Pilot study of Botulinum Toxin Type A (Xeomin®) uterine muscle injections in the treatment of acute dysmenorrhea, uterine pain and deep dyspareunia.

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Introduction
Dysmenorrhea is a common complaint with a major impact on women’s quality of life, work productivity, and healthcare utilization (1). Primary dysmenorrhea occurs in 60% to 91% of women, 16% to 29% have severe dysmenorrhea-limiting activity, and 5% to 7% have acute dysmenorrhea.

Uterine pain syndrome (UPS) is one of the main causes of Chronic Pelvic Pain (CPP) in women, as well as other visceral pelvic pain, as Bladder pain syndrome (BPS) or irritable Bowel syndrome (IBS).

After having eliminated other causes of pelvic pain and specially endometriosis, UPS can explain acute dysmenorrhea but can also include painful uterine cramping, uterine contractions, pelvic heaviness, sensation of having a permanent period outside menstruation and also deep dyspareunia.

UPS and acute dysmenorrhea are strongly associated with uterine contractility. Recent development in the ultrafast magnetic resonance imaging techniques has enabled to observe significant correlation between pain degree and uterine contractility during menstruation (2).

Our team has been using Botulinum Toxin Type A since 2009 into pelvic floor muscles in case of pain and perineal muscles overcontraction. Considering the good results (3) in this indication we have applied Botulinum Toxin type A injection into the uterine muscle since 2016.

Aim
To investigate if Botulinum Toxin Type A (XEOMIN®) injected into the uterine muscle decreases pain symptoms and improves quality of life in patients presenting with acute dysmenorrhea, uterine pain and deep dyspareunia.

Patients
- 30 Women aged between 17 to 44.
- Presenting:
  - UTERINE PELVIC PAIN CRITERIA:
    - Both dysmenorrhea and UPS were associated in 24 patients (80%).
    - All patients had a uterine trigger point at clinical examination.
    - For 2 patients, severe deep dyspareunia was the main symptom.
  - ULTRASOUND AND PELVIC MRI:
    - Excluded endometriosis and severe adenomyosis.
    - 21 patients (70%) had previous negative laparoscopy.

Method
- Design: Prospective study
- Setting: Pelvi-Perineal Rehabilitation Private Centre l’Avancée, Aix-en-Provence, France.
- Patients were injected with 100 to 200 IU of Xeomin® into the uterine muscle.
- Maximum dose injected was 200 IU
- Pregnancy was contraindicated during the 4 months after the BT injection.
- Review of files of patients and following elements were noted:
  - Evaluation of pain levels (VAS): improvement, stable, worsening.
  - Quality of life scores: Outcomes Study SF-36 (MOS SF-36).
  - Criteria for pelvic central sensitization (PCS) according to the Convergences PP criteria (4).
  - Adverse events after injection.

Results (Fig 2)
- 30 patients (no lost during follow-up) were injected with 100-200 IU of XEOMIN® into the uterine myometrium over a period of 14 months (Dec 2016 - Feb 2018).
- Few adverse events: 2 women had a worsening (6,7%) of their pain in the immediate postinjection period but showed improvement at their first follow-up visit at 8 weeks.
- VAS scores were significantly improved for dysmenorrhea (80 vs 25; p = 0,01), dyspareunia (71 vs 28; p = 0,02) and non menstrual pelvic pain (67 vs 28; p = 0,03).
- Quality of life scores were markedly improved, parameters in the Sexual Activity Questionnaire were also improved with a significant reduction in discomfort (4,8 vs 2,2; p = 0,02) and improvement in habit (0,2 vs 1,9; p = 0,03).

Conclusion
Evidence from the present pilot study suggests that women with acute dysmenorrhea, UPS, and uterine deep dyspareunia may respond to BT injections into the uterine muscle. In patients with associated criteria for PCS, the improvement was nonsignificant. Further research into this novel indication is strongly recommended.