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Comparing the Efficacy of Dorsal Root Ganglion Stimulation With Conventional Medical Management in Patients With Chronic Postsurgical Inguinal Pain: Post Hoc Analyzed Results of the SMASHING Study

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ABSTRACT

Objectives: Approximately 10% of patients who undergo inguinal hernia repair or Pfannenstiel incision develop chronic (> three months) postsurgical inguinal pain (PSIP). If medication or peripheral nerve blocks fail, a neurectomy is the treatment of choice. However, some patients do not respond to this treatment. In such cases, stimulation of the dorsal root ganglion (DRG) appears to significantly reduce chronic PSIP in selected patients.

Materials and Methods: In this multicenter, randomized controlled study, DRG stimulation was compared with conventional medical management (CMM) (noninvasive treatments, such as medication, transcutaneous electric neurostimulation, and rehabilitation therapy) in patients with PSIP that was resistant to a neurectomy. Patients were recruited at a tertiary referral center for groin pain (SolviMáx, Eindhoven, The Netherlands) between March 2015 and November 2016. Suitability for implantation was assessed according to the Dutch Neuromodulation Association guidelines. The sponsor discontinued the study early owing to slow enrollment. Of 78 planned patients, 18 were randomized (DRG and CMM groups each had nine patients). Six patients with CMM (67%) crossed over to DRG stimulation at the six-month mark.

Results: Fifteen of the 18 patients met the six-month primary end point with a complete data set for a per-protocol analysis. Three patients with DRG stimulation had a negative trial and were lost to follow-up. The average pain reduction was 50% in the DRG stimulation and crossover group (from 6.60 ± 1.24 to 3.28 ± 2.30, $p = 0.0029$). Conversely, a 13% increase in pain was observed in patients with CMM (from 6.13 ± 2.24 to 6.89 ± 1.24, $p = 0.42$). Nine patients with DRG stimulation experienced a total of 19 adverse events, such as lead dislocation and pain at the implantation site.

Conclusions: DRG stimulation is a promising effective therapy for pain relief in patients with PSIP resistant to conventional treatment modalities; larger studies should confirm this. The frequency of side effects should be a concern in a new study.

Clinical Trial Registration: The Clinicaltrials.gov registration number for the study is NCT02349659.

Keywords: Dorsal root ganglion, spinal cord stimulation

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INTRODUCTION

A male person in the industrialized world has a lifelong risk of up to 27% of requiring surgery for an inguinal hernia,[1] and approximately 10% to 12% of these patients report moderate-to-severe chronic pain after the operation.[2–4] Chronic postsurgical inguinal pain (PSIP) is defined by the International Association for the Study of Pain as "pain lasting more than three months after inguinal hernia surgery," and this is currently the most disabling and costly complication of groin hernia surgery. In women, PSIP can also occur after a lower abdominal Pfannenstiel incision for cesarean section.[5]

PSIP after surgery may be nociceptive or neuropathic,[6,7] and neuropathic pain is typically characterized as burning or shooting in nature. In addition, paresthesia (tingling) and dysesthesia (spontaneously induced unpleasant abnormal sensations) that radiate toward the corresponding skin area of the involved inguinal nerve are frequently reported. Pain with neuropathic characteristics is generally more severe than is nociceptive pain and is associated with a reduced health-related quality of life; reported scores are similar to those in patients with depression, coronary artery disease, myocardial infarction, or poorly controlled diabetes.[8]

Recently, a consensus was achieved regarding the treatment of PSIP.[9] If nonsurgical options fail, a neurectomy of inguinal nerves is suggested. Success rates range from 50% to 100%, depending on the surgical technique and the surgeon's experience.[10–12] However, few therapeutic options are available if neurectomy provides insufficient pain relief. The remaining treatments usually include medications such as antineuropathics or opiates that can be supplemented with procedures such as pulsed radio frequency ablation and transcutaneous electric neurostimulation (TENS).[13]

Dorsal root ganglion (DRG) stimulation may provide pain relief in these patients resistant to therapy. This new variant of traditional spinal cord stimulation (SCS) has proven to be an important innovation in a wide range of intractable pain conditions, such as persistent spinal pain syndrome, complex regional pain syndrome type 1 and type 2, and phantom limb pain.[14–16] The advantage over traditional SCS is the direct stimulation of the inguinal dorsal root ganglia (specifically T12–L3), which eliminates potential side effects, such as undesired sensations in structures near the groin (eg, the bladder and urinary tract), that were common with traditional non-subthreshold SCS.[17] This therapy has been proven to be safe and effective in small cohorts of patients with PSIP since its introduction in 2011 in Europe, but few large randomized controlled trials have been conducted.[18–20] The aim of this study is to investigate the efficacy of DRG SCS for PSIP in a randomized design.

The study was discontinued by the sponsor owing to slow enrollment. Consequently, this report contains the post hoc analysis results of patients who were enrolled at the time of closure of the study. Of the 78 planned participants, 18 were randomized (nine each in DRG and conventional medical management [CMM]). Fifteen patients reached the six-month follow-up mark and were available for per-protocol analysis.

MATERIALS AND METHODS

Study Design, Outcomes, Patient Selection, and Randomization

This study was designed to evaluate the efficacy of DRG SCS using the Axium® SCS System (Abbott, Plano, TX) combined with CMM, compared with CMM alone in patients with PSIP who failed to respond to an inguinal neurectomy. The study design was a multicenter, randomized crossover trial. Primary outcomes are the percentage of patients who experienced pain relief and the difference in pain relief between groups as measured by average pain scores that were collected using the numeric pain rating scale (NPRS) and patients' pain diaries, which they recorded for seven consecutive days at one-, three- and six-month follow-up intervals. Secondary outcomes include safety, quality of life measured using the EuroQol-5D instrument, and pain interference in daily activities using the brief pain inventory. Primary and secondary outcomes are compared with baseline values.

The study was conducted at eight independent sites with staff who had extensive experience implanting SCS devices. Central Review Board approval was obtained at Maxima Medical Center, and local approval was obtained from the board of directors of each site. The study is registered at Clinical Trials.gov (NCT02349659) and meets Dutch guidelines for neuromodulation.

Inclusion criteria were age of 18 years or older; ability and willingness to comply with the follow-up schedule; chronic inguinal pain (> six months) after a Pfannenstiel incision or an open or laparoscopic inguinal hernia repair; previous neurectomy as a treatment for chronic inguinal pain; minimum daily average baseline pain rating of 5 (of 10) in the inguinal area on an 11-point (0–10) NPRS scale; and neuropathic pain as described by a score of ≥ 4 on the douleur neuropathique en 4 (DN4) questionnaire. Excluded were participants who were pregnant, nursing, or planned to become pregnant during the trial; those with escalating or changing pain conditions within the previous month that were objectified by examination, injection, or radiofrequency treatment of a targeted neural structure within the previous three months; and those with active implantable devices, including implantable cardioverter-defibrillator, pacemaker, SCS system, or intrathecal drug pump. Moreover, patients were excluded if they were unable to operate the device; had an active infection; had a coagulation disorder or a cancer diagnosis in the previous two years (with the exception of skin malignancies, such as squamous or basocellular carcinoma); had participated in another clinical investigation in the previous 30 days; had an ongoing condition that was likely to require magnetic resonance imaging investigation in the next two years; had undergone spinal surgical procedures at or between vertebral levels T10–L2; or had progressive neurologic disorders, such as diabetic polyneuropathy or multiple sclerosis.

Patients eligible for the study were identified from a data base of neurectomy nonresponders at a tertiary referral center for groin pain (SolviMáx Center of Excellence for Abdominal Wall and Groin Pain, Eindhoven, The Netherlands) and were invited for an informational visit if they met the criteria. Independent providers were also permitted to refer patients. Written informed consent was obtained after additional screening by a multidisciplinary team that included a psychologist, a pain specialist, and a surgeon who was qualified as a groin pain expert. After the baseline visit, patients were randomized to either the DRG SCS or CMM group using a centralized web-based system in a 1:1 fashion.

Interventions and Follow-up

Members of the DRG SCS group were referred to an implantation center closest to their place of residence and underwent one or two intake visits with the implanter before the actual implantation procedure. The patients underwent implantation in a protocolized two-phase procedure. During the first procedure, leads were positioned, and treatment was tested with an external stimulator

for one to two weeks. If the patient achieved adequate pain relief (≥ 50% pain relief), they underwent implantation with an internal neurostimulation system (INS) during a second procedure. Follow-up visits were scheduled at the designated center at intervals of four weeks, three months, and six months after the neurostimulator implantation. For patient safety reasons, some patients did not undergo a trial and underwent implantation with a total system in a single procedure. In these situations, this approach was discussed and agreed upon in consultation with the principal investigator.

The CMM group also received follow-up visits at intervals of four weeks, three months, and six months after randomization. Medication, TENS, and rehabilitation therapy could be initiated or continued at a follow-up visit. Nerve root blocks, pulsed radiofrequency treatment of the dorsal root ganglia (from T10–L2), and epidural injections were discouraged because these treatments would be exclusion criteria if patients switched to the DRG SCS treatment after six months. After a crossover, patients with CMM were followed for an additional six months, which was according to the schedule of the DRG SCS group.

Sample Size, Statistics, and Interim Analysis

The sample size estimation was based on a responder analysis, with an estimated 10% of responders (> 50% pain reduction) in the CMM group and a 40% difference in effect size between groups. With a power of 90% and a two-tailed alpha of 0.05, the authors calculated that 31 subjects were necessary in each group to achieve the study aim. Allowing a 20% attrition rate, the authors aimed to enroll 78 individuals. However, the actual inclusion rate was considerably lower (Fig. 1), and the study was discontinued by the sponsor because of slower than anticipated enrollment. This prompted the authors to conduct a post hoc analysis of patients who had enrolled through November 2016 to validate results. A one-way repeated measures analysis of variance (ANOVA) was used with the mean pain reduction scores (as rated according to the NPRS) at four time points instead of the proposed per-protocol chi-square analysis on the number of favorable responders; this was dictated by the low sample size. Categorical demographics were compared using the chi-square test. Continuous data were compared using the independent *t*-test or Mann-Whitney U test

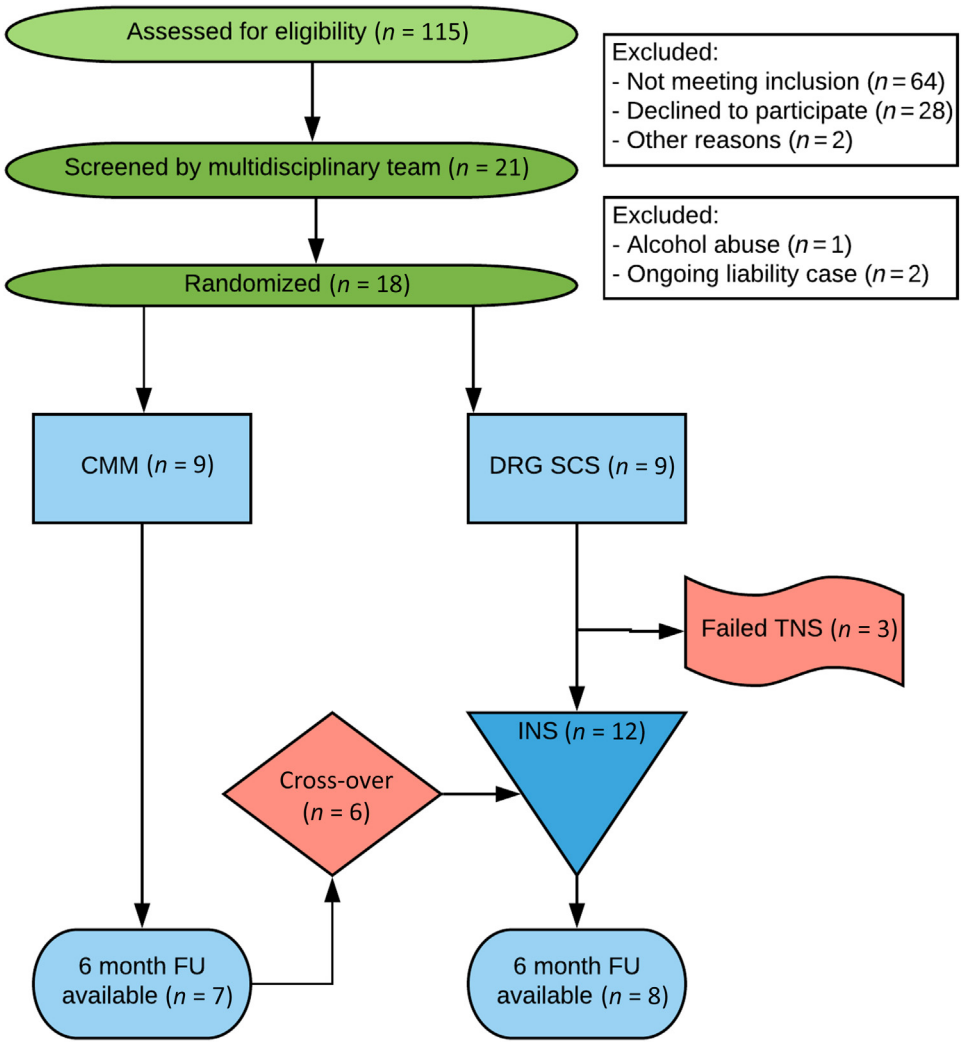

Figure 1. Patient enrollment, allocation, and flow; this reporting follows the Consolidated Standards of Reporting Trials diagram. FU, follow-up; TNS, trial neuro stimulation. [Color figure can be viewed at www.neuromodulationjournal.org]

when appropriate. Results were presented as the mean with SDs or as the median with a range. Data were analyzed using SPSS version 22.0 software (SPSS Inc, Chicago, IL).

RESULTS

Recruitment and Patient Flow

Study enrollment, group assignment, and follow-up are summarized in the Consolidated Standards of Reporting Trials flow chart (Fig. 1).[21] After Institutional Review Board approval, 78 patients were screened from a data base of 418 patients who underwent a neurectomy between 2002 and 2013 and were coded as having an unsuccessful or unsatisfactory result. Of these 78, 42 patients did not meet the study criteria. The remaining 36 patients were approached, of whom an additional 30 were excluded or chose not to participate. Between 2014 and 2016, 37 additional patients were evaluated after an unsuccessful neurectomy either at a tertiary referral center or at another medical facility. Fifteen of these patients met the study eligibility criteria and were interested in participating in the study. A total of 21 patients were screened by the multidisciplinary implantation team, and 18 were considered suitable for implantation.

Between March 2015 and November 2016, these 18 patients were randomized to a DRG SCS ($N = 9$) or CMM ($N = 9$) group. Three patients in the DRG stimulation group experienced a negative trial (eg, did not experience 50% pain relief), did not proceed to an implantation, and withdrew from the study. The remaining 15 enrolled patients reached the primary six-month follow-up end point and had data available for a per-protocol analysis. Six of the nine patients who were randomized to the DRG SCS group received a permanent INS. In the other group, six of the nine patients with CMM (67%) chose to cross over after their six-month follow-up appointment and received a permanent INS. The remaining patients with CMM chose not to cross over to the active treatment group for reasons that included significant comorbidities and fear of surgical complications.

Baseline Characteristics and Assessments

Patient demographics are presented in Table 1. The data were normally distributed, except for pain duration in months. Otherwise, there were no significant differences between groups. Furthermore, pain distribution was similar in both groups, sometimes radiating from the groin area to the thigh or even the back.

Primary and Secondary Outcomes

Of the 12 patients who received permanent INS, eight completed the six-month follow-up appointment, and a significant pain reduction of 50% (6.60 ± 1.24 to 3.28 ± 2.30, $p = 0.0029$) was observed (Fig. 2). In the CMM group, a nonsignificant increase in pain of 13% was observed (6.13 ± 2.24 to 6.89 ± 1.24, $p = 0.42$). Group differences were highly significant over time (repeated measures ANOVA, group by time interaction, $p = 0.001$ at a power of 96%) and significant at the six-month follow-up appointment (as determined by an independent t-test; $p = 0.0047$). In addition, the patients in the DRG group experienced an improved quality of life and a decrease in pain interference, although group differences were not significant for these parameters (Figs. 3 and 4).

The CMM group experienced no adverse events. However, nine of 15 patients (60%) who received DRG stimulation—including those with a negative trial period—experienced adverse events, for a total of 19 incidents (Table 2). The main complications were lead migration or lead fracture, which caused suboptimal stimulation, pain at the battery site, and painful stimulation. One patient experienced postspinal headache and refused permanent implantation. A second patient had a technical software problem that caused low impedances, which were resolved by using a new patient programmer. A third patient developed fever and pain at the site of the stimulator pocket. Because ultrasound and laboratory testing suggested infection, intravenous antibiotics were administered, leading to recovery without explantation. However, the patient reported fatigue and frequent episodes of recurrent subfebrile temperatures during follow-up, without abnormalities in blood test results. Finally, a fourth patient experienced a syncope and brief loss of function of the right arm, which was likely unrelated to the device but caused by adjustments to the medication regimen.

DISCUSSION

Preliminary results in this small cohort of 18 patients with chronic refractory PSIP, 15 of whom achieved the six-month follow-up end point, indicate that DRG stimulation may contribute to significant

Table 1. Baseline Characteristics.

Characteristics	DRG SCS ($n = 9$)	CMM ($n = 9$)	p Value
Sex m:f	4:5	4:5	–
Age in years*	44 (10)	45 (15)	0.24
BMI*	26 (7)	25 (5)	0.16
Duration of pain in mo*	54 (35)	64 (49)	0.02
Time since neurectomy in mo*	16 (8)	16 (8)	0.40
PSIP: Post-Pfannenstiel syndrome	4:5	4:5	–
Pain average (NPRS)*	5.9 (1.3)	6.0 (2.1)	0.22
Pain worst (NPRS)*	7.1 (1.7)	7.2 (1.0)	0.49
Pain least (NPRS)*	3.8 (2.7)	4.1 (2.5)	0.33

SDs are in parentheses, and ratios are presented as N:N.
BMI, body mass index; f, female; m, male.
*Mean scores.

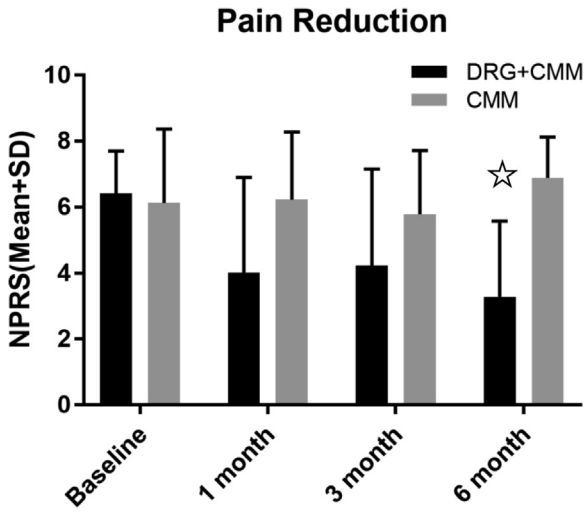

Figure 2. Pain levels at various time points in patients with PSIP who received DRG (n = 8) or standard treatment (n = 6). Group differences were highly significant (p = 0.001 according to repeated measures ANOVA).

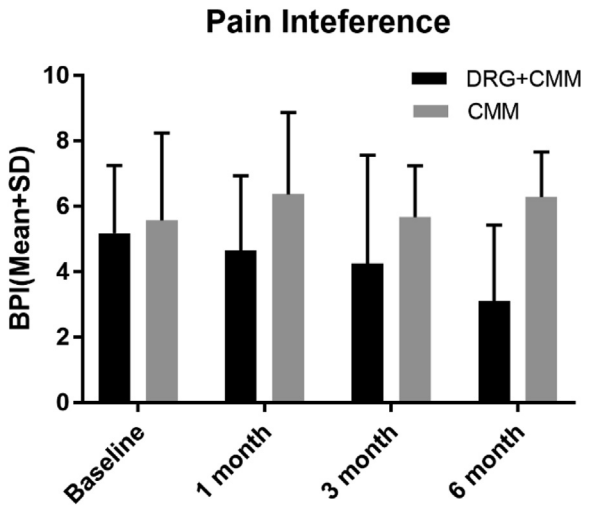

Figure 4. Pain interference with daily life at various time points in patients with PSIP receiving DRG (n = 8) or standard treatment (n = 6). BPI, brief pain inventory.

pain relief. Secondary outcomes such as quality of life and functionality also improved, which confirms the potential of this novel therapy for patients with PSIP.

The study design of a crossover, nonblind randomized controlled trial (RCT) was inspired by a conventional SCS trial that was conducted by Kumar et al.[22] Although all patients received subthreshold stimulation, they could still feel stimulation occasionally; thus, conducting a truly blind study was difficult. Other limitations of the study are the small sample size and the heterogeneity of the control group. The duration of pain symptoms varied between the two groups (54 vs 64 months). However, this difference likely did not influence the outcome. There may have been a bias regarding the slight increase in pain symptoms in the CMM group. The desire to be eligible for the DRG stimulation may have caused patients to exaggerate their pain intensity (although the increase is both small and insignificant from the baseline). This bias may have led to an overestimation of the effect of the DRG stimulation treatment.

The incidence of device-related adverse events, such as lead dislocation and lead fracture, was higher than reported in studies in traditional SCS and DRG stimulation in patients with groin pain.[23–27] This rate may be explained by the change in implantation technique, which occurred shortly before the start of this study and may have warranted a learning curve for all participating implantation surgeons.[28,29] Patients who suffered from battery-site pain, lead dislocation, or lead fracture underwent revisions with a potential risk of fibrosis in the epidural space, which would prevent reimplantation. Several lead migrations occurred while the battery was being repositioned. Lead migration may have masked the true effect of neurostimulation at specific time points (most lead dislocations occurred between the one- and three-month follow-up visits, resulting in higher pain scores at these moments due to suboptimal stimulation). It is therefore more likely that the efficacy of DRG stimulation is underestimated because of this significant complication rate. Notably, this study is essentially a pilot study, and the device design has changed since the study was performed. The reported incidence of adverse effects in this study is considerably higher than that observed in, for example, the ACCURATE

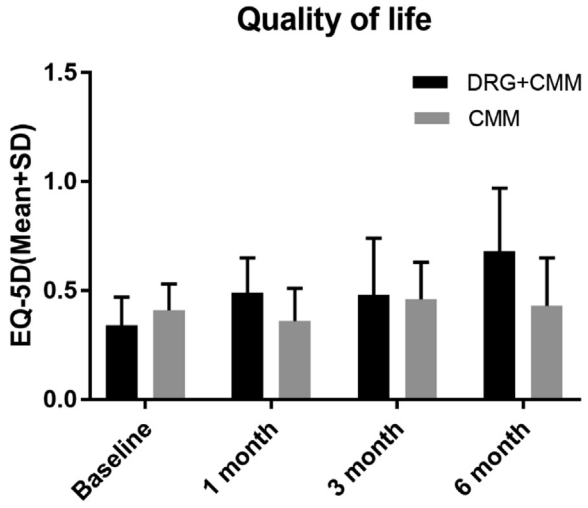

Figure 3. Quality of life at various time points in patients with PSIP who received DRG (n = 8) or CMM (n = 6). EQ-5D, EuroQol-5D instrument.

Table 2. Incidence of Adverse Events and Events Requiring Follow-up Surgery.

Event etiology	Number of events (n = 19)	Events requiring surgery (n = 7)
Total device-related events	13	
Lead dislocation	6	2
Lead fracture	3	3
Painful stimulation	3	
Low impedance	1	
Technique (postspinal headache)	1	
Total biological issues	5	
Pain at battery site	4	2
Infection	1	

study.[19] Nevertheless, vigilance against side effects remains important and should also be considered in a larger study.

A nonresponse rate of up to 30% is similar to the percentage reported in the literature.[30] In this study, the variation in treatment outcomes may be explained by the fact that covering the painful area in patients who have already undergone a neurectomy is potentially challenging. Paresthesia mapping during a separate preimplant visit could significantly optimize the results, although this had already been performed in many subjects of this study.[18]

However, it is valid to ask why these patients did not respond to a neurectomy in the first place and whether the diagnosis of neuropathic PSIP was challenged. The authors assume that they abolished any ambiguity because strict inclusion and exclusion criteria, such as appropriate DN4 scores and psychologic assessments, were used. Furthermore, the original study protocol dictated quantitative sensory testing to investigate the effect of DRG SCS on sensory deficits, such as allodynia. Because of the small group size, these results are not presented, but the sensory profiles of all patients at baseline were consistent with neuropathic pain and featured symptoms and signs including hypesthesia, wind-up, and allodynia.

The study was discontinued by the sponsor owing to its slow inclusion rate. The threshold for exploring a novel technique in this patient population appeared to be higher than expected. Future RCTs in the field of neuromodulation are required to objectively evaluate the efficacy of DRG stimulation and to identify measures for adequate patient selection.

CONCLUSIONS

When the study sponsor chose to discontinue the work because of its slow inclusion rate, 18 patients with neuropathic PSIP were randomized to either DRG ($n = 9$) or CMM ($n = 9$) groups. A post hoc analysis of the complete data sets of the 15 patients who reached the six-month follow-up point indicates that DRG stimulation is significantly more effective in pain reduction than is CMM. Further research is warranted to define the exact potential of this novel therapy.

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Authorship Statements

The authors contributed as implanters or provided input for the trial set-up. Frédérique Mol, Marc Scheltinga, and Rudi Roumen were involved in patient selection. Frédérique Mol, Dirk L. Stronks, and Frank J.P.M Huygen prepared the manuscript. Acknowledgments to further contributors are included in the manuscript. All authors approved the final manuscript.

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COMMENTS

This study echoes a larger study performed by Morgalla in 2017. They have similar outcomes with activity improvement and reduction in pain scores. An unusual number of technical issues plagued this study, and that may be attributed to the varying skill set of the implanters. This study differs from the Morgalla study in that it had a control arm.

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