Original Article

OxyMask is not superior to a non-rebreathing oxygen mask for oxygen supply in a post-anesthesia care unit in Korea: a comparative study

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Running title:

Hypoxia incidence according to mask type in post-anesthesia care unit

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Abstract

Objectives: OxyMask, a novel product, has recently been used to administer oxygen postoperatively to patients who have undergone general anesthesia. This study aimed to evaluate the incidence of hypoxia in patients under general anesthesia upon arrival to the post-anesthesia care unit (PACU) using arterial blood gas analysis, and to compare the effectiveness of OxyMask with a non-rebreathing oxygen mask for oxygen administration.

Methods: We retrospectively investigated anesthesia-related data from the electronic medical records of 460 patients treated from April to November 2021. We analyzed patients aged 20 years or older who had undergone general anesthesia and whose perioperative arterial blood gas analysis results were available upon arrival to the PACU. These patients were grouped into the non-rebreathing oxygen mask (n=223) and OxyMask (n=237) groups, and statistical analysis was performed utilizing their anesthesia records.

Results: No patients exhibited hypoxia upon arrival to the recovery room. The oxygen concentration increased after oxygen administration; its concentration during the recovery room period ($\Delta 2$ PaO_2) was 10.7±42.3 and 13.9±38.5 mmHg in the non-rebreathing oxygen mask and OxyMask groups, respectively. This difference was not statistically significant. Moreover, the arterial oxygen saturation between the end of surgery and upon arrival to the PACU ($\Delta 1$ SaO_2) and the arterial oxygen saturation 20 minutes after oxygen administration at the PACU ($\Delta 2$ SaO_2) did not significantly differ between the groups.

Conclusion: OxyMask was not superior to a non-rebreathing oxygen mask in terms of the effectiveness of oxygen supply.

Keywords

Introduction

Background

The immediate postoperative period is a risky time when hypoxia is highly likely to occur. Should respiratory complications arise during post-anesthesia management, they can lead to serious consequences. Thus, comprehensive management is essential to ensure thorough monitoring of the patient. Postoperative hypoxia, which develops immediately after surgery, is significantly associated with factors such as anesthesia duration, surgical incision site, age, obesity, and pain [1−5].

All general patients are transferred from the operating room (OR) to the post-anesthesia care unit (PACU) after surgery, breathing room air; at this point, there is a risk of developing hypoxia. Upon arrival in the PACU, patients receive oxygen through various devices such as masks and cannulas. Previously, our institution administered oxygen using a non-rebreathing oxygen mask (Teleflex, Morrisville, NC, USA; Fig. 1); however, we have recently begun using the OxyMask (Southmedic, Barrie, ON, Canada), a novel product (Fig. 2).

A non-rebreathing oxygen mask is a closed-type mask, which leads to air re-circulation at the lower part of the mask, specifically around the chin area. This can result in the accumulation of carbon dioxide (CO_2) in the expiratory gas [6]. The flow of oxygen in this mask is almost parallel to the face and directed toward the nose, which may not effectively support oxygen inhalation through the mouth. In contrast, the OxyMask is an open-type mask designed to prevent the accumulation of CO_2 inside the

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mask by allowing oxygen to flow from the center of the mask towards both the nasal and oral cavities [6]. This design could facilitate oxygen inhalation and improve CO_2 removal from the mask. However, there is a concern that the open structure of the mask might lead to oxygen dispersion.

Objectives

We assessed the incidence and severity of hypoxia during patient transfer from the OR to the PACU in individuals who had undergone general anesthesia and were extubated. Additionally, this study compared the effectiveness of a non-rebreathing oxygen mask and OxyMask in the PACU by utilizing arterial blood gas analysis (ABGA).

Methods

Ethics statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (IRB) of Ewha Womans University Mokdong Hospital (IRB number: 2021-12-048-001). The requirement to obtain written informed consent was waived by the IRB since this study was performed retrospectively.

Study design

This was a comparative study. The manuscript was described according to the STROBE statement (https://www.strobe-statement.org/).

Setting

We reviewed and analyzed patients' data from their electronic medical records from April to November 2021 at Ewha Womans Medical Center. A non-rebreathing oxygen mask was used from May 1, 2021 to July 31, 2021. The OxyMask was used from August 1, 2021 to November 30, 2021.

Participants

We investigated 460 patients aged 20 years or older who had undergone general anesthesia in non-cardiac surgery, were extubated at the end of anesthesia, and had perioperative ABGA results available upon arrival to the PACU and before leaving the PACU. Patients with severe cardiopulmonary disease who experienced hypoxia and dyspnea and were therefore administered supplemental oxygen from the OR were excluded. The general protocol for anesthesia at our institution was as follows: Perioperatively, the management of anesthesia was at the discretion of the attending anesthesiologist. All patients were extubated in the OR and then transferred to the PACU after confirming spontaneous breathing with an oxygen supply via a bag-mask at 6 L/min for at least 5 minutes. During the transfer to the PACU, all patients breathed room air (FiO$_2$ 0.21) spontaneously. Upon arrival to the PACU, all patients received supplemental oxygen at 6 L/min (FiO$_2$ 0.44) using a non-rebreathing oxygen mask or an OxyMask, and an ABGA was performed (the first ABGA in the PACU). After at least 20 minutes of oxygen administration in the PACU, a second ABGA was performed for all patients. The attending anesthesiologist determined whether to discharge patients from the PACU based on the discharge criteria, following the Aldrete score system, which evaluates activity, respiration, circulation, consciousness, and skin color (Supplement 1) after discontinuation of the oxygen supply.

Variables (study outcomes)

The primary outcome was a comparison of the effectiveness of oxygen delivery between the OxyMask and the non-rebreathing oxygen mask during the stay in the PACU, as determined by ABGA results.

Postoperative hypoxia was defined as an oxyhemoglobin saturation (SpO_2) of 90% or less for at least 2 minutes, or an SpO_2 of 85% or less at any time point. The secondary outcome focused on the incidence of postoperative hypoxia upon arrival to the PACU, which was also assessed using ABGA results.

Data sources and measurement

The collected data included the patients' demographic and clinical characteristics, as follows: sex, age, American Society of Anesthesiologists physical status, height, weight, body mass index, the presence of pulmonary disease, operation time, and anesthesia time. Intraoperative and postoperative vital signs and ABGA results were collected, and the following vital signs were recorded at the time of ABGA sampling: systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, SpO_2, respiratory pattern, level of consciousness, and numerical pain scores were recorded every 5 minutes in all patients. From the ABGA results, pH, arterial oxygen partial pressure (PaO_2), arterial carbon dioxide partial pressure, and arterial oxygen saturation (SaO_2) were also recorded. Additionally, we calculated the difference in PaO_2 and SaO_2 between the last ABGA in the OR and the first ABGA in the PACU (Δ_1 PaO_2 and Δ_1 SaO_2, respectively). Moreover, we calculated the difference in PaO_2 and SaO_2 between the first and second PACU measurements (Δ_2 PaO_2 and Δ_2 SaO_2, respectively).

Bias

There was no selection bias reportable in this study.

Study size

Sample size estimation was not performed because this study included all target patients, with the exclusion of those who received supplemental oxygen in the OR. Additionally, the authors did not

allocate participants to specific groups.

Statistical methods

Statistical analyses were performed using the anesthesia records of 460 patients, divided into two groups: the OxyMask group (n=237) and the non-rebreathing oxygen mask group (n=223; Fig. 3). Continuous variables were analyzed using either the Student t-test or the Mann–Whitney U test following a normality assessment with the Shapiro–Wilk test. Results were presented as means±SDs or as medians (interquartile ranges). Categorical variables were analyzed using the chi-square test or Fisher exact test, which was applied when more than 20% of the expected frequencies were fewer than 5. These results were presented as percentages (%). All statistical analyses were carried out using SPSS version 25 (IBM, Armonk, NY, USA). A P-value of less than 0.05 was considered statistically significant.

Results

Participants' demographic and clinical characteristics in the non-rebreathing oxygen mask and OxyMask groups

We analyzed 460 patients, who were divided into the OxyMask group (n=237) and non-rebreathing oxygen mask group (n=223). The two groups did not differ significantly in terms of demographic or clinical characteristics, except the operation time (167.9±125.2 vs. 192.9±139.8 min, P=0.044; Table 1). Patients who had pulmonary disease were comparable between the OxyMask and non-rebreathing oxygen mask groups (Table 1).

Incidence of postoperative hypoxia upon arrival to the post-anesthesia care unit

No hypoxia episodes occurred among the patients. One patient in the OxyMask group had a minimum PaO_2 value of 111.8 mmHg upon arrival to the recovery room (RR), with spontaneous breathing of room air after surgery.

Arterial blood gas analysis during the operation and the post-anesthesia care unit period

Upon arrival to the RR, PaO_2 was significantly lower in the OxyMask group than in the non-rebreathing oxygen mask group (162.1±50.3 vs. 181.9±62.0 mmHg, respectively, P<0.001). Similarly, upon discharge from the RR, PaO_2 was significantly lower in the OxyMask group than in the non-rebreathing oxygen mask group. (176.0±49.2 vs. 192.6±64.5 mmHg, respectively, P=0.002).

$\Delta_1 PaO_2$, the gradient of arterial oxygen partial pressure between the end of surgery and upon arrival to the PACU, was significantly higher in the OxyMask group than in the non-rebreathing oxygen mask group (40.5±48.7 vs. 19.9±52.8 mmHg, respectively, P<0.001; Table 2). However, $\Delta_2 PaO_2$, the gradient of arterial oxygen partial pressure 20 minutes after the administration of oxygen in the PACU, was not

significantly different between the OxyMask and the non-rebreathing oxygen mask groups (13.9 ± 38.5 vs. 10.7 ± 42.3 mmHg, respectively, P=0.393; Table 2).

Δ_1 SaO$_2$, the gradient of arterial oxygen saturation between the end of surgery and arrival to the PACU, was not significantly different between the OxyMask and non-rebreathing oxygen mask groups (0.13 ± 0.70 vs. 0.14 ± 0.77 mmHg, respectively, P=0.912; Table 2). Moreover, Δ_2 SaO$_2$, the gradient of arterial oxygen saturation 20 minutes after the administration of oxygen supply in the PACU, was also not significantly different between the OxyMask and non-rebreathing oxygen mask groups (0.51 ± 4.93 vs. 0.32 ± 1.02 mmHg, respectively, P=0.544; Table 2).

Δ_1 PaCO$_2$, the gradient of arterial carbon dioxide partial pressure between the end of surgery and upon arrival to the PACU, was not significantly different between the OxyMask and non-rebreathing oxygen mask groups (40.0 ± 5.4 vs. 39.3 ± 5.4 mmHg, respectively, P=0.153; Table 2). Moreover, Δ_2 PaCO$_2$, the gradient of arterial carbon dioxide partial pressure 20 minutes after the administration of oxygen supply in the PACU, was also not significantly different between the OxyMask and non-rebreathing oxygen mask groups (38.1 ± 5.3 vs. 37.4 ± 4.8 mmHg, respectively, P=0.155; Table 2).

Discussion

Key results

Upon arrival to the PACU, there were no cases of postoperative hypoxia; furthermore, there was no difference in the effects of oxygen delivery between the OxyMask and the non-rebreathing oxygen mask groups during their stay in the PACU, as indicated by ABGA results.

Interpretation

Postoperative hypoxia during the early recovery period after general anesthesia is primarily due to respiratory depression caused by residual anesthetics. Therefore, it is crucial to provide appropriate and prompt oxygen supply to all patients during this time. Typically, healthy patients are transferred from the OR to the PACU breathing room air. However, breathing room air immediately after surgery can pose a risk of hypoxia, as lung function tends to deteriorate. This deterioration is characterized by a decrease in functional residual capacity, an increase in airway closure, and the development of both a ventilation/perfusion mismatch and atelectasis [7]. Further, CO_2 retention caused by hypoventilation can bring about hypoxia by replacing the oxygen from the alveoli; this is particularly important when the inhaled air is not oxygen-enriched [8].

Daley et al. investigated the incidence of hypoxemia in the PACU among adult patients who had undergone general anesthesia for elective surgery. They monitored SpO_2 levels using continuous, non-invasive pulse oximetry [9]. Their findings indicated that 41% of patients experienced hypoxemia after the oxygen supply, which had been administered for 30 minutes during their PACU stay, was discontinued. However, the condition rapidly improved with the reintroduction of oxygen, suggesting that supplemental oxygen is necessary following general anesthesia. Tyler et al. continuously monitored SaO_2 using pulse oximetry [8]. They reported that hypoxemia, which was defined as $SaO_2 \leq 85\%$ for

patients who were breathing room air during their transfer from the OR to the PACU after general anesthesia and after discontinuation of oxygen supply, occurred in 35% of all patients (33 of 95 patients). The mean time interval taken for SaO_2 to decrease from 100% to 85% following the discontinuation of oxygen was 155±74 s. They reported that postoperative hypoxemia was not related to the anesthetic agents, age, anesthesia time, or level of consciousness. In their study, all patients were transferred from the OR to the PACU in 5 minutes with breathing room air and did not experience hypoxemia, as PaO_2 was 111.8 mmHg upon arrival to the PACU. In our study, hypoxemia did not occur during the immediate transfer to the PACU. This was likely due to the very short elapsed time following the discontinuation of oxygen for transfer and the maintenance of PaO_2 at 150 mm Hg or higher, facilitated by oxygen administration during surgery.

Oxygen was discovered centuries ago and has been administered to patients using various devices, such as the conventional simple mask or cannula. The FiO_2 range delivered to patients depends on individual patient factors and the choice of oxygen delivery device. The simple mask typically used is a mostly closed-type mask that can cause air re-circulation at the lower part of the mask, near the chin, potentially leading to the accumulation of CO_2 due to the rebreathing of expired gases. Additionally, it may be unsuitable for oral oxygen inspiration because the direction of the oxygen flow is almost parallel to the face and directed towards the nose.

OxyMask features an open design that enables oxygen to diffuse directly into the mouth and nose through a structure shaped like a pentagon with five arms extending from the base of the mask [6]. This open design aims to minimize the buildup of expired CO_2 in the re-circulation area and offers several advantages. Additionally, it directs the flow of oxygen from the central area of the mask towards the middle of the nasal and oral cavities. However, our results did not show a difference in $PaCO_2$ levels. At PACU discharge, the $PaCO_2$ was 38.1 mmHg in the simple mask group and 37.4 mmHg in the OxyMask group, indicating that conventional simple masks also do not cause CO_2 retention.

Lamb and Piper compared the effectiveness of the OxyMask and the non-rebreathing oxygen mask

using a mannequin head. They reported that the OxyMask was superior, demonstrating higher inspired oxygen, lower inspired CO_2, and more efficient CO_2 clearance [10]. DeJuilio et al. retrospectively evaluated patients pre- and post-implementation of OxyMask and reported that the previously used simple mask could be switched to the OxyMask because the OxyMask was favorable in terms of safety and cost-effectiveness [11]. Paul et al. achieved a mean FiO_2 of 25.4%–80.1% using the OxyMask, delivering 1.5–15 L/min of oxygen in healthy volunteers [6]. The OxyMask is an open-system mask with an oxygen diffuser directed toward the nasal and oral cavities, allowing control over the flow rate and oxygen concentrations. Yanez et al. investigated whether FiO_2 ranges depend on the mask type when delivering oxygen to the lips and oropharynx [12]. For 10 healthy volunteers, two sampling lines were attached and FiO_2 was measured. One sampling catheter was attached to the patient's lips and the other one was attached to the oropharynx through a nostril. The FiO_2 levels were not significantly different between the lips and oropharynx with the simple mask. However, the measured FiO_2 at the lips was higher than that at the oropharynx with the OxyMask. This drop in FiO_2 at the oropharynx was attributed to the open design of the OxyMask, which lacks a perfect seal, and is considered a dilutional effect by nasal breathing or perioral room air entrainment [12]. We investigated the effectiveness of the oxygen supply between the simple mask and OxyMask by comparing the difference in measured PaO_2 during 20 minutes of oxygen administration in the PACU. The PaO_2 after 20 minutes of oxygen administration did not differ significantly between the non-rebreathing oxygen mask and the OxyMask in this study (10.7±42.3 vs. 13.9±38.5 mmHg, respectively; P=0.393), indicating that the OxyMask was non-superior compared to the non-rebreathing oxygen mask in delivering oxygen.

No hypoxia events occurred in any study patients during the period of transfer from the OR to the PACU following general anesthesia. Perioperative management was consistent in all patients in both groups, and no manipulation was conducted to assess the incidence of hypoxia under general conditions. The OxyMask group experienced a greater drop in PaO_2 levels than was observed in the non-rebreathing oxygen mask group, between the end of surgery and arrival to the PACU. The difference in measured PaO_2 levels from the end of surgery to arrival to the PACU in the OxyMask group (40.5±48.7 mmHg)

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was significantly greater than that in the non-rebreathing oxygen mask group (19.9±52.8 mmHg) (P<0.001). The reason for the greater drop in PaO_2 in the OxyMask group was difficult to determine because no significant between-group differences were observed in demographic characteristics and comorbidities such as pulmonary diseases, which could have affected the oxygen demand and could have increased the risk of postoperative pulmonary complications.

While there was a difference in weight (P=0.010) between the two groups, the effects of the two masks were considered insignificant, as there was no difference in BMI (P=0.073; Table 1). Although the operation time was significantly longer in the OxyMask group, there was no difference in the occurrence of hypoxia between the two groups (Table 1). Since this study did not demonstrate a significant difference in the occurrence of hypoxia between the two masks, it suggests that the OxyMask is not superior to the non-rebreathing oxygen mask in providing suitable oxygen. Further research is needed to establish the OxyMask as an alternative to the non-rebreathing oxygen mask for patients undergoing longer operations.

Limitations

Our study is subject to several limitations. Since the FiO_2 in the OxyMask group was not measured, it is challenging to confirm which mask delivered oxygen more efficiently. However, it can be hypothesized that the FiO_2 of the OxyMask might be lower than that of the non-rebreathing oxygen mask. However, further research is required to investigate this possibility. Another limitation is that, due to the retrospective nature of the study, there may have been a time difference between oxygenation and ABGA after PACU arrival, despite institutional protocols that dictate they should be performed simultaneously. Therefore, the timing of ABGA may not have been consistent. To compensate for this, we compared the change in PaO_2 between the two groups rather than the absolute values. Third, we did not investigate the types of surgery between the two groups, although the ABGA results could have differed according to whether patients underwent laparoscopic or open surgery. Unlike open surgery,

laparoscopic surgery involves CO_2 insufflation into the abdominal cavity, which may lead to differences in values of PaO_2 or $PaCO_2$ between the two groups. Therefore, to generalize our results, further prospective studies are required to clarify the differences between the OxyMask and the non-rebreathing oxygen mask, considering the influence of comorbidities.

Conclusion

No hypoxia events occurred upon arrival to the PACU in any of the patients in this study. Therefore, it is practicable for healthy adult patients to breathe room air without supplemental oxygen when being transferred from the OR to the PACU. The increase in PaO_2 levels following oxygen administration in the PACU did not differ significantly between the two types of masks. The OxyMask was not more effective in delivering oxygen than the non-rebreathing oxygen mask.

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Authors' contributions

Conceptualization:

Formal analysis:

Investigation:

Methodology:

Project administration:

Writing – original draft:

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Conflict of interest

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Data availability

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Supplementary materials

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Supplement 1. Aldrete score system comprising the evaluation of activity, respiration, circulation, consciousness, and skin color

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Table 1. Demographic characteristics of both groups

Demographic characteristic	Non-rebreathing oxygen mask (n=223)	OxyMask (n=237)	P-value
Age (years)	60.6±17.3	62.3±15.4	0.275
Sex (M/F)	91/132	105/132	0.448
Height (cm)	160.6±9.9	162.2±9.1	0.064
Weight (kg)	60.6±11.9	63.4±11.0	0.010
BMI (kg/m^2)	23.5±3.8	24.1±3.7	0.073
ASA physical classification (1/2/3/4)	41/137/45/0	27/154/55/1	0.141
Pulmonary disease (yes/no)	28/195	39/198	0.236
Operation time (min)	167.9±125.2	192.9±139.8	0.044
Anesthesia time (min)	215.4±130.3	237.8±141.8	0.079

Values are presented as mean±SDs.

The Student t-test was performed for continuous variables and the chi-square test for categorical variables.

P<0.05 is regarded as indicating statistical significance.

BMI, body mass index; ASA, American Society of Anesthesiologists.

Table 2. Arterial blood gas analysis during operation and the PACU period

Variable	During the operation (OR)			Arrival at the PACU (PACU[1])			Discharge from the PACU (PACU[2])		
	Non-rebreathing oxygen mask (n=223)	OxyMask (n=237)	P-value	Non-rebreathing oxygen mask (n=223)	OxyMask (n=237)	P-value	Non-rebreathing oxygen mask (n=223)	OxyMask (n=237)	P-value
SBP	117.8±17.1	119.4±16.9	0.310	129.8±8.3	133.5±21.3	0.049	129.6±18.6	134.6±21.7	0.009
DBP	66.6±12.0	66.3±11.4	0.807	77.1±14.3	79.3±16.3	0.115	75.7±11.6	77.8±14.2	0.095
HR	79.7±14.1	80.3±14.7	0.662	85.4±13.9	85.0±15.1	0.768	79.7±13.4	80.9±14.3	0.362
RR	13.2±4.4	12.9±4.3	0.471	17.7±4.1	17.6±6.8	0.769	16.6±6.2	16.4±3.7	0.686
SpO_2	100.0±0.3	100.0±0.4	0.941	100.0±0.0	100.0±0.2	0.207	100.0±0.0	100.0±0.0	-
pH	7.40±0.05	7.41±0.05	0.211	7.38±0.05	7.38±0.05	0.719	7.39±0.06	7.40±0.05	0.699
pCO_2	38.3±3.6	37.8±3.4	0.106	40.0±5.4	39.3±5.4	0.153	38.1±5.3	37.4±4.8	0.155
pO_2	201.8±48.4	202.6±47.6	0.850	181.9±62.0	162.1±50.3	<0.001*	192.6±64.5	176.0±49.2	0.002*
Δ_1PaO_2	-	-	-	19.9±52.8	40.5±48.7	<0.001*	-	-	-
Δ_2PaO_2	-	-	-	-	-	-	10.7±42.3	13.9±38.5	0.393
SaO_2	98.7±0.7	98.6±0.8	0.256	98.0±5.0	98.1±1.2	0.736	98.5±0.7	98.5±0.7	0.193
Δ_1SaO_2	-	-	-	0.13±0.70	0.14±0.77	0.912	-	-	-
Δ_2SaO_2	-	-	-	-	-	-	0.51±4.93	0.32±1.02	0.544

Values are presented as mean±SD.

The Student t-test was performed for continuous variables.

P<0.05 is regarded as indicating statistical significance, and * significant results are shown.

OR, operating room; PACU, post-anesthesia care unit; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; RR, respiratory rate; SpO_2, oxyhemoglobin saturation; $PaCO_2$, arterial carbon dioxide partial pressure; PaO_2, arterial oxygen partial pressure; Δ_1PaO_2, PaO_2 at OR–PaO_2 at PACU[1]; Δ_2PaO_2, PaO_2 at PACU[2]–PaO_2 at PACU[1]; SaO_2, arterial oxygen saturation; Δ_1SaO_2, SaO_2 at

OR–SaO_2 at $PACU^1$; $\Delta_2 SaO_2$, SaO_2 at $PACU^2$–SaO_2 at $PACU^1$.
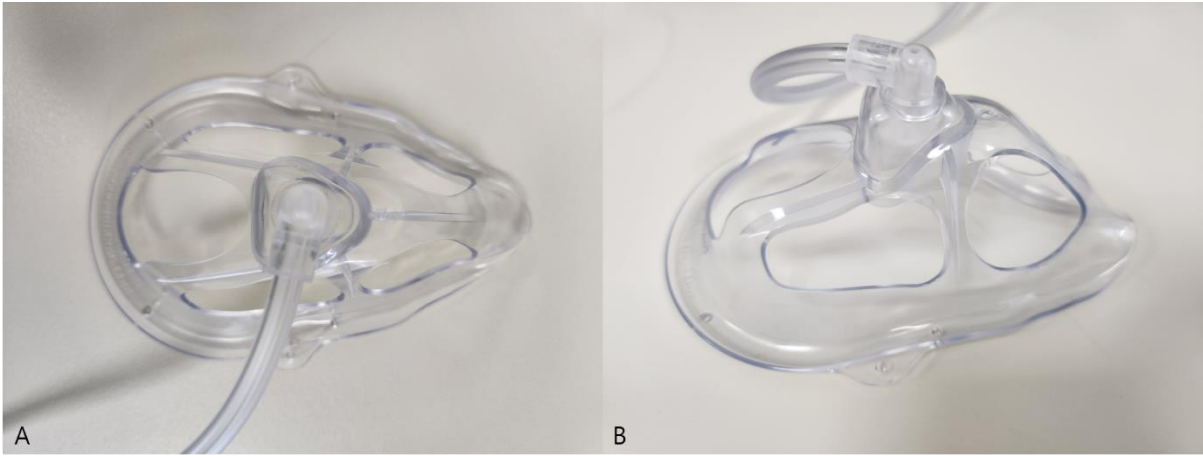
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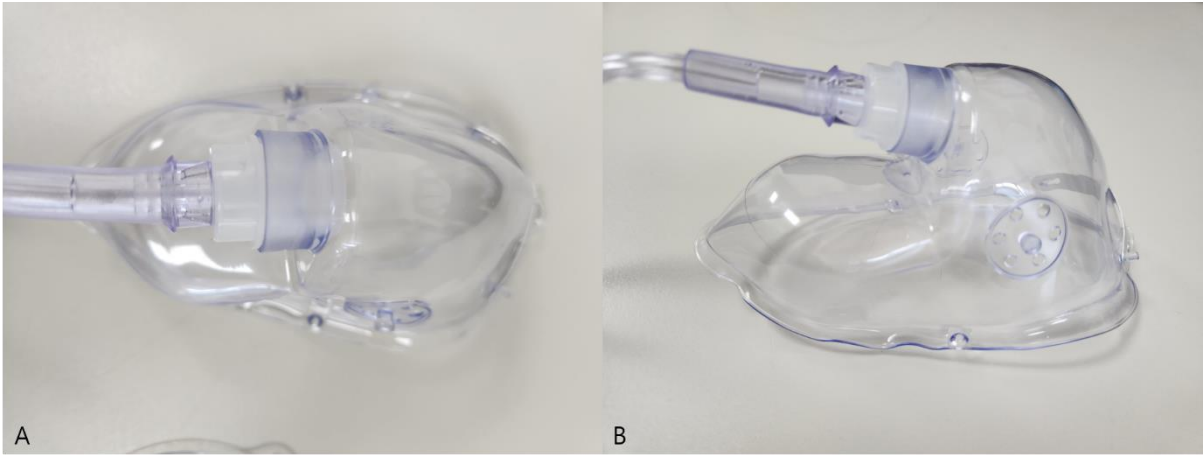
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4   **Fig. 1.** Hudson RCI non-rebreathing oxygen mask. (A) Top view, (B) side view.
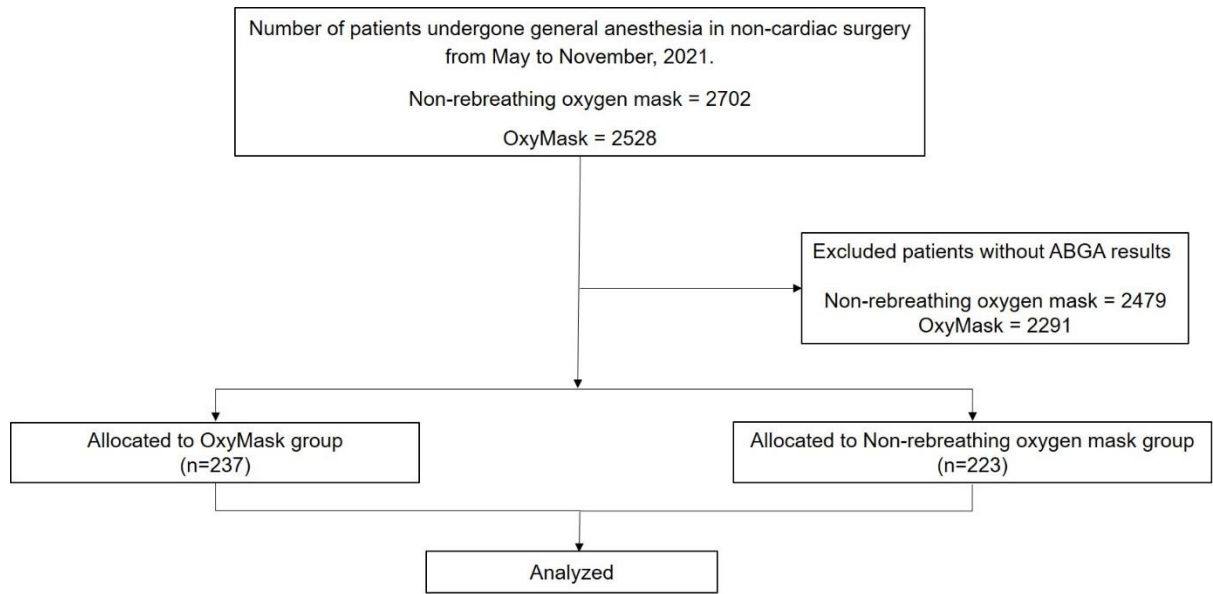
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8   **Fig. 2.** OxyMask. (A) Top view, (B) side view.

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12   **Fig. 3.** Flow diagram of the participants.