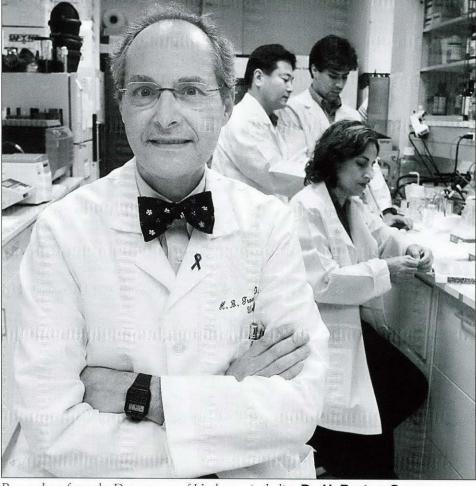


Focus on Improving Therapies and Identifying Biomarkers

by Katie Prout Matias

Binding the United States, has a high rate of recurrence, and kills more than 12,000 people each year. But the disease has developed a reputation for being nonlethal. This misperception, according to Colin P.N. Dinney, M.D., a professor in the Department of Urology at The University of Texas M. D. Anderson Cancer Center, is to



Researchers from the Department of Urology—including **Dr. H. Barton Grossman** (foreground), a professor; **Dr. Noriyoshi Tanaka** (left), a postdoctoral fellow; **Jorge Delacerda**, supervising clinical researcher; and **Afsaneh Keyhani** (right), laboratory coordinator—are investigating new treatment approaches for bladder cancer.

blame for the longtime dearth of funding for bladder cancer research. (Continued on **next page**)



'Hitting Bladder Cancer on All Fronts'

(Continued from page 1)

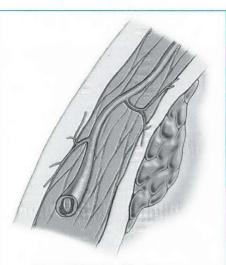
In recent years, however, the National Cancer Institute (NCI) has taken steps to reverse this trend. NCI funding for bladder cancer research increased from \$15.5 million in 1997 to \$32.3 million in 2002. And in 2001, the NCI awarded a \$13.9 million Specialized Program for Research Excellence (SPORE) grant for bladder cancer research to M. D. Anderson. Within the program, five core research projects will study everything from prevention to detection and treatment. "We're hitting bladder cancer or all fronts," said Dr. Dinney, who directs the bladder cancer SPORE.

One of the chief goals of researchers at M. D. Anderson is to improve on the current standards of care for superficial and muscle-invasive bladder cancer, which are far from perfect. Patients with superficial bladder cancer are often treated with transurethral resection and, in some cases, intravesical chemotherapy. Nevertheless, 50% to 75% of superficial bladder cancers recur, and these recurrent tumors are treated with bacille Calmette-Guérin (BCG). an attenuated tuberculosis bacterium that is used as immunotherapy. In this treatment, a saline solution containing the bacteria is deposited into the bladder via a catheter, where it triggers the body's immune response, destroying cancer cells. BCG is used more or less as a maintenance therapy, to delay the next recurrence that is likely to come.

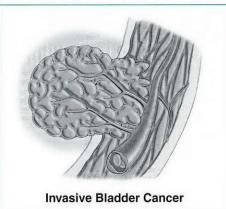
"Even though we have effective therapies for the treatment of superficial disease, most bladder carcers over time will recur," said Dr. Dinney. "And the salvage therapies that we have today are not very effective." Up to 30% of patients in whom superficial bladder cancer recurs will die within 15 years.

Approximately 25% of bladder cancers will invade the muscle, requiring a cystectomy, or total removal of the bladder. Cystectomy can have many troubling side effects, including impotence resulting from nerve damage and urinary incontinence. The prostate, ovaries, uterus, and part of the vagina are also commonly removed. Sadly, in many of the patients who choose to go through a cystectomy, the cancer will recur. "Up to 50% of patients who present with muscle-invasive disease will die of metastasis, as will a small percentage of patients who have superficial disease. So there is a real need to develop better therapies," said Dr. Dinney.

Researchers are investigating many different treatment approaches, including better chemotherapeutic strategies for metastatic, chemotherapy-resistant bladder cancer. One such strategy, still



Superficial Bladder Cancer



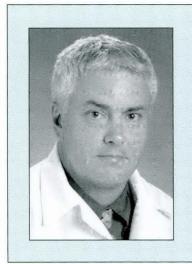
Superficial bladder cancers (top) are often treated with transurethral resection; immunotherapy is used in the 50% to 75% of superficial bladder cancers that recur. Approximately 25% of bladder cancers invade the muscle, requiring a cystectomy, or total removal of the bladder. Researchers at M. D. Anderson are studying better ways to prevent recurrence and treat patients with both kinds of bladder cancer. considered controversial by many, is neoadjuvant chemotherapy before cystectomy. According to Dr. Dinney, neoadjuvant chemotherapy not only is the first step toward bladder preservation but also allows physicians to observe whether the chemotherapy is working.

"If you take out the bladder and then give them chemotherapy after the fact, you really don't know if that chemotherapy has been effective because there's nothing to watch. If you leave the bladder tumor inside, you can actually evaluate it during the course of chemotherapy and determine how effective the therapy is," said Dr. Dinney. "And if it's not effective, you can change the course of treatment in the midst of it and not wait to see the cancer recur at the end of it all."

In patients with locally advanced bladder cancer, the survival benefit of neoadjuvant chemotherapy was recently confirmed by an 11-year study of 307 patients conducted by the Southwest Oncology Group and led by H. Barton Grossman, M.D., a professor in the Department of Urology at M. D. Anderson. The study's results, which were published in the August 28, 2003, issue of The New England Journal of Medicine, showed that patients treated with chemotherapy followed by surgery lived a median of 77 months, compared with 46 months for patients treated with surgery alone.

"This is an important advance, because the study shows a significant and clinically meaningful improvement in survival among patients who received chemotherapy before surgery," said Dr. Grossman. "Treatment of this disease varies across the country, but we believe neoadjuvant chemotherapy should be used more frequently."

Also being investigated to improve chemotherapeutic treatments is interferon, which has so far not been successful alone in treating muscle-invasive bladder cancer. In one study, patients will receive interferon systemically, and biopsies will be performed before and after treatment to see if the interferon is indeed killing cancer cells and enhancing the response to the chemotherapy.



"Up to 50% of patients who present with muscle-invasive disease will die of metastasis, as will a small percentage of patients who have superficial disease. So there is a real need to develop better therapies." - Colin P.N. Dinney, M.D., professor,

Department of Urology

In patients for whom the treatment does not work, the researchers will study the biological mechanisms behind the resistance and use the results to select patients for interferon treatment.

Another agent being combined with chemotherapy is ZD-1839 (Iressa), an epidermal growth factor receptor (EGFR)–blocking agent. EGFR, which is overexpressed in more than 80% of advanced bladder cancers, is involved in many important aspects of tumor cell growth and invasion, including angiogenesis. Patients whose disease responds to chemotherapy will receive ZD-1839 in the hope that it will increase the efficacy of the treatment.

The bladder has long been thought to be ideal for gene therapy, but past trials using adenoviral p53 did not deliver enough of the gene to the tumor cells. As part of an ongoing investigation, researchers will be delivering the interferon- α gene, combined with a compound called Syn3, intravesically in patients with superficial bladder cancer. "In our animal models, Syn3 has led to tremendous gene transfer across the bladder and caused regressions of human bladder cancers growing in mice when given intravesically," said Dr. Dinney.

In addition to looking for better therapies, the researchers are working to improve staging, detect recurrence earlier, and develop effective chemoprevention regimens. According to Dr. Grossman, who codirects the SPORE, several projects are under way to find genomic and proteomic biomarkers that would help physicians diagnose both primary and secondary bladder cancer earlier. Currently, cystoscopy is recommended every three to six months to test for bladder cancer recurrence. This invasive procedure can miss small tumors and carcinoma in situ lesions, however, and some patients do not return for their scheduled follow-up. If the biomarker studies are successful, physicians could instead test a patient's urine for certain genes or proteins, saving them from the discomfort and expense of a cystoscopy.

"Both the genomic and proteomic approaches are yielding very exciting information," said Dr. Grossman. "The proteomic approach has identified a series of protein peaks that appear to be very sensitive and specific for detecting bladder cancer."

Using genetic or proteomic markers for bladder cancer, physicians also could identify patients who would be good candidates for novel therapies (in place of cystectomy), said Dr. Dinney, as well as patients who are likely to have recurrent or invasive cancer and whose disease should be treated more aggressively sooner. "These markers may help us identify those patients who actually respond to the chemotherapy and have a complete pathologic response, which is very hard to determine clinically before taking the bladder out. Your error is probably 30%, and that can be a very serious error," he said. Physicians could

also know if and when to perform a cystectomy on someone with superficial bladder cancer, thus resolving one of the bigger controversies in urologic oncology.

Finally, biomarkers could also help corroborate the efficacy of chemopreventive drugs. Two chemopreventive agents currently being evaluated at M. D. Anderson for bladder cancer prevention are fenretinide and celecoxib, which is intended to prolong the response to BCG. Both drugs are being investigated to prevent or delay recurrences.

"One of the problems with chemoprevention trials is that our ability to determine response is still very limited," said Dr. Grossman. "If validated biomarkers were available that could be used as surrogate endpoints, you could assess chemoprevention in a much faster, more efficient way."

The epidemiology of bladder cancer recurrence is another area of investigation. Cigarette smoking and exposure to certain chemicals are known causes of bladder cancer initially, but it is not clear what triggers recurrences. Variations in normal genes are being investigated, including those involved in DNA repair, nicotine addiction, and the ability to break down carcinogens into nontoxic byproducts. Researchers hope that the knowledge gained from these studies could one day be used to develop not only chemopreventive drugs to prevent recurrence but also primary prevention methods for people at high risk of bladder cancer, such as smokers, industrial workers, and those who carry certain genetic markers.

The knowledge researchers gain in their efforts to improve the prevention, diagnosis, and treatment of bladder cancer may also be applicable to other solid tumors that are more difficult to evaluate. "The bladder is an internal organ that is very, very accessible, so it provides a unique opportunity for developing therapies," said Dr. Grossman.

FOR MORE INFORMATION, contact Dr. Dinney or Dr. Grossman at (713) 792-3250.

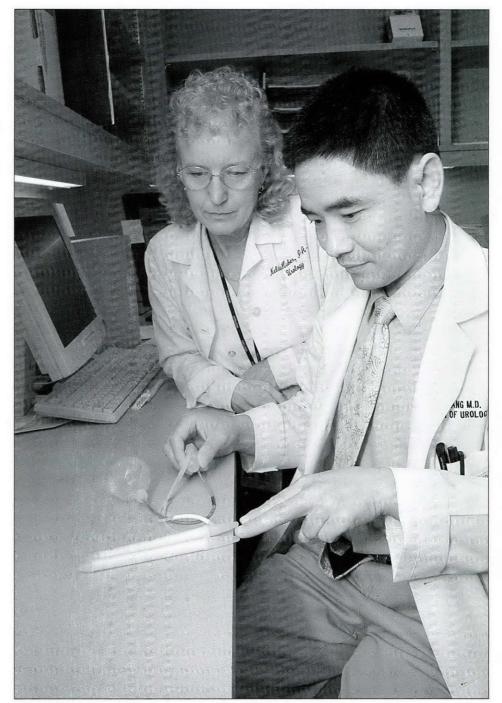
Restoring Erectile Function in Patients Treat Efforts across Disciplines Address Physical, Psychological, and Emotional Fo

by Mariann Crapanzano

he message for men facing prostate cancer and its treatment is clear: erectile dysfunction, a major morbidity associated with radical prostatectomy and radiation therapy, can be effectively treated. At The University of Texas M. D. Anderson Cancer Center. health-care professionals across disciplines work with patients to restore erectile function after treatment for prostate cancer, addressing the physiological, psychological, and emotional factors involved in penile erection from the time of surgery through rehabilitation. The results are promising.

In the effort to maintain or restore spontaneous erectile function in patients after prostatectomy, surgeons have devoted considerable attention to the preservation of nerve function, a fundamental component of tumescence. Radical prostatectomy involves removal of the prostate, surrounding lymph nodes and tissue, and occasionally, the surrounding cavernous nerve bundles that play a central role in penile erection. A nerve-sparing surgical technique that has beer. widely used since the 1980s for patients with localized prostate cancer has helped to increase the number of men who recover potency-defined as the ability to sustain an erection sufficient for sexual intercourse-after surgery.

The results with nerve-sparing surgery vary by patient, said Richard J. Babaian, M.D., a professor in the Department of Urology at M. D. Anderson, but three factors that help determine the outcome are the patient's



Nelda J. Huber (*left*), a physician's assistant in the Department of Urology, and **Dr. Run Wang**, ar. assistant professor in the department and director of the erectile dysfunction clinic, examine an inflatable penile prosthesis, one of several devices used in the clinic to help mer. regair. erectile function.

age, the disease stage, and the degree of erectile function before the surgery. Younger age, organ-confined disease, and good preoperative function lead to better results.

Some patients, such as those whose cancer is locally advanced, may not be

candidates for the nerve-sparing technique because of the risk of positive surgical margins. For these patients, a surgical procedure in which the sural nerve from the leg is grafted to the cavernous nerve stumps provides promise. In a study reported in the

d for Prostate Cancer tors Related to Sexual Potency

"Patients should start this rehabilitation as early as possible."

 Run Wang, M.D., assistant professor, Department of Urology

March 2003 issue of Plastic & Reconstructive Surgery, Dr. Babaian and his colleagues at M. D. Anderson evaluated the effectiveness of sural nerve grafting of the cavernous nerve bundles in preserving postoperative erectile function while providing the highest level of cancer control. The results were encouraging. Among 30 patients who underwent non-nerve-sparing prostatectomy and a bilateral sural nerve graft, 18 (60%) had spontaneous erectile activity during a mean followup period of 23 months after surgery. Thirteen (72%) of these 18 men were able to engage in sexual intercourse either spontaneously or after taking sildenafil.

According to Dr. Babaian, the recovery period after the nerve graft is necessarily longer than it is after nervesparing surgery because it takes time for the nerve to grow. The sural nerve that is grafted is not itself a live, functioning nerve; instead, it acts as a scaffold upon which the two ends of the cavernous nerve will regenerate and complete the path to the innervated tissue. This process takes 15 to 18 months.

Christopher G. Wood, M.D., a surgeon and assistant professor in the Department of Urology at M. D. Anderson and a coinvestigator in the bilateral sural nerve graft study, said that some patients who are not candidates for bilateral nerve-sparing surgery can undergo unilateral nerve-sparing surgery. According to Dr. Wood, biopsy results determine whether the patient has highgrade or locally advanced disease that would preclude sparing the nerve. Those who require unilateral nerve resection for cancer control are eligible for a phase II, randomized trial that is currently recruiting patients at M. D. Anderson to determine the benefits of unilateral sural nerve grafting. Potential participants are patients 65 years of age or younger who are candidates for unilateral nervesparing surgery and who have not received pelvic radiation therapy or hormone therapy for their prostate cancer. Participants will be randomly assigned to receive postoperative

erectile-function therapy only or erectile-function therapy plus a unilateral nerve graft.

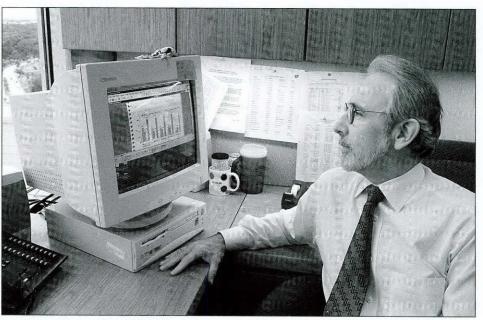
Preserving the nerves responsible for tumescence is just one method of recovering erectile function after prostate cancer treatment. Rehabilitation is an integral part of this recovery, regardless of the cancer treatment, and at M. D. Anderson, programs are in place to help patients not only physically but also psychologically and emotionally.

Dr. Wood, who recognized years ago that early erectile function rehabilitation is critical to the recovery and maintenance of spontaneous penile erections after treatment for cancer, was instrumental in developing the erectile dysfunction clinic in the Department of Urology. Here, patients with erectile dysfunction caused by their cancer treatment undergo therapy that includes one or more of the following regimens: oral sildenafil, penile injections, intraurethral suppositories, vacuum erectile devices, and penile implants, all of which help patients to achieve erections and thus exercise function during recovery.

The success of this therapy is explained physiologically, said Run Wang, M.D., an assistant professor in the Department of Urology and director of the erectile dysfunction clinic at M. D. Anderson. According to Dr. Wang, the penile erections caused by the therapy mimic the spontaneous nocturnal tumescence that occurs in healthy adult males; this increases blood flow to the penis, helping to prevent hypoxia and thus fibrosis, collagen formation, and loss of tissue mass.

"Patients should start this rehabilitation as early as possible," said Dr. Wang, who also serves as chief of urology at Lyndon B. Johnson General Hospital and assistant professor of surgery at The University of Texas Health Science Center at Houston Medical School. "With nerve-sparing or non-nervesparing surgery, every patient should do this to maintain the healthy tissues, to facilitate early recovery of their erection, and to make it easier for them to receive possible surgical help, such as penile implants, in the future."

How successful is the therapy? It depends on the patient and the regimen, said Dr. Wang. As an example, (Continued on page 6)



Dr. Richard J. Babaian, a professor in the Department of Urology, found that sural nerve grafting after the removal of the cavernous nerve bundles can preserve postoperative erectile function while providing the highest level of cancer control.

Restoring Erectile Function after Prostate Cancer Treatment (Continued from page 5)

he said, patients who undergo nonnerve-sparing prostatectomy have a 0% to 5% rate of spontaneous erections without therapy versus a rate of erections as high as 80% with the aid of penile injections.

Patients may also receive psychological support to guide thern through the restoration of sexual potency. Leslie R. Schover, Ph.D., a professor in the Department of Behavioral Science, is developing intervention programs to address the emotional and relationship issues faced by men with erectile dysfunction and help couples return to full, satisfying sexual intimacy after prostate cancer. As recognized by both Drs. Babaian and Schover, physiologic function is but one aspect of recovery. Dr. Schover's studies are designed to educate men and their partners about their medical options and to give them the tools to help overcome the inevitable hurdles they will face on the road to recovery.

In one pilot study, men who had undergone either radical prostatectomy or radiation therapy for localized prostate cancer and who were not receiving hormonal treatment for their cancer participated with their wives or partners in a four-session intervention program with a counselor. Filling out questionnaires before and after the counseling, the men and women reported on their sexual function and activity. The sessions focused on helping courles enhance their communication about sex and their sexual enjoyment, advising them about available medical treatment options for erection problems, and teaching them to troubleshoot in the event a particular treatment plan is unsuccessful. The preliminary results showed that couples who participated in the program experienced improved sexual function and satisfaction by three months after treatment and that a greater percentage of the men were successfully using a medical treatment to restore erectile function.

Dr. Schover and her colleagues were encouraged by these positive changes but recognized some barriers to providing this type of program: not all commu-



Dr. Leslie R. Schover, a professor in the Department of Behavioral Science, is developing intervention programs to address the emotional and relationship issues faced by men with erectile dysfunction after prostate cancer.

nities have the resources to provide such an intervention, many trained mental health professionals are not knowledgeable about both sex therapy and cancer, insurance does not always cover such specialized services, and many patients perceive a stigma associated with visiting a mental health professional. With an eye to overcoming these barriers and with the preliminary results of the pilot intervention in hand, Dr. Schover and her colleagues obtained funding from the American Cancer Society to develop a Web-based version of the intervention.

Aimed at couples, the Web-based intervention contains separate online bulletin-board-like support groups for men and women and provides medical information about the effects of cancer treatment and rehabilitative therapy for erectile dysfunction as well as exercises to improve sexual communication and enjoyment between couples. The participants complete the exercises and report their progress to a therapist via e-mail, who then replies with feedback. To evaluate the effectiveness of this intervention, couples are randomly assigned to see a counselor in person or participate in the Web-based version of the intervention program.

"If the Web-based treatment works almost as well or as well as face-to-face [treatment], then we'll have an intervention that's much more easily disseminated to the public," said Dr. Schover.

Dr. Schover and her coinvestigators are currently recruiting for this study, which is community based and not limited to M. D. Anderson patients. To be eligible, prostate cancer survivors must be between three months and five years beyond cancer treatment and not receiving hormonal therapy. They also must have a partner who is willing to participate in the study.

Ask Dr. Schover, and she will tell you that communication is the key to a successful outcome—honest communication between the health-care professionals and the patient and between the patient and the patient's partner.

Nelda J. Huber, P.A., who worked closely with Dr. Wood to develop the erectile dysfunction clinic and who now sees patients in the clinic with Dr. Wang, stressed that each patient requires individualized therapy. In many cases, the rehabilitation takes months, and it is imperative that patients be persistent in the therapy, be willing to try different methods, and not give up.

"Each patient is different," Huber said. "It's important to let patients know that we're going to get through this, together. We're going to keep at this, together. If (the first therapy) doesn't work, we'll do something else. But here's your likelihood of this being successful."

Dr. Wang agreed.

"Erectile dysfunction can be cured," said Dr. Wang. "If the patient is motivated to get treated, we can help him, there's no doubt."

FOR MORE INFORMATION, contact Dr. Babaian at (713) 792-3250, Dr. Wood at (713) 792-3250, Dr. Wang at (713) 500-7324, Dr. Schover at (713) 745-2681, or Nelda Huber at (713) 792-6410.



Note to Self: Get Screened for Colon Cancer

his memo is for everyone who is putting off colon cancer screening. You may have come across this article on your own, or it may have been given to you by someone who cares about you. No matter how it came to you, this could be the most important information you will read for some time.

Colon cancer screening is a sensitive issue, and most people would prefer not to think or talk about it. However, screening is especially important in colon cancer because most colon cancers develop from polyps that start out small and harmless but grow slowly and change into cancer. Colon cancer often has no special symptoms in its early stage, and it affects men and women in equal numbers. More than 100,000 people are diagnosed with colon cancer in the United States every year, and it is the second leading cancer killer in the U.S.

So when should you get screened for colon cancer? The type of screening used and its schedule will vary depending on your risk factors. Talk to your doctor if you've had symptoms of colon cancer, such as consistent presence of blood in your stool, changes in bowel habits, unexplained weight loss, or tiredness; if you or a relative has had cancer before; or if you have other possible risk factors, including certain bowel diseases, a history of tobacco use, or a diet high in fat or cholesterol. (But note: Three out of four people who have colon cancer had no known risk factors.) Even if you don't have any other risk factors, turning 50 years old is reason enough to get screened.

Screening Tests for Colon Cancer



- Fecal Occult Blood Test: Special cards are coated with a stool sample and returned to the physician or lab. This test examines a patient's solid waste (stool) for occult (hidden) blood. Studies show that a fecal occult blood test performed every 1 or 2 years in people between the ages of 50 and 80 years decreases the number of deaths due to colon cancer.
- Sigmoidoscopy: Sigmoidoscopy is an examination in which a doctor uses a thin, flexible tube with a light to look inside the rectum and colon for polyps, tumors, or abnormal areas. Studies suggest that fewer people may die of colon cancer if they have regular screening by sigmoidoscopy after the age of 50 years.
- Digital Rectal Examination: A digital rectal examination is performed during an office visit or prior to sigmoidoscopy or colonoscopy. For this examination, the doctor or nurse inserts a lubricated gloved finger into the rectum and feels for lumps or abnormal areas. The evidence available does not suggest that digital rectal examination is effective in decreasing mortality from colon cancer.
- Barium Enema: Barium enema is a procedure in which a liquid containing barium is put into the rectum and colon by way of the anus. Barium is a silver-white metallic compound that helps to show the image of the lower gastrointestinal tract on an x-ray. Barium enema may be effective in detecting large polyps.
- Colonoscopy: Colonoscopy is an examination of the inside of the colon and rectum using a thin, lighted tube (called a colonoscope) inserted into the rectum. If the doctor sees polyps or other abnormal tissue during the procedure, they can be removed and further examined under a microscope. Studies suggest that colonoscopy is a more effective screening method than barium enema.

Several tests can help determine whether you have colon cancer. Which test is best for you depends on your individual situation, for example, whether you've had symptoms of colon cancer or a family history of cancer or polyps. M. D. Anderson Cancer Center offers the following general colon cancer screening recommendations (see Screening Tests for Colon Cancer) for men and women beginning at age 50:

- An annual fecal occult blood test and a flexible sigmoidoscopy and digital rectal examination every five years, or
- A colonoscopy and digital rectal examination every 10 years, or
- A double-contrast barium enema and digital rectal examination every five to 10 years.

Now the good news: Colon cancer can be cured if it is found early enough. It can even be prevented if polyps are found and removed before they have a chance to turn into cancer. And removing polyps when they are small and harmless is usually a simple procedure.

But here's the catch: You have to *get* the test. You can't just say "Great idea!" and go on about your business. You have to actually go see a doctor or other health-care provider, find out what test is recommended for you, and then *do it*.

When it's all over, you'll know that you've done something really important for yourself, your family, and everyone who depends on you. There will be peace of mind for all involved. And you'll have made someone who cares about you very, very happy.

For more information, contact your physician or contact the M. D. Anderson Information Line:

(800) 392-1611, Option 3, *within the United States*, or

(C) (713) 792-3245 in Houston and outside the United States.

October 2003

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DiaLog

Sexual Function and Prostate Cancer: The Importance of Realistic Expectations

Leslie R. Schover, Ph.D. Professor, Department of **Behavioral Science**

Many men choose a treatment for prostate cancer based on the unrealistic expectation that it will spare their sexual function. When they do end up with problems, the stigma of



being a "treatment failure" adds yet another barrier to their seeking medical help.

New treatments that are designed to eradicate prostate cancer without compromising sexual function have been highlighted in the professional literature and the lay press, but they typically include only younger, healthier patients who are treated in academic medical centers. A consistently less positive picture comes from published findings in studies of unselected patients treated in community settings, especially when sexual function is assessed using detailed, validated questionnaires.

The marketing of sildenafil has encouraged more men to get treatment for erectile dysfunction, but it does not help many prostate cancer survivors. In our recent follow-up study of mer. treated for localized prostate cancer, only 16% of 549 men who tried sildenafil found that it greatly improved their sex lives, and 61% had stopped using it. More invasive treatments such as penile injections or a penile prosthesis had much higher success rates.

A narrow focus on erectile rigidity overlooks the role of the partner in successful sexual recovery after prostate cancer. In our survey, 66% of men noted that their partner had a problem that interfered with sex, most commonly a loss of desire. Not surprisingly, men whose partners enjoyed sex were themselves more satisfied.

What then can physicians do to prepare men to resume having sexual intercourse after prostate cancer treatment?

- Use realistic estimates of the percentage of men whose sexual function is spared after prostate cancer treatment.
- Emphasize that men who retain or regain normal erections are almost always younger than 65 (the younger, the better) and had normal erections before treatment.
- . Encourage men to try phosphodiesterase-5 (PDE-5) inhibitors, but with the caveat that they work best for men who already have erections that are close to normal and more invasive options may be needed.
- Include the partner in counseling as much as possible. Assess her sexual function and give referrals when needed.
- If you do not have the time to educate patients about the sexual impact of treatment, delegate that task to one of your treatment team members.

At least half of all prostate cancer survivors are concerned about staying sexually active. They and their partners need your help and encouragement to get their sex lives back on track.

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