

# AT NANS 2017, NEW DATA EXPANDS THE BODY OF EVIDENCE SUPPORTING BURSTDR™ STIMULATION FOR CHRONIC PAIN

- BurstDR stimulation offers benefits to patients suffering from failed back surgery syndrome, chronic limb pain and chronic intractable pain

**Abbott Park, Ill., Jan. 22, 2017** — A series of data presentations this week continued to expand the growing body of clinical evidence supporting the use of Abbott's proprietary BurstDR™ stimulation for the treatment of chronic pain. The latest research was presented during the 2017 North American Neuromodulation Society (NANS) annual meeting, and focused on the benefits of BurstDR stimulation for patients with a variety of chronic pain conditions.

Data were collected at centers across Europe, where BurstDR stimulation has been approved since 2014. Researchers highlighted potential benefits of BurstDR stimulation over 10 kHz high-frequency stimulation for patients with Failed Back Surgery Syndrome (FBSS), as well as significant improvements for patients with chronic upper and lower limb pain. The data also emphasized the ability of this therapy to improve quality of life and reduce catastrophizing (irrational thinking) among chronic pain patients.

"For years, data from single-center, multi-center and randomized controlled clinical trials have confirmed the benefits of BurstDR stimulation for patients suffering from chronic pain," said Allen Burton, M.D., medical director of neuromodulation at Abbott. "Throughout NANS 2017, the data presented on BurstDR stimulation consistently demonstrated that the therapy is a good option for new groups of patients currently underserved by existing therapy options. It was exciting to receive direct clinical feedback on the impact of this transformational therapy."

## **BurstDR Stimulation Shows Benefits over 10 kHz High-Frequency Stimulation for FBSS Patients**

Researchers at the Rheinische Friedrich Wilhelms University Hospital in Bonn, Germany, reported on an extended long-term follow-up of a previously published comparative study assessing the safety and efficacy of both BurstDR stimulation and 10 kHz high-frequency stimulation in patients with failed back surgery syndrome (FBSS) with predominant back pain. FBSS is characterized by continued back or leg pain despite undergoing lower spinal surgery.

While both technologies have demonstrated an improvement in failed back surgery syndrome with predominant back pain over traditional tonic SCS, this trial is the first randomized, controlled study directly comparing BurstDR stimulation and 10 kHz high-frequency tonic stimulation.

In the study, led by Thomas Kiefe, M.D., Ph.D., professor of neurosurgery at the Rheinische Friedrich Wilhelms University Hospital in Bonn, Germany, a total of 16 patients were followed for up to 20 months. Patients were evaluated for intensity of back and leg pain as measured by the Visual Analog Scale (VAS). The study found:

- Both BurstDR stimulation and high-frequency stimulation significantly decreased back pain.
- BurstDR stimulation demonstrated a significant clinical advantage over high-frequency stimulation in reducing the intensity of leg pain over time. Leg pain was found to persist in patients receiving 10 kHz high-frequency stimulation.
- Patients receiving 10 kHz high-frequency stimulation experienced two trial failures and two treatment failures. BurstDR stimulation therapy was subject to zero trial failures and

zero treatment failures.

## **Additional Benefits of BurstDR Stimulation**

Throughout NANS 2017, researchers from Germany, the U.K., and Belgium showcased the ability of BurstDR stimulation to positively impact patients suffering different types of chronic pain. Researchers also examined the ability of the therapy to improve quality of life. In addition, researchers assessed the ability of BurstDR stimulation to favorably impact on psychological characteristics frequently seen in combination with chronic pain. These psychological traits frequently seen in combination with pain include catastrophizing, anxiety, and depression.

- In a retrospective multicenter analysis of nine patients, researchers in Belgium found that BurstDR stimulation resulted in a significant improvement in patients with chronic upper limb pain and significant improvements in upper limb pain during activities of daily living, social activities and at rest.
- In a retrospective analysis from data collected from five patients at the North Bristol NHS Trust in England, researchers found BurstDR stimulation resulted in a significant improvement in both chronic upper and lower limb pain over conventional tonic SCS.
- Within a prospective, multicenter, single-arm clinical follow-up study of 100 patients, researchers from Germany and Belgium found that after one year of therapy, BurstDR stimulation had improved quality of life for patients while significantly reducing catastrophizing of pain.

These real-world results expand on the outcomes reported in the SUNBURST IDE Study, which led to a superiority labeling from the FDA in October 2016 for BurstDR stimulation vs traditional tonic stimulation.

## **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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