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GIBS NEWSLETTER

GLOBAL INTERSTITIAL CYSTITIS BLADDER PAIN SOCIETY

BOTOX - NEW AVATARS IN IC/BPS

Clinical symptoms of interstitial cystitis/bladder pain syndrome (IC/BPS) are shared with other comorbid diseases such as irritable bowel syndrome, fibromyalgia, chronic fatigue anxiety and depression. To date, there are no gold standards in the diagnosis or detection of IC/BPS and clinicians have to rule out several symptoms and classify the patients in different phenotypes of the disease. The current therapy has been concentrating on symptom relief with topical agents and bladder irrigations as well as thermal treatment of the Hunner's lesions and hydrodistension.

The role of Botulinum Toxin A (BoNT-A) in IC/BPS treatment have been the subject of many studies. It has been proposed in several studies that BoNT-A is effective in reducing bladder hypersensitivity and increasing capacity through the effects of anti-inflammation in the bladder urothelium; however, studies on the treatment outcome of IC/BPS are lacking.

Both animal and human studies have investigated a possible effect of BoNT-A on the afferent pathways of the lower urinary tract (LUT), exploring markers of neurochemical inflammation - sensory neuropeptides such as calcitonin gene-related peptide (CGRP) and substance P (SP), nerve growth factor (NGF), inflammatory markers (mast cell tryptase, prostaglandins and cyclooxygenase), as well as on histological inflammation.

Furthermore, a possible attenuation of bladder afferent activity following BoNT-A administration could be associated with a reduction of the increased urothelial ATP release during bladder distension, as in an animal model of chronic bladder inflammation induced by repeat cyclophosphamide treatments. Nerve growth factor (NGF) has also been found to be increased both in the bladder tissue and urine of patients with IC/BPS compared to controls.

nterestingly, urinary NGF levels only increased during bladder distension and were not shown to correlate with either VAS scores or cystometric bladder capacity at diagnosis, or maximum bladder capacity during hydrodistension. Despite such discrepancies, decrease of urine NGF post-treatment with BoNT-A was higher in treatment responders.

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ISeveral clinical studies have confirmed the efficacy of BoNT-A in patients suffering from IC/BPS. Long term results of repeated injection have confirmed clinical efficacy of BoNTA in IC/BPS associated with decrease of chronic inflammation and apoptosis. However, inconsistency in the results of these studies makes interpretation of the efficacy of BONTA in IC difficult.

Moreover, BoNTA in IC/BPS was not shown to be effective in randomized controlled studies. A meta-analysis found that injection of BoNTA led to statistically significant improvement in subjective indices such as OLS, ICPI and VAS as compared to placebo. There was a statistically significant difference only in frequency and PVR among objective indices including nocturia, Q max and functional bladder capacity.

There was no statistical difference, except for dysuria in adverse events. A randomized study that investigated the efficacy of the intravesical administration of liposome-encapsulated BoNT-A vs. intravesical administration of plain BoNT-A vs. placebo in patients with refractory IC/BPS, found that improvements in the patient-reported outcomes in the active treatment groups were no better than the placebo effect.

A very recent retrospective study on treatment outcome in IC/BPS patients receiving 100 U intravesical BoNT-A injection. in the past 20 years showed that about 40% of the included patients had significantly satisfactory treatment outcomes. The satisfactory group showed significantly larger voided volumes, and lower levels of both the urinary inflammatory protein MCP-1 and the oxidative stress biomarker 8-isoprostane in comparison to the unsatisfactory group.

In conclusion, despite level of evidence 1 data available on the effect of intravesical BoNT-A treatment on symptoms of IC/BPS (randomized trials), a consistent overall conclusion cannot be drawn at the moment as these studies do not appear to consistently support a positive effect. In addition, the most studies are small and heterogeneous in design, particularly in administration technique, including variability in injection sites, doses used and method of administration.

There is a clear need for large, prospective randomized trials with long term follow-up. Both symptom and treatment evaluation should be conducted in a standardised, uniform way in order to adequately compare results. Patient-reported outcomes and quality of life should be assessed in addition to urinary and pain symptoms. It is thus proposed, that centres of excellence become involved in such future research using not only urine but also bladder specimens, which should aim at elucidating both the current theories concerning the pathophysiology of the disease, as well as at phenotyping of patients, possibly resulting in more patient-tailored treatments.

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