TMLT
TEXAS MEDICAL LIABILITY TRUST
Special issue: Pathology 2004

the Reporter

BIOPSY CROSS-CONTAMINATION

PATHOLOGY CLOSED CLAIM STUDY

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The following closed claim study is based on an actual malpractice claim from TMLT. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own case, please be assured it is presented solely for the purpose of emphasizing the issues of the case.

Presentation

A 34-year-old woman, who reported right mandible and tooth pain for six months, was referred to an oral surgeon for a possible root canal. The surgeon obtained x-rays that revealed a cyst or abscess in the right mandible under the gum line.

Physician action

The patient was referred to a facial plastic surgeon who performed a biopsy of the cyst. The specimen was sent to a local pathology lab where the slides were prepared by one of the group's histotechnologists. The pathologist, the defendant in this case, interpreted the slides as containing "atypical small cell infiltrate." She further commented in the medical record "the histologic and immunohistochemical findings suggest the possibility of a small cell carcinoma with neuroendocrine features." It was later discovered the slides had been contaminated by another patient's specimen read earlier by the defendant pathologist.

During her deposition, the pathologist testified she was concerned about the atypical cells and that she wanted to make sure the clinical information fit with what she saw on the slides. She called office personnel for the group and asked them to review the pathology reports from the day she read the patient's slides to see if any other reports indicated small cell carcinoma. It was reported back to her that there were no other small cell carcinomas processed that day. The patient's slides were then sent to an out-of-state pathology laboratory, and were interpreted as showing metastatic small cell neuroendocrine carcinoma of primary lung origin.

The plastic surgeon conferred with the defendant pathologist, who recommended a mediastinal biopsy and a re-biopsy of the cyst in the jaw because she felt this was very unusual. The re-biopsy was never done and the pathologist's recommendation was not put in writing. According to testimony from all parties, the patient was never informed of the need for a re-biopsy.

The plastic surgeon explained the biopsy results to the patient and she was referred to an oncologist. The patient underwent a CT scan of her head, abdomen and pelvis and a body bone scan, all found to be unremarkable. A CT scan of the chest revealed a 3 x 2 cm soft tissue mass near the ascending aorta, characterized as worrisome for neoplasm.

The oncologist questioned the diagnosis of small cell carcinoma, stating in the medical record "tumor board review of her history and scans still is not definitive." The patient did have a mediastinal mass, but the oncologist indicated this could also be a normal thymus. He requested that the patient undergo a PET scan. In his deposition, the oncologist stated that he planned to inform the patient of the need to re-biopsy the jaw cyst, but was unable to specifically recall discussing this with the patient. There was no mention of a re-biopsy in the medical record.

At this point, the oncologist went out of town and left instructions with his partners that if the PET scan came back as normal thymus, then refer the patient to an otolaryngologist. The PET scan found the mediastinal mass was consistent with normal thymus and did not reveal any abnormalities in

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the mandibular region. Based on these results, the patient was referred to an otolaryngologist.

This physician had the patient's pathology slides reviewed by another pathologist, who concurred that the tissue revealed metastatic small cell carcinoma. This pathologist recommended that a clinical correlation should be made, but he did not specifically recommend a re-biopsy. A CT scan of the neck and larynx did not show any masses in the soft tissues of the neck, but did show complete opacification of the right maxillary sinus. There were no other suspicious masses in the nasopharynx, oropharynx, hypopharynx or larynx. The radiologist could not identify any lesions in the oral cavity, mandibular glands, thyroid glands and no enlarged lymph nodes.

Despite the negative findings, the otolaryngologist recommended surgical removal of the lesion because he felt the patient's cancer would not respond well to chemotherapy. He performed a right hemimandibulectomy, lymph node dissection, tracheostomy with reconstruction utilizing a left fibula free-flap and right neck dissection. The pathology on the specimen came back as normal for bone, teeth and other tissue and negative for tumor.

After these findings, the defendant pathologist was contacted and asked to check all the specimens and reports from the day she interpreted the patient's biopsy. The pathologist had a technician check the reports and again, it was reported that there were no records reflecting small cell carcinoma processed that day. The pathologist then rechecked all the reports herself and discovered there had been another patient who had undergone a lymph node biopsy that showed metastatic small cell carcinoma of the lung origin. This report had also been generated by the defendant pathologist.

Interviews with office staff later revealed a possible explanation for why the small cell carcinoma case was not found initially. The patient's specimens were processed over the weekend, but were not reported until Wednesday. The small cell carcinoma slides were processed over the weekend, but were reported out on Monday. Therefore, since office personnel were looking for cases reported on the same date, they would not have found the small cell carcinoma.

Since the initial surgery, the patient has undergone multiple reconstructive procedures to rebuild the mandible and re-implant teeth. The patient's face was disfigured due to the resection. The patient had been told she had a very aggressive form of cancer and had notified her family, including her two young children, that she was going to die.

Allegations

The patient filed suit against the pathologist and the pathology group, alleging improper interpretation of the biopsy specimen.

Legal implications

The cross-contamination of the pathology slides did occur and this exposure fell to the pathology group regarding their handling of the tissue specimen. The contamination most likely occurred during the processing of the specimen into a parafin block or during the creation of the slides. It was alleged by the plaintiff's experts that the pathology group fell below the standard of care in not discovering the cross-contamination when it was first suspected by the pathologist.

Regarding the liability of the pathologist, the plaintiff's expert did not express any opinions as to whether the pathologist appropriately read the pathology slides, and he even acknowledged that contaminations can occur. The plaintiffs alleged the pathologist fell below the standard of care when she herself did not investigate the possibility of cross contamination and assigned office personnel to check the pathology reports. The investigation should have been conducted either by the pathologist or by experienced lab technicians or medical transcriptionists.

Defense experts felt the pathologist appropriately interpreted the slides, such as they were, and that it was appropriate to request office personnel to conduct the search of the records as long as those individuals were qualified to understand the terminology. It was also helpful to the defense that two other pathology laboratories reviewed the patient's slides and did not mention any suspicion of contamination. However, the defense of the case was weakened because it was the pathologist herself who had reviewed and reported the other small cell carcinoma case. The question being, why didn't the pathologist recall this seemingly rare diagnosis?

Also of issue in this case was the otolaryngologist's decision to proceed with radical surgery when there were still unanswered questions about the patient's diagnosis. In his deposition, the otolaryngologist stated that he knew the oncologist was questioning the diagnosis and that there was no clinical-pathological correlation between the slides and the patient's condition. He testified this did not make any difference because he had pathology slides with metastatic small cell carcinoma.

Disposition

This case was settled with the consent of the pathologist and the pathology group for an amount in the high six figures. Defense experts were concerned that a jury would not understand why the pathologist did not look for evidence of contamination herself and why she did not recall reviewing another slide revealing a small cell carcinoma. These concerns, along with the patient's disfigurement and mental anguish, were major factors in the decision to settle this case.

Risk management considerations

Documenting the recommendation for a second biopsy and it being done may have prevented this unnecessary surgery and the subsequent suit. When a patient's condition and care involves multiple physicians, some with differing opinions, it is advantageous for one physician to function as the primary coordinator with all the medical information available. This patient went from an oral surgeon to a facial plastic surgeon who biopsied the mandibular cyst. The specimen was interpreted by the defendant pathologist and the plastic surgeon then referred the patient to an oncologist who then recommended a consult with an otolaryngologist. This physician had the slides reviewed by another pathologist who concurred with metastatic small cell carcinoma but also recommended clinical correlation.

The defendant pathologist, upon conferring with the plastic surgeon who did the biopsy, recommended a second biopsy of the cyst but did not document this exchange in writing. Though pathologists may not routinely establish a direct patient/physician relationship, it behooves them to document every interaction regarding a patient.

Reliance on business office personnel to search for patient reports with the same diagnosis in retrospect was inadvisable. Had the defendant taken the time to focus on this search, the other report with this diagnosis may have been identified and contamination suspected.