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Wireless Spinal Cord Stimulation without the Costs and Complications of Implantable Pulse Generators: A Novel Technique in Neuromodulation

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Abstract

Aim: To provide the benefits of wireless SCS without an IPG and its costs or complications.

Background: For several decades spinal cord stimulation (SCS) has been in use to manage chronic pain, effectively at reduced cost compared to conventional medical management (CMM). However, in its conventional form, the equipment is bulky, and several components need to be implanted, most notably the implantable pulse generator (IPG). Advancements in nanotechnology and wireless devices minimized the SCS implant significantly in size incorporating the pulse generator within the electrode thereby eliminating the IPG along with its connection wires altogether, from implantation.

Material and Results: A review of the limited available literature on the costs of traditional SCS (TSCS) and IPG was performed and compared to the costs of wireless SCS (WSCS). For a nonrechargeable battery the expenses during TSCS were USD 13,150 (CSD 10,591; UK £ 7,243) in 2006 and a rechargeable battery had cost USD 20,858. TSCS maintenance costs included one battery change once in 4 years (sometimes earlier) at a cost of USD 3,539. (IPG replacement was priced at CAD 5.071). Stimwave WSCS device (without the IPG) had a 3-year maintenance cost of 1500 Euro only. WSCS also was devoid of the complications, especially infections, due to IPG. It was equally effective and probably with fewer complications or adverse events, especially due to the absence of the tethering effects of IPG that was shown to contribute to electrode displacements (up to 9 cm) during normal spine movements. TSCS was reported to have 50% of infections attributable to IPG and 10% non-infective complications caused by the IPG surgical procedures. Management of these complications was not seen with WSCS and the expenditure could be completely avoided. In several case series, WSCS has been reported to be effective in chronic pain secondary to failed spine surgery, herpes zoster infection and complex regional pain syndrome.

Conclusions: WSCS in its miniature form with nanotechnology does not require an IPG and thus was devoid of the costs or the complications related to IPG. TSCS equipment includes an IPG cost between 13,000 and 20,000 USD with a 4 year maintenance expenditure of 3,539 USD. WSCS had a 3 year maintenance cost of 1500 Euro only while the outcome of pain management, so far, were encouraging. Larger clinical data might eliminate IPG costs and complications entirely in the SCS therapy to improve the acceptability and increase the indications.

Keywords: spinal cord stimulation; implantable power generator; costs; complications; wireless;

Introduction

Several advancements in the SCS equipment as well as technique ensued over the past decade and IPG also underwent modifications to enhance its life expectancy over a period of time. This also improved the electronics and the dimensions of the implant. However, as an implant, IPG always carried the associated morbidity, additional costs, complications and the related expenditure for removal or reimplantation following infections, failures or technical short-comings. Very limited literature exists on the end of life (EOL) of IPG in an uncomplicated SCS case and about 48 months was an accepted figure as reported by Kumar et al, Van Buyten and Budd [1,2,3]. In best hands, it was 49 [2] months and just 27.9 months in 5-year-follow-up of 61 patients as reported by Van Buyten [3] with IPG replacement in 32 patients during the time. For a nonrechargeable battery, the EOL was at 49 months [4] with a range of 3-6 years. Apart from EOL, complications like infection or replacement for failed therapy were expensive adverse events to deal with.

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Material and Results

Very limited literature has been published regarding the EOL of IPG or the costs related to SCS implantation, maintenance and complications including failures. Relevant information was obtained from published material shown in table 1, which includes, experience from USA, Canada, UK and Europe (Table 1). Apart from adverse events original to itself, IPG also might contribute to additional complications and failures due to its bulk, location, tether and tug on the rest of the equipment. Laboratory data support such association implicating IPG in lead migration.

Bench data on IPG and electrode displacements

TSCS requires to have implanted electrode, IPG and connections between these two. The electrode and IPG get anchored in place at their respective surgical sites to avoid displacement during normal body movements, especially those of spine during routine activities. The tensile/stretch load transmitted to the electrode depends upon the IPG tethering effect, the tissue elasticity or scarring and degree of spine motion [5]. Laboratory evidence suggests that IPG location and spine movements exert a combined deleterious effect on the position of electrode. Up to 9 cm displacement of a thoracic SCS electrode was noted with spinal flexion/extension movements with an IPG located in buttock. This exertion was noted to a lesser extent when the IPG was implanted in the anterior abdominal wall. Lead displacement of 2mm with walking, and 17mm with trunk rotation were observed; gluteal IPG produced twice the movement compared to an abdominal wall IPG [6]. Technical modifications like a strain loop, anchoring materials ensued to reduce lead migrations; paddle electrodes for the cervical SCS were promising while multichannel devices also reduced revisions for lead migrations [7, 8].

Table 1: Literature on the costs of TSCS

	Author	Journal	Year	N of patients	Cost
1.	Manca et al	Europeal J Pain	2008	52	CAD 19,486, Euro 12,653
2.	Kumar et al	J Neurosurg spine	2006	160	CAD 23,205
3.	Kumar & Bishop	-do---	2009	197	CAD 21,595, USD 32,882
4.	Hornberger et al	Clin J pain	2008	NA	USD 26,005 (Nonrechargeable) USD 35,109 (Rechargeable)
5.	Babu et al	Neuromodulation	2013	4536 4536	USD 30,200 (Percutaneous) USD 29,963 (Paddle electrodes)

For better performance and EOL, nonrechargeable batteries were replaced by rechargeable batteries since battery changes and reimplantations were part of SCS health care budget which were expected to be fewer than 6 in a patient life span [9].

Costs of IPG: Rechargeable and nonrechargeable

Rechargeable IPG had a higher cost (CAD 10,591 or USD 10,988) but preferred due to its longevity (2,5), ranging between 5-9 years depending upon the manufacturer; 9 years for Medtronic, 5 years for Boston Scientific (claimed 10-25 years) and 6 years for Abbott (earlier St Jude). Accordingly the maintenance costs differ between the two types of IPG; 2-3 for rechargeable compared to 5 or 6 for nonrechargeable IPG [9].

Costs of complications due the hard ware implantation

Revision of electrodes was indicated for several reasons, including displacement, loss of stimulation. IPG might be a contributing factor as described above [6]. An abdominal wall IPG had less incidence compared to an IPG in gluteal region (10% and 21% respectively). The electrode revision, although had a learning curve, was indicated in 11.3% over 10 years follow up [10]. In addition to revision surgery for displaced lead, surgery was indicated for pain over IPG site or a rotated IPG [6,10]. In 9-11.8% patients, IPG related pain was reported [11-13] and relocation was indicated in some of these patients; 11.8% needed IPG revision surgeries in the experience of Quigley et al [12]. Battery failure ahead of the EOL had 1.5% incidence in Cameron's review of 20 year literature on SCS [11]. IPG lasted for 50 months on average estimate of battery life expectancy (usually within 5 years), according to Kumar et al and Van Buyten requiring replacement in most cases [2,3] notwithstanding the functional battery life of 25 years for a rechargeable generator from Boston Scientific (Precision IDE clinical study) or a low figure of 10 years [14]. In 1.2% cases, battery depletion necessitated complete explantation of SCS [15]. Most of the times, follow up costs for SCS did not include trial failures or these explantation costs [15,16]. Cost of minor complications following SCS was estimated to be about USD 350. No mortality, however, could be attributed to the morbidity associated with SCS when compared to the age adjusted general population [17].

Infections related to IPG

Overall infection rate following SCS implantation was about 5% and notably most infections occur in the IPG location (57%) [5]. According to Follet et al [18] common sites for infection following SCS were IPG pocket, the connection wire tracts and lumbar incision and 82% of these patients had to be explanted of the device [5]. Other adverse events related to IPG include pocket pain in up to 11.8% cases [5,11] indicating revision surgery in some patients. Burning pain due to electric leakage was reported in some.

Discussion

Today health care budget requires medical audits on treatment expenditure and clinical outcomes in a meaningful way to improve safety and efficacy. Therapeutic efficacy of SCS in chronic intractable pain has been established in several reports and refining the technology improved the patient comfort and treatment results. However, there exists scope for improvement in SCS outcomes exists to reduce complications or their associated costs. A large percentage of patients, as high as 50% reportedly have failed the trial period utilizing conventional SCS devices [11-13], while additional failures came from equipment complications contributed by the migration/fracture of the electrodes as well as IPG failures and complications in re-charging or re-implantation. Post-surgical complications like infection, hemorrhage and painful operative wounds were frequently seen associated with IPG and its extension wires. Additionally, SCS in its conventional form is incapable of reaching some anatomical locations to provide targeted therapeutic localized pain relief [11-13].The TSCS therapy, its complications and IPG related costs have been a matter of concern (Table 2 and 3) especially in the light of recent nanotechnology advances and wireless approaches to SCS, the most charming factor being the implantation of a single nanoelectrode device with capabilities of wireless access to a remove antenna.

Table 2: IPG costs

Parameters	SCS with IPG	SCS without IPG (Wireless)
Cost of Battery	USD 13,150 CSD 10,591 UK £ 7,243	None
(Rechargeable USD 20,858) Maintenance of SCS (4 years) (Includes IPG replacement)	USD 3,539 CAD 5,071	1500 € (3 years)

Table 3

AE Parameters	SCS with IPG	SCS without IPG (Wireless)
IPG pain	1-12%	None
Infection	50% of SCS infection	None
Rotation	1-2%	None
Premature Failure	2%	None
Lead displacements	9 cm with gluteal IPG	None

(AE=adverse events, SCS=spinal cord stimulaton, IPG=implantable pulse generator)

Nanoelectrodes combined with wireless technology: A novel neuromodulation

This wireless neuromodulation requires implantation of an electrode embedded with in-built receiver to contact an external wireless pulse generator (EPG or WPG) without any requirement for additional implants in the form of an IPG or its connection cables. Thus, WSCS is truly minimally invasive requiring minimal anesthesia and minimal hospital hours of stay to minimize health care expenses. In addition, the implant, in case of revision or failures requires simple procedures or explantation since the IPG and connecting wires were not implanted. The tethering effects due to the battery and its extensions are eliminated effectively [19] as the electrode communicates with the antenna that is located externally (Figure 1,2). This wireless device is fully programmable with a wide frequency range between zero and 10,000 Hz. Its effective neuromodulation therapy has been so far reported in several case series and illustrative cases demonstrating the safety as well as feasibility in the management of chronic intractable pain due to failed spinal surgery, herpes zoster and others [20-22]. Wireless neuromodulation exhibited outcomes comparable to TSCS in many cases and could be employed for SCS, peripheral nerve stimulation and dorsal root ganglion stimulation. Further experience in multiple disease conditions with larger patient groups might support this novel therapeutic approach to eliminate IPG form SCS and improve the acceptability by both the patients and third-party audit.

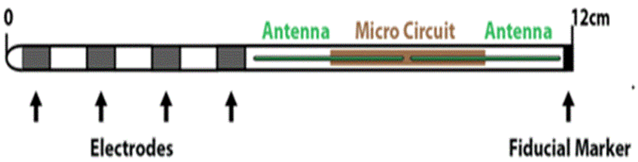

Figure 1: MRI compatible electrode with nanostimulator and micro circuit to contact wireless pulse generator. This is the only implantable component required for WSCS

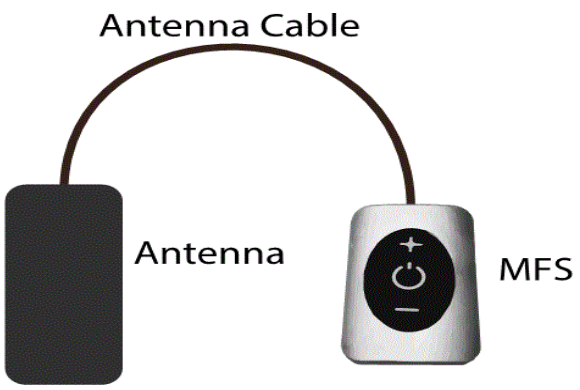

Figure 2: External pulse generator

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