

THE EFFECT OF CYSTISTAT TREATMENT ON PATIENTS WITH INTERSTITIAL CYSTITIS / PAINFUL BLADDER SYNDROME (IC/PBS)

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Definition

Interstitial Cystitis/Painful Bladder Syndrome is the pain or discomfort felt at the suprapubic or genital level, which intensifies as the bladder gets full and is accompanied by frequent urination at daytime and nighttime.

Diagnostic Criteria

- Clinical – hypogastric/urethral pain which intensifies as the bladder gets full; frequent urination, nocturia.
- Questionnaires – O’Leary/Sant, PUF, VAS pain scale
- Cystoscopy – bladder with glomerulations, ulcers
- Biopsy

Scopes

- Observational study to record the effect of Cystistat instillations on the pain felt by patients with IC/PBS, measured via VAS (Visual Analogue Scale) (main scope).
- Measuring urinary volumes and urination frequency prior to and after the treatment (secondary scope).

Method

- 12 week study, with 8 weeks of treatment:
- 8 weekly Cystistat instillations, after every one the patient to remain at bed rest for 20 minutes, changing his/her position every 5 minutes and then retaining the substance >1 hour.
- Patient tracking was executed using VAS (Visual Analogue Scale, where 0=no pain and 10=maximum pain) and an urination calendar at every 4-8-12 weeks.
- Statistical analysis of the mean VAS value trends – Wilcoxon test.

Investigations:

- Urinary calendar.
- Urinary summary, urine culture.
- Urinary system, pelvis ultrasound, post-urination residue
- Cystoscopy with a biopsy.
- VAS scale (maximum pain=score 10, no pain=score 0).

Included:

- 14 cases over a 4 month time period (OCT '08 – JAN '09).
- 12 cases had all the 8 instillations done and were evaluated:

- Age between 26-43 years old
- 11 females and 1 male
- VAS at inclusion between 7 and 9 (mean=8.2)

Conclusions

- Cystistat treatment reduced the pain in patients with IC/PBS.
- Administration is simple and accepted by the patients.
- An evaluation and tracking questionnaire for all patient symptoms is necessary.

Study Limitations

- The reduced number of subjects.
- Short tracking period.
- The lack of a control sample, seeing as 30% of IC/PBS cases can have spontaneous remissions.

Etiology

- IC/PBS is a chronic bladed inflammatory disease, of unknown etiology.
- A dysfunction of the urothelium leads to creating a sensitivity of the C fibers and to the activation of the mast cells.
- The GAG layer is essential in protecting the urothelium and in its homeostasis.

Treatment

- Substituting the GAG layer is the scope of instillation therapy.
- Used: heparin, hyaluronan, chondroitin sulfate.
- Cystistat = hyaluronic acid salt = hyaluronan.
- Is credited with ameliorations in 70% of treated cases.

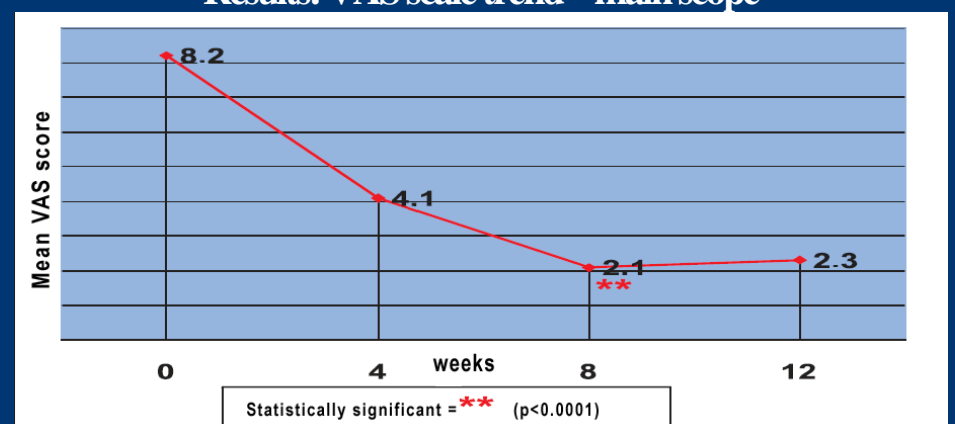
Inclusion Criteria

- Suprapubic or urethral pain which intensifies as the bladder gets full.
- >10 urinations per day and >1 urination at night
- Evolution >1 year and <3 years.
- Sterile urine culture.

Exclusion Criteria

- Patients previously treated with instillations or oral therapy.
- Prior urinal/gynecological system operations, irradiation, neurological problems.
- TV, post-urination residue > 100 ml.

Results: VAS scale trend – main scope



Results: secondary scopes

- The calendar showed a decrease in urination frequency by 1-4 urinations per day – mean values have no statistical significance
- Mean volumes per urination varied slightly, mean values have no statistical significance
- No adverse events were recorded
- No ITUs were recorded
- The patients are being tracked to determine the need for reintroducing the instillations; in literature, 34%.

Bibliography

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