Comparison of the Effectiveness of Transnasal Humidified Rapid Insufflation Ventilator Exchange (THRIVE) with Facemask Pre-Oxygenation in 40 Patients ≥65 Years of Age Undergoing General Anaesthesia During Gastrointestinal Surgery for Intestinal Obstruction

Wanling Wang
Wenwen Zhang
Yu Lu
Yajie Xu
Yong Zhang
Hongwei Shi
Xiaoliang Wang

Background: In this study, we aimed to compare the effectiveness of transnasal humidified rapid insufflation ventilator exchange (THRIVE) with facemask pre-oxygenation in 40 patients ≥65 years of age undergoing general anaesthesia during gastrointestinal surgery for intestinal obstruction.

Material/Methods: Patients with gastrointestinal obstruction were randomized to either a facemask group (group M, n=20) or THRIVE group (group T, n=20). During pre-oxygenation, the 2 groups used a facemask (100% oxygen, 6 L/min) and THRIVE (100% oxygen, 40 L/min) to supply oxygen, respectively. Induction of anesthesia was performed in both groups using facemasks and without mechanical or assisted ventilation. The intubation occurred after myorelaxant action began. When the peripheral oxygen saturation (SpO₂) dropped below 95%, or 480 s after administration of muscle relaxants, mechanical ventilation was initiated immediately. The primary outcome was arterial partial pressure of oxygen (PaO₂) at 5 min after pre-oxygenation. A secondary outcome was time to SpO₂ of 95% during apnea, with a cut-off time of 480 s.

Results: PaO₂ at 5 min after pre-oxygenation was (261.5±30.9) mmHg for group M and (446.1±84.4) mmHg for group T (P<0.001). Based on survival analysis, the median time-to-event in group T was 480 s (95% CI 415.7 s – upper limit unknown) and 240 s (95% CI 225.9-254.1 s) in group M (P<0.001).

Conclusions: In elderly patients undergoing rapid sequence induction, pre-oxygenation with THRIVE could improve oxygenation and extend safe apnea time, compared with facemask pre-oxygenation.

Keywords: Hyperbaric Oxygenation • Rapid Sequence Induction and Intubation • Aged

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Background

Hypoxia during the rapid sequence induction (RSI) of anesthesia is still an important issue that can considerably impact patient outcomes [1]. Normally, pre-oxygenation with 100% oxygen before intubation is used to denitrogenate, increase the oxygen reserve, and extend safe apnea time [2]. However, it is common for patients with gastrointestinal obstruction to have increased intra-abdominal pressure, diaphragmatic muscle activity, and decreased abdominal breathing [3]. Most of these patients are in an emergency situation and usually have a full stomach before surgery. The nasogastric tube and gastrointestinal tube are typically placed before surgery for gastrointestinal decompression or enteral nutrition, which prevents the facemask from fitting tightly in the pre-oxygenation stage. In addition, elderly patients with insufficient oxygen reserves are more likely to have hypoxia [4].

Transnasal humidified rapid-insufflation ventilatory exchange (THRIVE) is a new high-flow ventilation method that delivers warmed and humidified high-flow oxygen through a nasal cannula and is increasingly used in anesthetic practice and complex airway management [5]. Oxygen flow rates of up to 70 L/min can reduce anatomical dead space in the upper airway and improve end-expiratory compliance for ventilation and oxygenation [6]. Many studies have shown that THRIVE provides better oxygenation during induction of general anesthesia and can prolong safe apnea time by up to 17 min [7].

In 2020, Hua et al found that THRIVE extended the apnea time and provided better pre-oxygenation in elderly patients under general anesthesia [6]. However, they focused on using THRIVE during the peri-intubation period, including the phase of pre-oxygenation and apneic oxygenation. Because oxygen is provided continuously until intubation, this can raise intragastric pressure, possibly causing reflux or aspiration in patients with gastrointestinal obstruction. No studies have looked at the use of THRIVE alone during pre-oxygenation with RSI. Therefore, in this study, we aimed to compare the effectiveness of THRIVE with that of facemask pre-oxygenation in 40 patients ≥65 years of age undergoing general anaesthesia during gastrointestinal surgery for intestinal obstruction.

Material and Methods

Study Design

This single-blind and prospective trial was approved by the Ethics Committee of Nanjing First Hospital (KY20201102-04) and registered with the Chinese Clinical Trial Center (ChiCTR2100050184) before patient enrollment. All patients signed an informed consent form.

Patients

Patients with gastrointestinal obstruction requiring RSI of anesthesia, ≥65 year of age, with American Society of Anesthesiologists classification I-III, Mallampati score I-II, and correctly cooperating with the use of THRIVE after explanation, were selected. The gastrointestinal obstructions were all diagnosed by surgeons, based on computed tomography. Exclusion criteria included the following: anticipating difficult airways, body mass index (BMI) >30 kg/m², severe systemic disease (neurological, cardiovascular, pulmonary, hepatic, or renal disorders), epistaxis and nasopharyngeal abnormalities, and moderate or higher anemia.

Randomization and Blinding

The research equipment included THRIVE (Optiflow THRIVE, Fisher & Paykel Healthcare, Auckland, New Zealand) and facemasks (Zhejiang Sulia Medical Device Co., Ltd., Zhejiang, China).

Using computer randomization software (SPSS 24.0), each patient was randomly categorized into the facemask group (group M) or THRIVE group (group T) in a 1:1 ratio. The grouping results were secured in a sealed opaque envelope that was opened only by the researchers before anesthesia induction. A blinded research team member conducted postoperative interviews with the patients. All patients, preoperative and postoperative follow-up assessors, and statisticians were blinded to group allocation.

Intervention

Patients were decompressed through a nasal gastric tube before surgery. Negative pressure suction devices were prepared, as well as routine monitoring. The patients were placed supine with the head elevated approximately 25° to 30° [12]. In addition to routine monitoring, each patient underwent invasive blood pressure monitoring. Group M underwent pre-oxygenation via a facemask with a fraction of inspiration oxygen (FiO₂) of 100% at 6 L/min and opened adjustable pressure limiting valve. The THRIVE device was heated and humidified 5 min before use, and patients in group T were instructed to use THRIVE oxygen with a tightly closed mouth, with a FiO₂ of 100% at 40 L/min. Induction of anesthesia after 5 min of pre-oxygenation consisted of intravenous midazolam 0.02 to 0.05 mg/kg, propofol 1 to 2 mg/kg, rocuronium bromide 0.6 mg/kg, and remifentanil 1 to 2 ug/kg. When induction started in group T, THRIVE was removed, and the facemask was put with oxygenation as in group M. During the induction period, the upper airways of both groups were kept open with 2-handed airway maneuvers and breathing without using any pressure-assisted techniques. A video laryngoscope was inserted within the 60 s after rocuronium bromide was administered. The tracheal cuff was inflated immediately after successful intubation in both groups, and no mechanical ventilation was performed in
either group. When the peripheral oxygen saturation (SpO₂) dropped to 95% or the safe apnea time (the time between the start of rocuronium bromide injection and the drop of SpO₂ to 95%) reached 480 s, mechanical ventilation was started.

In cases of severe reflux, the patients were placed in the Trendelenburg position with the head tilted to the side, the oropharynx was suctioned and cleared, and an emergency endotracheal intubation was performed. Intubation was stopped when SpO₂ was greater than 90% during intubation, and oxygenation was maintained by manually ventilating (tidal volumes of 4-6 mL/kg, pressure-limiting valve set at 20 cmH₂O) until SpO₂ reached 98%. The 2015 Difficult Airway Society guidelines for unanticipated difficult endotracheal intubation in adults were used when the patient proved difficult for endotracheal intubation [13]. Patients with the above 3 situations were excluded from the study.

Outcomes and Data Collection

During this study, we defined different time points as follows: upon entering the operating room while breathing room air (T0), after 5 min of pre-oxygenation (T1), after successful endotracheal intubation (T2), and safe apnea time up to 480 s or SpO₂ down to 95% (T3).

The primary outcome was PaO₂ at T1. Secondary outcomes were the number of patients with safe apnea time up to 480 s, safe apnea time, re-oxygenation time, PaO₂ arterial partial pressure of carbon dioxide (PaCO₂), heart rate, and mean arterial pressure at each time point, intubation time, adverse events after induction of anesthesia, and complications related to THRIVE ventilation.

Apnea time was defined as the time from the start of rocuronium bromide injection until SpO₂ dropped to 95%. For patient safety, the maximum duration of the apneic period has been set at 480 s [6]. When the patient’s SpO₂ level did not drop to 95% within 480 s, it was finally recorded as 480 s.

Re-oxygenation time was defined as the time from the beginning of mechanical ventilation until SpO₂ reached 98%. When SpO₂ ≥98% was obtained at the end of the apnea, the re-oxygenation time was recorded as 0.

The intubation time was defined as the time from video laryngoscope placement into the mouth to passing a tracheal tube through the vocal cords.

Sample Size Estimation

A pilot study with 4 patients undergoing facemask pre-oxygenation was conducted to estimate the sample size for the study. With facemask pre-oxygenation, these patients’ mean PaO₂ was 305 mmHg, with an average standard deviation of 80 mmHg. The calculation of the sample size used a mean PaO₂ of 400 mmHg to achieve an adequate elongation of safe apnea margin with the 2 devices [14]. Based on mean PaO₂ values of 300 and 400 mmHg with a standard deviation of 80 mmHg, the significance criterion was set at α=0.05 (2-sided), power=90%, and in PASS11.0 software, a sample size of 16 was calculated for each group. Considering the data loss, the final sample size was 20 patients per group.

Statistical Analysis

SPSS software (version 24.0, IBM Corp, Armonk, NY, USA) was used for the statistical analysis. The Shapiro-Wilk test was used to determine the normality of the data. The variance was tested for homogeneity with Levene’s test. Means ± standard deviations were used to represent normally distributed data. The t test was used to compare the 2 groups. Repeated measures analysis of variance was used to compare the group at multiple time points. Using the Mann-Whitney U test, non-normally distributed data were expressed as medians and interquartile ranges (IQR). In the analysis of the numerator data, frequencies (%) and percentages (%) were used, and Fisher’s exact probability test was used to compare groups.

A secondary result was time to SpO₂ of 95% during apnea, with a cut-off time of 480 s. A maximum apneic period of 480 s was set to ensure patient safety. SpO₂ levels were initially documented as 480 s if they did not drop to 95% before 480 s. Since there were many patients whose SpO₂ fell below 95% within 480 s in the THRIVE group, the outcome was analyzed as a time-to-event analysis (survival framework) that censored a patient if their SpO₂ levels did not fall below 95% by 480 s. For comparison between group T and group M, a Kaplan-Meier survival analysis was performed, but not the Mann-Whitney U test [11]. Statistical significance was set at P<0.05.

Results

Forty-four patients were assessed for eligibility in the study, and 4 were not included (Figure 1). As shown in Table 1, the characteristics of participants in each group were similar.

Primary Outcome

The primary outcome, PaO₂ at T1, was 261.5±30.9 mmHg for group M and 446.1±84.4 mmHg for group T (Table 2, P<0.001). A higher PaO₂ was observed in group T than in group M at T1-T3. PaO₂ at T1-T2 in both groups was higher than that at T0. As for the intubation time, group M measured 42.7±8.1 s, and group T measured 41.6±6.5 s (P=0.640).
Safe Apnea Time

Figure 2 shows the Kaplan-Meier survival curves for both groups. The safe apnea time of group T was 377.5 (360, 480) s and for group M was 239 (217, 273.8) s. The safe apnea time for group T was significantly longer than that of group M ($P=0.01$). Group T had a higher percentage of safe apnea time up to 480 s and a shorter time to re-oxygenation than group M ($P<0.05$).

Comparison of PaCO$_2$ and PETCO$_2$ After Intubation

Both groups had higher PaCO$_2$ levels at T2-T3 than at T0-T1. At T2-T3, group T had a higher PaCO$_2$ than group M. At the beginning of mechanical ventilation, group T had a higher partial pressure of end-tidal carbon dioxide (PETCO$_2$) ($P<0.05$).

Hemodynamic Changes and Adverse Events

There was no statistically significant difference in hemodynamic changes or adverse events after induction of anesthesia between the 2 groups (Figure 4). No THRIVE ventilation-related complications were observed in the patients in group T.

Discussion

To study only the pre-oxygenation period and avoid gastric content regurgitation of THRIVE continuous oxygenation, we replaced THRIVE with a facemask during the apneic period in group T. Compared with PaO$_2$ with facemask pre-oxygenation, the study results showed that PaO$_2$ was significantly higher.

Table 1. Patient characteristics.

|                         | Group M (n=20) | Group T (n=20) | $P$  |
|-------------------------|---------------|---------------|-----|
| Age (year)              | 70.8±9.7      | 69.1±9.0      | 0.580|
| BMI (kg/m$^2$)          | 22.0±2.9      | 21.4±3.2      | 0.574|
| ASA (I/II/III, n)       | 1/18/1        | 2/16/2        | 0.695|
| Pre-operative Hb (g/L)  | 12.4±1.9      | 12.6±2.3      | 0.750|
| Mallampati score (I/II/III, n) | 15/5/0 | 16/4/0       | 1.000|
| Thyromental distance (I/II/III, n) | 15/5/0 | 16/4/0 | 1.000|
| Mouth opening (1/2/3, n) | 0/4/16       | 0/3/17       | 1.000|

ASA – American Society of Anesthesiologists; BMI – body mass index; Group M – pre-oxygenation with facemask; Group T – pre-oxygenation with THRIVE. Data are presented as mean±standard deviation and number (n). $P$: Group M vs Group T.
Table 2. Comparison of PaO₂ at different times and safe apnea time of 480 s between the 2 groups.

|                | Group M (n=20) | Group T (n=20) | P     |
|----------------|----------------|----------------|-------|
| **T0**         | 76.7±9.5       | 81.4±8.7       | 0.113 |
| **T1**         | 261.5±30.9     | 446.1±84.4     | <0.001|
| **T2**         | 144.3±40.5     | 263.9±70.6     | <0.001|
| **T3**         | 68.7±6.4       | 90.2±34.6      | 0.013 |

≥480 s time to SpO₂ <95%, n (%)
- 480s: 18 (90) vs 11 (55), P<0.05
- 480s: 2 (10) vs 9 (45)* , P<0.05

T0, entering the operating room while breathing room air; T1, after 5 minutes of pre-oxygenation; T2, after successful endotracheal intubation; T3, safe apnea time up to 480 s or SpO₂ down to 95%. Group M – pre-oxygenation with facemask; Group T – pre-oxygenation with THRIVE. Data are presented as mean ± standard deviation and number (n). P: Group M vs Group T; *, P<0.05, there were statistically significant differences compared with Group M; #, P<0.05, there were statistically significant differences compared with T0.

Table 3. Comparison of PaCO₂ and PETCO₂ after intubation between the facemask and THRIVE groups.

|                | Group M (n=20) | Group T (n=20) | P     |
|----------------|----------------|----------------|-------|
| **T0**         | 36.3±4.1       | 38.0±3.7       | 0.178 |
| **T1**         | 35.3±4.8       | 37.7±3.9       | 0.083 |
| **T2**         | 47.0±4.9*      | 50.7±6.0*      | 0.040 |
| **T3**         | 55.6±5.9*      | 63.4±7.2*      | 0.001 |
| PETCO₂ after intubation | 48.1±3.9       | 57.0±5.6*      | <0.001|

T0, entering the operating room while breathing room air; T1, after 5 minutes of pre-oxygenation; T2, after successful endotracheal intubation; T3, safe apnea time up to 480 s or SpO₂ down to 95%. Group M – pre-oxygenation with facemask; Group T – pre-oxygenation with THRIVE. Data are presented as mean±standard deviation. P: Group M vs Group T; *, P<0.05, there were statistically significant differences compared with Group M; **, P<0.05, there were statistically significant differences compared with T0; #, P<0.05, there were statistically significant differences compared with T2.
after pre-oxygenation with THRIVE in elderly patients undergoing RSI. In addition, the safe apnea time was extended, and the time to re-oxygenation was shortened in the THRIVE group.

In 2017, Mir et al used either THRIVE or facemask for oxygen supply during pre-oxygenation for RSI anesthesia [8]. Although they found no statistically significant difference in PaO₂, the THRIVE group’s arterial blood gases might have been more favorable if the intubation time was the same in both groups. In 2018, Lodenius et al randomly allocated patients having RSI anesthesia for emergency surgery to pre-oxygenation with 100% oxygen with a facemask or THRIVE [9]. There were no differences in apnea time or the lowest SpO₂, (1 min after intubation) between the groups. However, there were 5 patients (12.5%) whose oxygen saturation level fell below 93% on pre-oxygenation with the facemask, whereas there were none in the THRIVE group. Similar results have also been reported in patients with acute hypoxic respiratory failure [10]. Both of these reports and ours suggest that THRIVE may provide a pre-oxygenation benefit.

Due to the relative elevation of the diaphragm, increased intra-abdominal pressure, and lower effective lung volume, combined with the elderly patients’ diminished lung function, elderly patients with gastrointestinal obstruction are more at risk of hypoxia. However, THRIVE could provide continuous positive airway pressure by delivering heated and humidified high-flow pure oxygen, more than the patient needs, opening the upper airway and even the distal alveoli, thereby reducing dead space and decreasing the incidence of atelectasis and improving oxygenation [15]. Furthermore, THRIVE increased end-expiratory lung impedance, thus increasing functional residual air volume and preventing the collapse of alveoli and airways, which was beneficial for airway opening and improving pulmonary shunts in elderly patients [16]. Finally, the thin cheeks and lost teeth of elderly patients with gastrointestinal obstruction made facemask ventilation inefficient and less airtight, while THRIVE ventilation was not affected. Clinically, safe apnea time was usually defined as when SpO₂ dropped to 90% after stopping ventilation after induction of general anesthesia [17]. However, considering combined cardiovascular and cerebrovascular illnesses in elderly individuals and impaired respiratory capacity, we defined the safe apnea time as when SpO₂ dropped to 95% following breathing stoppage, and the end of the test was set to 480 s. In our study, PaCO₂ was elevated in both groups during the apneic oxygenation period compared with preoperative PaCO₂. Nevertheless, it was significantly higher in the THRIVE group than in the facemask pre-oxygenation group because the safe apnea time was significantly longer with THRIVE pre-oxygenation, which increased carbon dioxide accumulation.

In 2019, Wong et al found that the safe apnea time was significantly longer in the THRIVE group than in the facemask pre-oxygenation group [18]. Similar conclusions were obtained in a study by Guy et al on the duration of asphyxia in patients with obesity [11]. Hua et al discovered that THRIVE pre-oxygenation resulted in higher PaO₂ and longer safe apnea time than facemask pre-oxygenation, consistent with our findings [6]. In contrast, Pillai et al found no difference between THRIVE pre-oxygenation and facemask pre-oxygenation [19]. The difference between the 2 studies might be explained by pre-oxygenation time (3 min vs 5 min), and the index monitored (transcutaneous partial pressure of oxygen vs PaO₂). Compared with our study, Mir et al found that PaO₂ after endotracheal intubation was comparable with THRIVE or face-mask pre-oxygenation in patients with RSI undergoing emergency general anesthesia, which differed from our findings [8]. In their study, the endotracheal intubation time in the THRIVE group was longer than in the facemask group. With the exact duration of endotracheal intubation, PaO₂ should be higher in the THRIVE group than in the facemask group. According to Tan et al, THRIVE pre-oxygenation in full-term pregnant women did not achieve similar (EtO₂ ≥90%) results as facemask pre-oxygenation [20]. We speculate that this was associated with
flow rate, pre-oxygenation time, and respiratory status. Their study had a pre-oxygenation time of 3 min and a flow rate of 30 L/min, and the patients were not instructed to close their mouths before pre-oxygenation. On the other hand, in our study, the patients in the THRIVE group breathed nasally with their mouths shut, the pre-oxygenation time was 5 min, and the flow rate was 40 L/min. Open-mouth and closed-mouth use of THRIVE produces EtO₂ of 86 kPa and 49 kPa, respectively. Higher EtO₂ partial pressure promotes oxygen diffusion and ensures oxygen supply for the patient.

Additionally, THRIVE’s PEEP is flow-dependent, and higher flow rates create higher PEEP values, which are more beneficial for maintaining airway opening [19]. Depending on the patient’s physiological state, a relatively longer pre-oxygenation time may be necessary to maximize the pre-oxygenation effect. THRIVE was used at a flow rate of 50 L/min, pre-oxygenation was for 3 min, and pre-oxygenation resulted in better results than facemask for pregnant women with RSI [21]. Thus, the application of THRIVE for pre-oxygenation may have specificity in some patients.

This study had the following limitations. First, the optimal flow rate regarding the application of THRIVE was not explored, and further studies will be conducted subsequently. Second, whether the 2 pre-oxygenation methods will affect gastric volume was not evaluated. Third, we have not yet determined the best pre-oxygenation time.

Conclusions

Pre-oxygenation using THRIVE during RSI improved oxygenation and safe apnoea time. Once the patient’s airway is handled for a long period, THRIVE may be proven beneficial to maintain oxygenation and ensure patient safety.

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Declaration of Figures’ Authenticity

All figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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