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Prevention of Nasal Ala Pressure Injuries With Use of Hydroactive Dressings in Patients With Nasotracheal Intubation of Orthognathic Surgery

A Randomized Controlled Trial

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ABSTRACT

PURPOSE: To compare a hydroactive dressing to an adhesive tape standard of care in the prevention of nasal ala pressure injuries associated with nasotracheal intubation during orthognathic surgery.

DESIGN: Randomized controlled trial.

SUBJECTS AND SETTING: The study took place in a tertiary hospital of stomatology in China. Patients undergoing general anesthesia with nasotracheal intubation during orthognathic surgical procedures were invited to participate.

METHODS: Participants were divided into 2 groups: in the experimental group, a hydroactive dressing was applied to the nasal ala before the surgical procedures; the control group received standard prevention with a type of tape. Skin assessments were performed on the wards up to 72 hours after the procedures. Demographic information and potential contributing factors associated the development of nasal ala pressure injuries were collected from patients' electronic medical records. Pressure injury development was staged using National Pressure Injury Advisory staging guidelines. Pressure injury incidence was compared between groups using the χ^2 test and odds ratio.

RESULTS: The sample comprised 450 participants, 225 in each group. The incidence of nasal ala pressure injuries development was 14.222% and 4.444% in the 2 groups, respectively ($P = .000$). The odds ratio was 3.565 (95% confidence interval, 1.707-7.443).

CONCLUSIONS: The study findings indicate that the incidence of pressure injuries of nasal ala skin protected by hydroactive dressings was lower than the standard preventive method. Hydroactive dressings should be considered as a prevention method to reduce device-related skin injuries associated with nasotracheal intubation.

KEY WORDS: Hydroactive dressing, Medical device-related pressure injury, Nasal ala, Nasotracheal intubation, Pressure ulcer, Prevention.

Orthognathic surgery is a surgical procedure for the treatment of dental and maxillofacial deformities, and for correcting upper and lower jaws and facial morphological abnormalities. The most commonly used surgical techniques nowadays are 3 osteotomies, Le Fort I maxillary osteotomy, bilateral mandibular sagittal split osteotomy, and genioplasty osteotomy. Orthognathic surgery is an intraoral approach requiring temporary intermaxillary fixations repeatedly. In order to ensure the patient's intraoperative airway patency, to avoid affecting the surgeon's operation and to ensure minimal impact on the intraoperative observation of the facial profile, intraoperative airway maintenance requires the use of a preformed contoured nasotracheal tube.[1] At present, in our hospital, the method of intubating the nasotracheal tube is to fix the nasotracheal tube to the nasal ala with white adhesive plaster and firmly fix the connector part of the tube to the dressing surrounding the patient's forehead. The prolonged pressure to the nasal ala by the reverse point of the nasotracheal tube is prone to pressure injury (medical device-related pressure injury).[2-4] Medical device-related pressure injury refers to pressure injury that results from the use of devices designed and applied for diagnostic or therapeutic purposes, in this case, to maintain respiratory function during surgical procedures.

The visible part of the nose, external nose, is located in the center of the face and is an important sign for judging one's appearance. The slight defect of the nasal ala will influence the appearance of the face. The nasal ala is the lateral surface of

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the external nose. The skin of the nasal ala is thick and closely connected with the subcutaneous tissue, connective tissue, and cartilage tissue. The subcutaneous tissue is relatively thin, so it is difficult to reconstruct after damage. For orthognathic surgery patients who are looking for better face features, damage to the skin of the nose is difficult to accept. However, conventional materials for preventing pressure injuries are difficult to implement because the material is heavy, making it hard to adhere to the nose, possibly influencing the surgical procedure.

The purpose of this study was to compare the incidence of nasal ala pressure injury between the experimental group, receiving a hydroactive dressing on the nasal ala of patients undergoing orthognathic surgery to protect the skin, and the control group under the standard preventive methods.

METHODS

We conducted a prospective, double-blind, parallel-group randomized controlled trial. The study setting was the operating room (OR), postanesthesia care unit (PACU), and surgical ward of Peking University School and Hospital of Stomatology (PKUSS), Beijing, China, the largest center of orthognathic surgery in the world. Patients undergoing orthognathic surgery from November 2016 to September 2017 were invited to participate if they met the following inclusion criteria: (1) received all of the 3 surgical procedures including Le Fort I maxillary osteotomy, bilateral mandibular sagittal split osteotomy, and or genioplasty osteotomy; (2) older than 17 years; and (3) male and female sex. Exclusion criteria were: (1) patients with nasal ala lesions; (2) patients with severe skin allergies; and (3) patients with poor nutritional status such as diagnosis of anemia or hypoalbuminemia.

This study's procedures were reviewed and approved by the PKUSS institutional review board (approval number: PKUSSIRB-201629071). When a potentially eligible participant was identified by the nurses working in the orthognathic surgery wards, the principal investigator (G.Y.) approached the patient and described the study, and if interested, an informed consent form in Chinese was provided for review and discussion. If the patient agreed to participate, the principal investigator and the patient signed the consent form in duplicate and each held one copy.

Sample Size

For sample size determination, we estimated a 4% incidence of pressure injury in the experimental group and 11% in the control group. These figures were based on data obtained from our hospital records, which were recorded during the 2 years prior to the conduct of our study. We considered a reduction of 7% in pressure injuries to be statistically significant; thus, a sample size of 438 (219 per arm) was required to detect this difference with $\alpha = .5$ and power = 80%. Considering 3% to 5% of patients lost to follow-up during hospitalization time due to early discharge or transfer, the total sample size was 450 patients.

Randomization

According to the sequence of the surgical procedures, patients were randomly assigned to the experimental or control group using a 1:1 allocation sequence generated by the principal investigator via the RAND function in Microsoft Excel software. If there were 2 or more procedures that started at the same time, the OR number determined the sequence. The random number was sealed in an envelope not opened until before the surgery procedure started.

Double Blinding

Because the nasotracheal tube and hydroactive dressing used in the procedure were applied after anesthesia induction and consciousness was lost, participants were unaware of group assignment. After the tube and hydroactive dressing were removed in the PACU, the participant remained unaware of group assignment. After PACU discharge, ward nurses were also unaware of whether participants received the hydroactive dressing. The ward nurses then conducted the assessments for development of nasal ala pressure injuries during the remainder of hospitalization. Thus, the main observers (nurses) and participants were both "double" blinded from knowing to which group they were allocated.

Instruments

We designed a case report form upon which demographic information such as sex and age, pertinent clinical data, and factors that may be related to the development of nasal ala pressure injury, such as Braden Scale scores (the last evaluation performed by the ward nurse before surgery), were recorded. We also included operative time (time 1, refers to the time from the induction of anesthesia until the end of the procedure), intubation retention time (time 2, refers to the time from anesthesia-induced intubation to tracheal tube removal),[5] the amount of intraoperative bleeding (mL), and the American Society of Anesthesiologists (ASA) Physical Status Classification System grading score (ASA is scored from 1, a normal healthy patient, to 6, declared a brain dead patient).[6] The ASA class was included because it is helpful in predicting perioperative risk, evaluated by the anesthesiologist, and recorded on the anesthesia record sheet. Other data such as body mass index (body mass index, kg/m^2), and blood test results such as albumin and hemoglobin (selected from the results of the most recent laboratory test before surgery), were collected due to their influence, or reflection of the patient's nutritional status. Low nutritional status is a risk factor for pressure injury.

The primary outcome measure was nasal ala pressure injury associated with nasotracheal intubation assessed with the 2014 staging guidelines from the National Pressure Ulcer (Injury) Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance and in the 2016 NPUAP Staging Consensus Conference.[7] We anticipated most pressure injuries would be stage 1 nonblanchable erythema or stage 2 partial-thickness loss of skin with exposed dermis and would be visible within 3 days of removal of tracheal intubation, the length of data collection. Two ward nurses together assessed each participant after transfer from the PACU to the ward and every 2 hours (first 24 hours after the procedure) to 4 hours (48 hours after) until 72 hours after procedures and took photographs when a pressure injury was suspected. If there were inconsistencies between the 2 nurses, one of the investigators (J.C.) would review the patient and photographs. When the 3 nurses' opinions were discrepant and a decision could not be made about the presence or stage of the potential pressure injury, members of the Pressure Injury Management Group of the hospital were consulted.

Study Procedures

The control group received standard pressure injury preventive measures. After the rapid sequence induction and intubation, we placed a type of medical adhesive tape (Jiaozuo League Hygiene Group Co, Ltd, Jiaozuo, Henan, China) to the nasal ala to which the nasotracheal tube was affixed, which was then

inserted into the connection tubing. This tubing was placed on the midline of the forehead, secured with a cloth dressing wrapped around the head to prevent skin damage from friction, and adjusted to make sure the nasotracheal tube was not pulling against the ala. The surgical site was then disinfected and the procedure began.

In the experimental group, we used the hydroactive dressing (DermaPlast Hydro #5353672, Paul Hartmann AG, Germany). The dressing is spindle-shaped with a length of about 40 mm and a width of about 17 mm at its widest point. One side of the dressing has adhesive properties and can be easily bonded to the skin of the nose without trimming. Prior to its application, the nasal ala was cleaned with a 70% isopropyl alcohol pad; the dressing was applied with 20 seconds of gentle pressure to assure it was properly bonded and to make sure it covered at least 10 mm of nasal mucosa and skin of the nasal ala. After assuring a proper seal, the nasotracheal tube was fixed to the dressing (Figure 1). All the hydroactive dressing applications for study participants were performed by G.Y. After the procedure ended, participants were sent to the PACU where the tube, tape, or dressing was removed after the participant's condition was deemed stable, and transported to the surgical ward.

Data Collection and Management

Assessment of the nasal ala skin was performed and recorded by ward nurses every 2 hours (first 24 hours after the procedure) to 4 hours (48 hours after). If nasal ala pressure injury occurred at any time during the 72-hour study period, they were considered related to the nasotracheal intubation; if not, the observation ended. All the 14 ward nurses were formally trained by C. G. and J. C. in the diagnosis and stages of the pressure injury, the research procedure, and how to fill out the data collection form. Fidelity to the protocol was assessed every 2 weeks on 6 to 8 participants by a quality control group, which was composed of 6 senior nurses and nurse managers who worked in the OR, PACU and surgical wards.

Data Analysis

All data were inputted using Epidata 3.1 software (EpiData Association, Odense, Denmark). Data were analyzed using SPSS statistical software version 20.0 (Statistical Package of Social Sciences, Armonk, New York). Descriptive data were summarized using means and standard deviations for continuous variables, and counts and percentages for categorical variables. Inferential analyses of continuous variables were first assessed for normality. Independent *t* tests were used to compare the groups if the continuous data were normally distributed. If not, the Wilcoxon rank sum test was employed. For categorical variables, χ^2 tests were performed. *P* values $< .05$ were deemed statistically significant.

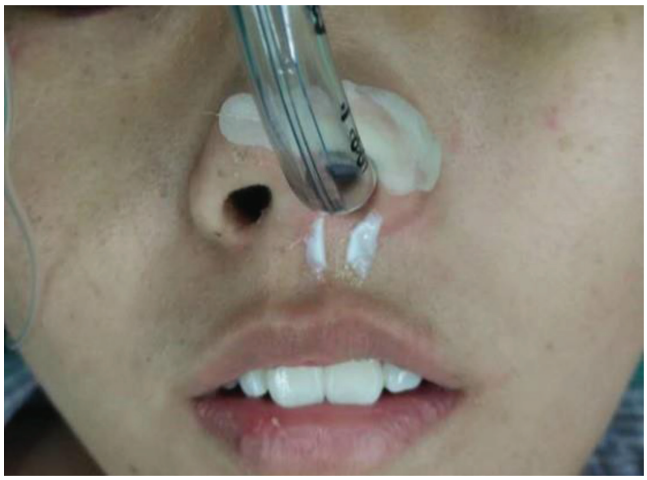

Figure 1. Hydroactive dressing in the surgical procedure.

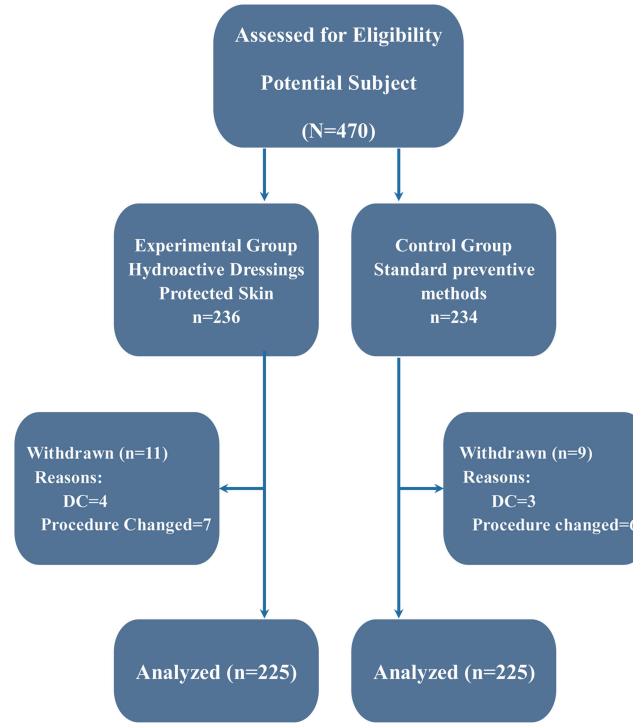

Figure 2. Flowchart.

RESULTS

Figure 2 shows the number of patients approached, consented, and recruited; 450 completed the study. Participants' characteristics are summarized in Table 1. The average age of the sample was 24.36 ± 5.37 years in the control group and 24.15 ± 5.20 years in the experimental group. Females comprised 65.3% (n = 147) of the control group and 68.0% (n = 153) of the experimental group.

In the control group, ASA class 1 comprised 90.2% (n = 203) of the total sample and ASA class 2 comprised 9.8% (n = 22); in the experimental group, 89.8% (n = 202) were ASA class 1 and 10.2% (n = 23) class 2. None were class 3 or higher. The average operative time was 3.93 ± 1.14 hours in the control group and, similarly, 3.95 ± 1.20 hours in the experimental group. For intubation time, the control and experimental groups were 5.54 ± 3.28 hours and 5.81 ± 3.14 hours, respectively. The average amount of intraoperative bleeding was 277.38 ± 119.56 mL in the control group and 294.84 ± 114.58 mL in the experimental group. All 450 participants' Braden Scale scores were 24, which suggests no pressure injury risk before surgery. There were no statistical significances noted in these demographic characteristics between the groups.

Participants in the experimental group had a significantly lower incidence of pressure injury development compared to the control group (4.4% vs 14.2%, $\chi^2 = 12.71$, $P = .000$, odd ratio 3.565, 95% confidence interval 1.71-7.44) (Table 2).

TABLE 1.
Patient Characteristics and Surgical Related Data (N = 450)

Group	Control n = 225 Mean ± SD	Experimental n = 225 Mean ± SD	*t* Test/χ^2 Test	*P* Value
Age, y	24.36 ± 5.373	24.15 ± 5.209	0.410	.682
Bleeding, mL	277.38 ± 119.563	294.84 ± 114.576	1.582	.114
Albumin, g/L	43.97 ± 3.990	44.50 ± 3.500	1.561	.119
Hemoglobin, g/L	136.63 ± 16.600	136.92 ± 14.881	0.197	.844
BMI, kg/m^2	21.35 ± 3.218	21.01 ± 2.924	1.203	.230
Time 1, h	3.925 ± 1.142	3.952 ± 1.200	0.241	.810
Time 2, h	5.54 ± 3.282	5.81 ± 3.144	0.888	.375
Sex				
Male	78	72	0.360	.549
Female	147	153		
ASA class				
1	203	202	0.025	.875
2	22	23		

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index ; Time 1, operative time; Time 2, intubation retention time.

DISCUSSION

The purpose of this randomized, double-blinded controlled trial was to assess the difference between a hydroactive dressing and standard of care using a type of tape applied to the nasal ala on the prevention of pressure injuries associated with nasotracheal intubation during orthognathic surgery in 450 patients. The samples in each group were relatively young and healthy, with an average age of 24 years, which is lower than the age of patients reported in European countries undergoing orthognathic surgery,[8] but similar to the results of studies conducted with Asian populations.[9,10] Younger individuals generally present with developmental deformities of jaws, such as maxillary or mandibular protrusion or deficiency, or several coexisting deformities. Corrective orthognathic surgical procedures can be performed at the age of 16 years or older.[11] Our population had better physical condition and fewer chronic diseases, as noted by the low ASA scores.

In our study, the incidence of pressure injuries in the experimental group was 4.4%, consistent with what we predicted (4%) based on our a priori estimates. However, the incidence of 14.22% in the control groups was higher than our prediction of 11%. Both incidences were much lower than 24.48% reported by Rastogi and colleagues[12] in a retrospective study of the incidence of nasal ala pressure injuries sustained by patients after head and neck reconstructive surgery. Unfortunately, the method used under the nasotracheal tube was not reported in that study. The differences in findings may be related to patient population, such as general health status, age, and the type and duration of the procedures. Patients in Rastogi's study underwent surgery for head and neck malignant tumors, with long surgical times ranging from 7 to 16 hours; the median age was 55 years.

TABLE 2.
Occurrence Rate of Nasal Ala Pressure Injury

Group	Yes	No	χ^2	*P*	OR (95% CI)
Control	32	193	12.710	.000	3.565 (1.707-7.443)
Experimental	10	215			

Abbreviations: CI, confidence interval; OR, odds ratio.

We found the incidence of pressure injury in the control group was 3.57 times higher than the experimental group, suggesting the hydroactive dressing used in this study reduced the occurrence of nasotracheal intubation-related nasal ala pressure injuries. The continuous pressure of medical devices on the skin and connective tissue is a major causative factor associated with medical device-related pressure injury. The material in the hydroactive dressing disperses the pressure of the nasotracheal tube over the nasal ala, protecting the fragile skin. Unfortunately, most of the dressings for preventing pressure injuries are not suitable for the protection of the nasal ala.[13] The characteristics of the nasal intubation tube require a thin dressing, yet substantial enough that the tube can be firmly affixed and not easily detached. The hydroactive dressing used in this study meets the above characteristics and is easy to apply without cutting. We found the hydroactive dressing was easy to apply, only requiring minimal pressure for 20 seconds to ensure it was properly bonded to the skin and was easy to remove after surgery simultaneously with the nasotracheal tube. Compared with a polyvinyl alcohol foam dressing used by Singh and colleagues,[14] we believe the hydroactive dressing is more convenient to observe the facial features during surgical procedures.

The prevention of nasal ala pressure injury associated with nasotracheal intubation requires multidisciplinary involvement, including anesthesiologists, anesthesia nurses, surgeons, OR nurses, and device manufacturers.[15,16] The current approaches to affix the nasotracheal tube include the use of elastic adhesive material such as tapes and paste, and sutures, and then raising the end of the tube to prevent the angle from being too small, which can lead to the contact area being too large. During surgery, the surgeon and the surgical assistant should avoid extruding the tube and changing the patient's head position too frequently, and keeping the nostrils dry. Postoperative assessment of the nasal ala is essential to early diagnosis of pressure injuries and prompts treatment when injuries occur.[17]

Strengths and Limitations

The major strengths of this study are the double-blind randomized controlled design and an adequately powered study with a relative large sample size to detect changes between the 2 groups. Weaknesses include conducting the study in a single center with a relatively young and healthy population; findings have limited generalizability to a diverse population of patients with respect to age, health conditions, and different Braden and ASA scores.

CONCLUSIONS

Our findings indicate that the use of a hydroactive dressing such as the one used in our study was related to a lower incidence of pressure injuries compared to the adhesive tape used as standard of care in the study population. Additional research is needed to confirm these findings and we recommend a multisite randomized controlled trial be conducted to compare this type of dressing with other prevention methods.

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