MULTI-CENTER STUDY IDENTIFIES TREATMENT FOR ADVANCED VULVAR CANCER

SAN ANTONIO – A large, multi-center study has shown that combining chemotherapy and radiation gives patients who have advanced vulvar cancer with unresectable lymph nodes their first chance to become eligible for potentially curative surgery.

“This is the first study to document an improvement in outcome using a protocol for treating unresectable lymph node disease,” said Dr. Gustavo Montana, principal investigator of the study, professor in the department of radiation oncology at Duke University Medical Center and a member of the Duke Comprehensive Cancer Center in Durham, N.C.

Previous smaller studies have examined radiation alone or with chemotherapy, but only for patients with less advanced vulvar cancer. Until now, there had been no attempt to use these techniques to help treat patients whose lymph nodes couldn’t be surgically removed, or respected.

In the current study, the combined chemotherapy and radiation regimen shrunk tumors and made possible surgical removal of initially unresectable lymph nodes in 95 percent of the patients. Almost half of the patients are still free of disease or were so when they died from non-cancer related causes. Without surgical removal of the cancerous lymph nodes, life expectancy is less than two years, the researchers said.

The results of the study were prepared for presentation today (Nov. 3) at the annual meeting of the American Society for Therapeutic Radiology and Oncology.

“I think the results of this study are going to make this approach standard treatment for patients with carcinoma of the vulva with or without unresectable lymph nodes,” Montana said. “Some patients even had no evidence of tumor after the combination treatment.”

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In patients with vulvar cancer, palpable lymph nodes in the groin region are considered cancerous. Cancerous nodes that seem fixed in place and are not mobile are considered unresectable because surgery alone is not beneficial.

The study, carried out from 1989 through 1994 and run by the Gynecologic Oncology Group (GOG), a cooperative, multi-center research group, accepted patients with advanced vulvar cancer with or without unresectable lymph nodes. Two 2-week cycles of radiation combined with chemotherapy were spaced 2-3 weeks apart and followed by four to eight weeks of recovery before surgery.

For the 73 patients with resectable lymph nodes who were treated as part of this study, results published in 1998 showed that the chemotherapy plus radiation treatment allowed less radical surgeries to be performed. The new findings are from 46 patients diagnosed with unresectable lymph nodes.

Carcinoma of the vulva is a relatively rare disease, with just 0.5 to 2 cases per 100,000 adult women. However, the risk increases dramatically with age, and occurs in 20 of 100,000 women over the age of 70. Traditional treatment is radical vulvectomy and surgical removal of the nearby inguinal lymph nodes, if possible. However, something better was needed, said Montana.

“This surgery can have a serious impact on a patient’s quality of life and self-image,” he said. “We wondered if we could treat patients with advanced carcinoma of the vulva in a way that is less mutilating and offers a chance of a cure. We have.”

While they hoped the radiation and chemotherapy combination would shrink tumors, they were worried about how well their experimental treatment would be tolerated because of the patients’ age and disease.

“It’s difficult to accrue enough patients to carry out studies on rare diseases even without such deaths, said Montana. For vulvar cancer, it is “impossible” to carry out a study like this one without a group like the GOG, he said. The GOG consists of about 70 institutions, and over the past 25 years or so has carried out numerous landmark studies in cancers of the female reproductive system.

In the current trial, of the 46 initial participants with unresectable lymph nodes, four patients did not complete the combined chemotherapy plus radiation, and two patients who completed the combination treatment died of non-cancer related causes before surgery. In two of the remaining 40 patients, the lymph nodes remained unresectable following the combination treatment. The lymph nodes in 38 of the 40 patients became resectable due to the treatment, but one of the 38 patients had the cancer spread to the lungs, so the lymph nodes weren’t removed.

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The chemotherapy and radiation regimen resulted in four complete remissions of the primary tumor, and the majority of primary tumors and about a third of involved lymph nodes appeared negative for cancer when tissue was examined under a microscope. Including those patients who had no evidence of disease at their deaths, 19 have remained disease-free, with follow-up ranging from 5 to 80 months.

Even though the current method showed a dramatic effect, the research cooperative is continuing to refine its treatment to offer the maximum possible benefit.

Co-authors on this study were Gillian Thomas of the Toronto-Sunnybrook Cancer Centre in Toronto; David Moore of the Indiana University Medical Center, Indianapolis; Angie Saxer of the Gynecologic Oncology Group, Buffalo, N.Y.; Charles Mangan of the Eastern Pennsylvania Gynecologic Oncology Cancer Center, Philadelphia; Samuel Lentz of Wake Forest University School of Medicine, Winston-Salem, N.C.; and Hervy Averette of the University of Miami.

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