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Outcomes of Sacral Neuromodulation and Intradetrusor Onabotulinum Toxin in the Management of Stroke Associated Urinary Incontinence

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Purpose: Urgency urinary incontinence (UUI) is a common finding in patients with a history of stroke or cerebrovascular accident (CVA). UUI is associated with impaired quality of life as well as increased morbidity, mortality, and need for institutionalization. Medical therapy is often limited by side effects and/or cost prohibitiveness. As a result, third-line therapy is often implemented. The objective is to determine the efficacy of sacral neuromodulation (SNM) and onabotulinum toxin (BTX) in the management of post-CVA UUI.

Methods: Retrospective analysis was performed to identify patients with post-CVA UUI who underwent SNM or BTX at a large academic medical center. The primary outcome was patient symptom response to third-line therapy. Treatment response was determined using the global response assessment scale. Patients reporting >50% improvement were categorized as having significant response. Secondary endpoints were proportion of patients achieving total dry and duration of therapy for those achieving significant response.

Results: One hundred seventy-seven patients were identified (95 BTX, 82 SNM). Patients in the BTX group were older (71.9 years vs. 67.4 years, P=0.02) with otherwise similar demographics. Rate of symptom improvement to >50% of baseline was similar between the groups (66% of BTX, 61% of SNM, P=0.46) as was rate of patients experiencing total dryness (24% of BTX, 16% of SNM, P=0.17). Among patients achieving significant improvement there was no difference in continuation of therapy between the BTX and SNM groups. Younger age was identified as a predictor of >50% symptom improvement (odds ratio, 0.96; P=0.04) and treatment discontinuation (hazard ratio, 0.97; P=0.04) in SNM. Most common adverse events were urinary tract infection in BTX (11%) and pain in SNM (4%).

Conclusions: BTX and SNM show roughly equal efficacy in the management of post-CVA UUI with nearly two-thirds of patients achieving significant benefit.

Keywords: Urge incontinence; Overactive bladder; Stroke; Neurogenic bladder

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INTRODUCTION

Stroke, or cerebrovascular accident (CVA), is an increasingly common condition within the adult population of the United States with a current prevalence of around 3% [1]. Patients experiencing a CVA may have short and long-term effects on multiple systems depending on the level and location of the CVA. Of particular interest to the urologist and urogynecologist are the symptoms of voiding dysfunction that can result. Initially, following CVA the most common urinary symptom is urinary retention [2]. This is typically self-limited, with the majority of patients experiencing resolution within 2 months [3]. In the longer-term, urgency urinary incontinence (UUI) is a common urologic manifestation of CVA which has been identified as a predictor of mortality, morbidity, and institutionalization in these patients [4]. Overall, the rate of UUI reported in the literature is wide ranging from between 37% and 79% [5].

UUI in this population is believed to be associated with detrusor overactivity (DO) as this represents the most common urodynamic abnormality when testing is performed [6]. Despite post-CVA UUI being a relatively commonly encountered entity, little literature exists regarding its treatment. As a result, patients are typically treated in concordance with guidelines aimed at nonneurogenic (idiopathic) overactive bladder (OAB) syndrome. Medication therapy in this population includes both anticholinergics and beta-3 agonists. Anti-cholinergic use has to be approached cautiously in this group given the association with negative cognitive effects [7]. Beta-3 agonists have demonstrated decreased incontinence episodes in this population in a small study [8], but these medications remain costly and insurance coverage remains a limitation. As a result, third-line therapy such as sacral neuromodulation (SNM), intradetrusor botulinum toxin (BTX), and peripheral tibial nerve stimulation (PTNS) represent reasonable treatment options in this population. PTNS failed to demonstrate a difference in continence among these patients [9, 10], while studies regarding BTX and SNM are lacking. The objective of this study is to evaluate the efficacy of BTX and SNM for management of UUI in post-CVA patients.

MATERIALS AND METHODS

Retrospective analysis was performed to identify patients with UUI following CVA who underwent third-line therapy with SNM or BTX between January 2016 and December 2022 at a large academic medical center. Current Procedural Terminology codes were used to query the electronic medical record. Stroke/CVA was defined as cerebral ischemia only. All patients were evaluated and treated by urologists with subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery. The diagnosis of UUI was made clinically with history and physical exam. Postvoid residual measurements and urinalysis are utilized in all patients to rule out other contributing etiologies to symptoms. Urodynamic studies are not routinely utilized when the diagnosis can be appropriately made clinically. Patient demographics and comorbidities were recorded including co-existing neurological conditions. Patients were divided into 2 groups: one treated with SNM and one treated with BTX. Details regarding implementation of the therapies have been previously described [11]. Prior to implementation of third-line therapies patients in our practice routinely are prescribed behavioral modification and medication prior to advancing to third-line therapy. Patients who either continue to have bothersome symptoms despite first and second-line therapy and/or have adverse effects limiting first and second-line therapy are counseled on third-line therapies as an option. The decision for which third-line therapy to pursue is made through a shared decision-making approach between the treating clinician and the patient. All clinicians involved in this study routinely perform all third-line therapy options.

The primary outcome was response rate to third-line therapy. Symptoms were compared before and after therapy and improvement was defined by the global response assessment (GRA) scale. Treatment response was defined as 0% (no improvement), 1%–50% (mild improvement), 51%–75% (moderate improvement), and >75% (marked improvement). A significant response was defined as an improvement of more than 50%. Secondary endpoints included the proportion of patients achieving complete dryness and the duration of therapy for those with a significant response. Patient assessments were performed at time of most recent follow-up or at time of treatment discontinuation.

Student t-test was used for numerical variables, while chi-square test or Fisher exact test was used for categorical data. The generalized linear regression model evaluated risk factors for significant responses. A Kaplan-Meier curve with a log-rank test estimated the duration of treatments. Cox proportional hazard model analyzed risk factors for the discontinuation of treatments. Statistical tests were performed with R 4.2.2 (R Core Team, 2021). All statistics were two-tailed, with P-value <0.05 considered significant.

Table 1. Demonstrates baseline patient characteristics

Characteristic	SNM (n = 82)	BTX (n = 95)	P-value
Age (yr)	67.4 ± 13.8	71.9 ± 12.8	0.02*
Female sex	70 (85.4)	81 (85.3)	1.00
Diabetes	36 (43.9)	44 (46.3)	0.86
Hypertension	75 (91.5)	87 (91.6)	1.00
Coronary heart disease	40 (48.8)	44 (46.3)	0.85
Chronic kidney disease	30 (36.6)	47 (49.5)	0.12
Dementia	14 (17.1)	24 (25.3)	0.25
Parkinson's disease	4 (4.9)	10 (10.5)	0.26
Traumatic brain injury	6 (7.3)	12 (12.6)	0.32
Spinal cord injury	1 (1.2)	3 (3.2)	0.63
Multiple sclerosis	30 (36.6)	25 (26.3)	0.19
Fecal incontinence	20 (24.4)	17 (17.9)	0.36
SUI	30 (36.6)	25 (26.3)	0.19

Values are presented as mean ± standard deviation or number (%).
SNM, sacral neuromodulation; BTX, onabotulinum toxin; SUI, stress urinary incontinence.
*P < 0.05, statistically significant differences.

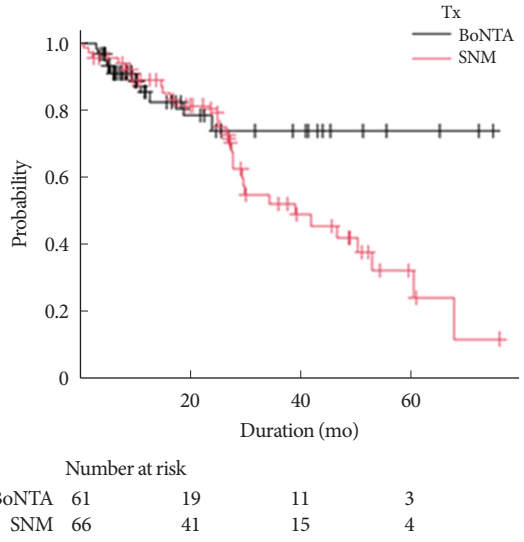

Fig. 1. The Kaplan-Meier curve illustrates the probability of adherence to treatment over time among patients undergoing full sacral neuromodulation (SNM) implant or one or more onabotulinum toxin injections. Each step in the curve represents the percentage of patients remaining adherent to treatment at specified time intervals (months). Tx, treatment; BoNTA, botulinum toxin.

RESULTS

We identified 177 patients with UUI following CVA who subsequently underwent third-line therapy (95 received BTX, and 82 received SNM). Baseline demographic data is represented in Table 1. Patients in the BTX group were older (71.9 years vs. 67.4 years, P = 0.02). The groups were similar with regard to concomitant neurologic diseases including Parkinson disease, traumatic brain or spinal cord injury, and multiple sclerosis. Prevalence of medical comorbidities was also similar between the groups as was the rate of preexisting stress urinary incontinence and fecal incontinence. BTX dose utilized was 100 units in 83 patients (83%) and 200 units in 17 patients (17%). Bladder management prior to therapy initiation included a volitional voiding rate of 87.3% in the BTX group and 89.4% in the SNM group. The remaining patients were managed with clean intermittent catheterization (3.2% in BTX group, 8.5% in SNM group) or indwelling catheter (9.5% in BTX group, 2.4% in SNM group) (P = 0.73).

The rate of symptom improvement to > 50% of baseline was similar between the groups, with 63 patients (66%) in the BTX group and 50 patients (61%) in the SNM group achieving this (P = 0.46). Further analysis revealed that 28 (29%) BTX patients and 23 (28%) SNM patients achieved subjective improvement of > 75%. There was no difference between the groups with regard to the rate of patients experiencing total dryness (24% of BTX, 16% of SNM, P = 0.17).

Among patients achieving significant improvement there was no difference in continuation of therapy between the BTX and SNM groups (Fig. 1). Younger age was identified as a predictor of significant response (OR, 0.96; P = 0.04) (Table 2) and treatment discontinuation (HR, 0.97; P = 0.04) in SNM (Table 3). No factors were identified as predictors of treatment discontinuation among the BTX patients (Table 4).

Most common adverse events were urinary tract infection in BTX (10 patients, 11%) and pain in SNM (3 patients, 4%). Within the BTX cohort, 7 patients (7%) experienced acute urinary retention, and 4 patients (4%) had hematuria which prompted evaluation, although, none required surgical intervention. Among the SNM group 1 patient (1%) experienced device implant site infection requiring explant and an additional 1 patient (1%) underwent explant for pelvic pain attributed to the device.

DISCUSSION

Our study demonstrates that both BTX and SNM are effective

Table 2. Evaluates factors associated with achieving significant response (>50% improvement)

Variable	SNM			BTX		
	OR	95% CI	P-value	OR	95% CI	P-value
Age (yr)	0.96	0.92–1.00	0.04*	1.02	0.99–1.05	0.28
Male sex	1.33	0.37–4.85	0.66	0.63	0.20–2.00	0.43
Diabetes	1.01	0.41–2.47	0.98	0.80	0.34–1.88	0.61
Coronary heart disease	0.92	0.38–2.24	0.86	0.66	0.28–1.56	0.34
Chronic kidney disease	0.75	0.30–1.88	0.54	0.45	0.19–1.08	0.07
Dementia	1.19	0.36–3.92	0.78	1.32	0.48–3.61	0.59
Multiple sclerosis	2.70	0.29–25.30	0.39	0.66	0.14–3.12	0.60
Fecal incontinence	1.69	0.57–4.97	0.34	1.82	0.54–6.12	0.33
SUI	1.47	0.57–3.75	0.42	0.87	0.33–2.27	0.78

SNM, sacral neuromodulation; BTX, onabotulinum toxin; CI, confidence interval; SUI, stress urinary incontinence.
*P < 0.05, statistically significant differences.

Table 3. Evaluation factors associated with treatment discontinuation in the SNM (with IPG implant, n = 66) group

Variable	HR	95% CI
Age	0.97	0.94–1.00
Sex	1.91	0.72–5.07
Diabetes	1.13	0.54–2.35
Coronary heart disease	1.05	0.51–2.17
Chronic kidney disease	1.30	0.62–2.71
Dementia	1.10	0.44–2.70
Multiple sclerosis	1.22	0.28–5.25
Fecal incontinence	0.38	0.14–1.02
SUI	1.16	0.54–2.47

SNM, sacral neuromodulation; IPG, implantable pulse generator; HR, hazard ratio; CI, confidence interval; SUI, stress urinary incontinence.

Table 4. Evaluation factors associated with treatment discontinuation in the BTX (>1 injections, n = 62) group

Variable	HR	95% CI
Age	1.01	0.96–1.05
Sex	0.49	0.06–3.89
Diabetes	0.86	0.24–3.05
Coronary heart disease	0.99	0.28–3.51
Chronic kidney disease	1.82	0.51–6.49
Dementia	1.82	0.47–7.07
Multiple sclerosis	1.01	0.13–7.98
Fecal incontinence	1.26	0.32–4.89
SUI	2.59	0.73–9.23

BTX, onabotulinum toxin; HR, hazard ratio; CI, confidence interval; SUI, stress urinary incontinence.

in managing post-CVA UUI, with nearly two-thirds of patients in each cohort experiencing >50% subjective improvement. The patient groups were overall similar, except for age, with SNM being younger. The only predictor of success (>50% improvement) identified occurred in the SNM group and was younger age. The clinical significance of this finding is likely minimal given the odds ratio being close to 1 (0.96); furthermore, the efficacy of SNM has previously been found to be independent of age in nonneurogenic OAB and nonobstructive urinary retention patients [12]. Maintenance of therapy was similar between groups among patients who achieved >50% improvement over a follow-up period just beyond 6 years. While a trend towards higher maintenance in the BTX group was observed over time, statistical significance was not achieved suggesting comparable efficacy between the therapies. We defined duration of therapy based on the patient's most recent follow-up which may explain the divergence noted in Fig. 1. Given the nature of BTX therapy requiring regular injection these patients are more likely to maintain consistent follow-up compared to those who receive SNM, even when therapy is proving beneficial.

SNM has well documented success in cases of idiopathic OAB/UUI [13]. However, there is limited data with regard to neurogenic cases. A prospective study by Peters et al. [14] concluded that clinical benefits of SNM in neurogenic OAB/UUI are similar to those observed in idiopathic patients. Likewise, a

meta-analysis in 2020 highlighted long-term benefit in 55% of patients with neurogenic bladder collectively [15]. More recently Liechti et al. [16] published prospective data analyzing SNM benefit in neurogenic patients. In their study patients were randomized to either continued therapy or discontinued therapy after a successful trial period. Overall, 52% of patients had a successful trial phase with short-term sustained success of 76% for the continued therapy group compared to 42% in the discontinued therapy group. These results are in line with the success rate reported in the 2020 meta-analysis. Despite increasing evidence for neurogenic dysfunction as a whole, evidence for specific neurogenic subtypes remains sparse. For example, the study of Peters et al. [14] included only 17 patients with a history of CVA while the study of Liechti et al. [16] included 7 CVA patients.

BTX also has well documented success in management of idiopathic OAB/UUI [13]. With regard to neurogenic dysfunction, a prospective study reported success rates ranging from 86.6% to 94.1% over 4 years [17]. Within this cohort, patients were treated with either 200 or 300 units BTX for symptom control. Notably, our cohort predominantly received 100 units of BTX, reflecting current practice patterns. Despite these successes, evidence guiding BTX management in specific neurogenic populations, particularly post-CVA patients, remains limited. With regard to post-CVA patients, the utility of BTX is limited by small studies evaluating this population. Early studies suggest varied success rates and potential complications like urinary retention [18, 19]. A recent review underscored the need for more robust evidence in this population [9] reiterating a Cochrane Review from 2019 [10]. To our knowledge, this study represents the largest patient reported patient cohort both for SNM and BTX in regard to post-CVA UUI.

As mentioned above, a high rate of urinary retention was reported when utilizing 200 units of BTX in post-CVA patients [18]. While 200 units is the approved dose for neurogenic dysfunction, the majority of patients within our cohort (83%) were managed with 100 units. Given the lack of robust evidence guiding management in post-CVA UUI treatment strategies for are often extrapolated from management of idiopathic OAB. Within our practice, patients who volitionally void undergoing BTX are initiated at a dose of 100 units with subsequent dose escalation based on their response to therapy and assessment of postvoid residual. The ROSETTA trial utilized an initial dose 200 units for idiopathic patients with favorable results, however 20% of patients in their BTX group required catheterization during the follow-up period [13]. Based on these findings and evidence of increased urinary retention in CVA patients receiving 200 units [18], we prefer initiating volitional voiders at 100 units and escalating based on clinical response. In patients already utilizing intermittent catheterization being treated to reduce UUI in between catheterization, the authors would favor an initial dose of 200 units.

Utilizing OAB guidelines is rational given that the primary driver for UUI in CVA patients is DO, but there are inherent limitations to these strategies. First line therapies include lifestyle modifications such as timed voiding and pelvic floor muscle training. Timed voiding showed promise in this population in a prior small study by Gelber et al. [20]. Their study indicated that patients managed with scheduled voiding had fewer incontinence episodes at discharge than patients managed pharmacologically. However, this study's impact is limited by its sample size, with only 13 patients in scheduled voiding group and 6 in the pharmacologic group. Furthermore, their findings revealed that larger strokes with more resulting disability were associated with the development of UUI. This underscores the point that these patients are often at least to some degree functionally dependent on caregivers for assistance due to physical and cognitive effects of their stroke. As a result, they are often unable to reliably participate in pelvic floor exercises or timed voiding.

Medications are often utilized in these patients with both anticholinergic medications [12] and beta-3 receptor agonists demonstrating efficacy in reduction of incontinence episodes [8]. Anticholinergics have long been known to have cognitive side effects. More recently, a white paper published by Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) highlighted concerns regarding the long-term use of this medication class, linking it to an increased risk of dementia, especially among older patients [7]. As a result, the SUFU expert panel recommended consideration of earlier progression to advanced therapies as opposed to long-term medication use. It is reasonable to generalize this sentiment to post-CVA patients given the rate of coinciding cognitive deficits at baseline. Beta-3 receptor agonists offer a more benign side effect profile with minimal cognitive effects, however, there are often limitations in coverage of these medications and studies have shown increased out of pocket costs associated with this medication class [21].

A primary limitation of our study was the reliance on subjective patient or caregiver-reported outcomes rather than validated questionnaires and voiding diaries. While a limitation, we do

believe that focusing on patient reported outcomes allowed us to evaluate our outcomes in a clinically meaningful way. Patient satisfaction with therapy is a primary driver in therapy continuation given that UUI is a "quality-of-life" disease and in most situations, patients are able to reliably identify the effect of their therapy. Furthermore, the GRA has been previously shown to correlate well with objective parameters in patients undergoing SNM [22]. With regard to subjective patient reported outcomes, our data is consistent with that seen in the nonneurogenic OAB population. The ROSETTA trial identified a small difference in the mean UUI episodes per day between SNM and BTX favoring BTX, however when strictly looking at quality of life measures, there was no difference noted [13]. Additionally, our patients were not treated with a standardized protocol in terms of BTX dose utilized. In general, volitional voiders within our practice are started at a dose of 100 units but dose may be escalated based on clinical response as well as ability to adequately empty their bladder while on therapy. While a limitation, BTX dose was not found to be predictive of success within our cohort.

In conclusion, UUI following CVA is a commonly encountered condition with limited evidence to guide management. Our results indicate that roughly two-thirds of patients with post-CVA UUI will achieve clinically meaningful benefit when treated with either BTX or SNM. Patients achieving significant response were found to maintain reliable follow-up for both therapies.

AUTHOR CONTRIBUTION STATEMENT

· Conceptualization: *TT, OA, HBG, PMC*
· Data curation: *TT, MC*
· Formal analysis: *TT, OA, HBG, PMC*
· Methodology: *TT, HBG, PMC*
· Project administration: *OA, HBG*
· Writing - original draft: *TT, OA, HBG, PMC*
· Writing - review & editing: *TT, OA, HBG, PMC*

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