Spinal Cord Stimulation:

An Under-utilized and Under-recognized Pain Treatment Modality

Abstract

There is increasing concern in Canada about the overuse and misuse of opioids. While there are no simple answers to this complex societal problem, adequate and timely access to proper multidisciplinary chronic pain care is important in decreasing the reliance on opioids when treating chronic pain in Canada. Neuromodulation therapy, especially spinal cord stimulation (SCS), offers patients the potential for pain relief without repeated injections or ongoing medication use. SCS is effective in the treatment of persistent postoperative neuropathic pain and complex regional pain syndrome. Prospective SCS candidates should undergo a full multidisciplinary assessment to evaluate both physical and psychological factors that may adversely affect results.

Key words: chronic pain, spinal cord stimulation, opioids, neuropathic pain, persistent postoperative neuropathic pain

The "opioid epidemic" and Chronic Pain in Canada

Chronic pain affects approximately 1 in 5 Canadians.[1,2] Many Canadians have limited access to appropriate and timely chronic pain treatment; one study found the median wait time to access a publicly funded multidisciplinary pain clinic is six months, and many areas, especially outside major cities, do not offer specialist pain treatment services.[3]

Chronic pain therapy is best delivered in a multidisciplinary model utilizing: medications, interventions, psychological modalities, and rehabilitative measures. However, given the relative lack

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of access to multidisciplinary pain treatment services, many Canadians are treated primarily with medications, including opioids. Only a quarter of Canadian patients report that they feel they have had a good experience with their pharmacological treatment, while 23% report a less than satisfactory experience.[4] There are multiple downsides to long-term opioid therapy, including the potential for dependency and misuse, constipation, opioid induced hyperalgesia, respiratory depression, cognitive impairment, and hypothalamic-pituitary-adrenal dysfunction.[5]

There is increasing concern in Canada about the overuse and misuse of opioids, otherwise known as the "opioid crisis."[6] Canadian data is fragmented, but it is estimated that 500,000 to 1.25 million Canadians use oral opioids for non-medical purposes. American and Canadian data suggests that the vast majority of these opioids were obtained from family and friends who acquired the prescriptions for legitimate purposes or through fraudulent means such as "double-doctoring."[7] According to the International Narcotics Control Board, Canada is the second-largest per capita consumer of prescription opioids while America is the largest.[8] While there are no simple answers to this complex societal problem, adequate and timely access to proper multidisciplinary chronic pain care is important in decreasing the reliance on opioids when treating chronic pain in Canada.

Key Point

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Role of Interventional Pain Procedures in the Treatment Algorithm

Interventional pain procedures are only effective in a specific subset of chronic pain patients. While a detailed discussion about interventional pain procedures for the treatment of chronic pain is beyond the scope of this article, in appropriately selected patients the timely utilization of interventional procedures early in the course of the pain syndrome may result in such effective relief it can obviate the need for pharmacotherapy.

Unfortunately for many patients, interventions are sought after the pain condition is well established. As a result, even properly performed evidence-based interventions such as image-guided epidural steroid injections or medial branch ablations result in a duration of relief typically lasting only a few months. Patients then need to undergo repeated interventions. Given these limitations, many chronic pain patients seek longer-term solutions. Surgical procedures, especially spinal surgery, offer the chance of long-lasting pain relief, but complication rates may be as high as 16%.[9]

In contrast, neuromodulation therapy, especially spinal cord stimulation (SCS), offers patients the potential for pain relief without repeated injections or ongoing medication use, and with a lower risk of complications compared to spinal surgery.[10] Another key advantage of SCS is that it is a non-destructive procedure; the device can be explanted at any point if it no longer provides pain relief, and it does not preclude other treatment modalities, including spinal surgery, in the future.

Main Indications for SCS

SCS has been successfully utilized for many pain conditions with a peripheral neuropathic pain component, with the best studied indications being persistent postoperative neuropathic pain (so-called failed back surgery syndrome [FBSS]) and complex regional pain syndrome (CRPS).

Other common indications for SCS include: chronic axial back pain, radiating arm pain, and chronic radicular pain in patients who have not undergone spinal surgery, chronic neuropathic pain, and chronic pain from peripheral ischemia.[10] Conditions for which SCS has been less successful include: phantom limb pain, brachial plexopathies, central neuropathic pain syndromes (such as post spinal cord injuries, post stroke, or due to multiple sclerosis), and chronic abdominal pain. However, as technology evolves, it is anticipated that the range of conditions that may respond to SCS will increase.

The Technology and Mechanism of Action of Spinal Cord Stimulation

The idea of utilizing electricity in the treatment of chronic pain dates back to ancient Greece. The first commercially available spinal cord stimulator was manufactured by Medtronic in 1968[11] and was based upon technology originally developed to treat cardiovascular disease. While the technology has improved dramatically in intervening years, at its core the basic components of an SCS system remain unchanged. Stimulating electrodes or contacts (the electrically conductive point from which current passes into the tissues) are arranged into an array known as a lead. Leads can be broadly classified as cylindrical or paddle.

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Cylindrical leads are designed to be inserted percutaneously through a Tuohy epidural needle into the posterior epidural space. These leads consist of contacts arranged in a vertical array; modern cylindrical leads contain 8 contacts spaced closely together. Two or more cylindrical leads can be placed side by side to form a more complex array.

Modern paddle leads consist of 16 contacts spaced evenly across a silicone backing, either in a 5-6-5 configuration, or a 2x8 configuration. This type of lead usually is inserted following surgical exposure of the epidural space, although one manufacturer of SCS equipment has developed a paddle lead that can be inserted percutaneously through an epidural needle.

The leads are connected to an impulse generator (IPG), which consists of a battery (which can be rechargeable or non-rechargeable) and the computer hardware. Modern IPGs are often no bigger than a pacemaker IPG. The IPG is located in a subcutaneous pocket that is usually placed in the flank, the anterior abdominal wall, the buttock region, or the suprascapular fossa region,

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depending on patient preference and anatomical considerations. Patients can control SCS functions—such as turning the unit off and on, changing between preset stimulation programs, and altering the intensity of the stimulation—via a patient programmer. Clinicians communicate with the SCS via a more sophisticated programmer, which allows for more complex manipulation of stimulation parameters, as well as access to various diagnostic data.

TREATMENT SUCCESS IS GREATER THAN 85% IF THE SCS IS INSTITUTED WITHIN 2 YEARS OF THE BEGINNING OF THE CHRONIC PAIN SYNDROME...

The location of the contacts is determined by the location of the patient's pain—for example, patients with arm pain will have leads in the cervical region, and patients with back and leg pain will have leads in the low thoracic region. With conventional SCS systems, the leads are placed along the midline of the dorsal (posterior) epidural space above L1 (above the conus medullaris). The key to success with SCS is to generate a pattern of paresthesia that overlaps with the patient's area of pain while avoiding extraneous paresthesia that may cause discomfort.

A detailed discussion of the mechanism of action of SCS is beyond the scope of this article; however, it is much more complicated than just invoking the gate control theory. With regards to neuropathic pain, SCS results in inhibition of dorsal horn wide dynamic range (WDR) neuron hyperexcitability via many different mechanisms—including activation of inhibitory GABAergic interneurons—as well as: cholinergic, adenosinergic, serotonergic, and noradrenergic neural circuits.[12]

Key Point

SCS is a cost-effective treatment, whereby the long-term savings in terms of diagnostic imaging, physician visits, medications, and rehabilitative services outweighed the higher upfront cost.

Selection Criteria and Timing

Well-accepted positive predictive factors for long-term success with SCS include: patients whose etiology of pain have a predominately peripheral neuropathic pain component (as opposed to predominately somatic or widespread pain syndromes);[13] treatment early in the course of the pain syndrome;[14,15] and the presence of allodynia and other features suggestive of neuropathic pain.[16] Tools such as the Refractory Chronic Pain Screening Tool[17] are continually evolving to better help clinicians decide who should be referred for consideration for neuromodulation.

Treatment success is greater than 85% if the SCS is instituted within 2 years of the beginning of the chronic pain syndrome; the success rate decreases to 9% if there is a delay of 15 years.[15] As such, it is important for practitioners to consider SCS and a prompt referral to a neuromodulation program when a patient fails to respond to a reasonable course of conservative care.

Negative predictive factors include the presence of concurrent psychiatric illness as well as a history of substance abuse. Individuals with significantly depressed mood and

those with low energy levels are at higher risk of failing their SCS trial.[18] In addition, somatization, anxiety, and poor coping are important predictors of poor outcome.[19] It is important to note that the negative association between success with SCS and untreated psychiatric illnesses is not unique to neuromodulation; the same has been noted with other surgeries, including: spine, cardiac, and bariatric.[20,21] The negative association between the history of substance abuse and long-term success with SCS is likely multifactorial; substance abuse may indicate the presence poor coping skills and other psychopathology, and/or it may trigger changes in neuronal activity at spinal and supraspinal levels that render neural stimulation less efficacious.[16]

In order to appropriately assess the myriad of factors that may impact long-term success, the prospective SCS candidate should undergo a full multidisciplinary assessment to evaluate both physical and psychological factors that may adversely affect results. Psychological assessment often screens for risk factors such as: somatization, depression, anxiety, poor coping skills, kinesiophobia, job dissatisfaction, substance abuse, and litigation.[22] Degree of family support, ability to travel for clinic appointments, and access to emergency services also all need to be considered. It is important to elicit the patient's expectations with regard to SCS treatment. It must be stressed to the patient during consultation that SCS is part of a larger pain-management strategy, not a cure for all of the patient's pain.

Contraindications for SCS implantation include: systemic infection, cognitive impairment (as the patient might have difficulty interacting with the device), and low platelet counts. For patients on long-term anticoagulation treatment, the latest recommendations suggest that for the perioperative period the medication should be discontinued. Once implanted, SCS is not associated with an increased risk of spinal hematoma.[23]

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After the multidisciplinary assessment, patients who are deemed appropriate candidates for SCS undergo a trial whereby stimulation is initiated for a brief period of time to determine whether SCS is an effective therapy for the patient, and, perhaps more importantly, to identify patients who will not respond.[24]

The trial is a day procedure which usually takes 1 hour. Under local anesthesia with light sedation, the lead is threaded along the posterior epidural space in the midline to the appropriate level. The lead is then connected to an external stimulation device, and the patient is asked to describe the location and quality of the paresthesia generated. The goal is to create an area of stimulation that overlaps the patient's usual area of pain. Fine-tuning of the

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The key to success with SCS is to generate a pattern of paresthesia that overlaps with the patient's area of pain while avoiding extraneous paresthesia that may cause discomfort.

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lead location is made based on the patient's feedback of the stimulation coverage. Once satisfactory coverage has been obtained, the trial lead is affixed to the skin, and the patient is discharged home.

Patients who derive significant (>50%) improvement in pain levels,[16] and/or experience a significant improvement in functional status are deemed to have had a successful trial, and would go on to implant of the full SCS system.

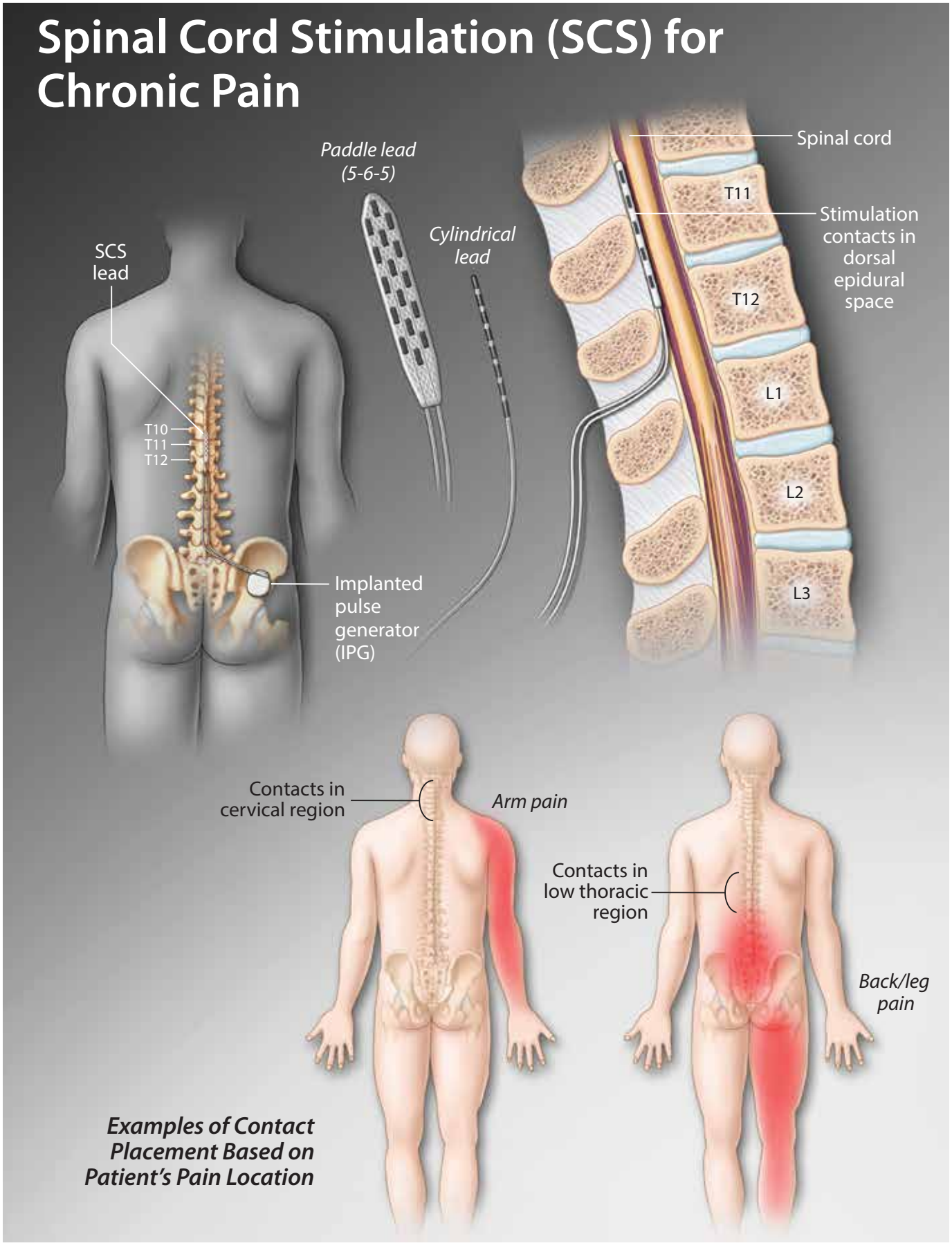
The implant procedure is a day procedure which usually takes 1-1.5 hours; it is normally performed under local anesthesia with sedation. One or two permanent leads are once again placed via the same method as during the trial; sometimes the implanting physician may decide to proceed with a surgical paddle lead which requires a laminotomy. After ensuring the stimulation is satisfactory based on patient feedback, the leads are anchored to the lumbodorsal fascia. Next, a pocket site is created where the IPG will sit, a short subcutaneous tunnel is created from the pocket site to the anchor site, and the lead and IPG are connected.

Frequent follow-up visits may be required in the immediate post-implant period, both to ensure proper healing of all incisions and to fine-tune programming of the stimulator to ensure paresthesia coverage of the painful area. Once the SCS is optimally programmed, patients often require significantly fewer physician visits and other medical resources.[25]

Clinical Evidence Available

Some of the largest studies done on SCS were led by Canadian neurosurgeon Dr. Krishna Kumar. In the landmark PROCESS trial, Kumar and his colleagues showed that at 6 months, 48% of SCS patients—as compared to 9% of conventional medical management (CMM) patients—achieved 50% relief of pain in the legs in those with failed back surgery syndrome. Compared with the CMM group, the SCS group experienced improved quality of life and functional capacity, as well as greater treatment satisfaction. It should be noted that it did not however, improve return-to-work-rates, nor did it result in decrease in opioid usage.[26]

Spinal Cord Stimulation (SCS) for Chronic Pain



Examples of Contact Placement Based on Patient's Pain Location

Clinical Pearls

Well-accepted positive predictive factors for long-term success with SCS include: patients whose etiology of pain have a predominately peripheral neuropathic pain component, treatment early in the course of the pain syndrome, and the presence of allodynia and other features suggestive of neuropathic pain. Significantly depressed mood, low energy levels, somatization, anxiety, and poor coping skills are important predictors of poor outcome.

SCS is a non-destructive procedure; the device can be explanted at any point if it no longer provides pain relief, and it does not preclude other treatment modalities, including spinal surgery, in the future.

In a follow-up analysis, the authors found that SCS is a cost-effective treatment, whereby the long-term savings in terms of diagnostic imaging, physician visits, medications, and rehabilitative services outweighed the higher upfront cost.[25]

Risks and complications

Risks and complications associated with spinal cord stimulation can be categorized as short- and long-term. Short-term risks are related to direct injury from the trial and implantation procedures: post-dural puncture headaches (0.3%), infection (3-6%), spinal/epidural haematoma (up to 0.75%), pocket site seroma (2.5%), allergic reactions (case reports), and, more rarely, spinal cord injury.

Long-term risks include: lead fractures (5.9%), lead disconnect (9.1%), lead migration (up to 13.6%), IPG failure (1.7%), compression from leads on neural tissues (case reports), and changes in coverage pattern or patchy simulation.[15]

Conclusion

Spinal cord stimulation is currently an under-recognized and under-utilized pain intervention in Canada.[4] In patients with neuropathic pain, especially those with persistent postoperative neuropathic pain (so-called failed back surgery syndrome) or complex regional pain syndrome, SCS is an effective treatment option that can provide long-term relief and should be considered earlier in the treatment algorithm.

References

1. Schopflocher D, Taenzer P, and Jovey R. The prevalence of chronic pain in Canada. Pain Res Manag 2011; 16: 445-450.
2. Reitsma ML, Tranmer JE, Buchanan DM, Vandenkerkhof EG. The prevalence of chronic pain and pain-related interference in the Canadian population from 1994 to 2008. Chron Dis Inj Can 2011; 31: 157-164.
3. Peng P, Choinere M, Dion D, Intrater H, Lefort S, Lynch M, Ong M, Rashiq S, Tkachuck G, Veillette Y. Challenges in accessing multidisciplinary pain treatment facilities in Canada. Can J Anesth 2007; 54: 977-984.
4. The Painful Truth Survey Report (2014 Oct 17). Retrieved from http://www.canadianpaincoalition.ca/index.php/en/about-us/media-room/2014/10/17/242
5. Benjamin R, Trescot AM, Datta S, et al. Opioid complications and side effects. Pain Physician 2008; 11(2 Suppl): S105-20.
6. Joint Statement of Action to Address the Opioid Crisis (2017 Nov 19). Retrieved from https://www.canada.ca/en/health-canada/services/substance-abuse/

opioid-conference/joint-statement-action-address-opioid-crisis.html?_ga=1.151650431.732537752.1490933782
7. Fischer B and Argento E. Prescription opioid related misuse, harms, diversion and interventions in Canada: A Review. Pain Physician 2012; 15: ES191-203.
8. International Narcotics Control Board. (2013). Narcotics Drugs: Estimated World Requirements for 2013; Statistics for 2011. New York: United Nations.
9. Nasser R, Yadla S, Maltenfort G, Harrop JS, Anderson DG et al. Complications in spine surgery. J Neurosurg Spine 2010; 13: 144-157.
10. Deer TR, Mekhail N, Provenzano D, Pope J et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: The Neuromodulation Appropriateness Consensus Committee (NACC). Neuromodulation 2014; 17: 515-550.
11. Gildenberg PL. History of electrical neuromodulation for chronic pain. Pain Med 2006; 7: S7-13.
12. Linderoth B. Spinal cord stimulation: a brief update on mechanisms of action. Eur J Pain Supp 2009; 89–93.
13. Deer TR, Mehkail N, Prvenzano D, Pope J et al. The appropriate use of neurostimulation: avoidance and treatment of complications of neurostimulation therapies for the treatment of chronic pain. Neuromodulation 2014; 17: 571-597.
14. Kumar K, Toth C, Nath R, Laing P. Epidural spinal cord stimulation for treatment of chronic pain-some predictors of success. A 15-year experience. Surg Neurol 1998; 50: 110–121.
15. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery 2006; 58: 481–496.
16. Williams KA, Gonzalez-Fernandez M, Hamzehzadeh S, Wilkinson I et al. A multi-center analysis evaluating factors associated with spinal cord stimulation outcome in chronic pain patients. Pain Med 2011; 12: 1142-1153.
17. Baron R, Backonja MM, Eldridge P, Levy R et al. Refractory Chronic Pain Screening Tool (RCPST): A Feasibility Study to Assess Practicality and Validity of Identifying Potential Neurostimulation Candidates. Pain Med 2014;15:281-291.
18. Olson KA, Bedder MD, Anderson VC, Burchiel KJ, Villanueva MR. Psychological variables associated with outcome of spinal cord stimulation trials. Neuromodulation 1998; 1: 6–13.
19. Celestin J, Edwards RR, Jamison RN. Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. Pain Med 2009; 10: 639–653.
20. Trief P et al. A prospective study of psychological predictors of lumbar spine surgery outcome. Spine 2000; 25: 2616-2621.
21. Ghoneim MM and O'Hara MW. Depression and postoperative complications: an overview. BMC Surgery 2016; 5.
22. Stephens KA and Ward A. Patient selection for spinal cord stimulators: mental health perspective. Curr Pain Headache Rep 2014; 18: 398.
23. Deer TR, Narouze S, Provenzano DA, Pope J et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations on Bleeding and Coagulation Management in Neurostimulation Devices. Neuromodulation 2017; 20: 51-62.
24. North RB. SCS trial duration. Neuromodulation 2003; 6: 4–5.
25. Kumar K and Rizvi, S. Cost-Effectiveness of Spinal Cord Stimulation Therapy in Management of Chronic Pain. Pain Med 2013; 14: 1631-1649.
26. Kumar K, Taylor RS, Jacques, L, Eldabe S et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery. Pain 2007; 132: 179-188.