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BOTULINUM TOXIN A INJECTIONS INTO PELVIC FLOOR MUSCLES UNDER ELECTROMYOGRAPHIC GUIDANCE FOR WOMEN WITH REFRACTORY HIGH TONE PELVIC FLOOR DYSFUNCTION: THREE MONTHS FOLLOW-UP DATA OF AN ONGOING PILOT STUDY

Hypothesis / aims of study
High tone pelvic floor dysfunction (HTPFD) is a debilitating chronic pain disorder for many women with significant impact on their quality of life (QoL). Our objective is to determine the efficacy of electromyography (EMG) guided botulinum toxin A (BoNT) injections in treating pelvic pain and improving QoL.

Study design, materials and methods
This is an interim analysis of an ongoing prospective pilot study of women with chronic pelvic pain and HTPFD who have failed conventional therapy. Enrollment started in January 2011. BoNT injections (up to 300 units) were done using needle EMG guidance to localize spastic pelvic floor muscles (PFM). All patients who have completed 12 weeks follow-up (n=14) were analyzed. Data were collected at baseline, 4, 8, 12, and 24 weeks after injections. This included demographics, visual analog scores (VAS) for pain and dyspareunia, validated questionnaires for symptoms, QoL, and sexual function , Global Response Assessment (GRA) scale for pelvic pain, digital exam of PFM for tone and tenderness, and vaginal manometry. Side effects were also recorded.

Results
Mean age was 36.6 years (SD ±10.9, range 22-52), mean body mass index 24.7 (±3.4). Comorbidities included interstitial cystitis/bladder pain syndrome (43%) and vulvodynia (57%). Overall, 71 % of subjects reported improvement on GRA at 4 weeks, and 79% at 8 and 12 weeks post injection, compared to baseline. Of the 10 subjects who were sexually active at baseline, 80%, 70%, and 60% reported less dyspareunia at 4, 8, and 12 weeks respectively. Two out of the 3 patients who avoided sexual activity at baseline secondary to dyspareunia resumed intercourse after BoNT. Sexual dysfunction as measured by the Female Sexual Distress Scale (FSDS) significantly improved at 8 weeks (25.36, $p=0.025$) and 12 weeks (25.93, $p=0.028$) compared to baseline (33.14). Short Form 12 (SF-12) showed improved QoL in the physical composite score both at 4 (43 vs 37.2, $p=0.014$) and 12 weeks (43.5 vs 37.2, $p=0.041$), and in the mental composite score at 12 weeks (45.69 vs 38.24, $p=0.03$). Vaginal manometry demonstrated significant decrease in both resting pressures and maximum contraction pressures at all follow-up visits ($p<0.05$). Digital assessment of PFM (on a scale from 0 to 4) showed decreased tenderness on all visits (mean of 1.79, $p=0.01$; 1.35, $p=0.001$; 1.46, $p=0.004$) compared to baseline (2.49). Reported side effects included constipation (50%), worsening of pre-existing stress urinary incontinence (SUI) and fecal incontinence (7%), and new onset SUI (14%).

Interpretation of results
Treatment of HTFPD with BoNT resulted in decreased pain, resumption of sexual activity, less sexual dysfunction, and better quality of quality of life, with a low incidence of side effects.

Concluding message
EMG guided BoNT injection into PFM could be beneficial for women with refractory HTFPD who have failed conservative therapy.

Disclosures
Funding: Allergan has provided an independent educational research grant to help defray costs in performing this study, as well as provision of medication needed for the study. **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Western Institutional review board **Helsinki:** Yes **Informed Consent:** Yes