

Nipple Aspirate Fluid Enables Ob-Gyn and Breast Surgeon to Better Identify Patients at Risk for Breast Cancer

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Objective

An automated device has emerged for collecting nipple aspirate fluid (NAF) to be analyzed for the presence of atypia, a valued biomarker for breast cancer risk in asymptomatic women. This device is the first means of collecting NAF to be practical for community care. The device motivated an ob-gyn practice and a breast care practice to explore a working relationship in which women with elevated breast cancer risk are presented with risk-reduction options.



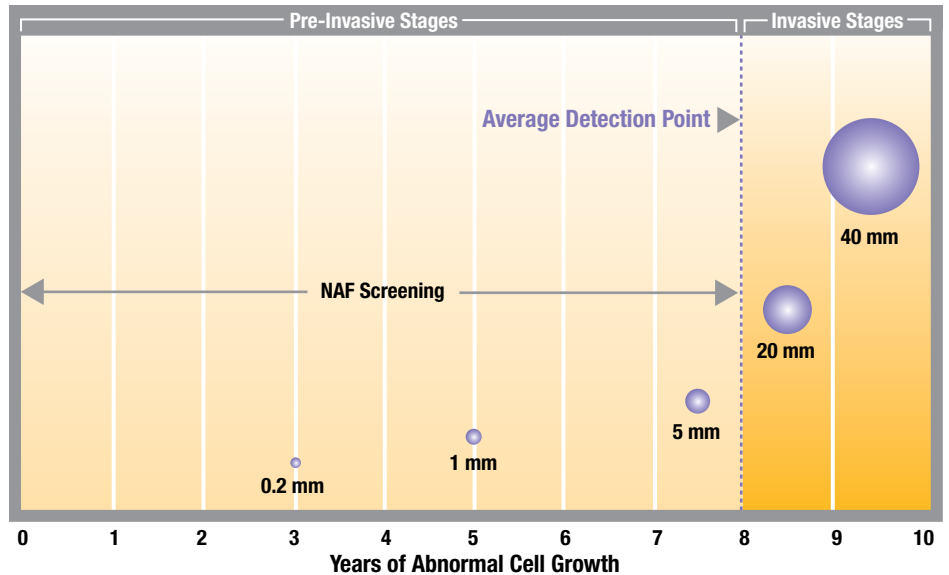
*HALO® Breast Pap Test
(NeoMatrix)*

NAF testing is a useful adjunct to regular breast cancer screening because it can identify precancerous changes years before a palpable or imageable lesion might be found. A cancer has been growing for 8 years on average before it can be detected by a mammogram, and 10 years before it can be palpated.

The clinical significance of atypia as a risk assessment tool has been validated through independent studies of samples collected from nipple aspiration, fine needle aspiration (FNA), or surgical biopsy. The studies show that women with abnormal cells (or atypia) in their NAF have a 4-5X greater risk of developing breast cancer than women who do not produce NAF.¹

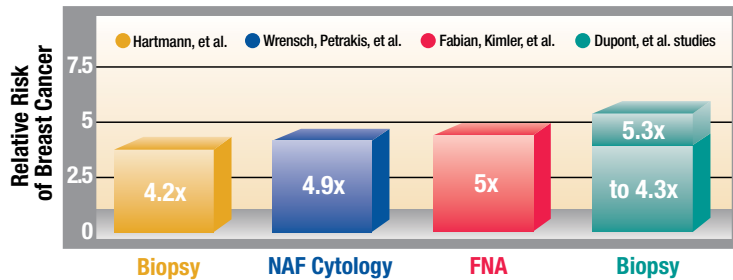
Despite established methods for reducing risk in women with atypia, previously there was no method for conveniently identifying these patients.

NAF Cytology Enables Early Detection of Precancerous Cellular Changes



Cytologic Assessment—Clinically Validated^{1,2,3,4}

Cytologic atypia and histologically identified atypia confer similar increase in breast cancer relative risk.



Methods

The NAF sample is sent to a cytology lab for evaluation and results are reported in 5 categories. Patients falling into the atypical or suspicious categories are considered to be at high risk.⁵

Once a patient with elevated risk is identified, risk reduction is more traditionally the province of a breast surgery practice. To better serve patients with atypia, an ob-gyn practice in Newport Beach, Calif. and a breast care practice in Costa Mesa, Calif. have established a relationship by which patients identified with atypia at the ob-gyn office are referred to the breast care practice.

NAF Reporting System and Corresponding Action

System for Reporting Nipple Aspirate Fluid Cytology ⁵			
Category	Interpretation	Characteristics	Action
No NAF			Continue annual HALO test
Category 0	Negative for atypical or malignant cells	No or <10 ductal cells. Foam cells	Continue annual HALO test
Category I	Benign – normal ductal epithelial cells identified	Ductal cells. Foam cells. Apocrine cells.	Continue annual HALO test
Category II	Benign – hyperplastic ductal epithelial cells identified	Cell distribution predominantly in cohesive groups with >10–50 cells. Minimal nuclear changes. Fine chromatin.	Continue annual HALO test
Category III	Atypical	Distinct nuclear enlargement, increasing N/C ratio, irregular nuclear borders and nuclear variation. Coarse chromatin. Prominent chromocenters.	Refer to Breast Center
Category IV	Suspicious for malignancy	Single cells and groups of cells with nuclear features suspicious for cancer.	Refer to Breast Center

At the breast care practice, the patient's atypia is considered along with other risk factors such as family history, genetic profile, number of children, age at time of first birth, and breast density. Depending on the patient's comprehensive risk profile, the breast surgeon will suggest various preventive strategies. These include:

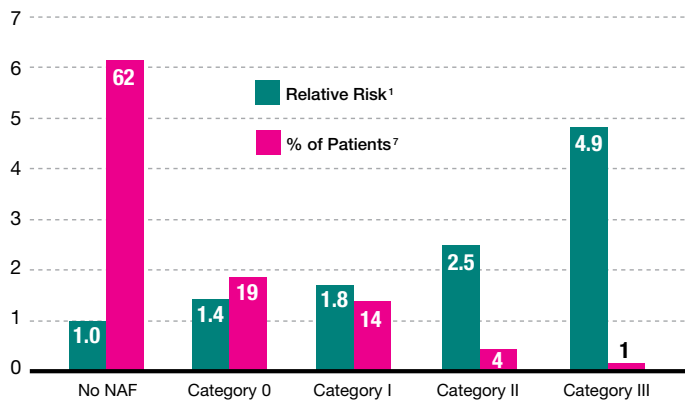
- Lifestyle changes
- Increased surveillance
- Genetic counseling/testing
- Chemopreventive medications

Results

The Newport Beach practice collected NAF from 1,083 women in 2008, of whom 9 had atypia (typically, 1% of patients tested have atypia – see “Typical NAF Cytology Results” graphic below). The impact of referring these women to the breast care practice could be dramatic. All the options offered by the practice are known to help prevent cancer or detect it at an earlier, more treatable stage. For example, chemoprevention can reduce risk by as much as 86% in patients with atypia.⁶

- **The approach developed by the two practices is particularly beneficial for women 25-50. Women in this cohort tend to have breasts that are too dense for mammograms to be effective.**
- **Breast cancer at younger ages is more likely to be fatal, which increases the importance of breast cancer risk assessment in the 25-50 age group.**

Typical NAF Cytology Results



Conclusion

The NAF device has enabled an ob-gyn practice and a breast care practice together to offer an important service that reduces breast cancer risk for younger women.

References

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