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Review Article

Enhanced Comfort with Spinal Cord Stimulation at Reduced Costs in the Management of Chronic Pain: An Introduction to Wireless Neuromodulation

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Abstract

Spinal Cord Stimulation (SCS) treatment has been a time tested, cost-effective neuromodulation modality in the management of chronic pain, with rapid technological advancements improving the trial success rate as well as the long-term results. So far, a few reports, however, came up with the comforts, costs and challenging complications of SCS to improve upon the indications. Advent of wireless nanotechnologies minimizing the implant size reduced surgical trauma and operating time and it is time to reevaluate the expenditure of a Traditional SCS (TSCS) and its impact on the health care budget. Advancements in wireless nanotechnology introduced miniature devices with wireless access to the stimulator which appear to reduce or mitigate the complications and costs associated with TSCS equipment. These smart devices are devoid of implantable pulse generators and their extensions inside the patient body thereby cutting the associated costs and complications. A TSCS cost was USD 32,882 with maintenance costs of 5,071 (4 yrs.) while wireless device (Stimwave) costs € 18,000 (maintenance of € 1500 for 3 years); there was no additional IPG expenditure of USD 13,150 (Canadian $ 10,591, £ 7,243) for WSCS. The WSCS involves implantation of a solitary miniature nano-electrode with access to remote antenna and has the advantages of reduced surgical trauma and surgical procedures, reduced hospital stays, fewer complications and follow up visits translating in to significantly lower costs for an equally efficient outcome.

Background: Decades of clinical experience supports Spinal Cord Stimulation (SCS) as an effective tool in the management of chronic pain. However, a review of results with TSCS revealed plenty of scope to improve upon the technology to increase acceptability of the technique at low complication risk and reduced costs. One alternative is employing wireless nano-technology with miniature pulse generators and external transmitters that reduce the bulk of surgical implants, notably the Implatable Pulse Generator (IPG), thereby improving the comfort, reducing the complications along with the treatment costs.

Material and Results: The limited available literature on the TSCS costs was reviewed to arrive at the implantation costs of USD 32,882 (CAD 21,595 and UK £ 15,081); nonrechargeable battery was USD 13,150 (CSD 10,591; UK £ 7,243) in 2006 while a rechargeable battery had cost USD 20,858. SCS maintenance required battery change every 4 years on average with additional expenses of USD 3,539. IPG replacement involved expenses of CAD 5.071. Additionally, IPG-related complications like pain, hematoma (10%) and infection (50% of SCS infections) incurred extra costs for replacement or treatment. Wireless SCS (WSCS) cost € 18,000 for implantation with a 3-year maintenance expenditure of € 1500. It was equally effective in pain management and devoid of IPG costs /complications.

Conclusions: Wireless miniature implant for SCS can reduce costs and complications with improved comfort to the patients

Keywords: Costs; Complications; Miniature Implants; Nanotechnology; Spinal Cord Stimulation; Wireless

Introduction

Intractable pain is a significant complaint and also a major consumer of opioids as well as research dollars. Following the gate theory for pain mechanisms, introduction of Spinal Cord Stimulation (SCS) therapy by Shealy and his team quickly ensued introducing the science of neuromodulation in the management of chronic intractable pain [1,2]. Several publications established the cost effectiveness of SCS to control chronic pain secondary to failed back surgery syndrome, neuropathic pain disorders, complex regional pain syndromes and others [3-8]. With literature support, SCS is being increasingly utilized and the number of surgeries performed annually have increased [9]. Also, technical advancements have refined the equipment to improve the outcome of therapy as well as the life span of the implants.

Nevertheless, very few reports have brought out the health care budget issues relevant to the SCS costs and complications or their impact on the failures of traditional SCS (TSCS) equipment.

The Costs of TSCS Implant

TSCS equipment appears today bulky since it utilizes implantable electrode enclosed inside a catheter, long extension cables connecting them to an IPG (all components are placed surgically inside the patient body). Hence complications following the surgical implantations as well as the failures of any of these components are considered as adverse events of SCS. In up to 40% of cases, complications occur, while in some the trial SCS fails necessitating explantation of the equipment [5,10-12].

The trial of complications of SCS have significant impact on the health care budget since the cost of therapy includes implantation, maintenance and complications. Nearly one-third of patients might experience complications which could be expensive to treat but not included in the initial budget [5,13,14]. Maintenance expenditure might appear nominal to begin with until a complication arises: thus, every case requires an additional 18% increase in the expenditure [3,4].

TSCS Implantation Costs

A comparative report on Canadian and North American (Medicare) experience on SCS expenditure (on consultations, diagnosis, trial and implantation) was published by Kumar et al [15]. The Canadian system charged CAD 21,595 for implantation of the SCS equipment and the US Medicare had a mean cost of USD 32,882 with a trial SCS cost of CAD 7671 and USD 10,900. Notably, the Canadian budget included a longer hospital stay (of 3 days) to cover a 1000-miles travel for most patients.

Maintenance: For an uncomplicated patient, the annual maintenance costs of SCS were CAD 3539 and USD 5071. On an average, the nonrechargeable IPG was replaced after 4 years; hence, the costs for IPG maintenance were amortized for 4 years [15]. IPG life expectancy was reported to be 49 months at best on an average [7,16,17]; it was 48 months in the experience of Kumar et al [17] and only 27.9 months for Van Buyten's cases [7]. Budd had fewer patients in 18 months follow up [16]. IPG life is an important factor in SCS expenses both as an implant and also as a source of complications which demand replacement before end of life (EOL)

IPG location also has an impact on electrode migrations due to its tethering effect during normal spine motion in bending and rotations [18-20]. Lead texture and multichannel devices reduced these migrations to certain extent [19,20]. Battery costs and extended EOL: An expensive rechargeable battery lasts for 5 to 9 years depending upon the manufacturer although, Boston Scientific team reported 10-25 years life, but costlier by nearly 11,000 USD (10,591 CAD) for implantation alone [15,21]. Even this EOL was influenced by demographic factors like age of the patient, tolerance to SCS and complications [16,21,22].

SCS Costs Due to Complications

Surgical complications tend to be expensive, especially when the implant gets infected and could cost nearly 20,000 CAD for antibiotics, explantation followed by reimplantation of a new system. The mean expenditure on complications in Canadian system was 5191 CAD while in the US it could vary between 381 USD and 28,495 USD (Medicare costs) depending upon the severity [15,23]. Total cost of complications over 3.65 years of mean follow up was CAD 327,057 CAD for a cohort of 161 Canadian patients which increased the annual maintenance costs by 1.4 times (twice in the US) [23].

Costs of Complications

Management of each complication differs from a minor one like a local pain to a major complication like infection which requires surgical intervention [15]. Mean cost of complication in Canadian patients was $7092 (range: 130-22,406). An uncomplicated case consumed CAD 3609 for maintenance (including one IPG replacement in 4 years). Replacement of an entire SCS system incurred CAD 23,205, a failed trial CAD 7859 (additional explantation chargers of $1739). Lead revision/ repositioning in failed SCS varies between uncomplicated and infected cases (Tables 1,2,3). European experience [23] has range between € 360 to 6192 and American experience [24] reported costs of $2700 to $19,600.

Author	Journal	year	N of patients	Cost
Manca, et al.	Europeal J Pain	2008	52	CAD 19,486, Euro 12,653
Kumar, et al.	J Neurosurg spine	2006	160	CAD 23,205
Kumar & Bishop	-do---	2009	197	CAD 21,595, USD 32,882
Hornberger, et al.	Clin J pain	2008	NA	USD 26,005 (Nonrechargeable); USD 35,109 (Rechargeable)
Babu, et al.	Neuromodulation	2013	4536	USD 30,200 (Percutaneous); 4536 USD 29,963 (Paddle electrodes)
Annemans, et al.	J LTE Med implants	2014	Model	UK£ 15,056 (HF SCS)

Table 1: Literature on TSCS cost.

Procedure	TSCS USD*	TSCS CAD*	TSCS UKS*	Stimwave WSCS
Implantation	32,882	21,595	15,081	€ 18,000
Complication cost	9,649	5,191	576	NA
Revision cost	5,450	-	5339 (lead)	€ 2,500
IPG cost	13,150	10,591	7,243	NIL
Maintenance	5,071 (4 yr)	3,539 (4 yr)	NA	1500 (3 years)
(HF SCS therapy was similar to TSCS in its costs and complications. USD*= US dollar, CAD* Canadian dollar, UKS*= United Kingdom Sterling Pound)				

Table 2: Reported costs of traditional SCS (TSCS) and the wireless SCS (WSCS).

	European experience [23]	American experience [24]
Repositioning of electrode	€ 360	$2700
Replacement	€ 1,530	$5450
Reimplantation following infection	€ 6,192	$19,600

Table 3: Costs for Lead revision/repositioning in TSCS.

There was a 5% decrease in the SCS complications after the first 10 years [25]. Also, reoperation rates for paddle electrode systems were significantly fewer compared to percutaneous electrodes. Out-patient costs were higher for percutaneous system compared to paddles (USD 100,486 vs 87,961) both at 2 and 5 years (USD 186,139 and 169,768) [26]. Experience with High Frequency SCS reported in a recent model [27] exhibited better quality therapy and was also more cost effective compared to TSCS and SCS with nonrechargeable IPG. Complications with all the 3 systems were identical and cost of complication management was £ 622.

Neuromodulation with Wireless Nanotechnology

A A better alternative to TSCS to reduce the bulk of implanted device and its complications is wireless SCS that has an external wireless power generator. (WPG) with a dipole antenna for electric field coupling. Very short wavelength microwaves at Giga Hertz (GHz) frequency are utilized in the wireless device (Stimwave technologies), powered by radiative electric field coupling through tissues [28]. Microwaves enable miniature implants to be surgically placed at significant depths and yet accessed wireless at minimal power loss. Feynman described this energy transfer phenomenon as the principle behind the frequency vs wavelength changes [29]. Accordingly, the skin depth decreases with square root of the scale (where frequency ascends and wavelength descends).

Stimwave implant in the WPG delivers the clinically relevant stimulation at 800-1350 um diameter; a very tiny implant when compared to the conventional bulky IPG of TSCS. The implant (electrode), equivalent to the lead body of the TSCS, incorporates the nanoelectronics within itself and can be included in to leads with 4 or 8 contacts in a paddle or cylinder electrode. The receiver wire mated to the implant, communicates with the WPG (Figure 1). Each contact on the lead has exclusive power capabilities due to an application-specific circuit to emanate very specific charge balanced wave forms (Figure 2). An oscillating electric field is created as the dipole antenna re¬ceiver intercepts the microwave frequencies emanated from the EPG. Antenna varies in length between 2 and 8 cm (depending upon the tissue depth of the implant) and the microwave electromagnetic energy can be dissipated at skin or bone depth traversing the tissues in between. GHz frequency was shown earlier to be more efficient in animal models [30].

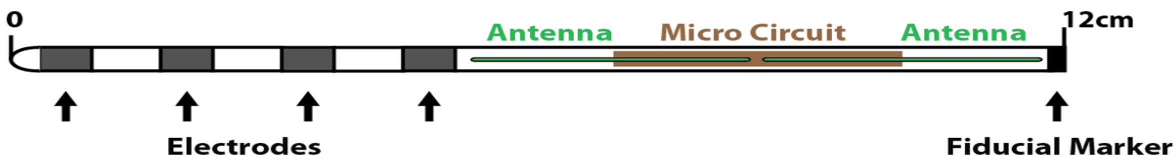

Figure 1: MRI compatible electrode with Nano-stimulator and micro circuit to contact wireless pulse generator. This is the only implantable component required for WSCS.

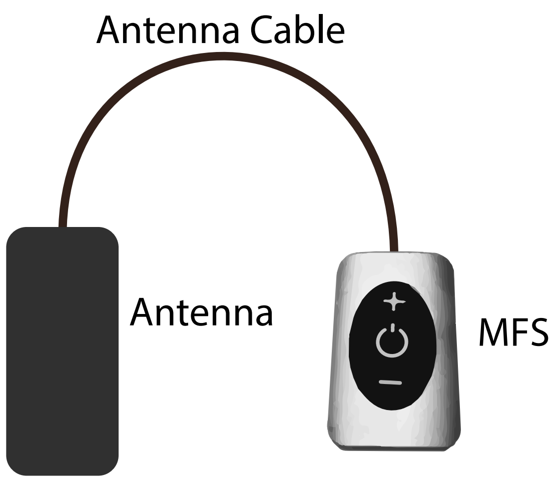

Figure 2: External pulse generator.

The Wireless External Power Generator in Place of an IPG

Wireless Power Generator (WPG) employs transfer technology similar to a cellular phone, with a Radiofrequency (RF) transmitter that transforms the stimulation waveforms in to a signal as per a given patient specific program setting while a microprocessor within the transmitter regulates the settings and data transfers (Figure 3). Up to a 1-Watt power output can be delivered depending upon the depth of the stimulator and the stimulation required. Both patient and clinician control the settings using a controller similar to Bluetooth [28]. It is important to note that with EM at microwave frequency, neuronal damage is very less likely since high frequency does not activate the cell mem¬branes. Thus, the Stimwave wireless nanotechnology device is a minimally invasive surgical implant with more biocompatible microwave energy for biological safety.

In several clinical conditions, Stimwave nano stimulation system has been utilized for SCS, DRGS and PNS throughout Europe and in the USA over the past few years with encouraging results in case studies. Clinically, successful wireless stimulation and significant pain relief was observed in several patients with back pain, leg pain, neuralgia following herpes zoster, craniofacial pain, occipital neuralgia, and complex regional pain syndrome [30-33]. There were minimal adverse events or complications. Especially, the surgical trauma or complications related to the IPG and its connections were avoided in this system yielding reduced surgical trauma, operating time, usage of consumables with increased comfort and cosmetic result to the patient.

Costs involved with nanotechnology wireless SCS: The initial implantation of the wireless electrode in Euro 18,000. IPG costs: Zero (0). Annual maintenance of the neuromodulation cost was 1500 Euro/3 years.

For clear reasons without IPG, WSCS is devoid of battery/ extension cable related complications and costs. Additionally, in due course with increased clinical experience, the wireless neuromodulation technology can be expected to yield far better outcomes, fewer complications, improved cosmetic results and very much reduced costs.

Conclusions

SCS is an effective pain management option evolving continuously with updated technology to improve the comfort of the patients at reduced rates of complications. WSCS appears to be an attractive approach in such direction not only decreasing the costs and complications but also improving the acceptability. More widespread usage of the technology might bring down the costs further.

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