

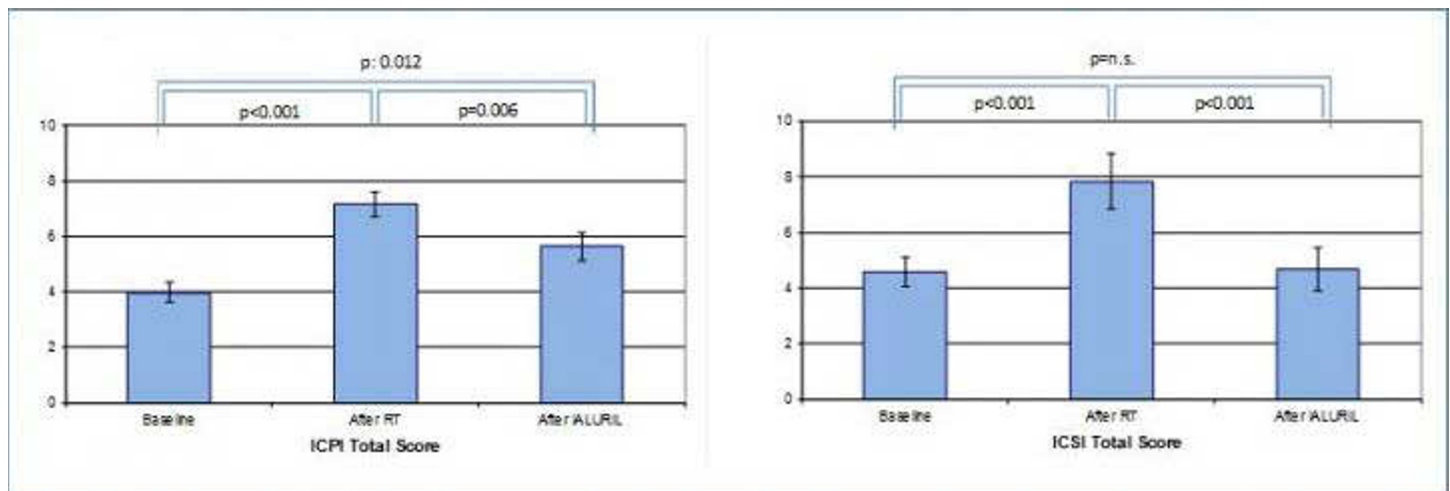
Saleh O.<sup>1</sup>, Gacci M.<sup>1</sup>, Giannesi C.<sup>1</sup>, Raugei A.<sup>1</sup>, Chini T.<sup>1</sup>, Della Camera P.<sup>1</sup>, Detti B.<sup>2</sup>, Livi L.<sup>2</sup>, Monteleone Pasquetti E.<sup>2</sup>, Masoni T.<sup>2</sup>, Finazzi Agro' E.<sup>3</sup>, Li Marzi V.<sup>1</sup>, Milanese M.<sup>1</sup>, Minervini A.<sup>1</sup>, Carini M.<sup>1</sup>, Gravas S.<sup>4</sup>, Oelke M.<sup>5</sup>, Serni S.<sup>1</sup>

<sup>1</sup>University of Florence, Dept. of Urology, Florence, Italy, <sup>2</sup>University of Florence, Dept. of Radiotherapy, Florence, Italy, <sup>3</sup>University Tor Vergata, Dept. of Urology, Rome, Italy, <sup>4</sup>University of Thessaly, Dept. of Urology, Larissa, Greece, <sup>5</sup>University of Hanover, Dept. of Urology, Hanover, Germany

**INTRODUCTION & OBJECTIVES:** After radiation therapy (RT) for prostate cancer (PCa), up to 50% of patients suffer of lower urinary tract symptoms (LUTS). It was hypothesized that post-radiation LUTS are caused by damage and discontinuation of the glycosaminoglycan (GAG) layer of the bladder mucosa. The combination of hyaluronic acid and chondroitin sulfate (Ialuril™) represents replenishment therapy of the GAG layer in the bladder. The aim of this prospective study was to evaluate the effects of intravesical Ialuril™ administration in men with LUTS after RT for localized PCa.

**MATERIAL & METHODS:** Thirty consecutive patients (mean age 69.1 years) with LUTS after external RT for PCa were prospectively enrolled from May 2012 to April 2014. Patients underwent intravesical instillation therapy with Ialuril™ once per week for the first month and, afterwards, on week 6, 8 and 12. All patients answered the Interstitial Cystitis Symptoms Index (ICSI)/Interstitial Cystitis Problem Index (ICPI) at baseline (before RT), after RT and after Ialuril™ treatment. Data were analyzed with paired-samples T-test and with binary logistic regression model.

**RESULTS:** Ialuril™ significantly improved LUTS and symptom bother after initial significant worsening due to RT (see figures). Age, Gleason Score and dose radiation were the main determinants of worsening of LUTS after RT (ICSI Total score baseline vs. post-radiation:  $p=0.047$ ,  $0.043$  and  $0.023$  respectively); multivariate analysis showed that only age remained significant ( $p=0.01$ ). Age, dose radiation and toxicity were related to the recovery of LUTS (ICSI Total score post-radiation vs. post-Ialuril™:  $p=0.041$ ,  $0.050$  and  $0.046$  respectively); however, in multivariate analysis no factor remained significant. The analyses of single items of the questionnaires demonstrated that age and dose radiation were the main determinants for the recovery of the "frequency" item ( $p=0.028$  and  $p=0.048$ , respectively).



CONCLUSIONS: We confirmed a significant worsening of LUTS and symptom bother after RT for PCA. Ialuril™ administration improves LUTS irrespective of age, pathologic features (stage and Gleason Score), dose radiation and toxicity, allowing full relief of symptom bother. Placebo effects or spontaneous recovery of LUTS remain to be elucidated in another study.