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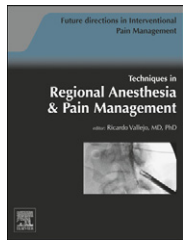

Injectable spinal cord stimulator system: Pilot study

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ABSTRACT

Spinal cord stimulation (SCS) is widely used for relief of chronic back and limb pain. However, numerous adverse events pose a hindrance to the widened acceptability of the treatment. A prospective, nonrandomized cohort study was conducted to compare the efficacy of a wirelessly powered SCS novel system with commercial SCS systems. Each of 12 patients were serially implanted with a Medtronic 1 × 8 SCS trial lead and a Stimwave Freedom trial lead for a 1-day evaluation. Patients were asked to report on pain relief, paresthesia coverage, paresthesia intensity, and paresthesia comfort. Ten of the 12 patients successfully underwent the trial whereas the remaining 2 procedures were terminated because of operating-equipment failures. Of the successful patients, all reported good pain relief and paresthesia for each device. The average pain reduction was reported as 80% for the Stimwave system and 66% for the Medtronic system. The average paresthesia coverage was 91% and 77%, respectfully. Differences in the averages reported by patients can be attributed to the fact that no randomization was designed in the study. The study showed that wirelessly powered, injectable SCS systems are just as effective as commercial products at relieving pain and at creating paresthesia coverage for patients who suffer from chronic back and limb pain and have the added advantages of shortened procedure time and elimination of open ports during the trial periods, as well as elimination of the need for tunneling and pocket creation for implantable pulse generators.

Introduction

Spinal cord stimulation (SCS) has been increasingly used since the 1970s and has become a powerful tool for the treatment of chronic pain.[1] Other regimes, such as physical therapy, nerve blocks, behavioral programs, and opioid drug regimes must be attempted before the use of SCS so as to fulfill insurance requirements[2-5] because of their efficacy rates and lower cost to implement. For patients who do not respond to alternative therapies, a percutaneously injectable wireless SCS would be a less invasive approach to administering pain management benefits.[6,7] Commercial SCS with implantable batteries are expensive to develop, test, and implant and often involve complex programming methods and increasingly invasive procedures.[4,8-10]

A wirelessly powered, injectable SCS addresses many current procedural problems by eliminating the implantable pulse generator (IPG) and relocating the functionality outside of the body. With this design, the procedure time is drastically reduced as there is no need for tunneling or IPG pocket surgery. Replacement surgeries also become a nonissue. The objective of this investigation was to ensure that wireless SCS (Figure 1) provides the same effective pain relief, paresthesia coverage, and intensity as commercial SCS in an acute setting.

Materials and methods

The primary efficacy end points were to compare the reported patient pain levels identified on body pain charts as well as

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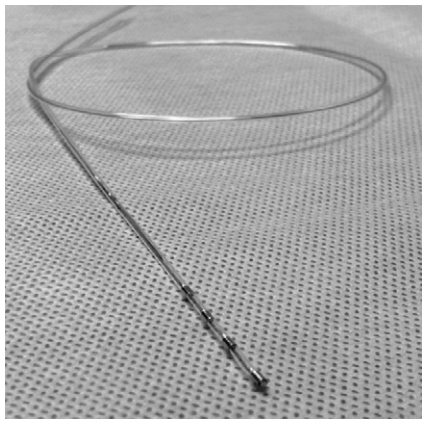

Fig. 1 – Stimwave Freedom SCS lead (standard model) that is implanted within the epidural space.

via a numerical visual analog scale (VAS) score from 0–10. Pain level was assessed before the procedure and after each placement. Paresthesia coverage was measured as the perceived overlap of paresthesia to the pain area. Paresthesia comfort was reported as a numerical value on a scale of 1–5 where a larger number correlated to comfortable and tolerable stimulation.

Twelve patients with failed back surgery syndrome were implanted serially with a Medtronic 3874 SCS trial lead (wired) and a Stimwave Freedom SCS lead (wireless), 1.3-cm diameter using 4 electrodes after recruitment, informed consent, and a physical and psychological examination. Both the wireless SCS leads and the commercial SCS wired leads were introduced percutaneously into the epidural space through 14-gauge Tuohy needles. The wired lead extended through the patient's skin. Functional verification to achieve the maximum amount of paresthesia coverage and pain relief was established. After explant and return of baseline VAS pain levels, the wireless lead was inserted into the same target location and powered from outside the patient's body. Electrode polarity, pulse width, and stimulation frequency were identical when stimulating with both systems. Stimulation parameters ranged from a frequency of 60–120 Hz at a consistent pulse width of 300 μs.

The therapy utilizes pulsed electrical current to stimulate nerves near the spinal cord to inhibit the transmission of pain signals. The wireless system consists of a lead that is placed in the epidural space and a portable, external device that transmits power wirelessly through the skin to a receiver embedded within the lead. The external power unit is programmable, to generate effective stimulation parameters including the waveform pulse shape, period, and duration; transmitted transcutaneously as an electromagnetic wave carrier. Two types of wireless leads were used, a standard model, with the receiver located near the distal end of the lead next to the stimulating electrodes, and a remote model, with the receiver located at the proximal end of the lead, buried just under the skin, as shown in Figure 2.

Results

Twelve patients with an average age of 55.3 years, 66% female, underwent the trial over the course of 4 weeks. All the patients who were implanted with a functional lead reported good paresthesia coverage and pain relief. Two patients experienced medical-equipment failures resulting in early procedure termination. All 10 successfully trialed patients reported sustained pain relief and paresthesia coverage of the primary pain area with both systems, as shown in Table 1. For the wired lead, the mean perception amplitude of intensity was 0.90 ± 0.18 V (range 0.3–2.2; $n = 10$) and comfort perception intensity was 2.30 ± 0.40 V (range 0.8-5.0). For the wireless lead, the mean perception amplitude of intensity was 1.12 ± 0.34 V (range 0.1-4.3; $n = 10$) and comfort perception intensity was 1.78 ± 0.46 V (range 0.5-5.9). The average pain reduction using VAS was 66% for the wired lead and 80% for the wireless lead. The average paresthesia coverage was 77% ± 10% for the wired lead and 91% ± 5% for wireless lead, for which the increase is attributed to a longer sustained time of treatment.

Discussion

In this study, 12 patients were screened and implanted with 2 comparable trial SCS leads and asked to report on pain relief, paresthesia coverage, and paresthesia comfort. The average relief reported for the wired lead was 66% (±28%) and 80% (±16%) for the wireless lead. A t-test was performed, which did not suggest that there was a significant difference in the average pain relief ($P > 0.05$). Any difference in reported pain relief is attributed to the acute nature of the study. Patients who are initially exposed to the stimulation typically require several days of stimulation to average out variations of demand for pulse stimulation; evaluating settings which are best throughout their daily activities. The wireless lead was

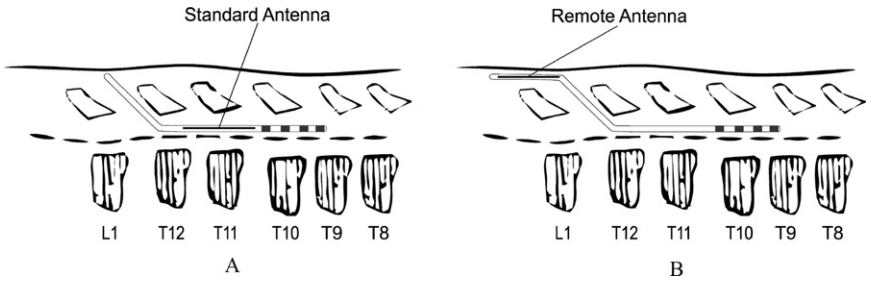

Fig. 2 – Diagram of the standard model (A) and the remote receiver model (B), where the black line indicates the location of the receiving antenna built into the lead body.

Table 1 – Patient reported VAS and coverage did not differ significantly between the Medtronic and Stimwave systems.

Case number	Diagnosis	Baseline VAS	Medtronic VAS	Stimwave VAS	Medtronic paresthesia coverage	Stimwave paresthesia coverage	Medtronic paresthesia comfort	Stimwave paresthesia comfort
1	FBS	10	4	NA[a]	NA[a]	NA[a]	NA	NA
2	FBS	10	0	0	100	100	4	4
3	Radicular	8	5	0	50	100	4	4
4	FBS	10	5	5	100	100	3	4
5	FBS	7	8	NA[b]	20	NA[b]	3	NA
6	Radicular	7	0	0	100	100	3	4
7	FBS	10	0	0	100	100	3	3
8	FBS	10	0	0	100	100	3	4
9	FBS	8	0	0	80	80	3	4
10	FBS	8	3	2	30	60	3	3
11	FBS	10	0	0	100	100	5	3
12	FBS	6	0	0	70	70	3	3

NA = not applicable, FBS = failed back surgery.
[a] Lead fractured in shipping and discovered in implant procedure.
[b] Fluoroscope malfunction, procedure aborted.

shown to be just as effective at creating paresthesia coverage and comfort as the wired system in this acute setting investigation. The average paresthesia coverage reported for the wired lead was 77% (±31%) and was 91% (±15%) for the wireless lead. A t-test was performed, which did not suggest that there was a significant difference in the paresthesia coverage generated ($P > 0.05$). With respect to paresthesia comfort, no significant distinctions could be made. After stimulating with the wired lead and soliciting feedback as to paresthesia coverage, corrections could then be made to steer the wireless lead to a better lateral position, yielding slightly better coverage for the secondarily implanted product.

The resulting voltages and power values for each system, as shown in Table 2, are not used as a comparison of the efficacy, but as verification that the resulting energy fields within the tissue were equivalent. The recorded power levels for the wireless lead were all lower than those for the wired lead, whereas the pulse width and pulse frequency were held constant between the two. The location of the electrode array along the spinal cord can play a role in the amount of energy required to generate nerve inhibition, and the wireless lead did have a distinct advantage with placement improvement being the later procedure. Lower power requirements for the wireless lead could be attributed to better lead placement. Figure 3A illustrates the placement of the external power unit over the patient's body and the location of the lead from the anterior-posterior view, and Figure 3B shows the distance between the external unit and a standard model wireless lead from the lateral view.

The transmit power of the external unit was also recorded for each patient after "strong but tolerable" stimulation was achieved. The range of power utilized was dependent upon the type of lead, either remote or standard. The difference in average powers used for the standard model and remote model is attributed to the depth of the receiver in the skin. The remote model has a receiver just under the skin near the proximal end of the lead, resulting in less tissue that the

Table 2 – Stimulation voltage and power measurements illustrating desired patient levels.

Case number	Wired lead voltage threshold—strong (Vdc)	Wireless lead voltage (Vdc)	Wireless lead transmit power threshold—strong (dBm)	Wireless lead
1	NA-5.0	NA	NA-NA	Remote
2	1.4-3.2	5.9[a]	42.5-45.7	Standard
3	0.6-0.8	0.5	24.0-26.7	Remote
4	0.3-0.8	1.5[a]	25.3-33.9	Standard
5	0.7-0.9	NA	NA-NA	Standard
6	0.5-3.2	2.7[a]	35.4-38.6	Standard
7	0.7-2.2	1.8	29.4-36.0	Remote
8	0.5-1.0	0.5	27.0-28.2	Remote
9	0.4-2.9	1.4	29.1-33.8	Standard
10	2.2-3.5	0.7	27.7-30.8	Remote
11	1.9-3.1	1.5	18.3-34.2	Standard
12	0.7-0.9	1.3[a]	32.8-NA	Standard

NA = not applicable.
[a] A calculated value.

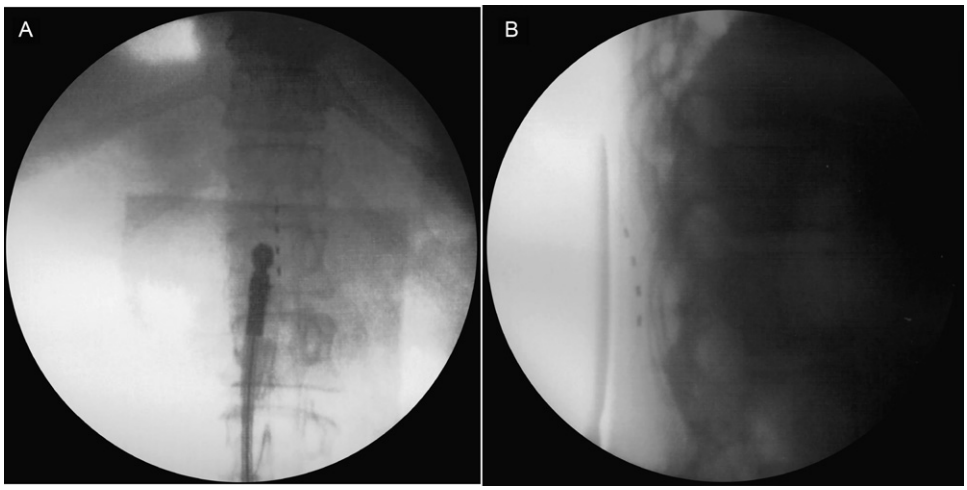

Fig. 3 – Anterior-posterior (A) and lateral (B) views of the remotely powered, SCS wireless lead and the external transmitting unit. The 4-electrode wireless lead is implanted in the epidural space and the external transmitting unit is in a sterile pouch placed on the patient's back.

wireless signal must transmit through. The standard model has a receiver located proximal to the electrodes, resulting in more tissue that the wireless signal must transmit through. The difference in implant depths is the reason why the transmit power reported for the standard model was more than that for the remote model.

Conclusion

This study has shown that a remotely powered, SCS wireless lead system is as effective as a contemporary, self-contained, percutaneous wired SCS trial system, at relieving pain and creating paresthesia coverage for patients with failed back surgery syndrome who suffer from chronic pain of the lower back and legs. Every successful patient who reported relief with a wired, trial system reported equal, if not better pain relief, paresthesia coverage, and paresthesia coverage with a wireless product with the same parameter settings and placement. The depth of the implant, dependent upon the patient's anatomy and the model of the lead, resulted in differences in power required for therapy with the wireless system. The remotely powered, SCS wireless lead system provides an alternative that could allow for longer trial periods, fewer infections by elimination of an open port, elimination of the need for surgery to place an IPG, and associated tunneling, as well as extensive reduction in procedure time.

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