



Kaiser Permanente Press Release: Kaiser Permanente Research: Study of Early Stage Breast Cancer Patients Identifies Women at Low Risk of Breast Cancer Mortality

21-gene test predicts mortality risk in epidemiological study

SAN ANTONIO - Kaiser Permanente researchers are presenting results of a large epidemiologic study of a unique breast cancer test at the 27th Annual San Antonio Breast Cancer Symposium. The KP study shows the test can identify patients with early stage disease who are at low risk of breast cancer death at 10 years.

Researchers at Kaiser Permanente designed a population-based, case-control study that evaluated node-negative, non-chemotherapy-treated breast cancer patients diagnosed between 1985 and 1994 at 14 Northern California Kaiser hospitals. The study among KP members (790 cases and controls) included many patients with small tumors, as seen in current practice - more than 30 percent had tumors less than or equal to 1 cm in size.

The results of the study showed a strong and graded association between the Oncotype DX "Recurrence Score" and 10-year breast cancer mortality ($p < 0.001$). These new results in a community-based patient population representing approximately one percent of the U.S. population were similar to those from the large clinical validation trial conducted previously by the National Surgical Adjuvant Breast and Bowel Project (NSABP).

"Our study is significant because it reinforces the NSABP validation study findings but in a community-based patient population," said Laurie Habel, Ph.D. leader of the Northern California Kaiser Permanente study. "The results demonstrate a strong and graded association with breast cancer mortality.

Using quantitative RNA analysis of tumor tissues, the study evaluated the Oncotype DX breast cancer assay and compared its use with standard measures of tumor size and tumor grade. The assay provided information that goes beyond tumor size and tumor grade. In addition, the assay identifies a large proportion of women who have a very low risk (less than 3 percent) of breast cancer death at 10 years.

The Kaiser study is one of the first to evaluate a multi-gene panel in a large community-based cancer patient population. The assay, Oncotype DX, used in this study includes 21 genes related to the estrogen receptor, HER2, proliferation and invasion as well as several other carcinogenic pathways. Oncotype DX assay has been developed and validated by Genomic Health in multiple independent studies involving over 2,600 patients. Kaiser Permanente's study was sponsored by Genomic Health Inc.

Kaiser Permanente has research departments in California, Oregon, Hawaii, Georgia, Colorado, Maryland, and Ohio. Results of research conducted by Kaiser Permanente physicians and investigators have been published in the Journal of the American Medical Association, the New England Journal of Medicine, the Permanente Journal, the American Journal of Public Health, Pediatrics, and other clinical journals.

Kaiser Permanente is America's leading integrated health plan. Founded in 1945, it is a not-for-profit, group practice prepayment program with headquarters in Oakland, California. Kaiser Permanente serves the health care needs of over 8.3 million members in 9 states and the District of Columbia. Today it encompasses Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals and their subsidiaries, and the Permanente Medical Groups, as well as an affiliation with Group Health Cooperative based in Seattle.

Nationwide, Kaiser Permanente includes approximately 134,000 technical, administrative and clerical employees and 11,000 physicians representing all specialties.

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