PRIMARY CELL LONGEVITY FOR SPINAL CORD STIMULATION: RESULTS FROM THE PRODUCT SURVEILLANCE REGISTRY

Jennifer Tinsley, MBA¹, Shanti Scheffler, PhD², Jeremiah S. Menk³, Rachel Slangen, PhD⁴, Eric Buchser, MD⁵, Sam S. Eldabe, MD⁶; Todd W. Weaver⁴

¹ Clinical Research, Medtronic Intl Trading Sarl, Tolochenaz, CH; ² Health Economics & Reimbursement, Medtronic Intl Trading Sarl, Tolochenaz, CH
³ Clinical Biostatistics, Medtronic, Minneapolis, MN, USA ⁴ Post Approval Clinical Surveillance, Medtronic, Maastricht, the Netherlands & Minneapolis, MN, USA
⁵ Department of Anesthesia, Analgesia and Neuromodulation, EHC Hôpital de Morges, Morges, CH
⁶ Department of Pain and Anaesthesia, The James Cook Hospital, Middlesbrough, UK

Background and aims

Spinal Cord Stimulation (SCS) is an effective and well-established treatment for chronic intractable pain of the trunk and/or limbs. SCS is powered by an implantable pulse generator, which can be rechargeable or non-rechargeable primary cell (PC). For PC devices, battery life is an important factor from a clinical and cost perspective. This analysis was conducted to assess the time to battery replacement/longevity in patients who underwent SCS in a real-world registry.

Methods

The Product Surveillance Registry (PSR, Medtronic) is a prospective, long-term, multicentre global registry to monitor the performance and safety of Medtronic SCS systems.¹

Battery longevity was analysed using 2,036 PC devices in 1,723 patients across 66 sites on three continents with 3,770 device-years of follow-up (report cut-off date of 30-Apr-2019).

Longevity analyses were completed using a marginal Cox Proportional Hazard regression and Kaplan-Meier methods.

Results

Median battery survival

The **median survival of PC devices was 50.6 months** for all primary cell devices.

Median survival was similar across implant primary indications:

49.9 months	50.3 months	56.0 months
in patients with Complex Regional Pain Syndrome (CRPS) (n=229)	in patients with Failed Back Pain (n=869)	in patients with other primary indications (n=938)

No statistically significant difference was observed in battery longevity by initial device versus replacement device. Median survival was:

56.0 months	48.5 months
in initial implant devices (n=475)	in replacement devices (n=1,564)

Results

Battery longevity survival plot

for primary cell devices, overall and by primary indication

Median battery survival

Battery longevity is impacted by programmed settings, impedance, and patient usage. Mean programmed parameters were summarized for a device along with the standard deviation: mean (SD) [N].

Variables	First-time IPG Implant			Replacement IPG		
	FBSS N=146	CRPS N=20	All N=377	FBSS N=222	CRPS N=33	All N=457
Amplitude	4.7 (3.1) [145]	2.8 (2.7) [20]	4.6 (3.0) [371]	5.2 (3.1) [219]	3.2 (2.3) [31]	5.0 (3.4) [447]
Frequency	51.4 (23.2) [145]	57.7 (27.0) [20]	55.7 (23.2) [371]	56.9 (23.7) [219]	72.4 (32.4) [31]	59.3 (25.5) [447]
Impedance	913.4 (598.2) [27]	840.5 (373.0) [5]	990.0 (570.2) [65]	1128.4 (1044.9) [72]	596.0 (282.6) [8]	1091.9 (1106.0) [116]
Pulse width	672.8 (401.6) [145]	464.3 (270.6) [20]	639.5 (382.2) [371]	553.0 (331.9) [219]	489.4 (276.8) [31]	603.6 (349.8) [447]

Discussion & conclusion

Overall, the analysis demonstrated the expected performance of battery longevity for PC devices used in SCS therapy from real-world data.

Battery longevity is impacted by programmed settings and patient usage, factors which should be considered when selecting battery type, owing to both the clinical and cost implications from a healthcare payer perspective.

Acknowledge: Thank you to the PSR Investigators

¹ Schultz DM et al. Spinal Cord Stimulation (SCS) The Implantable Systems Performance Registry (ISPR) Neuromodulation. 2016 Dec;19(8):857-863.