ASTRO News Briefing: Advances in Prostate Cancer Care
Tuesday, September 27, 8-9am ET
Moderator: Colleen Lawton, MD, FASTRO, Medical College of Wisconsin

- 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
  Deborah Watkins Bruner, RN, PhD, Emory University

- Five-Year Outcomes from a Multi-Center Trial of Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer
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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
  - sexual
  - urinary
  - 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 men 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 $^{60}$Co 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

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Five-Year Outcomes from a Multi-Center Trial of Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer

R. Meier¹, A. Beckman², G. Henning³, N. Mohideen⁴, S. A. Woodhouse⁵, C. Cotrutz¹, and I. D. Kaplan⁶

¹Swedish Cancer Institute, Seattle, WA, ²Central Baptist Hospital, Lexington, KY, ³Huron River Radiation Oncology, Brighton, MI, ⁴Northwest Community Hospital, Arlington Heights, IL, ⁵Community Cancer Center, Normal, IL, ⁶Beth Israel Deaconess Medical Center, Boston, MA
Background

• Stereotactic Body Radiotherapy (SBRT) is an advanced technology that precisely delivers high-dose RT to tumors, in a small number of fractions.

• Prostate cancer should be ideally suited for SBRT, as higher RT doses may improve cancer control, while accurate targeting avoids the bladder, rectum and sex organs, reducing side effects.

• SBRT is also more cost-effective than IMRT, and more convenient for patients, since treatment is completed in just five visits.

• Single institution studies of SBRT have shown promising results in early stage prostate cancer. This study evaluates if SBRT can be safely delivered across multiple institutions, while yielding favorable rates of cancer control.
Objectives

• To determine if SBRT is safe
• To determine if SBRT is effective

>10% rate of serious (grade 3-5) urinary or bowel side effects considered excessive

In low-risk pts, is the 5-yr freedom from cancer recurrence superior to a historical control of 93%?
Objectives

- To determine if SBRT is safe
- To determine if SBRT is effective

Method

- 309 patients enrolled

172 low-risk pts:
CS T1b-T2a, Gleason ≤6 & PSA ≤10ng/ml

137 intermediate-risk pts:
CS T1b-T2b; Gleason=7 & PSA≤10 or Gleason≤6 & PSA>10, ≤20
Objectives

• To determine if SBRT is safe
• To determine if SBRT is effective

Method

• 309 patients enrolled
• All pts treated with a robotic linear accelerator

Throughout treatment, robot tracks prostate & corrects for motion: in x-y-z dimensions & yaw, pitch, roll
**Objectives**

- To determine if SBRT is safe
- To determine if SBRT is effective

**Method**

- 309 patients enrolled
- All pts treated with a robotic linear accelerator

Beams converge upon prostate from spherical orientation, rather than a single plane.
Objectives

• To determine if SBRT is safe
• To determine if SBRT is effective

Method

• 309 patients enrolled
• All pts treated with a robotic linear accelerator
• Prostate given 5 doses of 8Gy each
• RT dose to bladder, rectum, testes & penile bulb rigorously constrained
• Pts followed an average of 5.1 yrs
Results: Safety

- No grade 4-5 toxicities
- Five grade 3 side effects occurred in 4 pts, far below the 10% considered excessive:
  - Two low-risk pts (1.2%), $p<0.001$
  - Two interm-risk pts (1.5%), $p<0.001$

Efficacy

Based on Nadir + 2 definition:
- 97.1% of pts free from recurrence at 5 yrs
Results: Safety

- No grade 4-5 toxicities
- Five grade 3 side effects occurred in 4 pts, far below the 10% considered excessive:
  - Two low-risk pts (1.2%), p<0.001
  - Two interm-risk pts (1.5%), p<0.001

Efficacy

Based on Nadir + 2 definition:
- 97.1% of pts free from recurrence at 5 yrs
- In low-risk pts, 97.3% free from recurrence
  (superior to 93% historical control rate)
Results: Safety

- No grade 4-5 toxicities
- Five grade 3 side effects occurred in 4 pts, far below the 10% considered excessive:
  - Two low-risk pts (1.2%), $p<0.001$
  - Two intermediate-risk pts (1.5%), $p<0.001$

Efficacy

Based on Nadir + 2 definition:

- 97.1% of pts free from recurrence at 5 yrs
- In low-risk pts, 97.3% free from recurrence (superior to 93% historical control rate)
- In intermediate-risk pts, 97.1% free from recurrence at 5 yrs
Conclusions

For men with newly-diagnosed prostate cancer, when appropriate technology and planning is employed:

• SBRT is safe, with a low rate of serious side effects
• SBRT cancer control rates are very favorable compared to historical data
• SBRT is a suitable option for low- and intermediate-risk prostate cancer, and may be preferable to other treatment approaches.
• This is another example of how advanced technology has radically improved our ability to target cancer
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Background

• Low risk prostate cancer may be treated with either surgery, external beam radiation or brachytherapy (“seed implant”) equally successfully

• Patients with intermediate risk prostate cancer have conventionally received either external beam radiation alone or in combination with brachytherapy, but not brachytherapy alone

• **Hypothesis**: Patients with intermediate risk prostate cancer who receive External Beam Radiation Therapy (EBRT) + prostate brachytherapy (PB) will have a 10% improvement in FFP at 5 years compared to those receiving PB alone.
Eligibility Criteria

• Histologically confirmed prostate adenocarcinoma, stages T1c-T2b (AJCC 6th Edition)

• Zubrod Performance Scale 0-1

• One of the following combinations of factors:
  • Gleason score 2-6, and prostate-specific antigen ≥10 but < 20
  • Gleason score 7, and prostate-specific antigen < 10
  • Prostate volume < 60 cc

• No prior ADT (beginning < 2 months or > 6 months prior to registration)

• International Prostate Symptom Score (IPSS) < 16

• No distant metastases (M0) or clinically or radiographically suspicious nodes
**RTOG 0232: Study Schema**

<table>
<thead>
<tr>
<th>Stratify</th>
<th>Record</th>
<th>Randomize</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage</td>
<td></td>
<td>Arm 1:</td>
</tr>
<tr>
<td>1. T1c</td>
<td>45 Gy EBRT</td>
<td>45 Gy EBRT</td>
</tr>
<tr>
<td>2. T2a – T2b</td>
<td></td>
<td>Partial pelvis (1.8 Gy/fraction M-F for five weeks) followed 2-4 weeks later by Pd-103 (100 Gy) or l-125 (110 Gy)</td>
</tr>
<tr>
<td>Gleason Score</td>
<td>Isotope 1. I-125</td>
<td>or</td>
</tr>
<tr>
<td>1. ≤ 6</td>
<td>2. Pd-103</td>
<td>Arm 2:</td>
</tr>
<tr>
<td>2. ≥ 7</td>
<td></td>
<td>Pd-103 (125 Gy) or l-125 (145 Gy)</td>
</tr>
<tr>
<td>PSA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. &lt; 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. 10-20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neoadjuvant Hormonal Therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Records:**
- Stage
- Gleason Score
- PSA
- Neoadjuvant Hormonal Therapy
Methods and Materials: Techniques

External Beam Radiation
Volume: CTV- Prostate + SV, nodes optional. PTV: CTV + 0.5-1 cm margin
Dose: PTV > 98%, 1.8 Gy x 25 = 45 Gy. 43% received IMRT

Brachytherapy – Low Dose Rate
Timing: 2-4 weeks post EBRT
Volume: CTV defined by pre-implant TRUS. PTV: CTV + 2-5 mm margin

<table>
<thead>
<tr>
<th>Dose</th>
<th>I-125 (482)</th>
<th>Pd-103 (81)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monotherpay</td>
<td>145 Gy</td>
<td>125 Gy</td>
</tr>
<tr>
<td>Boost</td>
<td>110 Gy</td>
<td>100 Gy</td>
</tr>
<tr>
<td>Source Activity</td>
<td>.277 - .548 U</td>
<td>1.29 - 2.61 U</td>
</tr>
</tbody>
</table>
## RTOG 0232 Accrual Summary

<table>
<thead>
<tr>
<th></th>
<th>EBRT + PB</th>
<th>PB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized</td>
<td>292</td>
<td>296</td>
<td>588</td>
</tr>
<tr>
<td>Ineligible</td>
<td>5</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Eligible</td>
<td>287</td>
<td>292</td>
<td>579</td>
</tr>
</tbody>
</table>

- **Date activated**: 6/11/2003
- **Date closed**: 2/8/2012
- **Target sample size**: 586
Results: Freedom from Progression

<table>
<thead>
<tr>
<th>First Failure</th>
<th>EBRT + PB (n=34)</th>
<th>PB (n=32)</th>
<th>Total (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF-ASTRO</td>
<td>23 (68%)</td>
<td>17 (53%)</td>
<td>40 (61%)</td>
</tr>
<tr>
<td>LP</td>
<td>1 (3%)</td>
<td>1 (3%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>LP, DM</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Death*</td>
<td>9 (26%)</td>
<td>14 (44%)</td>
<td>23 (35%)</td>
</tr>
</tbody>
</table>

*Not due to prostate cancer

Patients at Risk
EBRT + PB | 220 212 203 198 192 183
PB         | 223 219 213 207 198 186

Graph showing freedom from progression over years from randomization.
Results: Adverse Events

- Acute Grade $\geq 2$: 28% vs. 27%; $p=0.68$
- Acute Grade $\geq 3$: 8% vs. 8%; $p=0.97$
- Late Grade $\geq 2$: 53% vs. 37%; $p=0.0001$
- Late Grade $\geq 3$: 12% vs. 7%; $p=0.039$
Conclusions

• Among men with intermediate risk (IR) prostate cancer, the addition of external beam therapy to brachytherapy did not result in superior freedom from progression compared to brachytherapy alone at 5 years in this initial report.

• Toxicity in both groups was limited, but there were fewer late effects, mostly GU, noted in the brachytherapy alone arm.

• Implications for clinical practice: Men with intermediate risk prostate cancer may be well managed with brachytherapy alone.

• Further subset analysis will be required to determine if the unfavorable IR patients do as well as those with favorable IR disease.

• Longer follow up is needed to confirm the durability of the findings.
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• Identification and Validation of Intrinsic Subtypes of Prostate Cancer
    Daniel E. Spratt, MD, University of Michigan, Ann Arbor, MI
Identification and Validation of Intrinsic Subtypes of Prostate Cancer

D. E. Spratt¹, S. G. Zhao¹, S. L. Chang¹, M. R. Cooperberg², N. G. Erho³, C. Speers⁴, R. Mera¹, Y. S. Niknafs¹, P. L. Nguyen⁵, R. B. Den⁶, A. P. Dicker⁶, E. A. Klein⁷, R. J. Karnes⁸, E. M. Schaeffer⁹, E. Davicioni³, P. Carroll², A. Chinnaiyan¹⁰, S. A. Tomlins¹, A. E. Ross⁹, F. Y. Feng¹¹

¹University of Michigan, Ann Arbor, MI, ²University of California, San Francisco, San Francisco, CA, ³GenomeDx Biosciences, Vancouver, BC, Canada, ⁴Veteran Affairs Hospital Ann Arbor, Ann Arbor, MI, ⁵Brigham & Women’s Hospital, Dana Farber Cancer Institute and Harvard Medical School, Boston, MA, ⁶Sidney Kimmel Medical College at Thomas Jefferson University, Sidney Kimmel Cancer Center, Philadelphia, PA, ⁷Cleveland Clinic, Cleveland, OH, ⁸Mayo Clinic, Rochester, MN, ⁹Johns Hopkins University, Baltimore, MD, ¹⁰The University of Michigan Cancer Center, Ann Arbor, MI, ¹¹University of California at San Francisco, San Francisco, CA
Background

• Currently, risk grouping systems for prostate rely on imperfect tools, such as the digital rectal exam, to group patients by risk of recurrence.

• These systems do not provide information of the biology of the disease, do not always provide accurate prognostic information, and cannot assess which patient will truly benefit from our therapies.

• The goals of our project were to:
  1. Identify the intrinsic molecular subtypes of primary prostate cancer through tumor sequencing with an unbiased approach.
  2. Determine the prognostic significance of the molecular subtypes.
  3. Understand if the subtypes could predict who would benefit from post-operative radiotherapy.
Method

Cohorts 1-7

- 7 institutions: Mayo I and II, Cleveland Clinic, Johns Hopkins, Thomas Jefferson, Erasmus, and MSKCC
- Retrospective
- Affymetrix microarray
- FFPE and Fresh Frozen
- N=1626

Cohort 8

- The Cancer Genome Atlas (TCGA)
- Prospective
- RNAseq
- Fresh Frozen
- N=497

Cohort 9

- Decipher GRID™
- Prospective
- Affymetrix microarray
- FFPE
- N=2113

Total Samples: 4236
The 3 intrinsic molecular subtypes were identified.
Results

Subtype A has the lowest rate of Distant Metastases

Multivariable Analysis

<table>
<thead>
<tr>
<th>Co-variables</th>
<th>HR [95% CI]</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtype B vs. A</td>
<td>1.31 [1.03-1.65]</td>
<td>0.03</td>
</tr>
<tr>
<td>Subtype C vs. A</td>
<td>1.33 [1.04-1.71]</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Additional variables in MVA: Age, PSA, Gleason, surgical margins, ECE, SVI, and LNI

Multivariate Interaction with RT

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interaction of RT:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group A vs. B+C</td>
<td>0.44</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Subtypes B+C have a significantly improved response to post-operative RT than subtype A.
Conclusions

• We have identified the 3 intrinsic molecular subtypes of primary prostate cancer and rigorously validated them to show that they are highly reproducible.

• These subtypes can independently predict the risk of a patient developing distant metastasis after a radical prostatectomy.

• These subtypes appear to be able to predict who will respond most favorably to post-operative radiotherapy.

• The molecular subtypes will help us to personalize care for each prostate cancer patient to help inform us of their risk of recurrence and their potential benefit from radiation therapy.
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Q & A

Online attendees: Please use the Question function to submit questions.
Additional questions and interview requests:

ASTRO’s On-site Press Office in Boston

Room 151A, Boston Convention and Exhibition Center
September 25-27, 8am-4pm ET; September 28, 8am-12pm ET
703-286-1600
press@astro.org

Slides, photos, and audio will be available following the briefing at www.astro.org/AMpress