

TO ASSESS WHETHER BOTULINUM TYPE A TOXIN INJECTION TO THE PELVIC FLOOR IMPROVES SYMPTOMS AND QUALITY OF LIFE IN WOMEN WITH CHRONIC PELVIC PAIN (CPP) DUE TO PELVIC FLOOR MUSCLE HYPERALGESIA.

Hypothesis / aims of study

CPP is a common condition, affecting up to 15% of women [1]. Multiple aetiologies are implicated, including hyperalgesia of the levator ani secondary to muscle spasm [2]. Due to its muscle relaxing properties botulinum toxin type A has been proposed as a possible treatment in these women [3]. The toxin is produced from *Clostridium botulinum* and prevents acetylcholine release from peripheral presynaptic neurons at the neuromuscular junction. The exact mechanism of pain relief in women with CPP is still not fully understood, and effects on both the muscle and the sensory nerves may be involved.

Study design, materials and methods

Women with CPP were identified from tertiary centre gynaecology clinics. Women with confusable diseases, including other gynaecological, urological, colorectal, orthopaedic and/or neurological causes for pain were excluded. Patients were instructed how to report pain on digital palpation on a visual analogue scale (VAS). All women were assessed using a validated and reliable method of examination called the Pelvic Floor Muscle Hyperalgesia (PFMH) scoring system. Women underwent digital pelvic examination to determine levator ani muscle hyperalgesia. The right and left levator ani muscles including pubococcygeus, iliococcygeus, ischiococcygeus, obturator, bulbospongiosus, ischiocavernosus and deep/superficial transverse perineal muscle were palpated. All women were asked to report any discomfort evoked by digital palpation of the pelvic muscles and to rate severity of pain using a VAS. Those with a PFMH score ≥ 2 were consented to undergo injection of botulinum to the pelvic floor muscle under general anaesthetic. They received 200 IU of botulinum toxin type A, diluted in 20 mls of normal saline. The sites described above received 2 injections of 2mls of botulinum toxin type A bilaterally. Prior to treatment women completed the short form McGill pain questionnaire, and SF-12 questionnaire to assess physical and mental health. 4 weeks post treatment women completed the same questionnaires as well as the treatment satisfaction VAS. All patients were assessed with VAS for pain prior to discharge on the day of surgery. All terms and definitions used were in accordance with EAU & IASP terminology. The paired sample t test was used to compare scores pre and post treatment with the significance set at $p < 0.05$.

Results

A total of 24 women were recruited. 13 completed all the questionnaires pre and post treatment. The mean age was 42 (range 24 - 75yrs). All women had received previous treatments for pelvic pain, with a range from 1 to 12 treatments. These included pharmacological therapy (analgesic and opioids, neuromodulator agents including antidepressants and anticonvulsants), acupuncture, massage, psychotherapy and physiotherapy. All patients were discharged on the day of surgery with low VAS scores for pain (≤ 3).

Interpretation of results

There was a significant decrease in the mean sensory pain rating score after treatment. There was also a non-significant decrease in the mean affective pain rating score after treatment. The total pain rating index score significantly decreased after treatment. The intensity of pelvic pain experienced also decreased after treatment as did the overall intensity of total pain experience. Results summarised in table 1. Quality of life scores (SF-12) did not significantly improve after treatment. There was a non-significant improvement in emotional mood affecting work and other activities and an increase in the amount of energy women felt they had after treatment. Overall women reported 60-100% treatment satisfaction. There were no reported complications or side effects.

McGill Domain	Pre-treatment mean score	Post treatment mean score	P value
Sensory pain rating Index	19.6	13.6	0.012
Affective pain rating Index	4.6	3.4	0.166
Total pain rating Index	24.2	17.1	0.015
Present pain intensity	8.0	5.3	0.015
Overall intensity of total pain experience	4.0	2.4	0.018

Concluding message

This pilot study has promising results in a selected population where the cause of pelvic pain is secondary to pelvic floor muscle hyperalgesia. We have demonstrated a significant reduction in pain with botulinum toxin. Not surprisingly the SF-12, a generic quality of life questionnaire did not show a significant change due to lack of sensitivity of this tool. Future work should focus on the optimal dose and injection sites of botulinum toxin, and whether the procedure can be performed with local rather than general anaesthetic. Long term outcomes and larger studies are needed to confirm our preliminary data.

References

1. Best Pract Res Clin Obstet Gynaecol 2000;14:415-43
2. Journal of Reproductive Medicine, 51 (3), 185-189
3. Eur J Obstet Gynaecol Reprod Biol 2007; 133: 4-11

Disclosures

Funding: none **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Pilot study, using questionnaires, now applying for ethical approval **Helsinki:** Yes **Informed Consent:** Yes