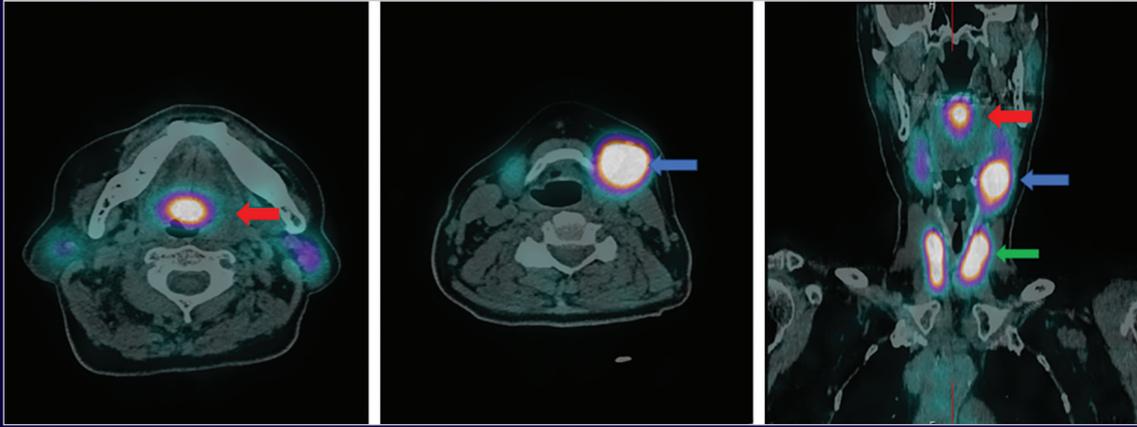


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## Editorial



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# Transparency in Research: What is Clinical Trial Registration and Why It Matters

Özlem Önerci Çelebi

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**Keywords:** Biomedical research, clinical trial, registries, research ethics

Clinical trial registration has been one of the most important developments in modern publishing and research. While the requirement for registering clinical trials has originally started as an editorial policy, today it is considered one of the most important factors in research ethics.

In 2004, the International Committee of Medical Journal Editors (ICMJE) reported that the registration of clinical trials is an essential requirement for publication (1). In their 2006 update, the ICMJE further clarified this requirement by clearly defining acceptable registries and pointing out that trials must be registered before patient enrollment begins (2). In the same year, the World Health Organization expanded these efforts globally by starting the International Clinical Trials Registry Platform to harmonize clinical trial registration worldwide (3-5). These efforts turned trial registration from a suggestion into an international requirement.

As the Turkish Archives of Otorhinolaryngology, our main goal is to maintain the highest standards of scientific quality for our journal. Considering this, we would like to, once again, draw attention to a critical requirement for ensuring that all submitted research fully comply with the ethical principles and the transparency standards: prospective clinical trial registration.

So, what is clinical trial registration? Clinical trial registration is the formal process of recording a clinical study in a publicly accessible database before or at the time of participant enrollment. It constitutes a fundamental component of ethical and methodologically strong clinical research. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome (2). Thus, any study designed to evaluate the effects of an intervention (drug, device, surgical technique, or other therapeutic approach) in human participants as a randomized controlled trial should be registered together with its protocol details.

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The main responsible authority for clinical trial registration in Türkiye is the Turkish Medicines and Medical Devices Agency (*Türkiye İlaç ve Tıbbi Cihaz Kurumu*) under the Ministry of Health. Within this agency, the clinical trials department is mainly responsible for clinical trial registration.

Registration of a clinical trial is a key part of honest and responsible research. By openly sharing their studies, researchers show that their methods are honest and take responsibility for their findings (1-3). Making the study protocol public from the beginning prevents hidden changes and selective reporting, so that the results can be trustworthy for the patients, clinicians, and the scientific community (1,2). Registration also reduces publication bias by making sure that all initiated trials are publicly documented. When trials are visible within registries, studies with negative or inconclusive results are less likely to remain unpublished. Nevertheless, evidence shows that registration alone does not fully eliminate reporting problems. Scott et al. (6) showed that discrepancies between registered and published outcomes continue to occur in journals that mandate prospective registration. These findings support the conclusion of Smith and Dworkin (7) that prospective registration is “not sufficient, but always necessary.” Similarly, Showell et al. (8) reported that a proportion of registered trials remain unpublished.

Beyond methodological considerations, clinical trial registration also protects research participants and patients and upholds the ethical principles in human research by encouraging openness and responsibility (3). We can ensure that no study, regardless of its outcome, is lost by registering all clinical trials. This provides researchers and medical professionals with the whole picture and gives them confidence that the information guiding patient care is transparent, honest, and reliable (4,5).

Registration is declared as necessary by many major organizations like the ICMJE, WAME, and COPE (1,2). The 2007 consensus statement on mandatory registration of clinical trials showed that prospective registration should be considered as both an ethical obligation and a professional responsibility in scientific publishing (9). Therefore, during submission to the Turkish Archives of Otorhinolaryngology Journal, we ask that all clinical research manuscripts include a valid trial registration number. This helps us be confident that the research we share earns the trust of doctors, researchers, and readers everywhere.

In conclusion, registration of a clinical trial is a very important and a major step in honest, responsible, and ethical scientific research. Clinical trial registration helps us keep the editorial process open and clear and make sure that the research is

done in an ethical way. We strongly encourage all authors to ensure that trial registration has been completed prior to manuscript submission.

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## Commentary



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# Toward Dynamic and De-escalated Care: Insights from the ATA 2025 DTC Guidelines

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**Keywords:** Thyroid neoplasms, differentiated thyroid carcinoma, risk assessment, active surveillance, conservative management, practice guidelines as topic

Since the publication of the first guidelines addressing thyroid nodules and differentiated thyroid cancer (DTC) in 1996, the American Thyroid Association (ATA) has released four subsequent revisions (1-5). The presented commentary aimed to highlight the major conceptual and practical differences between the 2015 and 2025 ATA guidelines with special reference to clinically relevant updates.

### General Aspects of the 2025 ATA Guidelines for DTC

In contrast to previous editions, the 2025 ATA guidelines for DTC solely focus on DTC and guidelines for thyroid nodules will now be published separately. Therefore, the number of recommendations is reduced from 101 (2015) to 84 (5). The quality of evidence and strength of recommendations are revised, and the categories include: “strong,” “conditional,” and “no recommendation” according to the GRADE recommendation grid. For the first time, a patient representative was included in the guideline development process. Additionally, patient-focused assessments such as psychosocial support and treatment-related financial burden or toxicity are added for the first time, while long-term survival issues and quality of life are also emphasized.

### A Dynamic, Risk-Adaptive Management Framework (DATA Model)

The 2025 ATA guidelines adopt a dynamic disease management framework rather than a static strategy, encapsulated by the acronym DATA: “Diagnosis, risk/benefit Assessment, Treatment decisions, and response Assessment.” This approach emphasizes the selection of optimal treatment strategies by balancing risks and benefits while incorporating individual patient characteristics. Following initial intervention, the 2025 ATA risk assessment tool is used to guide subsequent management decisions, including additional therapy and/or ongoing surveillance, with an individualized and adaptive care model. In addition to graded recommendations, the guidelines introduce the concept of a good practice statement (GPS), applied in selected scenarios with unanimous expert consensus.

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Although supported by low or insufficient evidence, GPS-labeled recommendations are considered to provide clear clinical benefit and are intended to be followed as strong guidance.

### De-escalation as a Guiding Principle

Perhaps the most striking evolution from the 2015 to 2025 ATA guidelines is the formal endorsement of “active surveillance” (AS) as a first-line management strategy for carefully selected patients. Patients with cT1aN0M0 papillary thyroid carcinoma (PTC) are now recognized as candidates for AS through shared decision-making between the patient and the clinical team, with careful consideration of risks and benefits. Patients who are eligible for AS are recommended to undergo ultrasound evaluation every 6 months for 1-2 years, followed by annual surveillance by an experienced radiologist, with transition to surgery based on disease progression or patient preference. In addition, ultrasound-guided percutaneous tumor ablation is introduced as an alternative management option for selected patients with cT1aN0M0 PTC, again emphasizing shared decision-making.

The 2025 ATA guidelines place clear emphasis on surgeon volume, recommending that thyroid cancer surgery be carried out by high-volume surgeons, defined as those undertaking at least 25 thyroidectomies annually. Lobectomy is endorsed as the initial surgical approach for tumors  $\leq 2$  cm without extrathyroidal extension (ETE) or metastases and may be considered in selected patients with tumors  $> 2$  cm and  $\leq 4$  cm (cT2N0M0). Tumors  $> 4$  cm, or those with ETE or nodal involvement, should be managed with total thyroidectomy and appropriate neck dissection. Intraoperative nerve monitoring may be utilized to facilitate identification of the recurrent laryngeal nerve (RLN) and the external branch of the superior laryngeal nerve, particularly during total or completion thyroidectomy. Routine placement of surgical drains is discouraged and should be reserved for selected cases such as very large (predominantly retrosternal) glands, excessive intraoperative bleeding, or coagulopathies. Patients undergoing total thyroidectomy and/or central lymph node dissection, as well as completion thyroidectomy, should receive parathyroid hormone-guided calcium and vitamin D supplementation, either routinely or selectively. Furthermore, patients with documented postoperative RLN injury should be promptly referred to a speech-language pathologist or a voice-specialized physician.

### Risk Stratification: From Three to Four Tiers and Beyond

The 2025 ATA Risk Stratification System is strongly recommended and represents a central component of contemporary DTC management. This system integrates histopathologic tumor features, cervical lymph node involvement, AJCC staging, postoperative imaging, and

serum thyroglobulin (Tg) and anti-thyroglobulin antibody (TgAb) measurements (when appropriate) to estimate the risk of structural disease persistence or recurrence and disease-specific survival. Notably, the risk-of-recurrence (ROR) framework has been refined from a three-tier to a four-tier system, comprising “low,” “low-intermediate,” “intermediate-high,” and “high” ROR categories. This subdivision of the former intermediate-risk group enables improved alignment between surgical extent and recurrence risk, more precise tailoring of radioactive iodine (RAI) therapy, and more accurate counseling regarding prognosis and follow-up intensity. Although routine postoperative molecular profiling is not recommended, molecular features are more explicitly incorporated into risk assessment when such data are available.

The 2025 ATA guidelines extend the recommended timing for postoperative Tg and TgAb measurement to 6-12 weeks rather than 3-4 weeks, reflecting improved understanding of postoperative Tg nadir kinetics for the assessment of ROR. Updated Tg thresholds have also been introduced for patients undergoing total thyroidectomy without RAI therapy: Tg  $< 2.5$  ng/mL defines an “excellent response,” 2.5-5 ng/mL an “indeterminate response,” and  $> 5$  ng/mL a biochemically “incomplete response.”

Histopathologic evaluation is further aligned with the latest World Health Organization classification of thyroid tumors (6). The reclassification of noninvasive encapsulated follicular variant of papillary thyroid carcinoma as noninvasive follicular thyroid neoplasm with papillary-like nuclear features effectively downgrades this entity to a low-risk neoplasm, eliminating the need for completion surgery or RAI. Encapsulated follicular variant of papillary thyroid carcinoma with minimal capsular invasion is now regarded as a variant with a favorable prognosis. In contrast, oncocytic thyroid carcinoma and high-grade follicular cell-derived non-anaplastic thyroid carcinoma are recognized as distinct subtypes associated with poorer outcomes. Collectively, these changes reinforce a biologically informed, outcome-driven approach to postoperative risk assessment.

The updated risk stratification framework tightly aligns RAI recommendations with the 2025 ATA guidelines. It is strongly discouraged in low-risk patients based on high-quality evidence. When compared with the 2015 guidelines, a more flexible and individualized approach is advocated for patients in the low-intermediate and intermediate-high risk categories, underscoring the importance of pretreatment counseling.

### Long-Term and Advanced Disease Management

Several clinically meaningful refinements are introduced in the long-term management of DTC. TSH suppression strategies have been simplified, with targets categorized

as either within or below the normal reference range. Maintaining TSH levels within the normal range is recommended for patients with excellent or indeterminate responses after total thyroidectomy, while suppression below normal is reserved for patients with biochemical or structural incomplete responses. Prolonged TSH suppression is no longer recommended for low- or intermediate-risk patients without evidence of recurrence, reflecting a deliberate shift toward less aggressive and more individualized therapy.

Recognizing the cumulative burden of long-term surveillance, the guidelines introduce a formal recommendation for stepwise de-escalation. Low-risk patients with a durable excellent response may end ultrasound surveillance after 5-8 years and continue follow-up with thyroglobulin monitoring every 1-2 years. After 10-15 years of persistent excellent response, patients may be considered in complete remission, permitting discontinuation of biochemical surveillance.

Ongoing, iterative response-to-therapy based risk stratification is emphasized as a cornerstone of long-term follow-up, guiding both surveillance intervals and therapeutic decision-making. Management of radioiodine-refractory metastatic DTC is increasingly individualized, balancing observation with timely systemic therapy based on disease kinetics and molecular features. Integration of targeted therapies, immunotherapy, and selective local interventions enables tailored treatment while minimizing unnecessary toxicity.

## Conclusion

The 2025 ATA guidelines reflect a measured shift away from uniformly aggressive treatment toward more individualized, risk-adapted care. The updated guidance acknowledges DTC as a generally indolent disease in many patients, while emphasizing the importance of robust risk stratification and careful long-term surveillance to maintain oncologic safety.

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## Original Investigation



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# Assessment of the Learning Processes of Otorhinolaryngology Residents in Performing Rhinomanometry and Acoustic Rhinometry

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### Abstract

**Objective:** To develop an assessment tool for evaluating the ability of otorhinolaryngology (ORL) residents to perform rhinomanometry and acoustic rhinometry (R-AR), and therewith to assess their learning processes in acquiring R-AR skills.

**Methods:** Firstly, a “procedural skill rating scale (PSRS)” was designed for the assessment process. The R-AR performances of 10 residents, each performing 20 procedures, were observed and scored using the PSRS. The correlation between the increase in the number of procedures performed, the improvement in scores, and the reduction in procedure duration was studied. Interrater reliability was evaluated independently by two raters using 20 R-AR procedures. Cronbach’s alpha was calculated for reliability.

**Results:** The correlation between the number of procedures performed and the increase in scores was  $r=0.911$  ( $p<0.001$ ) for rhinomanometry-PSRS and  $r=0.832$  ( $p<0.001$ ) for acoustic rhinometry-PSRS. Mean procedure duration was  $2.11\pm0.39$  minutes (min: 1.17, max: 3.95) for rhinomanometry and  $1.55\pm0.34$  minutes (min: 1.07, max: 3.19) for acoustic rhinometry. The correlation between the increase in the number of procedures performed and the reduction in duration was  $r=-0.937$  ( $p<0.001$ ). Interrater reliability was  $r=0.788$  for rhinomanometry-PSRS and  $r=0.795$  for acoustic rhinometry-PSRS ( $p<0.001$ ). Cronbach’s alpha was 0.971 for rhinomanometry-PSRS and 0.969 for acoustic rhinometry-PSRS.

**Conclusion:** A valid and reliable assessment tool has been developed to evaluate ORL residents’ skills in performing R-AR. Both tools are recommended for assessing ORL residents’ proficiency and determining their achievement of competence.

**Keywords:** Rhinomanometry, acoustic rhinometry, competency-based training, residency training

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## Introduction

During residency training, otorhinolaryngology (ORL) residents learn to medically or surgically treat patients presenting with nasal obstruction and similar nasal complaints. Rhinomanometry and acoustic rhinometry (R-AR) are tools that allow for the objective assessment of nasal obstruction symptoms and identifying anatomical pathologies. These instruments are tools that every ORL resident should be able to use after completing residency training (1).

Rhinomanometry provides an objective measurement of nasal airway resistance. A pressure-flow curve is obtained by simultaneously recording intranasal air pressure and airflow. Consequently, inspiratory and expiratory resistance values, as well as mean resistance, are determined (2). In acoustic rhinometry, acoustic signals are transmitted into the nasal cavity via a tube, and the reflections from the intranasal structures are amplified and digitized. The cross-sectional area of each point in the nasal cavity can be calculated

with the area-distance graphs obtained (3). Both tools enable an objective evaluation of the human nose in two distinct ways. In competency-based residency training, the acquisition of professional skills by ORL residents is expected to be documented through assessment and evaluation processes (4-6). In literature, assessment tools are frequently reported for evaluating professional, particularly surgical, skills (7-10). However, no assessment tool has been identified for assessing ORL residents' ability to learn and perform rhinomanometry and/or acoustic rhinometry.

The purpose of this study was to develop an assessment tool [procedural skill rating scale (PSRS)] to evaluate ORL residents' ability to perform R-AR and, through this tool, to assess their learning processes in acquiring these skills.

### Methods

Firstly, for the planned assessment process, a "PSRS" was developed (Tables 1 and 2). The workplace-based assessment tools reported in the literature and user manuals for R-AR were reviewed, and the Turkish scale items and the PSRSs

were developed accordingly (2-4,10-12). Before data collection, written consent was obtained from all residents who volunteered and were observed in the study. A total of 10 residents participated in the study, with the following seniority distribution: 2 fourth-year, 1 third-year, 3 second-year, and 4 first-year residents. All residents received theoretical training on the indications for performing R-AR, how to use the instruments, and how to interpret results. Clinical diagnosis, identification of pathology, and treatment decisions were not included in the evaluation criteria. Additionally, demonstration-based skills training was conducted on how to perform R-AR and evaluate the outcomes. Evaluations were conducted by two ORL specialists (one professor and one associate professor) with experience in R-AR.

For a tool to be valid, it must be appropriate for its intended purpose. Accordingly, to demonstrate the progression of residents' R-AR application skills, those learning the procedure for the first time were observed from their initial attempts, and their performances were evaluated using the PSRS. As residents performed more procedures, increases in

**Table 1.** "Rhinomanometry" procedural skill rating scale

	Unable to perform	Performs with verbal support	Performs successful without support	Performs easily/good flow
Informing the patient about the procedure	1	2	3	4
Preparing and assembling the rhinomanometry system components	1	2	3	4
Positioning the patient and inserting the nasal adapter	1	2	3	4
Ensuring proper placement of the mask on the face	1	2	3	4
Performing system calibration	1	2	3	4
Conducting the measurement by delivering clear instructions to the patient	1	2	3	4
Interpreting the curves displayed on the results screen	1	2	3	4
Identifying potential pathologies and communicating findings to the patient	1	2	3	4

**Table 2.** "Acoustic rhinometry" procedural skill rating scale

	Unable to perform	Performs with verbal support	Performs successful without support	Performs easily/good flow
Informing the patient about the procedure	1	2	3	4
Preparing and assembling the acoustic rhinometry system components	1	2	3	4
Positioning the patient appropriately	1	2	3	4
Initiating the test by holding the device correctly	1	2	3	4
Conducting the measurement by delivering clear instructions to the patient	1	2	3	4
Combining and evaluating the measurements obtained from each nasal passage	1	2	3	4
Interpreting the curves displayed on the results screen (nasal piece, I-notch, C-notch)	1	2	3	4
Identifying potential pathologies and communicating findings to the patient	1	2	3	4

their PSRS scores were expected, thereby demonstrating the validity of the PSRS. The correlation between the number of R-AR procedures performed and the corresponding increase in scores was analyzed statistically. For reliability, Cronbach's alpha was calculated to assess internal consistency.

Competence was defined as achieving a performance level considered "independently acceptable" for each step. The number of procedures in which a resident scored three or higher on all steps, without subsequently dropping below 3, was defined as the "number of cases required to achieve competence."

During data collection, residents' R-AR performances were assessed and scored during "routine patient services." The measurement of procedure duration began with the initiation of the R-AR application and ended with the interpretation of test results. Ethical approval for this study was obtained from the Pamukkale University Ethics Committee (approval no: E-60116787-020-561697, date: 06.08.2024).

### Statistical Analysis

For statistical analysis, SPSS version 25 (IBM Corp., Armonk, NY, USA) was used. Continuous variables were presented as mean ± standard deviation, along with minimum and maximum values. Categorical variables were presented as frequency and percentage. Cronbach's alpha coefficients were calculated to demonstrate internal consistency. Pearson correlation analysis was used for correlation testing. A p-value <0.05 was considered statistically significant.

### Results

Two hundred and twenty adult patients who presented to our outpatient clinic with complaints of nasal obstruction were included in the study. As in routine practice, the procedure was explained in detail to the patients before R-AR measurement. Of the patients, 112 (51%) were male and 108

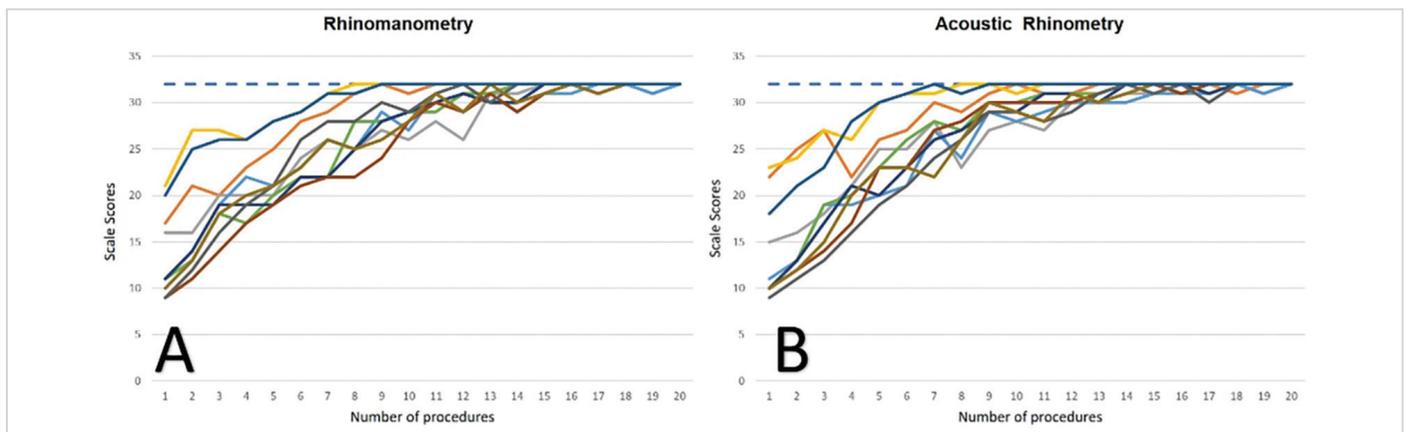
(49%) were female, and their mean age was 32.64±11.80 years (min: 18, max: 65).

Each of the ten residents performed 20 R-AR procedures. To facilitate graphical evaluation, learning curves were generated for each resident (Figure 1). Examination of the learning curves revealed that, although the pace varied among residents, they generally began to acquire the skill in the initial cases, subsequently demonstrated rapid improvement, and reached maximum scores in the later cases. In the graphs, the plateau line at full score represents the maximum score obtainable from the PSRS. The correlation between the increase in the number of procedures performed and the increase in PSRS scores was statistically significant, with  $r=0.911$  ( $p<0.001$ ) for rhinomanometry-PSRS and  $r=0.832$  ( $p<0.001$ ) for acoustic rhinometry-PSRS.

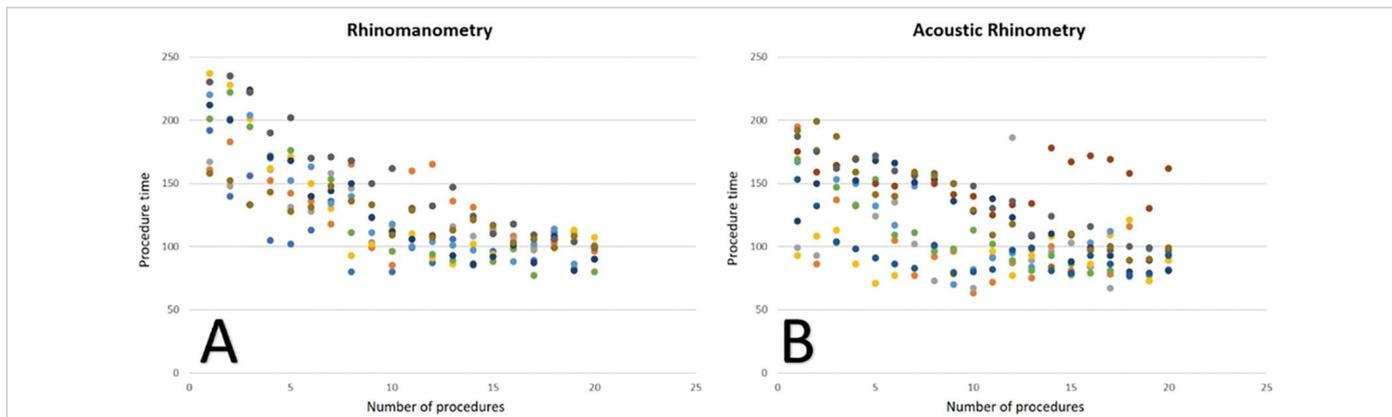
The number of cases required for residents to achieve competence was median: 8 (min: 4, max: 9) for rhinomanometry and median: 8.5 (min: 4, max: 10) for acoustic rhinometry. A statistically significant negative correlation was observed between residents' year of seniority and the number of cases required to achieve competence for both rhinomanometry ( $r=-0.773$ ,  $p=0.009$ ) and acoustic rhinometry ( $r=-0.830$ ,  $p=0.003$ ).

Cronbach's alpha was found to be 0.971 for rhinomanometry-PSRS and 0.969 for acoustic rhinometry-PSRS. With both values exceeding 0.95, the reliability of both PSRSs was found to be very high.

The mean procedure duration was 2.11±0.39 minutes (min: 1.17, max: 3.95) for rhinomanometry and 1.55±0.34 minutes (min: 1.07, max: 3.19) for acoustic rhinometry. As procedures were repeated, a reduction in procedure duration was also observed graphically (Figure 2). The correlation between the increase in the number of procedures and the reduction in duration was statistically significant ( $r=-0.937$ ,  $p<0.001$ ).



**Figure 1.** Residents' learning curves based on PSRS results: **A.** Rhinomanometry, **B.** Acoustic rhinometry (each color represents a different resident)  
PSRS: Procedural skill rating scale



**Figure 2.** Procedure duration for **A.** Rhinomanometry, **B.** Acoustic rhinometry (times are given in seconds; each color represents a different resident)

To evaluate interrater reliability, 20 R-AR procedures performed by different residents were simultaneously assessed by two raters. Interrater reliability coefficients were  $r=0.788$  ( $p<0.001$ ) for the rhinomanometry PSRS and  $r=0.795$  ( $p<0.001$ ) for the acoustic rhinometry PSRS. These results demonstrate a strong, statistically significant positive correlation between raters for the two PSRS instruments.

When all evaluation results were considered, comparisons of initial and final scores and durations revealed reduced procedure times and a statistically significant increase in total scores. These findings provide evidence supporting the validity of the developed PSRS.

## Discussion

Nasal obstruction is among the most common reasons for presenting to ORL outpatient clinics. As future specialists, ORL residents will encounter patients with nasal obstruction, diagnose them, and provide treatment. In this process, they will use R-AR as objective measurement tools. The results of these tests can be employed in both the diagnosis and the post-treatment follow-up of patients presenting with nasal obstruction. Therefore, ORL residents must learn to perform and interpret R-AR during their training. In this study, R-AR PSRS was developed to guide residents in learning R-AR and to evaluate their skills.

Competency-based residency education is becoming increasingly widespread worldwide, as well as in our country (4-6). The Turkish Medical Specialty Board's efforts are directed toward improving this education. These efforts began with the development of a core curriculum that is continuously updated. In competency-based programs, it is necessary to evaluate whether residents have achieved the expected competencies using valid assessment tools. Accordingly, various assessment tools have been developed to demonstrate residents' achievement of expected

competencies. A review of the literature reveals that most workplace-based assessment tools primarily focus on surgical skills, particularly operative procedures (6-10). However, assessment tools have also been developed for outpatient procedures such as R-AR, which are included in the core curricula (11-14).

This study also aimed to determine the time it takes for an ORL resident to learn to perform and interpret R-AR. On average, residents reached the level of competence by the eighth case. However, the learning process is individual for each resident. Both the learning curves and the numerical results demonstrated that residents achieved competence with different numbers of cases. This result supports the fundamental principle of competency-based residency education. There is no standard number of cases required to achieve competence, and each resident must continue practicing until they attain competence. Furthermore, a significant correlation was observed between residents' years of experience and the number of cases required to reach competence, suggesting that senior residents' greater familiarity with nasal anatomy and endoscopic or instrumental examinations positively influences their learning curves.

## Study Limitations

There are some limitations in our study. Since skills training and assessments were conducted in real-life patient care settings, numerous variables, such as the clinical environment, examination times, and communication difficulties with patients, may have influenced the results. Additionally, blinding the evaluators to the residents' level of experience was not feasible due to the nature of direct, competency-based procedural assessment. This lack of blinding may represent a potential source of observer bias and should be considered when interpreting the results.

## Conclusion

In this study, valid and reliable assessment tools (PSRS) were developed for evaluating ORL residents' skills in performing R-AR. Both PSRSs can be used to assess ORL residents' skills in R-AR and to determine their achievement of competence. Based on the data obtained, it can be said that residents generally reach the expected level of competence in performing and interpreting R-AR after approximately eight applications. However, it is essential to acknowledge that learning processes vary individually. The achievement of competence should be assessed separately for each resident.

## Ethics

**Ethics Committee Approval:** Ethical approval for this study was obtained from the Pamukkale University Ethics Committee (approval no: E-60116787-020-561697, date: 06.08.2024).

**Informed Consent:** Written consent was obtained from all residents who volunteered and were observed in the study.

## Footnotes

### Authorship Contributions

Concept: A.A., C.O.K., Design: A.A., E.M., C.O.K., Data Collection and/or Processing: A.A., E.M., C.O.K., Analysis or Interpretation: A.A., E.M., C.O.K., Literature Search: A.A., E.M., C.O.K., Writing: A.A., E.M., C.O.K.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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### Main Points

- Assessment tools are frequently employed to evaluate professional skills, particularly those required in surgical training.
- In this study, valid and reliable tools were developed to assess the proficiency of otorhinolaryngology residents in performing rhinomanometry and acoustic rhinometry.
- Both instruments can be used to evaluate residents technical skills in these procedures and to determine whether they have achieved the required level of competence.
- According to the findings, residents generally reach the expected level of competence in performing rhinomanometry and acoustic rhinometry after approximately eight practice sessions.

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## Original Investigation



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# Clinical Outcomes Following Revision Cochlear Implantation: A Single-Center Experience

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### Abstract

**Objective:** Cochlear implant surgery enables individuals with severe hearing loss to regain auditory function. With the increasing number of implant recipients, complications have become more common, leading to a greater need for revision procedures. This study aimed to analyze and assess the underlying causes of revision surgeries performed in our clinic.

**Methods:** This retrospective study reviewed 1,800 patients who underwent cochlear implantation in our clinic. Of these, 118 patients who required revision operations were included in the analysis. Causes of revision, observed complications, and demographic profiles of the patients were studied.

**Results:** No significant differences were found in age, gender, implantation side, presence of inner ear anomalies, or etiology between patients with and without complications ( $p>0.05$ ). Complications were observed in 22.9% of female patients ( $n=11$ ) and 8.6% of male patients ( $n=6$ ). The cochlear implant brand, failure type (soft or hard), and revision indication were not statistically related to complication status ( $p>0.05$ ). Although not significant, complication rates were higher among patients who required revision due to device malfunction or cholesteatoma.

**Conclusion:** Revision cochlear implantation should be considered in patients presenting with symptoms such as hearing deterioration, tinnitus, pain or swelling at the implant site, redness, delayed wound healing, or atypical facial sensations. This study summarizes our clinical experience and highlights the primary causes leading to revision cochlear implantation.

**Keywords:** Cochlear implant, revision surgery, complications, device failure, postoperative outcomes

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## Introduction

Cochlear implants have significantly improved the quality of life for individuals with profound or severe hearing loss by restoring auditory perception. These devices stimulate the spiral ganglion cells through electrical signals, offering an effective rehabilitation method for both congenital and acquired hearing loss. Since its initial clinical use in the 1980s, cochlear implant technology has evolved rapidly, leading to wider global application. As the number of implant recipients continues to rise, the occurrence of complications and the necessity for revision surgeries have also increased (1).

In cochlear implant surgery, the need for revision arises due to malfunctions of the device, infections, displacement of the device, or complications related to the surgery. The need for revision is indicated by clinical conditions such as device performance failure, skin redness, pain, ulcerative lesions, and extruded electrodes (2). Previous reports indicate an overall rate of device removal or revision surgery between 4% and 10% for different

clinical series (3-5). The presented study aims to share our institutional experience with revision cochlear implant operations, analyze their causes and outcomes, and compare our findings with current literature. Through this evaluation, we hope to contribute to the optimization of surgical strategies and patient management protocols in future clinical practice.

## Methods

### Study Design and Patients

This retrospective study included 118 patients who underwent revision cochlear implant surgery among 1,800 cochlear implant recipients operated on in our clinic between January 1999 and July 2023. All primary surgeries were performed at our clinic by surgeons with comparable experience. Patients who had previously received cochlear implantation at our center and subsequently required surgical revision due to any complications were included in the study. Primary implant cases, cases where complications were resolved using non-surgical methods, and primary implant cases performed at an external center with revision performed at our center were excluded.

### Preoperative Evaluation

Before surgery, all patients were assessed by a multidisciplinary team consisting of an audiologist, an audiometrist, a speech and language therapist, and an otorhinolaryngologist. Surgical indications were determined after consensus within this team. The decision for revision surgery was made based on the medical history of the cases, findings from periodic physical examinations, radiological imaging, and audiological examination results. Skin lesions that cannot be treated with non-surgical procedures, mastoid cavities, and middle ear pathologies requiring surgery, dislodged electrodes, physically damaged devices, and intermittent or continuous device malfunction are criteria used when deciding on revision.

### Hard Failure and Soft Failure

The reasons constituting indications for revision surgery were evaluated under two general headings: hard failure and soft failure.

Hard failure refers to a situation where the implant does not function due to hardware-related issues that can be objectively proven. In other words, there is a physical or electronic malfunction in the implant's internal components, and this malfunction can be definitively demonstrated through telemetry tests. Electrode breakage, extrusion of the electrode from its position, internal component failure, and short circuits in the electrode channels are examples of such situations (1).

Soft failure refers to a condition in which the cochlear implant appears to function appropriately on technical evaluation, yet clinical findings raise suspicion of device malfunction after exclusion of other causes. Soft failures manifest as decreased auditory performance, distorted or altered perception of sounds, slowed or stunted language development in children (1).

### Surgical Technique

In revision surgery, the procedure begins with an incision following the primary incision. Fibrotic structures in the mastoid cavity are meticulously cleaned. The facial nerve is identified. The electrode is separated from the receiver. First, the receiver is removed. If present, fibrotic tissues in the implant bed and subperiosteal pocket are cleaned. The subperiosteal pocket and bed for the implant are prepared again. If an infectious process is ongoing in the surgical area, the electrode is left in the cochlea and reimplantation is postponed to a second session. However, if there is no infection and the mastoid cavity is confirmed to be clean, the electrode is removed from the cochlea during the same session, and a new device is reimplanted. The surgery is concluded with intraoperative telemetry.

### Statistical Analysis

Demographic data, initial implant characteristics, revision indications, interval between first implantation and revision, cochlear implant brands, and postoperative management were reviewed.

Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as numbers and percentages, while continuous variables were summarized as mean, standard deviation, median, minimum, and maximum values. Normal distribution of continuous data was checked using skewness and kurtosis (acceptable range  $\pm 1.96$ ). Since age and time-to-revision did not meet normality assumptions, appropriate non-parametric tests were applied. Comparisons of complication status across demographic and clinical characteristics, etiology, implant brands, and revision causes were performed using the chi-square test. The independent samples t-test was used for comparing continuous variables (age and revision duration) between groups. A p-value  $<0.05$  was considered statistically significant.

The study protocol was reviewed and approved by the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital Ethics Committee in 2023 (approval no: 2023/136, date: 06.09.2023).

## Results

### Demographic Characteristics

Out of 1,800 cochlear implant recipients, 118 underwent revision surgery and were included in this analysis. Of the patients who underwent revision surgery, 27.1% (n=32) were 4 years old or younger, 41.5% (n=49) were between 4 and 18 years old, and 31.4% (n=37) were adults. The mean age was 17.82 years (range 1-75 years).

Table 1 summarizes the descriptive characteristics. Of the patients, 40.7% (n=48) were female and 59.3% (n=70) were male. The right ear was implanted in 61% (n=72), the left ear in 38.1% (n=45), and bilateral implantation was performed in one case (0.8%). Inner ear malformation was detected in 7 patients (5.9%), including Mondini deformity, wide vestibular aqueduct, incomplete partition type 2, and cochlear ossification (Table 1).

### Etiological Findings

Etiological evaluation revealed that the cause of hearing loss was unknown in 44.1% (n=52) of the patients. Among those with identified causes, consanguineous marriage was the most frequent (8.5%), followed by hereditary (6.8%) and febrile illnesses (6.8%). Other less frequent etiologies included progressive loss (4.2%), meningitis (3.4%), otitis media (5.1%), genetic causes (2.5%), ototoxicity (2.5%), and prematurity (2.5%) (Table 2).

### Implant Brands, Revision Reasons, and Postoperative Complications

The implant brand distribution was as follows: Advanced Bionics 11.8% (n=14), MED-EL 63.5% (n=75), and cochlear 24.5% (n=29). This difference between brands was parallel

to primary surgeries. The implant brands mentioned were those used in primary surgeries. The same brands were used in revision surgeries, taking the primary surgeries into account.

Among device manufacturers, MED-EL implants were most frequently used (63.5%), followed by cochlear and Advanced Bionics. In our study, the brands used in 1,800 primary surgeries retrospectively screened were distributed as follows: MED-EL 61.6% (n=1,110), Cochlear 28.4% (n=512), and Advanced Bionics 9.8% (n=178).

The revision rates per brand were MED-EL at 6.8%, cochlear at 5.6%, and Advanced Bionics at 7.8%. The need for revision was more common with Advanced Bionics, while it was relatively less common with cochlear brand implants.

Revision indications were mainly device failure (hard failure: 77 patients; soft failure: 17 patients). Other causes included chronic otitis media (16), infection (2), flap necrosis (3), skin dehiscence (1), and electrode malposition (Figures 1 and 2). Hematoma is also a common complication after cochlear implant surgery, but at our clinic, hematoma management is performed using non-surgical procedures. There has been no case at our clinic where revision cochlear implant surgery was performed due to hematoma. The most common indications were device-related problems. Patient-related problems were encountered less frequently (Table 2).

Postoperative complications occurred in 14.4% (n=17) of the revision group, consisting primarily of hematoma, infection, or skin breakdown. The mean time interval between primary implantation and revision was 5.51±5.09 years (range: 0-19 years). The earliest revision was due to flap necrosis, while the longest interval was observed in a case with chronic otitis media (Table 3).

**Table 1.** Descriptive characteristics of patients who underwent cochlear implantation

Features	n	%	
Gender	Female	48	40.7
	Male	70	59.3
Age	Pediatric (18 years or under)	81	68.6
	Adult (over 18 years)	37	31.4
Side	Right	72	61.0
	Left	45	38.1
	Both sides	1	0.8
Inner ear anomaly-damage	None	111	94.1
	There is	7	5.9
		Mean±SD (min-max)	
Age	17.82±18.80; 11 (1-75)		

SD: Standard deviation, n: Sample size

**Table 2.** Findings regarding the etiologies of patients who underwent cochlear implantation

Features	n	%	
Etiology	Unknown	52	44.1
	Consanguineous marriage	10	8.5
	Hereditary	8	6.8
	Progressive	5	4.2
	Meningitis	4	3.4
	Otitis media	6	5.1
	Feverish illness	8	6.8
	Genetic	3	2.5
	Ototoxicity	3	2.5
	Prematurity	3	2.5
Other	16	13.6	

**Table 3.** Findings regarding cochlear implant brands, reason for revision and postoperative complications of patients who underwent cochlear implantation

Variables		n	%
Cochlear implant brand	AB	14	11.8
	Medel	75	63.5
	Cochlear	29	24.5
Soft/hard failure	Soft failure	17	
	Hard failure	77	
Reason for revision	Hard failure	77	
	Soft failure	17	
	Infection	2	
	Chronic otitis media	16	
	Flap necrosis	3	
	Skin dehiscence	1	
Postoperative complications	Electrode malposition	2	
	None	101	85.6
Time until revision (years)	Yes (hematoma, skin dehiscence, infection)	17	14.4
	5.51±5.09; 3.42 (0-19)		

### Complication Distribution by Demographic and Clinical Factors

No statistically significant differences were found in the distribution of gender, age, implant side, inner ear anomaly, or etiology between patients with and without postoperative complications ( $p>0.05$ ). However, a higher, though non-significant, complication rate was observed among female patients (22.9%) compared to males (8.6%) (Table 4).

Analysis stratified by implant brand, soft/hard failure status, and revision cause revealed no statistically significant differences ( $p>0.05$ ). However, complication rates were higher in patients with Advanced Bionics implants, soft failures, and chronic otitis media as the underlying indication for revision.

**Table 4.** Characteristics of patients who underwent cochlear implantation and distribution of complications according to etiology

Features		No complications (n=101)		Complications (n=17)		p
		n	%	n	%	
Gender	Female	37	77.1	11	22.9	0.056
	Male	64	91.4	6	8.6	
Age	Pediatric	70	86.4	11	13.6	0.924
	Adult	31	83.8	6	16.2	
Side	Right	60	83.3	12	16.7	0.650
	Left	40	88.9	5	11.1	
	Both sides	1	100.0	0	0.0	
Inner ear anomaly-damage	No	95	85.6	16	14.4	1.000
	Yes	6	85.7	1	14.3	
Etiology	Unknown	45	86.5	7	13.5	0.952
	Consanguineous marriage	9	90.0	1	10.0	
	Hereditary	6	75.0	2	25.0	
	Progressive	4	80.0	1	20.0	
	Meningitis	4	100.0	0	0.0	
	Otitis media	5	83.3	1	16.7	
	Feverish illness	7	87.5	1	12.5	
	Genetic	3	100.0	0	0.0	
	Ototoxicity	2	66.7	1	33.3	
	Prematurity	3	100.0	0	0.0	
Other	13	81.3	3	18.8		
		Mean±SD (min-max)		Mean±SD (min-max)		p
Age		17.68±18.64 11 (1-75)		18.65±20.28 12 (1-75)		0.840

SD: Standard deviation



**Figure 1.** Flap necrosis



**Figure 2.** Electrode malposition, implant electrode in external auditory canal

## Discussion

The first report of cochlear implant revision surgery was published by House (6) in 1976. Cochlear implantation, which restores hearing through direct electrical stimulation of the cochlear nerve, has become a widely accepted surgical treatment for severe sensorineural hearing loss (7). As the use of these devices has expanded, complications and subsequent revision surgeries have been reported more frequently. According to published data, the overall rate of implant removal ranges from 4% to 10% (3-5). Revision indications are commonly categorized as hard failures, soft failures, or medical/surgical causes. Hard failure represents confirmed hardware malfunction verified by device integrity testing, whereas soft failure refers to unexplained performance decline despite an apparently functional implant (8). Additional causes include wound infection, migration of device components, or electrode-related problems (9). In most series, device failure accounts for nearly half of all revision cases (10,11).

In the presented study, device-related causes represented 79.6% of all revision indications, aligning with previous literature. Chronic otitis media and related inflammatory

processes contributed to 13.5% of the cases, while a smaller subset involved tissue or flap complications. Flap necrosis presents a particular surgical challenge, and some authors recommend contralateral reimplantation as a preferred option when feasible (12). The predominant reason for revision in our cohort was device failure, consistent with prior reports.

In our study, revision rates by brand were 6.8% for MED-EL, 5.6% for cochlear, and 7.8% for Advanced Bionics. We found that the likelihood of revision is higher in Advanced Bionics brand implants, while the risk of revision is lower in cochlear brand implants compared to other brands. A study comparing brands showed that MED-EL had the highest revision rate (5.9%), followed by Advanced Bionics (5.3%) and cochlear (4.7%) (13). In another study, Advanced Bionics had the highest revision rate (6.2%), while cochlear and MED-EL devices had revision rates of 5.3% and 2.6%, respectively (14).

Children require revision surgery more than adults. A comparative study between adults and children found that the need for revision was greater in children than in adults (15). Studies have shown that revision rates are higher in the pediatric population compared to the adult population as a result of increased surgical complications and greater exposure of the implanted internal unit to trauma (16). When considering this situation in children specifically, we professionals should explain to their families the importance of protecting them from head trauma and providing a suitable environment for this purpose by giving them detailed information.

The postoperative complication rate of 14.4% found in our study is comparable to those described in earlier large-scale series (17,18). One of the complications mentioned arose due to a malfunction of the implant's internal component, while the other complications were hematoma and wound site infections (18). Various complications such as seroma, hematoma, infection, gusher, misplacement of the electrode, facial nerve palsy, and vertigo may occur after cochlear implantation (19). In our study, 16 of the 17 cases that developed complications were treated with non-surgical conservative methods. Reimplantation was performed in a case where device failure occurred. In various studies in literature, we see that conservative approaches, as applied in our center, are mostly used in the management of complications (20).

Management of complications may range from non-invasive device reprogramming to complete reimplantation, reflecting both the technological adaptability of cochlear implant systems and the necessity for individualized patient follow-up. The mean interval between implantation and revision (5.51 years) demonstrates that while modern implants are durable, long-term vigilance is essential (21,22).

Overall, our results are comparable with previously reported revision and complication rates (23,24). Certain discrepancies such as the low number of meningitis-related cases, may indicate advances in device safety features and refined surgical techniques (25). A slightly higher complication rate among female patients was noted; however, this finding was not statistically significant and may be influenced by biological or anatomical differences that warrant further investigation. Additionally, soft failure cases exhibited somewhat higher complication frequencies than hard failures, likely due to diagnostic uncertainty and challenges in determining the precise etiology of device malfunction.

In summary, the continuous advancement of cochlear implantation technology and the improvement of perioperative protocols are essential for minimizing complications and improving long-term outcomes. The findings of this study emphasize the importance of comprehensive follow-up and multidisciplinary management based on collaboration in maintaining the functional success of cochlear implants.

## Conclusion

Although continuous advancements in cochlear implant design and surgical methods have improved safety and outcomes, the risk of complications and the need for revision procedures persist. Meticulous preoperative assessment, careful surgical technique, and structured postoperative monitoring remain key factors in preventing complications. Sustained collaboration between surgeons, audiologists, and rehabilitation specialists is essential to ensure long-term implant performance and patient satisfaction.

## Ethics

**Ethics Committee Approval:** The study protocol was reviewed and approved by the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital Ethics Committee in 2023 (approval no: 2023/136, date: 06.09.2023).

**Informed Consent:** Informed consent was obtained from all adult participants and from the parents or legal guardians of pediatric participants for inclusion in the study and the use of anonymized clinical data.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: A.D., Concept: C.K., Design: H.B.Y., Data Collection and/or Processing: E.A., Analysis or Interpretation: A.D., Literature Search: C.K., Writing: C.K.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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## Main Points

- This study presents our clinical experience regarding revision cochlear implant surgeries.
- Revision-related complications are complex and should be managed by experienced surgeons.
- Postoperative cochlear implant failures can be classified as soft or hard failures, and awareness of these distinctions is crucial for clinical management.

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## Original Investigation



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# Pediatric Tracheostomy: A Five-year Retrospective Review at a Tertiary Care Center

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### Abstract

**Objective:** Tracheostomy in the pediatric population is a technical and demanding procedure due to the smaller, more pliable trachea and the limited exposure of the operating field. It has been documented to have higher morbidity and mortality, especially among low birth weight and pre-term infants. A review of the existing literature shows that indications, epidemiology, and complications are changing dynamically, and no definite guidelines have been established.

**Methods:** A five-year retrospective observational study on pediatric tracheostomy was carried out at a pediatric tertiary care center. All children aged between 1 day and 18 years who had undergone tracheostomy were included. Case records of all children were analyzed meticulously for age, sex, indications, procedure, and complications of tracheostomy.

**Results:** During the study period, 148 children underwent tracheostomy at our pediatric tertiary care center. The most common indication for tracheostomy was neurological causes, noted in 77 patients (52.02%). The most common early postoperative complication was tube obstruction in 13 patients (8.78%), and the most common delayed postoperative complication was suprastomal collapse in 52 patients (35.13%). In total, 104 patients (70.27%) underwent successful decannulation.

**Conclusion:** Pediatric tracheostomy is a very demanding and challenging procedure owing to the alterations in the neck anatomy, variations in the airway, and several associated complications. There is a growing need to know the change in indications, complications, and overall outcome of pediatric tracheostomies for better care and efficient management of children requiring tracheostomies.

**Keywords:** Tracheostomy, child, infant, postoperative complications, decannulation

## Introduction

Tracheostomy is one of the oldest documented surgical procedures in history (1). It is a lifesaving procedure in which the trachea is exteriorized, creating a surgical opening between the external environment and the trachea, bypassing the upper airway (2). The present-day tracheostomy can be attributed to Armand Trousseau, who initially used the procedure to manage patients with diphtheria associated airway distress. The procedure was later modified and standardized by Chevalier Jackson in the early 20<sup>th</sup> century (3). Although tracheostomy is deemed a life-saving procedure, it is also associated with significant complications, morbidity, and mortality.

Pediatric tracheostomy is a more demanding and challenging procedure in comparison to the one performed in adults. This can be attributed to the smaller airway, more pliable trachea, and limited extension of the operating field in children. The procedure in children has shown an overall higher morbidity and mortality, particularly among syndromic, pre-term, and low birth weight infants (4,5).

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Tracheostomies in the pediatric population have been historically employed for emergency indications such as laryngotracheobronchitis, diphtheria, and upper airway obstruction (6). In recent years, however, better intensive care protocols and anesthetic management have led to a significant shift in the indications, complications, and overall management of pediatric tracheostomy.

Hence, the present retrospective study was carried out to analyze the indications, complications, and outcomes of pediatric tracheostomy at our pediatric tertiary care center.

### Methods

A retrospective observational study was done on pediatric tracheostomies between July 2020 and July 2025 at a tertiary care center in Southern India. The study included all children, aged 1 day to 18 years, who underwent tracheostomy for various indications. Case records of all children were analyzed meticulously for age, sex, indications, procedure, and complications of tracheostomy. Patients with incomplete records, patients who had undergone tracheostomy outside our center, and those requiring revision tracheostomy were excluded from the study.

A total of 148 children aged 1 day to 18 years who had undergone tracheostomy at our center were included in the study over a period of five years. The tracheostomy procedure was performed by a single pediatric otorhinolaryngology unit in the operating theater to maintain uniformity and strict asepsis. Patients were followed up regularly for up to 6 months post-surgery.

### Statistical Analysis

Data was collected and tabulated in an Excel sheet. A total of 148 patients who underwent tracheostomy over a period

of five years at our center were included in the study. Mean, range, and standard deviation were used for quantitative data such as age, sex, indications for the surgery, and complications, while counts and percentages were used for data in the categorical form. Statistical analysis was done using SPSS software (version 20.0).

### Ethics Approval

The ethical clearance was taken from the Institutional Review Committee Indira Gandhi Institute of Child Health, where the study was done (reference number: IRB/12/25/May/2024, date: 25.05.2024).

### Results

During the study period, a total of 148 children underwent tracheostomy at our pediatric tertiary care center. All tracheostomies were conducted in the operating theater to maintain absolute sterility and by a single pediatric otorhinolaryngology team to maintain surgical uniformity. Of the 148 patients, 80 (54%) were male and 68 (46%) were female. The most common age group was less than one year of age (35.13%), followed by the children in the pre-school age group (19.59%) (Figure 1).

The most common indication for tracheostomy was neurological causes, seen in 77 patients (52.02%) (Figure 2). This was followed by upper airway obstruction seen in 41 patients (27.70%). The most common neurological cause requiring tracheostomy was Guillain-Barré syndrome, seen in 28 patients (18.91%) (Table 1).

The complications were categorized as intraoperative, early postoperative (up to seven days of tracheostomy), and delayed postoperative (beyond seven days of tracheostomy). There were no intraoperative complications documented

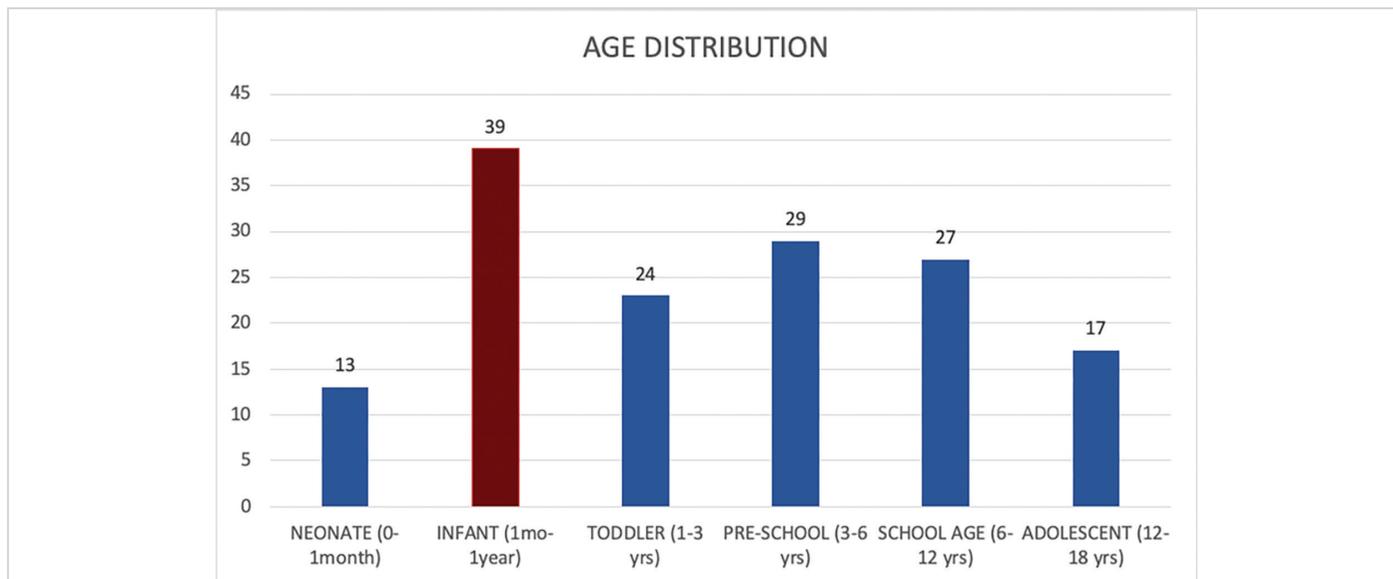
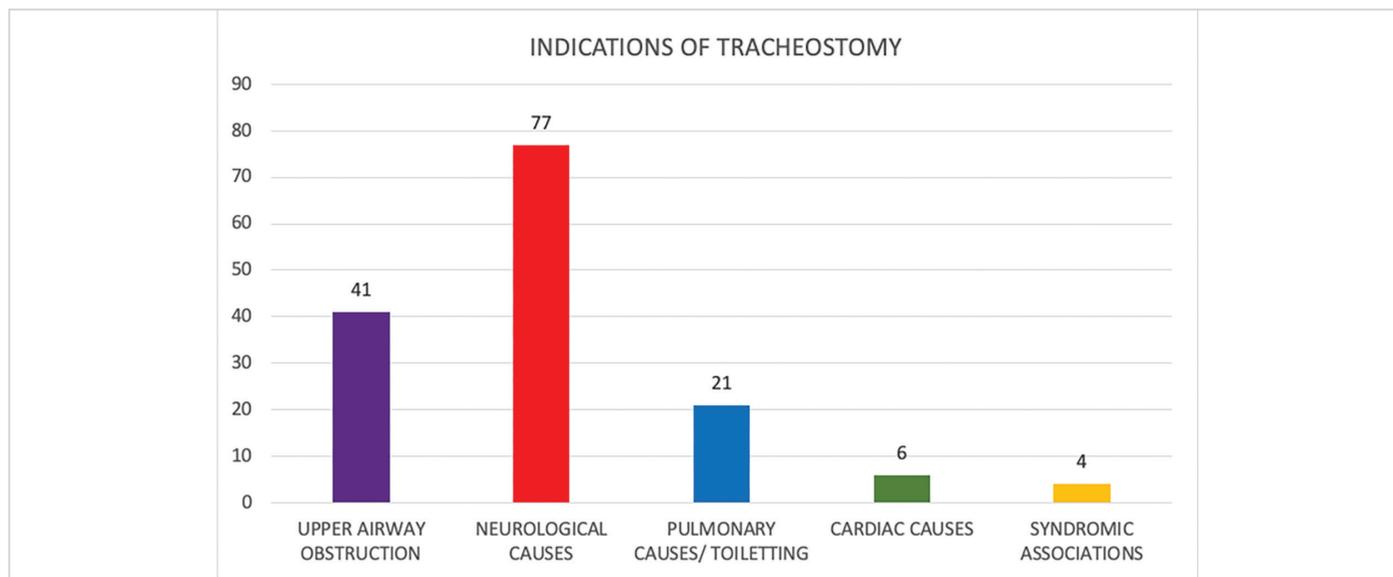


Figure 1. Age distribution of tracheostomized patients



**Figure 2.** Indications of pediatric tracheostomy

in our study. The most common early postoperative complication was tube block, which was noted in 13 patients (8.78%). The second most common early complication was accidental decannulation in 10 patients (6.75%) (Figure 3). The most common delayed postoperative complication was suprastomal collapse in 52 patients (35.13%), followed by tip granulations noted in 24 patients (16.21%) (Figure 4).

During the study period and the follow-up period of six months, 104 patients (70.27%) underwent successful tracheostomy decannulation. Of these, 16 patients (15.38%) developed further complications of tracheocutaneous fistula, which was surgically corrected.

Five patients (3.38%) among our study population died which was attributable to the primary condition of the patient. None of these were due to the tracheostomy procedure or its associated complications.

## Discussion

Tracheostomy is a life-saving procedure that involves creating an opening in the neck to maintain the airway in critically ill patients. When tracheostomy is performed in pediatric patients, especially on low birth weight and preterm infants, the procedure has been associated with higher morbidity and mortality in comparison to adults (5).

Tracheostomy was more frequently done in males in our study population (80 patients, 54.05%) in comparison to females (68 patients, 45.95%). This is in accordance with a study by Yukkaldiran and Doblan (7), in which 51.4% of their tracheostomies were performed on male patients. The most common age group in our study population was less than one year of age (52 cases, 35.13%). This is in accordance

**Table 1.** Indications of tracheostomy

Serial number	Indications	Number of cases	Percentage
<b>1.</b>	<b>Upper airway obstruction</b>	41	27.70
A.	Diphtheria	3	2.02
B.	Laryngomalacia	15	10.13
C.	Subglottic stenosis	9	6.08
D.	Tracheomalacia	4	2.70
E.	Vocal cord palsy	3	2.02
F.	Laryngeal cleft	1	0.68
G.	Recurrent respiratory papillomatosis	1	0.68
H.	Post tracheo-esophageal fistula repair	3	2.02
I.	Acid consumption	2	1.35
<b>2.</b>	<b>Neurological causes</b>	77	52.02
A.	Guillain-Barré syndrome	28	18.91
B.	Acute encephalitis	13	8.78
C.	Traumatic brain injury	4	2.70
D.	Myopathies	7	4.73
E.	Spinal injury	1	0.68
F.	Central hypoventilation syndrome	2	1.35
G.	Seizure disorder	6	4.05
H.	Leigh's disease	2	1.35
I.	Acute flaccid paralysis	2	1.35
J.	Meningitis	10	6.78
<b>3.</b>	<b>Pulmonary causes/toileting</b>	21	14.18
A.	Pneumonia	13	8.78
B.	Acute respiratory distress syndrome	8	5.40
<b>4.</b>	<b>Cardiac causes</b>	6	4.05
<b>5.</b>	<b>Syndromic associations</b>	4	2.70
A.	Pierre Robin sequence	2	1.35
B.	Edward's syndrome	1	0.68
C.	Down's syndrome	1	0.68

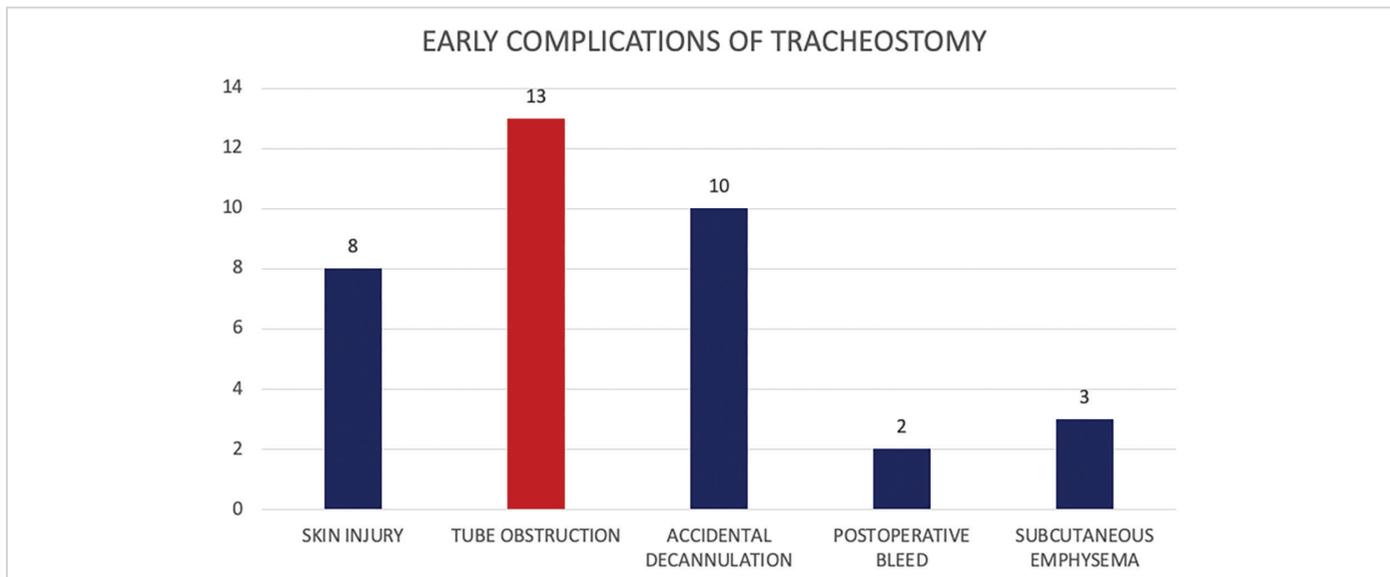


Figure 3. Early complications (up to seven days of procedure)

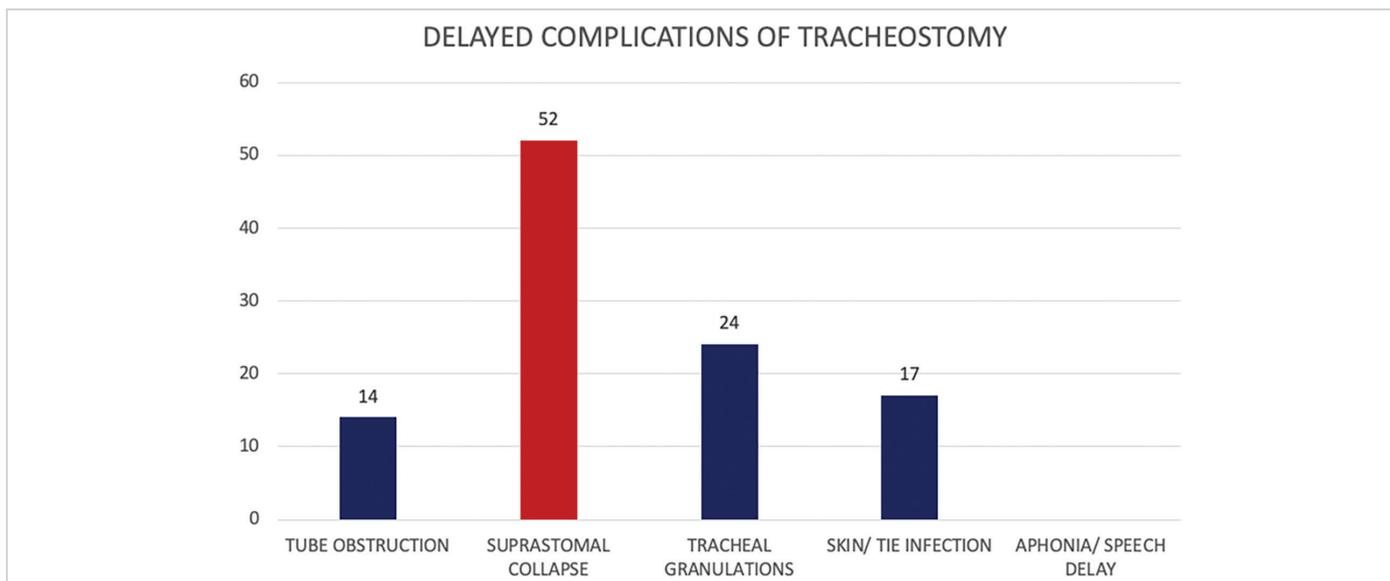


Figure 4. Delayed complications (beyond seven days of procedure)

with a study by Schweiger et al. (8), where the majority of tracheostomies were performed in patients less than one year of age.

Recent advances and developments have emerged in endotracheal intubation, intensive care units, and vaccinations, leading to a significant decline in acute infectious diseases requiring tracheostomy (9). Only three patients (2.02%) in our study underwent tracheostomy for acute airway obstruction (laryngeal diphtheria). A study by Waki et al. (10) noted that there has been a significant decline in tracheostomies done for acute upper airway obstructions.

The most common indication for tracheostomy in our study population was neurological disorders, seen in 77 patients

(52.02%). Among the neurological causes, Guillain-Barré syndrome was the most common etiology, seen in 28 patients (18.91%), followed by encephalitis in 13 patients (8.78%). This was in accordance with a study by Tolunay et al. (11), in which 60.4% of their study population had undergone tracheostomy for neurological causes. In the study of Akcan et al. (12), 59.86% of their population had undergone tracheostomy for neurological causes.

Pediatric tracheostomy is associated with a higher incidence of complications in comparison to the tracheostomy done in adults (13). These complications can be broadly classified as intraoperative and postoperative. Postoperative complications can be further subclassified into early (within

seven days of procedure) and late (beyond seven days of procedure) postoperative complications (14). In our study, there were no intraoperative complications.

Early postoperative complications can include, among others, bleeding at the stoma site, accidental decannulation, tube obstruction, and peri-tracheostoma skin infections. The most common early postoperative complication noted in our study population was tube obstruction within seven days of tracheostomy, seen in 13 patients (8.78%). This was marginally higher compared to the study by Van Buren et al. (15), in which early tube obstruction was noted in only 4.7% of their study population. This complication could be attributed to the presence of blood clots within the tube, improper and irregular suctioning, and alterations in the quantity and quality of the tracheal secretions, which could lead to a tracheostomy tube block (16).

Accidental decannulation is a dreaded complication associated with tracheostomy tubes and is a significant cause of tracheostomy-related morbidity and mortality (17). It is considered a serious early postoperative complication, with an incidence ranging from 0.9% to 20% in the literature (18). In our study, it was the second most common early complication, occurring in 10 patients (6.75%), and was more frequently observed in patients with uncuffed tubes. This finding is consistent with a Scottish series by Douglas et al. (19), in which tube displacement occurred in 5.2% of 111 pediatric patients who underwent tracheostomy. Accidental decannulation can be minimized by placing stay sutures from the anterior tracheal wall to the chest, thereby reducing tube displacement and effectively anchoring the tracheostomy tube (16).

The complications that occurred after seven days of performing tracheostomy were termed as late complications. These can include suprastomal collapse, tracheal granulations, local skin infections, accidental decannulation, and tracheo-vascular fistula. Suprastomal collapse occurs due to damage to the mucosa and the tracheal cartilage. In particular, it occurs due to weakening of the anterior tracheal wall superior to the tracheostoma (16). In a study by Antón-Pacheco et al. (20), suprastomal collapse was noted in 20% of their study population. The presence of significant suprastomal collapse can impede the decannulation of the tracheostomy tube. Fifty two patients (35.13%) in our study had suprastomal collapse, which was higher than in other studies. This could be attributed to the technique of tracheostomy being used, as the authors did not fix the tracheal wall to the tracheostoma skin at the time of surgery to prevent development of tracheocutaneous fistula, as was being followed in other studies (16).

The second most common late complication noted in our study was lower tracheal granulations, seen in 24 patients (16.21%). Across literature, the rate of tracheal granulations

was noted as being 12.3% to 66% (21). The presence of these granulations is usually non-obstructive and asymptomatic and does not warrant any surgical treatment. Only the granulations that would impede decannulation should be excised. These can be managed endoscopically, or in case they are large and firm, should be removed via an open excision (16).

Of the 148 patients in our study population, 104 patients (70.27%) were successfully decannulated. These were mostly patients who had been tracheostomized in view of neurological or pulmonary causes. In a study by Schweiger et al. (8) in Southern Brazil on 123 children who had undergone tracheostomy, only 35 (28%) were successfully decannulated. They attributed a lower rate of decannulation in their study to patients having more comorbidities. In another study by Bandyopadhyay et al. (22), 147 of 189 (77.8%) patients were successfully decannulated. They concluded that decannulation without adequately addressing comorbidities could result in adverse outcomes.

Tracheocutaneous fistula is a complication of tracheostomy decannulation. Failure of the tracheostoma to close spontaneously after decannulation results in a tracheocutaneous fistula. In our study, it was noted in 16 patients (15.38%) post decannulation. Failure to spontaneously close the tracheostomy for up to six months was considered a tracheocutaneous fistula. Our study was in accordance with a study done by Tasca and Clarke (23) in Liverpool, where 11.9% of their study population had a tracheocutaneous fistula requiring surgical closure. It was noted in this study that children who had the tracheostomy tube for more than two years were more prone to developing a tracheocutaneous fistula.

### Study Limitations

The study design is retrospective in nature, which could have potentially introduced a selection bias. The study is limited to being carried out at a single institution which could lead to difficulty in generalizing the findings to a wider population.

### Conclusion

Tracheostomy in children is a very demanding and challenging procedure owing to the alterations in the neck anatomy, variations in the airway, and several associated complications. The procedure remains a common practice in tertiary care hospitals due to varied conditions and indications. Regardless of the indication and the protocol used, there are several complications described in literature which the operating surgeon and caregivers should keep in mind. There is a growing need to know and understand the indications, complications, and overall outcome of pediatric tracheostomy for better care and efficient management of children requiring this procedure.

## Ethics

**Ethics Committee Approval:** The ethical clearance was taken from the Institutional Review Committee Indira Gandhi Institute of Child Health, where the study was done (reference number: IRB/12/25/May/2024, date: 25.05.2024).

**Informed Consent:** Retrospective study.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: A.F., P.K.P., Concept: A.F., P.K.P., Design: A.F., P.K.P., Data Collection and/or Processing: A.F., S.R., Analysis or Interpretation: A.F., P.K.P., Literature Search: A.F., S.R., Writing: A.F.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

**Financial Disclosure:** The authors declare that this study has received no financial support.

### Main Points

- Pediatric tracheostomy is a more challenging procedure due to the smaller, more pliable trachea, and the limited extension of the available operating field.
- In recent years, there has been significant change in the indications and complications of tracheostomy in the pediatric population.
- 52.02% of patients in our study population underwent tracheostomy due to an underlying neurological cause. • The most common early complication related to tracheostomy was tube block seen in 8.78% of the patients.
- The most common delayed complication noted in our study was suprastomal collapse seen in 35.13% of the patients.

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## Original Investigation



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# Animal Research in Otorhinolaryngology: Shifts in Publication and Practice Over Two Time Periods

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### Abstract

**Objective:** The aim of this bibliometric analysis is to assess the evolving trends in animal research in otorhinolaryngology over two different time periods.

**Methods:** Articles published in the Science Citation Index Expanded general otorhinolaryngology journals in 2005-2007 and 2018-2020 were retrieved. The relationship of these studies to the Replacement, Reduction, and Refinement (3Rs) principles, emphasizing evidence of Reduction, and Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines were examined, and the predominant subspecialties and the contributions of journals and countries were evaluated. Keyword, research focus, and citation analyses were performed using VOSviewer.

**Results:** Despite a 51.8% increase in the total number of publications between the two study periods, the number of animal studies decreased by 41.5%, along with a 49.1% reduction in the number of animals used. *In vivo* studies lacking reported animal numbers constituted 10.9% in the first period and 10.3% in the second. "Cochlea" and "ototoxicity" were the most frequent keywords, with seven of the top ten appearing in both periods. Although 58.6% of the animal studies received ten or fewer citations, The Laryngoscope published the most animal studies and was the most-cited journal.

**Conclusion:** This study underscores the importance of adopting the 3Rs and enhancing adherence to guidelines such as ARRIVE. Evaluating the outcomes of animal studies will be essential for responsible and impactful research in otorhinolaryngology. By revealing current research focuses, leading journals, and countries, this study also presents clues for future animal research in the field.

**Keywords:** ARRIVE, animal research, otorhinolaryngology, quality of reporting, 3Rs

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## Introduction

Animal use in scientific research has long been debated, raising concerns despite the contributions it has made to science (1). In response, the Replacement, Reduction, and Refinement (3Rs) were established to support responsible animal research (2). Likewise, the Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines were introduced and updated to promote standardization in reporting animal studies (3,4). With the growing use of animals in research, the volume of publications related to these studies has also increased (5-7).

The aim of this bibliometric analysis is to assess the evolving trends in animal research in otorhinolaryngology by revealing subspecialties, keywords, research focuses, citations, and contributions over two different time periods.

## Methods

Two different three-year periods (2005-2007 and 2018-2020), separated by a 10-year interval, were selected to evaluate the 3Rs principles, with an emphasis on evidence of Reduction; to compare the periods before and after the publication of the ARRIVE guidelines; and to provide an up-to-date assessment of the literature and its trends.

Articles published in otorhinolaryngology journals listed in the Science Citation Index Expanded during these years were retrieved. On the website “<https://jcr.clarivate.com/jcr/browse-journals>” the category “Otorhinolaryngology” was chosen in the “Category” area, and “Science Citation Index Expanded” was selected in the “Citation Index” part for the specified years. Only English-language journals with accessible archives for both periods were included, while subspecialty-specific journals were excluded. The lists of included and excluded journals for each study period are presented in Supplementary Tables S1-S4.

For the total number of publications, the journal title was entered into the search field of the Web of Science (WoS) Core Collection database, and “Article” was selected under the “Document Types” category in the “Refine Results” section. Review articles, editorials, and letters were excluded by not selecting these document types.

For the animal study publications, “Custom Range” was selected in the “Publication Date” column in the PubMed database. For each journal and year, the start and end dates for the specified years were entered separately. Then “Other Animals” was selected in the “SPECIES” section of the “Additional Filters” field. Further, each journal archive was manually searched and compared to publications obtained from the PubMed database.

The Methods section of each publication was reviewed to determine the study type and the source of the animal subjects. *In vivo* animal studies and *ex vivo/in vitro* studies using animals euthanized specifically for research purposes were included. Studies using animals obtained from slaughterhouses or euthanized for unrelated purposes were excluded. Additionally, three animal studies that were not indexed in the WoS Core Collection database were excluded from the VOSviewer-based analysis.

Categorization decisions were made by evaluating the full text of the article and keywords. Each animal study was assigned to one subspecialty—otology, rhinology, or head and neck/laryngology—based on the anatomical site studied and the research focus. Research topics were determined through keyword analysis and article review, with attention to anatomy, pathophysiology, and the interventions studied.

Data was extracted from the WoS Core Collection and PubMed databases on March 1, 2023, and journal archives were manually verified. The relationship of these studies to the 3Rs principles, with an emphasis on evidence of Reduction, and to the ARRIVE guidelines was examined. ARRIVE guideline adherence was assessed solely based on whether the number of animals used was reported in the publication. Other guideline items were not analyzed.

Ethics committee approval was not required because the study involved a retrospective bibliometric analysis and did not include any human participation or personal data.

## Statistical Analysis

Microsoft Excel (Microsoft 365, Microsoft Corp., Redmond, WA, USA) was used for data organization, preliminary statistical aggregation (e.g., annual publication counts, percentage changes), and cross-tabulation of publication trends across journals, years, countries, and subspecialties. Keyword, research focus, and citation analyses were performed using VOSviewer (version 1.6.19, Leiden University Center for Science and Technology Studies, The Netherlands).

## Results

A total of 12 journals were studied in 2005, 13 in 2006 and 2007, 18 in 2018 and 2019, and 19 in 2020. The initial period (2005-2007) included 7,193 publications across 13 journals, while the subsequent period (2018-2020) included 10,921 publications across 19 journals, representing a 51.8% increase.

During both periods, The Laryngoscope exhibited the highest article publication numbers, rising by 69.6% from 1,225 to 2,077 articles. Certain journals, such as the American Journal of Otolaryngology (112.9%) and the European Archives of Oto-Rhino-Laryngology (118.6%), experienced notable growth, while JAMA Otolaryngology-Head & Neck Surgery declined by 42.9% (Table 1).

A total of 518 animal study publications were identified during the first period (174, 168, and 176 annually, respectively) and 303 during the second period (122, 116, and 65 annually, respectively). These numbers corresponded to 63.1% of animal studies in the first period and 36.9% in the second, indicating a 41.5% decrease. The Laryngoscope published the most animal studies, accounting for 27.2% in the first period and 32.3% in the subsequent period. The four journals with the highest number of animal studies accounted for 71% of these publications in the first period and 61% in the second. In the first period, Clinical Otolaryngology and B-ENT, and in the second period, European Annals of Otorhinolaryngology-Head and Neck Diseases, published no animal studies (Table 1).

**Table 1.** Total publications, animal study publications, and animal study citations by journals

Journal	First period		Second period		Animal study citations
	Publications	Animal study publications	Publications	Animal study publications	
American Journal of Otolaryngology	286	9	609	5	126
Clinical Otolaryngology	190	0	386	1	5
JAMA Otolaryngology-Head & Neck Surgery	517	37	295	1	723
Otolaryngology-Head and Neck Surgery	1,175	73	873	19	1,140
The Annals of Otolaryngology, Rhinology & Laryngology	465	63	517	12	1,491
Auris Nasus Larynx	243	15	471	25	272
B-ENT	115	0	162	2	0
European Archives of Oto-Rhino-Laryngology	630	28	1,377	28	520
International Journal of Pediatric Otorhinolaryngology	757	27	1,399	35	675
The Journal of Laryngology & Otolaryngology	676	9	512	4	94
The Laryngoscope	1,225	141	2,077	98	5,019
ORL-Journal for Oto-Rhino-Laryngology, Head and Neck Surgery	174	21	110	5	299
Acta Oto-Laryngologica	740	95	597	22	1,270
Ear, Nose & Throat Journal			586	8	15
Acta Otorhinolaryngologica Italica			174	2	4
Brazilian Journal of Otorhinolaryngology			247	15	94
European Annals of Otorhinolaryngology-Head and Neck Diseases			229	0	0
Clinical and Experimental Otorhinolaryngology			131	18	109
Laryngoscope Investigative Otolaryngology			169	3	4
<b>Total</b>	7,193	518	10,921	303	

Animal study citations represent the total number of citations received by animal studies in both periods

Overall, 34 countries contributed to animal study publications in the first period and 23 in the second. Countries contributing more than 5 animal study publications are shown in Table 2. The top four contributors in both periods were the United States, Japan, Türkiye, and South Korea. The United States led with 320 publications (39.1% of the total 818 animal study publications), followed by Japan (127 publications) and Türkiye (113 publications).

In the first period, the United States (220 publications), Japan (84), Türkiye (48), and South Korea (42) were the four leading contributing countries. In the second period, the United States, Japan, Türkiye, and South Korea contributed 100, 43, 65, and 43 publications, respectively. Contributions from the United States and Japan decreased by 54% and 48%, respectively, whereas publications from Türkiye increased by 35% between the two periods.

The animal species most commonly utilized in the study periods were rats, mice, rabbits, guinea pigs, and dogs. The number of *in vivo* animal studies was 449 in the first period and 290 in the second. In the first period, 49 studies (10.9%) did not specify the exact number of animals utilized, while in the second period, this was 30 studies (10.3%). In total,

13,173 animals were used in the first period, whereas 6,695 were used in the second period, accounting for a 49.1% decrease (Table 3).

Among the subspecialties, otology accounted for the highest number of animal studies (358, 43.6%), followed by head and neck/laryngology (355, 43.2%) and rhinology (96, 11.7%). Frequently investigated topics included physiology, treatment methods, ototoxicity, and pathophysiology in otology; oncology, treatment methods, reconstruction, and wound healing in head and neck/laryngology; and allergy, sinusitis, nasal/paranasal pathophysiology, and treatment methods in rhinology (Table 4).

The keywords “cochlea” and “ototoxicity” were the most frequently used keywords in animal study publications, each appearing 38 times. The keyword “larynx” followed with 34 occurrences, “wound healing” with 27, and “hearing loss” with 26. Other commonly used keywords included “vocal fold” with 25 occurrences, “tissue engineering” with 24, “inner ear” with 19, “recurrent laryngeal nerve” with 18, and “otitis media” with 15. At least half of the top ten keywords were directly related to otology, and seven of these were present in both periods.

**Table 2.** Animal study publications and citations by country (both periods combined)

Country	Number of animal study publications	Percentage	Citations
USA	320	39.1%	6,490
Japan	127	15.5%	1,572
Türkiye	113	13.8%	1,131
South Korea	85	10.4%	883
China	65	7.9%	465
Sweden	32	3.9%	556
Germany	28	3.4%	531
Australia	16	2.0%	178
Brazil	16	2.0%	164
Canada	14	1.7%	132
England	12	1.5%	172
Spain	12	1.5%	114
Egypt	7	0.9%	67
France	7	0.9%	100
Denmark	6	0.7%	79
Taiwan	6	0.7%	47

**Table 3.** Number of animals used by species and study period

Animal species	First period	Second period
Rat	5,719	3,122
Mouse	2,633	1,594
Guinea pig	1,878	419
Rabbit	1,738	958
Gerbil	289	0
Dog	279	146
Chinchilla	215	159
Pig	158	71
Hamster	96	0
Monkey	50	0
Cat	46	35
Ferret	20	34
Bullfrog	18	0
Asian house shrew	15	0
Pigeon	10	0
Sheep	7	22
Cow	1	0
Camel	1	0
Zebrafish	0	125
Lamb	0	10
Total	13,173	6,695

**Table 4.** Research topics of animal studies by subspecialty

Topic in otology	Number of studies
Physiology	68
Treatment technique/method	66
Ototoxicity	57
Pathophysiology	48
Otitis media	30
Noise-induced hearing loss	22
Facial nerve	19
Wound healing	17
Otitis media with effusion	11
Endolymphatic hydrops/Meniere's disease	8
Cochlear implantation	6
Cholesteatoma	6
Topic in head and neck/laryngology	Number of studies
Oncology	63
Treatment technique/method	46
Reconstruction	45
Wound healing	40
Physiology	33
Laryngotracheal stenosis	32
Pathophysiology	28
Recurrent laryngeal nerve and laryngeal innervation	24
Injection laryngoplasty	14
Reflux	10
Thyroid and parathyroid	8
Swallowing and swallowing disorders	8
Laryngeal transplantation	4
Topic in rhinology	Number of studies
Allergy	24
Sinusitis	14
Nasal and paranasal sinus pathophysiology	12
Treatment technique/method	11
Smell	9
Septorhinoplasty	8
Wound healing	6
Immunity	5
Snoring and obstructive sleep apnea syndrome	4
Nasal polyposis	2
Anatomy	1
Number of studies indicates the number of animal studies addressing each topic across both periods	

The co-occurrence overlay visualization (Figure 1) encompasses both study periods; nevertheless, unique keyword networks specifically evolved during the second period. In otology, keywords such as “DPOAE,” “cisplatin,” and “hydrogel” appeared alongside “ototoxicity” and “electromyography” was associated with the “facial nerve.” In head and neck/laryngology, “platelet-rich plasma,” “vocal fold scar,” and “subglottic stenosis” clustered around “wound healing,” while “thyroidectomy,” “electromyography,” and “vocal fold paralysis” were linked to the “recurrent laryngeal nerve.” In rhinology, “inflammation” was linked to “allergic rhinitis” (Figure 1). Collectively, these keyword networks highlight the principal research focus studied in the second period.

A total of 818 animal study publications received 11,860 citations (range 0-478, mean 14.4). Among these, 480 publications (58.6%) received 10 or fewer citations, while 36 earned no citations at all (Table 5).

The Laryngoscope was the most cited journal, with 5,019 citations (Table 1). The United States had the highest number of citations (6,490), followed by Japan (1,572) and Türkiye (1,131) (Table 2).

### Discussion

Overall, this bibliometric analysis shows that, although total otorhinolaryngology publications increased by 51.8% between the two periods, animal studies, the number of animals used, and the number of contributing countries all decreased. This shift shows a changing practice in animal research within the field. The increase in total publications is consistent with the literature showing the rise in publications within otorhinolaryngology (8). In addition to the emergence

of new journals, financial support, collaboration, and academic promotion requirements may be the reasons for this increase (9).

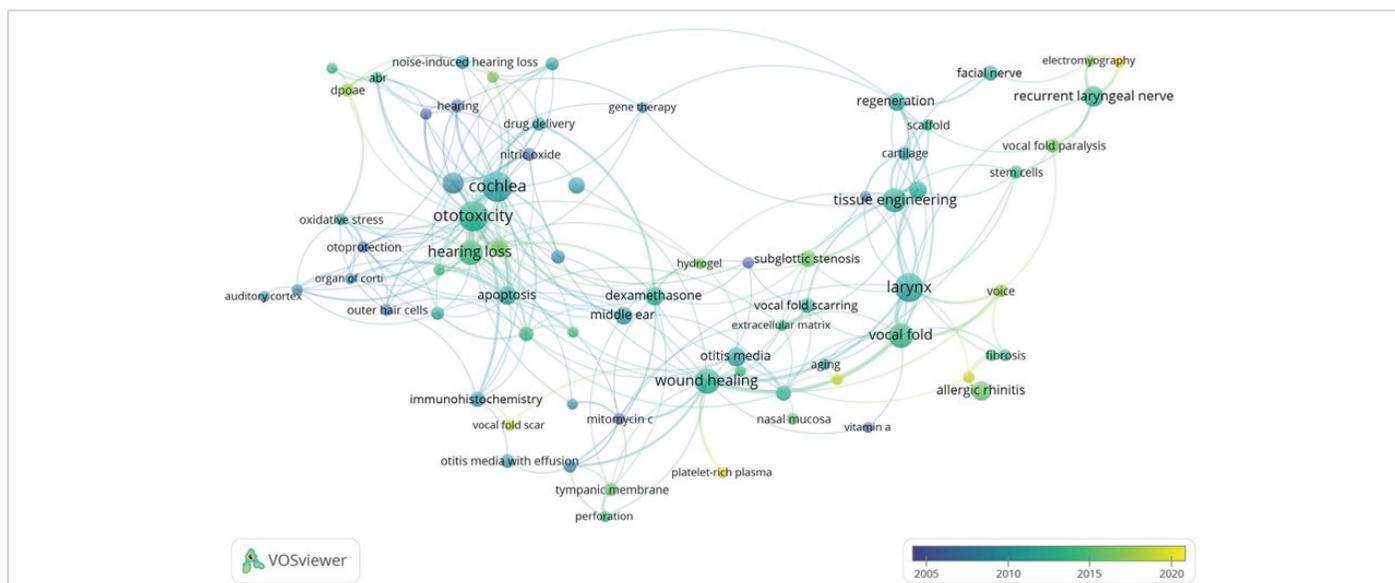
A review of the journals revealed that The Laryngoscope was the leading journal in both periods, with the majority of animal study publications appearing in only four journals. Moreover, some journals published few or no animal studies. The choice of an appropriate journal influences a study’s visibility, impact, and publication timing (10). In this regard, our study may help researchers in choosing an appropriate journal for their study.

It has been reported that the contribution to animal research can reflect the economic and scientific development of countries (11). In terms of country contributions, the United States was the leader in animal study publications, consistent

**Table 5.** Number of animal study publications by citation count

Citation/s	Publications
0	36
1	54
2	39
3	54
4	42
5	64
6	51
7	43
8	29
9	39
10	29

Only animal study publications with 0-10 citations are presented; data represent both study periods



**Figure 1.** Keyword co-occurrence overlay visualisation map

with prior reports of its prominent role in animal research (12). However, while contributions from the United States and Japan, the top two contributors, decreased between the two periods, Türkiye, the third leading country, showed an increase in animal study publications. Identifying countries with significant engagement in animal research may facilitate collaborations, enhance experience, and ultimately improve research outcomes.

Animal studies are widely conducted worldwide, while underlying motives may differ. Mayir et al. (13) reported that in Türkiye's general surgery clinics, such research was frequently undertaken for thesis preparation or academic advancement. The authors emphasized that animal studies should be conducted for scientific purposes and that goals must be clearly defined. Considering Türkiye's significant contributions to animal studies in otorhinolaryngology, it is seen as an important issue whether similar motivations lead to this result.

The low publication rates of completed animal studies represent a significant issue. ter Riet et al. (14) reported that approximately 50% of animal studies submitted to journals could be published. While another study found that only 23% of animal studies conducted for thesis preparation were published (15). These findings indicate that the number of animal studies conducted far exceeds the number published in literature. This shows how important a meticulous approach is in the design and execution of animal studies.

Analysis of the number and species of the animals used in otorhinolaryngology revealed a decrease. Species selection is critical in study design (16). Researchers should review the literature to select species based on study focus. Choosing the appropriate species may improve clinical translatability and support more effective research (17).

Studies in medicine or other fields reported variable levels of animal use over time (12,18). Here, we noted that the number of animal studies, along with the total number of animals used, decreased. This result may suggest adoption of 3Rs over time. This shift may also result from ethical considerations, financing limitations, stricter regulations, and editorial policies. The fact that only general otorhinolaryngology journals were included in the analysis, and subspecialty-specific journals were not, may have influenced the findings.

Insufficient reporting of animal numbers is an ongoing issue in scientific papers. Previous studies have identified deficiencies in research reporting, and one of the common deficiencies is to report the number of animals used (19,20). Smith et al. (19) reported that 30% of the studies failed to report animal numbers, while Frommlet and Heinze (21) noted that poor reporting of animal numbers could result in biased outcomes and compromise reproducibility.

Research by Bezdjian et al. (22) and Leung et al. (23) suggest that adherence to ARRIVE guidelines is insufficient in otorhinolaryngology. This bibliometric analysis revealed that 10.9% of the articles in the first period and 10.3% in the second did not report the numbers of animals. This shows that the underreporting of animal numbers in publications still seems to be a significant problem. Strict control by ethical committees and further studies into reporting quality may improve the standard of reporting in animal research.

This study is the first to reveal the topics that animal studies focus on and trends through keyword analysis in otorhinolaryngology. Such information can direct future research strategies and focal points.

Citation analysis is a method frequently used to evaluate the scientific impact of a publication and the status of a research field (24,25). Although open to discussion, it is considered one of the important elements that provide information on this issue (25,26). Kinikoğlu et al. (26) stated that animal studies did not receive a significant number of citations; consequently, their scientific contribution was questionable. Öztürk and Ersan (27) reported that 38% of the 142 animal studies in orthopedics were cited only once or not at all. Hackam and Redelmeier (28) reported that even highly cited animal studies were adapted to randomized clinical trials by about one-third. In this study, 58.6% of animal studies received ten or fewer citations. This is notable given this study examined the leading, high-impact journals in otorhinolaryngology. Considering this, the necessity of using animals and the quality of research should be assessed carefully.

### Study Limitations

One limitation of this study is that the assessment of adherence to the ARRIVE guideline was limited to whether or not the numbers of animals used were reported. Further studies evaluating all items of the guideline would be valuable to provide an overview of their adoption. Second is the lack of comparisons with citation counts from clinical studies conducted concurrently. Further, the number of publications or citations are not a definitive indicator of the quality or impact of research. A significant measure of scientific contribution is the development of patented treatments. While there are studies evaluating patenting outcomes in medicine, there is presently no data available for animal research in otorhinolaryngology (29,30). There is a need for studies in our field that will more definitively demonstrate the impact of animal studies on science.

### Conclusion

This bibliometric analysis shows persistent reporting gaps in animal numbers and highlights a deficiency in adherence

to guidelines. This emphasizes the necessity of improving reporting standards. By revealing current research focuses, leading journals, and countries, this study also gives clues for future animal research in the field. The adoption of the 3Rs, enhanced adherence to guidelines such as ARRIVE, and evaluation of the outcomes of animal studies are essential for responsible and impactful otorhinolaryngology research.

## Ethics

**Ethics Committee Approval:** Ethics committee approval was not required because the study involved a retrospective bibliometric analysis and did not include any human participation or personal data.

**Informed Consent:** Bibliometric analysis.

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## Footnotes

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## Main Points

- Despite the overall growth in otorhinolaryngology publications (51.8%), the number of animal studies and animals used significantly declined (41.5% and 49.1% respectively), reflecting a trend toward the Reduction principle of the 3Rs.
- A lack of animal number reporting was observed in 10.9% of in vivo studies during the first period and in 10.3% during the second period.
- Seven of the ten most frequently used keywords were the same in both study periods.
- Citation analysis revealed that 58.6% of the animal studies received ten or fewer citations.
- Strengthening the impact of animal research in otorhinolaryngology requires improved study design, responsible animal use, and consistent reporting, as underscored by this study.

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## Original Investigation



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# Translation and Validation of the Turkish Parotidectomy Outcome Inventory-8

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### Abstract

**Objective:** Salivary gland tumors are common tumors of the head and neck region, and most are located in the parotid gland and the majority are benign. Parotidectomy, which is applied in the treatment of these tumors, is a very specific procedure in terms of both surgical technique and complications. Many quality of life (QoL) questionnaires have been used to evaluate the patient after parotid surgery; however, none are specific to parotidectomy. The Parotidectomy Outcome Inventory-8 (POI-8) was developed and validated in German to measure QoL after parotidectomy in patients with benign tumors. In this study, our aim was to translate POI-8 into Turkish and study its validity and reliability.

**Methods:** Fifty patients had parotidectomy due to benign pathologies and they were included in the study. All participants were administered the Turkish version of the University of Washington QoL questionnaire (UW-QoL), which had previously been validated in Turkish, and the Turkish version of the POI-8, which was prepared with expert committee evaluation. Validity assessment, internal consistency analysis, intra-rater and inter-rater reliability assessment were performed for POI-8.

**Results:** In the Turkish version of POI-8, a high level of intra-rater and inter-rater reliability was detected. A high-level, negative correlation was observed between POI-8 and UW-QoL. A strong internal consistency was detected with a high Cronbach's alpha coefficient.

**Conclusion:** POI-8, which we translated into Turkish and validated, can be used safely by head and neck surgeons to measure QoL after parotidectomy with its high reliability values.

**Keywords:** Parotidectomy, parotid neoplasms, quality of life questionnaires, surveys and questionnaires, validation study

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## Introduction

Parotid tumors are well-known tumors of the head and neck region and most of them are benign. Pleomorphic adenoma and Warthin's tumors are the most common. However, unlike malignant masses, their true incidence is difficult to determine because there are no clear national registries for benign masses. Although most parotid masses are benign,

accurate diagnosis prior to parotid surgery is critical for surgical planning and selecting the most appropriate treatment modality for the patient (1).

In the 1940s, intracapsular dissection was performed for benign tumors. However, superficial parotidectomy, which removes the tumor along with the surrounding salivary gland tissue and exposes the facial nerve, was suggested to be safer and have a lower recurrence rate. Over time, superficial parotidectomy for benign tumors became more common (2). Complications that may occur after surgery for benign parotid tumors include palsy of the facial nerve, loss of sensation around the auricle, Frey's syndrome, salivary fistula, sialocele, hematoma and hemorrhage (3).

Health-related quality of life (QoL) represents a patient's subjective assessment of how a disease, and its treatment influence their physical, psychological, social and functional well-being. Unlike purely clinical parameters, QoL captures the multidimensional impact of illness on daily life and overall life satisfaction. Recently, it has become an essential endpoint in clinical research, complementing traditional outcomes such as disease-free and overall survival. This concept holds particular relevance for patients with head and neck cancer, as communication, social interaction and self-expression are intimately linked to the structural and functional integrity of the head and neck region. Consequently, in modern head and neck oncology, functional and rehabilitative outcomes have gained increasing prominence, often guiding surgical planning and reconstructive strategies. Evaluating QoL in this patient population provides critical insight into the broader consequences of treatment and supports a more holistic approach to patient care (4-6). Various QoL questionnaires, such as the European Organization for Research and Treatment of Cancer questionnaire and University of Washington QoL questionnaire (UW-QoL) have been used to assess patient status after salivary gland surgery (5,7-9). However, the primary shortcoming of these questionnaires is that most of them are not oriented towards parotid surgery and may be impractical to administer. Baumann et al. (10) originally developed the Parotidectomy Outcome Inventory-8 (POI-8), validated in German to measure the QoL after parotidectomy for benign disease.

In this prospective study, we aimed to translate POI-8 into Turkish and examine its validity and reliability. This will provide a reliable QoL questionnaire that can be used by otolaryngologists for Turkish-speaking patients undergoing parotidectomy for benign pathologies.

## Methods

This study was initiated after obtaining permission from the Necmettin Erbakan University Decision of the Ethics Committee for research other than drug and medical device investigation (approval no: 2023/4259, date: 17 March 2023).

In our study, we aimed to translate the POI-8 questionnaire into Turkish and study its validity and reliability in the Turkish population. Therefore, Ingo Baumann was first contacted via e-mail for copyright permissions, and his approval was obtained to design and conduct this study.

## Patient Selection and Study Design

Patients over the age of 18 who underwent superficial parotidectomy for benign disease in our clinic between June 2023 and June 2024 were included in the study. Detailed information was provided to the participants before the study. Those who wanted to participate were evaluated according to the study's inclusion and exclusion criteria, and appropriate volunteers were included after signing a voluntary consent form. Patients' age, sex, tumor localization, pathology results, POI-8 and UW-QoL results were recorded.

Volunteer patients of both sexes, aged over 18 years, who underwent surgery for a benign parotid mass in our clinic between the specified dates were included. Since malignant cases were not included in Baumann's original study describing POI-8, they were excluded. In addition, patients diagnosed with facial paralysis in the preoperative period, those who underwent total parotidectomy or revision parotid surgery, and those with a history of previous facial surgery were also excluded.

## Surgical Technique

All patients were operated on by the same surgeon under general anesthesia with a facial nerve monitor using a superficial parotidectomy method. In this surgery, we preferred the modified Blair incision and started the parotidectomy, exposed the main trunk of the seventh nerve, and the peripheral branches were revealed with antegrade follow-up. The tumor was then removed along with the surrounding salivary gland tissue. We did not choose any flap to replace the parotid tissue removed during closure. We tried to preserve the great auricular nerve (GAN) as much as possible, but it was sacrificed in many patients. Therefore, a grouping between the patients could not be made in this respect.

## Stages of Study

### Expert Committee Evaluation

Firstly, the POI-8 questionnaire was translated from its original language, i.e., from German into Turkish, by professional translators whose native language is Turkish (forward translation). Then, a team of otolaryngologists with at least five years of parotid surgery experience and an adequate command of German reviewed the Turkish questionnaire, comparing it with the original in terms of meaning. The Turkish questionnaire was double-checked by a linguist. In the next stage, the Turkish version of the questionnaire was back-translated from Turkish into

German by a different person (who had a good command of Turkish) who had never read the test before (backward translation). The same team of otolaryngologists evaluated this translation, reviewing in terms of semantic integrity. Thus, the final version of the questionnaire was created. The questionnaire was pilot tested on a small sample of 24 Turkish patients to evaluate its clarity, readability and question interpretation. No significant issues were identified, so the final version was approved as-is. Turkish version of the POI-8 is given in Table 1.

### Validity and Reliability Assessment

In addition to POI-8, all patients were evaluated using the UW-QoL, which was previously validated in Turkish (11-13). This assessment was carried out by a team of otolaryngologists. Validity was tested by performing correlation analyses between the results of both questionnaires.

### Internal Consistency Analysis

A single otolaryngologist administered the Turkish adaptation of the POI-8 questionnaire to all participating patients. To evaluate the internal reliability of the test, Cronbach's alpha coefficient was calculated. A value of Cronbach's alpha  $\geq 0.70$  was regarded as indicating strong internal consistency. Furthermore, Spearman's correlation tests were performed to examine the relationships between each item. Correlation coefficients were categorized as follows: 0.81 and above indicated excellent; 0.61 to 0.80 indicated very good; 0.41 to 0.60 indicated good; and 0.21 to 0.40 indicated acceptable correlation. Correlations of 0.20 or lower were considered inadequate.

### Intra-rater Reliability Assessment

To test intra-rater reliability, an otolaryngologist was asked to administer the POI-8 questionnaire to the same patients at two different times. To avoid time-related bias, an interval of more than 60 minutes was left between two measurements performed on the same day. All patients were subjected to this assessment. The POI-8 scores obtained as a result of

both assessments were tested with intraclass coefficient correlation (ICC) analysis. An ICC value of 0.7 and above was defined as acceptable reliability.

### Inter-rater Reliability Assessment

To test inter-rater reliability, two otolaryngologists were asked to administer the POI-8 questionnaire to the same patients at different times. To avoid time-related bias, an interval of more than 60 minutes was left between two measurements performed on the same day. All patients were subjected to this assessment. The POI-8 scores obtained as a result of the evaluations of the patients by both otolaryngologists were tested with ICC analysis. An ICC value of 0.7 and above was defined as acceptable reliability.

### Statistical Analysis

All statistical analyses were done using the SPSS software. The Kolmogorov-Smirnov test was preferred to study whether numerical variables were normally distributed. For comparisons between independent groups, the Student's t-test and the Mann-Whitney U test were used. To compare categorical variables between independent groups, either the chi-square test or the Fisher's exact test was used. In all analyses,  $p < 0.05$  was accepted as statistical significance level.

## Results

There were 50 patients in our study. The median age of patients was 57 years and most of the patients were male (33/50). The most common pathological diagnoses were found to be Warthin's tumor and pleomorphic adenoma. The total POI-8 median score was 4.

Comparison between male and female patients showed no statistical differences in terms of age, POI-8 total scores, pathological diagnoses and tumor localizations ( $p > 0.05$ ). The median of the 8<sup>th</sup> question from the POI-8 subgroups was found to be higher in female patients (5 vs. 3 points,  $p < 0.001$ ). Detailed analysis results are shown in Table 2.

**Table 1.** Turkish version of the Parotidectomy Outcome Inventory-8

Bireysel semptomların ciddiyetini değerlendirebilmek için, lütfen her bir soru için ilgili numarayı işaretleyin	Sorun değil	Çok küçük sorun	Küçük sorun	Orta derece sorun	Yüksek derece sorun	Daha kötüye gidemez
1. Ameliyat bölgesinde ve/veya yüzde ağrı	0	1	2	3	4	5
2. Ameliyat bölgesinde ve/veya boyunda duyuşal bozukluklar	0	1	2	3	4	5
3. Yara izinin belirginliđi	0	1	2	3	4	5
4. Yüz felci nedeniyle deđişen görünüm	0	1	2	3	4	5
5. Parotis bezinin çıkarılmasına bađlı olarak deđişen görünüm (doku kaybı)	0	1	2	3	4	5
6. Ameliyat bölgesinde terleme (özellikle yemek yerken)	0	1	2	3	4	5
7. Ameliyatın bir sonucu olarak ađız kuruluđu	0	1	2	3	4	5
8. Tekrar ameliyat olmak zorunda kalma olasılıđından korkuyorum	0	1	2	3	4	5

**Table 2.** Comparison of study data by sex

Parameters	All patients (n=50)	Male (n=33)	Female (n=17)	p
Age	57 (25-81)	57 (29-81)	55 (25-74)	0.412
<b>POI-8 questions</b>				
- Question-1	0 (0-3)	0 (0-3)	0 (0-3)	0.097
- Question-2	1 (0-4)	0 (0-4)	1 (0-4)	0.501
- Question-3	0 (0-4)	0 (0-4)	0 (0-4)	0.621
- Question-4	0 (0-4)	0 (0-4)	0 (0-0)	0.029
- Question-5	0 (0-4)	0 (0-4)	0 (0-1)	0.209
- Question-6	0 (0-5)	0 (0-5)	0 (0-2)	0.684
- Question-7	0 (0-4)	0 (0-4)	0 (0-4)	0.713
- Question-8	0 (0-5)	0 (0-5)	3 (0-5)	<0.001
<b>Total POI-8 score</b>	<b>4 (0-22)</b>	<b>3 (0-22)</b>	<b>5 (0-20)</b>	<b>0.090</b>
<b>UW-QoL score</b>	<b>96.54 (75.75-100.00)</b>	<b>97.91 (81.34-100.00)</b>	<b>90.34 (75.75-100.00)</b>	<b>0.014</b>
<b>Pathologic diagnosis</b>				
- Pleomorphic adenoma	20 (40.0)	12 (36.4)	8 (47.1)	
- Warthin's tumor	22 (44.0)	18 (54.5)	4 (23.5)	
- Non-specific	7 (14.0)	3 (9.1)	4 (23.5)	
- Oncocytic cystadenoma	1 (2.0)	0 (0.0)	1 (5.9)	
<b>Tumor localization</b>				
- Right	25 (50.0)	17 (51.5)	8 (47.1)	0.765
- Left	25 (50.0)	16 (48.5)	9 (52.9)	

UW-QoL: University of Washington quality of life questionnaire, POI-8: Parotidectomy Outcome Inventory-8

**Table 3.** Intra-rater and inter-rater reliability analysis results

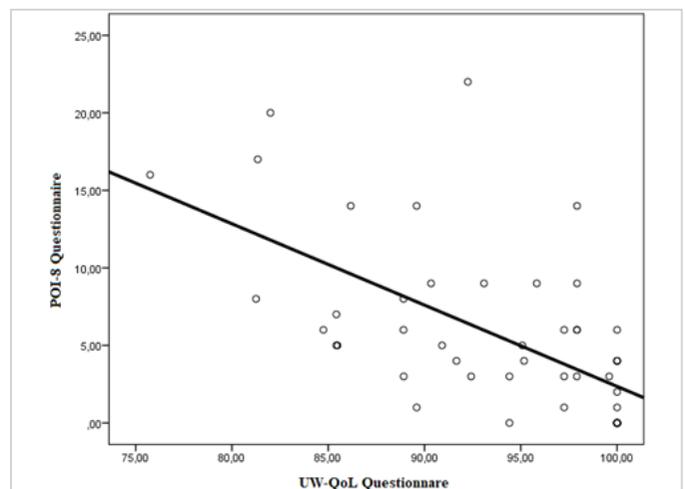
	ICC	95% confidence interval		p-value
		Lower limit	Upper limit	
Intra-rater	0.984	0.972	0.991	<0.001
Inter-rater	0.985	0.973	0.991	<0.001

ICC: Intraclass coefficient correlation

POI-8 demonstrated high reliability, with ICC values of 0.984 for intra-rater and 0.985 for inter-rater assessments (p<0.001) (Table 3). The validity analysis between POI-8 and UW-QoL revealed a high, statistically significant, negative correlation (rho=-0.661, p<0.001) (Figure 1).

Internal consistency analysis of the POI-8 questionnaire showed a high level of Cronbach's alpha coefficient (0.706). It was determined that there were comparisons with low correlation coefficients, especially in the eighth question (there were values of 0.200 and below). Detailed findings regarding the internal consistency results are given in Table 4.

Exploratory factor analysis (EFA) initially suggested a three-factor structure with eigenvalues greater than one, explaining 70.6% of the total variance. However, due to overlap between certain items, the analysis was repeated after the removal of item 5. The revised analysis indicated a two-factor structure. The Kaiser-Meyer-Olkin (KMO) measure of sampling



**Figure 1.** Correlation analysis results between Parotidectomy Outcome Inventory-8 and University of Washington quality of life questionnaires (rho=-0.661, p<0.001)  
UW-QoL: University of Washington quality of life questionnaire, POI-8: Parotidectomy Outcome Inventory-8

adequacy was 0.706, and Bartlett's test of sphericity was significant ( $\chi^2=65.378$ , p<0.001), supporting the suitability of the data for factor analysis. The two-factor model explained 55.2% of the total variance. Item 1 demonstrated a relatively low factor loading (<0.40) and was therefore excluded, and

**Table 4.** Internal consistency analysis results of the Parotidectomy Outcome Inventory-8 (Cronbach's alpha coefficient =0.706)

POI-8 questions	Question-1	Question-2	Question-3	Question-4	Question-5	Question-6	Question-7	Question-8
Question-1	1.000							
Question-2	0.188	1.000						
Question-3	0.333	0.313	1.000					
Question-4	0.226	0.110	0.374	1.000				
Question-5	0.259	-0.049	0.609	0.593	1.000			
Question-6	0.222	-0.061	0.418	0.319	0.690	1.000		
Question-7	0.340	0.445	0.566	0.245	0.297	0.242	1.000	
Question-8	0.186	0.179	0.146	-0.162	0.102	0.119	0.288	1.000

POI-8: Parotidectomy Outcome Inventory-8

the analysis was repeated. In the final EFA model, a two-factor structure was retained, with KMO=0.655 and Bartlett's test remaining significant ( $\chi^2=56.950$ ,  $p<0.001$ ). The total variance explained increased to 60.2%. Items 3, 4, and 6 loaded onto factor 1, while items 2, 7, and 8 loaded onto factor 2.

Subsequently, confirmatory factor analysis was performed using analysis of moment structures (version 22.0) to evaluate the two-factor structure. During this process, item 8 was excluded due to a low standardized factor loading (<0.40). The final model consisted of two factors including a total of five items. Model fit indices indicated an acceptable level of fit ( $\chi^2/df=4.526$ , Tucker-Lewis index =0.969, goodness of fit index =0.965, root mean square error of approximation =0.052, standardized root mean square residual =0.068). Standardized factor loadings ranged from 0.42 to 0.93, and all items loaded significantly onto their respective factors ( $p<0.05$ ). These findings suggest that the Turkish version of the scale demonstrates a two-factor structure with acceptable psychometric properties.

## Discussion

QoL surveys provide subjective data to measure how a disease or treatment affects a patient. This information is obtained by answering questions about life satisfaction, which only the patients themselves can assess. Therefore, it is essential that every QoL survey be conducted in the patient's own language. To the best of our knowledge, this study is the first study designed and published to investigate the translation and validity of POI-8 from German into Turkish. POI-8 has been translated into English, Spanish and Danish and used in studies so far. However, only validation was done in Spanish and Danish. Chiesa-Estomba et al. (14) reported that they obtained an internal consistency over 0.8. Therefore, they argue that this form can be applied reliably in Spanish-speaking patients (14). Hilton et al. (15) translated POI-8 into Danish. The authors reported a weighted kappa coefficient value of 0.74, a Cronbach's alpha coefficient value of 0.78 and an ICC value of >0.50 and stated that this form

had moderate to good reliability, which is sufficient to use POI-8 after parotidectomy surgery (15).

The inventors of POI-8, Baumann et al. (10), designed this form as a 20-question alpha and 8-question beta version. In their study, the authors determined the Cronbach's alpha value to be 0.84 and this was a good result in terms of internal consistency. In our study, when we tested the POI-8 for reliability, we found high levels of both intra-rater (ICC: 0.984) and inter-rater (ICC: 0.985) reliability. The internal consistency analysis revealed a high level of Cronbach's alpha coefficient (0.706). Additionally, we determined that there were comparisons with low correlation coefficients in the eighth question. With values of 0.200 or below, we speculated that this might be related to the relatively small patients sample size and low correlation coefficients.

We observe that POI-8 has attracted more attention from head and neck surgeons over the years and is increasingly used in the evaluation of both early and long-term complications and health-related QoL after parotidectomy. The early period generally refers to the first year after parotidectomy surgery, while the long-term refers to the first year and beyond. In their study, Ciuman et al. (7) evaluated symptom-specific QoL with POI-8 and argued that parotidectomy has little effect on general QoL and general health status. In another study in which POI-8 was used, esthesia was the most bothersome issue six months after superficial parotidectomy, followed by concern of re-surgery and dissatisfaction with pain and scarring. Although the effects of esthesia and pain decreased during follow-up, the same symptoms were reported to still affect symptom-specific QoL after two years. Complaints related to Frey's syndrome were found to worsen (9). A study examining the QoL of patients who underwent parotidectomy with a 13-year follow-up reported that hypoesthesia and concern of re-surgery were the most significant long-term disorders, while palsy of the facial nerve was considered a minor issue. However, hypoesthesia has been shown to improve significantly over time without reducing QoL in patients with long-term follow-up (16). In our study, we also found that the most disturbing situation

for patients was hypoesthesia or dysesthesia in the operation area. We attribute this to the fact that our study was conducted in the early postoperative period of six months, as stated in similar studies in literature. We believe that patients' complaints may change with long-term follow-up.

Hypoesthesia is one of the most disturbing issues that patients experience after parotidectomy surgery. Preserving the GAN (especially the posterior branch) has been shown to be beneficial in reducing this complication. However, there are also publications reporting that this only reduces early-stage esthesia, does not provide significant positive effects in the long-term, and does not significantly affect health-related QoL (17-19).

The POI-8 questionnaire aims to measure patient satisfaction only in the postoperative period. However, symptoms experienced by patients preoperatively (such as visual disturbance due to the size of the mass) can also affect postoperative satisfaction. Therefore, measuring postoperative QoL independently of preoperative symptoms can be considered a shortcoming of this questionnaire. Another shortcoming of the POI-8 questionnaire is that it is designed for patients undergoing parotidectomy for benign diseases. Patients with malignant lesions will experience all the troubles experienced by patients with benign lesions, as well as additional troubles. Malignant diseases may present different symptoms and have a completely different clinical course. Surgical treatment may require more extensive surgery and additional procedures such as neck dissection along with parotidectomy. This may lead to changes in postoperative symptoms and a decrease in QoL. We believe that malignant patients will score higher on the eighth question, which specifically addresses the fear of reoperation after surgery. Therefore, additional questionnaires are needed to evaluate the QoL of patients with malignant diseases. Alternative questions that could impact postoperative QoL, such as changes in surgical site skin, pre- and post-symptom differences, bleeding and discharge, could be added to the survey. Furthermore, questions about the surgical site and neck could be asked separately (especially for malignant lesions). While increasing the number of questions could increase the survey's value, it would also make it more difficult to administer.

### Study Limitations

In this study, the number of patients was limited to emphasize language validation, construct validity, intra-rater and inter-rater reliability. For this reason, factor analysis could not yield meaningful results for all survey questions. Therefore, it is necessary to evaluate the results of factor analysis using studies with larger patient numbers.

## Conclusion

The POI-8 questionnaire, which was translated into Turkish and validated for the first time in this study, can be used safely to measure QoL after parotidectomy surgery for benign disease in Turkish-speaking patients with its high reliability and consistency values.

### Ethics

**Ethics Committee Approval:** This study was initiated after obtaining permission from the Necmettin Erbakan University Decision of the Ethics Committee for research other than drug and medical device investigation (approval no: 2023/4259, date: 17 March 2023).

**Informed Consent:** Those who wanted to participate were evaluated according to the study's inclusion and exclusion criteria, and appropriate volunteers were included after signing a voluntary consent form.

### Footnotes

#### Authorship Contributions

Surgical and Medical Practices: H.Y., Concept: H.Y., A.Y., M.A.E., Design: H.Y., M.A.A., M.C.K., Data Collection and/or Processing: M.C.K., B.D., E.B., M.G., Analysis or Interpretation: A.Y., M.A.A., M.C.K., Literature Search: A.Y., M.A.E., B.D., M.G., Writing: H.Y., M.G.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

**Financial Disclosure:** The authors declare that this study has received no financial support.

### Main Points

- The Parotidectomy Outcome Inventory-8 (POI-8) is a German questionnaire developed in 2009 to assess quality of life after parotidectomy.
- The most important point that distinguishes POI-8 from other quality of life questionnaires is that it is specific to parotidectomy surgery.
- POI-8 has been previously translated into Spanish and Danish and validated.
- In our study, POI-8 was translated into Turkish and validated, and made available to Turkish-speaking head and neck surgeons.
- High levels of intra-rater and inter-rater reliability and high and negative correlations between University of Washington quality of life were observed in the Turkish version of POI-8.

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## Case Report



Turk Arch Otorhinolaryngol 2026; 64(1): 40-44

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# Oncocytic Sialolipoma of the Submandibular Gland: Case Report and Literature Review

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### Abstract

Sialolipoma is a rare benign salivary gland tumor, most commonly arising in the parotid gland. Its oncocytic variant is exceedingly uncommon, particularly in the submandibular gland. We report a 58-year-old woman presenting with a painless, enlarging left submandibular mass. Imaging revealed a heterogeneous fat-containing lesion with calcifications and suspicious lymphadenopathy, and fine-needle aspiration suggested a salivary gland neoplasm of uncertain malignant potential. The patient underwent submandibular gland excision with selective neck dissection. Histopathological examination confirmed oncocytic sialolipoma, and no recurrence was observed during 24 months of follow-up. A literature review identified only nine previously reported submandibular sialolipoma cases, several with oncocytic features. Preoperative findings, including calcifications and oncocytic cytology, may mimic malignancy. However, a well-circumscribed lesion composed of mature adipose tissue with salivary gland elements is diagnostic. Oncocytic sialolipoma of the submandibular gland is exceptionally rare. Despite its potential to mimic malignancy, it is benign, and complete excision provides definitive diagnosis and excellent prognosis.

**Keywords:** Sialolipoma, submandibular gland, salivary gland neoplasms, lipoma, case reports

### Introduction

Sialolipoma is a rare benign salivary gland tumor characterized by islands of normal salivary gland tissue encased by mature adipose tissue without any atypia, preserving the normal ductal and acinar structures. First described by Nagao et al. (1) in 2001, it accounts for 0.3-0.5% of all salivary gland tumors. While it is most commonly observed in the parotid gland, its occurrence in the submandibular gland is exceedingly rare (1). An uncommon subtype of sialolipoma, known as oncocytic sialolipoma, is characterized by oncocytic metaplasia and has been reported in a limited number of cases in the literature (2).

In this case report, we present the clinical, radiological, and histopathological findings of a submandibular sialolipoma, a tumor rarely reported in the literature.

### Case Report

A 58-year-old female patient presented to our clinic with a complaint of swelling in the left submandibular region. She reported that the swelling had been present for eight years

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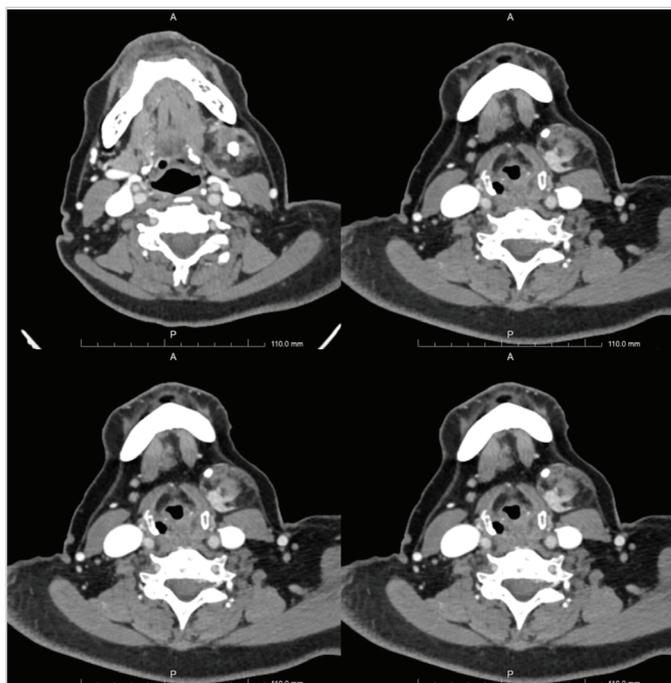
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but had progressively enlarged following a recent dental procedure. At the time of presentation, there were no signs of compression or infiltration associated with the mass. There was no evidence of facial nerve involvement. The patient had no history of prior surgical procedures, no personal or family history of malignancy or radiotherapy. The mass measured 4×3 cm in size, was mobile and painless, had irregular borders without causing any skin involvement or discoloration.

Ultrasonography revealed a hypoechoic solid mass measuring 41×32×25 mm with irregular borders occupying nearly the entire left submandibular gland and exhibiting minimal vascularity on Doppler imaging. Additionally, two adjacent lymph nodes measuring 8.5 mm and 6.5 mm in short-axis diameter were noted; both were round, showed cortical thickening and a markedly narrow/effaced fatty hilum, and were therefore considered suspicious. Computed tomography (CT) revealed a lobulated mass within the left submandibular gland containing calcifications and heterogeneous fat density separated by septa, accompanied by adjacent lymph nodes with loss of fatty hilum and heterogeneous enhancement as shown in Figure 1. Fine-needle aspiration biopsy (FNAB) revealed groups of oncocytic cells, leading to a diagnosis of salivary gland neoplasm of uncertain malignant potential (SUMP). Considering the suspicion of malignancy based on preoperative radiological and FNAB results, the mass was excised along with the submandibular gland and selective neck dissection of levels I-III lymph nodes. Intraoperatively, a lobulated, lipomatous mass was observed in the left submandibular gland as shown in Figure 2. No complications occurred intra- or post-operatively.



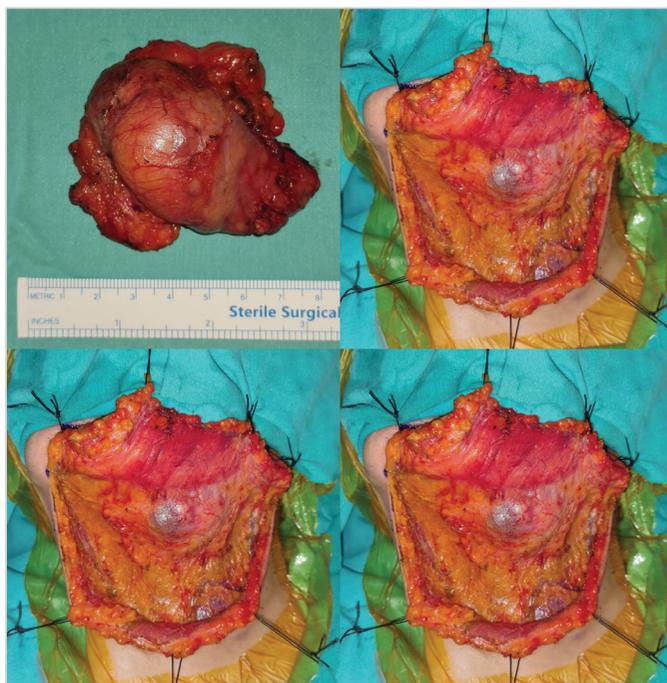
**Figure 1.** Contrast-enhanced axial CT images of the case  
CT: Computed tomography

Histopathological examination revealed a 35 mm lesion with extensive intercalated ductal hyperplasia and focal areas of ossification. Normal salivary gland tissue and clusters of oncocytic cells were observed within mature adipose tissue. The oncocytic cells had eosinophilic cytoplasm and prominent nuclei as shown in Figure 3. Surgical margins were negative. The pathological diagnosis was oncocytic sialolipoma. The patient expressed satisfaction with the surgical outcome and relief upon confirmation of the benign nature of the lesion. No signs of recurrence were detected during 24 months of clinical and radiological follow-up. Written informed consent for publication was obtained from the patient for the data included in this case report.

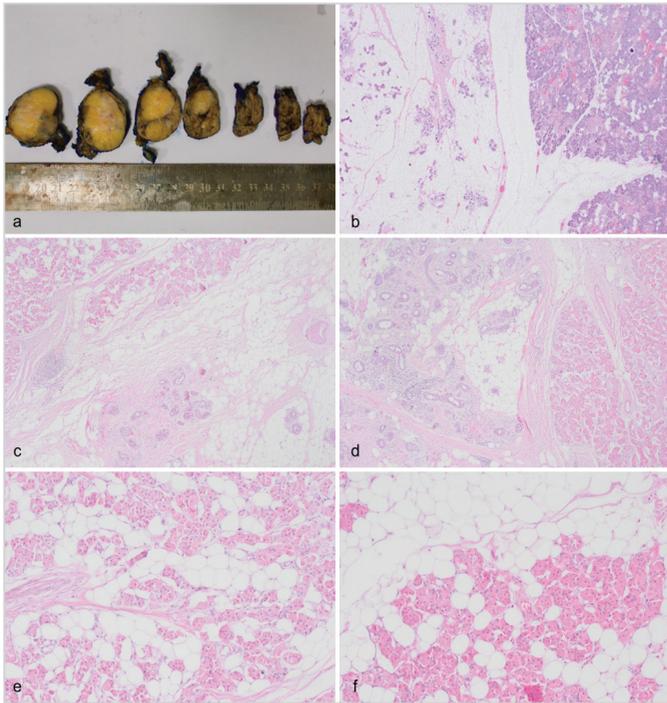
## Discussion

Our case was diagnosed as oncocytic sialolipoma. These tumors are exceedingly rare in the literature, with most reported cases originating from the parotid gland (3). This pathological entity, oncocytic sialolipoma, was first described by Pusiol et al. (2) in 2009, and the scarcity of the cases involving the submandibular gland highlight the significance of this report.

A review of the English-language literature indexed in PubMed was conducted to identify the reported cases of sialolipoma and oncocytic sialolipoma arising in the submandibular gland demonstrated a limited number of case reports. Based on this search, a total of nine well-documented cases of submandibular sialolipoma were identified in the literature as shown in Table 1 (2,4-11).



**Figure 2.** Intraoperative view of the mass



**Figure 3.** a) The cut surface is composed of well-circumscribed and bright yellow to pale brown tumoral lesion. b) Tumoral lesion (left side) with a sharp transition to the salivary gland parenchyma (right side) (H&E×40). c-d) Oncocytic and non-oncocytic epithelium and intercalated duct hyperplasia within the adipose tissue (H&E×100, H&E×100). e-f) The tumor consisted of salivary gland lobules with oncocytic features and mature adipose tissue (H&E×200, H&E×400) H&E: Hematoxylin and eosin

The mean age of the reported patients was 49.1±22.3 years, indicating that sialolipoma in the submandibular gland generally affects adults. With the exception of a single pediatric case reported by Sato et al. (4), all cases occurred in older individuals, with a higher incidence after the fifth decade of life. The mean tumor size across the reported cases was 53.0±32.8 mm. Notably, several of these cases, including our case, demonstrated oncocytic metaplasia, supporting the proposition that oncocytic sialolipoma may constitute a distinct histological variant (2,8,10).

Despite being a benign tumor, this lesion, which is extremely rare in the submandibular gland, can display features of malignancy in preoperative imaging and/or FNAB. Due to radiological features mimicking malignancy, such as irregular borders and/or suspicious lymphadenopathy, the differential diagnosis can be confusing.

In major salivary gland tumors categorized as SUMP on FNAB, most contemporary algorithms recommend surgical excision of the involved gland for definitive diagnosis and treatment. The need for additional neck management is then tailored to the clinical and radiologic suspicion of lymph node involvement, rather than to the SUMP category alone (12). Consequently, the diagnostic value of FNAB in sialolipoma is considered limited.

**Table 1.** Clinicopathologic features of submandibular sialolipoma

Case no	Reference	Date	Age	Sex	Duration (months)	Region	Side	Tumor size (mm)	LN count	Largest LN size (mm)	Diagnosis	Oncocytic metaplasia	Treatment	Follow-up (month)	Recurrence
1	Presented case	2025	58	F	96	SMG	L	41×32×25	2	8.5	Oncocytic sialolipoma	Yes	SMG excision + level I-III ND	24	No
2	Parente et al. (5)	2008	77	F	Several months	SMG	R	30×20×18	NR	-	Sialolipoma	Yes	SMG excision	22	No
3	Pusiol et al. (2)	2009	73	M	NR	SMG	R	90	NR	-	Oncocytic sialolipoma	Yes	Tumor excision, gland preserved	NR	No
4	Jang et al. (6)	2009	62	F	36	SMG	R	50	NR	-	Sialolipoma	Yes	SMG excision	17	No
5	Sato et al. (4)	2011	3	M	2	SMG	L	40×30	0	-	Sialolipoma	NR	SMG excision	36	No
6	Akrish et al. (7)	2011	52	M	NR	SMG	NR	35×20×15	NR	-	Sialolipoma	Yes	SMG excision	12	No
7	Ahn et al. (8)	2014	43	F	2	SMG+PPS	R	40	NR	-	Oncocytic sialolipoma	Yes	Tumor excision, gland preserved	NR	NR
8	O'Rourke et al. (9)	2015	33	F	36	SMG	R	40×30	NR	-	Sialolipoma	NR	SMG excision	12	No
9	Parmar (10)	2015	45	M	12	SMG	L	27×17	0	-	Oncocytic sialolipoma	Yes	Tumor excision, gland preserved	NR	No
10	Subramaniam et al. (11)	2020	54	M	84	SMG+PPS	R	125×95×85	0	-	Sialolipoma	NR	SMG excision	1	No

SMG: Submandibular gland, PPS: Parapharyngeal space, ND: Neck dissection, LN: Lymph node, NR: Not reported, F: Female, M: Male, L: Left, R: Right

In our case, several features raised a strong preoperative suspicion of malignancy: (i) a long-standing mass with recent enlargement, (ii) heterogeneous fat-containing lesion with calcifications on CT, (iii) radiologically suspicious level I lymph nodes with round morphology, cortical thickening and loss of fatty hilum, and (iv) FNAB categorized as SUMP with oncocytic cells. Taken together, these findings were considered worrisome for a primary submandibular gland carcinoma with possible nodal involvement. For this reason, and in line with common practice for suspected submandibular gland malignancies, we elected to perform submandibular gland excision with selective neck dissection of levels I-III in a single stage.

Final histopathology confirmed a benign oncocytic sialolipoma with negative lymph nodes, and no recurrence was observed at 24 months. In light of the published literature, we do not propose routine neck dissection for sialolipoma; rather, we emphasize that neck dissection should be reserved for cases with convincing radiologic and/or intraoperative suspicion of malignant disease.

From a surgical decision-making standpoint, intraoperative frozen-section examination of the gland and/or lymph nodes or a staged approach (initial gland excision with or without node sampling, followed by delayed neck dissection only in case of malignancy on permanent sections) could also be considered in similar scenarios. In our case, because of the combination of a SUMP cytology with oncocytic cells, radiologically suspicious lymph nodes, and the heterogeneous calcified fatty mass, the multidisciplinary team favored a one-stage procedure including selective neck dissection. Nevertheless, we acknowledge that in retrospect, and particularly in light of the final benign diagnosis, a more conservative strategy such as gland excision with intraoperative frozen section followed by selective neck dissection only if malignancy was confirmed may have reduced the risk of overtreatment. We therefore highlight these alternative strategies in order to guide individualized management in future cases.

All published cases of submandibular sialolipoma, surgical resection was the definitive and uniformly applied treatment modality as shown in Table 1 (2,4-11). This consistent management approach underscores that complete surgical excision is both the diagnostic and therapeutic gold standard for sialolipoma.

## Conclusion

Oncocytic sialolipoma is a rare salivary gland tumor, and its presence in the submandibular gland is particularly unusual only 10 cases, including our case, have been described in literature. The clinical, radiological, and cytological differential diagnosis is challenging. To date, no recurrences

have been reported in sialolipoma of the submandibular gland which may indicate the benign nature and clinical course of these tumors. Complete surgical excision remains the gold standard for both definitive diagnosis and treatment.

## Ethics

**Informed Consent:** Written informed consent for publication was obtained from the patient for the data included in this case report.

## Footnotes

## Authorship Contributions

Surgical and Medical Practices: U.K., G.E., Concept: U.K., G.E., Design: G.E., Data Collection and/or Processing: U.K., M.D., S.M., A.T., Analysis or Interpretation: U.K., M.D., A.T., G.E., Literature Search: U.K., S.M., Writing: U.K., G.E.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

**Financial Disclosure:** The authors declare that this study has received no financial support.

## Main Points

- Oncocytic sialolipoma of the submandibular gland is an exceptionally rare benign tumor that can mimic malignancy on imaging and cytology.
- Heterogeneous fat-containing lesions with suspicious lymph nodes should include sialolipoma in the differential diagnosis to avoid misinterpretation and over treatment.
- Definitive diagnosis is histopathological, and complete surgical excision ensure an excellent prognosis with no reported recurrence.

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## Case Report



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# Herniation of the Flocculus Cerebellaris into the Internal Auditory Canal: A Rare Anatomical Variant Mimicking a Vestibular Pathology

© Mehmet H. Atalar<sup>1</sup>, © Nisa Başpınar<sup>1</sup>, © Serdar Aktı<sup>2</sup>, © Adem Bora<sup>3</sup>

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### Abstract

We report a rare case of herniation of the flocculus cerebellaris into the internal auditory canal (IAC) and discuss the radiologic features and clinical implications in light of the current literature. A 19-year-old male with vestibular symptoms underwent high-resolution magnetic resonance imaging (MRI), which revealed cerebellar tissue within the right IAC. Multiplanar MRI sequences showed extension of the flocculus into the IAC with no evidence of mass effect or neurovascular compression. Herniation of the flocculus cerebellaris into the IAC is a rare anatomic variant that can mimic neoplastic lesions. Awareness of this entity is critical to avoid misdiagnosis and unnecessary intervention. This case report highlights the importance of a rare anatomical variant in the differential diagnosis.

**Keywords:** Cerebellum, flocculus cerebelli, internal auditory canal, magnetic resonance imaging, vestibular diseases, otology, case reports

### Introduction

The cerebellar flocculus is a small lobe in the cerebellar angle that is closely associated with the vestibular system. It contributes to the coordination of eye movements and the control of balance. Although it typically lies outside the internal auditory canal (IAC), herniation of the flocculus into the IAC is a rare radiologic finding that can simulate other pathologies of the IAC, such as a vestibular schwannoma or meningioma. The etiology remains unclear, and only a few cases have been documented in the literature (1-5). We present a case of inadvertent herniation of the cerebellar flocculus into the IAC in a patient with vertigo and provide a comprehensive review of the current literature.

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### Case Presentation

A 19-year-old male presented with a 3-month history of intermittent vertigo and balance disturbances. There was no history of trauma, otologic surgery, or neurodegenerative disease. The neurological examination was unremarkable. The patient's otologic examination revealed progressive sensorineural hearing loss predominantly in the right ear, accompanied by intermittent tinnitus and occasional imbalance. Audiometric examination revealed a moderate sensorineural hearing loss on the right side. Vestibular evaluation was performed using videonystagmography, including positional testing and bithermal caloric irrigation. The results revealed a mild right-sided canal paresis,

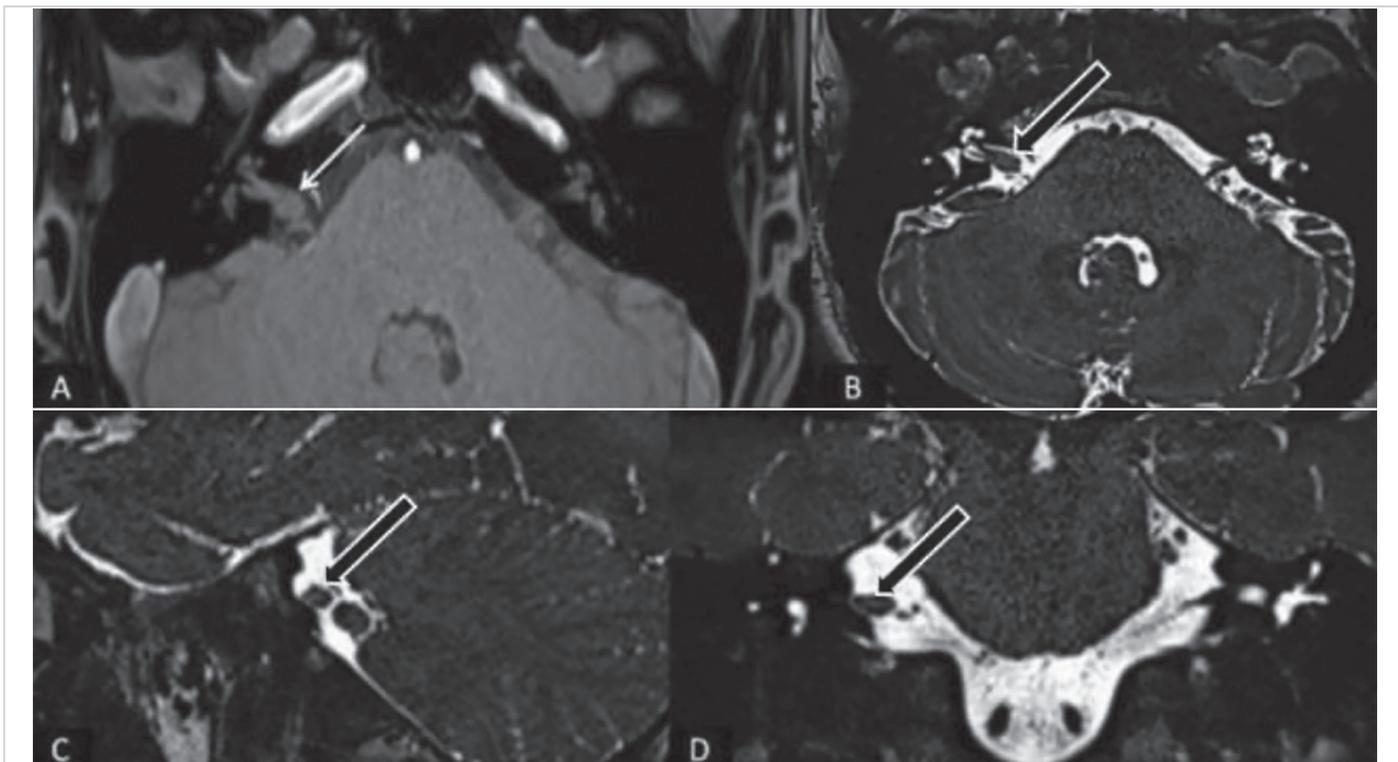
indicating unilateral peripheral vestibular hypofunction consistent with the patient's clinical symptoms. Otoloscopic examination showed intact and normal tympanic membranes on both sides. High-resolution magnetic resonance imaging (MRI) of the brain and the IAC was done using a 3 Tesla system. Sequences included axial T1-weighted (T1W), T2-weighted (T2W), and three-dimensional (3D) SPACE, fluid attenuated inversion recovery, diffusion-weighted imaging, and T1W post-contrast images. The findings showed a tongue-like projection of tissue into the proximal right IAC, iso- to hypo-intense on T2W images and continuous with the ipsilateral cerebellar flocculus (Figures 1a-1d). In consecutive T2-SPACE images, the cerebellar flocculus was observed to advance its course towards the IAC (Figures 2a-2e). The tissue was not swollen. There was no diffusion restriction or pathological contrast enhancement. The cranial nerves within the IAC were preserved and not compressed. The brainstem, cerebellar hemispheres, and flocculus were otherwise unremarkable. Imaging findings were consistent with herniation of the cerebellar flocculus into the IAC. Surgical intervention was not indicated. A conservative management strategy was adopted, consisting of vestibular rehabilitation therapy, symptomatic medical treatment (including vestibular suppressants during acute episodes), and patient education. The patient was advised to

avoid sudden head movements and known vertigo triggers. Regular clinical, audiometric, and radiologic follow-up was planned to monitor symptom progression and ensure lesion stability. Informed consent was obtained from the patient.

## Discussion

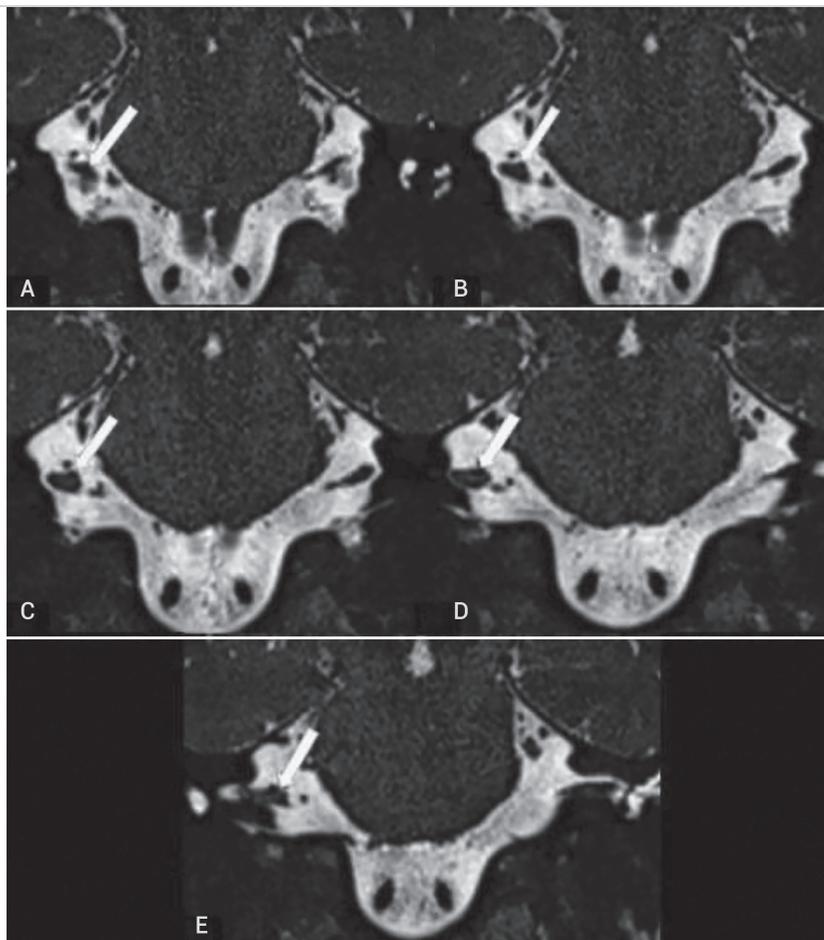
Herniation of cerebellar structures into the IAC is a rare but increasingly recognized finding with the advent of high-resolution MRI techniques. The cerebellar flocculus, part of the vestibulocerebellum, plays a role in gaze posture and vestibulo-ocular reflexes. It is normally located in the cistern of the cerebellar angle and is separated from the IAC by the arachnoid and subarachnoid space. The mechanism underlying the herniation of the cerebellar flocculus into the IAC remains speculative. Proposed factors include congenital variants, arachnoid defects, intracranial hypotonia, cerebellar atrophy, or chronically elevated intracranial pressure (1,2). However, in most reported cases, including ours, no underlying cause has been identified.

The pathophysiologic relationship between floccular hernia and sensorineural hearing loss remains incompletely understood, but several mechanisms have been proposed. The cerebellar flocculus, when herniated into or adjacent to



**Figure 1.** A 19-year-old patient with herniation of the cerebellar flocculus into the internal auditory canal. The axial T1-weighted MR image (A) shows a herniation of the cerebellar flocculus into the right internal auditory canal (white arrow). The herniated structure is iso-intense with the cerebellar parenchyma. The axial (B), sagittal (C) and coronal (D) T2-SPACE MR images show that the cerebellar flocculus extends into the right internal auditory canal, mimicking a mass lesion (thick arrows)

MR: Magnetic resonance



**Figure 2.** In consecutive coronal T2-SPACE MR images (A-E), the course of the cerebellar flocculus from the level of the pons to the entrance of the internal acoustic canal is observed (arrows)  
MR: Magnetic resonance

the lateral aspect of the IAC, may exert a subtle mass effect or mechanical irritation on the adjacent vestibulocochlear nerve, particularly its cochlear portion. Even if there is no obvious compression on imaging, this altered anatomical relationship could lead to local ischemia, demyelination, or disruption of axonal transport within the nerve fibers, resulting in hearing loss (3,5). In addition, herniated cerebellar tissue may alter cerebrospinal fluid (CSF) dynamics within the IAC, resulting in increased pressure or turbulence that could disrupt neural signaling. These hypotheses are supported by case reports describing improvement of auditory symptoms after surgical decompression or spontaneous regression of the hernia (3-6).

In this study, a systematic literature search was done in the PubMed and Google Scholar databases, focusing on cases of herniation of the flocculus cerebellaris into the IAC. The literature identified four cases, including ours, of herniation of the flocculus cerebellaris into the IAC. The cases of herniation of the flocculus cerebellaris into the IAC are summarized in Table 1. Michiwaki et al. (4) documented

a case series in which herniation of the flocculus was associated with sensorineural hearing loss, supporting the hypothesis that herniated cerebellar tissue may exert a subtle mass effect or alter CSF dynamics near the vestibulocochlear nerve, even without obvious compression on imaging. Their work emphasizes the theoretical clinical relevance of this rare anatomical variant and suggests a possible correlation with auditory symptoms in selected cases. In another report, Parlak et al. (7) described a flocculus hernia in a case of incomplete partition type I and suggested that congenital inner ear anomalies may favor a hernia due to altered subarachnoid architecture. Parlak et al. (7) emphasized the importance of high-resolution 3D T2W techniques for the reliable diagnosis of floccular herniation, especially for the differentiation of neoplasms of the IAC and cystic lesions. Their study highlights the non-progressive nature of this variant and emphasizes incidental detection. They also suggested a possible association with non-specific vestibulocochlear symptoms. Kowalski et al. (5) reported a pseudomass in a 73-year-old female with sensorineural hearing loss that was consistent with flocculus cerebellaris and extended into the

**Table 1.** Demographic, clinical, and radiologic findings of cases of herniation of the flocculus cerebellaris into the IAC in the literature

Case	Author/year	Age/gender	Etiology	Symptoms	MRI findings	Management
1	Michiwaki et al. 2018 (4)	50/F	Tentorial meningioma, hydrocephalus	Mild hearing loss	Flocculus in the right IAC	Tumor resection
2	Parlak et al. 2023 (7)	3/F	Inner ear anomaly	Congenital SNHL	Bilateral IP-I, flocculus in the right IAC	Conservative
3	Kowalski et al. 2024 (5)	73/F	Idiopathic	SNHL	Flocculus in the right IAC	Conservative
4	Presented case	19/M	Idiopathic	Vertigo, imbalance	Flocculus in the right IAC	Conservative

F: Female, M: Male, MRI: Magnetic resonance imaging, IAC: Internal auditory canal, SNHL: Sensorineural hearing loss, IP-I: Incomplete partition type I

right IAC. Bluher and Moody-Antonio (8) reported a case of brainstem herniation into a bulbous IAC, which involved a different structure but emphasizes the importance of abnormal CSF pressure dynamics and congenital canal dilatation in such cases. The authors pointed out that this finding may mimic vestibular schwannomas, especially on low-contrast imaging. Our idiopathic case in an adult patient gives us valuable information about the spectrum of this anatomic variant and supports the hypothesis that floccular protrusion can occur independently of a mass effect or congenital ear abnormalities. Recognition of this variant is important for radiologists and otolaryngologists.

On 3D T2W sequences, a floccular herniation typically appears as a smooth, tongue-shaped, non-enhancing structure with CSF signal intensity surrounding it and in continuity with the cerebellum (7-9). This is in contrast to enhancing lesions such as vestibular schwannomas or meningiomas, which often compress or displace adjacent nerves. Epidermoid cysts show diffusion restriction, and arachnoid cysts are CSF-isointense in all sequences and show no tissue continuity. While most cases are incidental and asymptomatic, in rare cases a flocculus hernia may cause vestibular symptoms due to its anatomical proximity to the vestibular nerve. However, direct causal relationships are difficult to establish. In our case, the symptoms were transient and resolved spontaneously, suggesting either an independent etiology or a mild transient vestibular disorder (6-9).

## Conclusion

If a lesion in the IAC is smooth, has no contrast enhancement, is adjacent to the cerebellar tissue, and is surrounded by CSF, a flocculus hernia should be considered as the primary diagnosis rather than neoplastic or cystic lesions. Awareness of this benign variant by radiologists and ear nose and throat specialists may prevent unnecessary diagnostic examinations, interventions, and patient anxiety. This underappreciated entity reminds us that not every mass-like structure in the IAC is pathologic sometimes the anatomy simply takes an unusual course. We believe that the incidence of such cases will increase with the routine use of high-gradient MRI machines and high-resolution MRI sequences.

## Ethics

**Informed Consent:** Informed consent was obtained from the patient.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: M.H.A., A.B., Concept: M.H.A., N.B., S.A., Design: M.H.A., N.B., S.A., Data Collection and/or Processing: M.H.A., Analysis or Interpretation: M.H.A., N.B., S.A., A.B., Literature Search: M.H.A., N.B., S.A., A.B., Writing: M.H.A., S.A., A.B.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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### Main Points

- Herniation of the flocculus cerebellaris into the internal auditory canal is a rare anatomical variant.
- It can mimic a tumor but shows characteristic magnetic resonance imaging features without enhancement or nerve compression.
- Patients may exhibit vestibular or auditory symptoms or remain asymptomatic.
- Awareness of this variant helps to avoid misdiagnosis and unnecessary treatment.

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## Case Report



Turk Arch Otorhinolaryngol 2026; 64(1): 50-54

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# Dual Ectopic Thyroid Tissue: Diagnostic Approaches to a Rare Clinical Anomaly

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### Abstract

Dual ectopic thyroid tissue represents an exceedingly rare developmental anomaly, with only a handful of cases described in the literature. The simultaneous occurrence of two ectopic thyroid foci in the presence of a normally sited gland is particularly uncommon. We present the case of a 60-year-old Chinese woman who presented with a painless swelling in the left mid-lateral neck of six months' duration. Clinical assessment and contrast-enhanced computed tomography suggested thyroid-like tissue in the mid-lateral neck area, while thyroid function tests remained normal. Fine needle aspiration cytology yielded benign follicular nodules, and radionuclide single photon emission computed tomography demonstrated two hyperfunctioning ectopic thyroid foci at the base of the tongue and in the left mid-lateral neck region, with preserved uptake in the orthotopic gland. The left neck mass was excised and confirmed histologically as thyroid tissue without evidence of malignancy. The patient made a full recovery with no further treatment required. This case illustrates the value of considering ectopic thyroid tissue in the differential diagnosis of neck masses, particularly when encountered in atypical locations.

**Keywords:** Ectopic thyroid, thyroid gland, lingual thyroid, neck mass, radionuclide imaging, case report

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## Introduction

The thyroid gland, the earliest endocrine structure to arise during embryogenesis, originates between the third and fourth weeks of gestation (1). The gland arises chiefly from the endoderm, forming the isthmus and the lateral lobes, with additional contributions from paired lateral anlagen that supply C-cells and parts of the lateral thyroid (1,2). During development, the thyroid descends from the foramen caecum at the tongue base to its definitive cervical position.

Ectopic thyroid tissue is defined as thyroid tissue located outside of its normal anatomical position and results from aberrations in this migratory process. It is most commonly found at the lingual site but may also occur in the subhyoid, mediastinal, or lateral neck regions. Ectopic thyroid tissue may therefore arise if descent is incomplete, migration is arrested at any point, or the tissue develops aberrantly at an alternative site (1-3).

The prevalence of solitary ectopic thyroid is estimated at 1 in 100,000 to 1 in 300,000 individuals, with a clear female predominance (3). Dual ectopic thyroid tissue is far rarer.

Meng et al. (4) reported a prevalence as low as 0.05% for dual ectopic thyroid tissue among patients undergoing thyroid scintigraphy, highlighting the rarity of this entity. Our case is especially noteworthy for the coexistence of dual ectopic thyroid foci alongside a normally positioned thyroid gland. Such a presentation exemplifies a rare embryological event, offering unique insights into the complexities of thyroid development and migration.

## Case Presentation

A 60-year-old Chinese female with treated hypertension presented with persistent, painless left neck swelling for six months. She reported no symptoms suggestive of thyroid dysfunction or malignancy of the upper aerodigestive tract. On physical examination, a firm, mobile 6x4 cm left mid-lateral neck mass was noted (Figure 1); it was fluctuant on external palpation and not associated with cervical lymphadenopathy. Flexible nasolaryngopharyngoscopy revealed no visible mucosal lesions, masses, or airway compromise. The lingual ectopic thyroid tissues identified on radionuclide single photon emission computed tomography (SPECT) were limited in size, submucosally and located at the base of the tongue, explaining its absence on endoscopic examination.

Fine needle aspiration cytology (FNAC) demonstrated benign thyroid follicular nodules without nuclear atypia. Thyroid function tests were within normal reference limits. Contrast-enhanced computed tomography (CT) demonstrated a heterogeneous enhancing lesion in the left mid-lateral neck region with imaging characteristics resembling thyroid parenchyma (Figures 2a, 2b). The orthotopic thyroid gland was identified in its normal cervical



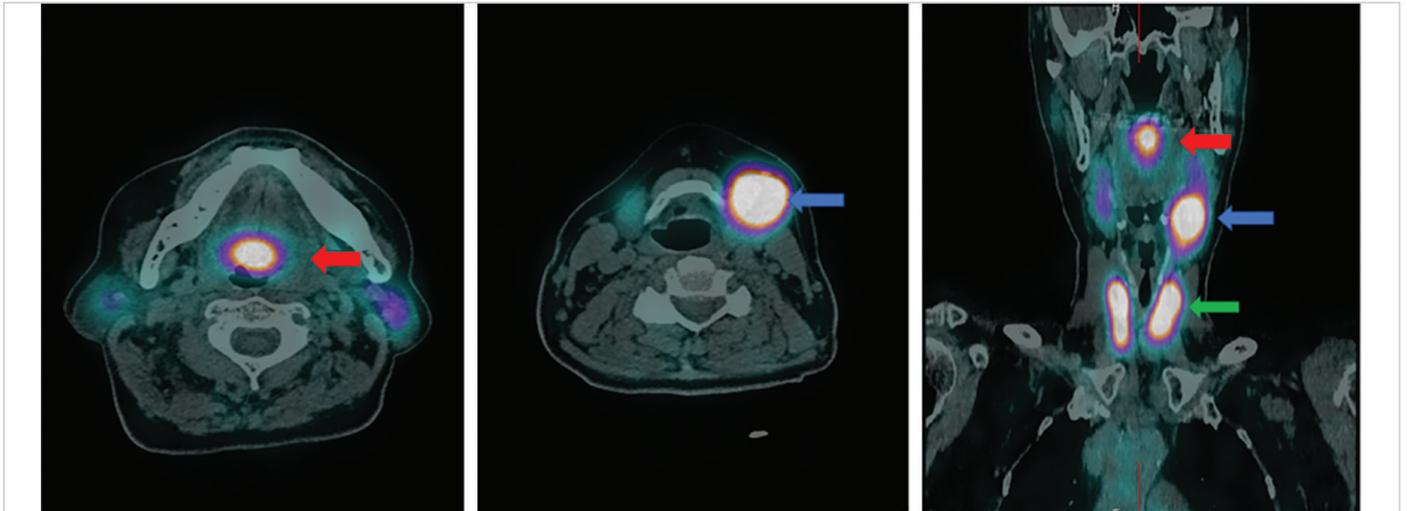
**Figure 1.** A large left mid-lateral neck swelling is seen (yellow arrow)

location, without significant nodal enlargement (Figure 2c). No direct communication was observed between the left lateral neck lesion and the left thyroid lobe. Radionuclide thyroid SPECT detected increased uptake in both the lingual and the left mid-lateral neck regions, with preserved uptake in the orthotopic thyroid gland (Figures 3, 4) confirming dual ectopic thyroid tissue.

The left mid-lateral neck mass was excised under general anesthesia (Figure 5) due to its significant size, progressive enlargement, cosmetic concern, and the need for definitive histopathological confirmation, as ectopic thyroid tissue may occasionally harbor malignancy despite benign FNAC findings. In contrast, the lingual ectopic thyroid was left in place, and no further treatment was planned, as it was asymptomatic, demonstrated physiological radionuclide uptake, and showed no features warranting biopsy or

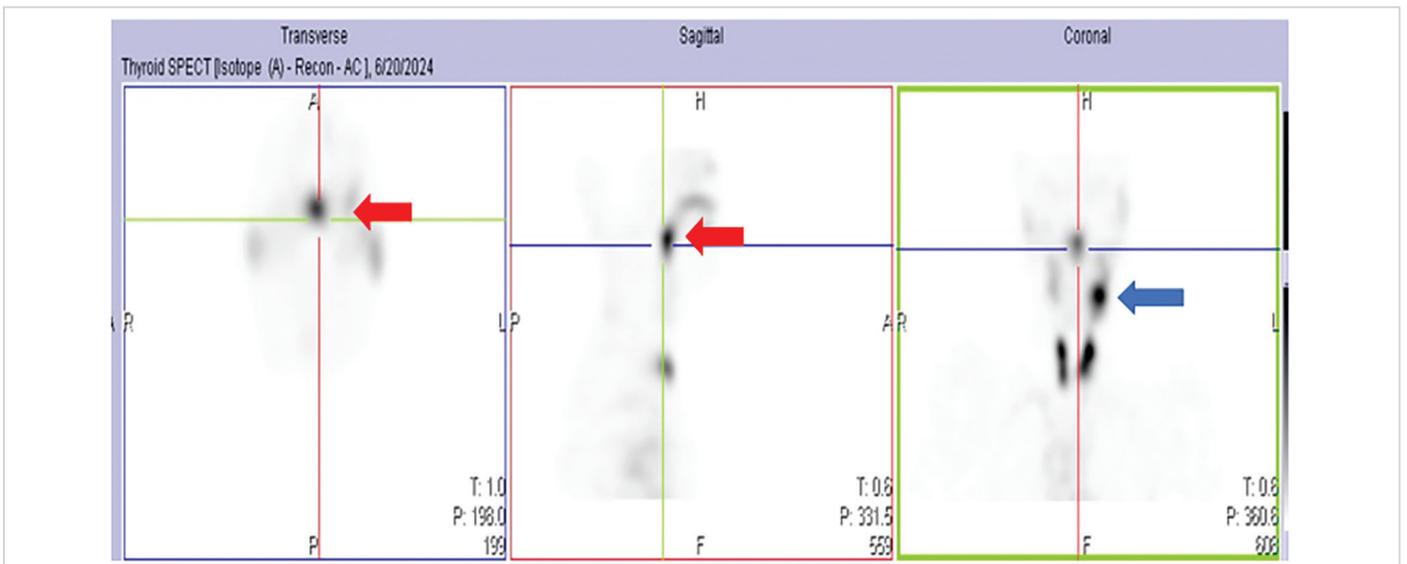


**Figure 2.** a. A heterogeneous enhancing lesion at the left lower lateral neck region in axial view CT (red arrow), b. which shows similar enhancement with the thyroid parenchyma (red arrow). c. Contrast CT in coronal view, which shows no direct communication within the left mid-lateral neck region lesion (red arrow) with the upper pole of the left thyroid lobe (blue arrow)  
CT: Computed tomography

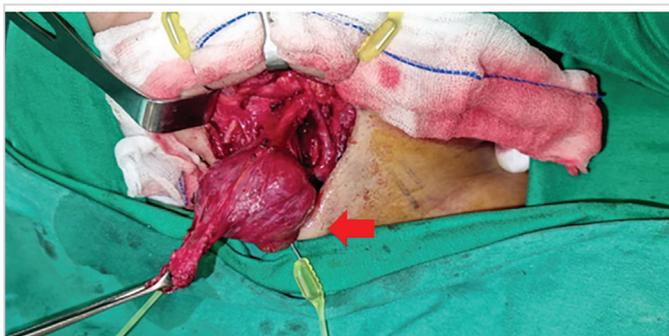


**Figure 3.** Radionuclide imaging thyroid single photon emission computed tomography fused with CT image, which shows uptake at the lingual region in axial view (red arrow) and left mid-lateral neck region lesion in axial view (blue arrow) and normally located thyroid nodules (green arrow)

CT: Computed tomography



**Figure 4.** Radionuclide imaging with thyroid single photon emission computed tomography image, which shows uptake at the lingual region in sagittal view (red arrow) and left mid-lateral neck region lesion in coronal view (blue arrow)



**Figure 5.** Intraoperative clinical picture showing a mass in the mid-lateral neck region lesion (red arrow)

excision. Histopathologic examination confirmed benign thyroid tissue without malignant features. Postoperative follow-up confirmed an uneventful recovery, with stable thyroid function and no need for additional treatment. Written informed consent was obtained from the patient.

### Discussion

The coexistence of multiple ectopic thyroid tissues in the presence of a normally located thyroid gland is an extraordinary phenomenon, posing significant diagnostic and management challenges due to its rarity and limited documentation (5). Meng et al. (4) identified six cases of dual

ectopic thyroid tissue in a five-year review of 11,905 thyroid scintigraphy scans, with the most frequent ectopic sites being lingual, subhyoid, and sublingual. Recognition of this rare entity is essential to prevent misdiagnosis and unnecessary surgical interventions.

Although ectopic thyroid tissue is a congenital developmental anomaly, it often remains clinically silent for many years. Most cases are discovered incidentally or become symptomatic only when the tissue enlarges or causes a local mass effect related to its size or anatomical location (6,7). Enlargement later in life has been attributed to hormonal fluctuations, such as those occurring during puberty, pregnancy, or menopause; compensatory hypertrophy in response to increased thyroid-stimulating hormone (TSH) stimulation; and degenerative or cystic changes within the ectopic tissue itself (6,7). Pathological processes similar to those affecting the orthotopic thyroid gland, including multinodular goiter, cystic degeneration, or neoplastic transformation, may also occur in ectopic thyroid tissue and contribute to delayed clinical presentation (6,8). These mechanisms explain the late onset of symptoms in the presented case, despite the congenital nature of the condition.

Wildi-Runge et al. (5) reported that dual ectopy could be seen in up to 9% of the congenital hypothyroidism cases, suggesting a specific association within this subgroup. The mechanisms underlying dual ectopic thyroid tissue remain incompletely understood. One postulated mechanism involves insufficient signaling gradients during embryonic thyroid migration, leading to the arrest of precursor cells at multiple points. This is further supported by the occurrence of dual ectopy in congenital hypothyroidism, indicating early divergence of thyroid cell populations (5). Alternatively, a polyclonal origin has been proposed, whereby distinct thyroid cell populations migrate independently (2,5). Genetic factors, including mutations in the *Sonic hedgehog* gene, have

also been implicated in the pathogenesis of ectopic thyroid development (2).

The diagnosis of ectopic thyroid tissue is often challenging, as it can mimic salivary gland neoplasm, lymphadenopathy, or metastatic deposits given overlapping clinical and radiological features (3). A multimodal diagnostic approach is therefore essential. Ultrasound provides a non-invasive initial assessment for evaluating thyroid morphology; however, its diagnostic accuracy can be limited, as ectopic tissue can exhibit sonographic features similar to other neck masses (9). Fine-needle aspiration cytology is a valuable adjunct but is occasionally inconclusive and cannot reliably exclude malignancy in all cases (4).

A comprehensive diagnostic approach often requires multiple imaging modalities, including ultrasonography, CT, magnetic resonance imaging (MRI), and thyroid scintigraphy. Of these, thyroid scintigraphy is particularly valuable, serving as the cornerstone for identifying ectopic thyroid tissue and distinguishing it from metastatic disease or other neck lesions (10). In the presented case, CT failed to identify the lingual ectopic thyroid, underlining the value of employing a multimodal imaging approach. Routine thyroid function testing including TSH, T3, and T4 levels, is vital not only in assessing thyroid function but also in determining the necessity of lifelong thyroid hormone replacement therapy (4). The diagnostic performance values and imaging characteristics summarized in Table 1 are derived from previously published studies evaluating imaging modalities for ectopic thyroid tissue.

Radionuclide imaging combined with SPECT/CT currently offers the highest reported specificity and sensitivity for detecting ectopic thyroid tissue (10). Although ultrasound is widely accessible and non-invasive, its sensitivity decreases in cases where ectopic tissue is small or exhibits low echogenicity. CT and MRI provide excellent anatomical

**Table 1.** Summary of diagnostic modalities for ectopic thyroid

Modality	Sensitivity	Specificity	Diagnostic features
Ultrasound (9)	55.0%	100.0%	<b>Advantages:</b> Readily available, non-invasive, low cost. <b>Disadvantages:</b> Limited resolution for scattered echotexture, echogenicity, or small ectopic tissue. Combination with radionuclide imaging is recommended for comprehensive evaluation.
CT (10)	84.6%	100.0%	<b>Advantages:</b> Better at differentiating hard tissues; ectopic thyroid tissue typically has a higher density than the surrounding soft tissues. <b>Disadvantages:</b> Limited diagnostic accuracy, potential interference with other procedures, radiation exposure.
MRI (10)	71.4%	100.0%	<b>Advantages:</b> Superior for soft tissue assessment. <b>Disadvantages:</b> May fail to detect small thyroid tissue due to signal intensity similar to adjacent muscles.
Scintigraphy (10)	92.3%	100.0%	<b>Advantages:</b> Highly diagnostic; provides detailed information on size, location, nature, and radioactive iodine uptake of ectopic thyroid tissue. <b>Disadvantages:</b> Both benign and malignant ectopic thyroid tissues can show tracer uptake, limiting differentiation.

detail, assisting in the differentiation of ectopic thyroid tissue from other neck masses, though CT involves exposure to ionizing radiation and MRI may struggle to distinguish small foci from the adjacent muscle (3). As both benign and malignant ectopic thyroid tissues may demonstrate tracer uptake, histopathological confirmation is essential in any suspicious case (8).

Management of dual ectopic thyroid tissue must be tailored according to clinical symptoms, risk of malignancy, and thyroid function. Asymptomatic patients with benign cytology and preserved thyroid function may be managed conservatively with regular follow-up, whereas surgical intervention is reserved for those with compressive symptoms, suspicion of malignancy, or functional compromise (9,10).

## Conclusion

Dual ectopic thyroid tissue in the lingual and lateral neck regions in the presence of a normally located gland is exceptionally rare. Comprehensive imaging, including radionuclide scintigraphy, and histopathological confirmation are essential for accurate diagnosis and appropriate management. Clinicians should maintain a high index of suspicion for ectopic thyroid in an atypical neck mass to avoid misdiagnosis and guide appropriate management.

## Ethics

**Informed Consent:** Written informed consent was obtained from the patient.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: N.E.A.F., K.A.M., M.R.M.Y., Concept: A.H.M.Y., Design: A.H.M.Y., Data Collection and/or Processing: A.H.M.Y., C.J.K., Analysis or Interpretation: N.E.A.F., K.A.M., M.R.M.Y., Literature Search: A.H.M.Y., N.E.A.F., K.A.M., Writing: A.H.M.Y., C.J.K., N.E.A.F., K.A.M., M.R.M.Y.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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## Main Points

- Dual ectopic thyroid tissue is a very rare condition, especially in the presence of a normally located thyroid gland.
- Ectopic thyroid tissue should be considered in the differential diagnosis of atypical lateral neck masses.
- Radionuclide imaging, particularly single photon emission computed tomography, is essential for accurate identification of ectopic thyroid tissue.

- A multimodal imaging approach improves diagnostic accuracy and helps avoid unnecessary surgical intervention.
- Management should be individualised based on clinical symptoms, thyroid function, and risk of malignancy.

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## Letter to the Editor



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# Commentary on “Comparing Flexible Nasal Endoscopy and Lateral Neck Radiography When Diagnosing Children with Adenoid Hypertrophy”

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**Keywords:** Adenoid hypertrophy, diagnostic accuracy, nasal endoscopy, pediatric otorhinolaryngology, preoperative assessment, radiography

### Dear Editor,

I read with interest the recent article by Hosri et al. (1), entitled “Comparing Flexible Nasal Endoscopy and Lateral Neck Radiography When Diagnosing Children with Adenoid Hypertrophy” published in the Turkish Archives of Otorhinolaryngology. The authors are to be commended for addressing an important diagnostic issue in pediatric otorhinolaryngology.

Adenoidectomy is one of the most frequently performed procedures in the pediatric population worldwide. Adenoid hypertrophy is a significant condition associated with nasal congestion, recurrent middle ear infections, chronic mouth breathing, and craniofacial changes in children. In this context, one of the first steps in clinical practice is to assess adenoid hypertrophy. However, due to its location, it can be difficult to assess the size and extent of the adenoids during clinical examination (2).

I would like to raise several additional points that may complement the authors’ discussion and underscore the broader diagnostic and safety advantages of direct nasopharyngeal visualization.

Lateral radiography, although widely used as a non-invasive alternative to endoscopy for evaluating adenoid hypertrophy in children, inevitably involves radiation exposure. Moreover, physiological variations during image acquisition, including changes in the respiratory cycle related to inspiration, expiration, phonation or swallowing patterns may also lead to incorrect assessment of the nasopharyngeal airway. Importantly, not only is image interpretation, but the acquisition of an optimal radiograph itself also requires technical expertise to ensure appropriate penetration and direct lateral projection without soft palate elevation (2).

Flexible nasal endoscopy provides direct visualization of the nasopharyngeal airway. Although uncommon, a range of benign or malignant nasopharyngeal pathologies may be encountered in the pediatric population. Endoscopic examination can help

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identify the causes of airway narrowing that may clinically mimic adenoid hypertrophy. Evaluating a patient solely through radiological imaging such as lateral radiography may lead to overlooking benign or, in rare cases, malignant nasopharyngeal pathologies (3). Nasal endoscopy also allows for the assessment of the anatomical extent of the adenoid tissue prior to performing surgery, which may be clinically important given that the distribution of hypertrophy could affect symptomatology (4).

Endoscopic evaluation is also crucial for detecting rare vascular anomalies, such as an aberrant internal carotid artery (ICA). Unrecognized nasopharyngeal ICA aberrancy may lead to life-threatening hemorrhage during adenoidectomy. Nasal endoscopy may show a submucosal pulsatile mass in such cases (5). These considerations underscore the importance of thorough preoperative examination by otorhinolaryngologists before surgery.

I congratulate the authors for their contribution and believe these considerations may further strengthen the message of their study.

#### Footnotes

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#### Reply

##### Dear Editor,

We would like to thank the author for their interest in our article entitled “Comparing Flexible Nasal Endoscopy and Lateral Neck Radiography When Diagnosing Children with Adenoid Hypertrophy” and for their thoughtful and constructive comments.

We appreciate the emphasis on several important aspects of adenoid evaluation in pediatric patients. In particular, the points raised regarding the limitations of lateral neck radiography, including radiation exposure and potential variability during image acquisition, are well taken. These factors are indeed relevant in daily clinical practice and should be considered when selecting diagnostic modalities.

We also agree that flexible nasal endoscopy offers significant advantages by enabling direct visualization of the nasopharynx. As highlighted, endoscopic assessment may provide additional diagnostic information beyond the estimation of adenoid size, including the identification of alternative causes of nasopharyngeal obstruction. Furthermore, the role of endoscopy in preoperative evaluation, particularly in recognizing rare but potentially critical conditions such as vascular anomalies, is of clear clinical importance.

At the same time, we would like to emphasize that lateral neck radiography may still have a role in selected clinical settings. In situations where endoscopic examination is not feasible, limited, or not well tolerated, radiography can serve as a useful adjunctive tool. Therefore, rather than considering these modalities as mutually exclusive, they may be better viewed as complementary, depending on the clinical context and available resources.

Overall, we believe that the author’s comments enrich the discussion and highlight important diagnostic and safety considerations in the evaluation of adenoid hypertrophy.

We thank the author again for their valuable contribution.

Sincerely,

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