Dr. James Cox explains why prostate isn't the end-all be-all for proton therapy

By Carol Ko

Dr. James Cox, professor of radiation oncology at the MD Anderson Cancer Center, says that his interest in proton therapy started when one of his faculty colleagues performed a randomized trial comparing 3-D radiation therapy with old-fashioned 2-D therapy for prostate cancer. He saw that patients receiving the new therapy had a better outcome — or more specifically, in his own words, "a biochemical freedom from relapse."

Around 1998, he successfully proposed building a proton center at MD Anderson — the project broke ground in 2003 and the center treated its first patient in 2006. Back then, there were only three or four proton facilities in the United States.

Yet, even as proton therapy gains traction worldwide, with two more centers slated to be built in the UK alone, its growth in the U.S. faces serious challenges due to the high cost of the treatment and volatile CMS reimbursement coverage. Most industry insiders agree that a sustainable future business model for proton centers will increasingly rely on the engagement and support of private payers.

Worried about declining margins, private payer scrutiny and sustaining a high enough patient volume to make a profit, many proton centers are basing their de facto business model around treating a high number of prostate cancer patients to ensure insurance will cover the cost.

But given that the treatment comes with such a high price tag, many critics have voiced concern that at least some of the hype around proton therapy for prostate may be fueled by a self-serving financial agenda, and that there isn't yet enough clinical data to back up its efficacy compared with other, less expensive alternatives.

While this controversy promises to be a hot topic of discussion at this year's National Association of Proton Therapy conference in March 31st at Washington D.C., Dr. Cox is delivering a talk at the meeting that proposes something even more controversial: he wants to move the discussion away from prostate altogether.

HCBN: I understand that proton therapy in the United States is facing something of a Catch-22: you're at the mercy of private payer coverage and reimbursements, yet Medicare coverage for proton has been very volatile, declining by nearly 32 percent in 2013, following a 15 percent increase in 2012 from 2011 rates. But getting good clinical evidence on the scale needed for coverage is hard to come by with so few proton centers in the country. What are your thoughts on this?

JC: The problem with that is the focus has been proton therapy for cancer of the prostate where there are several other competing strategies for management of early prostate cancer. I wish the arguments in favor of proton therapy were not based on prostate cancer because I think that distorts picture.

HCBN: So if you were to rewrite the script around the argument for proton therapy, what would that sound like?

JC: We've been doing a lot of work in advanced cancer of the lung. I think that's

a promising area. If you have a malignant tumor of the lung it's critical to avoid the normal lung while giving a very high dose to the tumor.

I would rewrite the script starting out with the value and treatment of children. There's very little dispute around the value of proton therapy in treatment of tumors in children when they need radiation therapy. The ability to avoid late effects is so great that if you look at the costs over a lifetime of a young person, by the time they reach 30 years of age you have saved money with proton therapy — you don't cost the system money — you've saved money. There's been mathematical modeling by a Swedish group on this.

Then I would go to tumors in the brain. Brain tumors in children are among the most common malignant diseases after leukemia. The ability to preserve IQ and neurocognitive function and preserve the growth of the skull and the normal brain is paramount, so that's where I would start.

With that recognition then you can say, where else are such issues important? Where there are not really competing strategies for treatment. They tried to treat malignant diseases in childhood with only chemotherapy and when many of those trials were finished they came to the conclusion you can't do away with radiation therapy. So if you do need it, then proton is of great value.

There are also less common tumors like thymomas, in the central part of the chest. Then there are head and neck cancers. Proton therapy can reduce a lot of the acute side effects that make people suffer while receiving radiation therapy with chemotherapy for oropharynx cancer.

I think back to where we were with high energy X-rays four decades ago or more. We're still learning about the best things to do with proton therapy. There may be more indications that become more evident as time goes on, and so that's the future.

HCBN: What do you think is going to be the hottest topic of discussion this year at the conference?

JC: A lot of the people at the conference are going to be talking about cancer of the prostate and as I've already indicated to you, I'm not.

It's hard to say otherwise what the major interest will be. There are certain institutions that don't see many children with cancer and I think it's really notable that St. Jude's hospital in Memphis is installing a proton unit and theirs has to be paid for completely by cash since they don't charge their kids anything for their treatment.

So it's considered of such value there that they are putting a huge investment into proton therapy for an institution that treats only children. And then of course, we treat a lot of children, University of Florida does as well, so major areas where they're going to be treating children for cancer rely a lot on proton therapy.

HCBN: I know that these conferences also focus on ongoing challenges such as patient selection, treatment techniques, and standardization. I was wondering if you could speak to some of these issues.

JC: Proton therapy is a major investment in technology and we have a very large physics group whose expertise we benefit enormously from to make proton therapy more certain.

People in the field always talk about uncertainties. We want uncertainties to drop down to zero. So quality assurance is a major issue in proton centers and how that is managed from one center to another — I hope that will be discussed at the conference. I think there's more variability than I wish, but that's true with standard radiation therapy also.

The technical commitment, the expense of operating a center, and then the case selection — those are the main challenges. There were some centers that justified their \ existence based on the treatment of patients with prostate cancer. It's a way of keeping their center from not losing money. I don't think it's a wise strategy. I do think there are issues to be addressed that are not actually on the drawing boards right now — that is, reimbursements for proton therapy for patients who clearly need it.

HCBN: Can you tell me a little bit more about proton therapy for prostate? Why is focusing on this treatment a losing strategy? Do you think the patients that seek proton treatments for prostate could seek out equivalent, cheaper options?

JC: They're being touted as equivalent options.

For example, what is now euphemistically termed "watchful waiting." The problem is we're not wonderfully adept at predicting which patients are going to progress and which ones are not. We have some biomarkers, but it's far from perfect. Same thing is true in cancer of the breast.

The second option is external radiation therapy with X-rays using a technique called intensity-modulated radiation therapy. The third is radioactive seed implants. The fourth is radical prostatectomy. Those are all options available to men with early cancer of the prostate.

The former head of radiation oncology at Stanford some years ago told me when they first started treating prostate cancer, men from Silicon Valley came to the center already having done their own research and told them what they wanted. Even if somebody said, "you're not a good candidate for our treatment," they said, "fine, I'll go somewhere else."

Right now it is driven by patient preference. I think lots of the men see urologists, and they don't give them much in the way of many other options besides "we need to remove your prostate," and that's why proton therapy seems like an attractive alternative.

The other issue is, there are also men who are not from Silicon Valley who are not adept at making informed decisions influenced by referring physicians. Urologists sometimes hire radiation oncologists and refer patients to them to get intensity-modulated radiation therapy, developing practices where urologists and radiation oncologists work together — it's become a vast referral problem that's made its way to Congress.

Essentially, the prostate issue distracts people from thinking about the greatest value of proton therapy and I think we need to shy away from that. Let's not spend 50 percent of the conference or even a huge percentage of the conference discussing something that's controversial and people are going to give their opinion instead of educating or providing new facts or information.

In these other areas I was mentioning, there are a lot of other things going on, especially in head and neck, or in the thorax.

I have become an advocate for proton therapy not because of money or hype, but because of the scientific evidence that supports it. Avoiding normal tissues while giving higher doses to the tumor by whatever techniques you choose — those things are of immense medical value.

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