

ROCKING THE ROAD FOR A CURE

Risk Factors, Screening, & HALO FAQ's

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Why is screening for breast cancer risk so important?

1 in 8 women will develop breast cancer in their lifetime, but to date, it's been very difficult to identify who is at risk. Traditional methods of breast cancer screening have limiting factors. Women under the age of 40 are not usually getting regular mammograms. For women over 40, mammograms often do not detect abnormal changes until about 8 years after changes have begun to take place. Mammograms are also not as effective in women with dense breasts. HALO is a screening tool that can help identify women at greatest risk, years earlier, allowing for earlier intervention and increasing chances for survival.

What is the difference between a risk screening test and a diagnostic test? ?

A risk screening test allows physicians to group patients without symptoms in different categories from low to high risk. A diagnostic test confirms whether or not patients with symptoms actually have a disease. HALO is a risk screening test and works much like a cholesterol screen for potential cardiovascular disease. Just because you have high cholesterol doesn't mean you have heart disease. Similarly, just because you have atypia does not mean you have breast cancer.

Does HALO replace mammograms?

No, HALO is a complement to mammograms. Mammograms look for lesions (cancer) and are most effective as women age. HALO is looking for abnormal cells, years before they might turn into a lesion, and the test is effective in women as young as 25. If you already have a growth in your milk ducts when you first have a HALO test, it's possible that the affected duct could be blocked so that HALO could not collect a fluid sample. This is why it's important to continue with routine mammograms and breast exams.

What about family history?

Those who have a mother, sister or daughter with breast cancer are approximately 2 times more likely to develop the disease. Those who have atypia are 4 to 5 times more likely to develop breast cancer. Screening for atypia with HALO will help you and your doctor identify cellular changes, closely monitor them and develop an optimal care path.

How does the HALO Breast Pap Test work?

HALO combines warmth, massage and suction to bring nipple aspirate fluid (NAF) to the surface. NAF is found in the milk ducts where 95% of all breast cancers originate. The entire cycle is five minutes and is easily incorporated into your well-woman visit. If you produce fluid, the sample is then sent to the lab and analyzed for cellular abnormalities.

Who should have HALO and how often?

This is an annual test for all non-lactating women 25 and over. Women over 55 tend to decrease their production of NAF and mammograms become more effective at this stage. Women over 55 who produce NAF should continue to have annual HALO tests.

Is the procedure painful?

Most women find the test easy to tolerate. In a clinical study with 500 women, 88% said they would recommend it to their friends. On a 1 – 10 scale, the average discomfort rating for the HALO was about a 4 while those same women rated their mammogram an 8.

How many women produce fluid?

About half of all women will produce fluid. Not producing fluid with the HALO test is considered a normal result, meaning you are at normal risk, not elevated risk for developing breast cancer.

What if I don't produce fluid?

If you don't produce fluid, this is considered a normal result. You are at normal risk, not elevated risk for developing breast cancer. Women who do not produce NAF one year may produce NAF the next year, therefore the HALO Breast Pap Test should be conducted annually.

If I have atypia, does it mean I have breast cancer?

No. It simply means you are at a higher risk than someone without atypia. In fact, only about 1% to 2% of women screened have atypia and often atypia corrects itself.

What do I do if I get an abnormal result?

There are specific carepaths for your consideration. In general, if you have an abnormal result you will likely be referred to a breast center. The breast specialist has several options in 3 broad categories:

Full risk assessment questionnaire and counseling about preventive measures

Diagnostic mammogram, Ultrasound, or MRI

More aggressive options to include medication such as tamoxifen; procedures like ductal lavage, ductoscopy, or ductal excision, etc.

How long does it take to get results?

Typically it takes three to five days. Your doctor's office will notify you of the results.

Is HALO FDA cleared?

Yes, HALO is FDA cleared.

Is HALO reimbursed by my insurance company?

The collection of NAF with the HALO system is not yet reimbursed by insurance companies. Contact your doctor about your cost for the HALO test. If you produce fluid during the HALO test, your doctor's office will send the sample to the lab to be evaluated. The charges associated with the lab are covered by most insurance companies.

Can I have a HALO if I have breast implants?

It depends on the type of implant. If your incision is not around the entire nipple and the milk ducts are not compromised, you may have the HALO.

Can I have a HALO if I've had a breast reduction?

It is best to discuss this with your doctor. You may be a candidate for HALO if your entire nipple was not removed and the milk ducts were not compromised.

Can I have a HALO if I have a nipple ring?

Yes, however you must remove the ring(s) and the milk ducts must not be compromised.

Is color of Nipple Aspirate (NAF) important?

No. NAF can be any color.

Can I have a HALO test if I am breast feeding?

No. You must wait at least 6 months after your last breast feeding to have a HALO test.

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