PROTON THERAPY:
Can you afford it?

Newer technologies promise to bring proton therapy centers within financial reach of more hospitals. Will they? And perhaps more importantly, should they?

By Brendon Nafziger
This spring, huddled inside a Philadelphia hotel room, proton therapy community leaders listened to a spruce, academic man with a trim beard as he crushed the optimistic projections for the industry.

For the two or three dozen assembled guests, mostly equipment vendors or managers of the handful of proton therapy centers in the United States, the bubble was popped. The United States would not witness the construction of 100 or 200 of the hugely expensive, high-tech cancer treatment rooms, as was previously speculated. It would bear at most 20 to 30 centers over the next decade.

The speaker, Alan Morrison, an investor who had helped arrange funding for proton therapy centers for the past decade with equity group ZAC Capital Partners, said that capital costs had risen too much for the rosiest projections to come true.

"It has been the dream of every radiation oncologist to have access to a proton beam," reads a note by Dr. David E. Wazer, radiation oncologist chief with Tufts Medical Center in Boston, on the website of Still River Systems.

Still River, a startup with a "budget" one-room system in the works, hopes that its lower-cost systems could turn that dream into a reality. The company also hopes to expand access to the technology -- and not just to providers. Sick patients often have to travel across the country to receive proton treatments.

But it's unclear if the lower-cost technology will give every radiation oncologist access to protons. What's more, some critics of proton therapy worry about its spread. A few high-profile academics, executives and researchers fret that proton therapy is driven more by profits than by science, with one influential former health care executive saying the advent of protons signaled a worrisome turn in the industry.

"President Eisenhower warned us about the military-industrial complex," wrote Paul Levy, former CEO of Beth Israel Deaconness Medical Center and author of the popular blog "(Not) Running a Hospital", on a post at Kevin MD last fall. "We have now entered the era of the health care finance industry complex."

Big potential
Although the technology has been around since shortly after World War II, few proton therapy centers exist in the world. Since the first "commercial" center opened at Loma Linda University Medical Center in California in 1990, about nine have been built in the U.S. and 21 or so worldwide. Close to half a dozen U.S. centers are currently in development, but the exact number is disputed, as many projects are what Morrison dubbed "press release projects," announced amidst a fanfare of publicity only to die quietly from neglect.

The draw for protons is that, in principle, the way they work should make them far superior to photons. Like other forms of radiation treatment, proton therapy uses ionizing radiation to scramble the DNA of cancer cells, killing them off. But the benefit of protons is the radiation dose is deposited in what's called the "Bragg Peak," where the dose falls sharply away from the target area, sparing more of the surrounding healthy tissue. This is critical for children, whose bodies are more radiosensitive and who have more years ahead of them in which to develop radiation-induced cancers. But -- and here's where some of the controversy lies -- it should, in theory, at least, also be better for adults with prostate, lung and other solid cancers.

But there's no scientific consensus on any of this. However, waiting for head-to-head studies from different modalities is not the only obstacle to adoption. The main obstacle is cost.

8 out of 9 proton therapy centers prefer...
Cyclotrons and synchrotrons are both types of particle accelerators that use powerful magnetic fields to speed up protons. The cyclotron uses constantly applied magnetic and electric fields to move the proton in a spiral, while the synchrotron increases the strength of the magnetic field to match the change in particle energy (that is, they are "synchronized"). Except for a Hitachi-made synchrotron at M.D. Anderson in Texas, the other eight working proton therapy centers in the U.S. run cyclotrons built by Belgian manufacturer Ion Beam Applications S.A.

Big numbers
The final price tag for all construction, furnishings and equipment for the football-field-sized proton therapy centers in the United States has been between roughly $120 million and $300 million.

A good chunk of the cost is the price of the mammoth, multimillion dollar particle accelerators -- either cyclotrons or synchrotrons -- that fire the protons at nearly two-thirds the speed of light. Further, the beam is often directed by huge, rotating metal devices called gantries. Typically, the accelerator and gantries run about $60 million to $100 million for a center with about four treatment rooms.

ProCure Treatment Centers Inc., a for-profit company which has two centers with four more in the works, has a somewhat cheaper model that uses one gantry and three gantry-less rooms with fixed beams. ProCure said it cuts costs through what could be termed a McDonald's model: the New York City-based company uses prefab construction plans they replicate (down to the office furniture) in every city. Also, the company says using a two fixed-beam system, instead of a gantry, shaves off about half the construction costs. But their most recently opened center, in Illinois, still cost about $140 million.

Another big chunk of the expense comes from the shielding. Cyclotrons need a 12-foot-thick, or one-story-thick, ceiling above them. And walls between treatment rooms are 6- to 8-feet thick. That means a four-room proton therapy center can use up to 15,000 cubic yards of concrete, equivalent to the load carried by 1,800 concrete trucks.

Service -- with a price
Another factor for cyclotron and synchrotron costs is service: according to industry experts DOTmed News spoke with, the proton therapy equipment essentially needs daily maintenance. For instance, most U.S.-sold cyclotrons come
with 10-year service contracts. At many centers, an engineer is almost always on-site; when the doctors and technologists go home for the night, the night-shift engineer is there to recalibrate the machine.

There are other labor costs, too. Radiologic techs and other staff have to be trained on the new machine. This training averages six to eight weeks, at least for ProCure’s staff, who are sent to a training center with a mock unit in Indiana.

Building a center is also a lengthy process—from start to finish, it usually takes nearly two years. In the best case, it’s at least 10 months till building occupancy date (assuming permits acquisition goes smoothly—this varies considerably from state-to-state). Once that happens, the cyclotron-provider—in the U.S., basically Ion Beam Applications S.A.—moves in. They handle all the shipping, crating, installation and set-up through their own subcontractors. This takes, on average, another 14-16 months.

New technology brings it within reach?
However, some developers believe that new technologies might bring proton therapy in reach of more providers. The new technology does this by shrinking the size of the cyclotron or synchrotron and cutting out additional rooms.

Arguably, the two cheapest solutions in the works are one-room solutions. They have estimated total construction and equipment costs at around $20 million, between one-tenth and one-fifth the price of existing three- and four-room U.S. proton therapy centers.

“The future I believe is going to be single room systems, though not necessarily in all cases,” Bill Hansen, director of marketing with IBA, told DOTmed News.

Monarch250
A single-room treatment system designed by the Littleton, Mass.-based startup Still River Systems is among the cheapest known proton therapy options in development. Still River Systems’ cyclotron, dubbed the Monarch250, was developed in collaboration with Massachusetts Institute of Technology physicists. In an interview with Mass High Tech last year, Still River’s CEO Joe Jachinowski said that the superconducting magnet developed with MIT lets them “miniaturize the physics” and build a “much smaller cyclotron.”

Early published figures put the total cost of equipment and construction at only around $20 million. However, Jason Merrill, a spokesman for Barnes-Jewish Hospital in St. Louis, a 1,228 -bed hospital getting the first Monarch250 installed this fall (first-treatment date is next year), said the costs have gone up slightly.

Proteus One
Belgian firm IBA has its own single-room solution in production. IBA said the Proteus One is a very “compact” cy-
clotron, with a short beam line and a smaller gantry so it has a footprint about one-third the volume of other IBA systems. For construction and the complete system—cyclotron, gantry, beam line and software—the company also expects a total cost of $20 million.

“We’ve said that it will be under $20 million to put in a full facility, that includes cyclotron and everything,” IBA’s Hansen said.

Of course, single-rooms systems aren’t the only way to go. A little over twice the cost of the single-room systems but well below current systems is a new synchrotron design by ProTom International.

ProTom’s three-room project
McLaren Health System, a nine-hospital system in Michigan, is building a proton therapy center with ProTom’s tech. Day-to-day work on the site, expected to be finished in the fall, can be seen by anyone thanks to a webcam the hospital set up to record its progress. But that’s not the interesting part. According to McLaren, the cost for the whole center—synchrotron plus construction—is only around $50 million, one-third of the original $168 million estimate when McLaren first announced the project.

Cost savings mostly come from the synchrotron’s smaller footprint, ProTom said. It weighs 15 tons, making it much lighter than a typical 200-plus-ton cyclotron. There’s also less radiation exposure, so less shielding is needed. “The shielding at McLaren at the greatest width is five and a half feet,” ProTom’s CEO Steve Spotts said.

It’s also less of a power hog, and Spotts said the power savings could total “several hundred thousands of dollars” per year.

A matter of economics
But not everyone is convinced by the economic logic of one-room and lower-cost systems. While they might drive down the price of the equipment, they might not truly change the economics of proton therapy, according to skeptics.

“A one-room facility is a bit of a me-too strategy—we’d like to provide it, but we’re not going to make a $200 million bet,” Morrison told DOTmed News by phone.

He said while anything that reduces the capital costs of proton therapy will slightly increase adoption, the “real question is, what are the economics of some of these single-room solutions,” he said. “When you look at the all-in costs of a proton system, the facility and the staffing and all that stuff, and the throughput at least at current numbers, they just don’t work.”

However, he says some smaller hospitals or academic research institutions might take proton therapy up—at a loss—because they think it’s the best treatment and want to offer it to their patients.

But designers of smaller systems counter that with the

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throughput expected – for instance, around 400-500 a year for Proteus One. IBA estimates – they could be economically feasible. “We believe [we won’t be] sacrificing any throughput capacity even with four rooms versus three,” ProTom’s CEO said. “We believe the throughput will be very comparable.”

Should protons expand?

Of course, there remains the question of whether there should be more facilities.

“My basic argument with regard to protons, before they’re generally accepted, they need to be studied,” said Dr. Joel E. Tepper, a radiation oncologist and cancer researcher with University of North Carolina in Chapel Hill, who in 2008 won ASTRO’s prestigious gold medal for contributions to radiation oncology.

Critics contend that proton therapy might be superior to X-ray treatments, but that rigorous comparative studies need to be done to prove it. Others note the medical industry has an interest in promoting more lucrative treatments even if the evidence for their superiority to cheaper ones is lacking.

“In many of these cases, you can argue (and companies do) that the more expensive treatment will prove the better one once all the evidence is in. And sometimes it will. But sometimes it won’t. In the meantime, life-and-death decisions are too often made based not on the best reading of the evidence, but on the best profit margin,” business reporter David Leonhardt wrote in the New York Times last October.

The crux of the argument is that for prostate cancer, Medicare reimburses more for proton therapy than for other radiation therapy treatment methods. The exact reimbursement schedules for the total cost of prostate cancer proton therapy versus other radiation therapy treatments are hard to come by – the Centers for Medicare and Medicaid Services told DOTmed News it tracks physician fees but not the whole cost for a course of treatment.

But estimates have been made. According to a 2009 Forbes article, Medicare pays $34,000 for protons versus $16,000 for X-rays. However, the National Association of Proton Therapy, an industry group, said the difference suggested by that article is exaggerated. The most commonly used radiation therapy technique, intensity-modulated radiation therapy, costs Medicare $42,000, while protons cost about $50,000 for a course of treatment, according to NAPT’s figures.

But other researchers have suggested that the cost-per-quality-adjusted-life-year gained doesn’t justify the slightly pricier treatment. A 2007 article in the Journal of Clinical Oncology by Dr. Andre Koncki, then with the Fox Chase Cancer Center in Philadelphia, used a treatment model to argue that the mean cost of treatment for protons was $65,000 and $39,000 for IMRT, for a 60-year-old man with prostate cancer.

“Even when based on the unproven assumption that protons will permit a 10-Gy escalation of prostate dose compared with IMRT photons, proton beam therapy is not cost-effective for most patients with prostate cancer using the commonly accepted standard of $50,000 [per quality-adjusted-life-year],” the researchers concluded.

This news could put the crunch on centers if CMS increase its scrutiny of expenses and goes through with its vows to promote comparative effectiveness research – tying reimbursement changes to solid evidence that one treatment is better and more cost-effective than another.

“I would say that’s an issue the proton community is dealing with, and there will be, they will have to do more clinical studies,” Leonard Arzt, executive director of the NAPT, told DOTmed News.

But some observers think the evidence for its superiority to other forms of radiation therapy could be hard to obtain, as the effects, while real, could be too small to show up on studies because of limitations on sample size. A 2010 article co-written by Tepper in the Journal of Clinical Oncology, “Technology Evolution: Is It Survival of the Fittest?” suggested that whatever benefits could be had by proton therapy might apply only to “very limited subpopulations” and that the benefits could be “too small to be quantifiable, even in randomized clinical trials with realistic numbers of patients.”

Small after all?

Whatever the case, proton therapy backers note that even if CMS pays more for proton therapy treatment, ultimately, the payments are small when looking at U.S. health care expenses as a whole. They’re even small when looking at just the overall Medicare radiation therapy budget.

In response to Paul Levy’s blog post last year, which worried that the proton industry was the sign of the clout of the “health care-financial complex,” the NAPT said even if there were 15 centers treating at full capacity, “they would only be able to treat 2-2 percent of the entire radiotherapy population in the country. That’s hardly a blip on the total health care landscape.” In other words, for all its huge size and expense – 1,800 concrete trucks! the size of a football field! – proton therapy is relatively modest, the argument goes. After all, proton proponents reason, what is a $200 million center against the $23 trillion spent yearly on U.S. health care?

The makers of the newer, smaller systems are, of course, optimistic, as they have to be. “Short of a complete government takeover of our health care system,” ProTom’s Spotts said, “I believe proton therapy systems will continue to grow.”

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58 DOTmed Business News | MAY 2011

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