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Simultaneous Closed-Loop Inceptiv Spinal Cord Stimulator and Bladder InterStim Implantation - A Case Report

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Background: Overactive bladder (OAB) syndrome and chronic pain are 2 highly prevalent conditions often comorbid with one another. Though the mechanism is not fully elucidated, it is suspected that the presence of one may predispose individuals to the other. Neuromodulation has gained traction as a promising treatment modality for both conditions.

Case Report: Our case report describes a 69-year-old man with severe lumbar stenosis with debilitating pain, painful diabetic peripheral neuropathy, and OAB. After failing to achieve relief with conservative modalities, he underwent simultaneous closed-loop spinal cord stimulator (CL-SCS) and sacral stimulator implantation. At follow-up, he reported significant pain relief, improved sleep and mobility, alongside reduced urinary frequency symptoms.

Conclusions: To our knowledge, this is the first reported case of simultaneous CL-SCS and sacral stimulator implantation. The existing literature describing dual neuromodulatory techniques is sparse, focusing primarily on single indications. Our case uniquely describes 2 indications managed with dual neuromodulatory approaches.

Key words: Spinal cord stimulation, sacral stimulation, neuromodulation, overactive bladder syndrome, case report

BACKGROUND

Chronic pain impacts one in five US adults, or roughly 50.2 million US individuals, impacting quality of life and driving disability (1,2). Given its prevalence and widespread etiologies, providers often face challenges in managing various comorbidities while selecting an optimal treatment protocol.

Overactive bladder (OAB) syndrome is frequently encountered in the management of chronic lower back pain (cLBP) patients. OAB is a syndrome of urgent urination, accompanied by frequent urination, with or without urinary incontinence. The prevalence of OAB is estimated to be approximately 42 million individuals in the United States, though may be disproportionately higher in the cLBP population (3-5). Several large epidemiologic studies (6) suggest that the presence of one condition may predispose individuals to develop the other. Though the mechanism behind this predisposition remains uncertain, several theories exist, including pelvic floor dysfunction leading to spinal instability or lower back pain leading to weakened pelvic floor muscles (6,7).

The management of refractory cLBP and OAB has many similarities. Both rely upon a stepwise treatment algorithm starting with conservative measures, including behavioral modifications, physical therapy, and/or

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pharmacologics, and advancing as indicated (8,9). If these ultimately fail to provide adequate relief, more invasive interventions, including neuromodulation, may be considered.

Neuromodulation has gained traction as a promising treatment modality for both cLBP and OAB (8,10). Spinal cord stimulation (SCS) is a neuromodulation technique utilized for > 50 years in the management of cLBP (10). While SCS was initially reserved for cases of failed back surgery syndrome and complex regional pain syndrome, recent advancements have supported its use for a broader array of conditions, including chronic refractory back and leg pain, nonsurgical back pain, persistent spinal pain syndrome, and painful diabetic neuropathy, amongst others (10). Similarly, sacral stimulation is a form of neuromodulation initially utilized in the management of bladder or bowel urge incontinence, but was revised in 2002 to include OAB (11). Sacral neuromodulation is often utilized to manage refractory urge incontinence, urinary frequency symptoms, and nonobstructive urinary retention (8). Other emerging indications include neurogenic urge incontinence, interstitial cystitis, pelvic pain syndrome, fecal incontinence, and fecal constipation (12).

The neuromodulation techniques of SCS and sacral stimulation work similarly, though on different targets. SCS involves the delivery of stimulation via electrodes placed in the epidural space to the dorsal column of the spinal cord, targeting the Aβ sensory fibers, which contribute to inhibition of pain signals and subsequent analgesia (13). Closed-loop SCS (CL-SCS) is a recent technological advancement in SCS. CL-SCS allows for continuous monitoring of evoked compound action potentials (ECAPs), which are the summation of action potentials within the spinal cord in response to a delivered stimulation pulse, and thus serve as a measurement of spinal cord fiber recruitment in response to the stimulation provided by the SCS (13,14). By utilizing ECAPs, CL-SCS is able to detect and appropriately adjust to changes created by postural dependence, and thus maintain a therapeutic level of stimulation (15). In sacral neuromodulation, electrical impulses are supplied to the S3 nerve either unilaterally or bilaterally (16). Research (12,17) suggests that sacral neuromodulation modulates the micturition reflex via stimulation of the somatic afferent inhibition of sensory processing of the bladder within the spinal cord. Alternatively, it may provide direct inhibitory input to the bladder, and thus suppress bladder overactivity (17).

We introduce a case of simultaneous dual neuromodulation to treat concurrent cLBP and OAB. While the utilization of multiple forms of neuromodulation has been reported for pain management, as well as alternative indications, including epilepsy, the overall research remains scarce and an area of clinical interest (18-20). To our knowledge, this is the first reported case of simultaneous CL-SCS and sacral stimulator implantation, contributing to the growing demand for insight into dual neuromodulatory techniques.

CASE PRESENTATION

A 69-year-old man with a history of diabetes, OAB with benign prostatic hypertrophy resulting in an outflow obstruction, and severe lumbar stenosis with epidural lipomatosis has been following up with pain medicine for cLBP and painful diabetic peripheral neuropathy.

The patient reported debilitating pain in his lower back, bilateral hips and legs, and gluteal muscles that was a 6-8 out of 10 the numeric rating scale. The pain was constant without any relief, triggered by "being alive." He also reported severe burning in his feet, interfering with his ability to exercise. At a maximum, he was able to walk 20-30 feet with a cane and otherwise relied upon a wheelchair for community ambulation.

Additionally, the patient had a history of OAB and had been following up with Urology. He was taking tolterodine and tamsulosin after having failed to achieve relief with a trial of solifenacin. He had, however, achieved relief with transcutaneous electrical nerve stimulation targeting the tibial nerve.

Physical exam was notable for tenderness over the lumbar spinous processes, paraspinal muscles, and bilateral hips along the bilateral greater trochanters and anterior hips. Pain was noted with both lumbar flexion and extension. He had decreased sensation to his bilateral feet and generalized 4/5 strength in his lower extremities.

Magnetic resonance imaging of his lumbar spine revealed severe multilevel degenerative changes with severe multilevel spinal canal stenosis and neuroforaminal narrowing.

The patient's pain was suspected to be multifactorial, resulting from the bilateral multilevel neural foraminal stenosis, advanced degenerative disc disease, and diabetic peripheral neuropathy affecting both feet.

His most recent pharmacological pain regimen included amitriptyline 50 mg nightly for pain and sleep, meloxicam 15 mg daily, and pregabalin 100 mg 3 times

daily. He also used capsaicin 0.025% and menthol 10% to 15% creams for his bilateral feet. Previously, he tried courses of hydrocodone-acetaminophen 5-325 mg, tramadol 50 mg, gabapentin 600 mg, morphine 40 mg, and ibuprofen 800 mg. He had also completed an extended course of physical therapy with some relief.

Over the last 20+ years, the patient had undergone 25 lumbar epidural steroid injections (ESIs), which resulted in diminishing to no relief. Due to the patient's lipomatosis and severe central canal stenosis, it was advised to avoid future ESIs. He had also previously undergone bilateral L3-L5 medial branch blocks with pulsed radiofrequency (PRF) ablation. Greater trochanter injections alleviated the lateral hip pain, though only temporarily. Intraarticular hip injections failed to provide any relief. The spine surgery team determined that he was not a surgical candidate.

The patient agreed to pursue SCS treatment. An SCS trial resulted in 100% paresthesia coverage with 70% pain reduction immediately postprocedure. At a one-week follow-up, he reported 100% relief of pain, as well as improved sleep, mobility, and posture. He was even able to ambulate without an assistive device. A Medtronic SCS (Medtronic, Inc, Minneapolis, MN) was subsequently implanted to level T6, providing 90% relief. Soon after implantation, the patient was able to be weaned off opioids.

Approximately 4 years after SCS implantation, the patient had a ground-level mechanical fall and subsequently reported a return to pre-SCS pain levels. He noted recurrence of 10/10 pain radiating down his legs with associated numbness. Device interrogation revealed a nonfunctional left lead, and that the right lead had 3 contacts that resulted in overstimulation when tested. At this time, it was decided to pursue reimplantation with an Inceptiv® battery (Medtronic, Inc, Minneapolis, MN).

The patient underwent an SCS revision with Medtronic closed-loop Inceptiv implantation with leads terminating at T6. At a one-week postoperative visit, the patient reported significant efficacy with the new device. He simultaneously underwent stage II of a 4-lead bladder InterStim® peripheral nerve stimulator implantation (Medtronic, Inc, Minneapolis, Minnesota). After stage I of the InterStim implantation, he reported 70% to 90% improvement in urgency and nocturia, with a postvoid residual improved to 72 mL. Stage II was completed 10 days later. At a 2-week postoperative check, he reported voiding at 50% less frequency since device implantation. He has continued plans for optimization of stimulation settings.

DISCUSSION

This is the first reported case of simultaneous implantation of an Inceptiv CL-SCS with an InterStim sacral stimulator. With these new devices, the patient reported significant pain reduction in addition to a 50% reduction of voiding frequency, highlighting the efficacious benefits of both neuromodulation devices. This is not surprising, given the proven efficacy of both CL-SCS and sacral neuromodulation in large-scale studies assessing each individually (16,21-23). However, the impact of combining these neuromodulatory techniques remains a key area of interest for future research. Our case supports the use of simultaneous neuromodulatory techniques for cLBP and OAB, which are frequently comorbid conditions (6).

Though the evidence remains limited, several theories explain the coexisting relationship between cLBP and OAB. Some suggest that pelvic floor dysfunction may lead to spinal instability, while others propose that degenerative disc disease could irritate the sacral nerve roots (6,24). Additionally, neurologic remodeling due to the viscerosomatic convergence of the sacral nerve roots in the lumbar spine may also contribute to cLBP and OAB's connection (25). Alternatively, it has been proposed that lower back pain may lead to increased truncal activity, and thus possibly increase intraabdominal pressure or weaken pelvic floor muscles (6). Lastly, impaired function and mobility related to cLBP may also contribute to increased rates of urinary incontinence. The interconnectedness of cLBP and urinary symptoms is supported in cases discussing the incidental improvement of urinary symptoms following both an SCS implant as well as an ESI (24,26).

Both CL-SCS and sacral stimulation have proven efficacy individually across large-scale studies. The Evoke trial (13) found a significantly greater meaningful reduction in pain relief for CL-SCS compared to the open-loop SCS group at both 12 months and 24 months (53 of 67 [79.1%] in the closed-loop group vs 36 of 67 [53.7%] in the open-loop at 24 months). Similar results were noted in the Avalon study (22), which found CL-SCS resulted in 89.5% of patients reporting ≥ 50% reduction in pain and 68.4% reporting a ≥ 80% reduction in pain at 24 months with significant improvements in quality of life, physical and emotional functioning, and sleep, alongside 82.8% of patients reporting reduced or eliminated opioid use. For InterStim

sacral neuromodulation, a 3-year study by Chartier-Kastler et al (27) found a significant reduction of OAB symptoms, including daily voids and urinary leaks, and improvement in disease-specific quality-of-life scores. This is supported by a 5-year study completed by Siegel et al (23), which found 67% of patients with OAB managed with sacral neuromodulation reported a ≥ 50% improvement in average leaks, voids per day, or return to normal voiding.

The efficacy of simultaneous dual neuromodulatory techniques remains a crucial area of interest. An example includes a study by Li et al (18) exploring the efficacy of SCS in comparison to SCS combined with dorsal root ganglion PRF for the management of zoster-associated pain. It has also been reported in the management of zoster ophthalmicus, via the peripheral nerve stimulation and PRF of the trigeminal nerve (19). It has also been explored for refractory epilepsy, for individuals who received combination neuromodulation with vagal nerve stimulation, deep brain stimulation, and responsive neurostimulation (20). Notably, while the existing evidence on dual neuromodulation techniques focuses on single indications, our case uniquely explores the management of 2 indications using dual neuromodulatory approaches.

While our case offers a promising example of successful dual neuromodulation to manage cLBP and OAB, it is important to recognize the limitations that exist, as this is a case report. Most notably, the findings are derived from a single patient's experience, which limits their generalizability to a broader patient population. Future research should focus on the efficacy of dual neuromodulatory implantation to assess whether they may have synergistic or antagonistic effects on each other. Special attention should be paid to SCS for cLBP and sacral stimulation for OAB, as this is a coexisting relationship commonly encountered in the pain medicine community. Additionally, future research should focus on long-term effectiveness, optimal stimulation parameters, and whether dual integration may increase the risk of possible complications, such as device interference or neural damage.

CONCLUSIONS

Neuromodulation has a growing presence across health care for an increasing number of indications. As technology continues to advance, so too does the potential impact neuromodulation can have for patients. Our case explores the first reported dual implantation of a closed-loop Inceptiv SCS and InterStim sacral neuromodulation system.

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