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Radiation therapy on trial

Proton beam and other modalities work to prove themselves in practice

By Nancy Ryerson

Proton therapy has a prostate problem

Because prostate cancer is the most common form diagnosed in men and can be treated more quickly compared with other forms of cancer, centers are able to treat a steady flow of prostate cancer patients. It

also gets reimbursed by CMS, unlike most other proton therapy treatments. But after several studies questioned the long-term benefits of proton therapy for prostate cancer, the therapy's image took a beating.

"Unfortunately, the discussion around

coverage for proton therapy is clouded by this controversy with prostate cancer," says John Kerstiens, COO and CFO at Indiana University Health Proton Therapy Center. "You see articles where all they write is 'outcomes for proton therapy are no different from other therapies,' and they drop the word prostate."

Two studies published in April 2012 kicked off that debate on the value of proton beam therapy for prostate cancer. While proponents say the treatment reduces side effects, such as urinary incontinence and sexual dysfunction, one study published in the Journal of the National Cancer Institute found that though urinary incontinence side effects were less severe for proton therapy than other treatments

in the first six months, after that time, those benefits faded and there was no difference in side effects between proton therapy and IMRT, another radiation therapy technique.

Now, advocates hope the copious amounts of clinical trials in place at proton centers around the country will help salvage the treatment's reputation and move insurance providers and CMS to provide better coverage for proton therapy. They're also hunting for more sustainable solutions to keep centers afloat.

And controversy aside, vendors and physicians report better results and promising experiences in treating a swath of cancers, from challenging breast cancer cases to stubborn liver tumors, for both proton therapy and traditional radiation therapy. Practitioners and OEMs hope results and feedback can dispel any controversy.

Proton proliferation

At time of writing, there are 11 operating proton therapy centers and 17 under development or construction. Proton therapy is popular, despite the fact that building a center can cost upwards of \$100 million — and for the most part, the return on investment is slow.

"Proton therapy is extraordinarily expensive in terms of the equipment, the staff, treatment times — it just doesn't allow for you to get the reimbursements you need to cover a lot of those costs," says Kerstiens. "With the exception of prostate cancer, patient treatment times are very lengthy. So if you're not treating a lot of prostate cancer, it's going to be a challenge to recover your original investment."

Kerstiens says that at some proton therapy centers, prostate treatment makes up 80 to 90 percent of their cases. For Indiana University's center, just 25 to 30 percent of the treatments are for prostate. Many of Indiana's patients are children covered by Medicaid, which provides low reimbursements for the treatment.

Times are even tougher when it comes to for-profit proton therapy centers. ProCure, the largest for-profit chain of proton therapy centers, was in danger of defaulting on a \$30 million loan when it missed an interest payment in December 2012. The center's partner, Cadence Health, agreed to pay \$25 million to buy out the center.

Kerstiens collaborated on a paper describing the further challenges debt-financed proton beam therapy centers will face after ACO implementation, which the report says could reduce daily revenues by up to 32 percent.

In light of these financial challenges, it may come as a surprise that so many proton therapy centers are still in development. Kerstiens says some centers are one-room facilities that have sprouted up to become competition for established centers.

"I've talked with people in Jacksonville who want to put in a one-room center that's going to be 10 miles away from the University of Florida's proton center," says Kerstiens. "It's been my belief that there should be proton therapy centers on a map that should be similar to what you would see if you look for NBA franchises. What we're seeing right now is a structure that won't be sustainable."

Scripps Proton Therapy Center, for one, has partnered up with

several area hospitals to support the new center. The center is slated to open in October.

"I think what we did was unique, but going forward, [working together] is going to be more common because the technology is so expensive," says Chris Van Gorder, Scripps Health president and CEO. "This isn't something where you want to have several sites in one community, or even half a dozen in the state of California."

Van Gorder hopes that future centers will work like more regional hubs where hospitals will allow their physicians to practice.

Clinical trials galore

Meanwhile, proton therapy centers are enrolling patients in clinical trials to help prove the efficacy of various cancer treatments.

"Since we opened in 2006, we've treated about 4,500 patients, and about 97 percent are on an outcome tracking study," says Nancy Mendenhall, medical director of the University of Florida Proton Therapy Institute.

That includes those controversial prostate cases.

"I think a lot of the initial data from that study is from patients who were treated with an earlier form of proton therapy," says Steven Frank, MD, associate professor of radiation oncology at the MD Anderson Cancer Center. "We here at MD Anderson have the most



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novel and newest form of proton therapy, which is intensity modulated proton therapy. It allows us to shape the radiation around the tumor, and avoid the radiation around structures.”

He says he understands why prostate has gotten so much attention, and agrees that proton therapy needs to demonstrate in a randomized trial that it's truly better for patients in order to put the debate to rest.

As the debate on the value of proton treatment for prostate cancer rages on, many centers continue to perform a large volume of head and neck cancer treatments. At Indiana Proton Therapy Center, for one, head and neck treatments make up 55 percent of its patient volume.

In preliminary studies, MD Anderson Cancer Center found a 50 percent reduction in feeding tube use when treating head and neck cancer compared with photon treatment. Randomized trials are in the works.

“There is currently an epidemic in this country of HPV-related head and neck cancer,” says Frank. “These tumors are affecting younger patients who are going to have to live with the side effects of treatments for 40 to 50 years, so proton therapy is ideal for them.”

The same logic follows for pediatric cancer treatment, as children have even longer to live with the effects of radiation.

Help for liver and lung

Other radiation therapy equipment manufacturers and oncologists are working to get treatments like SBRT (stereotactic body radiation therapy), which uses advanced localization and targeting technologies to treat cancer, into more clinical trials.

Early-stage lung cancer, for example, is starting to be treated with SBRT more frequently, says Calvin Huntzinger, senior director of surgical sciences at Varian. Recently, the National Comprehensive Cancer Network and the American College of Chest Physicians have both included SBRT for lung in their national guidelines.

Ironically, the treatment's promising early results may be one factor holding it back from more clinical trials.

Liver cancer is the next disease SBRT will tackle, Huntzinger says. He says that traditional radiotherapy liver cancer treatments had limited success and that treatment options are sometimes limited for frail patients, creating a need for a different, less invasive treatment.

“It's hard to get patients to agree to be randomized between radiotherapy and minimally invasive surgery, for example, when the early evidence for SBRT is so compelling, and they're such different treatment modalities,” says Huntzinger.

He predicts that the increased support for screening of people at high-risk of developing lung cancer may also help drive an increase in SBRT treatment for the disease.

Image-guided treatment is especially useful for lung cancer because tumors move as the patient breathes. Versa HD, released by Elekta in March, includes capabilities that support specialized treatment for patients with breast, prostate and lung cancer, among others. Image-guidance is helpful for some of these lung cancer patients because often these tumors move as the patient breathes. Symmetry technology (part of the Versa HD lung treatment package) helps to manage the tumor motion during respiration, and targets that tumor in a way that minimizes dose to normal tissue during breathing.

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“I think the treatment of liver cancer with SBRT is about where lung was five or six years ago,” says Huntzinger.

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"We've been using it for very complicated breast cancer patients, especially for left sided tumors where you're trying to protect the heart," says Daniel Landis, a practitioner at Swedish Cancer Institute, who uses Accuray's TomoTherapy. TomoTherapy combines CT imaging with radiation treatment to better follow tumors as they move.

Accuray reports that sites are also investigating applicability of the CyberKnife System for breast cancer.

Proton therapy, too, hopes to get in on treating the most common cancer in women.

"One of the things that just came out recently was a large study in breast cancer patients that showed that even low radiation doses to the heart resulted in increased risk of death from heart disease in breast cancer survivors," says Mendenhall of Florida Proton. "Protons are remarkable in their ability to minimize the dose in the heart. Today, breast cancer's not one of the common sites for proton therapy, but it will become one of the most important ones in the future."

Better images and fewer fractionations

As clinical trials continue and debates inevitably break out, OEMs still work to plan for the next stage of radiotherapy. Experts predict that next incarnation will bring MRI-aided therapy into the picture.

Elekta, for one, has a system in the works that Joel Goldwein, senior vice president of medical affairs, says will likely roll out in the next three to five years. He also predicts that improved image-guided techniques will allow physicians to plan and adapt treatment in real time as tumors move.

"As of now, you can make changes to a plan before and after the treatment, but it still takes typically on the order of at least minutes

to re-plan" says Goldwein. "If you see a change, your options are to turn the beam off and wait until the anatomy returns to the planned positions, or move the beam or the patient, but an option today is not to completely build a plan on the fly. That option will come with more robust treatment planning."

He says that the next Gamma Knife will also include image guidance for the first time.

Experts predict that future radiotherapy patients will also spend less time receiving treatments, no matter the disease. Fewer, more intense fractionations will become the norm, Goldwein says.

As in all of health care, radiation therapy is moving towards more patient-centered, catered treatment. Goldwein cites the growing use of informatics in radiation therapy as one of the most important advances that will help the treatments get there.

"You'll combine image-guided treatment with informatics from registries and your own systems that will allow you to select the most appropriate treatment for the patient," he says. "If you asked me what the largest contribution worldwide to improvement in patient care will be, it's the informatics side."

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NYC takes a new approach to proton centers

In New York City, area hospitals have found a unique solution to financially supporting a proton therapy center. Mount Sinai Medical Center, Memorial Sloan-Kettering Cancer Center, Continuum Health Partners, NYU Langone Medical Center, and Montefiore Medical Center -- five systems that are usually major competitors — along with developer 21st Century Oncology, are creating a consortium to build a proton therapy center. It's the only project of its kind in development so far in the U.S., according to VOA Associates, Inc., the architecture firm involved in the project.

The project came about when 21st Century Oncology approached the state to receive "certificate of need" clearance. The state said that it would only approve one center, so the group of hospitals created a proposal that was ultimately cleared.

"They were really ahead of their time because no other jurisdiction has required this," says John Jessen, managing principal at VOA Associates, Inc. "I'm surprised others aren't doing it."



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