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Large-scale proton therapy study confirms long-term survival, quality of life for prostate cancer patients

UF Health Proton Therapy Institute reports excellent tumor control rates, low incidence of gastrointestinal or urologic toxicity

JACKSONVILLE, Florida (May 5, 2016) — A large-scale study of men treated with proton therapy for prostate cancer confirms proton therapy is a highly effective treatment for low-, intermediate-, and high-risk prostate cancer. The cohort of 1,327 men was treated at the University of Florida Health Proton Therapy Institute between 2006 and 2010 with median follow-up of five-and-a-half years.

Researchers report that 99 percent, 94 percent and 74 percent of men with low-, intermediate-, and high-risk prostate cancer, respectively, have no signs of cancer recurrence after five years of follow up. Less than one percent in the cohort experienced serious gastrointestinal side effects and approximately three percent experienced serious urologic side effects.

“This study is the largest published series to date documenting the efficacy of dose-escalated proton therapy for localized prostate cancer with prospectively collected patient-reported quality of life and toxicity data,” reported lead researcher Curtis Bryant, M.D., M.P.H., UF Health Proton Therapy Institute radiation oncologist in the [article *Five-Year Biochemical Results, Toxicity, and Patient-Reported Quality of Life Following Delivery of Dose-Escalated Image-Guided Proton Therapy for Prostate Cancer*](#).¹ The study is published in the *International Journal of Radiation Oncology Biology Physics*, the main journal of the American Society of Radiation Oncology.

The primary goal of the study was to find out if the results from three benchmark clinical trials² with prospectively reported data by UF Health Proton Therapy Institute could be replicated in a larger population of unselected consecutive patients treated in a similar fashion. The researchers also wanted to identify factors that could predict either disease recurrence or urologic toxicity.

Proton therapy is a form of external beam radiation therapy that uses the positive-charged particles of atoms, protons, to deliver targeted treatment in cancerous tumors.

Tumor control data

The new study confirms similar results as the benchmark study for rate of tumor control in low-risk (both 99 percent) and high-risk prostate cancer (74 percent in the new study versus 76 percent in the benchmark study). Intermediate-risk prostate cancer tumor control was slightly lower in the new study – 94 percent versus 99 percent in the benchmark study. The reason for the difference in patient outcomes in intermediate-risk is unclear, researchers say, though may be related to a larger, broader sample of patients in the larger study. Overall, the presence of more than one intermediate-risk or high-risk factor may predict whether the disease will recur following treatment.

Toxicity data

Toxicities were graded using the Common Terminology Criteria for Adverse Events version 4.0. Incidence of serious urologic toxicity in the larger series study is 2.9 percent vs. 1 percent in the benchmark study. Incidence of serious gastrointestinal toxicity in the larger series study is consistent with the benchmark study, 0.6 percent and 0.5 percent, respectively.

The risk of developing a serious urologic toxicity appears to be higher in men who have one or more of the following predictive factors: a large prostate volume, pretreatment use of alpha blockers, pretreatment prostate reductive (TURP) procedures, diabetes, or a higher volume of bladder tissue receiving a dose of 30 Gy (RBE).

Quality of life data

Patient-reported quality of life scores following proton therapy for prostate cancer were good for urinary and bowel function, but significant decreases were seen in sexual function. Comparing pretreatment scores with scores at five years after treatment, the median baseline International Prostate Symptom Score remained unchanged. Similarly, the median and mean EPIC summary scores for bowel, urinary irritative/obstructive, and urinary incontinence domains remained relatively stable. The only significant change reported was in sexual function scores. Between baseline and five years, mean scores in patients not receiving hormone therapy declined from 67 to 53 and median sexual summary scores fell from 75 to 55.

Comparative effectiveness

Currently there are no published prospective clinical trials comparing proton therapy with other forms of external beam radiotherapy that use X-rays to treat prostate cancer, intensity modulated radiotherapy (IMRT) and 3-dimensional conformal photon radiation (3DCRT). A few retrospective studies comparing proton therapy and IMRT have been published in recent years. However, the reliability of the study conclusions is limited since the studies had short follow up, lacked treatment-related information (e.g., radiation dose, field

size), lacked toxicity grading and reporting, or lacked quality-of-life patient-reported outcomes. “Prospective comparative studies are needed for definitive comparison of proton therapy with IMRT,” concluded Bryant.

About prospective clinical trials

Prospective studies have an advantage over retrospective studies because they are prospectively designed to answer a specific study question. In addition, participants must meet specific criteria for inclusion and exclusion to reduce the chance that results will be confused by confounding variables. Finally, specific times and methods of collecting the information on cancer control and problems related to treatment are defined. These factors improve the quality of the data and potential reliability of the conclusions associated with these studies.

About proton therapy

Proton therapy is a type of radiation treatment that uses particles of an atom, protons, to deliver radiation. Protons have the potential to improve the therapeutic ratio in patients: delivering more curative dose in the tumor while delivering little or no dose to surrounding healthy tissue, thereby increasing the chance for cure and reducing the risk of side effects. Until recently, only a handful of academic medical centers in the U.S. were equipped with proton therapy. Today, 23 facilities offer proton therapy in the U.S, but access remains limited. Approximately one million people are treated with some form of radiation annually in the United States.³ Proton therapy accounts for an estimated one percent of those treated.

About UF Health Proton Therapy Institute

UF Health Proton Therapy Institute is a nonprofit 501(c)3 organization affiliated with the UF College of Medicine and the UF Health Cancer Center, a Florida Cancer Center of Excellence, dedicated to delivering state-of-the-art cancer treatment and setting new standards for treating and curing cancer. It is an accredited radiation oncology facility by the American College of Radiology. The cancer treatment facility houses both conventional radiation and proton therapy, and delivers proton therapy to 100 patients a day. For more information about the UF Health Proton Therapy Institute, please visit www.floridaproton.org, or call toll-free 877-686-6009.

1. Bryant C, Smith TL, Henderson RH, Hoppe BS, Mendenhall WM, Nichols RC, Morris CG, Williams CR, Su Z, Li Z, Lee D, Mendenhall NP. Five-Year Biochemical Results, Toxicity, and Patient-Reported Quality of Life Following Delivery of Dose-Escalated Image-Guided Proton Therapy for Prostate Cancer. *International Journal of Radiation, Oncology, Biology, Physics*. [2016;95\(1\):435-43](#).

2. Mendenhall NP, Hoppe BS, Nichols RC, Mendenhall WM, Morris CG, Li Z, Su Z, Williams CR, Costa J, Henderson RH. Five-year outcomes from 3 prospective trials of image-guided proton therapy for prostate cancer. *International Journal of Radiation, Oncology, Biology, Physics*. [2014;88:596-602](#).

3. <https://www.astro.org/News-and-Media/Media-Resources/FAQs/Fast-Facts-About-Radiation-Therapy/Index.aspx>. Retrieved April 1, 2016.