

URO-RADIOLOGY PROSTATE INSTITUTE

The URPI is directed by Panos G. Koutrouvelis, M.D., who has practiced radiology/radiation oncology in Northern Virginia for over 35 years and is an professor of radiation oncology at Howard University. Dr. Koutrouvelis, a fellow in the American College of Nuclear Medicine, has performed brachytherapy in over 700 patients since 1994 and has presented his method at national and international meetings of brachytherapy, urology, and radiology societies. His findings have been published in peer reviewed journals.

PATIENT INFORMATION

About Our Institute

The Uro-Radiology Prostate Institute (URPI) in the metropolitan Washington, D.C. area is a multi-specialty medical team for diagnosis and treatment of prostate cancer. Headed by Panos G. Koutrouvelis, M.D., the group includes diagnostic radiologists, radiation oncologists, urologic oncologists, medical oncologists, anesthesiologists, medical physicists, and anatomical pathologists all of whom have wide experience with the diagnosis and treatment of prostate cancer. Among the physicians associated with URPI are radiation oncologist Alfred Goldson, and urologists Stuart Katz, Fred Hendricks, Niko Lailas, Guillermo Gilmontero, Nibil Khawand, Harold Bondy, and James Sehn.

URPI's use of CT with a 3-D stereotactic system patented in the US and abroad for brachytherapy of prostate cancer advances treatment, substantially diminishing complications and medical costs. The technique is safe and accurate, without limitations posed by prostate size, shape, TURP defects, urinary obstruction, or the pubic arch.

How Prostate Cancer is Diagnosed

The patient usually will have no symptoms although he may have urinary symptoms such as:

- frequency of urination,
- difficulty in urination,
- diminished and interrupted flow, and
- blood in the urine or sperm

Not all patients with these symptoms have prostate cancer. Other benign conditions may have the same symptoms. The patient usually has a digital rectal examination by his physician or urologist and a routine blood test for prostate specific antigen (PSA).

If the rectal exam results in a suspicion for cancer and/or the PSA is elevated above 4 ng/ml or increases by 0.9 ng/ml in one year, the patient should undergo ultrasound exam and biopsy of the prostate. Biopsy should include the seminal vesicles.



Physicians at URPI deliver high quality seed implant to the diseased prostate with a safe and innovative 3-D CT-

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Who Should Be Treated for Prostate Cancer

Prostate cancer is the most common cancer in men and the second leading cause of death in men from cancer. Prostate cancer is often multicentric and multigraded and one focal carcinoma can be sufficiently aggressive to spread. Because we do not know which cancer of the prostate will be aggressive and kill the patient, most patients diagnosed with prostate cancer should be treated.

Current Treatment for Localized Prostate Cancer

The recognized treatments for localized prostate cancer currently include:

- radical prostatectomy (removal of the prostate gland)
- external radiation therapy, or
- brachytherapy (interstitial radiation therapy involving implantation of radioactive sources into the prostate gland)

Radiation Sources That Have Been Used and What They Do

The radioactive sources that have been used are Iodine¹²⁵ seeds since 1970, Gold¹⁹⁸ since 1972, Iridium¹⁹² since 1977, and Palladium¹⁰³ since 1988. The absorbed energy of these sources within the prostate gland kills the cancer cells while protecting adjacent organs such as the urinary bladder and rectum from radiation toxicity.

The Quality of the Seed Implant

- is the most important determinant of success of brachytherapy.
- is evaluated only by post implant CT imaging and dosimetry.
- is dependent on exactness of insertion and uniformity of distribution of seeds.

A Good Quality Seed Implant

- has a maximum deviation of less than 10% from the prescribed radiation dose.
- has good coverage of the treated target and has no seeds in the urethral wall, urinary bladder or rectum.

Effectiveness of Seed Implant Quality

- Significant correlation found over time between quality of implant and morbidity.
- Significant correlation found over time between quality of implant and long term clinical and biochemical success rate.

Who Should Be Treated With 3-D Stereotactic Transischioirectal CT-Guided Conformal Brachytherapy

- Patients at any age who do not want to take the risks and complications of surgical prostatectomy including incontinence and impotence
- Patients who have previously been treated without success with external radiation
- Patients with local recurrence of failed radical prostatectomy

Uro-Radiology Prostate Institute Patient Profiles (n=716)

- *Age:* Range, 34-90; Median, 68; Mean, 67
- *Volume:* Range, 13 cm³ - 180 cm³; Median, 54 cm³; Mean, 57 cm³
- *Clinical Stage:* T1a,b,c,T2a: 310 patients (43%)
T2b,T3a: 322 patients (45%)
T3b: 71 patients (10%)
- *Initial PSA:* Range, 0.9 - 143 ng/ml; Median, 7.9 ng/ml; Mean, 11.9
- *Gleason's:* ≤ 6 in 62%, ≥ 7 in 38%

PATIENT INFORMATION

Advantages of Brachytherapy Over External Radiation Therapy

- Delivery of double or more dose of radiation to the prostate to kill the cancer
- Diminished radiation toxicity to the urinary bladder and rectum adjacent to the prostate
- Treatment within one day rather than 8 weeks
- Ability to repeat the treatment in the future if needed while protecting the integrity of the rectum and urinary bladder

Advantages of Brachytherapy Over Radical Prostatectomy

- Organ preservation
- Diminished complications such as impotence and incontinence
- Treatment on an outpatient basis without major surgery or hospitalization

Advantages of 3-D Stereotactic CT-Guided Brachytherapy Over the Transperineal Approach with Transrectal Ultrasound Guidance

- The transrectal ultrasound guided technique is usually not recommended for patients with prostates over 60 cm³. The transischiorectal space approach with CT guidance and 3-D stereotaxis can be used on patients with prostatic volumes of up to 180 cm³.
- Pubic arch interference may impede needle insertion under the transperineal approach. The transischiorectal space approach completely eliminates this obstacle, with the pubic arch serving to immobilize the prostate during implant.
- Verification and correction, if needed, of needle position during the procedure is possible under the transischiorectal space approach with a specially designed template.

- The transperineal method is usually not recommended for patients with TURP defects because of risk of developing incontinence. Of 55 patients with prior TURP defects treated with the transischiorectal space approach, 2 developed incontinence requiring pads. With this approach, the risk of incontinence is avoided as the urethral sphincter and the urethra are spared.
- Obstructive urinary symptoms are not contraindicated with the transischiorectal space approach as it usually is with transperineal approach with ultrasound guidance. Patients with such symptoms have been treated successfully with our approach.
- With the transischiorectal space approach, the prostate is separated from the rectum by approximately 1 cm. This is accomplished by the forward motion of the prostate during the dorsal approach of needle insertion. As a result, the likelihood of seeds being implanted in the rectal wall is minimized.

Complications

Patients may experience treatment-related symptoms such as transient diarrhea, constipation, frequency of urination and/or burning during urination, all of which usually subside 1-3 months after the procedure. In the case of iodine¹²⁵ implants, the peak of discomfort occurs 4-8 weeks after the procedure, while that for palladium¹⁰³ occurs 2 weeks after. However in some patients the symptoms may persist for a longer duration. Two percent (2%) of our patients have complained of burning during ejaculation. One percent (1%) of patients have required a catheter for 1-2 weeks after the implant to relieve acute urinary retention. In addition, patients may experience weak stream during urination; 1.5% of patients have had urinary retention requiring TURP. One percent (1%) of patients experienced grade 3 or 4 rectal complications.

PATIENT INFORMATION

Precautions Following Brachytherapy

Although radioactivity of the seeds is absorbed by 95% in 4 cm from the source, adherence to the following safety guidelines is recommended:

- Children under the age of 18 years should not be permitted to sit on the patient’s lap and should be kept at least 6 feet from him for the first four weeks in the case of palladium¹⁰³ seeds and for 8 weeks with iodine¹²⁵ seeds.
- Pregnant women should be at least 6 feet from the patient for the first 4 weeks with palladium¹⁰³ seeds and 8 weeks with iodine¹²⁵ seeds.
- A condom must be used with intercourse for first 4 weeks after implant.
- The patient should collect his urine in the provided plastic container for the first 24 hours after implant and return it to URPI.

Tests Required To Qualify for Treatment

A recent bone scan, CT scan of the upper and lower abdomen, and medical pre-op clearance for epidural anesthesia are required. If these have not been completed, they will be done as part of the pre-treatment planning at URPI. MRI of the prostate and pelvis are performed, if needed.

Treatment Time

The procedure itself actually lasts about 2 hours. Average time for pre-treatment planning and preparation, treatment and post-treatment follow-up is 5-6 days. Appointments are recommended 4-6 weeks prior to treatment.

How Many Treatments Will Patient Require?

Usually, only one. A second seeding may be required in some cases. In contrast, patients having external radiation therapy or surgery can be treated with only one such course of treatment. Brachytherapy with the 3-D stereotactic CT-guided approach can be used after failed external radiation or surgery.

Restrictions on Foods and Drinks

No spicy foods or fats are recommended. Furthermore, the patient is instructed not to take alcohol during the first three days after treatment.

Cost of the Procedure

Total cost of the treatment varies depending on the number of seeds implanted. Most insurances require pre-authorization and will cover the total cost or a percentage. Most insurances do not deny coverage of the patient’s choice of treatment.

Location and Accommodations

URPI is located in Tyson’s Corner, Virginia in the Washington, D.C. metropolitan area, less than 20 minutes from both National and Dulles airports. Several major hotels are within minutes from URPI and range in cost from \$80-\$175 per night.

IMPLANT PROCEDURE

Physicians at URPI perform permanent prostate seed implants with iodine¹²⁵ and palladium¹⁰³ with a patented 3-D stereotactic device designed by Dr. Panos G. Koutrouvelis, the Institute's founder and director. The implant is delivered under CT guidance through the ischiorectal space, thereby minimizing bleeding. The technique at URPI verifies needle placement and allows for needle correction, if necessary. Because no needles are inserted in the midline, penetration of the constricted rectum and urethral wall is diminished.

To begin the procedure, a Foley catheter with 7 cc of air injected in its balloon is placed in the urinary bladder. The catheter remains in place throughout the procedure, allowing good visualization of the prostatic urethra on CT images and the bladder to be empty during implant. The anesthesiologist administers epidural or spinal anesthesia and performs standard monitoring during the procedure.

The patient is placed in the prone position on the CT table and a bolster pad is placed under his pelvis. Aspiration of rectal fluid, if any, is performed with a rectal catheter. The patient is prepped and draped in the usual sterile manner.

The posterior skin and gluteus maximus muscle are stretched laterally with adhesive tape to avoid deflection of the needles and to ease needle penetration. The 3-D stereotactic

system is mounted on the CT table carrying the patient and moves in and out of the gantry. Five mm tomographic cuts of the prostate are obtained with the template of the 3-D stereotactic system above the gluteal

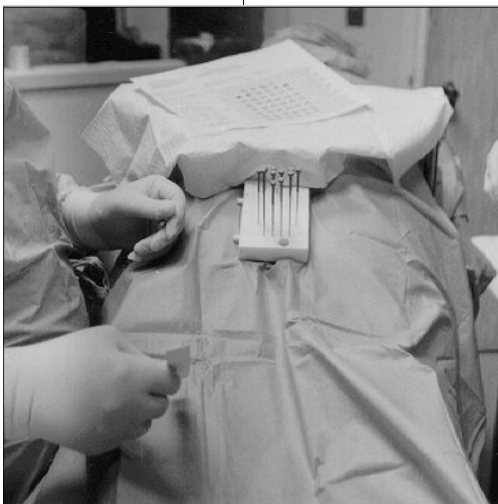


Figure 1. Patient in prone position with afterloading needles placed 10 mm apart through the template. Depth of each needle is determined by CT planning.

area (Fig. 1). The angle of the template matches the tilt of the gantry, which is usually 26°. An electronic 10-mm square grid is placed on every alternate 5mm tomographic cut to determine the depth of needle insertion

and the number of seeds. Data is posted to the treatment summary chart.

The afterloading needles are inserted through the template at a spacing of 10 mm apart throughout the prostate beginning from the apex as indicated in the summary chart. The needles are inserted nearly vertically through the ischiorectal space. No needles are inserted in the midline of

IMPLANT PROCEDURE

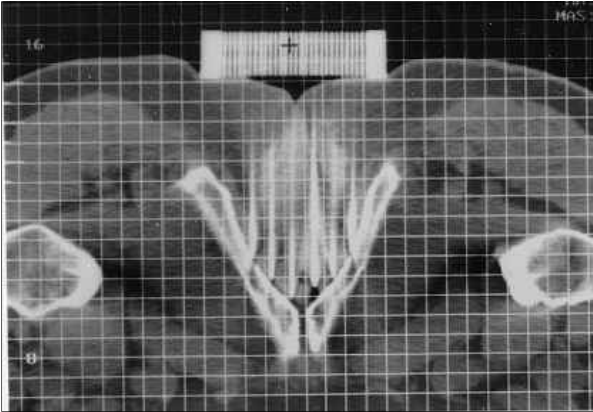


Figure 2. CT image of apex of prostate after needle insertion. The pubic arch does not interfere with needle insertion, and it serves to immobilize the apex of the prostate. Needles are spaced 10 mm apart, sparing the urethra.

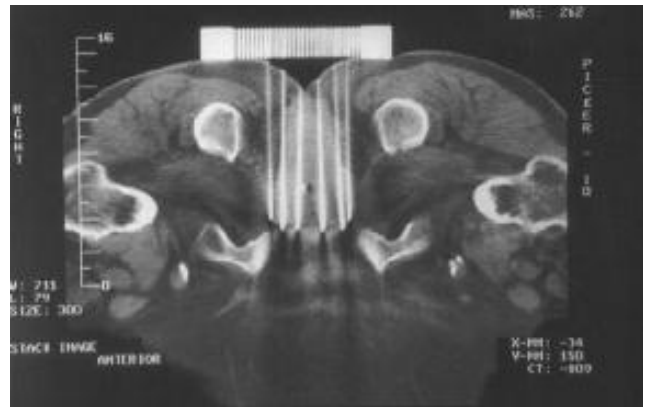


Figure 3. Transgluteal CT image of prostate verifying needle position in the mid-portion. Note the appropriate depth of each needle and 10 mm spacing into the prostate avoiding penetration of the urethra.

the prostate to minimize rectal and avoid urethral penetration (Fig 2). After insertion of all needles, CT is performed, and correction, if necessary, of needle position is done. The position of the needles is verified by repeat CT scan (Fig. 3). To account for any change in prostate geometry that may result from edema, final determination of number of seeds per needle is made.

CT images are reviewed on a monitor in the operating CT suite. With the Mick applicator, loose seeds are implanted in the prostate as calculated previously, avoiding placement in the urethral wall and membranous internal urethral sphincter. For I^{125} seeds in strand, instant loading and implant is accomplished with the post and bracket attachment to the 3-D stereotactic system.

Repeat CT immediately post implant is performed to determine the quality of seed coverage in the target area (Fig. 4). CT dosimetry is performed up to one week after implant (Figs. 5-7).

Radiation exposure readings at various distances from the patient are obtained. The catheter is removed and seeds are accounted for. Cystoscopy after the implant is not needed because no seeds are implanted into the urinary bladder, which is empty during the procedure.

Post-implant dosimetry CT images with 3-D reconstruction are taken to verify seed placement and number of seeds. Time for planning including patient preparation lasts 30 minutes to one hour, and the execution of the procedure lasts 45 minutes to one hour.

IMPLANT PROCEDURE

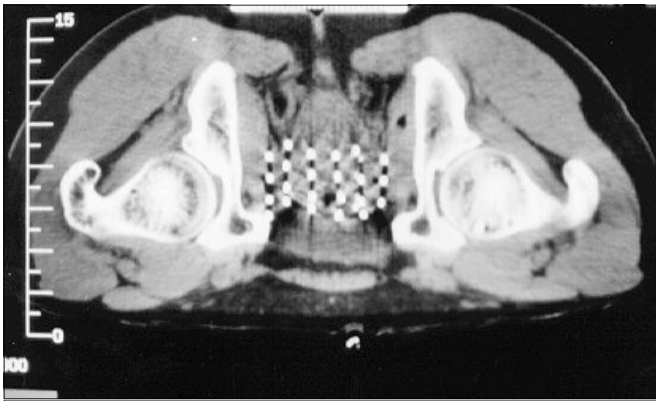


Figure 4. Post-implant CT image of seeds spaced 10 mm from center to center and implanted in the target 10 mm outside the prostate capsule. No seeds are placed in the urethral wall, rectum, or urinary bladder.

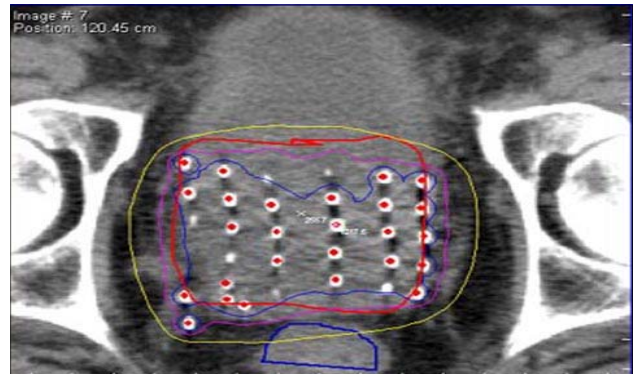


Figure 5. Post-implant CT dosimetry of large prostate with seeds in place as measured by MMS software. Prostate is outlined in red. The 100% prescribed dose is outlined in pink and 50% of the prescribed dose is outlined in yellow.

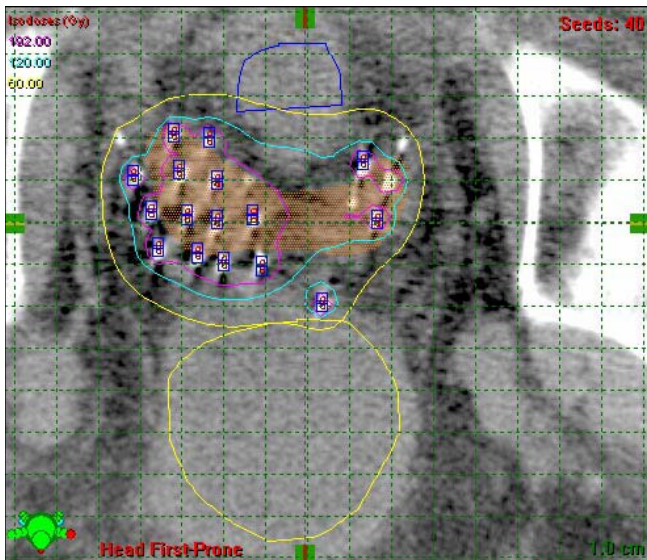


Figure 6. Post-implant CT dosimetry of seminal vesicles with iodine-125 seeds in place as measured by Varian BrachyVision. The seminal vesicles are highlighted in orange, and 100% dosage of 14,400 cGy is outlined in light blue .

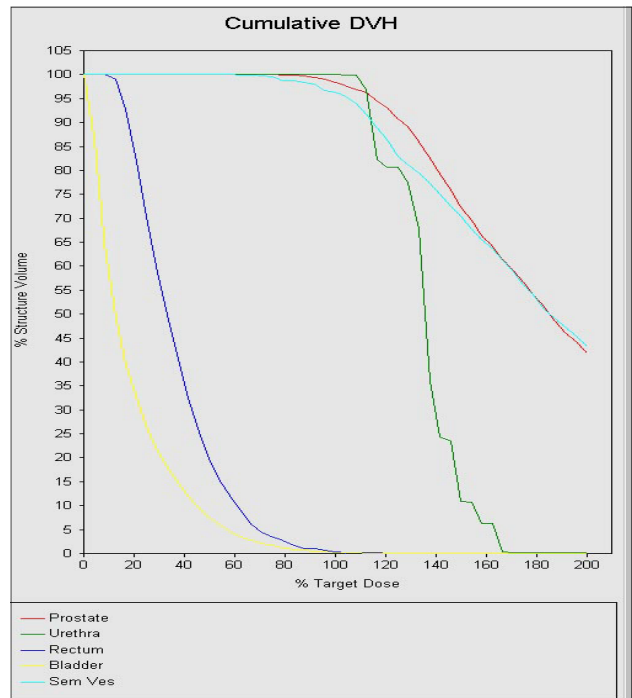


Figure 7. Dose volume histogram as calculated by MMS software. Prostate and seminal vesicles received 100% of the prescribed dose.

Patient Characteristics of High, Intermediate and Low Risk Prostate Cancer Treated with 3-D CT Brachytherapy June 1994—May 2002 n 665

Characteristics	n	%
Age: Range: 42-90, Median: 68, Mean: 67.2		
Prostate Volume < 50 cm ³	289	43%
Prostate Volume 50-59 cm ³	107	16%
Prostate Volume 60-79 cm ³	162	24%
Prostate Volume 80-100cm ³	70	11%
Prostate Volume > 100 cm ³	37	6%
Prostate Volume: Range: 14-180, Median: 53, Mean: 57.4		
PSA < 10 ng/mL	406	61%
PSA 10-20 ng/mL	177	27%
PSA > 20 ng/mL	82	12%
PSA >= 10 ng/mL	259	39%
PSA: Range: 0.71-143, Median: 8.15, Mean: 12.4		
Gleason <= 6	428	64%
Gleason = 7	181	27%
Gleason >= 8	56	9%
Prior TUR*	68	10%
HTx**	460	69%
Iodine ¹²⁵	366	55%
Palladium ¹⁰³	299	45%
Stage***		
T1a,T1b,T1c,T2a	299	45%
T2b,T3a	307	46%
T3b (biopsy-proven SV Invasion)	59	9%

*Trans-Urethral Resection (1 – 5 years prior to implant)

**Neoadjuvant androgen ablation (3 months prior to implant)

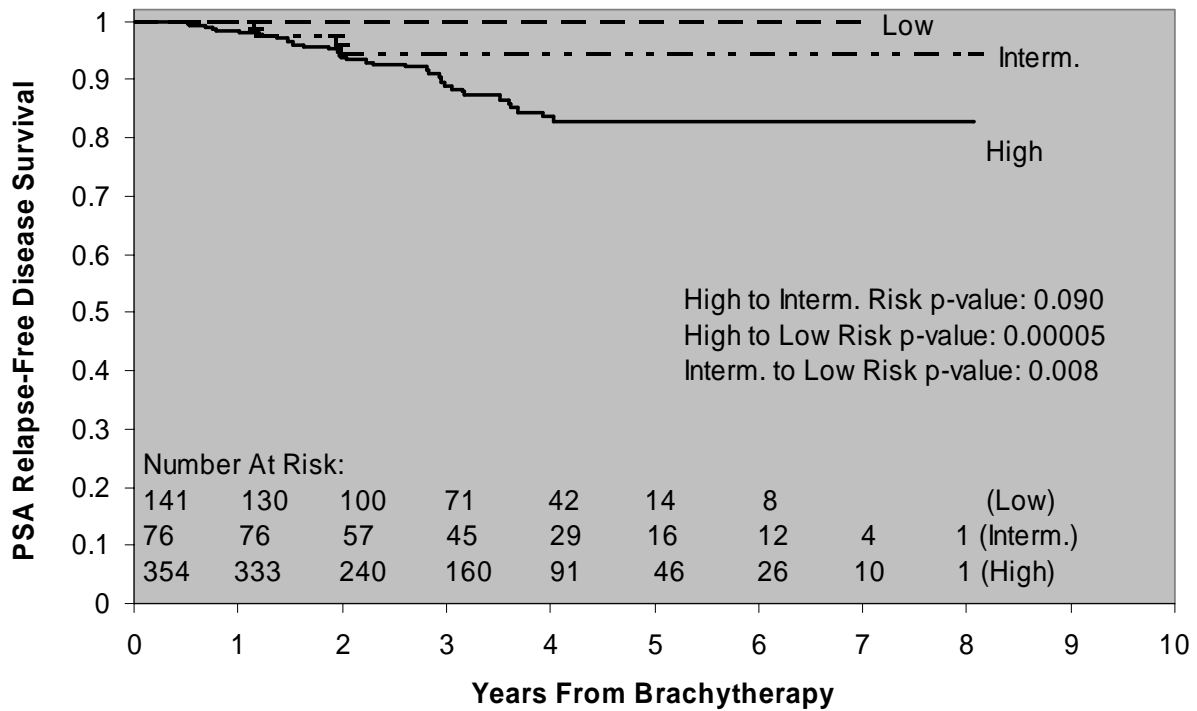
***1997 American Joint Committee on Cancer (AJCC) Tumor Stag-

Risk Profile and Biochemical Results of High, Intermediate and Low Risk Patients Treated with 3-D CT-Guided Brachytherapy 8 Years Follow-up (median 2.7 Years) n 571

Groups	Risk Factor(s)	# Patients	bNED* %
High Risk			
3 Risks			
3a	T3b, GL \geq 7, PSA 10-20 ng/mL	10	5 (50%)
3b	T3b, GL \geq 7, PSA > 20 ng/mL	18	11 (61%)
3c	T2b,3a, GL \geq 7, PSA 10-20 ng/mL	25	25 (100%)
3d	T2b,3a, GL \geq 7, PSA > 20 ng/mL	27	23 (85%)
	Subtotal	80	64 (80%)
2 Risks			
2a	T3b, GL \geq 7, PSA < 10 ng/mL	18	15 (83%)
2b	T3b, PSA 10-20 ng/mL, GL < 7	6	5 (83%)
2c	GL \geq 7, PSA 10-20 ng/mL, T1a,b,c,T2a	19	19 (100%)
2d	GL \geq 7, PSA > 20 ng/mL, T1a,b,c,T2a	2	1 (50%)
2e	T2b,3a, GL \geq 7, PSA < 10	65	60 (92%)
2f	T2b,3a, PSA 10-20 ng/mL, GL < 7	43	40 (93%)
2g	T2b,3a, PSA > 20 ng/mL, GL < 7	16	13 (81%)
	Subtotal	169	153 (91%)
1 Risk			
1a	T3b, PSA < 10 ng/mL, GL < 7	5	5 (100%)
1b	T2b,3a, PSA < 10 ng/mL, GL < 7	87	82 (94%)
1c	PSA > 20 ng/mL, GL < 7, T1a,b,c,T2a	12	11 (92%)
1d	GL > 7, PSA < 10 ng/mL, T1a,b,c,T2a	1	1 (100%)
	Subtotal	105	99 (94%)
	High Risk Total	354	316 (89%)
Intermediate Risk			
1a	GL = 7, PSA < 10 ng/mL, T1a,b,c,T2a	26	26 (100%)
1b	PSA 10-20 ng/mL, GL < 7, T1a,b,c,T2a	50	46 (92%)
	Intermediate Risk Total	76	72 (95%)
Low Risk			
	PSA < 10 ng/mL, GL < 7, T1a,b,c,T2a	141	141 (100%)
	High, Intermediate and Low Risk Total	571	529 (93%)

*Biochemical no evidence of disease

Actuarial Disease Free Survival of High, Intermediate and Low Risk Patients n 571



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Koutrouvelis PG. Stereotactic Percutaneous Lumbar Discectomy using the PGK Stereotactic Device, RSNA Scientific Exhibit, November 1991.

Koutrouvelis PG, Lang ER. Percutaneous Lumbar Discectomy using the PGK Stereotactic device, Under CT Guidance: Annual Orthopedic Convention of Spine Disorders, September 21, 1990, Greece.

Koutrouvelis PG. Fine needle aspiration biopsy of tumor masses, lungs, liver, kidneys, adrenals, etc., under CT guidance. Presented at the Cyprus Medical Convention, Limasol, Cyprus, June 1987.

Koutrouvelis PG. Non-invasive evaluation of coronary artery disease with Thallium 201 and radionuclide ventriculography. Presented at the XII World Congress of Angiology, Athens, Greece, 1980.

The URPI offers 1-3 days workshop for training physicians in 3-D CT-guided brachytherapy. For further information, please contact the URPI office at 703.356.9674 or by email at pgk@prostate-ca.com.

PATIENT FEEDBACK



As an experimental scientist and a full professor of cell biology, I can vouch for Dr. Panos Koutrouvelis's procedure both as a patient and as a careful and concerned observer for the following reasons:

- It is a minimum trauma procedure in comparison to other methods.
- It is an accurately controlled procedure in three dimensions through the careful use of 3D stereotaxis and computer tomography.
- It undoubtedly reduces high PSA values to significantly lowered levels. (My own PSA dropped from 9.4 to 0.7 within seven months of the procedure and to 0.4 within one year.)
- It is an office procedure throughout which one remains woozy but awake, and the post-anesthesia recovery is quick and without after effects. (I enjoyed my dinner the same evening.)
- It can significantly reduce the volume of greatly enlarged prostates in gentlemen of a wide range of ages up to and including the age of ninety.

Post procedure discomfort is minimized and essentially ends after 48 hours; since for example two days after the procedure I was able to take a long train ride home, sitting for 8 to 10 hours. As promised, the burning pain of urethritis, which was noticeable but not intolerable, rapidly diminished and ended within two to three months. Micturation was continuously successful. There is no trauma to the rectum, and therefore no subsequent difficulties.

I can also vouch for the effectiveness of this technical approach as a method for needle biopsy of the prostate. I have had both ultrasound-controlled needle biopsy sampling, and just recently Dr. Koutrouvelis's procedure under local anesthesia. Both involve some endurable but rapid discomfort. The accuracy of visualisation with 3D computer tomography and a dorsal approach is made easily accessible to the patient visually on a computer screen, and for someone like me with technical and computer interests, is a fascinating option in Dr. Koutrouvelis's procedure, which I enjoyed witnessing as a patient.

—*Professor Sam McGee-Russell M.A., D.Phil. (Oxon)*
Albany, New York

There must be men, just like me, scared to death by the “C” word and told by their urologists that the only options available are radical surgery or external radiation...You have pioneered this procedure and millions of other men like me will benefit from it, without all those nasty side effects like incontinence and impotency. Please give our heartfelt thanks to all of your staff.

—*Oscar T, & Barbara Ward*
Newport News, Virginia

I was diagnosed with prostate cancer with seminal vesicle invasion, Gleason's score 8 (aggressive cancer). I got pretty interested in treatment options for prostate cancer. Being a scientist by education and experience equipped me to evaluate the various methodologies out there for the treatment of prostate cancer. Almost universally doctors are using ultrasound-guidance to place needles in the transperineal area (a very sensitive area). Dr. Koutrouvelis places the needles through the backside (less sensitivity). It was clear that with CT-guidance he could more accurately place the needles. Dr. Koutrouvelis' procedure was clearly superior because he can see where the needles are placed. Accuracy of placement and minimal impact on my body— That convinced me!

—*Tom Hendrickson*
Former Undersecretary of Energy