

NRG Oncology/RTOG 0415, Phase III Non-Inferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer: Prostate Specific Quality of Life Results

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Background

- Hypofractionated (HF) radiation therapy (RT), which is a shorter course of RT with a larger dose at each treatment, was found to be similar in disease free survival compared to longer course of RT.
 - In 1092 analyzable men with low-risk PrCa, 70 Gy in 28 fxs over 5.6 wks is **non-inferior** to 73.8 Gy in 41 fxs over 8.2 wks (DFS HR=0.85, 95% CI: 0.64, 1.14)
 - However, there was some concern that HF arm had slight increase over the conventional fraction (CF) arm in late grade 2 (mild) clinician reported adverse events
 - GI adverse events HF arm 18% vs CF arm 11% p=0.002
 - GU adverse events HF arm 26% vs CF arm 20.5% p=0.06
- WR Lee et al ASTRO plenary 2015
- The purpose of this study was to assess difference in patient reported outcomes between arms

Method

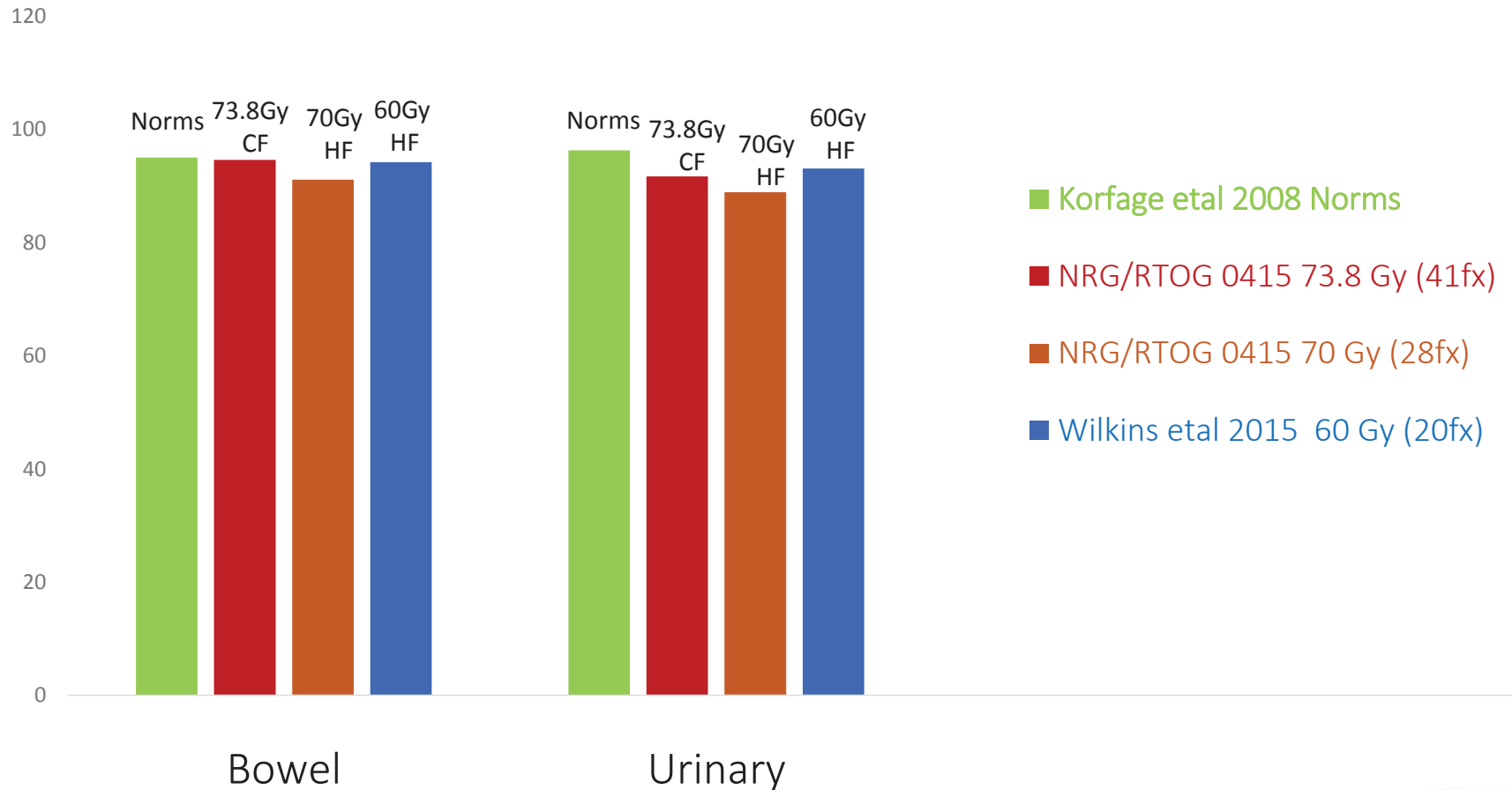
Expanded Prostate Index Composite (EPIC) used to measure health related quality of life and symptoms

- 50 item patient reported outcomes (PRO) questionnaire measured on a Likert scale (e.g. 0- no problem up to 4- big problem):
 - Responses transformed to 0-100
 - Higher scores indicating better HRQoL
- EPIC has 4 domains:
 - bowel
 - urinary
 - sexual
 - hormonal
- Measured at baseline, 6 and 12 months

Results: EPIC PRO at 1 year

- Hormonal scores had no change from baseline in either arm
- Sexual function had a large similar decline on both arms of about 15 points on the CF arm and 11 points on the HF arm but these changes were not significantly different
- Urinary scores exhibited almost no decline from baseline in both arms: 0 points for CF and 2 points for HF and these changes were not significantly different between arms
- Bowel scores exhibited a small decline from baseline in both arms: 0 points for CF and 2 points for HF and these changes were not significantly different between arms
- As compared with CF, pts treated with HF had a statistically larger decline in bowel scores, however this change was not deemed clinically significant – meaning the patients could not tell the difference in bowel changes between the shorter HF arm and the longer CF arm

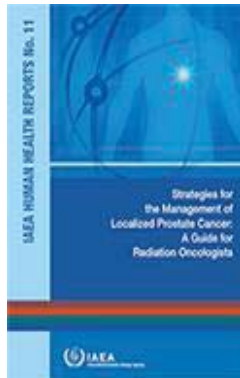
Our findings are similar to studies of bowel and bladder function in men without cancer and me treated with even shorter courses of RT



Conclusions

- Patient reported outcomes are comparable between arms, supporting value based care with HF for low risk prostate cancer
- There is now a significant body of evidence showing that men can safely be treated with shorter course radiation for low risk prostate cancer, which can save men 2 and one half weeks of treatment (from 8.2 weeks to 5.6 weeks)
- These 2½ weeks of treatment that are no longer needed save on cost, inconvenience, time lost from work or time having to get a ride to treatment
- These results are now ready for consideration for changing RT practice guidelines for men with low risk prostate cancer

Question – is this data practice changing?



Strategies for the mgmt of low risk prostate cancer

Active surveillance / watchful waiting

3-D/IMRT external beam radiation 74–78 Gy
Note: This is the preferred treatment method.
The use of ⁶⁰Co for EBRT in this setting is not recommended

LDR brachytherapy
Note: Not preferred due to difficulties with source procurement

Investigational:
— HDR brachytherapy monotherapy
— Hypofractionated EBRT

IA EA Strategies for the Management of Localized Prostate Cancer: A Guide for Radiation Oncologists, 2014