



MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS AND SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 15 NUMBER 17

MAY 2008

REPRINT

HALO® BREAST PAP TEST BY NEOMATRIX

The First Fully Automated, Noninvasive Screening Device to Assess Risk of Breast Cancer

The **HALO® Breast Pap Test**, developed by **NeoMatrix (Irvine, CA)**, is the first fully automated, noninvasive breast screening device that offers a new method to assess a woman's breast cancer risk safely and effectively. The HALO Breast Pap Test has been approved by the FDA for the collection of nipple aspirate fluid for cytological evaluation. This five-minute test was specifically designed for use in the primary care setting as part of an annual well-woman visit. The collected fluid is analyzed by a laboratory to detect the differentiation of normal cells versus pre-malignant cells versus malignant cells from the milk ducts of pre-menopausal, asymptomatic women. Like the cervical Pap test, the HALO system can detect abnormal cells up to eight years before a larger, potentially cancerous lesion might develop. HALO is a screen or risk stratifier, not a diagnostic test. Routine assessment with HALO will allow for closer monitoring of breast health.

Ernie B. Bodai, MD, Director, Breast Surgical Services, Kaiser Permanente (Sacramento, CA), notes that "The HALO appears to be very effective in identifying high risk patients who have no other means of being identified. It is a valuable screening tool for the select population of asymptomatic women aged 25 to 50 years old. These are the women who have dense breasts and mammography can be less effective in these younger, pre-menopausal women." Dr. Bodai explains that many people equate the HALO system with the less popular procedure ductal lavage. "It's not the same at all. The HALO uses



The HALO Breast Pap Test has been approved by the FDA for the collection of nipple aspirate fluid for cytological evaluation.

a different technique to obtain nipple aspirate fluid, combining gentle vacuum, massage and heat." About 50 percent of women will produce nipple aspirate fluid. Dr. Bodai points out that those women who do not produce nipple aspirate fluid can be placed in a relatively "low-risk" group. "Of those who do produce fluid, approximately one percent of these asymptomatic women will have atypia and once identified, can be managed as high-risk cases." According to Dr. Bodai, multiple studies concur: cellular atypia in asymptomatic women increases lifetime risk of developing breast cancer four- to five-fold.

Monthly self-breast examination, annual professional breast examination, and mammography have thus far been the most effective screening tools available. MRIs

can be expensive and therefore impractical to use for screening all women, and ultrasound has proven useful as an adjunct to mammography. “HALO does not replace routine mammograms and breast exams. Although mammography is a very good tool, it is only about 80 percent effective,” comments Dr. Bodai. “That means that about 20% of the time when a woman has a breast cancer, the mammogram will miss it. This is because the density of the tumor and the surrounding breast tissue are the same, which greatly decreases the sensitivity of the mammogram. That being said, it is still the best tool that we have available for screening.”

K. Warren Volker, MD, PhD, Women’s Specialty Care—Las Vegas (Las Vegas, NV), notes that “Current breast cancer screening methods are based on imaging—detection of a tumor already there; yet, the earliest that we can detect a tumor with enhanced imaging is at about 1 cm. With HALO, instead of early detection of a tumor, we can detect abnormalities under a microscope *prior* to the development of the most common breast mass.” Dr. Volker points out that the HALO is based on the same principle as a cervical pap test. “Due largely to the success of the cervical pap test, deaths from cervical cancer in the United States have dropped dramatically. Since we started using HALO in our practice about nine months ago, we have identified just over a dozen patients with atypical cells. This has allowed us to follow these patients very

*“... With HALO,
instead of early
detection of a tumor,
we can detect
abnormalities under
a microscope prior
to the development
of the most common
breast mass.”*

Warren Volker, MD

closely, where we wouldn’t have known to do so otherwise.”

“HALO is a huge step toward screening the low-risk population,” notes Jonathan Daniel Herman, MD, FACOG, an OBGYN in private practice (New Hyde Park, NY). “Those known as high risk have already been plugged into the system and are watched more closely. Right now, we assess risk by saying that a woman who has no history of breast cancer in her family is at low risk, even though 89 percent of people who get breast cancer have no family history. Therefore, we don’t know which of these women are actually at high risk. We send them annually for a mammogram and hope if there is something there that we catch it at an early stage. The beauty of HALO is that it looks for precancerous cells and can help me predict which low risk women will get cancer. This

way, we can put them in the high-risk category and follow them more closely.” Dr. Herman continues, “The whole trick is to find cancer early or to decrease the risk of a woman getting cancer. If we find a breast cancer in Stage I, 90 to 100 percent of women will have a 5-year survival rate. So if we could find breast cancer even before it appears, then we will be doing an even better job. I think with HALO we are just seeing the tip of the iceberg in reducing breast-cancer related deaths.”

All women are at risk for developing breast cancer, the leading cause of death in women ages 35 to 50. Seventy percent of the women who are diagnosed have no identifiable risk factors and eight out of nine women diagnosed have no family history of the disease. There are 250,000 women in the U.S. under the age of 40 living with breast cancer. Our country spends \$3 billion annually on breast cancer screening, yet more than 70% of lumps are discovered during self-exams. When found early enough, the five-year survival rate is nearly 100%. Unfortunately, by the time a woman can actually feel the lump, the disease is no longer in its earliest, most treatable stage. Early detection is the key to better outcomes. ◆

To Learn More

For more information about the HALO Pap Breast Test, please visit the company’s Web site at www.neomatrix.com, or call 1-877-HALO PAP or 1-949-753-7844.