The Efficacy of Two Oxygen Therapy Devices (Nasal Cannula vs. Simple Mask) for Preventing Hypoxemia after General Anesthesia: A Randomized Controlled Non-Inferiority Trial of 500 Patients

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Objective: *To compare the efficacy of two oxygen devices (nasal cannula and mask) and two flows for preventing hypoxemia in post anesthesia care unit (PACU).*

Material and Method: *Five hundred (18-70 year old) patients were enrolled into a randomized, controlled non-inferiority trial at Siriraj Hospital, Mahidol University from May 2013 to December 2014. They received oxygen therapy after general anesthesia according to their groups by computer-generated randomization. Group I received oxygen nasal cannula 4 liters per minute and group II received oxygen mask 5 liters per minute. Both methods gave comparable FiO_2 (FiO_2 = 0.35). Inclusion criteria were elective surgery, American Society of Anesthesiologist (ASA) physical status 1-3. Exclusion criteria were unstable pulmonary disease, BMI >35 kg/m^2, baseline SpO_2 <94%, myopathy, alteration of consciousness, and nasal problems. The high-risk operations for post operative hypoxemia were excluded. The efficacy of two oxygen devices and flows were compared in term of preventing hypoxemia in PACU.*

Results: *Five hundred patients were analyzed (249 patients in the cannula group and 251 patients in the mask group). They were comparable in demographics and operations. At PACU, none of 500 patients had SpO_2 <94% (non-inferiority trial, 95% CI -0.0152, 0.0152). They were mildly sedated or fully awake and had no respiratory complications.*

Conclusion: *In low risk patients undergoing low risk operations, both nasal cannula or simple mask with FiO_2 = 0.35 are equally effective for preventing hypoxemia in PACU.*

Keywords: *Oxygen, PACU, General anesthesia, Nasal cannula, Simple mask, Hypoxemia, Desaturation*

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After general anesthesia, the residual anesthetics could cause several respiratory complications such as upper airway obstruction, hypoventilation, atelectasis, ventilation-perfusion mismatch (V/Q mismatch) or apnea, which lead to hypercarbia and/or hypoxemia[1-3]. In our hospital, many variable flow oxygen devices (nasal cannula, simple mask or mask with reservoir bag) have been used in PACU. The actual oxygen delivery was determined by several factors such as patient breathing pattern, oxygen device and oxygen flow[4]. In theory, patient with normal breathing, nasal cannula with oxygen flow 1-6 liters/minute provides fractional inspired oxygen concentration (FiO_2) from 0.24 to 0.40[5] and 5-10 liters/minute of oxygen mask gives FiO_2 from 0.35 to 0.50[5]. These two devices are widely used in our PACU without clear instruction.

Only a few studies[6,7] explored the efficiency of the low flow oxygen devices. The aim of this study was to compare the efficacy of nasal oxygen flow 4 liters/minute (FiO_2 = 0.36) with oxygen mask flow 5 liters/minute (FiO_2 = 0.35) for preventing hypoxemia in PACU. Both oxygen devices and flows have comparable FiO_2. Nasal oxygen with greater flow (>4 L/min) can dry

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nasal mucosa. Simple oxygen mask with lesser flow (<5 L/min) can cause exhaled carbon dioxide rebreathing[5]. The hypoxemia was defined as the SpO_2 <94% according to British Thoracic Society guideline[8,9], and desaturation was defined by SpO_2 <94% for more than 30 seconds[10].

Material and Method

After approval by IRB (066/2556), an un-blinded, randomized, controlled non-inferiority trial was conducted in 500 patients having general anesthesia at Siriraj Hospital Faculty of Medicine, Mahidol University, Thailand from May 2013 to December 2014.

Inclusion and exclusion

Inclusion criteria were patients 18-70 years who were scheduled for elective surgery under general anesthesia and had American Society of Anesthesiologists (ASA) physical status 1-3. Exclusion criteria were patients who had unstable pulmonary disease, BMI >35 kg/m^2, SpO_2 <94% in room air, myopathy, alteration of consciousness, on mechanical ventilator, had diseases of nasal cavity or on nasogastric tube, denied to be a part of this research, and who were undergoing high risk operations for post operative hypoxemia such as upper abdominal surgery, thoracotomy, airway surgery, intracranial surgery, and opened heart surgery.

Randomization and intervention

The allocation sequence was generated by a computerized random generation program and the patients were divided into two groups: Group 1 (Cannula, C) received non-humidified oxygen 4 liters per minute by nasal cannula and Group 2 (Mask, M) received non-humidified oxygen 5 liters per minute by simple face mask. We stratified randomization by using operative procedures.

All of patients received general anesthesia with either endotracheal tube (ETT) or laryngeal mask airway (LMA). After removal of ETT or LMA, all patients received 100% oxygen via anesthetic mask for evaluation of the airway and breathing for 1 minute then received oxygen therapy according to their groups during being transferred to PACU. During transferring the patients to the PACU, the patients could be put into any position such as semi-Fowler, supine or others upon the anesthesiologist's decision. The SpO_2, respiratory rate, sedation score and pain score were routinely monitored and recorded every 15 minutes in PACU. If SpO_2 <94%, the PACU nurse would stimulate patient to take deep breaths. If SpO_2 was still lower than 94%, the oxygen flow would be increased or oxygen delivery device would be changed into other type for higher FiO_2 level and reported to anesthesiologists for further management. PACU nurses would record the duration of desaturation.

Before being transferred to ward, the oxygen device was removed and SpO_2 was continuously monitored. If SpO_2 was lower than 94%, then oxygen would again be given. The researcher would record the duration and compliance of the oxygen therapy.

Sample size calculation

We use non-inferiority trial based on the hypothesis that oxygen cannula was as effective as oxygen mask for preventing hypoxemia or desaturation in PACU. From old data[2,11], the incidence of mild hypoxemia in PACU was relatively high (25-55%). These data came from late 1980s to early 1990s with old anesthetics and the old PACU care but the critical respiratory event in PACU requiring intervention was extremely low (1.3%)[1]. With modern anesthetics, routine prophylaxis oxygen therapy and good PACU care, we estimated the success rate in both methods of oxygen delivery for preventing hypoxemia = 98%. The calculated sample size (for non-inferiority = 5% with type I error 0.01 and type II error 0.05). There were 248 patients per group.

Statistical analysis

All data were analyzed using SPSS program. The quantitative data were presented as mean $\pm$ standard deviation (SD) and qualitative data were presented as number and percent. Demographic data between the two groups were compared by an independent samples t-test or the Mann-Whitney U-test as appropriate for comparison of continuous variables. Qualitative data were compared with Chi-square test. The non-inferiority statistic was used to compare the two groups in term of the incidence of hypoxemia or desaturation (SpO_2 <94%) in PACU.

Results

We enrolled 500 consecutive patients in the study. Two hundred and forty-nine patients were analyzed in the cannula group and 251 patients were analyzed in the mask group because one patient in cannula group received oxygen mask (Fig. 1). The two groups were comparable in demographics (Table 1). Most patients in both groups had ASA physical status I and II and hypertension was the most common

underlying disease.

There were no differences in types of operations. Most of the patients received general anesthesia with endotracheal tube (ETT), FiO_2 = 0.6, volume controlled ventilation (VCV) and a few with PEEP. Sevoflurane had been used more in the cannula group than in the mask group (p = 0.040) (Table 2).

In both groups, the extubation criteria were met in most of the patients in both groups. The patients were transferred in semi-Fowler or supine position (Table 3).

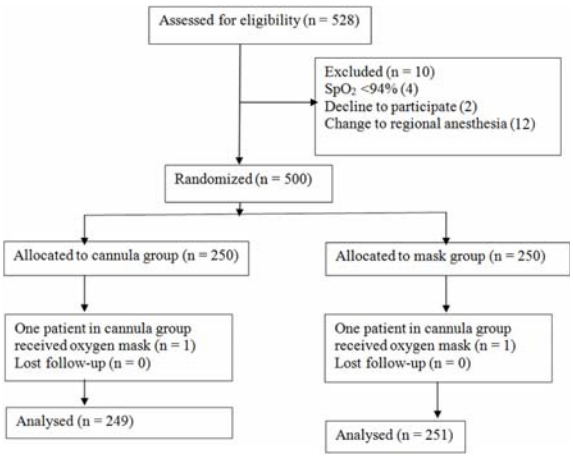

Fig. 1 Consort diagram of the study.

At recovery room, none of the patients had low respiratory rate (<10 breaths/minute), no hypoxemia or desaturation occurred (95% CI -0.0152, 0.0152 non-inferiority trial). In the first 15 minutes at PACU, there were no differences in sedative condition and pain scores in two groups. Pain occurred frequently in PACU. Most of the patients had oxygen saturation more than 92% without oxygen therapy (Table 4).

At ward, only 13 patients (6 patients in cannula group and 7 patients in mask group) received oxygen therapy no longer than 6 hours. Oxygen had been prescribed either by physician or on nurse's discretion. None of the patients had respiratory complications within 24 hour.

Discussion

There were no hypoxemic episodes in all of 500 patients in this study. In both groups, the oxygen supplement, either 4 L/minute of oxygen cannula or 5 L/minute of oxygen mask might prevent hypoxemic episodes that might occur without oxygen therapy. The hypoxemia or desaturation incidence was 0% in both groups (95% CI -0.0152, 0.0152, non-inferiority trial). Zero incidence could be explained by adequate reversal and little anesthetics left. All of our patients were fully

Table 1. Patients' demographics

	Group I (C) (n = 249) (%)	Group II (M) (n = 251) (%)	*p*-value
Sex: male	89 (35.7)	70 (27.9)	0.059
Age (years)	48.7±13.8	48.6±14.0	0.943
Weight (kg)	60.0±11.2	60.1±11.7	0.957
Height (cm)	160.0±7.7	159.8±7.9	0.741
BMI (kg/m^2)	23.3±3.8	23.4±3.9	0.726
ASA physical status I/II/III	112/117/20	116/112/23	0.827
Underlying disease: yes	135 (54.2)	130 (51.8)	0.587
HT	81 (32.5)	77 (30.7)	0.656
DM	34 (13.7)	25 (10.0)	0.200
CAD	8 (3.2)	9 (3.6)	0.818
Asthma	7 (2.8)	8 (3.2)	0.805
COPD	0	2 (0.8)	0.158
Smoker	6 (2.4)	5 (2.0)	0.750
OSA	5 (2.0)	7 (2.8)	0.568
CVD	3 (1.2)	1 (0.4)	0.312
Anemia (Hct <30%)	9 (3.6)	5 (2.0)	0.272
Others	19 (7.6)	18 (7.2)	0.845

BMI = body mass index, CAD = coronary artery disease, COPD = chronic obstructive pulmonary disease, OSA = obstructive sleep apnea, CVD = cerebrovascular disease

Table 2. Intraoperative data

	Group I (C) (n = 249) (%)	Group II (M) (n = 251) (%)	*p*-value
Operation			
Orthopedics	45 (18.1)	45 (17.9)	0.371
General/urology	63 (25.3)	72 (28.7)	
Gynecology	50 (20.1)	50 (19.9)	
ENT/head & neck	55 (29.7)	45 (18.0)	
Others	45 (18.0)	40 (16.0)	
Airway			
ETT	233 (93.6)	235 (93.6)	0.981
LMA	16 (6.4)	16 (6.4)	
Ventilator setting			
VCV	241 (96.8)	237 (94.4)	0.330
PCV	8 (3.2)	13 (5.2)	
PS	0	1 (0.4)	
Ventilator with PEEP	22 (8.8)	19 (7.5)	0.600
Relaxant			
None	6 (2.4)	8 (3.2)	0.447
Atracurium	225 (90.4)	220 (87.6)	
Cisatracurium	15 (6.0)	22 (8.8)	
Rocuronium	3 (1.2)	1 (0.4)	
Inhalation			
None	0	1 (0.4)	0.040*
Isoflurane	82 (32.9)	89 (35.5)	
Sevoflurane	166 (66.7)	152 (60.6)	
Desflurane	1 (0.4)	9 (3.6)	

* $p<0.05$, statistical significance
ETT = endotracheal tube, LMA = laryngeal mask airway, VCV = volume controlled ventilation, PCV = pressure controlled ventilation, PS = pressure support

Table 3. Extubation data

	Group I (C) (n = 249) (%)	Group II (M) (n = 251) (%)	*p*-value
Extubation criteria			
Spontaneous breathing	248 (99.6)	249 (99.2)	0.567
Eye opening	236 (94.8)	238 (94.8)	0.983
Follow command	235 (94.4)	234 (93.2)	0.594
Head lift >5 sec	182 (73.1)	166 (66.1)	0.091
Strong hand grip	209 (83.9)	215 (85.7)	0.592
Position during transfer			
Semi-Fowler	137 (55.0)	155 (61.8)	0.127
Supine	112 (45.0)	96 (38.2)	

awake or mildly sedated and no one had low respiratory rate (<10 breaths/minute). The oxygen supplement in both groups could adequately prevent hypoxemia. No patient needed higher oxygen flow or other intervention. Siddiqui et al[12] found that the incidence of hypoxemia in PACU was 19.2% and significant

Table 4. PACU data

	Group I (C) (n = 249) (%)	Group II (M) (n = 251) (%)	*p*-value or 95% CI
Position			
Semi-fowler	133 (53.4)	146 (58.2)	0.358
Supine	115 (46.2)	105 (41.8)	
Lateral	1 (0.4)	0	
Desaturation (SpO_2 <94%)	0	0	95% CI -0.0152, 0.0152*
Sedative condition (15 minutes)			
Fully awake	53 (21.3)	55 (21.9)	
Mildly sedated	143 (57.4)	142 (56.6)	
Moderately sedated	53 (21.3)	53 (21.1)	
Deeply sedated	0	0	
Problems			
Pain	94 (37.7)	101 (40.2)	0.568
Nausea & vomiting	2 (0.8)	5 (1.9)	0.258
Unstable BP	1 (0.4)	0	0.315
Abnormal bleeding	0	0	
Modified aldrete score for oxygen**			
0	0	0	0.790
1	6 (2.4)	7 (2.8)	
2	243 (97.6)	244 (97.2)	

* Non-inferiority trial, no differences between groups

** 0 = SpO_2 <92% despite oxygen therapy, 1 = SpO_2 >90% with oxygen therapy, 2 = SpO_2 >92% without oxygen therapy

predictors were patients' sedation scores, low respiratory rate and no oxygen supplement during transport but with the use of oxygen therapy the incidence of hypoxemia was only 0.8%. From their study, the use of oxygen almost completely prevented desaturation.

During the study period, the oxygen supplement and patient position in the PACU is now formally prescribed in every case. The patient factors, surgical factors and anesthetic management may contribute to respiratory complications and desaturation. The baseline variables in both groups and surgical sites were comparable. The high-risk patients[13] such as obese patients were excluded. We also excluded the high-risk operations such as upper abdominal surgery, thoracotomy, intracranial surgery and opened heart surgery.

Despite randomization, we did not blind the attending anesthesiologists so in the cannula group, they might choose sevoflurane over isoflurane for providing better recovery[14]. Desflurane had rarely been used due to its higher cost.

The neuromuscular blocking agents and the reversal agent (neostigmine) were routinely administered in nearly all of the patients. The residual effects of neuromuscular blocking agent could contribute to respiratory complications and desaturation[15]. The use of neostigmine (especially high doses or unguided by neuromuscular transmission monitoring) did not guarantee the appropriate reversal or decrease respiratory complications[16]. The patients in both groups had met the extubation criteria and had no respiratory complications, so the clinical signs (head left 5 seconds, strong hand grip, etc) for adequate reversal may be enough.

Although this study did not interfere with everyday practices, all anesthesiologists knew that they were being observed that might lead to modifying their practices. This might explain why there were no significant respiratory complications. The researcher did not get any call from the PACU nurses and the PACU nurses did not exercise any special intervention.

During transfer, in our hospital, prophylaxis oxygen therapy is our standard of practice. To the contrary, oxygen therapy during transfer from operating theatre to PACU was not routinely practiced in every country[17]. In our hospital, anesthetic staffs routinely spend some time in PACU for checking vital signs.

From the Thai AIMS study, more than half of PACU desaturation occurred upon arrival[3]. Although no anesthetic staff in charge in PACU, the PACU nurses can contact anesthesiologist in the operating room if any doubts or problems.

From recent study from 137,757 PACU patients, they found desaturation in 11.3% of the patients. Respiratory complications occurred after 30 minutes and resolved themselves slowly and suggested to have anesthesiologist assigned to cover PACU[18]. These results were different from our study because they included all kinds of patients and operations.

At PACU, the most common complication was pain and was treated according to PACU order. The intravenous opioid given to at-risk-patients in the PACU could induce respiratory depression in the unsafe levels[19].

In Siriraj Hospital, the price of oxygen cannula and oxygen mask were 18 baht and 37 baht, respectively. We provided more than 40,000 cases per year and more than half (20,000 cases) of them were low risk patients undergoing low risk surgery. With the use of oxygen cannula, we could have saved 19x20,000 = 380,000 baht per year.

Our study has a few limitations. First, we study only low risk adult patients with low risk operations so this study could not apply for all of the patients having general anesthesia. Second, the incidence of hypoxemia or desaturation is extremely low (0%) because we got data from PACU record not from electronic data and very brief period of hypoxemia might not be recognized by PACU staff. Third, the study was unblinded so all of the anesthetic personals and PACU staffs knew that they were observed. Nevertheless, during the study period, there were no serious respiratory complications, which might need treatment or intervention such as intubation.

Further research should explore the need of oxygen therapy in low risk patients undergoing low risk operations. With continuous monitoring of oxygen saturation, fully awake patients may have good oxygenation with very little or no oxygen therapy.

Conclusion

For low risk patients undergoing low risk surgeries, nasal cannula with oxygen flow 4 L/minute is as effective as a mask with oxygen flow 5 L/minute for preventing hypoxemia in the PACU.

What is already known on this topic?

Oxygen therapy might prevent or reduce the incidence of hypoxemia in PACU.

What this study adds?

The FiO_2 = 0.35 by nasal cannula or simple mask provides adequate oxygen therapy in preventing hypoxemia in PACU.

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Potential conflicts of interest

None.

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การเปรียบเทียบประสิทธิภาพการทำงานของอุปกรณ์ 2 ชนิดสำหรับให้ออกซิเจน (ท่อจมูกกับหน้ากาก) หลังการให้ยาระงับความรู้สึกทั้งตัว

มานี รักษาเกียรติศักดิ์, หรินทร์ อัมพรโชติ, เสาวภาคย์ จำปาทอง, อรุโณทัย ศิริอัศวกุล, ธนาภรณ์ นภาโชติ, ลัดดา เพิ่มผลประเสริฐ, สุปราณี ปวงจันทร์

วัตถุประสงค์: เปรียบเทียบประสิทธิภาพของอุปกรณ์ 2 ชนิดสำหรับให้ออกซิเจน (ท่อจมูกกับหน้ากาก) ในการป้องกันภาวะออกซิเจนต่ำหลังการได้รับยาระงับความรู้สึกทั้งตัว

วัสดุและวิธีการ: ศึกษาในผู้ป่วย 500 คน (อายุ 18-70 ปี) ที่มารับการระงับความรู้สึกทั้งตัวที่โรงพยาบาลศิริราช ตั้งแต่เดือนพฤษภาคม พ.ศ. 2556 ถึง ธันวาคม พ.ศ. 2557 ผู้ป่วยได้รับการแบ่ง 2 กลุ่มโดยการสุ่มด้วยคอมพิวเตอร์หลังการการระงับความรู้สึกทั้งตัวกลุ่มที่ 1 ได้รับออกซิเจนผ่านสายท่อจมูก 4 ลิตร/นาที กลุ่มที่ 2 ได้รับออกซิเจนผ่านหน้ากาก 5 ลิตร/นาที ทั้งสองกลุ่มได้ออกซิเจนความเข้มข้นใกล้เคียงกันคือ ร้อยละ 35 เกณฑ์คัดเลือกคือ การผ่าตัดไม่ฉุกเฉิน มีสภาพร่างกายตาม American Society of Anesthesiologists (ASA) 1-3 เกณฑ์คัดออกคือ มีโรคปอดที่ไม่คงที่ ดัชนีมวลกาย >35 กิโลกรัม/ตารางเมตร มีค่าความอิ่มตัวของออกซิเจนในเลือด (oxygen saturation, SpO_2) ต่ำกว่าร้อยละ 94 โรคกล้ามเนื้ออ่อนแรง สมองผิดปกติ และมีปัญหาของจมูก มารับการผ่าตัดที่เสี่ยงสูงต่อการขาดออกซิเจนหลังผ่าตัด หาอุบัติการณ์ของการเกิดภาวะออกซิเจนต่ำที่ห้องพักฟื้น ขณะที่ได้ออกซิเจนดังกล่าวโดยคำจำกัดความของภาวะออกซิเจนต่ำคือ มีค่า SpO_2 ต่ำกว่าร้อยละ 94 นานกว่า 30 วินาที

ผลการศึกษา: ผู้ป่วย 500 คนได้รับการวิเคราะห์ข้อมูล (249 คนในกลุ่มท่อจมูกและ 251 คนในกลุ่มหน้ากาก) ทั้งสองกลุ่มไม่แตกต่างกันในลักษณะทั่วไปและชนิดของการผ่าตัด ที่ห้องพักฟื้นไม่มีผู้ป่วยคนใดเกิดภาวะออกซิเจนต่ำ (non-inferiority trial, 95% CI -0.0152, 0.0152) ผู้ป่วยทุกคนตื่นดีหรือง่วงเล็กน้อยและไม่พบภาวะแทรกซ้อนทางระบบหายใจ

สรุป: ผู้ป่วยที่มีความเสี่ยงต่ำที่มารับการผ่าตัดที่มีความเสี่ยงต่ำต่อการขาดออกซิเจน ออกซิเจนท่อจมูกหรือหน้ากากที่ให้ออกซิเจน ความเข้มข้นประมาณร้อยละ 35 มีประสิทธิภาพดีพอๆ กันในการป้องกันภาวะออกซิเจนต่ำที่ห้องพักฟื้น