How the Investment Industry Tries to Tap into Researchers’ Inside Information

Although confidentiality agreements are in place for industry trials, financial analysts may try to skirt the legality by asking for just “critical insights” or “impressions” of where a trial is going, and after several such interviews, there may be enough of a picture to manipulate the market. And although physicians themselves may not be technically guilty of insider trading, a case could be made that they are at least aiding and abetting the practice.

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By Devon Schuyler

Previous research has shown that a substantial percentage of women with early-stage breast cancer stop chemotherapy early. Now, a new study suggests that such undertreatment affects survival, and that premature termination of chemotherapy and death are both more common among black women than among their white counterparts.

“This was the first study to find a relationship between early termination of chemotherapy and survival, and also the first to show that black women are more likely than white women to terminate early,” said lead researcher Dawn Hershman, MD, MS, Assistant Professor of Medicine and Epidemiology at Columbia University.

The study found that 23% of white women vs 31% of black women stopped treatment prematurely. Those who halted treatment early were more likely to die than those who completed treatment, and black women were more than twice as likely to die as white women.

Researchers already know that black women are more likely than white women to die of breast cancer, despite having a lower incidence of this disease.

"Physicians should encourage their patients to stick with treatment. Patients really need a full course of therapy."

Two of the factors contributing to this inequality are that black women tend to present with later-stage disease, and that their tumors are more likely to have unfavorable characteristics, such as negative estrogen receptor (ER) status, high nuclear grade, and high S-phase fraction.

But significant differences in survival persist even after controlling for these factors, which is one of the reasons Dr. Hershman and her colleagues decided to look at treatment factors. The results were published in the September 20 issue of the Journal of Clinical Oncology (2005;23:6639-6646)

Study Design

The study included 472 women from the Henry Ford Health System tumor registry who were diagnosed with Stage 1 or 2 breast cancer between 1996 and 2001 and who received adjuvant chemotherapy.

Billing records were used to identify the type of chemotherapy received, the number of cycles, and the duration of treatment. Patients were excluded from the analysis if they were being treated for a recurrence, if they had received neoadjuvant chemotherapy, if the chemotherapy record was incomplete, or if their treatment was not listed in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology.

The researchers used the NCCN guidelines to define how long treatment should last, and defined treatment as complete if the patient received at least 85% of the expected number of cycles. Treatment delays were defined as delays of at least a week.

A total of 472 of the women in the analysis (43%) were black and 270 (57%) were white. The researchers found that only 72% of the women received the full course of treatment, and that only 41% of these received all their treatments without delay.

Delays did not appear to reduce survival as long as all treatments were received, but the study authors note that the statistical power of this finding is limited by the small number of deaths.

Women age 50 and older; black women; women with Stage 2 cancer; and those with comorbid conditions, such as arthritis, diabetes, and chronic obstructive pulmonary disease, were most likely to stop treatment early.

Black women were more likely than white women to have Stage 2 disease, ER-negative tumors, higher tumor grade, and incomplete treatment.

Being black, receiving 75% or less of the expected number of cycles, being age 50 or older, having ER-negative tumors, and having comorbid conditions were associated with shorter survival.

All of the women in the study had health insurance, with 25% covered by a health maintenance organization or preferred provider organization—74% covered by the Henry Ford Health Plan and 1% by Medicaid alone. No association was found between insurance coverage and race, early termination of treatment, or survival.

Generalizability

Asked to comment on the study, Sue A. Joslyn, PhD, Professor of Epidemiology and Associate Dean of Graduate and Academic Affairs at the University of Northern Iowa, said that the study was very well done, with a good sample size and complete, accurate follow-up.

Still, she added, “The population in this study may have had a higher socioeconomic status than the general population, which limits how far you can generalize the results. Although receiving the full dose of chemotherapy could reduce racial disparities in mortality, it would not eliminate them.”

Dr. Joslyn said that investigating the reasons for these disparities should be a continuing priority for breast cancer researchers, and suggested that a good follow-up study would be one that looked at the reasons people discontinue chemotherapy.

Dr. Hershman and her colleagues are planning just such a study. The group has received funding from a Department of Defense Center of Excellence Award to conduct a large, collaborative study that will look at a number of different factors that may contribute to initiation and completion of adjuvant chemotherapy and hormonal therapy.

Now underway is a large, collaborative study that will look at a number of different factors that may contribute to initiation and completion of adjuvant chemotherapy and hormonal therapy.

“Identifying barriers to optimal treatment will enable us to intervene to help women adhere to therapy, reduce racial disparity, and improve survival in all women with breast cancer,” Dr. Hershman said.

Alfred I. Neugut, MD, PhD, Professor of Medicine and Epidemiology, Columbia University, who was part of Dr. Hershman’s research team, said that the study underscores the importance of completing chemotherapy.

“Just as before, physicians should encourage their patients to stick with treatment,” he said. “Patients really need a full course of therapy.”

Dr. Zhuang said FDG-PET would most likely be used in conjunction with different imaging modalities for a truer picture of infection.

He added that FDG has been used in PET imaging for more than 20 years, but only in the past seven or eight has it become popular for diagnosing malignancies because it is now reimbursed by Medicare and private insurers.

“But it is still rarely used to detect infection,” he said, again mainly because of lack of insurance coverage.

Clinical Oncology (2005;23:6639-6646)