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THE USE OF HYALURONIC ACID (HA) BLADDER INSTILLATION PLUS HYDRODISTENSION IMPROVE SUBJECTIVE SYMPTOMS BUT NOT URODYNAMIC PARAMETERS IN PATIENTS WITH INTERSTITIAL CYSTITIS / BLADDER PAIN SYNDROME (IC/BPS) - PROSPECTIVE CASE CONTROL STUDY

Hypothesis / aims of study

Bladder epithelium is not only defence to infections but also a tissue with afferent and efferent function as release of mediator and playing an important role in the pathogenesis of lower urinary tract dysfunction (LUTD). IC/BPS is one of LUTD that can be pathophysiologically linked to defects in the glycosaminoglycan (GAG) mucosal layer. Recent studies supported that 65% of positive response rate after bladder instillation of HA was noted in IC/BPS patients but lack of control group and outcome parameters only subjective symptoms were included. The aim of this study was to compare efficacy with HA bladder instillation plus hydrodistension and only hydrodistension by using subjective symptom scores and urodynamic parameters.

Study design, materials and methods

This is a prospective case control study. 64 patients (age 27-65 year-old) compatible with the NIDDK criteria and all patients were not previously treated for IC/BPS before hydrodistention were enrolled in this study. Among the patients, 32 patients were assigned to receive hydrodistension and four times weekly plus two tomes monthly bladder instillation of 40mg HA (HA group) and other 32 patients were assigned to receive hydrodistension only as control group. Validated questionnaire including O'Leary-Sant Symptom (ICSI) and Problem Index (ICPI), bladder pain visual analogue scale (VAS), bladder urgency score, and Global response assessment (GRA) were collected at 4^{th} month, 6^{th} month, and baseline as before therapy. Urodynamic examination was also performed at baseline and 4^{th} month.

Results

Patient demographics showed no difference between two groups. Highly significant improvement of ICSI/ICPI, PUF, VAS, urgency score, and GRA was observed at 4^{th} month compare to control group respectively (6.9 v 10.2, 4.7 v 9.2, 11.3 v 15.5, 3.2 v 4.4, 3.4 v 5.5, 57.8% v 45.3%, $p<0.05$). The trend was also observed significantly compare to control group at 6^{th} month except VAS. (Table 1) The change from baseline to 4^{th} month and 6^{th} month showed significant improvement including all subjective symptom score in HA group ($p<0.001$). (Table 2) However, there was no difference between 4^{th} month, 6^{th} month and baseline in control group. The change of urodynamic parameter including maximum flow rate (Qmax), the volume of first desire to void (FDV), and maximum cystometric capacity (MCC) showed no significant difference from baseline to 4^{th} month. Finally, no serious adverse events were recorded in this study except urinary tract infection (UTI).

Interpretation of results

The results of this study revealed that hydrodistension plus HA instillation improved subjective irritative symptoms and pelvic pain compare to hydrodistension only. Although there was no significant improvement in control group, the trend that improvement of subjective symptom score from baseline to 4^{th} month was observed but symptom relapse from 4^{th} to 6^{th} month was also noted. Hydrodistension provide short-term effect in patients with IC/BPS no more than 6 months.

Concluding message

The use of hydrodistension plus HA instillation provided effect in reducing subjective symptoms but not objective urodynamic parameters in IC/BPS patients compare to hydrodistension only . However, bladder pain syndrome was relapse first in our follow-up at 6^{th} month. The improvement of pain was difficult to complete by using HA instillation plus hydrodistension due to multi-pathogenesis of IC/BPS.

Table 1 Change at 4^{th} & 6^{th} month in HA compare to control group showed significant improvement except VAS at 6^{th} month

(A) 4^{th} month ($p<0.05$)

	VAS Pain	Urgency	ICSI	ICPI	PUF	GRA
HA x 9	3.2	3.4	6.9	4.7	11.3	57.8%
Control	4.4	5.5	10.2	9.2	15.5	45.3%
P value	0.05	0.0004	0.0001	0.0001	0.0062	0.02

(B) 6th month (p<0.05 except VAS pain)

	VAS Pain	Urgency	ICSI	ICPI	PUF	GRA
HA x 9	3.4	3.6	7.6	5.7	12.1	52.5%
Control	4.4	5.5	10.	9.7	17.4	38.2%
P value	0.07	0.014	0.01	0.0004	0.0025	0.02

Table 2 Change from baseline to 4th & 6th month in HA group showed significant improvement in subjective symptoms

(A) Change from baseline to 4th month (p<0.01)

	VAS Pain	Urgency	ICSI	ICPI	PUF
HA x 9	-2.0	-3.4	-6.0	-6.8	-9.2
P value	0.0004	<0.0001	<0.0001	<0.0001	<0.0001

(B) Change from baseline to 6th month (p<0.01)

	VAS Pain	Urgency	ICSI	ICPI	PUF
HA x 9	-1.9	-3.1	-5.2	-5.8	-8.3
P value	0.001	<0.0001	<0.0001	<0.0001	<0.0001

Disclosures
Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Research Ethics Committee of Fong Yuan Hospital **Helsinki:** Yes **Informed Consent:** Yes