Investigation of pathology malpractice claims in China from 2002-2015

Yuan Li [a], Dong Gao [b], Meng Tu [a], Ying-zhen Luo [a], Zhen-hua Deng [a, *]

[a] Department of Forensic Pathology, West China School of Preclinical and Forensic Medicine, Sichuan University, Chengdu 610041, PR China
[b] Shanghai Key Laboratory of Forensic Medicine, Institute of Forensic Science, Ministry of Justice, No. 1347 West Guang Fu Road, Shanghai 200063, PR China

ABSTRACT

Objective: To examine pathology-related medical claims in China and identify the most common errors to result in such claims.

Method: A retrospective analysis was performed of 71 forensic evaluation reports carried out in two Chinese institutes of forensic medicine between 2002 and 2015 due to suspicion of medical malpractice. The judicial outcomes of each case were also reviewed when available.

Results: Of 71 cases, 54 cases had judicial outcomes. The most frequently claimed events were false-negative diagnoses of skin cancer, invasive ductal carcinoma of the breast, and osteosarcoma; and false positive diagnoses of uterine cervical squamous cell carcinoma, gastric carcinoma, and soft tissue carcinoma. The most common cause of error (82%, 56 of 68) was pathological misinterpretation. Plaintiffs in most cases (89%, 48 of 54) received compensation.

Conclusion: Our data are in agreement with other findings regarding the most frequent medical malpractice allegations related to pathology. Addressing the issues at the root of these claims would lead to a decline in the number of medical errors. Quality assurance programs and good pathologist-clinician communication may decrease the risk of litigation.

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1. Introduction

Pathological diagnoses serve as an important basis of treatment decisions. It seems more difficult for patients to tolerate and comprehend a pathology-related medical mistake than other types of medical mistakes. However, the formation of a pathological diagnosis is characterized as an exercise of judgment under conditions of uncertainty. As Foucar says, pathologists function as a black box, processing information and outputting diagnoses.[1] There are also external factors that contribute to potential errors, such as obtaining accurate and pertinent clinical information from clinicians, the existence of a clear and consistent array of diagnostic criteria, and the standardization of staining technology.

A medical malpractice claim is defined as a lawsuit against a health care provider or facility filed by a patient or his relatives for an alleged injury arising from medical care. The Chinese judicial system consists of the Supreme Court, high courts, intermediate courts, and district courts. No jury is present. All malpractice claims are filed in district courts first. If the litigants disagree with the adjudication, appeals are made to intermediate courts, then high courts, and finally the Supreme Court.

In civil court, to establish the validity of a medical malpractice claim, medical negligence, the patient's injury, and causation must be proved by the litigants. Negligence is defined as medical practice that breaches the reasonable standard of care expected of professionals, either by omission (failing to do something) or by commission (doing something wrong). Regarding causation, patients must prove the injury is a consequence of the medical negligence–in other words, that pathological misdiagnosis resulted in the patient's injury. Our legal system recognizes that judges do not have the medical knowledge necessary to determine whether or not there has been medical negligence, so it is mandatory that they request a forensic evaluation.

The West China Medical Expertise Center in Sichuan and The Forensic Science Institute in the Ministry of Justice are institutes of forensic medicine that provide evaluation reports to help judges reach final verdicts. For cases with complaints of pathological misdiagnoses, evaluations are performed by forensic experts and at least two expert clinical pathologists. First, pathologists re-examine

samples using blinded review, with either a unanimous or mixed outcome. Then the results are collected by forensic experts to make the final diagnosis and forensic evaluation report.

Published data regarding pathology malpractice claims in China is lacking. Our study reviewed forensic evaluation reports of pathology malpractice claims and accompanying judicial data from 2002 to 2015 to better quantify pathology-related medical claims and the most frequent pathological errors.

2. Materials and methods

We analyzed forensic evaluation reports related to alleged medical liability in pathology from The West China Medical Expertise Center in Sichuan and The Forensic Science Institute in the Ministry of Justice, as well as their judicial outcomes, from 2002 to 2015.

We extracted the following variables from the materials: specimen type by site on the body, diagnostic section, original diagnosis, final diagnosis, type of error, results of forensic evaluation reports, and judicial outcomes.

Diagnostic sections were categorized as surgical pathology (frozen section and permanent section) and fine-needle aspirate (FNA). According to recommendations from the Association of Directors of Anatomic and Surgical Pathology, errors were classified as false negative, false positive, or error within the same category of interpretation.[2] Based on criteria laid out by Zarbo et al., reasons for error were classified as pathological misinterpretation, specimen sampling, technical error, or defective reporting.[3]

This study was performed with the approval of the ethics committee of the West China Hospital of Sichuan University.

3. Results

3.1. Cases, specimens, and diagnostic section

In total, 71 cases with forensic evaluation reports were analyzed (Table 1). The most common specimen types involved were uterine (n = 10), followed by breast (n = 8), ovarian (n = 7), bone (n = 7), and skin (n = 7). Regarding frozen sections, the majority of complaints involved lung and ovarian specimens.

3.2. Types of error

Of the cases, 32 were false-negative diagnoses and 32 were false positives. Seven cases were errors within the same category of interpretation. Among the false positives, soft tissue carcinoma (n = 5), gastric carcinoma (n = 5), and sarcoma of the uterus (n = 4) were the most frequent diagnoses involved. Among the false negatives, the most common correct diagnoses were invasive ductal carcinoma of the breast (n = 4), osteosarcoma (n = 4), and skin cancer (n = 3).

3.3. Results of forensic evaluation reports

Forensic evaluation reports established medical negligence in 68 of the 71 cases, and a causal nexus between the medical negligence and injury in 65 cases (Table 1). Medical negligence was not confirmed in cases 1, 27, and 53, and causality was negated in cases 5, 23, and 25 (Table 2).

3.4. Reasons for error

In 82% of the 68 cases (n = 56) with negligence confirmed, errors were due to misinterpretation. Other sources of error were specimen sampling (n = 6), technical errors (n = 4), and defective

reporting (n = 2) (Table 1).

3.5. Judicial outcomes

Among our 71 cases, 10 were still undergoing court proceedings and 7 were withdrawn by the plaintiffs, leaving 54 cases with judicial decisions available (Table 1). Of these, 48 were ruled in favor of the plaintiffs, who received an average of $24,188 (median: $19,267) in compensation (Tables 1 and 2).

4. Discussion

Like other specialists, pathologists may be faced with medical claims and held liable for their misdiagnoses. However, in China, no published studies have examined medical liability in pathology.

We found that the most frequent misdiagnosis events in the medical malpractice allegations analyzed were false-positive diagnoses of soft tissue carcinoma, false-positive diagnoses of gastric carcinoma, breast carcinomas misinterpreted as fibroadenomas, borderline ovarian tumors diagnosed as invasive epithelial cancer, false-negative diagnoses of melanoma, and misdiagnoses of non-Hodgkin lymphoma. These data were similar to previously-reported causes of malpractice claims.[4–8] Thus, these kinds of differential diagnoses may be particular challenges in clinical practice, and pathologists should be hesitant to diagnose patients with these diseases before an adequate diagnostic evaluation.

In this study, the proportion of analyzed cases in which medical negligence was confirmed by forensic evaluation was high (n = 68, 94.5%). We believe there may be two major reasons for this. The first is that pathological misdiagnosis can be easily and reliably proved by secondary review during a forensic evaluation. The second is that before bringing a lawsuit, patients often have collected sufficient evidence of negligence. For example, misdiagnosis manifests itself when new information becomes apparent during the course of the illness, in particular in false-negative cases where the symptoms of tumor recurrence are much too obvious for patients to ignore.

It has been reported that pathology had a relatively low diagnostic error rate, ranging from 0.08% to 1.2%.[9–11] Pathologists in the United States ranked 20th among 25 specialties for average annual proportion with a claim.[12] Although the proportion of pathological claims was low, our samples showed that claims are more likely (89%) to result in a payment to the plaintiff, as compared with 35% of surgical claims and 38% of obstetrics and gynecology claims.[13–15] Simply stated, most malpractice claims in pathology indeed involve medical negligence.

Misinterpretation, a knowledge-based interpretive error attributable to the individual pathologist, is a common reason for pathological errors.[4,16–19] It was by far the most common reason for error in our study (82%, 56 of 68). With the exception of cases 1, 27 and 53, all of the misinterpretation negligence cases were ruled in the plaintiffs' favor in court. Since the courts hold that a medical professional must take reasonable care to formulate a diagnosis using good judgment, his or her skill and judgment must be in step with his or her colleagues. In these cases, however, physicians were unable to show that their actions conformed to acceptable standards of care.

Medical liability was negated mainly under two conditions (Table 2). One condition was that the act did not violate the standard of care. For example, one biopsy specimen had ambiguous histological features of two diseases; misdiagnosis could have occurred even if a second opinion had been sought or other safeguards had been employed. The other condition was that the act did not injure the patient. Reason et al. has defined "near lesson" and "free error" to describe these acts.[20] For example, the misdiagnosis