

## Review Article

# Implantable Pulse Generators in Spinal Cord Stimulation Therapy: The Burden of Costs of Complications Compared to Wireless Technology

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Submitted: 21 September 2018

Accepted: 09 November 2018

Published: 12 November 2018

ISSN: 2333-6641

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## Keywords

- Spinal cord stimulation
- Implantable power generator
- Costs
- Wireless

## Abstract

**Background:** Spinal cord stimulation (SCS) has been a time tested and cost-effective treatment to manage intractable chronic pain syndromes following spinal surgery, peripheral neuropathy, complex regional pain syndromes and others. However, the surgically implantable nature of all the components of SCS not only increases the surgical complications but the costs associated with the device also. Recent advancements in wireless technology appear to reduce these collateral burdens since the wireless device does not require an implantable pulse generator (IPG) or its connection cables.

**Material and results:** A review of the available literature on traditional SCS (TSCS) and costs incurred, revealed that cost of a nonrechargeable battery was USD 13,150 (CSD 10,591; UK £ 7,243) in 2006 while a rechargeable battery had cost USD 20,858. Maintenance costs for the SCS equipment included a battery change every 4 years, on an average costing USD 3,539. IPG replacement involved expenses of CAD 5,071. A wireless device (Stimwave) is devoid of IPG costs and required 3-year maintenance costs of 1,500 Euros only.

Additionally, the wireless SCS (WSCS) is effective and without the complications of IPG which include pocket area pain, hematoma (in nearly 10% patients) and infection that accounts for 50% of infections following SCS implantation. Bench data had shown that a gluteal IPG location could produce nearly 9 cm of a thoracic lead displacement following spine motion in flexion, extension and rotation. Management of IPG complications costs additional health care budget, while with wireless SCS, this could be an avoidable expenditure. WSCS has been reported to be as effective as TSCS in patients with chronic pain following back surgery, herpes infection and complex regional pain syndrome in case illustrations.

**Conclusions:** SCS has been an effective tool in chronic pain management. Traditional equipment includes an IPG cost between 13,000 and 20,000USD with a maintenance expense of 3,539 USD over 4 years (for battery change). On the other hand, wireless SCS had been reported to have nearly half of this maintenance cost for SCS therapy and without IPG costs and complications. Further clinical studies might indicate IPG expenditure as a redundant and unnecessary cost.

## INTRODUCTION

IPG, an integral component of all TSCS systems at present, underwent several modifications over the recent past to improve its life expectancy, reduce costs over a period of time and decrease the size of the battery. Yet, as an implant, it carries associated morbidity as well as expenditure for reimplantation or removal (for failures of stimulation, infection and other reasons).

End of Life (EoL) of an IPG has been about 48 months as described by Budd, Kumar et al., and Van Buyten [1-3], as a measure of cost effectiveness as well as performance. Budd reported on fewer patients with 18 months follow up. Considering the best figures, it was 49 months, while Kumar et al., had an estimate of 48 months in a follow up study of 104 patients [2], and just 27.9 months in the 5-year experience of Van Buyten [3], with 61 patients (32 of them required IPG replacement during this time). Mean battery life of a nonrechargeable battery was

reported as 49 months (3 to 6 years range) by Taylor et al. [4]. Both life span and complications of IPG play vital roles in cost management of SCS since replacement due to EoL or infection of the battery are very expensive incidents during treatment.

## MATERIAL AND RESULTS

There has been limited literature published on the costs of SCS implantation and maintenance or the expenditure related to the battery failures, complications as well as failures. Table (1) shows the articles we have reviewed for relevant information about the IPG.

## IPG contribution to electrode migration and revision surgery

The implanted electrode gets stabilized and stays in place depending upon the strength of the anchor, while the spine motion, IPG tethering, elasticity of the surrounding tissues

alter the tensile load distributed on to the electrode. All these variables, with contributions from IPG, play significant role in the displacement of electrode [5]. IPG location coupled with spine motion affects the lead position via the connection cables and laboratory examination revealed a 9 cm displacement of electrode with flexion and extension movements of thoracic spine when the IPG is implanted in gluteal region. With an abdominal implantation such lead displacements occur to much less degree. Even with walking, 0.2 cm lead displacements occurred while twisting of the trunk produced 1.7 cm movement. IPG in gluteal region doubled the displacement compared to abdominal wall implantation [5,6].

Measures have been recommended to counter the IPG tether, like a strain loop, to reduce these movements until the scar tissue tethers the cables and other implanted material. Paddle electrodes in the cervical region have shown some promising results in reducing the displacement associated with normal cervical spine movements. Multichannel devices (quadripolar and octapolar) also reduced lead migration and revision surgery compared to simple bipolar electrodes [7,8].

To improve IPG performance nonrechargeable batteries got replaced by rechargeable batteries. Battery replacement is an integrated part of SCS therapy and the maximum number of SCS procedures over a patient's life time could be limited to 6; this includes the initial placement of SCS equipment followed by battery replacements [9].

### IPG: costs of rechargeable and nonrechargeable pulse generators

The initial cost of rechargeable IPG may be higher compared to the nonrechargeable and there is increasing trend to implant the former, which could be more expensive (CAD 10,591 or USD 10,988) at the initial implantation time [2,5]. This also implies the longer life span of the rechargeable IPG varying between 9 years and 5 years as quoted by the leading manufacturers. An overwhelming 10-25 years life span of the rechargeable IPG was reported by some manufacturers [9], and accordingly the maintenance costs differ for rechargeable one which requires 2-3 reimplantation procedures compared to 5-6 procedures for a non rechargeable system [9].

### Expenditure due to complications from hardware

Displacements of electrodes occur for several reasons, but loss of stimulation/therapy requires surgical revision. This displacement is twice more often seen in cervical region due to its normal range of motion being more than that of thoracic

region. Revision was required in 11.3% patients followed up for 10 years in the experience of Kumar et al, who also stated that the rates of surgical revision came down in recent years [10]. They also found correlation between the IPG implantation site and lead displacement; abdominal wall IPG had less incidence compared to gluteal IPG (10% and 21% respectively) supporting the bench data reported earlier [5,6]. In addition, pain over the IPG surgical site or rotation of IPG required repositioning of the IPG [6,10]. IPG related pain was reported in 9 to 11.8% cases [11-13], necessitating redo surgery to relocate the battery in some of these patients as their symptoms worsened. Quigley et al., had 11.8% revision rate for IPG [12].

IPG Battery Failure is an adverse event, especially when it occurs before EoL requiring replacement and had 1.5% incidence in a 20-year literature review by Cameron [11]. Based on average estimates of battery life from Kumar et al., and Van Buyten [2,3], IPG lasted for 50 months (usually before 5 years) and most cases needed replacement. Laboratory calculations based on engineering testing for low to high stimulation parameters came up with a functional battery life (Precision IDE clinical study) for rechargeable generator as 25 years or as low as 10 years [14]. However, total explanation of SCS after battery depletion is reported in 1.2% of cases [15], and the chances of complete implant removal was enhanced by the chances of SCS removal due to IPG depletion (10.9% vs 11.1%).

### Maintenance costs

The annual maintenance costs of SCS were CAD 3539 and USD 5071 for uncomplicated cases. Since the nonrechargeable IPG needed replacement after 4 years, the costs for battery and maintenance were calculated for 4 years [5].

Follow up costs for SCS after implantation have been published [15,16] although the trial failures were not included or the costs after explantation. Minor complications had cost around USD 350. However, there was no mortality attributed to any of these SCS complications, specifically compared to age adjusted general population [17].

### Infection and IPG

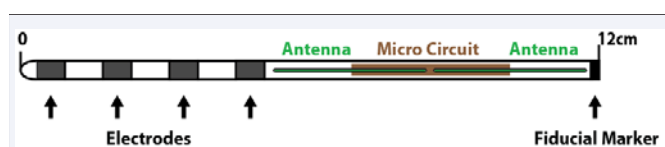
Following SCS implantation, infection is reported to occur in approximately 5% patients on average [5,10-12,18]. Of importance here is the fact that most infections are in or around the IPG. Kumar et al., reported that among 7 infections following SCS, 4 (57%) occurred at the IPG site and one along the connectors [5]. Most common sites for infection were IPG pocket, connector cord tract and lumbar incision, according to Follett et al. [18], and

**Table 1:** Literature on the costs of TSCS.

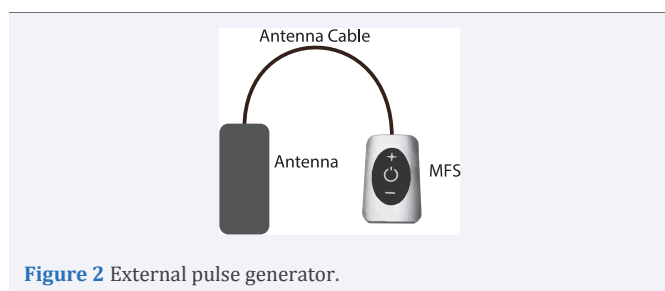
S. No	Author	Journal	Year	N of patients	Cost
1	Manca et al.,	Europeal J Pain	2008	52	CAD 19,486, Euro 12,653
2	Kumar et al.,	J Neurosurg spine	2006	160	CAD 23,205
3	Kumar & Bishop -do---		2009	197	CAD 21,595, USD 32,882
4	Hornberger et al.,	Clin J pain	2008	NA	USD 26,005 (Nonrechargeable), USD 35,109 (Rechargeable)
5	Babu et al.,	Neuromodulation	2013	4536	USD 30,200 (Percutaneous) USD 29,963 (Paddle electrodes)

**Table 2:** IPG costs and complications.

Parameters	SCS with IPG	SCS without IPG (Wireless)
	USD 13,150	None (there is no IPG)
Cost of Battery	CSD 10,591	
	UK £ 7,243	
(Rechargeable USD 20,858)		
Maintenance of SCS (4 years)	USD 3,539	1500 € (3 years) *
(Includes IPG replacement)	CAD 5,071	
IPG Complications		
IPG pain	1-12%	No IPG
Infection	50% of SCS infection	No IPG
Rotation	1-2%	No IPG
Premature Failure	2%	None <sup>(20-22)</sup>
Lead displacements *Stimwave	9 cm with gluteal IPG	None <sup>(20-22)</sup>



**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.

82% of the cases required explanation [5].

Miscellaneous adverse events reported due to IPG and connectors include, pocket pain in 0.9 to 11.8% [5,11] and revision surgery to relocate the battery was indicated in some cases. The connector site also becomes symptomatic in terms of wound pain and irritation in thin built patients and in an occasional patient there might be body fluid leakage leading to electric short circuits, burning pain and subsequently surgical revision [12]. In rare occasions, rotation of IPG occurs necessitating surgical intervention [5,6]. Literature reported incidence of hematoma in nearly 10% patients [11,13] and a subcutaneous hematoma required aspiration in 4.9% cases [6] For management of this complication Kumar and Bishop reported a cost of 136 CAD or 381 USD [6].

## DISCUSSION

There is enough evidence to support the therapeutic efficacy of SCS in many chronic pain syndromes and the technology has evolved to improve patient comfort and outcomes. In the present-day scenario, where medical audits scrutinize the health care expenditure thoroughly, there are several areas that demand attention to reduce costs with improved safety.

Table 2 shows the costs incurred by the IPG component in traditional SCS therapy and the reported incidence of complications. In view of the recent advancements in wireless technology which offers equal efficacy, it is time to review the available options.

## Wireless PNS (WPNS) technology

The WSCS requires only implantation of the electrode that has an in-built receiver and is devoid of implantable power source (an accessory like IPG) or the additional surgeries to place lengthy connector wires. This could make the procedure a minimally invasive with minimal anesthesia care and health care resource expenses [19-22]. Additionally, in case of revision, the surgical procedure would be far less invasive since the single implanted electrode does not carry connectors and the IPG. Thus, the tethering effects of both connectors and IPG are eliminated in the therapy [19]. The implant utilized nanotechnology to provide wireless access to the outside pulse generator (Figure 1) and with the advanced wireless technology; it is fully programmable with a wide spectrum of frequency between zero and 10,000 Hz.

WSCS has been reported so far in several case reports and demonstrated safety and feasibility in the treatment of chronic pain disorders following failed back surgery, herpes infection and complex regional pain syndrome WPNS had demonstrated safety and feasibility in earlier reports and wireless technology yielded results comparable to the traditional implantable SCS equipment in several previous reports [20-22]. In one-year follow-up so far, the patient with CRPS [22] did not require any revisions or replacements. Patient did not make any unscheduled visits or emergency calls during this time for stimulation failure or device related issues (Unpublished data). Further larger scale studies in multicenter randomized patient populations are being conducted to establish the consistency and durability of this technology.

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#### Cite this article

Perryman LT (2018) Implantable Pulse Generators in Spinal Cord Stimulation Therapy: The Burden of Costs of Complications Compared to Wireless Technology. *Int J Clin Anesthesiol* 6(2): 1093.