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DISCREPANCY OF THE IMPACTS OF INTRAVESICAL HYALURONIC ACID ON PAIN AND URINARY SYMPTOMS IN WOMEN WITH REFRACTORY INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME AND PREDICTORS OF TREATMENT OUTCOMES: RESULTS FROM A MULTICENTER STUDY INCLUDING 103 PATIENTS.

Hypothesis / aims of study
Interstitial cystitis/bladder pain syndrome (IC/BPS) is a symptom syndrome characterized by bladder pain accompanied by other urinary symptoms (i.e., urgency, frequency and nocturia). Intravesical therapy with a hyaluronic acid (HA) solution is an acceptable treatment, however, with variable success rates reported. The primary aim of this study was to test our hypothesis that a discrepancy of the impacts of intravesical HA on pain and urinary symptoms of IC/BPS affects treatment outcome measures. The secondary aim was to evaluate factors that may have associations with treatment outcomes.

Study design, materials and methods
This was a prospective multicenter study. A total of 103 women with treatment refractory IC/BPS were enrolled and underwent a standard protocol of intravesical HA therapy. Symptoms, bother and sexual function were assessed using the Interstitial Cystitis Symptom and Problem Index (ICSI&ICPI), pain Visual Analog Scale (VAS), and a short-form sexual function questionnaire (PISQ-9). A Scaled Global Response Assessment (GRA) also provided patients' perception of overall changes in pain and urinary symptoms, respectively. Data were analyzed with univariate methods or multivariate logistic regression analysis accordingly.

Results
Demographic data was presented in **Table 1**. Mean age and duration of symptoms was 43.6±11.8 and 5.1±5.0 years, respectively. No severe adverse events from the instillation were noted. ICSI, ICPI, pain VAS and PISQ-9 scores were significantly (P<0.001) improved after treatment (**Table 2**). Meanwhile, there were 73.3% and 47.2% of patients, respectively, reported a moderate/marked (≧ +2) improvement in pain and urinary symptoms on GRA (**Figure 1**), and the difference was statistically significant (P < 0.001). Besides, a multivariate logistic regression analysis showed “baseline pain score” (P=0.026) and “functional bladder capacity before treatment” (P=0.003) were correlated positively with the responses of pain and urinary symptoms to the treatment.

Interpretation of results
Intravesical HA is a safe and effective treatment for refractory IC/BPS. However, the treatment seems to be more efficacious in reducing pain compared to other urinary symptoms. Those patients who reported a lower pain score and reduced functional bladder capacity before treatment might be less likely to benefit from the treatment.

Concluding message
Intravesical HA is more efficacious in reducing pain compared to other urinary symptoms associated with refractory IC/BPS in women, and that may affect treatment outcome measures. Besides, several predictors for treatment outcomes were found in this study.

Table 1. Demographic data (n=103).

Patient characteristics	Value	Range
General data		
Mean age (years)	44.3 ± 11.5	(22-69)
% Menopause	32.0	(33/103)
Mean symptomatic years	5.1 ± 5.0	(0.5-30)
Mean functional bladder capacity (ml)	228.6 ± 70.8	(80-400)
*Urodynamic (filling & voiding cystometry) results		
Mean volume at first sensation to void (ml)	134.7 ± 53.0	(53-296)
Mean maximum cystometric capacity (ml)	258.6 ± 93.0	(87-615)
Mean bladder compliance at urgency (ml/cmH_2O)	89.2 ± 107.7	(1-464)
Mean voided volume (ml)	259.2 ± 116.0	(73-663)
Mean maximum flow rate (ml/sec)	15.3 ± 6.2	(5-30)
Mean average flow rate (ml/sec)	6.6 ± 3.5	(2-19)
Mean voiding pressure (cmH2O)	30.2 ± 19.3	(2-108)
Mean residual urine amount (ml)	24.6 ± 26.6	(0-148)
% Bladder hypersensitivity	49.4	(38/77)
% Detrusor overactivity	11.7	(9/77)
% Dysfunctional voiding	32.5	(25/77)
Cystoscopic findings with hydrodistention		
Mean anesthetic bladder capacity (ml)	506.3 ± 198.2	(200-1000)
% Advanced (grade II & III) glomerulations	93.2	(96/103)
% Hunner's ulcers	13.6	(14/103)

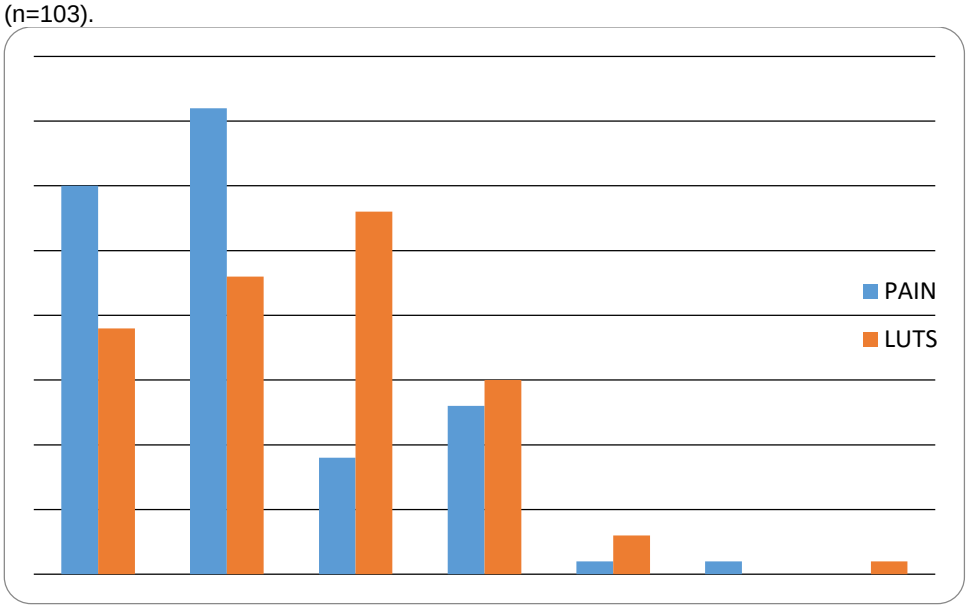
*: Urodynamic study was performed in 77 (74.8%) of the 103 patients.

Table 2. Changes of symptoms, bother, and sexual function (n=103).

	Baseline	1 month	6 months	*P-value
Pain VAS	6.3 ± 2.7	4.3 ± 2.5	3.3 ± 2.2	<0.001
ICSI	14.2 ± 3.8	10.3 ± 3.9	7.8 ± 4.0	<0.001
Urgency	3.5 ± 1.4	2.6 ± 1.3	1.9 ± 1.3	<0.001
Frequency	4.3 ± 1.1	3.1 ± 1.2	2.3 ± 1.3	<0.001
Nocturia	3.5 ± 1.3	2.7 ± 1.2	2.2 ± 1.3	<0.001
Bladder Pain	2.9 ± 1.7	1.9 ± 1.4	1.3 ± 1.2	<0.001
ICPI	13.0 ± 3.3	9.9 ± 3.3	8.4 ± 4.3	<0.001
Frequency	3.2 ± 0.9	2.7 ± 1.0	2.2 ± 1.2	<0.001
Nocturia	3.4 ± 0.9	2.7 ± 1.0	2.3 ± 1.4	<0.001
Urgency	3.1 ± 1.0	2.4 ± 1.1	2.0 ± 1.3	<0.001
Bladder pain	3.1 ± 1.2	2.3 ± 1.2	1.6 ± 1.2	<0.001
PISQ-9	18.9 ± 6.4	20.4 ± 5.8	21.5 ± 5.6	<0.001
Behavioral/emotive Factors	6.9 ± 4.0	7.0 ± 3.7	7.3 ± 4.0	0.260
Physical Factors	4.8 ± 2.2	5.5 ± 1.9	5.9 ± 1.9	<0.001
Partner-related Factors	7.6 ± 2.6	8.2 ± 2.4	8.5 ± 2.3	<0.001

VAS: visual analog score (range 0-10); ICSI: interstitial cystitis symptom index (range 0-20); ICPI: interstitial cystitis problem index (range 0-16); PISQ: pelvic organ prolapse/urinary incontinence sexual function questionnaire (PISQ-9 range 0-36); *: Friedman Test.

Figure 1. Distribution of responses of pain and urinary symptoms to intravesical therapy with a HA solution on the 7-point GRA (n=103).



Disclosures
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