

Screening Asymptomatic Women for Breast Cancer Risk

One in five breast cancers occur in women under 50 and younger women tend to have more advanced disease with worse outcomes. Yet our most widely used screen, the mammogram, is not very effective in this age group due to breast density challenges. For younger women who are known to be at high risk we can justify more costly imaging methods, like MRI. But most women who develop breast cancer have no known risk factors, other than age. If we had better tools to identify high risk women, we could better allocate our resources to the women who could benefit most.

Now there is a risk stratification method used in various breast centers and primary care setting: the HALO® Breast Pap Test.

Nipple Aspirate Fluid Evaluation

HALO is a 5-minute, noninvasive way to collect Nipple Aspirate Fluid (NAF) from asymptomatic women as young as 25 as part of their annual well-woman visit. NAF is cytologically evaluated for the presence of atypical cells, which will be found in about 1% of asymptomatic women and confers a 4 to 5-fold increased risk for developing breast cancer. Multiple studies involving over 20,000 women followed for up to 25 years produced consistent results. Dr. Papanicolaou first discovered the utility of NAF in the 1950s, but, until now, lack of a practical method of collecting the fluid has limited its use primarily to the research setting.

HALO should not be confused with ductal lavage. Ductal lavage is invasive and time-consuming so its use was limited (by FDA and by practicality) to women already identified as high risk. Therefore it didn't add much as a risk assessment tool. Instead it was used as a semi-diagnostic. While NAF is a proven predictor of breast cancer risk, it is a poor diagnostic for cancer.

Risk assessment using NAF cytology follows a similar model to the cervical Pap, but there are some key differences. In both cases, epithelial cells follow a similar progression from normal to abnormal to malignant cells, though abnormalities often self correct. With the cervical Pap, cells are scraped directly from the cervix, whereas NAF cytology is dependent on cells exfoliating into the breast fluid and subsequent collection of that fluid. While studies show that women who don't produce fluid or produce acellular fluid are statistically at lower risk, we can never be certain that an individual woman's lack of fluid or cells is due to healthy breasts rather than our inability to collect fluid from the entire ductal system. For this reason we act on the "positives" and draw limited conclusions (i.e., "normal risk") from the negatives. Like most screening tests, NAF cytology cannot be used to rule out the possibility of cancer. HALO is not a replacement for mammograms or breast exams; it is an adjunct to current breast screening routines.

Care Path for Women with Abnormal Results

Atypia alone cannot determine appropriate follow up care; these women need a complete risk assessment, usually by a breast specialist. If a woman has atypia but no other significant risk factors, she might be upgraded to a diagnostic mammogram or ultrasound, and simply be monitored more frequently. However, atypia along with another significant risk factor quite often elevates risk above the 20 to 25% level where the American Cancer Society suggests MRI. Women at very high risk are typically referred for enhanced imaging, and will be counseled on risk reduction options including lifestyle changes and chemoprevention. Biopsies or surgical options should not be pursued unless follow up diagnostics reveal suspicious findings.

Some Radiologists feel pressured to find abnormalities with imaging if the patient has atypia. But it's important to remember that NAF abnormalities are at the cellular level; suspicious findings on follow up imaging are a possibility but should not be expected.

"The key takeaway is that NAF cytology gives us an objective measure of an individual woman's risk, helping us to triage patients and allocate our resources more effectively," said Brian Englander, Chief of Breast Imaging at Pennsylvania Hospital. "I think in the long run, this will help us prevent some cancers and find others at an earlier stage than we might have otherwise."



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