Received: March 31, 2016 Revised: May 23, 2016 Accepted: June 13, 2016

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12477

Spinal Cord Stimulation (SCS)—The Implantable Systems Performance Registry (ISPR)

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Objectives: The Implantable Systems Performance Registry (ISPR) was created to monitor the product performance of Medtronic Spinal Cord Stimulation (SCS) and implanted intrathecal drug infusion systems available in the United States.

Materials and Methods: Data were collected on 2605 patients from 44 centers from various geographic regions across the United States implanting and following patients with SCS systems between June 25, 2004 and January 31, 2014. Actuarial life table methods are used to estimate device performance over time. Of the 2605 patients, 1490 (57.2%) were female, 1098 (42.1%) were male and 17 (0.7%) did not provide gender data. The average age at enrollment was 56.3 years (range: 4–97, SD = 14.3) and average follow-up time was 20.1 months (SD = 22.5).

Results: Currently the estimates of device survival from neurostimulator-related events exceed 97% for all neurostimulator models across the applicable follow-up time points and all applicable extension models had greater than 95% survival from extension events. The majority of product performance events were lead-related. At 5 years of follow-up, all applicable lead families, with the exception of the Pisces-Quad LZ family, had greater than 75% survival from lead events.

Conclusions: The ISPR is designed to serve as an ongoing source of system and device-related information with a focus on "real-world" safety and product performance. ISPR data continue to be used to guide future product development efforts aimed at improving product reliability and quality.

Keywords: neuromodulation, neurostimulator, pain, registry, stimulation

Conflict of Interest: Drs. Schultz, Calodney, Mogilner, Konrad, and Sasaki are paid consultants of Medtronic. Drs. Mogilner and Konrad also receive grant support from Medtronic. Dr. Schultz is a board member of the American Society of Interventional Pain Physicians. Todd Weaver, Michelle Wells, Katherine Stromberg, and Mollie Roediger are all employees of Medtronic, plc.

INTRODUCTION

Unresolved pain diminishes quality of life and negatively affects patient outcomes, which ultimately impacts health care and increases societal costs. Spinal cord stimulation (SCS) and targeted drug delivery (TDD) are chronic pain therapies that have been shown to improve patient outcomes and quality of life, increase function, and reduce costs of care (1–8). Despite multiple clinical studies demonstrating the efficacy and cost effectiveness of SCS, it has not gained full acceptance by all third party payers, and in fact coverage for SCS has been withdrawn by some payers due to claims of insufficient efficacy and safety data. Additional data regarding product performance and therapy outcomes for both SCS and TDD is thus clearly needed.

Registries allow for the systematic collection of prospectively defined longitudinal clinical and product performance data that can provide insight into current medical practices and real-world application of therapies. The development of patient registries has gained momentum and has become increasingly important in recent years. One of the best-known patient outcomes registries is the Surveillance Epidemiology and End Results (SEER) Program which is managed by the National Cancer Institute, and publishes data on cancer patients. SEER currently collects and publishes cancer incidence and survival data from population-based cancer registries covering more than 25% of the US population (9). Several other well-established registries

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For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please go to http://www.wiley.com/WileyCDA/Section/id-301854.html.

Source(s) of financial support: Medtronic, plc, Minneapolis, MN, USA.

Table 1. Spinal Cord Stimulators by Model.

Model name	Number of spinal cord stimulators (%)
PrimeAdvanced	604 (20.3%)
RestoreUltra	558 (18.7%)
Synergy	459 (15.4%)
Restore	447 (15.0%)
RestoreAdvanced	346 (11.6%)
RestoreSensor	232 (7.8%)
Itrel 3	101 (3.4%)
RestoreSensor Surescan MRI	73 (2.5%)
RestorePrime	57 (1.9%)
Synergy Versitrel	38 (1.3%)
PrimeAdvanced SureScan MRI	27 (0.9%)
SynergyPlus+	24 (0.8%)
RestoreAdvanced SureScan MRI	10 (0.3%)
RestoreUltra SureScan MRI	1 (.03%)
Unspecified model	1 (.03%)
Total	2978 (100%)

are evaluating treatment outcomes for conditions such as emphysema, heart disease, depression, and Parkinson's disease.

The Implantable Systems Performance Registry (ISPR) created by Medtronic, Inc. is the first registry voluntarily developed to monitor the product performance of Medtronic SCS and implanted intrathecal drug infusion systems available in the United States. The ISPR allows Medtronic to prospectively capture real-world product performance data for populations treated with SCS and TDD. The purpose of the current manuscript is to examine SCS data from registry. Additional information regarding the methods of the ISPR and data specific to drug infusion systems are provided in a separate manuscript (reference TBD).

MATERIALS AND METHODS

The ISPR has collected data from 44 centers from various geographic regions across the United States implanting and following patients with SCS systems since June 25, 2004. This manuscript includes data collected through January 31, 2014. Sites were selected using a stratified randomized sampling technique to ensure results could be generalizable, and that inferences could be made regarding the patient population as a whole. Appropriate institutional review board approval was granted before the study began and all institutional guidelines were followed. After enrollment and initial data collection, all patients are followed prospectively for events. Participating investigators reported patient symptoms and outcomes for each event. In early versions of the protocol, an event was reportable in the ISPR only if it required a surgical intervention, led to therapy abandonment, or resulted in death. In April 2010, event data collection was expanded to capture any event associated with the device, therapy, or implant procedure, as well as any event that resulted in death (regardless of relatedness to the device). Patient status updates have been obtained every 6 months or until discontinuation from the registry (e.g., all devices are explanted, therapy has been abandoned, patient death, patient lost to follow-up, or site closure). Data presented in this manuscript includes information on all lead placements to manage chronic pain. The ISPR is registered on clinicaltrials.gov.

For analysis purposes, events collected through the ISPR were separated into two categories: product performance events and non-product performance events. Product performance events were defined as events that were possibly due to a device-related issue (performance issues or malfunctions). One example includes SCS lead fracture. Product performance events were considered the primary endpoint of interest for this manuscript. A non-product performance related event was any undesirable experience (associated with signs, symptoms, illnesses, or other medical events) occurring to the patient that appeared or worsened during the clinical study, that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and could not be classified as product performance-related. Examples include neurostimulator pocket infection or pain at neurostimulator pocket site. Although these types of events are related to the device implant procedure or therapy, they are not considered device performance issues or malfunctions.

All events reported in the ISPR were coded using version 8.0 of the Medical Dictionary for Regulatory Activities (MedDRA). Medtronic's own coding system for events related to implanted neuromodulation systems was integrated with the MedDRA dictionary.

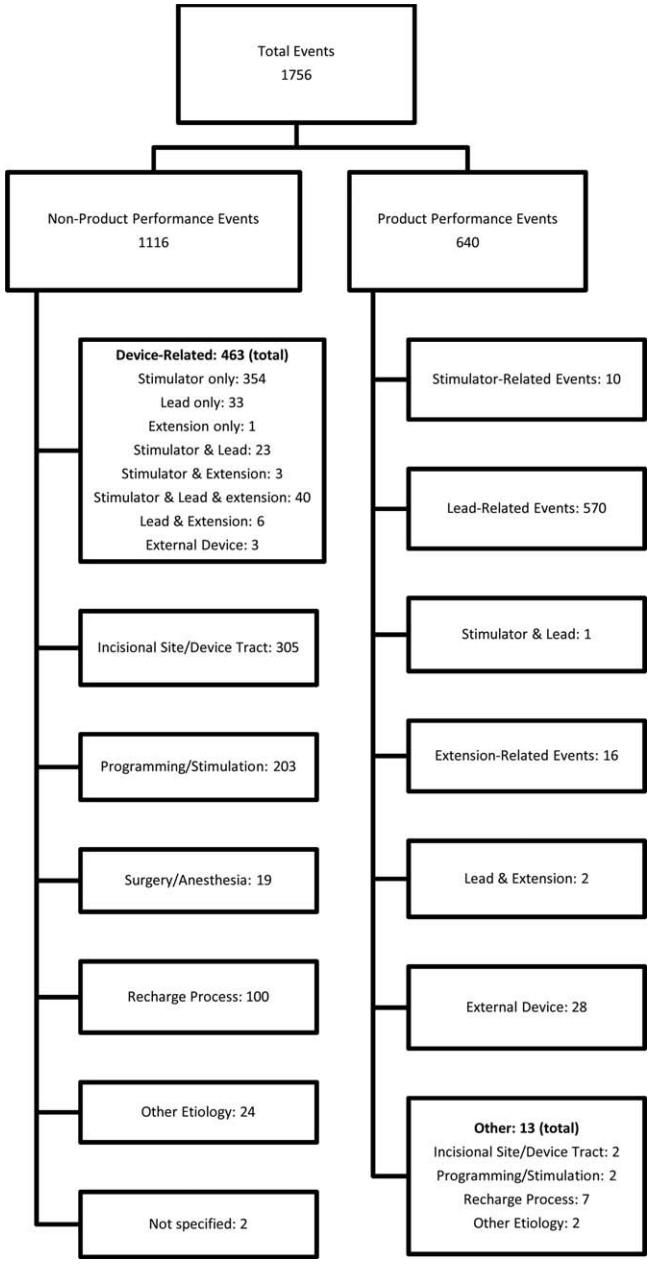

Figure 1. Events by category.

Table 2. Neurostimulation System Product Performance Events.

Event*	Number of product performance events	Number of patients with event†	Percent of patients with event ($n = 2605$)
Lead migration/dislodgment	337	175	6.72%
High impedance	92	42	1.61%
Lead fracture	46	31	1.19%
Undesirable change in stimulation‡	45	25	0.96%
Medical device complication§	43	24	0.92%
Low impedance	18	6	0.23%
Recharging unable to recharge¶	16	15	0.58%
Device malfunction**	15	8	0.31%
Extension fracture	13	8	0.31%
Device failure††	6	5	0.19%
Not Coded‡‡	3	2	0.08%
Paraesthesia§§	2	2	0.08%
Therapeutic product ineffective¶¶	2	1	0.04%
Broken bond wire***	1	1	0.04%
Impedance, not otherwise specified	1	1	0.04%
Total	640	298	11.44%

*Medical Dictionary for Regulatory Activities (MedDRA) Lower Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
†The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.
‡Undesirable change in stimulation reported by the physician as being caused by the neurostimulator ($n = 2$) or lead ($n = 43$).
§Includes six events reported as electrodes out of range, four leads no longer providing stimulation, four broken recharge belt, three error messages on patient programmer, two events reported as damaged leads, two damaged electrodes, two lead electrodes 0–7 not functional, two lead malfunction secondary to open circuit, two broken recharging unit, two events reported as unable to pass stylet into lead, two lead failures, one lead with pinched outer insulation, one separation of the material on the end of the neuroelectrode, one broken recharger strap, one antenna was not working, one broken antenna cord, one excessive heating of the charging unit, one broken patient programmer, one malfunctioning programmer, one SCS not working properly—losing charge, one frayed cord to recharge antenna, one lead damaged contacts, and one unknown problem with an extension.
¶Patient was unable to recharge due to device related issue.
**Includes eight electrodes out of range too high, two events reported as impedance not measurable, one antenna malfunction, one increased lead impedance, one malfunction of the spinal cord stimulation system, one device malfunction: problems with reprogramming, and one SCS stopped working abruptly.
††Includes one broken jack and antenna, one failure of lead electrodes, one extension failure, one defective patient programmer, one frayed wire to recharger, and one broken antenna on recharger.
‡‡Included two lead migrations with damaged leads and extensions and one code 006 noted on patient programmer.
§§Shocking sensation was reported at battery/extension connection.
¶¶Includes two events reported as loss of paraesthesia to bilateral lower extremities due to a lead related issue.
***Broken bond wire event was confirmed by Returned Product Analysis. The broken bond wire was a failure in the wire that bonds the battery and the hybrid in the neurostimulator.

Device performance over time was estimated using life table survival methods (10). The survival estimates were calculated more than 3-month intervals and include experience for each device up until a product performance-related event occurs (considered a failure event), or until the device is removed or therapy is abandoned for non-product performance reasons (including normal battery depletion, patient death, patient lost to follow-up), or for as long as the device has been followed in the study, whichever occurs first. Linear 95% confidence intervals were constructed around the product performance survival estimates for each year post-implant (11).

Cumulative device survival plots are used to show the percentage of implanted devices that remain free from product performance-related events at various time points. For example, a device survival probability of 90% indicates that through the stated follow-up time, the device had a 10% risk of incurring a product performance event since the time of implant.

RESULTS

Between June 25, 2004 and January 31, 2014 data were collected from 44 centers and 2605 patients. Of the 2605 patients, 1490 (57.2%) were female, 1098 (42.1%) were male, and 17 (0.7%) did not provide gender data. The average age at enrollment was 56.3 years (range: 4–97, SD = 14.3) and average follow-up time was 20.1 months (SD = 22.5). Of the SCS patients enrolled in the ISPR, 42.4% were implanted with a SCS system for the treatment of failed back pain, 11.3% for treatment of complex regional pain syndrome, 45.6% for treatment of other indications such as radicular pain syndrome, degenerative disc disease, and other chronic pain and 0.7% for unspecified indications.

Neurostimulators

During the reporting period, data on 2978 spinal cord stimulators were recorded in the ISPR. Fifty-six percent of the spinal cord stimulators were rechargeable devices (Restore, RestoreAdvanced, RestoreUltra, and RestoreSensor). The difference between the total number of patients and spinal cord stimulators was due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted. Table 1 provides the number and percentage of spinal cord stimulators by model.

There were 1756 events reported between June 25, 2004 and January 31, 2014 in patients with SCS systems. Figure 1 provides the

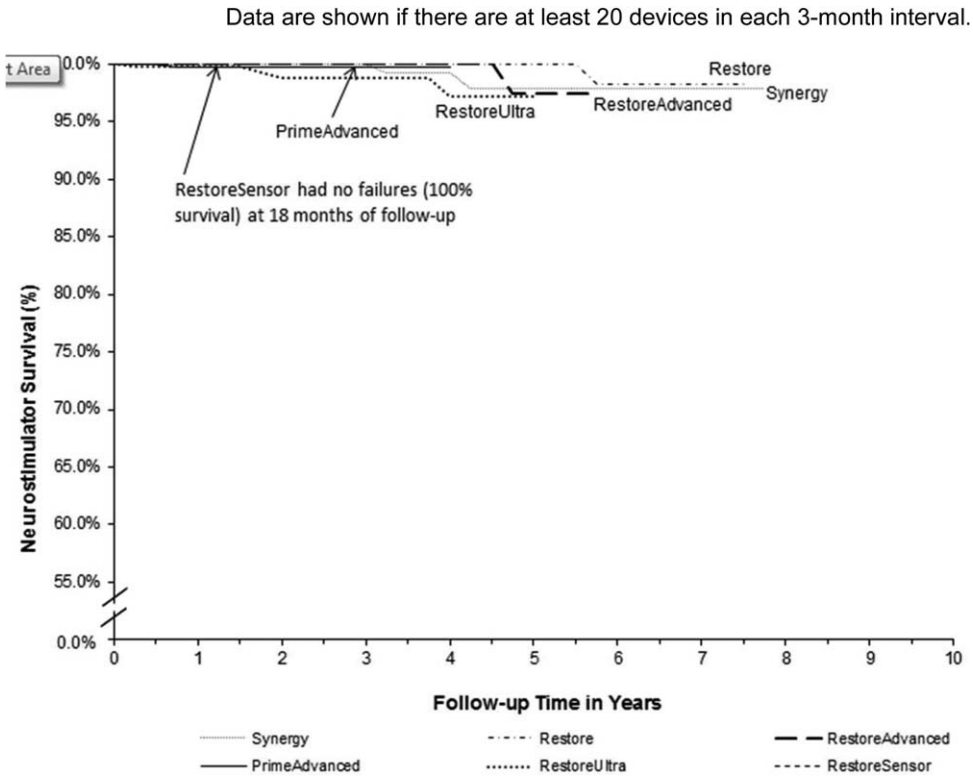

Figure 2. Neurostimulator survival from neurostimulator events.

events by category/etiology. The summary of product performance-related events are presented in Table 2.

The results of the ISPR to-date indicate that the number of product performance-related events ($n = 640$) were substantially less than non-product performance-related events ($n = 1116$). In addition, during the reporting period, 81 patient deaths were reported in the ISPR. None of the 81 patient deaths were attributed to a device-related event or neurostimulation therapy.

Of the 640 product performance-related events, 11 were related to the neurostimulator. The 11 product performance-related events related to the neurostimulator included three device malfunctions, three medical device complications, two undesirable change in stimulation, one broken bond wire, one high impedance, and one recharging issue attributed to the neurostimulator. Of the 11 events, nine were the first event attributable to the neurostimulator. Table 3 and Figure 2 provide neurostimulator survival and 95% confidence intervals for models where at least 20 spinal cord stimulators contributed to each interval.

Currently estimates of device survival from neurostimulator-related events exceed 97% for all neurostimulator models (lower confidence intervals exceed 92%) at the applicable follow-up time points.

Leads

During the reporting period, data on 5205 leads were followed in the ISPR. The difference between the total number of leads and spinal cord stimulators ($n = 2978$) is due to the fact that some patients were implanted with more than one lead at the outset or were subsequently re-implanted with a new lead.

Ninety percent (90.1%) of leads in ISPR were percutaneous (cylindrical) leads ($n = 4690$) that included 55.5% ($n = 2888$) in the Pisces-Octad lead family, 26.0% ($n = 1354$) in the Pisces-Quad lead family, 5.0% ($n = 261$) in the Pisces-Quad LZ lead family, and 4% ($n = 186$) in the Vectris SureScan MRI family. About nine percent (8.9%) of leads ($n = 462$) were surgical (paddle) leads. One percent of leads were categorized as Other.

There were 573 product performance-related events related to the lead. Of these 573 events, 334 were lead migration or dislodgement, 90 high impedance, 46 lead fractures, 43 undesirable change in stimulation, 25 medical device complication, 18 low impedance, 11 device malfunction, two therapeutic product ineffective, one device failure, one was impedance not otherwise specified, and two were not coded.

Of the 573 events, 502 were the first event attributable to an enrolled lead. Four hundred and seventy-four of the 502 events (94.4%) occurred in 10.1% of the 4690 percutaneous leads. Twenty-five of the 502 events (5%) occurred in 5.4% of the 462 surgical leads. The remaining three events occurred in leads that could not be identified as either percutaneous or as surgical. Table 4 and Figure 3 illustrate lead survival and 95% confidence intervals for families where at least 20 leads contributed to each interval.

As indicated in Table 4, for surgical leads, currently the estimates of device survival from lead-related events exceed 89% (lower confidence intervals exceed 82%) through 7 years of follow-up. For percutaneous leads, currently the estimates of survival from lead-related events exceed 75% (lower confidence intervals exceed 72%) through 5 years of follow-up with the exception of the Pisces-Quad LZ family. As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Extensions

During the reporting period, there were 2785 extensions followed in the ISPR. Almost 40% (39.7%, $n = 1106$) of the extensions were Model 37081, 24.5% ($n = 683$) were Model 7489, 19.7% ($n = 549$)

Table 3. Device Survival From Neurostimulator Events Summary.

Spinal cord stimulator characteristics				Device survival probability (95% confidence intervals)			
Model name (description)	Number of neurostimulators in the ISPR (number active at time of data cut-off)	Device events*	Follow-up time (months) Mean ± SD	1 year	3 years	5 years	7 years
Synergy (primary cell)	459 (17)	2	23.9 ± 20.5	100.0% NA $n = 271$	100.0% NA $n = 143$	97.9% (95.0%, 100.0%) $n = 50$	97.9% (95.0%, 100.0%) $n = 21$
PrimeAdvanced (primary cell)	604 (177)	1	14.7 ± 14.0	99.7% (99.2%, 100.0%) $n = 315$	99.7% (99.2%, 100.0%) $n = 58$		
Restore (rechargeable)	447 (52)	1	29.2 ± 25.7	100.0% NA $n = 318$	100.0% NA $n = 148$	100.0% NA $n = 71$	98.2% (94.6%, 100.0%) $n = 32$
Restore Advanced (rechargeable)	346 (132)	1	22.2 ± 21.7	100.0% NA $n = 209$	100.0% NA $n = 81$	97.4% (92.4%, 100.0%) $n = 34$	
RestoreUltra (rechargeable)	558 (155)	4	19.2 ± 17.6	99.8% (99.4%, 100.0%) $n = 329$	98.8% (97.3%, 100.0%) $n = 115$	97.2% (93.8%, 100.0%) $n = 22$	
RestoreSensor (rechargeable)	232 (192)	0	7.6 ±6.2	100.0% NA $n = 78$			

*There were 11 neurostimulator-related events reported to the ISPR, but only nine events included in this summary table. The remaining neurostimulator-related events were subsequent events that did not affect the device survival estimate.

were Model 37082, 7.6% ($n = 212$) were Model 7495, 6.8% ($n = 190$) were Model 37083, and less than 1% were Model 7472 ($n = 10$), Model 7496 ($n = 9$), Model 7471 ($n = 8$), and other models ($n = 18$).

There were 18 product performance-related events related to the extension (three for Model 7489, seven for Model 37081, three for Model 37082, and five for Model 37083). The majority ($n = 13$,

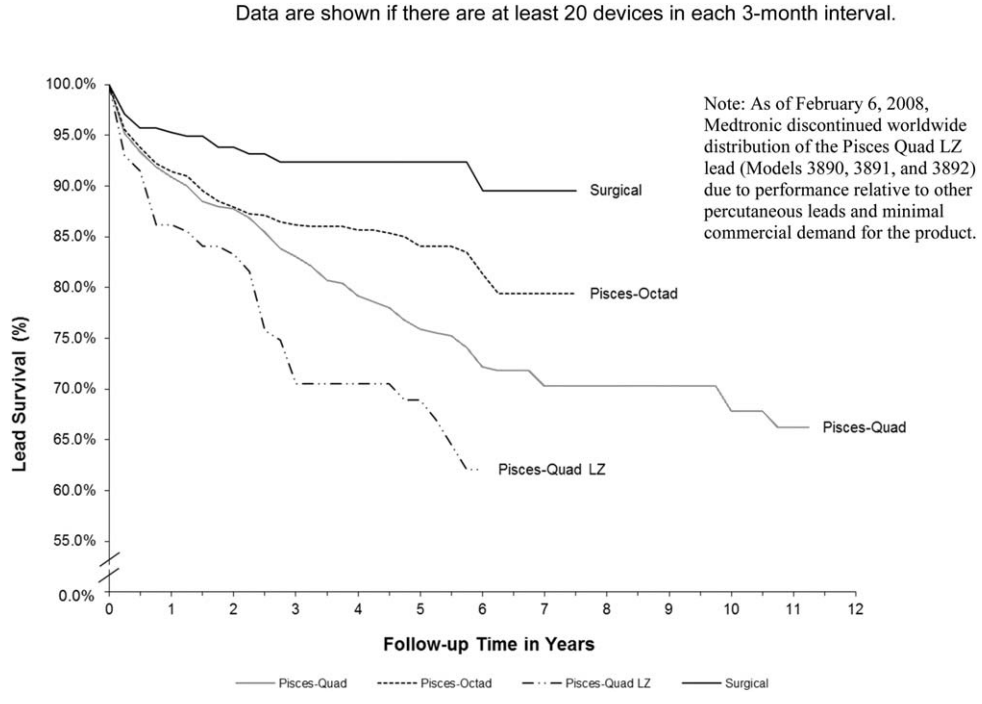

Figure 3. Lead family survival from lead events.

Table 4. Device Survival From Lead Events Summary.

Lead characteristics				Device survival probability (95% confidence intervals)				
Lead family	Leads in the ISPR (number active at time of data cut-off)	Device events*	Follow-up time (months) Mean ± SD	1 year	3 years	5 years	7 years	11 years
Pisces-Octad	2888 (995)	261	18.6 ± 20.2	91.4% (90.2%, 92.6%) $n = 1570$	86.2% (84.4%, 88.0%) $n = 526$	84.1% (81.6%, 86.6%) $n = 193$	79.4% (75.0%, 83.9%) $n = 49$	
Pisces-Quad	1354 (436)	167	27.5 ± 27.2	90.9% (88.9%, 92.9%) $n = 670$	83.0% (80.0%, 85.9%) $n = 416$	75.9% (72.1%, 79.6%) $n = 245$	70.3% (65.7%, 74.8%) $n = 139$	66.2% (59.9%, 72.5%) $n = 37$
Pisces-Quad LZ	261 (30)	39	22.7 ± 23	86.2% (80.2%, 92.3%) $n = 121$	70.5% (61.9%, 79.1%) $n = 70$	68.9% (60.0%, 77.9%) $n = 41$		
Surgical	462 (112)	25	21.4 ± 21.9	95.3% (92.9%, 97.8%) $n = 239$	92.4% (88.8%, 95.9%) $n = 90$	92.4% (88.8%, 95.9%) $n = 48$	89.5% (82.9%, 96.1%) $n = 27$	

*There were a total of 573 lead-related events reported to the ISPR, but only 492 events included in this summary table. The remaining lead-related events occurred in lead models for which no device survival curves are presented due to an insufficient number of enrolled devices, were subsequent events that did not affect the survival estimates, or were events that could not be attributed to an enrolled lead.

72.2%) of these were extension fractures. Currently the estimates of device survival from extension-related events exceed 95% for all extension models at the applicable follow-up time points.

DISCUSSION

There were a total of 1756 events reported between June 25, 2004 and January 31, 2014 in 851 patients (32.7%) with SCS systems. More than 63% of total events (1116/1756) were non-product performance related and 36% of events (640/1756) were categorized as product performance-related events. The majority of product performance events were lead-related (89.5%, 573/640), followed by extension-related events (2.8%, 18/640) and neurostimulator-related events (1.7%, 11/640).

The numbers of neurostimulator- and extension-related product performance events were 11 and 18 events, respectively. Currently the estimates of device survival from neurostimulator-related events exceed 97% for all neurostimulator models across the applicable follow-up time points and all applicable extension models had greater than 95% survival from extension events. The majority of product performance events were lead-related. At 5 years of follow-up, all applicable lead families, with the exception of the Pisces-Quad LZ family, had greater than 75% survival from lead events. As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product. The ISPR was an important source of data to guide this decision.

The data in this registry provides information about the clinical use and product performance of the implantable systems, which helps to elucidate commonalities of patients, conditions, and/or environments that result in events. The ISPR enables Medtronic to better quantify different types of issues with the devices and use the data as input for efforts to improve quality and safety and for the development of new products. For instance, there were a total of 45 product performance events reported in the ISPR related to undesirable change in stimulation. The ISPR data confirmed the issue of undesirable stimulation and supported the need for the development of new product features designed to address this therapy need. In November of 2011, Medtronic received approval in the United States for RestoreSensor, a new neurostimulator developed to automatically adapt stimulation amplitude to accommodate the spinal cord movement in relation to the stimulation field when patients change positions.

This review reflects a snapshot of information restricted to 2605 patients with neurostimulation and various follow-up times for device models. Thus, conclusions should be understood with the limitation that the information will continue to grow, be reviewed and clarified, and results will change as more centers are activated and new patients are enrolled and followed for longer periods of time. Medtronic regularly releases updates of the product performance data in the form of the Medtronic Neuromodulation Product Performance Report. This report can be found at www.professional.medtronic.com/ppr.

Limitations

Registries are not designed to test cause and effect relationships; they facilitate hypothesis generation and provide descriptive data. In addition, registry information makes it possible to track therapy and device performance over extended follow-up intervals, providing long-term data not available in typical clinical trials. Acceptance of product and outcome registries by FDA and the medical community is increasing (12). Future phases of the ISPR will expand the scope of the registry to integrate patient outcomes information and incorporate data collection in additional geographies to provide greater value and wider application of the data generated.

CONCLUSION

Registries allow for the systematic collection of valuable longitudinal product performance data and clinical outcomes. The ISPR is designed to serve as an ongoing source of system and device-related information with a focus on "real-world" safety and product performance. Medtronic was the first company to develop a registry to voluntarily monitor product performance of its SCS and implanted intrathecal drug infusion systems available in the United

States. Device survival from product performance events has been shown to exceed 97% for all neurostimulator models and greater than 95% for all extension models across the applicable follow-up time points. At 5 years of follow-up, all applicable lead families, with the exception of the Pisces-Quad LZ family, had greater than 75% survival from lead events. Within the lead families, surgical leads had the highest lead survival (92.4%) at 5 years of follow-up. ISPR data continue to be used to guide future product development efforts aimed at improving product reliability and quality.

Authorship Statements

Drs. Schultz, Calodney, Mogilner, Konrad, and Sasaki were all primary investigators in the registry and critically reviewed and edited the manuscript. Katherine Stromberg and Mollie Roediger analyzed the data and prepared/edited the manuscript. Todd Weaver and Michelle Wells managed the conduct of the registry and prepared the draft manuscript. All authors approved the final manuscript.

How to Cite this Article:

Schultz D.M., Calodney A.K., Mogilner A.Y., Weaver T.W., Wells M.D., Stromberg E.K., Roediger M.P., Konrad P.E., Sasaki J.T. 2016. Spinal Cord Stimulation (SCS)—The Implantable Systems Performance Registry (ISPR). Neuromodulation 2016; 19: 857–863

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COMMENTS

Registries are an important part of determining common issues and beginning strategies for root cause analysis of problems with technology and clinical algorithms. While somewhat rudimentary in nature, this registry manuscript may be the basis of what can hopefully become a more robust repository of information to guide clinicians (and industry) concerning device-related issues.

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Implantations of medical devices in humans have long been practiced in the treatment of chronic pain. Although acute pain is also treated with devices that provide temporary relief from pain, they are usually explanted after a few days or when a patient is ready for discharge. Permanent devices implanted for the treatment of chronic pain syndromes require a much higher rate of success, durability and quality.

Implanted devices, especially electronic devices such as spinal cord stimulators and implantable intrathecal drug delivery systems, have a tendency to fail during the course of their use (1). Apart from common complications such as infections, lead migrations, etc., device specific issues such as lead connection failure (9.5%), lead breakage (6%), lead extrusion (2) have been reported.

Authors in this article have attempted to create a registry to monitor product performance of the Medtronic spinal cord stimulation systems and implantable intrathecal drug delivery systems. The registry confirms some of the known complications such as lead related issues. One lead family (Pisces-Quad LZ family) seems to have a lower than usual survival rate (>75% compared to <75%). Data from 44 centers across the United States involved in implanting such devices has been collected and analyzed during the period of 10 years (June 2004 – January 2014). The data has also been classified into product related and non-product related issues. Non-product performance related events such as infection, drug overdose, etc., cannot be directly related to device failure. Maintenance of such a registry will not only help future product development, safety and efficacy but will also permit certain recalls. Such data can help guide better product development and also improve reliability and quality of implantable devices.

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Comments not included in the Early View version of this paper.

