

NEWSBRIEFING 4

168 A Phase III Randomized Study Of High Dose Conventional Vs. Hypofractionated Radiotherapy In Patients With High Risk Prostate Cancer

G. Arcangeli, B. Saracino, S. Gomellini, M. Petrongari, S. Arcangeli, S. Sentinelli, L. Strigari

Regina Elena National Cancer Institute, Rome 00144, Italy

Purpose/Objective(s): To compare the efficacy and toxicity of hypofractionated (62 Gy/20 fractions/5 weeks, 4 fractions per week) vs. conventional fractionation radiotherapy (80 Gy/40 fractions/8 weeks) in patients with high risk prostate cancer.

Materials/Methods: From January 2003 to December 2007, a total of 168 patients were randomized to receive either hypofractionated (85 patients) or conventional (83 patients) fractionated schedules of 3D Conformal Radiotherapy (CRT) to the prostate and seminal vesicles. All patients received a 9-month course of total androgen blockade (TAB). CRT started 2 months after TAB initiation. All patients underwent an accurate clinical evaluation before treatment, including PSA determination, rectal endoscopy, AUA score evaluation, testosterone determination, DRE, abdomino-pelvic TC, and prostate US scan or MR endorectal coil. All biopsy specimens were reviewed by the same pathologist (S.S.). Patient assignment to a risk category was done following the NCCN guidelines. Biochemical failure was determined according to the nadir+2 Phoenix definition.

Results: No differences between the two groups were found with regard to age, GS, T-stage and pre-treatment PSA level (iPSA). The median follow-up was 32 (23-43 interquartiles) and 35 (24-45 interquartiles) months in the experimental and conventional arm, respectively. A nadir PSA \leq 0.5 ng/ml was observed in 100% and 94% of patients in the experimental and control group, respectively. The 3-year freedom from biochemical failure (FFBF) rates were 87% and 79% in the former and latter group, respectively ($p=0.035$). The 3-year FFBF in patients at a very high risk (i.e. iPSA $>$ 20 ng/ml, GS \geq 8, or T \geq 2c), were 88% and 76% ($p=0.014$) in the experimental and control arm, respectively. The multivariate Cox analysis confirmed fractionation, iPSA and bGS as significant prognostic factors. No patient died. The 3-year rates of freedom from distant metastases were 88% and 82% in the experimental and control arm ($p=0.82$), respectively. Based on RTOG/EORTC toxicity criteria, no patient experienced a G4 acute toxicity; G3 toxicity was observed in only 1 patient. Acute G2 toxicity developed and disappeared earlier in the experimental vs control group. No difference was found for late toxicity between the two treatment groups, with 3-year G2 rates of 17% and 16% for GI and 14% and 11% for GU in experimental and control group, respectively.

Conclusions: Our findings suggest that the hypofractionated schedule used in this trial is superior to conventional fractionation in terms of FFBF, and that late toxicity is equivalent between the two treatment groups.

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