

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

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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 ≤ 10 ng/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



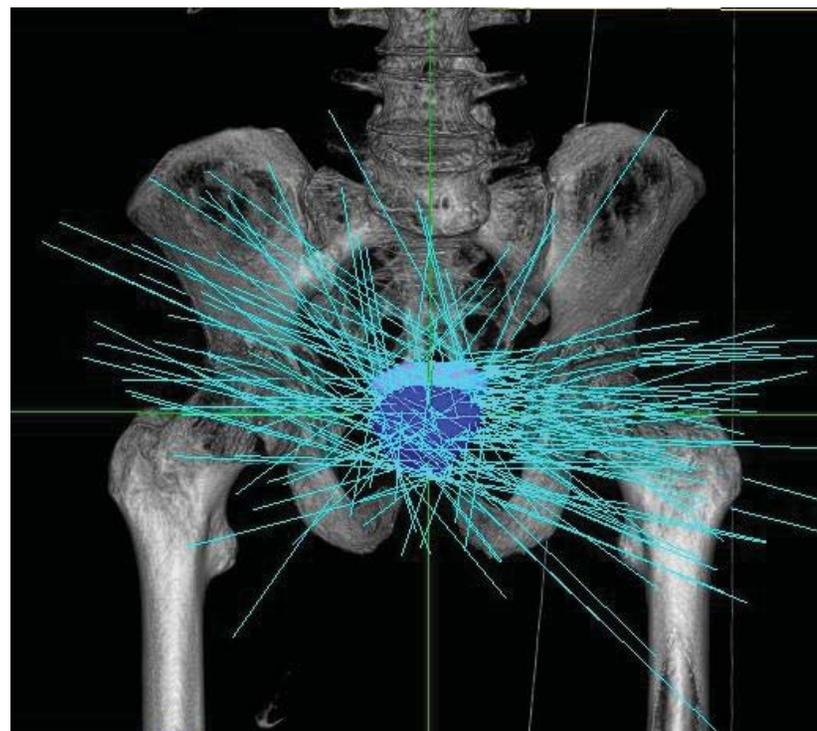
Throughout treatment, robot tracks prostate & corrects for motion: in x-y-z dimensions & yaw, pitch, roll

Objectives

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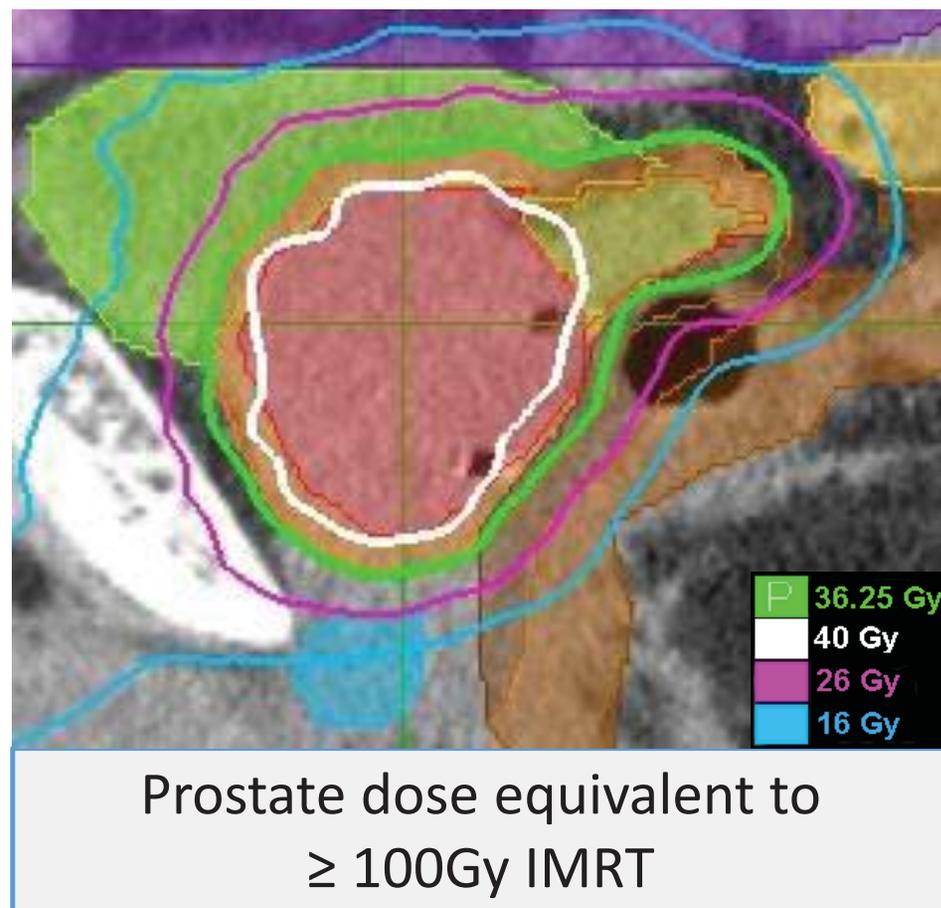
Beams converge upon prostate from spherical orientation, rather than a single plane

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

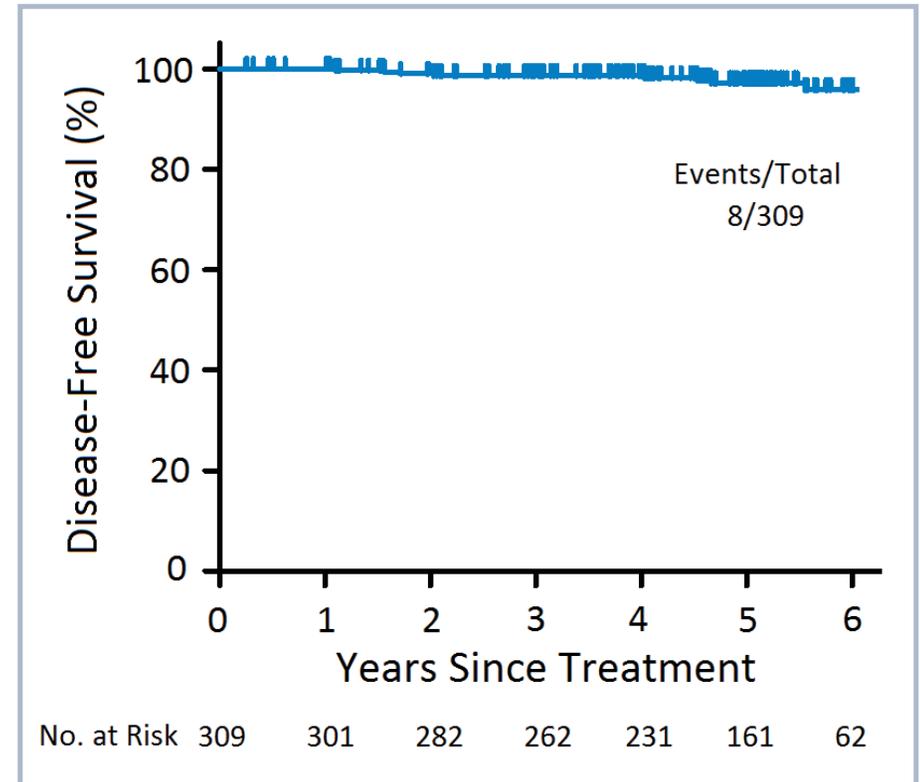
- No grade 4-5 toxicities
- Five grade 3 side effects occurred in 4 pts, far below the 10% considered excessive:
 - Two low-risk pts (1.2%), $p < 0.001$
 - Two interm-risk pts (1.5%), $p < 0.001$

Efficacy

Based on Nadir + 2 definition:

- 97.1% of pts free from recurrence at 5 yrs

All Patients: Nadir + 2 RFS



Results: Safety

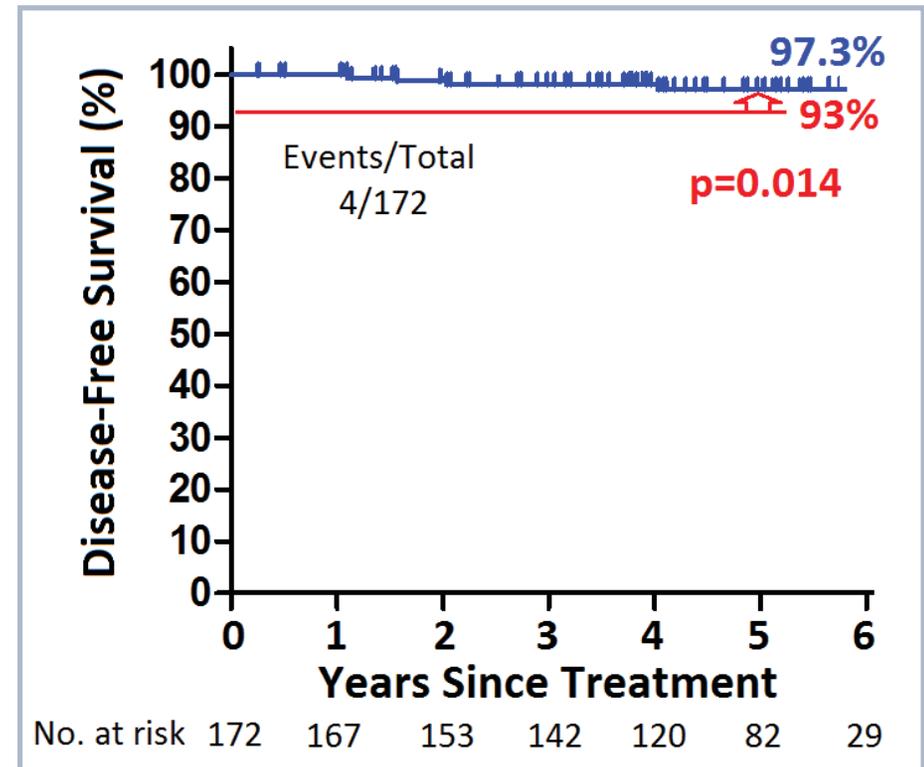
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Efficacy

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)

Low-Risk Patients: Nadir + 2 RFS



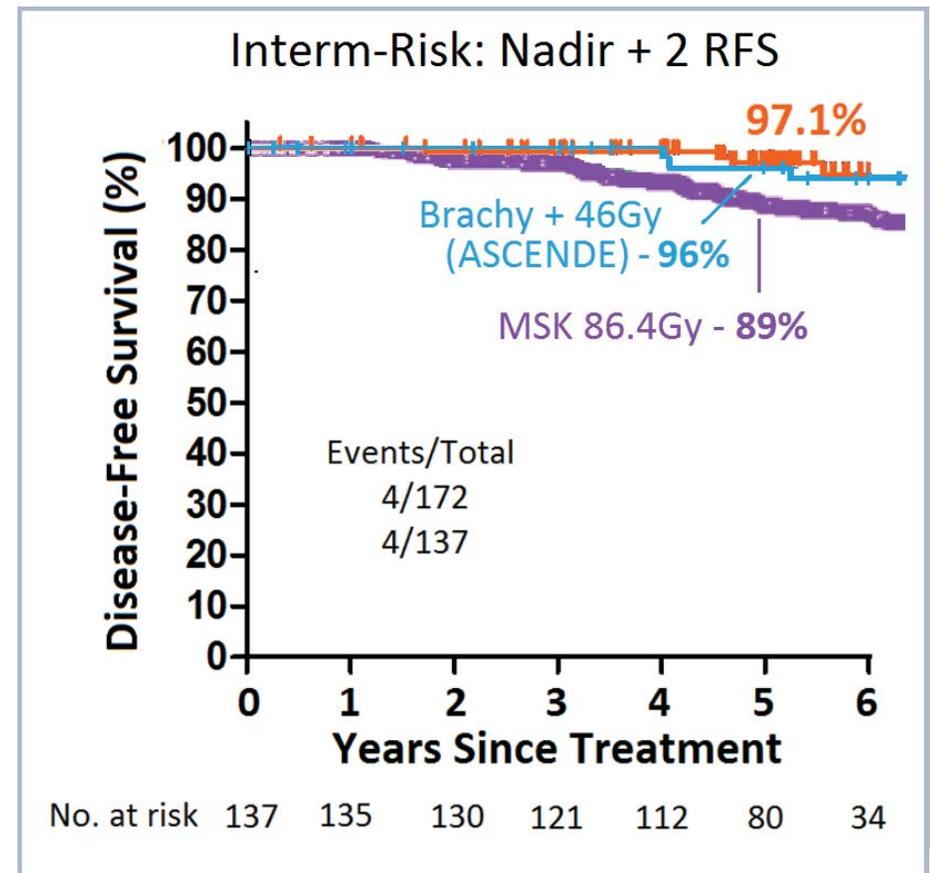
Results: Safety

- 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)
- 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