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Assessment of survival and toxicity of hypofractionated versus conventionally fractionated radiation therapy for prostate carcinoma: A phase III randomized trial
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We have performed a randomized trial to compare the gastrointestinal (GI) and genitourinary (GU) toxicity of radiation therapy (RT) for early stage (T1 and T2, N0 M0 on TNM classification) carcinoma of the prostate, using a hypofractionated (55 Gy/20 fractions/4 weeks) versus a conventionally fractionated (64 Gy/32 fractions/6 Vi weeks) dose schedule and also to determine the efficacy of the respective treatment schedules. GI and GU toxicity (using patient and physician based symptom questionnaires incorporating elements of the late effects of normal tissues - subjective, objective, management, analytic [LENT-SOMA] classification of late effects and the EORTC sexual function questionnaire) were evaluated before RT and after its completion at three monthly intervals for the first 2 years and then six monthly for the next 3 years. Efficacy of RT was assessed both clinically (digital rectal examination and radiological imaging) and biochemically (PSA assay) at baseline, and subsequently 3 monthly for 2 years after RT, 6 monthly for the next 3 years and then yearly thereafter. Multivariate analysis showed that (i) increased total GI and GU symptom scores at 1 month independently predicted for increased GI symptoms at 2, 3, and 4 years and increased GU symptoms at 2,3, and 5 years,(ii) the hypofractionated dose schedule was of independent prognostic significance for increased GI symptoms at 2 years only and (iii) somewhat surprisingly, 3D RT independently predicted for increase GU symptoms at 2 years. RT for prostate carcinoma, using a predominately two dimensional 6-23 MV photon 4 field technique is an under- estimated cause of persistent clinically significant GI morbidity which is independent of the two RT dose schedules. The hypo fractionated RT schedule is as effective than the conventional RT dose regimen after a median follow- up of 4 years.