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Cystoscopic injection of botulinum toxin for urgency incontinence

SHORT REPORT

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Background

Urgency incontinence is a common condition that can be difficult to treat. Cystoscopic injection of botulinum toxin into the bladder wall is a treatment option when conservative treatment has failed. The aim of the study was to evaluate the treatment outcomes and clinical benefits of botulinum toxin injection.

Material and method

We performed a retrospective record-based study at the Department of Gynaecology, Vestfold Hospital, of women who received intravesical botulinum toxin for urgency incontinence in the period 2014 - 2022 after failing to respond to conservative treatment. The primary endpoint was treatment satisfaction. Secondary endpoints were self-reported continence, repeated injections, treatment interval and complications.

Results

A total of 167 women received treatment, with 403 injections administered. At the outpatient follow-up six months post-injection, 297/391 (76 %) reported being satisfied with the treatment and 272/384 (71 %) reported having regained continence. One or more complications were recorded in 79 of 395 (20 %) injections: 48 urinary tract infections, 25 cases requiring catheterisation due to impaired bladder emptying, and 6 cases of pain.

Interpretation

Cystoscopic injection of botulinum toxin may be useful when conservative treatment for urgency incontinence has not led to adequate improvement. However, the method is not without risk of complications.

Main findings

167 women with urgency incontinence received a total of 403 botulinum toxin injections by cystoscopy.

At the six-month follow-up, the women reported satisfaction after 76 % of injections.

Similarly, continence was regained after 71 % of injections.

Complications were reported after 20 % of injections.

Urgency incontinence is a common condition that can be difficult to treat. Cystoscopic injection of botulinum toxin into the bladder wall is a minimally invasive surgical option in both women and men when conservative methods such as lifestyle changes, bladder training, pelvic floor exercises, medicines such as antimuscarinics or beta stimulators, and/or electrical stimulation treatment have not led to adequate improvement (1).

Injection of botulinum toxin into the bladder wall causes local muscle paralysis. The effect manifests within days to weeks but is transient because new neuromuscular connections are formed (1). The symptoms then return. The standard injection interval is six months, but over 20 % of patients experience effects lasting longer than one year (1). The treatment can be safely administered repeatedly (1, 2), and individual response appears to be consistent with repeated injections (1, 3).Botox® is the only drug approved for

this indication in Norway. Response rates, variably defined in the literature as '> 50 % improvement', 'better' or 'much better', exceed 60 % in most studies (range 37 - 70 %); typically with a 20 - 50 % reduction in leakage episodes and 23 - 55 % regaining continence (1, 3, 4). Most studies show statistically significant improvement in self-reported quality of life (1).

Reported complications include a 5 - 36 % risk of urinary tract infection (1, 3, 4, 5) and a 4 - 17 % risk of voiding difficulties requiring catheterisation (1, 4). Some patients also experience postoperative pain and dysuria, while systemic effects are rare (1, 3).

The Department of Gynaecology at Vestfold Hospital has offered cystoscopic injection of botulinum toxin to women since 2014. The standard dose per treatment is 100 Allergan units of Botox® distributed at ten sites in the bladder wall (6). All patients are offered a six-month outpatient follow-up with a urotherapist, and patients who want repeat injections may contact the department directly.

The aim of the study was to evaluate the treatment outcomes and clinical benefits of cystoscopic injection of botulinum toxin.

Material and method

This retrospective record-based study was conducted at the Department of Gynaecology, Vestfold Hospital, in the period June 2014–December 2022. The study included women who received cystoscopic injections of botulinum toxin in the bladder wall for urgency incontinence with refractory urinary leakage despite receiving conservative treatment.

The primary endpoint was patient-reported satisfaction with the injection at the routine six-month outpatient check-up with a urotherapist. Secondary endpoints were repeated injections (number), treatment interval (months), self-reported continence and pain, as well as postoperative complications such as bladder emptying problems (confirmed post-void residual urine or urinary retention requiring catheterisation at least once) and urinary tract infection (treated with antibiotics for diagnosed or suspected infection).

The study was approved by the hospital's data protection officer, and the Regional Committee for Medical and Health Research Ethics determined it to be a quality assurance study and not subject to approval.

Results

During the study period, 167 women received between 1 and 11 injections, totalling 403 injections (Table 1). At a six-month follow-up with a urotherapist, patients reported being satisfied with their treatment in 297 of 391 (76 %) consultations. The corresponding figure for self-reported continence was 272 of 384 consultations (71 %).

The mean interval between repeat injections was six months (range 0–30) (Table 1).

A total of 79 complications were reported after 395 injections (20 %), with urinary tract infection twice as frequent as voiding difficulties (Table 2). The need for catheterisation due to impaired bladder emptying ranged from once to intermittent catheterisation for up to three months.

Discussion

Patients with urgency incontinence often have an inadequate response to conservative (non-invasive) treatment, and poor adherence is common (7). Cystoscopic injection of botulinum toxin into the bladder wall could represent a viable alternative.

A total of 403 injections of botulinum toxin into the bladder wall were administered to 167 women during the study period. At the routine six-month follow-up, the women reported satisfaction with treatment after 76 % of injections and regained continence following 71 % of injections. This is consistent with international reports (1, 3, 4). One or more complications occurred after 20 % of injections.

Women with urgency incontinence are at increased risk of urinary tract infection (8), and the manufacturer of Botox® recommends antibiotic prophylaxis for the procedure (9). Most guidelines do not take a clear position on antibiotic prophylaxis (8), but it is commonly used in clinical practice (1). The actual benefit of antibiotic prophylaxis, as well as the choice of agent and treatment duration, remains a matter of discussion (1, 8), but a recent review supports the use of antibiotic prophylaxis (5). Our patients provide their general practitioner with a urine sample for culture two weeks before the procedure and any significant bacteriuria is treated preoperatively. In addition, all patients receive antibiotics starting the evening before the injection. Despite these measures, antibiotics were given for suspected or confirmed urinary tract infection following 12 % of injections.

Impaired bladder emptying after botulinum toxin treatment is an inherent risk since the purpose of the injections is to weaken the bladder musculature. In our study, catheterisation was required after 6 % of injections, ranging from once only to three months of catheterisation. Incomplete bladder emptying with residual urine can predispose to urinary tract infection, making postoperative follow-up important. Patients should be prepared for the possibility of postoperative voiding difficulties and the potential need for catheterisation. Urgency incontinence is a chronic condition, and repeated treatment may be necessary.

Limitations of the study are its retrospective design and reliance on data extracted as yes/no responses from unstructured medical records, largely based on self-reporting from patients of treatment effect and complications. Accordingly, the findings are associated with some uncertainty and should be interpreted with caution. Furthermore, the study was conducted at only one

hospital and primarily reports results per treatment (*n*=403) rather than per patient (*n*=167). External validity may therefore be limited. Nevertheless, the treatment outcomes appear to be consistent with those reported to date in international literature.

Cystoscopic injection of botulinum toxin for urgency incontinence appears to be a useful alternative when conservative treatment has proved inadequate, although some complications must be expected.

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