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Effectiveness and patient perspective on the use of intravesical gentamicin instillations to treat recurrent urinary tract infections in neurogenic lower urinary tract dysfunction

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Abstract

Introduction: Patients with neurogenic lower urinary tract dysfunction (NGLUTD) who require catheterization either with clean intermittent catheters (CIC) or indwelling catheters suffer with frequent urinary tract infections (UTIs). This study assessed the efficacy, patient persistence, satisfaction, and the impact on quality of life (QoL) of gentamicin nightly bladder instillations with 15 mg.

Methods: This is a prospective survey of 36 patients with NGLUTD and recurrent UTIs prescribed long-term gentamicin to prevent UTIs. Eligible patients completed a questionnaire about their use and satisfaction with gentamicin therapy, as well as survey questionnaires to address QoL. A retrospective chart review was also performed to obtain medical history, confirm drug persistence, and obtain accurate UTI data for the 12 months preceding and after starting instillations.

Results: The rate of laboratory proven symptomatic UTI requiring antibiotic treatment decreased from 3.9 to 1.1 infections per year with no increase in antibiotic resistance and no significant side effects reported by patients. Eight patients stopped therapy before a full year for various reasons, but the remaining 72% of patients have continued to use the therapy now with a mean of 4.2 years later. Satisfaction among those continuing the medication was very high.

Conclusion: Gentamicin bladder instillations with 15 mg nightly in patients with indwelling catheters or CIC with NGLUTD are very effective and safe with high patient satisfaction. This therapy can be maintained long-term with continued efficacy.

KEYWORDS
antibiotics, neurogenic bladder, spinal cord injury, urinary tract infection

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1 | INTRODUCTION

People with neurogenic lower urinary tract dysfunction (NGLUTD) who require catheterization for bladder management often suffer with recurrent urinary tract infections (UTIs). These infections require antibiotic treatment and can cause multiple complications such as sepsis, incontinence, development of stones and have a significant impact on patient quality of life.[1] Unfortunately, there are limited options[2] that are effective for preventing these UTIs other than daily oral low-dose prophylaxis, which is only modestly effective[3] in patients who perform clean intermittent catheterization (CIC) and has no efficacy for patients with indwelling catheters. At our center, we offer intravesical instillation with a gentamicin solution performed nightly to this patient population. A previous retrospective review demonstrated a 75% reduction in the rate of UTI after starting gentamicin instillations compared to before this therapy.[4] The primary aim of this study was to assess the reduction in UTIs in patients with NGLUTD and recurrent UTI (≥3 per year) who were prescribed gentamicin bladder instillations performed nightly.

The rate of UTI was compared 12 months before and 12 months after initiating therapy. Secondary aims of this study included assessing patient satisfaction, bladder-related quality of life, and symptoms among patients utilizing gentamicin instillations, as well as assessing patient persistence with the treatment since the patient choice to continue long-term use of the therapy is a surrogate for the perceived benefit. Also, antibiotic resistance is a common concern with any antibiotic therapy, hence, we sought to assess if this treatment increased bacterial resistance.

2 | MATERIALS AND METHODS

Adult (>18 years old) patients in urinary retention with NGLUTD due to traumatic or nontraumatic spinal cord injury/disease (SCI/D). The latter includes nontraumatic conditions to cause spinal cord impairment, such as multiple sclerosis, spina bifida, and other neurological diseases, and who had been prescribed gentamicin bladder instillations for long-term prevention of UTIs and were eligible to be recruited for this study. All bladder management methods were acceptable, including CIC via urethra or catheterizable stoma, indwelling urethral or suprapubic tube, as well as patients with urostomy. To be included, patients had to have some form of urinary retention requiring catheter intervention. Those patients who solely performed catheterization to instill the medication but were otherwise voiding were not included. Patients utilizing gentamicin bladder instillations were identified from a query of Michigan Medicine patient records via DataDirect™ searching for any adult patient (>18 years old) who had received a prescription for more than a month of instillations, which would exclude those people who were only treated for an acute UTI. Patients were also identified when they requested a prescription refill from the urology clinic at Michigan Medicine. Patients included in Cox et al.[4] prior retrospective study of gentamicin efficacy were excluded. Similarly, patients included in our gentamicin clinical trial were excluded.[5]

Those eligible received up to three phone calls from a study coordinator inviting them to participate and consented electronically to participate in the study. Once consented, patients completed an interview consisting of questions about their demographic characteristics and impairment level, UTIs and bladder health, their satisfaction with gentamicin flushes, and to report any complications.

To assess the quality of life and symptoms, they answered the Neurogenic Bladder Symptom Score (NBSS),[6] the SCI-QOL: Bladder Complications SF scale, the SCI-QOL Bladder Management Difficulties SF scale,[7] and the PROMIS Global Health.[8] The NBSS is a tool to measure urinary symptoms and consequences in patients with acquired or congenital neurogenic bladder. The SCI-QOL is a patient-reported measure designed to assess quality of life after SCI/D, and the PROMIS Global Health is a 10-item questionnaire that evaluates the patient's physical, mental, and social aspects of health.

They also reported the start date, and if applicable, their end date of the gentamicin. For those who discontinued the use of gentamicin, they were asked to indicate the reasons.

Medical chart review was conducted to confirm the date of the original gentamicin prescription and if prescriptions were continued. Information such as catheter management plan, medical history, serum creatinine, comorbidities predisposing to immune suppression, presence of bladder or kidney stones on ultrasound or other imaging and neurologic history were extracted from the medical chart. Prior use of UTI prevention strategies such as daily oral prophylaxis with antibiotics or cranberry were queried from the medical record. All urinary tract procedures and reconstructions were collected, as well as current bladder management method with either oral medications or botulinum toxin injections.

UTI data were collected for 12 months before and 12 months after beginning the prescription. These infections were defined as a positive urine culture with greater than 100 000 colony-forming units accompanied

by patient symptoms consistent with an UTI that was assessed by a clinician and treatment with antibiotics. Patient self-reported UTIs data was also collected and analyzed separately. Data was collected on the UTI organism, multidrug resistance (defined as 3 or more classes of antibiotics resistance), and which antibiotic was prescribed, as well as if this infection required an emergency department visit, IV infusion, or hospitalization with complications. Any medical record of UTI that did not have complete infection data was not included in the primary analysis. For example, a patient simply being prescribed antibiotics was not considered an infection without a positive culture and symptom assessment. Patients were prescribed gentamicin in the clinical setting sometimes based on self-reported infections, hence, some patients will not have complete UTI data pre-gentamicin, and these were excluded from UTI analyses. Among the 36 participants, nine had started the gentamicin medication very long ago (>5 years) or had medical records that were not able to be fully accessed; these participants were excluded from the UTI analysis.

Descriptive statistics were provided using means, standard deviations, and ranges for continuous variables; frequencies and percentages were provided for categorical variables. Comparisons were made using Kruskal–Wallis and *t* tests for continuous variables and chi-square tests for categorical variables. An intention-to-treat analysis was utilized including those patients who discontinued treatment.

3 | RESULTS

Among the 39 patients contacted, 36 met the eligibility criteria and were consented for the study. The median age of the cohort was 60.5 years (51.5–69.0 IQR), 58% ($n = 21$) identified as male and 92% identified as White. SCI was the most common cause of NGLUTD in 69% of the cohort with multiple sclerosis comprising 11%, spina bifida 6% and other neurological conditions comprising 14% (Table 1).

For the bladder management method, 29 were managed with CIC (mean 6.1 times per day), 6 with an indwelling suprapubic tube, and 1 with a urostomy. The mean serum creatinine for the group was 0.6 mg/dL (range 0.3–1.2), and none had hydronephrosis. Upper tract imaging identified seven participants with current asymptomatic renal stones that were being observed and none required treatment and no patients had hydronephrosis. Medical bladder management for this population included oral anticholinergics in 45% of participants and beta 3 agonists in 16%. For procedural management, 71% of the group were receiving bladder botulinum toxin and 15% had a bladder augmentation in the past, while one participant had an urinary diversion. Prior treatment strategies employed to try to prevent urinary infections before starting gentamicin included daily oral antibiotics in 47%, oral methenamine in 26%, and cranberry supplementation in 36% of participants (Table 1).

There were 27 participants with complete infection-related data 12 months before and 12 months after starting gentamicin. Among these, there were 3.9 (1.94 SD) mean UTI ($n = 106$ UTIs) 12 months before and a mean of 1.1 UTIs (1.11 SD) ($n = 29$ UTIs) in the 12 months after starting gentamicin ($p < 0.001$). The most common organism both before and after the start of the medication was *E. coli*. See Table 2 for organism information and antibiotic resistance data. All bladder management methods had significant improvements in UTIs, with the CIC group decreasing from 4.14 to 1.14 UTIs in 12 months ($p < 0.0001$) and the suprapubic tube group decreased from 2.80 to 0.80 ($p = 0.04$). Patient self-reported UTI rate (with or without the laboratory criteria) among all participants was 4.6 UTI in the 12 months preceding and 0.86 UTI in the year following gentamicin instillation ($p < 0.0001$). All patients received their UTI care at our center once prescribed the gentamicin, with no patients lost to follow-up.

There was no difference in the presence of multidrug resistance among the 106 individual UTIs present before gentamicin (31.1% resistant) and the 29 UTIs (41.3% resistance, $p = 0.35$) present after the start of gentamicin (Table 2). Only one patient reported side effects from the gentamicin that the flushes caused mucus to clog their indwelling catheter. Before gentamicin, of the 106 UTIs, 17 required emergency department visit and 10 of them required hospitalization. After gentamicin among the 29 reported UTIs, 2 received care in the emergency department, and both were hospitalized, which was not significantly different before and after gentamicin ($p = 0.19$ and 0.64, respectively) (Table 2).

Among all patients, eight (22%) stopped using the gentamicin less than 12 months after starting. Three stopped because the instillations were inconvenient, one had resolution of his UTIs, hence discontinued, one patient stopped since they did not notice a decrease in UTIs, and three stopped for unknown reasons but did not report complications. Comparing those who continued with the gentamicin to those who stopped the drug, there was no difference in pre-gentamicin UTI counts or any other demographic or medical factors (Table 1). Among those 28 participants who continued the instillations when asked "How satisfied are you with your experience using Gentamicin?" 22/28 (78.6%) reported being "very satisfied," 5/28 (17.8%) were "somewhat

TABLE 1 Patient characteristics and bladder management among those stillutilizing gentanicin instillations and those who discontinued.

Characteristic	Overall ($n = 36$)	Not still using gent ($n = 8$)	Still using gent ($n = 28$)	p Value
Current age				0.32
Mean (SD)	58.5 (13.48)	54.6 (14.61)	59.6 (13.21)	
Median (IQR)	60.5 (51.5–69.0)	54.5 (44.0–65.0)	61.0 (54.5–70.0)	
Range	32.0–79.0	33.0–77.0	32.0–79.0	
Gender, *n* (%)				
Male	21 (58)	6 (75)	15 (54)	0.28
Race, *n* (%)				
White	33 (92)	7 (88)	26 (93)	0.55
Black	2 (6)	1 (13)	1 (4)	
Asian	1 (3)	0 (0)	1 (4)	
Employed, *n* (%)				
Yes, full-time	2 (6)	1 (13)	1 (4)	0.37
Yes, part-time	2 (6)	1 (13)	1 (4)	
No	32 (89)	6 (75)	26 (93)	
Marital status, *n* (%)				
Single (never married)	10 (28)	3 (38)	7 (25)	0.75
Married or significant other	17 (47)	4 (50)	13 (46)	
Divorced	7 (19)	1 (13)	6 (21)	
Widowed	2 (6)	0 (0)	2 (7)	
Spinal cord diagnosis, *n* (%)				
Traumatic spinal cord injury	25 (69)	6 (75)	19 (68)	0.26
Spina bifida	2 (6)	0 (0)	2 (7)	
Multiple sclerosis	4 (11)	1 (13)	3 (11)	
Transverse myelitis	1 (3)	1 (13)	0 (0)	
Other	4 (11)	0 (0)	4 (14)	
UTI prevention strategy before gent				
Cranberry	12(36)	3 (43)	9 (35)	0.69
D-mannose	2 (6)	1 (14)	1 (4)	0.29
Daily oral antibiotics	16 (47)	4 (57)	12 (44)	0.55
Methanamine hippurate	9 (22)	1 (14)	8 (30)	0.41
Bladder management, *n* (%)				
Currently using anticholinergics	15 (45)	3 (38)	12 (48)	0.60
Currently using beta three agonists	5 (16)	0 (0)	5 (20)	0.20
Currently using botulinum toxin of bladder	24 (71)	6 (75)	18 (69)	0.75
Currently using bladder augment	5 (15)	2 (25)	3 (12)	0.35

Abbreviation: UTI, urinary tract infection.

satisfied," and 1 patient was "neither satisfied nor dissatisfied" (Table 3). The mean duration of instillation usage was an average of 1527 days (4.2 years, 1071 days SD) with a range of 34–3686 days (10.0 years) and none of the patients who continued on the drug for 12 months stopped utilizing it at a later date. Many patients had narrative comments regarding positive experiences when using the gentamicin instillations (Figure 1).

TABLE 2 UTIs and their Treatments 12 months before gentamicin and 12 months after.

Characteristic	Pre-gent ($n = 106$ UTIs)	Post-gent ($n = 29$ UTIs)	p Value
E. coli	48 (45)	13 (45)	0.97
Proteus	3 (3)	1 (3)	0.86
Klebsiella	22 (21)	5 (17)	0.68
Staph aureus	1 (1)	0 (0)	0.60
Enteroccus	10 (9)	6 (21)	0.10
Pseudomonas	6 (6)	1 (3)	0.63
Enterobacter	6 (6)	1 (3)	0.63
Coagulase negative staph	2 (2)	0 (0)	0.46
Citrobacter	6 (6)	0 (0)	0.19
Organism = Other	14 (13)	4 (14)	0.93
Trimethoprim sulfamethoxazole	17 (16)	8 (28)	0.16
Antibiotics = Other	8 (8)	2 (7)	0.91
Cefalexin	17 (16)	7 (24)	0.31
Nitrofurantoin	20 (19)	5 (17)	0.84
Ciprofloxacin	16 (15)	1 (3)	0.09
Levaquin	3 (3)	0 (0)	0.36
Ampicillin	12 (11)	5 (17)	0.39
Fosfomycin	5 (5)	1 (3)	0.77
Antibiotics given via IV	10 (9)	2 (7)	0.67
Resistance to 3 or more antibiotic classes	33 (33)	12 (43)	0.35
ER treatment of UTI	17 (17)	2 (7)	0.19
Hospitalized for UTI	10 (10)	2 (7)	0.64

Abbreviation: UTI, urinary tract infection.

There were no differences in bladder symptoms as shown by NBSS scores across its three domains: incontinence, storage and voiding, consequences, and related quality of life between those who were still using gentamicin at the time of the interview and those who were not (Table 3). However, differences were noted ($p < 0.04$) with respect to quality of life in relation to bladder complications as measured by the SCI-QOL. Items reflect the impact of these complications in different aspects of one's life activities. In this respect, the group still using gentamicin scored slightly lower (42.8 vs. 48.1) showing fewer complications as compared to those no longer using it. Higher scores are suggestive of a greater number of complications.[7] There were also no differences between the two groups in terms of global health as measured by PROMIS. Overall, global health scores for the sample indicated lower function and quality of life when compared to a normal able-bodied population, reflecting impairments associated with SCI/D.

4 | DISCUSSION

In this retrospective study combined with prospective interviews and data, people with NGLUTD with recurrent UTIs had a 72% reduction in the rate of culture-proven symptomatic UTI after initiating gentamicin nightly bladder instillations. The therapy was well-tolerated by most patients and 78% of patients persisted with the medication for at least a year. Long-term persistence with the therapy up to 10 years was not uncommon in this series. Patients were very satisfied with their experience and there was no change in antibiotic resistance patterns in the UTIs that occurred after starting the instillations. Patients using gentamicin also reported fewer bladder complications affecting their QOL. Other QOL measures were not significant in detecting changes among these users. It is possible that symptoms and management difficulties are quite common in this group of patients (gentamicin users and nonusers), making it difficult to distinguish these differences.

This therapy is not a new concept, having been reported in 1987 by McGuire and Savastano.[9] We previously reported a 75% reduction in UTI in a population of NGLUTD patients, all performing CIC[4] (none of these patients are included in this current analysis). Other authors have noted similar success in children[10] with NGLUTS and many having bladder augmentations, women with recurrent UTI[11] (79% reduction), and a reduction of 69% in a study of an adult population with NGLUTD and many bladder management methods (catheters, CIC, conduits)[12] which is similar to this study population and had a similar rate of patients discontinuing the therapy. Doses of gentamicin range from 15 mg nightly (our typical dose), up to 80 mg per instillation[11,12] but the reduction in UTIs is quite consistent across studies despite the variable dosing, hence, we have continued using the lower dosing of 15 mg. All but one of these studies had their patients perform the instillations daily, except one where patients gradually spread out dosing to once a week with persistent efficacy.[11] Thus, it is unknown if the therapy needs to be done nightly, but in our experience daily dosing improves compliance since it is easier to remember a daily task rather than one only a few times a week. None of these other studies, however, explored patient perception and satisfaction.

TABLE 3 Patient quality of life among those continuing on gentamicin instillations and those who discontined.

Characteristic	Overall ($n = 36$)	Not still using gent ($n = 8$)	Still using gent ($n = 28$)	p Value
NBSS: Incontinence score				0.44
Mean (SD)	8.2 (7.62)	10.1 (8.20)	7.6 (7.50)	
Median (IQR)	7.0 (0.0–12.5)	7.5 (5.5–15.5)	6.5 (0.0–12.5)	
Range	0.0–25.0	0.0–24.0	0.0–25.0	
SNBSS: Storage and voiding score				0.27
Mean (SD)	5.3 (3.88)	6.5 (3.46)	4.9 (3.98)	
Median (IQR)	5.0 (2.0–8.0)	6.0 (4.0–8.5)	5.0 (1.0–8.0)	
Range	0.0–14.0	2.0–13.0	0.0–14.0	
NBSS: Consequences score				0.40
Mean (SD)	7.7 (2.55)	8.3 (2.55)	7.5 (2.57)	
Median (IQR)	8.0 (6.0–9.0)	8.5 (6.5–10.0)	8.0 (6.0–8.0)	
Range	2.0–14.0	4.0–12.0	2.0–14.0	
NBSS: Quality of life score				0.38
Mean (SD)	1.3 (0.99)	1.6 (1.19)	1.3 (0.93)	
Median (IQR)	1.0 (1.0–2.0)	1.5 (1.0–2.0)	1.0 (1.0–2.0)	
Range	0.0–4.0	0.0–4.0	0.0–4.0	
SCI-QOL: Bladder complications				0.04
Mean (SD)	44.0 (7.19)	48.1 (9.21)	42.8 (6.22)	
Median (IQR)	39.7 (39.7–48.3)	46.5 (39.7–54.9)	39.7 (39.7–39.7)	
Range	39.7–63.1	39.7–63.1	39.7–55.9	
SCI-QOL: Bladder management difficulties				0.28
Mean (SD)	50.3 (6.75)	53.3 (8.92)	49.4 (5.90)	
Median (IQR)	49.8 (47.6–52.5)	50.8 (48.7–58.9)	49.8 (47.6–51.8)	
Range	40.9–69.1	40.9–69.1	40.9–62.9	
PROMIS Global Health Scale				0.19
Mean (SD)	33.2 (5.60)	35.4 (4.84)	32.6 (5.72)	
Median (IQR)	33.0 (28.0–38.0)	36.5 (31.0–39.5)	33.0 (27.5–36.5)	
Range	25.0–43.0	28.0–41.0	25.0–43.0	
PROMIS Global Physical Health Score				0.08
Mean (SD)	43.8 (6.80)	48.0 (7.47)	42.5 (6.19)	
Median (IQR)	44.9 (39.8–44.9)	44.9 (43.6–51.3)	42.3 (37.4–44.9)	
Range	32.4–61.9	42.3–61.9	32.4–57.7	
PROMIS Global Mental Health Score				0.95
Mean (SD)	47.6 (7.91)	47.6 (7.90)	47.6 (8.06)	
Median (IQR)	45.8 (43.5–53.3)	45.9 (42.3–54.7)	45.8 (43.5–53.3)	
Range	33.8–62.5	36.3–59.0	33.8–62.5	

There are always concerns about safety when using aminoglycosides since there is possible ototoxicity or renal toxicity with systemic administration. Gentamicin bladder instillation in an animal model and a human study showed no systemic absorption as measured by serum studies by Wan et al.[13] in 1994. Other series, including both native bladders[11] and those with bowel interposition, have confirmed the same,[10,12] hence, absorption is not a concern

"I find the gent flushes to be a very beneficial procedure; had numerous UTI's prior to using them..."

"Very satisfied with gent flushes. They've been wonderful in preventing UTI's for me".

"Did not get the benefit I thought I would using the gent flushes. Didn't work well for me and it was too expensive paying for them myself."

"I would recommend gent to anyone w/UTI's. Finally found Dr. X who started me on this program and I'm so happy it's worked for me long term so far".

"The best thing I've experienced in many years. The foley cath and gent flushes have made my life wonderful. And my life was like dirt. Then these two things were introduced to me, making it so much more pleasant. Not to have to worry about UTI's, PICC lines and antibiotics on a monthly basis, is the best feeling ever!"

"I am having a terrible problem getting gentamicin bags from my compounding pharmacy! Can no longer get it from the University. My insurance company pays for my flushes. I need this problem to be fixed."

Currently shortage of gentamycin for flushes. On Macrobid for prevention. "Can't wait to get Gent going again. It's so helpful for me"

"Gent flushes have definitely improved my quality of life; hardly any UTI's any longer. Super important procedure for me. Can often go 8-10 hrs without cathing. I found the the longer I leave it in my bladder, the better it is for my bladder health; 9 hours."

"The procedures I've had since I've been treated have been 'life-saving'; Botox and gent flushes. Having a neurogenic bladder for the past 50 yrs, I am aware how wonderful it's been and how far we've come to assist people with this great problem that people like myself suffer from."

"Every time I use gentamicin, it helps me considerably. Prior to gent, I would most always have to resort to antibiotics".

"I believe gent washes have been helpful. My aide performs the procedure at night and overall they must be effective since it's been over a year and a half since my last UTI."

"I am very pleased with the results of the gent flushes I'm using."

"One issue with gentamicin is finding the sterile syringes that are usable with his hand function (C5-6 quad) so manipulating the 60 cc syringes and inserting it gets difficult; he was able to find one that works. Delivery service is also not always reliable and can be costly; sometimes in Summer the gentamicin gets exposed to hot temps with the heat and can't be used."

"Very pleased with gentamicin flushes via her suprapubic catheter. If she feels she may have a UTI, she increases flush to twice daily for several days."

"Gent takes a lot of time and she gets bladder spasms where she will sometimes lose the gentamicin, seems to be okay since she's not getting UTI symptoms"

FIGURE 1 Patient or primary careteker comments regarding gentamicin bladder instillations. All negative comments in red and positive in black.

for intravesical gentamicin, and we do not routinely do serum gentamicin levels.

The importance of this study was to assess patient perception and satisfaction with gentamicin, which is a potentially time-consuming therapy, and the prescription can be difficult to obtain since it is being used off-label. We were not surprised that patients who continued the therapy reported a very high level of satisfaction, and this likely explains why, even after a mean of 4.2 years, 78% of those patients prescribed gentamicin were still taking it. Our anecdotal experience has noted that these patients also have a better ability to know when they truly do have an UTI since their urine is less cloudy and smelly, and we have reported on decreased number of patient phone calls.[4] More recent information from our clinical trial evaluating the efficacy of gentamicin among patients with SCI/D with recurrent infections suggests similar results in terms of satisfaction with its use.[5]

UTIs are defined in many ways in the literature, but this population has an extremely high rate of bacteriuria, hence, a strength of this study is that we used a very rigid diagnosis of UTI requiring symptoms, a positive culture, and a physician clinical impression that this was an UTI that was in need of antibiotic treatment. Hence, we are confident that these were truly UTIs rather than asymptomatic bacteriuria which is not pathological. A weakness, however,

is that the very long follow-up of some of these patients means that their medical records were incomplete and there are likely UTIs that were undercounted. Another strength of this study is the very long follow-up data on these patients, but given their medical complexity, it is not surprising they chose to continue care at a tertiary medical center.

5 | CONCLUSION

Gentamicin bladder instillations with 15 mg performed nightly reduce the rate of UTI in patients with recurrent UTI and NGLUTD performing CIC and those with indwelling catheters. Patients stayed with this treatment for a mean of 4.2 years to date and reported great satisfaction with the therapy. We will continue to offer this therapy off-label since it is safe, well tolerated, and effective.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data for this study is available in deidentified format for review upon request and the corresponding author has full control of the data.

ETHICS STATEMENT

This work was performed under the supervision of the University of Michigan Institutional review Board following the Declaration of Helsinki and all participants were consented for the study.

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