SBRT-Early Stage Non Small Cell Lung Cancer
SRS for Brain Metastases

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Cancer Education Day
Friday, October 12, 2018

No conflict of interest

SBRT-Early Stage NSCLC
Objectives

- Review rationale, process, toxicity and evidence for SBRT in stage 1 NSCLC
- Update on the outcome after 3 years of our center experience with SBRT

SBRT-Early Stage NSCLC
Introduction

- Lung cancer is the leading cause of cancer related death worldwide.
- Incidence is expected to rise due to aging population.
- Majority of patients present with advanced or metastatic disease.
- Incidence of early stage NSCLC is expected to rise due to wider use of CT thorax in general practice and implementation of CT screening which has shown to lead to earlier detection.

Stage 1 NSCLC Treatment Options

- **Surgery:**

  -Lobectomy

  -Wedge resection

- **Radical Radiation therapy:**

  -Conventional fractionation RT

  6000cGy/30 fractions:200cGy/fraction daily(old, no longer used)

  -Hypo-fractionated RT

  6000cGy/15 fractions:400cGy/fraction daily

  -SBRT: Stereotactic Body Radiation Therapy

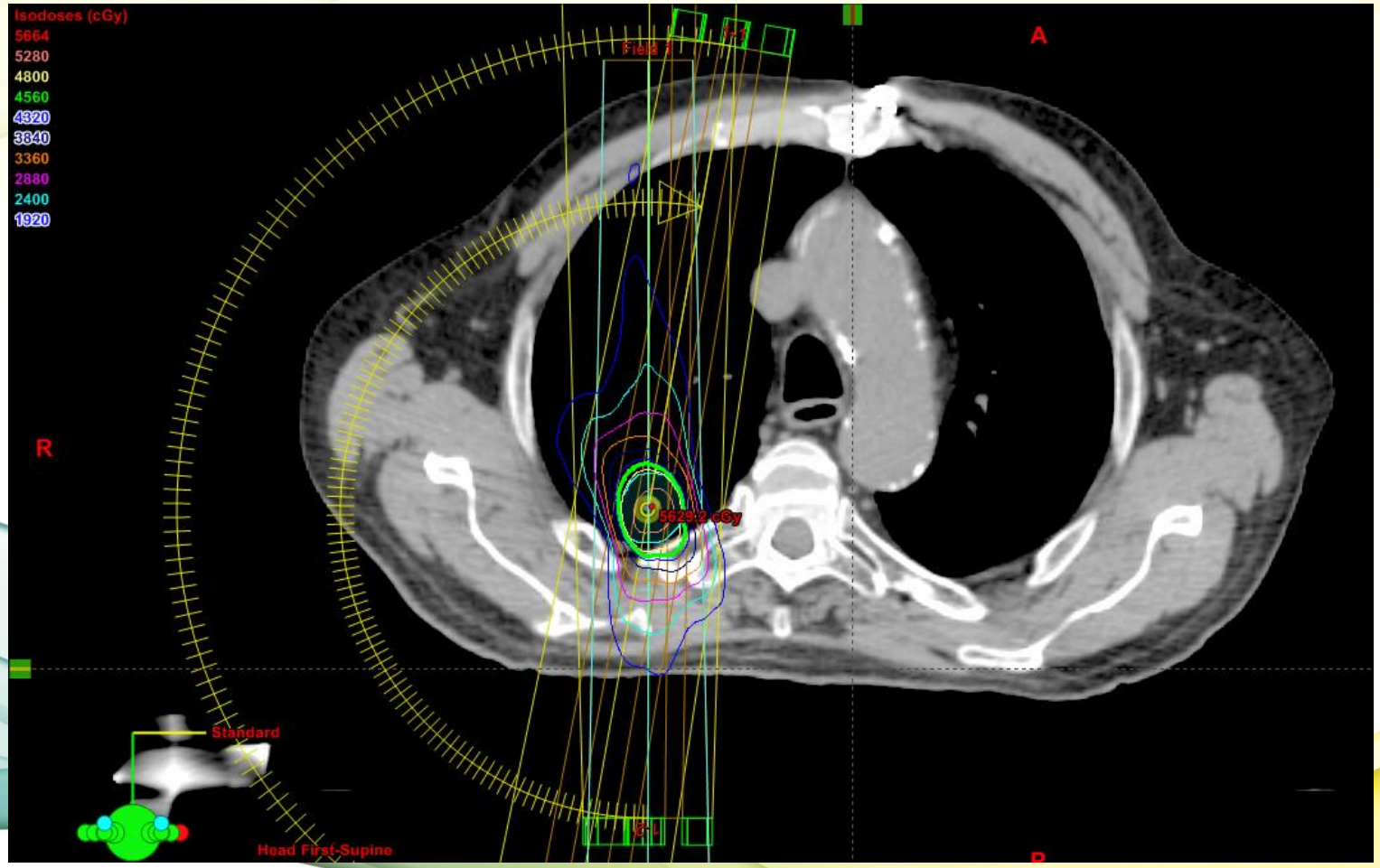
  6000cGy/8 fractions:750cGy/fractions daily for central tumors

  4800cGy/4 fractions:1200cGy/fraction every other day for peripheral tumors

SBRT

- Delivering high dose RT to the tumor in a limited # of fractions using highly conformal technique IMRT or VMAT.
- Sparing normal adjacent tissue due to rapid dose fall off beyond PTV.
- Several beams are directed at the tumor from different angles.
- Strict breathing motion control.
- 4D CT for planning, fusion with diagnostic PET scan.
- Image-guided Radiation Therapy (IGRT).

SBRT Delivery



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SBRT Outcome

- Early Phase 2 Data:
  - Timmerman JAMA 2010
  - Taremi IJROBP 2012
  - Lagerwaard IJROBP 2008

- Local control at 2-4 years: 89%-97%
- Overall survival at 2-3 years: 55%-64%
- Distant mets at 2-3years: 20-23%

SBRT Toxicity

- Fatigue
- Skin irritation
- Radiation pneumonitis
- Rib pain, #
- Rare: esophageal, bronchial, pericardial, brachial plexus injury, death.

SBRT at WRCC

- A Randomized Trial of Medically-Inoperable Stage I Non-Small Cell Lung Cancer Patients Comparing Stereotactic Body Radiotherapy Versus Conventional (hypo-fractionated) Radiotherapy (LUSTRE)
- T1/T2a N0 M0 NSCLC,biopsy proven or a suspicious growing nodule on serial imaging with malignant PET FDG avidity for which a biopsy would be extremely risky
- Deemed medically inoperable due to medical comorbidities
- Radiotherapy is preferred by the patient due to high operable risk.

SBRT at WRCC

- First SBRT treated on LUSTRE protocol in October 2015
- A total of 9 patients treated with SBRT on Study.
- A total of 14 patients treated with SBRT off study.
- So total of 23 patients treated with SBRT over 3 years.

SBRT
Outcome at WRCC

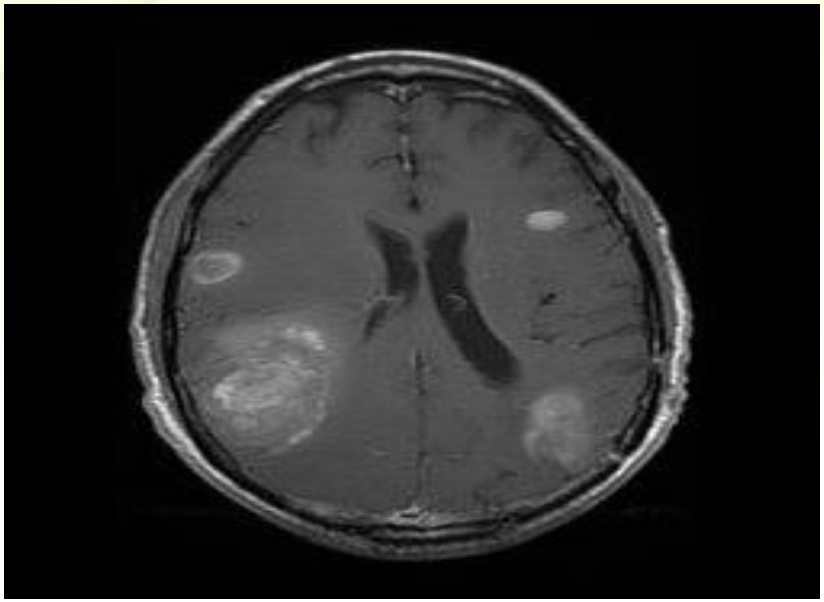
October 2015-April 2018:

- No local recurrence within the radiation field so far.
- 2 patients died, 1 died from a second and different malignancy and 1 died from lung cancer progression in the contralateral lung and mediastinum
- No severe grade 3 or 4 toxicity reported

Conclusions

- SBRT is a good alternative treatment to surgery for early stage NSCLC.
- A good option for medically inoperable high risk patients.
- Comparable local control rates to surgery in stage 1 NSCLC.
- Well tolerated with minimum toxicity.
- SBRT for early stage NSCLC is well established in Windsor with excellent outcome over 3 years.
- Our next goal in Windsor is to use SBRT in other malignancies.

SRS Brain Metastases



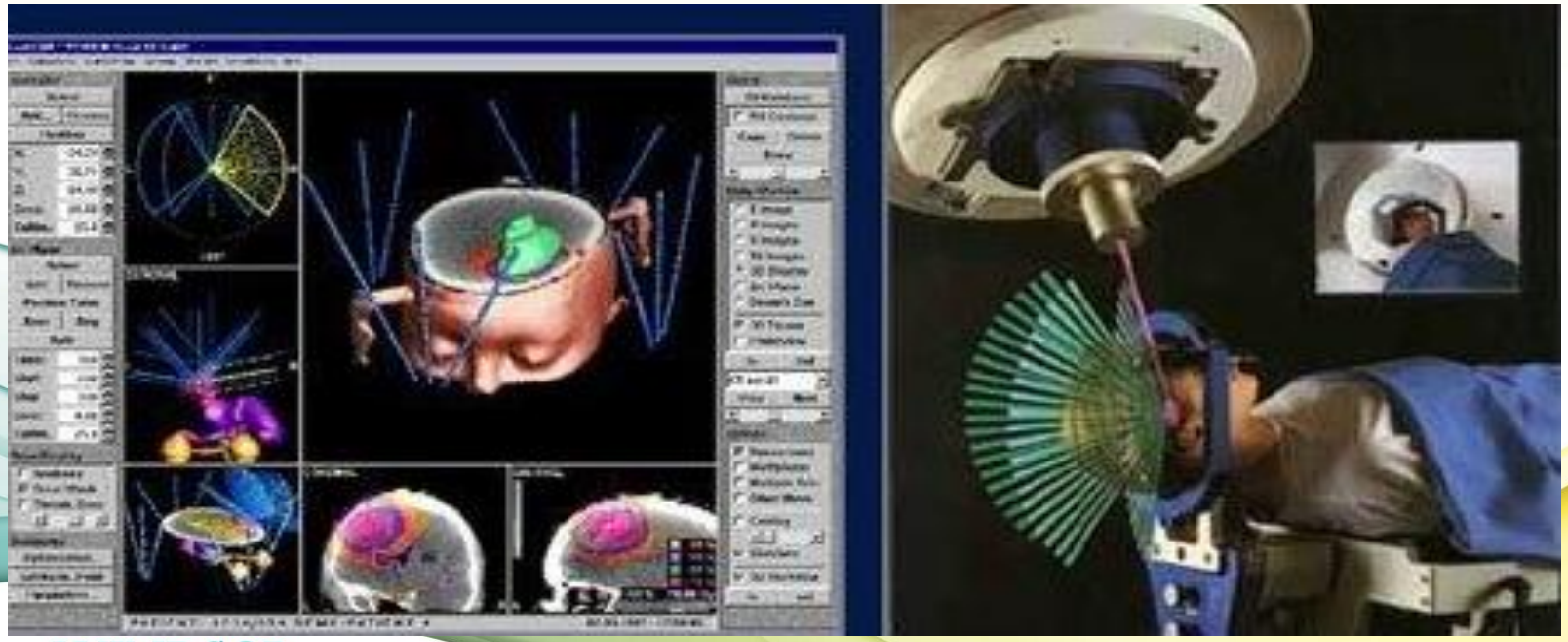
- 20-40% of cancer patients will develop brain metastases during the course of their disease.
- Median survival without treatment is estimated at 1-2 months.

SRS Brain Metastases
Objectives

- Review treatment options for brain mets
- Discuss and review SRS as a very important modality for the treatment of brain mets
- Compare the benefits and toxicity of different treatment modalities for brain mets

SRS
Definition

- Stereotactic Radio Surgery is a non-surgical radiation therapy used to treat functional abnormalities and small tumors of the brain, It can deliver precisely-targeted radiation in fewer high-dose treatments than traditional therapy, which can help preserve healthy tissues and achieve a superior tumor control.



Treatment Modalities

- Surgical resection
- Whole brain radiation therapy (WBRT)
- Stereotactic Radio-Surgery (SRS)
- Surgery+SRS
- Surgery+WBRT
- WBRT+SRS
- Systemic therapy
- Supportive and palliative care (steroids only)

Surgery

- Histological diagnosis
- Improves neurological symptoms
- Improves functional independence
- Improves survival
- Indicated as initial treatment for selected pts with solitary or few brain mets and large (>3cm) causing mass effect or refractory edema and significant neurological deficit

Whole Brain Radiation Therapy (WBRT)

- Improves Intracranial disease control
- It is better than best supportive care for pts with multiple (>4) brain mets and good performance status.
- Improves intracranial disease control when added to surgery or SRS in selected pts with few mets and good performance status.
- Improves median survival vs best supportive care.
- Concern with side effects: late neuro-cognitive dysfunction.

Surgery vs Surgery+WBRT

Patchel RA et al JAMA1998

- Multicenter RCT,95 pts with solitary brain met
- Adding WBRT reduced intracranial relapse from 70% to 18% ($p<0.001$)
- Reduced neurological death 44% to 14% ($p=0.003$)
- No difference in median survival 48 weeks with surgery+WBRT vs 43 week with surgery ($p=0.39$) and in length of time patients remained functionally independent (median length of time remained at KPS>=70% was 37 weeks with surgery+WBRT vs 35 weeks with surgery, $p=0.61$)
- For solitary brain met, WBRT added to Surgery improved intracranial control and neurological death but without effects on survival or duration of functional independence.

WBRT vs WBRT+SRS Boost

Andrews et al RTOG 9508 study Lancet 2004

- Multi-institutional RCT,333pts, 1-3 mets, unresectable, <4cm size, KPS>70%, RPA class 1-2.
- Univariate analysis showed a survival advantage in the WBRT and stereotactic radiosurgery group for patients with a single brain metastasis (median survival time 6·5 *vs* 4·9 months, p=0·0393
- Patients who had WBRT+SRS are more likely to have a stable or improved KPS, at 6 months 43%vs 27%, p=0.03.
- Multivariate analysis showed survival advantage in favor of WBRT+SRS group with RPA class 1 (p<0.0001) and favorable histology-NSCLC-squamous (p=0.012)
- SRS should be the standard of care for solitary unresectable brain mets and should be considered for 2-3 mets.

SRS vs SRS+WBRT

Aoyama et al JROSG-99-1 JAMA 2006

- RCT, 132 pts, 11 Japanese centers
- 1-4 brain mets, <3 cm size, KPS>70, RPA class 1-2
- Adding WBRT reduced intracranial recurrence 76.4% to 46.8% at 1 year ($p<0.001$)
- No difference in 1 year actuarial survival (28.4% vs 38.5%, or MS=8 months vs 7.5 months ($P=0.42$)
- Salvage brain radiation required more in SRS group (29 pts) vs SRS+WBRT group (10 pts), $p<0.001$.
- No difference in neurological or functional preservation and toxic effects.
- Adding WBRT to SRS improved intracranial control not survival probably due to good salvage therapy.

Surgery or SRS vs Surgery or SRS+WBRT

Kocher M et al EORTC 22952-26001, JCO 2011

- 359 pts, 1-3 brain mets, size: up to 4cm (SRS) and up to 7cm (surgery), WHO PS=0-2
- Adding WBRT reduced 2 yr intracranial relapse:
  - at SRS site: from 31% to 19% (p=0.04)
  - at Surgical site: from 59% to 27% (p<0.001)
  - elsewhere in brain: SRS:48% to 33% (p=0.023), surgery: 42% to 23% (p=0.008)
- Intracranial progression caused death in 44% of SRS or surgery alone arms vs 28% in WBRT added to SRS or surgery arms (p=0.02)
- No difference in median overall survival 10.7 months vs 10.9 months (p=0.89) or in median time to WHO PS>2: 10 months vs 9.5 months (p=0.71), so no improvement in the duration of functional independence
- Adding WBRT to SRS or surgery improved intracranial control but no survival benefit and no improvement in the duration of functional independence

SRS vs SRS+WBRT

Chang E et al Lancet Oncology 2009

- RCT from MDACC, 58 pts, 1-3 brain mets, RPA class 1-2
- Primary endpoint: Neurocognitive function
- Trial was halted because of 96% confidence that total recall at 4 months for SRS+WBRT 64% vs only 20% SRS alone, and it persisted at 6 months.
- Adding WBRT to SRS improved 1-year intracranial relapse from 73% to 27% (p=0.0003)
- Median survival was higher for SRS only group (15.2 months vs 5.7 months) and 1 year survival for SRS only group was higher(63%vs 21%), p=0.003
- More decline in learning and memory at 4 months (52% vs 24%) using HVLT-R scoring
- SRS alone group tolerated treatment well with less fatigue and appetite loss, less steroids dependence, less delay in chemo and better tolerance to chemo
- Recommends SRS alone then close monitoring

WBRT and Impact on Quality Of Life (QOL)

EORTC 22952-26001 Soffietti R et al JCO 2013

- Analysis of **"Health Related Quality Of Life (HRQOL)"** results of the EORTC 22952-26001 trial, of 359 pts with 1-3 brain mets receiving SRS or Surgery +/-WBRT
- Analysis of QOL using QLQ-C30 analysis at baseline, every 3 months for 3 years (6 HRQOL scales: global health status, physical, role, cognitive and emotional functions,and fatigue), compliance was 88.3% at baseline and dropped to 45% at 1 year.
- SRS or Surgery only arm reported better HRQOL scores for global health assessment at 9 months and physical function at 8 weeks and cognitive function at 1 year and fatigue at 8 weeks.
- Exploratory analysis for all other HRQOL scales suggested worse scores for the WBRT group but none was clinically relevant.
- WBRT may negatively impact some aspects of QOL
- Recommends observation with MRI's which is not detrimental on QOL.

SRS vs SRS+WBRT and Impact of Neurocognitive Function

Brown PD et al JAMA 2016

- RCT, 34 centers, North American, 213 pts with 1-3 brain mets, Feb 2002-Dec 2013
- Primary endpoint: **"Cognitive function"** using **H**opkins **V**erbal **L**earning **T**est-**R**evised (HVLT-R) to assess immediate memory and learning, fine motor control, verbal fluency, processing speed, executive function, delayed memory and recognition.
- Adding WBRT caused more cognitive deterioration at 3 months (94% vs 45%, p=0.007) and 12 months (94% vs 60%,p=0.04).
- Adding WBRT caused more decline in QOL, mean change from baseline -10.9 points vs -1.3 points (p=0.002)
- Longer time to intracranial relapse with WBRT+SRS vs SRS(p<0.001),without difference in median OS(SRS 10.4months vs SRS+WBRT 7.4 months(p=0.92)
- No difference in functional independence with mean change from baseline of -1.5 points for SRS vs. -4.2 points for SRS+WBRT (p=0.26)
- It is WBRT not recurrent disease that impairs QOL and function
- Recommends SRS alone due to absence of survival benefit and deterioration of cognitive function at 3 months when adding WBRT to SRS.

SRS Brain Mets
Conclusion

- Highly effective and precise targeted radiation therapy for limited number of brain mets
- Good alternative to surgery in selected cases
- Preserves cognitive and learning functions, and better QOL without compromising overall survival compared to adding WBRT in selected patients with 1-4 mets.
- Higher intracranial relapse rates compared to WBRT but salvageable and deferring WBRT did not affect functional independence
- We are hoping to get the technique to Windsor

Thank you

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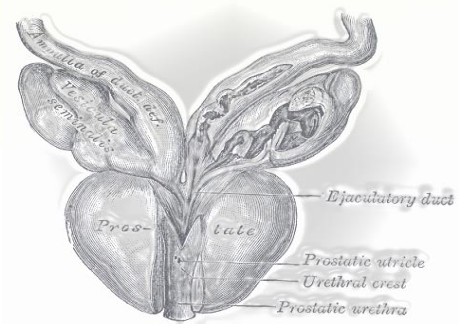
SBRT for Prostate Cancer
It's Coming to Windsor!



Cancer Education Day
October 12, 2018
Windsor, ON

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Disclosures

- **Relationships with financial sponsors:**
  - ✓ **Other:** TerSera, Bayer (Advisory Board), Sanofi (Clinical Trial)

- **Potential for conflict(s) of interest:**
  - ✓ No speakers present any conflicts with sponsoring organization
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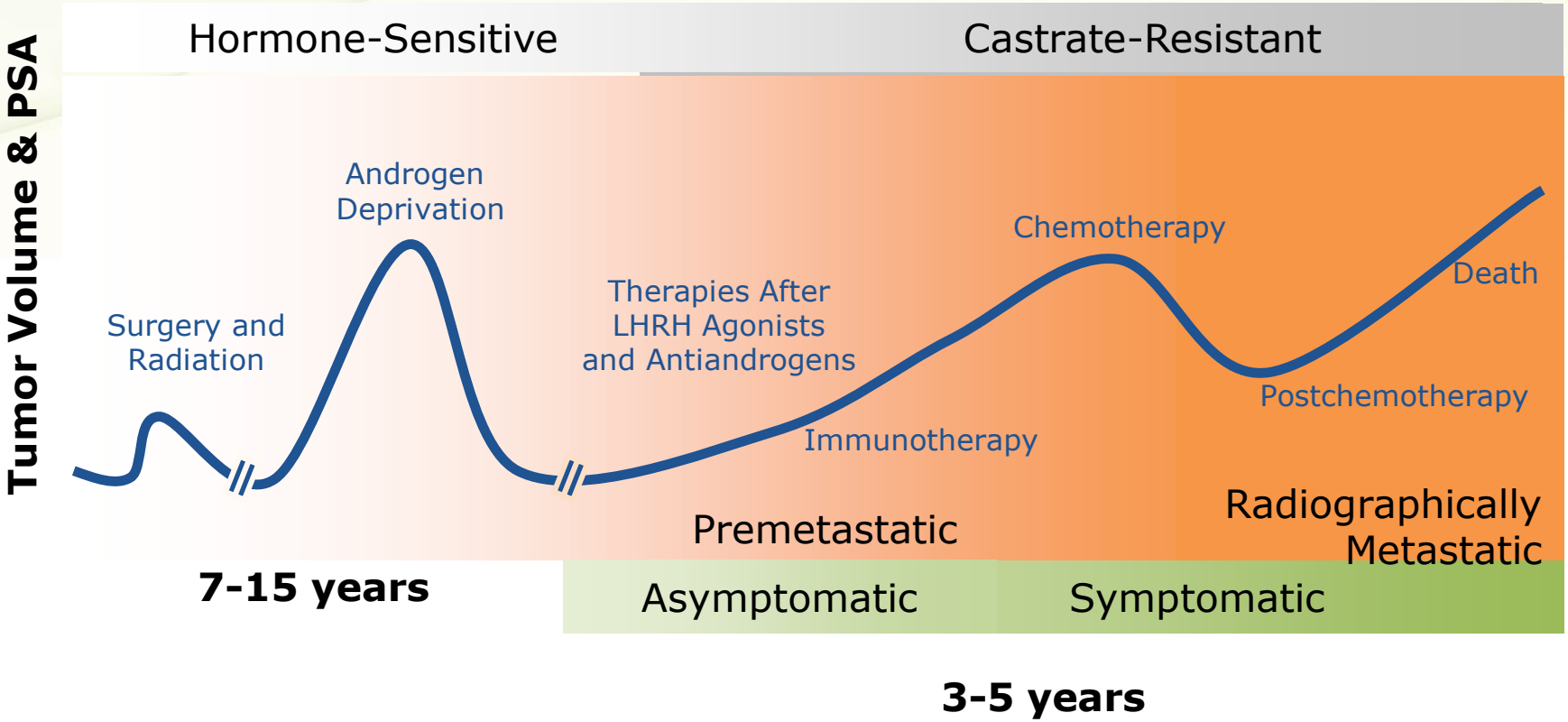
Natural History of Prostate Cancer



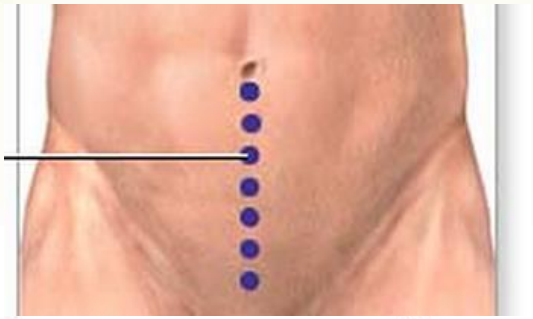
NOTE: This diagram represents *typical* disease progression. Note that some patients are metastatic at diagnoses, and are thus still hormone-sensitive.

1. Chen Y, et al. *Lancet Oncol.* 2009;10:981-991.
2. Hofland J, et al. *Cancer Res.* 2010;70:1256-1264.

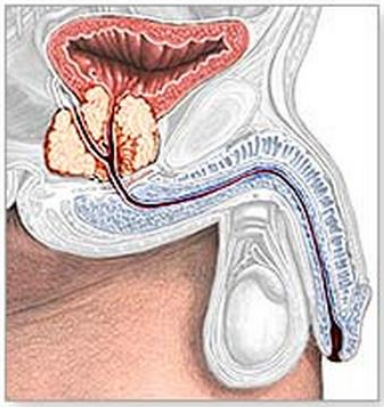
Curative Treatment Options!

- Active Surveillance
- Surgery
  - Open
  - Laprascopic
  - Robotic
  - Perineal
- External Radiation
  - Dose Escalated EBRT
  - HypoFractionated EBRT
  - SBRT
- Brachytherapy:
  - LDR/HDR Monotherapy
  - LDR/HDR + EBRT
- Cryotherapy
- High Intenstify Frequency Ultrasound (HIFU)
- Photodynamic Therapy (PDT)
- Clinical Trials

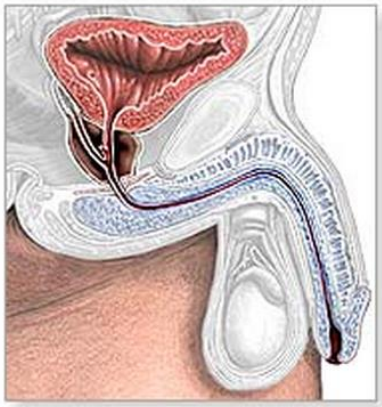
Radical Prostatectomy



Before



After



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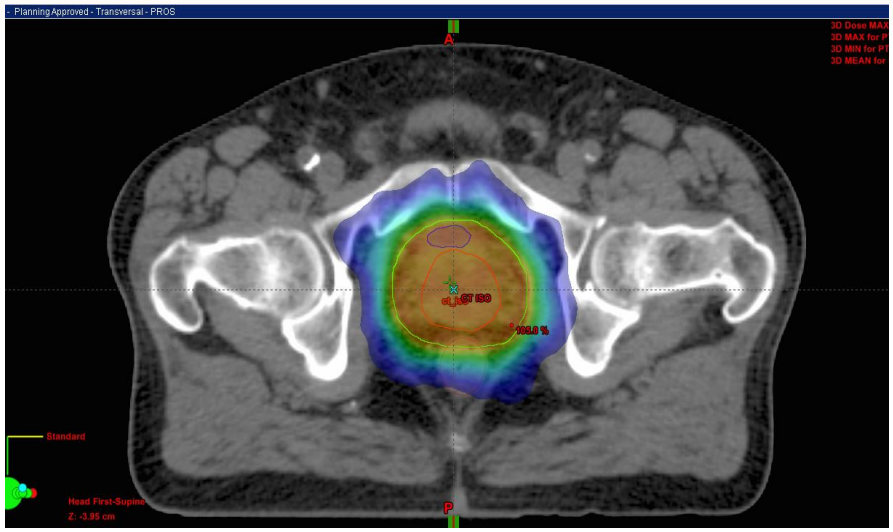
External Beam Radiotherapy



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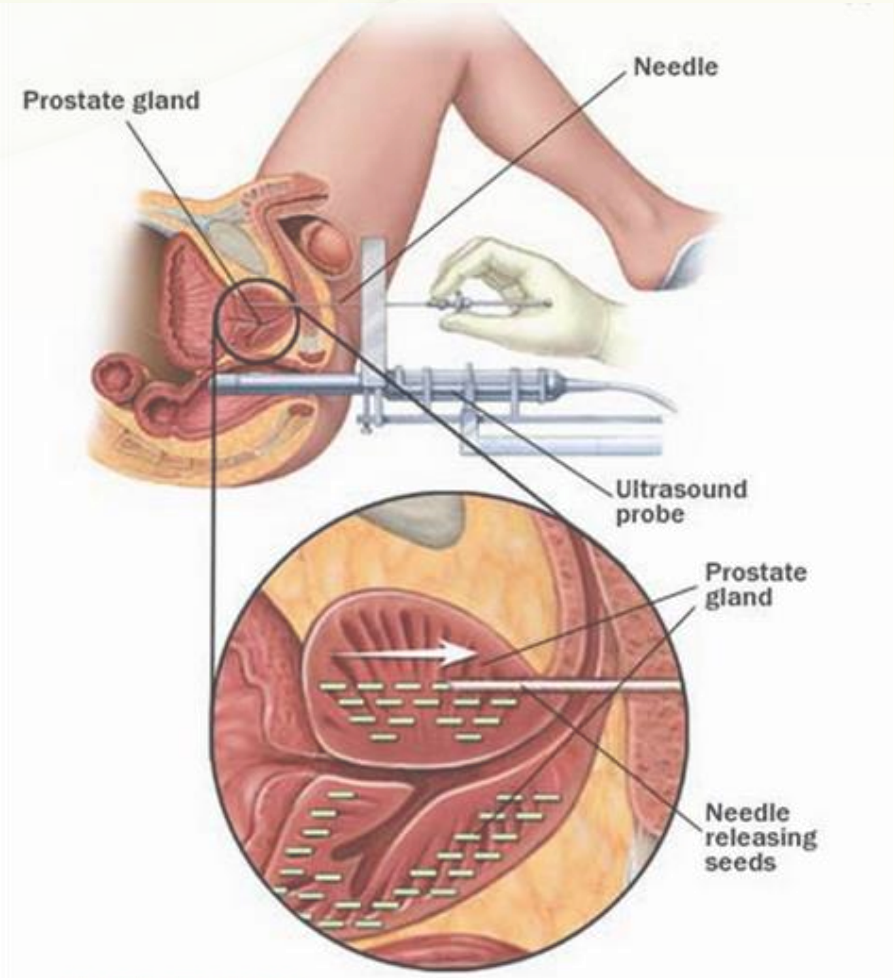
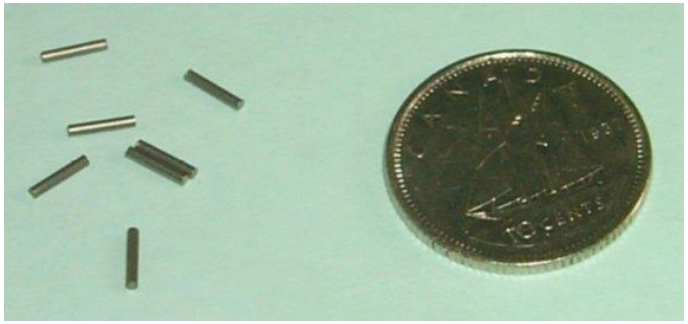
Seed Brachytherapy





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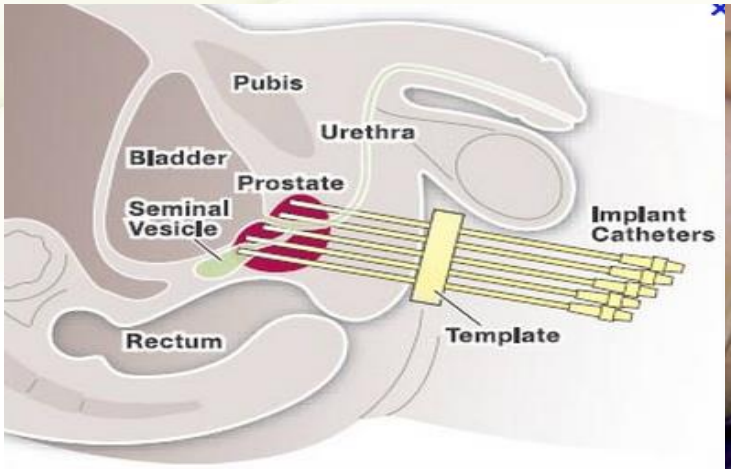
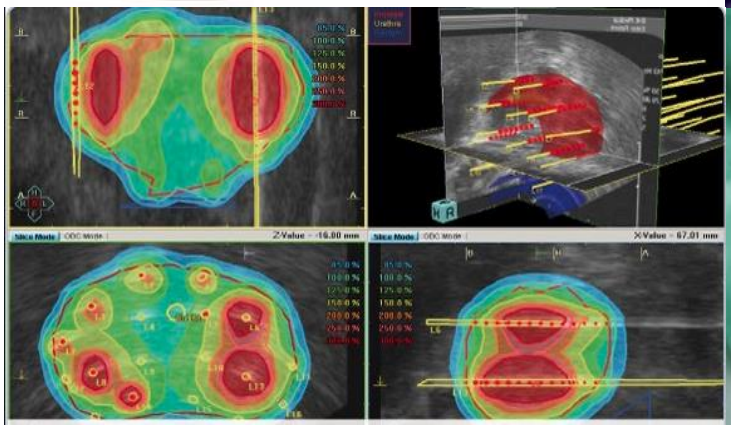
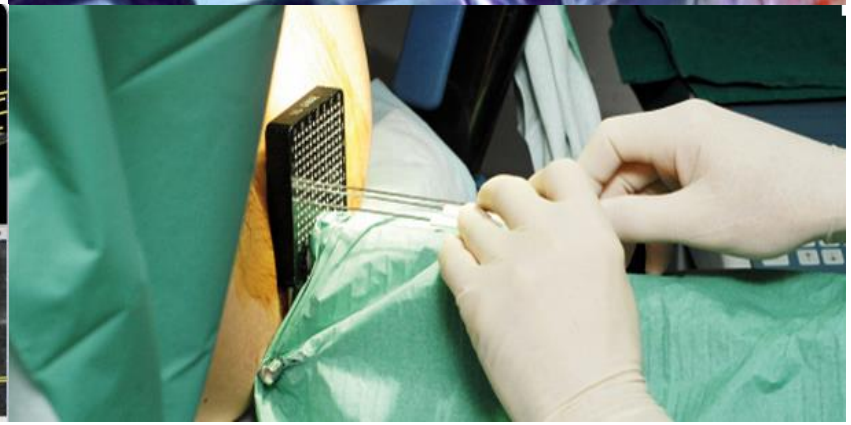
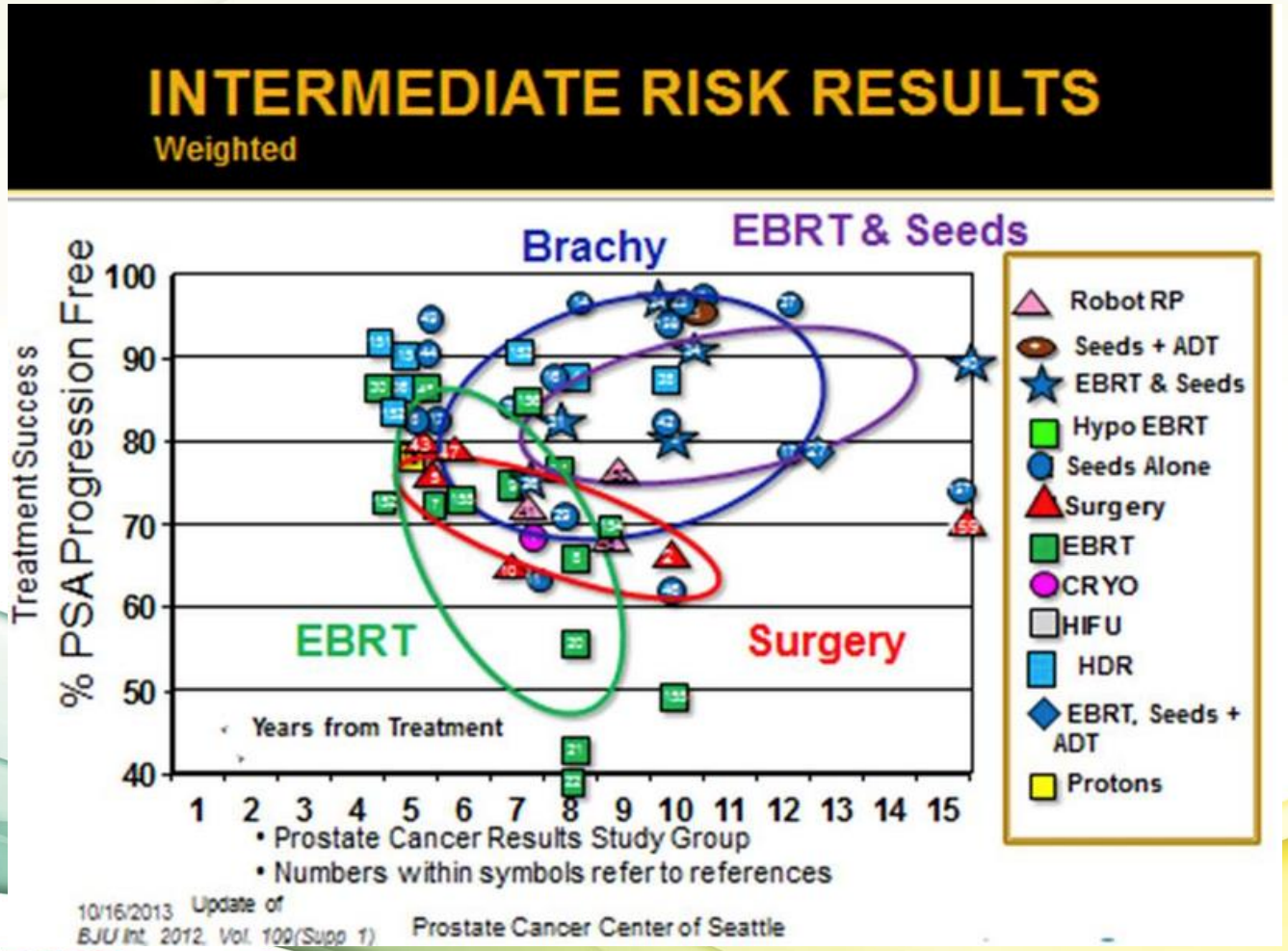
HDR Brachytherapy







Curative Treatment Options!



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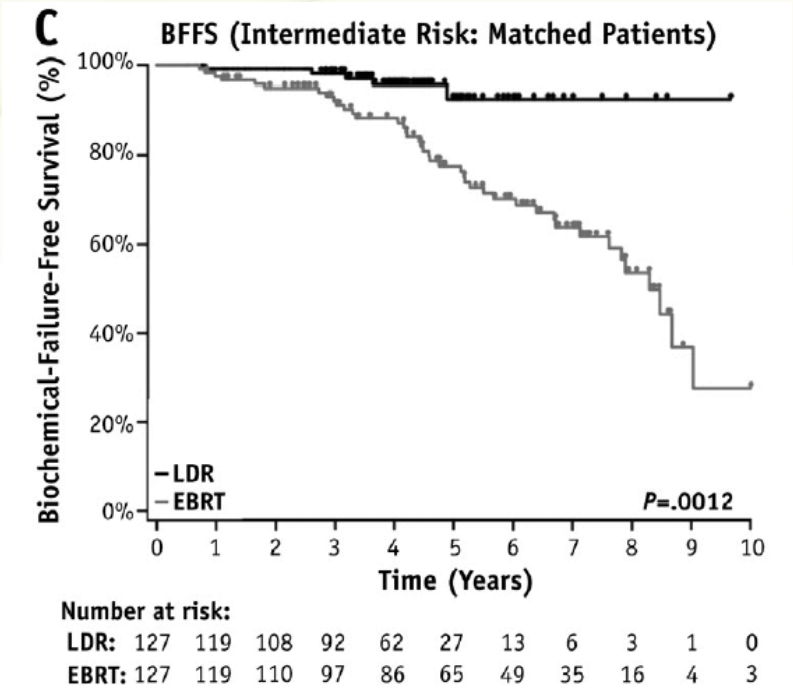
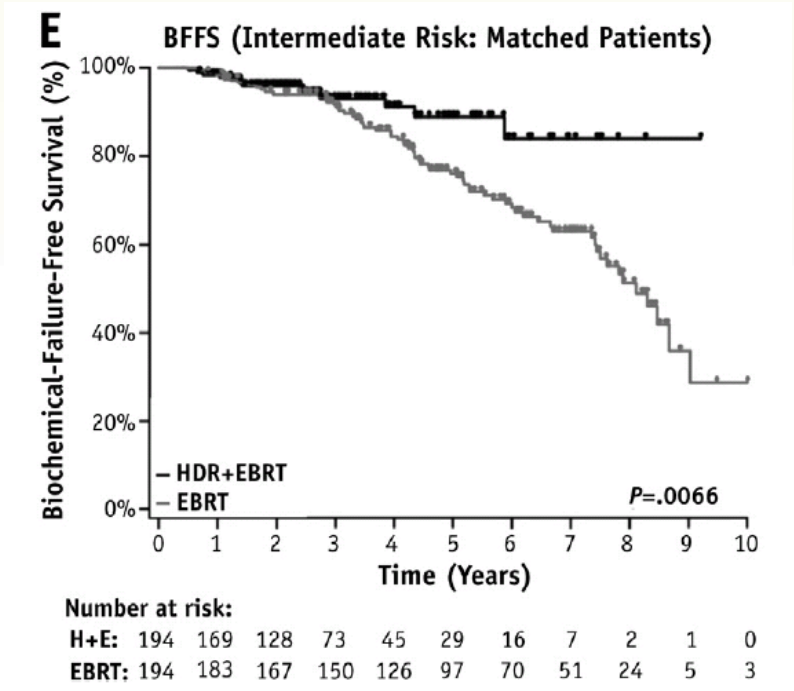
Brachytherapy vs EBRT





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The Silver Tsunami

Scenario	% Increase	# of cases
2006 Incidence	-	25,355
Best case in 2021	73%	35,121
Most-likely case in 2021	288%	78,799
Worst-case in 2021	1260%	275,796

CCO estimates are close to most-likely scenario

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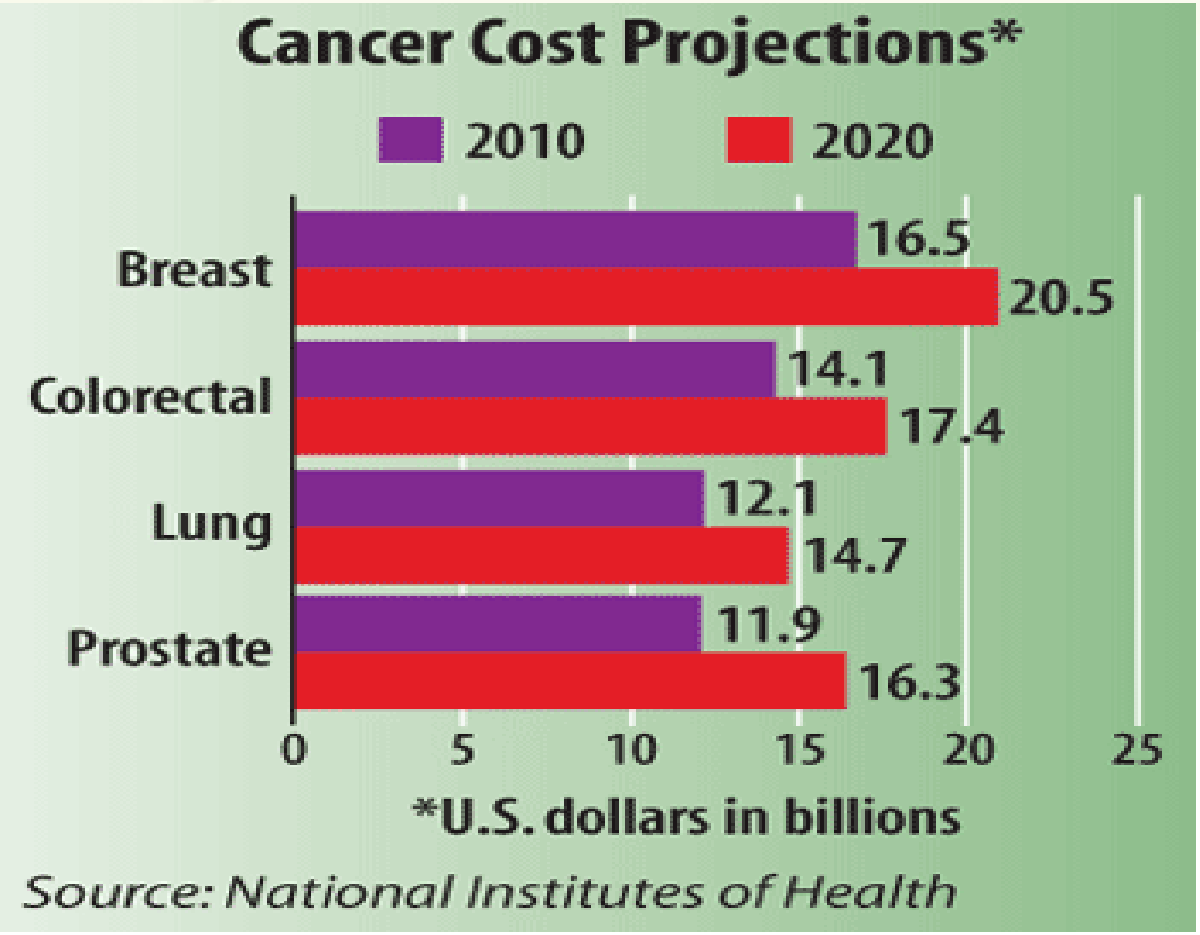
Prostate Cancer: Largest Increase in Cost



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Radiotherapy Terms...

SABR (Stereotactic Ablative Body Radiotherapy)

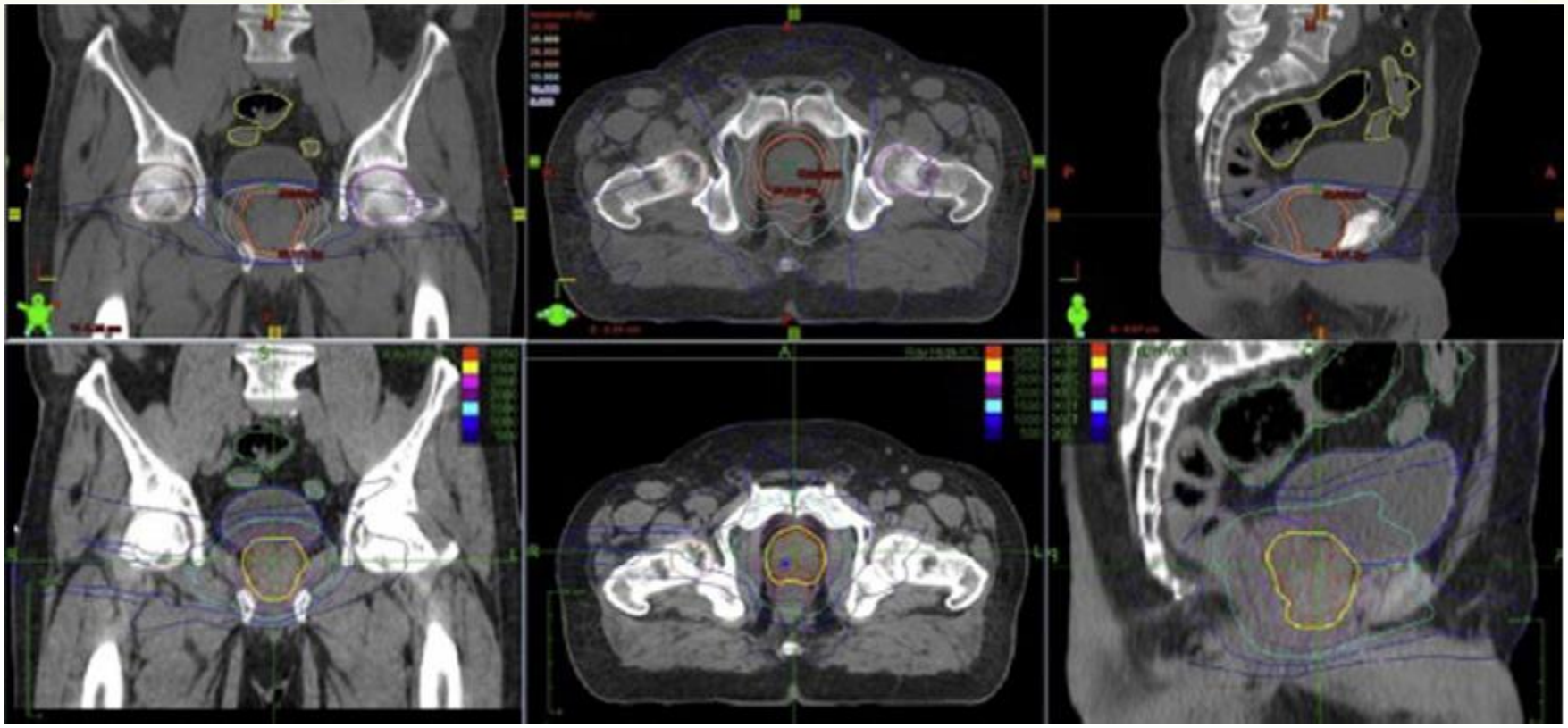
=

SBRT (Stereotactic Body Radiotherapy)

=

Hypofractionated Radiotherapy

RapidArc vs SBRT



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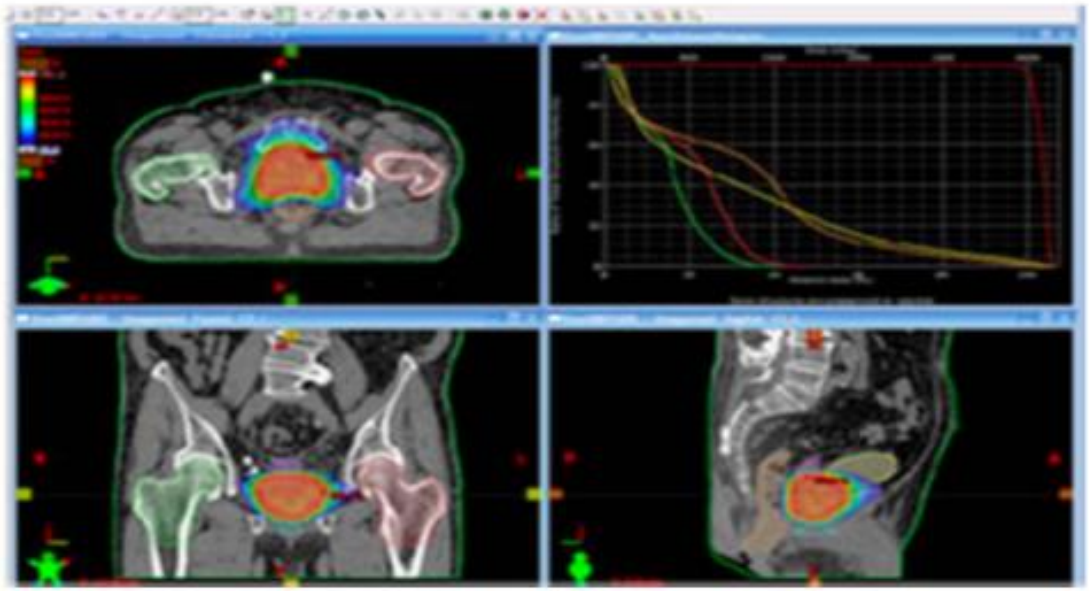
PROSTATE SBRT: 5 fractions or less
Faster, Better, Cheaper

Faster (more convenient): 5 vs 45 treatments
Cheaper: In US: SBRT $20,571 vs Fractionated IMRT $36,837
Better?: Multiple studies, showing excellent control



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Summary of SBRT Studies

Author (Year)	Dose/f/wks	EQD2 (Gy)	n	Percentage Gleason 6	Median Follow-up (mo)	bDFS (actuarial timepoint)	Acute Grade 3(4) Toxicities		Late Grade 3(4) Toxicities		
							GU	GI	GU	GI	ED
Pham[35] (2010)	34/5/1	84	40	100%	60	93% (5y)	2%	0%	3%	0%	50%
Menkarios[36] (2011)	45/9/9	84.7	80	100%	33	97% (3y)	5%	0%	(1)%	0%	nr
Loblaw (this series)	35/5/4	86.5	84	100%	55	98% (5y)	1%	0%	0%	(1)%	
King[16] (2012)	36/5/2*	88.9	67	100%	32	94% (4y)	5%†	0%‡	4%	0%	nr
Kang[37] (2011)	32-36/4/1	88.5 – 110.1	44	13%	40	94% (4y)	0%	0%	0%	0%	nr
Quon[33] (2011)	40/5/4	110.6	30	73%	12	100% (1y)	0%	0%	0%	0%	
Meier [38] (2010)	40/5/1	110.6	211	nr	<12	100% (crude)	1%	0%	1%	0%	9%
Boike[12] (2011)	45/5/2 48/5/2 50/5/2	111.2 117.4 123.5	15 15 15	45%	30 18 12	100% (crude)	0%	0%	0% 7% 7%	0% 0% (7)%	nr
TOTAL**			586	80%	29	96%¥	1%	0%	1%	0%	13%

*First 22 patients were treated over 1 week; **weighted average; †terrible urinary QOL at 3 months; ‡ big problem Expanded Prostate Cancer Index Composite; ¥weighted average for studies with actuarial biochemical disease-free survival between 3-5 years

ASTRO Model Policies

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.

Cyberknife

LINAC based SBRT

UCLA

Planning and Delivering SBRT
IG – EBRT technique

UCLA

Planning

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

SBRT: (8 Gy x 5)

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%

Delivery

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Delivery Platform

Linac based vs Robotic delivery:

- Most experience with robotic delivery
- Coplanar vs non-coplanar delivery
- Platforms seem comparable

Contents lists available at ScienceDirect

Physica Medica

journal homepage: http://www.physicamedica.com

Original paper

Treatment plan comparison between stereotactic body radiation therapy techniques for prostate cancer: Non-isocentric CyberKnife versus isocentric RapidArc

Yu-Wei Lin [a,b,c,*], Kuei-Hua Lin [a], Hsiu-Wen Ho [a], Hsiu-Man Lin [a], Li-Ching Lin [a,d], Steve P. Lee [e], Chen-Shou Chui [f]

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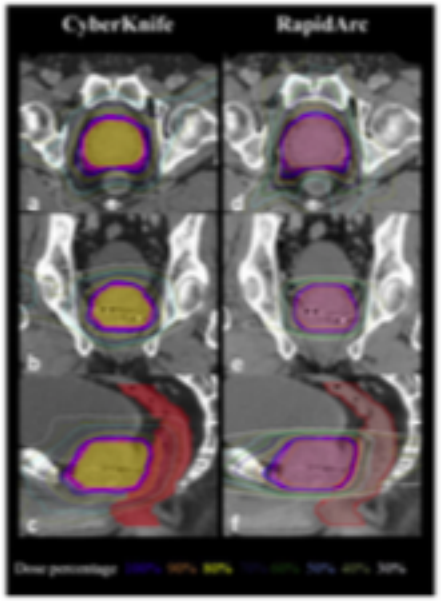
Delivery Platform



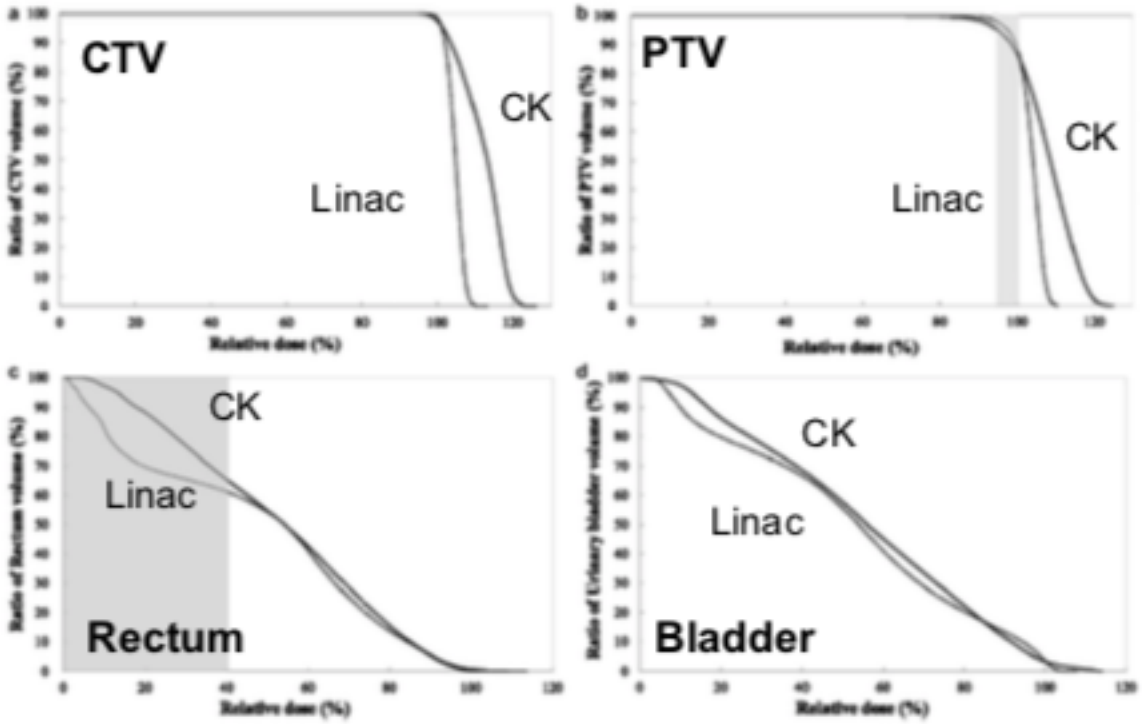


Figure 3. Comparison of mean dose–volume histograms for the CyberKnife (CK, the solid line) and RapidArc (RA, the dot line) techniques used for Group 1. The gray zone indicated the statistically significant differences between the CK and RA plans ($P < 0.05$). (a) Clinical target volume. (b) Planning target volume. (c) Rectum. (d) Urinary bladder.

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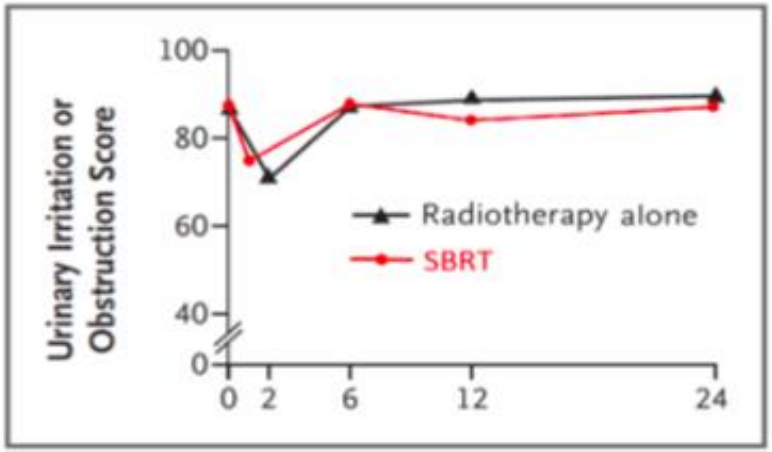
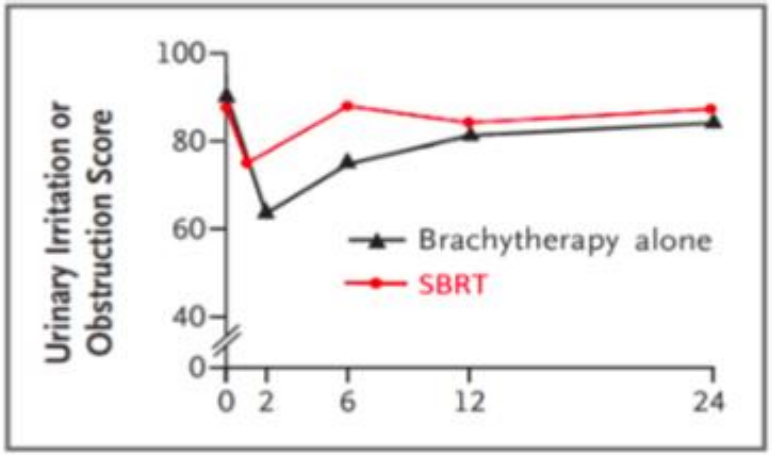
EPIC Urinary Irritation or Obstruction Score

External Beam RT →



LDR Brachytherapy →

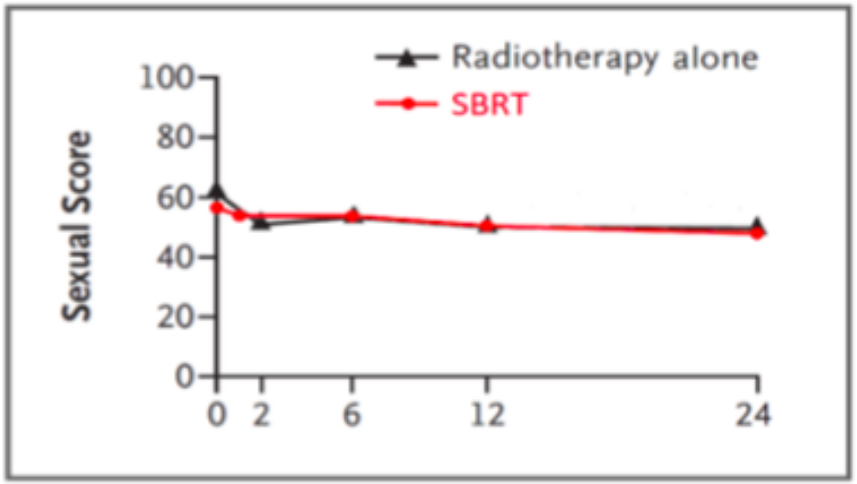


Sanda M. *Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors.* N Engl J Med 2008;358:1250

Meier et al., ESTRO 2014

EPIC Sexual Score

External Beam RT →



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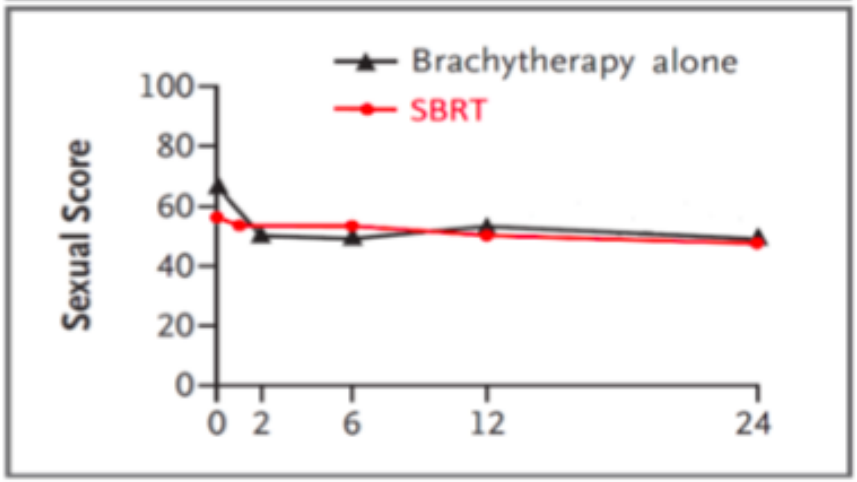
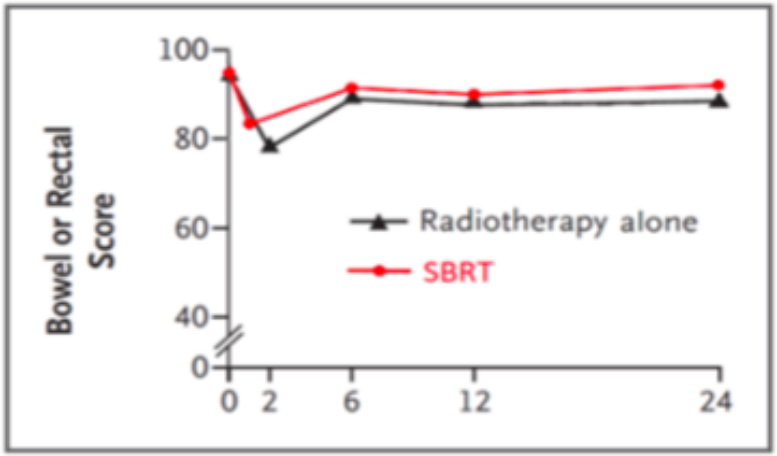


Sanda M. *Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors.* N Engl J Med 2008;358:1250

Meier et al., ESTRO 2014

EPIC Bowel Score

External Beam RT →



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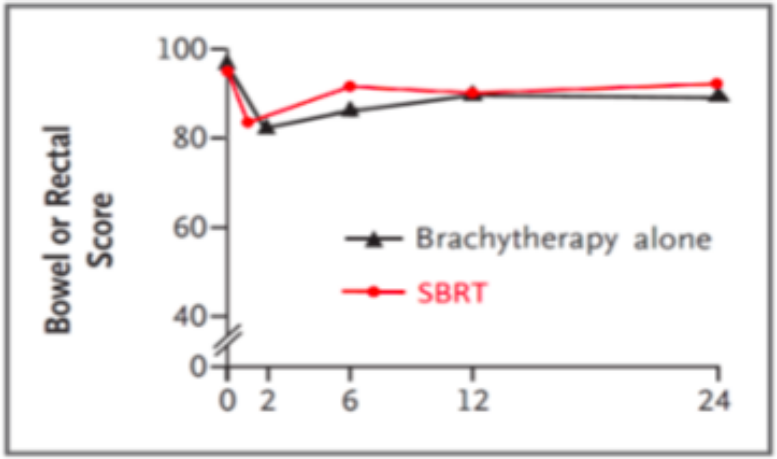


Sanda M. *Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors.* N Engl J Med 2008;358:1250

Meier et al., ESTRO 2014

Out of Pocket Costs

TABLE 2. Treatment related patient costs by patient group

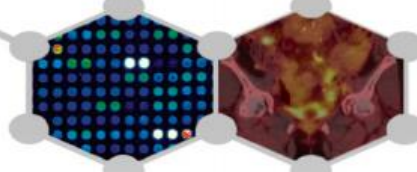
	Patient costs (range)		
	39 Treatment group	5 Treatment group	Difference
Travel	$1,918 ($40-$15,564)	$246 ($5-$1,995)	$1,672 ($35-$13,569)
Parking	$624 ($312-$897)	$80 ($24-$115)	$544 ($288-$782)
Travel + parking			$2,216 ($323-$14,351)
Average patient (47% paid for parking)			$1,928 ($170-$13,937)

Departmental Costs

(not charges or reimbursement rates)

Category	Standard IGRT 78/39	HDR/EBRT	LDR brachy	SBRT 40/5
Personnel Costs Total	$4,387	$2,825	$442	$1,047
Variable Costs				
Variable Costs Total	$2,600	$1,345	$172	$333
Disposable Costs				
Disposable Costs Total	$0	$400	$2,936	$90
Dept costs (per pt)	**$6,987**	**$4,569**	**$3,550**	**$1,470**

The Litmus Test of Public Healthcare



NRG ONCOLOGY

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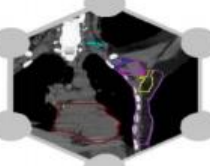

NRG-005 Schema

ELIGIBILITY

Previously untreated localized prostate cancer with the following Baseline Screening features:

- IPSS score <15
- SHIM score >14
- Prostate volume <60 cc
- Total biopsy cores + <50%
- ECOG PS 0-1
- Modified Charlson Comorbidity ≤3

Risk features:

- PSA ≤20 ng/mL
- Gleason score ≤7(3+4) or 6(3+3) with PSA >10ng/mL
- T stage ≤T2a N0M0 (IIA)

STRATIFICATION

1. Gleason score 7(3+4) with PSA<10 ng/mL
2. Gleason score 7(3+4) with PSA≥10 ng/mL
3. Gleason score 6(3+3) with PSA >10 ng/mL

RANDOMIZATION

ARM I: IMRT

70 Gy in 28 fractions of 2.5 Gy
to the prostate +/- proximal
1 cm of seminal vesicles
if indicated by MRI
Minimal Margins:
8 mm uniform expansion,
5 mm posteriorly

ARM II: SBRT

36.25 Gy in 5 fractions of 7.25 Gy
to the prostate +/- proximal
1 cm of seminal vesicles
if indicated by MRI
Minimal Margins:
5 mm superior inferior & laterally,
3 mm anterior & posterior

Prostate specific antigen (PSA); Gray (Gy); International prostate symptom score (IPSS); Sexual health inventory for men (SHIM) Eastern Cooperative Group Performance Status (ECOG PS)

Summary

Prostate SBRT is:

- Feasible
- Effective
- Well tolerated (especially with high quality planning / delivery)
- Cheaper than all alternative treatments
- More convenient

Questions?

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