



Delivery of urethral sphincter botulinum toxin injections for treating urinary retention during the COVID19 pandemic

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ABSTRACT

Aims: Urethral sphincter botulinum toxin injections is an alternative treatment for urinary retention in women with Fowler's syndrome and when access to health services were curtailed during the Covid19 pandemic, we continued to offer treatment to prevent increased demand on catheter services due to a recurrence of urinary retention. We describe our experience delivering safe and timely treatment during this period of lockdowns and restricted access to healthcare.

Methods: We retrospectively reviewed the records of all women with Fowler's syndrome treated with transperineal urethral sphincter botulinum toxin injection between 23rd March 2020 and 31st December 2021 in a tertiary university hospital and clinical outcomes were recorded.

Results: 15 women (mean age 35.6 ± 10.1 years) received 100U OnabotulinumtoxinA injected into the external urethral sphincter as an out-patient procedure adopting hospital infection control guidelines. 41 injections were administered in total, and 8 (53%) patients received more than 1 injection (median 2 injections/patient, median inter-injection interval 108.5 days). 10 (66.7%) patients reported improvements in urinary symptoms across 31/41 (75.6%) of injections. Side effects were reported after 21.4% of injections which were mild and transient. No patients developed Covid19 within 4 weeks of the hospital visit.

Conclusion: Real-world data shows that transperineal urethral sphincter botulinum toxin injections could be continued safely and effectively during the Covid19 pandemic. This essential outpatient service played an important role in treatment and quality of life for women with Fowler's syndrome, and avoided an additional burden on the NHS at the time of a health crisis.

1. Introduction

Primary disorder of urethral sphincter relaxation, or Fowler's syndrome, is the cause of chronic urinary retention in nearly 40% of young women [1]. The typical clinical presentation is with painless urinary retention due to dysfunction of the external urethral sphincter often associated with an elevated urethral pressure profile and an abnormal urethral sphincter electromyography (EMG) [2]. Sacral neuromodulation effectively treats urinary retention in nearly 70% of women with Fowler's syndrome [3], however this treatment is not feasible for all patients due to medical co-morbidities, patient choice, and restricted health resources. An alternative treatment, OnabotulinumtoxinA injection into the external urethral sphincter, has been demonstrated to be an effective and safe outpatient-based treatment in an open label trial for managing urinary retention in Fowler's syndrome [4]. Our urethral sphincter botulinum toxin injection service was set up in 2011

to manage chronic urinary retention in women with Fowler's syndrome. In order to manage symptoms effectively and prevent recurrence of urinary retention, 3–4 monthly injections are required.

During the period of restricted access to healthcare and lockdowns in the Covid19 pandemic, most non-essential hospital services were closed. Anticipating that a closure of the urethral sphincter botulinum toxin injection service would result in an increased demand on all catheter services due to women going into urinary retention, we decided to continue to offer treatment this treatment as an essential service throughout the pandemic, following COVID19 related hospital infection control guidelines. We describe our experience delivering safe and timely injections to our patients during the Covid19 pandemic.

2. Methods

We retrospectively examined the records of all patients with Fowler's syndrome who received urethral sphincter botulinum toxin

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injection between 23rd March 2020, the day that the first lockdown started, and 31st December 2021 in a tertiary university hospital. The treatment was offered to women meeting diagnostic criteria for Fowler's Syndrome (abnormal concentric needle EMG of the striated urethral sphincter and/or abnormally elevated urethral pressure profile) deemed suitable for this treatment following a multidisciplinary team discussion. OnabotulinumtoxinA was injected into the external urethral sphincter as an outpatient procedure by the transperineal approach. In the supine position 0.5 ml mL of 2% lidocaine was injected on either side of the external urethral meatus, followed by 100 units of OnabotulinumtoxinA dissolved in 1 mL saline injected into the striated urethral sphincter bilaterally. Once the local anaesthetic took effect, the duration of the procedure was approximately 10 min. Efficacy and side effects were assessed at baseline and 4 weeks after the injection through a telephone consultation. At the 4 week telephone consultation, patients were questioned for Covid symptoms as an ongoing review of patient safety after visiting the department. Patients contacted the department for repeat injections when effects began to diminish, after an embargo period of 12 weeks.

Staff followed hospital infection control guidelines with the use of stipulated personal protective equipment, and weekly staff Covid19 PCR testing. Patients attending the department were required to be asymptomatic and a temperature was performed on arrival. There was restricted access to the department, and patients were socially distanced by 2 metres and wore surgical masks in the department. These precautions were approved by the Infection control service as part of the COVID19 'green' pathway. This was undertaken as part of a locally approved audit programme.

3. Results

15 Women (mean age 35.6 ± 10.1 years) received 100U OnabotulinumtoxinA injected EMG-guided into the external urethral sphincter as an out-patient procedure. Baseline characteristics are shown in Table 1. 13 (86.7%) women were dependent on intermittent self-catheterisation (ISC) and 2 (13.3%) had voiding difficulties but were not ISC dependent. 14 Women had an urethral sphincter EMG diagnostic for Fowler's syndrome and abnormal urethral pressure profile, and $n = 1$ had abnormal urethral sphincter EMG only. 41 Injections were administered in total and 8 (53%) women received more than 1 injection (median 2 injections/patient, median inter-injection interval 108.5 days, interquartile range 51.8). 10 (66.7%) patients reported improvements in urinary symptoms across 31/41 injections (75.6% of injections). The improvements observed by patients who responded ($n = 10$ patients) were reduced frequency of ISC ($n = 8$), and 6 patients became catheter free.

Side effects ($n = 4$ patients, $n = 9$ injections, 21.4% of injections) reported were relatively mild and included transient stress incontinence ($n = 2$ patients, $n = 6$ injections) resolving within 2 weeks, short-lasting pain and bleeding ($n = 3$ injections), resolving within 24 h. No patient developed symptoms of Covid19 infection within 4 weeks of the hospital visit when they were contacted over telephone.

4. Discussion

Real-life data suggests that urethral sphincter OnabotulinumtoxinA is effective and safe in female patients with non-neurogenic external urethral sphincter dysfunction, and can be successfully delivered during times of health crisis as an essential service. 66.7% of patients in this cohort reported an improvement in their urinary symptoms. Importantly, it led to a reduction in frequency of ISC in 80% of patients who responded, and 60% of responding patients became catheter-free. These improvements are consistent with earlier studies [4,5].

Healthcare utilisation for therapeutics reduced by 30% in the UK during the Covid19 pandemic [6], and access to community and hos-

Table 1

Baseline characteristics.	
Patients, n	15
Injections, n	41
Age at symptom onset, yrs (mean \pm SD)	35.6 ± 10.1
Co-morbidities n%	
Depression	3 (20)
Joint Hypermobility or Ehlers's Danlos	3 (20)
Polycystic ovarian syndrome	2 (13.3)
Anxiety	2 (13.3)
Chronic pain syndrome or Fibromyalgia	2 (13.3)
Previous surgery – gynaecological or abdominal	2 (13.3)
Asthma	1 (6.7)
Migraine	1 (6.7)
Catheterisation	
-Non-catheter dependent	2 (13.3)
-Intermittent self-catheterisation	13 (86.7)
Investigations for voiding dysfunction	
EMG diagnostic for Fowler's syndrome ($n = 14$)	12 (85.7)
Urethral pressure profile abnormal for age ($n = 14$)	14 (100)
Urodynamics ($n = 12$)	
-impaired bladder sensation	7 (58.3)
-Detrusor underactivity	7 (58.3)

pital services, particularly during the first and second waves, were limited. We considered continuation of urethral sphincter OnabotulinumtoxinA injections an essential service, as patients with chronic urinary retention were at risk of increased reliance on catheterisation, subsequent health risks such as urinary tract infections and difficulty accessing resources to safely manage a catheter.

Provision of this treatment with appropriate infection control guidance was effective and safe, and none of the patients developed Covid19 infection after attending the department. Patients were able to be brought in quickly at short notice, and due to the short duration of the procedure spent only a limited time in hospital.

5. Conclusion

In conclusion, transperineal urethral sphincter OnabotulinumtoxinA injections were delivered safely and effectively without interruption during the Covid19 pandemic. This essential outpatient service played an important role in maintaining treatment and quality of life for female patients in urinary retention due to Fowler's syndrome, and avoided an additional burden on the NHS.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jalesh Panicker reports a relationship with Wellspect HealthCare UK that includes: speaking and lecture fees. Jalesh Panicker reports a relationship with Idorsia Pharmaceuticals Ltd that includes: consulting or advisory. Jalesh Panicker reports a relationship with Coloplast Ltd that includes: consulting or advisory and speaking and lecture fees. Jalesh Panicker reports a relationship with Corporate Allergan Inc that includes: speaking and lecture fees. Jalesh Panicker reports a relationship with Novartis that includes: speaking and lecture fees. JNP Cambridge University Press: royalties JNP Continence Reports Editorial Board. Sarah Wright report a relationship with Merck that includes speaking and lecture fees.

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