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Single-lead Percutaneous Peripheral Nerve Stimulation for the Treatment of Hemiplegic Shoulder Pain: A Case Report

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Abstract

Previous studies demonstrated the efficacy of 6 weeks of a 4-lead percutaneous, peripheral nerve stimulation system in reducing hemiplegic shoulder pain. This case report describes the first stroke survivor treated for 3 weeks with a less complex, single-lead approach. The participant was a 59-year-old male who developed hemiplegic shoulder pain shortly after his stroke 7.5 years prior to study enrollment and was treated with multiple modalities without sustained pain relief. After study enrollment, a single intramuscular lead was placed percutaneously into the deltoid muscle. He was treated 6 hours per day for 3 weeks and the lead was removed. The primary outcome measure was the Brief Pain Inventory (Short-Form) Question 3 (BPI-3), which queries the worst

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Disclosures: NDI Medical (the sponsor of this study) and SPR Therapeutics (a subsidiary of NDI Medical) have a commercial interest in the device presented in this case report. John Chae, MD is a consultant to SPR Therapeutics, Maria Bennett and Tina Lechman are employees of SPR Therapeutics, and Kathryn Stager is an employee of NDI Medical.

Suppliers and Device Status: An investigational percutaneous peripheral nerve stimulator system (NDI Medical, Cleveland, Ohio) including a percutaneous intramuscular lead and a commercially available external stimulator (Rehabicare NT2000) was used during this clinical study.

pain in the last week on a 0–10 numeric rating scale. At baseline, BPI 3 was an 8. At the end of treatment and at 1 and 4 weeks after end of treatment, BPI 3 scores were 3, 2 and 2 respectively. Substantial improvements in quality of life measures were also observed. The participant remained infection-free and the lead was removed fully intact. After completing the study protocol, the participant was followed clinically for 13 months post-treatment with complete resolution of hemiplegic shoulder pain. This case report demonstrates the feasibility of a single-lead peripheral nerve stimulation for the treatment of chronic hemiplegic shoulder pain. Additional studies are needed to further demonstrate safety and efficacy, determine optimal dose, define optimal prescriptive parameters, expand clinical indications, and demonstrate long-term effect.

Keywords

Stroke; shoulder pain; electrical stimulation

Hemiplegic shoulder pain (HSP) is a common complication following stroke with reported incidence between 9% and 40%^{1–5} and up to a third of patients exhibiting pain refractory to treatment.^{6–7} The only intervention for HSP with evidence of efficacy supported by multiple randomized controlled trials (RCTs) is surface neuromuscular electrical stimulation (NMES).^{8–10} Postulated mechanisms by which neurostimulation reduces shoulder pain include partial restoration of mechanical integrity of the glenohumeral joint and sensory neuromodulation.^{11–12} However, surface NMES is difficult to implement due to the discomfort of stimulation and expertise required to place the electrodes properly and iteratively adjust stimulation parameters to maximize tolerance.¹³ Thus, an alternative treatment using a peripheral nerve stimulation (PNS) system was developed at Case Western Reserve University to deliver stimulation to the motor points of the supraspinatus, posterior deltoid, middle deltoid and upper trapezius muscles.¹⁴ Pilot studies suggested that PNS was better tolerated than surface NMES¹⁵ and efficacious in reducing HSP without the need of expertise in daily application of surface electrodes.^{14–16–17} A multicenter RCT, using the 4-lead PNS system, subsequently demonstrated the efficacy of PNS in reducing HSP and improving pain related quality of life.^{11–12}

During the RCT, a subcutaneous tunneling procedure was used to ensure that all four leads exited at approximately the same site to facilitate skin care and connection to the stimulator. However, in reviewing the clinical trial experience, it was determined that a single-lead approach that stimulated the axillary nerve via placement in the middle and posterior deltoid may lead to similar results and wider physician adoption. Since the middle and posterior deltoids are contiguous and stimulation of these two muscles consistently produced strong muscle contraction and subluxation reduction, it was hypothesized that a single lead placed mid-way between the motor points of these muscles could activate both muscles simultaneously. It was determined that stimulation of the trapezius was not necessary as it does not cross the glenohumeral joint, and stimulation of the supraspinatus was not necessary because in prior trials, this muscle rarely produced adequate contraction to reduce the subluxation. Review of the RCT data further suggested that the duration of treatment could be shortened. Pain reduction at the end of the 6 weeks of stimulation therapy was similar to pain reduction at mid-treatment (not published). Thus, treatment for 3 weeks may be equally efficacious.

If successful, the single-lead approach would substantially simplify this treatment by using three fewer leads, eliminate the need for subcutaneous tunneling, and reduce the duration of the treatment period by half. A single-lead procedure would be more time efficient and less complicated to perform, and reduce the risk for infection and retained lead fragments. The first participant treated with this revised approach is described in this case study.

Case Report

Pre-intervention Clinical Course

The participant is a 59-year-old man with history of diabetes mellitus type II, hypertension, peptic ulcer disease, and seizure disorder who experienced a right hemisphere cortical, thrombotic stroke with hemorrhagic conversion 7.5 yrs before receiving the single-lead PNS therapy. He developed HSP shortly after the stroke. Prior treatments for his shoulder pain included sling, opiate and non-opiate oral analgesics, physical and occupational therapy, massage therapy, subacromial steroid injection, botulinum toxin injection, surface NMES and transcutaneous electrical nerve stimulation. He also enrolled in a trial of the 4-lead PNS approximately 4-yrs prior to enrollment in the present study. No treatment modality provided lasting pain relief. The 4-lead PNS trial provided complete resolution of pain during the 6 week treatment phase; however, when the treatment ended, his pain returned to pre-treatment levels. Just prior to enrollment in the single-lead study, he was using acetaminophen and massage therapy to control his shoulder pain.

On the pre-procedure physical examination, the participant exhibited left hemiplegia with flexor synergy, left shoulder pain with 1.5 finger breadth glenohumeral subluxation (as measured by palpation) and mild left neglect. His left arm was non-functional and his score on Fugl-Meyer Assessment for the upper extremity was 11 out of a possible 66. He had adequate cognition and communication skills to participate in the trial. He did not have any evidence of overlying skin infection of the affected shoulder. His diabetes was well controlled (HbA1c of 5.4%). He was taking acetaminophen as needed for pain. He had not received any intra-articular, subacromial, or botulinum toxin injections to the shoulder in the prior 3month. He was not receiving outpatient physical or occupational therapies for shoulder pain and his massage therapy was stopped during treatment. Baseline assessments are shown in Table 1.

Methods

The intervention protocol was approved by the local institutional review board. The formal 2 month intervention protocol included lead placement, 1week of lead stabilization, 3 weeks of stimulation therapy, and 4 weeks of follow-up.

Assessment

The primary outcome was the Brief Pain Inventory (Short-Form) Question 3 (BPI 3), which rates the worst pain in the last week on a 0–10 numeric rating scale, where 0 indicates “no pain” and 10 indicates “pain as bad as you can imagine.”¹⁸ The reduction in pain that has been determined as the minimal clinically important difference of numeric pain of a reduction of 2 points or 30%.¹⁹ Secondary outcomes were pain interference (Brief Pain Inventory, question 9 or BPI 9), quality of life measured on the Short Form 36 (SF-36v2),²⁰ the Patient Global Impression of Change scale (PGIC)²¹, and pain-free external rotation ROM of the glenohumeral joint.

The BPI 9 is a measure of pain-related quality of life that measures how pain interferes with physical function. It has been recommended that physical interference be a core outcome in pain studies.²² The BPI 9 assesses the degree to which pain interferes with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life during the last week on a 0–10 numeric rating scale, where 0 indicates “does not interfere” and 10 indicates “completely interferes.” The BPI 9 score is the average of the scores for the seven domains. The SF-36v2 is a health survey of 36 questions in 8 domains that provides a profile of health and well-being in a preference-based quality of life index. The SF-36v2 can be broken down into mental and physical health summary scores so that

relative change within each area can be assessed, as was done in this study. The mental and physical subscores of the SF-36v2 are scored on a 0 – 100 index with a higher score indicating a higher quality of life. The scores in this case were not normalized to the general population. The PGIC asks participants to rate the change in their quality of life since they enrolled in the study as a result of the stimulation therapy on a 7-point scale from “very much worse” to “very much improved.” In prior studies, a clinically important change in PGIC has been at the category “much improved” and beyond (points 6 or 7.)^{19,23} Pain-free external rotation ROM was assessed with a goniometer while abducting the shoulder to 45 degrees and externally rotating the shoulder from the fully internally rotated position.

Intervention

The skin overlying the deltoid muscle was cleaned with povidone-iodine topical antiseptic. Monopolar needle electrodes were inserted perpendicular to the skin surface at the axillary nerve motor points of the middle and posterior deltoids.²⁴ Motor points were confirmed by stimulating each muscle separately and demonstrating full reduction of subluxation. A third needle electrode was placed at the midpoint between the two motor points. The position and depth of the needle electrode and the pulse duration were iteratively adjusted until a strong contraction of both heads of the deltoids with full reduction of subluxation was achieved.

After placement of local anesthetic, a 20-gauge insulated introducer loaded with a percutaneous lead was inserted at approximately 45 degrees relative to the skin surface to the depth and location indicated by the third needle electrode. The characteristics of the percutaneous lead were previously described.²⁵ The lead was stimulated through its introducer to ensure proper position. Pressure was maintained at the skin surface to anchor the lead’s barb in the belly of the muscle and the introducer was withdrawn leaving the lead in place. The lead was stimulated again to verify proper placement. Prior to leaving the clinic the participant was instructed on the proper care of the lead exit site. He returned 48 hours later for examination of the skin.

Following a one-week stabilization period, the stimulator (Rehabicare NT2000) was connected to the lead and parameters were set to stimulate the middle and posterior deltoids at 12 Hz and 20 mA with pulse duration of 120 μ s. The first contraction motor threshold was measured and compared to the first contraction motor threshold collected at the lead placement visit to assess the stability of the lead. The participant was prescribed 6 hours of stimulation per day in two, 3 hour sessions for 3 weeks. The stimulator completed a cycle every 30 seconds consisting of 5 seconds to ramp up, 10 seconds at maximum stimulation, 5 seconds to ramp down, and 10 seconds of no stimulation. He was advised that as long as he was in an upright position during stimulation he could perform his typical daily routines. During the 3 week stimulation therapy, the participant was contacted by telephone weekly and queried for pain intensity (BPI 3), adverse events, and medication usage.

At the end of the 3-wk stimulation therapy, the participant returned for evaluation of primary and secondary endpoints including BPI 3, BPI 9, pain free passive external rotation ROM, SF-36v2, the PGIC scale, and a participant satisfaction survey. Medication usage and adverse events were also recorded. Stimulation therapy usage data were electronically captured by the stimulator. The first contraction motor threshold was measured again and compared to the first contraction motor threshold collected at the lead placement and start of treatment visits to assess the stability of the lead. The lead was then removed by gently pulling on its exposed end. The participant underwent anterior-posterior and scapular-Y view radiographs of the shoulder for surveillance for retained lead fragments. He returned at 1 and 4 weeks post-treatment for skin evaluation and outcomes assessments. The participant was followed thereafter per usual clinical follow-up. Thus, BPI 3 data were also available at 2, 3, 7.5, 11.5 and 13monthpost-treatment.

Results

The participant tolerated the lead placement and stimulation test procedure with a reported maximum discomfort of 4 on a 0–10 numeric rating scale. The 3-week stimulation therapy was completed without complications. The stimulator recorded 116 hours of stimulation therapy usage, which yields 92% compliance with the prescribed stimulation therapy of 126 hours. There were no signs or symptoms of infection or skin irritation at the lead site or any other complications. The lead was removed intact and the radiographs revealed no retained fragments.

The outcome measurements for each study time point are listed in Table 1. He chose to stop using all analgesics during the 2 month study period. There was improvement in pain interference (BPI 9) as well as both physical and mental quality of life (SF-36v2), which were sustained at 1 and 4 weeks after EOT. This reported quality of life improvement was confirmed by the PGIC scale, which showed that at 1 and 4 weeks post-treatment, his quality of life was the highest category of “very much improved.” The participant reported complete resolution of HSP during routine clinical evaluations at 2, 3, 7.5, 11.5 and 13 month post-treatment. Per clinical exam, the participant experienced no change in motor function or subluxation as measured by palpation.

Discussion

This case report describes the first stroke survivor, that we know of, treated with a single-lead percutaneous PNS system for HSP. Although the participant was treated for only 3 weeks, he experienced substantial pain reduction that was maintained for at least 13 months after completion of treatment. BPI 9, SF-36v2 and PGIC data suggested that the intervention affects a broader aspect of the participant’s quality of life than simply reducing pain. The participant was also satisfied with the intervention to the point of being willing to undergo it again in the future.

Two case reports of implanted microstimulators have been studied for the treatment of HSP. In both a device is permanently implanted in close proximity to the axillary nerve trunk 26–27 with one study also having an implanted microstimulator near the motor point of the middle deltoid muscle.²⁶ The stimulation dosages in each were greater than the 6 hours per day for 3 weeks in this study. Shimada²⁶ used a stimulation protocol of 50 to 180 minutes per day for six months whereas Yu²⁷ used 6 hours per day for 6 weeks. Post-stimulation outcomes were only measured in one case report.²⁷ These differences make direct comparison of outcomes difficult to interpret. However, it is noteworthy that the case reported by Yu²⁷ experienced a 50% pain reduction by EOT and a 63% pain reduction at 3 months after stimulation which are similar to the results we observed in our case study at EOT and 4 weeks.

The participant in this case report had already received 6 weeks of treatment with the prior 4-lead approach. Although he experienced substantial pain reduction at the EOT, pain recurred. This is consistent with our post-hoc analysis of the multi-center RCT, which suggested that participants who receive PNS therapy beyond 18 months from stroke are likely to experience pain recurrence.²⁸ However, with a repeat short-term therapy, this participant has remained pain-free for over a year. At the present time we don’t know the optimal dose for these patients but future studies will explore this.

Limitations

There are limitations to this study. Foremost, as a single case study, these results may not be generalizable beyond what was observed for this individual. The positive results could be

due to placebo response, assessor bias, natural recovery, or other phenomenon. It is also unfortunate that we do not have data to demonstrate the case's stability prior to the intervention. While we have data for the primary outcome up to 13 months past EOT, the last formal outcomes assessments were at 4 weeks after EOT. The remaining pain assessments were from routine clinical examination visits. Finally, we did not formally assess motor impairment and ADLs; however, this was because we did not think there would be an effect based on prior studies.

Conclusion

Although the single lead percutaneous NMES system has shown to be effective for treating HSP in this case report, additional studies are needed to further evaluate the efficacy and safety, elucidate the mechanism of action, define optimal prescriptive parameters, expand clinical indications, and demonstrate long-term effect.

Acknowledgments

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Acronyms

BPI-3	Brief Pain Inventory, question 3
BPI-9	Brief Pain Inventory, question 9
EOT	end of treatment
HSP	Hemiplegic Shoulder Pain
MRC	Medical Research Council
NMES	neuromuscular electrical stimulation
PGIC	Patient Global Impression of Change Scale
PNS	peripheral nerve stimulation
RCT	randomized controlled trial
ROM	range of motion
SF-36v2	Short Form-36 version 2

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Table 1

Baseline, during treatment, and post-treatment outcome measures.

	Baseline	week 1	week 2	week 3	week 4	week 5	1 week post	4 weeks post
BPL-3*	8	5	4	3	2	2	2	2
BPL-9 [†]	6.43			0.57	0.71	0.14		
External Rotation Range of Motion (degrees)	22			28	25	20		
SF-36v2 [‡] Physical Health Scale	38.53			48.40	42.11	48.85		
SF-36v2 [‡] Mental Health Scale	42.34			60.38	61.29	56.40		

* Brief Pain Inventory, question 3 - Worst pain in last week, 0 (no pain) – 10 (pain as bad as can be imagined)

[†] Brief Pain Inventory 9 - Degree to which pain interferes with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life during the last week (average 7 domains)

[‡] Short Form 36, version 2

[§] End of Treatment