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Chewing gum on postoperative oral Malodor in patients undergoing general anesthesia: a randomized non-inferiority trial

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Abstract

Background We aimed to determine whether preoperative chewing gum is non-inferior to Chlorhexidine (CHX) mouthwash in reducing halitosis in patients undergoing elective general anesthesia with endotracheal intubation.

Methods We conducted a randomized, single-blind, non-inferiority controlled trial involving patients undergoing surgery requiring endotracheal intubation for ≤ 3 h. Participants were randomly assigned to either the CHX mouthwash group (Group M) or the chewing gum group (Group N). Thirty minutes before general anesthesia, patients in Group M rinsed their mouths with 10 ml of CHX mouthwash, while those in Group N chewed Trident mint gum. The primary outcome was the incidence of halitosis in both groups, assessed before endotracheal intubation and at extubation.

Results A total of 733 patients were included, with 365 patients in Group M and 368 patients in Group N. The incidence of halitosis in both groups was significantly reduced compared to baseline. Before extubation, the improvement in halitosis was greater in Group N than in Group M ($P < 0.05$). After extubation, the improvement in halitosis in Group N was non-inferior to that in Group M ($Z = 1.96$, 95% *CI*: -0.0898 to 0.0944, $p = 0.0023$).

Conclusions In patients undergoing elective general anesthesia with endotracheal intubation, chewing gum was found to be non-inferior to CHX mouthwash in improving postoperative halitosis.

Trial registration Chictr.org.cn ChiCTR2400082035 (date of registration: 19/03/2024).

Keywords Halitosis, Chewing gum, CHX mouthwash, Endotracheal intubation

Introduction

Halitosis is clinically significant yet often overlooked. Epidemiological data demonstrate a 27.5% prevalence rate among individuals aged 15 to 64 years. In surgical patients, the incidence of halitosis increases significantly, with reported rates ranging from approximately 58.8–65% [1]. Beyond its characteristic malodor, halitosis can impair collagen synthesis and degradation, accelerate bone resorption, and result in periodontal tissue damage [2]. Volatile sulfur compounds (VSCs) are the primary constituents responsible for halitosis. It can be absorbed into the bloodstream and distributed to various

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organs, potentially disrupting the normal function and metabolic processes of these tissues and organs [3]. Additionally, halitosis may cause discomfort or aversion to clinicians during intubation procedures. As a result, it has increasingly become a significant concern for healthcare professionals.

CHX is the most used oral antiseptic in clinical practice. In adult patients undergoing elective general anesthesia, pre-intubation chlorhexidine oral care significantly reduces perioperative halitosis, decreasing its incidence from 58.8 to 16.7% according to epidemiological studies [4]. However, the safety of CHX continues to be a subject of debate. In addition to reports indicating an increased risk of mortality, CHX has also been linked to various adverse effects, such as staining of the oral mucosa and dental crowns, mucosal lesions, alterations in taste perception, and abnormal oral sensations [5, 6].

Chewing gum, commonly utilized as a breath freshener in daily life, has been demonstrated to effectively alleviate halitosis [7]. The study by Mayra et al. demonstrated that chewing gum can reduce or neutralize the concentration of VSCs in exhaled breath, thereby decreasing the incidence of halitosis [8]. Furthermore, preoperative chewing gum has been shown to be safe. The study by Chen et al. demonstrated that chewing gum before surgery does not alter gastric pH or volume, nor does it impact gastric emptying or increase the risk of aspiration reflux [9–12]. To the best of our knowledge, no study has yet compared the effects of CHX and chewing gum in intubated patients undergoing elective general anesthesia. Consequently, we conducted this study to evaluate the different impact of preoperative chewing gum use versus preoperative CHX use on postoperative halitosis. We hypothesized that preoperative chewing gum is non-inferior to CHX in improving postoperative halitosis in these patients.

Methods

Ethics approval and trial registration

This was a prospective, single-center, single-blind, randomized controlled trial approved by the Medical Ethics Committee of Jinling Hospital, affiliated with the Medical School of Nanjing University (approval number: 2024DZKY-023-01, Registration Date: 29/01/2024), and registered with the Chinese Clinical Trial Registry (registration number: ChiCTR2400082035, Registration Date: 19/03/2024). All patients and their families signed an informed consent form before surgery. All study procedures were conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. This study adheres to the CONSORT guidelines for reporting clinical trials.

Patient inclusion and exclusion criteria

The inclusion criteria were as follows: (1) intubated patients undergoing elective general anesthesia with an expected intubation duration of ≤ 3 h; (2) age between 18 and 65 years; and (3) patients with American Society of Anesthesiologists (ASA) physical status I, II, or III.

The exclusion criteria were: (1) patients with a known allergy to CHX or chewing gum; (2) patients with a recent history of using medications that affect breath odor, including acetaminophen, anti-allergy drugs, or chemotherapy agents; (3) patients with a history of smoking, dental caries, periodontal disease, oral ulcers, poor oral hygiene, or oral infections; (4) patients who were unconscious or currently participating in other clinical trials; (5) patients for whom the endotracheal tube could not be removed post-surgery; and (6) patients who undergo gastrointestinal, oral, otolaryngological, or cardiothoracic surgery.

Sample size calculation

Research indicates that CHX mouthwash can reduce the incidence of halitosis by 71.6%, decreasing from 58.8 to 16.7% [4]. In this context, we set the non-inferiority margin at -0.10, employed a 1:1 allocation ratio, and conducted a one-sided Z-test with 90% power and an alpha level of 0.05. Using PASS 15.0.5 software, we determined that 353 patients were required per group. To account for a 10% dropout rate, a total of 392 patients per group was needed at least; therefore, 787 patients were ultimately included for analysis in this study.

Randomization and blinding

Eligible patients will be randomly allocated to Group M or Group N after baseline data collection. The randomization sequence will be generated by an independent statistician using computer software (SAS 9.4) and concealed until intervention assignment. Patients cannot be blinded due to the inherent nature of the intervention. However, outcome assessors and data analysts will remain blinded to group allocation throughout the study.

Test design

24 h before the procedure, we collaborated with the surgical team to estimate the anticipated operative duration, screened for eligible patients meeting the inclusion criteria. Then, we documented demographic and clinical data including age, sex, height, weight, ASA physical status classification, and admitting department. On the surgery day, a standardized halitosis assessment was conducted prior to any intervention after the patient entered the operating room immediately. This assessment comprised two components: (1) a sensory evaluation performed by a trained anesthesiologist using a 0–5 organoleptic scale, and (2) quantitative measurement of volatile

sulfur compounds (VSCs) using a portable sulfide monitor (Halimeter), administered by an anesthesia nurse. Concurrently, a second anesthesiologist documented tongue coating characteristics (area and thickness) and the dental plaque index (using a standardized plaque scoring system). All assessments were performed independently to ensure blinding, and data were recorded in a secure electronic database.

30 min prior to surgery, patients in Group M used 10 ml of CHX mouthwash (Jiangsu Chenpai Bond Pharmaceutical Co., Ltd., YBH28282005), while patients in Group N chewed Green Arrow Mint Gum (Wrigley Sugar Co., Ltd.) for 10 min before expectorating it. Subsequently, a second halitosis assessment was performed before anesthesia induction, which included both a sensory evaluation and breath detector measurement. The halitosis status and fasting time were recorded. Following this, all patients underwent endotracheal intubation under general anesthesia performed by the same anesthesiologist, who was blinded to the group allocation.

After the procedure, the patient was transferred to the Post-Anesthesia Care Unit (PACU) for postoperative recovery. The patient's recovery status was continuously monitored and evaluated until the endotracheal tube was removed. The tube was removed once the patient met the extubation criteria. Immediately following extubation, the third halitosis assessment was conducted using both a sensory evaluation and a breath detector. The post-extubation halitosis status and extubation time were recorded.

Evaluation of halitosis

Halitosis was assessed using a combination of organoleptic evaluation and a portable sulfide monitor. If both evaluations were negative, the outcome was recorded as negative. If either evaluation was positive, the outcome was recorded as positive. Organoleptic evaluation involved assessing the mouth air by a trained evaluator (NCPR). The participant was instructed to count to 10 while the evaluator's nose was positioned approximately 20 cm from the participant's mouth. Scoring was performed on a scale from 0 to 3 points [13]:

- 0 points: no halitosis;
- 1 point: barely perceptible halitosis;
- 2 points: mild but noticeable halitosis;
- 3 points: severe halitosis.

A score of 2 points or higher is considered indicative of halitosis.

Halimeter

The portable sulfide monitor (Halimeter; INTERSCAN, USA) is used to measure the concentration of VSCs in the oral cavity [14]. The measurement process is as follows:

Calibration

Before each measurement session, the instrument is calibrated using ambient air to establish a zero-point reading. This ensures accurate baseline measurements.

Measurement Procedure

During the measurement, the tester inhales deeply through the nose and exhales through a straw into the device. The exhaled air from the mouth is directed into the instrument, where a pump draws in the sample.

Data collection

The instrument quickly analyzes the sample and displays the reading. The highest value appears within a few seconds, and then the reading gradually stabilizes. The measurement is taken in parts per billion (ppb).

Repetition and averaging

Three separate measurements are taken for each subject, and the average value of these readings is recorded. Halitosis is defined as a VSC concentration greater than 150 ppb.

Standardization

The measurement process adheres to a standardized protocol to ensure consistency among all patients. The tester performs the identical inhalation and exhalation procedure, and that the instrument is accurately calibrated prior to each use. Additionally, the equipment undergoes regular checks for calibration and accuracy, according to manufacturer recommendations.

The area and thickness of the tongue coating

The tongue coating score is calculated using a modified version of the Rosenberg system. It is assessed by trained dental hygienists. The scoring criteria considers both the coverage area and the thickness of the tongue coating.

Area score

- 0 points: no tongue coating.
- 1 point: less than 1/3 of the tongue is covered by coating.
- 2 points: 1/3 to 2/3 of the tongue is covered by coating.
- 3 points: more than 2/3 of the tongue is covered by coating.

Thickness score

- 0 points: no tongue coating.
- 1 point: thin coating, with the tongue papillae clearly visible.
- 2 points: medium coating, with the tongue papillae partially obscured.
- 3 points: thick coating, with the tongue papillae completely covered.

All assessments are performed by professionally trained dental hygienists and subsequently reviewed by senior dental professionals to ensure consistency and standardization [15].

Plaque index (PLI)

Plaque assessment was conducted using a standardized plaque scoring system and was performed by professionally trained dental hygienists. The scoring criteria are as follows:

- 0 points: no plaque on the tooth surface.
- 1 point: scattered dot-shaped plaque at the gingival margin of the cervical area.
- 2 points: continuous narrow band-shaped plaque at the cervical area of the tooth, with a width no greater than 1 mm.
- 3 points: plaque covering more than 1 mm but less than 1/3 of the tooth surface.
- 4 points: plaque occupying 1/3 to 2/3 of the tooth surface.
- 5 points: plaque covering more than 2/3 of the tooth surface.

All assessments were performed by trained PACU and reviewed by experienced dental professionals to ensure the consistency and standardization of scoring [16].

Statistical analysis

All analyses were performed using the statistical software packages R 4.4.1 (R Core Team, Vienna, Austria) and GraphPad Prism (version 9.5.1). Normally distributed quantitative variables were expressed as mean ± standard deviation (SD) and compared using the Student's t-test. Non-normally distributed data were presented as median or interquartile range (IQR) and compared using the Mann-Whitney U test. Categorical data were presented as frequencies (N) and percentages (%), with differences analyzed using the χ^2 test or Fisher's exact test. Non-inferiority was assessed using the 95% confidence interval (CI), with a lower limit of > -10%. Generalized estimating equations (GEE) were employed to analyze changes across different time points, and $P < 0.05$ was considered statistically significant.

Results

Initially, 784 patients were recruited for this study. Prior to surgery, 5 patients were excluded for refusing to participate, and 1 participant was excluded for not meeting the inclusion criteria, leaving 778 patients (389 patients in each of the CHX and chewing gum groups). Additionally, in the CHX group, there were 18 patients excluded due to the catheter remaining in place for > 3 h post-tracheal intubation, 1 patient excluded due to delirium, and 2 patients without extubated, resulting in 365 patients. In the chewing gum group, there were 22 patients excluded for the catheter remaining in place for > 3 h post-tracheal intubation, 1 patient excluded due to delirium, and 1 patient without extubated, resulting in 368 patients (Fig. 1). Consequently, 733 patients were included in the final analysis (365 in the CHX group and 368 in the chewing gum group). There were no significant differences between the two groups in general characteristics and oral indicators ($p > 0.05$) (Table 1).

According to the results of the generalized estimating equation (GEE) analysis, oral malodor before intubation and extubation was significantly reduced compared to baseline in both groups. It is indicated that both interventions effectively alleviated oral malodor. Prior to intubation, the improvement on oral malodor in the chewing gum group was significantly greater than that in the CHX group, with statistical significance. No statistically significant difference was observed in the improvement rates between the two groups at the time of extubation (Table 2; Fig. 2).

The non-inferiority margin was set at -10%, as indicated by the red dotted line. According to the results, the chewing gum group was non-inferior to the CHX group in improving halitosis ($Z = 1.96$, 95% *CI*: -0.0898 to 0.0944, $p = 0.0023$) (Fig. 3).

Discussion

Our study aimed to compare the effects of preoperative chewing gum and CHX on halitosis in patients undergoing general anesthesia with endotracheal intubation for ≤ 3 h. Our primary finding was that both chewing gum and CHX significantly reduced the incidence of postoperative halitosis, and the efficacy of chewing gum is non-inferior to that of CHX. Furthermore, we observed that preoperative chewing gum use prior to endotracheal intubation demonstrated a greater reduction in halitosis compared to CHX. No significant complications were reported in either group. It is indicated that preoperative chewing gum use is both safe and effective for patients undergoing elective general anesthesia with intubation. This study represents the first comparison of the effects of chewing gum and CHX in intubated patients undergoing elective general anesthesia surgery.

Halitosis is caused by mixture of breath with malodorous compounds emanating from different areas of the respiratory and upper digestive tracts [17]. This study found that the incidence of halitosis in surgical patients was 60%, which is higher than the commonly reported 50% [14]. This increased incidence can be attributed to several factors: First, the subjects underwent 8 to 10 h of fasting, which resulted in reduced salivary secretion and elevated oral pH, fostering the growth of Gram-negative bacteria and increasing of the production of VSCs [10]. Second, the unfamiliar environment of the operating room may induce increased psychological stress, which

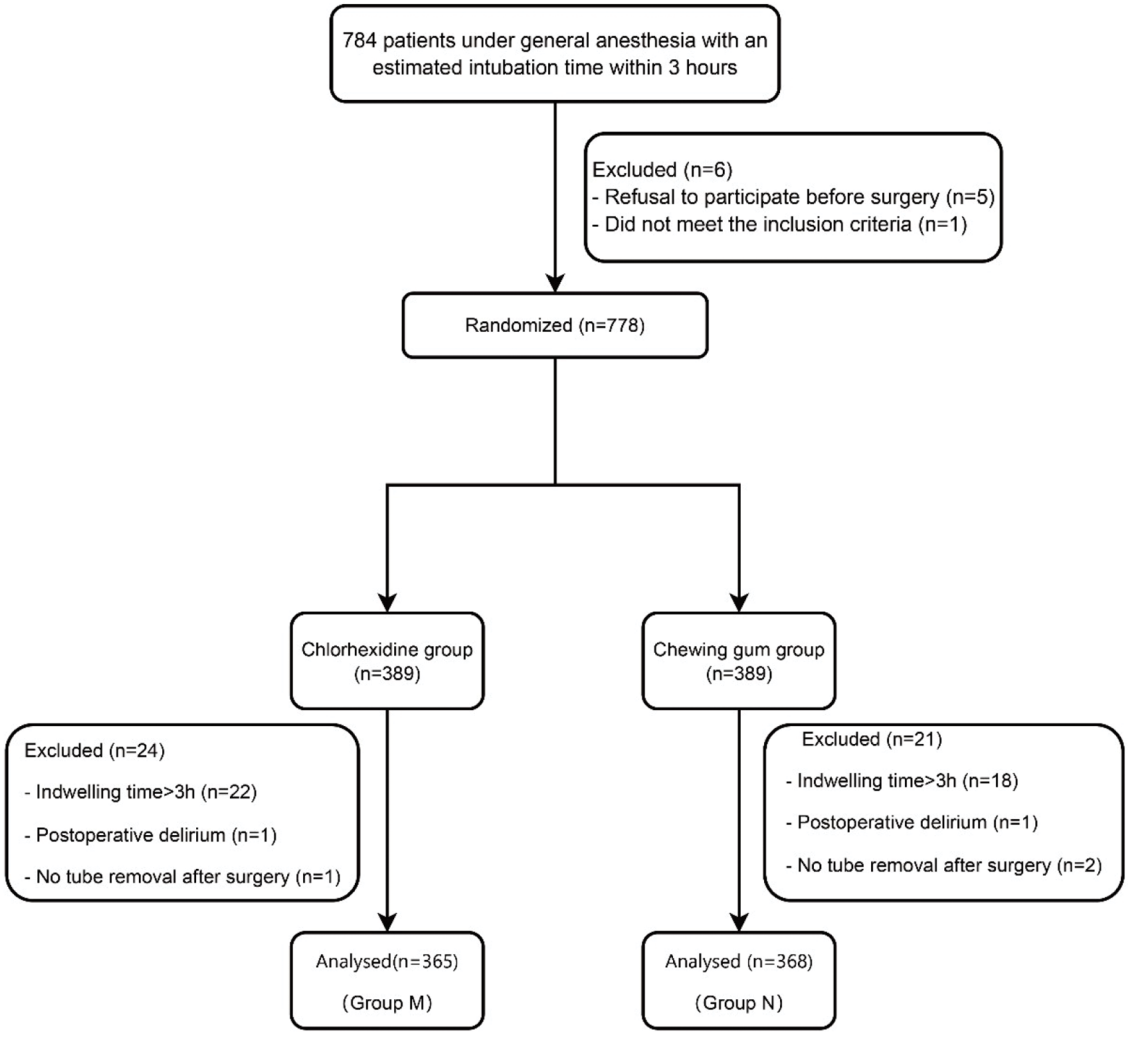

Fig. 1 Study flow chart of the screening process

can further elevate the incidence of halitosis. This is consistent with the study by Miho et al., who found that social anxiety is a major cause of halitosis [18]. Lastly, the incidence of halitosis is exacerbated by reduced salivation and heightened microbial metabolic activity during nighttime [19]. This is also a key consideration in our study. The high incidence of halitosis not only affects patient health but also causes discomfort and disgust among clinicians during intubation, warranting our attention [11].

In our study, the patients' basic characteristics and scores were similar, with no statistically significant differences between the observed values. We included the tongue coating area and thickness, as well as the dental plaque index, as preoperative observation indicators, because both are important factors contributing to halitosis [3, 15, 20]. Additionally, we selected patients whose time from endotracheal intubation to extubation was within 3 h, primarily to standardize the study. This approach is similar to the exploratory study on halitosis conducted by Ken et al., and helps to avoid baseline variability issues often encountered in long-term clinical studies [21].

CHX is effective in eliminating various types of bacteria and provides long-lasting antibacterial effects. Thus, it becomes a popular oral care agent in clinical practice for reducing halitosis [3–6]. However, it is associated with certain adverse reactions, including allergic responses, oral burning sensations, and a bitter taste. These issues have driven the development of alternative oral cleansers, such as nutmeg mouthwash, a herbal-formulated mouth rinse, and a green tea-based mouth rinse [22–24]. Despite their potential, these alternatives often face challenges, such as limited availability, high costs, and inconvenience of use, which hinder their widespread adoption in clinical practice.

Chewing gum before surgery is considered safe. Both the American Society of Anesthesiologists and the

Table 1 Patients' general characteristics and oral-related indicators

Group	Group M(*N* = 365)	Group *N* (*N* = 368)	*p*-value
Age, years	46.2 ± 12.9	46.6 ± 12.4	0.685
Height, cm	167 ± 8.53	166 ± 9.36	0.173
Weight, kg	70.6 ± 12.9	69.6 ± 12.7	0.307
BMI, kg/m^2	25.1 ± 3.78	24.9 ± 3.28	0.327
Fasting Time, hours	8.94 ± 0.370	8.97 ± 0.410	0.255
Intubation time, hours	2.24 ± 0.342	2.27 ± 0.392	0.414
Dental plaque index	1.17 ± 0.967	1.18 ± 0.979	0.865
Tongue coating area	0.956 ± 0.854	0.861 ± 0.781	0.117
Tongue coating thickness	0.978 ± 0.895	0.905 ± 0.828	0.251
Sex [n (%)]			0.3207
Male	181 (49.6)	168 (45.7)	
Female	184 (50.4)	200 (54.3)	
ASA physical status [n (%)]			0.1791
I	144 (39.5)	170 (46.2)	
II	202 (55.3)	182 (49.5)	
III	19 (5.21)	16 (4.35)	
Department [n (%)]			0.5985
Orthopedics	158 (43.3)	157 (42.7)	
Urology	104 (28.5)	102 (27.7)	
Neurosurgery	33 (9.04)	24 (6.52)	
Thyroid and Breast Surgery	25 (6.85)	31 (8.42)	
Gynecology	27 (7.40)	37 (10.1)	
Burns and Plastic Surgery Department	18 (4.93)	17 (4.62)	

BMI, Body Mass Index; Fasting time, The time from the last meal to the start of anesthesia; Intubation time, the duration from intubation to extubation; ASA, American Society of Anesthesiologists

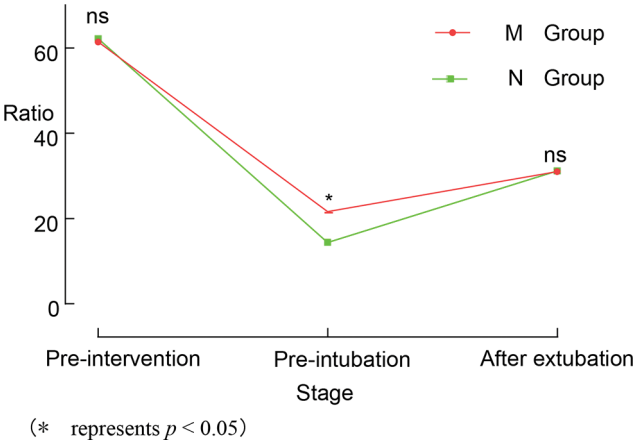

Fig. 2 Line chart of oral odor incidence in the two groups at different time points

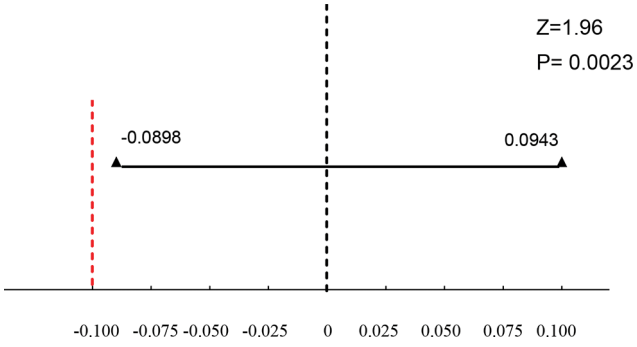

Fig. 3 Non-inferiority test

European Society of Anesthesiologists have stated that chewing gum prior to surgery has minimal impact on gastric volume and pH, and that there is no need to delay elective procedures requiring general anesthesia [25, 26]. The effect of chewing gum on halitosis is relatively modest, primarily due to the ingredients in the gum. Sugarless chewing gum may even increase VSCs [27]. Studies have shown that chewing gum containing zinc acetate, magnolia bark extract, eucalyptus extract, probiotic bacteria, and xylitol can improve oral hygiene and reduce VSCs in the mouth [28–31]. In our study, we used chewing gum containing mint, which is more commonly used in daily life. The mint flavoring in the gum has antibacterial, antioxidant, and odor-masking properties, effectively reducing the concentration of VSCs in the mouth and decreasing the incidence of halitosis [7, 8, 32, 33]. As acceptance of medicated chewing gum continues to rise, its use in clinical practice has gradually gained popularity. In addition to its pleasant taste and refreshing mouthfeel, medicated chewing gum offers a variety of health, nutritional, and cognitive benefits [34]. Furthermore, chewing gum can also reduce preoperative anxiety, promote intestinal recovery, and alleviate thirst discomfort [35–37].

Our study had certain limitations. It was a single-center randomized controlled trial, limited to general anesthesia with endotracheal intubation and a tube-in-tube duration

Table 2 The relationship between the changes in the oral odor ratio between the two groups at different periods

Variables	Estimate	Std.err	Wald	Pr(>|W|)
Pre-intubation vs. Pre-intervention	-1.21733	0.38006	10.259	$p < 0.05$
After extubation vs. before intervention	-1.24215	0.34886	12.678	$p < 0.05$
Comparison between groups before intervention	0.03636	0.15204	0.057	0.81099
Comparison between groups before intubation	-0.5321	0.24762	4.618	$p < 0.05$
Comparison of extubation time between groups	-0.02278	0.22042	0.011	0.91769

Pre-intervention, prior to the administration of chewing gum or chlorhexidine mouthwash; Pre-intubation, after the intervention but before the induction of anesthesia and endotracheal intubation; After extubation, at the time of endotracheal tube removal following surgery; Extubation time, Time from intubation to extubation

of less than 3 h. This may limit its applicability to longer procedures. The study primarily focused on the incidence of halitosis. It did not assess its severity or the impact of interventions on oral bacterial community composition. Additionally, while efforts were made to control for confounding factors, comorbid conditions that may influence oral odor (diabetes, kidney disease, and cirrhosis), as well as patients' dietary habits (e.g., consumption of garlic, alcohol, or high-fat foods), were not fully considered. The effects of these factors should be explored further in future studies.

Conclusions

Preoperative chewing gum effectively reduced postoperative halitosis in intubated patients, showing non-inferior efficacy to CHX and offering a convenient, low-cost alternative. Future studies should explore its impact on oral microbiota and its use in longer surgical procedures.

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Author contributions
All authors reviewed the final manuscript and approved it. Baohua Zhang registered, collected, and analyzed the data and wrote the main manuscript text. Yang Han collected data, helped within the design of the study, and wrote the abstract. Huan He prepared the tables and figures, helped with the study design, and wrote the review and edited the manuscript. Lidong Zhang, Li Jin supervised the study, analyzed the data, and helped with the study design.

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Data availability
The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study has been reviewed by the Ethics Committee of Jinling Hospital, affiliated with the Medical School of Nanjing University (2024DZKY-023-01, Registration Date: 29/01/2024) and submitted to the Chinese Clinical Trial Registry (Registration number: ChiCTR2400082035, Registration Date: 19/03/2024). All study procedures were carried out in accordance with the ethical standards of the Helsinki Declaration. All patients and their families signed an informed consent form before surgery.

Consent for publication
Not applicable.

Writing process
Authors did not use AI in the writing process of this research.

Competing interests
The authors declare no competing interests.

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