

## **The Halo Effect**

**A new breast pap test could help physicians better allocate diagnostic imaging resources.**

By Steven M. Schonholz, MD, FACS

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Breast imaging has continued to evolve significantly over the past decade. Through heightened compliance with mammography screening, the broad adoption of computer-aided detection and greater use of breast ultrasound and magnetic resonance imaging (MRI), we've seen a slight decline in death rates associated with breast cancer. Unfortunately, this drop doesn't match the dramatic decreases in cervical cancer mortality since the 1950s. Despite advances in diagnostic imaging tools, more than 70 percent of all women who develop breast cancer still have no known risk factors.

Therefore, as we continue to improve our imaging modalities, we must determine how to best allocate these finite resources. Since multiple imaging pathways exist, determining the optimal form of imaging-and which patients would benefit most-has been controversial. Our goal as breast specialists must be to clearly identify high-risk women and focus our resources on them. A new screening test might change the discussion, at least in part.

### **Pap profile**

The HALO<sup>T</sup> Breast Pap Test from Irvine, Calif.-based NeoMatrix LLC is performed in a primary care physician's or ob/gyn's office, where women generally present for basic health care. This five-minute, noninvasive exam-which involves the placement of cups over the breast-uses warmth, compression and a vacuum to collect nipple aspirate fluid, which is sent to the lab for analysis like cells from a cervical pap. About 1 percent of women are expected to have atypical ductal hyperplasia, and they'll likely be referred to breast specialists such as surgeons and radiologists to be managed as high-risk patients.

The medical community has long recognized ADH as a significant risk indicator. Several studies on more than 20,000 patients, followed for up to 20 years, reach the same conclusion: A woman with ADH is four to five times more likely to develop breast cancer. Most women with breast cancer have no known risk factors, so by the time we see them, we're already later in the disease management process than we'd like. A noninvasive test capable of identifying a high-risk woman from an asymptomatic population could change this statistic and enable more at-risk women to receive care from a specialist.

### **Identification, then what?**

Once the high-risk patient is identified, the key question becomes, "What do you do about it?" The ADH patient should undergo a complete risk assessment, understand how lifestyle can increase her risk of developing breast cancer and—depending on the above, as well as imaging results—be counseled on chemopreventive and surgical options. These last two points are complex and merit exploration elsewhere. For this article, we'll restrict the care-path discussion to imaging.

Perhaps the most important management of this patient is to boost surveillance. While simplistic, it's made a difference in cervical cancer with pap smears, as well as women with atypia on a breast biopsy. Increased surveillance provides us with the best opportunity to find cancers as early as possible. In addition to increasing surveillance, we should review imaging options on these patients.

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### **Role of MRI**

MRI can also be of benefit, but while it can detect smaller growths than traditional mammograms, two concerns are associated with greater MRI usage: more false positives and a higher cost that precludes their use on most women as an asymptomatic screening tool. While most physicians agree that high-risk women should receive MRI, we haven't been able to adequately and consistently answer the question: "When is a woman at sufficient risk to justify the decision?"

In its March guidelines, the American Cancer Society tried to help by suggesting an absolute risk of 20 to 25 percent as a basis for receiving MRI and specifically urging that an MRI upon atypia be handled on a case-by-case basis, considering age, family history, atypia characteristics, breast density, etc. Coupling atypia with a direct relative, for example, can change the imaging a woman receives from a standard mammogram to MRI or ultrasound, because her absolute risk has now passed the arbitrary threshold.

For the woman who lacks other risk factors to elevate her into a threshold for MRI, a switch from a screening to a diagnostic mammogram makes sense. We know the woman is at a higher risk and that mammogram sensitivity, particularly in younger patients, will result in undetected growths, so the small step up to a diagnostic mammogram is warranted.

### **High-risk patient management**

Should imaging reveal something of interest, the next steps are generally well-established. More complex is the high-risk patient who doesn't exhibit anything visible upon imaging. This situation occurs regularly, because most cancers progress before they can be imaged (or are palpable). For this reason, physicians should establish a management plan. The care path for those receiving an MRI should include increased surveillance and, depending on age, breast density, etc., consider mammography and ultrasound annually (perhaps more frequently if the patient is young and the atypia is marked). Additionally, the patient will be counseled on chemopreventive and surgical options. For example, tamoxifen or raloxifene might be indicated, depending on the patient's background.

### **Better detection**

The important point is, this new screening test could allow us to identify high-risk patients that otherwise go

undetected. It has particular value in identifying women younger than we often see. Many fortysomething women have breasts that are too dense to benefit from a standard mammogram, and women below 40 aren't routinely screened. The HALO test can be used on women as young as 25, providing a tool for those women who are harder to diagnose and are diagnosed with larger tumors.

The most exciting aspect of this easy-to-use, cost-effective tool may be that it better enables us to manage our breast imaging resource and apply the best diagnostic modalities to high-risk women, where we'll have the greatest impact on breast health care.

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