ORIGINAL ARTICLE
GENERAL OTOLARYNGOLOGY, CASE REPORTS, AND CLINICAL PEARLS
DOI: 10.5152/B-ENT.2026.251971

Effect of Topical Anesthesia Application to the External Auditory Canal on Gag Reflex Suppression

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Cite this article as: Temirbekov D, Bursa MÇ, Alkan S, et al. Effect of topical anesthesia application to the external auditory canal on gag reflex suppression. B-ENT. 2026, 22, 1971, doi: 10.5152/B-ENT.2026.251971.

ABSTRACT

Objective: An exaggerated gag reflex (GR) in some patients can substantially hinder oral and dental procedures, making this condition an important healthcare issue that demands effective solutions. This study aimed to evaluate whether topical anesthesia application to the external auditory canal (EAC) can modulate the GR and offer a novel strategy for managing this reflex in dental and clinical settings.

Methods: The study was conducted using a randomized controlled double-blind method. A total of 60 healthy adult volunteers, aged 18-35 years, participated in the study and were randomly divided into 3 groups: Group A (topical anesthesia, test), Group V (petroleum jelly, placebo), and Group C (control group, no intervention). After initial GR assessments conducted by a dentist, interventions were applied corresponding to their group allocations. Group A had cotton soaked in lidocaine pomade inserted into their ears, while Group V received petroleum jelly-soaked cotton, and Group C received no intervention. A second GR measurement was performed after a 10-minute wait period. Data were collected and analyzed statistically.

Results: No significant differences were observed in the pre- and post-procedure GR measurements between groups ($P > .05$). Neither topical anesthesia nor vaseline application in the EAC demonstrated any significant impact on the GR.

Conclusion: These findings suggest that EAC stimulation alone may not be a reliable method for managing the GR in clinical practice. The trigeminal and vagal reflex pathways associated with the EAC are highly complex, necessitating further detailed investigations in this area.

Keywords: Arnold's nerve, ear canal occlusion, external auditory canal, gag reflex, gag reflex modulation, trigeminal nerve

Introduction

The gag reflex (GR), or pharyngeal reflex, is an involuntary defense mechanism that protects the upper airway by expelling foreign objects from the oral cavity. This reflex is primarily mediated by the glossopharyngeal nerve (CN IX) and the vagus nerve (CN X), with sensory input from the former and motor response from the latter.[1] An exaggerated GR in dental practice poses significant challenges, potentially hindering procedures such as taking impressions, radiographs, and delivering dental appliances.[2] Studies indicate that approximately 8.2% of dental patients experience this heightened reflex, with even higher prevalence during denture try-ins.[2,3]

Anatomically, the external auditory canal (EAC) is innervated by Arnold's nerve, a branch of the vagus nerve (CN X). Stimulation of this area can elicit responses such as coughing or gagging, known as the ear-cough or ear-gag reflex.[4,5] This neural connection has been explored in various studies aiming to modulate the GR through interventions targeting the EAC. For instance, the application of earplugs has been investigated as a method to suppress the GR during dental procedures.[1,3]

However, the efficacy of such interventions remains inconclusive, with some studies reporting positive outcomes, while others find minimal or no effect.[1,6,7] Additionally, techniques such as ear acupuncture have been explored, but their effectiveness

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Received: December 30, 2025 **Revision Requested:** February 23, 2026 **Last Revision Received:** June 1, 2026 **Accepted:** June 18, 2026
Publication Date: August 17, 2026
Available online at www.b-ent.be

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in GR management is still under debate.[2] These observations raise the possibility that sensory input from the EAC could influence GR processing through shared central neural pathways. The afferent limb of the GR is primarily mediated by the glossopharyngeal nerve (CN IX), with central integration occurring in the nucleus tractus solitarius (NTS). The auricular branch of the vagus nerve (Arnold's nerve), which innervates portions of the EAC, also projects to the NTS. Based on this potential convergence at the brainstem level, it was hypothesized that modulation of auricular vagal input through topical anesthesia of the EAC might alter central reflex integration and thereby influence the GR threshold.

Given the challenges posed by an exaggerated GR in clinical settings, especially in dentistry and otolaryngology, there is a pressing need to explore and validate effective management strategies. This study was designed as an initial exploratory investigation to assess the feasibility and potential trends of GR modulation through EAC anesthesia, potentially offering a novel approach to managing this reflex in susceptible patients.

Methods

This prospective randomized controlled double-blind study was approved by the İstanbul Aydın University Institutional Ethics Committee (Approval number: 118/2024; Date: December 11, 2024) and was conducted in accordance with the principles of the Declaration of Helsinki.

Sample Size and Power Analysis

An a priori power analysis was performed using G*Power version 3.1 (Heinrich-Heine-Universität Düsseldorf, Germany) for a 1-way analysis of variance (ANOVA) comparing 3 independent groups. The primary outcome variable for the power calculation was the change in objective GR tolerance (Δ mm) between pre- and postintervention measurements.

The expected effect size was estimated based on previously published intervention studies investigating GR modulation, particularly the study by Agrawal et al,[8] which demonstrated a clinically meaningful between-group difference in GR severity following auricular stimulation. As no prior studies used the same continuous outcome measure (Δ GR tolerance in mm), the effect size was not directly derived mathematically but was approximated based on the magnitude of differences reported in the literature and interpreted according to Cohen's classification. Therefore, an effect size of f = 0.33 was selected to represent a medium, clinically meaningful effect. Because no prior studies evaluated the same primary outcome measure, the selected effect size should be regarded as a literature-guided assumption for an exploratory trial rather than a formally derived estimate for the exact study endpoint.

With a two-sided alpha level of 0.05 and a statistical power (1–β) of 0.80, the required minimum sample size was calculated as 18 participants per group. To enhance statistical precision, ensure balanced randomization across groups, and reduce the risk of type 2 error, a total of 60 participants (approximately 20 per group) were enrolled in the present study.

Inclusion Criteria

Volunteers aged 18-35 years, without any ear diseases, and generally in good health.

Exclusion Criteria

History of pathology or surgery in the external, middle, or inner ear; ages above 35 years or below 18 years; presence of neurological disorders; allergy to vaseline or lidocaine; and pregnancy.

Preparation of Double-Blind Randomization

To ensure double-blind implementation and proper randomization, 60 envelopes were prepared, each containing a group designation and participant number (e.g., Participants assigned to group A as A1, A2,..., A20; Participants assigned to group V as V1, V2,..., V20; Participants assigned to group Control as C1, C2,..., C20).

Participants were randomly divided into 3 equally distributed groups.

Group A: Lidocaine 5% (Lokalen 5% Pomad, Toprak İlaç, Türkiye)
Group V: Petroleum Jelly (Vaseline, Unilever, USA)
Group C: Negative control.

After detailed information about the study was provided and informed consent was obtained, participants were instructed to select 1 envelope randomly.

Subjective Gag Reflex Assessment and Classification of Gagging Problem

The GRs of all participants were assessed and recorded using self-reported subjective classification of Gagging Severity Index (GSI) defined by Dickson and Fiske.[9] Gagging was classified into five grades: normal gagging but not desensitized (G1); mild gagging (G2); moderate gagging (G3); severe gagging (G4); and very severe gagging (G5) (Table 1). Subjective classification of Gagging Problem Index (GPI) measurements described by Saita et al.[10] Gagging Problem Index is based on the degree of GR on intraoral examination; those who could not place a dental mirror in their oral cavity at all (G5), those for whom the anterior teeth could not be examined when using a dental mirror (G4), those for whom the posterior teeth could not be examined when using a dental mirror (G3), those for whom periodontal pockets in the entire oral cavity could not be measured with a probe (G2), and those for whom periodontal pockets in the entire oral cavity could be measured with a probe (G1) (Table 2).

Measurement of Gagging Reflex And Intra-aural Topical Anesthesia Application

Each participant underwent GR measurement by an experienced dentist (M.C.B), who recorded the results and placed

Main Points

- External auditory canal (EAC) topical anesthesia and sham occlusion did not significantly change gag reflex tolerance.
- Findings contradict earlier studies that suggested ear-canal interventions reduce gagging.
- Gag reflex management likely requires multimodal strategies rather than isolated EAC-based methods.

Table 1. Classification of Gagging Severity Index (GSI) Proposed by Dickinson and Fiske[9]

Severity Grading	Description
Grade 1 Normal gagging reflex	Very occasional gagging occurs during high-risk dental procedures such as maxillary impression taking or restoration to the distal, palatal or lingual surfaces of molar teeth. This is basically a "normal" gag reflex under difficult treatment circumstances. It is generally controlled by the patient.
Grade 2 Mild gagging	Gagging occurs occasionally during routine dental procedures such as fillings, scaling and impressions. Control can usually be regained by the patient, but may need assistance and reassurance from members of the dental team, and treatment continued. No special measures are generally needed to facilitate routine treatment but may be required for more difficult procedures.
Grade 3 Moderate gagging	Gagging occurs routinely during normal dental procedures. This may include simple physical examination of high-risk areas, such as the lingual aspect of lower molars. Once instigated, control is difficult to regain without cessation of the procedure. Recommencement may be difficult. Gagging prevention measures are usually required. The gag may influence treatment planning and may limit treatment options.
Grade 4 Severe gagging	Gagging occurs with all forms of dental treatment including simple visual examination. Routine treatment is impossible without some form of special measure to attempt to control the gag reflex. Treatment options may be limited and the gagging problem will be a major factor in treatment planning.
Grade 5 Very severe gagging	Gagging occurs easily and may not necessarily require physical intervention to trigger the reflex. The patient's behaviour and dental attendance may be governed by the gagging problem and it will be one of the prime factors when planning treatment. Treatment options may be severely limited. Dental treatment will be impossible to carry out without specific, special treatment for control of the gagging problem.

them in a second envelope. The participants then proceeded to a different room, where an otolaryngologist (D.T) opened the first envelope to identify the participant's group. Ear canal occlusions were performed based on group allocation: participants in "Group A" had cotton soaked in 5% lidocaine topical pomade (Lokalen 5% Pomad, Toprak İlaç, Türkiye) which is commonly used as topical anesthesia for EAC applied to their ears; those in "Group V" had petroleum jelly (Vaseline, Unilever, USA) soaked cotton applied, and "Group C" received no intervention. Cotton pieces were placed in a way that completely plugs the ear canals. After waiting for a minimum of 10 minutes according to instructions for use, the participants returned to the dentist for a second GR measurement. The cotton plugs were removed after the second measurement. The results were recorded by the research secretary.

All GR tolerances were measured in the upright position on the dental unit under 22-27°C room temperature; 28%-69% humidity. All measurement procedures were explained to each participant. Participants were not informed about the study methods with which they were treated. For the measurement of the GR, an index was prepared for each participant using an addition-cured dental silicone putty material (Variotime Putty, Kulzer, Germany) that covered the maxillary central incisors, as described in a study by Karibe et al. A hole was created in the middle part of the index to allow the insertion of a disposable dental aspirator tip (Monoart, Euronda, Italy) into the oral cavity (Figure 1).[11] The aspirator tip was advanced toward the soft palate at a speed of 10 mm/s, which was described in a previous study by Karibe et al.[11] Participants were instructed to signal using a smartphone (iPhone 11, Apple Inc., USA) when they reached the threshold that triggered the GR. Upon receiving the signal, the clinician immediately removed the aspirator tip along with the index from the participant's mouth and marked the aspirator tip at the level corresponding to the anterior teeth using a marker pen on the silicone index. This distance was measured with a digital caliper (Digimatic Caliper CD-15AX, Mitutoyo, Japan) and recorded as the GR tolerance value for each participant (Figure 2).

Statistical Analysis

All statistical analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics are presented as mean ± SD for normally distributed variables and as median (minimum–maximum) for non-normally distributed variables. Categorical variables are expressed as frequencies and percentages. Normality of distribution was assessed using the Shapiro–Wilk test. Homogeneity of variances was evaluated using Levene's test.

For comparisons of continuous variables among the 3 independent groups, 1-way ANOVA was used when assumptions of normality and homogeneity of variance were satisfied. Tukey's post-hoc test was applied for pairwise comparisons when variances were equal. If the assumption of homogeneity of variances was violated, the Games–Howell post-hoc test was used.

Table 2. Classification of Gagging Problem Index (GPI) Proposed by Saita et al.[10]

Grades Gagging	Reflex features
Grade 1. Normal	Can tolerate periodontal examinations
Grade 2. Mild gagging	Can not tolerate simple periodontal examinations
Grade 3. Moderate gagging	Can not tolerate examination of molars
Grade 4. Severe gagging	Can not tolerate examination of the front teeth
Grade 5. Very severe gagging	The dental mirror cannot be inserted into the mouth

Figure 1. Measurement of gag-reflex threshold using a disposable dental aspirator tip. A custom addition-cured silicone index was positioned over the maxillary central incisors, and the aspirator tip was advanced toward the soft palate at a constant speed until the participant signaled discomfort, indicating the gag-reflex threshold.

For variables that were not normally distributed, the Kruskal–Wallis test was applied for comparisons among the 3 groups, followed by Bonferroni-adjusted pairwise comparisons when appropriate.

Within-group pre–post comparisons were performed using the paired-samples *t*-test for normally distributed data and the Wilcoxon signed-rank test for non-normally distributed data. Categorical variables were analyzed using the chi-square test. The primary outcome was defined as the change in objective GR tolerance (Δ mm). The analysis strategy consisted of (i) assessing within-group pre–post differences to evaluate intra-group change, and (ii) comparing the change scores (Δ mm) across the 3 groups to determine between-group intervention effects. A two-tailed *P*-value < .05 was considered statistically significant.

Results

The age and sex distribution of patients among Groups A, V, and C showed no significant differences ($P > .05$). The minimum, median, and maximum ages of participants were 18, 24, and 34 years, respectively. Although the sex distribution of study groups A (female 45%-male 55%) and C (female 50%-male 50%) was very close, the proportion of female participants was higher in Group V compared to the other groups (female 65%-male 35%).

The subjective survey results also showed no significant differences among Groups A, V, and C ($P > .05$). GSI results of groups A and C were concentrated at grade 2, and group V was concentrated at grade 3. Similarly, the GPI results revealed no significant differences among Groups A, V, and C ($P > .05$)

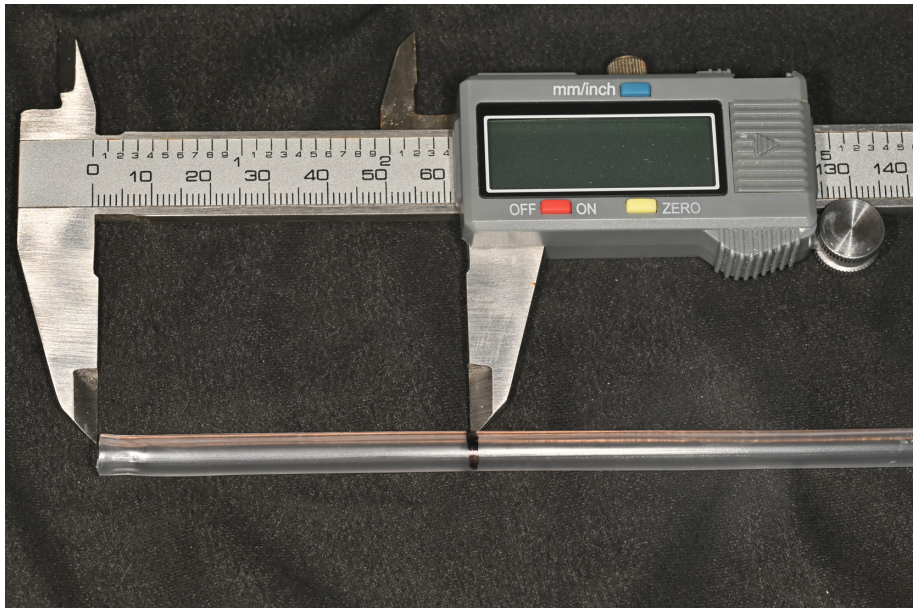

Figure 2. Measurement of marked aspirator-tip length with a digital caliper. The distance between the mark corresponding to the anterior teeth and the aspirator-tip end was measured in millimeters (mm) using a precision digital measuring device to determine gag-reflex tolerance.

Table 3. Demographic and General Characteristics of Study Participants (n = 60)

Variable		Min	Max	Median	Mean ± SD/n(%)
Age (years)		18	34	24	24.7 ± 3.9
Sex	Women				32 (53.30)
	Men				28 (46.70)
GSI (grade)		1	5	2	2.5 ± 2
GPI (grade)		1	5	1	1.3 ± 0.5
Objective GR (mm)					
Before		55	116	80	80.6 ± 10.5
After		55	117	81.5	81.8 ± 10.5
	Group A				20 (33.30)
	Group V				20 (33.30)
	Group C				20 (33.30)

GPI, Gagging Problem Index; GR, gag reflex; GSI, Gagging Severity Index; Max, maximum; Min, minimum; mm, millimeter; n, number of participants.

(Table 3). Gagging Problem Index results of all groups concentrated at grade 1.

Although the pre-procedure GR measurement of groups A and V was lower than the post-procedure measurement, the differences were not statistically significant ($P > .05$). In Group C, post-procedure GR measurements were lower than pre-procedure values; however, this difference was not statistically significant ($P > .05$). (Table 4) (Figure 3). The mean change scores (Δ mm) were 2.4 ± 6.2 mm (95% CI: −0.5 to 5.3) in Group A, 1.9 ± 6.6 mm (95% CI: −1.2 to 5.0) in Group V, and −0.7 ± 3.8 mm (95% CI: −2.5 to 1.1) in Group C. No statistically significant difference was observed among groups in the comparison of change scores (Kruskal–Wallis test, $P = .089$).

Discussion

Ear-gag reflex, considered a type of protective reflex. When movement or disturbance occurs within the external ear canal, it is perceived as a "threat." The mechanoreceptors in this region are tasked with maintaining chemical, thermal, bacteriological, and ionic homeostasis. Consequently, these receptors respond to such perceived threats by triggering protective reflexes, such as gagging, vomiting, or coughing.[4] An example of this protective mechanism is that cerumen (ear wax) in the EAC can cause chronic cough due to referred irritation affecting the laryngeal inlet. Consequently, removing the cerumen may alleviate chronic cough symptoms.[12] On the contrary, some researchers declared that using an earplug can be an effective method to suppress GR, which is also a kind of protective mechanism of the upper airway.[1] In order to clarify this complexity, this study aimed to understand whether placement of a cotton piece into the EAC can exacerbate or inhibit the GR. Based on this rationale, cotton plugs soaked in lidocaine were placed in the ears of the first study group. The application of lidocaine spray or pomade to the EAC to anesthetize the skin is a technique already utilized in clinical practice.[13,14] This approach was evaluated to determine whether it could reduce gagging by preventing stimulation of the skin of the EAC. In the sham group, the application of petroleum jelly-embedded

Table 4. Comparison of Objective and Subjective Gag Reflex Measurements Among Study Groups

Variable			Group A (n = 20)	Group V (n = 20)	Group C (n = 20)	P	
Age (years)	Mean ±SD		25 ± 3.9	24.6 ± 3.2	24.6 ± 4.5	.934	A
	Median		24.0	24.0	25.5		
Sex	Women	n (%)	9 (45.00)	13 (65.00)	10 (50.00)	.419	X^2
	Men	n (%)	11 (55.00)	7 (35.00)	10 (50.00)		
GSI (grade)	Mean ± SD		2.3 ± 1.9	3.2 ± 2.4	2 ± 1.6	.319	K
	Median		2.0	3.0	2.0		
GPI (grade)	Mean ± SD		1.2 ± 0.4	1.3 ± 0.6	1.4 ± 0.6	.484	K
	Median		1.0	1.0	1.0		
Objective GR (mm)							
Before	Mean ± SD		77.1 ± 8.2	81.8 ± 8.8	83.1 ± 13.3	.13	K
	Median		76.5	82.0	82.0		
After	Mean ± SD		79.4 ± 8.5	83.6 ± 9.4	82.4 ± 13.2	.357	K
	Median		78.5	83	80.5		
Before/after	Mean ± SD		2.4 ± 6.2	1.9 ± 6.6	−0.7 ± 3.8	.089	K
Δ (mm)	Median		2	2.5	0.0		
Intragroup change (P)			.093[W]	.073[W]	.569[W]		

A, one-way analysis of variance (ANOVA); Δ, change (post–pre); GPI, Gagging Problem Index; GR, gag reflex; GSI, Gagging Severity Index; K, Kruskal–Wallis test for between-group comparisons; mm, millimeter; n, number of participants; P, probability value; W, Wilcoxon signed-rank test for within-group comparisons; X^2, chi-square test.

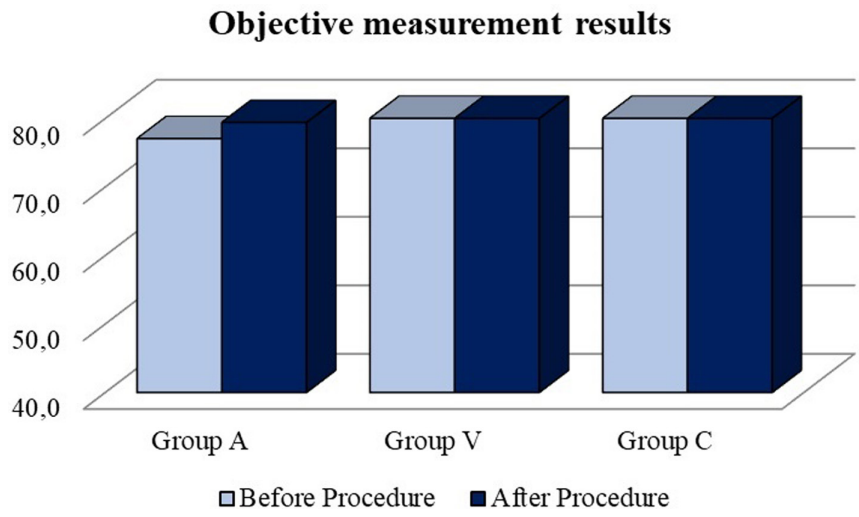

Figure 3. Objective gag-reflex (GR) measurement results. Mean GR tolerance values (mm) of the 3 participant groups—topical anesthetic (Group A), petroleum-jelly placebo (Group V), and no-intervention control (Group C)—before and after the procedure. Error bars indicate SD.

cotton was intended to mimic the lidocaine and to facilitate a double-blind methodology.

The GR threshold in this study was elicited by intraoral stimulation of the soft palate, primarily activating glossopharyngeal (CN IX) afferents, whereas the intervention targeted the EAC, innervated in part by the auricular branch of the vagus nerve (Arnold's nerve). Any potential interaction would therefore occur not through direct peripheral mechanisms but via central convergence of glossopharyngeal and vagal inputs within the NTS. As brainstem activity was not directly assessed, this proposed mechanism remains theoretical and was evaluated indirectly through behavioral threshold measurements.

The GR, while a vital protective mechanism for the upper airway, presents significant challenges in clinical practice, particularly in dentistry and otolaryngology. Various methods have been investigated to mitigate this reflex, yet a universally effective and clinically viable solution remains elusive. Saliba et al proposed a simple and safe injection technique of 2% lidocaine into the palatoglossal fold.[15] Despite being effective, due to its invasiveness, there is a need for alternative techniques. Therefore, 5% lidocaine topical anesthetic was used as a noninvasive method that can suppress GR via the external ear canal. By contrast with Saliba et al, topical anesthesia application did not affect the GR in the research. It was declared that this result arises from the necessity of a deeper blocking of the neural pathway that suppresses the GR, despite suppressing the sensory activities of the ear canal.

Five intraoral areas are recognized as "trigger zones" for the GR: the palatoglossal and palatopharyngeal folds, the base of the tongue, the palate, the uvula, and the posterior pharyngeal wall. Among these, the palate and uvula are the most commonly associated with gagging during dental procedures. The measurement approach recommended by Karibe and colleagues was adopted due to its practicality and reliability as a validated objective method.[11] According to their results, visual stimuli and habituation did not affect GR measurement so they were also not included in the study. As a contrast to their study, all measurements were done by 1 experienced dentist in the study in order not to cause any iatrogenic GR for the participants as a result of exaggeration of repeated measurements.

The connection between the EAC and the GR has been explored in prior studies with diverse outcomes. For instance, interventions such as earplugs, acupuncture, and laser application have shown varying degrees of success in modulating the GR.[1,8,16-19]

Agrawal et al demonstrated that microcurrent electrical stimulation on the Hegus (Li4 point) and auricular acupuncture points effectively reduces the severity of the GR during dental procedures, with the Hegus point being more effective than the auricular point.[8] The underlying mechanism is explained by the flow of impulses to the nucleus of the raphe magnus in the midbrain, a key serotonin (5-HT) source. This activation enhances serotonin release, which is subsequently converted to beta-endorphin, an antiemetic agent that helps suppress the GR.[8]

Çakmak et al conducted a study suggesting that the application of an earplug can reduce the GR.[1] Unlike the study, they performed measurements by touching four different areas: the soft palate, uvula, posterior pharyngeal wall, and the root of the tongue. They found the most significant reduction in the GR in the soft and hard palates, while the least change was observed in the posterior pharyngeal wall, although the posterior pharyngeal wall is known to be directly associated with Arnold's nerve.[1] They proposed that this effect may result from the overlapping innervation between the oropharyngeal trigeminal areas and the EAC skin territories, both innervated by the trigeminal nerve. However, the exact level of neuronal overlap was not elucidated in their study, highlighting the need for further investigation using advanced imaging techniques in humans. Although measurements were obtained from the soft palate, where the greatest suppression of the GR was observed in the study by Çakmak et al, the study did not demonstrate a statistically significant suppression.

Additionally, they speculated that the earplug technique might also exert a sedative effect beyond its trigeminal blocking

action.[1] Another previous study has demonstrated that electrical stimulation of ear skin areas innervated by Arnold's branch of the vagus nerve can have mood-enhancing effects.[20]

Neurologically, the cranial, cervical, and auxiliary nerves are involved in the neurocomplex that innervates the external canal region. While most of these nerves are unrelated to hearing, they influence the ear and surrounding tissues. This intricate network includes the tympanic branch of the glossopharyngeal nerve (CN IX), the mandibular and maxillary branches of the trigeminal nerve (CN V), the mandibular and submandibular branches, chorda tympani, greater petrosal nerve, and tympanic plexus of the facial nerve (CN VII), as well as Arnold's branch of the vagus nerve (CN X), among others, creating a complex and unpredictable system of interconnections.[4] The auricular branch of the vagus nerve shows marked anatomical variability—it may arise from different rootlets, travel through variable courses within the cartilaginous portion of the EAC and form anastomoses with the auriculotemporal branch of the trigeminal nerve or the posterior auricular branch of the facial nerve.[21] Such variability influences the degree of vagal activation that can be achieved through external ear stimulation. Consequently, the extent of vagal–trigeminal overlap and interindividual differences in neural connectivity might explain why some individuals respond more strongly to auricular stimulation than others.[21]

In contrast, the study's findings align with those of Jawdekar and Samaleti, who found minimal impact of auditory canal stimulation on GR modulation.[6] These discrepancies highlight the complexity of the reflex and the potential influence of individual variability, methodological differences, and placebo effects.

Jawdekar and Samaleti compared the "earplug and temporal tap technique" with the conventional distraction method to determine their effectiveness in reducing the GR during maxillary impression-making in children. While the earplug and temporal tap technique enhanced the overall experience, it did not lead to a reduction in the GR.[6]

The findings suggest that this intervention, along with the use of vaseline-soaked cotton as a sham control, does not significantly impact the GR. These results contribute to the growing body of evidence that EAC stimulation or anesthesia alone may not be sufficient to alter this reflex. Several factors may explain these results. First, the GR is a complex response involving multiple neural pathways, including sensory input from the glossopharyngeal nerve and motor output mediated by the vagus nerve. While Arnold's nerve connects the EAC to the vagus nerve, the strength of this neural connection may vary among individuals, potentially limiting the effectiveness of interventions targeting this region. Second, the topical anesthesia application may not provide sufficient penetration or concentration to block neural transmission effectively. The 10-minute application period for the lidocaine pomade was determined based on the manufacturer's prospectus, which states that clinical onset occurs within approximately 10 minutes, depending on skin thickness. Because the EAC has very thin epithelium, this duration was expected to provide adequate local anesthetic diffusion while maintaining safety and procedural practicality. Longer exposure times were deliberately avoided to minimize potential discomfort, excessive absorption, or mucosal irritation. Nevertheless, interindividual differences in epithelial permeability may have influenced the extent of neural desensitization achieved, and future studies could explore prolonged or alternative delivery methods—such as sprays, gels, or iontophoretic systems—to ensure deeper and more uniform anesthesia of the canal wall.

The study's randomized, double-blind design strengthens its validity by minimizing bias and ensuring robust comparisons between intervention and control groups. The use of a sham control group (petroleum jelly soaked cotton) further allows differentiation between specific effects of lidocaine and general effects of EAC occlusion. However, the lack of significant findings across all groups underscores the need for caution in interpreting previous studies that have reported positive outcomes. The subjective nature of GR assessments in some studies may contribute to inconsistent results, as participants' perceptions can be influenced by psychological factors and prior expectations.

The GR threshold in this study was determined by participants' self-signaling when the stimulus first triggered discomfort. Although this method has been validated in previous studies and allows consistent intra-individual comparison, it inevitably introduces some subjectivity related to perception and reaction time. Objective recording techniques, such as electromyography or sensor-based monitoring, could be incorporated in future research to reduce this potential bias.

Additionally, the role of psychological and behavioral factors in GR modulation cannot be overlooked. Techniques such as desensitization training, cognitive-behavioral therapy, and hypnosis have demonstrated efficacy in managing exaggerated GRs, suggesting that a multifaceted approach may be more effective than isolated physical interventions.[1,9,17] Combining auditory canal stimulation with psychological techniques could be an avenue for future research.

The limitations of the study include its relatively exclusive focus on healthy adult volunteers without significant GR hypersensitivity. While this homogeneity enhances internal validity, it may limit the generalizability of the findings to clinical populations with pronounced GRs. Future research should consider larger, more diverse samples and investigate the potential role of individual variability, such as differences in vagus nerve sensitivity or psychological predisposition, in determining the effectiveness of auditory canal interventions.

Because participants were assigned to groups through double-blind randomization rather than by selection, equal gender balance across groups could not be ensured. This resulted in a slightly higher proportion of female participants in the placebo group. Although no significant gender effect on GR outcomes was found, such an imbalance may have contributed to minor variability, and future studies should aim for gender-stratified randomization to minimize this limitation.

In conclusion, the study provides evidence that neither anesthetic-soaked cotton nor vaseline-soaked cotton in the EAC significantly alters the GR. These findings challenge the premise that EAC stimulation alone can serve as a reliable method for GR management. Future studies should explore alternative

approaches, potentially integrating physical, psychological, and pharmacological strategies, to address this complex clinical challenge more effectively.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Artificial Intelligence Usage Statement: During the preparation of this manuscript, ChatGPT (OpenAI, San Francisco, CA, USA) was used to assist with language refinement, structural organization, and formatting of the text. The scientific concepts, hypothesis development, interpretation of the literature, and all substantive intellectual content were conceived, critically evaluated, and finalized by the authors. The authors take full responsibility for the accuracy, integrity, and originality of the work.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of İstanbul Aydın University (Approval no: 118/2024, Date: December 11, 2024).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – D.T., M.Ç.B.; Design – M.Ç.B., S.A.; Supervision – M.Ç.B., I.Y., S.A.; Materials – S.A., I.Y.; Data Collection and/or Processing – S.A., I.Y., Y.K., S.A., A.P.B., S.H.A.; Analysis and/or Interpretation – I.Y., Y.K., S.A., A.P.B., S.H.A.; Literature Search – D.T., Y.K., S.A., A.P.B., S.H.A.; Writing – S.A., I.Y.; Critical Review – D.T., M.Ç.B., A.P.B., S.H.A.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: The authors declared that this study has received no financial support.

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