SBRT for localized prostate cancer

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Disclosures

• The purpose of this presentation is educational and scientific exchange

• This is not a sales promotional presentation
FRACTIONATION

CONVENTIONAL FRACTIONATION

versus

HYPOFRACTIONATION

versus

STEREOTACTIC BODY RADIOSURGERY (SBRT) or SABR

<table>
<thead>
<tr>
<th>Number of fractions</th>
<th>~35</th>
<th>45</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

“EXTREME”
“AGGRESSIVE”
“ULTRA HIGH DOSE”

“PROFOUND”

“MILD”
“MODERATE”
“CONSERVATIVE”

Ablative?? Normal tissue sparing

Biological Rationale
STEREOTACTIC HYPOFRACTIONATED ACCURATE RADIOTHERAPY OF THE PROSTATE (SHARP), 33.5 GY IN FIVE FRACTIONS FOR LOCALIZED DISEASE: FIRST CLINICAL TRIAL RESULTS

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Prostate SBRT

RESULTS

Recent Review Article:

Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer
Amar U. Kishan, MD, and Christopher R. King, MD, PhD

Kishan AU. Semin Radiat Oncol. 27(3):268-278, 2017
# SBRT DOSE SCHEDULES

**Dose ranges:**  
BED ($\alpha/\beta=2$)

<table>
<thead>
<tr>
<th>Dose</th>
<th>Gy</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.70 x 5 = 33.5</td>
<td>146</td>
<td>Madsen IJROBP 2007</td>
</tr>
<tr>
<td>7.25 x 5 = 36.25</td>
<td>168</td>
<td>King IJROBP 2009</td>
</tr>
<tr>
<td>7.5 x 5 = 37.5</td>
<td>178</td>
<td>Friedland TCRT 2009</td>
</tr>
<tr>
<td>9.0 x 4 = 36.0</td>
<td>198</td>
<td>Fuller IJROBP 2008</td>
</tr>
<tr>
<td>8.0 x 5 = 40.0</td>
<td>200</td>
<td>King RO 2013</td>
</tr>
<tr>
<td>9.0 x 5 = 45.0</td>
<td>248</td>
<td>Meier TCR 2014</td>
</tr>
<tr>
<td>9.5 x 5 = 47.5</td>
<td>273</td>
<td>Kim IJROBP 2014</td>
</tr>
<tr>
<td>10.0 x 5 = 50.0</td>
<td>300</td>
<td>Mantz FO 2014</td>
</tr>
<tr>
<td>24 x 1 = 24</td>
<td>312</td>
<td>Greco, Lisbon</td>
</tr>
</tbody>
</table>

**BED equivalent to LDR or HDR prostate RT**
### Table 4 | Prostate SBRT series with mature follow-up.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Dose fractionation</th>
<th>Median F/U years</th>
<th>Risk group</th>
<th>Pts</th>
<th>5-Year bDFS(^a) (%)</th>
</tr>
</thead>
</table>

Median FU range: 3 - 7 years

5 yr bRFS
Low Risk: 90-99%
Int Risk: 84-97%

Patient numbers: 40-1100

\(^a\)Nadir + 2 definitions.
\(^b\)Four-year bDFS reported.

bDFS, biochemical disease-free survival; SBRT, stereotactic body radiotherapy.
Prostate SBRT Consortium Pooled Data

• Pooled database: 1100 patients (2012)
  Follow PSA profiles / QOL data

  Not a meta-analysis

• 8 institutions (US & international)
• Prospective phase II trials
• Median follow-up: 3 years (1 to 7+ yrs)

Disease-free Survival after SBRT

PSA Relapse-Free Survival at 5 years

- **Low-Risk**: 95%
- **Intermediate-Risk**: 84% (p=0.03)
- **High-Risk**: 81% (p<0.0001)

Time following SBRT (months)
Prostate SBRT Consortium Pooled Data

UPDATE 2017

Pooled database;
10 institutions
>1500 patients
>10 year results
>7 year median follow-up

Report in 2018
Late G3 GU 1.7% - all in higher dose group
Late G3-4 GI 0%

**Stereotactic body radiotherapy as treatment for organ confined low- and intermediate-risk prostate carcinoma, a 7-year study**


**EFFICACY in 457 patients**

- 96% 7y bDFS (Log-rank p<0.001)
- 89.3% (95% CI: 67.9% - 100%)

Median time to PSA nadir: 48 mo
Median PSA nadir: 0.11

Median FU: 72 mo

### FIGURE 8 | Median PSA value in the entire patient cohort
Error bars reflect interquartile range. The Number of patients with PSA data at each time point is listed below. Patients with biochemical recurrence are excluded.
PHYSICIAN PERSPECTIVE:

Physician-Reported Toxicity Scores
Physician reported toxicity

![Graphs showing late toxicity comparison between SBRT vs EBRT & LDR Brachy with specific institutions and their respective toxicity rates for late urinary and GI toxicity.](https://example.com/graphics)

Meier. Frontiers in Oncology, vol 5, Art 48, 2015
UT Southwestern Protocol (R. Timmerman)
Kim et al, IJROBP 89, p 509-17, 2014

Median follow-up is 24.5 months (range 1-66)
Dose groups: 9.0 Gy x 5 = 45 Gy
9.5 Gy x 5 = 47.5 Gy
10.0 Gy x 5 = 50 Gy

7% (6/91) developed High Grade Rectal Toxicity (Grade 3-4); 5/6 required colostomy

Predictors of Gr4 rectal toxicity:
• > 35% of rectal wall at 39 Gy (p=0.03)
• Volume of rectal wall receiving 50 Gy (p=0.01)

Gr4 toxicity: All had > 3.5 cm³ of rectal wall ≥ 50 Gy (p < .0001).
All patients with no rectal toxicity had < 3.5 cm³ rectal wall at 50 Gy.
PATIENT PERSPECTIVE:

QOL Differences:

SBRT Vs Fractionated EBRT Vs Brachytherapy
EPIC Urinary Incontinence Score

Comparison:
Sanda M. Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors. N Engl J Med 2008;358:1250

External Beam RT →

LDR Brachytherapy →

EPIC Urinary Irritation or Obstruction Score

External Beam RT →

Comparison:
Sanda M. Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors. N Engl J Med 2008;358:1250

LDR Brachytherapy →

EPIC Bowel Score

Comparison:
Sanda M. Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors. N Engl J Med 2008;358:1250

External Beam RT →

LDR Brachytherapy →

EPIC Sexual Score

Comparison:
Sanda M. Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors. N Engl J Med 2008;358:1250

External Beam RT →

LDR Brachytherapy →

Meier. SBRT for Organ-confined prostate cancer

Transl Cancer Res 2014;3(4):320-332
Sexual Function after SBRT

U Michigan, N= 373, Med FU: 56 mos

Predictors of long-term erectile function:
Age, baseline sexual function, and BMI.

Erection rates after SBRT not statistically different from model-predicted rates after EBRT or brachytherapy.

Dess et al. BJU Int. 2017
PATIENT PERSPECTIVE:

Regret After Treatment:

SBRT
Vs
Fractionated EBRT
Vs
Brachytherapy
Regret after treatment

Validated questionnaire on patient-centered domains including:

- Treatment decision making experience
- Original expectations of toxicities vs. realities
- Treatment decision regret

Responders had a median of 47 months of post-treatment follow-up

Shaverdian et al, IJROBP, 2017, 1;97(3):516-525
# Regret after treatment

## Toxicity Perceptions

<table>
<thead>
<tr>
<th>Factor</th>
<th>IMRT</th>
<th>SBRT</th>
<th>HDR</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short-term side effects?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exactly as I had expected</td>
<td>35%</td>
<td>32%</td>
<td>42%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Significantly less than I had expected</td>
<td>30%</td>
<td>39%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Slightly less than I had expected</td>
<td>26%</td>
<td>16%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Slightly more than I had expected</td>
<td>7%</td>
<td>13%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td><strong>Significantly more than I had expected</strong></td>
<td>3%</td>
<td>0%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td><strong>Long-term side effects?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exactly as I had expected</td>
<td>41%</td>
<td>21%</td>
<td>30%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Significantly less than I had expected</td>
<td>20%</td>
<td>43%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Slightly less than I had expected</td>
<td>14%</td>
<td>20%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Slightly more than I had expected</td>
<td>15%</td>
<td>12%</td>
<td>36%</td>
<td></td>
</tr>
<tr>
<td><strong>Significantly more than I had expected</strong></td>
<td>11%</td>
<td>3%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td><strong>“My doctor fully informed me about side-effects”</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>0.42</td>
</tr>
<tr>
<td>Disagree</td>
<td>7%</td>
<td>2%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Neither agree nor disagree</td>
<td>7%</td>
<td>4%</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>32%</td>
<td>47%</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>Strongly agree</td>
<td>51%</td>
<td>45%</td>
<td>46%</td>
<td></td>
</tr>
</tbody>
</table>

Shaverdian et al, 2017, 1;97(3):516-525
Regret after treatment:
19% IMRT vs. 18% HDR and 5% SBRT ($p<0.01$).

Table 5 — Predictors of regret on multivariate logistic regression analysis

<table>
<thead>
<tr>
<th>Factor</th>
<th>OR(95% CI)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learned enough about treatments</td>
<td>52.63 (12.8-200)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Mutually worked with physician</td>
<td>16.13 (5.03-52.63)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Doctor fully informed me</td>
<td>10.75 (3.34-34.48)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Short-term side effects worse than expected</td>
<td>8.06 (2.57-25.26)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Long-term side effects worse than expected</td>
<td>42.42 (8.41-213.95)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>IMRT vs. SBRT</td>
<td>11.11 (2.65-46.01)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>HDR vs. SBRT</td>
<td>7.42 (1.78-31.03)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>HDR vs. IMRT</td>
<td>0.67 (0.19-2.34)</td>
<td>0.54</td>
</tr>
</tbody>
</table>

Shaverdian et al, 2017, 1;97(3):516-525
SBRT RANDOMIZED TRIALS
## RANDOMIZED SBRT TRIALS

<table>
<thead>
<tr>
<th>SBRT Arm</th>
<th>Arm 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RTOG 0938:</strong></td>
<td>Small trial – QOL endpoint</td>
</tr>
<tr>
<td>36.25 at 7.25 Gy vs 51.6 at 4.3 Gy</td>
<td></td>
</tr>
<tr>
<td>5 fractions vs 12 fractions</td>
<td></td>
</tr>
<tr>
<td><strong>PCG GU 002:</strong></td>
<td>Protons, N=82</td>
</tr>
<tr>
<td>38 at 7.6 Gy vs 79.2 at 1.8 Gy</td>
<td></td>
</tr>
<tr>
<td>5 fractions vs 44 fractions</td>
<td></td>
</tr>
<tr>
<td><strong>U Miami Heat:</strong></td>
<td></td>
</tr>
<tr>
<td>31.25 at 6.25 Gy vs 70.2 at 2.6 Gy</td>
<td></td>
</tr>
<tr>
<td>5 fractions vs 26 fractions</td>
<td></td>
</tr>
<tr>
<td><strong>HYPO-RT-PC:</strong></td>
<td></td>
</tr>
<tr>
<td>42.7 at 6.1 Gy vs 78 at 2 Gy</td>
<td></td>
</tr>
<tr>
<td>7 fractions vs 39 fractions</td>
<td></td>
</tr>
<tr>
<td><strong>PACE trial:</strong></td>
<td></td>
</tr>
<tr>
<td>36.25 at 7.25 Gy vs 78 at 2 Gy</td>
<td></td>
</tr>
<tr>
<td>5 fractions vs 39 fractions</td>
<td></td>
</tr>
</tbody>
</table>
HYPO-RT-PC trial  (PI:A. Widmark)
Randomized multi-institutional phase III trial in Scandinavia

42.7 at 6.1 Gy    vs    78 at 2 Gy
7 fractions       39 fractions

N=866, Minimum FU: 2y, Median FU: 4.2y

Eligible patients:  INTERMEDIATE RISK
T1c to T3a, PSA \leq 20 and one or two of three risk factors:
Stage T3a
Gleason \geq 7
PSA >10

TECHNIQUE:  3DCRT  80%
VMAT        20%
HYPO-RT-PC trial - ASTRO 2016

Extremely hypofractionated radiation therapy shows promising toxicity results for intermediate risk prostate cancer patients

Large Scandinavian trial finds comparable side effects at two years following 42.7 Gy delivered in seven fractions compared to 78 Gy delivered in 39 treatments

N=866, Minimum FU: 2y. Median FU: 4.2y

<table>
<thead>
<tr>
<th>Grade 2+ toxicities at 2 yrs</th>
<th>Urinary</th>
<th>Bowel</th>
</tr>
</thead>
<tbody>
<tr>
<td>42.7 at 6.1 Gy:</td>
<td>5.4%</td>
<td>2.2%</td>
</tr>
<tr>
<td>78 at 2 Gy:</td>
<td>4.6%</td>
<td>3.7%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Impotence</th>
<th>Baseline</th>
<th>At 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>42.7 at 6.1 Gy:</td>
<td>16%</td>
<td>34%</td>
</tr>
<tr>
<td>78 at 2 Gy:</td>
<td>16%</td>
<td>34%</td>
</tr>
</tbody>
</table>

**Quality of life at 2 years:** NO DIFFERENCE

Urinary (p=0.17), Bowel (p=0.12), Sexual Function (p=0.71)
PACE TRIAL

Randomized trial. UK. N=1716.
LOW AND INTERMEDIATE RISK
PSA < 20 ng/ml
Gleason score ≤ 3 + 4 = 7
Clinical stage T1c -T2c, N0-X, M0-X

Surgical candidate?

Yes
Surgery: RALP,LP
vs
SBRT

No
SBRT
vs
Conventional fractionated IMRT

PI: N. Van As
UK Clinical Research Network.
SBRT CONTEXT TODAY
Randomized Study:
78 Gy at 2 Gy vs 46 Gy at 2 Gy + 115 Gy I125 boost
N= 398 (276 high risk, 122 intermediate)
12 months ADT (RT after 8 months)
Med FU: 6.5 years

DE-EBRT:
13 recurrent
11 metastatic

LDR-PB:
7 recurrent, all 7 metastatic

Loblaw et al., ESTRO 2015
Comparison of outcomes between EBRT and Brachytherapy for localized prostate cancer
Original Article

Stereotactic Ablative Radiotherapy Versus Low Dose Rate Brachytherapy or External Beam Radiotherapy: Propensity Score Matched Analyses of Canadian Data


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Received 11 April 2016; received in revised form 25 August 2016; accepted 22 September 2016
SBRT v EBRT v LDR: Low Risk Prostate Ca - Canadian Data

N= 602 patients, low risk
Median FU: 5.1, 5.7 and 6.9 yrs for SBRT, LDR and EBRT.

Loblaw et al, Clinical Oncology 29, 161-70, 2017
COST
Utilizing time-driven activity based costing to understand the short- and long-term costs of treating localized, low-risk prostate cancer. Laviana et al. Cancer 122 (3), 447-455
GUIDELINES

SBRT: ROUTINE CLINICAL PRACTICE?
Stereotactic Body Radiation Therapy (SBRT)

Prostate Cancer:

Many clinical studies supporting the efficacy and safety of SBRT in the treatment of prostate cancer have been published. At least one study has shown excellent five year biochemical control rates with very low rates of serious toxicity. Additionally, numerous studies have demonstrated the safety of SBRT for prostate cancer after a follow-up interval long enough (two to three years) to provide an opportunity to observe the incidence of late GU or GI toxicity. While it is necessary to observe patients treated for prostate cancer for extended intervals to gauge the rate of long term (beyond 10 years) biochemical control and overall survival, the interim results reported appear at least as good as other forms of radiotherapy administered to patients with equivalent risk levels followed for the same duration post-treatment.

It is ASTRO’s opinion that data supporting the use of SBRT for prostate cancer have matured to a point where SBRT could be considered an appropriate alternative for select patients with low to intermediate risk disease.
PRINCIPLES OF RADIATION THERAPY

Primary External Beam Radiation Therapy (EBRT)
• Highly conformal RT techniques should be used to treat prostate cancer.
• Doses of 75.6 to 79.2 Gy in conventional fractions to the prostate (± seminal vesicles for part of the therapy) are appropriate for patients with low-risk cancers. For patients with intermediate- or high-risk disease, doses up to 81.0 Gy provide improved PSA-assessed disease control.
• Moderately hypofractionated image-guided IMRT regimens (2.4 to 4 Gy per fraction over 4-6 weeks) have been tested in randomized trials reporting similar efficacy and toxicity to conventionally fractionated IMRT. They can be considered as an alternative to conventionally fractionated regimens when clinically indicated.

• Extremely hypofractionated image-guided IMRT/SBRT regimens (6.5 Gy per fraction or greater) are an emerging treatment modality with single institutional and pooled reports of similar efficacy and toxicity to conventionally fractionated regimens. They can be considered as a cautious alternative to conventionally fractionated regimens at clinics with appropriate technology, physics, and clinical expertise.

• Patients with high-risk cancers are candidates for pelvic lymph node irradiation and the addition of neoadjuvant/concomitant/adjuvant ADT for a total of 2 to 3 y (category 1).
• Patients with intermediate-risk cancer may be considered for pelvic lymph node irradiation and 4- to 6-mo neoadjuvant/concomitant/adjuvant ADT.
• Patients with low-risk cancer should not receive pelvic lymph node irradiation or ADT.
• The accuracy of treatment should be improved by attention to daily prostate localization, with techniques of IGRT using CT, ultrasound, implanted fiducials, electromagnetic targeting/tracking, or an endorectal balloon to improve oncologic cure rates and reduce side effects.
SBRT Utilization - USA

TECHNIQUE
Planning and Delivering SBRT
IG – EBRT technique

Planning
PTV: 95% of PTV volume to get 95-110% of Rx dose.

Target dose: 8 Gy x 5 = 40 Gy

OAR Dose Constraints:

Rectum
- V50 (20 Gy) ≤ 50%
- V80 (32 Gy) < 20%
- V90 (36 Gy) ≤ 10%
- V100 (40 Gy) ≤ 5%

Bladder
- V50 (20 Gy) ≤ 40%
- V100 (40 Gy) ≤ 1.1%

Femurs
- V40 (16 Gy) ≤ 5%

Small Bowel
- V50 (20 Gy) < 1%
Fiducial positions need to be pre-defined in the treatment plan.
CBCT for anatomy check (initial setup)

KV-MV paired marker-marker match (initial setup and during treatment)
**Arc 1**
- CW rotates from 180° to 0°
- kV - MV Imaging with gantry at 180°
- No gantry motion required

**Arc 2**
- CW rotates from 0° to 180°
- kV - MV Imaging with gantry at 180°
- No gantry motion required

**Arc 3**
- CCW rotates from 180° to 0°
- kV - MV Imaging with gantry at 0°
- No gantry motion required

**Arc 4**
- CCW rotates from 0° to 180°
- Arc 4
- Coll = 315
SBRT for High Risk Prostate CA?

UCLA High-Risk SBRT Trial:

High-Risk Prostate Ca → Fiducials → CT MRI → Optional:
- Pelvic node RT
- 9 months ADT

Aim 1: PSA RFS
Aim 2: toxicity (CTCAE)
Aim 3: QOL (EPIC)

Eligibility: High risk:
- Pre-biopsy PSA ≥20
- Biopsy Gleason score 8-10
- Clinical stage T3

Doses:
- 8 Gy x 5 (40 Gy*) to prostate PTV
- 5 Gy x 5 (25 Gy) to pelvic LN (optional)
- SV: Full dose (if ROI constraints met)

Predict 85% 5-year bNED (c/w 75% IMRT)
Expected accrual 220 pts in 2 years
UCLA High-Risk SBRT Trial: SBRT with Pelvic Node RT
Technical Considerations

- MRI based planning
- Need for soft tissue imaging (deformation check)
- Fiducials vs CBCT
  - Intra-fraction motion management
- Spacer Gels
  - Is Rectal Toxicity a concern?
  - Improvement of Potency Rates?

- SBRT as boost:
  - Pelvic RT + Whole gland SBRT boost
  - Whole Gland RT + Focal lesion SBRT Boost
  - Whole Gland SBRT + Focal lesion SBRT Boost
- Focal SBRT
CONCLUSION
Prostate SBRT = Faster, Better, Cheaper

Who Says You Can't Have All Three?
Conclusions

Hypofractionation (SBRT) for prostate Ca is:

- Effective
- Safe
- Convenient for patients and providers
- Less costly to deliver
- Less resource intensive
- Should be standard of care
BETTER
FASTER
CHEAPER