No Reports of IPG Pocket Pain in 1-year Clinical Data with a Novel, Micro Spinal Cord Stimulator

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Introduction

A recent retrospective study has reported that pocket pain occurs in up to 31% of patients who receive a traditional sized implantable pulse generator (IPG). A significant percentage of pocket pain patients will have either revision (70%) or explant (47%) surgery. Although the underlying factors are not well established, multiple authors have theorized that a miniaturized IPG (mIPG) may mitigate the incidence of pocket pain.

Methods

Two prospective, multi-center, clinical trials were initiated in Australia and the USA to evaluate a mIPG system with a volume of approximately 1.5 cc (Nalu Medical, Inc. Carlsbad, CA). Subjects with intractable chronic pain were followed for up to 1-year post-implant. All mIPG implant sites were in the low back. Studies were approved by independent Ethics Committees and conducted in compliance with local regulations.

Results

Overall, study subjects demonstrated a robust decrease in back pain using the mIPG system. The average baseline back pain score was 6.9 (AUS Study) and 8.0 (USA Study), which dropped to 1.7 (AUS) and 1.1 (USA) at 3 months post activation. Following post-surgical healing of the incision, there have been no reports of pocket pain in any patient from either study; data is available for up to 1 year post activation.

Discussion

The incidence of pocket pain and related revision surgeries can increase the burden on patients and the health care system. The mechanism of action of pocket pain is not entirely understood and may have multiple contributing factors. Based on the preliminary data to date presented above, no pocket pain has been reported by participants who received the micro-IPG investigated in this ongoing study. These results warrant additional investigation.

References