Does Pterygoid Hamulotomy During Palatoplasty Affect Hearing Outcomes in Nonsyndromic Cleft Palate Patients?

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Background: Cleft palate repair aims to achieve tension-free closure without compromising Eustachian tube function and hearing outcomes. The effect of pterygoid hamulotomy on postoperative hearing remains inconclusive.

Purpose: This study evaluated the effect of pterygoid hamulotomy during palatoplasty on hearing thresholds and middle ear status in nonsyndromic cleft palate patients.

Study Design, Setting, Sample: This prospective double-blind study was conducted at the Department of Oral and Maxillofacial Surgery at a tertiary care hospital. Eighty nonsyndromic cleft palate patients aged 10 to 60 months were included and allocated alternately to 2 groups: Group I (palatoplasty with hamulotomy, n = 40) and Group II (palatoplasty without hamulotomy, n = 40). Those with prior palatal or ear surgery, syndromic conditions, or congenital hearing loss were excluded.

Predictor Variable: The predictor variable was operative technique (with or without pterygoid hamulotomy), and patients were alternately allocated to 2 groups upon enrollment.

Main Outcome Variable(s): The primary outcome variable was hearing threshold measured using brainstem-evoked response audiometry preoperatively, and at 1 and 6 months postoperatively. The secondary outcome was middle ear status assessed by otoscopic examination at the same time points.

Covariates: Covariates included age, sex, and cleft type (complete or incomplete).

Analyses: Data were analyzed using a mixed-effects repeated measures analysis of variance (ANOVA) to evaluate changes in brainstem-evoked response audiometry hearing thresholds over time and between groups. χ^2 tests were used for comparing categorical outcomes such as otoscopic findings. A significance level of $P < .05$ was considered statistically significant.

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Results: The final sample included 80 patients (mean age 32.7 ± 12.4 months; 53% male). At 6 months postoperatively, mean hearing thresholds improved in both groups (group I: 32.5 ± 6.4 dB to 22.8 ± 4.9 dB; group II: 33.1 ± 6.2 dB to 23.4 ± 5.1 dB), with no statistically significant difference between groups (mean difference: 0.6 dB, 95% CI: −1.3 to 2.5, P = .6). Normal middle ear status improved at 6 months in both groups (group I: 75.0%, group II: 72.5%), with no significant intergroup difference (P = .8).

Conclusions and Relevance: Hearing thresholds and middle ear status improved following palatoplasty in both groups. Pterygoid hamulotomy did not adversely affect hearing outcomes, suggesting it may be used without impacting auditory function.

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Cleft lip and palate, like other congenital anomalies, present significant psychological challenges not only for the affected child but also for their parents. This is primarily because cleft anomalies are associated with a range of critical complications, including speech and swallowing difficulties, impaired growth, malocclusion, nasal regurgitation, unpleasant facial aesthetics, developmental deformities, and notably, impaired hearing.[1] Although impaired hearing is a prominent feature in these patients, its clinical significance is often underestimated. The association between cleft palate and the development of otitis media with effusion (OME) was first documented in 1878 when Alt reported otorrhoea in a child with cleft palate.[2]

There is universal agreement regarding the presence of OME and subsequent hearing impairment in patients with unrepaired cleft palates.[3] However, controversy remains about the degree of hearing improvement following surgical repair.

Palatoplasty techniques aim to achieve tension-free closure of palatal flaps while minimizing complications such as oronasal fistula and velopharyngeal incompetence. Fracturing the pterygoid hamulus to release the tensor veli palatini (TVP) muscle facilitates flap mobilization, but concerns remain about potential impairment of Eustachian tube (ET) function and its impact on middle ear health.[4,5]

There is a notable gap in the existing literature regarding the specific effect of pterygoid hamulotomy during palatoplasty, leading to differing opinions about its safety and necessity. Therefore, the purpose of this study was to evaluate the effect of pterygoid hamulotomy during palatoplasty on hearing thresholds and middle ear status in nonsyndromic cleft palate patients. We hypothesized that pterygoid hamulotomy does not significantly alter postoperative hearing outcomes. The specific aims were to compare hearing thresholds and middle ear status between patients undergoing palatoplasty with and without hamulotomy.

Material and Methods

STUDY DESIGN AND SAMPLE

This prospective double-blind study was conducted at the Department of Oral and Maxillofacial Surgery from September 2013 to April 2022, following approval by the Institutional Ethics Committee dated 30th September 2013 (Ref No. DMIMS(DU)/IEC/2013-14/134). The study population included nonsyndromic cleft palate patients aged 10 to 60 months scheduled for primary palatoplasty under general anesthesia.

INCLUSION CRITERIA

Patients aged 10 to 60 months with isolated cleft palate or cleft palate with previously operated cleft lip.

EXCLUSION CRITERIA

Patients with any prior palatal or ear surgery (including myringotomy, ventilation tube, or grommet insertion), recurrent suppurative OME, tympanic membrane perforation, congenital auricular malformation, congenital hearing loss, or any middle ear disease affecting function. Patients with systemic illnesses, associated syndromes, craniofacial anomalies, developmental delays, or immunocompromised status were also excluded.

Written informed consent was obtained from parents or guardians prior to inclusion.

Predictor Variables

The predictor variable was operative technique (palatoplasty with or without pterygoid hamulotomy). Patients were alternately allocated to group I (hamulotomy) or group II (no hamulotomy) upon enrollment, ensuring equal distribution irrespective of cleft characteristics.

Outcome Variables

The primary outcome variable was hearing threshold, measured in decibels (dB) using brainstem-evoked response audiometry (BERA) at 3 time points: preoperatively, and at 1 and 6 months postoperatively. The secondary outcome variable was middle ear status, assessed by otoscopic examination at the same intervals and categorized as either normal or pathological. Each ear was assessed independently, and all evaluations were performed by blinded specialists.

Covariates

Covariates included age (in months), sex (male/female), and cleft type (complete/incomplete).

Data Collection Methods

Surgical Protocol. All surgeries were performed by 4 surgeons, each with a minimum of 5 years of cleft surgery experience, following the same standardized technique. A highly standardized surgical protocol was followed.

- Patients with complete cleft palate underwent Bardach's 2-flap pushback palatoplasty technique.[6]
- Patients with incomplete cleft palate underwent Veau-Wardill-Kilner pushback palatoplasty technique.[7]

General anesthesia was induced via orotracheal intubation with a south-pole endotracheal tube. After surgical site preparation and draping, Dingman's mouth gag was secured. All patients received an infiltration of 1:100,000 epinephrine into the palate. Mucoperiosteal flaps were elevated with midline and lateral incisions to relieve tension. Greater palatine vessels were carefully teased to allow free flap movement.

In group I, the hamular processes were fractured by applying inward pressure with an elevator, dislocating the TVP muscle to facilitate closure. Proper hamulotomy was confirmed intraoperatively by direct visualization of fractured hamulus and palpation to ensure dislocation of the TVP tendon insertion. No postoperative computed tomography scans were performed for verification.

Closure in both the groups was performed using polyglactin sutures in 2 layers (nasal and oral), approximated at select points to minimize dead space. Postoperatively, all patients were monitored in the intensive care unit for 24 hours and received analgesics and injectable antibiotics.

MIDDLE EAR EVALUATION

Preoperative middle ear evaluation was performed for all patients within 1 week prior to surgery. This included otoscopic examination conducted by a single otolaryngologist to assess tympanic membrane status and BERA conducted by a single experienced audiologist to assess hearing thresholds. Postoperative assessments using otoscopy and BERA were performed at 1 month and 6 months to evaluate changes in middle ear status and hearing.

- Otoscopy was performed by a single otolaryngologist using a Welch Allyn otoscope (Welch Allyn Inc., Skaneateles Falls, NY) to assess tympanic membrane status.
- BERA was conducted by a single audiologist.

Both examiners were blinded to the surgical procedure performed.

Findings of otoscopy and hearing thresholds identified through BERA were documented in a detailed proforma. Blinding was maintained throughout data collection and analysis phases to minimize observational bias.

BERA PROTOCOL

Whenever possible, BERA was conducted during natural sleep; otherwise, syrup Phenergan (promethazine hydrochloride, 0.5 to 1 mg/kg/dose) was administered for sedation. Testing was performed in a sound-attenuated, air-conditioned room. Awake patients were instructed to keep their eyes closed to minimize blink artefacts. The scalp (forehead and mastoids) was cleaned with alcohol and root mean square (RMS) recording paste, and silver-silver chloride disc electrodes were applied, maintaining electrode impedance at ≤ 5 kΩ. RMS POLYRITE, AD, Mark II, Version 2.2, was used to record scalp evoked potentials following the 10 to 20 international system of electrode placement. Active recordings were made from 2000 click stimuli delivered at 11.1 Hz and 60 dB above hearing threshold through shielded headphones, with −30 dB white noise masking of the contralateral ear. Signals were filtered between 100 Hz and 3 kHz and averaged over 2000 stimuli. Absolute latencies of waves I and V, interpeak latencies of waves I to V, amplitude ratios of waves Vto I, and latency-intensity functions were calculated separately for each ear.[8]

Data Analysis

The sample size was calculated based on detecting a 20% expected difference in hearing improvement between groups, with 80% power and a 2-sided alpha level of 0.05. The minimum required sample size was estimated at 36 patients per group; thus, 40 patients were included in each group to account for attrition, totaling 80 patients.

Statistical analysis was performed using SPSS (Version 17; IBM Corporation, Armonk, NY) and

Table 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENTS BY GROUP

Variable	Group I (Hamulotomy) (n = 40)	Group II (No Hamulotomy) (n = 40)	Mean Difference (95% CI)	*P* Value
Age (mo), mean ± SD	33.1 ± 12.7	32.4 ± 12.2	0.7 (−4.8 to 6.2)	.8
Sex, n (%)				.7
Male	22 (55.0%)	20 (50.0%)	–	
Female	18 (45.0%)	20 (50.0%)	–	
Cleft type, n (%)				.6
Complete	27 (67.5%)	26 (65.0%)	–	
Incomplete	13 (32.5%)	14 (35.0%)	–	

Note: Mean differences calculated for continuous variables only. *P* values calculated using unpaired t-test for continuous variables and χ^2 test for categorical variables.

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Statsmodels (Python). Descriptive statistics were used to summarize demographic characteristics, with continuous variables presented as means ± standard deviations and categorical variables as frequencies and percentages. A mixed-effects repeated measures analysis of variance (ANOVA) was conducted to evaluate the effect of time (preoperative, 1 month, and 6 months), group (hamulotomy vs no hamulotomy), and their interaction on BERA hearing thresholds. Group and time were treated as fixed effects, and patient ID as a random effect to account for within-subject variability. χ^2 tests were used for comparing categorical outcomes (eg, normal vs pathological otoscopic findings) between groups at each time point. A significance level of $P < .05$ was considered statistically significant.

Results

A total of 80 patients were included in the final analysis, with 40 patients in each group. The mean age was 32.7 ± 12.4 months, and 42 (52.5%) were male. Among the total, 53 (66.3%) had complete cleft palate and 27 (33.8%) had incomplete cleft palate. There were no statistically significant differences in baseline demographic characteristics (age, sex, cleft type) between group I (hamulotomy) and group II (no hamulotomy) ($P > .05$; Table 1). The age and diagnosis distributions are shown in Figures 1 and 2, respectively.

A mixed-effects repeated measures ANOVA was conducted to assess changes in BERA hearing thresholds over time and between the 2 groups. There was a significant main effect of time ($P < .001$), indicating overall improvement in hearing thresholds across the 3 time points. However, there was no significant main effect of group ($P = .175$) and no significant time × group interaction ($P = .940$), suggesting that the pattern of hearing improvement was comparable between patients who underwent palatoplasty with and without hamulotomy.

Group-wise means and standard deviations at each time point are shown in Table 2, and the ANOVA results are summarized in Table 3. Figures 3 and 4 illustrate the trajectory of hearing improvement and otoscopic findings, respectively.

Preoperative otoscopic examination revealed pathological findings in 69 (86.3%) ears in group I and 63 (78.8%) ears in group II. The most common finding was dull tympanic membrane, followed by tympanic membrane retraction; a few cases showed bulging of the tympanic membrane. At 1 month and 6 months postoperatively, both groups demonstrated significant improvement in otoscopic findings compared with their preoperative status ($P < .05$). Normal tympanic membrane appearance improved to 60 (75.0%) ears in Group I and 58 (72.5%) ears in Group II at 6 months. However, intergroup comparisons at all time points remained statistically insignificant ($P = .8$; Table 4).

Subgroup analysis comparing Bardach's two-flap and Veau-Wardill-Kilner pushback techniques did not reveal any statistically significant difference in postoperative hearing thresholds or middle ear status ($P > .05$). Another subgroup analysis by cleft type (complete vs incomplete) and age categories (10 to 24, 25 to 36, 37 to 48, 49 to 60 months) showed no statistically significant differences in outcomes ($P > .05$).

Postoperative complications included oronasal fistula in 3 (3.8%) patients overall—2 (5.0%) in group I and 1 (2.5%) in group II—with no statistically significant difference between groups ($P = .5$; Table 5).

Discussion

The purpose of this study was to assess the effect of pterygoid hamulotomy during palatoplasty on hearing thresholds and middle ear status in nonsyndromic cleft palate patients. We hypothesized that pterygoid

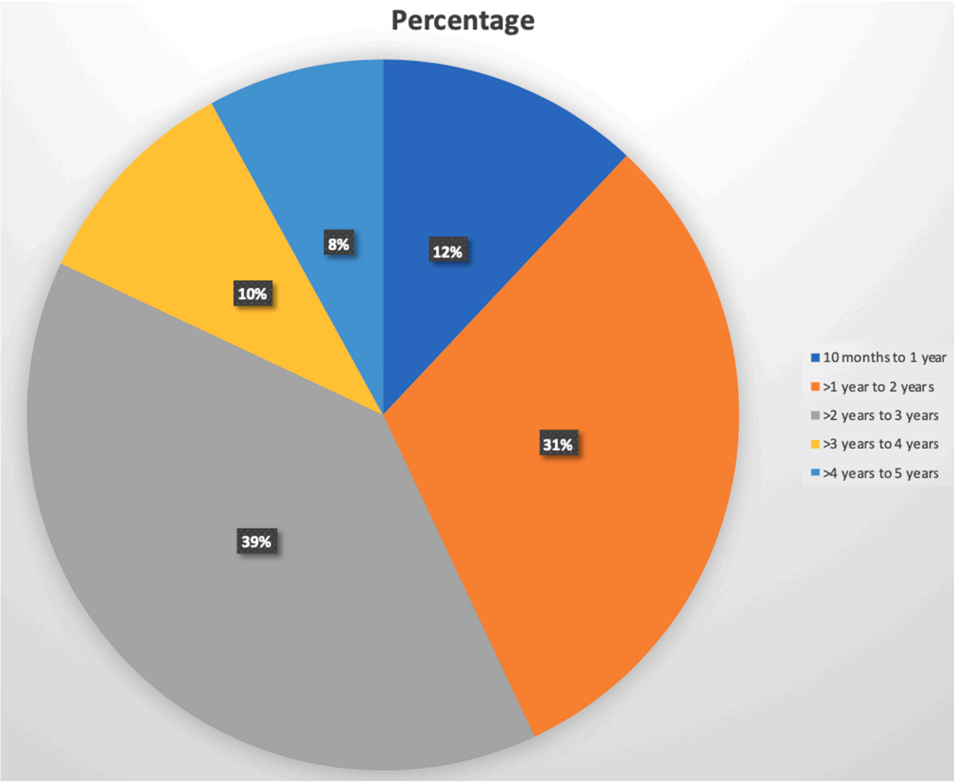

FIGURE 1. Age distribution of patients undergoing palatoplasty with and without pterygoid hamulotomy.

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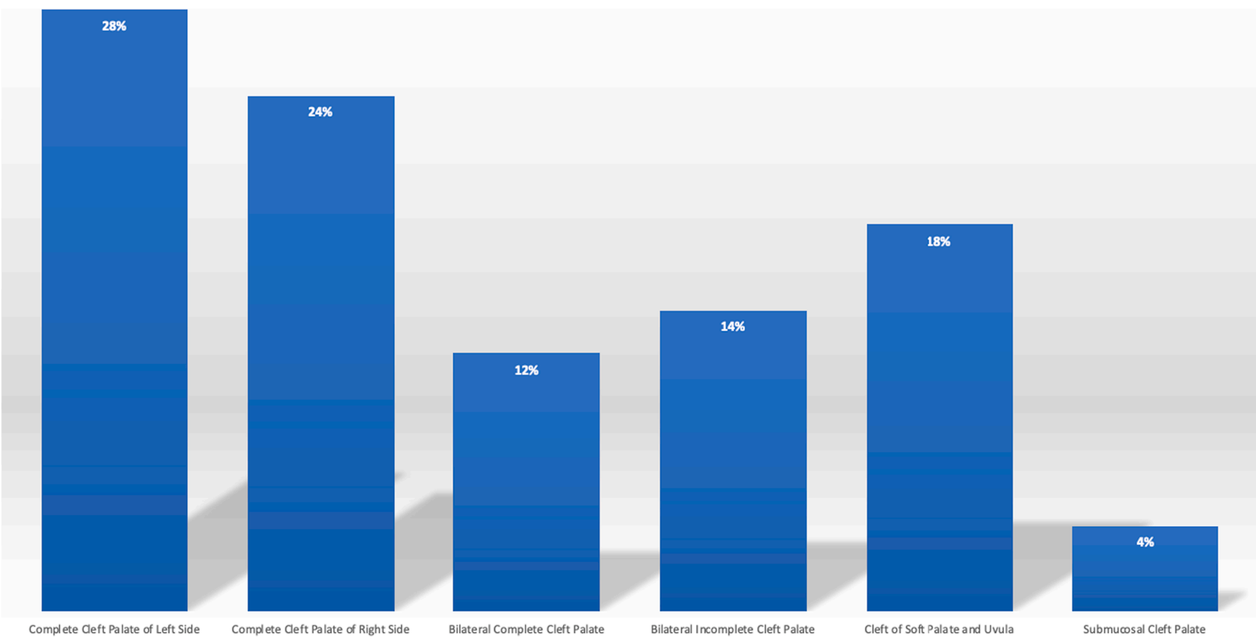

FIGURE 2. Diagnosis distribution of patients undergoing palatoplasty, showing proportions of complete and incomplete cleft palate in each group.

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Table 2. BERA HEARING THRESHOLDS OVER TIME: GROUP-WISE MEAN ± SD AT EACH TIME POINT

Time Point	Group I (Hamulotomy) Mean ± SD (dB)	Group II (No Hamulotomy) Mean ± SD (dB)
Preoperative	32.5 ± 6.4	33.1 ± 6.2
1 mo postoperative	26.4 ± 5.3	26.9 ± 5.5
6 mo postoperative	22.8 ± 4.9	23.4 ± 5.1

Note: Statistical comparisons performed using a mixed-effects repeated measures ANOVA.

Abbreviation: BERA, brainstem-evoked response audiometry.

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hamulotomy would not significantly alter postoperative hearing outcomes. The specific aims were to compare hearing thresholds and middle ear status between patients undergoing palatoplasty with and without hamulotomy. Our results showed that both groups demonstrated postoperative improvement in hearing thresholds and middle ear status, with no statistically significant differences between groups, supporting our hypothesis.

Additionally, subgroup analyses showed that the type of palatoplasty technique used—Bardach's 2-flap or Veau-Wardill-Kilner pushback—did not significantly affect postoperative hearing thresholds or middle ear status. Analyses by cleft type (complete vs incomplete) and age categories (10 to 24, 25 to 36, 37 to 48, 49 to 60 months) also revealed no significant differences in outcomes, suggesting that surgical technique, cleft type, and age category did not influence otologic results in this cohort.

The introduction of the pterygoid hamulus fracture during palatoplasty by Billroth[9] in 1889 aimed to alleviate tension and enable a tension-free closure of the cleft palate, a procedure now widely practiced. However, concerns regarding the impact of this procedure on ET function and middle ear health have been raised. Millard[10] and other researchers[11,12] cautioned against the hamulotomy procedure, citing potential adverse effects on the ET function, possibly contributing to OME and hearing impairments. Experimental animal studies have shown contradictory results. Some studies suggest that hamulotomy does not affect middle ear pressure,[13] while others note an increased incidence of middle ear effusion after the procedure.[14] Specifically, research by Chaudhari PK and Bowen-Jones E indicated that the hamulotomy did not lead to a rise in hearing loss among cleft palate patients.[15] Despite these findings, there remains a gap in the literature regarding the effect of hamulotomy on middle ear function in human cleft palate populations.

Few studies have specifically compared the effects of pterygoid hamulus fracture versus nonfracture procedures on middle ear function in cleft patients, and even fewer studies have focused on the Indian subcontinent. This lack of standardization across studies and the absence of definitive evidence led to the current investigation, aimed at addressing this gap and exploring whether pterygoid hamulotomy impacts postoperative hearing ability. This study's methodological strengths, including its prospective double-blind design, standardized assessment protocol, and focus on a homogenous cohort of nonsyndromic cleft palate patients from an Indian tertiary care setting, enhance its contribution to the existing evidence base, despite the findings aligning with previous studies.

The choice of study participants was deliberate: children aged 10 months to 5 years, diagnosed with isolated cleft palate or cleft palate with previously repaired cleft lip, were recruited. Excluding patients with isolated cleft lip was essential, as hearing issues are notably less frequent in this cohort, compared to

Table 3. MIXED-EFFECTS REPEATED MEASURES ANOVA SUMMARY

Effect	Coefficient (β)	Standard Error	Z Value	*P* Value	95% CI
Time	−5.10	0.60	−8.50	<.001	−6.28 to −3.93
Group (II vs I)	+1.49	1.10	+1.36	.175	−0.66 to +3.64
Time × Group Interaction	−0.06	0.85	−0.08	.940	−1.73 to +1.60

Note: Group = surgical technique; Time = preoperative, 1 month, and 6 months postoperative. Statistical comparisons performed using a mixed-effects repeated measures ANOVA.

Abbreviation: BERA, brainstem-evoked response audiometry.

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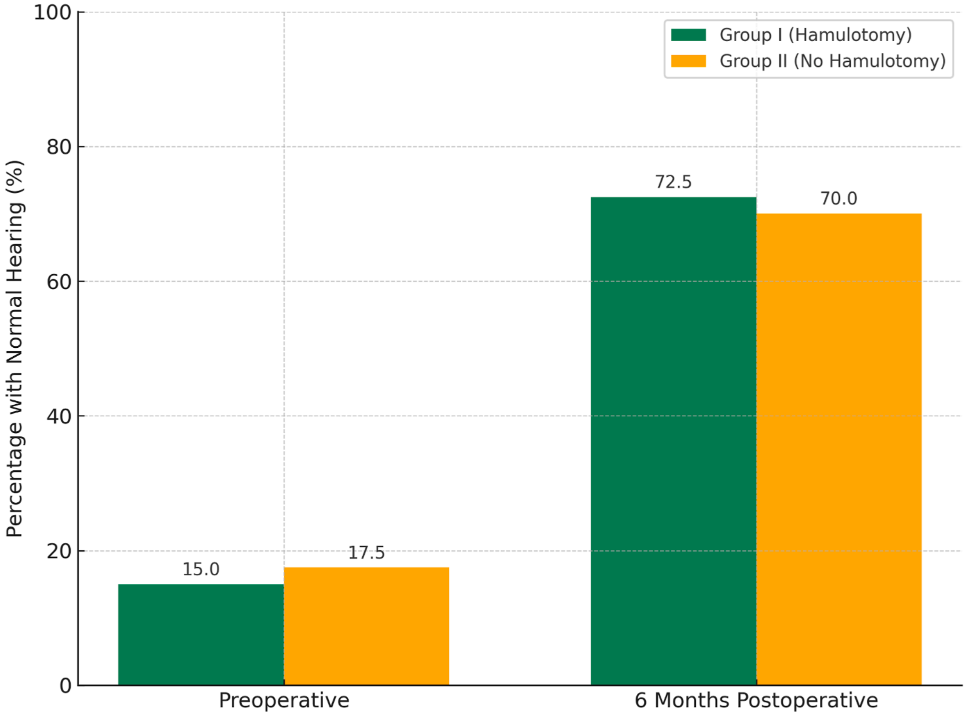

FIGURE 3. Comparison of preoperative and postoperative (6 months) BERA hearing thresholds in group I and group II. Abbreviation: BERA, brainstem-evoked response audiometry.

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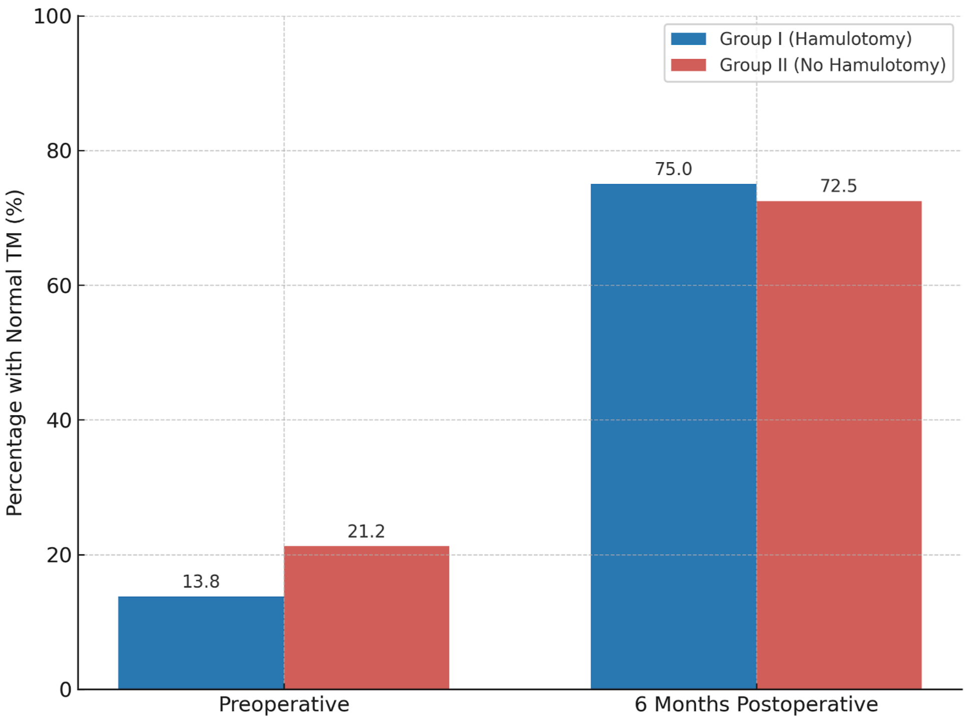

FIGURE 4. Comparison of preoperative and postoperative (6 months) otoscopic findings in group I and group II. Abbreviation: TM, tympanic membrane.

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Table 4. OTOSCOPIC FINDINGS PREOPERATIVE AND POSTOPERATIVE

Time Point	Group I: Normal TM, n (%)*	Group II: Normal TM, n (%)*	*P* Value	95% CI
Preoperative	11 (13.75%)	17 (21.25%)	.28	−6.1 to 20.1%
1 mo postoperative	34 (42.5%)	32 (40.0%)	.81	−14.3 to 19.3%
6 mo postoperative	60 (75.0%)	58 (72.5%)	.78	−11.6 to 16.6%

Abbreviation: TM, tympanic membrane.

* Values indicate number of ears with normal TM appearance (percentage of total). 95% CI indicates difference between groups. No statistically significant difference observed at any time point.

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cleft palate cases. In addition, inconsistent age groups and methodological differences across previous studies necessitated a focus on a uniform preschool-aged group for consistency in evaluation.

Conducting middle ear assessments in young children poses challenges, primarily due to their uncooperative nature. Objective tests like otoscopy and BERA are particularly useful for this age group, as subjective tests like pure tone audiometry are impractical. Tympanometry, although an effective tool, has limitations in infants and young children, further justifying the use of BERA for auditory status assessment in this study.

The results of this study showed that both groups, whether undergoing hamulotomy or not, demonstrated postoperative improvement in middle ear function. This aligns with previous researches[16-19] suggesting that palatoplasty, as a procedure, generally improves ET function and reduces OME. A mixed-effects repeated measures ANOVA revealed a significant main effect of time ($P < .001$), confirming that hearing thresholds improved significantly across all postoperative time points. However, no statistically significant group effect ($P = .175$) or time × group interaction ($P = .940$) was observed, indicating that the pattern of hearing recovery over time was similar between the hamulotomy and non-hamulotomy groups. Additionally, the type of palatoplasty technique used did not show any significant difference in postoperative hearing or middle ear status, suggesting that the choice of surgical approach did not influence otologic outcomes in this cohort.

Notably, the current findings support the conclusions of similar studies, such as those by Noone et al.[20] Kane et al[9] and Sheahan et al[21] who also observed no significant difference in middle ear function or hearing outcomes after pterygoid hamulotomy. These findings collectively suggest that pterygoid hamulotomy can be safely performed during palatoplasty without adversely affecting the middle ear function, thus ensuring tension-free closure of the cleft without additional risk for hearing loss. Although our findings align with previous reports, this study contributes new evidence from the Indian subcontinent, with a strict prospective double-blind design, exclusion of syndromic patients, and uniform BERA evaluation. These factors address limitations of heterogeneity in earlier studies and provide robust region-specific data.

Limitations of this study include the relatively small sample size, which, although powered to detect a 20% difference, may have limited the ability to identify smaller effect sizes between groups. Additionally, while allocation was done on a strictly alternating basis, true randomization using computer-generated sequences was not performed, which could introduce allocation bias. The surgeries were performed by 4 different surgeons, and although all followed a standardized protocol, surgeon variability cannot be entirely ruled out. Tympanometry was not used due to unavailability in our institution during the study period and challenges in performing the test in uncooperative young children, which may have limited comprehensive assessment of middle ear function. The exclusion of cleft lip and syndromic patients ensured sample homogeneity but may restrict the generalizability of findings to broader cleft populations. Furthermore, no postoperative imaging such as computed tomography scan was performed

Table 5. POSTOPERATIVE COMPLICATIONS BY GROUP

Complication	Group I (n = 40)	Group II (n = 40)	Risk Difference (95% CI)	*P* Value
Oronasal fistula	2 (5.0%)	1 (2.5%)	2.5% (−5.2 to 10.2%)	.5

P value calculated using χ^2 test.

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to confirm hamulotomy, and reliance on objective tests such as otoscopy and BERA alone may not fully capture the entire spectrum of hearing and middle ear status. While 6 months of follow-up allowed assessment of intermediate outcomes, long-term evaluation is essential to determine persistent otologic status and potential delayed effects of hamulotomy, which is planned in future studies. Expanding sample size, incorporating long-term auditory outcomes, using postoperative imaging verification, and employing a wider range of diagnostic tools such as tympanometry and otoacoustic emissions remain important directions for future research to strengthen generalizability, clinical applicability, and scientific contribution of these findings.

In conclusion, middle ear function improves following palatoplasty in cleft palate patients regardless of whether pterygoid hamulotomy is performed. No significant difference was observed between groups, supporting the idea that hamulotomy does not affect postoperative hearing outcomes. Therefore, pterygoid hamulotomy can be safely utilized during palatoplasty as a technique for achieving tension-free closure without detrimental effects on hearing.

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