

ANALYSIS OF CLINICAL RESULT OF PBS/IC PATIENTS TREATED WITH SODIUM HYALURONATE AND FOUR-DRUG COMBINATION INTRAVESICAL INSTILLATION

Hypothesis / aims of study

Painful bladder syndrome/Interstitial cystitis(PBS/IC) is characterized by pelvic pain, usually with urinary urgency and frequency, in the absence of infection or other identifiable causes. Although the aetiology of PBS/IC is still uncertain, urothelial dysfunction/GAG layer defects hypothesis has been widely accepted. Both hyaluronate and heparin can help to restore the GAG layer. But hyaluronate is too expensive for most Chinese patients, heparin is not as effective as hyaluronate for patients with PBS/IC, so we combined heparin with lidocaine, sodium bicarbonate, gentamicin as a cocktail to treat PBS/IC. This study aimed to assess the different outcome between patients treated with four-drug combination and sodium hyaluronate intravesical instillation. To seek a safe, practical, economic, effective therapy for PBS/IC.

Study design, materials and methods

There were 23 female patients with PBS/IC in total from Jan. 1, 2011 to Mar. 1, 2013. Ten patients received four-drug combination instillation (group A). Other 13 patients were given instillation of sodium hyaluronate therapy (group B). Clinical symptoms (frequency of urination per day, maximal micturition volume, visual analog scale (VAS) of pain, O'Leary-Sant symptom and problem index) were assessed at baseline and then again after 1, 6 and 12 months. Compare two therapies within curative effect and side effect, and assess their safety and efficiency. O'leary.sant index or frequency of urination decreasing no less than 25% was defined as symptom improvement.

Results

Twenty-two out of the 23 patients were followed up to 12 months. Patients of group A had no adverse events. One case of B group stopped treatment for recurrent urinary tract infection, and the other two cases felt painful in bladder area during instillation. 1, 6, 12 months after intravesical chemotherapy, IC symptom index (ICSI), IC problem index (ICPI), frequency of urination(FU), the maximal micturition volume (MMV) were improved in both groups of patients. Both group maintained about 70% improving rate after one year.

Interpretation of results

All indicators in group A and B were improved statistically significant after treatment compared to pretreatment ($P < 0.05$). But there were no significant differences between two groups in all time points for the outcomes ($P > 0.05$). The improving rate decreased with the time going, and the two groups had no significant differences in all time points as to the improving rate.

Tab1. ICSI, ICPI, FU, MMV before and after instillation in group A ($\bar{x} \pm s$).

Time	0	1m	6m	12m
ICSI	17.30±1.16	10.00±2.45**	10.20±2.94**	10.10±3.63**
ICPI	12.70±1.70	7.00±3.43**	7.50±3.41**	8.00±3.65**
FU	24.20±12.59	13.20±7.05*	13.90±8.11*	14.90.33±7.87*
MMV (ml)	226.40±44.23	358.00±60.33**	345.00±86.44**	348.00±84.30**

* $P < 0.05$ vs. pretreatment. ** $P < 0.01$ vs. pretreatment.

Tab2. ICSI, ICPI, FU, MMV before and after instillation in group B ($\bar{x} \pm s$).

Time	0	1m	6m	12m
ICSI	16.83±3.27	9.25±2.05**	9.92±3.42**	10.17±3.74**
ICPI	13.17±2.55	7.00±3.19**	7.33±3.82**	7.75±4.29**
FU	25.92±11.79	13.08±5.76**	13.75±5.62**	13.92±5.76**
MMV (ml)	188.33±39.50	328.33±105.47**	283.33±116.80*	297.50±104.63**

* $P < 0.05$ vs. pretreatment. ** $P < 0.01$ vs. pretreatment.

Tab3. Comparative analysis between two groups

Time	1m	6m	12m
ICSI-ICSI0	P=0.829	P=0.908	P=0.774
ICPI-ICPI0	P=0.723	P=0.691	P=0.689
FU-FU0	P=0.685	P=0.713	P=0.888
MMV-MMV0	P=0.800	P=0.592	P=0.573

Tab4. Improving rate after instillation in A and B groups

Time	1m	6m	12m
Group A	100%(10/10)	80.0%(8/10)	70.0%(7/10)
Group B	100%(12/12)	83.3%(10/12)	75.5%(9/12)

P value was determined using the Fisher exact test for proportions.

P value refers to the comparison of improving rate between Group A and B.

* P<0.05

Concluding message

Heparin focused four-drug combination intravesical instillation can achieve a similar effect with hyaluronic acid therapy in patients with urinary frequency, urgency, nocturia and severe lower abdominal or perineal pain symptoms. Four-drug combination therapy is safe and more economic.

Disclosures

Funding: no **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Medical ethics committee of peking university people's hospital **Helsinki:** Yes **Informed Consent:** Yes