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Comparison Of Health-related Quality Of Life 5 Years After Brachytherapy(BT) Or Radical Prostatectomy(RP): The SPIRIT (Surgical Prostatectomy vs. Interstitial Radiotherapy Intervention Trial) Cohort

J. M. Crook[1], A. Gomez-Iturriaga[2], K. Wallace[3], S. Fung[3], S. Alibhai[4], M. Jewett[4], N. Fleshner[4], *[1]University of British Columbia, Kelowna, BC, Canada, [2]Cruces Hospital, Barakaldo, Spain, [3]Princess Margaret Hospital, Toronto, ON, Canada, [4]University Health Network, Toronto, ON, Canada*

Purpose:

- The American College of Surgeons Oncology Group phase III trial (SPIRIT):
- RP vs BT, low risk prostate cancer, opened in 2002 but closed in 2004 due to poor accrual.
- Health related quality of life (HRQOL) at a mean of 5.3 years for 168 trial-eligible men who either chose or were randomized to RP or BT.

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Materials/Methods:

- Multi-disciplinary educational session for eligible patients during which a urologist and a radiation oncologist together compared and contrasted the 2 treatment options and explained the trial rationale.
- 47 sessions were attended by 263 men, of whom 34 consented to randomization, 62 chose RP, and 94 BT.
- 5 years later, after university and host hospital IRB approval, these 190 men underwent HRQOL evaluation using the cancer-specific 50-item EPIC, the SF-12 PCS and MCS.
- Response rate was 88.4%.
- Descriptive statistics were used to summarize demographics and the Wilcoxon Rank Sum Test to compare summary scores between the two interventions

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Results:

- 60.1% had BT (8.9% on trial) and 39.9% had RP (8.9% on trial).
- Median age was 61.5 years (range: 45-73) for BT and 59.5 (47-71) for RP.
- Median follow-up is 5.2 years (3.2-6.5).
- For BT vs. RP there was no difference in bowel (93.0 vs. 94.3; p=0.43), or hormonal (93.5 vs. 90.0; p=0.09) domains or in the SF-12 PCS score (55.8 vs. 55.5; p=0.37).
- However, men treated with BT scored better in the urinary (91.9 vs. 88.2; p=0.02) and sexual (52.3 vs. 39.7; p=0.002) domains, and in the satisfaction score (93.6 vs. 77.2; p<0.0001).

Comparison Of Health-related Quality Of Life 5 Years After Brachytherapy(BT) Or Radical Prostatectomy(RP): The SPIRIT (Surgical Prostatectomy vs. Interstitial Radiotherapy Intervention Trial) Cohort

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- **Examination of questions within the urinary domain revealed that urinary control, frequency of leakage and the degree of problem with leaking all showed a p value <0.0001 in favour of BT whereas none of the questions on irritative/obstructive symptoms favoured either modality.**
- **In the sexual domain, many questions showed a highly significant difference in favour of BT, including:**
  - **those on the ability to have an erection (p=0.0007),**
  - **quality of erections (p=0.0002),**
  - **and frequency of erections (p=0.003).**
- **Erections firm enough for sexual activity were reported by 79% in the BT cohort compared to 48% for RP (p=0.0002).**

Comparison Of Health-related Quality Of Life 5 Years After Brachytherapy(BT) Or Radical Prostatectomy(RP): The SPIRIT (Surgical Prostatectomy vs. Interstitial Radiotherapy Intervention Trial) Cohort

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Conclusions:

- Side effects stabilize by 3-5 years after treatment.
- Although treatment allocation was only random in 17% of cases, all subjects received identical and unbiased information in a multi-disciplinary setting prior to selecting RP, BT or randomization.
- HRQOL evaluated 3.2 - 6.3 years after treatment shows an advantage in the urinary and sexual domains, and in patient satisfaction, for men treated with BT.

Socioeconomic and Racial Disparities in the Selection of Prostate Brachytherapy

D. Schreiber[1], E. Nwokedi[1], J. Rineer[2], E. Katsoulakis[1], A. Surapaneni[1], D. Boo[1], P. Han[1], K. Choi[1], M. Rotman[1], D. Schwartz[1], *[1]SUNY Downstate Medical Center, Brooklyn, NY, [2]MD Anderson Cancer Center, Houston, TX*

Purpose/Objective:

- Several reports have indicated that there are significant racial and socioeconomic disparities in the selection of definitive therapy for prostate cancer.
- We analyzed the Surveillance, Epidemiology and End Results database to analyze whether these disparities still exist in the selection of external beam radiation (EBRT) or brachytherapy, once these patients agree to definitive radiation.

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Materials/Methods:

- We selected patients with cT1c-T4Nx-0M0 prostate adenocarcinoma who were diagnosed between 2004-2006 and treated with EBRT alone, EBRT + brachytherapy, or brachytherapy alone.
- All patients had complete data regarding preoperative prostate specific antigen and Gleason scores and this information was used with clinical T-stage to broadly group patients into National Comprehensive Cancer Network (NCCN) risk groups.
- Data regarding race (White or Black) and socioeconomic status (divided into quartiles based on cost of living adjusted household income of the SEER county from which the patient was treated) were also collected.
- Pearson Chi Square was used to compare all groups. Pair-wise comparisons were also used for groups with more than 2 variables.

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Results:

- A total of 38,731 patients met the selection criteria.
- EBRT alone 57%,
- brachytherapy 43.0%:
  - alone 30.2%,
  - in combination with EBRT 12.8%.
- Patients who were black (p<0.001), increasing NCCN risk grouping (p<0.001) and were in the lowest income quartile (p<0.001) were all associated with decreased use of brachytherapy.
- Regarding socioeconomic status, 31.5% of those in quartile 1 received brachytherapy as a component of their treatment compared with 42.9% of quartile 2, 47.3% of quartile 3 and 48.7% of quartile 4.

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- These differences between income quartiles were significant on pair-wise analysis ($p<0.001$ for all comparisons except quartile 3 and 4 where $p=0.008$).
- When stratifying by risk-grouping, whites were more likely to receive brachytherapy for low ($p<0.001$) and intermediate ($p<0.001$) risk disease but not high risk disease ($p=0.821$).
- The economic disparities were also maintained regardless of risk grouping ($p<0.001$).
- On pair-wise analysis these differences remained significant except for comparisons between income quartiles 3 and 4 for low risk disease ($p=0.373$) and intermediate risk disease ($p=0.412$).

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Conclusions:

- **In this large national database review, once patients agree to treatment with radiation, there still appears to be racial and socioeconomic disparities with the selection of brachytherapy.**
- **Those with higher socioeconomic status and white race are significantly more likely to select brachytherapy as a component of treatment.**

Estimated New Cases*

Males				Females		
Prostate	217,730	28%		Breast	207,090	28%
Lung & bronchus	116,750	15%		Lung & bronchus	105,770	14%
Colon & rectum	72,090	9%		Colon & rectum	70,480	10%
Urinary bladder	52,760	7%		Uterine corpus	43,470	6%
Melanoma of the skin	38,870	5%		Thyroid	33,930	5%
Non-Hodgkin lymphoma	35,380	4%		Non-Hodgkin lymphoma	30,160	4%
Kidney & renal pelvis	35,370	4%		Melanoma of the skin	29,260	4%
Oral cavity & pharynx	25,420	3%		Kidney & renal pelvis	22,870	3%
Leukemia	24,690	3%		Ovary	21,880	3%
Pancreas	21,370	3%		Pancreas	21,770	3%
All Sites	**789,620**	**100%**		**All Sites**	**739,940**	**100%**

Estimated Deaths

Males				Females		
Lung & bronchus	86,220	29%		Lung & bronchus	71,080	26%
Prostate	32,050	11%		Breast	39,840	15%
Colon & rectum	26,580	9%		Colon & rectum	24,790	9%
Pancreas	18,770	6%		Pancreas	18,030	7%
Liver & intrahepatic bile duct	12,720	4%		Ovary	13,850	5%
Leukemia	12,660	4%		Non-Hodgkin lymphoma	9,500	4%
Esophagus	11,650	4%		Leukemia	9,180	3%
Non-Hodgkin lymphoma	10,710	4%		Uterine Corpus	7,950	3%
Urinary bladder	10,410	3%		Liver & intrahepatic bile duct	6,190	2%
Kidney & renal pelvis	8,210	3%		Brain & other nervous system	5,720	2%
All Sites	**299,200**	**100%**		**All Sites**	**270,290**	**100%**

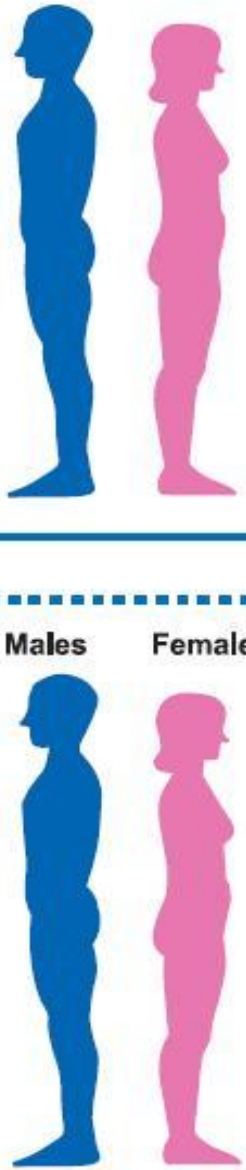

FIGURE 1. Ten Leading Cancer Types for the Estimated New Cancer Cases and Deaths by Sex, 2010.

*Excludes basal and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates are rounded to the nearest 10.

Potential National Utilization of Active Surveillance as a Treatment Approach for Prostate Cancer Using NCCN Guidelines

T. Dvorak[1], J. M. Martin[2], T. A. DiPetrillo[1], D. E. Wazer[1], *[1]Tufts Medical Center, Boston, MA, [2]Tufts University, Boston, MA*

Purpose:

- Active surveillance (AS) is gaining increasing acceptance as a treatment strategy for some patients with prostate cancer.
- National Comprehensive Cancer Network (NCCN) guidelines are becoming an accepted standard of care in the U.S.
- We estimated the number of patients with prostate cancer who could be treated with active surveillance using NCCN guidelines from the SEER database,
- and extrapolated the estimate to the entire U.S. population of prostate cancer patients.

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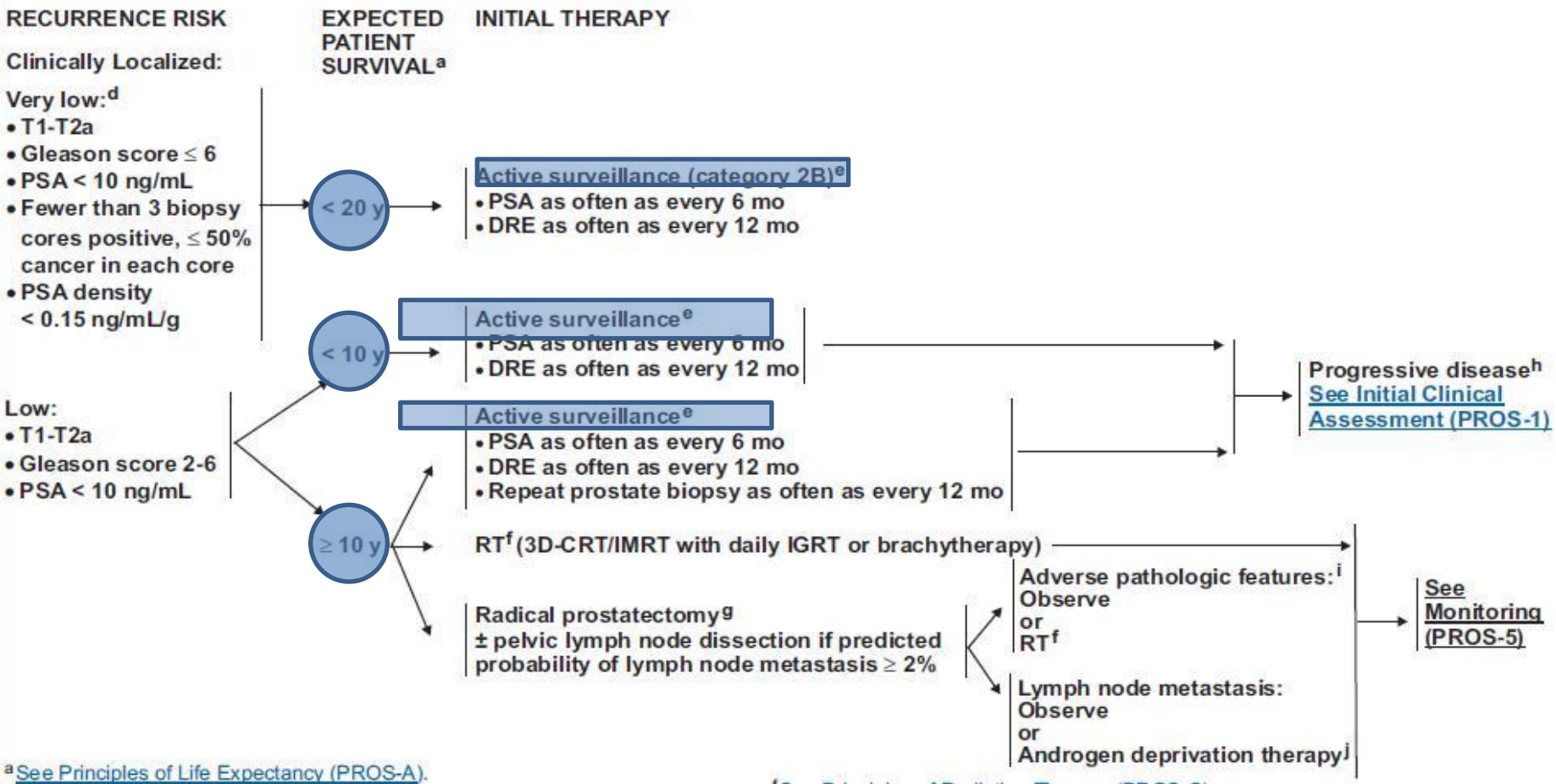
Methods:

- The SEER database was used to identify individual records of 37,646 men diagnosed with non-metastatic prostate cancer in 2006 with sufficient information regarding TNM stage, PSA, and Gleason score.
- NCCN treatment guidelines (v1.2010) were used to estimate the number of patients for whom AS would be recommended either as the only recommended treatment or as one of several accepted treatment options.
- For the AS candidate patients not treated with AS, we analyzed which treatment they actually received.
- Finally, we extrapolated the SEER data to the entire U.S. population.

Prostate Cancer



[a] See Principles of Life Expectancy (PROS-A).

[d] The Panel remains concerned about the problems of over-treatment related to the increased diagnosis of early prostate cancer from PSA testing (see NCCN Prostate Early Detection Guidelines v1.2010). Active surveillance is preferred for this subset of patients.

[e] Active surveillance involves actively monitoring the course of disease with the expectation to intervene if the cancer progresses See Principles of Active Surveillance (PROS-B).

[f] See Principles of Radiation Therapy (PROS-C).

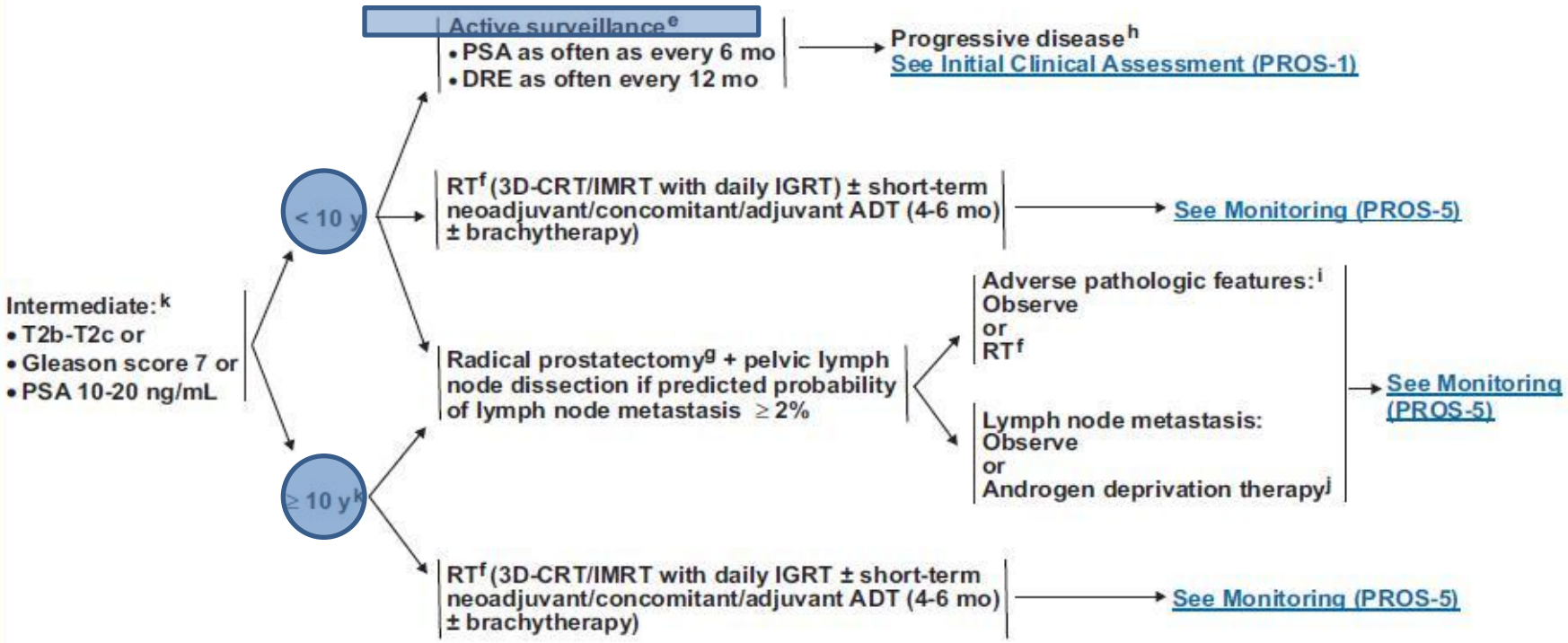
[g] See Principles of Surgery (PROS-D).

[h] Criteria for progression are not well defined and require physician judgement; however, a change in risk group strongly implies disease progression.

[i] Adverse pathologic features include: positive margins, seminal vesicle invasion, extracapsular extension or detectable PSA.

[j] See Principles of Androgen Deprivation Therapy (PROS-E).

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.



[a] See Principles of Life Expectancy (PROS-A).

[c] Patients with multiple adverse factors may be shifted into the next higher risk group.

[e] Active surveillance involves actively monitoring the course of disease with the expectation to intervene if the cancer progresses. See Principles of Active Surveillance (PROS-B).

[f] See Principles of Radiation Therapy (PROS-C).

[g] See Principles of Surgery (PROS-D).

[h] Criteria for progression are not well defined and require physician judgement; however, a change in risk group strongly implies disease progression.

[i] Adverse pathologic features include: positive margins, seminal vesicle invasion, extracapsular extension or detectable PSA.

[j] See Principles of Androgen Deprivation Therapy (PROS-E).

[k] Active surveillance of intermediate and high risk clinically localized cancers is not recommended in patients with life expectancy > 10 years (category 1).

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PRINCIPLES OF ACTIVE SURVEILLANCE

- The NCCN Prostate Cancer Guideline Panel and the NCCN Prostate Cancer Early Detection Panel (see NCCN Prostate Early Detection Guidelines v1.2010) remains concerned about over-diagnosis and over-treatment of prostate cancer. The Panel recommends that patients and their physicians consider active surveillance based on careful consideration of the patient's prostate cancer risk profile, age and health by the patient and all his physicians (urologist, radiation oncologist, medical oncologist, primary care physician).
- Active surveillance is usually appropriate for men with very low risk prostate when life expectancy < 20 y or men with low risk prostate cancer when life expectancy < 10 y. See Recurrence Risk Criteria (PROS-2)
- Active surveillance involves actively monitoring the course of disease with the expectation to intervene if the cancer progresses
- Patients with clinically localized cancers who are candidates for definitive treatment and choose active surveillance should have regular follow up. Follow up should be more rigorous in younger men than older men. Follow up should include:
  - PSA as often as every 3 mo but at least every 6 mo
  - DRE as often as every 6 mo but at least every 12 mo
  - Needle biopsy of the prostate may be repeated within 6 mo of diagnosis if initial biopsy was < 10 cores or assessment discordant (eg, palpable tumor contralateral to side of positive biopsy)
  - Needle biopsy may be performed within 18 mo if initial biopsy ≥ 10 cores
- Cancer progression may have occurred if:
  - Primary Gleason grade 4 or 5 cancer is found upon repeat prostate biopsy
  - Prostate cancer is found in a greater number of prostate biopsies or occupies a greater extent of prostate biopsies
  - PSA doubling time < 3 y
- A repeat prostate biopsy is indicated for signs of disease progression by exam or PSA
- Advantages of active surveillance:
  - Avoid possible side effects of definitive therapy that may be unnecessary
  - Quality of life/normal activities retained
  - Risk of unnecessary treatment of small, indolent cancers reduced
- Disadvantages of active surveillance
  - Chance of missed opportunity for cure
  - Risk of progression and/or metastases
  - Subsequent treatment may be more complex with increased side effects
  - Nerve sparing may be more difficult, which may reduce chance of potency preservation after surgery
  - Increased anxiety
  - Requires frequent medical exams and periodic biopsies
  - Uncertain long-term natural history of prostate cancer

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PRINCIPLES OF RADIATION THERAPY

External Beam Radiotherapy:

- 3D conformal and IMRT (intensity modulated radiation therapy) techniques should be employed. Image guided radiation therapy (IGRT) is required if dose ≥ 78 Gy.
- Doses of 75.6-79 Gy in conventional 36-41 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 between 78-80+ Gy provide improved PSA-assessed disease control.
- Patients with high-risk cancers are candidates for pelvic lymph node irradiation and the addition of neoadjuvant/concomitant/adjuvant ADT for a total of 2-3 y (category 1).
- Patients with intermediate risk cancer may be considered for pelvic lymph node irradiation and 4-6 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 such as IGRT using CT, ultrasound implanted fiducials, electromagnetic targeting/tracking, or an endorectal balloon to improve oncologic cure rates and reduce side effects.
- Evidence supports offering adjuvant/salvage RT in all men with adverse pathologic features or detectable PSA and no evidence of disseminated disease.

Brachytherapy:

- Permanent brachytherapy as monotherapy is indicated for patients with low-risk cancers. For intermediate-risk cancers consider combining brachytherapy with EBRT (40-50 Gy) ± 4-6 mo neoadjuvant/comcomittant/adjuvant ADT. Patients with high-risk cancers are generally considered poor candidates for permanent brachytherapy; however, with the addition of EBRT and ADT, it may be effective in some patients.
- Patients with a very large prostate or very small prostate, symptoms of bladder outlet obstruction (high IPSS), or a previous transurethral resection of the prostate (TURP) are more difficult to implant and may suffer increased risk of side effects. Neoadjuvant androgen deprivation therapy may be used to shrink the prostate to an acceptable size.
- Post-implant dosimetry should be performed to document the quality of the implant.
- The recommended prescribed doses for monotherapy are 145 Gy for 125-Iodine and 125 Gy for 103-Palladium. The corresponding boost dose after 40-50 Gy EBRT are 110 Gy and 100 Gy, respectively. In addition, high dose rate (HDR) brachytherapy can be used in combination instead of lower dose.

Palliative Radiotherapy:

- 800 cGy as a single dose should be used instead of 3000 cGy in 10 fractions for non-vertebral metastases.
- Widespread bone metastases can be palliated using strontium 89 or samarium 153.

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Results:

- There were 12,183 low risk, 17,236 intermediate risk, 7,622 high risk, and 605 locally advanced patients.
- In the low risk group, AS was the only recommended treatment option for 2941 patients;
  - 712 (24%) were treated with AS,
  - the remainder were treated with EBRT (25%),
  - brachytherapy (20%),
  - EBRT+brachytherapy (3%),
  - radical prostatectomy (18%).
- In the low risk group, AS was an accepted option for 9,242 patients;
  - 1624 (18%) were treated with AS,
  - the remainder were treated with EBRT (17%),
  - brachytherapy (21%),
  - EBRT+brachytherapy (3%),
  - radical prostatectomy (35%).

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- In the intermediate risk group, AS was an accepted option for 5,084 patients;
  - 1,281 (25%) were treated with AS;
  - the remainder were treated with EBRT (29%),
  - brachytherapy (9%),
  - EBRT+brachytherapy (6%)
  - radical prostatectomy (24%).
- The NCCN guidelines do not recommend AS for the other risk groups.
- Overall, 46% of all patients could be managed with AS according to the guidelines; 9.6% actually received it.

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- Based on an annual U.S. prostate cancer incidence of 192,000; we estimate that approximately 88,000 patients could initially be treated with AS by following the NCCN guidelines, while 18 thousand were actually treated with it.
- The remaining 70,000 were treated with:
- radical prostatectomy (25,000),
- EBRT (19,000),
- brachytherapy (15,000),
- EBRT + brachytherapy (3000),
- and other treatments (6000).

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Conclusions:

- **Based on NCCN guidelines, active surveillance could be an acceptable treatment option for almost half of all patients diagnosed with prostate cancer, though less than 10% actually received it in 2006.**

- **Nationally, up to 70,000 additional patients with prostate cancer could be managed initially with active surveillance rather than radical therapy.**

Compliance With NCCN Treatment Guidelines For Prostate Cancer: A SEER Database Analysis

J. M. Martin[1], L. L. Price[2], K. E. Huber[3], T. A. DiPetrillo[3], D. E. Wazer[3], T. Dvorak[3], *[1]Tufts University School of Medicine, Boston, MA, [2]Biostatistics Research Center, Tufts University, Boston, MA, [3]Department of Radiation Oncology, Tufts Medical Center, Boston, MA*

Purpose/Objective(s):

- Compliance with treatment guidelines has been shown to improve outcomes, decrease morbidity, and decrease cost of care.
- National Comprehensive Cancer Network (NCCN) guidelines are emerging as a recognized standard in the U.S.
- We analyzed compliance with NCCN guidelines for initial therapy for patients with non-metastatic prostate cancer on a population level, by using individual patient data from the SEER database.

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Materials/Methods:

- We used the SEER database to identify 37,646 men diagnosed with non-metastatic prostate cancer in 2006 with sufficient information regarding T-stage, PSA, and Gleason score.
- We stratified each case into low risk, intermediate risk, high risk, or locally advanced based on the criteria set forth in the 2005 NCCN guidelines.
- We then assessed whether the initial treatment approach for each patient was concordant, discordant, or unknown based upon the NCCN guidelines.
- Guideline compliance was scored as unknown if different treatment alternatives were available depending on patient's expected survival, which was not readily available through SEER data.
- We also performed a subset analysis based on risk group, age, race, and geography.

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Results:

- Overall, therapy was:
  - concordant with NCCN guidelines in 65% of patients,
  - discordant in 17% of patients,
  - and unknown in 18% of patients.
- By risk group:
  - 8% of low risk,
  - 12% of intermediate risk (OR 1.5),
  - 43% of high risk (OR 8.5),
  - and 39% of locally advanced patients (OR 7.4) received discordant therapy.

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Results:

- By age:
  - 6% of men in their 40s,
  - 10% in 50s,
  - 14% in 60s,
  - 21% in 70s,
  - and 40% in 80s received discordant therapy.
- By race:
  - 17% of white patients,
  - 19% of black patients (OR 1.2) received discordant therapy.

Compliance With NCCN Treatment Guidelines For Prostate Cancer: A SEER Database Analysis

J. M. Martin[1], L. L. Price[2], K. E. Huber[3], T. A. DiPetrillo[3], D. E. Wazer[3], T. Dvorak[3], *[1]Tufts University School of Medicine, Boston, MA, [2]Biostatistics Research Center, Tufts University, Boston, MA, [3]Department of Radiation Oncology, Tufts Medical Center, Boston, MA*

- By state:

  - therapy discordant from guidelines ranged from a low of 8% in Alaska to a high of 30% in Georgia.

- Reasons for discordant care included:

  - cryotherapy,

  - combination of brachytherapy and external beam RT for low risk patients,

  - brachytherapy alone for intermediate patients,

  - watchful waiting/active surveillance for high risk patients,

  - and radical prostatectomy for locally advanced patients.

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Conclusions:

- There was a reasonably high level of compliance in 2006 with NCCN guidelines for patients with non-metastatic prostate cancer;
- however, it varied significantly with risk groups, age, and geographic location.
- It will be important to evaluate whether non-compliance with guidelines impacts clinical outcomes on a national level.

Single (15 Gy) Versus 2 Fractions (of 10Gy) HDR Prostate Brachytherapy Boost: A More Practical Approach With Less Sexual Toxicity.

A. Martin, E. Vigneault, W. Foster, S. Aubin, M. Lavallée, N. Laflamme, L. Beaulieu, *CHUQ - Hotel Dieu de Quebec, Quebec, QC, Canada*

Purpose/Objective(s):

- Report dosimetric factors and compare:

  genito-urinary (GU),

  gastro-intestinal (GI)

  and sexual toxicity (SxT)

  in patients with intermediate risk prostate cancer treated with inverse-planned HDR brachytherapy boost, using two different fractionation scheme (10 Gy x 2 vs 15 Gy x 1).

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Materials/Methods:

- Prospectively collected data from 345 patients treated between 1999 and 2010 for localized intermediate risk prostate cancer.
- They received external beam pelvic radiation (40-44 Gy) followed by HDR (Ir-192) brachytherapy boost.
- 20 Gy in 2 fractions (TF) using inverse-planning with simulated annealing (IPSA) were given to the gland until March 2009.
- Thereafter, 15 Gy in a single fraction (SF) was administered.
- Dosimetric values were compared.
- IPSS score, GU/GI toxicities and sexual function questionnaires were completed (by the patient) at each follow-up visit.
- Pearson Chi-Square test was done.

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Results:

- The SF and TF groups included 65 and 280 patients respectively.
- There were no statistically significant differences in regards to age, initial PSA, Gleason score and stage.
- Median age was 65 years.
- Clinical stage distribution is: 59,7% T1 and 40,3% T2.
- 88,1 % of the population is of Gleason score 7 while 11,9% is Gleason score 6.
- Initial PSA is ≤10ng/ml for 76,5% of our patients while 23,5% is between 10-20ng/ml.
- 14,2% of patients received hormonotherapy and were excluded of our sexual toxicity analysis.

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- **The IPSS scores at baseline, 6 weeks and at 3 months follow-up presented no statistically significant differences between groups.**
- **GI symptoms also did not differ for the same periods.**
  The baseline sexual function was similar in both groups.
- **Within the first 6 months after brachytherapy, the sexual function was evaluated (SHIM-like test scoring) to be adequate in 80% of the SF group compared to 56,9% (TF) p=0,005.**

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- The low sexual function patients represented respectively 16,4 and 27,8% of each group.
- Sexual dysfunction needing medication to obtain an erection were reported in 3,6% (SF) and 15,3% (TF) respectively.
- The relative risk of having acute SxT in the TF was 2,1 compared to the SF (p=0,0412).
  The SF gave a median D90 of 15,6 +/- 1,3 Gy and the V100 was 93,9 +/- 7,9 % with a urethral V125% of 0 +/- 0,17 cc and a rectal V75% of 0,91 +/- 0,66 cc.
- As compared to the TF, the D90 was 10,6 +/- 0,6 Gy per fraction and the V100 was 95,8 +/- 6,7 % with a urethral V125% of 0,02 +/- 0,16 cc and a rectal V75% of 1,1 +/- 0,77 cc.

Single (15 Gy) Versus 2 Fractions (of 10Gy) HDR Prostate Brachytherapy Boost: A More Practical Approach With Less Sexual Toxicity.

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Conclusions:

- A SF (15Gy) IPSA planned HDR brachytherapy boost for localized prostate cancer does not increase acute side effects and seems to induce less acute SxT as compared with a standard TF (10Gy x 2) regimen.

Five-Year Clinical Outcome in Intermediate Risk Gleason 7 Cancer Patients Treated with Image-Guided Adaptive Radiation Therapy vs. Image-Guided Brachytherapy as Monotherapy

M. Wallace[1], M. Ghilezan[1], C. Mitchell[2], L. Kestin[1], C. Shah[1], K. Marvin[1], D. Brabbins[1], G. Gustafson[2], H. Ye[1], A. Martinez[1], *[1]William Beaumont Hospital, Royal Oak, MI, [2]William Beaumont Hospital, Troy, MI*

Purpose:

- 5-year clinical outcome
- patients with Gleason 7 prostate cancer
- definitive radiation therapy with dose escalation irradiation using CT-based offline
- image-guided adaptive radiation therapy (IGRT) technique
- or a brachytherapy (IGBT) implant as monotherapy.

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Methods:

- From 7/95-7/09,
- 335 patients with Gleason 7 (3 + 4) prostate cancer,
- IGRT (n=246),
- IGBT [(n=89); 78 HDR (High dose rate)/11Pd (Palladium)].
- Patients with Gleason 7 (4 + 3) were excluded from this analysis.
- Using 3D-CRT or IMRT, the median dose for IGRT was 75.6 Gy (70.2 - 82.3 Gy).
- Brachytherapy was performed via interstitial implant.
- HDR was delivered in 4 fractions of 9.5 Gy each (38 Gy) or 2 fractions of 12 Gy each (24 Gy), with a median dose of 38.0 Gy (24.0 - 38.0 Gy).
- Pd dose was 120 Gy. Clinical outcomes were measured and biochemical control was reported as defined by the Phoenix definition.

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Results:

- Mean/median follow up for IGRT was 4.8/4.3 yrs vs. 3.3/2.0 yrs for IGBT ($p<0.01$).
- Mean/median age, as a continuous variable, was 71/72 yrs for pt treated with IGRT vs. 64/65 yrs for IGBT ($p<0.01$).
- Median age (yrs), when stratified as < 65 vs. 65-75 vs. >75, was statistically significant between the two groups ($p<0.01$), with the majority (50%) being 65-75 yrs of age at the time of diagnosis.

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Results:

- Patients less than 65 years old more frequently opted for IGBT (49%) vs. IGRT (19%).
- Men older than 75 opted for IGBT less frequently, representing 7% of the total population who were > 75 yrs at diagnosis (23%).
- T-stage was not significantly different between the groups.
- For all patients, the mean pre-treatment PSA was 7.6.

Five-Year Clinical Outcome in Intermediate Risk Gleason 7 Cancer Patients Treated with Image-Guided Adaptive Radiation Therapy vs. Image-Guided Brachytherapy as Monotherapy

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- Neoadjuvant androgen deprivation was administered in 17%, with the majority of those being IGRT (81%) vs. IGBT (19%) (p=0.04).
- There was a significant difference in pre-treatment PSA between IGRT (8.2) vs. IGBT (5.7) (p<0.01).
- Time to nadir was significantly different between IGRT 2.0 yrs vs. IGBT 1.5 yrs (p=0.01).
- 5 year clinical outcomes for IGRT and IGBT were
  - DFS (84% vs. 98%, p=0.02),
  - OS (85% vs. 98%, p=0.058),
  - CSS (100% vs. 100%),
  - LR (0.7% vs. 0%),
  - DM (0.5% vs. 0%),
  - BC (85% vs. 88%).

Five-Year Clinical Outcome in Intermediate Risk Gleason 7 Cancer Patients Treated with Image-Guided Adaptive Radiation Therapy vs. Image-Guided Brachytherapy as Monotherapy

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Conclusions:

- With the exception of DFS, no difference in 5 year clinical outcomes was seen between IGRT and IGBT in Gleason 7 (3+4) patients.
- These findings suggest that IGBT as monotherapy may be suitable for a subset of intermediate risk prostate cancer patients.

Low Dose(LDR) Or High Dose Rate(HDR) Brachytherapy For Gleason Score(GS) 7 T1-2 Prostate Cancer, A Preferred Radiotherapeutic Approach: The UCSF Experience

C. C. Hsu, I. C. Hsu, V. K. Weinberg, B. Pickett, A. R. Gottschalk, K. Shinohara, M. Roach, *UCSF, San Francisco, CA*

Purpose/Objective(s):

- Optimal treatment of intermediate-risk prostate cancer is controversial, with RTOG 0232 assessing the need for external beam radiation (EBRT) with brachytherapy(BT) and RTOG 0815 assessing the additional use of short-term hormone therapy (HT).
- Some argue radical prostatectomy(RP) offers better control, with 5-year(y) biochemical progression free survival (surgical definition, PSA<0.4) of at least 65% for GS 7.
- To address some of these issues, we present the UCSF experience with BT for these patients.

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Materials/Methods:

- N=132 men with GS 7 cT1-T2c N0 prostate cancer receiving LDR (73%, performed 1997-2003)
- or HDR (27%, performed 1997-2005) BT were included.
- More than half received EBRT (58%) and/or HT(51%). Median(med) follow-up (FU) was 78 mos. FU time was from BT date until last PSA or death.
- PSA nadir was defined as current post-implant PSA nadir as of last visit;
- given FU from 1mos to 141mos, some patients still had a trend towards declining PSA, not having reached true nadir.
- Disease failure was defined as PSA failure (Phoenix consensus definition of PSA nadir+2.0) or metastatic disease.

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Results:

- Mean age of LDR and HDR patients was comparable (64.2 vs 66.4 y).
- However, compared to LDR, the HDR patients had more T2 disease (59% vs 83%) and higher maximum pre-treatment PSA (median(range): 6.2(0.1-18.6) vs 8.6(1.0-99.3)).
- PSA nadir <=0.4 for LDR patients was 85% and for HDR patients was 94%.
- PSA nadir among LDR patients was lower with than without EBRT (medPSA=0.05 vs. 0.10, p=0.01, respectively) and lower with than without HT (medPSA=0.05 vs. 0.10, p=0.003).

Low Dose(LDR) Or High Dose Rate(HDR) Brachytherapy For Gleason Score(GS) 7 T1-2 Prostate Cancer, A Preferred Radiotherapeutic Approach: The UCSF Experience

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- This difference was not statistically significant with HDR.
- 5-y disease control was 93% among LDR patients (8 PSA failures occurring 5-121 mos post-implant)
- and was 94% among HDR patients (1 PSA failure at 90 mos and 2 patients with distant metastases at 22 and 23 mos post-implant).
- 5-y disease control was 98% (3 failures of N=67) with and 88% (8 failures of 65) without additional hormone therapy (p=0.08).
- 5-y disease control was 95% (4 failures of N=76) with and 90% (7 failures of 56) without additional EBRT (p=0.09).

Low Dose(LDR) Or High Dose Rate(HDR) Brachytherapy For Gleason Score(GS) 7 T1-2 Prostate Cancer, A Preferred Radiotherapeutic Approach: The UCSF Experience

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Conclusions:

- BT as a component of treatment offers exceptional biochemical control for patients with GS7 T1-T2 prostate cancer, with >88% of patients having a nadir PSA<=0.4 and 5-year disease control of 93%, possibly offering biochemical PFS comparable to RP for this population.
- Our study suggests HT and/or EBRT with BT may improve 5-year disease control, though our sample size precludes definitive conclusions.
- Given similar results with these forms of BT, quality of life or cost considerations may be considered to help define optimal management for these patients.

Monotherapeutic High-Dose-Rate Brachytherapy for Prostate Cancer: 15 years Experience of Osaka University

K. Konishi, Y. Yoshioka, I. Sumida, Y. Takahashi, T. Ogata, F. Isohashi, M. Koizumi, T. Inoue,
Departament of Radiation Oncology, Osaka University Graduate School of Medicine, Suita Osaka, Japan

Purpose/Objective(s):

- High-dose-rate brachytherapy (HDR-BT) is at a clinical trial phase, with an expectation that it can treat even an extracapsular invaded prostate cancer with more escalated biological dose, using a precise dose distribution and extreme hypofractionation.

- HDR-BT had been performed only in a combination with external beam radiotherapy (EBRT) until our previously reported initial and unique experience of HDR-BT as monotherapy (*Int J Radiat Oncol Biol Phys, 2000*).

- The purpose of the current report is to evaluate the feasibility, toxicity and efficacy of monotherapeutic HDR-BT for prostate cancer, with more patient accrual and longer follow-up.

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Materials/Methods:

- From May 1995 through December 2009,
- 163 patients with prostate cancer without nodal or distant metastasis were treated with HDR-BT alone, without EBRT, at Osaka University Hospital, Japan.

- Median age was 68 (range 45-81),
- T1:T2:T3:T4 = 42:55:58:8,
- Median Gleason Score 7 (range 2-10),
- Median pretreatment PSA level 15 ng/ml (range 3.8-337).

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Materials/Methods:

- 15 patients were considered low-risk,
- 57 intermediate-risk,
- 91 high-risk.
- Twice daily irradiation with more than 6-hour intervals was adopted, with the total dose of:
- 48 Gy/8 fractions/5 days,
- 54 Gy/9 fractions/5 days, or
- 45.5 Gy/7 fractions/4 days.
- Of the 163 patients, 124 also received neoadjuvant and/or adjuvant hormonal therapy.
- Median follow-up time was 54 months.

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Results:

- All the patients completed the treatment regimen.
- No significant intra- or peri-operative complications occurred.
- Acute toxicities of Grade 3, 2, and 1 occurred in 6, 24, and 60 patients, respectively.
- Late toxicities of Grade 3, 2, and 1 occurred in 4, 14, and 32 patients, respectively.
- Acute and late toxicity of Grade 4 or more did not occur.

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Results:

- The 5-year
  - PSA failure-free - 83%,
  - disease-free survival - 87%,
  - overall survival rate – 96%.

- The 5-year PSA failure-free rate
- - low - 91%,
- - intermediate - 93%,
- - high-risk patients – 77%.

Monotherapeutic High-Dose-Rate Brachytherapy for Prostate Cancer: 15 years Experience of Osaka University

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Conclusions:

- Monotherapeutic HDR-BT associated with hormonal therapy was feasible and its toxicity was acceptable.
- Short-term tumor control was promising, even for patients with locally advanced disease.
- The presented extreme hypofractionation regimens of 45.5-54 Gy in 7-9 fractions of 6-6.5 Gy might be referred to by other terms, such as stereotactic body radiotherapy.
- Studies with longer follow-up periods and from multiple institutions are needed to confirm the efficacy of this novel approach.

Partial Volume High-dose-rate Brachytherapy Boost for Localized Prostate Cancer: Toxicity and Outcome

U. Schick[1], Y. Popowski[1], P. Nouet[1], C. Ares[2], G. Dipasquale[1], S. Bieri[3], M. Rouzaud[1], H. Khan[4], D. C. Weber[1], R. Miralbell[1], *[1]University hospital of Geneva, Geneva, Switzerland, [2]Paul Scherrer Institute, Villigen, Switzerland, [3]Hospital of Sion, Sion, Switzerland, [4]Institut Jean Violette, Geneva, Switzerland*

Purpose:

- Approximately one in five men with prostate cancer have unilateral tumors amenable to hemi-irradiation or hemi-ablation.
- We aimed to evaluate the feasibility, toxicity and outcome of a brachytherapy (BT) boost to a single lobe of the prostate for patients with unilateral cancers.

Partial Volume High-dose-rate Brachytherapy Boost for Localized Prostate Cancer: Toxicity and Outcome

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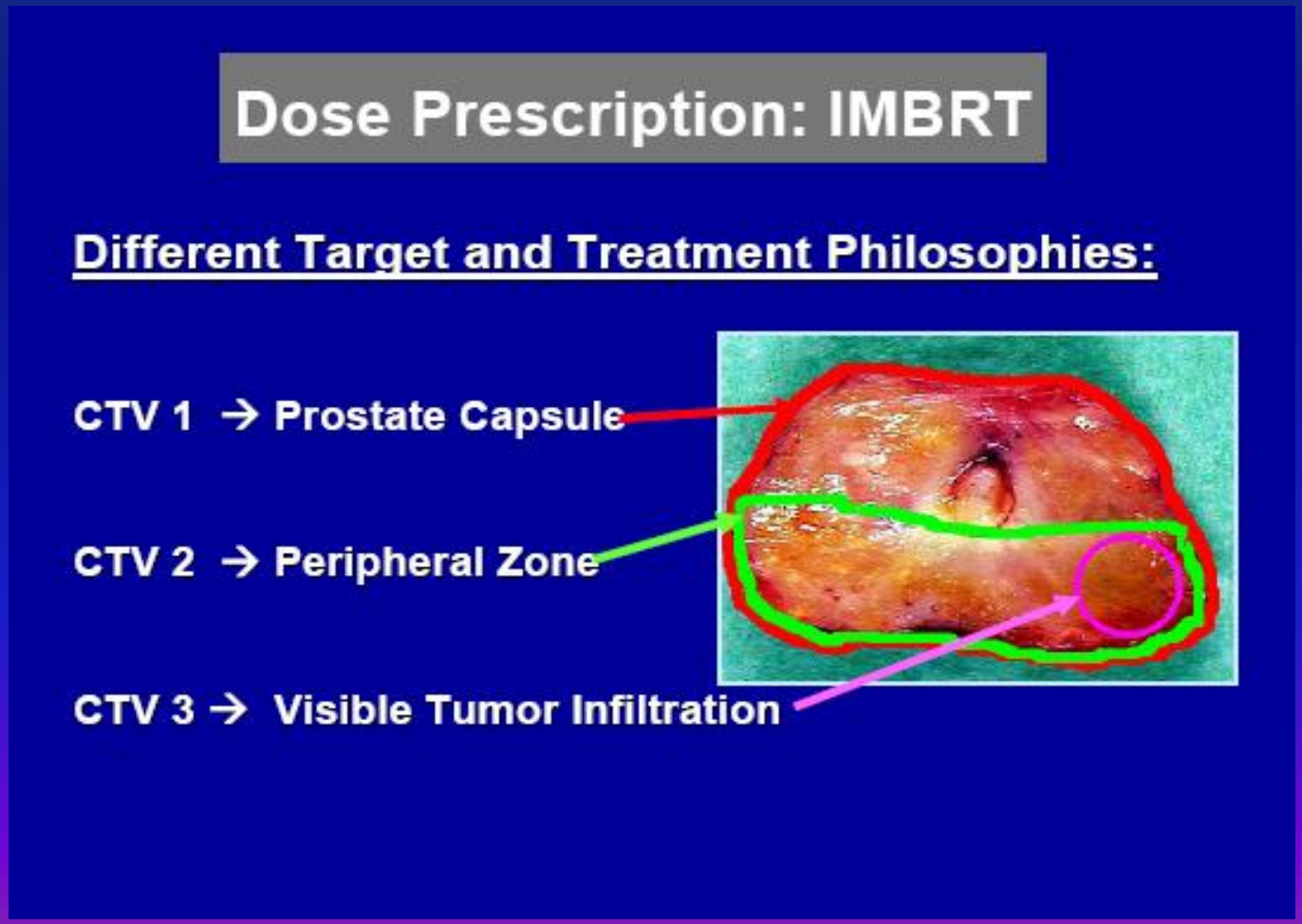

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Methods and Materials:

- 77 patients with locally advanced prostate cancer were treated in Geneva from 2000 to 2004
- with a protocol including a high-dose rate (HDR) BT boost using open MRI-guided 192 Ir implants after conventional fractionated 3D-conformal external radiotherapy to 64-64.4 Gy,
- with or without androgen deprivation.
- 20 (26%) of these patients presented with unilateral tumours (based on endorectal MRI with T2 weighted images, on rectal examination, and on unilateral positive biopsies only) and were boosted to a partial volume.
- A dose of 12, 14 and 16 Gy in 2 fractions was delivered to 5, 6, and 9 patients, respectively.

Partial Volume High-dose-rate Brachytherapy Boost for Localized Prostate Cancer: Toxicity and Outcome

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Results:

- Median follow-up of 68 months (range 4-109),
- 5-year biochemical relapse-free survival was 79.7% vs 70.5% for the unilateral and bilateral boost groups, respectively (p= 0.99).
- There was no significant difference in late grade ≥ 2 rectal toxicity between the two groups (5-year grade ≥ 2 rectal toxicity free survival of 84.4 vs 90.6 % for unilateral and bilateral irradiation, respectively, p=0.72).
- Surprisingly, late grade ≥ 2 urinary toxicity-free survival was significantly worse in the partial volume boost group (5-year risk-free survival of 70 vs 86%, p=0.03).

Partial Volume High-dose-rate Brachytherapy Boost for Localized Prostate Cancer: Toxicity and Outcome

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- However, grade ≥ 3 urinary toxicity at 5 years was similar in the unilateral and bilateral boost groups (i.e., 10% vs 8.7%, respectively), and no patients in the unilateral boost group developed grade 4 late toxicity, while 5 (9%) patients in the bilateral group did.
- Urinary toxicity was not correlated with dose-volume parameters for the urethra.

Partial Volume High-dose-rate Brachytherapy Boost for Localized Prostate Cancer: Toxicity and Outcome

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Conclusions:

- **Partial volume HDR-BT boost to a unilateral lobe of the prostate is feasible with biochemical control similar to patients undergoing a boost to the whole prostatic gland.**

- **While grade ≥ 2 rectal and grade 2-3 urinary toxicity were similar with a unilateral and bilateral boost, unilateral treatment significantly reduced grade 4 urinary toxicity.**

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

Purpose/Objectives:

- To explore dosimetric advantages of using beta-emitter P-32 in permanent prostate brachytherapy with current treatment planning platform and implantation techniques.

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

Materials /Methods:

- P-32 - beta emitter - 14.3 day half-life - maximum beta energy of 1.71 MeV - average energy of 0.695 MeV.
- The mean range of P-32 beta particles in water is about 0.3 cm, and the maximum range is approximately 0.8 cm.
- As such, the dosimetric parameters, such as radial dose function, dose rate and anisotropy function will be heavily dependent on seed internal design.
- As a first approximation, isotropic point source is used in this study.
- The geometry factor is simplified to inverse square function.
- Monte Carlo calculated radial dose function for point source is implemented in a commercially available treatment planning system, with reference point at a radial distance of 0.2 cm.

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

- Dose calculations are performed using AAPM TG-43 point source formalism.
- Initial dose rate 10 cGy/hr at reference point is used for calculation throughout the study.
- 10 seed implants cases are utilized for this study.
- The TRUS images are obtained intra-operatively using B&K ultrasound unit with a standard template in 5 mm steps.
- The prescription dose is 100 Gy for numerical simplicity.
- The prostate volume ranges from 20 to 50 cc with a mean of 36 cc.
- Dose coverage (V_{100}, D_{90}) and inhomogeneity (V_{200}, V_{500}) in target are evaluated. D_{90} and D_{10} for urethra, D_5 for rectum is also presented.

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

Results:

- On average, dose coverage for prostate, V_{100} and D_{90} are 95.4% and 167.7 Gy respectively.
- Target dose inhomogeneity, V_{200} and V_{500} are 87.2% and 63.0%. D_{90} and D_{10} for urethra are 21.8 Gy and 137.3 Gy respectively.
- D_5 for rectum is essentially zero.

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

Conclusion:

- From the preliminary results, 95% or higher target dose coverage is achievable with D_{90} about 70% higher than prescription dose.
- Due to the fact that almost all energy emitted by P-32 will be absorbed inside the prostate, the dose to surrounding healthy tissue/organs, such as bladder, rectum, and penile bulb will be very close to zero.
- Urethra dose can be significantly lower as well.
- The dose inhomogeneity in prostate increases drastically; more than half of the prostate receives 5 times of the prescription dose.
- This dosimetric feature is desired dose escalation in cancerous target and can be advantageous for achieving favorable biochemical outcomes.

Potential Dosimetric Advantages using Beta-emitter P-32 in Permanent Prostate Brachytherapy-Preliminary Study

T. Li, B. Fountain, E. Duffy, *Tuomey Cancer Center, Sumter, SC*

- **While lacking technical details for actual P-32 seeds, the physical properties of this nuclide shows promising improvements over photon-based seed implants.**
- **Certainly, radiobiology aspect of this new modality, refinements in treatment planning and implanting techniques, along with other issues, such as post-implant evaluation, warrant further investigation.**

Interstitial High Dose Rate (HDR) Brachytherapy + IMRT vs. HDR Monotherapy : Median 8 Year Follow-Up in 421 Patients

D. White[1], R. J. Mark[1,2], P. J. Anderson[1], R. S. Akins[1], M. Nair[1], *[1]Joe Arrington Cancer Center, Lubbock, TX, [2]Texas Tech University, Lubbock, TX*

Purpose/Objective(s):

- **The role of supplemental External Beam Radiation Therapy (EBRT) in brachytherapy is controversial.**
- **We compare our results of**

HDR + IMRT vs. HDR monotherapy.

Interstitial High Dose Rate (HDR) Brachytherapy + IMRT vs. HDR Monotherapy : Median 8 Year Follow-Up in 421 Patients

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Materials/Methods:

- Between 1997 and 2010,
- 421 patients with T1 and T2 localized prostate underwent TRUS guided interstitial implant.
- There were no Gleason Score or PSA exclusions.
- After discussion of treatment options:
  - 109 patients elected HDR Implant + IMRT
  - 312 patients underwent HDR monotherapy.
- No patient received Hormonal Blockade.

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Materials/Methods:

- Median Gleason Score was 7 (range : 4 to 10).
- Median PSA was 9.8 (0.60 to 39.8).
- IMRT treatment volume included the prostate + seminal vesicles + 2 cm margin.
- Implant treatment volumes ranged from 32 cm^3 to 196 cm^3.
- In patients who received IMRT + HDR, 4500 cGy in 25 fractions was given via IMRT and 1650 cGy to 2000 cGy in 3 fractions via HDR.

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- **Our protocol for HDR alone, has called for two HDR Implants.**

- **The treatment volume received 2,250 cGy in 3 fractions prescribed to the 100% Isodose line, given over 24 hours.**
- **A 2nd implant was performed 4 weeks later, delivering a further 2,250 cGy in 3 fractions, bringing the final dose to the prostate to 4,500 cGy in 6 fractions.**

- **Urethral dose points (12-16) were followed, and limited to ≤ 105% of the prescription dose.**

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Results:

- There was no significant difference between the treatment groups with respect to T-Stage, Gleason Score, and PSA.
- With a median follow-up of 98 months (range : 6 months to 168 months), the overall PSA disease free survival was 88.1% (371/421).
- In patients undergoing IMRT + HDR Implant, PSA disease free survival was 87.2% (95/109) vs. 88.5% (276/312) for patients undergoing HDR alone (p=0.73).
- The 8 year actuarial survival was 82% for the group receiving IMRT + HDR vs. 84% with HDR monotherapy (log rank = 0.5).
- Urethral stricture requiring dilatation has developed in 5.0% (21/421) of patients.
- Urinary stress incontinence has occurred in 2.9% (12/421).

Interstitial High Dose Rate (HDR) Brachytherapy + IMRT vs. HDR Monotherapy : Median 8 Year Follow-Up in 421 Patients

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- RTOG late bladder toxicities were:
  - 0% Grade 4,
  - 0% Grade 3,
  - 2.9% (12/421) Grade 2.
- RTOG late rectal toxicities were:
  - 0.2% (1/421) Grade 4,
  - 0% Grade 3,
  - 2.6% (11/421) Grade 2,
  - 3.1% (13/421) Grade 1.
- RTOG rectal toxicity was higher in patients undergoing HDR + IMRT with 15.6% (17/109) of patients experiencing Grade 2 and 1 symptoms, vs. 2.2% (7/312) receiving HDR alone ($p < 0.0001$).

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Conclusions:

- With median 8 year follow-up, we have observed no significant difference in PSA disease free survival in patients undergoing HDR monotherapy vs. HDR + IMRT.
- Complications were similar, though RTOG Grade 1 and 2 late toxicity was higher in patients receiving HDR + IMRT.
- By omitting EBRT, rectal complications may be reduced.

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

B. Guix, J. Bartrina, J. Tello, J. Solé, L. Quinzaños, T. Lacorte, J. Fernández, C. León, I. Guix, G. Galdón,
IMOR Foundation, Barcelona 08017, Spain

Purpose/Objective(s):

- To report early and late toxicity and preliminary biochemical outcome in 445 patients with intermediate- or high-risk clinically localized prostate cancer treated with

either HD-3D-CRT

or with LD-3D-CRT+HDR-B.

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

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IMOR Foundation, Barcelona 08017, Spain

Materials/Methods:

- Between 12/1999 and 10/2005,
- 445 patients (pts) with PSA›10,
- Gleason score›6
- and/or T2b-T3 N0 M0 prostate cancer entered the study.
- Pts were assigned to one of the two treatment groups:

  - 76 Gy HD-3D-CRT to the prostate in 38 fractions (group 1; 223 patients)

  - 46 Gy LD-3D-CRT+ 16 Gy HDR-B given in 2 fractions of 8 Gy (group 2, 222 patients).

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

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Materials/Methods:

- Both groups were well balanced taking into account patient's as well as tumors' characteristics.
- Toxicities were scored by the EORTC /RTOG morbidity grading scales.
- Special attention to local, regional or distant recurrence, survival, late effects, PSA and testosterone levels and quality of life was done.

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

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Results:

- All pts completed treatment.
- None pts included in the group 1 or 2 experienced grade 3 rectal toxicity.
- 28 pts of group 1 (12.5%) and 6 pts of group 2 (2.7%) developed grade 2 rectal toxicity (rectal bleeding or urgency).
- 15 pts in group 1 (6.7%) and 3 pts in group 2 (1.3%) developed grade 1 rectal bleeding (less than 2 times/week).
- In group 1 and 2, 81.8%and 95,9% of pts were free from rectal reactions respectively ($p<0.005$).

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

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- **19 pts in each group developed acute Grade 2 urinary symptoms (mainly dysuria), and none experienced urinary retention.**
- **No pts (0%) developed Grade 3 or 4 rectal or urinary complications.**
- **With a mean follow-up of 77 months, the 5-year actuarial PSA relapse-free survival rates for intermediate- and high-risk group 1 pts were 90 and 89 % respectively and 97 and 96 % for group 2 pts ($p<0.05$).**

Treatment Of Intermediate-or High-risk Prostate Cancer By Dose Escalation With High-dose 3d-conformal Radiotherapy (hd-3d-crt) Or Low-dose 3d-conformal Radiotherapy Plus Hdr Brachytherapy (ld-3d-crt+hdr-b): Early Results Of A Prospective Comparative Trial.

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IMOR Foundation, Barcelona 08017, Spain

Conclusions:

- High-dose 3D-EBRT +HDR brachytherapy is a safe and effective method of escalating the dose to the prostate without increasing the risk of late effects.
- Acute and late rectal and urinary complications were significantly reduced with the combined treatment, compared with what was observed with high-dose conventional, 3D-CRT.
- Intermediate-term PSA control rates tends to be better with in the HDR-boosted patients as expected by higher effective-dose.

Urinary and Sexual Morbidity in Prostate Cancer Patients Treated with Brachytherapy Alone vs. Brachytherapy Plus External Beam Radiation Therapy

I. E. Friedman, K. Forsythe, N. N. Stone, R. G. Stock, *The Mount Sinai School of Medicine, New York, NY*

Purpose/Objective(s):

- To compare urinary and sexual morbidities experienced by prostate cancer patients treated with

brachytherapy (BR)

vs.

brachytherapy + external beam radiation therapy (BR + EBRT).

Urinary and Sexual Morbidity in Prostate Cancer Patients Treated with Brachytherapy Alone vs. Brachytherapy Plus External Beam Radiation Therapy

I. E. Friedman, K. Forsythe, N. N. Stone, R. G. Stock, *The Mount Sinai School of Medicine, New York, NY*

Methods/Materials:

- From 1993-2007,
- 1,338 patients (group 1) with localized prostate cancer were treated with BR (either I-125 with D90=160 Gy, or Pd-103 with D90=124 Gy) +/- hormonal therapy (HR),
- 704 patients (group 2) were treated with BR (Pd-103 with D90=100 Gy) and EBRT (45 Gy) +/- HR.
- All data was prospectively collected.
- Urinary symptoms were graded using the International Prostate Symptom Score (IPSS) questionnaire (0-7 = mild, 8-19 = moderate, 20-25 = severe);

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- erectile dysfunction (ED) was measured using the Sexual Health Inventory for Men (SHIM) questionnaire (22-25 = no ED, 17-21 = mild ED, 12-16 = mild to moderate ED, 8-11 = moderate ED, and 1-7 = severe);
- ED was also graded by the physician-assessed Mount Sinai Erectile Function (MSEF) score (0 = no erectile function, 1 = erections insufficient for intercourse, 2 = erections sufficient for intercourse but suboptimal, and 3 = optimal erections).

- Multivariate analysis was also performed to take into account HR and total dose delivered (measured in BED).

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Results:

- Mean IPSS scores for group 1 at 1 yr, 2 yr, 5 yr, and 7 yr follow-up, were 10.2, 9.4, 7.4, and 7.5, respectively.
- In comparison, mean IPSS scores for group 2 at 1 yr, 2 yr, 5 yr, and 7 yr follow-up, were 10.2, 9.6, 8.5, and 8.3, respectively.
- For groups 1 and 2, average changes in SHIM scores were, respectively, -4.0 and -6.6 at 1yr (p =2, post-treatment scores =<1 were noted, respectively, in 26% and 56% of patients at 1yr; 27% and 47% at 2yr; 35% and 60% at 5yr; and 42% and 64% at 7yr (p < .001 for all years).

Urinary and Sexual Morbidity in Prostate Cancer Patients Treated with Brachytherapy Alone vs. Brachytherapy Plus External Beam Radiation Therapy

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- Multivariable analyses identified both treatment group and HR as significant causes of decreases in MSEF at year 1 ($p < 0.001$ and $p = .001$, respectively),
- but at year 2, only the treatment group was significant and HR was not ($p = .005$ and $p = .191$, respectively);
- at year 5, treatment group remained significant and HR was not ($p = .016$ and $p = .507$, respectively).

- Total dose delivered did not independently predict a decrease in MSEF.

Urinary and Sexual Morbidity in Prostate Cancer Patients Treated with Brachytherapy Alone vs. Brachytherapy Plus External Beam Radiation Therapy

I. E. Friedman, K. Forsythe, N. N. Stone, R. G. Stock, *The Mount Sinai School of Medicine, New York, NY*

Conclusions:

- Patients receiving BR + EBRT are more likely to experience erectile dysfunction than patients receiving BR alone;
- HR was also noted to independently predict decreases in ED in the first year after treatment, but was no longer significant after 2 yr follow up.
- No difference in urinary symptoms were observed.

Nonrandomized Comparison of Multicatheter Accelerated Partial Breast Irradiation Versus Whole Breast Radiation Therapy for Breast Conservation: Five Year Outcomes

D. J. Ferraro, I. Zoberi, *Washington University, St. Louis, MO*

Purpose/Objective(s):

- Adjuvant radiation therapy has been shown to increase local control when delivered as a part of breast conservation surgery for *carcinoma in situ* and early stage invasive breast cancer.
- In an effort to expedite radiation therapy and make it more appealing and accessible to women, accelerated partial breast techniques have been developed.
- We review our experience with partial breast irradiation via a multi-catheter interstitial brachytherapy technique versus a concurrent cohort of patients treated with whole breast radiation therapy by a single radiation oncologist.

Nonrandomized Comparison of Multicatheter Accelerated Partial Breast Irradiation Versus Whole Breast Radiation Therapy for Breast Conservation: Five Year Outcomes

D. J. Ferraro, I. Zoberi, *Washington University, St. Louis, MO*

Materials/Methods:

- 2003-2007,
- Selection criteria: patients > 40 years of age at diagnosis,
- Tis-T2 disease, N0, negative surgical margins,
- who underwent BCS followed by adjuvant radiation therapy,
- Patients who received multi-catheter interstitial brachytherapy (MC) are compared to a cohort of patients with the same selection criteria who received external beam irradiation (EB) to the whole breast.

Nonrandomized Comparison of Multicatheter Accelerated Partial Breast Irradiation Versus Whole Breast Radiation Therapy for Breast Conservation: Five Year Outcomes

D. J. Ferraro, I. Zoberi, *Washington University, St. Louis, MO*

Results:

- 192 patients - MC cohort,
- 188 patients - EB cohort.
- The median age for the patients at diagnosis was 61.9 years with a range of 43.6-84.3 years in the MC group and 59.1 years with a range of 43.4-84.7 years in the EB group.
- Median follow-up for the MC cohort was 55 months with a range of 3-86 months and the median follow-up for the EB cohort was 57 months with a range of 4-98 months.
- In the EB cohort, tumor stage breaks down as follows: 27% Tis, 2% Tmic, 9% T1a, 21% T1b, 31%T1c, and 16% T2.
- In the MC cohort, tumor stage breaks down as follows: 19% Tis, 2% Tmic, 11% T1a, 35% T1b, 26%T1c, 7% T2.

Nonrandomized Comparison of Multicatheter Accelerated Partial Breast Irradiation Versus Whole Breast Radiation Therapy for Breast Conservation: Five Year Outcomes

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- Invasive breast cancer subtyping was based on estrogen and progesterone receptor status as well as expression levels of human epidermal growth factor Receptor 2 (HER2/Neu).
- The breast cancer type for the two groups were as follows: -
  - 79% (MC) and 46% (EB) luminal A/B;
  - 9% (MC) and 8% (EB) Her2;
  - 9% (MC) and 15% (EB) basal type.
- Overall survival - 92% - MC cohort with 4 local failures.
- Overall survival – 94% - EB cohort with 7 local failures (nonsignificant).

Nonrandomized Comparison of Multicatheter Accelerated Partial Breast Irradiation Versus Whole Breast Radiation Therapy for Breast Conservation: Five Year Outcomes

D. J. Ferraro, I. Zoberi, *Washington University, St. Louis, MO*

Conclusions:

- Our results suggest that accelerated partial breast irradiation via a multi-catheter technique provides similar local failure rates compared to standard whole breast irradiation at 5-years for selected patients.

- Excellent results with nearly five years of follow up were seen despite the high fraction of younger patients and patients with DCIS.

Interstitial High Dose Rate Brachytherapy for Early Stage Breast Cancer : Median 6 Year Follow-up of 268 Cases Using Multi-Catheter Technique

P. J. Anderson[1], R. J. Mark[1,2], R. S. Akins[1], M. Nair[1], *[1]Joe Arrington Cancer Center, Lubbock, TX, [2]Texas Tech University, Lubbock, TX*

Purpose/Objective(s):

- **External Beam Radiation Therapy (EBRT) has been the standard of care for breast conservation radiation therapy.**
- **Recent data indicates that Interstitial Implant and High Dose Rate (HDR) radiation afterloading compares very favorably to EBRT in selected patients.**

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Materials/Methods:

- Patients with Tis, T1, and T2 tumors measuring ≤ 4 cm, negative surgical margins, and ≤ 3 axillary lymph nodes were judged to be candidates for Interstitial Implant.
- Implants were performed under Stereotactic Mammographic guidance with conscious sedation and local anesthesia.
- The implants were placed with a custom designed template using from 3 to 8 planes, and 8 to 74 needles.
- Catheters were subsequently threaded thru the needles, and the needles removed.
- Catheter spacing was 1.0 to 1.5 cm.

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- **Radiation Treatment planning was performed using CT Scanning and the Plato System.**
- **Treatment volumes ranged from 25 cm^3 to 359 cm^3.**
- **HDR treatment was given using the Nucletron afterloading system.**
- **The breast implant volume received 3400 cGy in 10 fractions prescribed to the Planning Target Volume, given over 5 days.**

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Results:

- Between 2000 and 2010.
- 268 patients underwent Interstitial HDR Implant.
- The procedure was well tolerated. No patient required hospital admission.
- Median follow-up 72 months (range 6-128 months),
- Local recurrence occurred in 3.7% (10/268).
- Cosmetic results were good to excellent in 89.5% (240/268) of the patients.
- There were no infections.
- Wound healing complications developed in 3.0% (8/268).

Interstitial High Dose Rate Brachytherapy for Early Stage Breast Cancer : Median 6 Year Follow-up of 268 Cases Using Multi-Catheter Technique

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Results:

- **Three** of these patients had received anthracycline based Chemotherapy.
- The other **five** had large (> 200 cm^3) implant volumes, catheter spacing of 1.5 cm, and V-150% of > 30%.
- **Two** patients healed after 6 months of conservative treatment.
- Surgery was required in **six** patients who developed fat necrosis.

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Conclusions:

- With median 72 month follow-up, Breast Conservation radiation therapy utilizing Interstitial Multi-Catheter HDR Implant has yielded local recurrence rates and cosmetic results which compare favorably to EBRT in selected patients.
- Treatment with anthracycline based Chemotherapy, large (> 200 cm^3) implant volumes, and V-150% > 30%, appear to be relative contraindications to Interstitial HDR Implant.
- Finally, catheter spacing of 1 cm yielded optimal dosimetry and minimized complications.

Interstitial High Dose Rate Brachytherapy for Early Stage Breast Cancer : Median 6 Year Follow-up of 268 Cases Using Multi-Catheter Technique

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- **Compared to Mammosite and Contura techniques, the Interstitial Multi-Catheter method offers greater flexibility of radiation delivery.**

Advantages include:

no concern regarding surgical cavity shape irregularities, balloon conformality to surgical cavity, balloon rupture, balloon movement, air gaps, hematoma, seroma, skin balloon proximity to skin, balloon shape distortion, and catheter movement within the balloon.

Interstitial High Dose Rate (HDR) Brachytherapy for Breast Cancer in Women ≤ 50 Years of Age Compared to > 50 Years of Age : A Report of 264 Cases Using Multi-Catheter Technique

S. Haro[1], R. J. Mark[1,2], P. J. Anderson[1], R. S. Akins[1], M. Nair[1], *[1]Joe Arrington Cancer Center, Lubbock, TX, [2]Texas Tech University, Lubbock, TX*

Purpose/Objective(s):

- The American College of Radiology does not have an age limit for breast conservation candidacy.
- Recent data indicates that Interstitial Implant and High Dose Rate (HDR) radiation afterloading compares very favorably to EBRT in early stage breast cancer.
  - There is controversy regarding the use of HDR in patients ≤ 50 years of age.
- We present our data in patients ≤ 50 years of age compared to > 50 years of age.

Interstitial High Dose Rate (HDR) Brachytherapy for Breast Cancer in Women ≤ 50 Years of Age Compared to > 50 Years of Age : A Report of 264 Cases Using Multi-Catheter Technique

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Materials/Methods:

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- Implants were performed under Stereotactic Mammographic guidance with conscious sedation and local anesthesia.
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- The breast implant volume received 3400 cGy in 10 fractions prescribed to the Planning Target Volume, given BID over 5 days.

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Results:

- Between 2000 and 2010,
- 268 patients underwent Interstitial HDR Implant.
- The procedure was well tolerated. No patient required hospital admission.
- With a median follow-up 72 months (range 6-128 months), local recurrence (LR) occurred in 3.7% (10/268).
- Cosmetic results were good to excellent in 89.5% (240/268) of the patients.
- LR occurred in 6.3% (2/32) of patients ≤ 50 years of age vs. 3.4% (8/236) in patients > 50 years of age (p = 0.34).

Interstitial High Dose Rate (HDR) Brachytherapy for Breast Cancer in Women ≤ 50 Years of Age Compared to > 50 Years of Age : A Report of 264 Cases Using Multi-Catheter Technique

S. Haro[1], R. J. Mark[1,2], P. J. Anderson[1], R. S. Akins[1], M. Nair[1], *[1]Joe Arrington Cancer Center, Lubbock, TX, [2]Texas Tech University, Lubbock, TX*

- There were no infections.
- Wound healing complications developed in 3.0% (8/268).
- Three of these patients had received anthracycline based Chemotherapy.
- The other five had large (> 200 cm^3) implant volumes, catheter spacing of 1.5 cm, and V-150% of > 30%.
- Two patients healed after 6 months of conservative treatment.
- Surgery was required in six patients who developed fat necrosis.

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Conclusions:

- With median 72 month follow-up, Breast Conservation radiation therapy utilizing Interstitial Multi-Catheter HDR Implant has yielded local recurrence rates and cosmetic results which compare favorably to EBRT in selected patients.
- There was no statistically significant difference in LR between patients < 50 years of age vs. > 50 years of age.
- While there was a trend towards higher LR in patients ≤ 50 years, LR appears comparable to patients treated with EBRT.
- Therefore, we believe that age < 50 years should not be a contraindication for HDR for breast conservation.

Functional and Quality of life Assessment in Rectal Cancer Patients Treated with Pre-operative Endorectal Brachytherapy and Sphincter Preserving Surgery

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Purpose/Objective(s):

- Preoperative endorectal brachytherapy (PEB) was shown to improve local control in patients with locally advanced rectal cancer treated with total mesorectal excision (TME).

- Treatment with low anterior resection offers patients the advantage of preserving anal continence; however studies have shown that up to one third of these patients develop fecal incontinence (FI).

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The aim of this study

is to assess the extent of FI,

functional morbidity,

and the quality of life (QOL)

in rectal cancer patients treated with PEB

followed by sphincter preserving surgery (SPS).

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Methods:

- Quality of life and late morbidity were assessed using the QOL questionnaire adapted from the Dutch rectal cancer trial (DRCT).
- This questionnaire evaluated bowel, sphincter and urinary function, in addition to assessing overall patient satisfaction.
- All evaluated patients were stoma free and had an intact anal sphincter following treatment with PEB and SPS.
- PEB consisted of 26 Gy in 4 fractions delivered over 4 consecutive days; surgery followed 6-8 weeks later.
- Patients completed the questionnaires upon routine follow up; the analyzed data was collected at varying follow-up times for each patient.

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Results:

- **63 patients (39 males, 24 females) with rectal adenocarcinoma (Stage T2-T4) were assessed.**
- **The median age at diagnosis was 61 years (range 44 - 91).**
- **The majority of patients (56%) had lesions located within the middle third of the rectum, 39% were in the lower third and 5% in the upper third.**

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Results:

- After a median follow up of 28 months (range 3 - 116) between surgery and time of questionnaire,

  - 44% of patients retained normal sphincter function and remained free of day FI,

  - 37% developed day FI once a week or less,

  - 16% had it more than once a week

  - and only 3% experienced severe FI everyday.

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- **The odds ratio for the development of severe FI was 2.67 (0.52; 13.79) in patients with lesions located in the lower third of the rectum relative to patients with higher lesions.**
- **Pad wearing for FI was reported by 46% of patients, of which only half required a pad at all times.**
- **Only 12 patients (19%) reported urinary incontinence (UI) following treatment.**
- **Patients reported an average overall functional satisfaction score of 80%, on a 0 to 100 scale.**

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Conclusions:

- **Our results show that the rates of severe FI (3%) and UI (19%) are low in rectal cancer patients treated with PEB and SPS, and compare favourably with the previously reported results of the DRCT for patients treated with short course pre-operative RT followed by TME (severe FI 14% and UI 39%).**
- **Accrual of more patients, longer follow up and direct comparison to a second set of patients treated with pre-operative external beam radiation will be evaluated to further assess the outcome in patients treated with PEB.**

Twenty-year Experience In The Management Of Anal Carcinoma With Interstitial Brachytherapy

J. L. Lopez Guerra[1], A. J. Lozano[2], J. Pera[3], C. Gutiérrez[3], M. Cambray[3], F. Ferrer[3], M. J. Ortiz[1], F. Guedea[3], *[1]Hospitales Universitarios Virgen del Rocío, Sevilla, Spain, [2]Hospital Universitario Son Dureta, Mallorca, Spain, [3]Institut Català d Oncologia, Barcelona, Spain*

Purpose/Objetive(s):

- The management of anal cancer has undergone an interesting transformation over the last three decades.
- The idea of organ preservation emerged following the discovery of a high complete response rate from preoperative combined chemoradiation prior to abdominal-perineal resection.
- Radiotherapy, with concomitant chemotherapy for advanced tumours, is now the standard first-line treatment for anal carcinoma.

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- The **combination of external beam radiotherapy with interstitial brachytherapy** increases the dose to the tumour volume and limits the volume of irradiated normal tissue, thereby **decreasing late toxicity**.
- We present an analysis of a series of patients treated with iridium 192 **low-dose rate (LDR) or pulsed-dose rate (PDR)** interstitial brachytherapy for anal carcinoma.

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Materials/Methods:

- From 1989 to 2009,
- 38 patients with anal carcinoma were treated with brachytherapy at the Catalan Institute of Oncology in Spain, in 26 cases with LDR and in 12 cases with PDR.

- The median age was 62 years (range,38-86),
- with a male/female sex ratio of 20/18.

- The TNM classification was as follows:
  - 10 T1, 22 T2, 5 T3 and 1 T4;
  - 32 N0, 3 N1 and 3 N2.

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Materials/Methods:

- **Treatment started with:**
  - concomitant chemoradiotherapy in 22 patients
  - radiotherapy alone in 10 patients.

- **The mean dose of external beam irradiation given to the posterior pelvis was 45 Gy (range, 32-50 Gy).**

- **The median dose for interstitial brachytherapy was 20 Gy (range 15-35) for the boost and 60-65 Gy if monotherapy.**

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Results:

- Of the 38 patients:
  - CR - 34 (89.4%),
  - PR - 2 (5.3%),
  - Progression - 2 (5.3%).
- The procedure was well tolerated.
- With a median follow-up of 30 months (range, 3.7-200.7),
  2-year overall survival - 87% (95% CI: 74-98%),
  5-year overall survival - 76% (95% CI: 59-93%), respectively.
- 2-year local progression-free survival rate - 91% (95% CI: 81-100%),
- 5-year local progression-free survival rate - 87% (95% CI: 75-99%) ,
- 10-year local progression-free survival rate - 81% (95% CI: 67-97%), respectively.

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- **12 relapses occurred (3 regional and distant, 3 distant alone, 1 regional alone, and 5 local).**
- **Two patients had chronic mucositis grade III/IV (RTOG scale).**
- **No colostomy was required for necrosis.**
- **2 patients experienced serious late toxicity grade 3/4 mucositis and only 3 patients (7.8%) had incontinence after brachytherapy.**
- **No correlation was found between the dose rate and late mucositis (P=1) or dermatitis (P=0.4).**

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Conclusions:

- **LDR and PDR appear to be an effective treatment for anal carcinoma with good local tumour control at 10 years, low rates of late toxicity and preservation of the anal sphincter.**
- **Evaluating an optimised interstitial brachytherapy technique aimed at reducing toxicity to normal tissues and/or increasing the dose to the tumour volume remains to be done.**

Dziękuję za uwagę