INTRODUCTION

Typically, paddle type leads offer several advantages over percutaneous leads. For example, the electrodes lay closer to the spinal cord due to the dimensions and surgical placement of the paddle lead. This allows for increased stimulation of the posterior region, while avoiding uncomfortable stimulation of the anterior region, enhancing the likelihood of capturing elusive back pain. Paddle leads also provide greater energy efficiency by unilaterally directing current towards the spinal cord, thereby reducing power requirements and the likelihood of painful dysesthesia caused by stimulating the ligamentum flavum. In addition, cylindrical type leads are more likely to migrate post-operatively due to postural changes and this movement within the epidural space can result in changes in the parasagittal coverage and inadequate pain relief. Despite these advantages, paddle leads require a laminectomy, which is a more invasive surgical procedure than a percutaneous procedure. A newly developed SCS accessory called the Epicflex™ lead delivery system was developed to percutaneously implant slim line paddle leads, much like implantation of a percutaneous lead delivery system was developed to percutaneously implant slim line invasive surgical procedure than a percutaneous procedure. A

METHODS

Data analysis was performed on results obtained in an IRB-approved, prospective clinical research study and an IRB-approved, prospective, multicenter, international registry. Patients were stratified by lead configuration (dual cylindrical leads or single S-Series/single cylindrical lead combination) and the following outcomes were compared across groups 3 and 6 months post-implant: direct patient report of percentage of pain relief, categorical rating of pain relief, global impression of satisfaction, quality of life and power usage. The power and current settings of each patient’s favorite program were analyzed and recorded to calculate charge requirements. Percentages of device-related adverse events were analyzed across the groups. Group comparisons were performed using t-tests or Fisher’s exact test.

RESULTS

Pain Relief

Figure 1. On average, patients implanted with a single 5-contacts single percutaneous lead configuration reported higher patient-reported pain relief than patients implanted with dual 8-contact percutaneous leads. This difference did not reach statistical significance either at 3 (p=0.06) or 6 (p=0.06) months post-implant.

Figure 2. Significantly more patients implanted with a single S-Series/single percutaneous lead configuration reported “Excellent” pain relief than patients implanted with dual 8-contact percutaneous leads at 3 months post-implant (p=0.05).

Figure 3. More patients implanted with a single S-Series/single percutaneous lead configuration reported “Greatly improved” pain relief than patients implanted with dual 8-contact percutaneous leads at 6 months post-implant (p=0.05).

Figure 4. More patients implanted with a single S-Series/single percutaneous lead configuration reported “Excellent” pain relief than patients implanted with dual 8-contact percutaneous leads at 6 months post-implant. However, this difference was not statistically significant (p=0.06).

Power Consumption

Figure 5. Percentage of patients implanted with a single S-Series/single percutaneous lead configuration reported greater power usage than patients implanted with dual 8-contact percutaneous leads at 3 months post-implant. However, this difference was not statistically significant (p=0.06).

Quality of Life

Figure 6. More patients implanted with a single S-Series/single percutaneous lead configuration reported “Greatly improved” quality of life of their patients implanted with dual 8-contact percutaneous leads. However, this difference was not statistically significant either at 3 (p=0.06) or 6 (p=0.06) months post-implant.

Satisfaction

Figure 7. More patients implanted with a single S-Series/single percutaneous lead configuration reported being “Very satisfied” with their patients implanted with dual 8-contact percutaneous leads. However, this difference did not reach statistical significance since 2 (p=0.46) left & 4 (p=0.46) right months post-implant.