Therapeutic Efficacy of BurstDR™ Microdosing in Treatment of Chronic Pain

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16th Annual Pain Medicine Meeting

Introduction

BurstDR™ spinal cord stimulation has been shown to be safe and effective in the treatment of chronic refractory pain conditions. In this randomized, double-blinded, crossover study we compared the therapeutic efficacy of standard BurstDR™ stimulation to two energy efficient BurstDR™ Microdosing paradigms.

Methods

Thirteen chronic pain patients (59±14 years, 11 females)

- With failed back surgery syndrome or neuropathic pain
- Using only BurstDR™ for at least 3 months were enrolled in the study.

Subjects evaluated three stimulation paradigms in random order:

- **Standard BurstDR™ stimulation:**
  5 pulses per burst, 500Hz intraburst frequency, 40Hz interburst frequency, 1000μs pulse width
- **BurstDR™ Microdosing stimulation paradigm A:**
  BurstDR™ STIM ON for 5s followed by BurstDR™ STIM OFF for 5s
- **BurstDR™ Microdosing stimulation paradigm B:**
  BurstDR™ STIM ON for 5s followed by BurstDR™ STIM OFF for 10s

Clinical outcomes were evaluated at the end of each two week stimulation period using:

- Visual Analog Scale (VAS) scores
- European Quality of Life - 5 dimensions (EQ-5D)
- Satisfaction questionnaire
- Preference between different stimulation paradigms

Results

Changes in VAS were not statistically significant

- Microdosing A:
  -0.4±10.9mm; p>0.05
- Microdosing B:
  -1.5±18.8mm; p>0.05

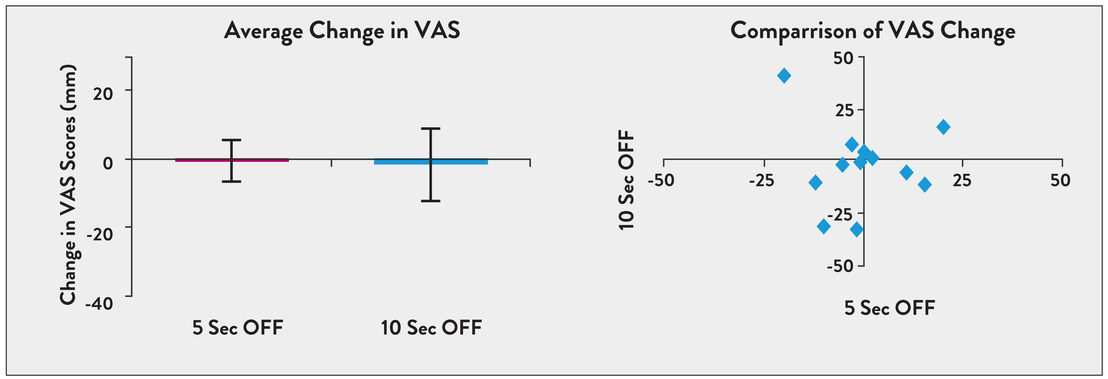

Figure 1: Average change in VAS scores between standard BurstDRTM microdosing paradigm A or B (left). VAS change with microdosing A and B for each patient (right).

Changes in EQ-5D were not statistically significant

- Microdosing A:
  -0.06±0.13; p=>0.05
- Microdosing B
  0.01±0.18; p=>0.05

Out of 13 subjects, 1 preferred continuous stimulation, 4 preferred Microdosing A, 6/13 preferred Microdosing B, 4/9 did not have a preference

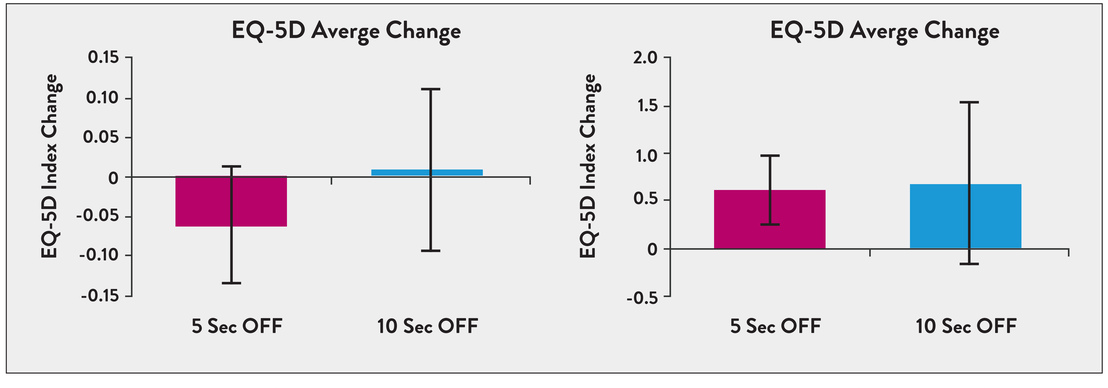

Figure 2: Average change in EQ-5D scores between standard BurstDR microdosing A or B (left). Change in satisfaction with microdosing (right).

Conclusions

Preliminary results from this study strongly suggest that use of BurstDR™ Microdosing stimulation paradigms (i.e. stimulating with alternating ON and OFF periods) can provide clinically equivalent results to standard BurstDR™ stimulation parameters while substantially reducing battery consumption

Disclosures

This study is sponsored by St. Jude Medical. Dr. Agnesi and Dr. Venkatesan are employees of St. Jude Medical.