By DENISE GRADY

Many women with early-stage breast cancer who would receive chemotherapy under current standards do not actually need it, according to a major international study that is expected to quickly change medical treatment.

“We can spare thousands and thousands of women from getting toxic treatment that really wouldn’t benefit them,” said Dr. Ingrid A. Mayer, from Vanderbilt University Medical Center, an author of the study. “This is very powerful. It really changes the standard of care.”

The study found that gene tests on tumor samples were able to identify women who could safely skip chemotherapy and take only a drug that blocks the hormone estrogen or stops the body from making it. The hormone-blocking drug tamoxifen and related medicines, called endocrine therapy, have become an essential part of treatment for most women because they lower the risks of recurrence, new breast tumors and death from the disease.

“I think this is a very significant advance,” said Dr. Larry Norton, of Memorial Sloan Kettering Cancer Center in New York. He is not an author of the study, but his hospital participated. “I’ll be able to look people in the eye and say, ‘We analyzed your tumor, you have a really good prognosis and you actually don’t need chemotherapy.’ That’s a nice thing to be able to say to somebody.”

The findings apply to about 60,000 women a year in the United States, according to Dr. Joseph A. Sparano of Montefiore Medical Center in New York, the leader of the study.

“The results indicate that now we can spare chemotherapy in about 70 percent of patients who would be potential candidates for it based on clinical features,” Dr. Sparano said.

But Dr. Sparano and Dr. Mayer added a note of caution: The data indicated that some women 50 and younger might benefit from chemo even if gene-test results suggested otherwise. It is not clear why. But those women require especially careful consultation, they said. (Most cases of breast cancer occur in older women: The median age at diagnosis in the United States is 62.)

The study, called TAILORx, is being published by The New England Journal of Medicine and was to be presented on Sunday at a meeting of the American Society of Clinical Oncology in Chicago. The study began in 2006 and was paid for by the United States and Canadian governments and philanthropic groups. Genomic Health, the company that makes the gene test, helped pay after 2016.

This year, about 260,000 new cases of breast cancer are expected in women in the United States, and 41,000 deaths. Globally, the most recent figures are from 2012, when there were 1.7 million new cases and more than half-a-million deaths.

Chemotherapy can save lives, but has serious risks that make it important to avoid treatment if it is not needed. In addition to the hair loss and nausea that patients dread, chemo can cause heart and nerve damage, leave patients vulnerable to infection and increase the risk of leukemia later in life. TAILORx is part of a wider effort to fine-tune treatments and spare patients from harsh side effects whenever possible.

Endocrine therapy also has side effects, which can include hot flashes and other symptoms of menopause, weight gain and pain in joints and muscles. Tamoxifen can increase the risk of cancer of the uterus.

Patients affected by the new findings include women who, like most in the study, have early-stage breast tumors measuring one to five centimeters that have not spread to lymph nodes; are sensitive to estrogen; test negative for a protein called HER2; and have a score of 11 to 25 on a widely used test that gauges the activity of a panel of genes involved in cancer recurrence.

The gene test, called Oncotype DX Breast Cancer Assay, is the focus of the study. Other gene assays exist, but this one is the most widely used in the United States. It is performed on tumor samples after surgery, to help determine whether chemo would help. The test is generally done for early-stage disease, not more advanced tumors that clearly need chemo because they have spread to lymph nodes or beyond.

The test, available since 2004, gives scores from 0 to 100. It costs about $3,000,
and insurance usually covers it. Previous research has shown that scores 10 and under do not call for chemotherapy, and scores over 25 do.

But most women who are eligible for the test have scores from 11 to 25, which are considered intermediate.

**A Landmark Study for Early-Stage Cases**

“This has been one of the large unanswered questions in breast cancer management in recent times, what to do with patients with intermediate scores,” Dr. Norton said. “What to do has been totally unknown.” He added, “A lot of patients in that range are getting chemo.”

Dr. Sparano said many patients have been receiving chemo because in 2000 the National Cancer Institute recommended it for most women, even those whose disease had not spread to lymph nodes, based on studies showing it could prevent the cancer from recurring elsewhere in the body and becoming incurable.

“Recurrences were being prevented, and lives prolonged,” Dr. Sparano said. “But we were probably overtreating a lot of these women. For every 100 women we were treating, we were probably preventing about 4 distant recurrences.”

Dr. Mayer said, “We couldn’t figure out who we really needed to treat.”

The availability of the gene test in 2004 helped researchers sort out women with very high or very low risk.

“But we really didn’t know what to do with women in the middle,” Dr. Mayer said. “Some seemed to benefit and some didn’t. We were back to square zero, safe rather than sorry, giving chemo to a lot who didn’t need it.”

Data began to emerge suggesting that women in the middle were not being helped by chemo, and many doctors began recommending it less often. But a definitive study was needed, which is how TAILORx came about.

The study began in 2006 and eventually included 10,253 women ages 18 to 75. Of the 9,719 patients with complete follow-up information, 70 percent had scores of 11 to 25 on the gene test. They had surgery and radiation, and then were assigned at random to receive either endocrine therapy alone, or endocrine therapy plus chemo. The median follow-up was more than seven years.

Over time, the two groups fared equally well. Chemo had no advantage. After nine years, 93.9 percent were still alive in the endocrine-only group, versus 93.8 percent in those who also got chemo. In the endocrine group, 83.3 percent were free of invasive disease, compared with 84.3 percent who got both treatments. There were no significant differences.

But the researchers wrote that the chemotherapy benefit varied with the combination of recurrence score and age, “with some benefit of chemotherapy found in women 50 years of age or younger with a recurrence score of 16 to 25.”

Bari Brooks, 58, a patient of Dr. Mayer’s from White House, Tenn., learned from a mammogram that she had breast cancer in 2009 when she was 49. Dr. Mayer told her she was a candidate for chemotherapy, and also for a study — in which she might or might not get chemo.

Could she handle the risk of missing out on a treatment that might save her life? Or the risk of side effects that might be needless?

“It wasn’t even a decision I had to think about,” said Ms. Brooks, who works in human relations for Vanderbilt University. “It was yes, I want to do it.” She added: “You realize how insignificant everything is. Money, it doesn’t matter how much you have. Work, what projects you have, it doesn’t matter. What have I contributed in my life and what do I want to contribute? This was a situation where I could also contribute. I was honored and grateful to be part of it.”

She decided that if she was assigned to chemo, “I would approach it that I was being cleansed rather than poisoned.”

She did land in the group that got both chemo and endocrine therapy. Did the chemo help? Maybe, maybe not. She has no regrets. And no evidence of cancer.

Dr. Mayer said that Ms. Brooks’ philosophical attitude was not unusual, and that women who signed up for studies understood they were taking a leap of faith and might wind up getting the ‘wrong’ or less desirable treatment.

“They’re grateful that they helped to advance knowledge for other women,” Dr. Mayer said. “I never underestimate how nice and how altruistic people can be. Women look out for each other.”