Otology & Neurotology
39:1012–1017 © 2018, Otology & Neurotology, Inc.

Complications in Endoscopic Ear Surgery

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Objective: The aim of this study was to examine the premise that endoscopic ear surgery (EES) is associated with a low rate of complications (intraoperative and postoperative).
Study Design: Retrospective review at two institutions.
Setting: Tertiary referral center.
Patients: The study included 825 patients who underwent exclusive EES between 2008 and 2016 at the Otorhinolaryngology-Head and Neck Surgery Department of Modena University Hospital, and between 2014 and 2016 at the Otorhinolaryngology-Head and Neck Surgery Department of Verona University Hospital.
Interventions: Exclusive endoscopic ear surgery between 2008 and 2016 (tympanoplasties, second look or revision tympanoplasties, myringoplasties, stapedoplasties, canalplasties, ossiculoplasties, and exploratory tympanotomies). All surgical procedures were performed by two experienced surgeons.
Main Outcome Measure: For each procedure, intraoperative, and early and delayed postoperative complications were evaluated.
Results: The most common ear pathologies for which patients were sent for EES were cholesteatoma (33.6%), chronic otitis media (36.3%) and otosclerosis (26.8%). There was no case of major intraoperative complications such as injury to the dura or vascular structures. We observed minor intraoperative complications in 4.1% of the cases. Only 1.3% of patients experienced early postoperative complications. Delayed complications affected less than 1% of the cohort.
Conclusions: Data from this study confirm the safety of the endoscopic technique, with very low complication rates, indicating that EES is a reliable therapeutic option, in particular, for tympanoplasties, myringoplasties, and stapedoplasties, as well as second look procedures. We have reported our experience with EES morbidity so that it can be compared with data from other centers using the same surgical technique. **Key Words:** Complications—Endoscopic ear surgery—Facial nerve palsy—Myringoplasty—Tympanoplasty.

Otol Neurotol **39:**1012–1017, 2018.

Endoscopic ear surgery (EES) is an innovative technique in the surgical management of a number of middle ear pathologies. Since its first application during the 1990s, extensive experience has been gained worldwide with this surgical approach. A rapidly growing body of international literature has shown several advantages of the endoscopic approach, especially when compared with traditional surgical microscopy. The possibility of good surgical field exposure, with direct access to hidden recesses, and high magnification and high resolution images, together with the avoidance of a postauricular incision and extensive drilling of bone, have made the use of the rigid endoscope an accepted support technique or alternative to the microscopic technique in ear surgery (1–5).

Theoretically, EES holds the promise of decreased operative time, reduced need for mastoidectomy and low postoperative morbidity (6). Nevertheless, few articles have specifically focused on these aspects and, in particular, there is a lack of scientific evidence showing that this approach has a low rate of intraoperative or postoperative complications.

Sensorineural hearing loss, accidental ossicular chain disruption, postoperative tympanic membrane perforation, labyrinthine fistula, dural injury, chorda tympani interruption and facial nerve paralysis are among the most relevant possible complications in ear surgery (1,4,6–9).

In total, 825 cases of exclusive endoscopic surgical procedures for ear pathology were reviewed, performed at two leading centers in endoscopic otologic surgery. The aim of this study was to examine the premise that EES is associated with a low rate of complications (intraoperative, early and delayed postoperative). The study has provided valuable information about EES

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All of the authors have participated in the planning, writing, or revising the manuscript.

The authors disclose no conflicts of interest.

DOI: 10.1097/MAO.0000000000001933

morbidity that can be compared with data from other centers using the same surgical technique.

METHODS

This is a retrospective review of patients who underwent endoscopic ear surgery between October 2008 and October 2016 at the Otorhinolaryngology-Head and Neck Surgery Department of Modena University Hospital and between November 2014 and December 2016 at the Otorhinolaryngology-Head and Neck Surgery Department of Verona University Hospital.

Only patients who underwent exclusive transcanal EES were included in this study. Patients affected by cholesteatoma, chronic otitis media, otosclerosis, external auditory canal stenosis, stapes anomalies and other pathologies (i.e. posttraumatic facial palsy, cholesterol granuloma, glomus tympanum, ossification of the ossicular chain and cerebrospinal fluid otorrhea) were included (Table 1).

Exclusive endoscopic procedures used in this study were: tympanoplasties, second look or revision tympanoplasties, myringoplasties, stapedoplasties, canalplasties, ossiculoplasties, and exploratory tympanotomies. The minimum follow-up period for patients included in the study was 6 months. All surgical procedures were performed by two experienced surgeons (D.M. and L.P.).

Exclusion criteria were surgical approaches that included microscopic, microscopic endoscopic-assisted, or combined surgical techniques.

Demographic data, pathological characteristics, surgical information, imaging, postoperative results, and follow-up data were collected. For each procedure, intraoperative, and early and delayed postoperative complications were evaluated. Intraoperative complications considered were: iatrogenic labyrinthine fistula, inner ear injuries, sensorineural hearing loss, and injuries to other anatomical structures (i.e., ossicular chain, tympanic membrane, facial nerve, vascular structures, chorda tympani, dura).

Accidental opening of the inner ear included the oval window, vestibule, round window, or cochlea opening. Sensorineural hearing loss was defined as a decrease equal to or greater than 30 dB (HL) on at least a single frequency (frequencies tested: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz). Vascular complications included jugular bulb or internal carotid artery injury.

TABLE 1. *Inclusion criteria of the study*

1. Exclusive endoscopic ear surgery
2. Pathologies included:
Cholesteatoma
Chronic otitis media
Otosclerosis
External auditory canal stenosis
Stapes anomalies
Other pathologies
3. Surgical procedures included:
Tympanoplasty
Second look tympanoplasty
Revision tympanoplasty
Myringoplasty
Stapedoplasty
Canalplasty
Other surgical procedures
4. Minimum of 6 months follow-up

An early complication was defined as a complication that occurred in a period between 1 week and 6 months after surgery. Early complications assessed in this study were: infections and otorrhea, and impaired wound healing at the site of the temporalis fascia or in a tragal cartilage sample (including infection and hematoma).

A complication was classified as delayed if it occurred later than 6 months after the operation. Delayed complications evaluated during the follow-up were: prosthesis extrusion following ossiculoplasty or stapedoplasty, iatrogenic cholesteatoma and persistent iatrogenic eardrum perforation. We considered tympanic perforations to be iatrogenic in those patients who did not have a preoperative perforation and who underwent procedures such as stapedoplasty, canalplasty, or exploratory tympanotomies, in which a perforation should not occur. If a perforation occurred and did not heal spontaneously within a 6-month period, it was considered to be a persistent perforation, and thus included in delayed complications.

Ossicular chain removal during endoscopic ear surgery for cholesteatoma was not considered to be a complication because it was a necessary procedure for total disease removal; on the other hand, ossicular chain disjunction during the surgical approach to lateral attic cholesteatoma was included as a complication. Vestibule or round window opening resulting in sensorineural hearing loss was not considered to be a complication in patients affected by infiltrative inner ear cholesteatoma since it was a surgical procedure necessary to obtain a radical removal of pathology. On the other hand, footplate fracture, vestibule, or cochlea opening during surgery for middle ear cholesteatoma was considered to be a complication.

Chorda tympani injury was taken into consideration only in patients who underwent a myringoplasty, stapedoplasty, or tympanoplasty for dry chronic otitis media in a sterile ear cavity and in whom the chorda tympani was anatomically intact.

Due to the retrospective nature of this study, it was granted an exemption by the IRB of the University Hospitals of Verona and Modena, Italy.

All procedures performed involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

RESULTS

Between November 2008 and November 2016, 918 patients underwent otologic surgery in the Otolaryngology-Head and Neck Surgery Department of Modena University Hospital. Between November 2014 and December 2016, 392 patients underwent otologic surgery in the Otolaryngology-Head and Neck Surgery Department of Verona University Hospital. Among these patients, 825 matched the inclusion criteria. Patients' information is listed in Table 2.

Medium age at surgery was 41 years (range, 2–89 yr). The male/female ratio was 1.09 (430 male and 395 female). Otologic surgery was on the right ear in 409 patients and on the left ear in 413; in three patients, surgery was performed on both ears at the same time. The underlying pathology for which patients underwent ear surgery was: cholesteatoma 277 (33.6%), chronic otitis media 300 (36.4%), otosclerosis 221 (26.8%), external auditory canal stenosis 6 (0.7%), stapes anomalies 5

TABLE 2. *Patients' information*

	41 (2–89)
Medium Age (Range)	Number of Patients (%)
Gender	
Male	430 (52.1%)
Female	395 (47.9%)
Side	
Right	409 (49.6%)
Left	413 (50.0%)
Both ears	3 (0.4%)
Pathology	
Cholesteatoma	277 (33.6%)
Chronic otitis media	300 (36.3%)
Otosclerosis	221 (26.8%)
External auditory canal stenosis	6 (0.7%)
Stapes anomalies	5 (0.6%)
Other pathologies	16 (1.9%)
Surgery	
Tympanoplasty	316 (38.3%)
Second look tympanoplasty	27 (3.2%)
Revision tympanoplasty	70 (8.5%)
Myringoplasty	146 (17.7%)
Stapedoplasty	226 (27.4%)
Canalplasty	6 (0.7%)
Other surgical procedures	34 (4.1%)
Ossiculoplasty	
PORP	126 (67%)
TORP	60 (32%)
Bone cement	3 (1%)
Ossiculoplasty material	
Autologus remodelled incus	110 (58%)
Mastoid cortical bone	34 (18%)
Other	45 (24%)

PORP indicates partial ossicular replacement prosthesis; TORP, total ossicular replacement prosthesis.

(0.6%), and other pathologies 16 (1.9%), as shown in Figure 1. In the last group, we included: posttraumatic facial palsy, cholesterol granuloma, glomus tympanum, ossification of the ossicular chain, and cerebrospinal fluid otorrhea.

A total of 316 (38.3%) tympanoplasties, 27 (3.2%) second look tympanoplasties, 70 (8.5%) revision tympanoplasties, 146 (17.7%) myringoplasties, 226 (27.4%) stapedoplasties, 6 (0.7%) canalplasties, and 34 (4.1%) other surgical procedures were performed (Fig. 2). We classified as ''other surgery'': tympanoplasties for glomus or cholesterol granuloma, ossiculoplasties for ossicular chain defects, facial nerve decompression, and exploratory tympanotomies.

In total, 277 patients who underwent a tympanoplasty were affected by cholesteatoma; in the remainder, the surgery was performed to treat chronic otitis media.

An ossiculoplasty was performed in 189 of 825 (22.9%) patients: in 126 (66.7%) of these patients, a partial ossicular replacement prosthesis (PORP) was used, while 60 (31.7%) received a total ossicular replacement prosthesis (TORP); in 3 (1.6%) cases, bone cement was used to achieve ossicular chain reconstruction. The ossiculoplasty material was autologous remodeled incus in 110 (58.2%) patients, mastoid cortical bone in 34 (18%) patients, and other materials such as tragal or conchal cartilage, remodeled malleus or artificial prosthesis in 45 (23.8%) patients.

A second look procedure was performed in 27 of 825 (3.3%) patients.

Regarding intraoperative complications, there were no cases of major intraoperative complications such as iatrogenic labyrinthine fistula, persistent facial palsy or injury to vascular structures.

In total, 34 of 825 patients (4.1%) had minor intraoperative complications: 16 (1.9%) chorda tympani injuries, 2 (0.2%) transient postoperative facial palsy (grades II and III, respectively, according to the House–Brackmann scale; both recovered spontaneously in approximately 1 month; in both cases, the nerves were not interrupted or grossly injured), 10 (1.2%) sensorineural hearing loss (none of which corresponded to anacusis), 2 (0.2%) cases of accidental intraoperative tympanic membrane perforation, 1 (0.1%) accidental disjunction of the ossicular chain, 1 footplate fracture and 2 cases of gusher. These last three (0.4%) cases were considered to be injuries to the inner ear.

Regarding early postoperative complications, 814 (98.7%) patients had a normal postoperative clinical course. Seven patients (0.8%) had postoperative otorrhea

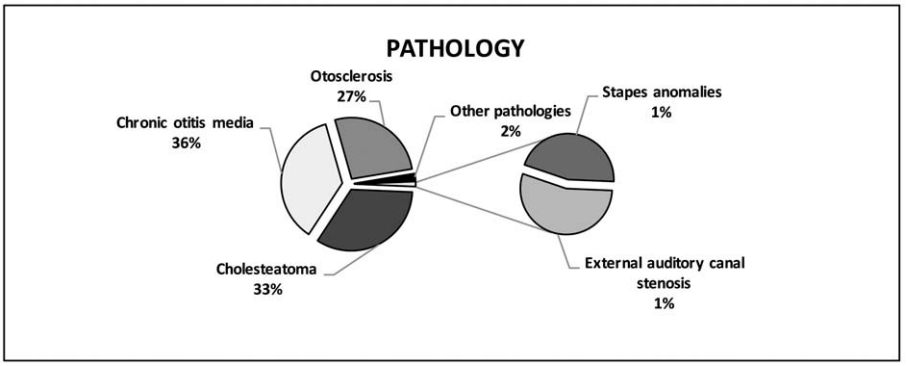

FIG. 1. Distribution of the pathologies for which the patients underwent endoscopic ear surgery.

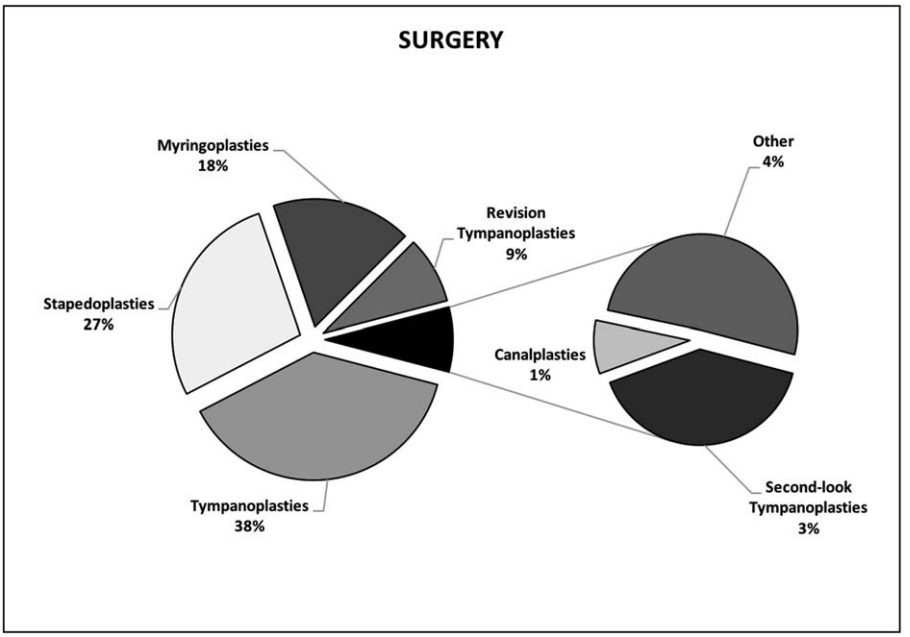

FIG. 2. Distribution of the surgical procedures performed.

or infection. In four (0.5%) cases, we observed an impaired wound healing at the site of the temporalis fascia or in the tragal cartilage sample used to perform myringoplasty. Thus, an early postoperative complication occurred in only 11 (1.3%) patients.

Regarding delayed postoperative complications, the ossiculoplasty graft was dislocated in three (0.4%) patients during follow-up and they successfully underwent revision surgery. In five (0.6%) patients, a persistent iatrogenic eardrum perforation was noted during the follow-up and a revision myringoplasty was needed. There was no case of iatrogenic cholesteatoma or prosthesis extrusion during stapedoplasty, so delayed complications affected less than 1% of the cohort (eight patients) (Table 3).

DISCUSSION

Endoscopic ear surgery (EES) is a relatively recent technique and is gaining popularity in the otolaryngology community worldwide (10,11). Over time, the surgical technique has greatly improved, and it has been adopted by many surgeons, but despite this, many otologists have some concerns about using EES, as is usual in recently introduced techniques, compared with those which have stood the test of time.

One potential drawback to the use of endoscopes in middle ear surgery is the elevated temperatures caused by transmission of heat from the light source to the endoscope. The heat could lead to a rise in temperature of labyrinthine fluids and injury to nervous structures, such as the facial nerve, especially if it is dehiscent. These side effects may become evident with greater frequency when a xenon light source is used and if the light intensity is very high, or if surgical timing is particularly protracted. Newer light emitting diode (LED) light sources may run at cooler temperatures; however, some considerations are necessary. Adequate

TABLE 3. *Complication rates*

	Number of Patients (%)*
Intraoperative complications	34 (4.1%)
Iatrogenic labyrinthine fistula	0
Inner ear injury	3 (0.4%)
Sensorineural hearing loss[a]	10 (1.2%)
Injury to other anatomical structures	21 (2.5%)
Ossicular chain	1 (0.1%)
Tympanic membrane	2 (0.2%)
Transient facial palsy	2 (0.2%)
Persistent facial palsy	0
Vascular structures	0
Chorda tympani[b]	16 (1.9%)
Dura	0
Early complications:	11 (1.3%)
Infection and otorrhea	7 (0.8%)
Impaired wound healing	4 (0.5%)
Delayed complications:	8 (<1%)
Prosthesis extrusion[c]	3 (0.4%)
Iatrogenic cholesteatoma	0
Persistent iatrogenic eardrum perforation	5 (0.6%)

*Total number of patients: 825.

[a]Defined as a decrease equal or higher than 30 db HL on at least one frequency.

[b]Only in patients who underwent myringoplasty, stapedoplasty, and tympanoplasty for dry chronic otitis media in a sterile ear cavity in whom chorda tympani was anatomically intact.

[c]Only for ossiculoplasty and stapedoplasty.

illumination of the middle ear space can be accomplished with lower intensity settings of the light source and with potentially cooler light sources such as LED systems. Also, the tip of the endoscope requires continuous cleaning with anti-fog solutions, which probably helps in cooling the endoscope. It has been shown that, while the tip of the endoscope heats up rather quickly, it also cools down quickly.

Some authors have studied the thermal tissue damage in EES. Ito et al. (12) simulated EES using a 3D model of human temporal bone and they measured the temperature using thermocouples attached to the tip of the endoscope and to the middle ear cavity. They found that the maximum temperatures measured within the middle ear cavity were below 31°C at clinical settings, while the temperatures rose to 44.1°C using a 4-mm endoscope with a xenon light source set at 100% intensity. The authors concluded that the 2.7-mm endoscope with an LED light source could be safely used in EES. However, operators should pay more attention when using 4-mm endoscopes with a xenon light source (12). Another study conducted by Lee et al. measured temperature fluctuations during EES in fresh human temporal bones maintained at body temperature (~36°C). An endoscope with a xenon or LED light source operating at 100% intensity resulted in a rapid temperature elevation up to 46°C within 0.5 to 1 mm from the tip of the endoscope after 30 to 124 seconds and the temperature decreased rapidly when turning off the light source or applying suction. They suggested using a submaximal light intensity, frequent repositioning of the endoscope, and removing the endoscope to allow tissue cooling (13).

A second issue with regard to EES is one-handed surgery, which can cause permanent hearing loss due to excessive manipulation of the ossicular chain. Moreover, these structures may suffer direct trauma from the tip of the endoscope.

The present study is the first work in the literature to comprehensively examine the possible complications of EES.

It includes a large group of patients who were followed for a prolonged period after surgery. All of the procedures were performed by a single group of surgeons (D.M. and L.P.) and this possibly constitutes a limitation since it makes our results less generalizable.

In our study group, we did not observe serious intraoperative complications such as iatrogenic labyrinthine fistula, persistent facial palsy, or injury to vascular structures.

As underlined by Tarabichi et al., in EES, the safety of the facial nerve is ensured by direct visualization of the horizontal segment of the nerve and by limiting any drilling in the posterior canal to the area close to it. Angled endoscopes may help to check the facial recess in an easy and safe manner, without any need to drill or handle bony structures close to the nerve (1). This makes gross injury to the facial nerve exceptionally unlikely in exclusive EES. Transient postoperative facial palsy may be caused by the effects of local anesthesia on the external auricular canal (with diffusion into the middle ear cavity) and/or by exposure of the facial nerve to endoscopic light, and/or stretching of the perineural tissue in a dehiscent Fallopian canal; however, studies assessing facial nerve impairment after otologic surgery in microscopic settings are lacking.

As reported by Migirov et al., EES avoids drilling of the mastoid, thereby obviating the risk of accidental trauma to the middle cranial fossa dura, dural exposure in the tegmen and sinodural angle, and brain herniation (4).

There were minor intraoperative complications in 34 of 825 (4.1%) patients. The great majority of these (16/24) were chorda tympani injuries during stapedoplasty. Qualitatively, these patients did not complain of any change to their quality of life (data not collected). The complications in two cases consisted of accidental tympanic membrane perforation while raising the tympano-meatal flap in stapedoplasty: in both cases, a myringoplasty was performed during the same operation. In the one case of accidental disjunction of the ossicular chain, an ossiculoplasty was performed with good acoustic results. Comparing this result to a similar experience reported by Preyer, we agree that the use of the endoscope may improve the preservation rate of the ossicular chain (14), although there are no reports on the rates of accidental ossicular chain disjunction in microscopic settings. The patients with footplate fracture and gusher had no complications in the postoperative period and they did not show sensorineural hearing loss after surgery.

Regarding early postoperative complications, the few cases of otorrhea/infection or impaired wound healing showed complete resolution after conservative medical treatment. Delayed postoperative complications consisted of three prosthesis extrusions and five persistent iatrogenic eardrum perforations; all of these patients underwent successful revision surgery.

In the future, a comparison of these endoscopic complication rates with those in microscopic middle ear surgery would be worthwhile. Most reports comparing endoscopic to microscopic ear surgery focus on outcomes or operative times, rather than complications. Recently, Kuo et al. compared the results of endoscope- and microscope-assisted tympanoplasty, with and without ossiculoplasty; in their experience, no difference was observed in complication rates between the endoscopic and microscopic groups (15). It would be of interest to conduct additional prospective studies assessing the difference in complication rates in large cohorts of patients treated endoscopically versus microscopically.

Our study has several possible limitations. All of the surgery was performed by two experienced surgeons particularly skilled in endoscopic ear surgery. This may be the reason for the low complication rates that we obtained in our research, and it is a possible cause of bias in the study. It is well known that EES has a long and difficult learning curve, because the surgeon has to learn the surgical technique using only one hand. Another issue is that, in endoscopy, the perspective view is lost because

of the 2D vision of the screen compared with the 3D microscopic view. For these reasons, it is possible that a less experienced surgeon, who uses the EES technique for the first time, may encounter more difficulties, and the complication rate may be higher. In particular, at the beginning of their surgical experience with EES, it may be more likely for apprentice surgeons to cause tympanic membrane damage during tympano-meatal flap elevation, or ossicular chain dislocation through contact with the tip of the endoscope. These considerations have to be made before starting with this technique. Despite this, a surgeon who is becoming more skilled will gradually lower his or her complication rate eventually achieving the rate that we found in our study. So the complication rate when learning the technique may be different, and that deserves further study.

CONCLUSION

Data from this study confirm the safety of the endoscopic technique, with very low complication rates, indicating that endoscopic ear surgery is a reliable therapeutic option, in particular for tympanoplasties, myringoplasties, stapedoplasties, as well as second look procedures.

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