14

Cervigni M[1], Sommariva M[2], Porru D[3], Ostardo E[4], Tenaglia R[5], Giammò A[6], Pappagallo G[7]
1. *Catholic University, Rome Italy,* ***2.*** *Urology Dept, "G. Fornaroli" Hospital, Milan,* ***3.*** *Urology Department, IRCCS San Matteo Polyclinic, Pavia,,* ***4.*** *Urology Department, Santa Maria Degli Angeli Hospital, Pordenone,* ***5.*** *Urology Department, "SS Annunziata" Hospital, Pescara,* ***6.*** *Neuro-Urology Dept, CTO-Maria Adelaide Hospital, Turin,* ***7.*** *Department of Medical Oncology, Mirano Hospital, Mirano*

A RANDOMIZED, OPEN-LABEL, MULTICENTRE STUDY OF EFFICACY AND SAFETY OF INTRAVESICAL HYALURONIC ACID AND CHONDROITIN SULFATE (HA 1.6% AND CS 2%) VS. DIMETHYL SULFOXIDE (DMSO 50%) IN WOMEN WITH BLADDER PAIN SYNDROME/INTERSTITIAL CYSTITIS (BPS/IC).

Hypothesis / aims of study
The aim of this study was to evaluate the efficacy and safety of intravesical instillations with high concentration HA 1.6% and CS 2.0% (Ialuril®, IBSA) *versus* DMSO 50% (RIMSO-50®, Bioniche Pharma) in female patients with diagnosis of BPS/IC.

Study design, materials and methods
Patients with ESSIC criteria, experiencing pain (pelvic pressure or discomfort) and at least one other urinary symptom (i.e. urgency or frequency) for at least six months were randomized using a 2:1 allocation ratio to receive 13 weekly instillations of Ialuril® or RIMSO-50®.
The primary endpoint was the difference in pain level on the Visual Analogue Scale (VAS) from baseline to 6 months (end of follow-up). The secondary endpoints were the difference in pain level on the visual analogue scale (VAS) from baseline to 3 months (end of treatment), urinary capacity and frequency (voiding diary) and the scores from three questionnaires (O'Leary–Sant Interstitial Cystitis Symptom Index and Problem Index, Pelvic Pain and Urgency/Frequency Symptom Scale and EQ-5D) from baseline to 3 and 6 months. The ITT population consisted of 110 patients, 74 treated with Ialuril® and 36 with RIMSO-50®, aged 50.24±15.86 years (range 18-88). At baseline, mean pain VAS scores of 65.53 (SD 21.00) and 64.58 (SD 20.53) were reported in the Ialuril® and the RIMSO-50® group, respectively. During the 3-month treatment period, only 3 patients in the Ialuril® and 4 in the RIMSO-50® group dropped-out for inefficacy.

Results
At the-end-of-treatment visit, the response to treatment in terms of pain decrease from baseline was statistically significant in both groups, with a VAS score reduction of *-39.27 (SD 24.52)* for Ialuril® and of *-31.00 (SD 26.38)* for RIMSO-50®. The responders at 6 months (30% VAS reduction from baseline) were 73% for Ialuril® and 58% for RIMSO-50®. There was a higher proportion of patients with adverse events in the RIMSO-50® (30.56%) than in the Ialuril® (14.86%) group. A case of strangury and a case of sovrapubic pain, both treatment-related, led to withdrawal of two patients, one per group.

Interpretation of results
The results from voiding diaries and the questionnaire scores were consistent with pain reduction.

Concluding message
According to our results, treatment with endovesical instillations of Ialuril® appears to be effective in improving pain, voiding frequency, urinary symptoms and quality of life in women with BPS/IC.

Disclosures
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