Prostate Cancer: IMRT vs Proton

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Massachusetts General Hospital
Harvard Medical School

PTCOG 53
Shanghai, China
June 13, 2014
Disclosures
Advisory Board for Medivation/Astellas and Bayer

Disclaimer
I treat men with both
We are conducting a RCT
If you want to know what is wrong with American health care today, exhibit A might be the two new proton beam treatment facilities the Mayo Clinic has begun building… which could cost taxpayers billions of dollars for a treatment that, in many cases, appears to be no better than cheaper alternatives.

There is no convincing evidence that proton beam therapy is as good as — much less better than — cheaper types of radiation for any one of these cancers. There has not been a single randomized trial…

If the United States is ever going to control our health care costs, we have to demand better evidence of effectiveness, and stop handing out taxpayer dollars with no questions asked.

…it is crazy medicine and unsustainable public policy.
“I believe that a comparison after 50,000 or so have already been treated worldwide with Protons, is simply a political decision with the heat coming from those doctors who do not have the Proton capability or have a stake driven in other treatments and do not want to buy this capability.”

“Since 2001, proton therapy has proven to be the most effective treatment available for prostate cancer that has not metastasized”

“A highly sophisticated form of radiation therapy, proton therapy is so precise to the exact target area — the tumor — that damage to nearby tissue is virtually non-existent. Standard radiation therapy directs a beam completely through the patient’s body, so other tissue gets irradiated as well.”
“The sharpness of a surgeon’s knife
The softness of an artist’s brush”
Gizmo Idolatry

Bruce Leff, MD

Thomas E. Finucane, MD
New technology and the enthusiasm curve

“Best thing since sliced bread”

Celebrity treated

“I wouldn’t give it to a dog”

Appropriate use

Technique introduced

Enthusiasm

Time

Courtesy of A. Zietman
Radiation therapy for prostate cancer 1994

Conventional external beam
Radiation therapy for prostate cancer 2014

- Conventional external beam
- Conformal external beam
- IMRT
- Proton
- Ultra-high-dose
- 3-D
- SBRT
- Cyberknife
- High-dose conformal
- Brachytherapy
- High dose rate
- Low dose rate
- Brachytherapy/external beam
- Any of the above with androgen deprivation
How did it come to this?

Local tumor control problem with radiation therapy in prostate cancer
The solution?

Increase radiation dose
High Dose Radiation in Prostate Cancer: Randomized phase III trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>stage</th>
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10-20% benefit in FFBF for 8-10 GY increase in total dose
PROG 9509: A Randomized Trial of Radiation Dose in Prostate Cancer$^{1,2}$

- Latest analysis: Median follow-up 8.9 years

**Table 2. Acute and Late GU and GI Toxicity**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>70.2 GyE (n = 196)</th>
<th>79.2 GyE (n = 195)</th>
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Abbreviations: GU, genitourinary; GyE, Gray equivalents.

*Testing grade 1 versus others using $\chi^2$ test.

Table 2. Acute and Late GU and GI Toxicity

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<tr>
<th></th>
<th>Assigned Dose</th>
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<td>123*</td>
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<td>0</td>
<td>79</td>
<td>41</td>
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</table>

Abbreviations: GU, genitourinary; GyE, Gray equivalents.
*Testing grade 1 versus others using \( \chi^2 \) test.

<table>
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<tr>
<th>Symptom</th>
<th>70Gy</th>
<th>79Gy</th>
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<tr>
<td>Urinary obstr/irritn</td>
<td>23.3</td>
<td>24.6</td>
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<td>Bowel</td>
<td>7.7</td>
<td>7.9</td>
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<tr>
<td>Sexual</td>
<td>68.2</td>
<td>65.9</td>
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</table>

Symptom scales

- 0 = no symptoms
- 100 = maximal distress/dysfunction

Improved radiation delivery systems: Hardware and software advances

2-D radiation – 70-90s
Improved radiation delivery systems: Hardware and software advances

3-D Conformal – 90s

Intensity Modulation – 00s
Comparative DVHs:
Volume of anterior rectum >70Gy

2-D – 55%

3-D – 30%

IMRT – <10%
MDACC 78 Gy Arm Grade ≥2 late rectal toxicity: Subdivided by percent rectum treated to ≥70 Gy

Conformal Radiation in Localized Prostate Cancer

Royal Marsden Randomized Trial 1999

Proctitis

<table>
<thead>
<tr>
<th></th>
<th>Grade 1</th>
<th>Grade 2</th>
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<tr>
<td>Conformal (3D)</td>
<td>37%</td>
<td>5%</td>
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<tr>
<td>Conventional (2D)</td>
<td>56%</td>
<td>15%</td>
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</tbody>
</table>

Utilization of IMRT for localized Prostate Cancer: SEER Data

Sheets, Goldin, Meyer, et al., JAMA 2012
External beam radiation: climbing the technological ladder

- Conventional EBRT
- 3D-conformal
- IMRT
- Protons

Proven advantage

$\ldots$$\ldots$
And now......proton therapy

Aims:

Better tumor eradication through higher doses

Reduced morbidity
Proton Beam Therapy

- The physics
- The clinical potential
Proton Beam Therapy

- The physics
- The clinical potential
Pristine Bragg Peaks of Selected Energies

Courtesy of H. Kooy, Ph.D.
Radiation deposition in tissue for photons vs protons

Proton Beam...a searchlight without a tail
Proton Beam Therapy

• The physics
• The clinical potential
MEDULLOBLASTOMA

PHOTONS

PROTONS

PHOTONS

PROTONS

Courtesy T. Yock, N. Tarbell, J. Adams
Orbital Rhabdomyosarcoma

Courtesy T. Yock, N. Tarbell, J. Adams
Prostate

Protons

IMRT
Excess Radiation Dose: IMRT vs protons

Whole body radiation dose: marked reduction in integral dose

Excess volume irradiation with IMRT

Courtesy of A. Trofimov
Beam Scanning Technology
Comparative DVHs for IMRT, Protons, and IMPT

Partial Prostate Boost using IMPT

Anterior fields

Proton vs. IMRT Target Coverage
Proton vs. IMRT: Rectal Dose

Vargas et al., IJROBP 2007
# Proton vs. IMRT Rectal Doses

Table 3. Percentage of volume of rectum and rectal wall receiving doses between 10 and 80 GE/Gy and mean dose (n = 20 plans)

<table>
<thead>
<tr>
<th></th>
<th>Proton therapy</th>
<th>IMRT</th>
<th>p</th>
<th>Benefit (%)</th>
<th>Relative</th>
<th>Absolute</th>
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<tr>
<td><strong>Rectum</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>$V_{10}$ (%)</td>
<td>29.8 ± 5.6</td>
<td>72.1 ± 7.6</td>
<td>&lt;0.001</td>
<td>58.7</td>
<td>42.3</td>
<td></td>
</tr>
<tr>
<td>$V_{30}$ (%)</td>
<td>20.7 ± 3.9</td>
<td>55.4 ± 5.7</td>
<td>&lt;0.001</td>
<td>62.7</td>
<td>34.7</td>
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<tr>
<td>$V_{50}$ (%)</td>
<td>14.6 ± 3.0</td>
<td>31.3 ± 4.1</td>
<td>&lt;0.001</td>
<td>53.4</td>
<td>16.7</td>
<td></td>
</tr>
<tr>
<td>$V_{70}$ (%)</td>
<td>7.9 ± 1.8</td>
<td>14.0 ± 2.9</td>
<td>&lt;0.001</td>
<td>43.6</td>
<td>6.1</td>
<td></td>
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<tr>
<td>$V_{78}$ (%)</td>
<td>2.9 ± 1.2</td>
<td>5.0 ± 1.2</td>
<td>0.01</td>
<td>42.0</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>$V_{80}$ (%)</td>
<td>0.1 ± 0.3</td>
<td>1.8 ± 1.8</td>
<td>0.01</td>
<td>94.4</td>
<td>1.7</td>
<td></td>
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<tr>
<td><strong>Mean dose</strong></td>
<td>14.2 ± 3.7 GE</td>
<td>34.8 ± 3.0 Gy</td>
<td>&lt;0.001</td>
<td>59.2</td>
<td>20.1 GE/Gy</td>
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<td><strong>Rectal wall</strong></td>
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<tr>
<td>$V_{10}$ (%)</td>
<td>27.9 ± 3.8</td>
<td>63.0 ± 6.0</td>
<td>&lt;0.001</td>
<td>55.7</td>
<td>35.1</td>
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<tr>
<td>$V_{30}$ (%)</td>
<td>23.8 ± 3.2</td>
<td>50.7 ± 4.5</td>
<td>&lt;0.001</td>
<td>53.1</td>
<td>26.9</td>
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<tr>
<td>$V_{50}$ (%)</td>
<td>19.0 ± 2.8</td>
<td>30.1 ± 4.9</td>
<td>&lt;0.001</td>
<td>36.9</td>
<td>11.1</td>
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<tr>
<td>$V_{70}$ (%)</td>
<td>13.2 ± 2.7</td>
<td>16.9 ± 2.6</td>
<td>0.006</td>
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<td>$V_{78}$ (%)</td>
<td>6.7 ± 2.5</td>
<td>9.3 ± 2.6</td>
<td>0.03</td>
<td>28.0</td>
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<td>$V_{80}$ (%)</td>
<td>0.1 ± 0.3</td>
<td>4.1 ± 3.3</td>
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<tr>
<td><strong>Mean dose</strong></td>
<td>16.5 ± 3.6 GE</td>
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### Patient-Reported QOL: Proton beam (Univ of Florida)

#### Table 3: Patient-reported outcomes according to IPSS and EPIC questionnaires, respectively

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<thead>
<tr>
<th>Protocol</th>
<th>No. of patients</th>
<th>Med</th>
<th>Min</th>
<th>Max</th>
<th>No. of patients</th>
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<td>100</td>
<td>138</td>
<td>96</td>
<td>42</td>
<td>100</td>
<td>&lt;.0001</td>
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Mendenhall et al., IJROBP 2014
Scatter Dose

Yoon et al., IJROBP 2009
Scatter Dose: Risk of Radiation Associated Second Cancers

ERR (factor increase in rate of cancer - 1)

RRR = 0.66

- IMRT protons LNT
- IMRT protons LEXP(10)
- IMRT protons LPLAT(10)
- IMRT protons LEXP(40)
- IMRT protons LPLAT(40)

Fontenot et al., IJROBP 2009
Does proton beam carry less morbidity in the treatment of prostate cancer?

- Despite the theoretical advantages of proton therapy, studies have yet to prove a clear clinical benefit to proton therapy compared to IMRT
“The Magic Bullet for Prostate Cancer” (2011)

“The Magic Bullet Falls Short” (2012)

SEER-Medicare studies question proton therapy for prostate cancer

Sheets et al., JAMA 2012; Kim et al., Eur Urol 2011
SEER-Medicare Studies

Treatment dose data? ✗
Target margins? ✗
Use of image guidance? ✗
Differentiates proton from mixed proton/photon? ✗
Includes >1 proton center? ✗
Differentiate screening colonoscopies from diagnostic colonoscopies? ✗
Includes patient-reported outcomes? ✗
Potential misclassification bias? ✓
Potential confounding by unrecorded variables? ✓
Lingering questions? ✓

Sheets et al., JAMA 2012; Kim et al., Eur Urol 2011
### Medicare Studies

<table>
<thead>
<tr>
<th>Complications category</th>
<th>IMRT, n = 842, No. (%)</th>
<th>PRT, n = 421, No. (%)</th>
<th>OR† (95% CI)</th>
<th>P‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genitourinary</td>
<td>80 (9.5)</td>
<td>25 (5.9)</td>
<td>0.60 (0.38 to 0.96)</td>
<td>.03</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>30 (3.6)</td>
<td>12 (2.9)</td>
<td>0.84 (0.42 to 1.66)</td>
<td>.61</td>
</tr>
<tr>
<td>Other</td>
<td>21 (2.5)</td>
<td>&lt;11 (&lt;2.6)§</td>
<td>0.69 (0.29 to 1.66)</td>
<td>.41</td>
</tr>
</tbody>
</table>

Yu et al., JNCI 2012
Patient Reported Bowel Toxicity

Bowel/Rectal Domain

Score change from baseline

Months

PBT
IMRT

Gray et al. Cancer 2013
Proton Beam Therapy for Prostate Cancer

Prostate cancer is the most common cancer among US men.

Prostate cancer can be treated either by surgical removal of the prostate gland or by radiation therapy. Radiation therapy kills cancer cells by delivering large amounts of energy to tumors. External radiation is usually given by intensity-modulated radiation therapy (IMRT), which sends many small radiation (x-ray) beams to the tumor in a way that maximizes the amount of radiation that reaches the cancer and minimizes radiation exposure of tissues around the tumor. IMRT has been proven to work and most men tolerate the side effects.

What is Proton Beam Therapy?
A new kind of radiation treatment using proton beams is now available. Protons are heavier than x-rays and tend not to scatter as much. Also, unlike x-rays, protons slow down as they travel through the body. It is possible that proton beam therapy delivers less unwanted energy to tissues around the tumor than IMRT, but studies have found mixed results, and some have shown that IMRT better spares certain tissues than proton treatment. But protons are very sensitive to the different densities of tissues they pass through, more so than x-rays. If healthy cells are spared, patients being treated for prostate cancer will have fewer side effects, such as bowel, bladder, or erection problems, from radiation treatment. Proton beam therapy is also more sensitive than IMRT to daily variations in a patient’s anatomy and positioning and theoretically can have more uncertainty in the dose delivered to the prostate.

Proton beam therapy has been shown to be better than older methods for treating children with certain brain and spinal cord cancers, but these cancers are very rare. Because prostate cancer is very common, it provides a greater opportunity to study the experience with proton beam therapy than do most other cancers.

Studies of Proton Beam Therapy
So far, only a few studies have compared IMRT and proton beam therapy for prostate cancer. The results showed that:
- There was no suggestion that proton beam therapy was better than x-ray radiation therapy in the treatment of prostate cancer.
- Although in the first 6 months after treatment there were fewer bladder problems with proton beam therapy, 1 year after treatment there was no difference in toxic effects.
- Patients report similar moderate problems with bowel function 2 years after either IMRT or proton beam therapy.
- IMRT was a little more than half the cost of proton beam therapy.

FOR MORE INFORMATION
- National Library of Medicine
  www.nlm.nih.gov/medlineplus/ency/article/007261.htm
- ClinicalTrials.gov
clinicaltrials.gov/ct2/show/NCT03662163

To find this and previous JAMA Patient Pages, go to the Patient Page link on JAMA’s website at jama.com. Many are available in English and Spanish. A Patient Page on prostate cancer was published in the July 9, 2008, issue on one on radiation therapy in the December 25, 2019, issue, and one on grading of prostate cancer in the October 3, 2007, issue.

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Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

JAMA April 9, 2014 Volume 311, Number 14
Low-Intermediate Risk Prostate Cancer

N=400

Randomize

Proton Beam

IMRT

79.2 Gy

79.2 Gy (RBE)

Patient-Reported Quality of Life
Cost-Effectiveness
Physics/Biology

clinicaltrials.gov identifier: NCT01617161
PARTIQoL RCT Update
(Prostate Advanced Technologies Investigating Quality of Life)

- 58 patients randomized as of May 31, 2014
- Trial now also activated at:
  - MD Anderson Cancer Center, Central DuPage Hospital
- Soon to be activated at:
  - Washington University in St. Louis, Princeton Radiation Oncology (includes ProCure New Jersey)
- In process of adding:
  - University of Washington, MSKCC
Closing Thoughts

• EBRT is a safe and effective treatment, dose escalation improves cancer control without increasing the risk of serious side-effects

• Proton therapy has physical/dosimetric advantages over IMRT

• Protons can spare normal tissues and avoid the low dose radiation bath (decrease integral dose)

• Retrospective studies have even shown decreased acute bowel and urinary morbidity compared to photons

• Second cancer modeling studies suggest benefit over IMRT

• We must continue to invest in and promote scientific innovation and creativity and develop the evidence to support proton therapy while looking to decrease its cost