## HYPOFRACTIONATED HELICAL TOMOTHERAPY FOR PROSTATE CANCER IN THE POST-OPERATIVE SETTING: A SINGLE-CENTER EXPERIENCE

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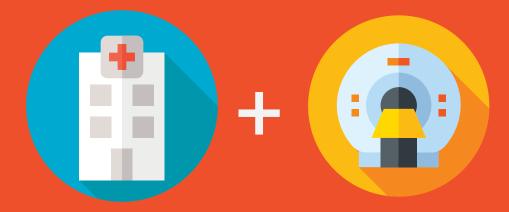
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**INTRODUCTION:** The use of hypofractionated radiotherapy currently represents a standard for the treatment of prostate cancer in the definitive setting, since several experiences reported excellent outcomes in terms of toxicity and biochemical control. Conversely, few data are available in literature about the use of hypofractionation in the post-operative patient. This is a retrospective mono-institutional analysis of a series of 85 patients with prostate cancer who underwent a moderate post-operative hypofractionated radiotherapy delivered by Helical Tomotherapy (HT). The primary endpoint was acute and late toxicity assessment and the secondary endpoint was early biochemical control.

**MATERIAL AND METHODS:** From April 2013 to November 2017, 85 consecutive patients with median age=68 (range, 54-84) received adjuvant (n=43) or salvage (n=42) moderate hypofractionated radiotherapy performed with Helical Tomotherapy. Adjuvant treatment was administered within 6 months after surgery for patients with PSA  $\leq 0.2$  ng/ml in presence of adverse pathological features like extracapsular extension, seminal vesicles invasion, positive margins, or lymph nodal involvement. Salvage therapy was delivered 6 months after surgery with PSA $\geq 0.2$  ng/ml or for patients with persistent post-surgery PSA. Our moderate hypofractionation schedule consisted of a total dose of 63.8 Gy (EQD2=67.4 Gy) delivered to prostate bed using 2.2 Gy fractions. For patients with pathological adverse features [pN+, inadequate lymph nodal dissection (<10 nodes), and/or Gleason Score>8] pelvic lymph nodes irradiation with conventional fractionation was indicated in 64% of cases for a median dose of 49.3 Gy (range, 48-55.1 Gy). Both for planning CT scan and for treatment, all patients were educated to rectal emptying and bladder filling with the assumption of 500 ml of water 30 minutes prior to every fraction. During the radiotherapy course, daily image guidance was performed with megavoltage computed tomography scan to verify setup accuracy and patients' preparation. Concurrent androgen deprivation therapy was administered according to the discretion of the referring urologist, in 44% of patients. Acute and late genitourinary (GU) and gastrointestinal (GI) toxicity evaluation was conducted basing on the Common Terminology Criteria for Adverse Events, v4.0 (CTCAE 4.0). Biochemical progression was defined as any PSA level rise of $\geq 0.2$  or more above the post-radiotherapy nadir. Chi-squared tests were applied for statistical analysis assuming p values  $\leq 0.05$  as significant. Survival estimates were performed with Kaplan-Meier method and log-rank test.

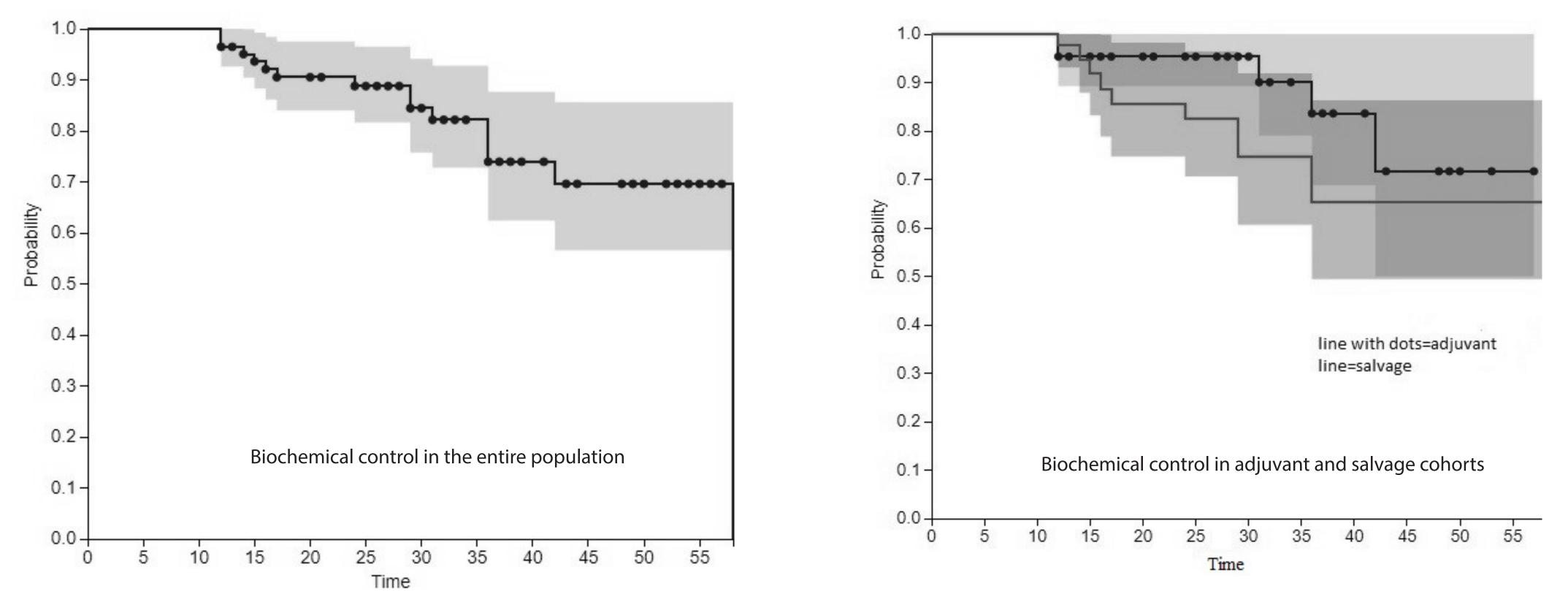
2018 2013 to 2017

Patient n= 85 Median Age = 68 years



Radical prostatectomy and adjuvant or salvage RT Adjuvant (n=43) or Salvage (n=42)

**RESULTS:** All patients completed the treatment without any interruption. Acute GU toxicities were as follows: G1 in 44% and G2 in 5.8%, detecting no G $\geq$ 3 events. For GI toxicity, we recorded G1 in 33% of patients and G2 in 22.3%. With a median follow-up of 28 months (range, 12-58), we detected G2 GI late toxicity in 5.8%, and G $\geq$ 2 GU late toxicity in 4.7%, including 2 patients who underwent surgical incontinence correction, respectively after 24 and 36 months from the end of treatment. Most common acute side effects were urinary tract pain and diarrhea, while, concerning for late adverse events, proctitis and urgency were the most frequently observed. At statistical analysis, acute GI $\geq$ 2 toxicity and diabetes were found to be predictive of late GI $\geq$ 2 toxicity (p=0.04 and p=0.0019), no other correlations were observed. Actuarial 2- and 3-years biochemical relapse free survival (bRFS) were respectively 88.5% and 73.7% for the entire population (Figure 1). In a subgroup evaluation (Figure 2), a statistical significance in terms of biochemical control between adjuvant and salvage patients failed to be found (p=0.23). All patients are alive except one who died because of cerebrovascular disease, resulting in 2- and 3-years overall survival rates of both 97.7%.



**CONCLUSIONS:** In the present experience, our schedule of moderate hypofractionated post-operative radiotherapy with Helical Tomotherapy collected mild acute and late toxicities, either lower or equivalent compared to other series. Also in terms of biochemical control, our study reports rates in agreement with literature data. A longer follow-up is advocated for a further evaluation of this analysis.

