

## INTRAPROSTATIC INJECTION OF BOTULINUM TOXIN TYPE A FOR THE TREATMENT OF CHRONIC PROSTATE PAIN SYNDROME.

### Hypothesis / aims of study

Chronic prostate pain syndrome (CPPS) is the most common urologic affection in men under the 5<sup>th</sup> decade of life. Chronic inflammation and a low sensory threshold seem to be involved in the pathophysiology.

Botulinum toxin type A has inhibitory effects on pain mediators and inflammation which can result in a relief of PPS symptoms. This is the first reported evaluation of intraprostatic injection of botulinum toxin type A (dysport®) on patients with CPPS refractory to medical therapy.

### Study design, materials and methods

Men older than 18 years old with the diagnosis of CPPS for more than 6 months, with a NIH-CPSI score > 14 were included.

The first evaluation consisted in a brief neurologic examination, determination of the peak flow rate on free uroflowmetry, determination of prostatic volume and post voided residual urine by suprapubic ultrasonography. Urine culture and PSA were collected. After ruling out exclusion criteria, patients signed an informed written consent and answered the NIH-CPSI, IPSS, IIEF5 and VAS questionnaires. Anti-inflammatory, x blocker or antibiotic drug treatment was suspended.

Two weeks after the initial evaluation, patients undergone a transrectal ultrasound guided injection of 500 units of botulinum toxin A distributed in 4 spots (1 cc each) of the peripheral and transitional zone of the prostate.

Patients were re-evaluated at 4, 12, 24 and 52 weeks after the injection.

### Results /Interpretation of results

Fourteen patients were included at screening, 10 were eligible to proceed the study.

Baseline results are presented in table 1.

One patient developed acute prostatitis after injection and was treated with oral antibiotics. No other complications occurred.

We registered an important relief of the symptoms, that translated in statistical significant improvement in the CPSI and VAS at each periodic evaluation (24% at 12 weeks and 44% at both 24 and 52 weeks for the CPSI and 25% at 4 weeks, 39% at 12, 56% at 24 and 53% at 52 weeks for the VAS respectively) (paired t-test; p<0,05).

No statistical significant differences were found in the IPSS and IIEF5 questionnaires neither on prostatic volume, PSA, peak flow rate, or PVR.

All patients stated that they would undergo the procedure again.

**Table 1- Baseline Results:**

	Mean	Standard deviation
Age (years)	55,9	8
Duration of symptoms (years)	2,4	1,1
VAS (0-10)	6,2	1,3
CPSI (0-43)	25,8	4,1
IIEF-5 (5-25)	17,2	5,3
IPSS (0-35)	13,7	6,6
PSA (ng/dL)	1,08	0,4
Qmáx (mL/s)	17,9	3,5
PVR (cc)	25	33,3
Prostate volume (cc)	27,5	4

### Concluding message

Intraprostatic injection of botulinum toxin A reduced significantly CPPS symptoms in patients refractory to other therapies. The treatment didn't interfere with the erectile function. Future randomized studies are needed to validate our findings.

### Disclosures

**Funding:** None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Comissão de Ética para a Saúde do Centro Hospitalar do Porto **Helsinki:** Yes **Informed Consent:** Yes