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Spinal Cord Stimulation Failures in Refractory Chronic Pain

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Abstract

Background: Spinal cord stimulation (SCS) is a well-established modality for the treatment of refractory chronic pain and may utilize percutaneous or paddle leads.

Methods: The study is conducted at the Unit of Functional Neurosurgery of University "Magna Græcia" of Catanzaro. We perform a retrospective review of our prospective database of 523 SCS patients undergoing surgery for routine indications between January 1993 and December 2013 to evaluate failures rates during trial period and during chronic stimulation.

Results: SCS trial was less effective for patients with differentiation neuropathic pain and post herpetic pain. Patients with allodynic dominant pain can feel unpleasant or painful parenthesis during trial stimulation. SCS trial has presented a very low hardware-associated complication rate (lead migration 1.3%) and absence of biological complications. During chronic SCS 29% of cases had equipment failures. In particular mechanical failures occurred in 18% of cases with 8.5% of lead displacements or migrations and 9.5% of lead breakages; biological failures occurred in 11% of cases with 6% of skin erosions and 5% of infections.

Conclusion: SCS is a minimally invasive procedure effective in managing medically intractable pain of various origins. Despite advances in the design and production of SCS systems, these devices remain prone to failure from various causes. A careful analysis of mechanical complications coupled to a clinical strategy to minimize the tensile loads on the components of the system should lead to an improvement of the performance of the SCS implanted system and the effectiveness of the stimulation and the long-term reduction in the rate of complications that currently it remains quite significant.

Keywords: Spinal cord stimulation; Hardware failure; Refractory chronic pain; Complications

Introduction

Spinal cord stimulation (SCS) is an effective surgical option for treatment of chronic neuropathic pain. It was described for the first time in 1967 by Shealy [1,2] as an alternative to the procedure of neurolesion, according to the pain gate theory proposed by Melzack and Wall in 1965 [3]. Nashold and Friedman published the first larger study on SCS in 1972 [4]. In the same year Hosobuchi proposed a two-step procedure with percutaneous testing of the electrode before final implantation of the impulse generator [5]. A typical SCS system consists of one or more electrodes, a subcutaneous implantable pulse generator (IPG) and extension wires between leads and IPG. Each of these components presents a possible failure point for the system. The exact mechanism of SCS is still under debate. According to the gate control theory [3], the effect of SCS is the inhibition of the nociceptive signal in the dorsal horn by antidromic activation of collateral fibers of the dorsal columns. Probably there is also an orthodromic stimulation, responsible of producing tingling sensation felt by the patient under stimulation [6]. According to their theory, activation of myelinated Aβ fibers inhibits pain transmission and is enhanced by activation of thinly myelinated Aδ fibers and unmyelinated C fibers [3,7]. A recent experimental study in a rat model of neuropathic pain also demonstrated spinal segmental and supraspinal mechanisms underlying the pain-relieving effects of SCS [8]. The supraspinal control of pain transmission was unknown when the gate control theory was described. SCS may be considered an established surgical treatment for intractable chronic pain when simple first-line therapies have failed [9]. The main indications are failed back surgery syndrome (FBSS), complex regional pain syndromes (CPRS) I and II, peripheral nerve injury, diabetic neuropathy, post herpetic neuralgia, stump or phantom limb pain, partial spinal cord injury, chronic low back pain, chronic back and leg pain, ischemic limb pain and angina pain [10-12]. The most frequent and best studied indication is FBSS. According to a recent review, FBSS evolves in approximately 30% of patients after lumbar disc surgery [13]. Despite advances in the design and production of SCS systems, these devices remain prone to failure from various causes. Although SCS is minimally invasive, repeated procedures expose patients to risk and hardware revisions result in additional expense for patients. Equipment failures over the course of the long-term treatment are still encountered in a relatively high proportion of treated cases. We conducted a retrospective study of SCS failures occurred during trial and chronic stimulation over a period of 20 years.

Material and Methods

We performed a retrospective analysis of 523 patients with chronic neuropathic pain that underwent SCS implantation (trials and trials+implant) at the Unit of Functional Neurosurgery of University "Magna Græcia" of Catanzaro (Italy) between January 1993 and December 2013. We reviewed all operative reports and hospital discharge summaries as well as the clinic visit notes for most patients to evaluate the type and the frequency of SCS system failures. All SCS systems and components were manufactured by Medtronic Neurological (Minneapolis, MN). Percutaneous leads were four contacts Pisces-Quad Mod. 3487/A or Pisces-Quad plus Mod. 3888, eight contact compact

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Mod.3778, eight contact standard Mod.3777. Laminotomy-type leads were four contacts Resume II Mod. 3587A, Specify 2 x 4 Model 3998, Specify 2x4 Hinged Mod. 3999. Implantable pulse generators were Itrel III (single-channel), Synergy Mod. 7427, Synergy Versitrel Mod. 7427V, Prime Advanced Mod 37702 (dual-channel).

Results

A total of 523 patients underwent a 7-10 days external trial implantation: in 496 cases (95%) we used quadripolar or octopolar percutaneous lead while in 27 cases (5%) quadripolar or octopolar (two parallel rows of four contacts) plate lead. As to the 439 patients who underwent definitive implantation, quadripolar/octopolar percutaneous leads were used in 85 % of the cases (373 patients) while in 15% of the cases (66 patients) quadripolar or octopolar plate leads were used. During the external trial period, 16% of patients (84 cases) failed to meet trial minimum requirement - 50% of pain relief - while 84% patients (439 cases) were definitively implanted. Despite advances in lead systems design ever more efficient, failed SCS trials may have different causes. We divided patients with failed trials in 3 groups:

- Cases of unacceptable pain relief in spite of sufficient paresthesia on pain area (37.3%=31 patients)

- Cases of unacceptable pain relief for insufficient paresthesia coverage (40.7%=34 patients)

- Cases of unpleasant or painful sensation during stimulation (22%=19 patients).

In presence of sufficient evocated paresthesias on painful area, we hypothesized that in these patients' primary pain mechanisms or the underlying disease was unsuitable to SCS. In patients with unacceptable pain relief for insufficient paresthesias coverage, the spine anatomy or the presence of spinal cord lesions prevented accurate lead placement.

The unpleasant or painful sensation during stimulation was due to electrical stimulation of ligamentum flavum by lead contacts or to presence of allodynic dominant pain. Concerning the 439 patients that underwent to definitive SCS implants, in 85% (373 cases) we used quadripolar/octopolar percutaneous leads; while in 15% (66 cases) quadripolar/octopolar (two parallel rows of four contacts) plate leads. Leads were implanted in cervical and thoracic region (Table 1).

If we look at equipment failures during the trial period, we found only 7 cases of lead migration (1.3%). Of the 439 patients with definitive implants, 29% of cases (127 patients) had equipment failures during chronic stimulation. In particular mechanical failures occurred in 18% (79 patients) with 38 lead displacements or migrations (8.5%) and 41 lead breakages (9.5%). Biological failures occurred in 11% of cases (48 patients) with 26 skin erosions (6%) and 22 infections (5%) (Table 2). Cervical leads were associated with higher failure rate: we noted for both percutaneous and laminotomy-type leads a significantly higher rate of lead migration (respectively 2.47% vs. 2.5%) and breakage (1.85% vs. 66.6%). Failure rate associated with cervical laminotomy-type leads tended to be extremely high. Migration rate for percutaneous leads were higher than that for laminotomy-type leads (9.11% vs. 6.06%). Paddle leads were twice more likely to break compared to percutaneous leads (15.15% vs. 8.31%).

Infection rate was higher for laminotomy-type leads, while skin erosions were more frequent in percutaneous leads (Table 3). Comparison of the published literature data on SCS failures with our own experience is difficult because of the lack of standardized evaluation. By analyzing our results we can make some considerations.

Definitive Implants N. 439			
	Cervical	**Thoracic**	**Total**
Percutaneous	50 (13.4%)	323 (86.6%)	373 (85%)
Laminotomy-type	12 (18.2%)	54 (81.8%)	66 (15%)

Table 1: Number of procedures arranged according to the region in which the lead was placed.

Causes of failures according to hardware type			
Cause of failure	**Percutaneous**	**Laminotomy-type**	**Total**
Migration	34 (9.11%)	4 (6.06%)	38 (8.5%)
Breakage	31 (8.31%)	10 (15.15%)	41 (9.5%)
Infection	18 (4.82%)	4 (6.06%)	22 (5%)
Skin erosion	25 (6.7%)	1 (1.5%)	26 (6%)
Total failures	108 (28.94%)	19 (28.77%)	127 (29%)

Table 2: Causes for failure according to hardware type in cases with SCS failure.

Hardware failures according to system type-lead level			
Failures	Cervical	Thoracic	Total
Percutaneous	50	323	373
Migration/displacement	8 (2.47%)	26 (8.04%)	34 (9.11%)
Breakage	6 (1.85%)	25 (7.7 0%)	31 (8.31%)
Infection	4 (1.20%)	14 (4.33%)	18 (4.82%)
Skin erosion	5 (10.00%)	20 (6.19%)	25 (6.70%)
Laminotomy-type	12	54	66
Migration/displacement	3 (2.50%)	1 (1.85%)	4 (6.06%)
Breakage	8 (66.60%)	2 (3.70%)	10 (15.15%)
Infection	1 (8.33%)	3 (5.55%)	4 (6.06%)
Skin erosion	0	1 (1.85%)	1 (1.50%)

Table 3: Summary of hardware failure data organized by system type and failure mode.

SCS trial was less effective for patients with deafferentation neuropathic pain and postherpetic pain. Patients with allodynic dominant pain can feel unpleasant or painful paresthesias during trial stimulation. SCS trial has presented a very low hardware-associated complication rate and absence of biological complications while during chronic stimulation SCS implants had a high incidence of mechanical complications. This demonstrates the common clinical practice of using percutaneous leads initially and converting to laminotomy-type leads if technical difficulties arise. There were significant differences in failure rates according to lead location (cervical vs. thoracic region), failure mode (lead migration and/or breakage, infection) and hardware types. Extensive published reviews suggest that approximately 30% to 40% of patients treated with SCS will have a complication requiring a revision [13-18]. The majority of the complications is minor and easily reversible with minor surgery and rarely affects patient's morbidity significantly. Neurological complications are exceptionally observed and can result generally from intraoperative root or spinal cord injury or spinal cord compression by intraspinal infection or epidural hematoma [19-21]. Broggi et al. reported 3% mechanical complication during the 2 years follow-up in 410 patients of a multicentric study [22]. Barolat reported only 4 hardware failures in 509 implanted electrodes [23]. Bel and Bauer experienced 7 hardware failures (39%) in 18 SCS procedures [24]. Turner et al. reviewed 39 published studies in which 30% of patients had one or more hardware-related complications, 24% had electrode insulation failures, 7% electrode wire failures and 2% IPG failures [25]. Quigley et al. reported a total of 64 hardware revision operations (62.7%) on 35 patients [26]. While revision procedures entail relatively minimally invasive surgery and the magnitude of their risk is usually low, their cost should not be underestimated. Interruption of effective SCS therapy results in the possibility of increased medication consumption and

patients' lost productivity. In addition each revision requires additional hardware, operating room time. It has been postulated that the risk of infection escalates with the increasing number of procedures involving hardware manipulation [27]. Electrode dysfunction cannot be detected by X-rays in all cases, but should always be suspected when a sudden disappearance of paresthesia in the painful dermatomes or appearance of differently located sensations are experienced. Disruption of insulation causes short-circuiting and electrode dysfunction and maybe caused or facilitated by superficial injuries of the electrode insulation by the edge of the percutaneous implantation needle during surgery. Increased axial tension stress and hypermobility of the percutaneous electrode in the spinal canal may be responsible of disruption of the plastic insulation or/and of the electrode wire. Sometimes the failure occurs immediately after a traumatic event caused by mechanical overload of the material [28].

Conclusion

In conclusion in spite of the best efforts in selecting candidates for SCS therapy, in making correct implant procedure and management of system the percentage of SCS failures remains significant. A careful analysis of mechanical complications coupled to a clinical strategy to minimize the tensile loads on the components of the system should lead to an improvement of the performance of the SCS implanted system and the effectiveness of the stimulation and the long-term reduction in the rate of complications. It is however necessary a new generation of electrodes, in which design takes into account the biomechanical variables of different levels of implantation.

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