

# The influence of biphasic positive airway pressure vs. sham biphasic positive airway pressure on pulmonary function in morbidly obese patients after bariatric surgery

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## Abstract

**Background:** The effect of biphasic positive airway pressure (BPAP) at individualized pressures on the postoperative pulmonary recovery of morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) and possible placebo device-related effects (sham BPAP) were investigated.

**Methods:** Forty-eight MOP scheduled for OBS were initially enrolled. Subjects were randomly assigned to: A) the BPAP group in which BPAP, at individualized inspiratory positive airway pressure/expiratory positive airway pressure (IPAP/EPAP), was applied for 3 days postoperatively and B) the sham BPAP group in which sham BPAP was applied for the same time. Pulmonary function was assessed by spirometry 24 h prior to surgery and at 24, 48 and 72 h postoperatively and respiratory complications were recorded.

**Results:** Thirty-five subjects, 21 in the BPAP group and 14 in the sham BPAP group, completed the study. Baseline characteristics and pulmonary function were similar between groups preoperatively. Subjects in the BPAP group showed in general better spirometric performance and SpO<sub>2</sub> values postoperatively and expedited pulmonary recovery. Atelectasis combined with respiratory distress syndrome (RDS) symptoms was observed in 21% of subjects in the sham BPAP group and one of these subjects developed lower respiratory tract infection. No respiratory complications were recorded in the BPAP group. Use of higher BPAP pressures was not associated with anastomosis leakage or disruption in any patient.

**Conclusion:** Use of BPAP, at individualized pressures, expedites postoperative pulmonary recovery and eliminates respiratory complications in MOP who have undergone OBS.

**Key words:** anesthesia, morbid obesity, surgery, bariatric, mechanical ventilation, BPAP, postoperative complications.

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Obesity is a systemic disease that affects respiratory function significantly, leading to the emergence of restrictive lung disease [1]. The already compromised respiratory function in obese individuals is further aggravated by abdominal surgery, as in the case of bariatric surgery, a fact that exponentially increases the risk of postoperative pulmonary complications [2, 3].

Anesthesia, pain and surgical manipulations also contribute to the aggravation of pulmonary function postoperatively. Meticulous management of anesthetic drugs, adequate analgesia, advanced surgical techniques and respiratory physiotherapy have all been reported to exert a positive effect on postoperative respiratory function [4–8].

The biphasic positive airway pressure (BPAP) system combines inspiratory support (inspiratory positive airway pressure – IPAP) with expiratory support (expiratory positive airway pressure – EPAP) and has been used, with good results, in a number of different clinical conditions such as chronic obstructive pulmonary disease (COPD), respiratory failure due to neuromuscular disease, cardiogenic pulmonary edema, and immediately post-operatively with prophylactic intent [9–11].

Despite the observed beneficial effects of BPAP in diverse clinical settings, there is a lack of randomized placebo-controlled trials using sham BPAP to compare different treatment options and neutralize any possible confounding results from device application.

In the present study we investigated the effect of BPAP on the postoperative respiratory function and related complications of morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) through a randomized sham-controlled design. BPAP was applied at individualized pressures in order to optimize respiratory support and sham BPAP was also used in order to neutralize a possible placebo device related effect and researcher related bias.

We hypothesized that the use of BPAP at individualized pressures in MOP undergoing OBS ameliorates postoperative respiratory function as well as diminishing related pulmonary complications, postoperative pain and duration of hospitalization. Our primary endpoints were the difference in pre- and postoperative measurements of certain pulmonary function parameters: forced expiratory volume in 1 second (FEV<sub>1</sub>), forced vital capacity (FVC), peak expiratory flow rate (PEFR) and SpO<sub>2</sub> and the incidence of certain pulmonary complications postoperatively (hypoxemia, atelectasis, lower respiratory tract infections). Secondary endpoints were postoperative pain and days of hospitalization.

## METHODS

This prospective randomized single-blinded study with a control group was conducted in a tertiary urban Greek hospital. The study, registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier: NCT03438383), received approval by the Scientific Board of the Evangelismos General Hospital, Athens, Greece (Pr.n. 142/23-5-11) abiding to the Greek Law for invasive clinical studies in humans and conforming to standards set out in the Declaration of Helsinki of the World Medical Association. Forty-eight Caucasian MOP, 24 male and 24 female, were initially enrolled and written informed consent explaining the specifics of the protocol and the treatment involved was obtained from all subjects. All subjects had been morbidly obese (body mass index – BMI > 40 kg m<sup>-2</sup>)

for at least 10 years and had unsuccessfully tried to lose weight by other non-invasive means. Exclusion criteria included cardiovascular and pulmonary disease not related to obesity status, and chronic renal disease. Subjects who were initially enrolled but did not use the allocated device (BPAP or sham BPAP) for at least 12 h daily were also excluded at a later point. All subjects enrolled were continuous airway pressure (CPAP) and BPAP naïve and had no knowledge about the BPAP apparatus prior to enrollment, and were informed in detail about the study protocol and all methods used at the time of enrollment by the primary investigators of the study. None of the subjects declared a history of sleep apnea.

All subjects underwent OBS (gastroplasty by Mason or gastric bypass) by the same operating team and were treated with the same standard anesthetic protocol (Table 1) [5, 6]. BPAP (Respironics Inc., Murrysville, PA, USA) or sham BPAP was applied immediately after transfer to the recovery unit and for 3 days postoperatively. BPAP was applied for at least 12 h day<sup>-1</sup>, subjects being suggested to use it for 2 h every 3 h.

**TABLE 1.** Standardized anesthetic protocol and post-anesthesia care

<b>Induction of anesthesia</b>
Reverse Trendelenburg position
Pre-oxygenation
Intravenous induction with:
propofol (1–2.5 mg kg <sup>-1</sup> TBW)
fentanyl (1–1.5 µg kg <sup>-1</sup> IBW)
succinylcholine (1 mg kg <sup>-1</sup> TBW)
<b>Maintenance of anesthesia with:</b>
sevoflurane in a mixture of 50% O <sub>2</sub> /air
remifentanyl (0.5–2 µg kg <sup>-1</sup> min <sup>-1</sup> IBW)
cis-atracurium (0.1–0.15 mg kg <sup>-1</sup> IBW)
Positive end-expiratory pressure 5–10 cm H <sub>2</sub> O (0.49–0.98 kPa)
Volume controlled ventilation in order to maintain SpO <sub>2</sub> > 93% and PaCO <sub>2</sub> < 45 mm Hg
<b>Emergence from anesthesia</b>
Reversal of neuromuscular blockade with atropine 1 mg <i>i.v.</i> and neostigmine 2.5 mg <i>i.v.</i>
Extubation in semi-recumbent position
Intravenous analgesia:
diclofenac 75 mg, paracetamol 1 g and morphine (15) with bolus dose of 0.1–0.2 mg kg <sup>-1</sup> of ABW (ABW = IBW + 0.25 (TBW – IBW))
<b>Post-anesthesia care unit (PACU)</b>
Morphine PCA device (1 mg of morphine with lockout interval 15 min and no continuous infusion)
Nausea and vomiting were treated with 4 mg of ondansetron <i>i.v.</i>

TBW – total body weight, IBW – ideal body weight, ABW – adjusted body weight, PCA – patient-controlled analgesia, *i.v.* – intravenously

Subjects were assigned to the following two study groups postoperatively:

1. Sham BPAP (control) group in which sham BPAP was applied through a nasal mask for 3 days postoperatively.
2. BPAP group in which BPAP through a nasal mask, at individualized IPAP/EPAP pressures, was applied for 3 days postoperatively.

Assignment to each study group was performed randomly using sealed envelopes by an external investigator belonging to a different department and hospital, who was totally unaware of the study protocol as well as patient demographics and background. Patient monitoring and documentation of pulmonary function was performed by a distinct team of anesthesiologists unaware of the study protocol.

IPAP and EPAP in the BPAP system were individualized for each subject by using acceptable values of  $SpO_2$ ,  $PaCO_2$ , and patient synchronization and tolerability with the device as criteria for the personalization of the parameters used in the ward.

This individualized setting of pressures in the BPAP group was applied gradually starting with 12/4 cm  $H_2O$  (1.2/0.4 kPa) (IPAP/EPAP) and up to 18/10 cm  $H_2O$  (1.8/1.0 kPa) (IPAP/EPAP) with consecutive increases of 2 cm  $H_2O$ , according to a previous study [10].

Sham BPAP was created by introducing a hole at the connection of the mask with the spiral tube of the BPAP. With this modality, also used in previous studies, the applied pressure by sham BPAP was constant and equal to 2 cm  $H_2O$  (0.2 kPa) [12, 13]. Supplemental oxygen at 2-5  $L\ min^{-1}$  was administered in all subjects while on and off BPAP and sham BPAP if needed, in order to keep  $SpO_2 > 93\%$ , as measured by pulse oximetry.

After surgery, subjects were kept at the recovery unit for two hours. During that period they were stabilized with the non-invasive positive pressure (NIPPV) system and were connected to a patient-controlled analgesia device (Table 1). Intensity of pain was assessed by a numerical rating scale (NRS) in which 0 = no pain, 10 = worst pain imaginable, and was < 4 before discharge from the recovery unit [14]. Subjects were kept at the post-anaesthesia care unit (PACU) for 24 h postoperatively and were subsequently transferred to general surgery wards. All subjects were kept on basic cardiopulmonary monitoring throughout the study period.

Pulmonary function was assessed by spirometry (spirometer MicroLab 3300, Micro Medical) 24 h before surgery and at 24, 48 and 72 h postoperatively. Subjects were off BPAP, breathing room air, half an hour before spirometry. Intensity of postoperative pain was also recorded immediately before spirometry. Blood gas analysis (including measur-

ing pH,  $PO_2$ ,  $PCO_2$ ,  $HCO_3$  and  $SaO_2$ ) was performed at the same conditions and time. Assessment was performed as single measurements at exactly 12:00 noon and no significant mouth leak was observed during the time of measurements.

Vital signs (respiratory frequency, blood pressure, heart rate and temperature), opioid consumption and fluid balance were recorded by the nursing staff every hour for the first 8 hours postoperatively, every three hours for the first 24 h and every six hours for the next 2 days. All subjects with aggravation of respiratory function and/or reporting dyspnea were further investigated for postoperative respiratory complications (hypoxemia, atelectasis combined with RDS symptoms, respiratory tract infection) with preoperative chest X-ray (CXR) as a reference.

All CXRs were diagnosed by an on call radiology attending physician who was also unaware of the study protocol and were scored for manifestation of atelectasis using a specific scoring system, as follows: 0 – normal; 1a – one-third of hemidiaphragm obscured; 1b – two-thirds of hemidiaphragm obscured; 1c – all of hemidiaphragm obscured; 2 – lobar consolidation; 3 – lobar collapse with consolidation, volume loss, and tracheal deviation; and 4 – bronchial consolidation (whole lung collapse).

Hypoxemia was considered as  $SpO_2 < 90\%$  and duration of hospitalization was also recorded for all subjects.

All subjects were encouraged to mobilize as soon as possible and had sessions of respiratory physiotherapy twice daily, consisting of manual techniques to enable chest clearance and the use of the Triflo II Inspiratory Exerciser, a flow-oriented, 3-ball incentive spirometer incentive spirometer device (Teleflex Medical, Inc, USA), while off BPAP or sham BPAP system.

### Statistical analysis

Sample size was calculated using the Do-It-Yourself (DIY) quantitative research sample size calculator (available online at: <https://blog.flexmr.net/sample-size-calculator>) by considering a confidence level of 95% and a 10% margin of error. Continuous variables were expressed as mean  $\pm$  standard deviation (SD) and non-continuous variables as absolute frequencies and percentages. Continuous variables were assessed for distribution normality graphically (by histograms and box plots) and statistically using the Kolmogorov-Smirnov test. Differences of continuous variables among repeated examinations were evaluated by ANOVA for repeated measures and post-hoc analysis for multiple paired comparisons was performed using Bonferroni correction. Chi-square and Fisher exact test, when appropriate,

were used to evaluate differences of non-continuous (i.e. categorical) variables between repeated examination sessions. A *P*-value lower than 0.05 indicated statistical significance. Statistical analysis was performed using IBM SPSS Statistics software version 19 (IBM Corp, Chicago, IL, USA).

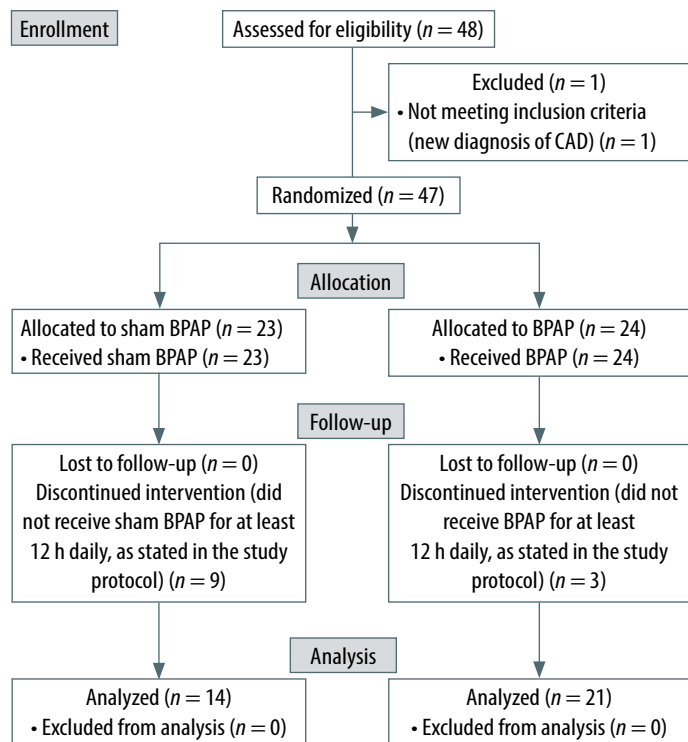
## RESULTS

Thirty-five individuals were eventually analyzed in the present study, 21 in the BPAP and 14 in the sham BPAP group, as shown in the CONSORT flow diagram (Figure 1). Subjects excluded due to non-compliance were retrospectively interviewed. Two subjects excluded from the BPAP group reported discomfort with device application and one patient reported a subjective feeling of not being helped by the intervention. From the sham BPAP group 5 subjects reported discomfort with device application and 4 reported a subjective feeling of not being helped. Arterial blood gas (ABG) analysis and spirometric indices (pre- and postoperatively) did not differ significantly for these subjects compared with the rest of subjects in the corresponding group, demonstrating that there was no actual danger of iatrogenic damage to control subjects.

Baseline characteristics and FVC, FEV<sub>1</sub>, PEFR, SpO<sub>2</sub> and ABG values (pH, pCO<sub>2</sub>, pO<sub>2</sub>, HCO<sub>3</sub>) did not differ significantly between study groups preoperatively (Tables 2-4). The mean pressures applied in the BPAP group were 15 ± 2/8 ± 2 cm H<sub>2</sub>O (1.5 ± 0.2/0.8 ± 0.2 kPa) (IPAP/EPAP) for the total duration of device use. On the 1<sup>st</sup> post-operative day, an average of 12 ± 0/4 ± 0 cm H<sub>2</sub>O (1.2 ± 0/0.4 ± 0 kPa) (IPAP/EPAP), on the 2<sup>nd</sup> post-operative day an average of 15 ± 2/8 ± 2 cm H<sub>2</sub>O (1.5 ± 0.2/0.8 ± 0.2 kPa) (IPAP/EPAP) and on the 3<sup>rd</sup> post-operative day an average of 18 ± 4/9 ± 3 cm H<sub>2</sub>O (1.8 ± 0.4/0.9 ± 0.3 kPa) (IPAP/EPAP) was reached. Daily average duration of use of BPAP and sham BPAP was similar for both groups (Table 4).

Postoperatively pulmonary function deteriorated significantly in both groups as indicated by FVC, FEV<sub>1</sub>, PEFR and SpO<sub>2</sub> values with gradual improvement in the following days (Figures 2-5). Subjects in the BPAP group showed in general better spirometric performance postoperatively (Table 4) as well as better SpO<sub>2</sub> and pO<sub>2</sub> values compared with subjects in the sham BPAP group. Postoperative pulmonary recovery was also accelerated in the BPAP treated group (Figures 2-5).

Regarding respiratory complications five subjects from the sham BPAP group (33%), three after gastric-bypass (3 from 4 subjects – 75%) and two after gastroplasty (2 from 10 subjects – 20%) developed hypoxemia during mobilization on the first postoperative day. Three of the above subjects (21%)



CAD – coronary artery disease, BPAP – biphasic positive airway pressure

FIGURE 1. CONSORT flow diagram of the present study

TABLE 2. Patient baseline data

Factor	BPAP (n = 21)	Sham BPAP (n = 14)	<i>P</i>
Age (years)	33 ± 8	31 ± 6	0.416
Height (cm)	172 ± 27	171 ± 7	0.760
Body mass (kg)	157 ± 27	151 ± 30	0.538
BMI (kg m <sup>-2</sup> )	53 ± 8	52 ± 6	0.612
Sex (Female/Male)	55%/45%	60%/40%	0.332
Smoking (No/Yes)	7/14 (33%/67%)	8/7 (53%/47%)	0.244
Type of OBS			
Gastroplasty	15 (71%)	11 (73%)	
Open gastric bypass	6 (29%)	4 (27%)	

Data are expressed as mean ± SD.

BPAP – biphasic positive airway pressure, BMI – body mass index, OBS – open bariatric surgery

TABLE 3. Patient preoperative pulmonary function

Parameter	BPAP (n = 21)	Sham BPAP (n = 14)	<i>P</i>
FEV <sub>1</sub> (L)	3.1 ± 0.6	3.1 ± 0.7	NS*
FVC (L)	3.5 ± 0.7	3.4 ± 1.0	NS*
PEFR (L min <sup>-1</sup> )	325.3 ± 75.2	376.9 ± 71.7	NS*
SpO <sub>2</sub> (mm Hg)	96.9 ± 1.1	96.9 ± 0.7	NS*

Data are expressed as mean ± SD.

\*Not significant

BPAP – biphasic positive airway pressure

TABLE 4. ABG values, pain score, device use duration and atelectasis radiographic score pre- and postoperatively

Parameter	Preoperative		1 <sup>st</sup> day		2 <sup>nd</sup> day		3 <sup>rd</sup> day		P-value
	BPAP	Sham BPAP	BPAP	Sham BPAP	BPAP	Sham BPAP	BPAP	Sham BPAP	
pH	7.41 ± 0.03	7.42 ± 0.02	7.42 ± 0.04	7.41 ± 0.03	7.43 ± 0.04	7.41 ± 0.04	7.43 ± 0.03	7.42 ± 0.04	0.21
pCO <sub>2</sub> (mm Hg)	38 ± 4	37 ± 3	37 ± 4	37 ± 3	37 ± 4	36 ± 4	37 ± 3	36 ± 4	0.21
pO <sub>2</sub> (mm Hg)	80 ± 8	78 ± 9	64 ± 9	62 ± 11	70 ± 8	62 ± 9	76 ± 9	64 ± 11	0.002**
HCO <sub>3</sub> (mEq L <sup>-1</sup> )	24.0 ± 1.6	24.4 ± 1.1	23.7 ± 2.1	23.5 ± 1.8	24.5 ± 2.0	24.1 ± 1.6	24.3 ± 1.7	23.8 ± 2.6	0.26
Pain (NRS)	0	0	6.5 ± 1.3	6.5 ± 1.9	5.3 ± 1.9	4.5 ± 1.5	3.5 ± 1.4	3.3 ± 1.2	0.42
Duration of device use (hours)	-	-	14.4 ± 1.3	13.6 ± 1.4	14.3 ± 1.5	13.8 ± 1.3	14.3 ± 1.4	13.6 ± 1.5	0.17
ARS	0	0	0	0.2 ± 0.4	0	0.2 ± 0.4	0	0.3 ± 0.6	0.03**

Data are expressed as mean ± SD.

\*\*Statistically significant ( $p < 0.05$ )

BPAP – biphasic positive airway pressure, NRS – numerical rating scale, ARS – atelectasis radiographic score

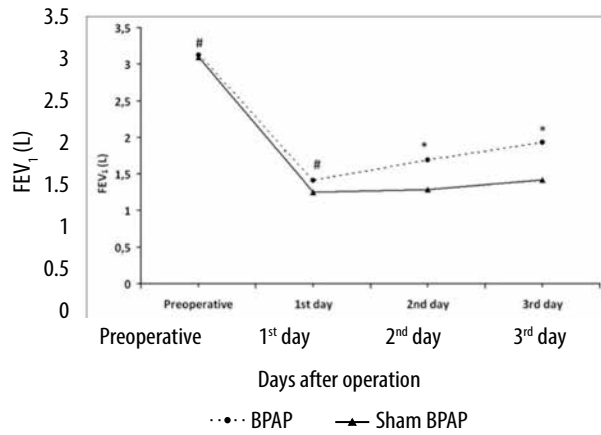


FIGURE 2. Forced expiratory volume in 1 second (FEV<sub>1</sub>) preoperatively and for 3 days postoperatively in morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) and treated with biphasic positive airway pressure (BPAP) at individualized pressures or sham BPAP for 3 days postoperatively. Data are expressed as mean ± SD, # indicates not-significant (NS), \* $P < 0.05$  and \*\* $P < 0.01$

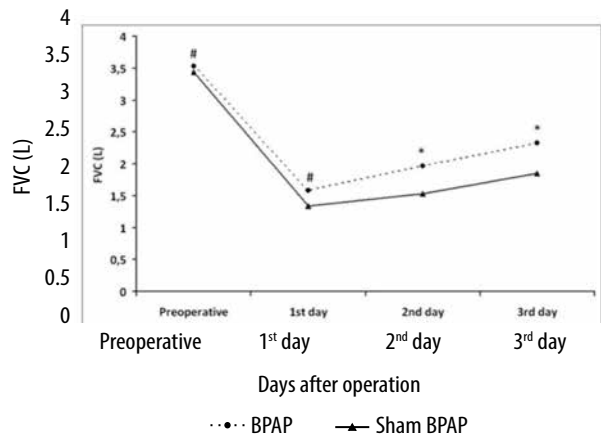


FIGURE 3. Forced vital capacity (FVC) preoperatively and for 3 days postoperatively in morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) and treated with biphasic positive airway pressure (BPAP) at individualized pressures or sham BPAP for 3 days postoperatively. Data are expressed as mean ± SD, # indicates not-significant (NS), \* $P < 0.05$  and \*\* $P < 0.01$

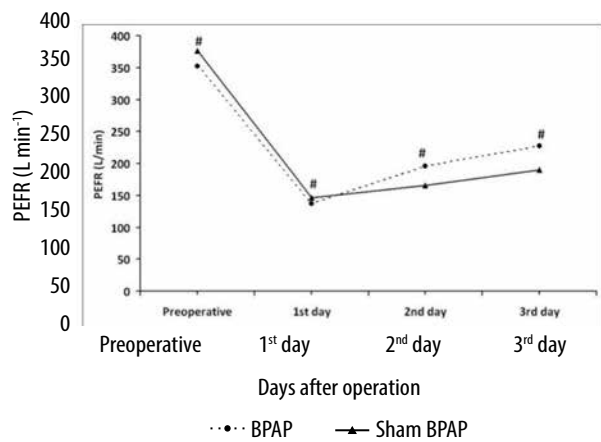


FIGURE 4. Peak expiratory flow rate (PEFR) preoperatively and for 3 days postoperatively in morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) and treated with biphasic positive airway pressure (BPAP) at individualized pressures or sham BPAP for 3 days postoperatively. Data are expressed as mean ± SD, # indicates not-significant (NS), \* $P < 0.05$  and \*\* $P < 0.01$

had chest radiography findings (all with a radiographic score of 1 on post-operative days 1 and 2) consistent with atelectasis (Table 4) and one of them submitted to gastropasty presented with fever, leukocytosis and productive cough on the third postoperative day and with chest X-ray findings (radiographic score 2) consistent with lower respiratory tract infection. All cases of hypoxemia were treated by administration of  $O_2$  (mean administration rate of  $3 \text{ L min}^{-1}$  and mean duration of treatment of  $6 \text{ hours day}^{-1}$ ), respiratory physiotherapy and antibiotics, where needed. None of the subjects in the BPAP group presented with respiratory complications.

Pain scores were similar for both groups postoperatively (Table 4) as well as opioid consumption. The hospitalization time also did not differ significantly between groups and was 5-7 days after gastropasty and 9-11 days after gastric bypass with the exception of the patient diagnosed with lower respiratory tract infection, who was hospitalized for 9 days.

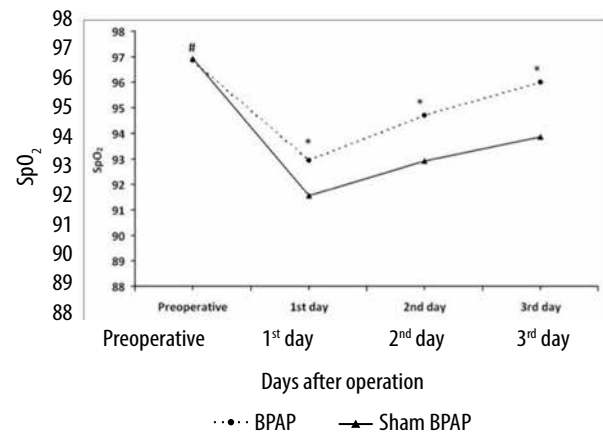
We computed (post-hoc) the observed power of the performed tests (ANOVA for repeated measures). We confirmed that the specific sample size yielded adequate statistical power ( $> 80\%$ ) for each of the examined variables.

## DISCUSSION

The detrimental effects of obesity on pulmonary function are well defined and are further aggravated by abdominal surgery [1]. Today there is no evidence that intraoperative manipulations, such as alveolar recruitment and positive end-expiratory pressure (PEEP), may improve postoperative hypoxemia while postoperative application of NIPPV, with the use of CPAP and BPAP, has proved to have beneficial effects [10, 11, 15, 16].

In previous studies in MOP undergoing OBS, BPAP was applied at fixed pressures for 24 h postoperatively while control groups received oxygen through a simple face mask or nasal cannula and BPAP application was accompanied by significant improvement of  $FEV_1$ , FVC and  $SpO_2$  for three days postoperatively in relation to the control group [10, 11].

In our study BPAP was applied for three days postoperatively assuming that the diaphragmatic dysfunction caused by abdominal surgery, the use of opioids for analgesia and the limited mobilization continue to affect pulmonary function beyond 24 h postoperatively. Our choice of prolonged BPAP application was also based on the temporal pattern of postoperative pulmonary complications that usually appear after the 2<sup>nd</sup> and 3<sup>rd</sup> postoperative day and our decision was also supported by the results of a preliminary pilot study, where the mean time for full mobilization of subjects was three days.



**FIGURE 5.**  $SpO_2$ , preoperatively and for 3 days postoperatively in morbidly obese patients (MOP) undergoing open bariatric surgery (OBS) and treated with biphasic positive airway pressure (BPAP) at individualized pressures or sham BPAP for 3 days postoperatively. Data are expressed as mean  $\pm$  SD, # indicates not-significant (NS), \* $P < 0.05$  and \*\* $P < 0.01$

In contrast with previous studies, BPAP was applied at individualized pressures in our study and not at fixed pressures in order for subjects to take most advantage of respiratory support since a simple pressure setting could have been suboptimal for some subjects [10, 11]. Sham BPAP, created by introducing a hole at the connection of the mask with the spiral tube of BPAP, was also used to neutralize any placebo device related effects and in order to minimize bias from attending physicians and subjects, and, even if this could be seen as a minor limitation of the present study, due to subjective manipulation of the BPAP device, this is the first study to use sham BPAP in MOP undergoing OBS [12, 14].

According to our findings, application of BPAP at individualized pressures, for three days postoperatively, significantly alleviated the postoperative restrictive lung disease in relation to sham BPAP. In the BPAP group values of  $FEV_1$  and FVC were significantly higher on the second and third postoperative day compared with the sham BPAP group and  $SpO_2$  values were significantly better for all three postoperative days. The small sample size in both groups, although calculated to provide adequate statistical power, has to be seen as a limitation of the present study. Low tolerance of the BPAP device, which led to the exclusion of some subjects from the study, may be seen as another limitation. Our results are similar to those of Ebeo [10] and Joris [11] from the qualitative point of view only and not completely comparable since our sample of morbidly obese patients contained a high percentage of smokers (66.6% in the BPAP group vs. 47.7% in the sham BPAP group). From the above point of view, even if smoking is considered to be a confounding factor in clinical studies, the observed beneficial effect of BPAP in our study is more pronounced given the ad-

ditional burden imposed by smoking in our population sample, and our findings not only strengthen the findings of previous studies but also expand them, since we investigated a population with a high proportion of smokers.

Application of BPAP at individualized pressures also nullified postoperative respiratory complications and especially atelectasis and a trend for earlier patient mobilization was also observed. Additionally, from the 2<sup>nd</sup> postoperative day subjects reached the minimum required time (12 h) on BPAP that was set in our study mainly using the apparatus during sleep and resting in bed, so that the NIPPV use did not prevent full patient mobilization.

Slower recovery of respiratory function in the control group with prolongation of postoperative atelectasis, delayed mobilization, and possibly late diaphragmatic dysfunction, seem to be in the basis of the recorded complications in the control group of subjects. Type of surgery, namely open gastric bypass, was associated with greater postoperative pulmonary dysfunction in our study and, as expected, with longer hospitalization time. Application of BPAP was not accompanied by shorter hospitalization time with the exception of one patient in the sham BPAP group, diagnosed with lower respiratory tract infection, who was hospitalized for longer (9 days). It should be noted though, given the increasing numbers of patients subjected to bariatric surgery, that this probably represents an important finding that would have resulted in significant reduction of hospitalization time in a larger sample of subjects.

Smoking in concert with morbid obesity and postoperative status seem to account for the observed high rates of atelectasis combined with RDS symptoms in the sham BPAP group. Unfortunately previous analogous studies did not provide data regarding respiratory complications in general and atelectasis in particular, although the percentage of smokers has been significantly lower in their population samples [10, 11]. MOP undergoing surgery are at extremely high risk for developing pulmonary atelectasis combined with RDS symptoms and the high rates observed in our study are comparable with those reported by other studies that specifically examined postoperative atelectasis in MOP undergoing surgery [17, 18]. In this setting BPAP application had a significant effect since it completely attenuated atelectasis combined with RDS symptoms when applied, and this is important given the ongoing debate about the efficacy and effect on real patient outcome of interventions applied in order to improve postoperative respiratory function of MOP [2].

Application of higher pressures in our study, compared with those in previous studies, was not

accompanied by significant complications such as gastric distension or leakage from the anastomosis, although the small population sample, comparable with that of previous relevant studies though, precludes the drawing of definitive conclusions [19, 20].

In conclusion, BPAP applied at individualized IPAP/EPAP pressures expedites recovery of postoperative respiratory function and eliminates pulmonary complications in MOP who have undergone OBS. Higher BPAP pressures seem also to be well tolerated by patients. Finally, this is the first study using a sham BPAP system in MOP undergoing OBS allowing neutralization of confounding factors related to device application and researcher bias.

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2. Conflict of interest: none.

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