

# Expanding the Use of Sacroneuromodulation

## Case Presentation

A male in his seventies with a history of Parkinson's disease was referred with urinary frequency urgency and urgency urinary incontinence. He had a history of chronic pelvic pain syndrome that an outside urologist had followed, but over the last few years, he had been relatively pain-free. More recently, he had noted an increase in the frequency of urination, but urodynamics ruled out bladder outlet obstruction. In addition to the increased frequency, he endorsed more urgency and episodes of urgency incontinence. He experienced a slight improvement on daily mirabegron 50 mg, solifenacin 10 mg, and tamsulosin 0.4 mg. However, he was still voiding hourly and having 3 to 4 nocturia episodes. He is also bothered by his daily urgency and frequent urinary incontinence.

The patient's Parkinson's disease, diagnosed in 2007, had been stable, with no change in motor symptoms for the last 2 years. He was on stable Parkinson's medication. He had developed hypotension, which was treated for a short time with midodrine, but the treatment was discontinued because he experienced more urinary symptoms and hesitancy of urination with it.

## Medications

- Carbidopa/levodopa 25/250 mg 1 tablet 4 times per day
- Entacapone 200 mg 1 tablet 4 times per day
- Primidone 50 mg daily
- Desvenlafaxine succinate 25 mg daily
- Ropinirole 2 mg daily
- Amantadine HCl 100 mg daily
- Melatonin 10 mg QHS
- Mirtazapine 30 mg daily
- Tamsulosin 0.4 mg daily
- Solifenacin 10 mg daily
- Mirabegron 50 mg daily

## Physical Examination

The patient was a well-appearing male in his seventies. He ambulated with a shuffled gate and had masked facial features.

- GU exam: circumcised phallus, bilateral descended testicles.
- Digital rectal exam: normal rectal tone, no hard stool in the rectal vault, prostate smooth, small, and benign.

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## Evaluation

- Urinalysis: negative.
- Post-void residual (PVR): 16 mL.

The patient's voiding diary showed frequency, small-volume voids, urgency, and daily urgency incontinence (see Figure 1).

Prior urodynamic testing (by outside urologist) showed no evidence of bladder outlet obstruction.

Time circle wake-up and bedtime	Fluid Intake Ounces/mls of liquid you drank	Volume of Urine Ounces/mls in urinary hat each time you urinate	Incontinence 1 = drops/damp 2 = wet/soaked pad 3 = bladder emptied	Urge/Stress Write "Urge" if strong urge, "Stress" if with activity
DAY 2				
6 am		20 ml		
7:30 am	8oz	10 ml		
8:30 am				
9:30 am	4oz			
9:45 am		10 ml		Urge
10:15 am		10 ml		Urge
11:30 am		10 ml		Urge
12:45 pm	2oz	15 ml		Urge
2 pm		10 ml	2	Urge
3:30 pm	8oz			
5 pm		20 ml		Urge
7:15 pm		20 ml		Urge
9 pm		15 ml		
1:30 am		15 ml		
3 am		15 ml		
4:30 am		15 ml		

**Figure 1.** A page from the patient's baseline bladder diary. Despite fluid restriction, he indicated significant urgency and frequent small-volume voids. He also noted an urgency incontinence episode on this day.

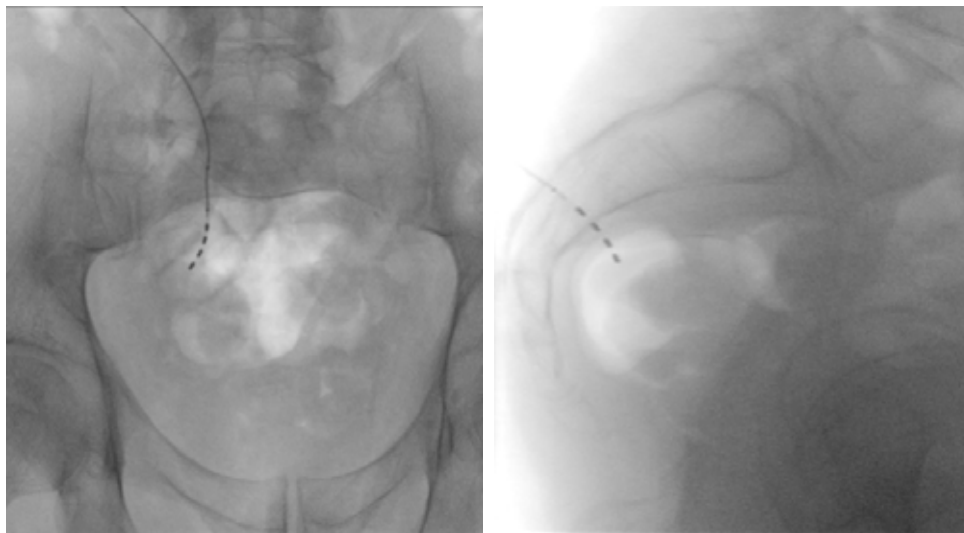
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### Management

The patient's treatment goals were assessed, and he was counseled about the treatment options for his refractory overactive bladder (OAB) symptoms. We reviewed chemodenervation with onabotulinum toxin A, tibial nerve stimulation, and sacral neuromodulation (SNM). He elected to move forward with a peripheral nerve evaluation (PNE), a test of neuromodulation, to better understand whether an implant would be appropriate for his refractory OAB.

Using local anesthesia and fluoroscopic imaging, we placed bilateral temporary PNE in the patient in the office setting. After the procedure, the patient continued to log his urinary symptoms over the next 4 days and noted the most profound improvement in his degree of urgency, which decreased from 4 to 5 out of 5 to 0 out of 5. He described feeling the need to void but felt he could suppress the urgency. The diary also showed an improvement in the patient's daytime urinary frequency, which decreased from 12 to 13 voids a day to 7 voids a day. These measures represented a greater than 50% improvement, thus reaching our threshold for moving forward with an SNM device. The temporary leads were removed in the office and the patient was scheduled for the procedure under IV sedation.

A few weeks later, the patient had an MRI-compatible device implanted, and intraoperative testing confirmed appropriate motor responses on all 4 electrodes, all under 2 amperes, indicating a successful lead placement (see Figure 2).



**Figure 2.** Intraoperative x-rays from a successful lead placement, showing S3 lead placement in the AP and lateral projections. The quadripolar electrode is MRI-compatible and was attached to a non-rechargeable prolonged battery life impulse generator (IPG) in a subcutaneous tissue in the patient's right upper buttock.

The patient returned for a wound check without any concerns. He is currently able to go 3 to 4 hours without voiding and his nocturia has decreased to once, and at most twice, a night. He is satisfied that he is not having any leakage episodes. Overall, he is thrilled with the improvement in his LUTS and feels very hopeful, very much in contrast to his despair prior to the implant, because his symptoms were causing so much disruption of his life.

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### Comments

SNM is a well-established third-line therapy for refractory OAB.<sup>1</sup> The original studies used to obtain FDA approval of SNM excluded patients with neurogenic bladder, so the approval was more limited, reflecting the lack of data in this population. Since approval, trials that have focused on SNM in the neurogenic patient population have been nonrandomized studies that enroll heterogeneous populations (perhaps reflecting the diverse nature of neurological conditions that affect the urinary system).<sup>2</sup> Further, these studies usually have not included descriptions or measures of the underlying neurological disease severity, limiting generalizability of the results. In addition to the complexity of the neurogenic populations, the original SNM devices lacked MRI compatibility, which further limited the use of SNM for neurogenic patients, especially those that might require future imaging.<sup>2</sup> However, more recently, SNM technology has been updated and newer devices may allow for full-body MRI compatibility. In addition, longer battery life has reduced the need to revise the device. These developments have likely contributed to the increased interest in SNM for the appropriately selected patient with a neurological condition and OAB symptoms.<sup>3</sup>

Parkinson's disease can have both storage and emptying symptoms, but, interestingly, when patients complained of OAB symptoms, we found that urodynamics almost universally (97.1%) demonstrated detrusor overactivity.<sup>4</sup> About a third of patients had concomitant bladder outlet obstruction, and about half the patients had detrusor underactivity. These findings are similar to those in the case presented here: a patient with complete bladder emptying and without any bladder outlet obstruction. Given the stability of his Parkinson's disease, his good functional status, the lack of bladder outlet obstruction, and complete bladder emptying, he was a good candidate for third-line therapies for OAB.

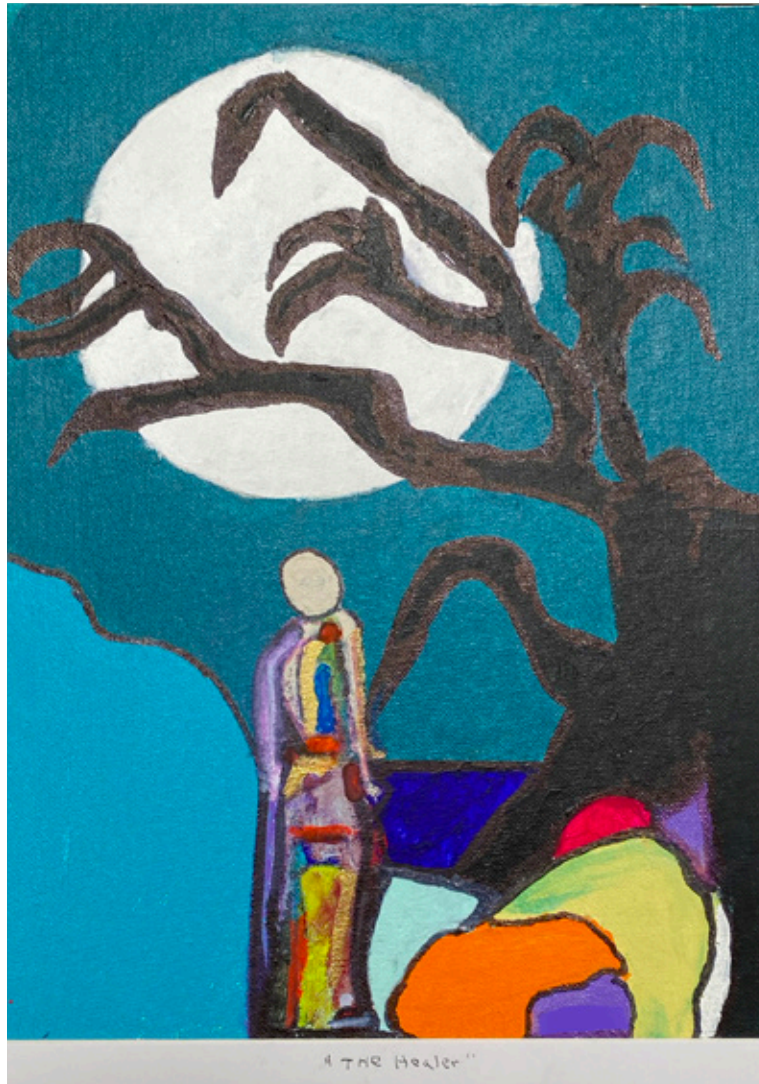
A treatment for refractory OAB that does have specific FDA approval for neurogenic patients is intradetrusor onabotulinum toxin A (200 U). However, it should be noted that the registration trials that led to the approval of this game-changing therapy (in many neurological populations) did not include patients with Parkinson's disease. Rather, the studies focused on patients with multiple sclerosis and spinal cord injury. Clinicians have used this treatment for patients with refractory OAB and Parkinson's disease, although the data are not as robust in this population.<sup>5</sup>

In our institution's treatment of patients with Parkinson's disease and refractory OAB with 100 U of intradetrusor onabotulinum toxin A, nearly 80% of patients had a subjective improvement in their OAB symptoms and about 30% had complete resolution of their urgency incontinence episodes. We did find that PVR increased significantly after the first injection, from 17.6 mL to 125.3 mL ( $p < .001$ ), with 12.5% of patients having to start clean intermittent catheterization (CIC) after the first injection. Higher pre-injection PVR was significantly associated with both a lower chance of symptomatic improvement and a higher risk of incomplete bladder emptying and institution of CIC.

Ultimately, there are many factors involved in the decision to progress to a third-line therapy, as well as in deciding which third-line therapy to use. This process is more difficult in some clinical scenarios, particularly when there are fewer data available. As clinicians, we rely on data to help in the shared decision-making. In this case, we examined our onabotulinum toxin A data in relation to similar single-institution data from a purely Parkinson's population with refractory OAB symptoms in which 82% of patients had successful implants.<sup>6</sup>

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In their article, and in their literature review, the authors did not identify any Parkinson's-related or urodynamic parameters that might predict successful implantation.<sup>6</sup> Finally, we don't fully understand the influence of physician and patient preferences on these important decisions. In the current scenario, the patient was inclined to pursue SNM based on the workup and the clinical evidence. I considered this a reasonable selection. Both the patient and I are impressed with the positive impact the SNM has had on his quality of life (see Figure 3).



**Figure 3.** This is a photograph of the patient's painting titled "The Healer." After retiring from the field of healthcare, he began pursuing art and painting as a form of expression and a means of therapy for managing his chronic condition. He noted that this painting depicts the hope he felt after the successful implantation. The dark tree represents chronic disease trying to block out the warm moonlight, and the colorful healer represents hope and healthcare providers' ability to provide treatment of his condition and free him from having to face otherwise overwhelming circumstances. (Reprinted with permission.)

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## Conclusion

The treatment of LUTS in patients with Parkinson's disease remains a challenge. Thankfully, advances in SNM have lowered the bar of entry, and preliminary data look promising. Therefore, we have a new treatment to offer this patient population.

Appropriate patient selection is critical, and indiscriminate testing and implantation should be avoided. We need to advocate for adequate insurance coverage and perhaps for funding for studies that could lead to regulatory approval of this therapy in the neurogenic patient population. Ideally, we will continue to hone our expertise, techniques, and technology and we will continue to improve our understanding of who may be the ideal candidates for the therapies we have available to treat urinary symptoms that have a huge negative impact on our patients' quality of life.

## References

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