Stereotactic navigation in sinus surgery

Clinical Policy ID: CCP.1455

Recent review date: 4/2021

Next review date: 8/2022

Policy contains: Computer-assisted sinus surgery; endoscopic sinus surgery; image-guided sinus surgery; surgical navigation.

Coverage policy

Stereotactic navigation (also known as 3-dimensional image guidance or computer-aided surgery) is considered standard of care when added to general endoscopic sinus surgery; therefore, it is not separately reimbursable as an add-on to the general procedure.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Clinical examination.
- Diagnostic rhinoscopy.
- Endoscopic or open sinus surgery.
- Preoperative and postoperative radiography, computed tomography, or magnetic resonance imaging.
- Professional consultation.

Background

Sinus surgery is one of the most frequently performed surgical operations in the United States, and the most common indication is chronic refractory rhinosinusitis (Bhattacharyya, 2010a, 2010b). Since the late 1990s, there has been a shift from open procedures to endoscopic procedures (Venkatraman, 2010) and a decrease in the incidence of major complications associated with endoscopic approaches in adults (Ramakrishnan, 2012).

Rhinosinusitis is a clinical diagnosis, dependent on clinical and rhinoscopic findings. Some diseases involving the sinonasal region and skull base are inaccessible to sinonasal endoscopy or are not directly visible on clinical examination. In such cases, imaging can determine the extent and possible nature of the disease and provide guidance for surgical planning.

Multidetector or cone-beam computed tomography is the preferred imaging modality for surgical planning in most circumstances for its clear delineation of the complex ethmoidal anatomy, ostiomeatal unit, and anatomic variations, including the presence of sphenoethmoidal (Onodi) air cells (American College of Radiology, 2017). Magnetic resonance imaging of the face and sinuses with inclusion of adjacent brain and orbits is preferred for soft-tissue masses, delineation of orbital, skull base, or intracranial involvement, and for suspected invasive fungal sinusitis.

Endoscopic sinus surgery is a set of minimally invasive techniques that apply endoscopic instrumentation to directly examine the sinuses, remove sinus blockages, and restore sinus ventilation and normal function. It is a treatment of choice for chronic rhinosinusitis refractory to medical treatment, and its role is expanding in the management of other sinus, orbit, and skull base diseases (Al-Swiahb, 2010).

Endoscopic sinus surgery is a technically demanding procedure due to anatomical complexity, variation in normal anatomy, and proximity to critical structures such as the olfactory fossa, skull base, vascular structures, and orbit. Anatomic distortion from chronically inflamed mucosa and absent anatomic landmarks from prior surgery further increase both potential risk of major and minor complications and operating time. Ramakrishnan (2012) estimated a 1% overall major complication rate for endoscopic sinus surgery that was attributed to cerebrospinal fluid leak (0.17%), orbital injury (0.07%), and hemorrhage requiring transfusion (0.76%). To optimize the visual surgical field and mitigate the risk of complications, stereotactic navigation has been proposed as an adjunct in endoscopic and external-approach sinus surgery.

The image guidance systems consist of a computer workstation, tracking system, and specially designed navigation instruments (Oakley, 2016). They require a compatible preoperative computed tomography scan of the sinuses using a special image guidance protocol, for example, a noncontrast axial image with 1 mm or thinner cuts. Three-dimensional computed tomography angiography and computed tomography-magnetic resonance fusion images may also be incorporated (Citardi, 2007). Image guidance systems digitally link the images and display them in axial, coronal, and sagittal planes. The image is coupled to the surgical instruments by an electromagnetic or optical tracking system. This gives the surgeon the ability to navigate the surgical instruments in real time within the diseased sinuses and improve the spatial orientation with vital structures while watching the monitor.

Findings

For this policy, we included two systematic reviews (Ramakrishnan, 2013; von Hofsten, 2013), two meta-analyses (Dalgorf, 2013; Vreugdenburg, 2016), and one consensus-based professional guideline (American Academy of Otolaryngology — Head and Neck Surgery, 2014) to address whether the perceived net benefit of stereotactic guidance translates into a clinically meaningful benefit and to identify the optimal candidates for the procedure. The evidence from the primary studies included in the systematic reviews and meta-analyses was of low-to-moderate quality and comprised of retrospective cohorts and case series of adult and pediatric patients from tertiary care settings. In general, allocation of stereotactic navigation was based on availability of equipment with likely selection bias toward those with more severe disease.

The perceived potential of increased safety and improved surgical outcomes with stereotactic navigation in endoscopic sinus surgery led to the introduction and diffusion of the technology in the early 2000s in the absence of a clear benefit demonstrated in clinical research. A survey of members of the American Rhinologic Society showed a growth in both the availability of stereotactic navigation to most practitioners and its use from 2005 to

2010 ($P < .0001$) (Justice, 2012). Since stereotactic navigation is widely available, randomized controlled studies would be impractical to perform at this point. Moreover, major complications in endoscopic sinus surgery are relatively rare, and sufficiently powered studies needed to detect statistically meaningful differences in outcomes attributable to stereotactic navigation would be prohibitive.

To illustrate, two qualitative systematic reviews (Ramakrishnan, 2013; von Hofsten, 2013) failed to show a definitive reduction in complications or definitive improvement in outcomes. Their conclusions may reflect the inability to carry out more definitive studies rather than a lack of efficacy, per se. The individual primary studies lacked the power to identify a statistically meaningful effect of stereotactic navigation added to endoscopic sinus surgery, if one existed.

Pooling results through meta-analysis from multiple studies may increase the statistical power over individual studies to detect a meaningful effect. A meta-analysis (Dalgorf, 2013) of 14 comparative cohorts found both major complications ($P = .007$) and total complications ($P = .02$) were more common in the non-image guided group, but there were no significant between-group differences in risk of orbital complications, intracranial complications, major hemorrhage, completion of operation, revision surgery, or patient-reported outcome measures. Another meta-analysis (Vreugdenburg, 2016) of nine studies demonstrated a statistically significant decrease in the likelihood of total, major, and orbital complications in participants who had stereotactic navigation. However, a statistical benefit in reducing surgical revisions, major hemorrhage, or minor complications was not observed.

The retrospective nature of the primary studies complicates the ability to identify the optimal candidate for stereotactic guidance, along with procedure complexity, variation in patient anatomy, inflammatory or neoplastic disease burden, and surgeon skill and training (Dalgorf, 2013). American Rhinologic Society survey respondents identified primary anterior ethmoidectomy, revision anterior ethmoidectomy, primary total ethmoidectomy, Lothrop procedure, cerebrospinal fluid leak repair, tumor surgery, orbital decompression, and optic nerve decompression (all $P < .05$) as major indications for stereotactic navigation (Justice, 2012). These indications illustrate that stereotactic navigation is best reserved for situations for which major surgical complications would be the greatest or in which suboptimal or incomplete surgery may lead to poorer outcomes or revision surgery.

The American Academy of Otolaryngology — Head and Neck Surgery (2014) recommends indications for stereotactic navigation based on consensus and current evidence and stresses it would be impossible to corroborate with Level 1 evidence. The technology should be used at the discretion of the operating surgeon in clarifying complex anatomy during sinus and skull base surgery for the following indications:

- Revision sinus surgery.
- Distorted sinus anatomy of development, postoperative, or traumatic origin.
- Extensive sino-nasal polyposis.
- Pathology involving the frontal, posterior ethmoid, or sphenoid sinuses.
- Disease abutting the skull base, orbit, optic nerve, or carotid artery.
- Cerebrospinal fluid rhinorrhea or conditions where there is a skull base defect.
- Benign and malignant sino-nasal neoplasms.

In 2021, we added one cost-effectiveness study based on the results of pediatric patients who underwent sinus surgery with intraoperative navigation ($n = 60$) and without intraoperative navigation ($n = 59$) between 2003 and 2016. Use of intraoperative navigation was associated with more complex surgeries with more sinuses opened ($P = .008$), increased presence of the attending surgeon and a trainee ($P < .001$ for both), and longer surgical time ($P < .001$). Ultimately, intraoperative navigation did not decrease complication rates or revision rates, and was not cost-effective. It was used primarily as an educational tool or to increase confidence in intraoperative identification of landmarks. These results warrant no policy changes.

References

On January 13, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “otorhinolaryngologic surgical procedures (MeSH),” “paranasal sinus diseases/surgery (MeSH),” and “Surgery, Computer-Assisted (MeSH),” and “endoscopic sinus surgery.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

4/2020: initial review date and clinical policy effective date: 5/2020

4/2021: Policy references updated.