

MEETING DATES: OCTOBER 18-21, 2015 EXHIBIT DATES: OCTOBER 18-20, 2015 HENRY B. GONZÁLEZ CONVENTION CENTER SAN ANTONIO



Long-term Patient Reported Outcomes From a Phase 3 Randomized Prospective Trial of Conventional Versus Hypofractionated IMRT Radiation Therapy for Localized Prostate Cancer

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Background

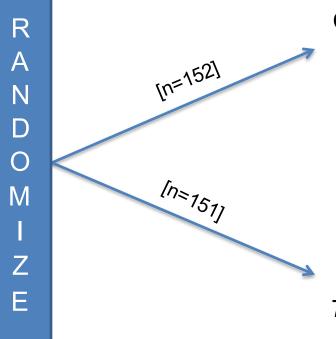
- The current standard definitive radiotherapy regimen for localized prostate cancer consists of conventionally fractionated radiation (1.8-2 Gy per fraction) for approximately 8 weeks (76-80 Gy).
- Hypofractionated radiation therapy delivers doses greater than 2 Gy per day
 with the potential advantages of reduced treatment cost and patient
 inconvenience, and a theoretical improvement in the therapeutic ratio for
 prostate cancer.
- The Fox Chase Cancer Center hypofractionation trial was a randomized phase III trial comparing hypofractionated radiation therapy with conventionally fractionated radiation therapy.
 - The final results were published in 2013 which demonstrated no significant difference in biochemical outcomes between subgroups (Pollack et al. JCO. 2013).
- Purpose: To assess the long term quality of life outcomes for patients undergoing conventionally fractioned radiation therapy versus hypofractionated radiation therapy for clinically localized prostate cancer.



Methods

**<u>Intermediate risk</u>: ≤4 months androgen deprivation therapy High risk: 2 years of androgen deprivation therapy

Clinically Localized
Prostate
Adenocarcinoma
(Stratified by PSA, GS, and Risk Group)



Conventional Fractionation 76 Gy in 38 fractions (2 Gy/fx)

Hypofractionation 70.2 Gy in 26 fractions (2.7 Gy/fx)

Patients completed quality of life self-assessment forms pre-radiation: 6 months, 12 months, 24 months, 36 months, 48 months, 60 months (EPIC, IPSS, EQ5D)

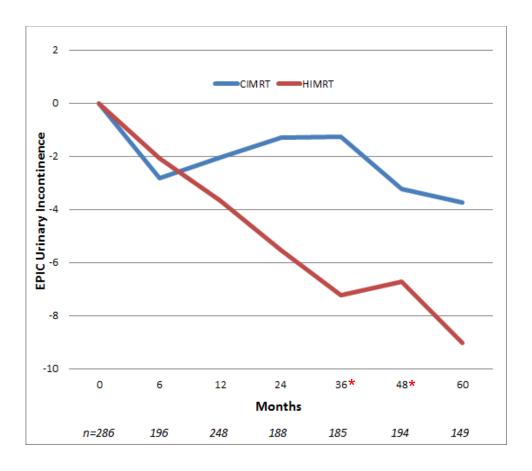


Baseline Characteristics

	CIMRT	HIMRT	p-value
Baseline EPIC, Median (Range)			
Urinary Irritative/Obstructive	92.86 (39.29-100)	91.67 (64.29-100)	0.90
Urinary Incontinence	92.35 (39.5-100)	100 (52-100)	0.40
Hormone	93.18 (56.82-100)	93.18 (54.44-100)	1.00
Sexual	47.77 (0-93.75)	53.23 (0-94.23)	0.70
Bowel	95.54 (58.93-100)	98.21 (60.71-100)	0.09
Baseline IPSS, Median (Range)			
Overall	6 (0-28)	6 (0-26)	0.8
QoL score	2 (0-6)	2 (0-6)	0.3
Baseline EQ5D, Median (Range)			
EQ5D Index	1 (0.4-1.0)	1 (0.51-1.0)	0.57
EQ5D VSAS	85 (50-100)	85 (30-100)	0.17

Results

- There was no significant difference in mean score change for the EPIC bowel, sexual, hormonal, or urinary irritative/obstructive domains between the two treatment groups.
- Patients receiving hypofractionated radiation had worse EPIC urinary incontinence summary scores at 3 years.
- There was a trend towards a worse IPSS score at 2 and 3 years in the HIMRT group although this improved with further follow-up
- On multivariate analysis, there was no association between radiation fractionation scheme and any parameter at 48-months.
- Baseline parameters were strong predictors of all outcomes at 48 months.



* Statistically significant difference between groups



Conclusions

- In general, hypofractionated and conventionally fractionated radiation result in similar long term quality of life outcomes.
- Patients receiving hypofractionated radiation appeared to have inferior genitourinary incontinence outcomes versus patients receiving conventionally fractionated radiation.
- Patients with poor baseline genitourinary function may have worse quality of life outcomes with hypofractionated radiation versus conventionally fractionated radiation.
- Baseline function is an important predictor of long term quality of life outcomes.

