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Neuromodulation in Male Chronic Pelvic Pain Syndrome: Rationale and Practice

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Abstract

This review explores the treatment of male chronic pelvic pain syndrome (CPPS) (i.e., chronic prostatitis) through the use of neuromodulation, which is the electrical stimulation of the nervous system. Neuromodulation has been used for the treatment of chronic pain for decades, and this review will examine the theory and use of neuromodulation and the various techniques available for the treatment of CPPS. Because of limited published research, much of the data presented will not be explicitly for male CPPS, but will be extrapolated from other chronic pelvic pain studies where neuromodulation has been used. Although several types of neuromodulation techniques are currently available for chronic pelvic pain conditions, none are considered standard therapies for treating CPPS. Despite the limited evidence, neuromodulation appears to provide benefits for some patients with CPPS. The improvement of urinary symptoms is more clearly defined than improvements in pain, but at least a subset of patients in most of the published studies and case series derive some benefit in the short term, and limited evidence suggests that long-term improvement of symptoms is possible. The debate about the pathophysiology of pelvic pain syndromes continues and the mechanism of action of neuromodulation on urinary and pain symptoms has yet to be defined. The fuller understanding of both will inform the evidence basis of using neuromodulation for male CPPS.

Keywords

Male chronic pelvic pain; neuromodulation; treatment

Introduction

Male chronic pelvic pain syndrome (CPPS)—historically known as chronic prostatitis—defines a syndrome of genitourinary pain and associated urinary dysfunction. Despite years of dedicated research, no biological etiologies have been identified to explain how pain symptoms are instigated and perpetuated. A number of mechanisms have been proposed, yet the intersection of pain and urinary dysfunction complicates its assessment. Because of this lack of etiologic definition, and perhaps because the syndrome encompasses a heterogeneous cohort of patients, clinicians remain at a loss for consistent and broadly effective evidence-based therapies. At this writing, treatments for male CPPS are largely empirical.

One therapeutic modality that is currently gaining recognition for the treatment of CPPS is neuromodulation. Neuromodulation has been used for the treatment of chronic pain for several decades¹ and has proven successful in achieving pain relief in a number of nonmalignant pain conditions, including migraine headaches, facial pain, back and limb pain, angina, and neuropathic pain.² Very little literature has been published that is specific

to the use of neuromodulation in male CPPS, although one of the first reports was published more than 25 years ago by Hellstrom and colleagues.³ Its application for the treatment of pelvic pain syndromes has been primarily described in the literature for interstitial cystitis or bladder pain syndrome (IC/BPS).

The objective of this review is to examine the theory and use of neuromodulation, and in particular, sacral nerve neuromodulation, for the treatment of CPPS. Much of the data presented will not be explicitly for male CPPS, for the reasons mentioned above. However, male CPPS and IC/BPS (a chronic pelvic pain condition seen primarily in women) share many clinical similarities, particularly the chronic nature of the pelvic pain and the associated urinary symptoms. In addition, because men and women have shared patterns of innervation for the pelvic organs, such as the bladder and urethra, it is conceivable that these conditions share common neuropathophysiological processes. Extrapolating results from studies of neuromodulation treatment for chronic pelvic pain conditions such as IC/BPS provides a rationale for the use of neuromodulation in male CPPS.

General concepts and applications of neuromodulation

Neuromodulation uses electricity to stimulate the nervous system to achieve a desired result, which for the purposes of this review, include ameliorating pain and urinary dysfunction. Although the ability to control electrical current arrived fairly late in the course of human history, the use of electrically stimulated local analgesia dates back millennia. In their historical review on electrical anesthesia, Kane and Taub described the use of electrogenic fish to produce numbness in ancient Egypt and Classical antiquity.⁴ For the treatment of pain, the efficacy of neuromodulation is based on the theory that by introducing exogenous electricity, the native electrical signals of the nervous system change and thereby alter the perception of pain. This altered *perception* of pain is crucial to understanding how this treatment works. In our current understanding, neuromodulation does not treat the inciting cause of pain, such as tissue inflammation or injury, but affects the neural circuitry mediating pain.

The electrical stimulus can be delivered to a peripheral nerve, a nerve root, the spinal cord, or the brain. The mode of delivery occurs either through a permanently implanted generator with electrodes attached to the target nervous tissue or via an external device that is applied to a body part on a temporary basis (e.g., percutaneous tibial nerve stimulation [PTNS]). The amplitude and frequency of the electrical impulses are set based on a number of variables, including tissue resistance, the distance between the stimulating electrode and the target tissue, the desired outcome, and the patient's threshold for discomfort from the electrical stimulation.

Neuromodulation of pelvic nerves

Understanding the effects of neuromodulation on pelvic nerves requires a basic understanding of the neurophysiology of the pelvis. The urogenital organs and the pelvic floor are innervated by a combination of somatic and autonomic nerves, the majority of which arise from the sacral spinal segments. The pudendal nerve and its branches mediate the somatic sensation and the skeletal motor function of the pelvis, and arise from sacral nerves S1–S4. The autonomic nerves are divided into parasympathetic and sympathetic fibers. The parasympathetic fibers also arise from S1–S4, yet the sympathetic fibers innervating the pelvis do not arise from the sacral segments, but from T10–L1.

The neurophysiology of the urogenital organs and pelvic floor can be explained in part as a series of reflexes. Afferent impulses from either the viscera or the somatic pudendal nerves travel to the sacral cord, then ascend through the spinal cord to the higher centers of the

central nervous system. From there, efferent messages are transmitted through the descending tracts, through the sacral cord and out to the peripheral endorgans. Neuromodulation may assert its pain-relieving effects at a number of points along these reflex pathways (a) by affecting the types of signals being transmitted via the afferent nerves (keeping in line with the Melzack and Wall “gate-theory” of pain⁵), (b) by altering the processing of afferent signals within the brain circuitry,⁶ or (c) by altering the efferent signals to the bladder or pelvic floor, which then mitigate the pelvic pain. Yet none of these hypotheses have been proven and other explanations may prove plausible.

The routine application of neuromodulation to pelvic nerves was initially used to treat urinary dysfunction through sacral nerve stimulation (SNS). First described by Schmidt⁷, electrical stimulation was applied at the sacral nerve root level and resulted in successful amelioration of medically refractory frequency, urgency, and urge incontinence⁸. Any benefits to pelvic or urologic pain reported from the early use of neuromodulation were considered distinct from urinary symptoms,⁹ but the use of neuromodulation specifically for pelvic pain did not gain momentum until after the widespread use of SNS.¹⁰

Techniques

Neuromodulation techniques used for chronic pelvic pain conditions include SNS, PTNS and pudendal nerve stimulation (Table 1). Only SNS and PTNS are currently approved by the US Food and Drug Administration for the treatment of urinary symptoms, and none of these methods are acknowledged as standard therapies for treating chronic pelvic pain syndromes. Transperineal electromagnetic stimulation, while not specifically a neuromodulation technique, is also presented, since its principles bear similarity to those of neuromodulation.

Sacral nerve stimulation

As noted previously, little research has been published about neuromodulation specific to the treatment of male CPPS. Yet, of the published works, SNS is the most common method for treating pelvic and urinary pain. One of the first case reports published by Hellstrom and colleagues in 1987³ cited the use of selective S3 nerve root stimulation with an implanted pulse generator. In this case report, the presumed mechanism of action was that the nerve root stimulation fatigued the external urinary sphincter (and other pelvic floor muscles), thereby relieving pain and voiding dysfunction caused by muscle spasm.³

In recent years, numerous reports have been published regarding the use of SNS to treat IC/BPS symptoms, most commonly using Interstim (Medtronic, Minneapolis, MN), although other techniques and devices have been studied.¹¹ The most common technique of sacral nerve root stimulation places a multipolar lead through a sacral foramen (e.g., S3) to stimulate the nerve root.

Alternatively, surgeons at some centers advance the lead through the sacral hiatus and align the electrodes adjacent to multiple sacral nerve roots¹². With each of these techniques, the efficacy of the stimulation is assessed over a trial period of days to weeks. If the stimulation is deemed to improve symptoms, an implantable pulse generator is attached to the lead, and the system is surgically implanted.

Most of the literature pertaining to sacral nerve root modulation presents case series. A number of studies, which include different types of chronic pelvic pain, have reported the results of short-term follow-up (i.e., <24 months). One short-term case series by Comiter¹³ prospectively evaluated 25 patients (mean age = 47 y) with refractory interstitial cystitis with a trial of SNS. A total of 17 patients showed 50% improvement in urinary symptoms (frequency, void volume, nocturia) and pain, qualifying them for permanent SNS

implantation. At 14 months after implantation, these patients showed continued improvements in daytime frequency and nocturia ($p < 0.01$), increased mean voided volume, ($p < 0.01$), and significant decreases in pain compared to baseline, from 5.8 to 1.6 points on a scale of 0 to 10 ($p < 0.01$). All but 1 of the 17 patients (94%) showed sustained improvement across all urinary and pain outcomes at 14 months. A smaller case series led by Siegal and colleagues¹⁰ evaluated SNS in 10 patients with chronic intractable pelvic pain. After 19 months, 9 patients (90%) reported decreased severity of their worst pain compared to baseline, that their daily time in pain decreased from 13.1 hours to 6.9 hours, and that their pain rating decreased compared to baseline from 9.7 to 4.4 on a 10-point scale. At 19 months, 6 patients (60%) cited that their pelvic pain symptoms substantially improved.

A few studies have reported longer-term follow-up (i.e., 3–6 years) of neuromodulation for chronic pelvic pain conditions. Everaert and colleagues followed 11 patients with treatment refractory pelvic pain, who passed a test stimulation and were implanted with a SNS device.¹⁴ With a mean follow up of 36 months, they reported 9 of the 11 were satisfied with the treatment, although the patient demographics and the metrics of satisfaction was not defined. A retrospective case-controlled review led by Marinkovic¹⁵ between 2002 and 2004, evaluated 30 women with IC (median age 41 y) who underwent SNS implantation. Significant decreases in pelvic pain were reported ($p < 0.01$) as were scores for urgency and frequency ($p < 0.01$) at the last follow-up point (minimum 72 months, mean 84 months). Thus, SNS demonstrated sustained improvement in the symptoms of refractory IC, including pelvic pain.

In addition, Gajewski and Al-Zahrani reported on a larger case series of 78 patients with bladder pain syndrome, 46 of whom underwent permanent sacral neuromodulation implantation.¹⁶ Success was defined as at least a 50% improvement on a Global Response Assessment scale, both during the testing period and after implantation. With an average follow-up of 5 years, the success rate of the patients receiving the implants was 72%, and the overall success rate was 43%. Powell and Kreder reported on 22 out of 39 patients with IC/BPS who went from test stimulation to permanent generator implantation.¹⁷ With a mean follow-up of 5 years, 64% reported no pelvic pain or dysuria at the last follow-up, and overall success (defined as >50% improvement in the chief complaint of urinary pain, urgency/frequency, or urge incontinence) was 86%, or 49% of the original group of 39 patients. The device explantation rate was 50%, but some patients underwent repeat implantation with return of symptom improvement.

All of the studies cited have used unilateral SNS, which, while promising, shows variable results. Recognizing this limitation, Zabihi and colleagues studied the use of bilateral sacral electrodes and reported >50% pain improvement in 10 out of 23 patients with debilitating pelvic pain (IC/BPS and male CPPS) who had bilateral sacral electrodes implanted.¹² The choice of this procedure followed the hypotheses that pain signals are transmitted through multiple spinal levels, that unilateral S3 stimulation was unable to capture all the possible pain foci, and that bilateral stimulation allows for bilateral neuromodulation of multiple spinal levels.

The pattern of pain in CPPS seems to parallel many common, centralized, neuropathic, and sympathetically driven pain models, such as chronic regional pain syndrome or reflex sympathetic dystrophy.^{18,19} With that in mind, most patients treated with neuromodulation for pelvic pain have electrodes placed at spinal levels that do not include these fibers. Hunter and colleagues have described placing epidural electrodes at novel targets in the thoracic spine region that achieved good pelvic and genital pain relief²⁰. While neuromodulation at these spinal levels seems beyond the reach of the sacral fibers complicit in the transmission

of pain from the pelvis, the organization of the spinal cord and sympathetic fibers seems to allow for sustained pain relief.²⁰

Neuromodulation of sacral nerve roots has demonstrated efficacy in treating chronic pelvic pain syndromes, and the limited studies with long-term follow-up suggest that the efficacy can be sustained over time. However, a substantial group of eligible patients do not respond positively during the test period, and in some series, the failure/explantation rate of those who do undergo implantation ranges from 25%- 50%.^{15,16,17} Thus, this technique must still be carefully considered before surgical implantation and patients must be counseled about its limitations.

Percutaneous tibial nerve stimulation

Theoretically, stimulating peripheral nerves allows for the modulation of nerve fibers from multiple spinal levels since most peripheral nerves are derived from several spinal segments. The posterior tibial nerve is a branch of the sciatic nerve, which is derived from the L4, L5, S1, S2, and S3 spinal segments, and has been the target of neuromodulation for urinary symptoms (Urgent® PC, Uroplasty, Inc., Minnetonka, MN). PTNS has shown modest efficacy in the short term for the treatment of pelvic pain as well.^{21,22} The benefit of this technique is its ease of application, with tiny percutaneous needles placed just beneath the skin of the lower leg, along the path of the posterior tibial nerve. Electrical stimulation is applied for 30 minutes once a week for 12 weeks. In theory, this method will not directly modulate the visceral afferent (parasympathetic) fibers of the sacral cord, but the modulatory effect is believed to take place within the sacral cord or higher, obviating the need for direct visceral afferent stimulation. Although research on this method for male CPPS is sparse, Kabay and colleagues reported on a trial of 89 men with the diagnosis of medically refractory NIH Category IIIB CPPS who were randomly assigned to receive either PTNS or sham treatment.²³ The PTNS group reported significant improvements in urinary symptom and pain scores, yet follow-up after the 12-week treatment period was not reported. The noninvasive nature of this technique makes this form of neuromodulation attractive, even if success rates have not been broadly reported. Furthermore, the cost differential between PTNS and SNS is substantial—with the cost of SNS being 5 times that of PTNS²⁴—and needs to be considered in the treatment algorithm.

Pudendal nerve stimulation

Pudendal nerve stimulation can be achieved using chronic or intermittent techniques. The pudendal nerve receives fibers from the sacral nerve roots, and thus peripheral stimulation of the nerve may prove more beneficial than transforaminal S3 neuromodulation because of the increased number of spinal segments exposed to neuromodulatory stimulation. Peters and colleagues described chronic pudendal nerve stimulation by implanting the standard SNS quadripolar tined lead adjacent to the pudendal nerve in the region of Alcock's canal.²⁵ In a prospective, single-blinded, randomized, crossover trial, 22 patients received both a transforaminal sacral (S3) lead and the pudendal lead to test independently. In 17 patients who responded to the SNS trial, pudendal stimulation gave an overall 59% improvement in symptoms, whereas SNS resulted in only 44% improvement overall. At the 6-month follow-up, a 10-cm visual analog scale for pain rating decreased by 49% with SNS and only 29% for pudendal nerve stimulation, but voiding symptom improvement was more pronounced in the pudendal nerve stimulation group. Considering the small numbers of patients, it is difficult to conclude that pudendal nerve stimulation has an advantage over transforaminal sacral nerve root stimulation, but its rationale for use remains valid.

Transperineal electromagnetic stimulation

The final form of neuromodulation used for pelvic pain occurs through the electromagnetic stimulation of the pelvic nerves and muscles. The rationale here is that applying a rapidly changing electromagnetic field noninvasively to the perineum of a patient with CPPS may result in neural excitation and muscle stimulation in the pelvic floor to a degree that breaks the cycle of tonic muscular spasm and neural hypersensitivity and inflammation, thereby restoring more normal pelvic floor muscular activity. Only one study has examined this methodology, yet it showed promising results.²⁶ A total of 21 men with CPPS, with a mean age of 47.8 years (range 25 to 67) were randomly assigned to receive to active electromagnetic stimulation of the pelvic floor using the Neotonus™ (Neotonus, Inc, Marietta, GA) electromagnetic chair vs. sham stimulation. At 3 months and 1 year, mean symptom scores decreased significantly in the actively treated group ($p < 0.05$), unlike the sham group, which showed no significant change. The subanalysis of those receiving active treatment showed that the greatest improvement occurred in pain-related symptoms.

Limitations of review/caveats

As stated earlier, many of the studies in this review are not specific to male CPPS. However, given that central nervous system derangement is likely present in all forms of chronic pelvic pain, regardless of the perceived organ of origin, the results of studies using neuromodulation techniques for chronic pelvic pain should not limit the extrapolation of their results to male CPPS. However, other caveats must be kept in mind when reviewing the literature on neuromodulation.

- *Measurements of success are highly variable.* The types of instruments, measurements of successful outcome, and degree of improvement deemed to be successful differ between studies, and so direct comparisons cannot be easily made.
- *Limited follow-up.* Most studies are small retrospective studies with short follow-up (e.g., 2 years or less).
- *Cohort heterogeneity.* Patients with chronic pelvic pain are a heterogeneous group. In the broadest sense, many studies have been conducted with women, and while many urinary mechanisms are similar between men and women, sex differences need to be taken into account. At a more granular level, larger cohorts of patients and more randomized trials will afford a broader patient pool to examine phenotypic distinctions in treatment response. Phenotyping studies are underway to examine subgroups.
- *Treatment-refractory patient population.* To date, the published studies on neuromodulation include only patients with pelvic pain that have had a number of therapies fail, most of them qualified as having severe, longstanding pain. The efficacy of neuromodulation in treatment-naïve patients with pelvic pain is unknown.
- *Undefined outcomes: urinary symptoms, pain symptoms, or both?* In CPPS, pain is often associated with other genitourinary symptoms (e.g., urinary frequency and urgency), so the question remains whether the overall efficacy of neuromodulation relates to pain relief or urinary symptom relief. Urgency and frequency are noxious sensations and so is pain. Teasing out the subtleties and the overlap of pain and urinary symptoms as they relate to efficacy of any neuromodulatory methodology is not clear cut. Defining which outcomes are measured and reported across studies will aid in clarifying these results.

Conclusion

Neuromodulation appears to provide benefits for patients with CPPS. The improvement of urinary symptoms is more clearly defined than improvements in pain, but at least a subset of patients in most of the published studies and case series derive some benefit in the short term, and limited evidence suggests that long-term improvement of symptoms is possible. However, explantation rates are high in all long-term series of patients receiving implantable neuromodulation devices. Because we are still becoming familiar with the pathophysiology of the pain syndromes and the mechanism of neuromodulation on urinary and pain symptoms, at this writing, we cannot yet predict a particular individual's response to neuromodulation. To determine the long-term efficacy of this therapy, more clinical study is needed to explore the use of neuromodulation in the treatment of male CPPS.

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Table 1
Neuromodulation techniques

Method delivery	Point of nerve stimulation	Type of electrode/stimulus
Sacral nerve stimulation	S3 nerve root	implanted electrode, constant stimulation
Percutaneous tibial nerve electrode, stimulation	peripheral nerve at ankle	percutaneous intermittent
Pudendal nerve stimulation	peripheral nerve at ischial spine	implanted electrode, constant stimulation
Transperineal electromagnetic stimulation * chair	peripheral nerve at perineum	no electrode, energy generated from

* Technically not considered neuromodulation, but shares basic principles