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EFFICACY OF TREATMENT WITH HYALURIL IN FEMALES WITH URETHRAL SYNDROME: A PROSPECTIVE ANALYSIS COMPARING NAIVE PATIENTS WITH SUBJECTS WHO EXPERIENCED PREVIOUS INEFFECTIVE TREATMENTS

Hypothesis / aims of study
Women affected by urethral syndrome (US) experience irritative disturbances, the urgency-frequency syndrome and/or pain associated. Usually, in these patients, cystocopy reveals typical lesions of the bladder mucosa characterized by the evidence of metaplastic tissue in the trigonal-bladder neck region (trigonitis). We prospectively evaluated efficacy of Hyaluril, a combination of ialuronic acid and chondroitin sulphate, on urinary and sexual symptoms in a cohort of females with US comparing treatment-naive patients (group 1) with those who previously discontinued other ineffective therapies (group 2).

Study design, materials and methods
All consecutive women who had been diagnosed with US were enrolled in the study. Exclusion criteria were: significant voiding dysfunction, stress urinary incontinence, neurologic status, pelvic organ prolapse >II stage, recurrent tract urinary infections. Three days-voiding diary, Overactive Bladder Questionnaire Short Form (OABq-SF), Indevus urgency severity scale (USS), the Patient Global Impression of Improvement (PGI-I) and Female Sexual Function Index were administered at baseline and after this treatment: intra-vesical administration of Hyaluril [sodium Hyaluronate 800mg/50ml (1.6% w/v) and sodium Chondroitin Sulfate 1g/50ml (2% w/v)] in prefilled syringes adopting the *following scheme:* 1 dose / week in the first 4 weeks, 1 dose every 2 weeks in the following 2 weeks and 1 dose / month for 2 months. Kolmogorov–Smirnov test, chi-squared test, Mann-Whitney Rank Sum, and Wilcoxon test were adopted to evaluate outcomes.

Results
66 women (30 in the group 1, 36 in the group 2) met the inclusion criteria, were treated and re-assessed after 4 months from baseline. The voiding diary showed a significant improvement in both groups; however this finding was significantly more relevant in the group of naive patients. The subjective success based on USS reduction and PGI-I was the 71.5% in group 1 and 39.4% in group 2 ($p<0.0001$). The FSFI data showed an improvement without any significant difference between the two groups. No systemic side effects were reported by patients; 8% of subjects described mild bother during catheterism. However, no symptoms or other disturbances were related after the administration of Hyaluril in the bladder and this procedure was well tolerated by all the cohort.

Concluding message
The US may be the consequence of a primary defective urothelium lining or from damaged glycosaminoglycans (GAGs) layer of the bladder. This condition may lead to chronic bladder epithelial damage and neurogenic inflammation. The main aim of new therapies is to restore the GAG layer and some favourable experiences have been already published in Literature regarding the administration of GAGs. In our experience treatment with Hyaluril improved urinary and sexual symptoms in women suffering from US. Naive patients achieved better results when compared to those patients who were previously submitted to other treatments. This results should clinicians to consider the chance to early administrate this type of treatment in subjects with this pathological condition.

	Group 1 (30 pts)	***Group 2 (36 pts)***	***p value***
Results of OABq-SF • Symptom severity scale • Quality of life scale	-32.50 +25.75	-15.25 +14.50	<0.0001 <0.0001
Change from baseline in USS	-2,5	-1.75	<0.0001
Efficacy PGI≤2	21.4 (75%)	14 (39.4 %)	0.005
Responders	25 (89.%)	14 (75 %)	<0.0001
FSFI Baseline	22.49±1.54	22.84±5.32	>0.05
FSFI Follow-up	26.98±3.28	26.32±2.95	>0.05
P value	<0.0001	<0.0001	

References
1. Phillip H, Okewole I, Chilaka V. Enigma of urethral pain syndrome: why are there so many ascribed etiologies and therapeutic approaches? Int J Urol 2014;21(6):544-8. doi: 10.1111/iju.12396.
2. Yoon SM, Jung JK, Lee SB, Lee T. Treatment of female urethral syndrome refractory to antibiotics. Yonsei Med J. 2002 ;43(5):644-51.
3. Kaur H, Arunkalaivanan AS. Urethral pain syndrome and its management. Obstet Gynecol Surv. 2007 May;62(5):348-51

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