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Prostate Brachytherapy: Establishing a Competitive Modality

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Excluding skin cancer, adenocarcinoma of the prostate has become the most common male cancer diagnosed in the United States in both the Caucasian and African-American populations.[1] An estimated 184,500 new cases will be diagnosed in 1998. Approximately 39,500 patients will die of the disease during that same period.

Fortunately, advancements in early detection methods are changing the way both physicians and the general population approach treatment of prostate cancer. Serum PSA (prostate specific antigen) and digital rectal examination, for example, have allowed large numbers of asymptomatic males to be screened in the routine office setting. Successful implementation of office screenings has resulted in a shift of detected cancers to earlier stages, i.e., organ-confined disease. As is true with many malignancies, early-stage disease is associated with lower incidence of debilitating symptoms and higher likelihood of long-term disease control. In general, such disease can be treated with a variety of approaches, offering the patient a number of choices that incorporate quality-of-life issues as well as disease-free survival.

Media attention to the various treatment options has fueled interest in the general population. The lay press has highlighted dramatic stories detailing the treatments selected by influential patients.[2] The explosion of information available on the Internet has contributed in large part to more active patient participation in treatment decisions. As a result, prostate cancer consultations have now become the most lengthy and complex consultations in both academic and community radiation oncology practices.

Prostatectomy and external beam irradiation have long been considered "standard" treatment in the therapy of prostate malignancy. Hormonal ablation, cryosurgery, hyperthermia, and observation have also been offered. However, the redefinition of disease control via PSA and the resurgence of prostate seed implants have resulted in a significant change in the approach to prostate cancer in community practices.

A community institution considering initiation of a prostate cancer program with prostate seed implantation must first explore a number of issues, including outcomes data, capital requirements, and community support for such a program.

THE MOBILE INFIRMARY EXPERIENCE

In 1996 data became available from Seattle,[3] Scottsdale,[4] New York,[5,6] Tampa,[7] and other locations suggesting that, in appropriately selected, early-stage patients, it is possible to achieve equivalent or superior results with prostate seed implantation as compared to conventional or "standard" therapies. The transperineal approach appears to carry low morbidity and high patient acceptance. At Mobile Infirmary Medical Center, physician interest was high, both at the family physician and specialist levels. Patients were requesting referral to distant facilities for second opinions regarding the use of seed implant in their particular cases.

The Mobile Infirmary Medical Center, a 702-bed, not-for-profit community hospital in Mobile, Ala., serves a primary population of 530,000 and a secondary population of 415,000. Much of the region is classified as rural. Between 1,000 and 1,200 analytic cancer cases are seen annually. In 1997, 140 patients were diagnosed with organ-confined prostate disease.

A panel of physicians, including radiation oncologists and urologists, administrators, nurses, and allied medical personnel was formed to investigate the establishment of a prostate brachytherapy program for the Mobile community. Early on, the panel determined that the physician specialists should receive the necessary training through a nationally recognized

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program offering both formal didactic and operative training. After evaluating a number of programs, the panel ultimately selected Northwest Hospital in Seattle, Wash., led by Drs. Haakon Ragde and John C. Blasko. The panel also reviewed the mechanics, equipment, and space requirements of the Seattle program.

All panel participants agreed to proceed with the establishment of a prostate brachytherapy program based on the Ragde/Blasko model. The implantation technique, as detailed by Blasko et al.,[8] uses transrectal ultrasound to guide placement of radioactive seeds into the prostate, which results in an intense dose of irradiation to the prostate but far lesser doses to the surrounding tissues. The permanently implanted seeds deliver a dose of irradiation that is 2.5 to 3.0 times that which can be administered via conventional external beam techniques. The individual seeds demonstrate rapid tapering of dose with distance from the seed.

IMPLEMENTATION

Implementation of this new procedure has centered on acquiring the necessary physical space, personnel, and capital to operate the program. For the most part, the costs of allocating these resources are not entirely prohibitive, due in large part to the sharing of resources across departments. More significant to success is the degree of coordination needed to ensure a smoothly operating program.

Ideally, a general operative suite should be acquired for the actual implant with a second room for conducting the preimplant prostate volume study. The latter is necessary to determine patient anatomy, i.e., prostate size and possible pubic arch interference. At Mobile Infirmary, an underutilized cystoscopy surgery suite has been deemed acceptable for the implant procedure. The second room for the volume study is located in radiation oncology. The urologists participating on the panel elected not to purchase additional ultrasound equipment for their respective offices, thereby allowing all volume studies to be performed in this "brachytherapy" suite. This space has recently been created to house high-dose remote afterloader equipment, a superficial X-ray machine, and the department's second simulator. Simply adding guide rails to the simulator table has allowed preimplant volume studies to be performed.

A surgical oncologist was contacted regarding the possibility of joint usage of the ultrasound equipment. The physician had expressed interest in using ultrasound to assist in the treatment of hepatic metastasis with cryosurgery techniques. Multiple physician use of this expensive equipment was fiscally attractive to all involved.

The preimplant volume study is a feature of the Ragde/Blasko approach[9] in contradistinction to the intraoperative planning technique of Stone and others.[10] Participation of both the urologist and the radiation oncologist during the preimplant volume study has enhanced our ability to assess the suitability of a patient for implantation. The senior certified medical dosimetrist underwent ultrasound training in house and became the operator of the unit during the volume study. His knowledge of implant dosimetry permits additional input during the session.

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Our initial capital outlay for equipment acquisition included:

- ultrasound unit: $78,000
- implant stabilization device: $4,000
- needle loading device: $1,600
- needle storage device: $800.

This list does not include a treatment planning computer (approximately $26,000) capable of prostate implant preplanning, which may already be available in some institutions. Additional items include implantation needles, coordinate system (grid) template, stabilization needles, bone wax and spacers, and radiation survey meters. The radioactive seeds, measuring 4.5 mm by 0.8 mm, account for the major cost of expendable supplies. Seed costs range from $39 to $46 per seed.

Prior to ordering seeds, it is necessary to have the appropriate radioactive materials license for the state in which the institution is located. Authorized users (radiation oncologists) must be named on the radioactive materials license. Maximum possession limits must be specified for both Iodine-125 and Palladium-103. The radiation safety officer for the institution and the medical physicist should be very familiar with these requirements. Radiation safety must be maintained in every step, including sterilization of seeds, seed loading into needles, the operative procedure, and recovery room.

As part of the program's implementation, the radiation oncology personnel were charged by the panel to develop a procedure-specific information booklet, take-home video, instruction sheets detailing volume study and seed implant prep procedures, and written discharge instructions. Today, an active nursing staff facilitates the transfer of information in a manner consistent with the age and educational level of the individual patient.

Finally, a decision was made concerning the treatment algorithms to be followed for each stage of disease presentation. Our panel adopted the Seattle approach, as well as its treatment planning techniques. A radiation oncology team consisting of a senior medical

physicist, senior radiation dosimetrist, and the brachytherapist traveled to Seattle to work with their counterparts in detailed treatment planning and intraoperative observation.

THE FIRST YEAR

The prostate brachytherapy program at Mobile Infirmary commenced in March 1997. The first-year experience included 150 consultations, of which fifty patients were implanted. Seventy-two percent of patients implanted had clinical stage T1c disease. Twenty percent of patients required replacement of the Foley catheter within seventy-two hours of implantation. Three patients retained these catheters for 1.5, 2, and 3 months, respectively. The initial ten patients were admitted overnight, but this practice was discontinued when experience demonstrated low patient morbidity. Reviewing our program experience, we estimate staffing time per patient to be 4.5 hours for physicians, 3.25 hours for the physicist, 7 hours for the dosimetrist, and 1.25 hours for the nurse/clerk.

Coordination challenges included insurance verification for each procedure and schedule coordination for the patient, team, and OR suite. In addition, seed availability was a major problem in 1997. Subsequently, the difficulties in procuring seeds have largely abated.

Certain trends have become apparent with year-end review. Primary external beam irradiation patients have declined by one-third. However, total prostate patient volume has increased by 20 percent when compared to 1995 and 1996.

Side effects of the implant procedure are well documented.[11] Additionally, one patient required admission for ileus secondary to excessive narcotic usage. Follow-up was performed by both the urologist and the radiation oncologist, with special attention focused on acute and perioperative symptoms. Dysuria, urinary urgency, nocturia, and rectal tenderness were commonly reported. Preliminary results of data for both pre-implant PSA and follow-up PSA at four months post-implant are encouraging, and mirror other series of patients treated with this approach. It appears, therefore, that the technique can be duplicated in a community setting.

REIMBURSEMENT CHALLENGES

In the present era of increased emphasis on cost-effective medicine, new programs must demonstrate the ability to pay a reasonable amount to cover the cost of the program for both fixed and variable expenses. Accordingly, emphasis was placed on outpatient status for both the preimplant volume study and actual implant. At Mobile Infirmary Medical Center, the cost accounting system includes both fixed and variable costs in the actual total cost. Thus, actual total cost includes fixed costs such as utilities, space, and equipment and the variable costs of seeds and other supplies. Profit is then derived from net revenue minus actual total cost.

Table 1 details representative hospital patient data for Medicare and third-party coverages. These figures indicate that the program is operating at a small loss, mainly due to HMO and outpatient surgery rates that were negotiated prior to initiation of this program. The rates are currently being renegotiated. At this time no CPT codes have been denied.

Physician reimbursement must also be reviewed to assess the overall impact of the brachytherapy program. CPT reimbursement by Medicare for urology and radiation oncology is detailed in Table 2. Note that there is a substantial difference in urologic reimbursement for seed implant ($815 to $1,176) compared to retropubic prostatectomy ($1,823).

From the physician's perspective, the Medicare total reimbursement for seed implant is greater than either prostatectomy or external beam irradiation:

- interstitial implant: $2,283 (urologist: $1,176; radiation oncologist: $1,107)
- retropubic prostatectomy: $1,823
- external beam irradiation: $1,944.

Total program savings are derived from lack of inpatient days and absent daily beam charges.

Analysis of HCFA Medicare data for 1995 can yield an actual cost comparison among treatment modalities:

- radical prostatectomy: $12,600-$19,100
- external beam radiation therapy: $13,700-$17,100
- brachytherapy: $6,000-$7,800.[12]

If, however, the analysis is extended to include managed care markets, it is necessary to incorporate treatment-related expenses over the twenty-four months following the initial procedure. The average length of patient participation in any one managed care organization is twenty-six months. Thus, global costs should include this twenty-four-month follow-up period. In a mature managed care market, Chircus[13] has estimated global cost for prostatectomy to be $12,900. The external beam irradiation national average is $13,700. Similarly, brachytherapy cost in such a market would be $9,000. Total costs for prostatectomy, external beam, and brachytherapy are estimated to increase by $2,000, $1,200, and $250, respectively, over the next twenty-four-month period. The end result is essentially

Table 1. Cost Accounting, Medicare & Private Payers

	Medicare (Patient A)		Private Payers (Patient B)	
	Volume Study	Implant Procedure	Volume Study	Implant Procedure
Total Charges	$2,700	$10,799	$2,678	$10,501
Actual Total Cost	$648	$3,942	$698	$4,593
Net Revenue	$818	$4,043	$1,133	$4,463
Profit	$170	$101	$436	($130)

TABLE 2. MEDICARE FEE SCHEDULES: RADIATION ONCOLOGY AND UROLOGY

		Code	Procedure	Reimbursement
Radiation Oncology	**Pre-implant volume study**	77470	Special treatment procedure	$103
		77328	Complex brachytherapy calculation	$103
	Implant	77290	Complex simulation	$77
		77778	Complex interstitial application	$541
		77328	Complex brachytherapy calculation	$103
	Post-implant Follow-up	77290	Complex simulation	$77
		77328	Complex brachytherapy calculation	$103
Urology	**Prostatectomy**	55845	Retropubic prostatectomy with node dissection	$1,823
	Pre-implant volume study and implant		Transperineal seed implant	$815 to $1,176
		55859	Transperineal placement of needles into the prostate (cysto)	$620
		76965	Ultrasonic guidance for radioelement application	$278
		76926	Ultrasonic guidance for radioelement application	$97

the same global costs for prostatectomy and external beam irradiation, both of which cost approximately 60 percent more than brachytherapy. A similar analysis can be performed for the patient who requires external beam irradiation combined with seed implant.

Considerable controversy exists regarding which men with prostate cancer should be treated,[14,15] how they should be treated,[16,17] and whether they should be diagnosed at all. For the time being, it appears that patients will continue to present with this disease, especially in an early, organ-confined stage. An informed patient can participate in the decision-making process and select the appropriate course of action for his particular situation. Prostate brachytherapy may be such an appropriate choice.

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Reimbursement Realities in Prostate Brachytherapy

By Ron Deisher, M.P.A.H., and John Sheldon, M.D.

With proven efficacy and cure rates comparable to radical prostatectomy, lower morbidity in terms of impotence and incontinence, and the growing public awareness and preference for this procedure, brachytherapy in the treatment of early stage prostate cancer is clearly here to stay.

The Cancer Institute of Health Midwest in Kansas City, Mo., is currently developing a Center for Brachytherapy Services within the Department of Radiation Oncology and Outpatient Surgery Center at Research Medical Center, one of the Institute's major sponsoring hospitals. Satellite brachytherapy clinics will eventually be located at several other Health Midwest hospitals.

Central to the program is a team approach exemplified by the collaboration of urologists and radiation oncologists. Under the leadership of Dr. John Sheldon, procedural guidelines were established to delineate roles and responsibilities for team members of various disciplines. Urologists and radiation oncologists collaborate in selecting prostate patients appropriate for brachytherapy and in recommending overall treatment regimens for patients. Urologists provide most of the pretreatment counseling and are responsible for securing the necessary diagnostic information. The radiation oncologist and staff are responsible for the technical planning of the implant prior to the procedure, technical evaluation of the implant following the procedure, and follow-up education and support of the patient and family.

Ron Deisher, M.P.A.H., is executive director and vice president for the Cancer Institute of Health Midwest, which represents and helps coordinate the cancer programs and services at eleven of the fourteen Health Midwest hospitals in the ten-county Kansas City metropolitan area. John Sheldon, M.D., is a radiation oncologist and brachytherapy specialist with the same organization.

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Planning analyses of potential costs and reimbursement issues have indicated that delivering prostate brachytherapy services in a hospital outpatient setting (vs. a freestanding facility) will help reduce startup costs and improve reimbursement. While the former has proven true, reimbursement results have been mixed. For example, reimbursement under various discounted fee-for-service arrangements has been adequate, with Medicare and Medicaid only marginally so. However, certain capitated and per diem arrangements have proven wholly inadequate—several per diem contracts do not even cover the cost of the seeds.

At the Cancer Institute of Health Midwest, we intend to aggressively pursue necessary changes in our reimbursement arrangements that are marginal or simply inadequate for prostate brachytherapy. In the early development of prostate brachytherapy, for example, management engineering and cost accounting were consulted to analyze and determine actual costs and necessary margins. Wherever necessary, we are attempting to renegotiate managed care contracts to reflect this new service.

Another major start-up issue has centered on proper coding and billing. Our reimbursement and billing offices have worked closely with radiation oncology and hospital administration to ensure that all procedures are properly coded and billed, including the costs of the radioactive seeds. Outside consultation has also been sought to review coding and billing decisions. As a result, early problems with coding and billing have now been largely resolved.

Our experience has shown that the time to pursue reimbursement changes is during the early programmatic phases of a new procedure, before inadequate reimbursement has a chance to modify or curtail improved therapies for cancer patients.