

Early Results of a Phase I Dose Escalation Study Using Stereotactic Body Radiosurgery for Patients with Clinically Localized Prostate Cancer

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Categories: Radiation Oncology, Urology

Keywords: stereotactic body radiotherapy, prostate cancer, organ-confined prostate cancer, sbrt, psa, psa nadir

How to cite this abstract

Zelefsky M, Kollmeier M, Cox B, et al. (June 16, 2016) Early Results of a Phase I Dose Escalation Study Using Stereotactic Body Radiosurgery for Patients with Clinically Localized Prostate Cancer. Cureus 8(6): a103

Abstract

Objectives: To report the acute and late toxicity outcomes as well as preliminary PSA relapse-free survival results among patients treated on a prospective dose escalation study using high-dose 5 fraction stereotactic body radiosurgery (SBRT) for patients with low and intermediate risk prostate cancer.

Methods: 136 patients were accrued to a Phase I dose escalation study to determine the tolerance of escalating radiation dose levels of SBRT in the treatment of localized prostate cancer. The initial dose level was 32.5Gy in 5 fractions delivered every other day. After 30 patients were accrued and at least 50% of these were followed for a minimum of 3 months, the dose level was escalated by 2.5 Gy increments. In this fashion 30 patients received a prescription dose of 32.5 Gy, 35 patients were treated to 35 Gy, 36 patients to 37.5 Gy and 35 patients to 40 Gy. Doses were prescribed to the planning target volume where 5 mm margins were used around the prostate and seminal vesicles except posteriorly where a 3 mm margin was used at the prostate-rectal interface. All patients were monitored with intra-fraction motion fiducial-based targeting (Calypso TM), and target positions were corrected if deviations were noted beyond a 2mm set threshold. Eligibility criteria included only low and intermediate risk patients, and patients treated with neo-adjuvant androgen deprivation were excluded. The CTC-4 clinical toxicity score was used to characterize acute and late toxicity. The median follow up for the 4 dose levels were 60 months, 48 months, 24 months, and 18 months respectively.

Results: The incidence of acute grade 2 rectal toxicities for dose levels 1-4 were 0%, 5.7%, 3.2% and 3.2% respectively. No grade 3 or 4 acute rectal toxicities were observed. The incidence of acute grade 2 urinary toxicities for dose levels 1-4 were 13.3%, 8.6%, 13.9% and 6.5% respectively. Only 1 patient at the 40 Gy dose level experienced a grade 3 acute toxicity (urinary retention requiring foley catheter placement). The incidence of late grade 2 rectal toxicities for dose levels 1-4 were 3.3%, 0%, 2.8% and 0% respectively. No grade 3 or 4 late rectal toxicities were observed. The incidence of late grade 2 urinary toxicities for dose levels 1-4 were 13.3%, 14.3%, 8.3% and 9.7% respectively. Only one late grade 3 urinary toxicity (urethral stricture) developed in the 32.5 Gy dose arm after treatment which was corrected with transurethral resection. No grade 4 late urinary toxicities were observed. The median PSA nadir value at 2

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Published 06/16/2016

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years for the first 3 dose groups were 0.7ng/ml, 0.59 ng/ml and 0.46 ng/ml respectively.

Conclusions: SBRT doses ranging from 32.5 Gy to 40 Gy in 5 fractions were well tolerated without significant urinary or rectal toxicities. PSA nadir responses at 2 years suggest that with higher doses improved responses may be observed. Longer follow up will be necessary to better assess tolerance profiles and biopsy outcomes reflecting true local disease control status.