

## 664 IMPACT OF ADJUVANT RADIOTHERAPY ON CANCER SPECIFIC SURVIVAL OF PATIENTS WITH SEMINAL VESICLE INVASION AND NODE POSITIVE DISEASE. RESULTS OF A MATCHED-ANALYSIS

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**INTRODUCTION AND OBJECTIVES:** Previous prospective, randomized trials have shown a positive impact of adjuvant radiotherapy (RT) in patients with seminal vesicle invasion (SVI) with or without positive surgical margins. However, none of these trials included patients with lymph node metastases. Nevertheless, recent trials have shown that prostate cancer with lymph node invasion (LNI) might not be always a systemic disease. We hypothesized that adjuvant RT might exert a beneficial effect on cancer specific survival (CSS) of patients with SVI and histologically documented lymph node metastases

**METHODS:** The study cohort included 1634 patients with SVI treated with radical prostatectomy (RP) and pelvic lymph node dissection (PLND) between 1987 and 2008 at two large Academic Institutions. Of these, 558 (34.1%) had LNI: 190 (34.1%) received adjuvant RT, while the remaining 368 (65.9%) did not receive adjuvant RT. For this study purposes, 64 patients out of 190 (33.7%) treated with adjuvant RT were matched with 124 patients of 368 (33.7%) not receiving adjuvant RT. Patients were matched for pre-operative PSA, pathological Gleason score, number of nodes removed, surgical margin status, year of surgery and administration of concomitant hormone therapy (HT). Kaplan-Meier and life table analyses were used to address CSS at 5, 8, and 10 years after treatment. The log-rank test was used to test the impact of adjuvant RT on CSS

**RESULTS:** Median follow-up was 7.9 years (mean: 7.9, range 0.1-19.1). Overall prostate cancer specific survival rate at 8 and 10 years was 85.7 and 80.9%, respectively. After matching for the aforementioned variables, no difference was found in terms of pathological and clinical characteristics as well as of use of adjuvant HT between patients treated with adjuvant RT compared to those not treated with adjuvant RT (all  $p \geq 0.2$ ). Patients treated with adjuvant RT had significantly higher CSS rates compared to patients not treated with adjuvant RT at 8 and 10 years after surgery (94.7 and 94.7% vs 81.2% and 74.6%, respectively;  $p=0.009$ ). Patients not treated with adjuvant RT had a 4.3 fold higher risk of dying for prostate cancer compared to patients treated with adjuvant RT ( $p=0.009$ )

**CONCLUSIONS:** Our results showed that adjuvant RT significantly improved CSS of patients with SVI even in presence of nodal metastases. These results reinforce the need for a multimodal approach in the treatment of patients with SVI and node positive disease

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## 665 PROSPECTIVE TRIAL WITH RADICAL PROSTATECTOMY AND INTRAOPERATIVE RADIATION THERAPY FOR CLINICAL LOCALLY ADVANCED PROSTATE CANCER: CLINICAL ASPETCS AND RESULTS AFTER 5 YEARS EXPERIENCE

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**INTRODUCTION AND OBJECTIVES:** Intraoperative radiation therapy (IORT) is a technique that can deliver high doses of radiation during surgery. 4 ago we started a prospective feasibility study of IORT during radical prostatectomy (RP) for locally advanced prostate cancer (PCa). We report functional outcome, morbidity, toxicity (RTOG Scoring Criteria) and oncological days

**METHODS:** 52 patients with locally advanced PCa were treated. 44 have a minimum follow up of 6 months. Inclusion criteria: age < 75 years, clinical stage T3-T4, N0-1, M0, probability of extracapsular

disease > 25% (Kattan's nomograms), no inflammatory bowel disease. During RP prostate is exposed with dissection of endopelvic fascia and pubo-prostatic ligaments. The distance between prostate and rectum is measured with ultrasound. A collimator (Mobetron, Intraop, California, USA) with diameter of 5.0-6.0 cm and an angle "bevel" of 15-30° is introduced in the surgical field and delivers a dose of 10-12 Gy with 9-12 Mev. The dose has been prescribed to the isodose of 90%. The volume treated includes prostate, seminal vesicles and periprostatic area. RP was then completed and an extended lymphadenectomy was performed. Mean IORT time was 30 minutes. Postoperative RT treatment 3 months after IORT was planned for 38/44 patients. A box technique (Foton X 6-15 MV) was used and a dose of 50 Gy, splitting of 2 Gy/die, was delivered. Hormonal therapy (HT) was prescribed when indicated

**RESULTS:** Median patients age was (IQR) 67.2 year (62.3-73.0), median PSA (IQR) 12.7 ng/ml (6.6-31.1) Biopsy Gleason Score ranged from 4 to 9; 11 patients received a neoadjuvant treatment. 75% of patients had clinically locally advanced PCa. No intra or peri-operative complications observed; the highest doses absorbed from rectum were 0.1-2 Gy. Pathological stage: 11pts T2, 30 pts T3, 3 pts T4, positive lymph node in 20.5% positive surgical margins in 59% 38 patients underwent postoperative RT treatment, with a median follow up of 24 months (6-46). Rectal and urinary RT toxicity was low (G0-G2). Minor surgical complications were observed in nine patients, including five lymphoceles, two pelvic haematomas, three bladder neck strictures. Mean hospital stay was 5 day. At follow up all patients are alive

**CONCLUSIONS:** IORT during RP represents a safe procedure, with acceptable surgical time and minimal toxicity for patients with locally advanced PCa. A larger number of cases and a longer follow-up is needed to confirm these findings and to assess long-term side effects and biochemical control

**Source of Funding:** None

## 666 CROSS SECTIONAL STUDY OF 1160 MEN TREATED BY GNRH AGONISTS – THE PRAGMA STUDY.

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**INTRODUCTION AND OBJECTIVES:** GnRH agonists are central to the treatment of locally advanced and metastatic prostate cancer. We took advantage of an industry-sponsored study to assess the conditions of their use in an unselected set of 1160 patients.

**METHODS:** Medical and personal histories were reviewed with special emphasis on life conditions (marital status, education level, car ownership), associated morbidities, supportive treatments (VitD, calcium, bisphosphonates, analgesics). Medical management was addressed through the estimation of the Karnofsky status and estimated life expectancy by the referring urologist and by the number of family doctor visits in the last year.

**RESULTS:** Mean age was 74.3±14.5 years confirming that GnRH are mainly prescribed in the senior citizen, the mean duration of the treatment was 3.52±12.5 years. While mean BMI did not suggest morbid overweight (26.4±5.04), a significant majority still suffered from overweight (BMI 25-29.9: 50.8%) or obesity (>30: 13.2%) but no relationship could be drawn between BMI (in classes) and duration of GnRH treatment. Estimated life expectancy (ELE) was less than 5 years in 23.2%, between 5 and 10 years in 52.8% and longer than 10 years in 24%. Such ELE was strongly related to the Karnofsky status (77.8, 89.8 and 97.4% mean KS in patients with ELE <5, 5-10 and >10 years, respectively,  $p<0.00001$ ), last PSA (24.9, 6.2 and 3.6 ng/ml, in patients with ELE <5, 5-10 and >10 years respectively,  $p=0.001$ ), the marital status ( $p=0.02$ ) and the level of education (lower ELE in patients with primary school only level of education). Diabetes was the most prevalent comorbidity (23%) and related to BMI ( $P<0.0001$ ) and duration of GnRH treatment ( $p=0.05$ ). Intriguingly in view of the current EAU-AUA recommendations regarding bone loss prevention in androgen suppression, only a minority of patients were given adjunctive VitD (3.7%), Calcium (2.9%) and Bisphosphonates (6.2%), those drugs