EFFICACY AND PHARMACOECONOMICS STUDY OF SPINAL CORD STIMULATION (SCS) CONDUCTED AT THE PAIN THERAPY HUB, SAN GIULIANO HOSPITAL ASL NAPOLI 2

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KEYWORDS: Pain, Chronic pain, Spinal Cord Stimulation (SCS), Impalntable Pulse Generator (IPG), Failed Back Surgery Sindrom (FBSS), Complex Regional Pain Syndrome (CRPS), Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), Quality of Life (QALY o HQRd).

ABSTRACT

Introduction:
Chronic Pain has been recognized by the World Health Organization as one of the major global public health issues. The condition has debilitating consequences from physical, psychological, and socio-relational perspectives due to its highly disabling nature. Spinal Cord Stimulation (SCS) involves the placement of one or more electrodes in the epidural space through surgical means, connected to a fully implantable battery that electrically stimulates the spinal nerve structures. This treatment is indicated for patients suffering from intractable chronic pain in the trunk and limbs, particularly demonstrating efficacy in treating neuropathic pain. This method has been in use since the mid-1970s. The study lasted 24 months, with the initial 8 months involving patient recruitment and the subsequent 16 months devoted to the follow-up period. Its purpose was to evaluate the cost-benefit ratio of SCS in patients with chronic pain, treated at the Pain Therapy Hub of San Giuliano Hospital, ASL Napoli 2 Nord. The primary goal was to assess the effectiveness of Spinal Cord Neurostimulation (SCS) when applied to these patients. By conducting a comparative assessment 16 months after the implantation, the study evaluated the reduction in pain and disability among patients treated with SCS. Additionally, the study analysed the costs incurred by the National Health Service (SSN) and the corresponding benefits achieved in treating patients with chronic pain using SCS. The study is aimed to assess the effectiveness of this treatment in terms of improving patients' health status and quality of life.
Materials and Methods:
The observational study is retrospective and single cantered, conducted at the regional Pain Therapy Hub of San Giuliano Hospital, ASL Napoli 2 Nord. The study lasted for 24 months, with the initial 8 months dedicated to patient recruitment and the subsequent 16 months for the follow-up period.
A total of 39 adult patients capable of managing or tolerating the devices used in SCS were recruited. These patients had a diagnosis of chronic back and/or leg pain and were non-responders to pharmacological therapy and other therapeutic treatments. The patients were provided with information about this study.
Sixteen patients were excluded due to psychological or psychiatric disorders, progressive neurological conditions, or being recipients of an intrathecal pump for pain-relief drug infusion or an IPG. The remaining 23 patients received the implantation of a pulse generator and two electrode catheters. This group constituted our cohort, to which questionnaires were administered to evaluate the level of disability using the Oswestry Disability Index (ODI) and pain measurement using the Visual Analog Scale (VAS). Data were collected at Time 0 (T0) and during the subsequent 16 months from the start of treatment (Follow Up). Only 4 out of the 23 patients removed the neurostimulator before the 16-month term due to incompatibility. Quality of life data related to health status were collected through parameters used to measure how health impacts physical, psychological, and emotional well-being (HRQoL). Additional informative sheets, in addition to the ODI, were administered both at Time 0 and at the Follow-Up point, with the intent to verify if changes in ODI corresponded to changes in HRQoL parameters. Furthermore, quantification of data on resource consumption attributable to costs borne by the National Health Service was conducted, related to the treatment of individuals with chronic pain. These costs were divided into costs related to hospitalization, materials and devices used during the implantation procedure, and instrumental and professional resources employed to carry out the procedure (direct costs), as well as those linked to specialist visits, medication use, instrumental and diagnostic analyses (indirect costs). Regarding direct costs at Time 0, the average costs of daily hospitalization in Campania were considered, along with the average costs of tools, equipment, instrumental and pharmacological resources for an SCS implantation procedure. The gross costs associated with professional resources involved in the procedure, with an average duration of two hours (anaesthesiologist, radiological technician, operating physician, and nurse), were also considered. Lastly, non-medical costs generated by personal habits of patients with chronic pain and their care and management were considered. These costs vary depending on the patient's general conditions. Generally, these are individuals with limited autonomy, leading to increased specialized care needs and subsequent rising costs, including decreased productivity due to absences from work and those temporarily dedicated as caregivers. All medical

and non-medical costs were assessed one year before and 16 months after the implantation procedure, the latter being normalized to a 12-month period for equal evaluation periods.

Results:

The study examined 23 out of 39 eligible patients, evaluating the cost-effectiveness and cost-utility ratio of SCS over a period of 12 months before the implantation and 16 months after the spinal cord neurostimulator implantation. Among the 23 recruited patients, 4 did not reach the 16-month follow-up as they had their spinal cord neurostimulator removed. Two patients removed it due to infection, while the remaining two patients could not tolerate the implanted device. Out of the 19 patients included in the analysis, those who had shown poor quality of life and low health levels in the twelve months prior to the device implantation displayed a significant increase in clinical outcomes at the 16-month mark after SCS intervention. Analysing data related to the Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) between T0 and Follow-Up, variations in disability levels for different groups were identified. The decrease in disability and pain perception corresponds to an increased quality of life for the patient and a reduction in the social costs of the disease. The utility index Eq-5D increased from 0.45 to 0.68, and a noticeable improvement began to be observed after six months post-intervention.

In terms of economic aspects, analysing monthly and annual medical and non-medical costs incurred by patients with chronic pain in conjunction with the direct and indirect costs of the SSN intervention shed light on the substantial expense to support therapies for this condition, borne by both the SSN and the patient. Nonetheless, these costs are to be considered one-time expenditures, such as those related to the implanted device and its procedure, or significantly reduced, like specialist visits and medication usage, due to the patient's improved health condition. Comparing costs one year before and 16 months after the intervention borne by the SSN highlighted reductions in certain categories in the final amount. Specifically, the number of diagnostic tests and tutoring expenses dropped to zero, while check-up visits reduced on average to two per year.

Similarly, when comparing non-medical costs incurred by the patient one year before and 16 months after the intervention, a significant decrease in the final amount was recorded, correlating with the overall improvement in health status and the resulting reduction in the frequency and costs of accessing individual requested services.

A notable increase in SSN expenditure was observed within the first 6 months after the neurostimulator implantation, primarily attributed to the device's cost and related implantation procedures. By 9 months post-implantation, a reduction in SSN expenses compared to the pre-implantation months could already be observed.

INTRODUCTION

Chronic Pain has been recognized by the World Health Organization as one of the major global public health issues. The disease has debilitating consequences from physical, psychological, and socio-relational perspectives due to its highly incapacitating nature.

The average age of individuals suffering from chronic pain is 62 ± 16.6 years, and the condition affects all age groups, with a peak in the 51-70 age group (47%). However, a significant percentage is also found in other age groups, with 27% in the 35-50 age group and 13% in the 18-35 age group.

In Italy, it affects 1 in 5 individuals, accounting for 21.7% of the population, and one out of four individuals experiences chronic pain for an average of 7 years.

Although 90% of cases are treatable and curable, surprisingly, 40% of people with chronic pain are still unaware of available treatments. One such treatment is Spinal Cord Stimulation (SCS), which represents one of the most important advancements in the management and therapy of refractory chronic pain. SCS, utilizing current medical devices, offers an effective alternative when conservative therapies have failed.

Spinal Cord Stimulation (SCS) involves the surgical placement of one or more electrodes in the epidural space, connected to a fully implantable battery that electrically stimulates the spinal nerve structures. This treatment is indicated for patients suffering from intractable chronic pain in the trunk and limbs, particularly showing efficacy in treating neuropathic pain. Developed since the mid-1970s, SCS has found its primary application in pain therapy for chronic neuropathic pain conditions such as Failed Back Surgery Syndrome (FBSS), Complex Regional Pain Syndrome (CRPS), or chronic ischemic diseases.

The theoretical basis for pain modulation through stimulation of non-receptive receptors finds its roots in the "Gate Control Theory" proposed by Melzack and Wall. This theory revolves around the regulation of pain impulse transmission from the periphery to the brain. The transmission is influenced by the balance between large-diameter fibers (non-nociceptive) and small-diameter fibers (nociceptive) within the spinal cord. If activity in the large fibers prevails, pain will be mild or absent (gate closed), whereas if transmission along the thin fibers predominates, pain will be perceived (gate open). We can observe the functioning of this gate when we burn our finger; the immediate response of blowing, rubbing, or pressing the affected area activates transmission along the large fibers, inhibiting pain transmission along the thin fibers (gate closed), resulting in reduced pain perception.

The study spanned 24 months, with the initial 8 months involving patient enrollment and the subsequent 16 months dedicated to the follow-up period. The study aimed to evaluate the cost-benefit relationship of SCS in patients with chronic pain treated at the Pain Therapy Hub of San Giuliano Hospital, ASL Napoli 2 Nord. The primary goal was to assess the effectiveness of Spinal Cord Stimulation (SCS) applied to patients suffering from chronic pain.

Through a comparative evaluation at 16 months post-implantation, the reduction in pain and disability in patients treated with SCS and the related

costs incurred by the National Health Service (SSN) were analyzed. The study examined the benefits obtained from treating chronic pain patients with SCS, focusing on its effectiveness in improving patients' health status and quality of life.

MATERIALS AND METODS

The observational, retrospective, and single-center study was conducted at the regional Campanian Hub for Pain Therapy, San Giuliano Hospital of the Local Health Authority Napoli 2 Nord.

A total of 39 adult patients with a diagnosis of chronic pain in the back and/or legs, non-responders to pharmacological therapy and other therapeutic treatments, and capable of managing and tolerating the medical devices used in therapy, were recruited. The patients were provided with information about the study objectives.

Sixteen patients were excluded due to psychological or psychiatric disorders, progressive neurological diseases, or because they were carriers of an intrathecal pump for infusion of pain-relieving drugs or an IPG.

The remaining 23 adult subjects capable of managing an implantable device, suffering from chronic pain for more than 2 years, non-responders to pharmacological therapy for more than 2 years, formed our cohort.

These patients received an implant of a pulse generator and two percutaneously inserted electrode catheters, fixed at a metamerically corresponding level of T7-T8-T9, and each received a paresthesia-free stimulation called Burst. Burst is a train of 5 pulses with a frequency of 500 Hz and a period of 25 ms, using an amperage lower than 1 mA.

The degree of disability was assessed using the Oswestry Disability Index (ODI), while the patient's pain measurement was evaluated through the Visual Analog Scale (VAS), with results being at least 6 cm out of 10 cm on the respective scale.

These data were collected during subsequent 16-month follow-up appointments after treatment, enabling the verification and comparison of the outcomes of applied SCS in relation to the baseline.

Below are the two questionnaires administered to patients in the pre-implantation phase and in the 16-month follow-up:

Oswestry Disability Index 2.1a –Italian version (ODI-I)
Monticone M, Baiardi P, Ferrari S, Foti C, Mugnai R, Pillastrini P, Vanti C, Zanoli G.
Spine 2009; 34(19): 2090–2095

OSWESTRY DISABILITY INDEX (ODI)

This questionnaire has been designed to provide us with information about how your back (or leg) problems affect your ability to manage daily life. Please answer all the questions in the questionnaire. Place a mark in only one box for each question, choosing the one that best reflects how you feel today.

Section 1 - Pain Intensity

- I currently have no pain.
- I currently have very mild pain.
- I currently have moderate intensity pain.
- I currently have fairly strong pain.
- I currently have very strong pain.
- I currently have the worst pain imaginable.

Section 2 - Personal Care (washing, dressing, etc.)

- I can take care of myself normally without feeling more pain than usual.
- I can take care of myself normally, but it hurts a lot.
- It hurts to take care of myself, and I'm slow and cautious.
- I need a little help, but I can mostly take care of myself.
- I need help every day in almost all aspects of self-care.
- I can't dress myself, wash myself with difficulty, and stay in bed.

- **Section 3 - Lifting Weight**
- I can lift heavy objects without feeling more pain than usual.
- I can lift heavy objects, but I feel more pain than usual.
- Pain prevents me from lifting heavy objects from the ground, but I can do it if they are positioned properly, for example, on a table.
- Pain prevents me from lifting heavy objects, but I can lift light or moderately heavy objects if they are positioned properly.
- I can only lift very light objects.
- I can't lift or carry anything at all.

Continues...

Section 4 – Walking **The pain does not prevent me from walking any distance.** **The pain prevents me from walking more than a kilometer.** **The pain prevents me from walking more than 500 meters.** **The pain prevents me from walking more than 100 meters.** **I can only walk with a cane or crutches.** **I mostly stay in bed and crawl to the bathroom.**
Section 5 – Sitting **I can sit on any chair for as long as I want without any pain.** **I can sit on my favorite chair for as long as I want without any pain.** **The pain prevents me from sitting for more than 1 hour.** **The pain prevents me from sitting for more than half an hour.** **The pain prevents me from sitting for more than 10 minutes.** **The pain completely prevents me from sitting.**
Section 6 – Standing **I can stand for as long as I want without feeling more pain than usual.** **I can stand for as long as I want, but I feel more pain than usual.** **Pain prevents me from standing for more than 1 hour.** **Pain prevents me from standing for more than half an hour.** **Pain prevents me from standing for more than 10 minutes.** **Pain prevents me from standing at all.**
Section 7 – Sleepping **My sleep is never disturbed by pain.** **My sleep is occasionally disturbed by pain.** **Due to pain, I sleep less than 6 hours.** **Due to pain, I sleep less than 4 hours.** **Due to pain, I sleep less than 2 hours.** **Pain prevents me from sleeping at all.**
Section 8 - Sex life (if applicable) **My sex life is normal and doesn't cause me more pain than usual.** **My sex life is normal, but it causes me more pain than usual.** **My sex life is almost normal, but it causes me a lot of pain.** **My sex life is greatly limited by the pain.** **My sex life is nearly nonexistent due to the pain.** **The pain completely prevents me from having a sex life.**
Section 9 – Social Life **My social life is normal and doesn't cause me more pain than usual.** **My social life is normal, but it increases the level of pain.** **The pain doesn't have significant effects on my social life, except for limiting some of my interests that require more energy (e.g., sports, etc.).** **The pain limits my social life, and I don't go out as often as usual.** **The pain restricts my social life to my home.** **I have no social life due to the pain.**
Section 10 – Travelling **I can travel anywhere without pain.** **I can travel anywhere, but feeling more pain than usual.** **It hurts, but I can travel for more than two hours.** **The pain limits me to trips lasting less than an hour.** **The pain limits me to short and necessary trips lasting less than 30 minutes.** **The pain prevents me from traveling, except for getting medical treatment.**

Fig. 1: *Example of questionnaire for the ODI (Oswestry Disability Index).*

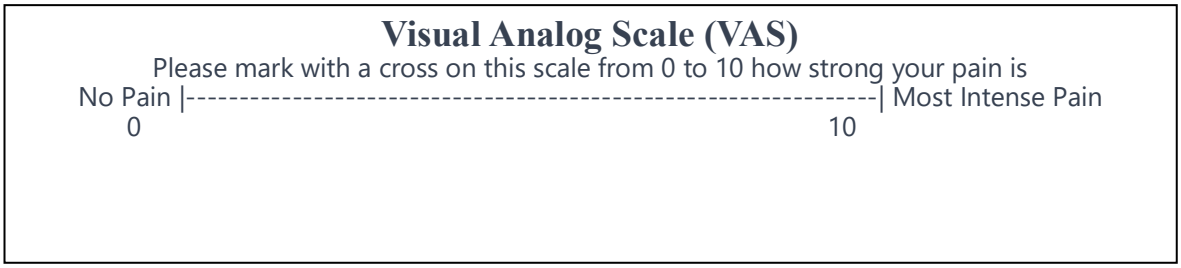

Fig 2: *Example of Visual Analog Scale Questionnaire*

Data on the quality of life in relation to health status, were collected using parameters used to measure how health affects physical, mental, and emotional well-being (HRQoL). Informational sheets were administered in addition to the ODI questionnaires both at Time 0 (T0) and at the Follow-Up, with the aim of verifying whether changes in ODI corresponded to changes in HRQoL parameters.

1. How would you currently rate your health status?
2. Does Chronic Pain interfere with your work?
3. Does Chronic Pain interfere with your social and relational habits?

Fig. 3: *Example of Health Status Information Sheet for Patients with Chronic Pain*

Furthermore, data on resource consumption related to costs borne by the National Health Service, associated with the treatment of individuals suffering from chronic pain, were also quantified. These costs were divided into direct and indirect costs related to the procedure. The direct costs encompassed expenses related to hospitalization, materials and devices used during the implantation procedure, as well as instrumental and professional resources employed to perform the procedure. On the other hand, specialist visits, medication usage, instrumental and diagnostic analyses were considered indirect costs and quantified.

Regarding the direct costs at Time 0 (T0), the average costs of daily hospitalization in Campania were taken into account. Additionally, the average costs of tools, medical supplies, instrumental and pharmacological resources for an SCS implantation were considered. The gross costs associated with the professional resources involved in the procedure, with an average duration of two hours (anesthetist, radiological technician, operating physician, and nurse), were also accounted for.

As for the indirect costs at Time 0, the gross annual costs to be borne by the National Health Service were considered. These costs were related to 6 average visits lasting 40 minutes over twelve months, as well as specialized analyses (1 CT scan at 200 euros, 1 MRI at 250 euros, and 1 EMG at 80 euros), medications, and assistive devices (corset and crutches) used by the patient for treatment. Regarding medications, it was taken into account that the patient consumes three different levels of drugs over time to manage this condition. Some of these are covered by the National Health Service, while others are private expenses. An average consumption of 10 packages per year was considered, with a mean cost of 5 euros each.

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FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
Paracetamol	Paracetamol+Codein	Morphine
Acetylsalicylic Acid	Tramadol	Oxycodon
Lysine Acetylsalicylate	Tapentadol	Fentanyl
Ibuprofen		Buprenorphin
Diclofenac		Methadone
Indomethacin		Hydromorphon
Metamizolo		
Nimesulide		
Ketorolac		
Adjuvant Medications: anticonvulsants, anxiolytics, sedative-hypnotics, antipsychotics, antidepressants, bisphosphonates, corticosteroids, levoacetylcarnitine, acid secretion-related drugs, gastrointestinal disorder medications, antiemetics, muscle relaxants.		

Table 1: *Various Types of Medications Used in Pain Management Therapy*

Finally, non-medical costs generated by the personal habits of patients suffering from chronic pain and their care and management were also considered. These costs vary depending on the patient's overall condition. In general, these are individuals with limited autonomy, leading to increased specialized assistance and subsequent rising costs. This also includes the impact of reduced productivity due to absences from work and temporary caregiving by family members. On average, it was assumed that 10 days per month would be required for accompanied travel with a driver, considering average reference rates for public transportation services. Costs were calculated based on standard national collective bargaining agreements for receiving part-time home support and 8 specialized assistance services, estimating gross compensation of €25,000 per year, assuming approximately 4 days of work absenteeism per month, and 3 days of leave under law 104/92.

All medical and non-medical costs were considered for one year before and 16 months after the implant procedure, and the latter were normalized to a 12-month period to ensure equal evaluation periods.

RESULTS

The study examined 23 out of 39 eligible patients, evaluating the cost-effectiveness and cost-utility of SCS over a period of 12 months before and 16 months after the implantation of the spinal cord neurostimulator. However, for comparison purposes, the data for the 12-month period were maintained. The first implantation was performed in July 2018, and the last in January 2020. The recruited patients had an average age of 69 years and had been suffering from chronic pain for at least 4 years.

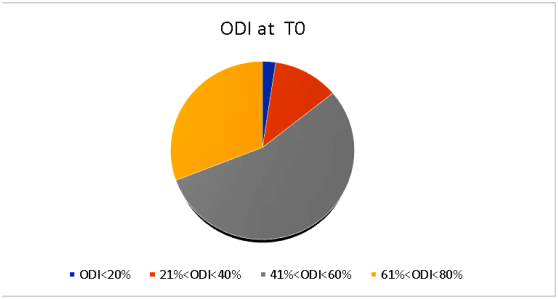
Out of the 23 recruited patients, 4 did not reach the planned 16-month follow-up due to the removal of the spinal cord neurostimulator. Two patients had to remove it due to infection, while the remaining patients did not tolerate the implanted device and did not experience satisfactory benefits.

Among the 19 patients who remained in the study and had demonstrated poor quality of life and low health levels in the twelve months prior to the device implantation, there was a significant improvement in clinical outcomes at the 16-month follow-up after the SCS intervention.

At Time 0 (T0), the average value on the Visual Analog Scale (VAS) for pain was 81 (out of 23 patients), while at the 16-month follow-up, the average VAS score reduced to 33 (out of 19 patients).

Regarding the Oswestry Disability Index (ODI) at Time 0, the following values were observed:

- 4.35% (1 patient out of 23) reported minimal disability (ODI < 20%);
- 13.04% (3 patients out of 23) reported moderate disability (21% < ODI < 40%);
- 56.52% (13 patients out of 23) experienced severe disability (41% < ODI < 60%);
- 26.08% (6 patients out of 23) were classified as paralyzed, with an ODI ranging from 61% to 80 %



Graph 1: *Distribution of patients in the cohort at Time 0 in relation to the ODI scale*

In the 16-month follow-up, the following data were observed for the ODI scale, considering that the patients who reached the Follow Up were 19: those with minimal disability (ODI < 20%) were 6 (35% of the monitored patients), those with moderate disability (21% < ODI < 40%) were 8 (37.5%), while those with greater disabilities, namely severe disability (41% < ODI < 60%) and those with paralysis (61% < ODI < 80%), were 3 (17.5%) and 2 (10%) respectively.

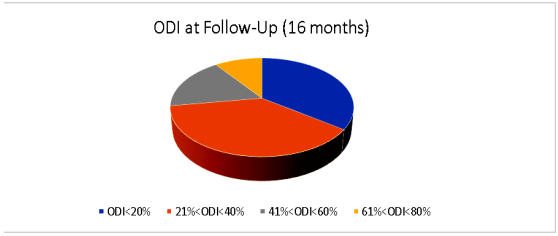
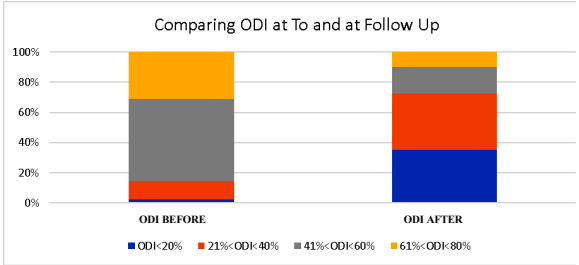


Fig. 2: *Distribution of the cohort patients at the completion of the 16-month Follow-Up in relation to the ODI scale.*

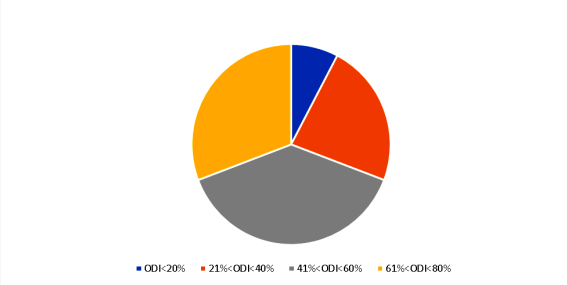
Below are the data related to the ODI at Time 0 and the 16-month Follow-Up, compared through a histogram:



Graph 3: *Data related to the ODI scale at Time 0 and Follow-Up*

Analyzing the data related to the ODI index between Time 0 and Follow-Up, variations in disability among different groups were identified. Specifically, it was observed that out of the 6 paralyzed patients, 2 of them remained paralyzed, 2 patients transitioned to a severe disability level, while 1 patient moved to a moderate disability level, and 1 patient's physical condition, according to the ODI questionnaire, could be conside-

red minimal in terms of disability.



Graph 4: *Variation in the distribution of paralyzed patients at Time 0 compared to Follow-Up*

Instead, out of the 13 patients with severe disabilities, 3 of them remained at the same level, while the majority of them experienced significant improvement in their physical condition. Specifically, 6 of them have a moderate disability and 4 have a minimal disability.

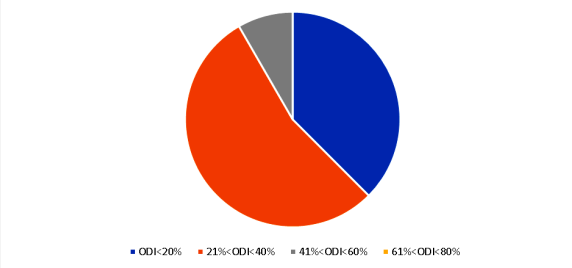
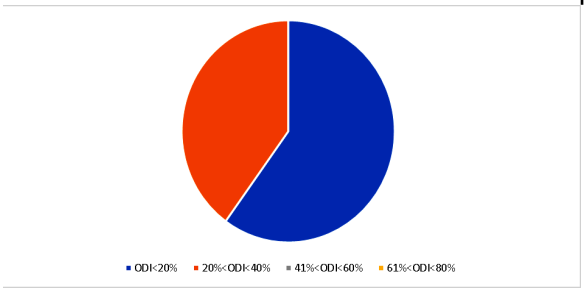


Fig. 5: *Variation in the distribution of patients with severe disability at T0 compared to Follow-Up*

Regarding patients with moderate disability, at Time 0 there were 3 of them, and one of them remained in the same disability range, while 2 patients improved to the minimal disability level (ODI<20%) at follow-up.



Graph 6: *Variation in the distribution of patients with moderate disability at Time 0 compared to Follow-Up*

The patient who, at Time 0, reported minimal disability based on the ODI questionnaire, remained within the same parameter range at 16 months post-implantation.

In Figure 7, the values of the ODI (Oswestry Disability Index) for all 23 patients who received the neurostimulator implant are depicted. A line graph was used, where one line represents the ODI values of the patients at Time 0, which is the time of device implantation, while another line represents the set of ODI values during the 16-month Follow-Up. It should be noted that 4 patients did not reach the follow-up, so the graph will also show two values where the ODI is the same both at Time 0 and Follow-Up.

Analyzing Figure 7, it can be observed that in all patients who reached the follow-up, there is a reduction in the disability percentage. Specifically, it is evident that in 22 patients, there is a reduction of more than 50% in the ODI index. As for the visual analog scale of pain (VAS), it decreased by an average of 60% in the follow-up compared to the baseline .

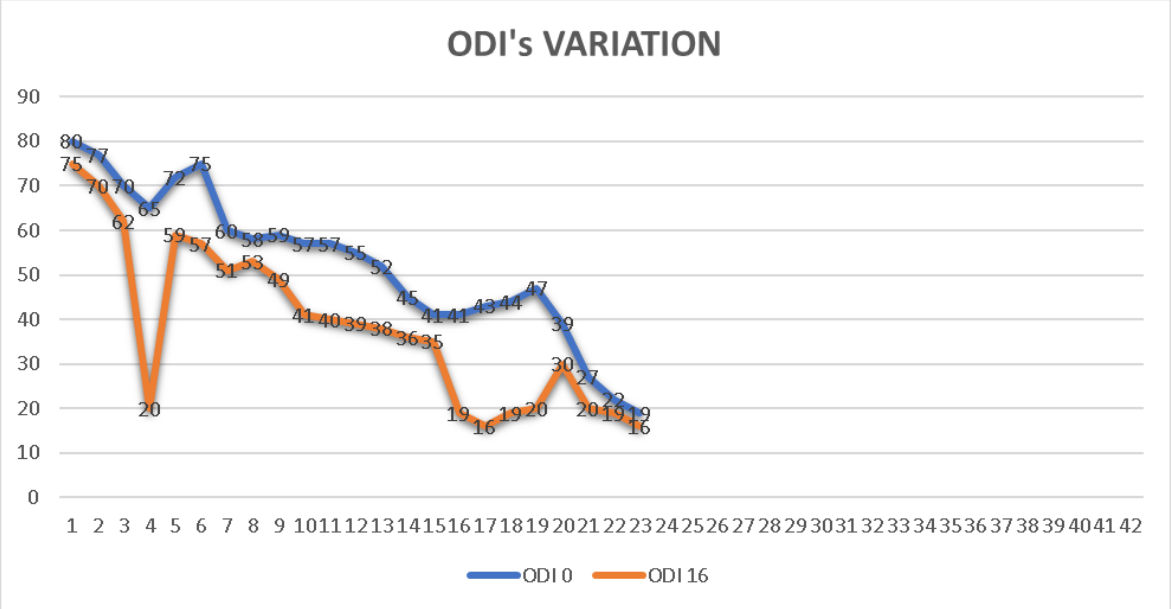
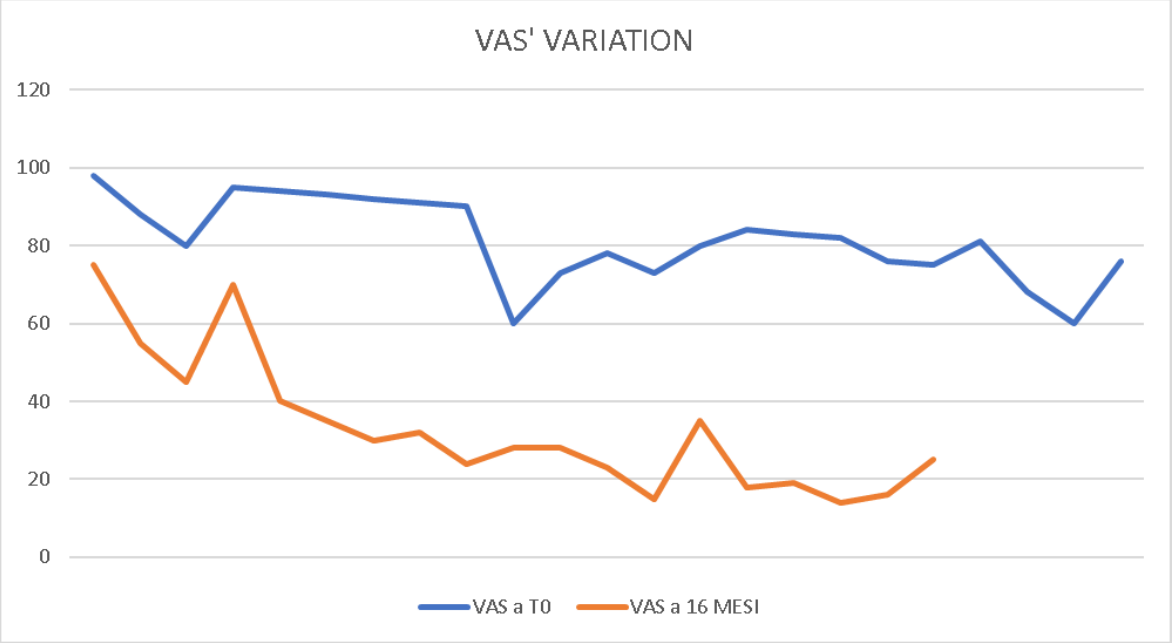


Figure 7: *Variation of the ODI index for each patient at Time 0 and Follow-Up*



Graf. 8 *Vas's variation for each patient at T0 and at FollowUp*

Graph 8 illustrates the values of the Visual Analog Scale (VAS) at Time 0 and Follow-Up for all implanted patients. Similar to the previous graph, the values at 16 months are based on 19 patients rather than 23. This graph allows us to assess how this average index reduces from 81 mm to 33 mm. Additionally, we can conclude that 14 out of 19 patients (73% of the Follow-Up cohort) experienced a reduction in the VAS index by more than 50%.

The decrease in disability and pain perception goes hand in hand with an increase in the patient's quality of life and a reduction in the social costs of the disease. The Eq-5D utility index increased from 0.45 to 0.68, with a noticeable improvement starting six months after the intervention.

Regarding the economic aspect, the analysis of monthly and yearly medical and non-medical costs incurred by patients with chronic pain, in comparison with the direct and indirect costs of the intervention covered by the National Health Service (NHS), highlights the significant expenditure required to support therapies for this condition, both by the NHS and the patients themselves. However, these costs are to be considered one-time, as in the case of costs related to the implanted device and its procedure, or significantly reduced, as in the case of specialist visits and the use of medications, in relation to the improvement in the patient's health status. Comparing the costs to be incurred one year before and one year after the intervention by the National Health Service (NHS) has highlighted how certain items begin to decrease in the final amount. Specifically, the number of diagnostic tests and tutoring aids to be supported reduces to zero, while follow-up visits on average decrease to two per year.

Direct Costs of the Intervention at Time 0	**Cost**	**Direct Costs of the Intervention at Time 0**	**Cost**
Hospitalization (1 night)	€ 620	Specialist visits	€ 150
Materials for the procedure	€ 45	Medications	€ 50
Devices for the procedure	€ 15000	Diagnostic tests	€ 530
Instrumental and pharmacological resources used	€ 30	Assistive devices	€ 50
Professional resources involved	€ 300		
Total	**€ 15995**		**€ 780**

Tab. 2: *Direct and Indirect Costs related to the intervention at Time 0*

Medical costs one year before and after the intervention		
Service	**Annual Cost Before**	**Annual Cost After**
Specialist Visits	€ 150	€ 50
Medications	€ 50	€ 15
Assistive Devices	€ 50	€ 0
Diagnostic Tests	€ 530	€ 0
Total	**€ 780**	**€ 65**

Table 3: *Medical Costs One Year Before and One Year After Intervention for the National Health Service (NHS)*

Similarly, in the case of non-medical costs borne by the patient, when comparing them one year before and one year after the intervention, a significant decrease in the final amount has been observed. This reduction is linked to the average improvement in health status and the consequent decrease in the frequency and associated costs of accessing individual services required.

There was a significant increase in expenses borne by the National Health Service (NHS) during the first 8 months after the neurostimulator implantation, mainly attributed to the cost of the device and the implantation-related procedures. By the 9th month, a reduction in expenses borne by the NHS compared to the pre-implantation months was already noticeable.

Non-Medical Costs One Year Before and After the Intervention				
Item	**Monthly Cost Before**	**Annual Cost Before**	**Before Monthly Cost**	**Annual Cost After**
Transportation with driver	€ 250	€ 3000	€ 80	€ 3000
Specialized home assistance	€ 600	€ 7200	€ 200	€ 7200
Daily home support	€ 700	€ 8400	€ 350	€ 8400
Law 104/92	€ 222	€ 2662	€ 111	€ 2662
Work absences	€ 295	€ 3550	€ 145	€ 3550
Totals	**€ 1867**	**€ 24812**	**€ 886**	**€ 10632**

Table 4: *Non-medical Monthly and Annual Costs Incurred by Chronic Pain Patients One Year Before and One Year After the Implantation*

CONCLUSIONS

The results have highlighted the efficacy of Spinal Cord Stimulation (SCS) performed through Burst stimulation in patients treated at the San Giuliano Hospital of the ASL Napoli 2 Nord. Indeed, Spinal Cord Stimulation (SCS) represents one of the most promising advancements in the management and therapy of refractory chronic pain. Thanks to the development of current devices in use, it constitutes an effective alternative where conservative therapies have failed, despite its high initial cost. It enables increased patient comfort and long-term cost reduction by decreasing both medical costs (specialist visits, diagnostic analyses, and medication usage) and non-medical costs (home care, patient transport, home support, and work absences).

This suggests that the cost-benefit ratio of using SCS compared to conventional therapies is advantageous for the patient in both economic terms and improvements in quality of life. Quality of life is becoming an increasingly important benefit indicator and has structurally entered the assessments of economic impact of new drugs and healthcare technologies. We have observed an enhancement in the quality of life associated with the reduction in the degree of disability and pain intensity, leading to benefits for the patients' families as well as society itself, as the social inclusion of patients who had previously been limited due to pain is promoted.

Although the healthcare cost may be higher when utilizing SCS, the benefits arising from it in terms of social utility for the improvement of the personal health status of patients treated with this procedure should lead to considering such treatments as significant therapeutic choices. Furthermore, it's important to note that ongoing research in the field of these devices is developing longer-lasting options, which can contribute to lowering the long-term cost.

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