

36- GIVE-ME-FIVE TRIAL: TOXICITY EVALUATION IN ULTRA-HYPOFRACTIONATED PROSTATE CANCER RADIOTHERAPY



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Aim: To evaluate the genitourinary (GU) and gastrointestinal (GI) toxicity after ultra-hypofractionated prostate cancer (PCa) radiotherapy.

Materials and Methods: As a part of the prospective phase II Give-me-five trial, 65 PCa patients underwent volumetric modulated arc therapy with simultaneous integrated boost to the dominant intraprostatic lesion (DIL). The treatment scheme was 36.25-37.5 Gy/5 fractions to the whole prostate gland and to the DIL, respectively. Univariate and multivariate logistic regression models were applied to identify independent factors associated with toxicity adjusting for confounding factors. The systematic analysis of urinary bladder and rectum dose-volume histograms (DVHs) was performed with the Fisher's exact test. The correlation between the relative volume receiving a given absolute dose and acute toxicity was investigated, with cutoffs at grade G>0 and G>1.

Results:

- Sixty-five patients met the inclusion criteria. At 1 month after the end of radiotherapy, 42 patients (65%) had no GU toxicity, whereas 18 (28%), 4 (6%) and 1 (1%) patients had G1, G2 and G3 GU toxicity. As concerning GI toxicity, 54 (83%) patients had no toxicity, whereas 11 (17%) reported G1 toxicity. IPSS changed significantly ($p<0.05$) from baseline to 1 month and changes during time are significantly different by symptomatic score at first month (mild, moderate and severe, $p<0.0001$).
- At univariate analysis, no relationship was found between the prostate volume and acute GU ($p=0.97$) or GI toxicity ($p=0.83$), nor between the urinary bladder volume and any grade of acute GU toxicity ($p=0.60$) whereas the correlation between the rectum volume and any grade of acute GI toxicity was at the boundary of statistical significance ($p=0.05$).
- At multivariate analysis adjusting for age and the presence of severe concomitant disease, IPSS at 1 month is positively significantly associated with acute GU G \geq 1 toxicity ($p=0.03$), whereas rectum volume is only borderline significantly associated with GI G \geq 1 toxicity ($p=0.06$). Prostate volume is not significantly associated with any toxicity ($p=0.78$). For urinary bladder, the area of DVH between 17-24 Gy vs. volume 12-22% was correlated with any acute GU toxicity and the region between 25-35 Gy vs. volume 2-6% was correlated with acute G>1 toxicity. As concerning the relation between rectum DVH and GI toxicity, the portion between 18-34 Gy was correlated with any acute GI toxicity (**Figure 1**).

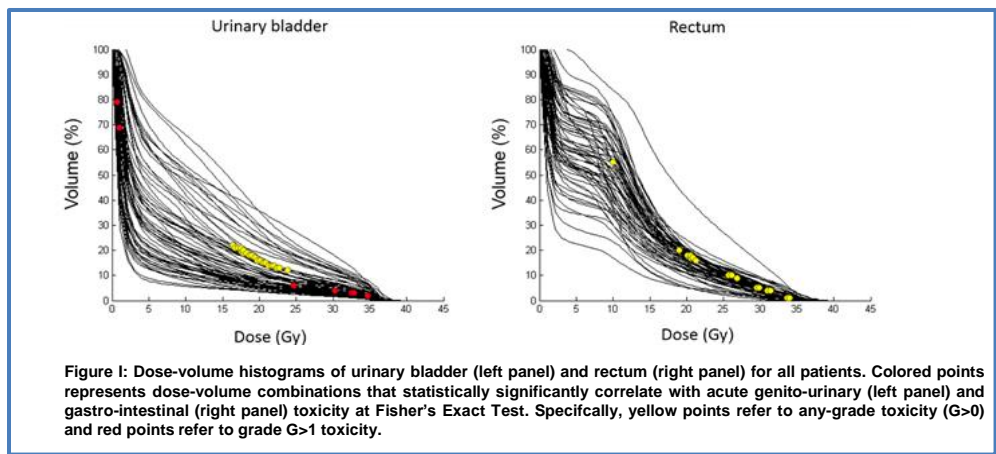


Figure 1: Dose-volume histograms of urinary bladder (left panel) and rectum (right panel) for all patients. Colored points represents dose-volume combinations that statistically significantly correlate with acute genito-urinary (left panel) and gastro-intestinal (right panel) toxicity at Fisher's Exact Test. Specifically, yellow points refer to any-grade toxicity (G>0) and red points refer to grade G>1 toxicity.

Conclusion:

The acute toxicity profile after ultra-hypofractionated radiotherapy for PCa is satisfactory.

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