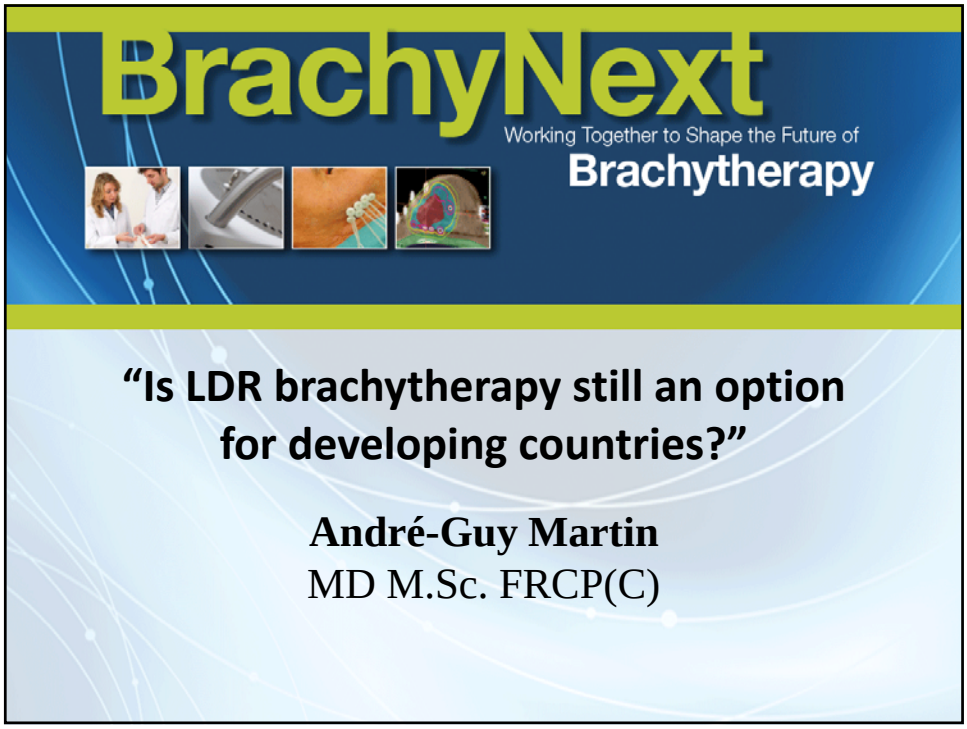

"Is LDR brachytherapy still an option for developing countries?"

André-Guy Martin
MD M.Sc. FRCP(C)

Disclosures

- CHU de Québec is an Elekta center of excellence
- Contribution to various advisory boards (pharmaceuticals) over the years
- Medical advisor for:
  - Polymer Robotics (no salary or shares)

Intro

- Prostate Cancer
  - Most common cancer in men
  - Life incidence ≈ 1 / 6-7 men
  - Represents ≈ 30 % of cancer in men
  - In USA (SEER 2012)
    - Incidence 241 740 cases
    - 28 170 deaths

Intro

Radiotherapy and Oncology 103 (2012) 217–222

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Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Phase III randomised trial

Randomised trial of external beam radiotherapy alone or combined with high-dose-rate brachytherapy boost for localised prostate cancer

Peter J. Hoskin [a], Ana M. Rojas [a,*], Peter J. Bownes [b], Gerry J. Lowe [a], Peter J. Ostler [a], Linda Bryant [a]

[a] Cancer Centre, Mount Vernon Hospital, Northwood, UK; [b] St. James's Institute of Oncology, St. James's University Hospital, Leeds, UK

Intro

- **Recently published literature on American & European society consensus on HDR Brachytherapy**
  - 1: Hsu IC, Yamada Y, Assimos DG, et al. ACR Appropriateness Criteria high-dose-rate brachytherapy for prostate cancer. Brachytherapy. 2014 Jan-Feb;13(1):27-31.
  - 2: Hoskin PJ, Colombo A, Henry A, et al. GEC/ESTRO recommendations on high dose rate afterloading brachytherapy for localised prostate cancer: an update. Radiother Oncol. 2013 Jun;107(3):325-32.
  - 3: Yamada Y, Rogers L, Demanes DJ, et al. American Brachytherapy Society. American Brachytherapy Society consensus guidelines for high-dose-rate prostate brachytherapy. Brachytherapy. 2012 Jan-Feb;11(1):20-32.
  - 4: Wojcieszek P, Białas B. Prostate cancer brachytherapy: guidelines overview. J Contemp Brachytherapy. 2012 Jun;4(2):116-20.

Intro

- HDR Prostate Brachytherapy
  - Is gaining in popularity
  - Is getting more widely used

LDR (permanent seeds) Brachytherapy

- Traditional LDR Prostate Brachytherapy
  - Takes its origin in early 1980's
  - Give DSF 10yrs > 95%[1,2]
  - It has been proven equal (or superior) to surgery [3,4]
    - DFS_{5yrs} = 91 versus 91,7% respectively[5]
  - Randomized study hard to recruit (SPIRIT) 56/1980[6]
  - Commonly used for low risk (T1-2, Gl 6, PSA ≤ 10)[1]

1. D'Amico A & al. JAMA 1998;280:969-74
2. Kupelian P & al. IJROBP 2004;58:25-33
3. Burdick MJ & al. IJROBP 2009;73:1439-45
4. Vassil AD & al. Urology 2010;76:1251-7
5. Gilberti C & al. World J Urol 2009;27:607-12
6. Crook JM & al. J. Clin Oncol 2011;29:362-8

LDR (permanent seeds) Brachytherapy

- **Society consensus on LDR Brachytherapy, have been published**
  - 1: Nag S, Beyer D, Friedland J, et al. American Brachytherapy Society (ABS) recommendations for transperineal permanent brachytherapy of prostate cancer. Int J Radiat Oncol Biol Phys. 1999 Jul 1;44(4):789-99.
  - 2: Ash D1, Flynn A, Batterman J, et al. ESTRO/EAU/EORTC recommendations on permanent seed implantation for localized prostate cancer. Radiother Oncol. 2000 Dec;57(3):315-21.
  - 3: Salembier C1, Lavagnini P, Nickers P, et al. Tumour and target volumes in permanent prostate brachytherapy: a supplement to the ESTRO/EAU/EORTC recommendations on prostate. Radiother Oncol. 2007 Apr;83(1):3-10
  - 4: Mohler J, Bahnson RR, Boston B, & al. NCCN clinical practice guidelines in oncology: prostate cancer. J Natl Compr Canc Netw 2010; 8:162-200.

LDR (permanent seeds) Brachytherapy

- LDR Prostate Brachytherapy

	No.	FU (years)	B-DFS (%)	Ref.
Zelefsky & al.	1444	8	74	IJROBP 2007;67:327-33
Taira & al.	575	12	98,6*	IJROBP 2011;79:1336-42
Henry & al.	575	10	76,7	J Urol 2010;76:50-6
Cosset & al.	533	5	97	IJROBP2010;76:50-6
Potters & al.	481	12	88	J Urol 2008;179:520-4
Zelefsky & al.	416	7	95	Urology 2011;77:986-90
Martin & al.	396	5	94,6	IJROBP 2007;67:334-41

B-DFS = Biochemical disease free survival (Phoenix definition ; * = nadir ≤ 0,4 ng/ml
FU = Follow-up ; No. = number ; IJROBP = Int J Radiation Oncol Biol Phys

LDR (permanent seeds) Brachytherapy

- LDR Prostate Brachytherapy
  - Overall and Specific Survival are > 95% @ 10 yrs [1-3]
  - ↑ OS & SS proven, compared to no treatments[4]
  - Commonly accepted to be equally effective[5]
    - Brachytherapy = External beam = Surgery
  - Existing literature to prove it better

1. Henry AM & al. IJROBP 2006;76:50-6
2. Potters L & al. J Urol 2008;179:S20-4
3. Taira AV & al. IJROBP 2011;79:1336-42
4. D'Amico A & al. JAMA 1998;280:969-74
5. Zhou EH & al. IJROBP 2009;73:15-23
6. Grimm P &al. BJU Int 2012;109(Suppl 1):22-9

LDR (permanent seeds) Brachytherapy

- LDR Prostate Brachytherapy
  - Better toxicity profile with higher dose (versus EBRT)
  - Short one day therapy
  - Rapid dose falloff allowing to preserve organs at risk
  - @ lowest cost compare to: Surgery < HDR < EBRT[2,3]
  - Excellent local control of disease

« LDR seeds brachytherapy has been a gold standard in low risk disease… »[1]

1. Skowronek J. J contemp Brachy 2013;5(1)33-41
2. Hannequin C. Progrès en urologie 2013;23:3778-85
3. Pommier P. Cancer/Radiothérapie 2013;17:178-81

LDR (permanent seeds) Brachytherapy

- LDR Prostate Brachytherapy
  - Intermediate Risk

	No.	FU (yrs)	B-DFS (%)	Ref.
Zelefsky & al.	900	8	61	IJROBP 2007;67:327-33
Taira & al.	608	12	96,5	IJROBP 2004;58:25-33
Potters & al.	554	12	76	J Urol 2008;179:520-4
Henry & al.	430	10	73,5	IJROBP2010;76:50-6
Cosset & al.	276	5	94	IJROBP 2008;71:1042-8
Vassil & al.	256	5	89,5	Urology 2010;76:1251-7
Zebentout & al.	157	8	81	Canc Radiother 2010;14:183-8

B-DFS = Biochemical disease free survival (Phoenix definition
IJROBP = Int J Radiation Oncol Biol Phys

LDR (permanent seeds) Brachytherapy

Population-Based 10-Year Oncologic Outcomes After Low-Dose-Rate Brachytherapy for Low-Risk and Intermediate-Risk Prostate Cancer

W. James Morris, MD, FRCPC[1,2]; Mira Keyes, MD, FRCPC[1,2]; Ingrid Spadinger, PhD[2,3]; Winkle Kwan, MD, FRCPC[2,4]; Mitchell Liu, MD, FRCPC[1,2]; Michael McKenzie, MD, FRCPC[1,2]; Howard Pai, MD, FRCPC[2,5]; Tom Pickles, MD, FRCPC[1,2]; and Scott Tyldesley, MD, FRCPC[1,2]

Cancer 2013;119(8): 1537-46

LDR (permanent seeds) Brachytherapy

TABLE 1. Actuarial 5-Year, 7-Year, and 10-Year Estimates for Disease-Free, Cause-Specific, and Overall Survival (all values are in percentages)

	Oncologic Endpoint, %		
Actuarial Time Point	DFS (95% CI)[a,b]	CSS (95% CI)[a,c]	OS (92-95.6)[d]
5 Years	96.7 (95.2-97.7)	99.8 (99.1-99.9)	93.8 (92-95.2)
7 Years	95.1 (93.3-96.4)	99.8 (99.1-99.9)	90.1 (87.8-91.9)
10 Years	94.1 (92-95.6)	99.1 (97.3-99.7)	83.5 (79.8-86.6)

Abbreviations: CCS, cause-specific survival; CI, confidence interval; DFS, disease-free survival; OS, overall survival.
[a] Fine and Gray competing risks analysis.
[b] DFS applied only to patients who had no clinical, imaging, or biochemical evidence of persistent or recurrent prostate cancer and no secondary intervention for prostate cancer.
[c] All patients who died of any cause who were not disease-free at the time of death were scored as prostate cancer-specific deaths for the calculation of CSS.
[d] The Kaplan-Meier method was used for OS estimates, because there were no competing risks.

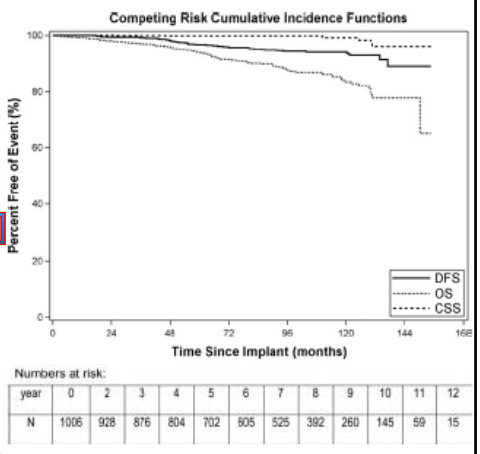


Figure 1. Fine and Gray competing risks estimates of disease-free survival (DFS) and cause-specific survival (CSS) and a Kaplan-Meier estimate of overall survival (OS) are illustrated for all patients in the cohort (N = 1006).

Cancer 2013;119(8): 1537-46

LDR (permanent seeds) Brachytherapy

Patterns of Failure

The site of first recurrence was established in 19 of 49 patients, including 8 who had clinical and/or histologic evidence of local relapse and 11 who had lymph node or distant metastatic relapse. The site of first recurrence was unknown in 30 patients who had biochemical relapse (61%), and all 30 had a normal digital rectal examination and either a normal postimplantation biopsy (N = 12) or no biopsy (N = 18, including 7 who also had no imaging studies). One individual underwent transurethral prostatic resection (TUPR) to relieve a stricture >10 years postimplantation, and the operative specimen revealed persistent/recurrent prostate cancer. Before the TUPR, that patient's PSA was unusually high at 0.83 ng/mL, but it was well short of triggering the Phoenix threshold, and recurrent cancer was not suspected preoperatively.

....

postimplantation biopsies, our results suggest that the rate of local persistent/recurrent disease in this cohort must be less than 3% and possibly much less than 3% (see Patterns of Failure, above).

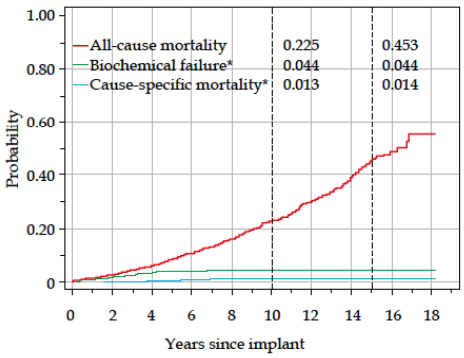
Cancer 2013;119(8): 1537-46

LDR (permanent seeds) Brachytherapy

- Intermediate +/- high risk disease
  - 2234 pts, (35% low, 49% inter. & 16% high risk disease)
  - 1111 (50.3%) with EBRT and 748 (33.5%) with ADT
    - primarily for int & high risk patients.
  - EBRT to 69.6% of inter. and 96.3% of high risk patients
    - 45-50.4 Gy covering prostate, seminal vesicles, and at-risk pelvic nodes
  - ADT used in 27.4% of inter. and 71.8% of high risk patients.
    - ADT (LHRH agonist + anti-androgen)
    - initiated 3 months prior to implantation duration range 3-36 months
      - for cytoreduction and for high risk disease.

1. Taira AV & al. J Contemp Brachytherapy 2013; 5, 4: 215–221

LDR (permanent seeds) Brachytherapy



*Cumulative incidence with non-prostate specific death as a competing risk

Fig. 1. Probabilities for all-cause mortality, biochemical failure, and cause-specific mortality are summarized at 10 years and 15 years post implant for the 2,234 patients in the population

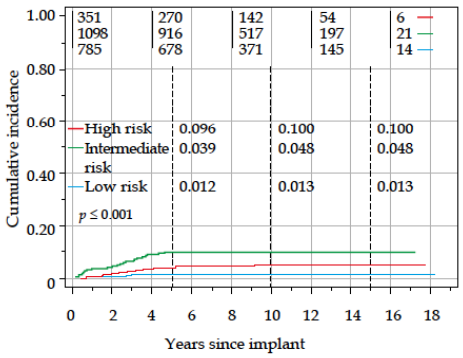


Fig. 2. Cumulative incidence of biochemical failure with non-prostate death as a competing risk, stratified by NCCN risk group, is summarized at 5, 10, and 15 years post implant. The number of patients remaining at risk in four year increments is listed at the top, stratified by risk group

1. Taira AV & al. J Contemp Brachytherapy 2013; 5, 4: 215–221

Title

Treatment Outcomes in Very High-risk Prostate Cancer Treated by Dose-escalated and Combined-Modality Radiation Therapy

Mark Shilkrut, PhD, MD,† Patrick W. McLaughlin, MD,* Gregory S. Merrick, MD,‡ Jeffrey M. Vainshtein, MD,* and Daniel A. Hamstra, MD, PhD**

Am J Clin Oncol 2014 Fev 10

TABLE 1. Patients' Clinical and Treatment Characteristics

Characteristics	Overall n = 238 (100%)	≤65 y Old n = 74 (31%)	>65 y Old n = 164 (69%)	P
Median follow-up (IQR) (mo)	61 (38-93)	63 (40-106)	60 (37-91)	0.048*
Those still alive	62 (38-97)	63 (41-106)	62 (38-95)	0.085*
Median age (IQR) (y)	70 (63-76)	59 (55-62)	73 (70-78)	<0.001*
PSA (ng/mL)				
Median (IQR)	30.7 (21.6-50.1)	30.8 (20.9-50.5)	30.6 (21.6-49.2)	0.79*
≤10	25 (11)	6 (8)	19 (12)	0.86†
10.1-20	26 (11)	9 (12)	17 (10)	
20.1-50	127 (53)	40 (54)	87 (53)	
>50	60 (25)	19 (26)	41 (25)	
T-stage				
T1-T2a	49 (21)	16 (22)	33 (20)	0.83†
T2b-T2c	57 (24)	17 (23)	40 (24.5)	
T3-T4	132 (55)	41 (55)	91 (55.5)	
Gleason sum				
2-6	8 (3)	3 (4)	5 (3)	0.81†
7	29 (12)	9 (12)	20 (12)	
8	92 (39)	26 (35)	66 (40)	
9-10	108 (45)	36 (49)	72 (44)	
High-risk features				
2	194 (82)	59 (80)	135 (82)	0.93‡
3	44 (18)	15 (20)	29 (18)	
ADT				
Yes	210 (88)	66 (89)	144 (88)	0.82‡
Duration				
Median (IQR) (mo)	24 (12-32)	24 (12-28)	24 (12-36)	0.95*
<12	46 (22)	17 (26)	29 (20)	0.61†
12-<24	46 (22)	16 (24)	30 (21)	
≥24	118 (56)	33 (50)	85 (59)	
Radiotherapy				
EBRT	165 (69)	42 (57)	123 (75)	0.006‡
Dose§ (IQR) (Gy)	77.4 (76-79.2)	77.4 (76-78)	77.4 (76-79.2)	0.63*
CMRT	73 (31)	32 (43)	41 (25)	0.006‡
Pelvic EBRT dose (IQR) (Gy)	46.8 (45-50.4)	50.4 (45-50.4)	45 (45-50.4)	0.45*
^{125}I implants		19	27	
Median prescribed dose (IQR) (Gy)	108 (108-108)	108 (108-108)	108 (108-108)	
Median D90 (IQR) (Gy)	116 (101-134)	123 (113-134)	113 (100-134)	0.27*
^{103}Pd implants	27	13	14	
Median prescribed dose (IQR) (Gy)	90 (80-90)	85 (80-90)	90 (80-90)	
Median D90 (IQR) (Gy)	110 (95-118)	101 (78-115)	115 (110-118)	0.86*

*ANOVA.
†χ^2 test for trend.
‡χ^2 test.
§Prescribed dose to a prostate gland.
ADT indicates androgen-deprivation therapy; CMRT, combined-modalities radiotherapy; D90, minimal dose to 90% of the planning target volume; EBRT, external-beam radiotherapy; IQR, interquartile range; PSA, prostate-specific antigen.

Am J Clin Onc

Title

TABLE 3. Estimated 5-, 8-, and 10-Year Survival Rates by Age and Treatment Modality

Age (y)	Survival	Treatment Modality	5 y	8 y	10 y	P
All	BPFS	EBRT	59.0 ± 4.5	43.7 ± 5.4	31.6 ± 6.3	0.001
		CMRT	80.4 ± 5.9	70.5 ± 8.6	69.9 ± 8.7	
	DMFS	EBRT	73.9 ± 4.1	65.3 ± 5.2	65.3 ± 5.2	0.035
		CMRT	84.9 ± 5.6	84.9 ± 5.6	75.5 ± 10.2	
	CSS	EBRT	89.7 ± 2.7	77.3 ± 4.4	72.9 ± 5.1	0.18
		CMRT	94.8 ± 3.1	81.8 ± 7.6	81.8 ± 7.6	
≤65	BPFS	EBRT	52.4 ± 8.8	33.2 ± 9.3	22.4 ± 9.1	0.005
		CMRT	91.5 ± 6.0	66.5 ± 16.8	65.9 ± 16.8	
	DMFS	EBRT	75.8 ± 7.1	52.0 ± 11.2	58.6 ± 10.5	0.18
		CMRT	84.7 ± 8.5	84.7 ± 8.5	63.5 ± 19.4	
	CSS	EBRT	97.1 ± 2.9	80.9 ± 7.8	74.2 ± 9.7	0.60
		CMRT	96.7 ± 3.3	82.9 ± 13.1	82.9 ± 13.1	
>65	BPFS	EBRT	61.5 ± 5.2	48.2 ± 6.4	36.6 ± 7.8	0.038
		CMRT	72.1 ± 9.1	72.1 ± 9.1	71.2 ± 9.3	
	DMFS	EBRT	73.3 ± 4.9	69.6 ± 5.3	69.6 ± 5.3	0.11
		CMRT	85.6 ± 7.1	85.6 ± 7.1	85.6 ± 7.1	
	CSS	EBRT	87.1 ± 3.5	75.8 ± 5.3	72.9 ± 5.9	0.39
		CMRT	92.8 ± 4.9	80.9 ± 9.0	80.9 ± 9.0	

BPFS indicates biochemical progression-free survival; CMRT, combined-modality radiation therapy; CSS, cancer-specific survival; DMFS, distant metastasis-free survival; EBRT, external-beam radiation therapy.

Am J Clin Oncol 2014 Fev 10

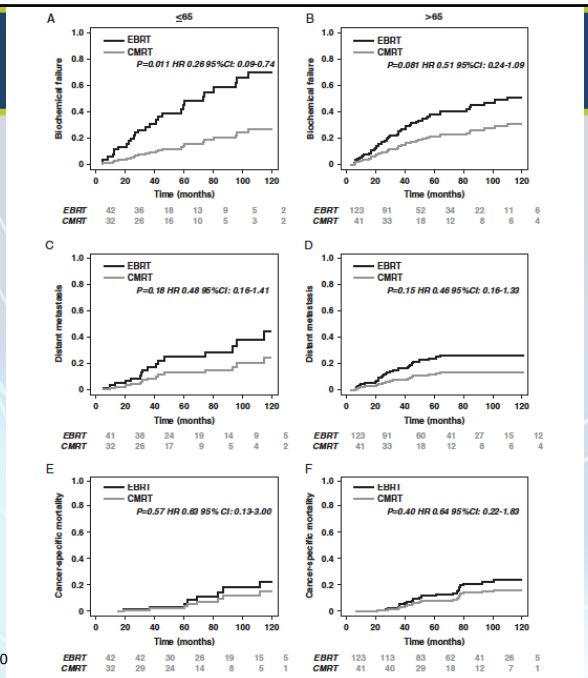


FIGURE 2. Cumulative incidence plots of BF, DM, and PCSM in patients grouped by age (A, C, E: ≤65 y old, and B, D, F: >65 y old) and treatment modality (dose-escalated external-beam radiotherapy, EBRT, versus pelvic irradiation and permanent interstitial brachytherapy, CMRT). BF indicates biochemical failure; CI, confidence interval; PCSM, prostate cancer-specific mortality; DM, distant metastasis; HR, hazard ratio.

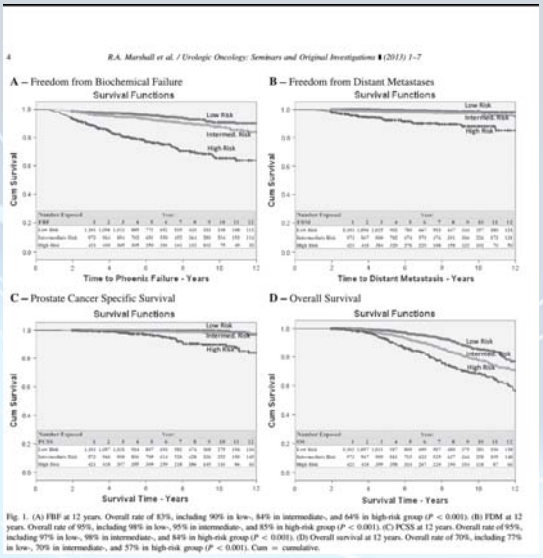
Am J Clin Oncol 2014 Fev 10

Title

- **Treatment outcomes and morbidity following definitive brachytherapy with or without external beam radiation for the treatment of localized prostate cancer: 20-Year experience at Mount Sinai Medical Center.**
  - Marshall, RA, Buckstein, M, Stone, NN, Stock, R. Department of Radiation Oncology, The Mount Sinai Medical Center, One Gustave L. Levy Place, New York, NY.
  - 12-year actuarial b-DFS = 83%
    - (low risk: 90%, intermediate risk: 84%, and high risk: 64%)
    - freedom from distant metastasis was 95%
    - prostate cancer-specific survival was 95%; and
    - overall survival was 70%.

Urol Oncol 2013 Jun 12

Title



Urol Oncol 2013 Jun 12

Title

Table 9. Comparison of high-dose-rate temporary implants and low-dose-rate permanent seed implants. The following table was compiled by the HDR Prostate Working Group and presented to radiation oncologists at the American Society of Therapeutic Radiology and Oncology (ASTRO) meeting in Phoenix, October 1998

	High dose rate	Low dose rate
Conformal treatment	++++	++++
Target accuracy	++++	++++
Ability to treat extracapsular extension	++++	+
Ability to treat seminal vesicles	++++	++
Ease of control of radiation	++++	++
Lack of cold/hot spots	++++	++
Control of critical organ dose	++++	++
Modify dose distribution	++++	+
Need for external beam	Yes/Sometimes	No/Sometimes
Monotherapy	+	+++
Experience of physician	Crucial	Crucial
Pre-planning dosimetry	Not needed	Extensive (TRUS)
Post implant dosimetry	Not needed	Extensive (CT)
Stages treated	All, T1-T3	T1-T2
Gland volume > 60 cc at time of implant	Less difficulty	More difficulty
Pubic arch interference at time of implant	Less of a problem	Can't be done
Prior TURP	Less of a problem	Can't always be done
Final Dose Verification	Pre-treatment	Post treatment
Symptom duration	Weeks	Months
Implant cost	Higher	Lower

Skowronek J. J contemp Brachy 2013;5(1)33-41

Title

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Title

Table 9. Comparison of high-dose-rate temporary implants and low-dose-rate permanent seed implants. The following table was compiled by the HDR Prostate Working Group and presented to radiation oncologists at the American Society of Therapeutic Radiology and Oncology (ASTRO) meeting in Phoenix, October 1998

	High-dose-rate	Low-dose-rate
Conformal treatment	++++	++++
Target accuracy	++++	++++
Ability to treat extracapsular extension	++++	+
Ability to treat seminal vesicles	++++	++
Ease of control of radiation	++++	++
Lack of cold/hot spots	++++	++
Control of critical organ dose	++++	++
Modify dose distribution	++++	+
Need for external beam	Yes/Sometimes	No/Sometimes
Monotherapy	+	+++
Experience of physician	Crucial	Crucial
Pre-planning dosimetry	Not needed	Extensive (TRUS)
Stages treated	All, T1-T3	T1-T2
Gland volume > 60 cc at time of implant	Less difficulty	More difficulty
Prior TURP	Less of a problem	Can't always be done
Final Dose Verification	Pre-treatment	Post treatment
Symptom duration	Weeks	Months
Implant cost	Higher	Lower

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Lack of cold/hot spots	++++	++
Control of critical organ dose	++++	++
Modify dose distribution	++++	+
Need for external beam	Yes/Sometimes	No/Sometimes
Monotherapy	+	+++
Experience of physician	Crucial	Crucial
Pre-planning dosimetry	Not needed	Extensive (TRUS)
Post implant dosimetry	Not needed	Extensive (CT)
Stages treated	All, T1-T3	T1-T2
Pubic arch interference at time of implant	Less of a problem	Can't be done
Prior TURP	Less of a problem	Can't always be done
Final Dose Verification	Pre-treatment	Post treatment
Symptom duration	Weeks	Months
Implant cost	Higher	Lower

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Title

"Is LDR brachytherapy still an option for developing countries?"

YES…

For developed & developing ones !