Imagine a prostate cancer therapy that has almost no side effects. Hospitals say it exists and they’re vying to be among the first to offer it. Too bad the treatment may not work as well as advertised and could boost America’s already spiraling health-care costs.

The technology uses narrowly focused proton beams to deliver precisely targeted blasts of radiation. The particle beams are delivered by 500-ton machines in facilities that cost from $100 million to $200 million, and can require a football-field sized building to house. A typical treatment costs about $50,000, twice as much as traditional radiation therapy though it is usually covered by Medicare or private insurance.

For U.S. taxpayers and employers facing spiraling health-care costs, that’s a worry.

“Proton-beam therapy is like the death star of American medical technology; nothing so big and complicated has ever been confronted by the system,” said Amitabh Chandra, a health economist at Harvard University’s John F. Kennedy School of Government. “It’s a metaphor for all the problems we have in American medicine.”

Yet even though the machines are breathtakingly expensive, hospitals and for-profit clinics are in a race to build proton-beam facilities for their prestige, perceived benefits, and potential revenue. One machine can generate as much as $50 million in annual revenue and new facilities are sprouting up around the country.

‘Nuclear Arms Race’

“It’s like a nuclear arms race now, everyone wants one,” said Anthony Zietman, a radiation oncologist at Boston’s Massachusetts General Hospital, which has had a proton-beam accelerator since 2001.

Proponents of the technology say it can zap cancerous tumors without damage to surrounding tissue. That’s a major benefit for the relatively small number of people who
suffer from tumors of the spine, brain and eyes, where stray radiation may blind or paralyze, or in children who are more sensitive to radiation.

The therapy has even wider appeal for treating prostate cancer, a much more common disease, since existing treatment often causes rectal bleeding as well as impotence. More than 240,000 American men were diagnosed with prostate cancer in 2011, making it the nation’s most-diagnosed tumor, according to the American Cancer Society. Most of those men are potential candidates for proton-beam therapy.

“The easiest group to market to in the country is a group of men worrying about the functioning of their penis,” said Paul Levy, former head of Beth Israel Deaconess Medical Center in Boston.

Debate Over Results

The problem is that despite the push to build proton-beam facilities and the groundswell of enthusiasm for the treatments, it remains unclear whether the therapy does a better job of shrinking tumors or avoiding side effects than the far less costly traditional therapy. Clinical trials haven’t yet provided a clear picture proving the treatment’s worth for common tumors such as prostate cancer.

Lower rates of impotence, for one, are unlikely from the use of proton therapy because proton and traditional treatments deliver high doses of radiation to the nerves to the penis, Zietman said. So whether the pricey treatments will do a better job managing prostate cancer while also preserving sexual function is an open question.

Deep Into Body

Proton-beam therapy and traditional X-rays are equally effective at killing tumor cells. The debate is over side effects. Proton-beam therapy works by shooting intense, narrow beams into targeted areas of the body. Protons slow down as they travel deep in the body. Doctors can manipulate the speed of the atomic particles, allowing them to deposit most of their radiation as they come to a stop inside a tumor.
X-rays used in conventional radiation therapy are made up of photon beams that zip through a patient, exposing tissues along the way to excess radiation. While modern machines use multiple beams sculpted to intersect and concentrate high doses on a tumor, lower doses are spread over a much larger region.

The proton technology isn’t new, but only in recent years has it caught on. Loma Linda University Medical Center in Loma Linda, California, built the nation’s first hospital proton-beam accelerator in 1990, but the treatment became more viable after the American Medical Association granted proton therapy an insurance billing code in 2000, making reimbursement easier, said Allan Thornton, a radiation oncologist at Hampton University’s proton-beam center, which opened in August 2010. “That brought proton therapy out of the closet,” he said.

**Patient Numbers**

So far, 35,000 Americans have gotten proton-beam treatment and reimbursement payments from Medicare and insurance companies amount to only a small fraction of that paid out for traditional radiation therapy.

In 2010, the most recent year for which figures are available, Medicare spent $41.8 million on outpatient proton-therapy treatments, versus $1.06 billion for standard external-beam radiation.

The amount so far reimbursed for proton-beam therapy is small because most of the 10 existing facilities have been open only a short while. Another 10 facilities are slated to open within the next few years, according to Leonard Arzt, executive director of the National Association for Proton Therapy based in Silver Spring, Maryland. Dozens more hospitals and medical centers have expressed an interest in developing their own proton-beam facilities.

‘More Expensive’

Some experts are concerned that the proliferation of these centers will put yet another heavy burden on the health-care system while providing unclear benefits to most patients. “It is an example of how our health-care system is set up to become more expensive without getting
necessarily better,” said Steven Pearson, president of the Institute for Clinical and Economic Review, a research institute at the Massachusetts General Hospital in Boston.

Ion Beam Applications, based in Louvain-la-Neuve, Belgium, is the leading proton-beam facility manufacturer with eight installed U.S. accelerators. Hitachi Ltd. (6501) of Tokyo and Varian Medical Systems Inc. (VAR) of Palo Alto, California, are among those companies also vying for part of the U.S. market.

The Mayo Clinic is spending $370 million for systems at its campuses in Minnesota and Arizona. In San Diego, Scripps Health is working with Advanced Particle Therapy LLC, a closely held proton-beam developer, on a $220 million facility in the San Diego area that is scheduled to open in 2013 and treat 2,400 patients a year. In New York, a group of five hospitals including Memorial Sloan-Kettering Cancer Center is working on a $250 million plan to build one of the machines adjacent to a planned tower on the Upper East Side.

‘Favorably Reimbursed’

The bottom line for proton centers, said Sean Tunis, chief executive officer of the Center for Medical Technology Policy, and a former Medicare official, is that hospitals can afford to build them because they are “extremely favorably reimbursed” by Medicare and many private payers.

“The finances are favorable to put in a lot of these centers and treat a lot of prostate cancer even though there is no evidence prostate cancer is treated better with it,” he said.

A report on proton therapy done by the U.S. Agency for Healthcare Research and Quality in 2009 suggests the benefits aren’t clear. After studying 243 published articles on the therapy, the group said it found only a handful that compared proton therapy to the standard treatment, and that “no trial reported significant differences in overall or cancer-specific survival or in total serious adverse events.”

Some evidence even suggests that proton therapy may be worse than traditional radiation treatments.
Side Effects

A University of North Carolina study of prostate cancer patients released in February found a somewhat higher rate of bowel side effects with the new machines, and similar rates of impotence and other side effects. While not definitive, the finding may indicate the protons lose precision as they penetrate the body, said lead researcher Ronald Chen, an oncologist at the university’s Lineberger Comprehensive Cancer Center in Chapel Hill, North Carolina.

“Statements about superiority are just unjustified, they are unsupportable,” said W. Robert Lee, a radiation oncologist and prostate cancer specialist at Duke University School of Medicine in Durham, North Carolina. “The bottom line is that it hasn’t been proved to be better.”

Proton-beam proponents aren’t fazed by those who doubt the value of the therapy.

‘Bogus’ Criticism

“Yes, there are critics, but the best minds in the cancer business think otherwise,” said Hampton University president William R. Harvey. He calls the argument that proton therapy may burden the medical system “bogus” because it doesn’t consider the potential cost savings from avoiding side effects.

Thornton, of Hampton’s proton-beam center, said that an as-yet-unpublished study he did found protons will lower rates of rectal bleeding that can occur years after radiation for prostate cancer. “The data is pretty clear,” he said.

In the analysis of 20 previous studies, Thornton and his colleagues found that 7 percent to 9 percent of prostate patients who received standard radiation experienced severe rectal effects, compared with 0.75 percent to 1.5 percent of proton patients who suffered such side effects.

Findings from some published studies show the treatment may reduce the rate of severe rectal side effects to 1 percent or less from the 2 percent to 4 percent rate seen with standard equipment, said Robert Foote, chairman of radiation oncology at the Mayo Clinic in Rochester, Minnesota.
Worth the Cost?

“The question people are really struggling with is ‘is that worth the extra cost?’” he said. The Mayo Clinic, which is building proton systems at its Minnesota and Arizona campuses, won’t use proton therapy for routine prostate cases where less expensive treatments work well, Foote said.

Once built, hospitals and treatment centers tend to keep proton-beam facilities running night and day. The University of Florida’s proton therapy institute in Jacksonville, for instance, treats patients from 6:30 a.m. to 11 p.m., five days a week, said Stuart Klein, its executive director. It generated $45.5 million in patient care revenue in its 2009 fiscal year, according to a tax filing.

“Radiation oncologists have gotten themselves into a trap,” said Zietman of Massachusetts General. “They’ve built very expensive centers, and the only way they can recoup the costs is to treat lots of prostate cancers. A lot of men are going to be channeled into proton therapy, not necessarily to their advantage, at a very great cost.”

Boomerang-Shaped Building

Hampton University is betting proton-beam technology will live up to its promise. Loans from PNC Financial Services Group Inc. and SunTrust Banks Inc. helped cover the $225 million cost of the machine and surrounding building. JPMorgan Chase & Co. managed the sale of $53.9 million in tax-exempt revenue bonds. The center in Hampton, Virginia, may pull in $47.5 million in annual revenue by 2014, according to Harvey, Hampton’s president.

The facility is housed about 7 miles from the university in a giant boomerang-shaped brick building in an office park overlooking a small lake. The glass-walled atrium facing the lake is filled with leather chairs and flat-screen televisions. A long hall goes to treatment rooms.

The guts of the system are hidden behind concrete walls as much as 16 feet thick. A cyclotron, a 200-ton gadget shaped like a giant hockey puck, uses magnets and alternating electric fields to accelerate ionized hydrogen gas to 93,000 miles a second, or half the speed of light.
‘Beam Line’

The protons are then unleashed from the gas down a pipe called a “beam line” and steered by magnets to four treatment rooms containing three-story tall 90-ton devices called gantries. The gantries rotate around the patient to deliver protons from any angle.

Technicians in a control room filled with laptops and flat-screen televisions monitor the beam, adjusting the energy and intensity according to patient treatment plans.

Alfred Scott visited the Hampton facility 44 times for his proton-beam therapy in 2010. When he was diagnosed with prostate cancer in 2009, the 76-year-old Army retiree put off conventional radiation treatment because he feared its side effects. Then he heard about Hampton’s new proton beam, and was one of the first patients treated there. Scott said his cancer is gone with “no adverse effects whatsoever.”

“Everyone who gets prostate cancer should try this,” he said, “There is no doubt in my mind.”

No Easy Answers

That’s music to the fledgling proton-beam industry. Still, the debate, like the broader health-care controversy, is likely to continue.

“We all agree that there is a vast majority of cases it should not be used on,” said William Hansen, director of global marketing for Ion Beam Applications (IBAB) Yet even if protons are only helpful in 1 in 20 cases, “we would have to be building these things as fast as we can.”

It’s not that simple, argues Harvard’s Chandra. “Every time we spend $15,000 to treat a patient with an unproven technology, we effectively decide to spend $15,000 less on our schools, our education, or on money covering the uninsured,” he said. “That tradeoff is something we have never confronted.”

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