Sinus Surgery: Key Lessons in Malpractice Risk

In partnership with The Doctors Company, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) Patient Safety and Quality Improvement Committee (PSQI) recently performed a comprehensive review of all otolaryngology claims closed from 2005–2008 and from 2009–2011.

Claims Analysis
Claims involving endoscopic sinus surgery represented 27 percent of all claims against The Doctors Company otolaryngologists—more than any other category except cosmetic procedures (Figure 1). Between 2009 and 2011, 35 claims were closed based on events related to endoscopic sinus surgery. Of these, approximately half were extremely serious (e.g., permanent visual deficit, fatal meningitis) or extremely difficult to defend (e.g., retained packing). At the other end of the spectrum, roughly 25 percent of endoscopic sinus surgery claims were based solely on patient dissatisfaction with the results of the procedure (Figure 2).

Using a case-control methodology, risk factors were identified. To obtain a representative set of controls, a brief questionnaire was mailed to 500 of The Doctors Company’s insured otolaryngologists that asked them to provide basic demographic and clinical information about their most recent endoscopic sinus surgery case. With over 200 returned questionnaires, a formal case-control risk factor analysis was performed.

This study was not definitive because of methodological limitations. The closed claims are often several years old, while the control cases are from the present. Moreover, data on the closed claims do not always include detailed information such as the exact endoscopic surgical technique performed, whether the case was a revision surgery, and whether powered instrumentation was used. Nonetheless, some interesting findings emerged.

Identification of Major Risks
- Patient age >60 was associated with a three-fold risk of a claim (p = 0.09). Unfortunately, because of limitations in the closed claims data, we are unable to determine if this is due to older patients being more likely to be a revision surgery. It is also possible that there are other factors at work: For example, older patients who sustain minor medial rectus injury may be less able to compensate and more likely to experience permanent diplopia.
- Revision surgeries were associated with a 13-fold increased risk of a closed claim (p = 0.005).
• Surgeries performed on Monday and Friday were twice as likely to result in a malpractice claim (compared to midweek surgeries). This finding did not reach statistical significance (p = 0.24) but is intriguing because it is certainly at least possible that the OR team is not functioning at peak efficiency on the day before or after a weekend.
• The use (or not) of powered instrumentation was not recorded in many of the closed claims, so it was impossible to test statistically whether it was a risk factor. However, in several descriptions of the events by the surgeons involved, powered instrumentation used in the ethmoids clearly played a key role in allowing a minor surgical error to quickly evolve into an orbital injury.

Data from the 2009–2011 claims were also entered into the Executive Information System (EIS) and coded for patient safety issues. Of the 167 claims involving ENT surgery, there were 367 risk management issues identified (more than one risk management issue can be found in each claim). The number-one allegation was improper performance of surgery (49 percent of the claims). This allegation was supported by the fact that several of the top individual risk management issues were also related to surgical care (such as possible technical problem, selection of surgical and invasive procedures, and poor technique).

Figure 2: Nasal/Sinus Events

The number-one individual risk management issue was possible technical problem. This code is used when a complication occurs but is a known risk of the procedure, and this risk was disclosed to the patient prior to surgery. However, in 8 percent of the cases, the provider failed to adequately document the informed consent discussion of risks.

A Case Study
A 62-year-old female with a history of nasal polyps and two previous sinus surgeries had bilateral endoscopic revision ethmoidectomy, antrostomy, and sphenoidotomy. The patient was well known to the physician. The consent documentation lacked any mention of the increased risk of double vision after these types of revisions; also, there was no discussion of the increased risk associated with an orbital wall defect. The physician did not use image guidance during the procedure. Postoperatively, the patient experienced periorbital bruising, mild disconjugate gaze, and possible medial rectus palsy. It was noted that there was heavy bleeding intraoperatively and a known preoperative orbital wall defect.

The patient was discharged from the surgicenter and was to follow up the next day. Shortly after discharge, the patient called complaining of severe eye pain and double vision. The patient was evaluated and sent for an orbital CT that showed a partial tear of the medial rectus. Although a number of surgeries were done, the patient suffered ongoing problems of limited range of gaze and exotropia.

Aware that these data are imperfect, the AAO-HNS PSQI and The Doctors Company are moving forward with a joint project to collect key demographic and patient data in real time as claims are analyzed. Once more current and statistically valid information is available and the risk factors for endoscopic sinus surgery are more clearly identified, we will share the results.

Patient Safety Tips
For all patients undergoing sinus surgery:
• Always document that the risks of major eye and brain complications were discussed during the informed consent process.
• Be extremely careful when using powered instruments in the ethmoids.
• Document that you ensured the patient was informed and educated on the early signs of postoperative problems, particularly cerebrospinal fluid (CSF) leak and vision problems.
• Promptly investigate and address postoperative complaints of vision changes, pain, or other potential signs of CSF leak.

For higher-risk patients:
• Assess the surgical risk carefully and consider whether endoscopic sinus surgery is the best choice for the patient in light of his or her relatively increased risk.
  – If surgery is clearly the best option, the informed consent process should include disclosure of the higher risk to the individual patient with clear documentation that the patient understands and accepts these risks.

• Schedule higher-risk cases on days when there is no time pressure to finish rapidly.
• Consider having a partner review the case and/or assist in surgery.
• Consider using image guidance for higher-risk cases and revision cases.

This article originally appeared in The Doctor’s Advocate, first quarter 2012 (www.thedoctors.com/advocate).

By David W. Roberson, MD, Associate Professor of Otology and Laryngology, Children’s Hospital Boston.

The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each health care provider in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.