The Medicolegal Aspect of Error in Pathology

A Search of Jury Verdicts and Settlements

Michael J. Kornstein, MD; Sean P. Byrne, JD

• ***Context.*—Identifying medical errors is a topic of current attention. Among the various approaches is the study of medical malpractice cases.**

***Objective.*—To identify the most common medical errors involving the practice of pathology from a medicolegal perspective by analysis of published jury verdict and settlement reports.**

***Design.*—Search approximately 50 publications that gather jury verdict and settlement information using LexisNexis, an on-line searchable archive, for pathology-related cases.**

***Results.*—One hundred seventy-one legal cases were identified from 1988 through 2005. Nearly one-half involved surgical pathology; among the remainder, cytology cases slightly outnumbered those pertaining to clinical pathology. Among the surgical pathology cases and overall, based on this database, the most common reason for a medical malpractice lawsuit related to pathology was the alleged missed diagnosis of melanoma on a skin biopsy specimen. Less commonly, the surgical pathology cases involved breast biopsy specimens, gynecological specimens, lung, genitourinary system, technical or preanalytic errors (eg, mixed-up specimens), soft tissue, hematopathology, head and neck, gastrointestinal/hepatobiliary system, or thyroid. Among the 48 cases related to cytology, 37 involved false-negative Papanicolaou smears. Less common were cases related to fine-needle aspirates of the breast or thyroid or cytology specimens of the lung. Among the 36 cases involving clinical pathology, 32 related to the blood bank—usually transfusion-acquired human immunodeficiency virus infection.**

***Conclusions.*—These data are in agreement with other publications as to the most frequent causes of medical malpractice allegations related to pathology. As these issues are addressed, the number of errors should decrease. Studying the jury verdict and settlements data may provide additional insight into medical errors and patient safety.**

(*Arch Pathol Lab Med.* 2007;131:615–618)

Reducing errors in pathology practice has recently been the subject of a symposium and individual articles.[1–3] Identifying the most likely errors is part of any effort at reducing them. One approach for identifying common errors involves the medicolegal system. Although not all medical errors result in litigation, a survey of legal claims is one method of identifying errors that generate adverse outcomes. One source for these data is the insurance industry. For example, Troxel has reviewed the pathology malpractice claims for The Doctors Company, a professional liability insurer based in Napa, Calif.[3,4] Another source is on-line searching of reported jury verdicts and settlements.

A published jury verdict and settlement report typically contains the dollar amount awarded to the plaintiff who prevails in a civil trial or receives a negotiated settlement, as well as an overview of the facts and issues in the case. A ''verdict'' is an award by a jury. A ''settlement'' in this context is an agreement between the disputing parties to resolve a civil case through a negotiated solution. Unlike appellate court opinions discussing points of law, which are often published in official reporters, jury verdicts and settlements at the trial court level are not systematically reported. Instead, they are reported unofficially on a case-by-case basis to an assortment of proprietary publications that solicit such information in order to share it with legal, insurance, and medical industry subscribers primarily for the purpose of assisting attorneys in negotiating settlements and evaluating cases.[5–7] Verdicts and settlements are also reported by legal practitioners as a marketing effort by the attorney who achieved a desired result for a client. Almost all verdict and settlement resources rely on a practitioner's submissions of information, and therefore the data should be relied upon cautiously. Like the anecdotal case report in the medical literature, the verdict and settlement report reflects the experience of one particular fact situation. The conclusions that can be drawn from any one report are limited; taken as a whole, however, this body of data provides some insight into common errors.

LexisNexis is a popular searchable archive of newspapers, magazines, legal documents, and other printed sources that claims to provide the world's largest collection of public records.[8] Among the offerings of the subscription service is the on-line capability to search jury verdicts and settlements. Such searches include the infor-

Accepted for publication September 12, 2006.

From the Department of Pathology, Henrico Doctors' Hospital, Richmond, Va (Dr Kornstein); and Hancock, Daniel, Johnson & Nagle, PC, Glen Allen, Va (Mr Byrne).

The authors have no relevant financial interest in the products or companies described in this article.

Reprints: Michael J. Kornstein, MD, Commonwealth Laboratory Consultants, Henrico Doctors' Hospital–Forest Campus, 1602 Skipwith Rd, Richmond, VA 23229 (e-mail: mkornstein@aol.com).

Table 1. Summary of 171 Jury Verdict and Settlement Cases			
	Surgical Pathology	Cytology	Clinical Pathology
1988–1993	26	9	16
1994–1999	25	20	14
2000–2005	33	19	9
Total	**84**	**48**	**39**

mation compiled by LexisNexis from approximately 50 publications that gather jury verdict and settlement information. Other services offer similar data.[7]

MATERIALS AND METHODS

Using LexisNexis, searches were performed of federal and state jury verdicts and settlements. Medical malpractice cases involving pathology were identified using broad terms expected to be included in the substance of relevant reports, including *pathology, pathologist, cytology,* and *laboratory*. Additional searches were then performed using more specific terms, such as the last names of recurring expert witnesses, specific types of specimens (aspirate, biopsy, core, Pap), blood bank, and the word *misread*. Duplicate cases were excluded.

RESULTS

One hundred seventy-one case summaries involving medical malpractice suits against pathologists or laboratories, from 1988 through 2005, were identified (Tables 1 and 2). Many of the summaries have incomplete information; for example, in some, the text is unclear as to whether the defendants were the pathologists individually or their institutions. As shown in Tables 1 and 2, the cases most commonly involve surgical pathology specimens, fol-

Table 2. Details of Jury Verdict and Settlement Cases				
	Total	False-Negative	False-Positive	Comment
Surgical pathology	84			
Skin	26	26	0	All related to missed diagnosis of melanoma; 3 specify original diagnosis of Spitz nevus; others originally diagnosed as "benign nevus" or other type of tumor; no defense verdicts
Breast	11	8	3	1 Case dismissed, 1 defense verdict; others either settled or had plaintiff verdict; 4 cases involved diagnosis of ductal carcinoma in situ (vs atypical ductal hyperplasia, ductal hyperplasia, sclerosing papillary lesion); 1 missed angiosarcoma; false-positives led to unnecessary mastectomy; false-negatives led to delay in diagnosis
Gynecology	9	6	2	2 Defense verdicts—1 on the basis of expired statute of limitations and the other on a vulvar adnexal tumor allegedly misdiagnosed as a basal cell carcinoma; other cases include 4 missed ovarian cancers; a case called "atypical fibrosis" on a frozen section of a pelvic mass that showed no tumor in the pelvic exenteration; 1 case of cervical cancer that was undercalled microinvasive; 1 where obstetrician was not notified of absence of chorionic villi in a curretting; 1 case of alleged negligence in failing to diagnose "atypical endometriosis"
Lung	5	1	3	1 Verdict for defense on false-positive diagnosis where defense argued that the cancer was masked by an infection; another defense verdict on an alleged missed diagnosis of tuberculosis; 1 case of a false-positive frozen section was dismissed on a technicality
Soft tissue	5	5	0	1 Defense verdict involving a 3-y delay in diagnosis and "large wide excision"–type of tumor not specified; other verdicts involved 3 undercalled sarcomas and 1 margin miscalled as negative
Hematopathology	5	5	0	2 Defense verdicts of which 1 was lymphoma misdiagnosed as carcinoma leading to a 9-mo delay in treatment and the other alleged misdiagnosis of lymphoma as atypical hyperplasia leading to unspecified delay; other cases involved lymphomas misdiagnosed as thyroiditis, sarcoid, and carcinoma
Central nervous system	4	2	2	2 Defense verdicts; 1 settlement, and 1 $26.9 million jury award for a case in which a meningioma was misdiagnosed as a pituitary adenoma with consequent complications; 2 cases involved overdiagnosis of astrocytoma
Otorhinolaryngology	4	4	0	3 Tongue biopsy specimens of squamous cell carcinoma allegedly misdiagnosed as benign; 1 defense verdict involved the diagnosis of an "ossifying fibroma"
Gastrointestinal/hepatobiliary	3	0	1	1 Case of an overcalled gastric biopsy and 2 cases with communication issues: 1 where the pathologist did not directly notify the surgeon that carcinoma was found unexpectedly in a colectomy for diverticulitis, and a similar claim in a case of a cholecystectomy
Genitourinary	5	4	1	2 Missed penile carcinomas, 1 missed prostate carcinoma in transurethral prostatectomy, 1 overcalled prostate biopsy specimen, 1 seminoma misdiagnosed as lymphoma
Thyroid	1	1	0	Papillary carcinoma missed on fine-needle aspirate and lobectomy
Technical problems	6	1	4	2 Uteri mixed up; 2 floaters leading to false-positive lung biopsy specimens; 1 lost specimen; 1 gastric biopsy specimen mislabeled
Cytology	48			
Breast fine-needle aspirates	6	2	4	2 Fibroadenomas overcalled; 1 cancer undercalled fibroadenoma
Papanicolaou smears	37	37	0	All false-negative Papanicolaou smears; 4 defense verdicts
Hematopathology	1	0	1	Cerebrospinal fluid overcalled lymphoma
Lung	3	0	3	2 Fine-needle aspirates and 1 bronchoscopic specimen overcalled malignant
Thyroid fine-needle aspirate	1	1	0	9-mo delay in diagnosis—defense verdict

Table 3. Clinical Pathology Cases*		
	No. of Cases	Comment
Blood bank	32	27 HIV acquired by transfusions; 2 Rh related; 2 hepatitis B acquired by transfusions; 1 delay in transfusion
Other	4	3 HIV related; 1 failure to telephone a critical value

* HIV indicates human immunodeficiency virus.

lowed in frequency by cytology aspirates/fluids and clinical pathology issues. Thirty-three (19%) of the 171 cases had a defense verdict or dismissal of the pathologist; the other 138 were decided in favor of the plaintiff. Jury awards or settlements ranged from $52,000 to $26.9 million. Among the various areas within surgical pathology, dermatopathology was most often involved and specifically related to the underdiagnosis of melanoma on skin biopsy specimens; all 26 cases involving the skin were alleged false-negative diagnoses of melanoma. Several case summaries referred to Spitz nevi as the erroneous diagnosis; most did not specify the original benign diagnosis. The breast was the second most common type of surgical pathology specimen; both false-negative (8) and false-positive (3) diagnoses occurred, resulting in litigation.

System errors (including those that were preanalytic) were identified in 7 surgical pathology cases. Four involved lost or mixed-up specimens. In 2 cases, floaters led to false-positive diagnoses (both for lung biopsy specimens). Another case involved a patient with a ruptured tubal pregnancy whose obstetrician was not informed about the absence of chorionic villi in a previously obtained uterine curetting. One case resulted in a defense verdict: a lost skin biopsy specimen in a patient whose rash resolved. The other 6 had jury awards or settlements ranging from $50,000 to $1.5 million.

In cytology, most cases involved false-negative Papanicolaou smears. Next most common were breast fine-needle aspirates where 5 were false-positive and 1 was a false-negative. The remaining cases were a cerebrospinal fluid specimen (false-positive diagnosis of lymphoma), 3 lung specimens (2 fine-needle aspirates and 1 fluid; all false-positive), and 1 false-negative thyroid aspirate. Among all 48 cytology cases, there were 8 defense verdicts. The remaining cases had awards or settlements from $75,000 to $7 million.

In clinical pathology, most cases were related to the blood bank with 90% involving transfusion-acquired human immunodeficiency virus (HIV); other cases involved Rh testing, hepatitis B, and a transfusion delay (Table 3). Issues pertaining to HIV predominated among the 6 non–blood bank cases, with 5 false-positive HIV tests (4 due to mixed-up tubes and 1 unexplained). The remaining non–blood bank case involved a failure to call back a critical value. Among the 39 clinical pathology cases, 12 resulted in defense verdicts or dismissal; awards on the remaining cases ranged from $58,700 to $8.1 million.

COMMENT

Review of the data reveals several recurring themes. Three situations account for 51% of all cases in this database: the melanoma allegedly missed on a skin biopsy specimen, the Papanicolaou smear in which the dysplasia or malignancy was apparently overlooked, and the transfusion-acquired HIV infection.

Further analysis of the data reveals several additional issues. For breast biopsy specimens, the diagnosis of ductal carcinoma in situ is a recurring problem. The case summary of one such case describes a ''small focus'' of intraductal carcinoma originally diagnosed as atypical ductal hyperplasia. After listening to expert breast pathologists debate the diagnosis, the jury found that the distinction between atypical hyperplasia and intraductal cancer ''could be readily made by a competent pathologist'' and awarded the patient (who subsequently developed metastatic cancer) a $3 million verdict. In contrast to the conclusion of the jury in that case, pathologists are generally well aware of overlapping, subjective features obscuring the reproducible distinction between atypical ductal hyperplasia and ductal carcinoma in situ.[9,10] For breast fine-needle aspirates, fibroadenomas were a problem that led to litigation. Two fibroadenomas were overcalled infiltrating carcinoma and in another case, a carcinoma was interpreted as a fibroadenoma. Several cases reflected inadequate communication; the pathologist assumed that the surgeon would learn of an unexpected diagnosis by reading a pathology report, but the report never reached the surgeon.

Five cases involved squamous cell carcinomas (3 of the tongue, 2 penile) that were missed on biopsy specimens. Four ovarian carcinomas were missed. Several cases involved frozen sections, including the one with the largest award from this population of case reports ($26.9 million), where the frozen section diagnosis was pituitary adenoma and retrospective review of the frozen section showed normal pituitary. The patient turned out to have a meningioma.

Comparison of these data to those of Troxel[3] reveals similarity, with the false-negative diagnosis of melanoma as the most common claim in surgical pathology, followed by those involving breast biopsy specimens. Regarding cytology, the present data show a greater percentage of Papanicolaou smear cases. Also, unlike in Troxel's data, the Papanicolaou smear cases do not appear to have decreased in more recent years. More clinical pathology cases are identified in the present study, presumably because many of the lawsuits involve institutions rather than individual pathologists; only the pathologists would likely be insured by Troxel's company and thus included in his data set.

In light of these data and the progress in the profession toward error reduction, one would hope to see decreasing numbers of the most common pathology-related lawsuits. Regarding melanoma, pathologists should be increasingly aware of the problem and more frequently seek pathology consultation. Papanicolaou smear cases might decrease with improving quality control, and eventually, from the effect of the human papillomavirus vaccine. Transfusion-acquired HIV infection should decrease with the increasingly sensitive tests for excluding HIV-contaminated blood.

Personal injury lawyers have used jury verdict research for decades as a guide to valuing their cases. These data have other valuable uses for the pathology practitioner. Reviewing the jury verdicts and settlement reports provides another avenue of insight into the range of errors related to the practice of pathology and thus is instructive as the

profession works to reduce those errors and improve patient safety.

References

1. Fletcher CD. Symposium on errors, error reduction, and critical values in anatomic pathology. *Arch Pathol Lab Med.* 2006;130:602–603.
2. Zarbo RJ, Meier FA, Raab SS. Error detection in anatomic pathology. *Arch Pathol Lab Med.* 2005;129:1237–1245.
3. Troxel DB. Medicolegal aspects of error in pathology. *Arch Pathol Lab Med.* 2006;130:617–619.
4. The Doctors Company. Specialty related risks: pathology. Available at: http://www.thedoctors.com/risk/specialty/pathology/default.asp. Accessed August 21, 2006.
5. Jury Verdicts and Awards. University of Minnesota Law School. Available at: http://www.law.umn.edu/library/tools/pathfinders/verdicts1.html. Accessed August 21, 2006.
6. Jury Verdicts and Settlements. Los Angeles County Law Library. Available at: http://lalaw.lib.ca.us/jury.htm. Accessed August 21, 2006.
7. Bisset J, Heinen M. Putting a price on it: researching jury verdicts and settlements. Available at: llrx.com/columns/reference18.htm. Accessed August 21, 2006.
8. LexisNexis. Available at: http://www.lexisnexis.com. Accessed August 21, 2006.
9. Rosai J. Borderline epithelial lesions of the breast. *Am J Surg Pathol*. 1991; 15:209–221.
10. Pinder SE, Ellis IO. The diagnosis and management of pre-invasive breast disease: ductal carcinoma in situ (DCIS) and atypical ductal hyperplasia (ADH)—current definitions and classification. *Breast Cancer Res*. 2003;5:254–257.