UPDATED RESULTS OF A PHASE II STUDY ON 5 FRACTIONS FFF SBRT FOR LOW AND INTERMEDIATE PROSTATE CANCER

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Aims

SBRT had been shown to be a potential treatment option for localized prostate cancer (PC) in selected population. Usually, prostate SBRT has been delivered every other day in order to favour normal tissues recovery, minimizing side effects. Flattening Filter Free (FFF) delivery is a treatment modality able to reduce treatment beam-on time, decreasing patient positioning uncertainties. We reported feasibility, side effects and biochemical control of FFF SBRT delivered in 5 consecutive days in a cohort of patients affected by localized PC.

Methods

The study, approved by Ethical Committee, started on January 2014. Inclusion criteria were: age ≤ 80 years, World Health Organization performance status ≤ 2, histologically proven prostate adenocarcinoma, low-to-intermediate risk according to D'Amico criteria, no distant metastases, no previous surgery other than TURP, no other malignant tumor in the previous 5 years, a pre-SBRT International Prostatic Symptoms Score (IPSS) ranged between 0 and 7.

The SBRT-schedules were: 35Gy for low risk and 37.5Gy for intermediate risk PC in 5 fractions, delivered in 5 consecutive days. SBRT was delivered with volumetric modulated radiation therapy (VMAT). Toxicity assessment was performed according to CTCAE v4.0 scale. Neoadjuvant/concomitant hormonal-therapy was prescribed according to risk classification.

Results

Fifty-two patients were enrolled at the time of analysis. Median age was 73 years (55-83), Median follow-up was 33 months (range: 6-55 months). Thirty-four (65.3%) had a low-risk PC and 18 (34.6%) an intermediate-risk PC. Median initial PSA was 5.9 ng/ml (range, 1.8-15.7 ng/ml). Median Gleason score was 6 (6-7). Median IPSS pre-SBRT was 4.5 (range, 0 - 7). All patients completed the treatment as planned.

Acute G1-2 toxicity occurred in 18 (34.6%) patients and was distributed as follows: 8 (15.3%) cases of G1 gastrointestinal toxicity, 1 (1.9%) patients had G2 gastrointestinal toxicity, 5 (9.6%) patients reported G2 genitourinary toxicity and 11 (21.1%) G1 genitourinary toxicity. Patients may have experienced more than one toxicity. Late G1 gastrointestinal toxicity occurred in 5 (9.6%) patients. No G3 toxicities occurred.

At the last follow-up median IPSS was 3 (1-19) and median PSA was 0.315 ng/ml (range 0.04-7.965 ng/ml). Biochemical control was 98%.

Conclusions

The results of our study showed that FFF SBRT in 5 fractions for low-to-intermediate PC is feasible and well tolerated. Longer follow-up is necessary to assess late toxicity and long-term effectiveness.