SP61 COST EFFECTIVENESS OF SPINAL CORD STIMULATION IN CHRONIC LOW BACK PAIN

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Low back pain (LBP) is a serious burden both for patients and the health care systems. One in five adults have LBP and approximately 90% will experience LBP at some point of their life. It has been the major leading cause of disability worldwide, it has impaired the quality of life(QoL) for the past several years and it is the most commonly cited reason for disability, lost work, and lost wages in industrialized nations. Comorbidities associated with chronic pain including depression, anxiety, and sleep disorders further add to this burden. Direct costs of LBP such as the cost of hospitalizations, surgeries, prescriptions and physical therapy are estimated to be hundred of billions of dollars per year in the US alone. The indirect costs such as lost wages for missing work, emotional impact of chronic pain and any treatment or aid are sought to help it, retraining for new jobs that are more tolerable for the patient, and even healthcare allocation opportunity costs are more difficult to calculate.

Failed Back Surgery Syndrome (FBSS), defined as spinal pain persisting or appearing after a surgical procedure that is meant to treat the pain, is prevalent in up to 19% of microdiscectomy patients and 40% of lumbar laminectomy patients. Lumbar fusions for degenerative spondylolisthesis and associated LBP have risen significantly over the past 20 years. As many as 40% of patients who receive lumbar fusions may continue to have unsatisfactory relief of their symptoms. Patients with chronic back pain after a fusion surgery are also deemed to have failed back surgery syndrome (FBSS). For patients with apparent imaging findings revision surgical treatment could improve symptoms. Nonsurgical treatments for patients with FBBS include conventional medical treatment (CMM) with analgesics, physical therapy, cognitive behavioral therapy and more interventional therapies such as the implantation of spinal cord stimulator. Proper clinical management of FBSS should aim not only to alleviate pain, but also to improve physical function, Health Related Quality of Life (HRQoL) and lower drug dependency. Since narcotic use in FBSS patients has become an issue accentuated by the ongoing opioid crisis, reevaluation of clinical approaches in the treatment of FBSS is important. Spinal cord stimulation (SCS) can be effective at reducing pain and disability while improving (HRQoL) among FBSS patients. There are some high quality studies that found SCS device implantation (SCSdi) to provide superior patient satisfaction when compared to reoperation in patients with FBSS. Additionally, it is also found that fewer patients chose to crossover from their SCS device to a re-operation, further establishing this treatment as patient-centric in addition to efficacious.

However SCS is still mostly recommended to FBSS patients only after CMM has failed and when the pain has a neuropathic component. In 2008, the National Institute of Health and Care Excellence (NICE) recommended the use of SCS for the treatment of neuropathic pain, including pain caused by FBSS . SCS is underutilized and this calls for an additional reevaluation in a real-world setting. First of all, it is important to also assess the costs but also the cost-effectiveness of this procedure.

In a study published in 2017, 122,827 FBSS patients were identified and of these, 5,328 underwent SCS implantation (only 4.34%), and 117,499 underwent conventional management from 2000–2012, across the United States. Long-term total annual costs for these patients were significantly reduced compared to patients with conventional management. Although implantation of a SCS system resulted in a short-term increase in costs at one year, the subsequent annual cumulative costs were significantly decreased long-term in the following 9 years after implantation. This study combined the largest group of FBSS patients studied to date along with the longest follow-up interval ever analyzed. Since SCS has repeatedly been shown to have superior efficacy to CMM in randomized clinical trials, the current study demonstrated improved long-term health economics at 1, 3, 6 and 9 years supports the long-term cost utility of SCS in the treatment of FBSS patients. Although placement of an SCS system was associated with an initial increase in total costs at the time of implantation, however there was a significant and sustained 68% decrease in cost in the year following SCS placement compared to CMM. There was also an aggregate time trend that for each additional year after SCS, cost decreased on average 40% percent annually, with follow-up up to 1, 3, 6 and 9 years post-procedure.

Elena Rojo et al in 2021 presented a real-world cost-effectiveness analysis of SCS vs CMM in the management of FBSS. They obtained data from a 2-year real-world study (SEFUDOCE) of adults diagnosed with FBSS who were treated with CMM or SCS. Incremental cost-effectiveness ratios (ICER) were estimated in terms of direct clinical cost and quality-adjusted life years (QALYs). Costs (€ for 2019) were estimated from the Spanish National Health Service (NHS) perspective. SCS had a 79% of probability of being cost-effective. SCS+CMM offers improved pain relief, physical functioning, and HRQoL in FBSS patients in comparison with CMM. SCS +CMM could be cost-effective during a longer time span.

Another Systematic Review of the Cost-Utility of Spinal Cord Stimulation for Persistent Low Back Pain in Patients with Failed Back Surgery Syndrome which was published in 2021. It includes all publications in the Medline database and Cochrane CENTRAL trials register within the last 10 years assessing the cost-effectiveness of SCS in patients with previous lumbar fusion surgery. This study suggests SCS is likely more expensive in the short term when compared to CMM or re-operation for patients with FBSS. This initial expense is likely negated by the improvements in quality of life SCS provides when compared to CMM or reoperation. The literature reported the cost/QALY for SCS to be lower than even the conservative estimate of $25 000/QALY for an insurer's willingness to pay. The break-even point for the initial up-front costs seems to be 24 months; there is more than a 50% reduction in overall medical cost-savings with SCS compared to CMM and/or re-operation. Using the GRADE approach, the studies reviewed provide a moderate quality of evidence. We believe the strong likelihood of confounders being present greatly reduces the quality. However, this is partially offset by the striking consistency and large magnitude of effect on lower ICERs found across FBSS patients receiving SCS devices across different settings and time frames compared to FBSS patients who received CMM or secondary operations.

In the past four decades, SCS therapy has achieved good results in reducing the pain of patients with chronic low back

pain and improving the functional status of patients. In addition, this type of treatment has shown great promise in treating patients who are not eligible for surgery. However, the increasing prevalence and economic burden should be addressed appropriately to make it easier for patients to obtain SCS treatment. Furthermore, spinal cord stimulation may significantly affect refractory low back pain treatment and benefit clinically considering its technology and mechanism of action. Thus, this therapy will occupy a special place in future, in multidisciplinary neuropathic pain management.

Nowadays the technology powering these devices continues to evolve and improve, as well with refining Patient Selection and the integration of new large scale, multicenter, randomized controlled trials currently ongoing, it is likely we will see much more robust and applicable cost-effectiveness analyses that would have greatly diminished if not absent confounders published in the coming years. These studies are also likely to include and differentiate the more novel high-frequency and burst devices as well as provide more encompassing costs of SCS compared to alternative treatments.

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SP62 PDPH IN NON-OBSTETRIC POPULATION. A PROBLEM OR MYTH? A PROBLEM

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Introduction the problem Postdural puncture headache (PDPH) is a common iatrogenic complication of neuraxial anesthesia following dural puncture.[1] It may occur after inadvertent dura mater puncture in epidural anaesthesia, after spinal anesthesia and after lumbar diagnostic or therapeutic procedures.

The overall incidence of PDPH after neuraxial procedures varies from 6 to 36%.[1] It is more common in younger populations and is significantly higher in teenagers compared to those aged 20–45 years.[2] The elderly may also develop postdural puncture headache.[3] The incidence of unintentional dural puncture is estimated to be approximately 1.5%. Furthermore, up to 36% and in some reports as high as 76 to 85% of these patients may experience PDPH symptoms.[1]

Etiology and clinical manifestations

PDPH is caused by leakage of cerebrospinal fluid through the dural hole created by the needle. It can be considered a clinical model of intracranial hypotension and is characterized by a headache that occurs within 5 days following the puncture, located in the frontal and/or occipital region.[4 5] It is usually of postural nature and is accompanied by associated symptoms like neck stiffness, dizziness, nausea, hearing symptoms (tinnitus, hearing loss) and vision changes (diplopia, blurred vision, or photophobia.[5]

PDPH Consequences The occurrence of PDPH is problematic as it causes functional and socio-professional disability leading to increased patient morbidity, delayed discharge and increased readmission.[6] It is also associated with increased risks of major neurological and long-lasting complications.[7] Cases of persistent headache have been reported and chronic back pain as well.[7] Hypoacusis and tinnitus have been seen after dural puncture and have been thought to stem from the loss of CSF leading to reduced intracranial CSF pressure. There is also increased risk of subdural hematoma (due to rupture of meningeal veins) and cerebral vein thrombosis.[8] These complications underscore the importance of prophylaxis, early diagnosis, treatment and follow up of PDPH.[4]

Risk Factors The risk factors for PDPH are classified as nonmodifiable and modifiable. Nonmodifiable factors include the female sex, young age, teenagers, lower body mass index (BMI), previous PDPH, and chronic headaches. Risk factors that are modifiable include needle size, needle shape, direction of the needle bevel, stylet replacement, and operator experience.[8] The use of atraumatic, noncutting needles is the most effective intervention for post-lumbar puncture headache prevention.[9–11] Frequent attempts during lumbar puncture and increased cerebrospinal fluid leakage were associated with PDPH.[12 13] Neither bed rest nor fluid supplementation decreases the incidence of headache after dural puncture[14]; bed rest may even worsen post-lumbar puncture headache.[6] Insertion of an intrathecal catheter at the site of ADP significantly reduces the incidence and severity of PDPH.[15] PDPH incidence after lumbar puncture using a 22 G Tuohy needle was higher than that after lumbar CSF drainage using an 18 G Tuohy needle, suggesting that catheter insertion may reduce PDPH risk.[12]

Diagnosis The diagnosis of PDPH is made clinically by identifying the typical headache within 5 days after a dural