Independent Validation of Rectal Dose-volume Constraints using MRC RT01 (ISRCTN47772397) Trial Data


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Introduction: Treatment plan evaluation requires knowledge of the effect of the plan, not only on the intended target, but also the surrounding normal tissues that are unavoidably irradiated. Recent literature has provided estimations of tolerance doses and proposed dose-volume constraints for many of the organs at risk. However, very few of these recommendations have been independently validated. This study details how constraints proposed for the rectum were tested using data from the RT01 randomised prostate radiotherapy trial.

Method: An independent validation of the rectal dose-volume constraints used in the CHHiP trial and proposed recently by Fiorino et al. was performed. The constraints were applied retrospectively to the treatment plans collected from the RT01 trial. Odds ratios (OR) were calculated to compare the reported incidence of specific late rectal toxicity end points in the group of patients whose treatment plan met a specified dose-volume constraint compared to the group of patients who failed that constraint.

Results: Statistically significant ORs were observed for every constraint tested (except 75 Gy) for at least one clinical end point. For the CHHiP constraints between 60 and 70 Gy, the ORs calculated for rectal bleeding (RMH score defined in protocol) exceeded 2.5 (P<0.02). Similarly the ORs for CHHiP constraints between 30 and 65 Gy exceeded 2.4 (P<0.021) for urgency (UCLA PCI). The Fiorino constraints between 40 and 60 Gy resulted in ORs 2 (P<0.02) for loose stools (UCLA PCI).

Conclusion: Implementing rectal dose-volume constraints from 30 Gy up to the prescription dose will result in a decrease in the incidence of late rectal toxicity. Constraints for doses as low as 30 Gy were statistically significant, further challenging the concept that the rectum is a serial structure where the maximum dose to the organ is the only consideration.