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Nonsurgical Cryotherapy for Prostate Cancer, the “Male Lumpectomy,” Preserves Sexual and Urinary Function in Most Men

Related Study Shows 3-D Global Mapping Biopsy Catches More Than Half of False Negatives

NEW ORLEANS, Louisiana (April 1, 2005) – A new nonsurgical treatment for prostate cancer preserves urinary and sexual function in a majority of men and offers an effective treatment, according to a study presented today at the Society of Interventional Radiology’s 30th Annual Scientific Meeting. The “male lumpectomy” uses focal cryoablation — freezing the tissue with extremely cold gas — to target only the tumor itself, which spares the healthy tissue in and around the prostate gland, rather than destroying all of it, as the traditional approaches do.

Prostate tumors do not tend to spread quickly, and up to 35 percent are solitary and unilateral. Thus, many of them can be treated with a local treatment that pinpoints only the tumor, which is less likely to cause side effects. Sexual dysfunction and urinary incontinence are common complications of surgery, occurring in 75 percent¹ and 10 percent² of cases respectively, according to the published literature. Patients undergoing brachytherapy, another common treatment using implanted radioactive seed particles, have a 50 percent impotence rate in the long term. Both brachytherapy and surgery treat the whole prostate gland.

“Treating only the tumor instead of the whole prostate gland is a major and profound departure from the current thinking about prostate cancer,” said study author Gary Onik, M.D., interventional radiologist at Florida Hospital/Celebration Health, Celebration, Florida, who pioneered prostate cancer cryoablation in the early 1990s. “Focal cryoablation changes the whole picture in terms of complications, and the cancer control is as good as for any other treatment. Focal cryoablation appears to preserve urinary and sexual function superior to any other treatment yet available,” said Onik.

Cryoablation of the whole prostate gland has been approved by Medicare for over five years as a primary treatment for prostate cancer. Recent data show that cryoablation has a 10-year disease-specific survival rate of over 98 percent. Cryoablation is also the only procedure specifically approved by Medicare to treat patients with prostate cancer who have failed radiation therapy.

Prostate cancer is the most common cancer affecting American men. More than 230,000 men are diagnosed every year in the United States and 30,000 die from the disease.

According the Prostate Cancer Foundation, a non-smoking American male is more likely to get prostate cancer than the next seven most common cancers combined. Historically, prostate cancer has been considered an older man's disease, however the incidence is increasing in men in their 40s and 50s.

Focal Cryoablation for Prostate Cancer (Abstract 506)

In this ongoing study, 60 patients were treated with focal cryoablation. The preliminary results for the 42 men who have completed between one-year and eight years follow-up showed 95 percent (40) had stable prostate-specific antigen tests, showing no evidence of cancer. High rates of potency were also maintained. Of the 32 patients who were potent prior to the procedure, 78 percent (25) remained potent afterwards. This compares with 20-40 percent potency rates in patients who are treated with unilateral nerve-sparing radical prostatectomy and 50 percent long-term potency rates for radiation therapy, including brachytherapy. And, just as importantly, no patient reported incontinence. "Incontinence becomes a big issue with many patients," said Onik. "For some it's a more important side effect than impotence."

Onik refers to focal cryoablation treatment for prostate cancer as "male lumpectomy," reflecting the origins of the approach in the breast-sparing surgery that has in recent years replaced radical mastectomy as the preferred treatment for breast cancer.³ Unlike breast lumpectomy, which requires surgery, cryoablation is even better because it is not surgical. The dead tumor cells are naturally reabsorbed by the body. Nonsurgical cryoablation spares as much as possible of the prostate gland and its neurovascular bundles, limiting the side effects of incontinence and impotence that result from more radical prostate cancer treatments, such as surgical prostatectomy. It also represents an advantage over "watchful waiting," because the surgical option is preserved, but the risk of missing the treatment window early in the cancer's progression is lower.

About Cryoablation

In a cryoablation procedure, the interventional radiologist inserts a probe through the skin, using imaging to guide the needle to the location of the tumor. The probe then circulates extremely cold gas to freeze and destroy the tumor. The procedure, which is carried out under general anesthesia, is routinely done on an outpatient basis and patients return to normal activities within one to two weeks, depending on the extent of treatment needed.

Cryoablation has been used for many years by surgeons in the operating room for a variety of tumors, but in the last few years, the probes have become small enough, and are now insulated, so that they can be used by interventional radiologists through a small nick in the skin, without the need for an operation or stitches.

3D GLOBAL BIOPSY MAPPING (Abstract 525)

This related paper shows that a new image-guided interventional biopsy method is dramatically more accurate than the current transrectal ultrasound (TRUS) biopsy method and improves staging of prostate cancer and therapeutic decision making. In this technique, a grid placed over the perineum (the area of skin between the rectum and the scrotum) allows the physician to accurately map the location of each biopsy core removed. Further, the cores are taken through the skin rather than through the rectum,

allowing many more cores to be removed — up to 75 compared to 6-12 in a TRUS biopsy. This greatly increases the accuracy of the biopsy in diagnosing cancer — the technique caught tumors in over 50 percent of patients that had been inaccurately labeled negative by the old biopsy method. The mapping grid also allows the location of the tumor to be known much more precisely, allowing the interventional radiologist to cryoablate only the tumor and not the whole prostate gland.

Management of prostate cancer is in great part determined by the Gleason score, a cancer ranking method indicating tumor grade and stage, and the extent and location of the patient's disease. A high Gleason score or bilateral cancer may preclude brachytherapy. Location of cancer in areas close to the neurovascular bundle makes nerve-sparing radical prostatectomy not feasible.

“This biopsy technique allows us to map the location of the tumor with tremendous precision and has the potential to greatly affect the decisions we make about treating prostate cancer,” Onik said.

In the study, 59 patients underwent transperineal mapping biopsies using ultrasound for guidance. Cores were removed from their prostates at 5 mm intervals. Seventeen patients had bilateral biopsies and 42 had unilateral biopsies. Of the 42 patients who had had previously negative TRUS biopsies on one side (unilateral), 56 percent (23) were found to have cancer in the previously negative lobe. Of the 17 patients with bilateral biopsies, 15 had their treatment changed based on the new information from the biopsy. The new information provided by the biopsies had a major impact on cancer management for two-thirds of the patients.

About Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology's 30th Annual Scientific Meeting in New Orleans. Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat diseases nonsurgically through the blood vessels or through the skin. By combining diagnostic imaging expertise with advanced procedural skills, interventional radiologists perform minimally invasive treatments that have less risk, less pain, and less recovery time than open surgery. Interventional radiologists pioneered minimally invasive modern medicine with the invention of angioplasty and the catheter-delivered stent, which were first used to treat peripheral arterial disease. More information can be found at www.SIRweb.org.

Abstracts can be found at www.SIRmeeting.org in the program section and click on scientific sessions.

¹ Meyer JP, Gillatt DA, Lockyer R, McDonagh R. The effect of erectile dysfunction on the quality of life of men after radical prostatectomy. *BJU Int* 2003 Dec; (92)9:929-931.

² Borchers H, Kirschner-Hermanns R, Brehmer B, Tietze L, Reineke T, Pinkawa M, Eble MJ, Jakse G. Permanent 125I-seed brachytherapy or radical prostatectomy: a prospective comparison considering oncological and quality of life results. *BJU Int* 2004 Oct; 94(6):805-811.

³ Onik, Gary M. *The Male Lumpectomy: A Rational New Approach to Treating Prostate Cancer*.

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