Published in final edited form as:

Breast J. 2017 September ; 23(5): 583–588. doi:10.1111/tbj.12797.

Specimen Identification Errors in Breast Biopsies: Age matters. *Report of Two Near-Miss Events and Review of the Literature*

Gary Tozbikian, MD,

Department of Pathology, Wexler Medical Center at The Ohio State University, Columbus, OH 43210

Mary L. Gemignani, MD, MPH, and

Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY 10065

Edi Brogi, MD PhD

Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, NY 10065

Abstract

Background—The consequences of patient identification errors due to specimen mislabeling can be deleterious.

Methods—We describe two near-miss events involving mislabeled breast specimens from two patients who sought treatment at our institution. In both cases, microscopic review of the slides identified inconsistencies between the histologic findings and patient age, unveiling specimen identification errors.

Results—By correlating the clinical information with the microscopic findings we identified mistakes that had occurred at the time of specimen accessioning at the original laboratories. In both cases, thanks to a timely reassignment of the specimens, the patients suffered no harm.

Conclusions—These cases highlight the importance of routine clinical and pathologic correlation as a critical component of quality assurance and patient safety. A review of possible specimen identification errors in the anatomic pathology setting is presented.

Keywords

Laboratory Error; Specimen Misidentification; Lactating Adenoma; Monckeberg Medial Calcific Sclerosis; Breast; Biopsy; needle core

Introduction

Near-miss events are incidents that could have resulted in significant harm to a patient, but are identified and corrected before any deleterious consequence occurs. (1-3) We describe two near-miss events that occurred following specimen identification errors in the pathology

Name and address for correspondence and reprints (including fax, telephone, and email address): Edi Brogi, MD PhD Department of Pathology, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York, NY 10065, Office: 212-639-5364, Fax: 212-639-5365 brogie@mskcc.org.

Financial Disclosures: The authors have no financial interests to disclose.

laboratory. In both cases, a malignant diagnosis was rendered for the wrong patient. Fortunately, in both cases the errors were promptly recognized and rectified, and the patients did not suffer from unnecessary or inappropriate treatment. These cases underscore the importance of thorough clinical-pathologic correlation, including patient's age.

CASE 1: A 59 year-old woman diagnosed with lactating adenoma

A 59 year-old postmenopausal woman noted a thickening in the skin of the lower inner quadrant of the right breast. A right breast ultrasound study identified a “new hypoechoic mass measuring $9 \times 18 \times 10$ mm, located in the 5-6:00 axis of the right breast, approximately 7 cm from the nipple.” The lesion spanned approximately 3 cm and showed no abnormal vascularity on Doppler assessment. A right breast mammogram showed “a vague area of increased density” corresponding to a palpable lump at 5-6:00 in the inframammary fold. A punch biopsy of the skin overlying the right lump was performed. The final report of the skin punch biopsy read: “Core biopsy, right breast at 5:00: adenosis tumor with secretory changes”. The patient sought a surgical opinion at our center. On physical exam the skin in the right breast lower inner quadrant was reddened, and a 3 cm breast mass was palpable. As per our institutional policy, the outside pathology slides were re-reviewed at our center to confirm the diagnosis prior to treatment. Review of the outside report revealed a discrepancy between the specimen designation in the clinical diagnosis section, which stated “Punch biopsy over right 5:00-7:00 lump (red skin), metastatic carcinoma” and the specimen designation in the report, which read “1. Core biopsy, right breast, 5:00, 7 cm from the nipple, 3 cm palpable lump.” The tissue represented in the slides consisted of benign breast parenchyma with lobular hyperplasia and diffuse secretory change, with extensive cytoplasmic vacuolization and abundant intraluminal secretion (Figure 1); no skin was identified. Overall, the histologic findings were morphologically consistent with extensive lactation change, as typically seen in late pregnancy or during lactation, and were deemed incompatible with the patient's age and reported postmenopausal status. We contacted the in-house surgeon who had seen the patient as well as the outside pathologist who had originally seen the case to inquire about the accuracy of the clinical history, and raise concern that a specimen identification error might have occurred. Prompt investigation of the case at the outside pathology laboratory identified a possible specimen labeling error. It appeared that at the time of accessioning, the breast skin punch biopsy specimen of the index patient had been switched with the breast needle core needle biopsy of a breast mass in a 27 year-old woman who was 7 months pregnant. The young woman had undergone core needle biopsy of a palpable breast mass on the same day as the index patient and had received a diagnosis of invasive ductal carcinoma. The index biopsy specimen and the specimen from the pregnant woman had consecutive accession numbers. The young pregnant woman was contacted by the outside radiologist and agreed to undergo a repeat needle core biopsy of her palpable breast mass in her breast. The findings in the newly procured tissue were diagnostic of a lactating adenoma. DNA polymorphic marker studies were also conducted on the index biopsy material and on the core needle biopsy sample with invasive carcinoma and confirmed that the tissue with lactation changes belonged to the young pregnant woman, whereas the invasive carcinoma was from the 59 year-old index patient. The outside pathology reports were amended accordingly. We returned index slides to the outside laboratory and received a new set of correctly labeled

slides for the 59 year-old woman. The new slides showed an invasive ductal carcinoma, moderately differentiated, involving dermis and subcutaneous tissue, consistent with the clinical findings and specimen type (Figure 2). Meanwhile, the 59 years-old woman had also undergone a MRI study at our institution, which demonstrated a 1.7×1.3 cm enhancing and spiculated mass in the right breast at 5:00, abutting the pectoralis muscle. The overlying skin showed thickening and enhancement, suggestive of dermal extension. The patient underwent right breast lumpectomy and sentinel lymph node biopsy at our institution. The breast excision specimen contained a 3.6 cm invasive ductal carcinoma. The invasive carcinoma extended into the dermis and showed lymphovascular and perineural invasion. Changes of prior procedure were also noted. The sentinel lymph node biopsy yielded three benign lymph nodes. As per conversation with the outside pathologist, the pregnant patient did not undergo any further procedure and carried on with her pregnancy.

Case #2: An 18 year-old girl diagnosed with invasive ductal carcinoma

An 18 year-old girl noticed a periareolar palpable mass in her right breast. Sonographic examination at an outside institution showed a 4 cm right breast mass at the 9:00 position. No needle core biopsy was performed. Two months later the patient underwent excisional biopsy of the mass at an outside institution and was diagnosed with two separate foci of invasive carcinoma, namely a 1.1 cm invasive ductal carcinoma, well-differentiated and a 0.3 cm invasive tubulo-lobular carcinoma. Ductal carcinoma in situ (DCIS) with intermediate nuclear grade and lobular carcinoma in situ (LCIS) were also present. The invasive carcinoma was close (<1 mm) to multiple inked surgical margins.

At this point the patient sought a second opinion at our institution. Bilateral post-excision mammograms and MRI studies at our center showed post-surgical changes in the right breast and no abnormalities in the left breast. The patient's family history was negative for breast and ovarian carcinoma; her personal medical history was also unremarkable. The clinical team had extensive discussions with the patient and her parents regarding her diagnosis of invasive breast carcinoma. BRCA germline mutation testing was planned to explore the possibility of a genetic predisposition to breast cancer. Different treatment options were discussed. Given that the patient's young age predisposed her to a very high risk of local recurrence, and the risk posed by the secondary effects of radiation therapy, the patient and her family favored unilateral mastectomy.

As per our institutional policy, the outside pathology slides were re-reviewed at our center to confirm the diagnosis prior to treatment. Our pathology review confirmed the morphologic diagnosis of invasive and in-situ carcinoma (Figure 3). However we noted the presence of numerous dystrophic calcifications in the intima layer of few medium-sized arteries, a finding that we deemed inconsistent with the patient's age (Figure 4). We therefore contacted the surgeon caring for this patient, and raise the concern that a specimen identification error may have occurred in the outside laboratory. Our surgeon contacted the outside pathology department, where an investigation was promptly started. Additional inconsistencies in the outside pathology report were also noted. In particular, the specimen gross description mentioned a needle-localization wire, however, the outside surgeon confirmed that the index patient had not undergone needle localization before the excisional biopsy procedure.

After a thorough evaluation of the cases processed at the outside laboratory was conducted, it appeared that a specimen labeling error might have occurred there at some point, and the index patient's breast excision had been switched with that of a woman in her 7th decade of life. The elderly patient had received a diagnosis of mammary fibromatosis (desmoid tumor). DNA polymorphic marker analysis of blood samples obtained from the 18 year-old girl and from the index specimen confirmed that the specimen with invasive carcinoma was not hers. The outside laboratory and clinicians informed the 18 year old and 70 year old patients of the error, and the final reports were amended accordingly. We received for review the correct slides from the surgical excision specimen of our patient. The slides showed mammary fibromatosis (desmoid tumor) spanning 2.7 cm. The 18 years-old girl received no further treatment.

Discussion

In this report, we describe two near-miss events due to specimen identification errors that resulted in a malignant diagnosis being rendered for the wrong patient. In both cases the errors were recognized because the histologic findings were deemed inconsistent with the patient's age. Although it is common knowledge that patient's age is critical to narrow down the differential diagnosis of some lesions, such as bone or brain tumors, patient's age can play a role also in the evaluation of breast lesions.

In the first case, lobular hyperplasia and extensive secretory changes were inconsistent with the patient's postmenopausal status and age of 59 years. Lactating adenoma is a mass-forming lesion consisting of a tubular adenoma with secretory changes and is usually observed in the second or third trimester of pregnancy or during lactation. (4) It can present as a palpable mass or a mass-like lesion or density on imaging and is frequently sampled by needle core biopsy. (5, 6) Focal secretory change can also occur at in women who are neither pregnant nor lactating (7, 8), and its frequency ranges from 1.7% to 3% in surgical pathology and autopsy series. (7-9) In women who are not pregnant or lactating, pregnancy-like changes are always limited. The intraluminal secretion associated with secretory change sometimes undergo calcification (5) and are detected as mammographic calcifications, which can be sampled by needle core biopsy. (10) (11) Pregnancy-like change in the breast of a postmenopausal woman is never extensive or mass forming.

In the other case, we identified the presence of calcific deposits in the intima and media layers of small muscular arteries. These changes are the manifestation of Mönckeberg's calcific sclerosis, a non-inflammatory calcifying degenerative alteration of small and medium sized arteries distinct from atherosclerosis. Although its pathogenesis is not fully understood, this lesion is associated with diabetes mellitus, osteoporosis, chronic renal failure, and old age. (12-14) The median age of 12 patients Mönckeberg's sclerosis with was 74 years.(15) Breast cancer, in particular multifocal low-grade invasive mammary carcinoma, is more common in elderly women. In contrast, mammary fibromatosis usually occurs in women of fertile age (18 to 50 years old), although it can occur in women as old as 76 years (16).

Routine accessioning and processing of a tissue sample in a pathology laboratory involves multiple steps in which the specimen is transferred, divided, and relabeled. In the course of this process there are several points at which a specimen identification error might occur, and involve patient identifying information, tissue origin, and specimen laterality, among others. (3) The reported overall error rate in specimen identification and handling in the pathology laboratory ranges between 0.1% and 9%. (17-21). In particular, specimen identification errors are reported to range between 0.04% and 0.1%. These data, however, likely underestimate the phenomenon, as many incidents might be undetected or unreported. (3, 22-24)

A CAP study of the accuracy rate in specimen accessioning in anatomic pathology evaluated data from 1,004,115 cases processed by 407 different laboratories, and found an overall identification error rate of 0.57%. Most of these errors were recognized by accessioning and histology personnel, and were only minor inconsistencies that carried a low risk of causing an incorrect diagnosis for the wrong patient. (25) A similar study at a high-volume academic institution reported that mislabeling errors occurred in 91 of 21,351 (4 in 1000) specimens, and were most common for breast specimens. A total of 9 (4 in 10,000) specimens were mislabeled with the incorrect patient name.(26)

Any pathology specimen identification error has the potential to result in significant patient harm, as the pathologic diagnosis of a biopsy or excision specimen is usually critical for treatment planning. Needless to say, a specimen identification error can also have serious medicolegal consequences. In a review of 335 consecutive pathology malpractice claims made to a physician liability insurance company, the indemnity awarded for jury-verdicts against pathologists was significant.(27) In this series, breast specimens accounted for the second highest number of claims involving biopsy specimens. When considering all specimen types, including frozen sections and fine needle aspiration cases, breast-related litigations constituted the most common type of claim, adding up to 15.5% of the total. Although most claims involved interpretive errors, 13 (4%) involved specimen mix-ups, of which seven pertained to breast specimens. (27) In addition to specimen identification errors, other possible source of errors with clinical and legal impact can be related to problems during specimen transportation and processing; communication errors caused by incomplete or erroneous clinical information; sampling errors; in addition to interpretive errors caused by poorly reproducible or poorly defined diagnostic and prognostic criteria. (28) Each one of these errors has the potential of causing serious patient harm and lead to malpractice litigation. Despite increasing awareness and attention paid towards prevention of errors in pathology practice, errors still occur in pathology. In particular, mislabeling of specimen can occur, and pathologists need to be vigilant, both in the best interest of the patient and of their own. Before finalizing a diagnosis, it is the pathologist's responsibility to ensure that all facets of a case fit nicely together, including age, radiographic findings, and the background histologic changes, or at least that none is in obvious dissonance with the others.

Acknowledgments

Funding Acknowledgement: This research was funded in part through the NIH/NCI Cancer Center Support Grant P30 CA008748.

All Sources of Support: None

References

1. Smith ML, Wilkerson T, Grzybicki DM, Raab SS. The effect of a Lean quality improvement implementation program on surgical pathology specimen accessioning and gross preparation error frequency. *American journal of clinical pathology*. 2012; 138(3):367–73. [PubMed: 22912352]
2. Smith ML, Raab SS. Assessment of latent factors contributing to error: addressing surgical pathology error wisely. *Archives of pathology & laboratory medicine*. 2011; 135(11):1436–40. [PubMed: 22032570]
3. Valenstein PN, Sirota RL. Identification errors in pathology and laboratory medicine. *Clinics in laboratory medicine*. 2004; 24(4):979–96. vii. [PubMed: 15555752]
4. Lakhani, SR., International Agency for Research on Cancer. World Health Organization. WHO classification of tumours of the breast. 4. Lyon: International Agency for Research on Cancer; 2012. p. 240
5. Rosen, PP. Rosen's breast pathology. 3. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2009. p. xpx. 1116
6. Tobin CE, Hendrix TM, Resnikoff LB, Mendelson EB, Geyer SJ. Breast imaging case of the day. Multicentric intraductal papillary carcinoma. *Radiographics*. 1996; 16(3):720–2. [PubMed: 8897638]
7. Kiaer HW, Andersen JA. Focal pregnancy-like changes in the breast. *Acta pathologica et microbiologica Scandinavica Section A, Pathology*. 1977; 85(6):931–41.
8. Frantz VK, Pickren JW, Melcher GW, Auchincloss H Jr. Incidence of chronic cystic disease in so-called "normal breasts; a study based on 225 postmortem examinations. *Cancer*. 1951; 4(4):762–83. [PubMed: 14859197]
9. Sandison AT. An autopsy study of the adult human breast: with special reference to proliferative epithelial changes of importance in the pathology of the breast. *National Cancer Institute monograph*. 1962; 4:1–145. [PubMed: 14496858]
10. Shin SJ, Rosen PP. Pregnancy-like (pseudolactational) hyperplasia: a primary diagnosis in mammographically detected lesions of the breast and its relationship to cystic hypersecretory hyperplasia. *The American journal of surgical pathology*. 2000; 24(12):1670–4. [PubMed: 11117789]
11. Galman L, C J, Cordero A, et al. Secretory and Cystic Hypersecretory Changes at Breast Core Needle Biopsy: Clinical, Radiologic and Pathologic Findings in 67 Cases. United States & Canadian Academy of Pathology Annual Meeting. 2013
12. Goebel FD, Fuessl HS. Monckeberg's sclerosis after sympathetic denervation in diabetic and non-diabetic subjects. *Diabetologia*. 1983; 24(5):347–50. [PubMed: 6873514]
13. Amos RS, Wright V. Monckeberg's arteriosclerosis and metabolic bone disease. *Lancet*. 1980; 2(8188):248–9. [PubMed: 6105406]
14. Silbert S, Lippmann HI, Gordon E. Monckeberg's arteriosclerosis. *AMA archives of internal medicine*. 1956; 97(3):378–83. [PubMed: 13291917]
15. Micheletti RG, Fishbein GA, Currier JS, Fishbein MC. Monckeberg sclerosis revisited: a clarification of the histologic definition of Monckeberg sclerosis. *Archives of pathology & laboratory medicine*. 2008; 132(1):43–7. [PubMed: 18181672]
16. Neuman HB, Brogi E, Ebrahim A, Brennan MF, Van Zee KJ. Desmoid tumors (fibromatoses) of the breast: a 25-year experience. *Annals of surgical oncology*. 2008; 15(1):274–80. [PubMed: 17896146]

17. Safrin RE, Bark CJ. Surgical pathology sign-out. Routine review of every case by a second pathologist. The American journal of surgical pathology. 1993; 17(11):1190–2. [PubMed: 8214266]
18. Furness PN, Lauder I. A questionnaire-based survey of errors in diagnostic histopathology throughout the United Kingdom. Journal of clinical pathology. 1997; 50(6):457–60. [PubMed: 9378808]
19. Renshaw AA, Young ML, Jiroutek MR. How many cases need to be reviewed to compare performance in surgical pathology? American journal of clinical pathology. 2003; 119(3):388–91. [PubMed: 12645341]
20. McBroom HM, Ramsay AD. The clinicopathological meeting. A means of auditing diagnostic performance. The American journal of surgical pathology. 1993; 17(1):75–80. [PubMed: 8447511]
21. Raab SS, Nakhleh RE, Ruby SG. Patient safety in anatomic pathology: measuring discrepancy frequencies and causes. Archives of pathology & laboratory medicine. 2005; 129(4):459–66. [PubMed: 15794667]
22. College of American P. Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. Archives of pathology & laboratory medicine. 2006; 130(8):1106–13. [PubMed: 16879009]
23. Wagar EA, Stankovic AK, Raab S, Nakhleh RE, Walsh MK. Specimen labeling errors: a Q-probes analysis of 147 clinical laboratories. Archives of pathology & laboratory medicine. 2008; 132(10): 1617–22. [PubMed: 18834220]
24. Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. Archives of pathology & laboratory medicine. 2006; 130(11):1662–8. [PubMed: 17076528]
25. Nakhleh RE, Zarbo RJ. Surgical pathology specimen identification and accessioning: A College of American Pathologists Q-Probes Study of 1 004 115 cases from 417 institutions. Archives of pathology & laboratory medicine. 1996; 120(3):227–33. [PubMed: 8629896]
26. Makary MA, Epstein J, Pronovost PJ, Millman EA, Hartmann EC, Freischlag JA. Surgical specimen identification errors: a new measure of quality in surgical care. Surgery. 2007; 141(4): 450–5. [PubMed: 17383521]
27. Troxel DB. Medicolegal aspects of error in pathology. Archives of pathology & laboratory medicine. 2006; 130(5):617–9. [PubMed: 16683874]
28. Wick MR. Medicolegal liability in surgical pathology: a consideration of underlying causes and selected pertinent concepts. Seminars in diagnostic pathology. 2007; 24(2):89–97. [PubMed: 17633350]

Figure #1.

Patient #1. Images of the index core biopsy showing lobular hyperplasia and lactational changes. These findings were deemed incompatible for a 56-year old woman of postmenopausal status. (Image A: Low power. Image B: High power.)

Figure 2.
Patient #1. Images of the patient's correct skin punch biopsy showing invasive ductal carcinoma infiltrating the dermis and subcutaneous tissue. (Image C: Low power. Image D: High power.)

Figure 3.
Patient #2. Images of the index excisional biopsy showing invasive ductal carcinoma. (Image E: Low power. Image F: High power.)

Figure 4. Patient #2. Images of the index excisional biopsy showing invasive ductal carcinoma. In the non-neoplastic breast parenchyma, several vessels show Mönckeberg's medial sclerosis (Image G: Low power. Image H and I: High power.)