve 50% or more pain relief even at follow-up.[4]

SCS systems can be either percutaneously placed less invasive systems or the more invasive paddle lead systems. Percutaneous leads are placed using the hanging drop technique under fluoroscopic guidance.[17] Although the percutaneous systems boast of being less invasive, having fewer postoperative complication and are being performed more frequently, they are often fraught with complications such as lead migration, positional variation, higher energy/battery consumption, and breakage leading to higher reoperation rates as compared to the paddle lead systems.[3,18–20] In terms of amplitude requirement and coverage ratings too paddle leads outperform most percutaneous electrodes.[5,18–20] (►**Table 4**.)

Not many studies in the past have provided a comparison of paddle lead versus percutaneous leads. Most have been small studies. North et al have reported in their RCT of 24 patients comparing paddle and percutaneous leads that significantly more patients with laminectomy electrodes experienced better pain control at a mean follow-up of 1.9 years ($p < 0.05$).[12] Similarly, Villavicencio et al in their retrospective review of 27 patients demonstrated that those with paddle electrodes tend to have a greater overall reduction in VAS than those with percutaneous electrodes.[10]

One of the largest analyses of such patients undergoing SCS was reported by Babu et al in 2013.[20] Their results indicate that even at more than 5 years of follow-up, the reoperation rates of paddle lead systems were far lower (adjusted odds ratio: 0.33; 95% confidence interval: 0.18–0.60; adjusted p-value = 0.0018) as compared to the percutaneous electrodes. Their analysis also revealed that as the percutaneous lead systems utilized more outpatient services; therefore, the 2-year outpatient costs were significantly more in comparison to the paddle lead systems ($p < 0.0004$). Although the total health care-related costs at 5 years for the two systems did not differ much statistically, the charges for the percutaneous lead systems definitely showed a trend towards being comparatively higher ($186,139 vs. $169,768, $p = 0.30$).

Given the available literature and recent data suggesting superior cost-effectiveness of the SCS procedure in chronic pain,[21–24] we felt that there is a need to revisit our approach in the management of such patients. In our five patients, almost all of whom were FBSS and one CRPS1 with at least a single surgical procedure in the past, we proceeded to directly implanting permanent paddle leads as trial electrodes after proper counselling and informed consent. The reasons for our deviating from the time-tested norm of first placing percutaneous leads in the trial period are the following:

Table 4 Advantages and disadvantages of percutaneous and paddle leads

Condition	Percutaneous leads	Paddle leads
Minimally invasive	Yes	No
Fewer postoperative complications	Yes	No
Easier to perform	Yes	No
Performed more frequently	Yes	No
Higher lead migration	Yes	No
Higher battery consumption	Yes	No
Efficient coverage and amplitude performance	No	Yes
Higher lead breakage and hence reoperation	Yes	No

Obviating the Risk of Lead Migration and Achieving Replication of Trial Period Outcomes

The standard operating technique for placing paddle leads consists of two phases—a trial lead phase followed by removal of the entire trial lead and placement of permanent electrode. This technique often times carries the risk of inability to reproduce the trial lead outcomes. The most common reason of this being inability to replicate the exact neuroanatomical coverage area during the placement of the permanent leads. There is often a chance of lead migration during the trial period itself. Moreover, the number of contacts in the trial leads are usually fewer as compared to the permanent leads thus achieving lower coverage. The number of contacts in the permanent leads used in our patients is 16 (5-6-5 configuration) which therefore provides a much larger contact area. Once the trial period confirmed a good pain control, the IPG could be now directly connected to the permanent leads by simply removing the extension wires thus, obviating the necessity to tamper with the position of the anchored paddle trial leads thereby replicating the exact trial period pain relief in the final setting.

The Unfortunate Event of Aborted Percutaneous Screening Trials

There are reports in literature wherein often times the trial with percutaneous leads is declared a failure or is not attempted due to many factors such as multiple previous

surgeries leading to scarring, obstructive spinal instrumentation, and excessive spinal scoliosis.[25] Majority of patients with such pain and who benefit from SCS are FBSS/FNS patients. In all likelihood, these patients would have had at least more than one surgery in the past, consequently the possibility of them having epidural scarring, spinal instrumentation, or scoliosis is high. Declaring the percutaneous trial as a failure or not attempting one forecloses any opportunity of placing permanent paddle leads. This leads to the regrettable situation of depriving this very cohort of patients an implantation with SCS that would have otherwise in all likelihood improved their quality of life significantly as evidenced in literature.

The procedure of performing a small laminotomy offers us the opportunity to navigate through scar tissue (and also remove the scar tissue) at the time of paddle lead placement. In a scarred environment, the direct visualization and anchoring of the electrode increase the probability of accurate placement. Furthermore, instrumentation and scoliosis due to past procedures can be better dealt with during an open procedure/minimally invasive laminotomy while placing the electrodes rather than a blind percutaneous approach.

It can be argued that in situations that the trial paddle lead stimulation fails to achieve more than or equal to 50% pain relief, the patients will have to undergo an invasive procedure just to remove the implant. Although this is a justified argument, it is also important to realize that the most critical part of SCS electrode placement in all scenarios is proper patient selection. If the trial period fails, then a short procedure under local anesthesia is sufficient enough to remove the lead.

The other argument that can be put forward against this approach is the concern regarding exposing patients to the risks of general anesthesia twice. Here, it can be pointed out that the paddle lead trial procedure can be easily performed under local anesthesia and conscious sedation thus obviating the need for general anesthesia completely. Pahapil has reported in his case series of 22 such patients and demonstrated the feasibility of placing permanent paddle leads directly under local anesthesia and conscious sedation.[25] In all our five patients, we did offer them the option of undergoing the procedure under conscious sedation and local anesthesia; however, they did not prefer the same and hence general anesthesia was used.

Conclusion

The results of our five consecutive patients at follow-up confirm that with careful patient selection, meticulous planning, and good operative precautions it is fruitful to directly implant permanent paddle leads, thereby replicating and sustaining the trial period pain relief as well as obviating the risks of lead migration and positional variation. With the outcomes that were obtained in terms of patient pain relief and compliance, we believe that this can be a new cost-effective and reliable standard operating procedure for providing excellent pain control in this cohort of patient with chronic neuropathic pain amenable to SCS.

Ethical Approval

Ethics approval was sought and was granted vide IRB 1224/2021.

Informed Consent

No patient identifiers have been disclosed. Further all patients have provided informed and written consents prior to the procedures.

Authors' Contributions

Both A.D.B. and S.B. are responsible for conception and design of the study. S.B. was responsible for acquisition and analysis of data. A.D.B. and S.B. were responsible for drafting the manuscript. A.D.B. as the senior surgeon is responsible for performing the surgical procedures and maintaining the records of all cases.

Conflict of Interest

None declared.

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