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REPORTS OF ORIGINAL INVESTIGATIONS

A comparison between the Boussignac™ continuous positive airway pressure mask and the venturi mask in terms of improvement in the PaO_2/F_IO_2 ratio in morbidly obese patients undergoing bariatric surgery: a randomized controlled trial

Comparaison du masque de ventilation à pression positive continue Boussignac™ et du masque Venturi en termes d'amélioration du ratio PaO_2/F_IO_2 chez les patients obèses morbides subissant une chirurgie bariatrique: une étude randomisée contrôlée

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Abstract

Purpose *This study compared the Boussignac™ continuous positive airway pressure (CPAP) mask with the venturi face mask in terms of the postoperative PaO_2/F_IO_2 (PF) ratio in morbidly obese patients after bariatric surgery.*

Methods *Following hospital Research Ethics Board approval and written informed consent, morbidly obese (body mass index $> 35\ kg{\cdot}m^{-2}$) patients undergoing bariatric surgery were recruited. The patients were anesthetized and laparoscopic Roux-en-Y gastric bypass was performed. Patients were assigned randomly to receive either the Boussignac (Boussignac Group) or the venturi face mask (Venturi Group) immediately after tracheal extubation. Patients were transported to the postanesthesia care unit, and the respective devices were applied for one hour. The PF ratio was recorded after tracheal intubation and at one hour and two hours post extubation. The percent forced expiratory volume ($\%FEV_1$) and the percent forced vital capacity (%FVC) were recorded preoperatively and at one hour and two hours post extubation. Independent Student's t tests were used for continuous variables, and the Chi square test was used for categorical variables. $P < 0.05$ was considered statistically significant.*

Results *Eighty-one patients (Group Boussignac, $n = 43$; Group Venturi, $n = 38$) completed the study. Mean ages and body mass indices were similar in the two groups. At one hour post extubation, the PF ratio in the Boussignac Group was 361 (170) compared with 279 (91) in the Venturi Group ($P = 0.007$), and at two hours post extubation, the PF ratio in the Boussignac Group was 371 (162) compared with 323 (127) in the Venturi Group ($P = 0.1$). The postoperative $\%FEV_1$ and %FVC were comparable in both groups at all time points.*

Conclusion *Compared with the venturi mask, the Boussignac CPAP mask improves the postoperative PF ratio in morbidly obese patients after bariatric surgery. The postoperative $\%FEV_1$ and %FVC are comparable for both groups.*

Résumé

Objectif *Cette étude a comparé le masque de ventilation à pression positive continue (VPPC) Boussignac™ au masque facial Venturi en termes du ratio de PaO_2/F_IO_2 (PF) postopératoire chez les patients obèses morbides après une chirurgie bariatrique.*

Méthode *Après avoir obtenu le consentement du Comité d'éthique de la recherche de l'hôpital et le consentement*

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éclairé par écrit des patients, nous avons recruté des patients obèses morbides (indice de masse corporelle > 35 kg·m^{-2}) subissant une chirurgie bariatrique. Les patients ont été anesthésiés et une dérivation gastrique de Roux-en-Y par laparoscopie a été réalisée. Les patients ont été randomisés soit au masque Boussignac (groupe Boussignac), soit au masque facial Venturi (groupe Venturi) immédiatement après l'extubation trachéale. Les patients ont été transportés en salle de réveil, et les masques respectifs ont été appliqués pendant une heure. Le ratio PF a été enregistré après l'intubation trachéale, puis une heure et deux heures après l'extubation. Le pourcentage du volume expiratoire maximal seconde (%VEMS) et le pourcentage de capacité vitale forcée (%FVC) ont été enregistrés avant l'opération, puis une heure et deux heures après l'extubation. Des tests t de Student indépendants ont été utilisés pour mesurer les variables continues, et le test du Chi carré a été utilisé pour les variables catégoriques. Une valeur P < 0,05 a été considérée comme étant statistiquement significative.

Résultats *Quatre-vingt-un patients (groupe Boussignac, n = 43; groupe Venturi, n = 38) ont terminé l'étude. Les indices de masse corporelle et âges moyens étaient semblables dans les deux groupes. Une heure après l'extubation, le ratio PF dans le groupe Boussignac était de 361 (170) par rapport à 279 (91) dans le groupe Venturi (P = 0,007), et deux heures après l'extubation, le ratio PF était de 371 (162) dans le groupe Boussignac par rapport à 323 (127) dans le groupe Venturi (P = 0,1). Les %VEMS et %FVC postopératoires étaient comparables dans les deux groupes à tous les temps de mesure.*

Conclusion *Par rapport au masque Venturi, le masque de VPPC de Boussignac améliore le ratio PF postopératoire chez les patients obèses morbides après une chirurgie bariatrique. Les %VEMS et %FVC postopératoires sont comparables dans les deux groupes.*

In recent years, morbid obesity has emerged as a serious public health threat.[1] The World Health Organization describes "globesity" as an epidemic affecting at least 300 million people.[2] In 2001, in the United States, morbid obesity was present in 2.3% of the population.[3] Bariatric surgery is performed more than 10,000 times per month in the United States[4] and is increasing in frequency in Canada as well as elsewhere. Morbid obesity is associated with reduced functional residual capacity, altered ventilation-perfusion mismatch, shunting, atelectasis, and obstructive sleep apnea, which leads to postoperative hypoxemia.[5,6] General anesthesia and surgery also have a major impact on respiratory physiology postoperatively due to impaired coughing, hypoventilation, and respiratory depression caused by narcotics and residual effects of anesthesia.[7-11] Together, morbid obesity and general anesthesia have additive deleterious effects on respiratory physiology, leading to a propensity for postoperative hypoxemia in morbidly obese patients undergoing bariatric surgery.

Several studies have shown that the use of continuous positive airway pressure (CPAP) masks improves oxygenation and pulmonary function and reduces pulmonary complications after abdominal surgery.[12,13] However, these studies have not led to widespread use of the CPAP mask due to its complicated setup, lack of portability, and in some cases, lack of clinical familiarity. The Boussignac™ CPAP mask is a novel simple portable easy-to-use relatively inexpensive device that provides the benefits of the CPAP mask without the cumbersome setup. Neligan *et al.* showed that postoperative pulmonary function was significantly better in morbidly obese patients who received the Boussignac CPAP mask after bariatric surgery.[14] Gaszynski *et al.* showed that the use of the Boussignac CPAP mask significantly improves the PaO_2 in morbidly obese patients after bariatric surgery.[15] However, the effect of F_iO_2 on oxygenation has not been fully evaluated in this population. In order to determine the reason for improved oxygenation, we utilized the PaO_2/F_iO_2 (PF) ratio as the primary outcome to provide an index of pulmonary oxygenation that incorporates the effect of varying F_iO_2 levels. We hypothesized that the Boussignac CPAP mask would result in an improved PF ratio compared with the venturi face mask when applied in morbidly obese patients post bariatric surgery immediately after tracheal extubation. The primary objective of the study was to compare the Boussignac CPAP mask with the venturi face mask in terms of the PF ratio at one hour post extubation in morbidly obese patients after bariatric surgery.

Methods

Preoperative phase

After obtaining institutional Research Ethics Board approval from the Toronto Western Hospital and written informed consent, 90 morbidly obese patients (body mass index [BMI] > 35 kg·m^{-2}, aged 18 to 75 yr, American Society of Anesthesiologists class I to III) undergoing bariatric surgery were recruited for the study by the research coordinator. Patients were excluded from the study if they had pre-existing congestive heart failure, asthma, chronic obstructive pulmonary disease or interstitial pulmonary disease, hemoglobin < 70 g·L^{-1}, impaired gastric emptying, a severe psychiatric disorder, or a language barrier. Randomization of patients was done by the research

coordinator using a list of computer-generated numbers, and the group assignments were concealed in opaque sealed envelopes.

Demographic characteristics, including age, sex, height, weight, neck circumference, and BMI were recorded in the pre-admission clinic. Preoperative presence of obstructive sleep apnea, chronic obstructive pulmonary disease, and the use of CPAP were recorded. The baseline SpO_2 on room air and the respiratory rate at rest were recorded. The preoperative percent forced expiratory volume (%FEV_1) and the percent forced vital capacity (%FVC) were measured using bedside spirometry (SpiroPro®, Viasys Healthcare, San Diego, CA, USA). All patients were shown how to use the Boussignac CPAP mask (Vitaid Ltd, Toronto, ON, Canada) preoperatively (Fig. 1).

The Boussignac CPAP mask system consists of a portable CPAP system that includes a tight-fitting face mask attached to the face via a strap system, oxygen in-flow tubing, and a virtual valve (Fig. 1). The key component is the virtual CPAP valve. When the Boussignac CPAP system is attached to an oxygen source, oxygen is forced through a system of micro channels that accelerate the molecules. This accelerated flow meets a deflector that directs the oxygen molecules into a central zone within the device. The turbulence created when the oxygen molecules collide creates a positive pressure. An oxygen flow rate of 15 $L \cdot min^{-1}$ creates a CPAP pressure of 10 cm H_2O.[15] The CPAP is titrated by adjusting the oxygen flowmeter, and a side port can be connected to a manometer to measure the pressure generated.

Fig. 1 Boussignac continuous positive airway pressure mask consisting of **a** tight-fitting face mask, **b** oxygen in-flow tubing, and **c** a virtual valve

Operative phase

In the operating room, standard monitors, including ECG, non-invasive blood pressure, and pulse oximetry, were applied for all patients. The subject's SpO_2 value was recorded while breathing room air prior to preoxygenation. The patient was preoxygenated with 100% O_2 via face mask for three minutes. With provisions in place and due consideration for the anticipated difficult airway, general anesthesia was induced with remifentanil, propofol 1 to 2 $mg \cdot kg^{-1}$ *iv*, and succinylcholine 1.5 to 2 $mg \cdot kg^{-1}$ *iv*, and tracheal intubation was performed. Upon confirming endotracheal tube placement, the F_iO_2 was reduced to 0.50. An arterial line was inserted in the radial artery, and blood was sampled to determine the baseline arterial blood gas values. If the patient's SpO_2 was $< 95\%$, the F_iO_2 was increased to 0.60 to 0.80. A positive end-expiratory pressure (PEEP) of 5 to 8 cm H_2O was applied unless there was hemodynamic instability. The change of F_iO_2 or any addition of PEEP was noted. Balanced anesthesia was maintained using O_2/air/ desflurane at the end-tidal concentration of 5% to 7% and rocuronium. Adequacy of the depth of neuromuscular block was monitored by facial nerve stimulation. Anesthesia was continued according to the discretion of the attending anesthesiologist, and laparoscopic Roux-en-Y gastric bypass was performed. At the end of surgery, general anesthesia was discontinued, residual muscle relaxation was reversed, and when the patient was able to obey commands, tracheal extubation took place in the supine position. We recorded the duration of surgery, estimated blood loss, volume of fluid administered, and any surgical complications. The attending anesthesiologist was blinded to the study groups until the end of the surgery.

Postoperative phase

At the end of surgery, the sealed randomization envelope was opened, and the research coordinator allocated the patient either to the Boussignac Group or the Venturi Group (Fig. 2). Immediately upon tracheal extubation, the Boussignac Group received the Boussignac CPAP mask with oxygen flow of 15 $L \cdot min^{-1}$, whereas subjects in the Venturi Group received the venturi face mask (Cardinal Health Inc., Dublin, OH, USA) with an F_iO_2 of 0.40. All patients were transported to the postanesthesia care unit (PACU) where subjects had their respective devices applied for one hour. During the second hour in the PACU,

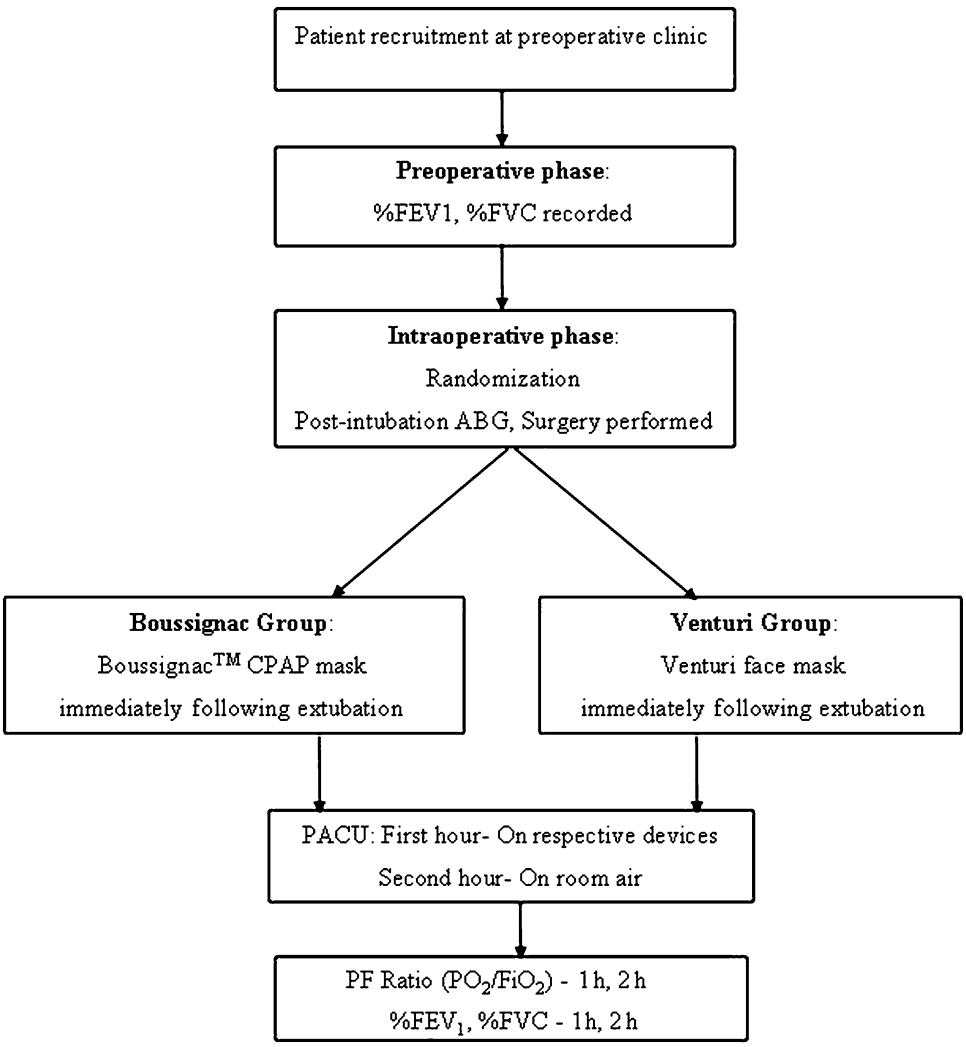

Fig. 2 Flow chart of the study methodology. 1 hr = one hour post extubation, 2 hr = two hours post extubation

subjects in both groups were managed on room air. If SpO_2 was $< 92\%$ for more than five minutes during the first hour post extubation, subjects in the Boussignac Group received a venturi mask with F_iO_2 of 0.40 titrated upwards as required to maintain $SpO_2 \geq 92\%$. In the Venturi Group, the F_iO_2 was titrated upwards as required to maintain $SpO_2 \geq 92\%$. If the SpO_2 in either group was $< 92\%$ for more than five minutes during the second hour post extubation, the venturi mask was applied with F_iO_2 of 0.40 and titrated upwards to maintain $SpO_2 \geq 92\%$.

The Boussignac mask was removed in patients who found it intolerable, in which case, the venturi mask with F_iO_2 of 0.40 was applied for five minutes. The Boussignac mask was then reapplied. Patients with persistent discomfort were administered O_2 through nasal prongs at 6 $L \cdot min^{-1}$ and analyzed according to the intention-to-treat principle. Similarly, patients in the Venturi Group who found the venturi mask intolerable received O_2 via nasal prongs at 6 $L \cdot min^{-1}$, and their data were analyzed according to the intention-to-treat principle. Subjects with known obstructive sleep apnea and on CPAP were managed according to the routine practice of the anesthesiologists. They continued their CPAP treatment at night in the hospital.

The following variables were recorded in the PACU at various time points: At one hour and two hours post extubation, PaO_2, F_iO_2, respiratory rate, pH, $PaCO_2$, $\%FEV_1$, %FVC, pain (visual analogue scale scores), and sedation scores were recorded; and upon discharge from the PACU, pain scores, and sedation scores were recorded. The PACU duration of stay, need for tracheal re-intubation, and intensive care unit (ICU) admission were also recorded.

Determination of F_iO_2

Boussignac group

A capnography sampling line was inserted via the external opening of the Boussignac mask until the tip of the sampling line was positioned within 0.5 cm of the patient's

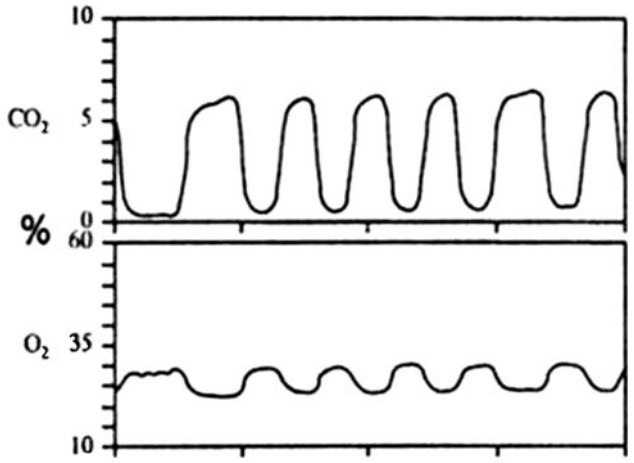

Fig. 3 Simultaneous O_2 and CO_2 waveform tracings from a sample capnography tracing

nares. Simultaneous O_2 and CO_2 waveform tracings were printed from capnography (GE Datex-Ohmeda S/5™, Helsinki, Finland) for two minutes (Fig. 3). For each respiratory cycle, the fraction of expired O_2 (F_EO_2) was derived from the O_2 level corresponding to the point where the end-tidal CO_2 reached a steady-state plateau prior to the initiation of the next cycle of inspiration on the waveform tracing. The final F_EO_2 was averaged from F_EO_2 values derived from ten respiratory cycles with well-visualized CO_2 flattened plateaus. F_ACO_2 was derived from averaging values of end-tidal CO_2 waveform from ten respiratory cycles on waveform tracings from capnography. The F_iO_2 was then calculated using the following equation:[16]

$$F_IO_2 = (F_EO_2 \times RQ + F_ACO_2)/ (RQ + F_ACO_2 \times (1 - RQ))$$

where RQ is the respiratory quotient.

In the Venturi Group, the F_1O_2 was maintained at 0.35 to 0.50 and noted. Intraoperatively, on confirming tracheal tube placement, the F_iO_2 was reduced to 0.50. In patients with $SpO_2 < 95\%$, the F_iO_2 was increased to 0.60 to 0.80. The F_iO_2 value at the first arterial blood gas measurement was recorded.

Statistical considerations

The primary outcome of this study, the PF ratio, was calculated using the formula: PaO_2 (mmHg)/ F_iO_2 at one hour post extubation. The data was analyzed using SPSS® version 13 (SPSS Inc., Chicago, IL, USA). Categorical variables were analyzed using Chi square tests, and the PF ratio was analyzed using the Student's *t* test. A *P* value < 0.05 was considered statistically significant.

To compare the Boussignac CPAP mask and the venturi mask using the PF ratio (our primary outcome variable), we used the variable, PaO_2, to assess oxygenation for sample size calculation. Based on previous studies,[15,17] we used an alpha of 0.05, a power of 0.8, with an expected difference of 14.8 and a standard deviation (SD) of 18. This generated a sample size of 48 (24 in each group). The sample size was increased by 10% to account for dropouts, resulting in a sample size of 54. Statistical analysis of the data obtained subsequently from 54 patients showed a trend towards a higher PF ratio (our primary outcome) at one hour in the Boussignac Group (392 [193]) compared with the Venturi Group (300 [113]) $P > 0.10$. A sample size of 82 (41 in each group) was obtained from this data using an alpha of 0.05, power of 0.8, with an expected difference of 100 and a SD of 160. Adding 5% for dropouts, a final sample size estimate of 86 was obtained. The hospital Research Ethics Board approved the increase in study sample size to 86.

Results

A total of 90 subjects were enrolled in the study. Nine subjects were excluded from data analysis either due to the inability to obtain arterial sampling intraoperatively, or one or two hours post extubation or due to patient refusal for arterial sampling (Fig. 4). The baseline demographic variables were comparable between groups (Table 1). The PF ratio, the primary outcome of interest, was measured in 81 patients (Boussignac Group, $n = 43$; Venturi Group, $n = 38$).

The primary outcome, PF ratio at one hour, was higher in the Boussignac Group compared with the Venturi Group (Table 2). By two hours, the PF ratios in the two groups were similar (Table 2). At one hour post extubation, the mean PaO_2 value in the Boussignac Group was higher (179 [88]) than in the Venturi Group (179 [88]) ($P < 0.001$), but it was comparable at two hours post extubation. The F_iO_2 value at one hour post extubation was also higher in the Boussignac Group than in the Venturi Group (0.50 [0.13] *vs* 0.43 [0.08], respectively; $P = 0.003$), but it was also comparable at two hours post extubation. The pH and respiratory rate values were comparable for both groups at all time points.

The $\%FEV_1$ was comparable in both groups preoperatively, and at one hour and two hours postoperatively. Similarly, the %FVC was comparable in both groups at corresponding time points.

None of the patients in either group developed intolerance to her/his mask. The pain and sedation scores were similar in the groups at all time points. The mean durations of surgery, volume of administered fluid, and PACU length of stay were comparable in both groups (Table 1). Nine subjects were admitted to the ICU: three admissions were due to $SpO_2 < 85\%$ to 90%; three subjects had baseline severe obstructive sleep apnea; two subjects had a high

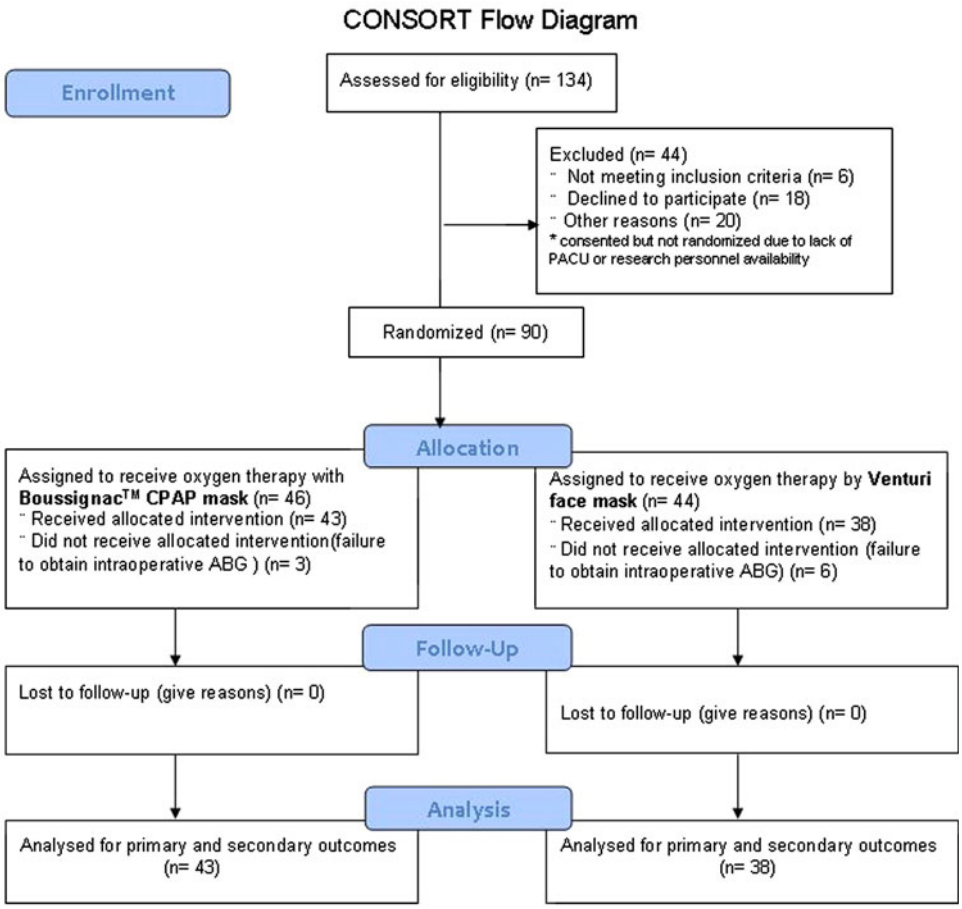

Fig. 4 CONSORT flow diagram

Table 1 Demographics, co-morbidities, intraoperative, and postoperative data

	Boussignac Group ($n = 43$)	Venturi Group ($n = 38$)
Age (yr)	42.9 ± 10.1	46.3 ± 10.4
Sex (female/male) (*n*)	26/17	31/7
Height (cm)	168.9 (9.2)	164.8 (8.9)
Weight (kg)	144.6 (29.6)	137.5 (23.5)
Body mass index $kg{\cdot}m^{-2}$	50.5 (8.4)	49.5 (8.2)
Obstructive sleep apnea (*n*)	33	23
CPAP (*n*)	26	18
Chronic obstructive pulmonary disease (*n*)	2	2
ASA ≥ III (*n*)	43	36
PACU duration of stay (min)	203.6 (41.7)	188.2 (32.6)
Re-intubation (*n*)	0	0
ICU Admission (*n*)	3	6

Numbers shown as mean (standard deviation); n = number of patients; ASA = American Society of Anesthesiologists; CPAP = continuous positive airway pressure; PACU = postanesthesia care unit; ICU = intensive care unit

Table 2 PF ratio values using Boussignac continuous positive airway pressure and venturi mask at various time points

PF ratio	Boussignac Group $n = 43$	Venturi Group $n = 38$
Intraoperative	329 (130)	309 (119)
1 hr	361 (170)*	279 (91)
2 hr	371 (162)	323 (127)

* P value < 0.05 between the Boussignac and Venturi groups

n = number of patients; PF ratio = PaO_2/ F_IO_2

$PaCO_2$; and one patient was admitted due to persistent hypotension. None of the subjects required tracheal re-intubation and there were no deaths.

Discussion

Our study shows that the Boussignac CPAP mask improves postoperative PF ratio in morbidly obese patients undergoing bariatric surgery. The primary outcome, PF ratio at

one hour postoperatively, was higher in the Boussignac Group than in the Venturi Group.

In considering the effects of CPAP on postoperative oxygenation after bariatric surgery, Gaszynski *et al.* compared the use of the Boussignac CPAP mask with use of the nasal catheter in 19 morbidly obese patients after bariatric surgery.[15] The PaO_2 was significantly higher with the use of the Boussignac CPAP mask at 30 min, four hours, and eight hours postoperatively. Our PaO_2 results are consistent with their findings in the Boussignac Group. However, in Gaszynski's study, the F_iO_2 for the Boussignac CPAP mask was not determined. It was unclear whether the improved oxygenation in their Boussignac Group resulted from a difference in F_iO_2 or from improved lung volume and less shunting due to the Boussignac CPAP effect. In order to determine the actual reason for improvement, we utilized the PF ratio (PaO_2/F_iO_2) as the primary outcome as this reflects pulmonary oxygenation taking into consideration the effects of different F_iO_2 values. Although the F_iO_2 was higher in the Boussignac Group, our results show that the PF ratio was still significantly higher in the Boussignac Group when compared with the Venturi Group. This finding suggests that improved oxygenation resulted from both a higher F_iO_2 and better ventilation/perfusion matching in the Boussignac Group.

Ebeo *et al.* compared the use of bi-level positive airway pressure (Bi-PAP) *vs* conventional postoperative care during two of three hours of the first 24 hr postoperatively in 27 patients following bariatric surgery.[18] On postoperative days 1, 2, and 3, the SpO_2 was significantly higher in patients receiving Bi-PAP compared with those receiving conventional postoperative care. Joris *et al.* also found that the application of Bi-PAP *vs* oxygen via face mask during two of three hours of the first 24 hr postoperatively significantly increased the SpO_2 values on postoperative days 1, 2, and 3 in patients after bariatric surgery.[19] Our SpO_2 results showing improvement of the Boussignac CPAP over conventional oxygenation are consistent with their findings.[18,19] Neither the PaO_2 nor the PF ratio was used as an outcome measure in the Ebeo or Joris study, rather, SpO_2 was used. SpO_2 is a less precise measure of pulmonary oxygenation than the PaO_2 or PF ratio.

In considering the effects of CPAP on postoperative lung function after bariatric surgery, Neligan *et al.* conducted a randomized controlled trial on 40 morbidly obese patients undergoing bariatric surgery who received either the Boussignac CPAP mask or nasal oxygen immediately post extubation.[14] The FEV_1 and FVC values were higher in patients receiving the Boussignac CPAP mask compared with those receiving supplemental oxygen. Ebeo *et al.* evaluated the application of Bi-PAP for the first 24 hr postoperatively on postoperative pulmonary function in 27 patients after bariatric surgery.[18] They found that FEV_1 and FVC values on postoperative days 1, 2, and 3 were significantly higher in patients receiving Bi-PAP than in patients receiving conventional postoperative care. Joris *et al.* studied the use of Bi-PAP during the first 24 hr following bariatric surgery in morbidly obese patients. They found a significant increase in FEV_1 and FVC values with Bi-PAP on postoperative days 1, 2, and 3.[19] In contrast, our results showed that the $\%FEV_1$ and %FVC were comparable in both groups. This difference may be due to a variety of reasons: First, we measured percent predicted FEV_1 and percent predicted FVC rather than absolute values of FEV_1 and FVC as measured in other bariatric studies.[14,18,19] The former may be more meaningful measures of pulmonary function as they account for body height and weight. Second, the patients in our study received CPAP for one hour post extubation rather than for a duration of eight to 24 hr.[15,18,19] Although a one hour application of the Boussignac CPAP mask was effective in improving the PF ratio, a longer duration of CPAP application may be necessary to improve the $\%FEV_1$ and %FVC postoperatively.

There are several limitations to our study: First, the study was conducted in a tertiary high-volume single-institution bariatric surgery centre, thus, our results may not be generalizable to other populations. Second, the Boussignac CPAP mask was applied for one hour post extubation, and we did not assess the impact of the duration of CPAP application on postoperative pulmonary oxygenation and function. Applying the Boussignac CPAP mask for more than one hour post extubation may lead to improvement in oxygenation for a longer duration postoperatively.

In conclusion, compared with the venturi mask, the Boussignac CPAP mask improves postoperative oxygenation as measured by the PF ratio. Postoperative $\%FEV_1$ and %FVC were comparable for both groups. The Boussignac CPAP mask may be a useful device in improving postoperative pulmonary oxygenation in morbidly obese patients after bariatric surgery.

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Conflicts of interest None declared.

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