Comparison of preoxygenation efficiency with Intersurgical Economy and Intersurgical QuadraLite anaesthetic face masks

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³ Clinic of Anaesthesiology and Intensive Care, Institute of Clinical Medicine, Faculty of Medicine, Vilnius University, Vilnius, Lithuania **Background.** Sufficient preoxygenation prevents arterial oxygen desaturation prior to intubation. An optimally sealed facemask is necessary for fast preoxygenation. The study was aimed at comparing the efficiency of preoxygenation using two different face masks.

Materials and methods. In 2018, a prospective study was conducted. Patients were classified into two groups: group A – Intersurgical Economy face masks, group B – Intersurgical QuadraLite masks. The circuit was flushed with 100% O₂ for 30s, preoxygenation started with flow of 8l/min, FiO₂100. The patients were asked to breathe deeply. Fentanyl (1–2 mcg/kg) was administered to increase mask toleration. End-tidal oxygen concentration (EtO₂) \geq 90% was the goal. EtO₂ was monitored after 30, 60, 90, 120, 180, 210, 240, 270 and 300 seconds. Data was analyzed using the Independent-Samples T-test and the Mann-Whitney-U test.

Results. Twelve patients were enrolled in group A and 19 in group B. Differences in sex, age, BMI and Mallampati class in the groups were statistically insignificant (p = 0.13, 0.39, 0.65, 0.43respectively). Patients assigned to ASA I – 25.8% ($n = 8 - \frac{2}{6}$), ASA II – 71.0% ($n = 22 \rightarrow 10/12$), ASA III – 3.2% ($n = 1 \rightarrow 0/1$), p = 0.64. The success rate of preoxygenation to EtO₂90 within 5 min was statistically significantly different in the groups, with 33.3% in group A and 94.7% in group B (p < 0.01). Mean time to EtO₂90 was 228.3 \pm 104.0/164.4 \pm 84.3. Mean EtO₂ after: $30s - 56.0 \pm 13.5/69.3 \pm 11.2 (p < 0.01); 60s - 63.8 \pm 15.3/76.1 \pm 11.7$ $(p = 0.02), 90s - 67.8 \pm 17.7/80.7 \pm 10.1 \ (p = 0.03); 120s 69.6 \pm 18.2/83.4 \pm 10.0 \ (p = 0.03), \ 150s-71.1 \pm 19.0/87.1 \pm 6.5$ $(p = 0.01); 180s - 72.9 \pm 16.8/88.5 \pm 5.3 (p = 0.01),$ $210s - 72.6 \pm 18.0/89.2 \pm 5.1 (p < 0.01); 240s - 74.17 \pm 15.4/90.0 \pm 4.3$ $(p < 0.01), 270s-76.3 \pm 16.3/90.2 \pm 3.6; 300s - 77.8 \pm 14.6/90.2 \pm 1.5$ (p < 0.01).

Conclusions. Preoxygenation was significantly more efficient and faster with Intersurgical QuadraLite face masks.

Keywords: preoxygenation, face mask, oxygen

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INTRODUCTION

Preoxygenation, also known as denitrogenation, is a routine procedure performed prior to the induction of general anaesthesia. Room air is replaced with oxygen and its reservoir in the lungs is created (1). Proper preoxygenation prolongs safe apnea time during airway instrumentation and also helps to avoid arterial desaturation if an unanticipated difficult airway is encountered (2). It is well established that arterial desaturation is the risk factor of arrhythmia, hemodynamic decompensation, hypoxic brain injury, and also death (3).

Sufficient preoxygenation is defined as reaching the end-tidal oxygen (EtO₂) concentration of \geq 90% (4, 5). An indicator of incomplete preoxygenation is EtO₂ lower than 90% at the functional residual capacity level. Three to five minutes of breathing 100% oxygen or eight deep breaths within 1 min is thought to be sufficient to reach 90% of EtO₂ (6).

Ineffective face mask seal is the most common cause of insufficient preoxygenation (7). An optimally sealed face mask that prevents entrainment of operating room air into the circuit and leaks is necessary for fast and efficient preoxygenation (8).

A new type of anaesthesia face mask (QuadraLite, produced by Intersurgical) has recently been introduced, which, in contrast to the regular face mask, has a soft edge instead of an air-filled cushion. The new face mask is comfortable for patients and is said to provide a superior seal in a variety of different face anatomy (9). Therefore, we conducted a prospective randomised study to compare preoxygenation efficiency using the regular anaesthesia face mask with air-filled cushion and the new-type anaesthesia face mask.

MATERIALS AND METHODS

A prospective study was conducted at Vilnius University Hospital Santaros Klinikos in July-August 2018. Permission from the institutional bioethics committee was obtained and every subject consented to participate.

The study subjects were patients undergoing general anaesthesia for elective surgery. Subject exclusion criteria were as follows: pulmonary comorbidities; modified Mallampati score III (soft palate and base of uvula visible) – IV (only hard palate visible); potentially compromised mask seal (≥ 2 of the following: missing teeth, snoring, bearded, obese) (5, 10). Prior to anaesthesia, the subjects were randomly assigned to two groups according to the mask to be used: group A – Economy anaesthetic face mask and group B – QuadraLite anaesthetic face mask, both produced by Intersurgical Ltd., UK. An appropriate mask size was chosen based on manufacturer instructions. (9, 11). GE Avance cS2 anaesthesia machines equipped with Datex-Ohmeda differential paramagnetic sensor were used for gas measurement.

The operating room table was set at 10° reverse Trendelenburg position for preoxygenation. After flushing the breathing circuit with 100% O_2 for 30 seconds, patient preoxygenation was initiated with FiO₂ 100% at 8 L/min. All the subjects were preoxygenated by a single anaesthesiologist using EC clamp face mask holding technique. Patients were instructed to breathe long, deep breaths. Meanwhile, 1-2 mcg/kg of fentanyl was administered to increase mask toleration. End-tidal oxygen concentration (EtO₂) was recorded every 30 seconds for a total of 5 min of preoxygenation. $EtO_2 \ge 90\%$ was set as the benchmark for optimal preoxygenation. In cases of suboptimal preoxygenation during the 5 min, additional manoeuvres were employed to achieve optimal EtO₂ values in order to prevent any potential harm to the patient.

Subject sex, age, body mass index (BMI), Mallampati score, and the ASA class were also collected. Statistical analysis was performed in IBM SPSS Statistics v.25.0. Demographic data were analysed using Fisher's exact test due to the small sample size. The independent-samples T test and the Mann-Whitney U test were used to compare EtO₂ values between groups.

RESULTS

A total of 31 patients were enrolled in the study. Twelve patients were assigned to group A and 19 to group B. There were no statistically significant differences in sex, age, BMI, Mallampati score, and the ASA class between the groups (Table).

After 3 min, optimal preoxygenation was achieved in 17 of 31 patients (54.8%), with success rates of 33.33% and 68.4% in groups A and B,

		Intersurgical Economy	Intersurgical QuadraLite	p
Sex	Male	50% (<i>n</i> = 6)	21.1% (<i>n</i> = 4)	0.127
	Female	50% (<i>n</i> = 6)	78.9% (<i>n</i> = 15)	
Age		59.83 ± 11.5	55.16 ± 16.24	0.393
BMI		27.01 ± 4.13	26.45 ± 2.47	0.655
Mallampati score	Ι	83.3% (<i>n</i> = 10)	68.4% (<i>n</i> = 13)	- 0.433
	II	16.7% (<i>n</i> = 2)	31.6% (<i>n</i> = 6)	
ASA class	Ι	16.7% (<i>n</i> = 2)	31.6% (<i>n</i> = 6)	0.644
	II	83.3% (<i>n</i> = 10)	63.2% (<i>n</i> = 12)	
	III	0	5.3% (<i>n</i> = 1)	

Table. Comparison of demographic data

respectively (p = 0.07). After 5 min, EtO₂ $\ge 90\%$ was achieved in 22 of 31 patients (70.97%), with the same success rate of 33.33% in group A and 94.73% in group B (p < 0.001).

In addition to the markedly increased success rate, preoxygenation in group B was also faster and less variable: 228.33 ± 104.03 vs. 164.37 ± 84.31 to $\text{EtO}_2 \ge 90\%$. A comparison of EtO_2 values at different durations of preoxygenation is shown in the Figure. EtO_2 was statistically significantly higher in group B after each 30 s interval (p = 0.006; 0.018; 0.034; 0.032; 0.01; 0.01; 0.006; 0.003; 0.004; 0.004)

DISCUSSION

We did not manage to find any other studies comparing different types of anaesthesia face masks during preoxygenation. A study conducted by Baillard et al., which evaluates incidence and prediction of inadequate preoxygenation, bears some similarity (1). This study enrolled 1050 patients undergoing general anaesthesia, excluding subjects with pulmonary comorbidities, trauma, or shock. The authors observed an inadequate preoxygenation (EtO₂ < 90% after 3 min) in 56% of the patients, while in our study the rate was 45.2%



Figure. Comparison of EtO, values at different duration of preoxygenation *

after 3 min. The success of a higher rate of preoxygenation in our study may be related with the type of a face mask used, a smaller subject group, and exclusion of patients with several risk factors for difficult face mask seal.

Taking a closer look into the conditions necessary for effective preoxygenation, tight face mask seal is essential. There are a number of possible factors predisposing air leakage, for example: inappropriate mask size, patient's obesity (BMI >30), toothlessness, patient's snoring, lolly beard, inserted nasogastric tube, etc. (2, 5, 12). We excluded patients with two or more risk factors mentioned above. Baillard and colleagues claim that incomplete preoxygenation is also associated with patient sex (males have an increased risk), age (patients over 55 years old), and the ASA score of IV. (2). These patients were not excluded so that the study subjects would represent a common population undergoing general anaesthesia for elective surgery. Comparing between the groups, our study showed that in the Economy mask group the mean age was lower and in the QuadraLife group there were fewer males, but these deviations were statistically insignificant.

Another reason for the inward air leak is that patients may feel discomfort from having the anaesthetic face mask tightly applied onto the face, which could result in less pressure applied by the anaesthesiologist and reduced tightness of the mask (12). We used Fentanyl (1–2 mcg/kg) to increase mask toleration and patient comfort. To reduce possible variations due to the human factors, all the subjects were preoxygenated by a single anesthesiologist using classic EC clamp technique for holding the face mask. There are some studies claiming that EO technique could provide a better mask seal, but the evidence is inconclusive (13, 14).

There is no uniform recommendation concerning the fresh gas flow to be used for preoxygenation. Recently, some authors recommended using 100% oxygen with a high fresh gas flow set to 12–15 l/min (2, 6, 12). However, there are studies evaluating preoxygenation efficiency using oxygen flow as low as 5 l/min (15). A lower oxygen concentration, which may result from the lack of tight fit of the mask, rebreathing expired gas, or an anaesthesia machine contour not primed with 100% oxygen, is associated with incomplete preoxygenation (2, 6, 12). In our study, we used 8 l/min flow and hypothetically sufficient preoxygenation rate could be higher with a higher flow. On the other hand, high oxygen flow may diminish the influence of inadequate face mask seal. Furthermore, higher oxygen flow needed for preoxygenation means higher expense for the institution and reduction of cost-effectiveness. Therefore it is reasonable to investigate how to ensure fast and efficient preoxygenation while using lesser gas supply.

There is also an ongoing debate concerning the optimal ventilation technique for preoxygenation. Most authors recommend the classic 3 min preoxygenation with patient breathing spontaneously as we did in the present study (2, 12), while others propose eight deep breaths in 60 seconds technique (6, 16). The latter technique is used for faster preoxygenation, usually before a rapid sequence induction. However, this method has limitation for obese or other risk group patients who cannot breathe deeply enough. A different approach is suggested by Hanouz et al. They found that more efficient preoxygenation (decreased time to reached EtO, at 90%) is achieved with positive pressure support ventilation (PPV) with or without PEEP versus patients who were breathing spontaneously (17). Meanwhile, Bignami et al. in their systematic review suggest that PSV with PEEP allow for the fastest rise in EtO_{2} (18). It would be reasonable to evaluate the performance of different types of anaesthesia face masks in the light of these new ventilation strategies.

CONCLUSIONS

In our study, the new type of anaesthesia face mask (QuadraLite) performed better than the traditional cuffed anaesthesia face mask (Economy). QuadraLite allowed the desired EtO_2 to be achieved faster and showed a higher optimal preoxygenation success rate. Further RCTs involving more subjects should be encouraged to obtain robust evidence.

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PREOKSIGENACIJOS EFEKTYVUMO PALYGINIMAS NAUDOJANT *INTERSUGICAL ECONOMY* IR *INTERSURGICAL* ANESTEZINES VEIDO KAUKES

Santrauka

Įvadas. Tinkama preoksigenacija prieš intubaciją apsaugo nuo deguonies frakcijos sumažėjimo arteriniame kraujyje. Sandariai prispausta veido kaukė yra būtina greitai preoksigenacijai.

Tikslas. Palyginti preoksigenacijos efektyvumą naudojant dvi skirtingas anestezines veido kaukes.

Metodika. Perspektyvinis tyrimas atliktas 2018 metais. Pacientai suskirstyti į dvi grupes: A grupėje naudotos *Intersurgical Economy*, B grupėje – *Intersurgical QuadraLite* veido kaukės. Per 30 sekundžių anestezijos aparato kontūras pildytas 100 % deguonimi, preoksigenacija pradėta 8 l/min. tėkme, FiO₂100. Pacientai kvėpavo spontaniškai. Fentanilis (1–2 mcg/kg) pasitelktas siekiant padidinti kaukės toleravimą. Preoksigenacijos tikslas – deguonies koncentracija iškvėptame ore (EtO₂) ≥90 %. EtO₂ buvo monitoruotas po 30, 60, 90, 120, 180, 210, 240, 270 ir 300 sekundžių. Duomenys analizuoti naudojant *Independent Samples T* ir *Mann Whitney* U testus.

Rezultatai. 12-a pacientų buvo įtraukta į A grupę ir 19-a į B grupę. Lytis, amžius, KMI ir Malampatii klasė tarp lyginamų grupių statistiškai reikšmingai nesiskyrė (atitinkamai p = 0,13; 0,39; 0,65; 0,43). Pacientai priskirti ASA I – 25,8 % (n = 8 – >2/6), ASA II – 71,0 % (n = 22 - >10/12), ASA III - 3,2 % (n = 1 - >0/1), p = 0,64. Pasiekta sėkminga preoksigenacija EtO₂90 iki 5 min. statistiškai reikšmingai skyrėsi: 33,3 % A grupėje ir 94,7 % B grupėje (p < 0,01). Vidutinis laikas iki EtO₂90 buvo 228,3 ± 104,0/164,4 ± 84,3. Vidutinis EtO₂ po 30 s - $56,0\pm13,5/69,3\pm11,2(p<0,01);60s-63,8\pm15,3/76.1\pm11,7$ $(p = 0.02), 90 \text{ s} - 67.8 \pm 17.7/80.7 \pm 10.1 \ (p = 0.03);$ 120 s - 69,6 \pm 18,2/83,4 \pm 10,0 (p = 0,03), 150 s - $71,1\pm 19,0/87,1\pm 6,5$ (p=0,01); $180s-72,9\pm 16,8/88,5\pm 5,3$ $(p = 0,01), 210 \text{ s} - 72,6 \pm 18.0/89,2 \pm 5,1 \ (p < 0,01);$ 240 s - 74,17 \pm 15,4/90,0 \pm 4,3 (p < 0,01), 270 s $-76,3 \pm 16,3/90,2 \pm 3,6; 300 \text{ s} - 77,8 \pm 14,6 / 90,2 \pm 1,5$ (*p* < 0,01).

Išvados. Preoksigenacija buvo reikšmingai efektyvesnė ir greitesnė naudojant *Intersurgical QuadraLite* veido kaukę.

Raktažodžiai: preoksigenacija, deguonis, veido kaukė