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From the Los Angeles Times

Localized prostate cancer rarely helped by hormone therapy

Medical castration to treat such tumors doesn't extend survival, and its side effects outweigh any potential benefit, a study finds.

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Medical castration to treat localized prostate tumors does not prolong survival and its side effects far outweigh any potential benefit for most patients, researchers reported today.

The technique, which involves using drugs to block the body's production of the male hormone androgen, is a powerful tool when used in conjunction with surgery or radiation for treating aggressive prostate tumors.

Many oncologists had assumed this treatment could be of benefit with localized tumors as well, and the use of the drugs surged a decade ago, with an estimated 30% to 50% of such patients receiving the therapy.

But its use has fallen in the last five years because of changes in Medicare's reimbursement policy, and some experts think this new finding might spell the end for the treatment.

"This study suggests that physicians who recommend hormonal therapy for localized tumors are not doing their patients any favors," said Dr. Howard M. Sandler, a radiation oncologist at the University of Michigan Medical School who spoke as a representative of the American Society of Clinical Oncology.

"I hope that it does change clinical practice and that fewer men do receive primary hormonal therapy," he said.

Added Dr. Matthew B. Rettig, an oncologist at UCLA's Jonsson Comprehensive Cancer Center, "There is no clear data that has ever shown that patients with early-stage disease benefit from primary hormone therapy . . . and this is further evidence to support that."

One in six American men will be diagnosed with prostate cancer during his lifetime. An estimated 186,000 new cases will occur this year, with nearly 29,000 deaths.

An estimated 85% of newly diagnosed prostate tumors are localized, so-called stages T-1 and T-2. Guidelines promulgated by national organizations recommend one of three approaches for treating such tumors: surgical removal, radiation therapy or expectant management, better known as watchful waiting.

The rationale for watchful waiting is that most of these tumors grow so slowly that an elderly patient is likely to die of something else before the tumor kills him.

"A lot of men think radiation and surgery are too aggressive, but observation sounds like you are not doing enough," said Dr. Siu-Long Yao of the Cancer Institute of New Jersey, who led the new study. Hormonal therapy, which sounds rather benign, "has become the second-most popular treatment after surgery, surpassing radiation," he said.

But it has dramatic side effects, including a 10% to 50% increase in the risk of fractures, diabetes, heart disease and sudden cardiac death; a 500% increase in hot flashes; and a 267% increase in impotence. It also has adverse effects on fats and cholesterol and causes enlargement of the breasts.

It is also expensive. Treatment with such drugs as leuprolide (Lupron, Viadur, Eligard), goserelin (Zoladex) and triptorelin (Trelstar) peaked at more than \$1.23 billion in the U.S. in 2003, the second-highest Medicare Part B drug expenditure that year.

Yao and his colleagues used national databases to collect information on 19,271 men -- who had a median age of 77 and were diagnosed with localized prostate cancer between 1992 and 2002 -- and followed them through 2006. About 41% received only primary hormonal therapy and the rest were merely observed.

The team reported in the Journal of the American Medical Assn. that the 10-year death rate from prostate cancer was 17.4% in those receiving no therapy, compared with 19.9% in those receiving hormonal therapy. There was, however, no difference between the two groups in deaths from all causes.

There was a slight benefit from the therapy for men who had what are known as poorly differentiated tumors, which are generally more aggressive. About 40.2% of the men with those tumors who received hormonal therapy died of prostate cancer, compared with 45.7% of those who received no treatment. No effect on deaths from all causes was seen, however.

Earlier studies seemed to show that the less advanced a tumor was at diagnosis, the less benefit there was from hormone therapy.

The therapy started to fall out of favor after the Medicare Act of 2003 reduced reimbursement for it by about 50%, according to a recent study by researchers at the Cleveland Clinic.

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