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Cost-Effectiveness Model Shows Superiority of Wireless Spinal Cord Stimulation Implantation Without a Separate Trial.

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Cost-Effectiveness Model Shows Superiority of Wireless Spinal Cord Stimulation Implantation Without a Separate Trial

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Objective: We evaluated the cost-effectiveness of wireless spinal cord stimulation (Wireless SCS) with single stage "direct to permanent" implantation vs. screening with temporary electrodes and an external pulse generator followed by implantation of a system for long-term use (IPG SCS).

Materials and Methods: We created a cost model that takes a 2019 United States (U.S.) payer perspective and is based on IPG SCS cost models for subjects with chronic back and/or leg pain. Our six-month decision tree includes the screening trial period (success ≥50% relief) and leads to various levels of pain relief with or without complications for IPG SCS and Wireless SCS and without complications for conventional medical management (CMM). Every three months in the follow-on 15-year Markov model (with costs and quality-adjusted life years discounted 3.5% annually), subjects remain stable or transition to deteriorated health or death. Subjects who fail SCS receive CMM. After 60 Markov cycles, a 100,000-sample simulation reveals the impact of maximum willingness-to-pay (WTP) from $10,000 to $100,000 per quality-adjusted life year on net monetary benefit (NMB). Sensitivity analyses considered the impact of the Wireless SCS screening success rate, Wireless SCS device cost, and IPG SCS device longevity.

Results: Compared with IPG SCS, Wireless SCS offers higher clinical effectiveness at a lower cost and a higher NMB for our WTP thresholds and is, thus, dominant. Wireless SCS is also cost-effective compared with CMM. Results remain robust with 1) Wireless SCS screening success rates as low as 85% (dominant), 2) the cost of the Wireless SCS devices as high as $55,000 (cost-effective), and 3) IPG SCS devices lasting 12 years (dominant).

Conclusions: In this model, compared with IPG SCS or with CMM, Wireless SCS is a superior strategy.

Keywords: Cost-effectiveness, modeling study, SCS health economics, spinal cord stimulation, wireless SCS

Conflict of Interest: The nonprofit Neuromodulation Foundation which employs Ms. Shipley, and of which Dr. North is an unpaid officer, has received grants and/or consulting income from Abbott (formerly St. Jude), Boston Scientific, Medtronic, Nevro, Nuvectra, and Stimwave. Dr. North has received royalties from Abbott and Nuvectra and consulting income from Nuvectra and Stimwave; his spouse has equity in Stimwave. Drs. Parihar and Spencer are consultants to TAMM Net, which has a contractual agreement with Stimwave. Mr. Spalding is the owner of TAMM Net.

INTRODUCTION

In the United States (U.S.), where spinal cord stimulation (SCS) is indicated as a treatment for chronic pain of the trunk and limbs, almost all public and private health insurance plans covering the therapy require that a patient achieve at least 50% pain relief during a screening trial with temporary electrodes before receiving an implanted pulse generator for long-term use (IPG SCS). Several clinicians have questioned the prognostic value of discrete SCS screening trials (1–4), but few have examined their impact on the cost-effectiveness of SCS therapy (1,5), even though this is obviously a primary goal of the screening trial with temporary electrodes, which is substantially less expensive than implanting an SCS system for long-term use.

The attendant risk of infection with a screening strategy that requires a percutaneous extension to an external pulse generator has deterred U.S. clinicians from extending the trial beyond approximately one week. New technology (Wireless SCS),

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however, facilitates single-stage complete implantation of an SCS system (Freedom-8A SCS System, Stimwave®, Pompano Beach, FL, USA) that is meant to remain *in situ* after a screening period that can be extended as long as necessary to enhance effectiveness by trying various stimulation parameters.

Given that the Wireless SCS system does not require a second procedure to insert additional components in an operating room, it is immediately apparent that Wireless SCS should be more cost-effective than IPG SCS. To test this hypothesis, we developed an economic model incorporating the clinical effectiveness data now available for Wireless SCS (6).

METHODS

To ensure that our results are congruent with those of other SCS cost-effectiveness studies (7–10), we adopted the assumptions and the decision analytic model popularly used for such analyses.

Perspective and Setting

We conducted this analysis from the perspective of a U.S health-care payer.

Description of Model Population

Our model population comprises 50% males and 50% females at least 40 years of age with back or back and leg pain refractory to medical management for at least 12 months after receiving a diagnosis of failed back surgery syndrome (FBSS). Every SCS patient undergoes a screening trial, either with Wireless SCS or with IPG SCS.

Description of the Economic Model

We based our work on a decision analytic/Markov model published in 2008 as part of the United Kingdom's National Institute for Health and Clinical Excellence (NICE) health technology assessment of the cost-effectiveness of a IPG SCS system (10). The platform for our model is TreeAge Pro 2018, R2 (11).

Our decision tree (Fig. 1) has three main branches: one begins with a Wireless SCS screening trial, the second with an IPG SCS screening trial, and the third with conventional medical management (CMM). The comparison of Wireless SCS and IPG SCS allows us to evaluate the cost-effectiveness of one treatment strategy vs. the other. The comparison with CMM validates our model against previously published studies (7–10) and quantifies the cost-effectiveness of the SCS strategies vs. CMM.

The decision tree represents the therapeutic outcomes during the first six months of treatment, which includes the SCS screening trial. A patient achieves SCS screening trial success by reporting at least 50% reduction in pain from baseline on a pain rating scale. Patients who fail the screening trial move to CMM as do those who fail longer-term treatment. Figure 1 illustrates the pathways that lead to the possible health states for each branch at the end of the decision tree period, and Table 1 displays the assumed trial success rate, complication rate during the decision tree period, and probability of leaving the decision tree in a specific health state (6,9,12).

During the decision tree period, we assume the following:

- IPG SCS patients receive two eight-contact electrodes, placed percutaneously with an external segment of the lead fixed to the skin.
- Wireless SCS patients receive two eight-contact electrodes anchored percutaneously and tunneled to a nearby subcutaneous receiver, with no emerging percutaneous component.

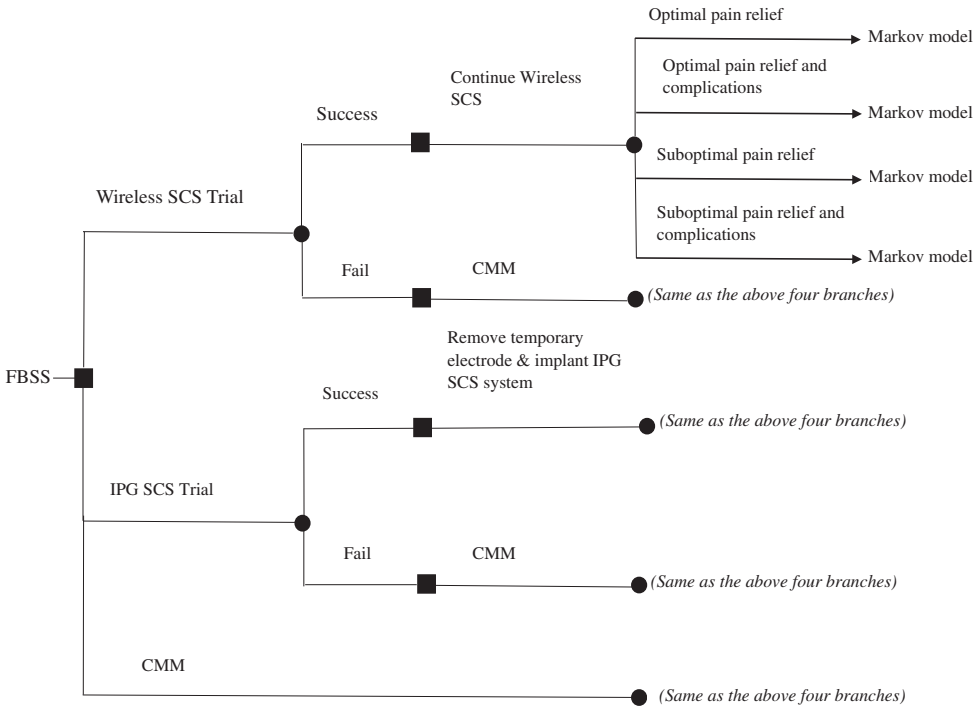

Figure 1. The first six months of treatment are represented by a decision tree that illustrates pathways to potential outcomes for patients receiving IPG SCS, Wireless SCS, or CMM alone. Success and optimal pain relief are defined as >50% pain reduction from baseline on a pain rating scale; suboptimal pain relief is more than zero and <50% pain reduction.

Table 1. Decision Tree Probabilities (%).

	Wireless SCS*	IPG SCS†	CMM‡
Trial success rate	92.0	86.7	N/A
Primary endpoint optimal pain relief	76.0	73.7	9.1
Complication rate§	15.7	15.7	0
Optimal pain relief no complications	64.1	62.1	9.1
Optimal pain relief with complications	11.9	11.6	N/A
Suboptimal pain relief no complications¶	20.2	22.2	90.9
Suboptimal pain relief with complications	3.8	4.1	N/A

*Wireless SCS pain relief from Bolash et al. Figures 6 and 7 (6).
†IPG SCS pain relief from Van Buyten et al. (12).
‡CMM from Annemans et al. (9).
§SCS complication rate from Van Buyten et al. (12). Multiplying this rate by the rate of optimal pain relief yields optimal pain relief with complications and subtracting this product from optimal pain relief yields optimal pain relief without complications.
¶Suboptimal pain relief is 100% minus optimal pain relief, with the breakdown for with/without complications calculated as for optimal pain relief.

- After the screening trial, the electrodes are removed from all IPG SCS patients, and those who had a successful trial receive two new percutaneous electrodes tunneled to an IPG for long-term use. In patients receiving Wireless SCS, the system implanted during the screening period remains *in situ* for long-term use.
- All Wireless SCS and IPG SCS patients who fail the screening trial receive CMM.
- Recovery from a complication will not affect the outcome; that is, the patient stays in the same health state "with complications."
- All patients survive.

Following the decision tree period, our patients progress through a Markov model (Fig. 2) that has a 15-year time horizon with three-month cycles. At the end of each cycle, patients either (1) die, (2) remain in a state of optimal or suboptimal pain relief, or (3) transition to a worse state. Table 2 presents the annual transition probabilities (7). SCS patients with no pain relief transition to CMM and experience optimal, suboptimal, or no pain relief with that treatment. We assume an annual complication rate during the Markov period of 18% for each SCS strategy (12) (with the conservative assumption that this rate does not decrease over time) and zero for CMM (7,9), an annual mortality rate of 0.94% (7), IPG SCS device longevity of nine years (13), and Wireless SCS external transmitter longevity of nine years.

Table 2. Annual Probability of Transitioning Between Health States During the Markov Model Period.*

	Wireless SCS	IPG SCS	CMM
Optimal to no pain relief	0.0324	0.0324	0
Suboptimal to no pain relief	0.0324	0.0324	0
Optimal to suboptimal pain relief	0	0	0
Mortality rate	0.0094	0.0094	0.0094

*Source is Simpson et al., in their table 30 (7).

Cost Data

All costs (Table 3) are in U.S dollars. The costs for IPG SCS and CMM are from a published report (9), and the costs for Wireless SCS are from the manufacturer and insurance reimbursement records. We conservatively assume no complication costs associated with CMM (7,9). All costs were converted to U.S dollars using the federal reserve exchange rate (14).

Utility Values

Utility values range from 1 representing perfect health to 0 representing death (e.g., 0.168 means that one year with no pain relief equals 16.8% of a year in perfect health). We use utility values published by Simpson et al. (7) and adopted by Taylor et al. (8) and Annemans et al. (9) to quantify the quality of life associated with each health state (Table 4).

Discounting During the Markov Model Period

After the first year in the Markov model, we discount costs and quality-adjusted life years (QALYs) at an annual rate of 3.5% (7–9).

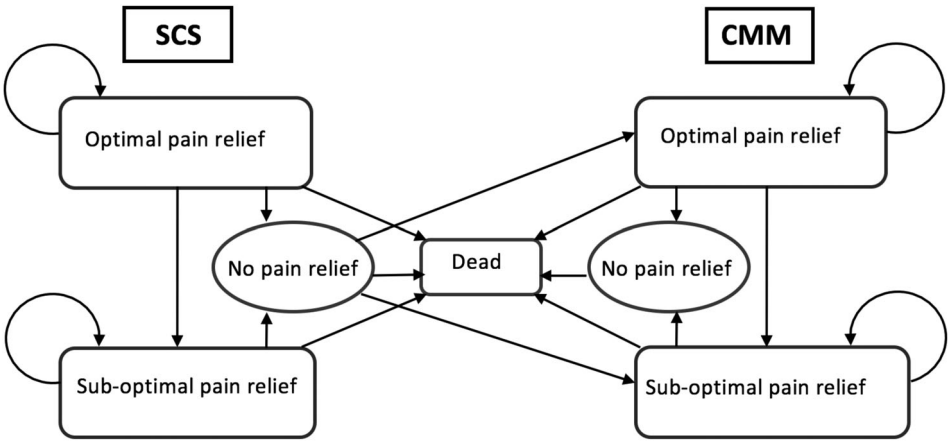

Figure 2. The 15 years following the decision tree period are represented by a Markov model. The definitions of optimal (> 50% reduction from baseline) and suboptimal (< 50% reduction) pain relief remain the same, as does the progression of SCS failure to CMM.

Table 3. Cost Inputs.*

	Base case value ($)
IPG SCS trial with two percutaneous electrode arrays	6,421
Wireless SCS implant for trial and potential long-term use	26,757
Removal of temporary electrodes after failed IPG SCS trial	0
Removal of Wireless SCS component after failed trial†	0
Implant of IPG SCS system for long-term use	26,757
IPG SCS replacement after complication	26,757
SCS follow-up after six months (annual)	13,649
Wireless SCS external transmitter replacement	4,501
IPG SCS complication	1,057‡
Wireless SCS complication	1,057‡
CMM first six months§	5,897
CMM after six months (annual)§	11,794
CMM complication (conservative assumption)	0

*These costs represent reimbursements; thus, means and SDs are not appropriate.
†Simpson et al. (7) report a cost of 1800 £ to remove a trial electrode; but as indicated here, removal of percutaneous trial electrodes is not reimbursable in the United States.
‡Converted into 2019 U.S. dollars from the report by Annemans et al. (9) of 622 £ based on Simpson et al. (7).
§Annemans et al. (9).

Table 4. Utilities.*

Perfect health	1
Optimal pain relief without complication	0.598
Optimal pain relief with complication	0.528
Suboptimal pain relief with or without a complication	0.258
No pain relief	0.168
Dead	0

*First reported by Simpson et al. (7); subsequently adopted by others (8,9).

Determining Cost Effectiveness

The difference in the cost of the therapies (incremental cost) divided by the difference in QALYs generated from 60 Markov cycles (four cycles per year for 15 years) yields the incremental cost-effectiveness ratio (ICER).

Determining Net Monetary Benefit

A Monte Carlo simulation with 100,000 samples was performed for the Markov cohort analysis. In addition to the ICERs, the analysis generated the cost-effectiveness scatterplots and revealed the impact of willingness-to-pay (WTP) per QALY on net monetary benefit (NMB) (15,16).

Table 5. Cost Effectiveness.

	Wireless SCS	IPG SCS	CMM
Cost ($)	184,206	204,092	140,656
Effectiveness	5.19	5.01	3.14
NMB($) (WTP $50,000)	75,371	46,485	16,211

NMB, net monetary benefit, summarizes the value of an intervention in monetary terms when a WTP, willingness-to-pay, threshold per unit of benefit is known. NMB is calculated as (effectiveness × WTP threshold) – incremental cost (NMB reported here reflects calculation without rounding-off). A higher NMB represents a more cost-effective strategy at the same WTP.

Table 6. Incremental Cost-effectiveness.

	Wireless SCS vs. IPG SCS	Wireless SCS vs. CMM	IPG SCS vs. CMM
Incremental cost ($)	−19,886	43,549	63,435
Incremental effectiveness	0.180	2.05	1.87
ICER ($)	Dominant	21,200	33,847
INMB ($)	28,886	59,160	30,274

ICER, incremental cost-effectiveness ratio; INMB, incremental net monetary benefit, which can be calculated as: $INMB_{C-B} = NMB_C - NMB_B$, where C refers to a comparator (Wireless SCS) and B refers to the baseline (IPG SCS).

Analyzing Sensitivity

With deterministic sensitivity analyses, we vary three factors that might have an impact on cost-effectiveness: (1) the Wireless SCS screening success rate from 85 to 100% (the base case is 92%), (2) the Wireless SCS device cost from $15,000 to $55,000 (approximately twice the base cost of $26,757), and (3) the nine-year base IPG replacement for IPG SCS from two to 12 years.

RESULTS

In our model, Wireless SCS results in higher clinical effectiveness at a lower cost when compared with IPG SCS. As represented in Table 5, Wireless SCS also offers a higher NMB compared with IPG SCS. Wireless SCS generates a negative ICER and is a dominant strategy compared with IPG SCS (Table 6).

Figure 3 displays the cost-effectiveness of the three strategies and shows that Wireless SCS dominates IPG SCS. Our finding that both SCS strategies are cost-effective vs. CMM confirms outcomes reported in previous SCS cost models (e.g., refs. 8,9).

Wireless SCS also has a higher NMB compared with IPG SCS in the range of WTP thresholds from $10,000 to $100,000 per QALY, indicating that Wireless SCS provides the best value for money spent (Fig. 4). At the WTP threshold of $50,000, for example, Wireless SCS provides a NMB of $68,488 vs. $38,458 for IPG SCS. When the WTP increases to $100,000, Wireless SCS provides a NMB of $328,065 vs. $289,035 for IPG SCS.

Sensitivity Analyses

Table 7 lists the parameters and results of deterministic sensitivity analyses of three variables considered to have an impact on SCS cost: (1) the trial success rate, (2) device cost, and (3) IPG battery life. The incremental net monetary benefit (INMB) of Wireless SCS vs. IPG SCS is positive (in other words, Wireless SCS is cost-effective) over the complete range of parameters in the sensitivity analyses (Figs. 5–8). The INMB tornado diagram (Fig. 5) illustrates the impact on the INMB associated with Wireless SCS vs. IPG SCS when assumptions about variables change. Figure 5, thus, presents the relative cost-effectiveness of these two strategies.

In terms of the ICER, Wireless SCS vs. IPG SCS remains a dominant strategy when the Wireless SCS trial success rate stays at or above 84%, which is below the IPG SCS trial success rate of

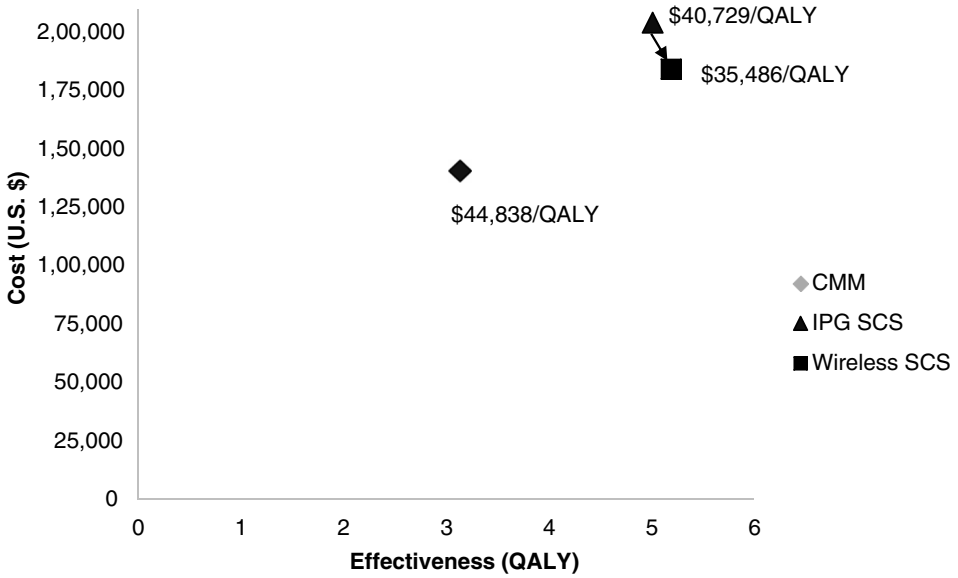

Figure 3. Cost-effectiveness graph showing that Wireless SCS is dominant compared with IPG SCS and that both SCS therapies provide a lower cost/QALY versus CMM.

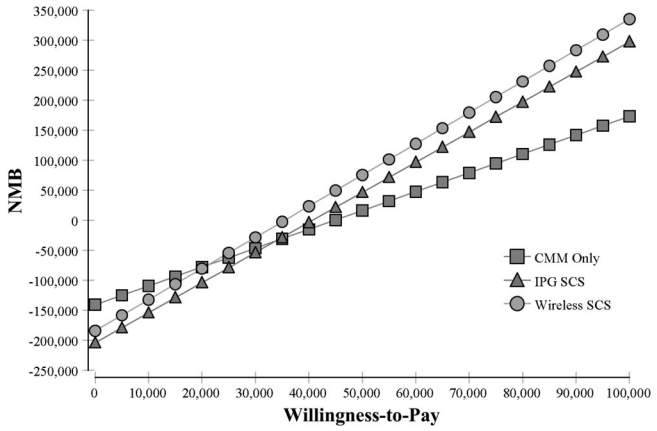

Figure 4. Net monetary benefit (NMB) versus willingness to pay (WTP).

86.7%. When the cost of Wireless SCS is varied from $15,000 to $55,000, the result is either dominant or cost-effective. When the cost range is between $15,000 and $48,334, Wireless SCS dominates IPG SCS. When the cost is in the range of $48,334 to $55,000, Wireless SCS is cost-effective vs. IPG SCS, as the ICER is positive but below the WTP threshold of $50,000 (the maximum ICER value is $40,074 when the cost of Wireless SCS is $55,000). Wireless SCS remains dominant through all variations of the IPG replacement interval (2–12 years).

DISCUSSION

Our economic analysis shows that, from the U.S. payer perspective, a single-stage procedure with Wireless SCS is more cost-effective than the current longstanding practice of conducting an SCS screening trial with temporary electrodes followed in successful cases by implantation of new electrodes and an IPG. This practice was motivated by a desire to improve cost-effectiveness; thus, a short review of the history of SCS screening trials will add context to our findings.

SCS screening trials using minimally invasive percutaneous electrodes were introduced in the mid-1970's (17,18). By 1979, in an obvious attempt to avoid the expense and morbidity of implantation of a complete SCS system in nonresponders, the U.S. Department of Health and Human Services required demonstration of pain relief during a screening trial as a condition of reimbursement by Medicare for SCS permanent systems. This health economic rationale has driven the policy of almost all payers ever since, making SCS a two-stage procedure in the U.S.

Table 7. Deterministic Sensitivity Analyses Parameters and Results.

	Wireless SCS trial success rate %	INMB $	Wireless SCS device and health-care service reimbursement $	INMB $	Years before IPG replacement and health-care service reimbursement	INMB $
Low value	85	22,058	15,000	40,643	2	26,399
Base case	92	28,886	26,757	28,886	9	28,886
High value	100	36,592	55,000	3,643	12	140,395

INMB, incremental net monetary benefit.

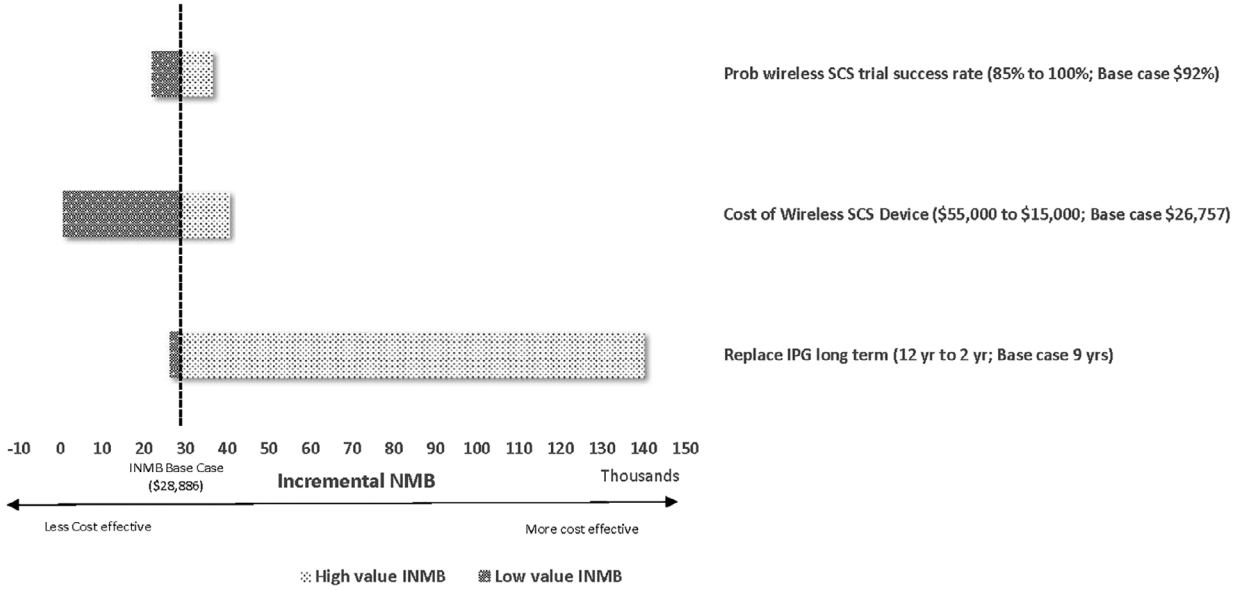

Figure 5. Tornado diagram representing one-way sensitivity analyses showing the impacton the INMB associated with Wireless SCS when assumptions are varied.

Because an indwelling trial electrode with a percutaneous extension connecting the electrode to an external pulse generator carries a risk of infection, SCS screening trials are limited in duration. In contrast, Wireless SCS technology that has been available since 2015 allows the electrodes, supporting electronics, and a receiver to be placed in a minimally invasive fashion initially, enabling a single-stage, "direct-to-permanent" implantation (19) and offering the opportunity to redefine SCS trials (20). Such single-stage SCS implantation allows the "trial" to continue for a extended period, months if needed, for example, to try a new waveform or combination of waveforms to optimize pain relief.

This redefinition is welcome because clinicians have long questioned the validity and utility of SCS screening trials. First, such trials should have high sensitivity so as not to deny treatment to those who would benefit (false negatives). Oakley et al., for example, reported long-term success in at least a third of a small group of patients who received an implanted SCS system for chronic use despite having failed their screening trials (3). Second, screening trials should have high specificity to avoid the costs of equipment and morbidity of implantation in patients who will fail before achieving useful results (false positives). SCS failures soon after implantation remain common notwithstanding successful trials. Accordingly, for many years, some clinicians have advocated single-stage implantation of IPG SCS systems after "on-table trials" conducted intraoperatively, accepting the high initial cost and reasoning that their observed success rates are sufficiently high that neither the additional expense nor the potential morbidity of staged procedures is justifiable (2,4).

To explore the cost consequences of requiring an SCS screening trial, Duarte and Thomson created a decision analytic model applicable to the United Kingdom's National Health Service (NHS) (5). This model showed that in cases when the potential IPG

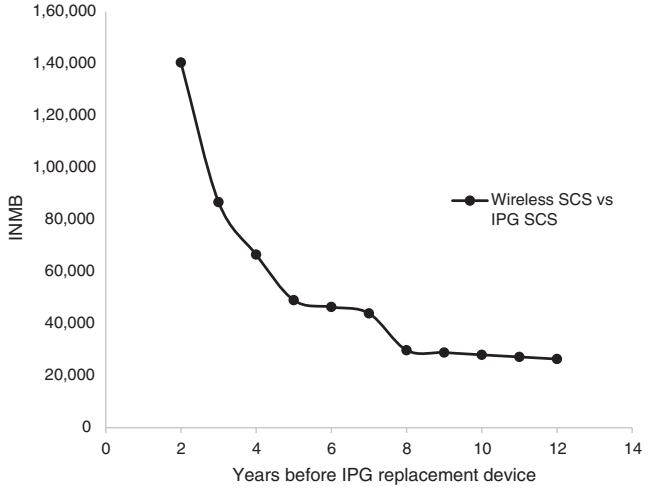

Figure 6. One-way sensitivity analysis of IPG replacement in years.

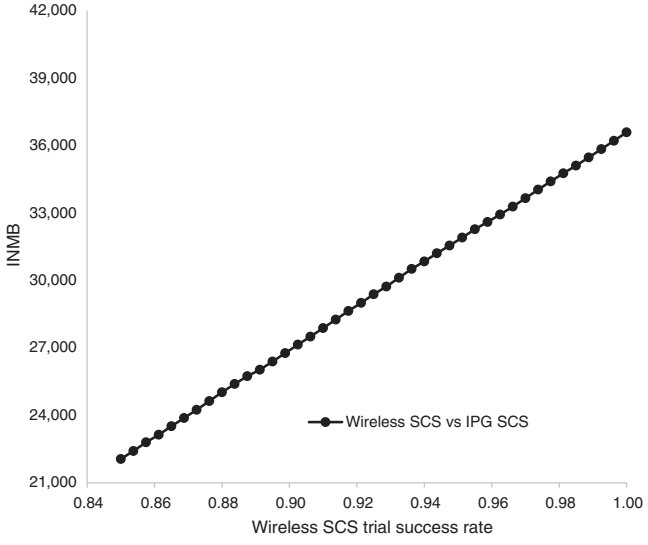

Figure 7. One-way sensitivity analysis of Wireless SCS trial success (%).

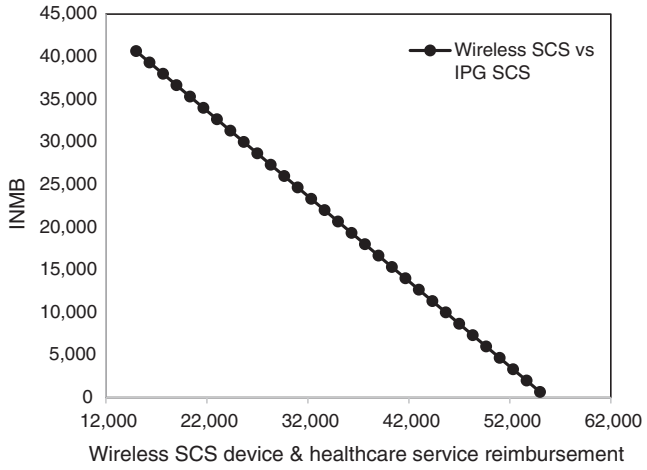

Figure 8. One-way sensitivity analysis of the cost of the Wireless SCS device.

would be nonrechargeable, screening trials that ruled out more than 45% of patients with the least expensive and 15% with the most expensive equipment would reduce costs. For rechargeable generators, the failure rates that would justify a trial would be 26% with the least expensive and 15% with the most expensive equipment. Had the model included the additional expense of implanting new electrode(s) after the trial, as is usual in the United States, the trial failure rates required to produce a positive financial impact for the NHS would have been lower. In other words, the more costly the second stage of SCS, the higher the screening trial success rate needed to justify the expense of the trial.

Our Wireless SCS trial success rate was only slightly higher than the IPG SCS success rate. Even if the success rate had been the same or lower for Wireless SCS, however, the cost consequences of using the Wireless system would remain favorable compared with IPG SCS because, with Wireless SCS, the expense of the screening trial is absorbed in that of chronic treatment.

An additional long-term cost advantage of using the Wireless SCS system accrues because its transmitter is external, making replacement an easy matter without the cost and potential morbidity associated with the surgical procedure needed to replace an IPG. When SCS was introduced in the 1960s, externally powered "radio-frequency" (RF) systems, which had this advantage, were the only systems available. Despite the eventual development of implanted generaters powered by primary cell batteries, some clinicians continued to use RF systems as long as they remained available (until the advent of rechargeable IPGs) (21). Whereas IPGs with rechargeable batteries are considered more cost-effective than devices powered by primary cell batteries, rechargeable batteries also lose capacity as they age and need to be replaced. Indeed, some manufacturers have deliberately limited the lifespan of rechargeable IPGs (13).

Wireless SCS technology, thus, changes the economic model that has driven clinical practice by offering substantial long-term cost savings.

Strengths and Limitations of Our Model and Its Inputs

In the absence of data from a head-to-head comparative study of Wireless SCS and IPG SCS, we derived the clinical data on Wireless SCS from the high-frequency arm of an RCT (6) in which patients with a Wireless SCS system were assigned to high- or low-frequency stimulation, with no opportunity to cross over and receive the other waveform. If the clinical study had allowed crossover, as would be expected in practice, the overall clinical study results, as well as the results in the high frequency arm, might have been more favorable.

For the sake of consistency and comparability, we used strategies (assumptions and model inputs, including the discount rate, death rate, utility values assigned to health states, and the probability of transitioning from one health state to another) from previously published SCS cost modeling studies (7–9). Thus, we inherited any associated limitations, errors, and biases, including a zero probability of transitioning from optimal to suboptimal pain relief with SCS during the Markov period (Table 2). This value, which has been incorporated in models since 2009 (7), means that SCS patients can transition only from optimal SCS to no pain relief (and thence on to CMM) or to death. As is customary, although its probability is zero, our Markov model schematic nevertheless shows the pathway that an SCS subject should be able to travel from optimal to suboptimal pain relief (Fig. 2).

As was the case in all of these studies, for example, our model falls well short of representing clinical experience by failing to permit the possibility of recovering from a complication (in contrast, see van der Wilt et al. (22) for an example of a cost modeling study in sacral neuromodulation that takes such recovery into account and the cost-utility analysis of sacral anterior root stimulation by Morlière et al. (23) that integrates "reversible conditions," such as device failure, into its "irreversible states.")

Annemans et al. (9) describe the utility scores we adopted for this study, which were first published in 2009 (10) and which they (9) and Taylor et al. (8) used in their studies, as "conservative" because in 2009 SCS equipment did not permit high-frequency stimulation, which Annemans et al. believe has improved the effectiveness of SCS in treating low back pain.

Finally, we have made additional conservative assumptions and decisions that both strengthen and limit our model: we did not include the cost of system removal, even though that would be higher for IPG SCS; we perpetuate the wildly conservative assumption we inherited from previous models (7,9) that CMM results in zero complications with zero associated costs; and we assume that base-case device costs for permanent implantation are the same for Wireless SCS and IPG SCS, that complications occur with the same frequency and severity with either technology (despite the fact that the clinical study of Wireless SCS reported an infection rate of only 1% (6)), that device removals occur at the same rate (even though the bulk of an IPG might be a common reason for removal), that the replacement interval for the Wireless transmitter and the IPG are the same, and that a reasonable MWTP threshold is $50,000 per QALY (even though an MWTP threshold of greater than $100,000 is now accepted (15,16)).

Future Studies

Our model takes the payer perspective; thus, patient and societal perspectives, using actual costs instead of Medicare reimbursement rates, remain to be explored.

We chose to model the typical U.S. practice for IPG-SCS of using two temporary trial electrodes; two alternative protocols remain to be considered:

1. Placing electrodes for a trial in such a way that they can remain *in situ* for chronic use with an IPG, thus reducing the cost of the definitive implanted system. This is necessary in

any case requiring open surgical electrode placement (by laminotomy or laminectomy) and is common practice outside of the United States even with percutaneous electrodes. Failed trials under this protocol, of course, incur the additional expense of returning to the operating room to remove the anchors and electrodes, but if trial failures and infections (the risk of which increases with this approach) are infrequent, these costs can be more than offset by the savings in successful cases.
2. Comparing implantation of an entire IPG-SCS system in a single stage ("direct-to-permanent") with implantation of Wireless SCS.

In addition, future studies should allow health economists to update SCS model inputs and assumptions, including new utility scores based on updated quality of life data and improved transition probabilities and pathways that better reflect real-life clinical experience.

CONCLUSIONS

Our economic model shows that from the payer perspective, single-stage "direct-to-permanent" Wireless SCS implantation achieves "dominance," that is, superior results at the same or lower cost, vs. the current U.S. practice of conducting a screening trial with temporary electrodes, followed in successful cases by implantation of new electrodes and an IPG in a second stage. Wireless SCS remains more cost-effective than IPG SCS over clinically relevant ranges of key variables.

The results of our modeling study can be reproduced to test their accuracy, and we have presented our findings in a way that should be of practical use to decision-makers.

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Authorship Statement

Dr. North oversaw the study, providing critical insights that guided its development, and wrote text. Drs. Parihar and Spencer collected and evaluated data from the literature, designed the model, and analyzed the study data. Mr. Spalding provided input for the design of the model for its target audience as well as advice about the interpretation and presentation of the data, and contributed to the text. Ms. Shipley provided quality control over the coherence and display of the data, searched the literature for pertinent citations, and wrote text. All authors approved the version to be published.

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