

Botulinum Toxin-A Injection Treat Chronic Pelvic Pain Syndrome

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Pain management of patients with chronic pelvic pain syndrome (CPPS) is challenging, because pain is often refractory to conventional treatments. Botulinum toxin A (BTX-A) may represent a promising therapeutic strategy for these patients. This entry summarizes the literature for prospective studies evaluating the use of BTX-A in the treatment of CPPS. A pooled meta-analysis of the included studies was performed considering only patients underwent BTX-A injection and comparing pain scores evaluated at baseline and at the last available follow up. We found that BTX-A could be an efficacious treatment for some specific CPPS subtypes. Higher level studies are needed to assess the efficacy and safety of BTX-A and provide objective indications for its use in CPPS management.

Keywords: chronic pelvic pain ; botulinum toxin A ; bladder pain syndrome ; prostate pain syndrome ; gynecological pelvic pain

1. Introduction

Chronic pelvic pain (CPP) is defined as a chronic or persistent pain perceived in structures related to the pelvis lasting for at least six months. It is often associated with negative cognitive, behavioral, sexual, and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor or gynecological dysfunction. When there is no evidence of proven underlying disease accounting for the pain, it refers to a chronic pelvic pain syndrome (CPPS).

The management of CPPS is based on pharmacological and non-pharmacological interventions such as psychotherapy, physiotherapy, drugs and invasive treatments.

Botulinum toxin is a neurotoxin currently used for the treatment of various pain disorders. Several studies have addressed the role of BTX-A in the treatment of CPPS, even though with no definitive conclusion and subsequently no absolute indication in favour of its efficacy can be assumed. Aim of this systematic review is to investigate the efficacy of BTX-A injection in CPPS management.

2. Botulinum Toxin-A Injection Treat Chronic Pelvic Pain Syndrome

This systematic review was performed following the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) statement. We reviewed the literature for prospective studies evaluating the use of BTX-A in the treatment of CPPS. Comprehensive search in the PubMed, Scopus, Web of Science, and Cochrane Central Register of Controlled Trials databases was performed from English-language articles published between January 2000 and October 2021. The primary outcome was to evaluate pain improvement after BTX-A treatment. A pooled meta-analysis of the included studies was performed together with meta-regression analysis, considering only patients underwent BTX-A injection and comparing pain scores evaluated at baseline and at the last available follow up.

After screening 1001 records, 18 full-text manuscripts were selected, comprising 13 randomised clinical trials and 5 comparative studies. They covered 896 patients and several subtypes of CPPS: interstitial cystitis/bladder pain syndrome (IC/BPS), chronic prostatitis/prostate pain syndrome (CP/PPS), chronic scrotal pain, gynecological pelvic pain (GPP) and myofascial pelvic pain.

All data extracted from the included studies were recorded in an electronic database. To facilitate data comparison and interpretation we have divided all the studies evaluated into major subtypes of CPPS. A narrative synthesis of the main findings for each studies was provided. However, the clinical and methodological heterogeneity of studies included regarding the study design, the definition of CPPS subtype, intervention and control groups, number and sexes

of patients, type and dose of drug administered, number and location of injections delivered, outcome measured and time of follow up, make it difficult to do an overall estimation of the effect of BTX-A on pain and other functional outcomes of various CPPS subtypes (frequency and nocturia episodes and sexual function).

For the pooled meta-analysis, we included 21 cohorts of BTX-A treated patients coming from 14 studies for a total of 447 patients. Funnel plot based on standard error by Hedges's g among selected cohorts showed a low heterogeneity between the study. A significant reduction in pain scores, related to the scale adopted, was showed in the overall cohort ($p < 0.001$). Considering treated patients grouped according to CPPS subtypes, we found a significant improvement in pain relief in IC/PBS ($p < 0.001$, 192 patients), CP/PPS ($p = 0.005$, 73 patients), and GPP ($p < 0.001$, 120 patients), even if some studies did not reach a significant improvement when independently considering.

Moderator meta-regression analysis did not find any significant influence of the considered factors. However, the number of site injection showed a significant trend in IC/BPS patients underwent only trigonal BTX-A injections ($p = 0.051$).

3. Discussion

Management of CPPS needs a holistic approach with the patient active involvement. Indeed, most of the times single interventions do not work in isolation and should be considered together in order to give the patients a personalized care. CPPS should be addressed in a multispecialty and multidisciplinary environment with the collaboration of different experts, such as urologists, gynecologists, pain therapists and physiotherapists to take in consideration all patients symptoms. History, followed by physical examination are the first step to evaluate patients with CPP and collect all functional and pain-related symptoms aiming to identify the CPPS subtype and select the best treatment options.

BTX-A for the treatment of CPPS is still an off-label use. In European Association of Urology (EAU) guidelines, BTX-A is reported as a treatment option only for CP/PPS, pelvic floor pain and chronic primary anal pain syndrome. However, there are conflicting results in literature, among studies assessing the real effect of BTX-A in the treatment of CPPS.

In this systematic review we investigated the efficacy of BTX-A injection in CPPS management. We have selected only prospective studies and then have grouped them among CPPS subtypes to facilitate data interpretation, analyses and comparison. However, the methodologically and clinical heterogeneity between the included studies make it difficult to interpret data uniquely and to draw definitive conclusions. The studies included in our work used different criteria to define the specific CPPS sub-category, and different BTX-A formulations. Moreover, several diagnostic tools were used to evaluate outcomes like lower urinary tract symptoms, sexual function, bowel function and quality of life as well as the time at which the measurement was done was different.

Another aspect poorly investigated is the real prevalence and nature of adverse events/side effects. Among IC/BPS studies the main complications associated with BTX-A injections included urinary tract infections, transient voiding difficulties, and gross hematuria. In CP/PPS no serious or systemic complications were recorded, except for mild gross hematuria or haematospermia, while in the GPP groups urinary incontinence, injection site pain and flu-like symptoms were reported. Future studies need to standardize the way to report of the adverse events/side effects and the time of their occurrence.

We performed a pooled meta-analysis and moderator meta-regression analysis including only BTX-A treated patients who were evaluated comparing pain at baseline and at last available follow up time. We showed a pain perception's improvement in all cohorts underwent treatment in the overall population and in specific disease populations (IC/BPS, CP/PPS, GPP), even if some studies did not reach a significant improvement when independently considering. In meta-regression analysis no clinical factors were found to influence the treatment efficacy. However, a trend was found for the number of site injections in IC/BPS patients who underwent BTX-A injection in the bladder trigone only.

4. Conclusion

The methodological heterogeneity of the included studies and the main data reported showed that, even if chronic pelvic pain as well as urinary and sexual symptoms may benefit often from the use of BTX-A injected in pelvic structures, with low rates of complications, the current level of evidence is too low to provide recommendations on its use in daily clinical practice.

However, we showed a pooled meta-analysis of prospective studies demonstrating a statistically significant pain relief after BTX-A injection compared to baseline values for some specific CPPS subtypes.

Higher level studies are needed to assess the efficacy and safety of BTX-A and provide objective indications for its use in CPPS management.

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