Alveolar recruitment manoeuvre results in improved pulmonary function in obese patients undergoing bariatric surgery: a randomised trial

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Alveolar Recruitment Manoeuvre results in improved pulmonary function in Morbidly Obese Patients Undergoing Bariatric Surgery: a randomised study

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Declaration of interests:

Dr M.S.: none declared

Dr W.C. has received a travel grant and a lecture fee from Sanofi

Dr F.S.: none declared

Dr O.P. has received a lecture fee from MSD

Dr J.C.O. has received a travel grant and a lecture fee from Fresenius Kabi.

Pr I.A. received research grant from GORE; travel grants from GORE, Medical Solution, SOS Oxygene, Medtronic, Baxter; honoraria for teaching from Ethicon Endosurgery, GORE, Medtronic; and was consultant for ENDOSTIM.

Dr T.D.: none declared

Pr J.G. was consultant for Covidien, Baxter, Ethicon, GORE, Johnson @ Johnson, Novartis, Astellas, MERCK.

Pr M.A.R.: was consultant for LFB and Viforpharma

Summary:

Perioperative ventilation is an important challenge of anaesthesia, especially in obese patients: body mass index is correlated with reduction of the pulmonary volume and they develop significantly more perioperative atelectasis and pulmonary complications. The alveolar recruitment manoeuvre is the most effective technique to reverse atelectasis. However, the clinical benefit on lung function in the perioperative period is not clear. The aim of the present study is to assess the perioperative clinical results of systematic alveolar recruitment manoeuvre associated with protective ventilation in patients undergoing laparoscopic bariatric surgery.

It was a single-centre, randomised, double blind, superiority trial: control group with standard protective ventilation and recruitment group with protective ventilation and systematic recruitment manoeuvre. The primary outcome was a composite clinical criterion of pulmonary dysfunction including oxygen saturation, oxygen needs and dyspnoea in recovery room and at day 1. Secondary outcomes were recruitment manoeuvre tolerance, pulmonary and non-pulmonary complications, length of hospital stay and proportion of Intensive Care Unit admission.

Two hundred and thirty patients were included: 115 in the recruitment manoeuvre group and 115 in the control group, 2 patients were excluded from the analysis in the control group. Patients in the recruitment manoeuvre group had significantly lower rate of pulmonary dysfunction in the recovery room (73% *versus* 84% (p = 0.043) and 77% *versus* 88% at postoperative day 1 (p = 0.043)). No significant differences were found for secondary outcomes. No patient was excluded from the recruitment manoeuvre group for intolerance to the manoeuvre.

Recruitment Manoeuvre is safe and effective in reducing early pulmonary dysfunction in obese patients undergoing bariatric surgery.

Keywords: obesity; bariatric surgery; recruitment manoeuvre; atelectasis; pulmonary

dysfunction

Introduction

Perioperative ventilation is one of the most important challenges of anaesthesia, as it is related to postoperative pulmonary morbidity and mortality [1]. Currently, pulmonary complications occur in 3 to 10% of patients undergoing all type of surgeries [1]. At risk populations are ASA 3 status, advanced age, abdominal surgery and obese patients, in whom complications rate rise above 40% [2]. General anaesthesia decreases functional residual capacity (FRC) and can result in small airway closure leading to atelectasis, ventilation – perfusion mismatch, hypoxemia and respiratory complications [3]. FRC diminution is more pronounced in case of upper abdominal surgery. Furthermore, FRC remains low in the early postoperative period [3,4].

In obese patients, body mass index is correlated with reduction of the pulmonary volume, and after the induction of anaesthesia, FRC decreases by 50% [5,6]. These patients develop significantly more perioperative atelectasis and experience more episodes of postoperative hypoxemia and a higher rate of postoperative pulmonary complications [5,7]. Perioperative ventilation strategy has evolved toward prophylactic lung-protective ventilation inspired by the management of acute respiratory distress syndrome to limit ventilator-associated lung injury. Lung protective ventilation is based on low tidal volumes (6-8 mL per kilogram of predicted body weight) with a plateau pressure less than 30 to 35 cm of water (cm H_2O) to avoid lung over distension. Positive end expiratory pressure is adjusted at the lower inflection point of the pressure/volume curve to limit airways closure and alveolar impairment [8]. In addition, periodic recruitment manoeuvres limit atelectasis [8]. Futier et al. demonstrated in 2013 the protective effect of lung-protective ventilation in patients undergoing abdominal surgery [9]. In this study, the rate of complications decreased from 27.5% to 10.5% and the length of hospital stay was reduced by 2 days.

The alveolar recruitment manoeuvre is the most effective technique to reverse atelectasis. Alveolar opening pressure is between 12 and 30 cmH_20, hence positive expiratory pressure (PEP) cannot be set at these levels of pressure without risks of barotraumas [3]. Recruitment manoeuvre applying 30 to 40 cmH_2O airway pressures allows reversing atelectasis [3]. Several studies based on tomodensitometry or spirometry showed

the safety and efficiency of recruitment manoeuvre in non-obese patients [6].

In recent years, bariatric surgery has expanded tremendously due to the epidemy of obesity and the application of minimally invasive techniques [10]. In obese patients undergoing bariatric surgery, perioperative recruitment manoeuvre improves intraoperative respiratory mechanics and oxygenation [11,12]. However, the clinical benefits on lung function in the perioperative period have not yet been investigated so far.

The aim of the present study is to show that systematic recruitment manoeuvre associated with protective ventilation can decrease pulmonary dysfunction in recovery room and at day 1 in obese patients undergoing laparoscopic bariatric surgery. The hypothesis is that recruitment manoeuvre could reopen atelectasis caused by anaesthesia and surgery, and permit to improve pulmonary function in the early postoperative period.

Methods

Study design

The study protocol was approved by the Regional Ethical Committee (Comité de Protection des Personnes Sud-Est, Nice, France, [protocol number: 2015-A01199-40]) and the protocol was published on Clinical Trials (Identifier: NCT02592226).

In this single-centre, randomised, double blind, superiority trial we investigated the effects of recruitment manoeuvre in obese patients undergoing bariatric surgery by comparing patients receiving the recruitment manoeuvre (recruitment manoeuvre group - protective ventilation with systematic recruitment manoeuvre) and patients receiving standard care (control group - standard protective ventilation).

Written informed consent was obtained from each patient at the time of the anaesthesiology visit before surgery. Investigators involved in recording postoperative parameters and patients were blinded to treatment allocation. Patients were enrolled between the 1st of November 2015, and the 25th of December 2016, at the Centre Hospitalier Universitaire de Nice, France.

Randomisation:

A computer-generated list using block sizes of eight patients was generated by an independent statistician. The group allocation numbers were concealed in sealed opaque envelopes that were opened after enrolment of the patients.

Patients were randomised into a Recruitment Manoeuvre (recruitment manoeuvre) group (protective ventilation with systematic recruitment manoeuvre) and a control group (standard protective ventilation). Investigators involved in recording postoperative parameters and patients were blinded to treatment allocation.

Patient population

• Inclusion/exclusion criteria

Patients were included if they were aged from 18 to 65 years old, were scheduled to undergo laparoscopic bariatric surgery for obesity and had given written informed consent to participate in the present study. Exclusion criteria were ASA physical status IV, emergency surgery, heart failure, history of pneumothorax, severe chronic obstructive pulmonary disease, and emphysema.

Anaesthesia

Anaesthesia was induced with propofol (Propofol, Panpharma®) 2 $mg.kg^{-1}$ and remifentanil (Remifentanil, Mylan®) using target-controlled infusion pumps with brain target at 5.0 ng/mL. Tracheal intubation was facilitated with succinylcholine (Suxamethonium chloride, Biocodex®). Anaesthesia was maintained with desflurane (Desflurane, Baxter®) 4.5-6.0% in oxygen, remifentanil with brain target between 3.0 and 5.0 ng/mL, neuromuscular blocking was maintained with atracurium (Tracrium, atracurium besilate, Hospira®) bolus monitored by train-of-four. At the end of surgery, neuromuscular block was antagonised using prostigmine and atropine if necessary.

Antimicrobial prophylaxis was performed by cefoxitine 4 g (Cefoxitine 2 g, Panpharma®) after the induction of the anaesthesia, and repeat by 2 g of cefoxitine every 2 hours of surgery.

Analgesia was performed by paracetamol 1 g (Paracetamol, B. Braun®) every 6 h, and infusion of 120 mg nefopam (Nefopam chlorydrate, Medisol®), 240 mg phloroglucinol (Phloroglucinol, Arrow® génériques), 50 mg ketamine (Ketamine chlorhydrate, Renaudin®) over 24 h. Morphine (Morphine chlorhydrate, Aguettant®) was infused in recovery room to provide a pain score inferior to 3 on a 0–10 verbal scale.

Nausea and vomiting prevention was realised by dexamethasone 8 mg (Dexamethasone 4mg, Mylan®) after the induction of anaesthesia, and if necessary ondansetron 4 to 8 mg (Ondansetron 4mg, Accord®) in recovery room.

Ventilation

Lung protective ventilation was performed for all patients with tidal volume of 6 to 8 $ml.kg^{-1}$ of ideal body weight, 5 to 10 cm H_2O PEEP, fraction of inspired oxygen (F_iO_2) of 50 to 80% (PEEP and F_iO_2 usually used in the centre to reach SpO2 > 95%)[9]. Surgery was performed in 30 to 40° reverse Trendelenburg position, the pneumoperitoneum was standardised with an abdominal pressure at 12 cm H_2O.

Recruitment manoeuvre consisted of maintaining the airway pressure at 30 cmH_2O during 30 seconds every 30 minutes for an easy reminding in the team (bundle

30-30-30). The manoeuvre was performed by using pressure support ventilation on the anaesthesia respirator, with a 30 cm H_2O PEEP and 0 cm H_2O support. In patients assigned to the recruitment manoeuvre group, recruitment manoeuvre was performed after intubation and every 30 minutes for the all duration of anaesthesia. In the control group, recruitment manoeuvre was performed only in case of high plateau pressure over 25 cm H_2O or hypoxemia during surgery.

Intolerance of the recruitment manoeuvre was defined as an episode of bradycardia under 50 bpm and/or diminution $\geq$ 20% of mean arterial blood pressure compared to initial values. Arterial blood pressure was monitored discontinuously by non-invasive device. Blood pressure was measured before and after the application of recruitment manoeuvre, and every 5 minutes in others cases. In case of poor tolerance, the recruitment manoeuvre was stopped and performed again after 500 mL of crystalloids fluid loading.

Neuromuscular blocking was reversed and patients were awakened once the TOF ratio obtained 90%. Extubation was performed with positive airway pressure. In the recovery room, oxygen was given to reach an oxygen saturation of at least 95%. For patient with sleep apnoea syndrome they also received their personal CPAP in recovery room.

Pneumoperitoneum was standardised in our centre by applying 14 cmH_2O of abdominal pressure.

Outcome measures

The primary outcome measure of this study was a composite clinical criterion of pulmonary function including blood oxygen saturation, oxygen needs and dyspnoea. Pulmonary dysfunction was defined as lack of one of these criteria: 1) blood oxygen saturation < than 95%; 2) oxygen need: oxygen administration (0.5 to 10 L/min) for hypoxemia or patient comfort; 3) dyspnoea: subjective difficulty to breath.

Pulmonary function was measured in recovery room one hour after extubation and at postoperative day 1 in the surgical ward. In the surgical ward blood oxygen saturation and dyspnoea were measured three times a day at day 1.

Secondary outcome measures include recruitment manoeuvre tolerance, need of recruitment manoeuvre in the control group, pulmonary complications, non-pulmonary complications, length of hospital and ICU stay. Pulmonary complications include pneumonia, atelectasis, acute asthma, exacerbation of chronic obstructive pulmonary disease, pneumothorax and pleural effusion.

Data handling:

Demographics data (age, gender, BMI, medical history), characteristics of surgery (type of surgery, duration of anaesthesia), perioperative data (oxygen saturation, haemoglobin level, fluids load, fraction of inspired oxygen, tidal volume, mean plateau pressure, driving pressure and PEP during surgery) and recruitment manoeuvre tolerance were collected.

In the postoperative period, oxygen need, oxygen saturation and dyspnoea were recorded in the recovery room 1 hour after extubation and at day 1. Postoperative morbidity, ICU and hospital stay were recorded.

Statistics:

The expected rate of respiratory dysfunction in recovery room in the control group was 50%. We assumed that this rate would be decreased by 20% in the experimental group (50% *versus* 30%). Sample size was determined to achieve an 80% power to detect this difference with an alpha risk of 5%. This hypothesis required randomising 200 patients (100 per group). Accounting for possible missing data, sample size was raised to 230 patients. Data were analysed on an intention-to-treat basis. Categorical variables are described with frequencies and percentages and quantitative variables with mean +/- standard deviation (SD) or median [interquartile

range (IQR) percentile] depending on the normality of the distribution. The χ^2 test or the Fisher's exact tests were used depending on the effectives to compare categorical variables between the two groups. Comparisons of quantitative variables were realised using Student's t tests or Wilcoxon tests when appropriate. Results are presented as risk ratios with their 95% confidence intervals. All statistical tests were 2-sided with *p*-values < 0.05 considered statistically significant. Statistical analysis involved use of R software version 3.2.2 (https://www.R-project.org/, R: A language and environment for statistical computing. (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patients' and treatment characteristics:

As shown in Figure 1, 230 patients were included: 115 in the recruitment manoeuvre group and 115 in the control group, 2 patients were excluded from the analysis in the control group. Patients' characteristics are reported in Table 1. The two groups were comparable regarding age, sex, BMI, comorbidities, preoperative SpO_2, preoperative haemoglobin level.

As reported in Table 1, one hundred and twenty-one patients underwent sleeve gastrectomy, 102 Roux-en-Y gastric bypass and 5 other bariatric procedures including 2 adjustable gastric band removal and 3 gastric pouch resizing. No differences were detected between the two groups regarding type of surgery, and per-operative variables including fluid load, duration of anaesthesia, reverse muscular blockade, FiO_2, tidal volume, PEP > 8 cmH_2O, plateau and driving pressure. The median duration of anaesthesia was 120 minutes [Q1-Q3: 80 -150]. (Table 1)

Primary and secondary outcomes (Figure 2):

Patients in the recruitment manoeuvre group had significantly lower rate of pulmonary dysfunction in the recovery room (primary outcome). Pulmonary dysfunction occurred in 73% of patients in the recruitment manoeuvre group *versus* 84% in the control group in the recovery room (p = 0.043) and in 77% *versus* 88% at postoperative day 1 (p = 0.043) (Table 2). No significant differences were found for secondary outcomes between the two groups, including the rate of pulmonary complications (2.6% in recruitment manoeuvre group *versus* 4.4% in control group), surgical and general complications, as shown in Table 2. Postoperative length of stay and proportion of ICU admission were similar in the two groups. Postoperative complications occurred in 35 patients (15%) with 8 (3.5%) pulmonary complications, and surgical exploration was needed in 8 cases (3.5%), as detailed in Table 3.

Complementary exploratory analysis was added to evaluate effectiveness on each pulmonary dysfunction criterion independently. This detailed analysis of respiratory outcomes is reported in Table 4. In the recruitment manoeuvre group, there were significantly less patients who needed oxygen or with a SpO2 < 95% than the control group,

in the recovery room as well as at postoperative day 1 (POD1). The incidence of dyspnoea was significantly lower at POD 1 in the recruitment manoeuvre group (7.9% *versus* 17.7%, $p = 0.027$). Recruitment manoeuvre was well tolerated. Twelve episodes of bradycardia and only one episode of hypotension were recorded, all reversed by temporary interruption of the recruitment manoeuvre. No patient was excluded from the recruitment manoeuvre group for intolerance to the manoeuvre. Thirty patients in the control group required rescue recruitment manoeuvre for high plateau pressure or per operative hypoxemia.

Discussion

In obese patients undergoing bariatric surgery the systematic use of alveolar recruitment manoeuvre reduced immediate postoperative pulmonary dysfunction compared with standard protective ventilation. Recruitment manoeuvre did not reduce pulmonary complication neither ICU nor hospital stay. Additional analysis showed also oxygen needs lower in the recruitment manoeuvre group.

Use of alveolar recruitment manoeuvres associated with a protective ventilation strategy may prevent lung atelectasis,[6] and control the driving pressure [13], which could decrease pulmonary dysfunction and pulmonary complications [3]. However, recruitment manoeuvre is not safe in any situation. Indeed, in ARDS, recent randomised studies [14,15] report increased mortality in particular case of pneumonia or vasopressor requirement. Indeed, use of a high level of pressure specially with recruitment manoeuvres can have some adverse effects, including barotraumas, hypotension or bradycardia [14]. In our study, the recruitment manoeuvre was safe and seemed efficient. In cardiac surgery alveolar recruitment strategy is efficient without side effects [16]. In patients under general anaesthesia, recruitment manoeuvre has been studied many times and seemed safe [17–20].Optimisation of intravascular volume is probably easier in anaesthetics patients than intensive care population and might have decreased haemodynamic adverse events. Benefits of recruitment manoeuvre have been previously shown on tomodensitometry and recent reviews of the literature suggest an improvement in oxygenation (ratio PaO_2/FiO_2), compliance and atelectasis [18–20] but benefits did not persist into the postoperative period [21].

The choice of a recruitment manoeuvre type was based on the literature where different alveolar recruitment manoeuvres techniques are described: increased PEP to 20 to 30 cmH_2O, sustained manual inflations of the anaesthesia reservoir bag to a peak inspiratory pressure of 30 or 40 cmH_2O, or increased the tidal volume to a plateau pressure of 30 cmH_2O. Recently, a review of six randomised trials showed that different recruitment manoeuvres are equally effective in improvement of compliance and PaO_2 [20]. For this reason, but also because of easiness and standardisation, we used in our study pressure support ventilation on the anaesthesia respirator, with a 30 cm H_2O PEEP and 0 cm H_2O

support. Recruitment manoeuvres were repeated at intervals of 30 minutes in the recruitment manoeuvre group to create a 30-30-30 bundle.

Thirty patients needed the rescue recruitment manoeuvre in the control group for hypoxemia or high plateau pressure. These results are consistent with others studies, which showed lung reexpansion in tomodensitometry and improvement in gas exchanges on normal weight and overweight patients [6,11]. Individual titration of PEEP was not performed in our study, PEP was left at the anaesthetist discretion and it appears that in our centre intermediate level of PEP around 8 cmH2O was used. A better setting of PEP could improve driving pressure, gas exchanges and pulmonary function [13,22].

The present study was not design for analysis of plateau and driving pressure but in perioperative data, a difference exists between the two groups. This difference was not statistically significant but seemed to be lower in the recruitment group. It is consistent with past studies on obese patients in which driving pressure was lowered by open lung strategies but did not result in improved clinical outcome measures [22,23].

The percentage of complications was 15% including all type of severity, represented by 3.5% pulmonary complications and 5.7% surgical complications with 3.5% patients needing surgical exploration. Our observed incidence of postoperative complications and pulmonary complications is comparable with previous studies [24,25]. In different studies, the complications rate is very variable, 2 to 30% depending on surgical technique and type of complications recorded [26] with a decrease in time [24].

Strengths of this trial were bias-minimised by randomisation and double blinding, enrolment during a short period minimising the influence of changes in clinical practice, intention-to-treat analysis, and no loss to follow-up.

This study has limitations and some aspects have to be interpreted with caution. The required number of patients was not calculated on previous findings because we could not find outcome similar to our composite criterion. The incidence of pulmonary dysfunction was based on questioning anaesthetists on their clinical experiences and studies based on tomodensitometry outcomes, lung volumes and pulmonary complications [5,6,11,12,26]. This extrapolation has undervalued the incidence of pulmonary dysfunction in our cohort. A

decrease of 20% of pulmonary dysfunction with recruitment manoeuvre seemed clinically pertinent. On these conclusions, we expected a rate of respiratory dysfunction in recovery room of 50%, which could decrease at 30% in the experimental group. Primary outcome occurred in 84% instead of 50% of patients in recovery room but decreased by only 13% with recruitment manoeuvre. In a very recent study [27], a rate of 80% of hypoxemia and 77% atelectasis was found in obese patients undergoing bariatric surgery, which is consistent with our results. The initial protocol was not appropriate to the final results, and had generated a loss of power with insufficient sample of patients.

In this study, the population did not have a major risk of pulmonary complication except from obesity: patients were young (age median 37), with medium obesity (BMI median 40) and with a low degree of comorbidity. This could have decreased the benefit of the intervention on the improvement of respiratory care.

A composite outcome of postoperative pulmonary dysfunction was selected to be closer to the clinical practice during the perioperative period, but do not seem relevant for bariatric surgery issues. Pulmonary complications rate and hospital stay would have been more relevant but it would have needed a number of patients too high to include in our only centre.

Complementary analysis of each criterion of the primary outcome is more attractive for the systematic use of recruitment manoeuvre but was not included in the initial protocol, so it is not possible to conclude.

The blinding is not complete, intraoperative anaesthesiologists could not be blinded, patients and postoperative assessors stilled fully blinded to the operative theatre period.

In the control group, thirty patients receiving rescue recruitment manoeuvre were included in the final analysis as we adopted an intention-to-treat analysis strategy. As a consequence, rescue recruitment manoeuvre, performed in 30% of patients in the control group may have contributed to improve the pulmonary function in the control group and limited the difference between the two groups.

Non-invasive positive pressure ventilation (NPPV) was not performed for pre-oxygenation

before anaesthesia induction neither in the postoperative period, except their own CPAP for patient with Obstructive Sleep Apnoea Syndrome. NPPV showed in past studies an increase in pulmonary volume, and limit pulmonary complications decreasing atelectasis rate [28,29]. Poor results of this study could be linked to loss of effect of alveolar recruitment by non-use of a recruitment strategy in the postoperative period. A prophylactic perioperative positive pressure ventilation is recently described [30] and consist in NPPV pre and postoperative period with protective ventilation and alveolar recruitment manoeuvre to limit the lung volume reduction induced by surgery and worsen by obesity. The recruitment manoeuvre could show results in this global strategy.

Humidified high-flow nasal oxygen in the perioperative period was not used in the study. This oxygen administration technique has recently showed an improvement of hypoxemia in obese patients undergoing bariatric surgery [27]. With a PEEP like effect, it has reduced hypoxemia from 80% to 28% and atelectasis from 77% to 31%. This study protocol is very close to our study with a similar primary outcome and rate of hypoxemia in the control group. Humidified high flow nasal oxygen could be a real improvement in the respiratory care in bariatric surgery and need to be investigated [31].

Obese patients undergoing bariatric surgery represent a challenge, with the advancement of ambulatory and one-day bariatric surgery. It is essential to optimise the pulmonary function and minimise complications. Previous studies have already focused on the adaptation of ventilation strategies to obese patients, put forward the interest of recruitment strategies using higher PEP, associated with low tidal volumes. The place of the recruitment manoeuvre is still unclear: the present study shows that Recruitment Manoeuvre is safe and effective in reducing early pulmonary dysfunction in obese patients undergoing bariatric surgery, but only for immediate postoperative period; it is uncertain that benefits persist days after surgery. Results need to be confirmed with studies focusing on pulmonary complication rate and length of hospital stay, designed on larger multicentric trial.

Clinical trials register:

ClinicalTrials.gov Identifier: NCT02592226

Acknowledgements

The authors are grateful to the anaesthesiologists and nurses for their help for the inclusion of patients and acquisition of data.

Fundings: This work was supported by internal resources of the University Hospital of Nice

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Flow Diagram

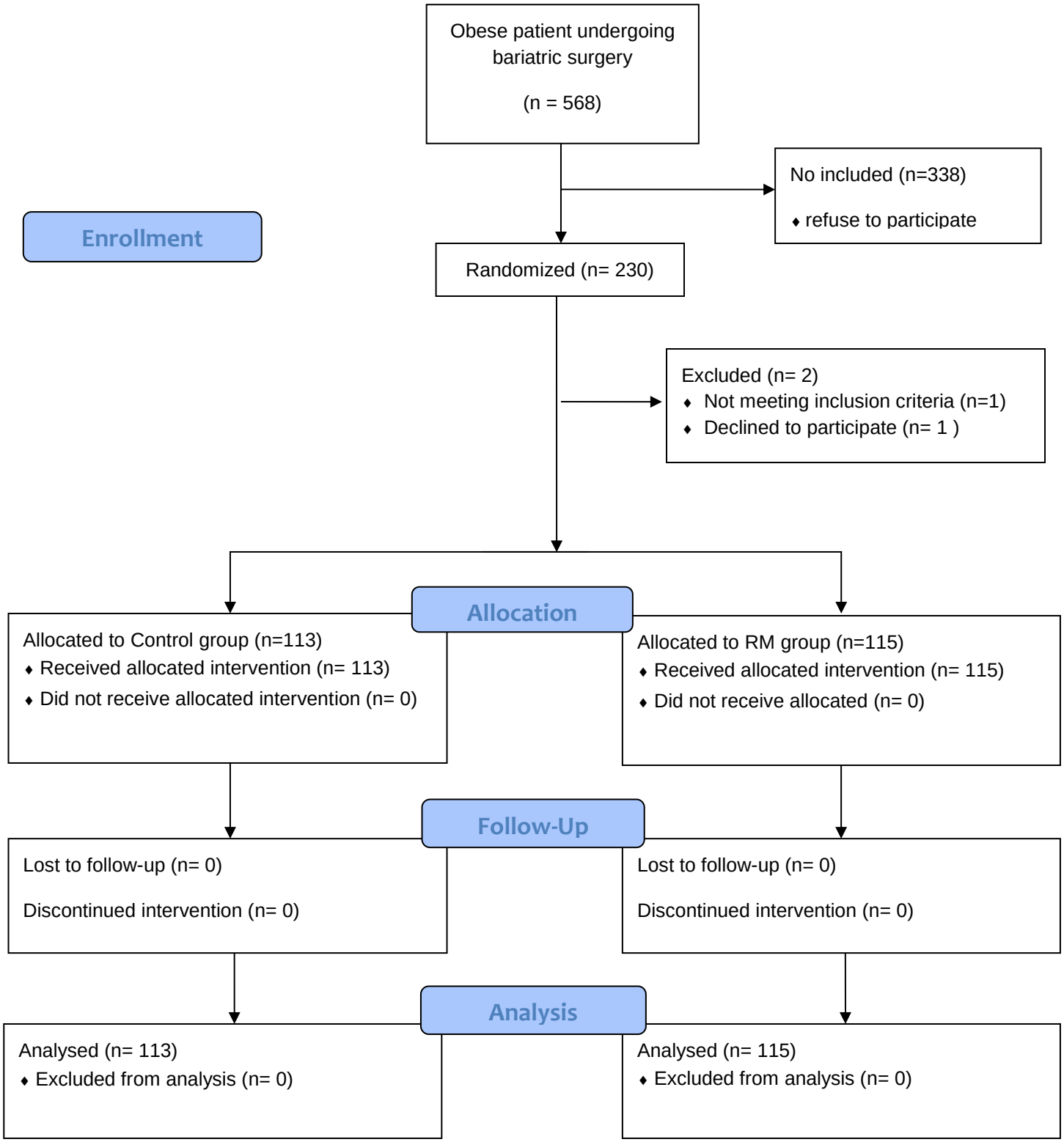

Table 1: demographics and perioperative data

	Control (n = 113)	RM (n = 115)	Total Population (n = 228)	P
Age - med [Q1- Q3]	36 [27-48]	38 [28-49]	37.5 [28-48]	0.674
Sex n (%)				0.219
woman	87 (77.0)	96 (83.5)	183 (80.3)	
man	26 (23.0)	19 (16.5)	45 (19.7)	
BMI - med [Q1- Q3]	40 [38-44]	41 [38-44]	40 [38-44]	0.954
Comorbidities n (%)				
Pulmonary failure	8 (7.1)	7 (6.1)	15 (6.6)	0.762
Asthma	20 (17.7)	16 (13.9)	36 (15.8)	0.687
OSAS	48	51	99	0.482
With CPAP	31 (27.4)	27 (23.5)	58 (25.4)	
No need CPAP	17(15.0)	24 (20.9)	41 (18.0)	
Heart rhythm disorder	0 (0)	4 (3.5)	4 (1.8)	0.122
Cardiac failure	1(0.9)	0 (0)	1 (0.4)	0.496
Active Smocking	10 (8.9)	10 (8.7)	20 (8.8)	0.300
Giving up smocking	42 (37.2)	32 (27.9)	74 (32.5)	
Surgery n (%)				0.661
Sleeve gastrectomy	57 (50.4)	64 (55.7)	121 (53.1)	
Gastric by pass	53 (46.9)	49 (42.6)	102 (44.7)	
Others	3 (2.7)	2 (1.7)	5 (2.2)	
SpO_2 preoperative (%) med [Q1- Q3]	98 [97-99]	98 [97-99]	98 [97-99]	0.460
Haemoglobin preoperative (g/dL) mean	13.7 (13.0-14.7)	13.8 (13.1-14.7)	13.8 (13.0-14.6)	0.721
Fluid load (mL) med [Q1- Q3]	1000 [1000-1500]	1000 [1000-1500]	1000 [1000-1500]	0.821

Duration of anaesthesia (min) – med [Q1-Q3]		120 [80-150]	120 [80-150]	120 [80-150]	0.986
Reverse Muscular blockade – n (%)		14 (12.4)	14 (12.2)	28 (12.3)	0.961
FiO_2 (%) – med [Q1-Q3]		60 [55-65]	60 [50-65]	60 [55-65]	0.182
Tidal volume (mL) – med [Q1-Q3]		430 [410-450]	400 [420-450]	420 [405-450]	0.541
PEP > 8 (cmH2O) n (%)		76 (67.3)	86 (74.8)	162 (71.1)	0.210
Plateau pressure (cmH_2O) [Q1-Q3]	med	21 [18-25]	20 [18-23]	21 [18-24]	0.198
Driving pressure (cmH_2O) [Q1-Q3]	med	13 [10-16]	13 [10-17]	12 [10-16]	0.065

RM: recruitment manoeuvre

med: median

IQR: interquartile range ; Q1-Q3 : first quartile – third quartile

BMI: body mass index; OSAS: obstructive sleep apnoea syndrome; CPAP: continuous positive airway pressure

SpO2: oxygen percutaneous saturation; FiO2: inspired fraction of oxygen; PEP: positive end expiratory pressure

Table 2: clinical outcomes

	Control (n=113)	RM (n=115)	Risk ratio (CI 95%)	p
Principal outcome:				
Pulmonary Dysfunction, n (%)				
- Recovery room	95 (84.1)	84 (73.0)	0.87 (0.76-1.0)	0.043
- Post-operative day 1	99 (87.6)	89 (77.4)	0.88 (0.78-1.0)	0.043
Secondary outcomes				
Pulmonary complications n (%)	5 (4.4)	3 (2.6)	0.59 (0.14-2.41)	0.497
Non pulmonary Complications n (%)	9 (8.0)	5 (4.4)	0.55 (0.19-1.59)	0.262
Surgical complications n (%)	6 (5.3)	7 (6.1)	1.15 (0.40-3.33)	0.788
Length of stay med [Q1- Q3]	5 [5.0 – 6.0]	5 [4.0 – 6.0]	-	0.993
ICU stay n (%)	3 (2.7)	4 (3.5)	1.31 (0.30-5.72)	1

CI: confidence intervals
med: median
IQR: interquartile range; Q1-Q3: first quartile – third quartile
ICU: intensive care unit

Table 3: Complications description

Type of complication	n.
Atelectasis or pneumoniae	6
Acute asthma	2
hypokalaemia	1
Post prandial hypoglycaemia	1
Chest pain without cardiac cause	2
Stones in parotid gland	1
Pyelonephritis	2
Difficulty in food intake	2
Fever and/or abdominal pain without identified aetiology	3
small bowel occlusion	1
splenic infarction	2
Clostridium Difficile colitis	2
intra-abdominal collection	2
explorative laparoscopy	2
post-operative bleeding	2
strangulation trocar hernia	1
evisceration	1
peritonitis and fistula	2
reintervention.	8

Table 4: respiratory data analysis

	Control (n=113)	RM (n=115)	Risk ratio (CI 95%)	P
SpO_2 < 95% - n (%)				
- Recovery room	95 (84.1)	84 (73.0)	0.87 (0.76-1.0)	0.043
- Post-operative day 1	99 (87.6)	87 (77.7)	0.89 (0.79-1.0)	0.049
Oxygen need – n (%)				
- in recovery room	91 (80.5)	76 (66.1)	0.82 (0.70 – 0.96)	0.014
- at postoperative day 1	30 (26.6)	18 (15.8)	0.59 (0.35 – 1.0)	0,047
Dyspnoea - n (%)				
- Recovery room	17 (15.0)	8 (7.0)	0.46 (0.21-1.03)	0.051
- Post-operative day 1	20 (17.7)	9 (8.0)	0.45 (0.21-0.94)	0.027

RM : recruitment manoeuvre

CI 95%: confidence interval

SpO2 : percutaneous oxygen saturation