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Session title

Track	**Late Breaking Abstract Submission**
Topic	**Late Breaking Abstracts**
Presentation preference	**Oral presentation**
Abstract title	**Ultrahypofractionation for prostate cancer: Outcome from the Scandinavian phase 3 HYPO-RT-PC trial**

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Purpose or Objective

Hypofractionated (HF) radiotherapy (RT) for prostate cancer has gained increased attention due to its proposed high radiation-fraction sensitivity. Recent reports from randomised studies comparing moderately hypofractionated (M-HF) and conventionally fractionated (CF) radiotherapy (RT) have supported the value of M-HF. Until now there are no prospective randomised data for ultrahypofractionation (U-HF) regimens. Recently, we presented 2-year toxicity results from the first large randomised trial on U-HF versus CF; the Scandinavian HYPO-RT-PC study[1]. We now report the first results on primary outcome and updated toxicity data from this trial.

Material and Methods

The Scandinavian HYPO-RT-PC study is a randomised, phase III, non-inferiority trial that recruited patients with intermediate/high-risk prostate cancer (T1c-T3a, PSA ≤20 with one or two of the following risk factors; T3a or Gleason ≥7 or PSA >10). Patients were randomly assigned (1:1) to either CF (n=602), 39 x 2.0 Gy=78.0 Gy over 8 weeks or U-HF

(n=598), 7 x 6.1 Gy=42.7 Gy over 2.5 weeks (RT every other weekday). No androgen deprivation therapy was allowed. The treatment schedules were designed to be equieffective for late normal tissue complication probability (α/β=3 Gy). Image guided RT (3DCRT or VMAT) based on fiducial markers was delivered to the prostate only (CTV) with a 7 mm isotropic CTV-PTV margin. The primary endpoint was time to biochemical or clinical failure and the treatment groups were compared by means of a Cox proportional hazards model. To conclude non-inferiority, a critical hazard ratio (HR) of 1.338 (one-sided α=0.025) was pre-specified, corresponding to a margin of 4% at 5 years. Physician's evaluation of side-effects was performed according to a modified RTOG scale. The trial number is ISRCTN45905321.

Results

Between July 2005 to November 2015, 1200 patients from 12 centres were randomised. Analysis was made per protocol and 1180 patients (591 CF and 589 U-HF) with a median follow-up time of 59.7 months [95%CI 57.6−51.8] were eligible for evaluation of primary outcome. The total number of events during the follow-up period was 102 and 100 in the CF and the U-HF group, respectively. The proportion of patients, free of biochemical or clinical failure at 5 years, was 83.8% [95%CI 80.4−87.3] in the CF arm and 83.7% [95%CI 80.3−87.1] in the U-HF arm (Fig. 1). U-HF was found to be non-inferior to CF: HR (95% CI) = 0.992 (0.753, 1.307).

There were no significant differences in the prevalence of physician reported late grade 2+ toxicity at four/six years (CF vs. U-HF): urinary 4.1 % vs. 4.1 %, p=0.38 / 3.5 % vs. 2.5%, p=0.75 and bowel: 1.6% vs. 1.6%, p=1.00 / 2.3% vs. 1.2%, p=0.69.

Fig. 1. Kaplan-Meier estimated failure-free survival (1=CF, 2=U-HF)

Conclusion

Ultrahypofractionated RT (42.7 Gy/7 fractions) is non-inferior to conventionally fractionated RT (78 Gy/39 fractions). U-HF resulted in a low incidence of side-effects with no significant differences compared to CF for late GU and GI toxicity.

I have no potential conflict of interest to disclose

Keyword **Prostate Cancer**

Kind regards,
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