Message from Stuart Klein, Executive Director

Welcome to the first issue of our electronic newsletter – Precision. We’ve designed it with you in mind as a way to stay in touch and to send updates about what’s happening in the world of proton therapy and here at the UF Proton Therapy Institute. We hope that you will find this monthly email informative. Feel free to share it with your friends and family. If you have a story you’d like to share or a comment about a newsletter article or topic, please email us. We’d love to hear from you.

Sincerely,
Stuart Klein

Comparative study of prostate cancer treatment options used questionable data and methods

Stuart L. Klein, Executive Director, University of Florida Proton Therapy Institute

On April 18, 2012, an article appeared in the Journal of The American Medical Association (JAMA)¹ that concluded that proton therapy is more toxic and no more effective than IMRT in the treatment of prostate cancer. We strongly disagree with this conclusion since multiple studies following outcomes of more than 1,000 proton therapy patients document a reduced risk of serious toxicity (side effects), at or less than 2 percent.² We question the value of printing such a poorly conducted and ill informed research study. The reasons for our concerns are as follows:

1. Single institution bias skews validity of conclusions.

The study utilized a Medicare database of prostate patient bills to compare outcomes for patients treated with conformal radiation therapy (CRT – a very basic form of radiation therapy), IMRT (a more advanced form of radiation therapy) and proton therapy. They included data for 12,000 patients described as representative of treatment outcomes in community cancer centers. Only 700 patients, or 6% of the total, were treated with protons, and all of these patients were treated at a single proton facility, Loma Linda University Medical Center (LLUMC). Utilizing a single institution’s data will bias the conclusions. Valid research studies utilize the data from multiple institutions to remove this single institution bias. The authors failed to identify this significant fact and their conclusions did not adequately take this bias into account.

2. Proton patients in the data set received higher doses of radiation than their counterparts in CRT or IMRT, a fact not adjusted for in the results leading to faulty conclusions.

At the time the data was collected, LLUMC was treating patients on various clinical studies using higher doses of radiation than was commonly used at the time, a practice later proven to be more effective for prostate cancer. Community cancer centers at that time typically used lower radiation doses to try and avoid toxicity (side effects). In addition, no less than 30% of the LLUMC patients were treated with both protons and conventional radiation therapy.³ For both of these significant issues were not taken into account nor mentioned by the authors.

3. Authors did not adjust for variables in radiation dose leading to faulty conclusions.

The authors failed to account for differences in the total dose of radiation delivered to each patient. There can be a fairly wide...
range in the radiation dose delivered to each respective patient depending on the physician, extent of tumor and type of treatment used, i.e., CRT vs. IMRT vs. protons. Differences in radiation dose will greatly influence patient outcomes and side effects. Failure to account for this difference greatly skews the data and leads to incorrect conclusions.

4. Authors assume that all colonoscopies post-proton treatment were a result of negative side effects of treatment. This is not accurate as LLLUMC patients had colonoscopies as part of their routine follow-up.

The authors utilized the same Medicare billing data to determine the supposed negative side effects for each of the various treatments. This type of analysis is not specific and can be very misleading. For example, they concluded that if a Medicare bill was generated for a colonoscopy on a prostate cancer patient, then it was assumed that the colonoscopy was needed to address the negative side effects of their radiation treatment. However, at LLLUMC some of the protocols required routine follow-up colonoscopy procedures that had nothing to do with toxicity. The authors did not mention this in the study.

5. Authors ignore multiple studies based on actual patient data that report serious bladder and rectal complication rates of less than or equal to 2%.

The authors also fail to mention that published research data from multiple proton institutions exists that documents significant bladder and rectal complication rates of less than or equal to 2%. These reports are based on actual patient data as opposed to assumptions from Medicare billing data.

We at the University of Florida Proton Therapy Institute are fully committed to gaining a better understanding of the impact of utilizing protons to treat prostate cancer. Our published data is based on treatments delivered with well-defined dose levels and toxicity documented by detailed follow-up questions and examinations of our patients. Actual results, as opposed to assumed conclusions based on Medicare billing data, are utilized in our research studies.

We currently offer treatment for a wide range of cancers with CRT, IMRT, brachytherapy (radioactive seeds) and proton therapy. We have both IMRT X-ray therapy and proton therapy available for the treatment of prostate cancer. We likewise have many patients on watchful waiting. Our physicians do not have an ownership stake in our facility nor our equipment. They are salaried faculty members of the University of Florida College of Medicine and have no direct financial incentive that might influence their recommendation regarding any particular treatment alternative. We strongly encourage all prostate patients to become better educated about their disease and the different options for treatment. We likewise encourage patients to take the time and effort to question the data from all sources. We find it very troubling that an article based on Medicare billing data, and containing faulty conclusions, has generated so much confusion among some patients and the physicians who are trying to advise them.

JAMA recently published a letter to the editor authored by UFPTI Medical Director Nancy P. Mandenhall, M.D. and other proton therapy center medical directors. To view the letter, click here.
Florida has the second highest number of new cancer cases of all the 50 states. To help raise awareness in this vulnerable population about the benefits of proton therapy, last month we launched our first television advertisement featuring Markus Mittermayr and his wife Susan. Markus was treated for prostate cancer at UFPTI in 2010 and chose proton therapy because he didn’t want to suffer the potential side effects of surgery. “I felt I was too young to deal with those sorts of things,” he said. Maintaining his active lifestyle as a competitive triathlete was important to him. Two years after proton therapy, on August 11, 2012, he competed in the Ironman NYC 2012, finishing 15th in division M55-59 and 961 overall. The television ad is airing through the end of September in select Florida markets. To see the spot, check it out on the Florida Proton YouTube channel.

Cancer Awareness Spotlight

September is a busy month for cancer awareness activities. Three types of cancers treated at UFPTI are in the spotlight this month: childhood cancer, lymphoma and prostate cancer.

Our pediatric cancer program is the busiest worldwide. Children from all over the United States and the world travel to Jacksonville for proton therapy. On average we treat 10-15 children per day for cancers such as craniopharyngioma that occurs in the brain and sarcoma that occurs in the soft tissues like muscles. Proton therapy is extremely beneficial for children since even small amounts of radiation exposure can create significant damage to growing healthy cells and tissues and have a negative impact on cognition (IQ). With proton therapy we can limit the amount of normal, healthy tissue exposure while at the same time delivering the optimal dose in the cancerous tumor. The aim is to potentially reduce the severity of side effects during and after treatment and the risk of secondary cancers later in life.

Lymphoma, both Hodgkin and non-Hodgkin, is a cancer of the lymph nodes that typically affects children and young adults. The cure rate is 90 percent using a combined standard treatment of chemotherapy and radiation. However, treatment side effects often show up later in life as second cancers and heart disease. With proton therapy we can reduce the amount of healthy breast, lung and heart tissue exposed to radiation and for this reason it is believed that Hodgkin lymphoma patients will have a much lower risk of heart disease and secondary cancer. We have an ongoing clinical trial using proton therapy for lymphoma patients with involvement of the mediastinum. Early results of the study were recently published and you can read more in the Proton Therapy Publications newsletter feature.

Our largest patient group is being treated for prostate cancer and accounts for approximately 60 percent of patients on treatment today. Since opening our center in August 2006, we have treated more than 2,700 prostate cancer patients. Most are on clinical trials and the collective data has produced benchmark studies for patient treatment and outcomes that is widely used by other proton therapy facilities. Significantly we have found that most patients tolerate the treatment well with fewer than 2 percent of men experiencing serious side effects. We expect to have five-year data to report very soon that will show patient survival and outcomes.
In the Community

The Historic Springfield Main Street Cruise has quickly become one of the most happening events in the neighborhood near UFPTI. Located on Main Street at the front doors of the Third and Main apartments where many patients reside during treatment, the classic car meet is a combination of street festival, music concert and block party. It takes place the last Saturday of the month and UFPTI participated on August 25 with the Proton Van on display and giveaways of old-fashioned, fresh-popped popcorn and proton therapy awareness bracelets. Director of Patient Intake Judy Taylor Holland and her husband Mitch along with Director of Patient Services Brad Robbert staffed the booth.