Results: Median PSA was 7.95 ng/ml (≤10 ng/ml in 65.8%, 10 to 20 ng/ml in 26.4% and >20 ng/ml in 7.8%). Post operative GS 6 was in 19.8%, GS 7 - in 71.8%, and >7 - 8.4%. Positive margins were detected in 54.8%. Median followup for survival was 56 mo. There were 6 deaths (4.5%) including 1 prostate CS death (0.8%). Median follow-up for BP and DP was 42 mo. During study period DP developed in 2.3% (1 local and 2 distant metastases) and BP in 29.0%. Additional treatment was administrated in 19.1% (adjuvant in 3.1% and salvage in 16.0%). At the last follow-up visit the PSA relapse was detected in 22% and there were no differences between administrated adjuvant or salvage therapy (log-rank test p=0.542) for biochemical recurrence treatment. The multivariable Cox regression models showed no associations between risk factors or additional treatment and overall, CS and DP free survival but increasing PSA (HR 2.316 (95% CI: 1.351-3.969), p=0.002) and Gleason score (HR 2.545 (95% CI: 1.565-4.136), p<0.0001) were associated with highly increasing risk for BP. According Cox regression analyzes all patients were divided into two risk groups: (1) PSA >20 ng/ml and/or Gleason ≥8 (n=19), (2) PSA <20ng/ml and Gleason ≤7 (n=112). Kaplan-Meier with log-rank test analysis showed significant difference between survival curves for BP (p=0.0001), DP (p=0.014), and CS survival (p=0.018) but not for overall survival (p=0.195) across two risk groups.

Conclusions: Study data shows that radical prostatectomy might be the preferred treatment option for T3a prostate cancer. Gleason ≥8 and PSA >20 ng/ml associated with highest risk for PSA progression and increasing risk for DP and CS survival for those patients. There is no priority comparing adjuvant/salvage treatment options for biochemical recurrence.

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RADICAL PROSTATECTOMY AND INTRAOPERATIVE RADIATION THERAPY FOR CLINICALLY LOCALLY ADVANCED PROSTATE CANCER: CLINICAL ASPECTS AND RESULTS OF A PROSPECTIVE SERIES

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Introduction & Objectives: Intraoperative radiation therapy (IORT) is a new technique that can deliver high doses of radiation during surgical treatment. Four years ago we started a prospective feasibility study of IORT during radical prostatectomy (RP) for locally advanced prostate cancer (PCa). Here we report data on morbidity, toxicity (RTOG Scoring Criteria), functional and oncological outcomes of our prospective series.

Materials & Methods: From September 2005 70 patients with locally advanced PCa were treated with IORT during RP. 44 patients have a follow up ≥6 months. Inclusion criteria were: age < 75 years, clinical stage T3-T4 N0-1 M0, probability of extracapsular disease > 25% (Kattan's nomograms), no inflammatory bowel disease. During surgery 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. Postoperative RT treatment 3 months after IORT was planned for 38/44 patients based on histological findings. 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 67.2 year (IQR 62.3-73.0, min-max 56-75) and median PSA at diagnosis 12.7 ng/ml (IQR 6.6-31.1, min-max 2.0-63.9). Biopsy Gleason Score ranged from 4 to 9. 11 patients (25%) received a neoadjuvant treatment. The majority of patients had clinically locally advanced PCa (75%). We observed no intra or perioperative complications. The highest doses absorbed from rectum were 0.1-2 Gy. Pathological stage was: 11pts T2, 30 pts T3, 3 pts T4. Positive lymph nodes were detected in 9 (20.5%) patients and positive surgical margins (PSM) in 26 patients (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 (20.4%), including five lymphoceles (11.4%), two pelvic haematomas (4.5%), three bladder neck strictures (6.8%). Mean hospital stay was 5 day (range 4-8). 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 series and a longer follow-up is needed to confirm these findings and to assess long-term side effects and biochemical control.

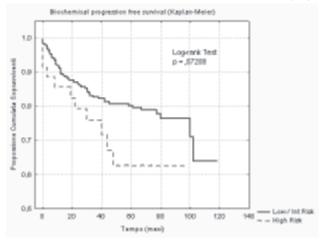
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LAPAROSCOPIC RADICAL PROSTATECTOMY FOR HIGH RISK PROSTATE CANCER

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Introduction & Objectives: The aim of this study was to evaluate the role of laparoscopic radical prostatectomy (LRP) in the treatment of high risk prostate cancer (HR), in comparison with low and intermediate risk prostate cancer (LIR). Materials & Methods: We divided the patients undergone LRP at our Department in two groups, according to D'Amico risk stratification. Group 1 consisted of 60 high risk patients (14.3%), while group 2 included 360 low or intermediate risk patients (85.7%). All patients had follow up. We evaluated complication rate, biochemical free survival rate (BFSR), positive margins rate, continence rate. Biochemical recurrence was defined as postoperative increase in PSA above the threshold of 0.2 ng/ml whilst we defined "continent" patient which did not use pads after one year from surgery. The differences between two groups were tested using long rank, t test or non parametric tests for continuous variables and chi-square test for dicotomic variables. A p-value < 0.05 was considered statistically significant.



Results: The median follow up was 60 months (7-118 months). We registered 37.5% positive surgical margins in group 1 and 28% in group 2 (p = 0.45), with no statistical differences concerning extent, location and number of margins. The median number of removed lymph nodes was 14.5 (4-38) in group 1 and 11 (4-32) in group 2, (p= 0.04). The number of positive lymph nodes was not different in the two groups. In group 1 we registered 19 complications (31.7%); according to Dindo-Clavien classification. In 10 cases we observed grade II complications (5 transfusions, 2 lymphoceles, 2 thorax pain, 1 acute urine retention (AUR), 1 deep venous thrombosis) and 8 cases grade III complications (4 lymphoceles , 2 hematomas, 2 hydronephrosis). In group 2 the complications were 100 (27.8%): 65 grade II complications (37 transfusions, 11 AUR, 3 thorax pain, 4 urinary tract infections, 4 hematomas, 6 lymphoceles) 35 grade III complications (10 lymphoceles, 9 urine leakages, 6 hematomas, 2 hydronephrosis, 3 epigastric lesions, 4 anastomosis stenosis, 1 rectal lesion). The continence rate was 77% in group 1 and 80% in group 2 (p = 0.65). BFSR was 42.5% in group 1 and 21% in group 2 (graph 1).

Conclusions: The outcomes of LRP were not different between patients with HR and LIR. These data suggest the maturity of the laparoscopic technique also in the treatment of HR.

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ADJUVANT RADIOTHERAPY REDUCES THE RATE OF URINARY CONTINENCE RECOVERY AFTER RADICAL PROSTATECTOMY IN INTERMEDIATE AND HIGH RISK PROSTATE CANCER PATIENTS

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Introduction & Objectives: Adjuvant radiotherapy (AdjRT) has been demonstrated as a potential factor in improving the prognosis in locally advanced prostate cancer (PCa) patients, treated with radical prosatatectomy (RP). However, only few studies addressed the impact of AdjRT on the functional outcome of RP patients. We hypothesized that AdjRT may negatively impact on the rate of urinary continence recovery after RP for clinically localized prostate cancer.

Materials & Methods: The study included 1123 patients treated with RP between 2001 and 2010. Complete data, including age, PSA, clinical stage, biopsy Gleason sum, nerve sparing status [non nerve sparing (nonNS), unilateral NS (UNS) and bilateral NS (BNS)], and AdjRT exposure were available for all patients. Patients were assessed post-operatively every 3 months for the first year, every 6 months for the second year and yearly thereafter. Post-operative UC recovery was defined as the absence of any protection device (no pads). Patients were divided into 3 risk groups: low (PSA<10 ng/ml, cT1, biopsy Gleason sum ≤6), high (cT3 or biopsy Gleason 8-10 or PSA >20 ng/ml) and intermediate (all the remaining patients). Kaplan-Meier curves assessed time to UC recovery according to AdjRT