Prospective Evaluation

Stimulation of the Spinal Cord and Dorsal Nerve Roots for Chronic Groin, Pelvic, and Abdominal Pain

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Background: Chronic neuropathic groin pain is a common problem. It can arise following surgery or trauma, or spontaneously as part of various pelvic pain syndromes. A number of different stimulation techniques have been reported in the literature to treat this area, but due to the complex anatomy of the region, it can be difficult to target effectively with paresthesias.

Objectives: In this study we report our results treating patients with chronic neuropathic groin, pelvic, and abdominal pain, using spinal cord stimulation and dorsal nerve root stimulation.

Study Design: Open label, prospective study that includes all patients treated with a new trial stimulator system at a single center between July 1, 2011, and October 31, 2013.

Setting: Academic university neurosurgical pain center, Canada.

Methods: Thirty-two patients had trials of spinal cord stimulation and/or dorsal nerve root stimulation in the thoracic or lumbar spine. Patients were evaluated on visual analog scale pain scores, SF-36, and morphine equivalent daily dose. Data were recorded at the pre-implant visit, and 3, 6, and 12 months following permanent implant.

Results: The 15 patients who went on to permanent implants had, on average, significant pain reduction and improvements in quality of life at the 12 month follow-up. The majority of patients who were taking opioids at the initial assessment were able to reduce their dose with treatment. Three patients with successful trials were long-term non-responders, of whom 2 had the permanent device removed.

Limitations: This study would benefit from a larger sample size that would have adequate power for comparisons between patient subgroups and stimulation techniques.

Conclusion: Dorsal nerve root stimulation is an effective long-term treatment for neuropathic groin pain.

Key words: Spinal cord stimulation, nerve root stimulation, lumbar, thoracic, neuropathic pain, groin pain, pelvic pain, abdominal pain, neuromodulation, clinical effectiveness

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Chronic groin, pelvic, and abdominal pain is a common problem with a significant burden on patient quality of life. Etiologies include post-surgical pain (1), post-traumatic pain, and various pelvic and visceral pain syndromes (including pudendal neuralgia, interstitial cystitis, and chronic prostatitis) (2). Post-surgical pain is a particularly common cause, occurring at an estimated rate of 11 – 12%

following hernia repair (3,4), and 5% after vasectomy (5). Approximately 30% of post-herniorrhaphy pain is neuropathic (1), and overall 1% of patients who undergo hernia repair will need to be referred to a chronic pain specialist for management (6). Potential methods for pain control include medications, psychotherapy, nerve blocks, and reoperation.

Spinal cord stimulation (SCS) is a well-established technique for chronic neuropathic pain, particular in the lower limbs (7). Studies of paresthesias mapping indicate that certain areas of the body, including the groin/perineum, are more difficult than others to cover consistently and specifically with paresthesias (8-10). The groin and lower abdomen are predominantly innervated by the ilioinguinal, iliohypogastric, and genitofemoral nerves, which derive from L1-2, while the perineum is innervated by S2-4. Due to characteristics of the fibers conveying information from this area, it is difficult to target without also stimulating other areas, particularly the posterior leg. Relative to adjacent tracts representing other areas of the body, the nerves corresponding to the groin contain both a smaller number of fibers and fibers of smaller diameter (which is inversely proportional to the amplitude required for activation).

Several studies have been published examining the treatment of groin pain using SCS (11-15), peripheral nerve stimulation (PNS) (16,18,19,21), peripheral nerve field stimulation (PNFS) (17,20), dorsal root ganglion stimulation (DRGS) (22), sacral nerve root stimulation (23-25), and combined SCS and PNFS (26). These studies have obtained excellent pain relief in some patients, however there remain difficulties with consistently treating these pain areas. As discussed above, SCS can result in unwanted stimulation of the lower limb and other body areas, while PNS has issues with erosion and migration (27).

In this paper we report our results using both SCS and dorsal nerve root stimulation (DNRS) for our patients with neuropathic groin, pelvic, and abdominal pain. While DNRS is reported infrequently in the literature (28), we have found that it is useful in providing specific and consistent coverage to body areas that are difficult to target with SCS. At 12 months follow-up, our patients obtained sustained pain relief, improved quality of life scores, and reduced opioid medication use.

Methods

The study had a single center, open label design and was approved by the university Research Ethics Board. All patients who had been treated at our institution between July 1, 2011, and October 31, 2013 with a new implantation of a spinal stimulation trial system for groin, pelvic, and/or abdominal pain entered the study.

Patient Selection

Patients were 18 years of age or older and had been referred for surgical management of pain that failed to respond to conservative measures. Exclusion criteria included pain in a distribution outside of this body area as well as our standard clinical contraindications to neuromodulation (an expected inability to manage or operate the SCS system; a history of a coagulation disorder; evidence of an active psychiatric disorder, another condition known to affect the perception of pain, or inability to evaluate treatment outcome; an existing or planned pregnancy; likelihood to undergo magnetic resonance imaging; and/or life expectancy of less than one year).

Procedures

Treatment involved a trial period of 3 weeks, followed by a mandatory washout period of at least 2 weeks. Successful trials were defined as a visual analog scale (VAS) decrease > 50% or a sufficiently large pain reduction to have a significant effect on the patient's quality of life. The stimulation technique was chosen was based on the surgeon's clinical assessment, as well as intra-operative test stimulation for some patients. Examples of imaging showing the placement of SCS and DNRS electrodes in the thoracic and lumbar spine, respectively, are shown in Fig. 1.

Data Collection and Analysis

Average pain intensity was assessed on a 0 to 10 cm VAS. Quality of life was assessed using the Short Form-36 questionnaire. These endpoints were assessed prospectively at the following time points: before trial stimulation, 3 weekly visits during the trial, and at 3, 6, and 12 month follow-up visits. Evaluations were performed by the pain specialist neurosurgeon, a nurse practitioner trained in neuromodulation, or a research student. Additionally, some patients were followed by a medical pain clinic, and data on pain scores and medication use were also obtained from these records. Results are reported at 12 months, with the exception of average VAS scores, which are plotted at 3, 6, and 12 month follow-up. Average values are presented as ± standard error of the mean (SEM). The error bars in Figs. 2 and 5 are 95% confidence intervals.

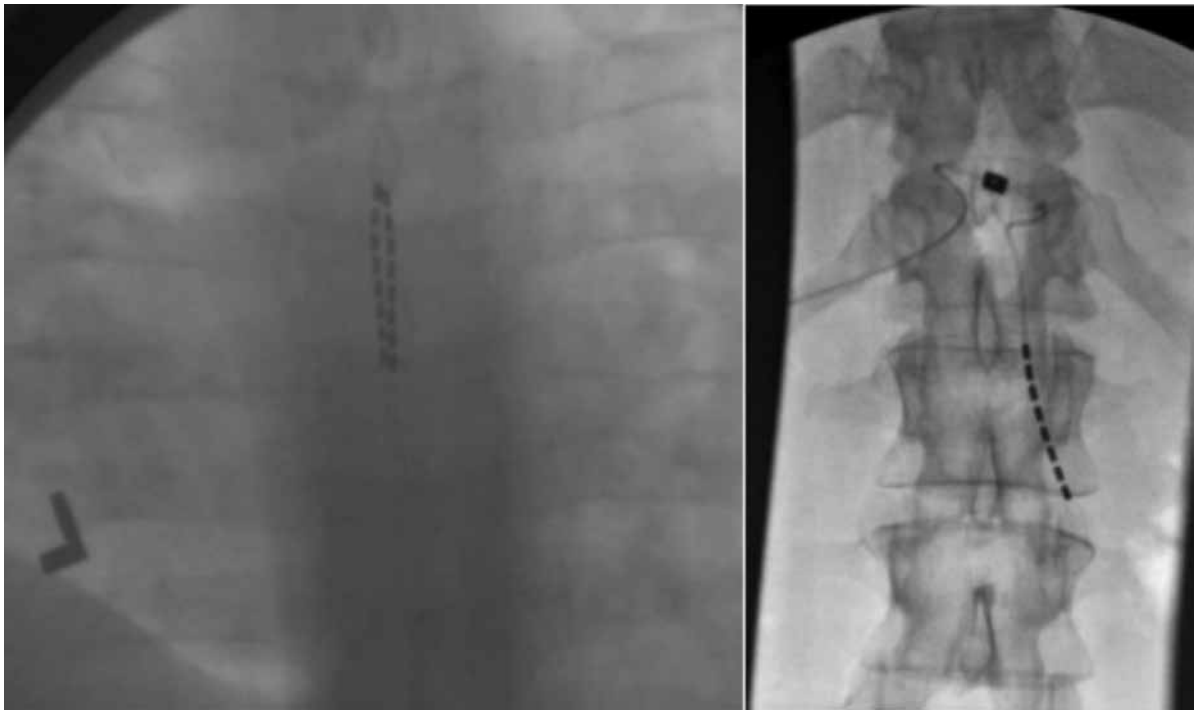

Fig. 1. *X-rays showing electrode placement over the thoracic spinal cord and L1 dorsal nerve root.*

Results

Patient Population and Trial Results

Patient characteristics and electrode placement for trial and permanent implants are shown in Table 1. Thirty-two patients had trials, among whom 8 had 2 trials and one had 3 trials. Seventy-five percent of patients were women, with an average age of 45.3 (± 9.9) years. The average time between pain onset and trial was 6.5 (± 4.2) years. The average VAS was 7.3 (± 1.3), the average MEDD was 175 (± 377), and 31% of patients were employed at initial assessment. Patients had significant impairments in SF-36 QOL, with average subscores (out of 100) ranging from 11.0 (Role Physical) to 61.9 (Mental Health).

The most common etiology was post-surgical pain in 13 patients (surgeries included inguinal hernia repair (4), vaginal hysterectomy (3), cyst/lump excision (2), umbilical hernia repair, cesarean section, varicose vein stripping, and laparotomy), followed by spontaneous/unknown for 10 patients. A number of the patients, whom we classified in the latter category, had remote histories of surgery in the groin region but it was not a clear inciting event. Other etiologies were post-childbirth pain, interstitial cystitis, pudendal neuralgia, post-traumatic pain, loin pain hematuria syndrome, postherpetic neuralgia, and post-infection pain.

Out of 32 patients with trials, 8 received SCS, 19 DNRS, and 5 both techniques. The majority of patients had electrodes in either the thoracic or lumbar spine, however some had electrodes in both locations or in the sacral spine. In total there were 22, 13, and 4 trials in the thoracic, lumbar, and sacral spines, respectively, keeping in mind that some patients had trials with electrodes in multiple locations. Fifteen patients (47%) went on to permanent devices. Of these, 3 received SCS, 10 DNRS, and 2 both. Nine patients had electrodes in the thoracic spine, 5 in the lumbar spine, and one had electrodes in both thoracic and lumbar regions. No patient had a permanent electrode in the sacral spine.

Pain Reduction

Average VAS scores (out of 10) for all patients with follow-up data are shown in Fig. 2 (with 95% confidence intervals). At baseline, the average VAS was 7.3 (± 1.3 SEM). This decreased to 3.1 (± 2.8), 3.8 (± 2.4), and 4.2 (± 3.2) at 3, 6, and 12 months, respectively.

Table 1. *Baseline patient characteristics.*

	N = 32	SD	95% CI
Age in years - mean	45.3	9.9	3.6
Years since pain onset - mean	6.5	4.2	1.5
Sex female - %	75.0		
Currently employed - %	31.3		
Visual analogue scale - mean	7.3	1.3	0.5
MEDD* - mean	175	377	136
Diagnosis	**n**	**%**	
Post surgical	13	41	
Post childbirth	2	6	
Interstitial cystitis	2	6	
Post trauma	1	3	
Pudendal neuralgia	1	3	
Loin pain hematuria	1	3	
Post infection	1	3	
Postherpetic neuralgia	1	3	
Spontaneous/unknown	10	31	
Electrode location	**Trial**	**Permanent**	
SCS	8	3	
DNRS	19	10	
SCS + DNRS	5	2	
T	18	9	
L	9	5	
T + L	4	1	
S**	4	0	

*excludes patients on methadone
**all patients with sacral electrodes also had at least one in the thoracic or lumbar spine

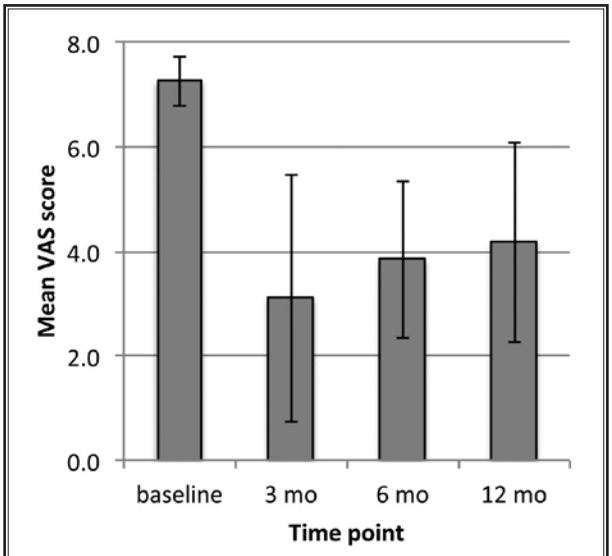

Fig. 2. *Aggregated average VAS pain score over 12-month follow-up.*

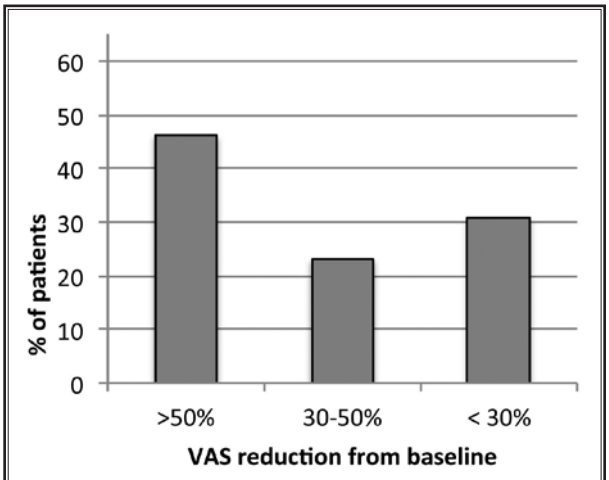

Fig. 3. *VAS reduction at 12 months, categorized as responders, partial responders, and non responders by % pain reduction from baseline value.*

In Fig. 3 patients were classified as responders, partial-responders, and non-responders based on pain reductions of > 50%, 30 – 50%, or < 30%, respectively. Out of 13 patients with pain data at 12 months, 6 (46%) were responders, 3 (23%) partial responders, and 4 (31%) non-responders.

Secondary Endpoints

Among the 5 patients with SF-36 data available at 12 months, on average there were improvements in all subscores, of which 4/9 were statistically significant. The change between the baseline and 12 month average scores for all subscores are shown in Fig. 4 (with 95% confidence intervals).

The average MEDD was 77 (± 140) for 13 patients with opioid use data at 12 months. As shown in Fig. 5, among these patients, 4 (31%) were never on narcotics, 6 (46%) had decreased their dose, 3 (23%) had increased their dose, and none had no change in dose.

On a clinical global impression scale where 1 = very much improved and 7 = very much worse, 6 patients responded with an average score of 1.50 (± 0.84).

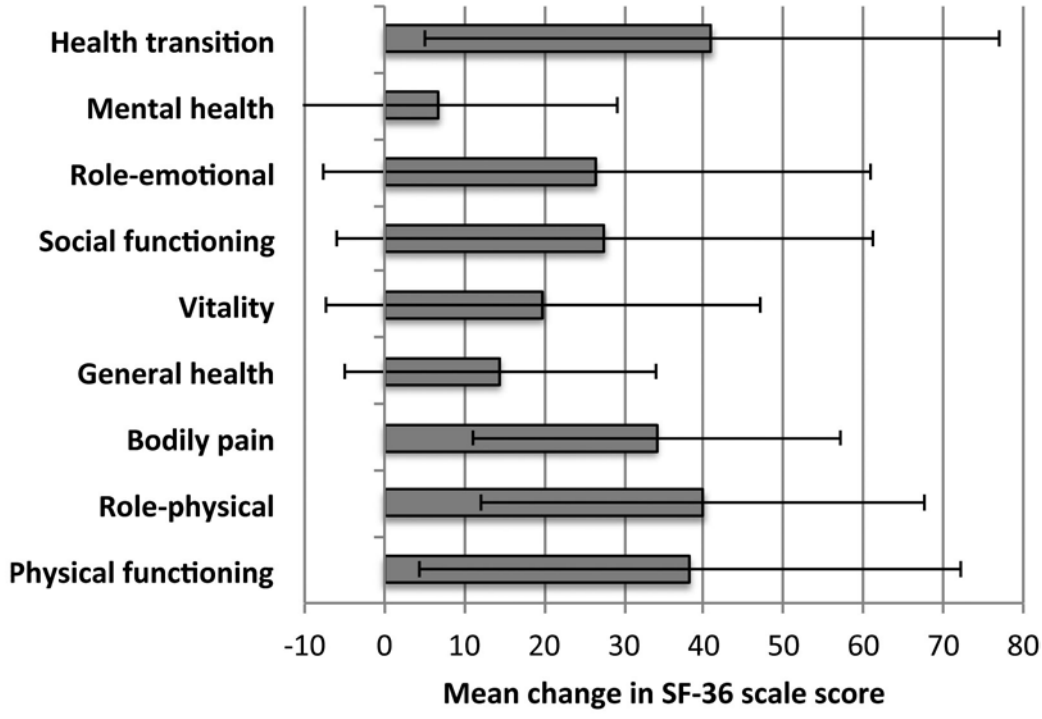

Fig. 4. *Short-form 36, change from baseline at 12 months.*

Complications and Revision Operations

Out of the 32 patients who underwent a total of 42 trial operations, 3 had a superficial skin infection, 5 had a lead migration, and one had a cerebrospinal fluid (CSF) leak headache. During the follow-up period, 8 patients required a total of 15 revision operations. Reasons for revision were lead migration (9), lead fracture (1), improvement of paresthesias (3), and device removal (2). There were 4 CSF leaks during the permanent implant and revision operations. The 2 patients who had the device removed were included in the 12 month data analysis.

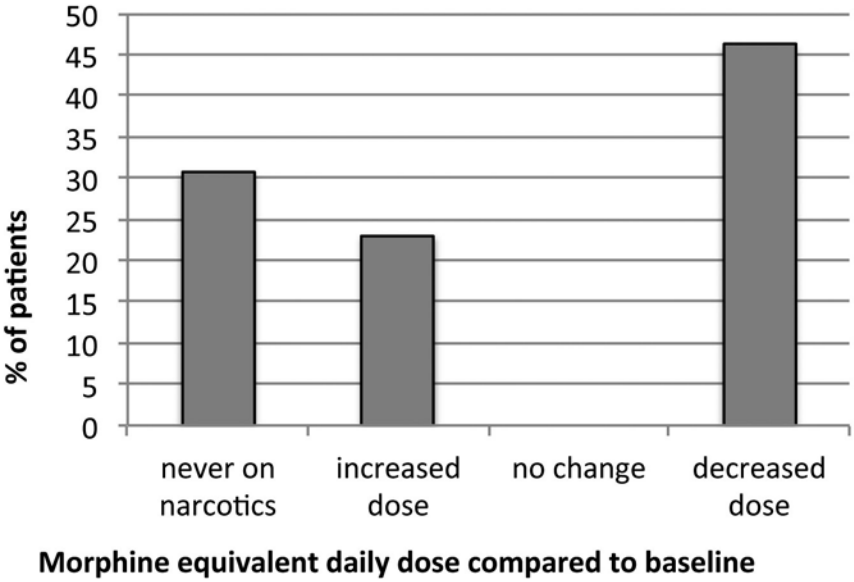

Fig. 5. *MEDD change at 12 months compared to initial assessment, categorized as patients who were never on narcotics, increased MEDD, decreased MEDD, or had no change in MEDD.*

Discussion

In this study we report our results on 32 patients who had trials of SCS and/or DNRS for neuropathic groin, pelvic, and abdominal pain. Fifteen patients went on to permanent implant. Additionally, 2 patients with excellent trial results had planned on permanent implantation but did not ultimately follow through for unknown reasons. Overall, our patients with permanent implants had significant pain decreases at 12 months, with corresponding improvements in QOL and decreases in opioid medication usage. Our study is the first to use predominantly DNRS for this pain distribution, as this technique is rarely cited in the literature. In our experience, it can provide consistent and localized paresthesias to areas that would be difficult to treat with traditional SCS.

While many of our patients obtained excellent pain reduction at 12 months, our findings are consistent with other reports that this pain area is particularly difficult to treat with spinal stimulation (2). Compared to our results for all spinal stimulation patients, the group in this paper had a lower rate of progression from trial to permanent implant and a higher number of long-term failures. There were 3 patients considered long-term failures of permanent implants. One patient had a good trial regarding pain reduction, but noted significant positional effects. During this follow-up period she developed additional pain consistent with complex regional pain syndrome (CRPS) in her leg in addition to the neuropathic pain in her groin. The second patient had trials for both SCS and DNRS and had good pain reduction with the SCS trial despite some unwanted stimulation in the legs. Unfortunately during the permanent period we were unable to obtain appropriate coverage despite multiple revision operations. Furthermore she noted unpleasant cramping in the ribs, which was possibly due to unwanted stimulation of the ventral nerve roots or dura despite the dorsal midline placement of the electrode. The third patient had a good trial with 60 – 70% pain reduction, but by 2 years following permanent placement had developed significant pain at the implantable pulse generator (IPG) site that was as severe as his initial groin pain. The latter 2 patients had the permanent device removed.

A number of papers have previously been published on the use of various neurostimulation techniques for groin, pelvic, and abdominal pain. There are several case reports and small case series reporting applications of PNS (18,19,21) and PNFS (16,17,20). Traditional SCS of the thoracic cord has been used for groin pain (12), abdominal visceral-type pain (14,15), and pelvic pain syndromes such as interstitial cystitis and chronic prostatitis (2). Specifically post-herniorrhaphy pain was successfully treated with SCS only (11,13), as well as a combined approach using SCS and PNFS (26). Schu et al (22) recently published a retrospective review of 29 patients treated with DRGS between T12 and L4, obtaining excellent pain reduction for the 25 patients with permanent implants at 27.8 weeks average follow-up. Another recent study found good pain reduction and improved sitting time in 20 patients treated with conus medullaris stimulation for pudendal neuralgia (29).

Strengths of our study include the broad range of pain diagnoses, extended follow-up period, and comprehensive set of outcome measures. While other papers have focused specifically on a single pain etiology, such as post-herniorrhaphy pain, our study includes a population that is more representative of that seen in a real world clinical setting at a tertiary referral center. Our data on QOL and medication use provide a broader perspective on the benefits of treatment, and the 12 month follow-up indicates that the benefit in these patients is stable over time. Our study has a larger patient population than many of the studies that have previously been published on this topic. However, as a self-funded study, our data collection has been limited at times by the time constraints of a busy clinical practice. In particular, the SF-36, being a fairly long survey, was only obtained for 5 patients at 12 months, while VAS and opioid data was collected for 13 patients. Additionally, it would be preferable to have an independent third party doing all data collection, however this was not feasible given our current resources. It should be noted that for the patients who were also followed by the medical pain clinic, that clinic's assessments were consistent with those done at our clinic.

Conclusion

In this paper we have discussed our experience using stimulation of the dorsal nerve root and spinal cord for chronic neuropathic groin pain. While a small number of patients with good trial results were ultimately long-term failures, overall, our patients had sustained pain reduction, opioid reduction, and improved quality of life at 12 months follow-up. This is the first study to use predominantly DNRS to treat groin pain, and contributes to the range of stimulation techniques avail-

able to the clinician in treating this difficult pain area.

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Conflicts of interest: Drs. Parrent and MacDougall have received a single honorarium from Boston Scientific. Otherwise, none of the authors has any financial conflict of interest, and none has received any remuneration or reimbursement related to this work. The authors are not affiliated in any manner with any of the companies that produce neuromodulation devices.

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