

METHODOLOGICAL APPROACHES TO USING BOTULINUM TOXIN FOR INJECTION OF THE PELVIC FLOOR FOR PAIN IN WOMEN



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Introduction

- Botulinum toxin is frequently used for pain conditions, especially those associated with muscle spasm.
- Little is known about how to best use botulinum toxin to treat chronic pelvic pain associated with pelvic floor muscle spasm in women.

Objectives

- Describe our method for injection of botulinum toxin into pelvic floor muscles used for treating endometriosis-related pelvic pain after optimized hormonal/surgical treatment.
- Place our methodology in the context of the current literature on techniques for this use of botulinum toxin.

- 38 reports were identified with technical information that provided information for ~1300 patients, many published within the past 6 years (Figures 1, 2).
- Many publications lacked complete information.
- Most were open-label prospective reports with 4 technical reports, 1 randomized, double-blind comparison of 2 doses and only 1 randomized, double-blind, placebo-controlled efficacy study (Figure 3).
- Pelvic floor muscles were approached transvaginally, transperineally, and transgluteally.
- Toxin brand, dose, and dilution varied widely (Figures 4, 5, 6).
- Type of anesthesia and needle localization method varied widely (Tables 1, 2).

Figure 2: Diagnosis studied

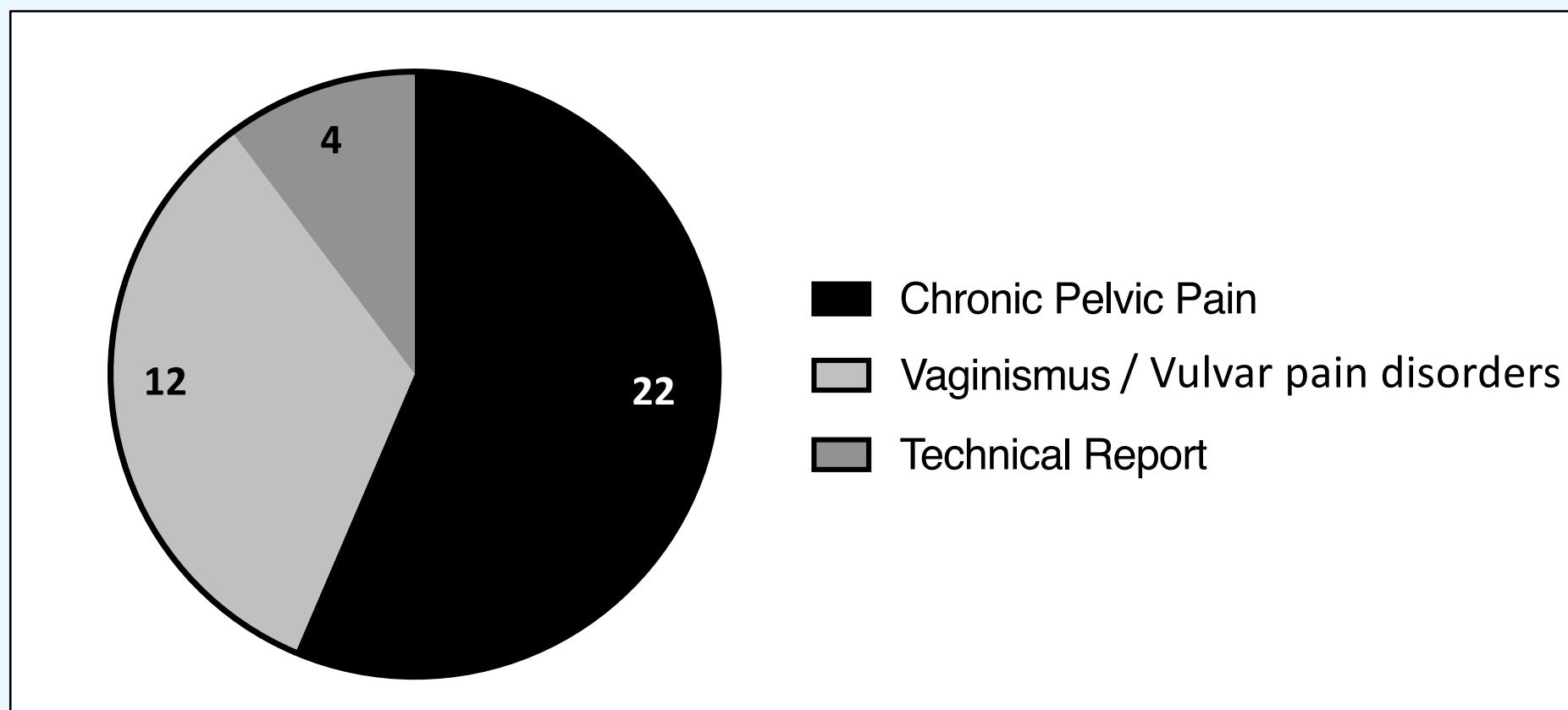


Figure 3: Type of report

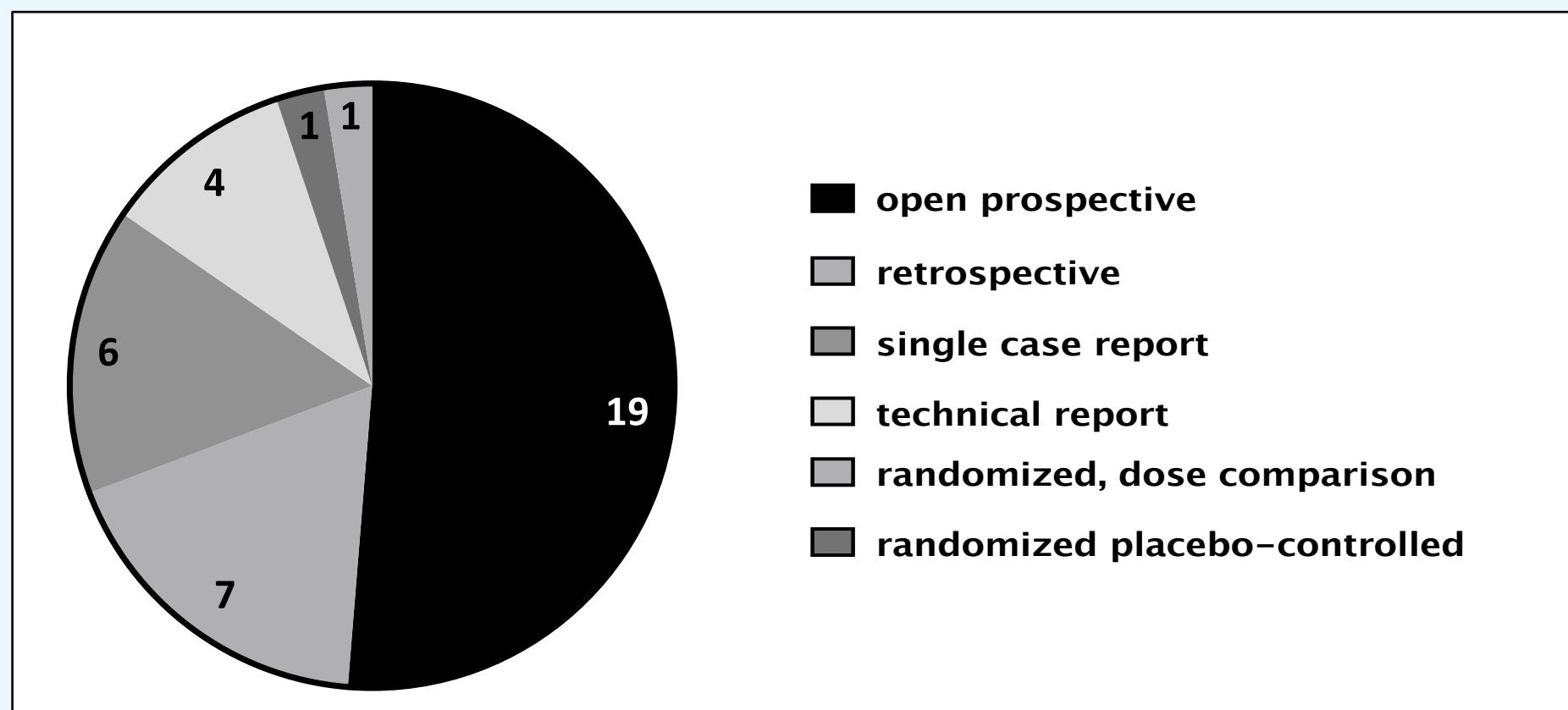
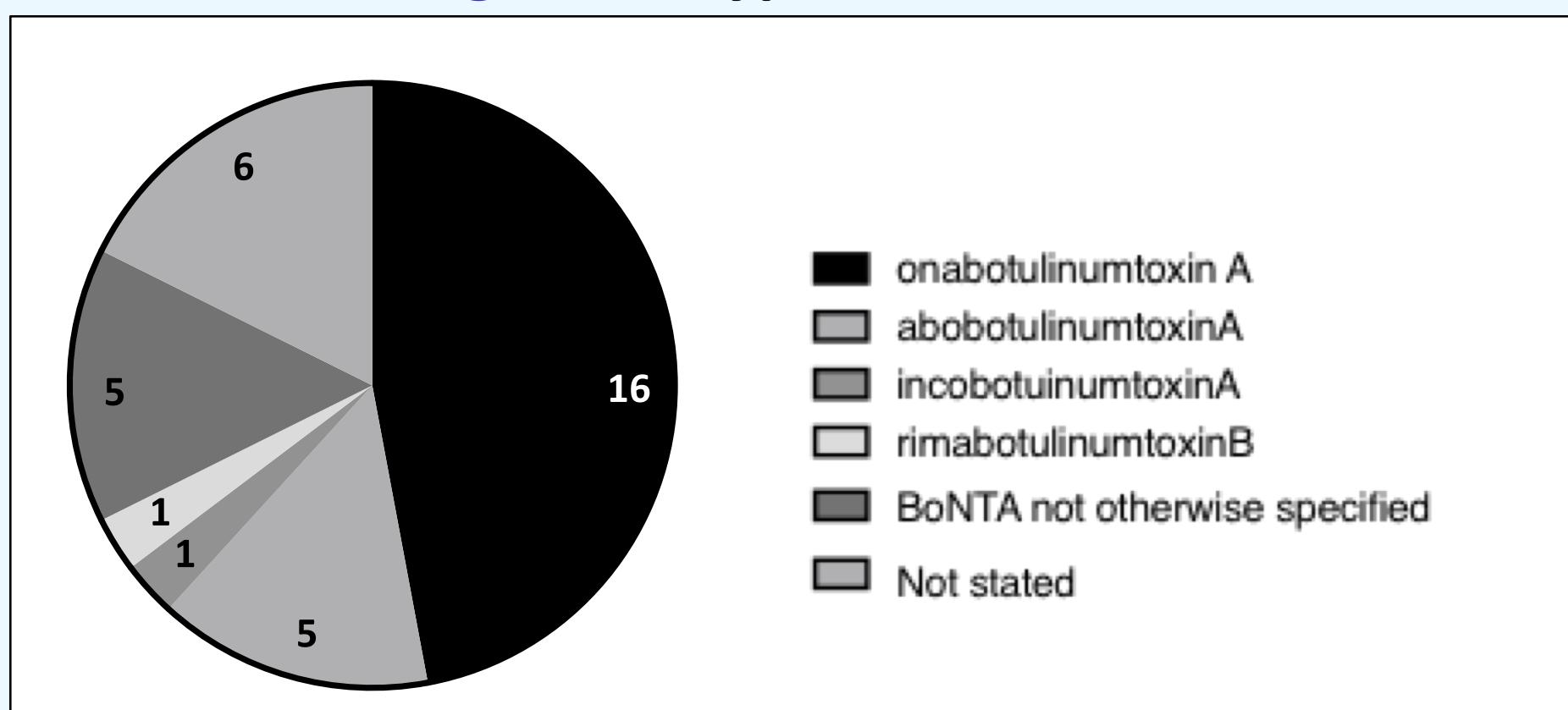
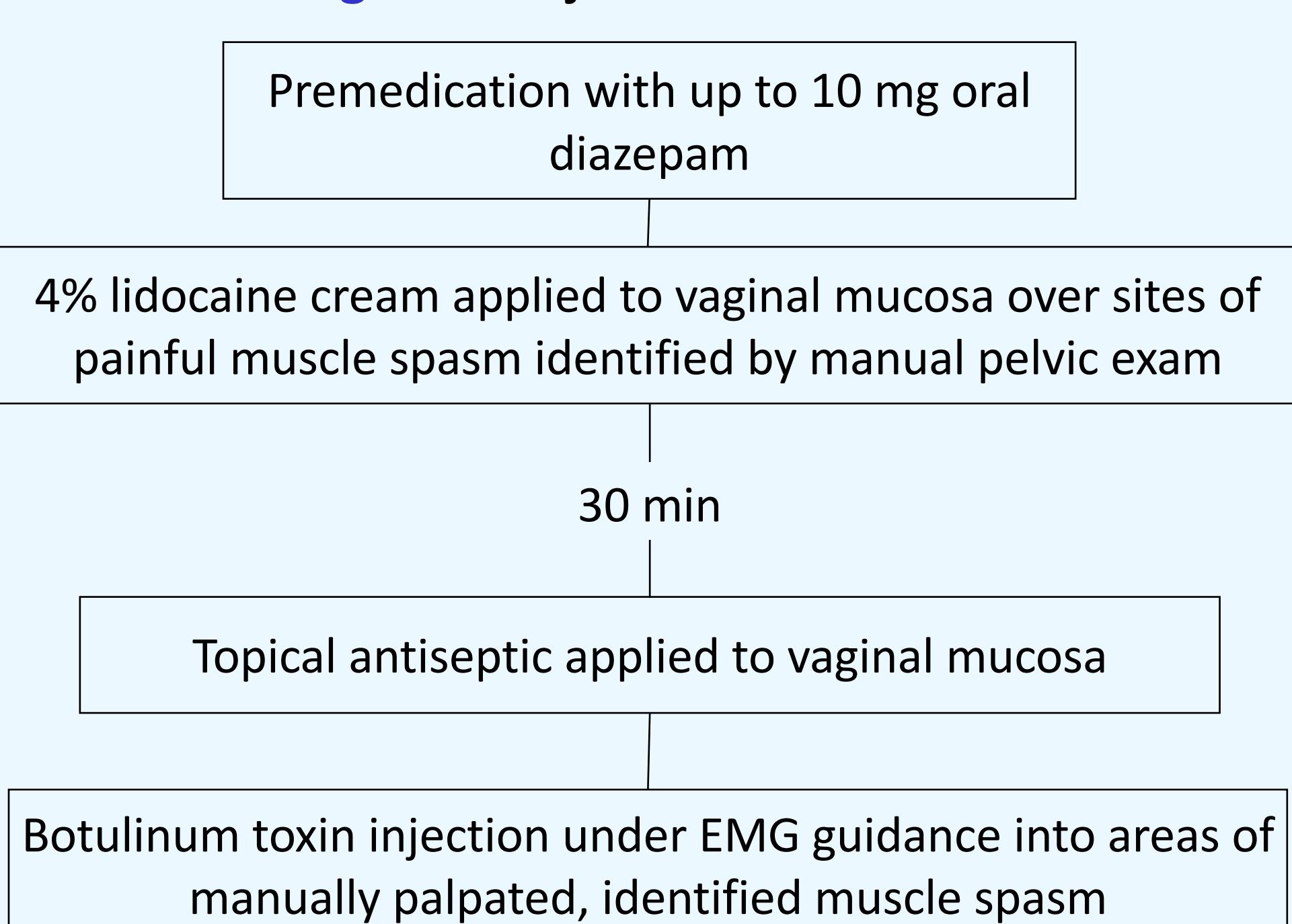


Figure 4: Type of toxin used



- Our injection technique (Figure 7) utilizes:
 - 100 u of onabotulinumtoxinA diluted in 4cc saline injected into areas of spasm
 - Conscious sedation and topical anesthesia
 - Vaginal antiseptic
 - Manual palpation to identify areas of spasm and anatomic landmarks, and EMG guidance for injection

Figure 7: Injection Procedure



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- ## Methods
- PubMed, Embase and Scopus databases were searched using the terms "botulinum toxin" "pelvic pain" and "vaginismus."
 - Data were extracted on the type of report, condition treated, toxin serotype/brand, dose, dilution, muscle selection, muscle guidance technique, anesthesia, and other methodologic information. Abstracts were included if they were at least partly informative about the technique of injection.
 - Publications on vaginismus and vulvar pain disorders were included ONLY if pelvic floor muscles were injected.
 - Publications from the same research group that described the same injection technique and did not provide unique technical information were combined for specific analyses.

Results

Figure 1: Publications on botulinum toxin for female chronic pelvic pain and vaginismus

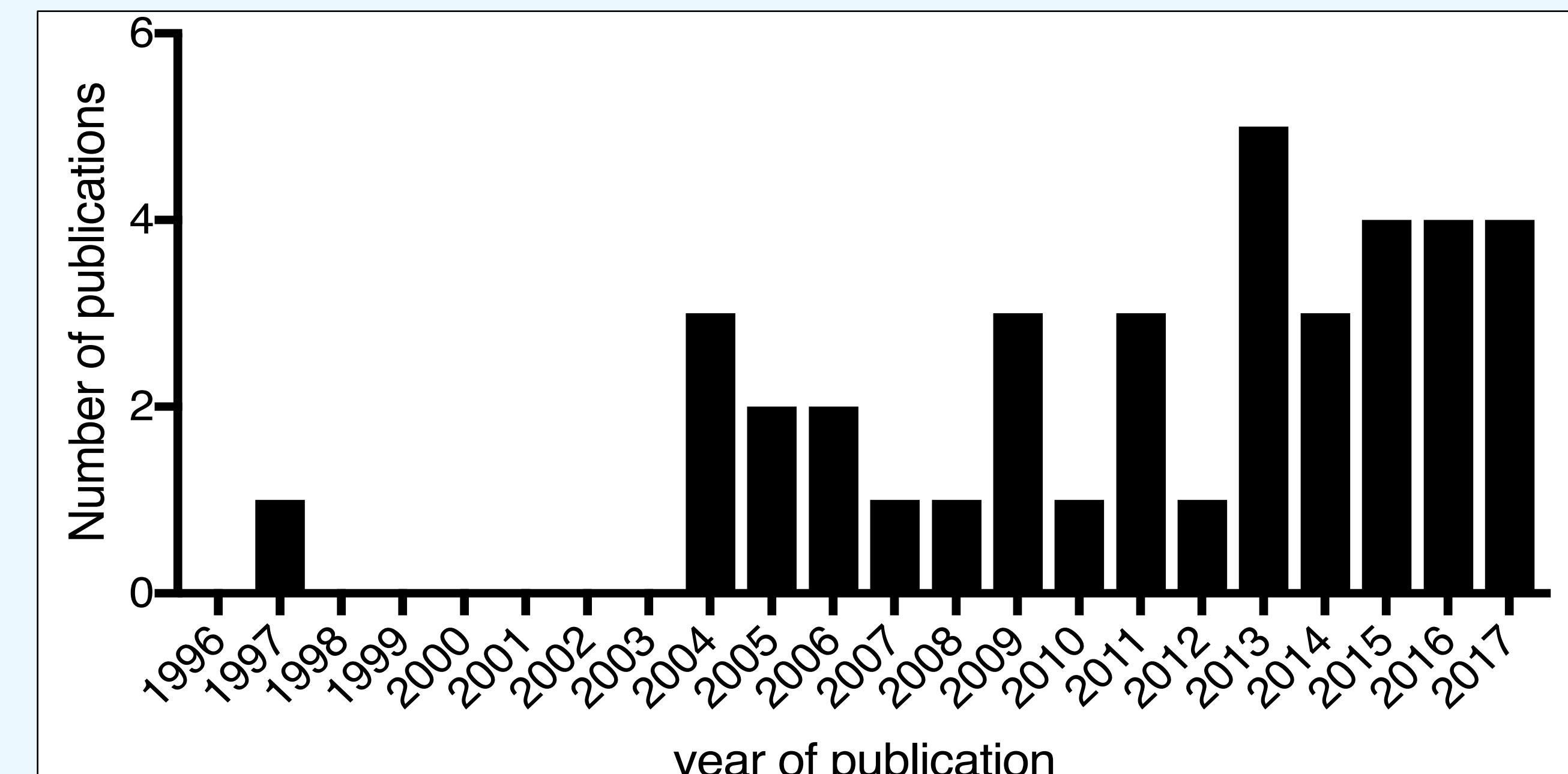


Figure 5:

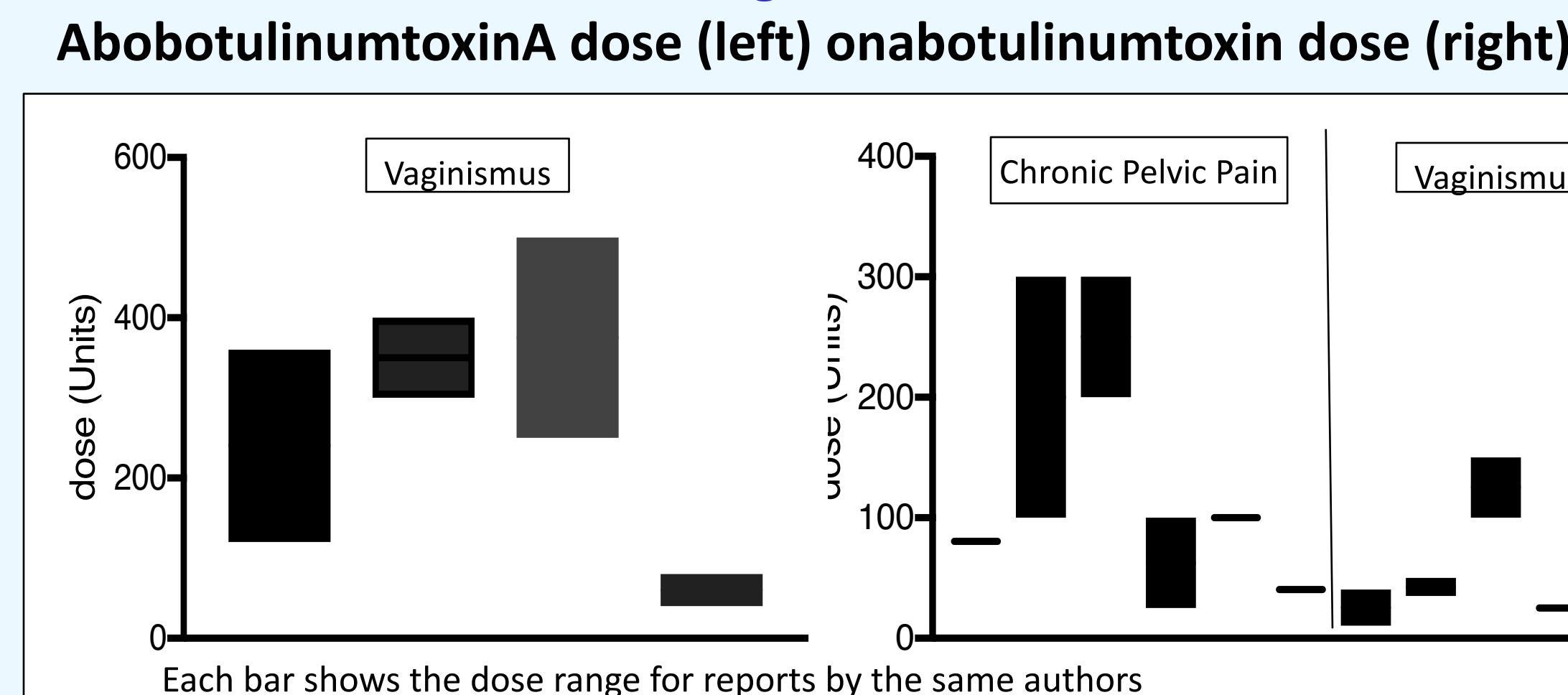


Table 1: Use of sedation/anesthesia

Anesthesia method	Number of reports (N=29 unique reports)
No anesthesia/sedation	2
General anesthesia	4
Conscious sedation with/without topical local anesthesia	7
Local agent only post injection	3
Pudendal block	2
No information	11

Outcome of Injection

The most common outcome measure was patient self-report. Excluding single case reports and duplicate reports, response rates ranged from 58-100%. In papers utilizing VAS to assess pain, scores decreased 19-100%. There were insufficient data to evaluate response by toxin brand, dose, or approach to injection. The sole double-masked, placebo-controlled study of randomized 60 women to 80U onaBoNTA or placebo. Pain decreased in both cohorts. The BoNT cohort only had a significant decrease in resting pelvic floor pressure and in nonmenstrual pelvic pain compared to baseline. For vaginismus, 71-100% achieved intercourse or reported significant decrease in pain with intercourse. Some patients with vaginismus had permanent resolution with a single injection.

Twenty unique reports provided information on adverse events; nine identified no adverse effects. Adverse events attributable to the mechanics of injection included injection site tenderness and minor bleeding. The most frequent adverse effect due to BoNT was new or worsening urinary incontinence. Urinary retention, constipation, and fecal incontinence were also reported. Adverse events were similar with transvaginal and transperineal approaches. There were enough studies on onaBoNTA to confirm that new fecal incontinence/constipation and new urinary incontinence/retention occurred predominantly with doses over 100 Units (Figure 8). It was not otherwise possible to associate drug-related adverse events with drug, dose or technique. Other adverse effects include flu-like symptoms, excessive vaginal dryness, and worsened vaginal prolapse. There was a single report of ischiorectal fossa abscess after transvaginal injection for chronic pelvic pain.

Conclusions

- Botulinum toxin can be used in outpatient settings to treat chronic pelvic pain in women.
- Bowel and bladder adverse events are more likely with higher doses.
- There is insufficient evidence to guide practitioners on optimal approaches to botulinum toxin injection for pelvic pain in women.
- Published reports omit information critical to the interpretation of results.
- Importantly, there is a critical lack of well-controlled clinical trials addressing the efficacy and safety of this emerging treatment.

Figure 6:

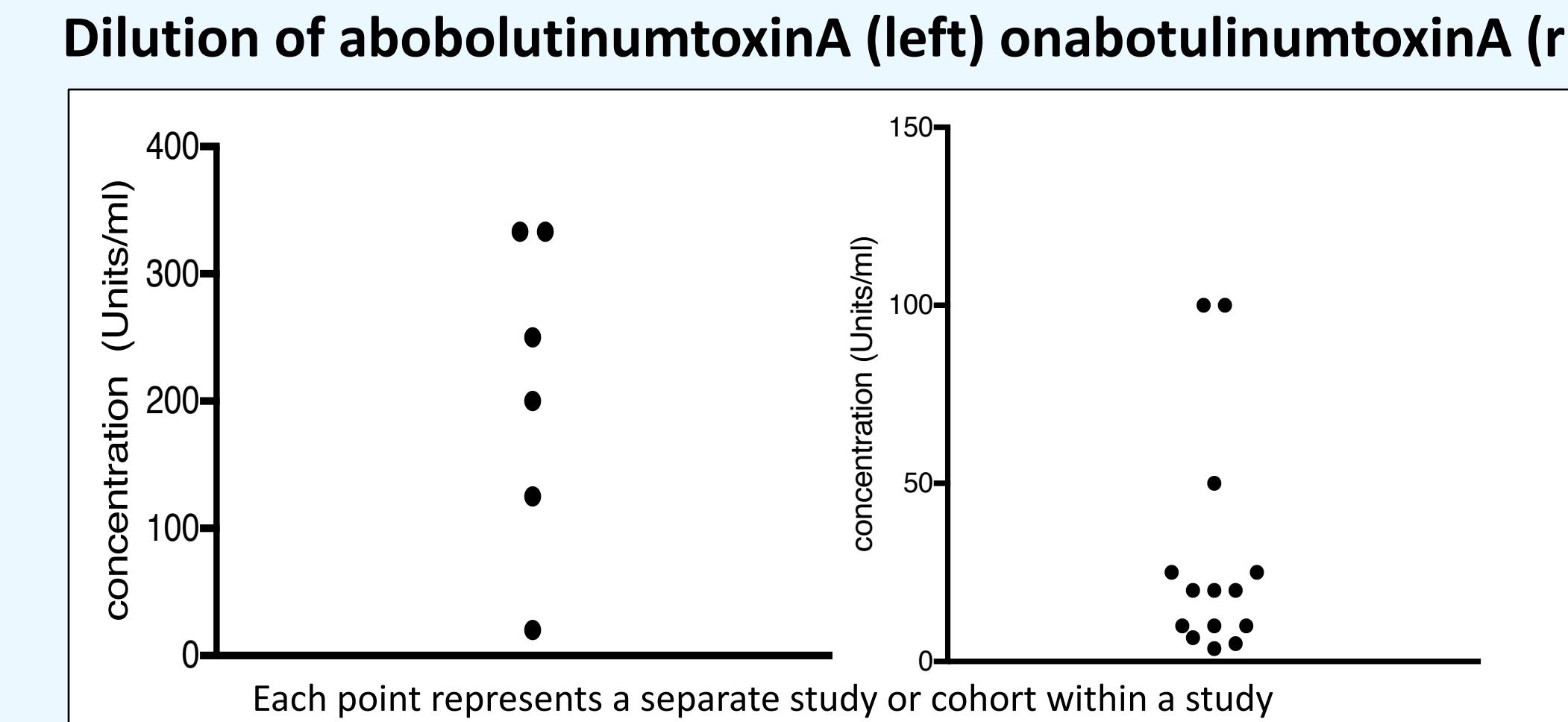


Table 2: Localization technique

Localization method	Number of reports (N=28 unique reports)
Anatomic landmarks	10
EMG	6
Electrical stimulation with/without ultrasound	2
Fluoroscopy/CT scanning	2
No information	8

Figure 8: Adverse effects by dose

