

Trial Results Support SBRT as a Standard Option for Some Prostate Cancers

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Some men receiving radiation therapy for prostate cancer can have their treatment compressed into just 5 sessions, compared with the minimum of 20 that is often used, according to [results from a large clinical trial](#).

Most trial participants had [prostate cancer](#) that was at intermediate risk of coming back (recurring) after treatment. Men who received the shortened treatment, called [stereotactic body radiotherapy \(SBRT\)](#), did not have a higher risk of cancer recurrence over the next 5 years than men treated with other commonly used radiation therapy regimens given over 4 to 8 weeks, the study found.

Results from the study were published October 16 in the New England Journal of Medicine.

SBRT very precisely targets radiation to the tumor while minimizing exposure to normal tissue, allowing for the delivery of a much higher radiation dose per session and, therefore, far fewer treatment days.

Trial participants who were randomly assigned to receive SBRT had a higher risk of developing some urinary problems over the first 2 years after treatment than men randomly assigned to the standard radiation therapy group, but over time this difference disappeared. And the urinary problems, primarily a frequent need to urinate, can be well controlled with medications, said Nicholas van As, M.D., of the Royal Marsden Hospital in the United Kingdom, who led the trial.

"[These side effects] are short-lived. For the great majority of men, they disappear," he said.

"These data support the use of SBRT as a [standard of care](#) for intermediate-risk prostate cancer," said Krishnan Patel, M.D., a radiation oncologist from NCI's Center for Cancer Research, who was not involved with the trial. "But ... it still may not be for everyone."

Some people who may not be good candidates for SBRT include patients with larger prostate glands or those who already have substantial urinary problems, which could be made worse by

SBRT, Dr. Patel explained. Additionally, many men with low-risk prostate cancer might now choose [active surveillance](#) at first, instead of either radiation therapy or surgery.

The new study's results support a shift in radiation therapy for prostate cancer that has been underway in the United States, said Dakim Gaines, M.D., Ph.D., a radiation oncologist from Vanderbilt-Ingram Cancer Center, who was not involved in the trial.

Results from earlier studies have suggested that neither of the two treatment schedules [are worse at controlling cancer than the other](#). So, radiation oncologists at his hospital and elsewhere have been using SBRT to treat patients with low- and intermediate-risk prostate cancer for years, Dr. Gaines said. "It's extremely convenient to be able to shrink your treatment from about 5 and a half weeks to about a week and a half."

Excellent cancer control, both with SBRT or longer treatment

Until fairly recently, radiation therapy for prostate cancer was given 5 days a week for 8 weeks or even longer, for a total of about 40 treatment sessions.

Over the last decade, however, studies have shown that this treatment could safely be compressed, with each of 20 sessions using a slightly larger than normal dose of radiation—a strategy called [hypofractionation](#).

Using SBRT to cut the number of treatment sessions further, from 20 down to 5, is not only more convenient but also has the potential to greatly reduce the cost of treatment for both hospitals and patients, said Dr. van As. But it had to be confirmed that a 5-day course of SBRT was not worse at controlling cancer than standard radiation therapy and also that it does not come at the cost of unacceptably high side effects.

The trial, called PACE-B, was primarily funded by Accuray, a manufacturer of SBRT equipment, through the Royal Marsden NHS Foundation Trust. It enrolled 874 participants from hospitals in the United Kingdom, Ireland, and Canada. About 92% of participants had intermediate-risk prostate cancer and 8% low-risk, and none received [hormone therapy](#) in addition to radiation therapy. Participants had a median age of about 70 years.

Men in the trial were randomly assigned to receive SBRT or the standard radiation therapy regimen used at the center where they received treatment: hypofractionated (20 sessions) or conventional (39 sessions).

After a median follow-up period of just over 6 years, about 95% of men in both treatment groups remained alive without a recurrence of their cancer, demonstrating that SBRT was not worse than conventional radiation therapy.

No differences in bowel problems or sexual difficulties were seen between the groups. At 5 years after treatment, less than 1% of men in both groups reported bowel problems. This number would

likely be even lower in men in the United States, explained Dr. Gaines, since U.S. hospitals use protective equipment called rectal spacers to reduce the potential damage to that region during SBRT.

About 10% of participants in both groups reported gastrointestinal problems, and about a quarter reported some degree of erectile dysfunction.

Over the 5 years of follow-up, a total of 27% of men in the SBRT group and 18% in the standard radiation therapy group reported urinary problems. However, this difference was largely seen right after treatment. The higher number of urinary problems in the SBRT group went away after 2 years, with similar numbers of men in both groups reporting irritation and an increased sense of urgency to urinate towards the end of the study.

More studies ongoing, more training required

An ongoing NCI-funded clinical trial called [NRG GU005](#) is comparing SBRT with [hypofractionated radiation therapy](#) for intermediate-risk prostate cancer, with early results about side effects expected next year, said Dr. Patel.

Neither trial applies to men with high-risk prostate cancer, Dr. Patel added. Another ongoing trial, called PACE-C, is testing SBRT with hormone therapy versus standard hypofractionation with hormone therapy in men with higher risk of disease recurrence, but no results have been released to date.

An additional unanswered question is whether some of the men at lowest risk of recurrence in the PACE-B trial could have postponed treatment.

“I think most of the men in the study required treatment. But there will have been [some] who could have had active surveillance, which wasn’t as widely accepted when the trial started,” said Dr. van As.

Another issue going forward will be ensuring access to SBRT as it was performed in PACE-B. Highly specialized radiation machines specifically designed for SBRT, including the CyberKnife device, were used in some of the treatment centers that participated in the trial, Dr. van As explained. However, SBRT can be delivered with most modern radiation therapy machines as well, he added.

Dr. Gaines’s center uses a standard [linear accelerator](#), or LINAC, to deliver SBRT, he explained. “We don’t have a CyberKnife, and we’ve been doing this [safely] for years,” he said.

But to ensure broader access to SBRT, Dr. van As said, “doctors will need training, physicists will need training, radiologists will need training,” he added.

Some U.S. hospitals won’t have the training yet to do this type of SBRT, Dr. Gaines said, but men in such situations shouldn’t feel like they’re getting worse treatment with a longer radiation

therapy schedule. “That may be less convenient, but it’s equally good in terms of cancer control,” he said.

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<http://beta.docker.cancerhealth.com/blog/trial-results-support-sbrt-standard-option-prostate-cancers>