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EFFICACY AND SAFETY OF BOTULINUM TOXIN INJECTION FOR INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME: A SYSTEMATIC REVIEW AND META-ANALYSIS

Hypothesis / aims of study
To investigate the overall treatment efficacy and safety of botulinum toxin type A (BTXA) injections compared with placebo in interstitial cystitis/bladder pain syndrome (IC/BPS).

Study design, materials and methods
We conducted a systematic review and meta-analysis of the published literature in PubMed, Cochrane Library, and Embase on BTX use in IC/BPS. Outcome measures included changes of OLS, ICSI, ICPI, VAS, frequency, nocturia, FBC, Qmax, and PVR from baseline, and also included adverse events.

Results
A total of five studies were included, with a total sample size of 252 subjects (133 subjects in the experimental group and 119 subjects in the control group). The duration of treatment ranged from 8 to 12 weeks. The BTX dosage was from 50 U to 200 U. The pooled overall SMD in the mean change of VAS for the BTXA group versus the placebo group was -0.50 (95% CI; -0.75, -0.24). There were also significant improvements in ICPI and frequency. The other outcomes (ICSI, nocturia, Qmax, and FBC) were not statistically different between the two groups.

Interpretation of results
Although evidence from clinical and basic research studies supports the use of BTXA in IC/BPS, no general consensus has been made regarding its application. The present study showed that subjective indexes such as OLS, ICPI, and VAS were significantly improved following BTXA treatment compared to treatment with a placebo.

Concluding message
This first evidence-based systematic review and meta-analysis of BTXA injection for IC/BPS showed significant differences in efficacy of treatment compared with placebo, especially for pain control, and also showed no differences in the rate of procedure-related adverse events.

Table. Characteristics of randomized trials of botulinum toxin for BPH

Study	**Country**	**Intervention** BTX / Placebo	**No. of** BTX / Placebo	**Study Duration**	**Description of Subjects**
Gottsch 2011	USA	Onabotulinum toxin 50 U diluted in 2 cm^3 normal saline / normal saline	9 / 11	12 weeks	20 women with IC/PBS. Mean age 47.7 years (normal saline), 43.9 years (BTX)
Kuo 2009	Taiwan	Onabotulinum toxin 200 U / 100 U / hydrodistention	15 / 29 / 23	12 weeks	56 women and 11 men. Mean age 45.7 years (BTX 200 U), 47.7 years (BTX 100 U), 52.5 years (bladder hydrodistention).
Manning 2014	Australia	*Abobotulinum toxin 500 U/ 30 ml normal saline	25 / 25	12 weeks	Mean age 54 years (BTX), 53 years (normal saline). 54 female patients
Kuo 2015	Taiwan	Onabotulinum toxin 100 U / normal saline hydrodistention	40 / 20	8 weeks	8 men and 52 women. Mean age 52.9 years (BTX), 50.2 years (normal saline).
Kasyan 2012	Russia	Onabotulinum toxin 100 U / standard hydrodistention	15 / 17	12 weeks	32 female patients with BPS/IC, randomly assigned to one of the two groups.

*One ampoule of Dysport 500 U is estimated to be equivalent to approximately 2 to 2.5 ampoules of Botox 100 U (Allergan, Highlands Ranch, CO, USA).

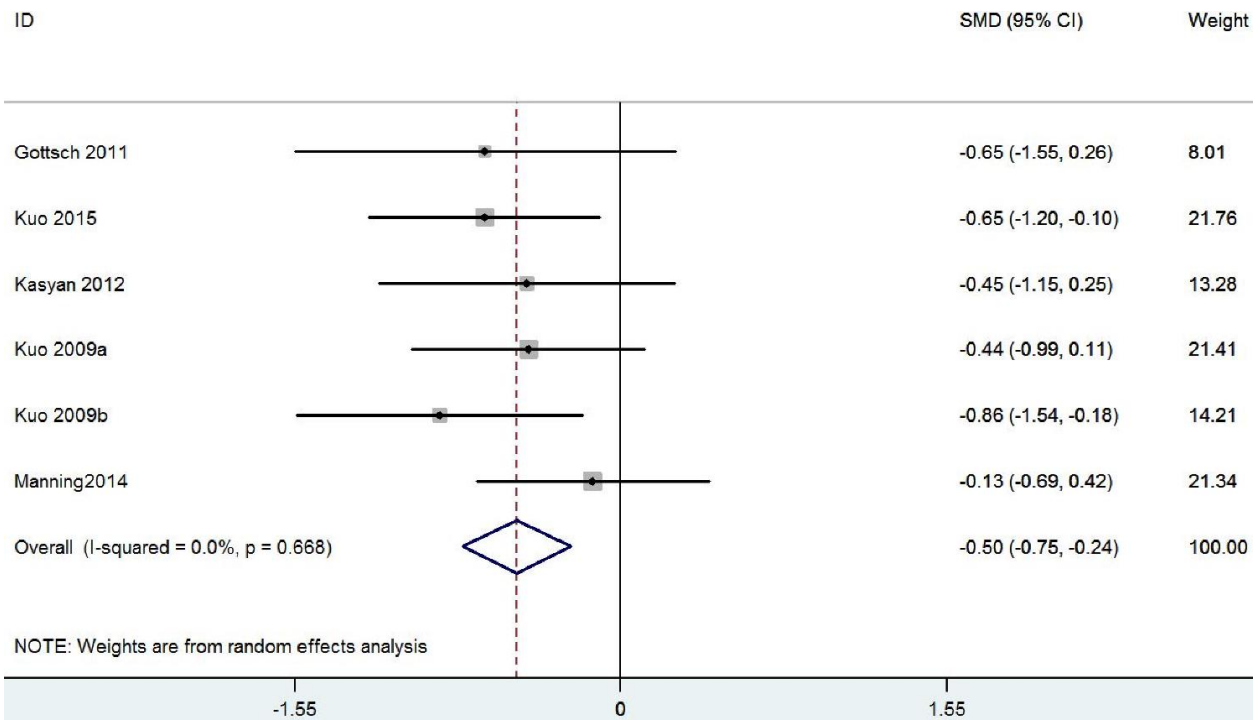

Figure. Standardized mean differences (SMD) in mean change from baseline of visual analogue scale (VAS) for botulinum toxin versus control

Disclosures
Funding: none **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** systematic review and meta-analysis **Helsinki not Req'd:** this is not clinical trials but systematic review and meta-analysis **Informed Consent:** No