

NEW DATA SHOWS RECHARGE-FREE SCS DEVICES CAN LEAD TO REDUCED SYSTEM EXPLANTS

- In the largest study of its kind to date, higher explant rates were observed for 10 kHz high-frequency devices and conventional, rechargeable systems

ABBOTT PARK, Ill., Jan. 22, 2017 — A new analysis presented today at the 2017 North American Neuromodulation Society (NANS) annual meeting found new benefits for patients receiving Abbott's non-rechargeable spinal cord stimulation (SCS) devices. The latest data analysis demonstrates that non-rechargeable devices – sometimes referred to as recharge-free – were subject to the lowest rates of explants whereas 10 kHz high-frequency devices had the highest rates of explants due to inadequate pain relief.

The results stem from real-world clinical data collected at four implanting centers in Europe. Physicians reviewed the results of 956 SCS systems implanted between 2010 and 2013. The research team tracked implants, follow-up visits and any explants of a system through mid-2016, excluding explants for patients who had their device replaced or who underwent an upgrade to a different device.

In their analysis, researchers found 10 kHz high-frequency rechargeable devices were subject to the greatest overall percentage of explants for inadequate pain relief (*14.1 percent*), followed by conventional frequency or conventional tonic rechargeable (*11.9 percent*) devices. Recharge-free devices delivering tonic stimulation were subject to the lowest overall percentage of explants (*6.9 percent*).

"Physicians today have multiple options to deliver spinal cord stimulation therapy to patients, and clinical evidence has established the safety and effectiveness of the therapy for many types of chronic pain," said Jean-Pierre Van Buyten, M.D., the study's lead author and professor from the Department of Anesthesia and Pain Management at AZ Nikolaas, St Niklaas, Belgium. "Yet as the options expand, we must validate clinical trial results with real-world data that confirm which devices provide strong, durable results for different indications and which are potentially subjecting patients to higher rates of explantation for inadequate pain relief."

Physicians offering SCS therapy aim to reduce patient exposure to explantation, which can subject patients to additional surgical risk. According to the researchers, with increasing technology available to patients, assessments related to rates and reasons for an SCS system explant are important to help physicians make the best decisions for patients.

Abbott has made recharge-free SCS systems a priority for the company to ensure a breadth of SCS therapy options for patients. The company currently offers the recharge-free Abbott Proclaim™ Elite SCS system. The system removes the recharge burden while offering tonic and Abbott's proprietary BurstDR stimulation.

Results of the Analysis

Within the review, 463 patients received a tonic non-rechargeable device, 328 patients received a rechargeable device delivering traditional tonic stimulation and 154 patients received a 10 kHz high-frequency device. In total, there were 178 unanticipated explants, more than half of which were due to inadequate pain relief. Patients who had received a 10 kHz high-frequency device suffered the highest rate of explantation. In fact, high frequency rechargeable had a 76 percent greater risk of explant than recharge-free devices.

"Real world clinical data is critical to helping physicians evaluate the therapies they're offering their patients and to gain insight into the therapies that may subject their patients to risks related to inadequate pain relief," said Allen Burton, M.D., medical director of neuromodulation at Abbott. "This study helps fill a gap in needed long-term outcome data and affirm the merits of primary cell, recharge-free devices that help physicians choose the right device for the right patient."

About Abbott's Chronic Pain Portfolio:

Chronic pain affects approximately 1.5 billion people worldwide, more than heart disease, cancer and diabetes combined. The condition can negatively impact personal relationships, work productivity and a patient's daily routine. Abbott is a global leader in the development of chronic pain therapy solutions and the only medical device manufacturer in the world to offer radiofrequency ablation (RFA) and spinal cord stimulation (SCS) therapy solutions including BurstDR stimulation and stimulation of the dorsal root ganglion (DRG) for the treatment of chronic pain.

About Abbott:

At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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