

Prospective trial with radical prostatectomy and intraoperative radiation therapy for clinical locally advanced prostate cancer: Clinical aspects and results after 6 years experience

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INTRODUCTION & OBJECTIVES: Intraoperative radiation therapy (IORT) is a new technique that can deliver high doses of radiation during surgical treatment. This study reports data on morbidity, toxicity (RTOG Scoring Criteria), functional and oncological outcomes of a prospective series of patients who underwent IORT during radical prostatectomy (RP) for high risk, locally advanced prostate cancer (PCa).

MATERIAL & METHODS: From September 2005 70 patients with locally advanced PCa were treated with IORT during RP. Sixty-five patients have a follow up ≥ 12 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 58 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 68 year (IQR 68 (63-73, min-max 52-75) and median PSA at diagnosis 17.6 ng/ml (IQR 7.6-33.1, min-max 2.0-63.96). Biopsy Gleason Score ranged from 4 to 9. Seventeen 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: T2 in 21 cases, T3 in 44 cases, T4 in 5 cases. Positive lymph nodes were detected in 19 (27.1%) patients and positive surgical margins (PSM) in 44 patients (62.8%). 58 patients underwent postoperative RT treatment. Median follow up is 37 months (3-69). Rectal and urinary RT toxicity was low (G0-G2). Minor surgical complications were observed in 13 patients, including 7 lymphoceles (10%), 2 pelvic haematomas (2.9%), 4 bladder neck strictures (5.7%). Mean hospital stay was 5 days (range 4-8). At follow up all patients are alive.

CONCLUSIONS: IORT during RP represents an easy and safe methodology, feasible in acceptable surgical time and with minimal toxicity for locally advanced PCa patients. Larger

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series and longer follow-up are needed to assess long-term side effects and biochemical control.