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ORIGINAL ARTICLE

Use of spinal cord stimulation in managing neuropathic foot pain: An observational pilot case series study

Uso de la estimulación de la médula espinal en el tratamiento del dolor neuropático pies: Un observacional piloto estudio de series de casos

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Abstract
Objective: In cases of complex regional pain syndrome where conservative treatment is unsuccessful in controlling neuropathic foot pain spinal cord stimulation may be considered. To our knowledge there have been no such cases reported in the foot & ankle literature. The aim of the study was to establish useful information that may supplement our understanding of this complex multifactorial problem and help to inform future management of similar cases.
Methods: A pilot observational case series study was undertaken to investigate the use of spinal cord stimulation in the management of neuropathic foot pain using five cases with complex regional pain syndrome (type I).
Results: Reduced pain following spinal cord stimulation was reported. The interval between diagnosis and commencement of spinal cord stimulation was variable between cases and maybe responsible for differing levels and timing of pain relief experienced.
Conclusion: Careful preoperative diagnosis, robust patient selection and close postoperative monitoring are vital for a successful outcome. The small sample size and potential for bias, limit the generalizability to a larger population. A larger study is therefore indicated to expand upon preliminary findings.

Key Words: Complex Regional Pain Syndrome; Spinal Cord Stimulation; Neuropathic pain; Foot; Management.

Resumen
Objetivos: En los casos de síndrome de dolor regional complejo en el que el tratamiento conservador no tiene éxito en el control del dolor en el pie neuropático la estimulación de la médula espinal puede ser considerado. Para nuestro conocimiento no ha habido tales casos reportados en la literatura vinculada a los pies y los tobillos. El objetivo del estudio fue establecer información útil que puede complementar nuestra comprensión de este complejo problema multifactorial y ayudar a informar a la futura gestión de casos similares.
Material y métodos: Un observacional piloto estudio de series de casos se realizó para investigar el uso de estimulación de la médula espinal en el tratamiento del dolor neuropático pies usando cinco casos con síndrome de dolor regional complejo (tipo I).
Resultados: Se informó de una reducción del dolor después de la estimulación de la médula espinal. El intervalo entre el diagnóstico y el inicio de la estimulación de la médula espinal fue variable entre los casos y tal vez responsable de los diferentes niveles y tiempos de alivio del dolor experimentado.
Conclusión: El Diagnóstico preoperatorio cuidadoso, la selección de pacientes y el seguimiento postoperatorio son vitales para un resultado exitoso. El tamaño pequeño de la muestra y la posibilidad de sesgo, limitan la posibilidad de generalizar a una población mayor. Por tanto, un estudio más amplio está indicado para expandir los hallazgos preliminares.

Palabras Clave: Síndrome de Dolor Regional Complejo; Estimulación de la médula espinal; Dolor neuropático; Pie; Administración.

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Conflicts of Interest
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Introduction

Neuropathic lower limb pain constitutes a significant portion of chronic pain and is an important, prevalent, and multifaceted problem. Numerous research studies have examined the complexities of chronic neuropathic pain (1-4).

Neuropathic pain arises from damage, or pathological change, in the peripheral or central nervous system (1). It is usually a chronic condition that can be difficult to treat because standard treatment with conventional analgesics does not typically provide effective relief of pain.

Neuropathic pain places a large cost burden on healthcare services and is usually associated with substantially greater impairment of quality of life compared with other types of chronic pain (1). The role of the spinal cord stimulation (SCS) in managing chronic neuropathic pain has been widely reported in the literature and is supported by evidence-based research (5-9). Spinal cord stimulation is a treatment used for chronic pain that uses a mild electric current to block nerve impulses in the spine. Stimulating electrodes are placed through a needle into the spine near the spinal cord and activated to provide a mapped paraesthesia in the painful area (9).

In the case of lower limb pain, the usual electrode position is T10-12 vertebral level. A two-step procedure is undertaken with a test phase before implantation of the Impulse Generator (IPG). Spinal cord stimulation has been reported to improve the subjective symptoms of the neuropathic foot pain of complex regional pain syndrome, enable objective functional improvement and reduces analgesic consumption (6-9). Spinal cord stimulation is generally reserved for patients who have CRPS, which is refractory to conventional conservative management (8). It is a relatively safe procedure and reversible with implant removal.

The neuromodulatory technique of SCS has evolved as a direct clinical application of the gate-control theory, the general conceptualization of which still provides the framework in explaining its mode of action (9).

A pilot observational case series study was undertaken of patients with neuropathic foot pain who had developed complex regional pain syndrome (type I) who were currently being managed by use of spinal cord stimulation (SCS). The diagnosis of complex regional pain syndrome (CRPS) was defined using clinical examination, a set of clinical diagnostic standards known as the Budapest criteria, hospital investigations and a validated pain assessment (1,6). The principal objective of the study was to undertake a detailed retrospective review of the case notes of a series of participants with neuropathic foot pain and establish the value of its management using SCS.

This was undertaken by carefully retrospectively examining and extracting anonymised data from the patients' medical records. The case series study was used to examine the multifaceted approach to the management of neuropathic foot pain with particular reference to the impact and value of the spinal cord stimulation. Its aim was to establish useful information that may supplement our understanding of this complex multifactorial problem and help to inform future management of similar cases.

Materials and methods

A pilot observational case series design was used to retrospectively collect data from patients' medical records (as part of routine clinical care and response to SCS) presenting with intractable foot pain due to Complex Regional Pain Syndrome - type 1 (CRPS-I). All patient were being treated with Spinal Cord Stimulation.

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This design highlights patients with a specific condition who has been given similar treatments and enabled the researchers to review the patients' medical records and chart retrospectively the medical history of their condition. No additional procedures or questioning were carried out for the purposes of data collection. Consecutive sampling was applied. Prof Raphael (JHR) recruited sequential patients with CRPS treated by spinal cord stimulation from the weekly pain review clinics at Russells Hall Hospital (RHH) Birmingham UK. The duration of patient recruitment was over a defined two-month period.

Ethical committee approved was obtained from London – City & East.

Inclusion criteria: Males and females, 18 to 85 years-of-age, chronic neuropathic foot pain, fitted with spinal cord stimulator. Exclusion criteria: Cancer pain, chronic back and limb pain, upper limb pain, diabetes, not fitted with spinal cord stimulator, other interventional procedures (intrathecal drug delivery or other types of neurostimulation).

Study participants were identified from those patients attending the pain clinic at RHH. Specialist centres such as this treat a range of pathologies presenting with neuropathic pain and have sufficient numbers of patients to warrant a closer examination of the variables that may influence management. The clinical care team under the guidance of JHR selected appropriate cases. Ethical approval was granted and written consent obtained. Participants were approached by the clinical care team to obtain consent to use data from their medical records.

The data was extracted and collated in anonymised form to ensure confidentiality. This included basic demographic data (gender, age, location/duration of pain, cause of pain, medication), a summary of the medical history to date and details of the SCS technology used.

Validated outcome measures were used to evaluate the progress of patients following the intervention of SCS. An online consumer classification (http://acorn.caci.co.uk/) was applied to assess the patients' home environment. This segments the UK population into neighbourhoods (six categories, 18 Groups and 62 types, three of which are not private households) based on postcodes and provides an analysis of social factors and population behaviour.

Validated clinical tools were used to confirm diagnosis including the Budapest criteria, thermography and X-ray's. The validated outcome measures applied to measure pain levels, anxiety and depression include: Visual Analogue Scale (VAS), Brief Pain Inventory (BPI), Hospital Anxiety and depression scale (HADS), Coping Strategy Questionnaire (CSQ).

Results

Reduced pain following spinal cord stimulation was reported in all cases. The interval between diagnosis and commencement of spinal cord stimulation was variable between cases and maybe responsible for differing levels and timing of pain relief experienced by the different cases reported. Much of what was reported in the patient's case notes was descriptive qualitative data.

In all cases the pain levels documented (Visual Analogue Scales and Brief Pain Inventory) were found to have reduced following implementation of Spinal Cord Stimulation (SCS). In addition the levels of anxiety and depression documented by the Hospital Anxiety and Depression Scale and Coping Strategy Questionnaire were found to have reduced after use of SCS. The patient's ability to cope with chronic pain was influenced by their levels of anxiety and depression.

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Cases

Case 1

A 67-year-old Caucasian female presented with a history of neuropathic pain. This had been diagnosed as possible CRPS type 1 at 61 years-of–age following left foot hammertoe surgery in 2008. Her home environment was graded as category five (Urban adversity, struggling estate, financially poor).

The patient underwent a lumbar sympathetic block in combination with anti-neuropathic medications. Benefits were reported as transiently with numbness in the foot for a short time. In May 2009 on examination the left foot presented as swollen, dusky in colour and colder than the ipsilateral limb. Allodynia was present across the entire dorsum of the foot with patch allodynia in the inter-malleolar region. She was unable to wear socks and used a padded foot splint.

Pharmacological management included Oxycontin, Pregabalin and Paracetamol. In November 2009 a psychologist assessed the patient. She was anxious and tearful at consultation saying her quality of life was poor and that she spent most of the day in bed. She scored 17 on the Hospital and Anxiety Depression scales (HADS). She was found to have signs of depression and referred to a psychiatrist for her anxiety. She was reviewed every three months.

The patient was recommended to increase Nortriptyline slowly. Lidocaine medicated patches (Versatis) were given to wear for 12 hours per day. A diagnosis of CRPS (type 1) was confirmed based upon the Budapest criteria. At this point in time her condition had been present for two years. It was explained to the patient and her family at her pain clinic consultation that the symptoms of pain were not going to subside without further interventions.

In early August 2010 she was admitted to hospital for a stage one SCS procedure and the SCS electrodes were implanted at thoracic vertebrae level 10. Octopolar nerve stimulation was provided for one week and her Visual Analogue Scale dropped from 8-9/10 to 1-2/10. On 26th August 2010 she underwent a stage two procedure to implant the Impulse Generator (IPG). She was discharged on 31st August. She was reviewed one-month later. She had responded well to SCS and her mobility had improved. Full coverage over the painful area had been achieved. The lidocaine patches were withdrawn at this stage. In July 2011 the patient reported 75% pain relief. She was still reliant on a wheelchair and crutches due to a loss of proprioception and balance. In February 2012 the pain relief had reduced to 50-60%. In July 2012 pain had reduced from 8-9/10 to 1-2/10 and the patient was able to tolerate bedclothes and in August 2012 her pain had reduced from 9/10 to 3/10 (VAS). At the last review in December the patient reported that ongoing relief of pain was good and that function was satisfactory.

Case 2

A 49-year-old Caucasian female presented with neuropathic pain in her right foot, back and right elbow and had a past medical history of pernicious anaemia. She worked as a housewife and her home environment was graded as category four (financially stretched, rural council estate).

The symptoms of neuropathic pain were precipitated by a road traffic accident in 2008. She was referred to orthopaedics in 2011 complaining of generalized pain in most joints. Inflammatory arthropathy and possible fibromyalgia were considered. Pain symptoms were managed pharmacologically with Ibuprofen, Capascin, Oramorph, Gabapentin and a lumbar sympathetic block.

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Following a referral by her General Practitioner (GP) to the pain clinic for further evaluation a diagnosis of CRPS (Type 1) was confirmed. The diagnosis of CRPS was confirmed based upon the Budapest criteria. In 2011 the patient had a psychological evaluation on the pain clinic and was found to be anxious and uncomfortable in crowed places. It was found that she had difficulty coping with her overall pain and woke in the mornings with pains in her hands but had no swelling. She also suffered occasional sweating and palpitations. Plain X-rays were normal. The patient was referred for physiotherapy and a Rheumatology consultation excluded any underlying rheumatological pathology.

Due to ongoing severity and magnitude of pain the patient was considered for SCS. In May 2012 she underwent a full psychological evaluation and was found to demonstrate a robust psychological profile with no psychological barriers to SCS. In March 2014 she was admitted for a stage one procedure to implant the electrodes. This was followed by a stage two procedure to implant the impulse generator (IPG). An evaluation of activities of daily living (ADL) was undertaken to provide a baseline against which subsequent assessment could be measured. She was then reviewed in May 2014 and the SCS was found to have good coverage. The patient reported a reduction in pain levels by 50%. At a follow up in November 2014 she had not been walking for the past two weeks. Her abdomen was painful at the operative site near the IPG but there were no signs of infection. In January 2015 she was reviewed, X-rays revealed that the leads were correctly sited.

Skin colour changes were present over her buttock. These were not painful and considered to be related to the CRPS rather than infection. The patient was advised to take photographs to monitor.

At a subsequent review technical support was provided to help re-program the IPG and any non-functioning electrodes. The patient reported that the function of the SCS was impaired when she bent over suggesting loose connections at the IPG. The technician modified the SCS program to include adaptive stimulation with regard to body position and further X-rays were taken to check that leads had not become disconnected.

Case 3

A 41-year-old Caucasian female presented in 2002 following a crush injury that she sustained to her right foot. She was found to have ligament damage but no fracture. A diagnosis of CRPS (type 1) was confirmed based upon the Budapest criteria. Clinical examination revealed a varus deformity of the right ankle. She worked as a housewife and her home environment was graded as category five (Urban adversity, struggling estate, financially poor).

Management of the condition included an intravenous injection of Guanethidine followed by a chemical sympathectomy at the third lumbar vertebrae level in 2003. The right foot developed an equinus deformity, which was treated with a cast and course of physiotherapy to stretch out the tight posterior structures of the ankle and leg. In 2011 due to ongoing pain in the right foot the patient initially underwent a right first metatarsophalangeal joint cheilectomy and calcaneo-cubiod arthrodesis. Due to persistent right ankle pain she underwent a talectomy and calcaneotibial fusion.

Due to on-going pain in the right foot a spinal cord stimulator (SCS) was implanted in January 2015 at the tenth thoracic vertebrae level. In July 2015 the patient reported a 70% pain reduction The SCS settings used were cathode 5, anode -6, 169 Hz, frequency 40Hz.

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Pharmacological management included the use of Tramadol, Naproxen, Amitriptyline and Pregabalin.

Case 4

A 62-year-old Caucasian male presented with a history of a left ankle fracture in 2003. His home environment was graded as category four (financially stretched, rural council estate). Due to ongoing left ankle pain an arthroscopy was undertaken in 2011. This revealed medial gutter synovitis but no joint damage. An MRI of the left ankle was found to be normal. His symptoms of ankle pain were initially managed with Ibuprofen and co-dydramol. Due to persistence of symptoms he underwent a talonavicular joint steroid injection.

In April 2013 he was referred to the pain clinic as his symptoms of ankle pain were deteriorating. Clinical examination revealed that the left foot/ ankle was sensitive to touch; temperature and colour changes and swelling were also evident. A diagnosis of CRPS (type 1) was confirmed based upon the Budapest criteria.

Pharmacological management was initiated, this included Tramadol and Dihydrocodeine. As this was not successful in managing symptoms Amitriptyline, Gabapentin and Pregabain were added. Lidocaine medicated patches (Versatis) were also tried. A chemical sympathectomy was undertaken but this provided no benefit.

In July 2013 a bone scan of the left ankle was undertaken. This revealed increased activity over the left ankle. Due to ongoing symptoms of pain a spinal cord stimulator was implanted in November 2014. This was reviewed in January 2015. It was reported that neuropathic pain symptoms had reduced from 8/10 to 1/10 (VAS).

Case 5

A 48-year-old Caucasian female, presented with neuropathic pain in her left foot. This had been present for three years. She was a housewife. Her home environment was graded as category four (financially stretched, urban council estate). The patient had undergone left hallux valgus surgery in 2011 and following this she had developed a chronic pain syndrome in her left foot. Pregabalin and Tramadol were initially used to manage the neuropathic pain symptoms.

As a result of progression of pain symptoms and disability she was referred to the Royal National Hospital for Rheumatic Disease, where a primary diagnosis of CRPS (type 1), and secondary diagnosis of plantar fasciitis were made. Subsequently she was referred to the pain medicine clinic at Russells Hall Hospital. On examination she presented with colour, temperature and nail changes in the left foot. Also oedema, excess sweating, hyperalgesia and allodynia were evident. In addition foot equinus/ overriding toe deformities and dystonia presented. All clinical features met the Budapest criteria confirming the diagnosis of CRPS (type 1). Pharmacological management was initiated to control pain and manage symptoms of depression and anxiety. This consisted of Codeine, Gabapentin, Amitriptyline, Disodium Pamidronate infusion, Duloxetine and Guanethidine.

The multidisciplinary team managing the patient consisted of a pain consultant, psychologist, psychiatrist and physiotherapist. Due to ongoing severity and magnitude of pain the patient was considered for a SCS. She underwent a psychological evaluation in May 2014 and demonstrated a robust psychological profile and presented with no psychological barriers to SCS.

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During her hospital admission an evaluation of activities of daily living was undertaken to assess her functional abilities. A number of validated measuring tools were used to quantify neuropathic pain and the levels of anxiety and depression experienced. The pain was rated as 10/10 using the Visual Analogue scale. The Brief Pain Inventory (BPI) long form rated pain as 9/10. The BPI measures both the intensity of pain (sensory dimension) and interference of pain in the patient's life (reactive dimension). It also queries the patient about pain relief, pain quality, and patient perception of the cause of pain. The Hospital Anxiety and Depression Scale (HADS) (10, 11) was also used, this was rated as 12/21. In addition the Coping Strategies Questionnaire (CSQ) was completed to evaluate the patients' ability to deal with her adjustment to chronic pain.

In December 2014 she underwent a stage one procedure to implant the octopolar (eight pole) lead at vertebral level T10. X-rays revealed that the leads were correctly sited and these were tested using an external controller to establish their patency. Following a successful trial period (≥50% pain relief during one week trial) a stage two procedure was undertaken for implantation of the impulse generator (IPG) (Advanced Bionics Precision SC-1110) and at a following review technical support was provided to check the function of the SCS. The patient was reviewed at one month to test coverage of the foot and check the settings (cathode at contact 4 (100%) and anode at contact 3 (100%) of octopolar lead; area (left lower limb), 3.5mA level, 210μs pulse width, 60Hz rate, 2.4 volts). She was found to have 25% relief of symptoms but still some muscle spasms.

This was considered to be a normal finding at only one month post-implant. Normally patients are expected to experience increased levels of pain relief (>50%) with time. A subsequent technical review to re-program the IPG to establish improved SCS function was undertaken.

Discussion

This case series study demonstrates the value of using SCS for managing a range of complex neuropathic foot pain where standard treatment modalities have failed to control symptoms. The potential benefits of this particular treatment modality are revealed in the case series presented. Patients suffering from CRPS (type I) were found to experience a reduction in their symptoms of neuropathic foot pain when using SCS, where other treatment modalities had failed. Indeed several cases experienced long term relief of their symptoms as a result of using SCS. Although not seen in this series some patients can experience spontaneous lead breakage with insulation failure or radiographic lead migration and a subsequent stimulation loss in SCS (12, 13). This can lead to the need for revision surgery. Advances in surgical techniques and use of silicone anchors help reduce revision rates (12, 13).

This case series provides information to help inform the future management of similar CRPS cases. It is appreciated that the implications for management need careful consideration due to the small sample size and potential for bias, limiting its generalizability to a larger population of patients. It is also appreciated that the quality of data obtained from a pilot observational case series study has limitations due to confounding factors.

However, the use of SCS is evidence-based and remains a valuable treatment modality, and should be considered in cases where conservative management has failed. The findings of a recent study support the use of SCS in CRPS (type I) (14). A careful preoperative diagnosis and robust patient selection is vital for the success of this method. The psychological profile of patients who are chosen for SCS must be taken into account (9).

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Spinal cord stimulation requires close patient monitoring postoperatively. Prudent aftercare is indicated, as reprogramming surveillance may be necessary to deal with any complications.

Future technological progress in the application of SCS has led to improved stimulation patterns adapted to the patients' needs. It also enables better control of the chronic symptoms that result from this complex neuropathic pain syndrome.

Conclusions

Neuropathic lower limb pain constitutes a significant portion of chronic pain and is an important problem that needs to be carefully managed. A pilot observational case series study was undertaken of patients with neuropathic foot pain who had developed complex regional pain syndrome (type I) who were currently being managed by use of spinal cord stimulation (SCS). Reduced pain following spinal cord stimulation was reported.

In addition the levels of anxiety and depression were found to have reduced after use of SCS. The patient's ability to cope with chronic pain was influenced by their levels of anxiety and depression. The interval between diagnosis and commencement of spinal cord stimulation was variable between cases and maybe responsible for differing levels and timing of pain relief experienced.

The development of a larger prospective study to control for confounding variables is being considered so as to expand upon the preliminary findings of this pilot observational case series study.

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