A PILOT STUDY ON A NEW COMPOUND CONTAINING PURIFIED COLOSTRUM AND CHONDROITINE SULFATE SODIUM (CONTROCYST®) IN THE TREATMENT OF BLADDER PAIN SYNDROME.

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Hypothesis / aims of study

Treatment of lower urinary tract symptoms (LUTS) and pain in bladder pain syndrome (BPS) after recurrent urinary tract infections or chemical or radiation chronic cystitis is challenging. The EAU guidelines and the International Consultation on Incontinence recommend GlycosAminoGlycans (GAGs) as a standard of care to obtain a restoration of damaged urothelium in patients with chronic BPS. Aim of this study was to evaluate a new compound containing purified colostrum and chondroitine sulfate sodium (Controcyst®) with a hyaluronic acid/chondroitin sulphate compound (Ialuril Prefill®) in the treatment of lower urinary tract symptoms and pain in chronic BPS patients.

Study design, materials and methods

This is a prospective interventional medical pilot study of non-inferiority in patients treated with Controcyst® and hyaluronic acid/chondroitin sulphate compound (Ialuril Prefill®). A total of 30 female patients had to be included and divided through 1:1 randomization into two groups: Group A (undergoing instillation with Controcyst®); Group B (undergoing instillation with Ialuril Prefill®). Exclusion criteria were pregnant or lactating women, pediatric patients, non-self-sufficient (non-cooperative) patients, hypersensitivity to any of the constituent components. All patients were evaluated before and after treatment (8 intravesical administrations) with IPSS (International Prostatic Symptoms Score), IPSS QoL (International Prostatic Symptoms Score Quality of Life), VAS (Visual Analogue Scale) score for pain. They completed also a PGI-I (Patient-Global-Impression of Improvement scale - in a 7-grade score) only at the end of the treatment. Non inferiority of Controcyst® in comparison to the hyaluronic acid/chondroitin sulphate compound was obtained if patients treated with Controcyst® had shown a reduction in IPSS was greater than or equal to 80% compared to the control group treated with the hyaluronic acid/chondroitin sulphate compound. T-test was used to examine differences in the evaluated parameters before/after the treatment and between groups.

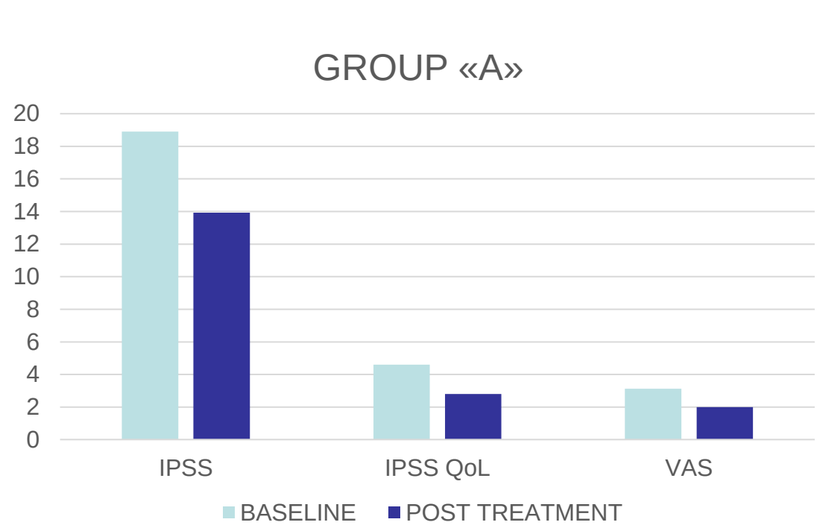
Results and interpretation

A total of 30 female patients (age range 35-72 years; average age 62,13 years) were included in the study. Patients with comparable baseline characteristics composed the two groups.

In Group A (Controcyst®), the value of IPSS showed a reduction from mean 18,9 to 13,93 (reduction of 26,30%, P value 0.02); IPSS QoL from mean 4,6 to 2,8 (reduction of 39,13%, P Value 0.0001); VAS from mean 3,13 to 2 (reduction 36,10%, P value 0.01) and PGI-I was 2,4. In Group B (Ialuril Prefill®), the value of IPSS showed a reduction from mean 20,9 to 17,53 (reduction of 16,12%, P value 0.02); IPSS QoL from mean from 3,86 to 2,73 (reduction of 29,27%, P value 0.02); VAS score from mean 2,46 to 1,86 (reduction of 25,60%, P value 0.12) and PGI-I was 2,93.

Non inferiority was demonstrated due to a comparable reduction of IPSS in the two groups, actually higher in the group treated with Controcyst® (-26,30% vs. -16,12%). Furthermore, no statistically significant difference in the reduction of IPSS, IPSS QoL, VAS and in PGI-I between groups was observed.

Although this pilot study shows only preliminary data on the efficacy of a new compound containing purified colostrum and chondroitine sulfate sodium (Controcyst®) in the treatment of chronic BPS, our results seem promising. This new compound shows comparable results in terms of reduction of IPSS, IPSS QoL and VAS as those observed using a product recommended in the EAU guidelines on chronic pelvic pain. Actually, the reduction of IPSS (that was used as measure of non-inferiority for Controcyst® vs. Ialuril Prefill®) was even higher in the group treated with the new compound. Finally, PGI-I was similar in the two groups.



Conclusions

This preliminary data seem to indicate a possible role of a new compound containing purified colostrum/chondroitine sulfate sodium in the treatment of chronic BPS after recurrent UTIs or chemical or radiation cystitis. Randomized controlled studies based on these findings will help to define the exact role of this agent in BPS patients.