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Pacik, P. **Treatment of vaginismus with onabotulinumtoxinA: results from a pilot study.** Female Pelvic Medicine & Reconstructive Surgery Volume 19, September/October 2013, Supplement 2 , pp. S45-S195 (Pacik pp S59)

Objectives: Vaginismus is a poorly understood condition that involves involuntary spasms of the vaginal muscles, resulting in an inability to have sexual intercourse. Prior evidence suggested that botulinum toxin may be an effective treatment for vaginismus. Thus, this open-label, single-center, pilot study (NCT01352546) was performed to evaluate the efficacy and safety of intravaginal injection of onabotulinumtoxinA (BOTOX®, Allergan, Inc.) combined with bupivacaine injection and progressive dilation under anesthesia along with post-procedure support in the treatment of vaginismus.

Methods: Eligible patients were non-pregnant females aged 20-40 with primary vaginismus who were naïve to any kind of botulinum toxin treatment. Patients under heavy sedation or general anesthesia received a one-time intravaginal injection of onabotulinumtoxinA 150U into the bulbocavernosus, pubococcygeus, and puborectalis muscles along each left and right lateral wall, along with 30 mL of 0.25% bupivacaine with 1:400,000 epinephrine, followed by insertion of progressively larger dilators coated with 2% xylocaine jelly mixed with surgical lubricant. Supervised dilation continued for 2-3 days post-procedure, and dilation was recommended for 15-30 minutes prior to attempted intercourse. The primary endpoint was the ability to achieve pain-free intercourse, or in the absence of a partner, to use a #5 or #6 dilator, within one year post-treatment. The Female Sexual Function Index (FSFI), a validated 19-item questionnaire, was also administered before and after treatment (FSFI scores range from 2-36; higher scores indicate better sexual function). Adverse events (AEs) were monitored throughout the study.

Results: A total of 31 patients were included in the study. The mean age was 27.3 y (range 20-37) with an average duration of vaginismus of 7.2 y (range 0.5-22 y) from time of discovery. Vaginismus was classified as Lamont level 4 (most severe) at baseline in 20 (64.5%) patients; 48.4% of patients had previously been unable to undergo a gynecological exam. Most patients had failed prior treatments, with the most common being dilator use and Kegel exercises, attempted by 80.6% and 64.5% of patients, respectively, with respective average durations of treatment of 33.7 (range 5-150) and 40.2 (range 1-312) weeks. After onabotulinumtoxinA treatment, 28 (90.3%) patients achieved pain-free intercourse by an average of 8.0 weeks (range 0.3-51). Two (6.5%) patients were without partners but were able to comfortably use the #5 or #6 dilators at 0.4 and 3 weeks post-procedure, respectively. One patient (3.2%) was unable to achieve intercourse despite the ability to use the #5 or #6 dilators 4 weeks post-procedure. Of the 19 patients with complete data for the FSFI, the median score was 17.1 (range 7.1-30.2) at baseline and 23.6 (range 2-34.3) 12 months post-onabotulinumtoxinA treatment. No recurrences of vaginismus and no AEs were noted within the follow-up period.

Conclusions: Intravaginal injection of onabotulinumtoxinA with progressive dilation and post-procedure support enabled patients with vaginismus to achieve pain-free intercourse and exhibit greater levels of sexual function within one year post-treatment in this pilot study. As such, this treatment warrants additional investigation in larger clinical trials.