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Medical Policy Manual

Topic: Epithelial Cell Cytology in Breast Cancer Risk Assessment and High Risk Patient Management (Ductal Lavage and Suction Collection Systems)

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Different collection systems have been investigated as techniques to obtain nipple aspirates. These techniques have been evaluated as a diagnostic and risk assessment tool in patients at high risk of breast cancer but without clinical or mammographic findings. For example, the finding of atypical hyperplasia may be associated with an increased risk of breast cancer. Malignant cells may also be identified in rare cases.

Ductal lavage involves several steps. First, fluid-yielding mammary ducts are identified using nipple aspiration. Next a microcatheter is inserted into the natural nipple opening of the individual mammary ducts, saline solution is infused, and ductal fluid withdrawn. The fluid is then analyzed microscopically for cytologic abnormalities.

Regulatory Status

Several breast duct collection systems have received US Food and Drug Administration (FDA) 510(k) clearance for distribution in the United States, including:

- The Mammary Aspiration Specimen Cytology Test (MASCT; Nastech, Inc.)
- Pro-Duct catheter (Pro-duct Health, Inc)

Suction collection systems (noninvasive alternatives to ductal lavage) which have received clearance from the FDA include the HALO® Breast Pap Test (Neomatrix), an example of a nipple aspirate fluid (NAF) collection system. In this system, small breast cups are placed on the breast and adjusted to fit. The system is then engaged and automatically warms the breast and applies light suction to bring nipple aspirate fluid to the surface. Similar to ductal lavage, the fluid is then analyzed microscopically for cytologic abnormalities. The web site for the HALO PapTest notes the following: "*HALO is not a diagnostic test and it cannot be used to exclude breast cancer*. Patients should continue to undergo other clinical breast screening procedures (mammography, clinical breast examination, self-breast examination) as determined by and with their physicians."[1]

Note: This policy addresses breast epithelial cell cytology (ductal lavage and aspirate collection systems) only. For discussions of breast duct endoscopy, see medical policy, Medicine, Policy No. 112.

MEDICAL POLICY CRITERIA

Cytologic analysis of epithelial cells from nipple aspirations as a technique to assess breast cancer risk and manage patients at high risk of breast cancer is considered **not medically necessary**. Techniques of collecting nipple aspiration fluid include but are not limited to, ductal lavage and suction.

SCIENTIFIC EVIDENCE

Validation of a diagnostic technology requires data regarding its technical performance, its diagnostic performance (i.e., sensitivity, specificity and positive and negative predictive value) compared to a gold standard, and finally data regarding how the diagnostic information will be used in the management of the patient and whether beneficial health outcomes result (i.e., clinical utility).

Literature Appraisal

The published literature on the use of epithelial cell cytology analysis for management of breast cancer risk consists of a technology assessment and subsequently published studies addressing the technological feasibility and diagnostic accuracy of this technique. No published studies were identified that specifically used the results of ductal lavage or suction techniques to direct patient management.

Technology Assessment

A 2002 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment offered the following observations and conclusions:[2]

- No studies directly compare routine surveillance vs. routine surveillance plus epithelial cell cytology analysis for the detection of breast cancer in high-risk women. No studies compared the outcomes of patients whose management was determined by the results of routine surveillance vs. routine surveillance plus epithelial cell cytology analysis. No studies have used ductal lavage, nipple

aspiration, or random periareolar fine-needle aspiration to influence patient management in the population of interest.

- There is some indirect evidence from the National Surgical Adjuvant Breast and Bowel Project (NSABP) Breast Cancer Prevention Trial (P-1), which enrolled 13,388 women at high risk and randomly assigned them to placebo or tamoxifen for five years. Women with a history of hyperplasia with atypia who received tamoxifen had a risk ratio for subsequent breast cancer of 0.14, compared to those who received placebo over a median follow-up time of 54.6 months. Thus, high-risk women with a history of hyperplasia with atypia benefited to a greater degree than the study population as a whole. It was noted, however, that the number of women in this subgroup was small, and that this was only one of five subgroups examined. Women without a history of hyperplasia with atypia who received tamoxifen also benefitted with a risk ratio of 0.56. Thus, the lack of a history of hyperplasia with atypia does not preclude improved outcomes with tamoxifen treatment.
- The results of the P-1 trial cannot address whether or not participants, particularly those with a negative history, had cytologic evidence of hyperplasia or hyperplasia with atypia at the time of enrollment. It is possible that some of the women who were negative for a history of hyperplasia with atypia would have been positive at study entry by random cytology, and may have accounted for at least part of the benefit in this subgroup. Nevertheless, it cannot be ruled out that women with no detectable hyperplasia with atypia may still benefit from tamoxifen treatment.
- Considering the above, the assessment concluded that the evidence was insufficient to support the use of cytologic hyperplasia with atypia as a clinically useful intermediate biomarker outside of clinical trials at this time. The existing evidence is of high clinical interest, but further follow-up studies of risk and trials of intervention in women with this marker are needed.

Technical Performance

Technical performance of nipple aspiration and ductal lavage has been repeatedly shown to be inefficient, producing inadequate specimens and lacking reproducible results, even when performed in the same patient.

- Nipple aspiration alone can be used to collect epithelial cells for cytologic analysis; ductal lavage is designed to harvest an increased number of cells for analysis. In a multicenter clinical trial of 507 women who underwent nipple aspiration followed by ductal lavage, nipple aspiration produced an adequate sample in 27% of women, while ductal lavage produced an adequate sample in 78% of women.[3] A median of 13,500 cells per duct was collected by ductal lavage compared to a median of 120 epithelial cells per breast collected by nipple aspiration.

- Loud et al reported adequate specimen collection for 25% and 41% of 171 women by nipple aspiration and ductal lavage, respectively.[4]

- Another study compared breast tissue acquisition by ductal lavage with random periareolar fine needle aspiration (immediately following lavage) in 86 women at high risk for breast cancer.[5] Sample retrieval was successful in 100% of the women by needle aspiration, and 97% had adequate samples (ten or more epithelial cells). In contrast, samples were retrieved in only 51% of subjects using ductal lavage; the sample was considered adequate in 71% of these, resulting in a total yield of 31%. The authors concluded that fine needle aspiration is a more practical option for clinical trials. A third study performed ductal lavage on 150 women (irrespective of the calculated risk level); 67 were patients with breast cancer.[6] Adequate samples (ten cells or more) for diagnosis were obtained from 90% of women but only 67% of ducts. Out of 83 women

without breast cancer, atypia was diagnosed in 34% of the 44 women with a 5-year Gail risk of <1.7% and 28% of the 39 women who had a 5-year Gail risk of 1.7% or greater.

- Johnson-Maddux and colleagues studied the reproducibility of cytologic atypia in repeat nipple duct lavage in 108 patients unselected for breast cancer risk.[7] Repeat lavage was performed in those with atypia found in the first lavage sample. Atypia was found in the second lavage sample in only 48% of cases. The authors conclude that the reproducibility of repeat lavage is low and that atypia may be either physiologic or artifactual.

- Visvanathan et al. evaluated the reliability of nipple aspirate fluid (NAF) and ductal lavage at two time points 6 months apart in women (n=69) at increased risk for breast cancer.[8] Eligible women had a 5-year Gail risk of 1.66% or higher or lifetime risk of >20%, and/or a family history or personal history of breast cancer. All ducts that produced NAF were cannulated. Participants (mean age, 47 years) were enrolled over 35 months. Forty-seven returned for a second visit. Of the women who returned for a second visit, 18 of 24 who produced NAF had at least one duct successfully cannulated. Twenty-four ducts in 14 women were lavaged twice. Among these ducts, cellular yield for the two time points was inconsistent and only fair cytologic agreement was observed. The authors concluded that the use of ductal lavage is limited by technical challenges in duct cannulation, inconsistent NAF production, a high rate of inadequate cellular material for diagnosis, fair cytologic reproducibility, and low participant return rates.

- Khan et al. reported on a proof-of-principle phase 2 study to assess the utility of ductal lavage to measure biomarkers of tamoxifen action.[9] The authors' conclusions are as follows: "…we observed the expected changes in tamoxifen-related biomarkers; however, poor reproducibility of biomarkers in the observation group, the 53% attrition rate of subjects from recruitment to biomarker analyses, and the expense of ductal lavage are significant barriers to the use of this procedure for biomarker assessment over time."

No published studies were identified that focused on suction techniques to collect nipple fluid.

Diagnostic Performance

When adequate samples are available, studies report very low sensitivity. For example:

- Dooley and colleagues reported on a multicenter clinical trial of 507 women who underwent ductal lavage.[3] A total of 57% of women had a prior history of breast cancer and 39% had a five-year Gail risk for breast cancer of 1.7% or more. (Using a Gail index of equal to or greater than 1.7%, all women over the age of 60 years would be considered at high risk.) For ductal lavage, 24% of women had abnormal cells that were mildly (17%) or markedly (6%) atypical or malignant (less than 1%). Ductal lavage detected abnormal cells 3.2 times more often than nipple aspiration. However, whether or not this increased sensitivity is accompanied by decreased specificity and thus a decreased overall risk of cancer using ductal lavage is unknown.

- Khan and colleagues published a study of 32 women who underwent ductal lavage in 44 breasts with known cancer prior to mastectomy.[10] In addition, ductal lavage was performed on eight breasts in seven women prior to prophylactic mastectomy, two of which were found to harbor occult cancer. The results of ductal lavage were compared with histologic specimens from the same lavaged ducts. The sensitivity of ductal lavage was 43% and the specificity was 96%. The

authors hypothesize that the low sensitivity of the test may be related to the fact that cancer contained in ducts fail to yield fluid or have benign or mildly atypical cytology.

- In a subsequent study focusing on women with microcalcifications, Kahn reported that similar to patients with larger invasive cancers, smaller cancers, such as ductal carcinoma in-situ (DCIS), often do not yield nipple fluid, leading to low sensitivity.[11]

- Brogi and colleagues report the results of a similarly designed study of ductal lavage in 26 women scheduled to undergo mastectomy for breast cancer. Only 48% of the lavaged specimens revealed any evidence of atypia.[12]

- In a prospective study authors registered 80 women at low-risk for breast cancer between ages 28 to 67 to evaluate samples obtained with ductal lavage (DL) and elucidate the efficacy of this diagnostic modality in evaluating fluid production.[13] Authors reported that 80% of results were within normal limits while 17.5% of the participants presented mild atypical and 2.5% markedly atypical rates. Authors suggested that DL was easy to perform, removed most clinician variability, and allowed discrimination of low risk women to those with breast disorders that require additional investigation, further follow-up or administration of preventive medication.

It is difficult to identify a gold standard test to validate the diagnostic performance of ductal lavage. For example, since ductal lavage is performed in patients without mammographic abnormalities, there is no obvious target for diagnostic confirmation with a tissue sample. In cases where cells suspicious for malignancy have been reported, some patients may have undergone either surgical resection of the involved duct or a broader surgical resection. However, there have been no studies published regarding the diagnostic performance in this setting.

Clinical Utility

Cytologic results of nipple aspiration can be broadly subdivided into those with an insufficient sample, those with malignant cells, those with hyperplasia (including atypical hyperplasia), or those with benign cells. Currently, no published studies have specifically used the results of ductal lavage or suction techniques to direct patient management. Since no published studies were identified for suction technique to collect nipple aspiration, the following discussion focuses on ductal lavage alone.

The following discussion suggests some potential applications:

- Insufficient Sample

  There would presumably be no impact on the management of the patient when an insufficient sample was produced. Based on the preliminary results published, this would occur in about 22% of the patients.

- Hyperplasia without Atypia

  Hyperplasia is relatively common among high-risk women (31%-42%) and, to a somewhat lesser extent, among various populations of women not specifically considered to be at high risk (12%-37%). Although hyperplasia without atypia is associated with increased cancer risk in some studies, its relatively high prevalence in both high- and low-risk populations decreases its utility as a risk

marker.

- Hyperplasia with Atypia

  The association between histologic hyperplasia with atypia and an increased risk of breast cancer has been most frequently studied in the setting of patients with mammographic abnormalities. The natural history of hyperplasia with atypia may be different in women without mammographic abnormalities, potentially representing a spontaneously resolving cytologic abnormality.

  Two studies offer related data. Wrensch and colleagues reported on a prospective study of 2,701 women at average risk of breast cancer who underwent nipple aspiration and then were followed for an average of 12 years.[14] The relative risk of cancer in women with cytologic atypia was 4.9 compared to non-yielders of nipple fluid or 2.8 compared to women with normal cytology. In women with cytologic atypia and a family history, the relative risk was 18.1 compared to non-yielders of fluid without family history. After 21 years of follow-up, the relative risks were lower, suggesting that risk decreased over time.[15]

  Fabian and colleagues reported on a group of 480 women without mammographic abnormalities who were considered at high risk of breast cancer and who underwent two random periareolar fine needle aspirations at six-month intervals.[16] Risk factors included a family history of breast cancer, a prior history of a precancerous lesion (i.e., hyperplasia with atypia or carcinoma in situ), or a prior history of breast cancer. In 21% of patients, results of the fine needle aspiration revealed hyperplasia with atypia. After follow-up of 45 months, the relative risk of cancer in women with cytologic atypia was 5.0 compared to women without atypical results. The two strongest predictors of cancer development were risk assessment based on the Gail model, and the presence of hyperplasia with atypia on fine needle aspiration.

  The relative risk results for nipple aspiration or fine needle aspiration cytology have been equated with a relative risk of 5.3 in women with histologic atypia compared to women without proliferative disease on biopsy of a lesion, reported in a retrospective study.[17] However, due to the different follow-up intervals, different baseline risk populations studied, and different referent populations, these results cannot be quantitatively compared. Thus, it is not known whether cancer risk associated with cytologic atypia is of the same magnitude as cancer risk associated with histologic atypia on biopsy of a lesion.

  Cytologic hyperplasia with atypia alone in low- to moderate-risk populations had poor sensitivity (4.2%) and low positive predictive value (13.8%).[15] Thus, this procedure has poor utility for general population screening to identify those at increased risk of breast cancer.

  For women already at high risk of breast cancer by Gail model analysis, the following treatment options are available: increased surveillance (i.e., increased frequency of breast self-examination or clinical exam or an increased frequency of mammography), a prophylactic mastectomy, or chemoprevention with tamoxifen or an aromatase inhibitor. Increased surveillance is recommended for all, and prophylactic mastectomies considered only by a relatively few women who have other strong risk factors (i.e., BRCA1 or BRCA2 mutation). The net benefits of tamoxifen, taking into account possible adverse events, are greatest for women of younger age with greater Gail risk, yet patients are reluctant to select chemoprevention.[18] For high risk women with no history of histologic hyperplasia with atypia of a biopsied lesion, it has been proposed that findings of cytologic atypia on ductal lavage may revise the risk estimate upward, increase the likelihood of

choosing chemoprevention, and decrease cancer incidence. However, no studies have specifically explored decision making or outcomes regarding these treatment alternatives in mammographically normal women with hyperplasia with atypia by cytologic analysis.

The role of hyperplasia with atypia as part of the decision making for prophylactic mastectomy is based on the hypothesis that atypia precedes the development of cancer. However, any patient with a BRCA1 or BRCA2 mutation may be considered a candidate for prophylactic mastectomy. The emergence of atypia may suggest a more immediate need for prophylactic mastectomy, and thus may affect the timing of the surgery. However, this strategy has not been formally tested.

- Malignant Cells

  It is unlikely that ductal lavage will be routinely used to diagnose malignancy. In the rare event of malignant cells, imaging, ductogram, or ductoscopy are possible follow-up procedures, but a negative imaging result or ductogram does not exclude significant pathology and the overall sensitivity of ductography is unknown. The value of terminal duct excision is also unknown. Prophylactic mastectomy on the basis of a malignant lavage is not encouraged.[19]

- Benign Cells

  Without an understanding of the sensitivity of ductal lavage, it is not possible to interpret a finding of benign cells, as this could represent a false negative result.

Clinical Practice Guidelines

Several clinical practice guidelines have been published on the use of breast cancer screening or risk reduction and/or the use of ductal lavage or suction. Recommendations from the guidelines formed a consensus against the use of epithelial cell cytology from ductal suction or lavage barring the publication of definitive clinical research.

National Comprehensive Cancer Network (NCCN)

The 2013 NCCN Clinical Practice Guidelines for Breast Cancer does not address ductal lavage[20] for the diagnosis of breast cancer. In Clinical Practice Guidelines for Breast Cancer Risk Reduction the NCCN noted that the clinical utility and role of ductal lavage is "still being evaluated and should only be used in the context of a clinical trial."[21]

American Society of Breast Surgeons

The 2007 Guidelines from the American Society of Breast Surgeons cautioned that ductal lavage should not replace standard cancer screening methods, stating, "Cytologic interpretation of fluid obtained by ductal lavage is not an approved screening tool for the detection of breast cancer."[22] The guidelines recommended long-term clinical trials to evaluate the contribution of ductal lavage to standard cancer screening methods.

American Cancer Society

In a review entitled, **"**Newer technologies for breast cancer screening," the American Cancer Society (ACS) noted that:[23]

- "Ductal lavage is an experimental test developed for women who have no symptoms of breast cancer but are at very high risk for the disease. It is not a test to screen for or diagnose breast cancer, but it may help give a more accurate picture of a woman's risk of developing it... It is not clear if it will ever be a useful tool. The test has not been shown to detect cancer early. It is more likely to be useful as a test of cancer risk rather than as a screening test for cancer. More studies are needed to better define the usefulness of this test."

- Regarding nipple aspiration, the ACS noted, "As with ductal lavage, the procedure may be useful as a test of cancer risk but is not appropriate as a screening test for cancer. The test has not been shown to detect cancer early."

National Cancer Institute

Regarding ductal lavage the National Cancer Institute stated, "no data are available to determine the efficacy or mortality reduction of ductal lavage use as a screening or diagnostic tool. Therefore, the use of this procedure as a screening tool remains investigational.[24]

American College of Radiology (ACR)

The 2009 Appropriateness Criteria® from the ACR state, "The use of … ductal lavage in evaluating clustered microcalcifications has not been established. In general, they should not be used to avoid biopsy of mammographically suspicious calcifications."[25]

Summary

A number of clinical trials have been published on the use of epithelial cell cytology from ductal lavage or suction for risk prediction in breast cancer. However, results from these studies suggest poor technical and diagnostic performance of this proposed technique. Because this technology has not been shown to improve the net health outcome, its use is considered not medically necessary for the assessment or management of patients at high risk of breast cancer.

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CROSS REFERENCES

Breast Duct Endoscopy (Ductoscopy), Medicine, Policy No. 112

CODES	NUMBER	DESCRIPTION
CPT	19499	Unlisted procedure, breast
	89240	Unlisted miscellaneous pathology test
HCPCS	None	