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A NEW COMBINED INTRAVESICAL THERAPY FOR THE TREATMENT OF REFRACTORY INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME: CHONDROITIN SULPHATE AND HYALURONIC ACID. PRELIMINARY RESULTS

Hypothesis / aims of study
The primary outcome of our prospective study is to evaluate the efficacy of the intravesical instillation of chondroitin sulphate and hyaluronic acid in patients with Interstitial Cystitis after failure of other conventional therapies. The secondary outcome is to evaluate the tolerability and the side effects.
Study design, materials and methods
All of the following inclusion criteria were necessary: pain during bladder filling relieved after micturition; suprapubic, pelvic, urethral, vaginal or perineal pain; presence of glomerulations during hydrodistension; positive potassium sensitivity test.
Exclusion criteria were compatible with the NIDDK exclusion criteria.
All patients, before undergoing therapy, were evaluated using: clinical history, voiding diary for 3 days, Visual Analogue Scale (VAS) for pain, urgency, frequency and dyspareunia, O'Leary-Sant and Pain Urgency Frequency (PUF) questionnaires, urinalysis with urine culture and vaginal and urethral cultures, colposcopy and vulvoscopy, conventional urodynamic study, hydrodistension and potassium sensitivity test.
The study involved weekly bladder instillation with a solution of 40 ml of hyaluronic acid (High Molecular Weight) 1.6% P/V and chondroitin sulphate 2.0% P/V for 20 weeks, then every two weeks for one month and then once a month. The statistical analysis was carried out using t-test for dependent variables. We considered statistically significant $p < 0.05$.
Results
23 women were included in our study: age ranged from 20 to 65 years (mean 46.68, SD 13.63); median parity was 1 (0-2 deliveries). 13 women were post-menopausal. Mean follow-up was 5 months, range 3 to 8 months.
The evaluation of the voiding diaries showed a significant difference in both the number of daily voids (pre: mean 15.5, post: mean 13.9, p= 0.012) and the mean voided volume (pre: mean 143.13, post: mean 191.26, p= 0.006).
The analysis of VAS data demonstrated the following: mean score for pain - pre 5.65 and post 3.83, p= 0.001; mean frequency score - pre 7.43 and post 5.45, p= 0.065; mean urgency score - pre 6.23, post 3.63, p= 0.00005). The evaluation of the pre and post-treatment urodynamic studies showed no significant differences in any parameters (first desire, maximum bladder capacity, maximum flow rate and maximum detrusor pressure at maximum flow).
The O'Leary-Sant questionnaire showed the following results: pre 17.37 (mean 25.8, SD 4.81) post 10-29 (mean 20.1, SD 5.69) – p= 0.04; pre symptoms domain 8-23 (mean 13.9, SD 3.67), post 6.20 (mean 11.2, SD 3.75) – p= 0.0004; pre problems domain 7-16 (mean 11.5, SD 2.15) post 4-16 (mean 10.13,SD 3.14) – p= 0.01.
The PUF questionnaire revealed: pre 10-31 (mean 22.3, SD 5.18), post 6-31 (mean 17.4, SD 6.19) – p= 0.00004; pre symptoms domain 8-19 (mean 13.7, SD 3.35), post 3-25 (mean 11.6, SD 4.60) – p= 0.001; pre bother domain 2-21 (mean 8.6, SD 3.55), post 2- 12 (mean 6.1, SD 2.85) – p= 0.06.
No cases of intolerance and no side effects were observed.
Interpretation of results
The results demonstrate a statistically significant variation in urinary symptoms as shown by the voiding diary. These objective data are supported by the subjective patient's perception using the VAS for both frequency and urgency symptoms. Moreover the VAS shows a significant reduction in pain. The analysis of the O'Leary-Sant questionnaire shows a statistically significant improvement in both the symptoms and problems domains. On the other hand, the PUF questionnaire only showed significant improvement in the symptoms domain and not the bother domain.
Concluding message
This preliminary experience seems promising for intravesical treatment with chondroitin sulphate and hyaluronic acid in interstitial cystitis refractory to conventional therapies. A longer follow-up is necessary to confirm our initial data.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the San Carlo-IDI Sanità Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.