

Study questions proton therapy for prostate cancer

February 1 2012, By MARILYNN MARCHIONE, AP Chief Medical Writer

A warning to men considering a pricey new treatment for prostate cancer called proton therapy: Research suggests it might have more side effects than traditional radiation does.

A study of Medicare records found that men treated with proton beams later had one-third more bowel problems, such as bleeding and blockages, than similar men given conventional <u>radiation</u>.

This is an observational study so it is not definitive, but it is one of the largest to compare these treatments. <u>Proton therapy</u> is rapidly growing in use - Medicare covers it - even though no rigorous studies have tested whether it is as safe or effective as usual care.

It costs around \$48,000 - at least twice as much as other prostate radiation treatments. Hospitals are rushing to build proton centers, and nine are operating now - sites include Boston, Chicago, Houston, Philadelphia, Jacksonville, Fla., and Loma Linda, Calif., east of Los Angeles. Promoters often claim it is less likely to cause complications.

"There's no clear evidence that proton therapy is better" for <u>prostate</u> <u>cancer</u>, and the new results suggest it may cause more complications, said Dr. Ronald Chen, a radiation specialist at the University of North Carolina, Chapel Hill.

He led the study and will give results at a medical meeting in San



Francisco later this week. They were discussed Tuesday in a telephone news conference sponsored by the <u>American Society of Clinical</u> <u>Oncology</u> and two other cancer groups.

Proton therapy uses proton particles instead of X-rays. In theory, it targets radiation more directly to tumors and spares healthy tissue, which should lead to fewer side effects. Its value is established for treating eye and certain pediatric tumors. But it often is marketed for prostate cancer - a far more common condition.

Researchers checked Medicare records on more than 12,000 men treated for early-stage prostate cancers from 2002 through 2007. Follow-up information was available for four years on average.

First they compared an older version of external beam radiation to a newer form that now dominates the field - intensity-modulated radiation therapy, or IMRT. It, too, targets radiation more precisely to the prostate, and this is the first large study to show it was better than the older method - even though it came into use a decade ago.

"We found that patients who were treated with IMRT required fewer additional treatments after radiation which indicates better cancer control," Chen said. There also were slightly fewer bowel problems, although there also were slightly more sexual problems among men treated with IMRT.

A second part of the study compared 684 men with proton therapy to a similar group treated with IMRT. There were 18 cases of bowel problems for every 100 proton therapy patients per each year of follow-up versus 12 such problems for those treated with IMRT.

"That's a red flag," said Dr. Bruce Roth, a cancer specialist at Washington University in St. Louis who is involved with the cancer



conference but had no role in the study.

It's too soon to know whether proton therapy will prove more effective to justify higher <u>side effects</u>, but seeing this difference so soon in its use is troubling, he said. Doctors don't want a repeat of the IMRT experience, "where it becomes the new standard of care without that comparative data," he said.

The federal Agency for Healthcare Research and Quality paid for the study, which included researchers from the National Cancer Institute. The government also is paying for a definitive study to compare proton therapy to other types.

It "clearly is a promising therapy," but it has not yet shown an advantage for treating prostate cancer, said Dr. Jason Efstathiou of Massachusetts General Hospital, who will lead the new study.

Early results from patients at his hospital suggests there are fewer complications in the first six months after proton therapy, but "maybe this is a short-term advantage" that disappears or does not occur at every hospital using it, he said.

Only a rigorous study will tell. It starts this summer and will give results in three to five years.

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Citation: Study questions proton therapy for prostate cancer (2012, February 1) retrieved 9 May 2024 from <u>https://medicalxpress.com/news/2012-02-proton-therapy-prostate-cancer.html</u>

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