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ORIGINAL ARTICLE

# Comparison of a simplified nasal continuous positive airways pressure device with nasal cannula in obese patients undergoing colonoscopy during deep sedation

## *A randomised clinical trial*

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**BACKGROUND** Continuous positive airways pressure (CPAP) with a CPAP machine and mask has been shown to be more effective at minimising hypoxaemia than other devices under deep sedation. However, the efficacy of a new and simple CPAP device for spontaneously breathing obese patients during colonoscopy is unknown.

**OBJECTIVE** We hypothesised that oxygenation and ventilation in obese patients under deep sedation during colonoscopy using CPAP via a new nasal mask (Super$NO_2$VA) would be better than routine care with oxygen supplementation via a nasal cannula.

**DESIGN** Randomised study.

**SETTING** Single-centre, June 2017 to October 2017.

**PATIENTS** A total of 174 patients were enrolled and randomly assigned to Mask group or Control group. Thirty-eight patients were excluded and data from 136 patients underwent final analysis.

**INTERVENTION** Patients in the Mask group were provided with nasal CPAP (10 cm$H_2O$) at an oxygen flow rate of 15 l min$^{-1}$. In the Control group, patients were given oxygen via a nasal cannula at a flow rate of 5 l min$^{-1}$.

**MAIN OUTCOME MEASURES** The primary outcome was elapsed time from anaesthesia induction to the first airway intervention.

**RESULTS** The elapsed time from anaesthesia induction to the first airway intervention was 19 ± 10 min in the Mask group ($n$=63) vs. 10 ± 12 min in the Control group ($n$=73, $P < 0.001$). In all, 87.5% (56/64) of patients achieved the target CPAP value. More patients in the Control group (63%) received airway intervention than in the Mask group (22%) ($P < 0.001$). Hypoxaemia (pulse oximeter oxygen saturation, $SpO_2 < 90\%$) occurred more frequently in the Control group (22%) than in the Mask group (5%) ($P = 0.004$). Minute ventilation$_{Postinduction}$/minute ventilation$_{Baseline}$ and minute ventilation$_{Procedure\text{-}end}$/minute ventilation$_{Baseline}$ was lower in the Control group than in the Mask group ($P = 0.007$ and 0.001, respectively).

**CONCLUSION** Application of a nasal mask at a target CPAP of 10 cm$H_2O$ improves ventilation and decreases the frequency and severity of hypoxaemia.

**TRIAL REGISTRATION** NCT03139448, registered at ClinicalTrials.gov.

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## Introduction

Colonoscopy as a routine screening procedure has been incorporated and frequently utilised within the healthcare system.[1–3] Sedation with spontaneous breathing via a natural airway is commonly used during gastrointestinal endoscopic procedures.[4] However, hypoxaemia and/or hypercapnia frequently occur during colonoscopy

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due to respiratory depression and upper airway obstruction.[5–9] Obese patients are particularly at risk of upper airway obstruction and hypoxaemia under sedation and may benefit from a device that helps to reduce this airway obstruction.[10–14] Furthermore, with the increase in obesity rates, a device that can reduce airway obstruction is clinically relevant.

Continuous positive airways pressure (CPAP), applied nasally or via face mask, has been shown to be effective at minimising hypoxaemia and upper airway obstruction under deep sedation.[13,15] However, it requires a special mask and CPAP machine which may not be routinely available in gastrointestinal endoscopy suites.[16] Recently, a new and simple CPAP device (Super$NO_2$VA$^{TM}$; Revolutionary Medical Devices, Tucson, Arizona, USA) was developed and a small pilot study demonstrated its safety and efficacy.[17] This device does not require a CPAP machine and an $O_2$ flow of 15 l min$^{-1}$ is able to generate the desired level of CPAP in most patients. We hypothesised that this new nasal mask would improve ventilation and oxygenation during colonoscopy in spontaneously breathing obese patients under deep sedation.

## Methods

The current prospective randomised nonblinded study was approved by the Institutional Review Board of Vanderbilt University Medical Centre, registered at ClinicalTrials.gov (NCT03139448), and conducted between 26 June 2017 and 15 October 2017. One hundred and seventy-four patients more than 17 years of age, with a BMI between 30 and 50 kg m$^{-2}$, American Society of Anesthesiologists' physical status classification of 1 to 3, and scheduled for elective colonoscopy under deep sedation were enrolled from the gastrointestinal endoscopy centre at Vanderbilt University Medical Center. The exclusion criteria included: untreated ischaemic heart disease; acute and chronic respiratory disorders, including chronic obstructive pulmonary disease and asthma; emergency procedures; planned use of an invasive airway (e.g. supraglottic device, endotracheal tube, etc.); pregnancy; and nasal or oral disease resulting in difficulty of either nasal breathing or mouth breathing.

The anaesthesia providers included an attending anaesthesiologist and certified registered nurse anaesthetists. Brief instructions on the use of the mask were provided to the care team prior to the procedure.

After obtaining written informed consent, patients were allocated randomly to the Mask group (Super$NO_2$VA) or the Control group (routine care with a nasal cannula). In the preprocedure holding room, a bio-impedance-based respiratory volume monitor (ExSpiron; Respiratory Motion, Inc., Waltham, Massachusetts, USA) electrode PadSet was attached to patients in the lateral position.[18,19] For 60 s, the patient breathed through a Wright/Haloscale Respirometer (nSpire Health, Inc., Longmont, Colorado, USA) with nostrils occluded and the measured minute ventilation was entered into the ExSpiron for calibration. After calibration, patients were allowed to breathe normally. Minute ventilation, tidal volume and respiratory rate were continuously recorded from this point until the end of the procedure.

In the Control group, the anaesthesia provider supplied oxygen via a nasal cannula at an oxygen flow rate of 5 l min$^{-1}$ supplied from an oxygen flowmeter. The standard practice for supplemental oxygenation for colonoscopies at our institution is to use 5 l min$^{-1}$ of oxygen via a nasal cannula. We used this practise for our control group rather than using a higher flow rate of oxygen because we considered this to be an outcome study rather than a physiological study. In the Mask group, the study team applied the nasal mask together with the hyperinflation bag, held in place with a head strap to ensure a proper seal. CPAP was created using the adjustable pressure limiting valve set to 10 cm$H_2O$ on the hyperinflation bag at an oxygen flow rate of 15 l min$^{-1}$, according to manufacturer recommendations. The intramask pressure was continuously recorded via a pressure sensor (Rusch Teleflex, LBL004953 R00, USA). The experimental set-up is shown in Fig. 1.

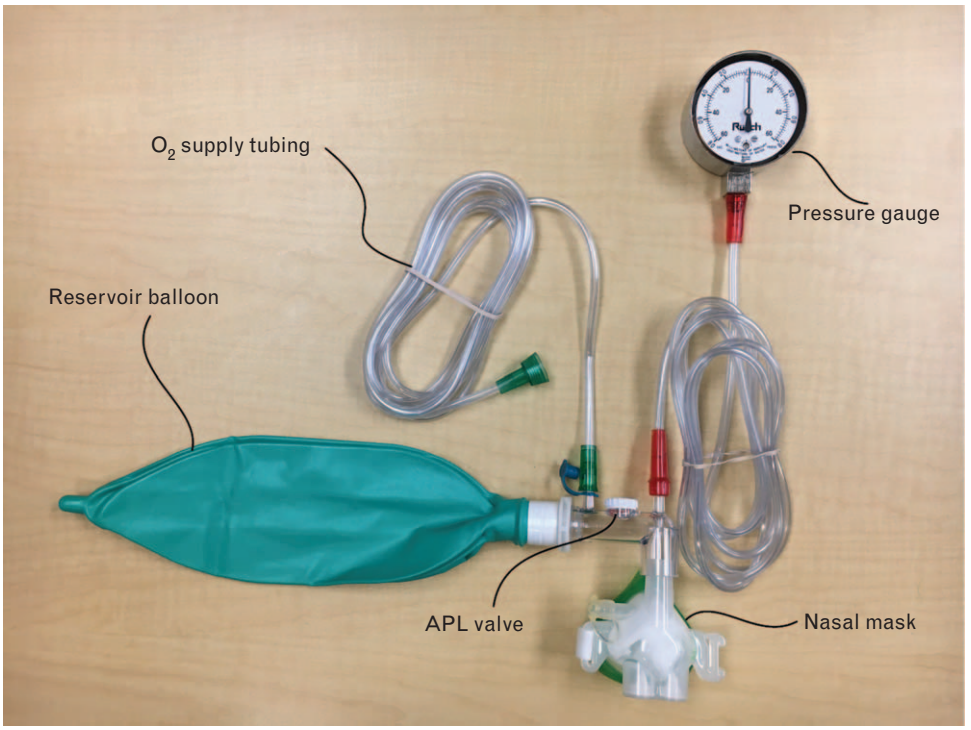
The use of anaesthetics and analgesics was at the discretion of the anaesthesia care team. The depth of sedation was not standardised. Most of the patients in each arm received a bolus of propofol in divided doses followed by a continuous infusion (Table 1). Providers were allowed to treat hypoxaemia and/or apnoea based on their clinical judgements and use any airway interventions as they needed. During the procedure, end-tidal carbon dioxide tension ($CO_2$), pulse oximeter oxygen saturation ($SpO_2$), noninvasive blood pressure, ECG, respiratory rate, tidal volume and minute ventilation were measured continuously. The primary outcome was the elapsed time from anaesthesia induction to first airway intervention. The secondary outcomes were the incidence and duration of the interventions, differences in $SpO_2$, tidal volume, respiratory rate and minute ventilation at 2, 4, 6 min postinduction, 5 min before the end, and at the end of procedure.

### Statistical analysis

A sample size up to 160 was determined to be sufficient to detect a 20% (1 min) mean difference in primary outcome (elapsed time from anaesthesia induction to first airway intervention) with 80% power, assuming an SD of 2 min, a 5% type I error rate and a 20% dropout rate.

Normal distribution of data was assessed using Kolmogorov–Smirnov tests of normality. Variability of the data was measured by Levene's test. The primary outcome was evaluated using an unpaired two-tailed *t* test. Respiratory parameters were evaluated using two way analysis of variance or Wilcoxon rank tests, according to normal/

Fig. 1




Experimental set up. Continuous positive airways pressure device includes a sealed nasal mask and disposable, flow-inflating hyperinflation bag (SuperNO$_2$VA Satellite Set, Revolutionary Medical Devices, Tucson, USA). The nasal mask was applied with a strap prior to anaesthesia induction. The strap was then tightened as needed after induction. The tubing for the oxygen supply and pressure measurement gauge were unfolded during the study.

abnormal distribution. Unpaired two-tailed $t$ tests and $\chi^2$ tests were used to compare quantitative and categorical outcomes respectively, with respect to baseline subject characteristics, intervention/oxygenation data and subsequent analysis of minute ventilation. Mann–Whitney $U$ tests were used to compare average/median number of apnoeic and hypopnoeic events.

Data were analysed using the Statistical Package for the Social Sciences 20.0 (IBM). Data are presented as mean ± SD, number (%) or median [IQR]. Significance was defined as a two-sided $P$ value less than 0.05.

**Table 1** Demographic data and characteristics of the surgery and procedure

| Characteristics | Mask group, $n$=63 | Control group, $n$=73 |
|---|---|---|
| Sex (male/female) | 30/33 | 26/47 |
| ASA physical status | | |
| 1 | 0 | 0 |
| 2 | 29 | 30 |
| 3 | 34 | 43 |
| Height (cm) | 171 ± 10 | 170 ± 12 |
| Weight (kg) | 104 ± 19 | 106 ± 23 |
| BMI (kg m$^{-2}$) | 36 ± 5 | 36 ± 6 |
| Routine diagnosis | | |
| Screening | 48 | 53 |
| Crohn's disease | 7 | 8 |
| Others | 8 | 12 |
| Intravenous anaesthetics and analgesics | | |
| Lignocaine (mg) | 87 ± 21 | 87 ± 25 |
| Propofol for induction (mg) | 94 ± 28 | 90 ± 35 |
| Propofol for infusion (mg) | 403 ± 200 | 440 ± 291 |
| Number of patients who received fentanyl | 3 | 7 |
| Number of patients who received ketamine | 1 | 3 |
| Number of patients who received midazolam | 1 | 3 |
| Procedure length (min) | 23 ± 9 | 24 ± 14 |

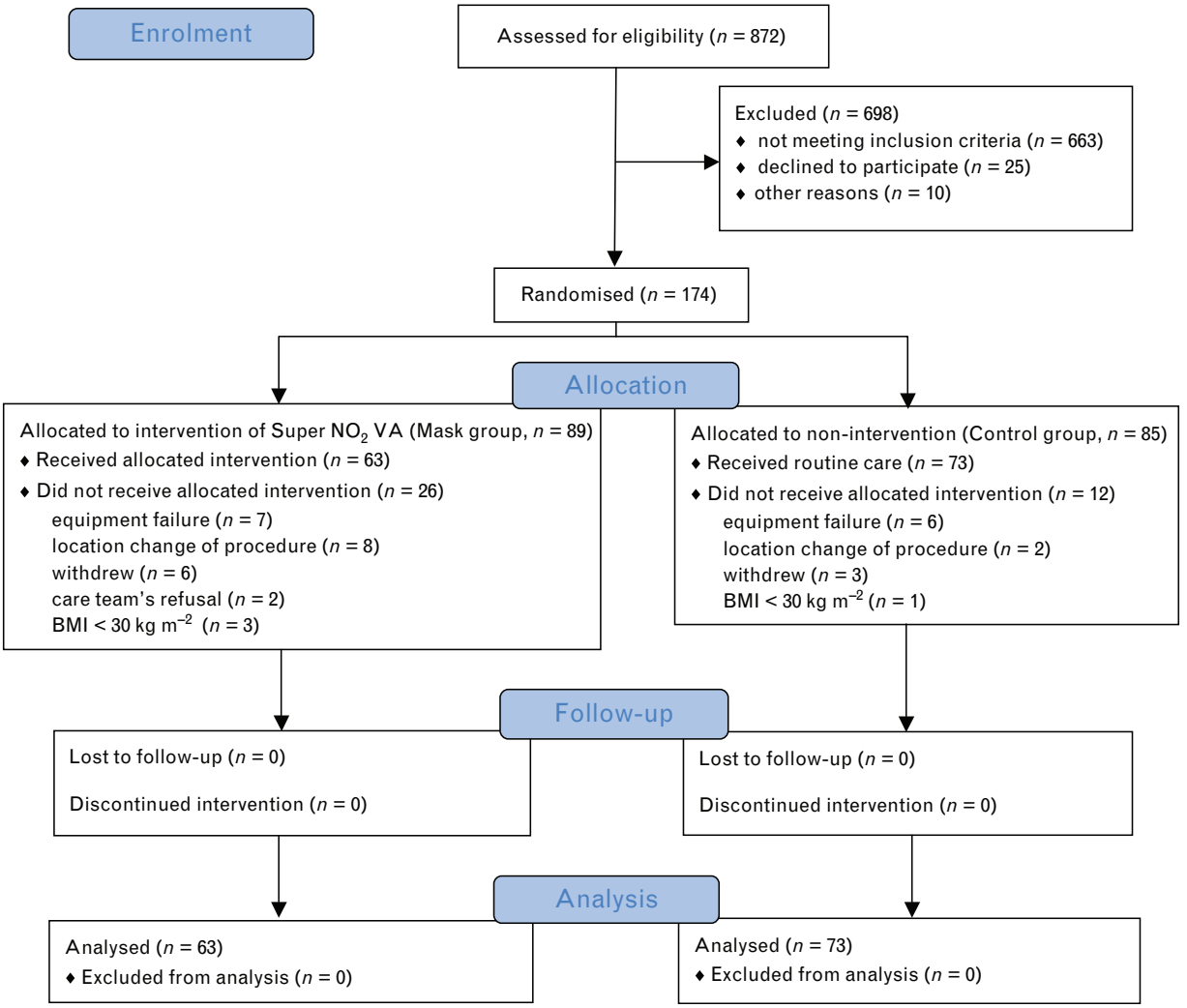
Values are mean ± SD or absolute number.

## Results

A total of 174 patients were enrolled. Thirty-eight patients were excluded with detailed information described in Fig. 2. One hundred and thirty-six patients underwent final analysis and their characteristics are listed in Table 1, with no significant differences found between the two groups. Using a bolus and an infusion of propofol, the providers titrated to achieve an appropriate level of sedation for colonoscopy. The initial bolus was given in divided doses and the total dose was 92 ± 31 mg or 0.88 ± 0.3 mg kg$^{-1}$ actual body weight. The total infusion dose was 421 ± 240 mg or 4.01 ± 1.27 mg kg$^{-1}$ actual body weight.

Elapsed time from anaesthesia induction to first airway intervention was 19 ± 10 min in the Mask group and 10 ± 12 min in the Control group ($P$ < 0.001). In all,

**Fig. 2**




Patients' enrolment and randomisation.

87.5% (56/64) patients achieved the target CPAP value. Less patients in the Mask group received airway interventions [14/63 (22%) vs. 46/73 (63%) in the Control group ($P < 0.001$)]. There was no statistically significant difference in the total intervention time/procedure length between groups (12 ± 31% in Mask group vs. 19 ± 28% in Control group, $P = 0.169$). Subgroup analysis of airway interventions showed that chin lift or jaw thrust occurred more frequently in the Control group [45/46 (98%) compared with the Mask group, 8/14 (57%)] ($P < 0.001$). There was no difference in the incidence of oral or nasal airway insertion between the two groups. None of the patients in either group needed laryngeal mask airway insertion or endotracheal intubation during the procedure.

In the Mask group, there was no significant difference between $SpO_2$ baseline values compared with 2 min ($Z$ −0.571, $P = 0.568$), 4 min ($Z$ −0.787, $P = 0.431$), 6 min postinduction ($Z$ −1.345, $P = 0.179$), 5 min before the end ($Z$ −0.462, $P = 0.644$) and at the end of procedure ($Z$ −0.282, $P = 0.778$). In the Control group, $SpO_2$ was significantly higher at baseline compared with 2 min ($Z$ −5.168, $P < 0.001$), 4 min ($Z$ −4.074, $P < 0.001$), 6 min postinduction ($Z$ −2.721, $P = 0.007$), 5 min before the end ($Z$ −4.029, $P < 0.001$) and at the end of the procedure ($Z$ −4.345, $P < 0.001$).

Hypoxaemia ($SpO_2 < 90\%$) occurred in 3/63 (5%) of patients in the Mask group vs. 16/73 (22%) in the Control group ($P = 0.004$) (Table 2). In addition, $SpO_2$ was significantly lower in the Control group than in the Mask group at 2 min ($Z$ −4.471, $P < 0.001$), 4 min ($Z$ −3.961, $P < 0.001$) and 6 min postinduction ($Z$ −3.535, $P < 0.001$), 5 min before the end ($Z$ −4.146, $P < 0.001$), and at the end of procedure ($Z$ −3.559, $P < 0.001$) (Fig. 3d).

**Table 2** Incidence and duration of airway intervention, oxygen desaturation, apnoea and hypopnoea

| Characteristics | Mask group, *n*=63 | Control group, *n*=73 | *P* |
|---|---|---|---|
| Airway intervention | 14/63 (22%) | 46/73 (63%) | <0.001 |
| Chin lift or jaw thrust | 8/14 (57%) | 45/46 (98%) | <0.001 |
| Oral or nasal airway insertion | 0 | 5/46 (11%) | 0.321 |
| Elapsed time to first airway intervention (min) | 19 ± 10 | 10 ± 12 | <0.001 |
| Total intervention time/procedure length | 12 ± 31% | 19 ± 28% | 0.169 |
| Oxygen saturation | | | |
| 90 to 100% | 60/63 (95%) | 57/73 (78%) | 0.004 |
| 95 to 100% | 57/63 (91%) | 41/73 (56%) | <0.001 |
| 90 to 94% | 3/63 (5%) | 16/73 (22%) | 0.004 |
| <90% | 3/63 (5%) | 16/73 (22%) | 0.004 |
| 85 to 89% | 3/63 (5%) | 10/73 (14%) | 0.077 |
| 80 to 84% | 0 | 4/73 (6%) | 0.124 |
| <80% | 0 | 2/73 (3%) | 0.499 |
| Average number of apnoeic episodes | 1 ± 2 | 2 ± 3 | 0.019 |
| Median number of apnoeic episodes | 1 [0 to 2] | 1 [0 to 3] | 0.019 |
| Total duration of apnoea (s) | 30 ± 45 | 55 ± 83 | 0.018 |
| Total duration of apnoea/procedure length | 2 ± 4% | 4 ± 5% | 0.026 |
| Average number of hypopnoeic episodes | 7 ± 5 | 9 ± 7 | 0.250 |
| Median number of hypopnoeic episodes | 6 (4 to 10) | 8 (4 to 12) | 0.250 |
| Total duration of hypopnoea (min) | 6 ± 6 | 9 ± 9 | 0.038 |
| Total duration of hypopnoea/procedure length | 27 ± 26% | 32 ± 27% | 0.139 |

Values are expressed as mean ± SD, absolute number (%) or median [IQR]. Apnoea, no spontaneous breathing for longer than 10 s; hypopnoea, tidal volume decrease by more than 50% of baseline value.

There were no statistical differences in minute ventilation, tidal volume or respiratory rate at 2, 4 and 6 min postinduction, 5 min before the end, and at the end of procedure when raw data were analysed (Fig. 3a to c). The ratios of minute ventilation$_{Baseline}$/minute ventilation$_{Predicted}$ were similar in both groups ($P = 0.143$). However, both the ratio of minute ventilation$_{Postinduction}$/minute ventilation$_{Baseline}$ and minute ventilation$_{Procedure-end}$/minute ventilation$_{Baseline}$ were significantly lower in the Control group than in the Mask group ($P = 0.007$ and 0.001, Table 3). Figure 3, panel e, depicts the time course of standardised minute ventilation following anaesthesia induction for patients in both groups. In addition, apnoea occurred less frequently and for shorter time periods in the Mask group than in the Control group ($P = 0.019$ and 0.018, respectively). Hypopnoea also occurred for shorter time periods in the Mask group than in the Control group ($P = 0.038$, Table 2).

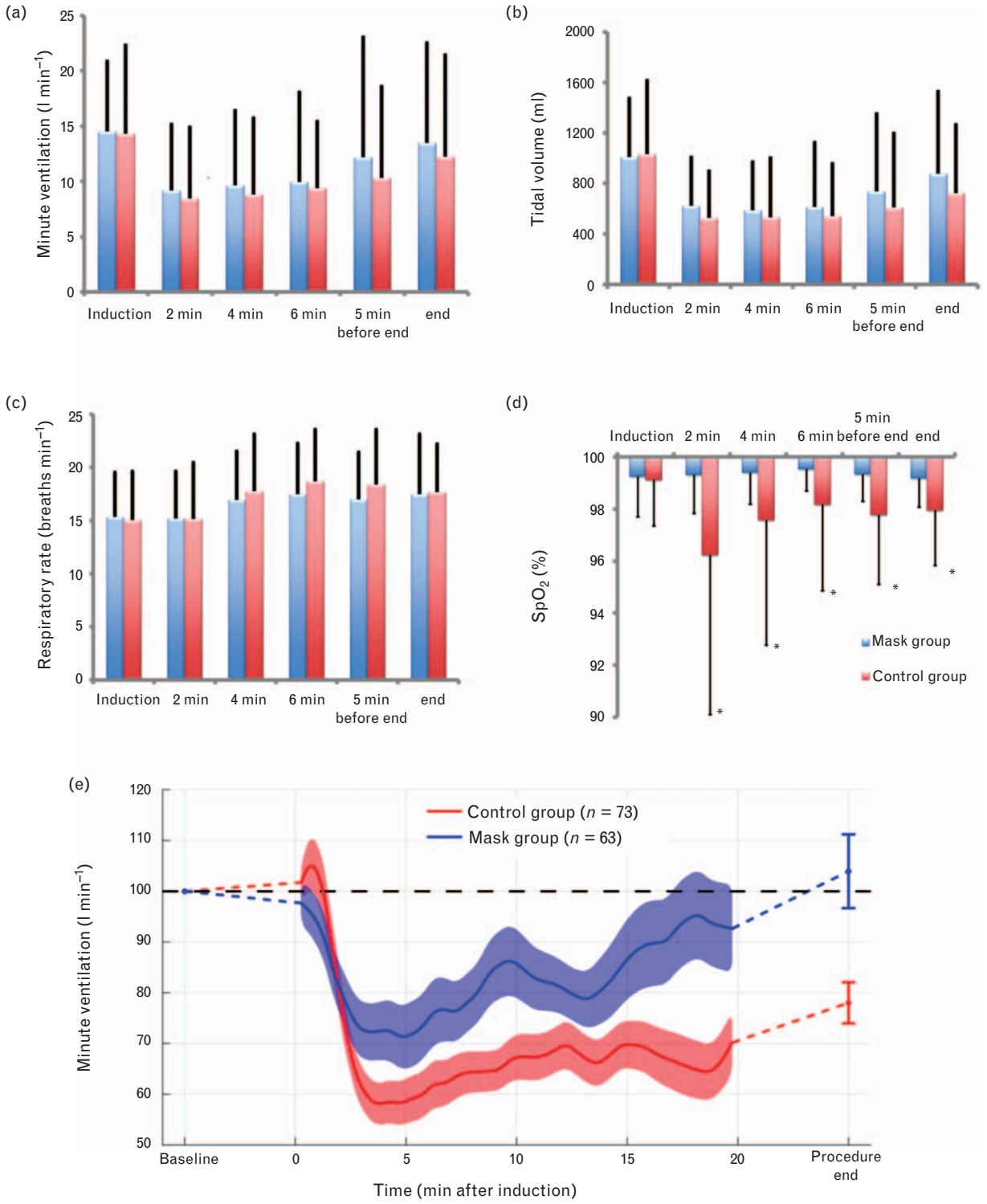
## Discussion

The major findings of the use of the Super$NO_2$VA in comparison with the nasal cannula were as follows: a CPAP value close to the target value of 10 cm$H_2O$ was achieved in the majority of patients; the need for airway intervention was reduced; the incidence and severity of hypoxaemia were reduced; and minute ventilation was improved.

It is well known that adverse events in comparable procedures performed outside the operating theatre occur more frequently than those occurring in the operating theatre.[8] Hypoxaemia has been thought to be a major issue and any intervention reducing the incidence and/or severity of hypoxaemia could potentially improve this outcome.[4,8] Conventional CPAP has been shown to improve ventilation and oxygenation in patients with obstructive sleep apnoea and in anaesthetised patients during spontaneous ventilation through maintenance of upper airway patency.[20,21] The advantage of the Super$NO_2$VA nasal mask in peri-operative settings is its simple design and ability to generate CPAP with a low oxygen flow already available in the procedure or operating theatre without the need for a conventional CPAP machine. We observed that apnoea occurred less frequently and for shorter time periods in the Mask group than in the Control group, and hypopnoea also occurred for shorter time periods with the use of the mask.

We believe that the nasal mask functions through the following principles. First, the mask together with the hyperinflation bag generates nasal positive pressure; thus, it is effective in treating anaesthesia-induced upper airway obstruction which commonly occurs in the obese population undergoing deep sedation. Second, it may improve breathing efficiency from dead space flushing. Positive pressure with the mask was applied through the nasal path with the mouth unsealed. Because of the CPAP, patients seemed to exhale via mouth only and inspired via nose only as we had difficulty detecting $CO_2$ sampled from the mask. Nose-in and mouth-out breathing may functionally reduce anatomical dead space and improve breathing efficiency without a significant increase in minute ventilation. Nose-in/mouth-out breathing has been shown to improve humans' breathing efficiency via an improved ratio of alveolar tidal volume to tidal volume.[22] The mask application together with intramask positive pressure also probably generates a washout effect and improves efficiency of carbon dioxide

**Fig. 3**




Respiratory measurements at six time points (panels a to d) and the time course of minute ventilation following anaesthesia induction (e). Values are expressed as mean ± SD, $^{*}P < 0.05$. In panel (e), minute ventilation is shown as a function of time following anaesthesia induction. Solid lines represent the mean across Control (red, $n$=73) and Mask (blue, $n$=63) groups and shaded regions are SEM. Minute ventilation was normalised by each patient's baseline minute ventilation (average minute ventilation 5 min prior to induction).

**Table 3** Normalised minute ventilation

| | Mask group, $n=63$ | Control group, $n=73$ | $P$ |
|---|---|---|---|
| $MV_{Baseline}/MV_{Predicted}$ | 122 ± 3% | 113 ± 3% | 0.143 |
| $MV_{Postinduction}/MV_{Baseline}$ | 85 ± 4% | 68 ± 3% | 0.007 |
| $MV_{Procedure\text{-}end}/MV_{Baseline}$ | 106 ± 5% | 78 ± 3% | 0.001 |

Values are mean ± SEM. $MV_{Baseline}$, average continuous minute ventilation (MV) for 5 min prior to induction; $MV_{predicted}$, MV based on BSA and sex; $MV_{Postinduction}$, average continuous MV after induction until the end of the procedure; $MV_{Procedure\text{-}end}$, MV in last 1 min of procedure.

removal. Third, the mask connected to the hyperinflation bag is used with an oxygen fresh gas flow of up to 15 l min$^{-1}$ and a reservoir bag of 2 l, reducing entrainment of room air during inspiration, resulting in a functional increase in $FIO_2$. Given these principles, one can see why the SuperNO$_2$VA Satellite Set was able to reduce the incidence and severity of hypoxaemia in this cohort compared with standard practice using a nasal cannula. Fourth, an increase in functional residual capacity (FRC) may also play a role in the improvement of oxygenation, particularly in this obese patient population; the increased abdominal weight raises intrathoracic pressure and reduces FRC, leading to alveolar collapse. With the application of CPAP, normal end-expiratory lung volume is restored.[2,3]

We chose the elapsed time from anaesthesia induction to first airway intervention as our primary outcome because it reliably shows the efficiency of ventilation and oxygenation without any airway intervention. Using the latency to first intervention allowed us to calculate indirectly the duration of intervention which is total procedure time minus the latency. It also allowed us to calculate the sample size nicely. We believe that the difference of several minutes on average in latency of applying an airway intervention between the two groups is clinically relevant. In this study, we found that airway intervention was delayed and the need for intervention decreased in the Mask group. However, a significant leak from the mouth occurred in 8/63 (13%) patients in the Mask group, preventing CPAP generation and requiring manual mouth closure. Quantitative analysis revealed that 78% patients in the Mask group did not need airway intervention at all, vs. 37% in the Control Group ($P < 0.001$).

Another important finding was the reductions in the incidences and severity of hypoxaemia in the Mask group. Only six patients (10%) in the Mask group had a lowest $SpO_2$ below 95% compared with 32 patients (44%) in the Control group. Furthermore, only three patients (5%) in the Mask group had a $SpO_2$ reading below 90% compared with 16 (22%) in the Control group. In addition, no patient in the Mask group had a decrease in $SpO_2$ below 80% compared with two patients (3%) in Control group.

A third finding was that the difference in minute ventilation between the two groups was NS when the raw data were analysed at the six given time points. However, after normalisation of the postinduction minute ventilation to the baseline minute ventilation, minute ventilation was significantly greater in the Mask group than in the Control group. We believe that this is due to the large variation in baseline minute ventilation among individuals and that normalisation of the postinduction minute ventilation to the baseline minute ventilation reveals the true effect of the mask.

There are several limitations to this study. First, the study was not blinded to the clinician or research staff, allowing for the possibility of bias. However, all parameters analysed were automatically recorded except for the elapsed time from induction to the first airway intervention and the number and length of airway interventions. Second, we did not perform follow-up after the completion of the study and the satisfaction of the patients in each group was not determined. Third, we did not observe any extreme safety issues with either group except for six cases of severe hypoxaemia ($SpO_2 < 85\%$) 85%) in the Control group, but our sample size was not powered to capture and analyse the effect of the mask on severe hypoxaemia. Fourth, we focused on obese patients because this population has a high incidence of upper airway obstruction and hypoxaemia during deep sedation.[5,7] The observation may extend to other patient populations but remains to be tested. Fifth, we did not control and monitor the sedation level and left it to the providers to control the sedation level appropriately for the procedure. Even though there was no difference in the total dose of sedatives between the two arms, sedation levels may have been different. However, since this study was randomised and the sample size was large, we assume that the difference in the sedation levels between the two arms is NS and does not affect our conclusion. Finally, the oxygen flow rate in the Mask group was higher than that in the control group, (15 vs. 5 l min$^{-1}$). An oxygen flow rate of 5 l min$^{-1}$ for the control group is the routine practice in our institute for colonoscopy. In contrast, an oxygen flow rate of 15 l min$^{-1}$ in the Mask group was used according to manufacturer recommendations. In addition, the $FIO_2$ obtained via the nasal cannula and a mask would not be comparable even if the flow rate of oxygen was the same. Therefore, the benefits observed in the study could have been from the higher oxygen flow rate, the mask, CPAP or a combination. We did not intend to determine the underlying mechanism in this study and further investigation is required to assess the benefit added by increased oxygen flow rates and the use of a mask versus a nasal cannula.

## Conclusion

The SuperNO$_2$VA Satellite Set used during colonoscopy under deep sedation with spontaneously breathing obese

patients improves ventilation and reduces the need for airway intervention, as well as the incidence and severity of hypoxaemia.

## Acknowledgements relating to this article

Assistance with the study: we thank ExSpiron, Respiratory Motion, Inc., Waltham, MA, USA for providing the respiratory volume monitor (RVM) in this study.

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Conflicts of interest: none.

Presentation: data from this study were presented as an abstract in 2018 at the Tennessee Society of Anesthesiologists' Annual Meeting, Nashville, Tennessee; Perioperative Leadership Summit, New Orleans, Louisiana; and AUA Annual Meetings, Chicago, Illinois.

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