Therapeutic effects of intravesical onabotulinumtoxinA injection on IC/BPS refractory to conventional treatment: a randomized, double-blind, placebo controlled study

Yuh-Chen Kuo1,2, Cheng-Ling Lee2, Yuan-Hong Jiang2, Hann-Chorn Kuo2
1Department of Urology, Taipei City Hospital, Taipei, Taiwan
2Department of Urology, Buddhist Tzu Chi General Hospital and Tzu Chi University, Hualien, Taiwan

Purpose

- Intravesical onabotulinumtoxinA (BoNT-A) injection has been demonstrated to be beneficial for the treatment of interstitial cystitis/bladder pain syndrome (IC/BPS) yet the therapeutic efficacy has not been validated by a placebo controlled study.
- We conducted a randomized, double blind, placebo controlled trial to elucidate the effects of intravesical BoNT-A injection on IC/BPS.

Materials and Methods

- Patients with IC/BPS refractory to conventional treatment for at least 6 months were recruited in this study.
- All the subjects were randomized in a 2:1 ratio to receive hydrodistention plus intravesical suburothelial injection of BoNT-A 100 U (Botox group) or equivalent amount of normal saline (N/S group) in a 20 sites setting.
- Post-baseline study visits/assessments were conducted at weeks 2, 4 and 8.
- The primary endpoint was improvement of pain visual analogue scale (VAS).
- The secondary endpoints included changes in the O’Leary-Sant symptom index (ICSI), global response assessment (GRA), functional bladder capacity (FBC), frequency, nocturia, maximum flow rate (Qmax), voided volume (VV), post-void residual urine (PVR), and cystometry bladder capacity (CBC).
- Patients with Hunner’s ulcer, PVR >150 ml or active urinary tract infection were excluded.
- An improvement of pain VAS >=2 or GRA >=1 was defined as treatment success.
- Safety was assessed by evaluating adverse events (AE).

Results

- A total of 53 patients (6 male, 47 female, aged 50.8±13.9) including 36 in Botox group and 17 in N/S group were enrolled in this study.
- At 8 weeks, significant changes in VAS, ICSI, ICPI, OSS, GRA, FBC, frequency, nocturia and PVR could be observed in Botox group while only significant improvements in ICSI, ICPI and OSS could be revealed in N/S group when compared with those at baseline (Table 1).
- Moreover, significantly greater decrease of VAS and increase of PVR could be demonstrated in Botox group than those in N/S group after 8 weeks follow-up.
- The overall successful rates were 59.3% (16/27) in Botox group versus 46.7% (7/15) in N/S group by VAS (p=0.525) and 70.4% (19/27) in Botox group versus 53.3% (8/15) in N/S group by GRA (p=0.325).
- There was no significant difference in prevalence of AE between the two groups (Table 2).

Conclusions

- The results of this randomized, double-blind, placebo controlled trial demonstrated single intravesical injection of BoNT-A is effective to release the pain symptom in patients with IC/BPS refractory to conventional therapy.
- The adverse events are acceptable.
- Large scale studies are warranted.