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High-frequency Spinal Cord Stimulation as a Palliative Treatment for Patients with Low Back and Lower Extremity Radiated Chronic Pain

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Abstract

Introduction: Since "Gate Control" theory was published, Spinal Cord Stimulation (SCS) has been used in palliative management of Low-back Pain (LBP) and lower extremity Radiated Pain (RP) and functionality in patients with Lumbar Stenosis (LS), Degenerative Scoliosis (DS) or Failed Back Surgery Syndrome (FBSS). Our aim is to describe our experience with High Frequency Spinal Cord Stimulation (HF-SCS).

Methods: Descriptive, retrospective study (n=30) between 2014-2017 with HF-SCS due to intractable LBP and RP. Mean age was 69 (45-87), mean Comorbidity Charlson Index (CCI) was 6; 80% female with minimum follow up of 12 months. Items reviewed were time to implantation, VAS for LBP and RP and Owestry disability index (ODI), improvement in hungry, emotional status or sleeping; and personal satisfaction. Complications related to procedure were also recorded.

Results: HF-SCS was indicated in 25% patients because of LBP and LERP secondary to LS or not operable DS. Median time to surgery was 3 years (ICR 1-6). Pre and post-surgery mean (SD) values were VAS-LBP 8.63 (1.09) 4.43 (2.5); VAS-LERP 7.03 (2.84) 4.77 (2.49); and ODI 67.2 (11.9) 48.33 (16.93). All of these were statistically significant ($p<0.01$); 60% improved in sleeping and mood. No patient presented lower limbs paraesthesia, but 13% had electrodes mobilization. 73% were finally satisfied with treatment received.

Conclusion: HF-SCS use for refractory LB and RP could be an effective tool to improve patient pain and functionality with high satisfaction. Especially in those who are not candidates for corrective surgery because of their age or comorbidities.

Keywords: Pain; Spinal cord stimulation; Neuromodulation; High-frequency

Level of Evidence

Level III-retrospective descriptive study.

Introduction

Low back pain (LBP) and lower extremity radiated pain (RP) are cause of chronic pain and disfunction in more than 1.500 million people around the world. One out of four people will experiment one or both of these conditions in a lifetime and will affect their daily life activities or their emotional or psychosocial spheres [1].

In case of refractory pain, recently Spinal Cord Stimulation (SCS) has proved superior results to re-surgery or non-operative management with pharmacology analgesic [2].

Neurophysiological principles, in which SCS sustains its functioning, begin in 1965, when Melzack and Wall published their revolutionary "Gate control" theory. They affirm that one Aβ myelin fibers stimulus in dorsal column, not only can an inhibit ascending pathway pain sensation vehicle by small C and Aδ sensory fibers by the stimulus of monosynaptic inhibitory interneurons; but also, stimulating the descending modulatory pain pathway, by stimulating the rostral central nuclei of the brainstem. The effect of these two actions results in a lower pain perception in cerebral cortex [3].

Opposite to conventional (low frequency) SCS, which generates electric pulses with lower frequency (50 Hz), longer lasting (300-600•sec) and higher amplitude (4-9 mA); new (high frequency) SCS (or HF-SCS), develops electric pulses with higher frequency (till 10.000 Hz), shorter lasting (30•sec) and a lower amplitude (1-5 mA). All these changes have proved to be secure, effective and clinical beneficious without low extremity paresthesia [4], for at least 2 years kept response [5].

Biochemically, SCS increase local levels of GABA, Glycine, Serotonin and P substance. It is used to treat neuropathic pain like in anger pectoris and peripheral vasculopathy minimal effort pain or complex regional pain syndrome (CRPS) types I and II. It is also used to treat mechanical pain associated or not, to radiated pain in no surgery candidates with failed back surgery syndrome (FBSS). In this last case, SCS has been proved cost-affectivity benefit [6].

The main aim of our study is to find out patient satisfaction and relevant clinical benefits (functionality, low back and radiated to lower extremity pain) obtained at one year follow-up after HF-SCS implantation in those who are not candidates for revision surgery, due

to lumbar stenosis (LS), degenerative scoliosis (DS) or FBSS with refractory pain.

Materials and Methods

A retrospective, descriptive study was carried out with a group of 30 patients treated at our institution (between November 2014 and June 2017) with a 10 kHz HF-SCS (Senza System; Nevro Corp, USA), with a diagnose of LS, DS or FBSS with refractory LBP associated or not RP to their low extremities. All patients had a minimum 12 months follow-up.

As inclusion criteria all the patients were older than 40-year-old, history of more than 6 months of LBP o RP to lower extremities with a VAS score 5 despite other treatments (opioid drugs, physical therapy, epidural steroid injections, radiofrequency neurotomy and previous surgery). All the patients were not candidates to a surgery because of their global health status or because there were no clear cause of pain after previous lumbar or thoracolumbar fusion. All patients without complete follow-up till month 12 after SCS implantation were excluded of the study.

Two types of electrodes were used in our population of study; the paddle type in 4 patients and the cable type the rest 26. Cable electrodes were placed percutaneously, meanwhile paddle electrodes need to be placed with a mini-open access through a 4 cm medial longitudinal approach, centered in the spinous process of T12, adding a 1 cm medial laminotomy at this level. In all patients electrode position was assessed by intraoperative radiographic control in which the electrode had to be in the AP view, centered to the spinous process between vertebral body of T8 proximally and intervertebral disc T10-T11; and the posterior epidural space in the lateral view (Figure 1).

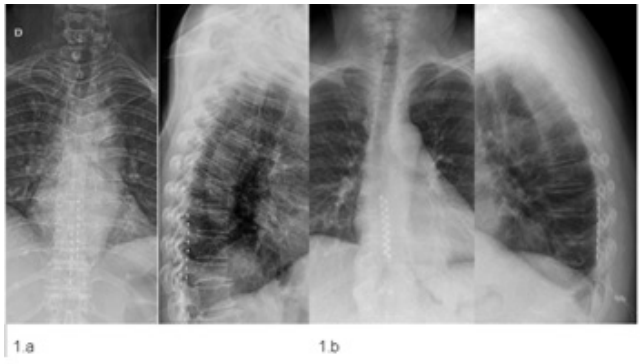

Figure 1: Electrodes position. AP and lateral view of plain Radiographs of patients treated with (1.a) HF-SCS with cable and (1.b) paddle electrodes.

After testing proper functioning of the electrodes and pulse generator, they were fixed to supraspinatus ligament and passed through the subcutaneous to the gluteal region where the pulse generator is implanted above gluteus major muscular mass, with an incision no longer than 6-7 cm oriented to Langer skin tension lines.

After the intervention, generator was activated in a program which stimulated electrodes closest to intervertebral disc T9-T10 (referenced by radiographic control) during first 24 h, while the patient is at hospital to assure there are no early complications related to intervention or paresthesias (location and intensity); and verify a proper pain control.

All patients were told to come back to the office by 12-14 days after intervention to control surgery wound closure and pain management. Posteriorly they were told to follow-up by first, third, sixth and twelfth month to complete some functional and pain scales, to make plane AP and lateral radiographs to discard implant mobilization and change pulse program (changing simulation between electrodes or changing intensity) if pain controlled was not satisfactory with an informatic software empowered by Nevro and transmitted to the generator wirelessly. In this case of modifying pain control program we arrange an additional visit just to confirm if pain was properly managed.

After first year from the surgery, visits were arranged between 6 and 12 months depending on patient necessities.

Epidemiological variables collected were age, sex, Charlson Comorbidity Index (ICC) and time of pain to implant HF-SCS. In addition, preparatory and postoperative variables, VAS value for LBP and RP to lower extremities, and Owestry Disability Index (ODI) 5 value were collected. Furthermore, patients were asked for their improvement in hunger, sleep and emotional status after implantation; if they were able to re-join their previous activity life (work if they were at age), and their finally satisfaction at 12 months after surgery.

Complications defined as circumstances which led in a worse result for the patient or needed reoperation (infection, hematoma, neurological dysfunction, electrode mobilization or break) were also recorded.

Statistical study was held by SPSS v24.0 (IBM). It included mean, median, standard deviation and percentages. Our principal analysis included differences between preoperative VAS values for LBP and RP for lower extremities and ODI, to postoperative ones using T-Student test for parametric variables, stablishing as statistical significative threshold, a p-value less than 1% ($p<0.01$). As an exploratory analysis we compared any differences between both types of electrodes used in the study, using de U-Mann-Whitney test for non-parametric variables, stablishing as signification threshold, a p value less than 5% ($p<0.05$).

Results

From our population of 30 patients with a minimum of 12 months of follow-up, 80% were female and the rest 20% were male, with a mean age of 69 (45-87 y.o.). Mean CCI was 6, and all patients had LBP and RP to lower limbs refractory to other treatments with a median time to HF-SCS implantation of 3 years (1-6 years); 25% were non-candidates to surgery patients with coronal misalignment measured by teleradiographs (DS) or LS. The other 75% were FBSS without any clear diagnose for their pain (Figure 2). Measured by intraoperative radiographs, 96% of electrodes were positioned between intervertebral discs T8-T9 and T10-T11. Only 1 patient was positioned distally to T11 superior vertebral endplate.

Preoperatively mean LBP-VAS value was 8.63 (SD•1.09); 7003 (SD•2.84) for RP-VAS value and 67.2 (SD•11.9) for ODI value. These postoperatively mean values were 4.43 (SD•2.5); 4.77 (SD•2.49) and 48.33 (SD•16.93) respectively (Table 1 and Figure 3). What means a statistically significant decline of 4.2 points in LBP-VAS; 2.26 RP-VAS and 18.87 ODI values (T-Student test $p<0,01$) (Table 2).

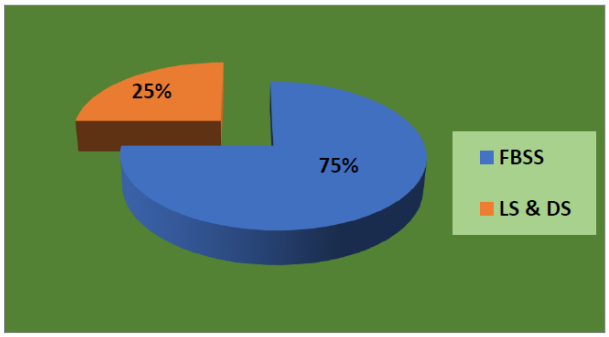

Figure 2: Diagnose before HF-SCS implantation. FBSS: Failed Back Surgery Syndrome; LS: Lumbar Stenosis; DS: Degenerative Scoliosis.

	M ± SD	MSE
LBP-VAS PREOP	8.63 ± 1.098	0.200
LBP-VAS POSTOP	4.43 ± 2.582	0.471
RP-VAS PREOP	7.03 ± 2.846	0.520
RP-VAS POSTOP	4.77 ± 2.459	0.449
ODI PREOP	67.20 ± 11.900	2.173
ODI POSTOP	48.33 ± 16.939	3.093

Table 1: Low Back Pain and lower extremities Radiated Pain (RP) VAS score and Oswestry Disability Index (ODI) preoperatively (PREOP) and 12 months after HF-SCS implantation (POSTOP). Mean (M) Standard Deviation (SD) and Mean Standard Error (MSD); n=30.

In 63.3% of patients improvement in sleeping was found, as well as hunger in 36% and in 60% for emotional status. No lower limb paresthesia was found post HF-SCS implantation, and 73.3% of patients were satisfied after 12 months with their stimulator effect in their life. Only 4 patients were at working age, and only one of them was able to rejoin to his previous job.

	M ± SD	MSE	IC 95%	T-Student	p
LBP-VAS PRE-POST	4.200 ± 2.952	0.539	3.098-5.302	7.791	0.000
RP-VAS PRE-POST	2.267 ± 3.290	0.601	1.038-3.495	3.774	0.001
ODI PRE-POST	18.867 ± 13.333	2.434	13.888-23.845	7.750	0.000

Table 2: Paired simple difference values for Low Back Pain and lower extremities Radiated Pain (RP) VAS score and Oswestry Disability Index (ODI) preoperatively (PRE) and 12 months after HF-SCS implantation (POST). Mean (M) Standard Deviation (SD) and Mean Standard Error (MSD), 95% Confidence Interval (CI 95%), Student test (T-Student) value & statistical significance (p value); n=30.

Complications requiring a second surgery were found in 13.3% (n=4) patients. Three of them needed to reposition their electrodes because of mobilization (all of them in first 3 months), and the other one to change generator position due to generator inconvenience when sitting, after subcutaneous atrophy. No hematoma or deep wound infection was recorded.

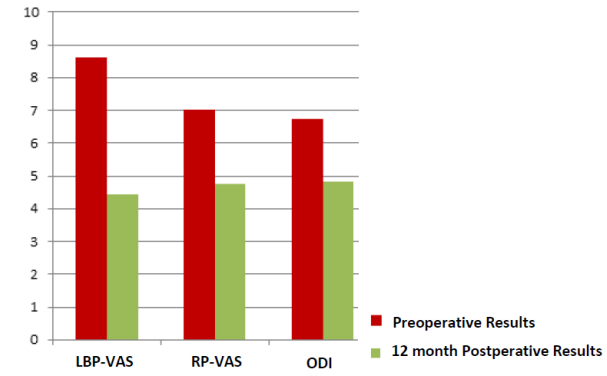

Figure 3: Clinical response to HF-SCS. Preoperative (red bar) and 12 month postoperative (green bar) results for low back pain (LBP-VAS) and lower extremities radiated pain (RP-VAS) score; and Oswestry disability index (ODI).

	Electrode	M ± SD	MSE	ΔM	95%CI	U-MannW	p-value
Δ ΛΒΠ-ςΑΣ	Cable (n=24)	-3.58 ± 2.63	0.53	3.08	0.54-5,62	2.48	0.019
	Paddle (n=6)	-6.66 ± 3.07	1.25				
Δ ΡΠ-ςΑΣ	Cable (n=24)	-1.79 ± 3.48	0.71	2.37	-0.61-5.36	1.62	0.115
	Paddle (n=6)	-4.16 ± 1.16	0.47				
Δ ≅ΔΙ	Cable (n=24)	-16,41 ± 13.33	2.72	12.25	0.48-24.01	2.13	0.042
	Paddle (n=6)	-28.66 ± 8.31	3.39				

Table 3: Difference () between preoperatively and 12 months after HF-SCS implantation values for Low Back Pain and lower extremities Radiated Pain (RP) VAS score and Oswestry Disability Index (ODI) for each type of electrodes (cable & paddle): Mean (M) Standard Deviation (SD) and Mean Standard Error (MSD). Results comparing both types of electrodes: difference of Means (M), with its 95% Confidence Interval (95% IC), U Mann-Whitney test value (assuming same variance) and its statistical significance (p-value).

Discussion

There are different several and recent published articles about SCS as a safe and cost-effective option for refractory LBP [7,8]. Last decade investigations showed SCS pain control superiority to pharmacologic (opioids, anticonvulsant or antidepressants drugs) or reoperation alternatives. Moreover, SCS effect has been shown to remain at least 2

years [9]. These results are also better with new HF-SCS which leads to higher pain control without associated paraesthesia with previous conventional low frequency SCS [9].

Pain is perceived after any thermic, chemical or mechanical stimuli activate our peripheral nociceptors. It unchains a nerve impulse which travels through neuronal axon till spinal dorsal root. From then it goes to the corresponding metameral dorsal horn where a new synapse is done activating a new fiber neuron that travels through lateral spinothalamic tract till brain stem where it synapses to rostral nuclei and thalamus, before finishing at cerebral cortex becoming conscious.

Last studies in chronic pain, give more importance to some neurons located at the spinal dorsal horn called Wide Dynamic Range (WDR) neurons. They belong to the thermoalgesic pathway which vehicles painful sensitivity. In chronic pain situations, WDR neurons experiment an abnormal cytoplasmic membrane ionic channels opening. It is called "wind-up" regulation, and leads into a neuronal hyperexcitation status due to an abnormal membrane depolarization (reduction of the activation threshold so neurons can be activated with lower stimuli and for a longer time). However, we also know that inhibitory descendent pathways from frontal cerebral cortex and brain stem can diminish pain perception by down regulation of this WDR neurons in the opposite way, by spinal and encephalic release of endorphins.

Conventional low frequency SCS, acts as painkiller by stimulating inhibitory GABA releaser interneurons which hyperpolarize WDR neurons. But also, stimulates neural proprioceptive and vibratory fibers in the dorsal column, causing paresthesia to lower limbs.

Opposite to this, HF-SCS, due to its high frequency pulses, in one hand penetrate deeper, directly to the inhibitory interneurons without stimulating dorsal column fibers, avoiding paresthesias. And in the other hand it is also able to give a major reduction of pain and longer in time [1].

Patients graded in ASA scale •3 or a CCI •6 (surviving probability •2.25% at 10 years), desirable surgery and its risk-benefit ratio can be unacceptable. Complications after spinal corrective surgery in people older than 65 y.o. are expected in 17.8% patients, even more in patients older than 80 y.o. However, complications requiring new surgeries after palliative positioning of SCS is expected between 6% as Kapural et al. [8] and 7% as Al-Kaisy et al. [2] reported, a little lower than our experience (13%), but substantially lower and less dangerous than corrective surgery alternatives.

Nowadays becomes very interesting not only calculate if there is any difference between therapeutic alternatives, but also if it is clinically relevant. It can be measured by minimally clinically important difference (MCID), which measures minimal variation in scales, which is perceived by patients as an improvement. MCID depends on pathology investigated and scale used. It is established as MCID in LBP and RP a descend of VAS value between 1,2 and 3,7 points; and in ODI a descend between 8,2 and 13,3 points [10].

According to these points, the result we experienced in our patients, of improvement of 4.2 and 2.26 points in LBP-VAS and RP-VAS values respectively, and 18.87 points for ODI, are clinically relevant and so SCS-HF can be recommended in elderly or with high comorbidity patients.

In addition, HF-SCS patient satisfaction in our experience (76%) according to others above 80% assured by Kapural et al. [5] and Al-Kaisy et al. [11-14] is a really interesting issue, even more in patient unsatisfied with lots of previous treatments.

At last, we observed that all the patients who suffered from electrodes mobilization, were patients with cable electrodes. None of them had paddle electrodes. Despite the small incision and laminotomy needed to place paddle electrodes, the precision to assure the posterior and medial correct position in unique attempt, can influence in this circumstance. Besides, paddle electrodes seem to decrease pain and improve functionality versus cable electrodes. All of these results were exploratory and not our principal aim, and also, small paddle electrode group (n=4) compared to cable electrode group (n=26) make comparison imprecise. Prospective studies and equivalent groups with longer follow up are recommended in the future to confirm this observation [15-17].

Conclusions

HF-SCS could be an effective and clinically relevant palliative treatment for patients with refractory low back pain associated, or not, to lower extremities radiated pain. Especially in the elderly or those with high comorbidities with lumbar spinal stenosis, degenerative scoliosis or failed back surgery syndrome who are not candidates to surgery. It can lead into pain and functionality improvement, with high satisfaction but not exempt of complications.

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References

1. Turk DC, Audette J, Levy RM, Mackey SC, Stanos S (2010) Assessment and treatment of psychosocial comorbidities in patients with neuropathic pain. Mayo Clin Proc 85: 42-50.
2. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, et al. (2008) The effects of spinal cord stimulation in neuropathic pain are sustained: A 24 month follow-up of the prospective randomized controlled multi center trial of the effectiveness spinal cord stimulation. Neurosurgery 63: 762-770.
3. Meyerson BA, Linderoth B (2012) Mechanisms of spinal cord stimulation in neuropathic pain. Neurol Res 22: 285-292.
4. CDRH (2013) Design considerations for pivotal clinical investigations for medical devices; guidance for industry, clinical investigators institutional review boards and food and drug administration staff. FDA 1: 1-57.
5. Kapural L, Cong Y, Doust MW, Burgher AH, Vallejo R, et al. (2016) Comparison of 10-kHz high frequency and traditional low frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multi center, randomized, controlled pivotal trial. Neurosurgery 79: 667-677.
6. Harrison BS, Jing BA, Aladino A, Elsamidicy BE, Yang S, et al. (2017) Long term cost-utility of spinal cord stimulation in patients with failed back surgery syndrome. Pain Physician 20: 797-805.
7. Zucco F, Ciampichini R, Lavano A, Mantovani LG, et al. Cost-Effectiveness and Cost-Utility Analysis of Spinal Cord Stimulation in Patients With Failed Back Surgery Syndrome: Results From the PRECISE Study. Neuromodulation 18: 266-276.
8. Walsh KM, Machado AG, Krishnaney AA (2015) Spinal cord stimulation: a review of the safety literature and proposal for perioperative evaluation and management. Spine J 15: 1864-1869.

9. North RB, Ewand MG, Lawton MT, Piantadosi S (1991) Spinal Cord Stimulation for chronic, intractable pain: superiority of multi-channel devices. Pain 44: 119-130.
10. Paul AR, Kumar V, Roth S, Gooch MR, Pilitsis JG (2017) Establishing Minimal Clinically Important Difference of Spinal Cord Stimulation Therapy in Post-Laminectomy Syndrome. Neurosurgery 81: 1011-1015.
11. Al-Kaisy A, Van Buyen JP, Smet I, Palmisani S, Pang D, et al. (2014) Sustained effectiveness of 10 kHZ High-Frequency Spinal Cord Stimulation for Patients with Chronic, Low Back Pain: 24-month results of a prospective multicentre study. Pain Med 15: 347-354.
12. Ahmed S, Yearwood T, De Ridder D, Van Neste S (2018) Burst and high frequency stimulation: Underlying mechanism of action. Expert Rev Med Devices 15: 61-70.
13. Elzahaf RA, Tashani OA, Unsworth BA, Johnson MI (2012) The prevalence of chronic pain with ananalysis of countries with Human Development Index less than 0.9: A systematic review without meta-analysis. Curr Med Res Opin 28: 1221-1229.
14. Fairbank JC, Pynsent PB (2000) The oswestry disability index. Spine 25: 2940-2952.
15. Imajo Y, Taguchi T, Neo M, Otani K, Iguchi T, et al. (2017) Complications of spinal surgery for elderly patients with lumbar spinal stenosis in a super-aging country: An analysis of 8033 patients. J Orthop Sci 22: 10-15.
16. Melzack R, Wall P (1996) Pain mechanisms: A new theory. Science 19: 971-979.
17. North RB, Kidd DH, Farrokhi F, Piantadosi SA (2005) Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized, controlled trial. Neurosurgery 56: 98-106.