EFFICACY AND SAFETY OF BOTULINUM TOXIN A BLADDER INJECTION IN THE TREATMENT OF PAINFUL BLADDER SYNDROME/IC

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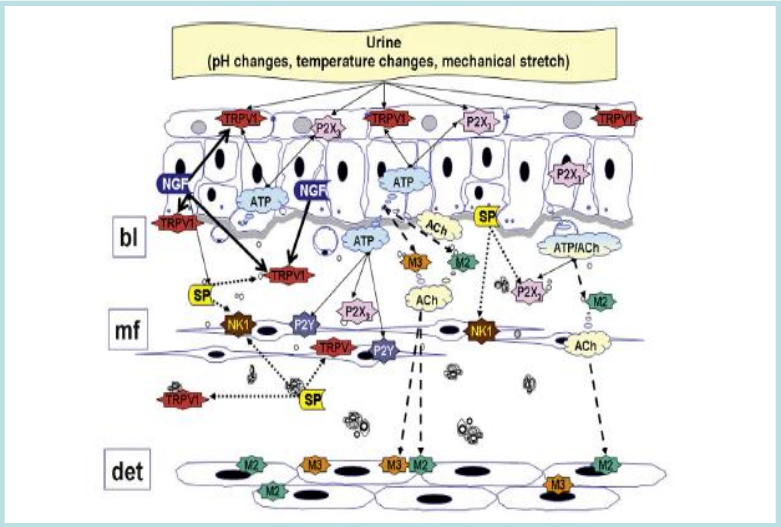
Introduction

- **BPS/IC defined as suprapubic pain related to bladder filling accompanied with other urinary sympton (ICS)**
- **PBS goal of treatment is pain relief but no effective treatment is established**
- **BoNT A decrease ATP release from urothelial cells and inhibits neuroplasticity sensory fibers in suburothelial space**
- **In addition, BoNT A inhibits P subtance, glutamate and CRPG in dorsal roots of spinal cord**



Recommendations on the Use of Botulinum Toxin in the Treatment of Lower Urinary Tract Disorders and Pelvic Floor Dysfunctions: A European Consensus Report

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OBJECTIVE

- **Evaluate the efficacy and tolerabilitty of Botulinum Toxine (BoNT A) bladder injections in patients with Painful Bladder Syndrome/IC refractory to conventional treatments**

- **To compare the efficacy and tolerability of BoNT A injections plus hydrodistension (HD) with BoNT A alone in patients with Painful Bladder Sd /IC refractory to conventional treatments**

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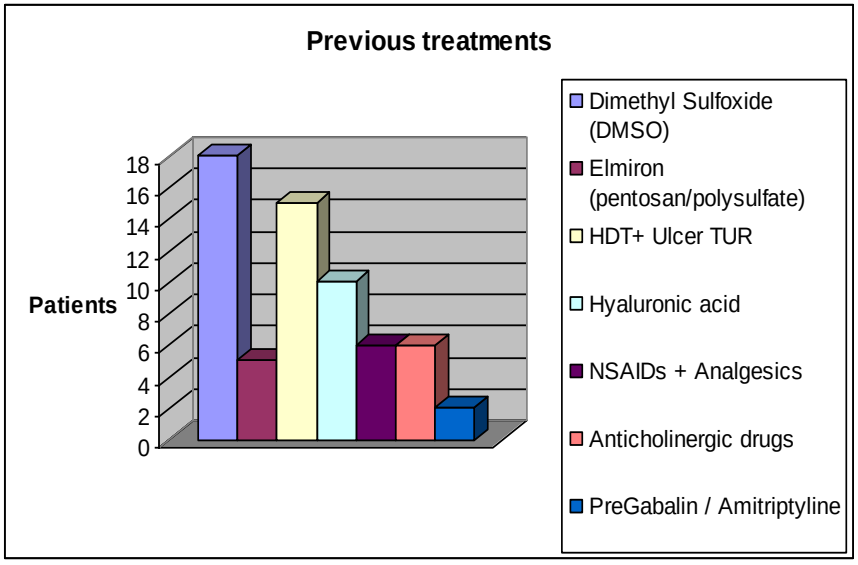
Patients&Methods

A Retrospective study of medical and functional outcomes of 41 patients with refractory PBS/IC, treated with BoNT A injections in our institution was performed



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Surgical Procedure

Under Sedation or Spinal cord anesthesia

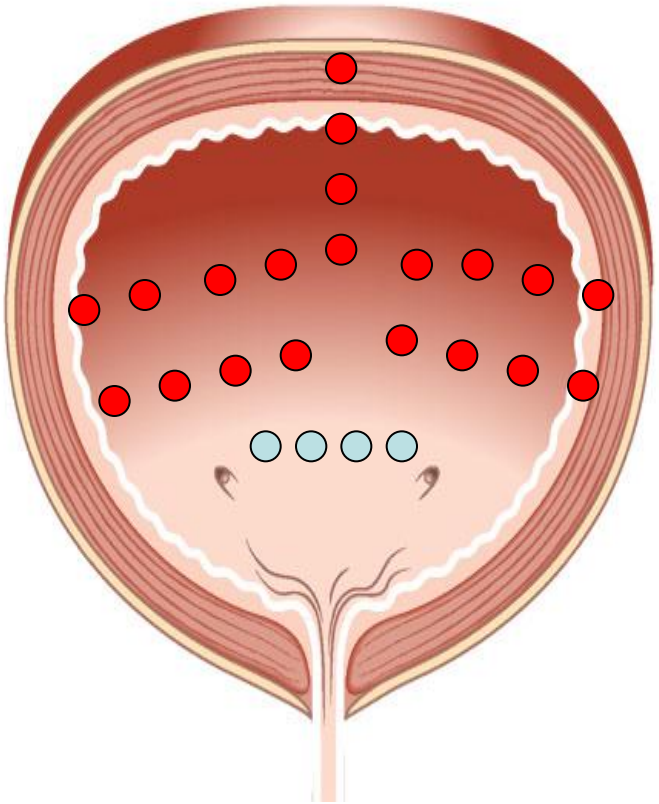
<u>Injection</u>

- 100 UI (250UI)/2cc SS submucosally in the trigone
- 100 UI (250 UI)/10cc SS: in detrusor floor

<u>Hydrodistension</u>

- 80 cm H2O
- 10 minutes

+ TUR biopsy if 1st procedure



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Outcome Measurements

- **Clinical and Functional parameters**
  - **Objetive :**
    - **3 days Voiding Chart**
    - **Uroflowmetry + PVR**
  - **Subjetive :**
    - **Visual Analogue Scale (VAS)**
    - **Global assesment responde (from 1-10)**

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Results

- Retrospective evaluation
- 2008- 3/2015
- 41 patients
- Surgical Procedure
  - 26 p BoNT A + Hydrodistension
  - 15 p BoNT A

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Objective Parameters

3 days voiding chart

Test Shapiro Wilk

	Baseline (Mean,sd)	Post (Mean,sd)	t Student	Mean Difference	IQR 95%
FBC (ml)	73(25)	115(55)	p ‹ 0.003	+ 42	42 / 40
Daytime frequency	20 (10)	16 (10)	NS	- 4.3 times	16/67
Night time frequency	7 (2,7)	4 (3)	p< 0.001	- 2.5 times	1/4

Objective Parameters

Uroflowmetry + Post Void Residual Volume

Uroflowetry (Mean / SD)		Baseline (Mean,sd)	Post (Mean,sd)	t Student	Mean Difference	IQR 95%
Voided volume	Wilcoxon	100 ml (56)	191ml (107)	p<0.001	+91	42-140
PVR volume	Wilcoxon	28 ml (42)	40ml (42)	NS	+ 11	16-40

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Subjective parameters/VAS

- Global response assesment : 0-10

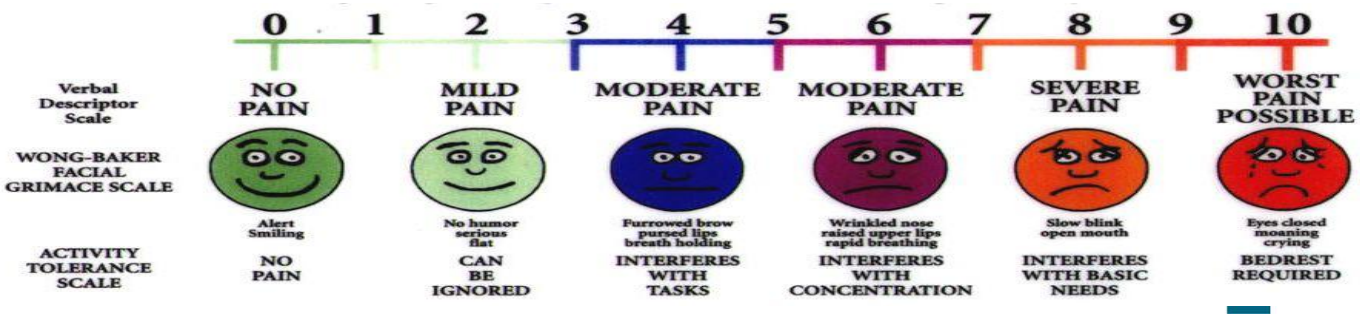
  ≥ 6 : 25p (61%)

  ≤ 5 : 16 p (40%)

8p
No PAIN (20%)

- VAS baseline: 6

VAS 3



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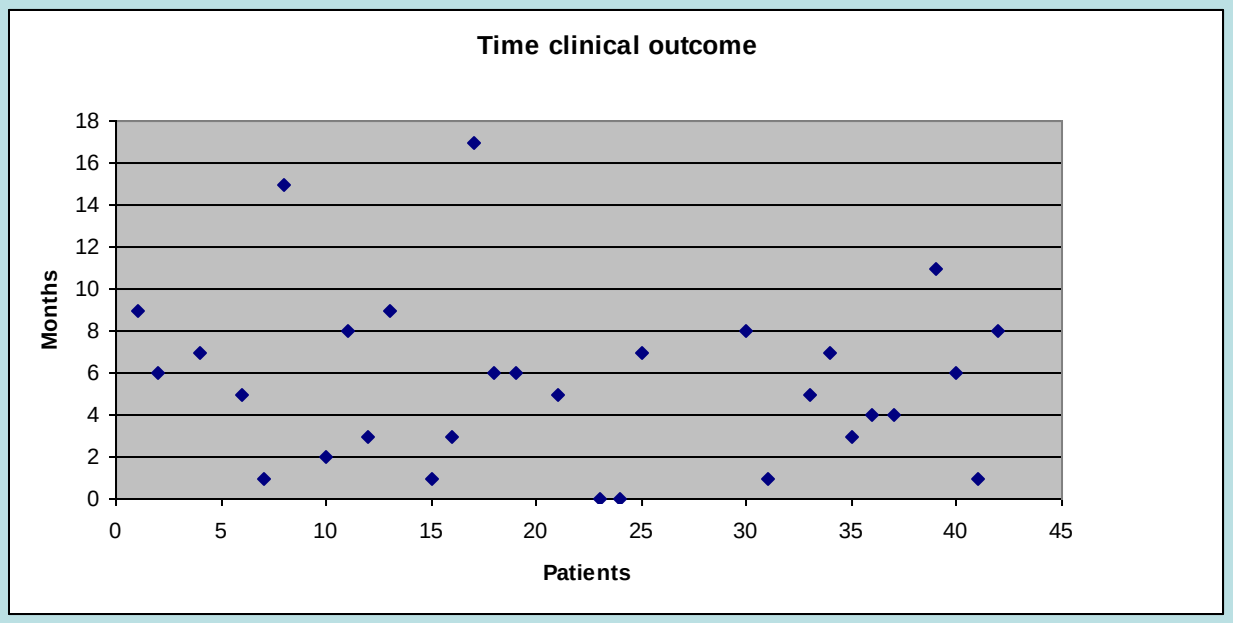
Time clinical outcomes

- **Clinical improvement lasted 7 months as an average (range 3-18 months)**



Adverse Events

- 4 patients reported incomplete bladder emptying
- No significant increase PVR

  28 ml to 40 ml
- 1 urinary retention (catheter for 1 month)
- 5 UTI

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BoNT A+HDT vs BoNT A

Mean (SD)	FBC (ml) Baseline	Post treatment	Day time Frequency Baseline	Post treatment	Night time Frequency Baseline	Post treatment
BoNT A+HD	88 (66-110)	154 (97-211)	21 (15-26)	15 (8-23)	7 (6-8)	4 (3-5)
BoNT A	62 (50-74)	109 (54-165)	20 (14-26)	16 (7-25)	7 (6-8)	5 (2-8)
Diference	NS		NS		NS	

BoNT A+HDT vs BoNT A

Mean (iqr)	BoNT A+ HD	BoNT A	Diference
GRA	7 (6-8)	4 (1-6)	p‹0.02
Clinical Response (months)	8 (6-10)	7 (1-14)	NS
Hospitalization Stay (days)	2.5 (2-3)	1.5 (1-2)	NS

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Conclusions

- **BoNT A (alone or combined with HDT) was an effective and safe treatment for refractory PBS/IC in our study**
- **Improvement in voiding chart , nighttime frequency and voided volume in uroflowmetry showed statistically significance**
- **Clinical improvement lasted an average of 7 months (3-18)**

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Conclusions

- **Injections of BoNT A+ HDT did not significally improve objective parameters compared with injections of BoNT A alone in the treatment of PBS/IC**
- **Subjectively patients reported better outcomes with BoNT A+ HDT than injections alone**
- **Association of HDT do not significally increase hospitalitation stay**

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