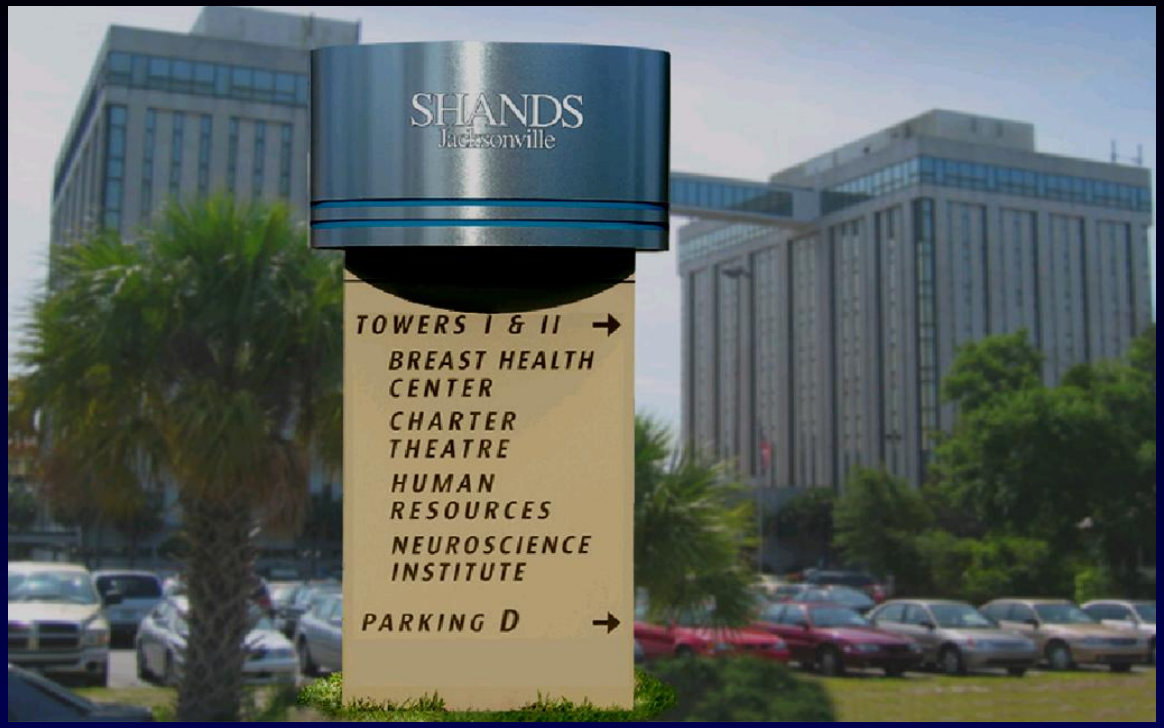

Minimizing Errors in Diagnostic Pathology

3rd International Congress of Breast Disease Centers

February 7, 2013

Paris, France

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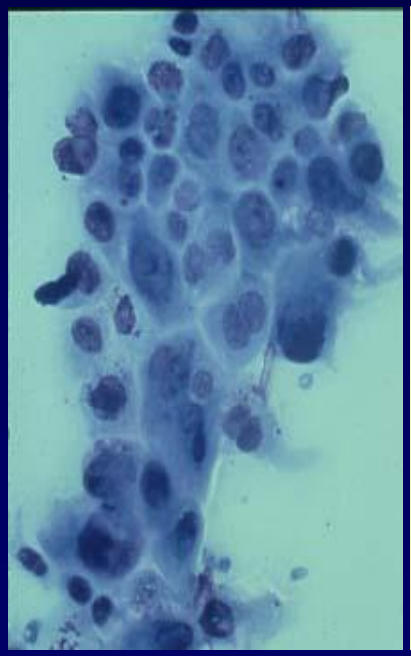
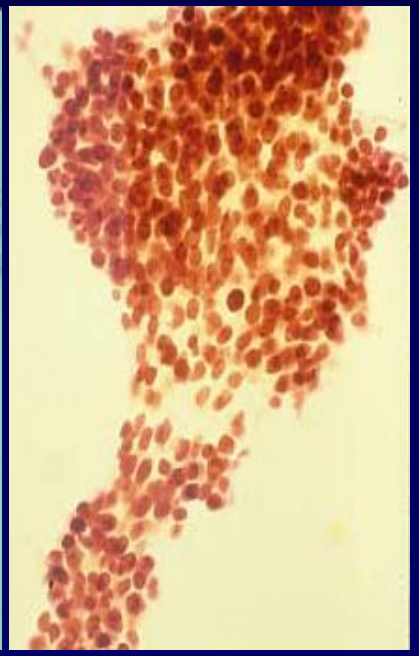
The Plan

- To outline the role of pathologists in breast cancer diagnosis and management
- To review the current challenges associated with the practice of breast pathology
- To suggest strategies for error reduction and patient safety

The Role of Breast Pathologists

- Establish a diagnosis
- Classify a neoplasm
- Differentiate between a primary versus a secondary tumor
- Predict a response to therapy
- Provide a prognosis
- Compose a comprehensive pathology report





Pathology Report

- Pathology report is the story of an illness in a patient
- Accuracy of pathology reporting is a shared responsibility among surgeons, radiologists, oncologists, and pathologists.

The Facts

- Breast pathology is the foundation of breast health care
- False-positive and false-negative diagnoses can result in under and over treatment

“The Current Challenges Associated with the Practice of Breast Pathology”

Current Issues In Breast Pathology

- Diversity in tissue handling, processing and reporting
- Insufficient evidence-based correlation between morphology and patient outcome
- Significant interobserver variability in diagnosis and test results
- Communication barriers among physicians involved in breast care

Current Issues in Breast Pathology

- Breast pathology is considered as a component of general surgical pathology
- Breast pathology fellowships are not accredited by Accreditation Council for Graduate Medical Education
- Referral of pathology samples to commercial laboratories impairs communication

Current Issues In Breast Pathology

- There are no uniform guidelines to measure the rate of diagnostic errors
- Fear of disclosure and medicolegal issues limits the reporting of diagnostic errors
- There are many look-alikes in breast pathology that can mimic cancer
- There is minimal standardization in breast pathology and biomarker studies

Current Issues in Breast Pathology

- Variability in the results of prognostic/predictive factors
  - 20% error rate for hormone receptor assay
  - 26% error rate for HER-2/neu oncogene testing

Current Issues in Breast Pathology

The Impact of Inaccurate Predictive Tests

- Inappropriate use of targeted drug treatment like Herceptin
  - 26% of patients may receive the drug when it will not be helpful for their breast cancer
    - Delay appropriate treatment
    - Unnecessary expenses of $70-100,000 / per patient
    - Unnecessary side effects

Minimizing Errors In Breast Pathology

Suggestions

- To acknowledge the challenges associated with the current practice of breast pathology
- To design studies that can appropriately analyze the problems and quantitate their impact on therapy, patient outcome and health economy

Minimizing Errors in Breast Pathology

Suggestions

- To establish quality assurance programs
  - Consensus slide conference
  - Mandatory second review of cancer cases
  - Mandatory adherence to established guidelines
  - Involvement in external quality assurance programs
- To Review the outside pathology slides and reports before the initiation of cancer therapy
- To seek a second opinion

Why Second Opinion is Important?

- **The estimated rate of change in surgical therapy following a second opinion is up to 7.5% of cases**
- **In 40% of cases additional prognostic information may alter the outcome and the course of additional therapy**

Staradub et al: Annals of Surgical Oncology 9(10):982-987, 2002.

Multidisciplinary Case Review

The Impact

	Imaging	Pathology
Interpretive Change	45%	29%
Surgical Management Change	16%	9%

Newman EA, et al: *Cancer* 2006, 107:2346-2351.

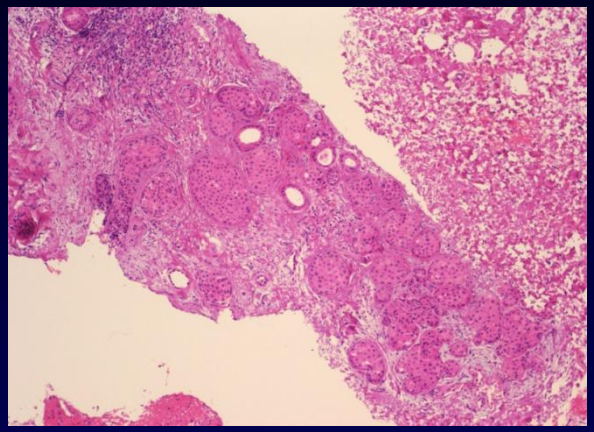
The story of a patient

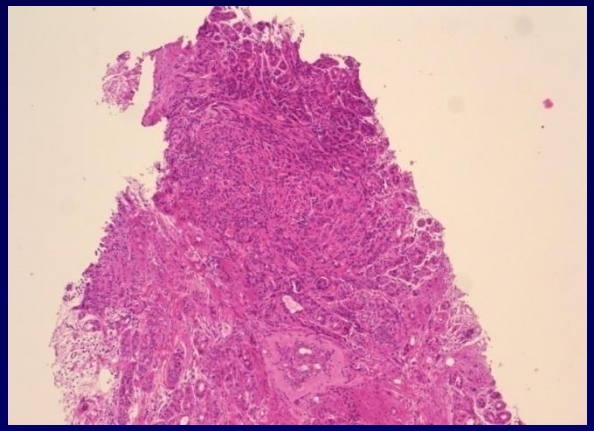
The Story

- A self-referred newly diagnosed breast cancer patient was scheduled to undergo mastectomy and lymph node dissection
- The patient was 32 years old with no risk factors and discovered the mass when showering
- The breast mass was sampled by core needle biopsy and was diagnosed as an invasive cancer
- A palpable lymph node was found and was assumed to represent a lymph node metastasis
- The patient was advised to have mastectomy and axillary dissection followed by chemotherapy

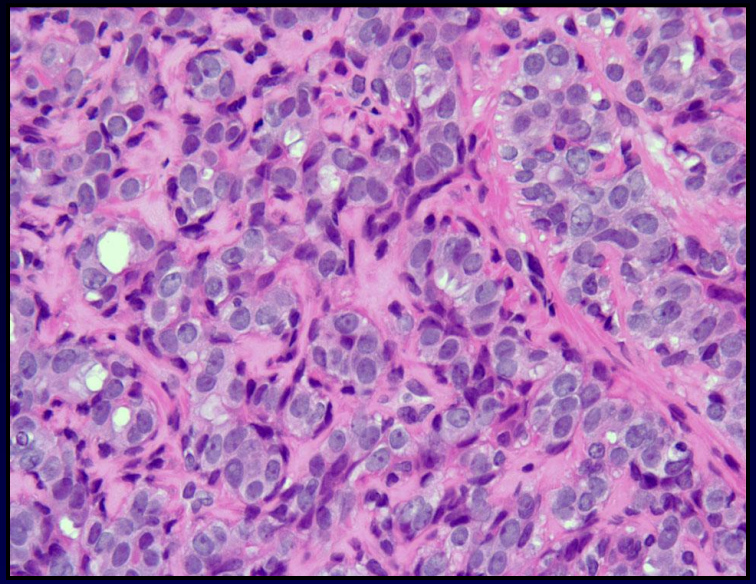
Biopsy Original Diagnosis

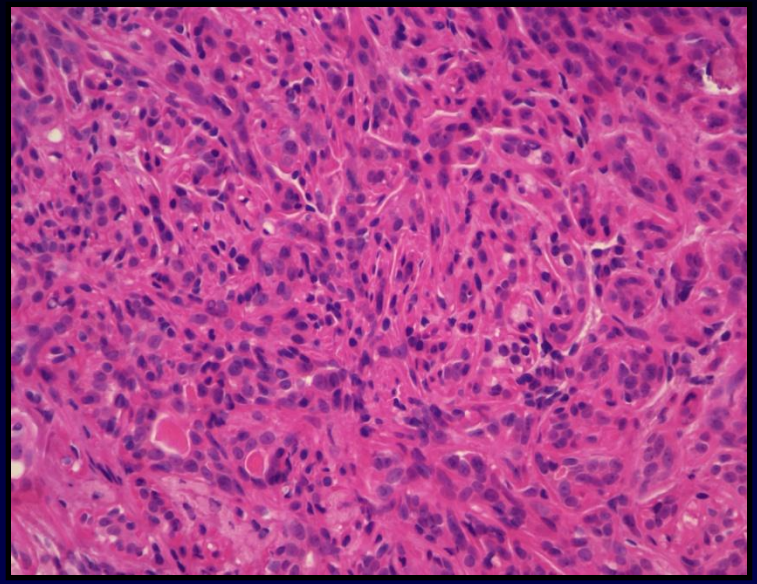
- Invasive moderately differentiated ductal carcinoma.
- Low grade ductal carcinoma in situ.

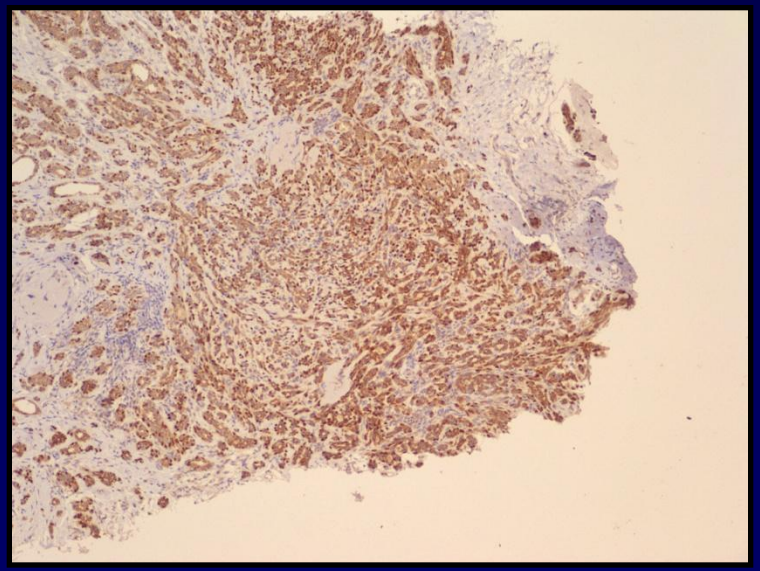


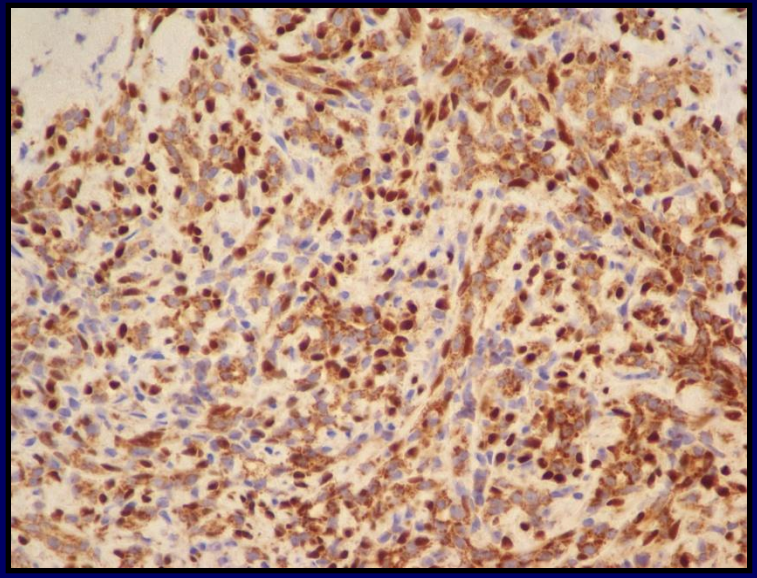


Review of the biopsy at our institution



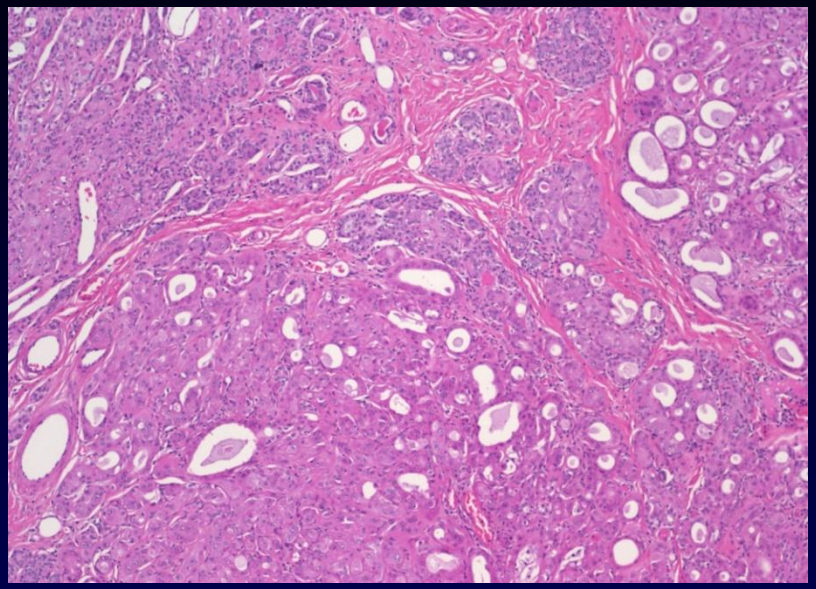


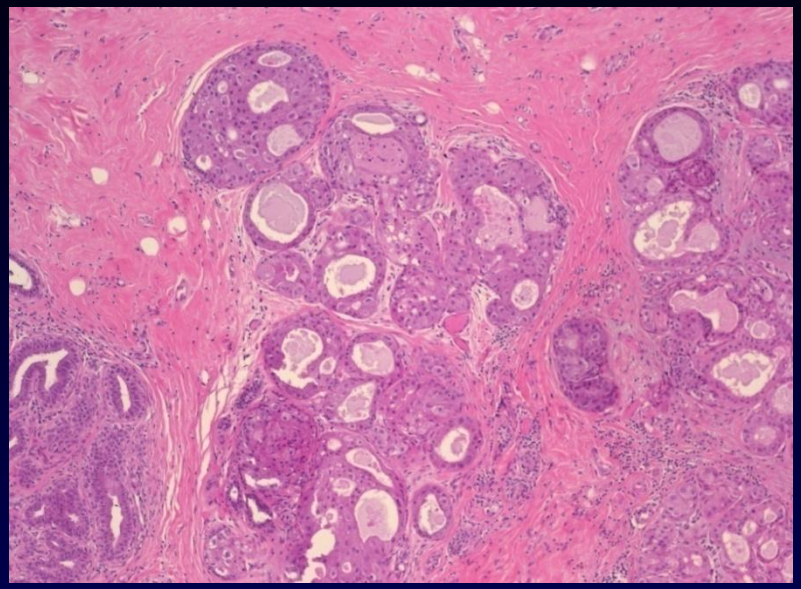


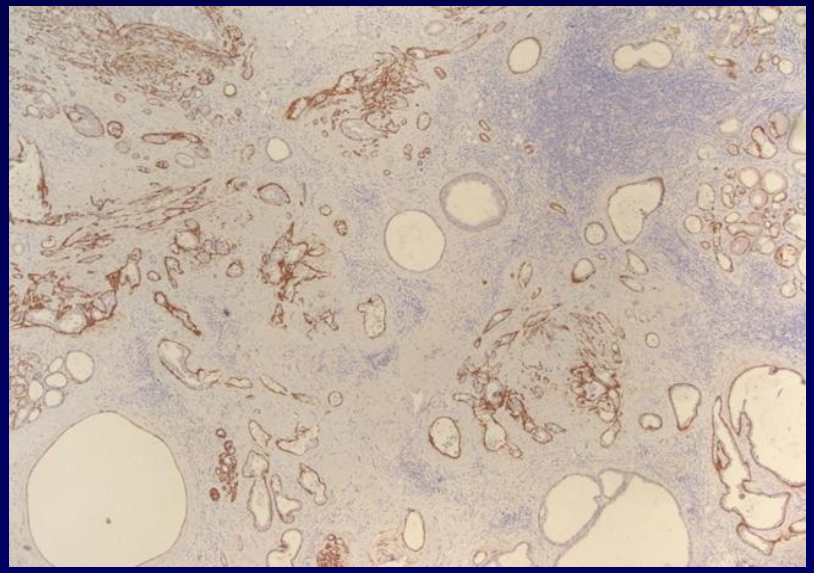


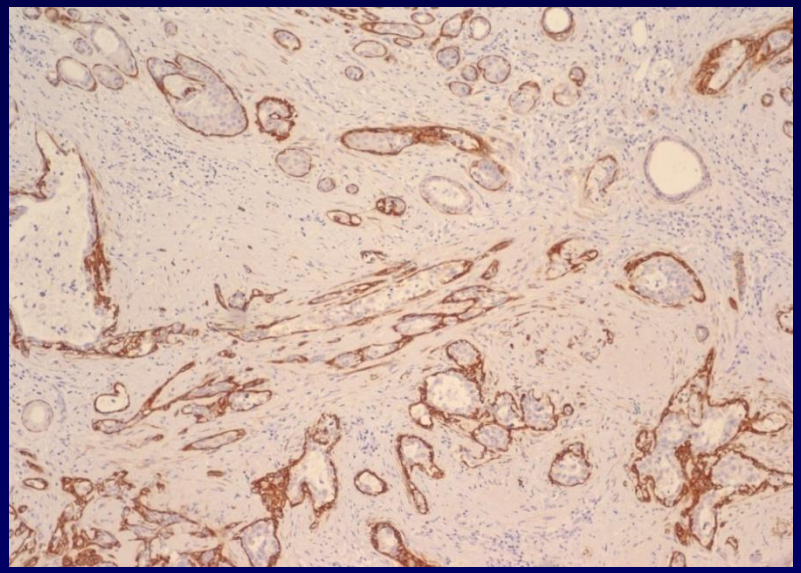
Calponin

Follow-up Excisional Biopsy









Calponin

Diagnosis

Consult Review #1

- **Atypical apocrine adenosis with associated florid sclerosis**

Consult Review #2

- **Low grade apocrine ductal carcinoma *in situ* with extensive sclerosis**

The Follow Up

- The decision was made to closely follow up the patient
- The patient underwent regular clinical breast exams and breast imaging for the last 10 years
- The patient is fine with no abnormality detected

The Impact

- Anxiety to the patient and her family
- Unnecessary expense
- Broken trust

Minimizing Errors In Breast Pathology

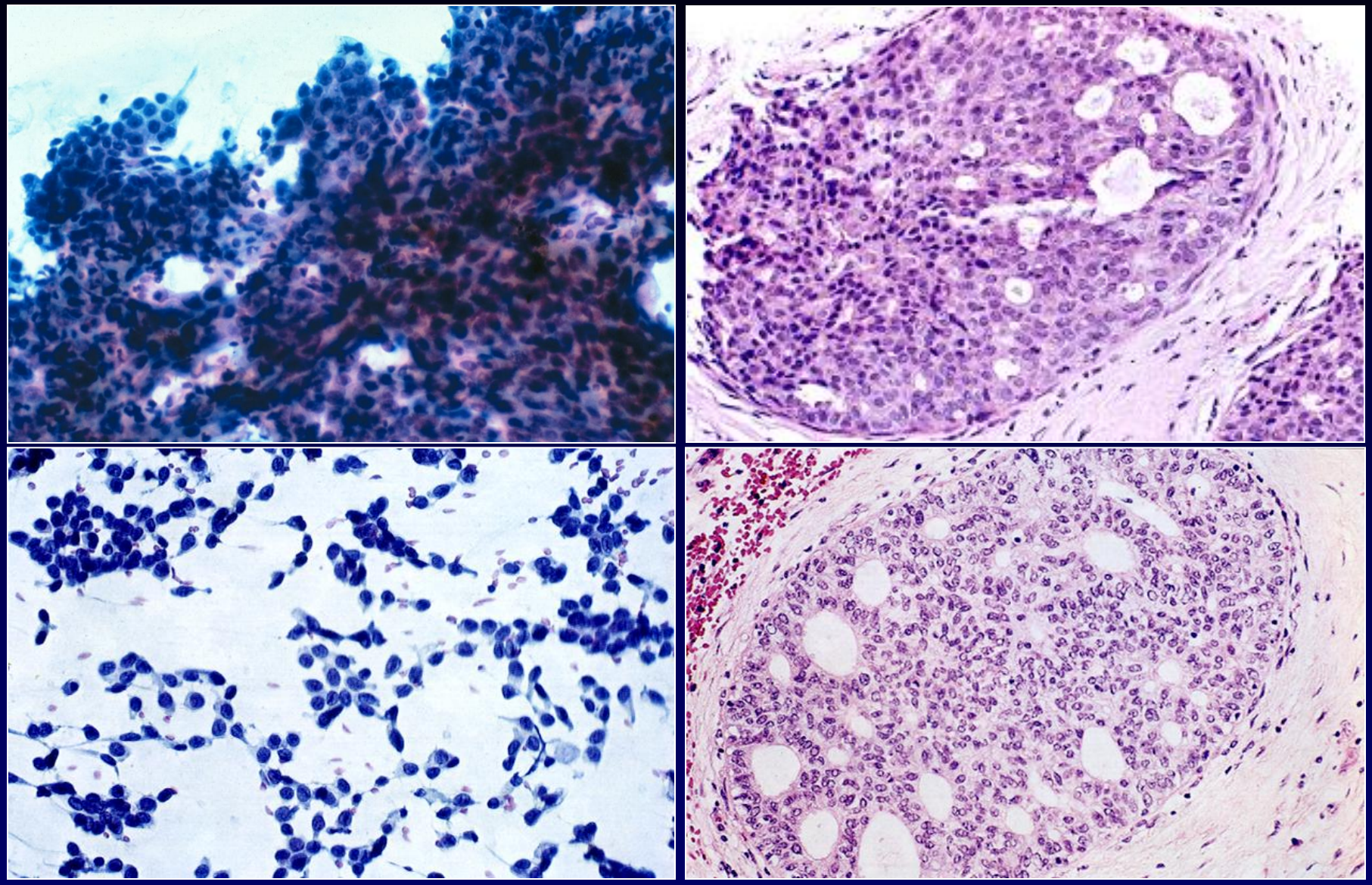
- To use appropriate immunostains as diagnostic adjuncts
  - Myoepithelial cell markers
    - Assessment of stromal invasion
    - Characterization of the nature of various breast lesions
  - E-Cadherin
    - Distinction between lobular versus ductal lesions
  - Others

Minimizing Errors in Breast Pathology

Recognition of Difficult to Diagnose Cases in Breast Pathology

- Atypical ductal hyperplasia versus low grade ductal carcinoma in situ
- Lobular neoplasia
- Papillary lesions
- Atypical sclerotic lesions
- Fibroepithelial tumors
- Mucinous lesions
- The status of microinvasion

ADH Versus DCIS



"An entity which has some but not all the features of low nuclear grade ductal carcinoma *in situ*"

ADH vs. DCIS

- **There is no consensus presently on the criteria that should be adopted and how they should be applied for the distinction between atypical hyperplasia and carcinoma *in situ***

Rosen P: Rosen Breast Pathology: Third Edition. 264-284, 2008.

The Issue

- Is it possible that ADH and low grade DCIS are in reality the same entity?
- Is it possible that we over-diagnose breast cancer?

The New York Times

The New York Times
Well
Tara Parker-Pope on Health

JULY 19, 2010, 9:01 PM

Doubt About Pathology Opinions for Early Breast Cancer

By TARA PARKER-POPE

Advances in imaging technology mean that more and more breast cancers are being detected at the earliest stages — sometimes when the rogue cells are as tiny as a few grains of salt. But now there are new questions about whether many pathologists are able to render reliable opinions on such tiny lesions, according to an extensive New York Times examination of breast cancer cases.

New York Times reporter Stephanie Saul reports that pathology errors put women at risk for unnecessary and disfiguring surgery and potentially harmful radiation treatment.

Discerning the difference between some benign lesions and early stage breast cancer is a particularly challenging area of pathology, according to medical records and interviews with doctors and patients. Diagnosing DCIS "is a 30-year history of confusion, differences of opinion and under and over treatment," said Dr. Shahla Masood, the head of pathology at the University of Florida College of Medicine-Jacksonville. "There are studies that show that diagnosing these borderline breast lesions occasionally comes down to the flip of a coin."

To learn more read the full report, "Cancer Errors May Increase With Early Test," and then please join Ms. Saul for a discussion below.

Minimizing Errors In Breast Pathology

Suggestions

- To use the term of “Borderline Breast Lesions” in difficult to diagnose cases
- To completely remove the entire lesion and suggest close follow up
- To offer risk assessment/risk reduction options in those with family history of breast cancer

The Significance?

- Over 1.1 million women are diagnosed with breast cancer each year across the globe
- Estimated diagnostic errors in breast pathology may be about 2%-9%
- It appears that a significant number of women will receive under/over treatment

Masood S: Women's Health. 2012;8(1):57-62.

The Message

Raising the Bar

- A plea for standardization and improved quality of breast pathology

Masood S: The Breast Journal 12(5):409-412, 2006.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