BCtect® for the early detection of breast cancer

BCtect® is a blood based, real-time polymerase chain reaction (PCR) assay that can identify some women who may have a genetic predisposition to developing breast cancer. Based upon the quantitative measurement of 96 ribonucleic acid (RNA) transcripts, BCtect® may be suitable for use as an adjunct to screening programmes for women deemed at high risk of breast cancer. BCtect® may also play a role as part of the diagnostic process in women presenting with breast cancer symptoms or in those whose mammograms are unclear.

Background

In 2008 over 2.3 million women in England were invited for breast screening. Just under 2 million women attended and around 78,000 (4.4%) were recalled for further assessment and 14,166 cancers detected. In 2007 there were almost 46,000 new cases of breast cancer diagnosed in the United Kingdom, around 9,000 of which were in women aged less than 50 years old. In 2008, around 11,000 women in England and Wales died from breast cancer, with around 1,300 of these deaths being in women aged less than 50 years old.

Current Practice

Mammography is the standard screening technique used in the National Health Service. Screening is currently offered to all women aged 50 years and over, and is currently being extended to all women aged 47 years and over. The accuracy of mammography is reduced in younger women who tend to have denser breast tissues, in women with small breasts, in lobular cancer and where there are multiple small lesions.

The diagnostic process for women with symptoms or with suspicious mammograms includes clinical examination, ultrasound imaging, contrast enhanced magnetic resonance spectroscopy, and tissue biopsy.

New Technology

Produced by DiaGenic ASA, BCtect® uses a real-time polymerase chain reaction to measure the quantity of 96 specific RNA transcripts in a sample of blood. Using a recognition algorithm, the pattern of gene expression is compared against reference values obtained from women with breast cancer and a test score generated. A test score of greater than zero is classified as positive and may reflect a gene expression profile seen in women with breast cancer. Diagenic ASA state that the time taken from receipt of the sample at their laboratory in Belgium to returning the result is around 7 days.
DiaGenic ASA have undertaken a number of multicentre studies during validation of BCtect®. A study obtained blood samples from 109 women with early and late stage breast cancer, benign breast lesions and those without abnormal mammographic findings. Overall the BCtect® assay correctly predicted the patient group in 78 of the 109 samples (72% sensitivity). For early stage cancers (stage 0 and 1) sensitivity was 74%. For ductal and lobular cancers sensitivity was 73%.

Another study obtained blood samples from 150 women in Europe, the United States and India with early and late stage breast cancer, benign breast lesions and without abnormal mammographic findings. BCtect® assay correctly predicted the patient group in 110 of the 150 samples (73% sensitivity). Diagnostic performance was similar for early and late stages of the disease and was independent of menopausal status and body mass index.

Clinical Studies and Research Questions

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Potential Impact

DiaGenic ASA believe that by assisting doctors to assess the genetic likelihood of women presenting with a suspected breast lesion actually having breast cancer, patients at high risk may be more easily identified and referred quickly to specialist surgeons for further investigations. This may improve detection rates for early stage breast cancer and result in fewer women requiring radical surgery, so potentially reducing morbidity and mortality.

A potential downside of the BCtect® assay may be the accidental identification of patients with a genetic pre-disposition to breast cancer but whose current symptoms are unrelated. Testing may also have implications for genetically-related family members, and a negative test does not rule out the presence of breast cancer.

References


