Clinical Highlights

BurstDR™ Stimulation Has Established Level 1A Evidence Revealing Superiority Over Traditional Waveforms

Comparison of Spinal Cord Stimulation Waveforms for Treating Chronic Low Back Pain: Systematic Review and Meta-Analysis

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OVERVIEW

Across the last decade, neuromodulation with spinal cord stimulation (SCS) has been utilized increasingly and with good effectiveness for treating chronic low back pain (LBP). Given the scarcity and variability of evidence comparing SCS waveforms, currently available evidence for each SCS waveform was systematically reviewed and meta-analyzed for its analgesic effectiveness in treating chronic LBP.

STUDY SUMMARY

A systematic review of 807 records based on conventional methodolgy described by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) identified 11 studies between 1966 and 2019 that included waveform comparison for treating chronic LBP, most of which explored failed back surgery syndrome. Of these 11 studies, six studies compared BurstDR™ stimulation versus tonic, two studies compared BurstDR stimulation versus high frequency and three studies compared tonic versus high frequency. One study comparing BurstDR stimulation versus tonic was excluded given technical challenges in data extraction.

For all studies, data syntheses and analyses were performed with assessments of risk of bias, quality and outcome measures. The authors noted the presence of a high degree of bias in at least one domain in most studies identified for inclusion.

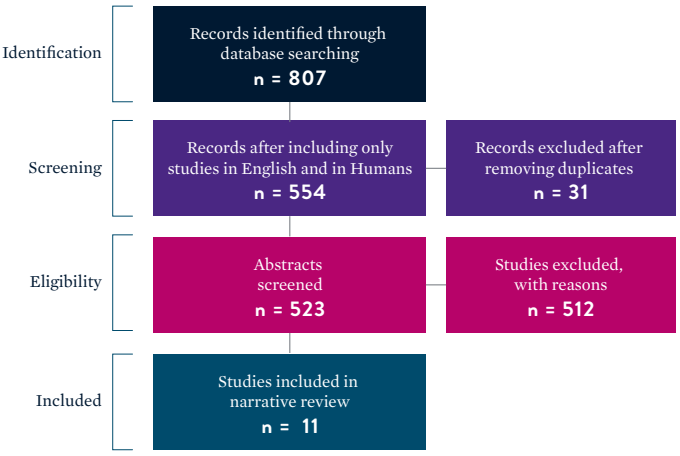
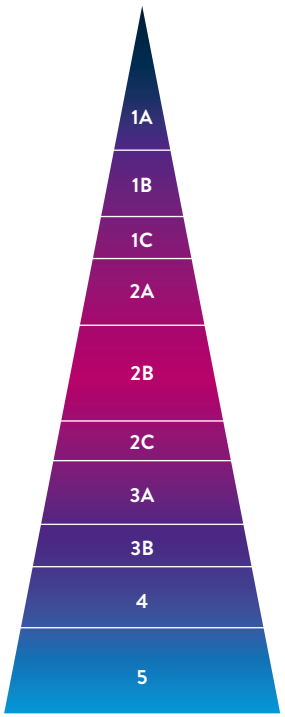


Figure 1: PRISMA flowchart of methodology utilized in systematic identification of studies.

LEVELS OF EVIDENCE FOR THERAPEUTIC STUDIES[1]

- **1A** Systematic review (with homogeneity) of RCTs
- **1B** Individual RCT (with narrow confidence intervals)
- **1C** All or none study
- **2A** Systematic review (with homogeneity) of cohort studies
- **2B** Individual cohort study (including low-quality RCT [e.g., < 80% follow-up])
- **2C** "Outcomes" research; ecological studies
- **3A** Systematic review (with homogeneity) of case-control studies
- **3B** Individual case-control study
- **4** Case series (and poor-quality cohort and case-control study)
- **5** Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"



RCT = randomized controlled trial

KEY RESULTS

- A pooled meta-analysis of five studies comparing BurstDR stimulation and tonic waveforms revealed a significant reduction in pain scores, favoring BurstDR stimulation over tonic ($n = 268$, $p < 0.001$)[2]
- Two out of three studies were unable to establish high-frequency waveform superiority over tonic stimulation[2]
- The BurstDR stimulation waveform is the first waveform to establish level 1A evidence for chronic low back pain

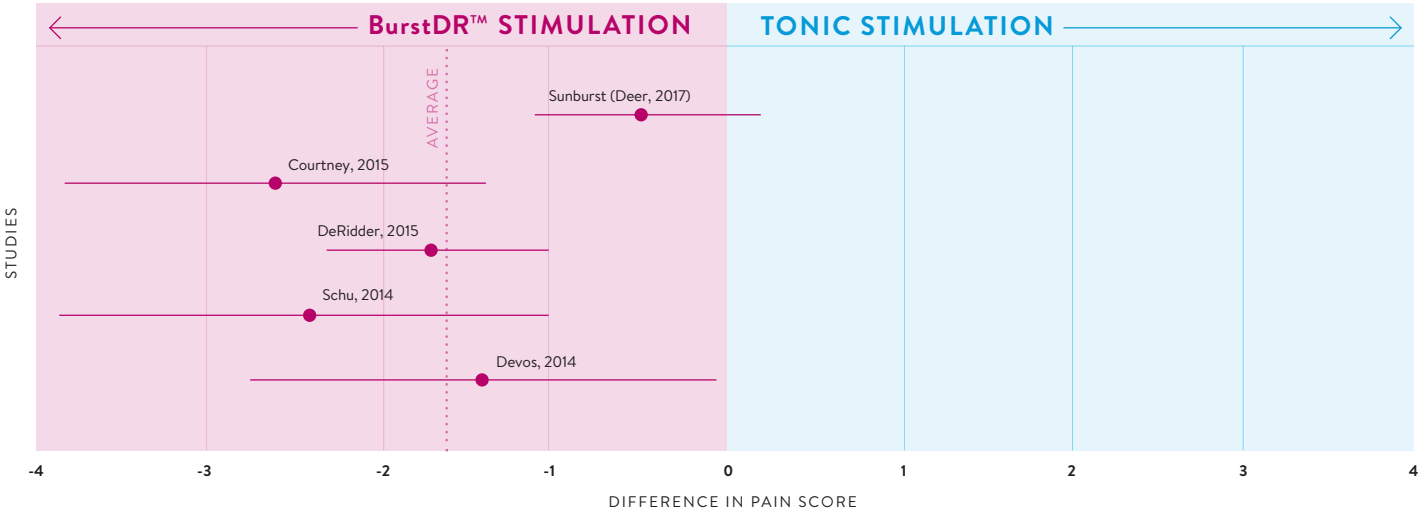


Figure 2: Meta-analysis of five studies comparing BurstDR™ stimulation and tonic spinal cord stimulation in reducing pain scores of patients with chronic low back pain. Favorability was based on pain outcomes (Visual Analog Scale [VAS] and Numeric Rating Scale [NRS-11]) and was consistently shown to favor BurstDR stimulation over tonic stimulation.

CONCLUSIONS

- BurstDR™ stimulation is the first waveform to establish level 1A evidence revealing superiority over traditional waveform for chronic low back pain
- The meta-analysis of traditional tonic versus BurstDR stimulation revealed superiority of the BurstDR stimulation waveform across data pooled from five separate studies
- Superiority of high-frequency stimulation relative to tonic stimulation could not be established in two out of three studies

1. Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery*. 2011;128(1):305-310.
2. Karri J, Orhurhu V, Wahezi S, Tang T, Deer T, Abd-Elsayed A. Comparison of spinal cord stimulation waveforms for treating chronic low back pain: systematic review and meta-analysis. *Pain Physician*. 2020;23(5):451-460.

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Brief Summary: Prior to using Abbott devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

Contraindications: Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Unpleasant sensations, undesirable changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain at the electrode or IPG site, seroma at IPG site, allergic or rejection response, battery failure. Clinician's Manual must be reviewed for detailed disclosure.

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