

BOTULINUM TOXIN THERAPY FOR INTERSTITIAL CYSTITIS.

Aims of Study

Interstitial cystitis (IC) is a chronic condition of the bladder manifested by pain associated with frequency and urgency. There is no consensus regarding the etiology and nature of the disease, however it seems possible that it might be an example of so-called neurogenic inflammation of the bladder. So far different treatment modalities were proposed for IC, e.g. anticholinergics, vanilloids, neuromodulation. No treatment however was proven to be successful on a long-term basis. The factor responsible for all IC symptoms could be increased sensory output from the bladder. Therefore, it is possible that sensory denervation could be helpful in releasing IC symptoms. As botulinum toxin is known to work well in case of bladder overactivity, we wanted to evaluate its action in IC patients. To the best of our knowledge we present the first case series of patients treated with botulinum toxin for IC.

Methods

Eleven female patients (7 in Poland, 4 in US) with interstitial cystitis were included in the present study. IC was diagnosed on the basis of the criteria of the National Institute of Arthritis, Diabetes and Digestive and Kidney Disease (NIDDK). In all women previous treatment modalities failed. The study protocol was approved by the Local EC Board. All patients signed the informed consent before entering the study.

Under short general anesthesia (Poland) or sedation (US), patients were placed in the lithotomy position and botulinum toxin type A (Dysport[®], Beaufour Ipsen) solution, final concentration 100 u/ml was injected into Polish patients while Botox[®] (Allergan, Irvine, CA) was injected into US patients at a final concentration of 10 u/ml. The injections were made through the cystoscope via a Cook[®] endoscopic needle into 10-20 sites submucosally in the trigonal and posterior bladder wall areas. 10-20 units of botulinum toxin were used per injection site, up to the total dose of 200 units (both Botox[®] and Dysport[®]). No catheter was left in the bladder after the treatment.

The pre and post-treatment evaluation for Poland patients included visual analog pain scale, urodynamic evaluation (filling and voiding phases) and voiding charts performed one and three months after treatment. US patient evaluation included pretreatment urodynamic evaluation, and pre and postop O'Leary-Sant validated IC questionnaire (US) which included Interstitial Cystitis Symptom Index (ICSI) and Interstitial Cystitis Problem Index (ICPI) voiding and pain indices.

Results

Mean patient age was 55 ± 13.4 years, mean disease duration was 3.5 ± 2.5 years.

No improvement was observed immediately after the therapy. Between 1st and 3rd week after the treatment, a transitional pain in the lower abdomen was noted by all the patients, however of a different nature than the IC pain. For Polish patients (n=5) it has been found that the pain decreased by 79% (from 7.8 to 1.6) one month after the treatment, as measured by visual analog scale.

One month after the treatment we observed a significant decrease in the number of day and night time micturitions (by 44% and 45% respectively or from 16.0 to 9.0 and from 7.6 to 4.2). Also a significant increase in the functional bladder parameters was observed. The bladder volume at first desire to void and maximum cystometric capacity increased by 58% (from 74.6ml to 118.0ml) and 57% (from 159.0ml to 250.0ml), respectively. For the US patients (n=3) the reduction in ICSI and ICPI was 71% (from 17 to 5.3) and 69% (from 15.7 to 4.5), respectively. The improvement lasted for a mean period of 3.69 months (from 1 to 8 months).

Treatment failed in 3 patients (neither pain, nor frequency/urgency improvement)

No post-operative complications were observed. No patient developed urinary retention.

Conclusions

Our results suggest that Botulinum toxin A has an antinociceptive effect on visceral afferent pathways innervating the bladder. Botulinum toxin type A therapy appears to be effective for interstitial cystitis. It produces both symptomatic and functional (bladder capacity) relief. The exact effect of botulinum toxin action on sensory nerve fibers in IC remains to be elucidated.