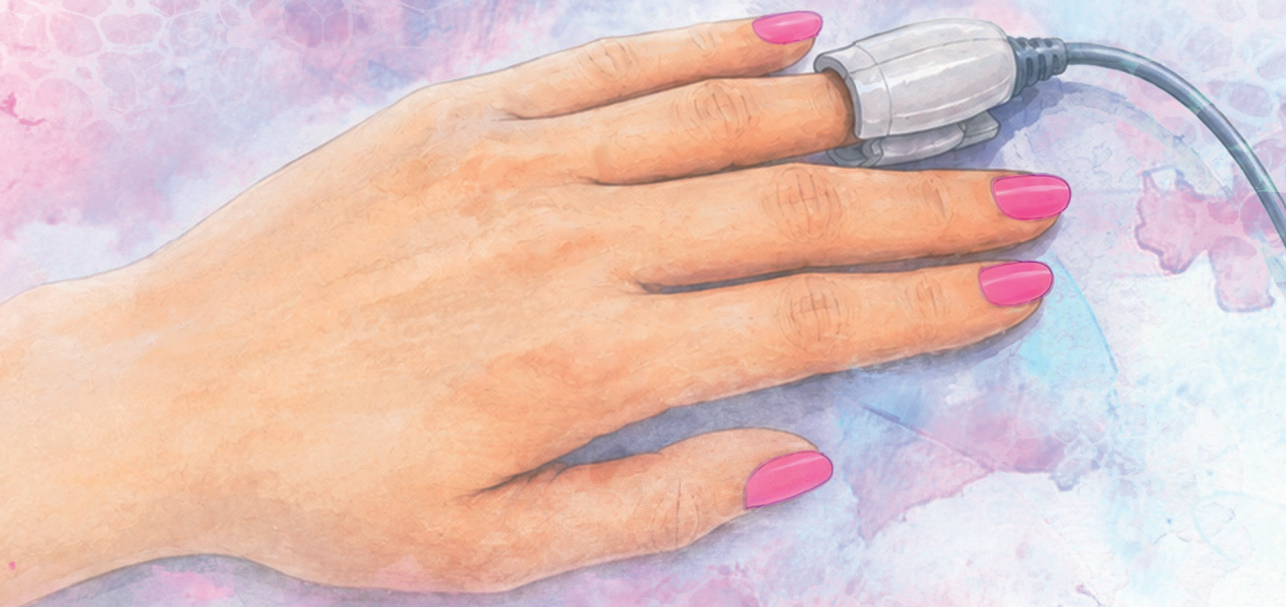
Optimizing the perioperative management of obstructive sleep apnea in metabolic and bariatric surgery

Toward minimizing excessive diagnostics and treatment



Claudia Berends

Propositions

1. Preoperative sleep testing has become obsolete in bariatric and metabolic surgery. (this thesis)
2. Same-day discharge is compatible with widespread adoption of the pulse oximetry strategy in metabolic and bariatric surgery. (this thesis)
3. A PhD trajectory with clinically relevant findings requires a clinical implementation phase.
4. The current peer-review system delays scientific publication unnecessarily.
5. Modern society is organized for male rather than female breadwinners.
6. The Dutch healthcare system is eroding the distinctive value of Family Medicine.

Propositions belonging to the thesis entitled:

Optimizing the perioperative management of obstructive sleep apnea
in metabolic and bariatric surgery.
Toward minimizing excessive diagnostics and treatment.

Claudia Berends
Wageningen, 28 September 2026

Optimizing the perioperative management of obstructive sleep apnea in metabolic and bariatric surgery

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Optimizing the perioperative management of obstructive sleep apnea in metabolic and bariatric surgery

Toward minimizing excessive diagnostics and treatment

Claudia Berends

Thesis

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Voor Gerrit, die ik zo graag bij mijn verdediging had gehad.

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Chapter 1

General introduction

Obesity is a chronic, relapsing disease with a multifactorial combination of causes including genetics, neurobiology, eating behavior, access to (healthy) food and market forces [1]. Currently there is a global pandemic of obesity, affecting more dan 890 million (13%) adults in 2022 [1, 2]. Obesity is defined as a body mass index (BMI) >30 kg/m^2 or BMI >27.5 kg/m^2 in the Asian population [3]. Obesity has profound consequences for both the individual and for society. On a societal level obesity causes an economic burden, due to increased medical needs and lost productivity associated with obesity, leading up to hundreds of billions of dollars a year on obesity-related costs in the United States [5]. For the individual, obesity can lead to multiple obesity-related complications, these complications can be divided into three categories [2]. First, metabolic complications including hypertension, type 2 diabetes, fatty liver disease, infertility, cardiovascular disease and cancer. Second, mechanical complications such as obstructive sleep apnea (OSA), urinary incontinence, gastroesophageal reflux disease and osteoarthritis. Third, behavioral and physical complications such as depression and anxiety, which are likely caused or aggravated by the stigma and discrimination associated with the body size of people with obesity. The effect of all these complications together reduces life expectancy by 2-10 years in individuals living with obesity [2, 6-8].

Treatment of obesity

Currently, there are multiple treatments for obesity including lifestyle interventions, pharmacotherapy, and metabolic and bariatric surgery (MBS). Lifestyle interventions lead to moderate initial weight loss of 4-10% after one year and 1-3% weight loss after 5-10 years [2, 6]. Lifestyle interventions are difficult to adhere to, as weight loss with calorie deficit induces metabolic adaptations which increase appetite and decrease satiety [9, 10].

Pharmacotherapy is a relatively new treatment, with specific anti-obesity medication (AOM) which reduces appetite and increases satiety [11]. These AOMs, in combination with lifestyle interventions, result in promising weight loss results of 5-17% [2, 12]. However, it must be noted that there is a high incidence of gastro-intestinal adverse effects which lower the tolerability of AOM. This leads to frequent discontinuation of these medications, while long-term use is often needed to maintain weight loss [6, 13]. Additionally, data regarding long-term safety of AOM is limited, costs are high, and the majority is not reimbursed by health insurance companies in most countries.

MBS has been utilized as a treatment for obesity since 1952 and has evolved in a safe and effective treatment with an expected total weight loss (TWL) of 25-29% 10-12 years after surgery [14-16]. In addition to weight loss, there is also reduction or even remission of obesity-related comorbidities such as type 2 diabetes, hypertension and OSA after MBS [17-19]. According to the global registry of International Federation for the Surgery of

Obesity and Metabolic Disorders (IFSO) nearly 600,000 bariatric procedures (both primary and revisional) were performed in 2023, of which laparoscopic sleeve gastrectomy (SG) accounted for 57% and laparoscopic Roux-en-Y gastric bypass (RYGB) for 32% of the performed procedures [20]. In the Netherlands, over 12,000 procedures are performed annually of which RYGB is most performed in both primary (53%) and revisional procedures (62%) [20]. In the SG, approximately 80% of the stomach is permanently resected, resulting in a tube-shaped gastric pouch (Figure 1b, with as reference the normal anatomy in Figure 1a) [21, 22]. In the RYGB, a small pouch (±30 mL) of the upper part of the stomach is created, which is connected to the small intestine, bypassing the lower part of the stomach, duodenum and proximal part of the jejunum (Figure 1c) [21, 22]. Besides restriction of food intake, both procedures alter gut hormones, leading to more post-prandial satiety [23]. In the Netherlands, the criteria for MBS are a BMI of ≥ 40kg/m^2 or BMI of ≥ 35.0 - 39.9 kg/m^2 with one or more obesity-related comorbidities (e.g. hypertension, type 2 diabetes) [24].

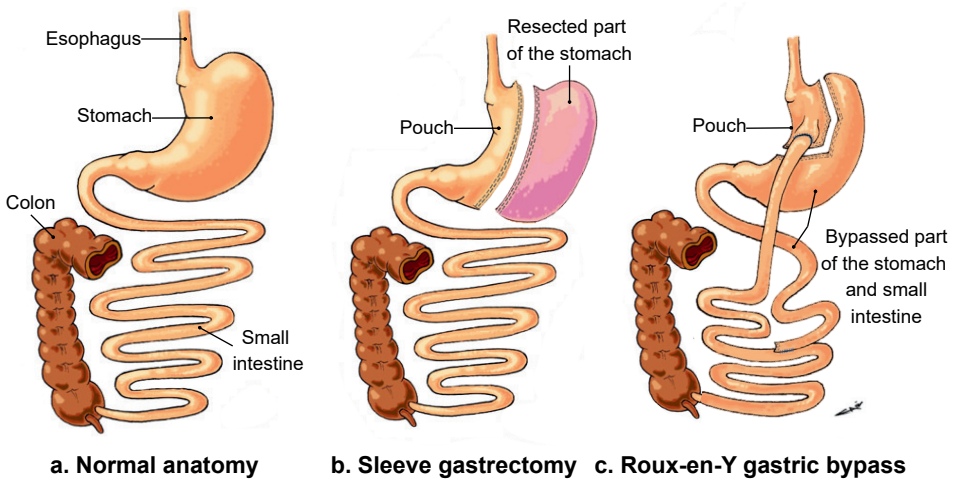

Figure 1. Normal anatomy (a), anatomy of the sleeve gastrectomy (b), and Roux-en-Y gastric bypass (c) (Reproduced from Aarts, E. O. & Mahawar, K., "From the Knife to the Endoscope - a History of Bariatric Surgery," Current Obesity Reports, 9, 348–363 (2020), Reproduced with permission from Springer Nature)

Overall complication rates of 0.8% to 5.6% after SG and 1.4% to 9.4% after RYGB are considered acceptable, and both procedures are associated with a low mortality rate ranging between 0.03% to 0.2% [25]. In 1994, the first laparoscopic RYGB was performed. This laparoscopic approach enhanced patient recovery by reducing wound related complications, postoperative pain, length of hospital stay and mortality [26]. To further improve perioperative outcomes, enhanced recovery after surgery (ERAS) protocols were introduced for MBS. ERAS has been widely used across various surgical fields and is an evidence-based multimodal perioperative care pathway aiming to reduce the surgical

stress response in patients, accelerating functional recovery and thereby improve quality of care, decrease complication rate and shorten hospital stay [27, 28]. In 2016, the first ERAS guideline for MBS was published, and it continues to evolve with the most recent revision dating from 2021 [29, 30]. Recommendations from ERAS include: no routine use of abdominal drains, early postoperative nutritional care and prophylactic oxygen supplementation for patients without OSA or with uncomplicated OSA, and continuous positive airway pressure in patients with OSA [30]. The implementation of ERAS protocols for MBS resulted in shorter hospital stay and reduced postoperative nausea and vomiting [28, 31].

Following the implementation of ERAS, the most recent development in perioperative MBS care is same-day discharge. Same-day discharge was utilized to reduce hospital resource utilization, costs and improve patient satisfaction. The implementation was accelerated during the COVID-19 pandemic to accommodate the high demand for bariatric procedures with less hospital capacity. Research in over 50,000 bariatric procedures with same-day discharge found that same-day discharge appears to be safe with high success rates (88-99%), but with varying 30-day emergency department visits (0.1-10%) and hospital readmission rates (0.6-20%) [32-36]. However, a retrospective analysis in 34,000 patients with same-day discharge matched with inpatient bariatric patients found an increased mortality rate for same-day discharge, while major complication rate was lower in same-day discharge [37]. The varying readmission rates and potential increased mortality rate could be explained by the fact that, unlike for ERAS, no standardized perioperative management protocols are available for same-day discharge MBS. Therefore, more studies are needed to establish same-day discharge protocols for MBS with evidence-based patient selection and discharge criteria.

Obstructive sleep apnea

OSA is a sleep disordered breathing disease, characterized by recurrent collapse of the upper airway during sleep, resulting in hypopnea in case of partial or apnea in case of complete upper airway collapse [38]. These hypopneas and apneas lead to cortical arousal and/or a decrease in oxygen blood saturation. This disruption of sleep can cause excess daytime sleepiness, which can influence daily functioning. Consequently, this may affect physical health, emotional well-being, social relationships, cognition and work productivity. The prevalence of OSA in the general population is 9-38%, while the prevalence in patients undergoing MBS is 34-94% [39, 40]. A constricted upper airway is commonly observed in patients with OSA, resulting in an upper airway that is more susceptible to collapse. This constricted upper airway has multiple causes including an elongated soft palate, shortened mandible length and increased fat deposition in the tongue and pharyngeal wall (Figure 2) [38, 41].

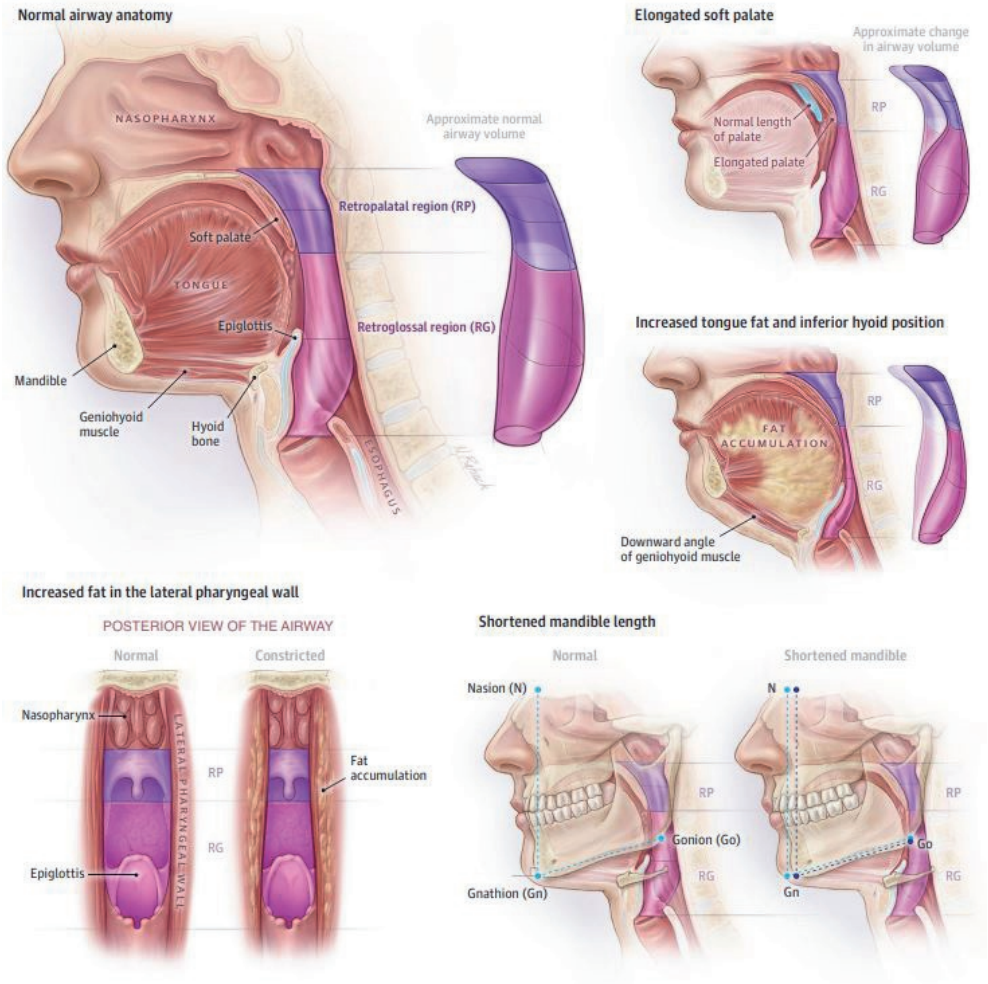

Figure 2. The normal airway anatomy and causes of a constricted upper airway (Reproduced from Gottlieb, D. J. & Punjabi, N. M., "Diagnosis and Management of Obstructive Sleep Apnea: A Review," JAMA, 323(14), 1389–1400 (2020). Reprinted with permission from JAMA)

This increased fat deposition is often observed in patients with obesity, which explains the high prevalence of OSA in patients undergoing MBS.

The severity of OSA is quantified by the apnea-hypopnea index (AHI), which is the average number of apneas and hypopneas per hour during sleep. The AHI can be determined using polysomnography (gold standard), polygraphy or for example with peripheral arterial tonometry (PAT) [42]. Polysomnography and polygraphy measure respiratory parameters such as airflow, respiratory effort and oxygen saturation to determine the AHI, and can be performed in a sleep laboratory or at home. Furthermore, polysomnography includes neurophysiological measurements (brain activity, eye movement), enabling the characterization of sleep stages [38]. PAT-based measurements are performed at home with

self-applied sensors, the airflow is not directly measured, but instead an algorithm uses peripheral arterial volume changes (measured by a finger-mounted plethysmograph), oxygen saturation, heart rate and actigraphy to calculate the AHI [43].

According to the third edition of the international classification of sleep disorders (ICSD-3-TR) OSA is defined as AHI ≥ 5 events/hour accompanied with symptoms (e.g. sleepiness, insomnia, fatigue) or an AHI ≥ 15 events/hour regardless of associated symptoms or disorders [44, 45].

In addition to excess daytime sleepiness, patients with OSA are at increased risk for cardiometabolic disease, including type 2 diabetes, hypertension and ischemic heart disease [42]. Therefore, treatment of OSA is important but unfortunately up to 80% of patients with OSA remain undiagnosed and therefore untreated [46].

Treatment of obstructive sleep apnea

Treatment modalities for OSA include positive airway pressure (PAP), oral appliance therapy, positional treatment, multilevel airway surgery, hypoglossal nerve stimulation and excess weight loss [42]. PAP is the primary and most effective treatment of OSA, as it maintains patency of the upper airway preventing collapse [38]. Continuous positive airway pressure (CPAP) is the initial and most commonly used type of positive airway pressure in the treatment of OSA [47]. Regrettably, the adherence to CPAP is relatively low with 60-75% of patients with an acceptable adherence, defined as ≥ 4 hours per night for at least five days a week [38, 48, 49]. Whereas CPAP is a symptomatic treatment for obesity-related OSA, obesity treatment with loss of excess weight can address the underlying cause of OSA, i.e. a constrictive upper airway due to excessive fat deposition. Therefore, in recent years, there has been a shift toward weight loss as primary treatment for obesity-related OSA.

Obstructive sleep apnea and metabolic and bariatric surgery

The prevalence of OSA in patients undergoing MBS is high, and often undiagnosed. In 2017, a consensus guideline for the perioperative management of OSA in MBS was developed. This guideline recommends preoperative OSA testing in all patients undergoing MBS, preferably with polysomnography [40]. However, as the guidelines itself notes, routine preoperative polysomnography is not universally feasible. Furthermore, polysomnography is expensive and time consuming and with the high numbers of bariatric procedures, a certain sleep laboratory capacity is needed. Additionally, weight

loss itself is a treatment against OSA, probably making CPAP unnecessary within three to six months after MBS [50]. Research showed that CPAP adherence of patients newly diagnosed with OSA preoperative to MBS is lower compared to patients with pre-existing OSA (39% versus 73% p<.001) [51]. An alternative option could be to monitor all patients postoperatively, rather than just those diagnosed with OSA, as is currently advised in the consensus guideline and ERAS protocol [29, 40]. A large prospective cohort study (POPCORN study) in patients undergoing MBS (n=1390) compared two strategies for the perioperative management of OSA in MBS. The first being the pulse oximetry strategy, in which participants were not preoperatively tested for OSA but instead continuously monitored postoperative with pulse oximetry accompanied with supplemental oxygen therapy. Second, the sleep test strategy, in which all participants underwent a preoperative sleep test (poly[somno]grapy) and subsequent treatment with CPAP if OSA was diagnosed [52]. The POPCORN study showed that complications and readmission rate were comparable between the strategies, and postoperative monitoring was more cost-effective [52].

Although the pulse oximetry strategy can be considered a cost-effective alternative to routine OSA screening in patients undergoing MBS, some factors have not been fully explored. First, patient-reported outcomes for sleep-related and health-related quality of life (HRQoL) should be compared, as participants in the pulse oximetry group may have untreated obesity-related OSA until sufficient weight loss is reached for OSA to improve. Therefore, participants could be prone to a decreased HRQoL and excess daytime sleepiness which can impact their daily functioning.

Second, supplemental oxygen therapy is administered in the pulse oximetry strategy, but its added value within this context is unknown. Oxygen therapy alone, unlike CPAP, does not maintain patency of the upper airway, and therefore does not prevent collapse of the upper airway. Thus, it is questionable if oxygen therapy prevents apneas and associated desaturations. This poses the question whether the pulse oximetry strategy is associated with a high desaturation rate and consequently a higher workload for the nursing staff due to potential interventions in case of a desaturation.

Third, a recent development in perioperative care is same-day discharge of patients undergoing MBS. Although same day discharge MBS appears to be safe and effective, no evidence-based recommendations for patient selection and discharge criteria are currently available. This could theoretically result in conservative and hospital-specific patient selection and discharge criteria, particularly for patients with OSA. Reluctance for same-day discharge in patients with (untreated) OSA may be due to reported adverse changes of sleep-disordered breathing and sleep architecture during the early postoperative period in patients undergoing general surgery [53]. Sleep architecture was reported to be disturbed, and AHI was increased in both OSA and non-OSA patients. However,

these sleep-related breathing disturbances were greatest during the third postoperative night, when MBS patients (either same-day discharge or inpatient) with a normal postoperative course will already sleep at home. This raises the question whether having (untreated) OSA should be a contra-indication for same-day discharge MBS. Therefore, research in the MBS population is needed to assess if the same postoperative changes in sleep disordered breathing occur in patients undergoing MBS.

Aim and outline of this thesis

The aim of this thesis was to evaluate and improve perioperative strategies for the management of OSA in MBS, with particular attention to minimizing excessive OSA diagnostics and treatment by:

- Comparing patient-reported HRQoL, sleep-related outcomes and weight loss in the pulse oximetry† and sleep test strategy‡.
- Characterizing the desaturation rate and nursing intervention rate in the pulse oximetry strategy.
- Assessing the value of supplemental oxygen therapy in the pulse oximetry strategy.
- Assessing the postoperative course of sleep disordered breathing in patients undergoing MBS with same-day discharge without preoperative OSA testing.

† Pulse oximetry strategy: No preoperative testing for OSA, but instead postoperative continuously monitoring with pulse oximetry accompanied with supplemental oxygen therapy.

‡ ‡Sleep test strategy: Preoperative routine testing for OSA, with subsequent treatment with PAP if indicated.

Outline of this thesis

In **Chapter 2** and **Chapter 3,** patient reported outcomes for excess daytime sleepiness, the impact of sleepiness on daily functioning and HRQoL and total weight loss were compared between the pulse oximetry and sleep test strategy in the population of the POP-CORN study. This was conducted by administering multiple questionnaires: the Epworth Sleepiness Scale (ESS) for excess daytime sleepiness, the Functional Outcomes of Sleep Questionnaire- short version (FOSQ-10) for the impact of sleepiness on daily functioning, and the medical outcomes study 36-item short form health survey (RAND-36) for HRQoL. This was compared until one year after MBS in **Chapter 2** and until five years postoperative in **Chapter 3.**

In **Chapter 4,** the desaturation and nursing intervention rate was characterized in the pulse oximetry strategy, as an initial assessment of the value of supplemental oxygen therapy within this strategy and to assess the workload for the nursing staff, in a prospective observational cohort study (SATBAR study).

In **Chapter 5,** a randomized non-inferiority trial aimed to evaluate if omitting supplemental oxygen is non-inferior to administering oxygen during the first night after MBS. This was performed by comparing respiratory indices between participants with and without supplemental oxygen therapy (O_2 group versus non-O_2 group, randomized allocation).

In **Chapter 6,** the postoperative course of sleep disordered breathing in MBS with same-day discharge was assessed in participants without preoperative OSA testing in a prospective observational cohort study. Participants underwent a home sleep apnea test during a preoperative night and during postoperative night one and three.

Chapter 7 is the final chapter of this thesis and includes a discussion of the main findings, concluding with clinical implications and future perspectives.

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Chapter 2

Excess daytime sleepiness, daily functioning and health-related quality of life during the first year after metabolic and bariatric surgery in patients with a known and unknown obstructive sleep apnea status

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Abstract

Purpose: Despite a high prevalence of obstructive sleep apnea (OSA) in patients undergoing metabolic and bariatric surgery (MBS), there is no consensus on the best perioperative OSA strategy. Supplemental oxygen therapy without preoperative OSA-testing (pulse oximetry strategy) is safe and more cost-effective compared to preoperative OSA-testing using poly(somno)graphy (sleep test strategy). This study aimed to compare these strategies on excess daytime sleepiness (EDS), its impact on daily functioning and health-related quality of life (HRQoL).

Methods: Multicenter prospective cohort study including 1388 patients, 691 in the sleep test and 697 in the pulse oximetry group based on local protocols. EDS (ESS), its impact on daily functioning (FOSQ-10), HRQoL (RAND-36) and total weight loss (TWL) were assessed preoperatively and 1, 3, 6 and 12 months postoperatively. (Sub)scores were compared over time between and within groups using linear mixed models.

Results: No differences between the pulse oximetry and sleep test strategy were found in EDS, its influence on daily life and HRQoL, and all improved after MBS. In the pulse oximetry group a lower TWL was found 1 month postoperative (-0.7%) and a higher TWL at 6 and 12 months postoperative (+0.6%, +1.6%), compared to the sleep test strategy.

Conclusion: Considering that pulse oximetry is more cost-effective, equally safe and comparable in EDS, its effect on daily functioning and HRQoL and no clinically relevant difference in TWL was found compared to the sleep test strategy, this study lends further support for pulse oximetry being the best strategy for managing OSA in patients undergoing MBS.

Introduction

Metabolic and bariatric surgery (MBS) is an effective treatment for obesity. In patients undergoing MBS, the prevalence of obstructive sleep apnea (OSA) is high, (35-95%), and mostly undiagnosed [1]. Patients with OSA have a potentially increased risk of postoperative cardiac events, respiratory failure and admission to the intensive care unit (ICU) [2, 3]. Despite the high prevalence and increased risk of postoperative complications, there is still no consensus for the best perioperative strategy to manage OSA in patients undergoing MBS.

In the Netherlands, there are currently two strategies that are mainly used. In the first strategy, patients are tested for OSA preoperatively by overnight poly(somno)graphy, and if indicated, treated with positive airway pressure (PAP), referred to as the sleep test strategy. In the second strategy, patients are not tested for OSA but receive supplemental oxygen therapy and are postoperatively continuously monitored with pulse oximetry (pulse oximetry strategy). The pulse oximetry strategy is based upon the hypothesis that losing weight itself can improve or resolve OSA in the long term [4, 5]. Perioperative safety is guaranteed by continuous monitoring, without the additional costs and use of healthcare resources for testing and (temporarily) treating bariatric patients for OSA.

The cost-effectiveness and patient safety of these two strategies was compared in a large prospective cohort study (POPCORN study), and found no differences in post-operative complications and unscheduled intensive care unit admissions between the two strategies, and the health-related costs were lower for the pulse oximetry strategy (-€534 per patient) [6].

In addition to patient safety and cost-effectiveness, the impact of both strategies should also focus on perhaps the most important outcomes for patients potentially suffering from OSA: excess daytime sleepiness (EDS), and related daily functioning and health-related quality of life (HRQoL). In the pulse oximetry group part of the patients will have untreated OSA, and given that it will take several months to lose sufficient weight for OSA to improve, these patients may experience more EDS during this first postoperative period. However, both obesity and OSA are found to be risk factors for EDS, and previous research showed a significant postoperative decrease in EDS in both bariatric patients with and without OSA [7-9]. This led to the hypothesis that having untreated OSA will not influence postoperative EDS following MBS.

Therefore, the aim of this study was to compare two perioperative strategies for OSA (sleep test and pulse oximetry strategy) on post-operative EDS, its impact on daily functioning and HRQoL before and after MBS.

Methods

Study design

This research was conducted as part of the POPCORN study, a multicenter prospective cohort study among patients undergoing MBS. Recruitment took place at seven hospitals in the Netherlands (Rijnstate, Arnhem; St. Antonius Hospital, Nieuwegein; Onze Lieve Vrouwe Hospital, Amsterdam; Dutch Obesity Clinic, the Hague; Zuyderland Hospital, Heerlen; Rode Kruis Hospital, Beverwijk and Máxima Medical Centre, Veldhoven) between April 2018 and February 2020. Patients undergoing primary laparoscopic Roux-en-Y gastric bypass (RYGB) or laparoscopic sleeve gastrectomy (SG) at one of the participating centers were eligible for this study. Exclusion criteria were prior MBS, prior OSA diagnosis or poly(smono)graphy, undergoing concomitant surgical procedures (e.g. cholecystectomy) and the inability to speak or read the Dutch language. Detailed information on the study design can be found in the previously published study protocol [10]. All participants gave written informed consent for their participation in this study. The study was approved by the Medical Research Ethics Committees United (MEC-U reference number W17.050) and adheres to the Declaration of Helsinki.

Participants received usual care as per local protocol, which included a 1-night postoperative hospital stay. Beyond usual care, patients were asked to complete several questionnaires including the Epworth sleepiness scale (ESS), functional outcome of sleep questionnaire (FOSQ-10), and RAND-36 pre-operatively and 1, 3 ,6 and 12 months after surgery. Participants in the pulse oximetry group were only enrolled at Rijnstate Hospital, as this was the only hospital among the participating centers that used this strategy. In this group, patients were not preoperatively tested for OSA. Postoperatively, patients were continuously monitored using pulse oximetry and received supplemental oxygen therapy through a nasal cannula (2L/min) until the next morning. Nurses were alerted in case of desaturations (peripheral oxygen saturation [Sp] <90%). In case of persisting desaturations, nurses intervened by waking up the patient and/or increasing oxygen flow. If these interventions were insufficient, the attending physician was informed for clinical evaluation and treatment. In the sleep test group, all patients were preoperatively tested for OSA by ambulatory P(S)G, and if indicated, PAP treatment was started.

Data collection

The following information was obtained from electronic patient records: age, gender, body mass index (BMI), waist circumference, OSA diagnosis (diagnosed with poly(somno) graphy), occurrence of obesity related comorbidities (hypertension, dyslipidemia, diabetes mellitus type 2), occurrence of OSA related comorbidities and events (asthma, chronic obstructive pulmonary disease (COPD), myocardial infraction, cerebral vascular accident (CVA)), type of surgery (RYGB, SG), total weight loss (preoperative weight - current weight) / (preoperative weight) x 100), smoking status (categorized as: smoker, former smoker,

non-smoker). Primary outcomes were EDS, the impact of EDS on daily functioning and HRQoL.

Excess daytime sleepiness

EDS was determined using the ESS. The ESS consists of 8 questions in which the patient has to rate, on a scale of 0 to 3, how high the chance is of dozing off or falling asleep in different situations. The ESS score equals the sum of these 8 ratings, giving a score between 0-24. If 1 or more of the ratings were missing, the ESS score was not calculated. Low scores indicate a low degree of sleepiness, an ESS score of >10 or higher indicates excessive daytime sleepiness [11, 12].

Impact of EDS on daily functioning

The impact of EDS on functioning in daily life was assessed by FOSQ-10 [13]. The version of the FOSQ-10 used in this study can be found in Supplementary Material 1. The score of the FOSQ-10 ranges from 5-20 points, a higher score indicating better functioning in daily life. If there were 1 or more missing answers, the score for FOSQ-10 was not calculated.

Health-related quality of life

HRQoL was assessed with the RAND-36 questionnaire. This questionnaire consists of 36 questions within 9 subscales: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, general health, and health change. The score for each subscale ranges from 0-100, with higher scores defining a better quality of life [14, 15]. If 1 or more answers were missing for a subscale, the score for that subscale was not calculated.

Statistical analysis

Based on normality, data were expressed as mean with standard deviation (normal distribution), or median with Q1-Q3 (non-normal distribution). Patient characteristics were compared between the groups using independent T-tests (normally distributed, continuous data), Mann-Whitney U tests (not normally distributed continuous data) or Chi-Square tests (binary data).

The (sub)scores of the ESS, FOSQ-10, RAND-36 and total weight loss were compared over time between the pulse oximetry and sleep test group using linear mixed models. Prior to analysis, the FOSQ-10 and the RAND-36 sub scores physical functioning, emotional well-being, social functioning, pain and health change were reflected and then square-rooted, for the ESS score square root transformation without reflection was applied. The model consisted of fixed effects for timepoint (preoperative and 1, 3, 6 and 12 months postoperative) and group (pulse oximetry; sleep test), the interaction between timepoint and group and a random effect for participants. Age, BMI and gender were added as covariates, as these were found to be confounders. If a significant difference was found,

post-hoc pairwise comparisons were done within the pulse oximetry and sleep test group for all questionnaires at each timepoint. The Bonferroni correction was applied to correct for multiple comparisons in the post-hoc pairwise comparisons. Data is presented as estimated marginal means with upper and lower range. All data were analyzed using SPSS 29.0 for Windows. A p-value below 0.05 was considered statistically significant.

Results

A total of 1432 patients were enrolled of whom 44 patients were excluded due to not undergoing MBS (n=28), undergoing concomitant surgical procedures (n=12), missing pre-operative sleep test data (n=2), or PAP treatment within the pulse oximetry strategy (n=2). This resulted in a total study population of 1388 patients: 697 in the pulse oximetry group and 691 in the sleep test group. Participants in the pulse oximetry group were less often men (18.2% versus 23.3%, p=.02), were younger (43.7 ± 12.0 versus 45.6 ± 11.6 years, p=.03), more often underwent RYGB (79.5% vs 74.7%, p=.03), exhibited a lower prevalence of hypertension (36.2% versus 42.5%, p=.02), and dyslipidemia (20.5% versus (30.0%, p<.001) before surgery compared to the pulse oximetry group (Table 1).

Excess daytime sleepiness

ESS scores before surgery and during follow-up were similar in the pulse oximetry and sleep test group (p=.24). In both groups, a significant improvement in ESS score was seen from 1 month post-operatively onwards (p<.001). In the pulse oximetry group, the mean score improved from 6.7 [95% CI: 6.2 to 7.2] pre-operatively to 3.5 [95% CI: 3.2 to 3.9] at 12 months post-operative and in the sleep test group from 6.7 [95% CI: 6.2 to 7.1] to 3.2 [95% CI: 2.8 to 3.5] (Figure 1). Pre-operatively, 25.2% of the patients in the pulse oximetry group and 26.4% in the sleep test group had an ESS >10 (p=.62). This improved in both groups to respectively 10.2% and 10.6% at 12 months after surgery (p=.83). Detailed data of the ESS scores and number of participants at each time point can be found in Supplementary Table 1.

Impact of EDS on daily functioning

FOSQ-10 scores were comparable before surgery and during follow-up in the pulse oximetry and sleep test group (p=.68). Within both groups, a significant improvement in the FOSQ-10 score was seen from 1 month post-operatively onwards (p<0.001). The mean score improved from 17.2 [95% CI: 16.9 to 17.4] pre-operatively to 18.4 [95% CI: 18.2 to 18.6] at 12 months post-operatively in the pulse oximetry group and from 17.0 [95% CI: 16.8 to 17.2] to 18.4 [95% CI: 18.2 to18.6] in the sleep test group (Figure 2). Detailed data of the FOSQ-10 scores and number of participants at each time point can be found in Supplementary Table 2.

Table 1. Patient characteristics for the total study population and in the pulse oximetry (unknown OSA status) and sleep test (known OSA status) group before MBS

Characteristic	All (n=1388)	Pulse oximetry (n=697)	Sleep test (n=691)	*p*
Gender (male)	288 (20.7)	127 (18.2)	161 (23.3)	.02*
Age (years)	44.6 ± 11.9	43.7 ±12.0	45.6 ± 11.6	.003*
BMI (kg/m^2)	42.3 [39.8 - 46.3]	42.5 [39.9 - 46.7]	41.9 [39.8-45.8]	.08
Waist circ (cm)	127 [119 - 137][1]	127 [119 - 136][2]	127 [119 - 137][3]	.84
OSA diagnosis	n/a	n/a	338 (48.9)	
Obesity related comorbidities				
Hypertension	546 (39.3)	252 (36.2)	294 (42.5)	.02*
Dyslipidemia	350 (25.2)	143 (20.5)	207 (30.0)	<.001*
DM type 2	245 (17.7)	113 (16.2)	132 (19.1)	.17
OSA related comorbidities				
Asthma	172 (12.5)[4]	91 (13.4)[5]	81 (11.7)	.36
COPD	37 (2.7)[6]	20 (2.9)[7]	17 (2.5)	.58
MI	38 (2.7)[8]	17 (2.4)[9]	21 (3.0)[10]	.50
CVA	14 (1.0)[11]	8 (1.1)	6 (0.9)[12]	.60
Smoking				
Non-smoker	841 (60.6)	424 (60.8)	417 (60.3)	.30
Smoker	104 (7.5)	59 (8.5)	45 (6.5)	
Former smoker	443 (31.9)	214 (30.7)	229 (33.1)	
Type of surgery				
RYGB	1070 (77.1)	554 (79.5)	516 (74.7)	.03*
SG[13]	318 (22.9)	143 (20.5)	175 (25.3)	

Data are presented as mean ± SD, median [Q1-Q3] or frequency (percentage), [1] n=1291, [2] n=623, [3] n=668, [4] n=1372, [5] n= 681, [6] n=1369,[7] n=678, [8]n=1385, [9]n=696, [10]n=689, [11]n=1387, [12]n= 690, [13] one partial sleeve gastrectomy, pulse oximetry: participants with postoperative continuous pulse oximetry, sleep test: participants with preoperative polysomnography, BMI: body mass index, waist circ: waist circumference, OSA: obstructive sleep apnea, DM: diabetes mellitus, COPD: chronic obstructive pulmonary disease, MI: myocardial infarction, RYGB: Roux-en-Y Gastric Bypass, SG: laparoscopic sleeve gastrectomy.

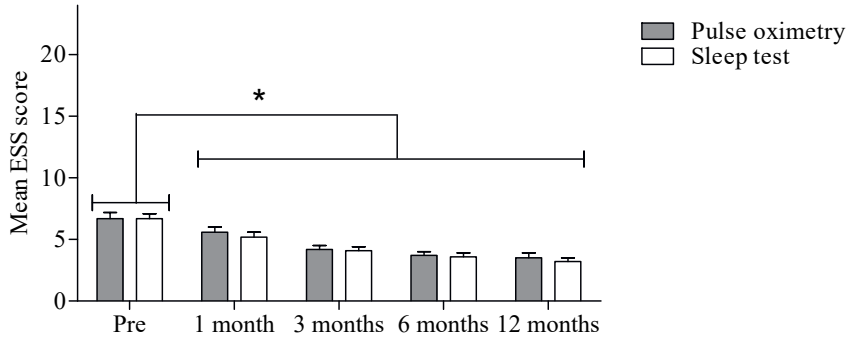

Figure 1. Estimated marginal mean ESS scores before and after MBS for the pulse oximetry group and sleep test group ESS: Epworth sleepiness scale, *significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.001).

HRQoL

The postoperative course of all nine categories of the RAND-36 was similar between the pulse oximetry and sleep test group (p>.05). Within both groups, RAND-36 scores of all subscales/categories improved after surgery. This significant improvement was seen from 1 month onwards in the categories physical functioning, energy/fatigue, emotional well-being, general health and health change (p<0.001; Figure 3a, 3d, 3e, 3g, 3i), and from 3 months onwards in the categories social functioning and pain (p<0.001; Figure 3f, 3h). In the categories role limitations due to emotional problems and role limitations due to physical health, there was a deterioration in scores at 1 month post-operatively, followed by an improvement from 3 months onwards (Figure 3b, 3c). The deterioration pre-operatively to 1 month postoperatively was for role limitations due to emotional problems from 91.8 [95% CI: 90.0 to 93.5] to 90.1 [95%CI: 88.3 to 91.8] in the pulse oximetry group and 91.4 [95% CI: 89.6 to 93.0] to 88.4 [95% CI: 86.4 to 90.2] in the sleep test group, and for role limitations due to physical health from 69.2 [95% CI: 65.5 to 72.7] to 55.4 [95% CI: 51.4 to 59.2] in the pulse oximetry group and 68.3 [95% CI: 64.6 to 71.8] to 57.8 [95% CI: 53.9 to 61.5] in the PG group. Detailed data of the RAND-36 scores and number of participants at each time point can be found in Supplementary Table 3.

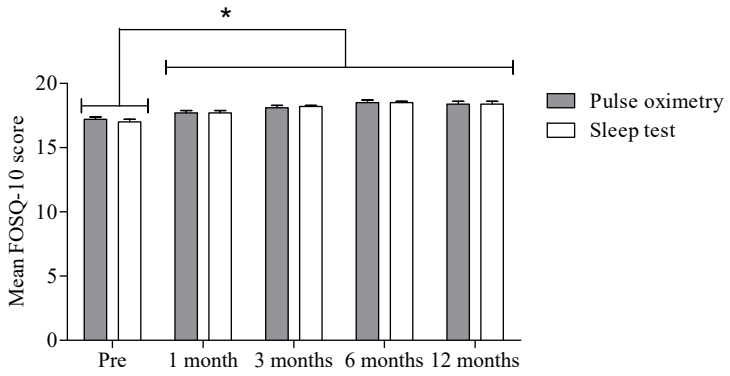

Figure 2. Estimated marginal mean FOSQ-10 scores before and after MBS for the pulse oximetry group and sleep test group *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.001).

Total weight loss

The postoperative course of total weight loss was different between the pulse oximetry and sleep test strategy. Post-hoc comparisons showed a significantly lower total weight loss in the pulse oximetry group 1 month after surgery (9.0% [95%CI: 8.7 to 9.5] versus 9.7% [95%CI: 9.3 to 10.1]; p=.03), and a higher total weight loss at six months (26.5% [95%CI: 26.0 to 26.9] versus 25.9% [95%CI: 25.5 to 26.3]; p=.04) and 12 months after MBS (34.0% [95%CI: 33.6 to 34.4] versus 32.4% [95% CI: 32.0 to 32.8], p<.001), when compared to the sleep test group. Within the strategies, total weight loss increased significantly

from 1 month postoperative onwards (p<.001). Estimated marginal means of total weight loss percentage and number of participants at each time point can be found in Supplementary Table 4.

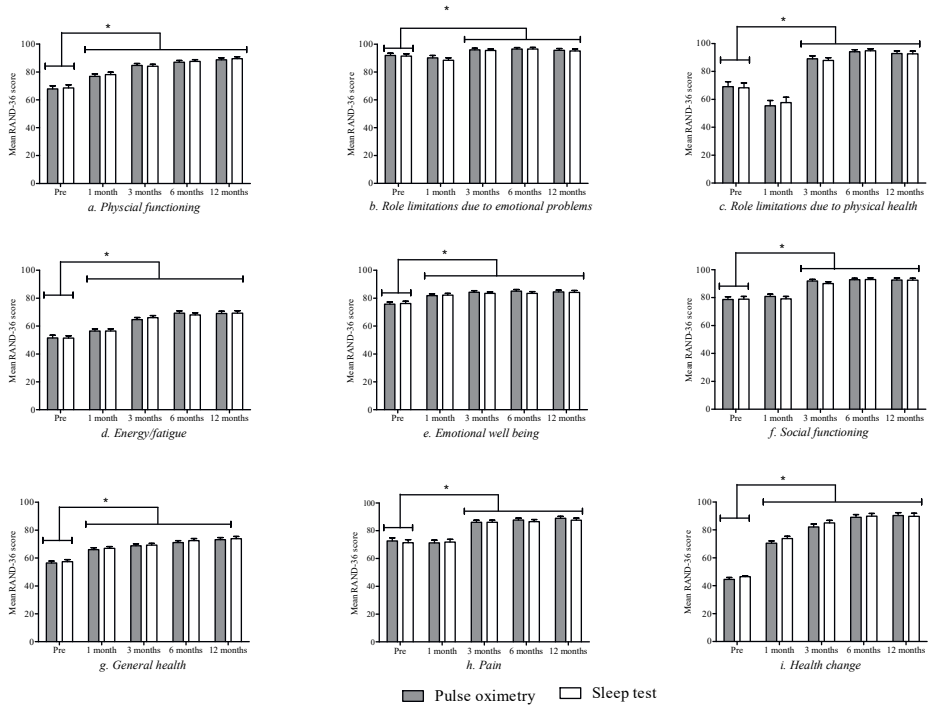

Figure 3. Estimated marginal mean RAND-36 score for each category before and after MBS for the pulse oximetry group and sleep test group *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.001).

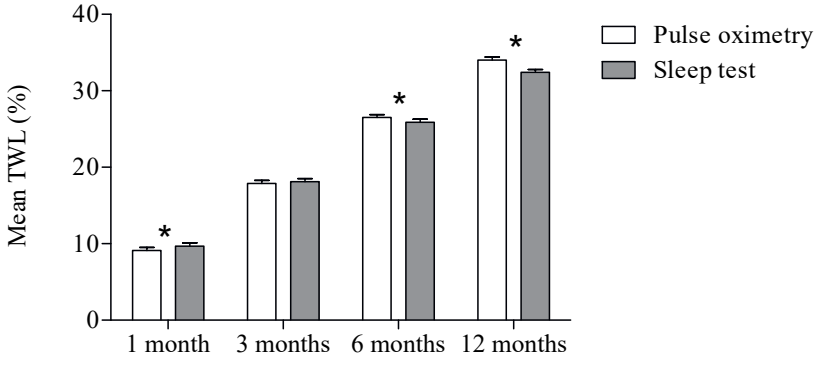

Figure 4. Estimated marginal mean total weight loss (%) after MBS for the sleep test strategy and pulse oximetry strategy. TWL: total weight loss, *significant difference between the pulse oximetry and sleep test group (p<.05)

Discussion

The aim of this study was to compare two perioperative strategies for OSA (sleep test and pulse oximetry) on post-operative EDS and its impact on functioning in daily life, HRQoL and total weight loss after MBS. We found no significant difference between the pulse oximetry and sleep test group in EDS, impact of EDS on daily life and HRQoL and all of these outcomes significantly improved during the first 12 months after MBS. In the pulse oximetry group, a lower total weight loss was found 1 month postoperative (-0.7%) and a higher total weight loss at 6 and 12 months postoperative (+0.6% and +1.6%), compared to the sleep test strategy.

In our study, EDS improvement was shown with increased ESS scores of 3.2 (pulse oximetry) and 3.5 (sleep test) points at 12 months after surgery. This meets the Minimum Clinically Important Difference (MCID) for ESS in OSA patients, which is set to an improvement of at least 2-3 points [16, 17]. Similarly, the prevalence of patients with an ESS score >10 decreased with 15.0% in the pulse oximetry group and 15.8% in the sleep test group after 12 months. This is comparable to two previous studies, the first study being performed in a population undergoing RYGB with a preoperative OSA prevalence of 71% and the second study in a population with unknown OSA status undergoing bariatric surgery [4, 18]. In these studies, ESS scores improved with 3.1 and 2.3 points and a decrease of 22% and 20% was seen in ESS ≥10 at 12 and 16 months after surgery. Two other studies found a higher improvement in ESS score, i.e. 6.0 points 5 months after SG in a population with unknown pre-operative OSA status and 4.9 points 12 months after SG or RYGB in a population with a pre-operative OSA prevalence of 96.3%. However, in these studies sample sizes were small, respectively 13 and 27 patients [19, 20].

The reason we did not find a difference in EDS between the pulse oximetry and sleep test group, may be because EDS is not always seen in patients with OSA, and EDS is not only associated with OSA [7, 21]. In two aforementioned studies in an MBS population, a pre-operative prevalence of OSA of 71% and 96.3% was found, while EDS was only found in 32.0% and 29.6% of the patients [4, 20]. In two other studies comparing participants with obesity to normal weight participants, both without OSA, a significant higher prevalence of EDS was found in patients with obesity, respectively 57% versus 1% and 34.7 % versus 2.7% [22, 23]. In a cross-sectional study, BMI was independently associated with EDS ($p<0.001$); in fact, the authors found that depression and metabolic factors (such as obesity) were more strongly associated with EDS than sleep disordered breathing or sleep disturbances [21].

The impact of EDS on daily functioning improved from 1 month postoperatively onwards with an improvement of 1.2 points in FOSQ-10 score in the pulse oximetry strategy and 1.4 point in the and sleep test group, 6 months after surgery. This is below the MCID,

which is set to an increase of 1.8 - 2.2 points in patients with OSA [24]. This is probably due to the already high pre-operative scores, i.e. 17.2 [95% CI:16.9 to 17.4] in the pulse oximetry and 17.0 [95% CI: 16.8 to 17.2] in the sleep test group on a scale of 5-20, leaving little room for improvement. To our knowledge, 1 other study compared the influence of EDS on daily life after MBS. This study found a slightly better improvement of 1.9 (non-OSA) and 2.3 (OSA) points, 6 months after surgery [9]. However, sample sizes were small with respectively 40 (non-OSA) and 50 (OSA) patients.

We found a significant improvement in HRQoL after MBS, which is consistent with previous research measuring HRQoL after MBS [25-28]. We did not find a difference in HRQoL between the pulse oximetry and sleep test group, probably because weight loss itself after MBS improves HRQoL [29]. Total weight loss was different during the first year after MBS between the pulse oximetry and sleep test strategy. One month after surgery, total weight loss was lower in the pulse oximetry group, after 3 months weight loss was comparable and from 6 months onwards the weight loss was higher in the pulse oximetry strategy compared to the sleep test strategy. This might be explained by the fact that reduced sleep quality and EDS, both associated with OSA, are known to impair weight loss after MBS [30, 31]. Additionally, OSA is known to improve 3-6 months after MBS, and as participants in the pulse oximetry group may have untreated OSA, this could potentially explain the reduced weight loss observed during the early postoperative period [32]. Nonetheless, this does not explain the higher weight loss from 6 months postoperative onwards in the pulse oximetry group. This might be due to differences in the postoperative lifestyle trajectory, as this is essential for weight loss results and all participants in the pulse oximetry group were included from 1 bariatric center, while the participants in the sleep test strategy were included in six centers. However, it must be noted that the maximum difference in weight loss was 1.6% (12 months after MBS). This difference is not considered clinically relevant as the absolute difference will only be 1-2 kg, and is not expected to influence HRQoL or EDS, as confirmed by the results in our study.

Strengths of this study were the large population and frequent follow-up moments. However, there are some limitations that should be acknowledged. First, despite our best efforts to obtain complete questionnaires, there was a relatively high number of missing scores due to unanswered questions, probably because the questionnaires were self-reported by participants (number of participants for each time point can be found in Supplementary Table 1, 2 ,3 and 4). Second, there may be selection bias due to a center effect as some base line characteristics differed between groups, and all participants in the pulse oximetry group were included in a single bariatric center. We partially corrected this by using confounding factors (age, BMI, gender) in the linear mixed model analysis. Hypertension and dyslipidemia were not accounted for as these conditions are typically managed by medical treatment. Therefore, we do not anticipate a significant impact of hypertension and dyslipidemia on HRQoL outcomes. Third, the pre-operative prevalence

of OSA in the pulse oximetry group and the postoperative prevalence of OSA in the total population are unknown. Therefore, it is not possible to conclude whether the changes in EDS, impact of EDS on daily life and HQoL are due to weight loss or less prevalent OSA.

Conclusion

The present study found no differences in post-operative EDS and its impact on functioning in daily life and HRQoL 12 months after MBS, between patients with a known and unknown OSA status when comparing two perioperative strategies for OSA, i.e. pre-operative polysomnography and subsequently treatment with PAP if indicated (sleep test strategy; known OSA status) to postoperative continuous monitoring by pulse oximetry and supplemental oxygen therapy without pre-operative testing for OSA (pulse oximetry strategy; unknown OSA status). Considering that the pulse oximetry strategy is more cost-effective, equally safe and comparable in EDS, its effect on daily functioning and HRQoL and no clinically relevant difference in total weight loss was found compared to the sleep test strategy, this study lends further support for pulse oximetry being the best strategy for managing OSA in patients undergoing MBS. Future research is needed to show whether these results persist in long-term follow-up and to differentiate between the effects of weight loss and OSA prevalence.

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Supplementary Material 1. Version of the FOSQ-10 used in the POPCORN study (Dutch version as used in the POPCORN study and the English translation).

Dutch

FOSQ-10: Kwaliteit van leven met slaperigheid

De komende vragen gaan over de relatie tussen de neiging om in slaap te vallen en de invloed daarvan op uw dagelijks leven.

Wij willen vragen om in de komende 10 situaties een score te geven wat het beste past bij uw leven.

Kies het getal dat het best past bij uw toestand in die situatie.
0= Ja, heel erg
1= Ja, behoorlijk
2= Ja, een beetje
3= Nee

	1	2	3
Heeft u moeite met het concentreren op alledaagse activiteiten omdat u moe of slaperig bent?			
Heeft u moeite met dingen onthouden omdat u moe of slaperig bent?			
Heeft u moeite met het autorijden van korte afstanden (minder dan 160 km) omdat u dan slaperig wordt?			
Heeft u moeite met het autorijden van lange afstanden (meer dan 160 km) omdat u dan slaperig wordt?			
Heeft u moeite met op bezoek gaan bij familie of vrienden omdat u moe of slaperig wordt?			
Is uw relatie met familieleden, vrienden of collega's veranderd doordat u moe of slaperig bent?			
Heeft u moeite met het kijken van een film omdat u slaperig of moe wordt?			
Heeft u moeite om 's avonds net zo actief te zijn als u graag zou willen, omdat u slaperig of moe bent?			
Heeft u moeite om 's ochtends net zo actief te zijn als u graag zou willen, omdat u slaperig of moe bent?			
Wordt uw stemming beïnvloedt doordat u slaperig of vermoeid bent?			

English

FOSQ-10: Quality of Life with Sleepiness

The following questions are about the relationship between the tendency to fall asleep and its impact on your daily life.

We would like to ask you to give a score for the next 10 situations that best fits your life.

Please choose the number that best describes your condition in that situation.
0 = Yes, very much
1 = Yes, quite a bit
2 = Yes, a little
3 = No

	0	1	2	3
Do you have difficulty concentrating on the things you do because you are sleepy or tired?				
Do you have trouble remembering things because you are tired or sleepy?				
Do you have trouble driving short distances (less than 160 km) because you become sleepy?				
Do you have trouble driving long distances (more than 160 km) because you become sleepy?				
Do you have trouble visiting family or friends because you become tired or sleepy?				
Has your relationship with family members, friends, or colleagues changed because you are tired or sleepy?				
Do you have trouble watching a movie because you become sleepy or tired?				
Do you have trouble being as active in the evening as you would like because you are sleepy or tired?				
Do you have trouble being as active in the morning as you would like because you are sleepy or tired?				
Is your mood affected because you are sleepy or tired?				

Supplementary Table 1. Mean scores and number of patients that completed the ESS questionnaire at baseline and 1, 3, 6 and 12 months after MBS

	Pulse oximetry % (n)	EMM [95% CI]	Sleep test % (n)	EMM [95% CI]
Baseline	96.3 (671)	6.7 [6.2 to 7.2]	97.7 (675)	6.7 [6.2 to 7.1]
1 month	85.9 (599)	5.6 [5.2 to 6.0]	83.8 (579)	5.2 [4.8 to 5.6]
3 months	80.6 (562)	4.2 [3.9 to 4.5]	77.1 (533)	4.1 [3.7 to 4.4]
6 months	77.6 (541)	3.7 [3.3 to 4.0]	76.7 (530)	3.6 [3.3 to 3.9]
12 months	82.8 (577)	3.5 [3.2 to 3.9]	77.7 (537)	3.2 [2.8 to 3.5]

MBS; Metabolic and bariatric surgery, ESS: Epworth sleepiness scale, EMM: estimated marginal mean, CI: confidence interval

Supplementary Table 2. Mean scores and number of patients that completed the FOSQ-10 questionnaire at baseline and 1, 3, 6 and 12 months after MBS

	Pulse oximetry % (n)	EMM [95% CI]	Sleep test % (n)	EMM [95% CI]
Baseline	97.0 (676)	17.2 [16.9 to 17.4]	96.4 (666)	17.0 [16.8 to 17.2]
1 month	84.9 (592)	17.7 [17.5 to 17.9]	82.1 (567)	17.7 [17.5 to 17.9]
3 months	79.3 (553)	18.1 [18.0 to 18.3]	76.4 (528)	18.2 [18.0 to 18.3]
6 months	75.6 (527)	18.5 [18.4 to 18.7]	75.4 (521)	18.5 [18.3 to 18.6]
12 months	79.8 (556)	18.4 [18.2 to 18.6]	75.4 (521)	18.4 [18.2 to 18.6]

FOSQ-10: functional outcome of sleep questionnaire, MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval

Supplementary Table 3. Mean scores and numbers of patients that completed categories of the RAND-36 questionnaire at baseline and 1, 3, 6 and 12 months after MBS

	Pulse oximetry % (n)	EMM [95% CI]	Sleep test % (n)	EMM [95% CI]
Physical functioning				
Baseline	95.4 (665)	67.9 [65.6 to 70.1]	94.6 (654)	68.5 [66.3 to 70.7]
1 month	83.8 (584)	76.9 [75.1 to 78.6]	82.2 (568)	78.2 [76.6 to 79.9]
3 months	68.1 (475)	84.7 [83.2 to 86.1]	75.3 (520)	84.2 [82.7 to 85.6]
6 months	75.6 (527)	87.0 [85.6 to 88.3]	74.2 (513)	87.6 [86.2 to 88.9]
12 months	82.2 (573)	88.7 [87.3 to 90.1]	76.6 (529)	89.6 [88.1 to 90.1]
Role functioning physical				
Baseline	94.5 (659)	69.2 [65.5 to 72.7]	94.6 (654)	68.3 [64.6 to 71.8]
1 month	83.8 (584)	55.4 [51.4 to 59.2]	82.1 (567)	57.8 [53.9 to 61.5]
3 months	66.7 (465)	89.0 [86.8 to 91.1]	75.0 (518)	87.9 [85.7 to 89.9]
6 months	74.2 (517)	94.2 [92.5 to 95.7]	73.5 (508)	94.8 [93.1 to 96.2]
12 months	81.1 (565)	92.9 [90.9 to 94.7]	76.3 (527)	92.7 [90.7 to 94.6]
Role functioning emotional				
Baseline	94.1 (656)	91.8 [90.0 to 93.5]	95.1 (657)	91.4 [89.6 to 93.0]
1 month	82.8 (577)	90.1 [88.3 to 91.8]	81.2 (561)	88.4 [86.4 to 90.2]
3 months	66.4 (463)	95.9 [94.5 to 97.0]	73.2 (506)	95.5 [94.1 to 96.6]
6 months	74.5 (519)	96.5 [95.2 to 97.6]	73.4 (507)	96.6 [95.4 to97.7]
12 months	81.5 (568)	95.6 [94.2 to 96.9]	76.6 (529)	95.2 [93.7 to 96.6]

Supplementary Table 3. Mean scores and numbers of patients that completed categories of the RAND-36 questionnaire at baseline and 1, 3, 6 and 12 months after MBS (continued)

	Pulse oximetry % (n)	EMM [95% CI]	Sleep test % (n)	EMM [95% CI]
Energy/fatigue				
Baseline	96.4 (672)	51.6 [49.9 to 53.4]	97.1 (671)	51.4 [49.7 to 53.0]
1 month	85.4 (595)	56.5 [54.9 to 58.0]	83.2 (575)	56.5 [54.9 to 58.0]
3 months	80.3 (560)	64.7 [63.2 to 66.2]	77.0 (532)	66.0 [64.4 to 67.5]
6 months	77.6 (541)	69.3 [67.7 to 70.9]	75.4 (521)	68.0 [66.3 to 69.6]
12 months	83.6 (583)	69.0 [67.2 to 70.7]	79.7 (551)	69.3 [67.5 to 71.0]
Emotional well-being				
Baseline	97.7 (681)	75.7 [74.0 to 77.3]	96.7 (668)	76.2 [74.6 to 77.8]
1 month	85.2 (594)	81.9 [80.7 to 83.2]	82.6 (571)	82.2 [80.9 to 83.5]
3 months	80.3 (560)	84.3 [83.1 to 85.4]	77.7 (537)	83.4 [82.2 to 84.6]
6 months	77.5 (540)	85.1 [83.9 to 86.3]	75.8 (524)	83.4 [82.1 to 84.7]
12 months	83.8 (584)	84.5 [83.1 to 85.8]	79.9 (552)	84.2 [82.8 to 85.6]
Social functioning				
Baseline	94.1 (656)	78.7 [76.7 to 80.7]	95.1 (657)	78.9 [76.9 to 80.8]
1 month	82.5 (575)	80.8 [79.0 to 82.5]	79.3 (548)	79.1 [77.2 to 80.9]
3 months	65.1 (454)	91.9 [90.6 to 93.1]	72.9 (504)	90.1 [88.8 to 91.4]
6 months	72.6 (506)	92.8 [91.5 to 93.9]	73.8 (510)	93.0 [91.7 to 94.1]
12 months	79.6 (555)	92.7 [91.4 to 94.0]	76.0 (525)	92.6 [91.2 to 93.9]
Pain				
Baseline	94.8 (661)	72.7 [70.4 to 74.9]	95.7 (661)	71.4 [69.2 to 73.6]
1 month	84.1 (586)	71.3 [69.2 to 73.3]	81.3 (562)	71.8 [69.8 to 73.8]
3 months	67.1 (468)	86.2 [84.7 to 87.6]	74.1 (512)	86.2 [84.7 to 87.6]
6 months	73.7 (514)	87.7 [86.2 to 89.1]	73.8 (510)	86.6 [85.0 to 88.0]
12 months	81.3(567)	89.0 [87.4 to 90.4]	77.0 (532)	87.6 [86.0 to 89.1]
General health				
Baseline	97.0 (676)	56.4 [54.9 to 57.9]	96.1 (664)	57.4 [55.9 to 58.9]
1 month	84.6 (590)	66.0 [64.7 to 67.4]	83.4 (576)	67.0 [65.6 to 68.3]
3 months	68.0 (474)	68.8 [67.4 to 70.2]	76.1 (526)	69.3 [68.0 to 70.6]
6 months	75.8 (528)	71.2 [69.8 to 72.6]	75.0 (518)	72.6 [71.2 to 74.0]
12 months	83.1 (579)	73.2 [71.6 to 74.7]	79.5 (549)	73.9 [72.4 to 75.5]
Health change				
Baseline	99.4 (693)	44.5 [43.1 to 45.9]	99.4 (687)	46.5 [45.1 to 47.9]
1 month	88.8 (619)	70.4 [68.7 to 72.1]	86.4 (597)	73.8 [72.1 to 75.5]
3 months	71.0 (495)	82.2 [80.3 to 84.2]	79.2 (547)	85.0 [83.1 to 86.8]
6 months	79.2 (552)	89.0 [87.0 to 91.0]	78.0 (539)	89.8 [87.7 to 91.8]
12 months	85.4 (595)	90.3 [88.2 to 92.4]	80.9 (559)	89.7 [87.6 to 91.9]

MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval

Supplementary Table 4. Mean total weight loss 1, 3, 6 and 12 months after MBS

	Pulse oximetry % (n)	EMM [95% CI]	Sleep test % (n)	EMM [95% CI]
1 month	97.7 (681)	9.0 [8.6 to 9.5]	97.1 (671)	9.7 [9.3 to 10.1]
3 months	97.1 (677)	17.9 [17.5 to 18.3]	94.8 (655)	18.1 [17.7 to 18.5]
6 months	95.7 (667)	26.5 [26.0 to 26.9]	90.2 (623)	25.9 [25.5 to 26.3]
12 months	93.7 (653)	34.0 [33.6 to 34.4]	91.5 (632)	32.4 [32.0 to 32.8]

MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval

Chapter 3

Five-year follow-up of a nation-wide prospective cohort study comparing two perioperative obstructive sleep apnea strategies for metabolic and bariatric surgery

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Abstract

Purpose: Despite a high prevalence of obstructive sleep apnea (OSA) in patients undergoing metabolic and bariatric surgery (MBS), there is no consensus on the best perioperative OSA strategy. Postoperative monitoring with oxygen therapy (pulse oximetry strategy) is safe and more cost-effective compared to preoperative OSA-testing using poly(somno)graphy (sleep test strategy). This study aimed to compare these strategies on excess daytime sleepiness (EDS), its impact on daily functioning, health-related quality of life (HRQoL) and total weight loss (TWL) during a 5 year follow-up period.

Methods: Multicenter prospective cohort study including 1388 patients, 691 in the pulse oximetry and 697 in the sleep test group based on local protocols. EDS (Epworth sleepiness scale), impact on daily life (functional outcomes of sleep questionnaire), HRQoL (RAND-36), TWL were assessed preoperatively and 1, 3, 5 years postoperatively. (Sub)scores were compared over time between and within strategies using linear mixed models.

Results: The postoperative courses were comparable between the strategies for all outcomes until five years after MBS, except the RAND-36 category energy/fatigue. The most favorable scores were observed one year after MBS. All outcomes remained significantly improved until five years after MBS, besides the RAND-36 category "role limitations due to emotional problems".

Conclusion: Postoperative pulse oximetry is more cost-effective, equally safe and comparable in outcomes for EDS, impact of sleepiness on daily functioning, HRQoL and TWL when compared to preoperative sleep testing. This lends further support for the pulse oximetry strategy as the best available strategy for perioperative management of OSA in patients undergoing MBS.

Introduction

Obesity, defined as a body mass index (BMI) greater than or equal to 30 kg/m2, is a health issue worldwide and affects more than 890 million adults (13%) globally [1]. Metabolic and bariatric surgery (MBS) is a proven effective treatment for obesity [1, 2]. In patients undergoing MBS, the prevalence of obstructive sleep apnea (OSA) is high (35-95%), and often undiagnosed [3]. Patients with OSA may have an increased risk of postoperative cardiac events, respiratory failure and admission to the intensive care unit [4, 5]. Despite the high prevalence and the potential increased risk for postoperative cardiorespiratory complications, there is no evidence based perioperative strategy to manage OSA in patients undergoing MBS. Recently, a multicenter prospective cohort study (POPCORN study) compared two strategies on cost-effectiveness and safety [6]. In the first strategy (sleep test strategy), patients were pre-operatively tested for OSA by overnight poly(somno)graphy, and treated when indicated (with e.g. positive airway pressure [PAP], mandibular repositioning device [MRD]). In the second strategy (pulse oximetry strategy), patients were not preoperatively tested for OSA, but postoperatively continuously monitored using pulse oximetry and received supplemental oxygen therapy (2L/min) until the morning after MBS. The pulse oximetry strategy is based on the hypothesis that weight loss itself is a treatment for OSA, with expected improvements three to six months after MBS [7, 8]. While perioperative safety is maintained by continuous monitoring and supplemental oxygen therapy. The POPCORN study found the pulse oximetry strategy to be more cost-effective. Moreover, post-operative complications and unscheduled intensive care unit admissions were comparable between the two strategies [6].

Patients in the pulse oximetry strategy potentially had untreated OSA, and therefore are prone to excess day daytime sleepiness (EDS) which consequently could impact their daily life and health-related quality of life (HRQoL). Additionally, OSA is accompanied with reduced sleep quality and both reduced sleep quality and EDS are known to impair weight loss after MBS [9-11]. Therefore this study aimed to compare EDS, impact of sleepiness on daily life, HRQoL and total weight loss (TWL) between the pulse oximetry and sleep test strategy. A comparison between these strategies until one year postoperative found no differences in EDS, the impact of sleepiness on daily functioning and HRQoL. The postoperative course of TWL differed between the strategies, but the significant differences observed were not clinically relevant [12]. However, a follow up of one year is relatively short, as the median time to research maximum weight loss is two years [13]. Particularly, because weight regain can occur after reaching the nadir weight, which consequently can affect the severity of OSA [14]. Moreover, the HRQoL improves until two years after MBS, after which it may deteriorate again [15]. Therefore, the aim of this study was to compare EDS, impact of sleepiness on daily functioning, HRQoL and TWL between the sleep test and pulse oximetry strategy until five years after MBS.

Methods

Study design

This research was conducted as part of the POPCORN study, a multicenter prospective cohort study among patients undergoing MBS. Recruitment took place at seven hospitals in the Netherlands (Rijnstate, Arnhem; St. Antonius Hospital, Nieuwegein; Onze Lieve Vrouwe Hospital, Amsterdam; Dutch Obesity Clinic, the Hague; Zuyderland Hospital, Heerlen; Rode Kruis Hospital, Beverwijk and Máxima Medical Centre, Veldhoven) between April 2018 and February 2020. Inclusion criteria were primary Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG) at one of the participating centers. Exclusion criteria were, prior OSA diagnosis or poly(smono)graphy, undergoing concomitant surgical procedures (e.g. hiatal hernia repair) and the inability to speak or read the Dutch language. Detailed information on the study design can be found in the previously published study protocol [16]. All participants gave written informed consent for their participation in this study. Informed consent was re-obtained for the extended follow-up period of five years postoperative (the initial follow-up was one year). The study was approved by the Medical research Ethics Committees United (MEC-U reference number W17.050) and adheres to the Declaration of Helsinki.

Participants received usual care as per local protocol, which included a one-night postoperative hospital stay. Beyond usual care, patients were asked to complete Epworth sleepiness scale (ESS), functional outcome of sleep questionnaire (FOSQ-10), and 36-item short form health survey (RAND-36), preoperatively, 1, 3 and 5 years after MBS.

Participants for the pulse oximetry group were exclusively enrolled at Rijnstate Hospital, as this was the only hospital among the participating centers that used this strategy. In this group, patients were not preoperatively tested for OSA. Postoperatively, patients were continuously monitored using pulse oximetry and received supplemental oxygen therapy through a nasal cannula (2L/min). Nurses were alerted in case of desaturations (peripheral oxygen saturation [SpO_2] <90%), and if (persistent) desaturations occurred, nurses intervened by waking up the patient and/or increasing oxygen flow. If these interventions were insufficient, the attending physician was informed for clinical evaluation and treatment. In the sleep test group, all patients were preoperatively tested for OSA by ambulatory P(S)G and if indicated treatment was started (e.g. positive airway pressure [PAP], mandibular repositioning device [MRD]).

Data collection

The following information was obtained from electronic patient records: age, gender, body mass index (BMI), waist circumference, OSA diagnosis (diagnosed with poly(somno) graphy), occurrence of obesity related comorbidities (hypertension, dyslipidemia, diabetes mellitus type 2), type of surgery (RYGB, SG), TWL (preoperative weight - current

weight) / (preoperative weight) x 100), smoking status (categorized as: smoker, former smoker, non-smoker), and educational level (categorized as low, median and high).

Primary outcomes were comparison over time (preoperative, 1, 3 and 5 years after MBS) for EDS, impact of sleepiness on daily functioning, HRQoL and TWL between and within the pulse oximetry and sleep test strategy.

Excess daytime sleepiness

EDS was determined using the ESS. The ESS consists of 8 questions in which the patient has to rate, on a scale of 0 to 3, how high the chance is of dozing off or falling asleep in different situations. The ESS score equals the sum of these 8 ratings, giving a score between 0-24. If 1 or more of the 8 ratings are missing, the ESS score cannot be calculated. Low scores indicate a low degree of sleepiness, an ESS score of >10 or higher indicates excessive daytime sleepiness [17, 18].

The impact of sleepiness on daily functioning

The impact of sleepiness on daily functioning was assessed using the functional outcomes of sleep questionnaire, short form (FOSQ-10) [19]. The version of the FOSQ-10 used in this study can be found in Supplementary material 1. The score of the FOSQ-10 ranges from 5-20 points, a higher score indicating better functioning in daily life. If there were 1 or more missing answers, the score for FOSQ-10 was not calculated.

Health related quality of life

HRQoL was assessed with the RAND-36. This questionnaire consists of 36 questions within 9 subscales: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, general health, and health change. The score for each subscale ranges from 0-100, with higher scores defining a better quality of life [20, 21]. If 1 or more answers were missing for a subscale, the score for that subscale was not calculated.

Statistical analysis

Data were expressed as mean with standard deviation in case of a normal distribution, median with 25th percentile [Q1] - 75th percentile [Q3] for a non-normal distribution. Categorical data were expressed as frequencies with percentage. Patient characteristics with continuous data were compared between groups using independent T-tests (normal distribution) or Mann-Whitney U tests (non- normal distribution), and categorical data with the a Chi-Square test.

The (sub)scores of the ESS, FOSQ-10, RAND-36 and TWL were compared over time (preoperative, 1, 3 and 5 years postoperative) between the pulse oximetry and sleep test group using linear mixed models (LMM). Prior to analysis, the FOSQ-10 and the RAND-

36 sub scores: role limitations due to emotional problems, emotional well-being and social functioning, were reflected and then square-rooted, for the ESS score square root transformation without reflection was applied. The model consisted of fixed effects for timepoint (preoperative, 1, 3 and 5 year postoperative) and group (pulse oximetry; sleep test), the interaction between timepoint and group and a random effect for participants. Age, BMI and gender were added as covariates, as these were found to be confounders. If a significant difference was found, post-hoc pairwise comparisons were done within the pulse oximetry and sleep test group for all questionnaires at each timepoint. The Bonferroni correction was applied to correct for multiple comparisons in the post-hoc pairwise comparisons. Data is presented as estimated marginal means (EMM) with upper and lower range of the 95% confidence interval (CI). All data were analyzed using SPSS 29.0. A p-value below 0.05 was considered statistically significant.

Results

A total of 1432 patients were enrolled of whom 43 patients were excluded because MBS was not performed (n=28), exclusion criteria (n=14) or because of missing preoperative poly(somno)graphy data (n=2) (Figure 1). This resulted in a total study population of 1388 participants, of whom 1029 were lost to follow-up over the 5-year period, leaving 361 participants at the 5-year follow-up time point. See Figure 1 for an overview of the number of subjects at each timepoint. At baseline, in the pulse oximetry group were less often men (18.2 % versus 23.3 %, p=.02), were younger (43.7 ± 12.0 versus 45.6 ± 11.6 years, p=.03), more often underwent RYGB (79.5 % vs 74.7 %, p=.03), exhibited a lower prevalence of hypertension (36.2 % versus 42.5%, p=.02), and dyslipidemia (20.5% versus (30.0 %, p<.001) compared to the sleep test group (Table 1). At 5-year follow-up, the groups became more comparable, with no significant differences in preoperative patient characteristics observed (Table 2). In the sleep test group 76.2% were diagnosed with OSA, of which 68.9% received treatment.

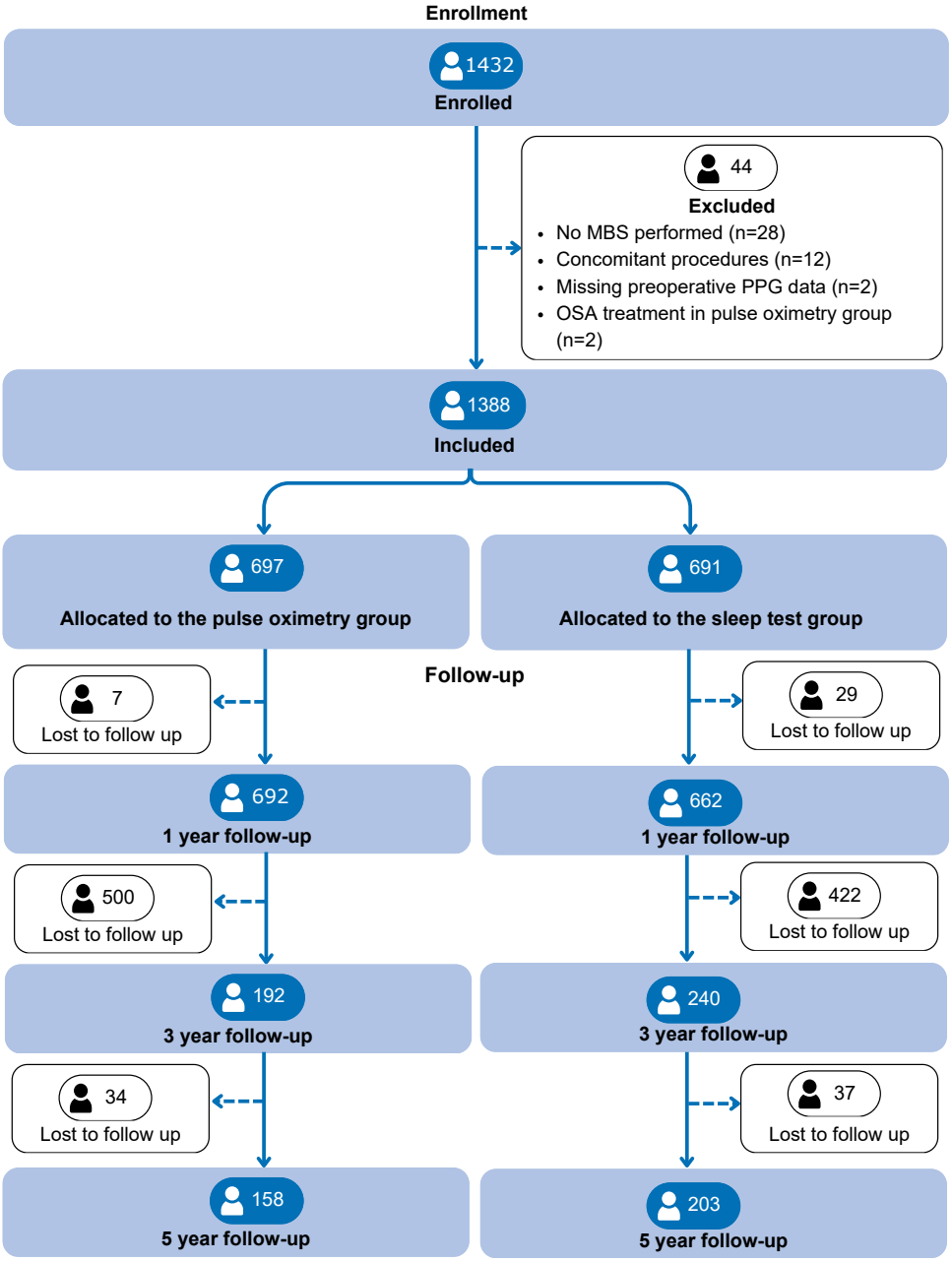

Figure 1. Flowchart illustrating participant inclusion and follow-up in the POPCORN study over the 5-year follow-up period.

Table 1. Preoperative patient characteristics for the total study population and stratified for the pulse oximetry and sleep test group

Characteristic	All (n=1388)	Pulse oximetry (n=697)	Sleep test (n=691)	p
Gender (female)	1100 (79.3)	570 (81.8)	530 (76.7)	.02*
Age (years)	44.6 ±11.9	43.7 ±12.0	45.6 ±11.6	.003*
Body Mass Index (kg/m^2)	42.3 [39.8-46.3]	42.5 [39.9-46.8]	41.9 [39.8-45.8]	.08
Waist circumference (cm)	127 [119-137][1]	127 [119-136][2]	127 [119-137][3]	.84
Obesity related comorbidities				
Hypertension	546 (39.3)[4]	252 (36.2)[5]	294 (42.5)	.02*
Dyslipidemia	350 (25.2)	143 (20.5)	207 (30.0)	<.001*
Diabetes mellitus type 2	245 (17.7)[6]	113 (16.2)[7]	132 (19.1)	.17
Obstructive sleep apnea			525 (76.1)[8]	
Mild (AHI 5.0-14.9 e/h)			244 (46.5)	
Moderate (AHI 15-29.9 e/h)			161 (30.7)	
Severe (AHI ≥30 e/h)			120 (22.8)	
With OSA treatment			252 (68.9)[9]	
Smoking				
Non-smoker	841 (60.6)	424 (60.8)	417 (60.3)	.30
Smoker	104 (7.5)	59 (8.5)	45 (6.5)	
Former smoker	443 (31.9)	214 (30.7)	229 (33.1)	
Type of surgery				
RYGB	1070 (77.1)	554 (79.5)	516 (74.7)	.03*
SG[10]	318 (22.9)	143 (20.5)	175 (25.3)	
Education level	[11]	[12]	[13]	.10
Low	397 (29.2)	208 (30.2)	189 (28.0)	
Medium	658 (48.3)	342 (49.7)	316 (47.0)	
High	306 (22.5)	138 (20.1)	168 (25.0)	

Data are presented as mean ± SD, median (Q1-Q3) or frequency (percentage), [1] n=1291, [2]=623, [3]n=668, [4]n=1387, [5]n=696, [6]n=1386, [7]n=695, [8]n=690, [9]n=366, continuous positive airway pressure n=234, mandibular reposition device n=2, unknown =16, [10] one partial sleeve gastrectomy, [11] n=1361, [12]n=688, [13]n=673. AHI: apnea-hypopnea index, e/h: events/hour, OSA: obstructive sleep apnea, RYGB: Roux-en-Y Gastric Bypass, SG: sleeve gastrectomy.

Table 2. Preoperative patient characteristics for the study population at five years after metabolic and bariatric surgery for the total population and stratified for the pulse oximetry and sleep test group

Characteristic	Total population (n=361)	Pulse oximetry (n=158)	Sleep test (n=203)	p
Sex (Female)	283 (78.4)	123 (77.8)	160 (78.8)	.82
Age (years)	49.9 ± 9.9	49.7 ± 10.7	50.1 ± 9.2	.76
Body Mass Index (kg/m^2)	41.9 [39.4 - 44.9]	42.1 [39.4 - 44.7]	41.6 [39.4 - 45.3]	.83
Waist circumference (cm)	128 [119 - 136][1]	129 [121 - 139][2]	126 [117 - 134][3]	.07
Obesity related comorbidities				
Hypertension	189 (52.4)[4]	81 (51.3)[5]	108 (53.2)	.76
Dyslipidemia	111 (30.7)	42 (26.6)	69 (34.0)	.13
Diabetes mellitus type 2	69 (19.1)	34 (21.5)	35 (17.2)	.31
Obstructive sleep apnea			166 (81.4)[6]	
Mild (AHI 5.0-14.9 e/h)			74 (44.6)	
Moderate (AHI 15-29.9 e/h)			51 (30.7)	
Severe (AHI ≥30 e/h)			41 (24.7)	
With OSA treatment			81 (71.7)[7]	
Smoking				.15
Non-smoker	226 (62.6)	102 (64.6)	124 (61.1)	
Smoker	14 (3.9)	9 (5.7)	5 (2.5)	
Former smoker	121 (33.5)	47 (29.7)	74 (36.5)	
Type of surgery				.22
RYGB	296 (82.0)	134 (84.8)	162 (79.8)	
SG[8]	65 (18.0)	24 (15.2)	41 (20.2)	
Education level	[9]	[10]	[11]	.15
Low	98 (27.1)	44 (27.8)	54 (26.6)	
Medium	143 (39.6)	70 (44.3)	73 (36.0)	
High	114 (31.6)	42 (26.6)	72 (35.4)	

Data are presented as mean ± SD, median (Q1-Q3) or frequency (percentage), [1] n=337, [2]=141, [3]n=196, [4]n=361, [5]n=157, [6] n=204, [7]n=113, continuous positive airway pressure n=77, unknown =4 ,[8]one partial sleeve gastrectomy, [9]n=355 , [10]n=156, [11]n= 199, AHI: apnea-hypopnea index, e/h: events/hour, OSA: obstructive sleep apnea, RYGB: Roux-en-Y gastric bypass, SG: sleeve gastrectomy.

Excess daytime sleepiness

The course of ESS scores before MBS and during the 5-year follow-up period were similar between the pulse oximetry and sleep test group (p=.10; Figure 2). Data regarding the ESS score (EMM) at each time point including number of participants can be found in Supplementary Table 1. Within both groups, the greatest improvement was observed from preoperative to 1 year postoperative (pulse oximetry: from preoperative 6.5 [95% CI: 6.1 to 6.9) to 1 year postoperative: 3.8 [95%CI: 3.4 to 4.1], sleep test from 6.4 [95% CI: 6.0 to 6.8) to 3.3 [95%CI: 3.0 to 3.6]. After that, the ESS score increased, but remained significantly improved until 5 years postoperative (5 years postoperative: pulse oximetry: 4.3 [95% CI: 3.7 to 4.9], sleep test 4.7 [95% CI: 4.2 to 5.3]). In the sleep test group differences were also observed between 1 year versus 3 years and 1 year versus 5 years postoperative (p <.001). Between the other timepoints no differences were observed (Supplementary Table 4).

The proportion of participants with an ESS >10 improved in both groups when comparing preoperative scores with those measured 5 years post-MBS (pulse oximetry: 25.2 % versus 11.7%, sleep test 26.4% versus 21.1%). The proportion of participants with an ESS >10 after 5 years was significantly lower in the pulse oximetry group (p=.02).

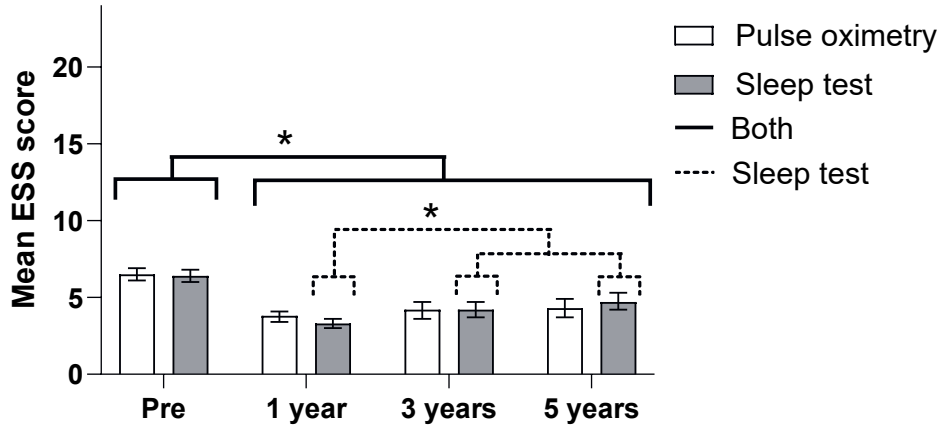

Figure 2. Estimated marginal mean ESS scores preoperative until 5 years after metabolic and bariatric surgery for the pulse oximetry and sleep test strategy. ESS: Epworth sleepiness scale. *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.001).

Impact of EDS on daily functioning

The FOSQ-10 scores before MBS and during the 5-year follow-up showed comparable postoperative courses between the pulse oximetry and sleep test strategy, (p=.29; Figure 3). Detailed data of the FOSQ-10 scores (EMM, number of participants) at each time point

is displayed in Supplementary Table 2. Within both groups, a significant improvement in the FOSQ-10 score was observed between the preoperative scores (pulse oximetry 17.3 [95% CI: 17.1 to 17.5], sleep test 17.2 [95% CI: 17.1 to 17.4] until 5 years after MBS (pulse oximetry 18.1 [95% CI: 17.7 to 18.4], sleep test 17.8 [95% CI: 17.5 to 18.1]. Additionally, in the sleep test group a significant difference between 1 year and 3 years and 5 years was found (Supplementary Table 4).

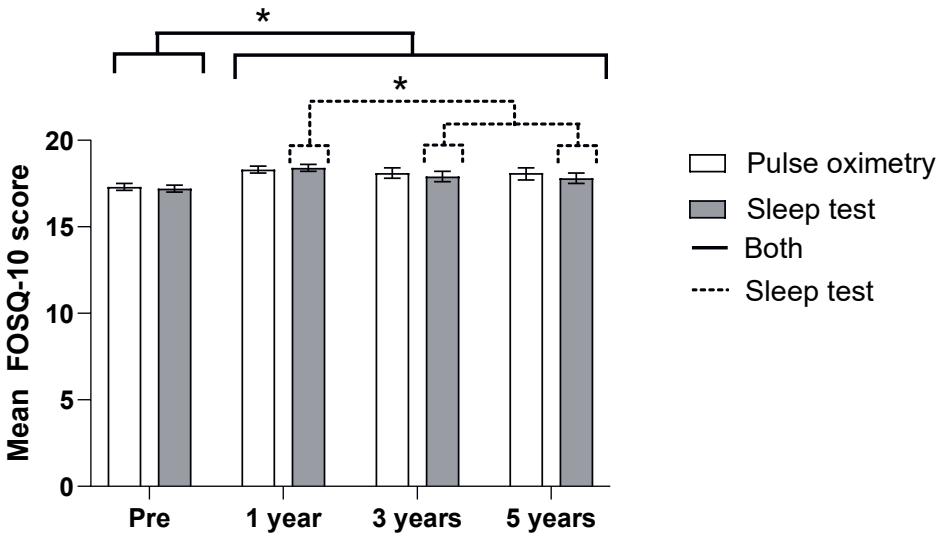

Figure 3. Estimated marginal mean FOSQ-10 scores preoperative until 5 years after metabolic and bariatric surgery for the pulse oximetry and sleep test strategy. *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.05).

Health related quality of life

From the RAND-36 questionnaire, the postoperative course of the category "energy/fatique" was different between the pulse oximetry and sleep test strategy (p=.044), in the post-hoc comparison no significant differences were observed between the timepoints. In all other categories the postoperative course during the 5-year follow-up was comparable. In all categories, the highest scores were observed at 1-year post-MBS, after which the scores decreased but remained improved until 5 years after MBS when compared to preoperative, except for the category "role limitations due to emotional problems" (Figure 4b, Supplementary Table 4). In this category RAND-36 scores for both strategies were improved 5 years after MBS compared to preoperative, but not statistically significant (pulse oximetry: 91.3 [95% CI: 89.7 to 92.8] versus 95.0 [95% CI: 92.5 to 97.2], sleep test: 90.3 [95% CI: 89.3 to 92.4] versus 91.7 [95% CI: 88.9 to 94.1]). Detailed data regarding RAND-36

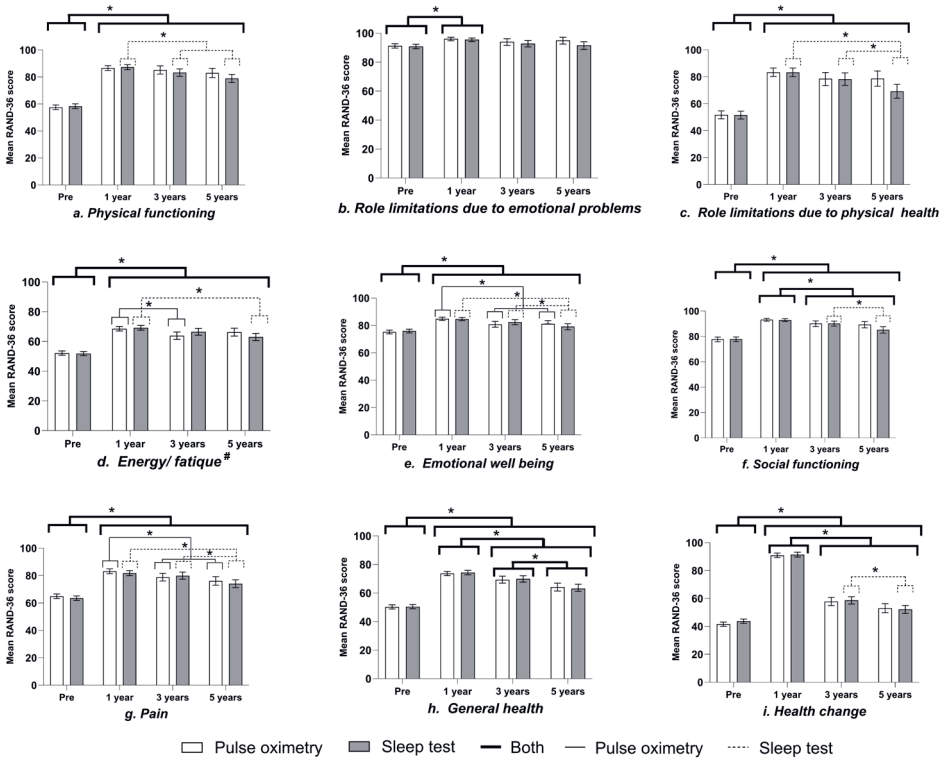

Figure 4. Estimated marginal mean scores for the categories within the RAND-36 questionnaire, preoperative until 5 years after metabolic and bariatric surgery for the pulse oximetry and sleep test strategy. *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.05), # significant different postoperative course between groups.

scores at each time point including number of participants and p-values can be found in Supplementary Table 3 and 4.

Total weight loss

The postoperative course until five years after MBS was comparable for TWL between the two strategies (Figure 5). TWL decreased significantly from 1 year onwards in both groups (p<0.001). TWL decreased from 1-year to 5-years post-MBS from 33.6% [95% CI: 33.0 to 34.2] to 28.8% [95% CI: 27.8 to 29.8] in the pulse oximetry strategy, and in the sleep test strategy from 32.4% [95% CI: 31.8 to 33.0%] to 28.6% [95% CI 27.7 to 29.5]. Detailed data for TWL at each time point and p-values can be found in Supplementary Tables 4 and 5.

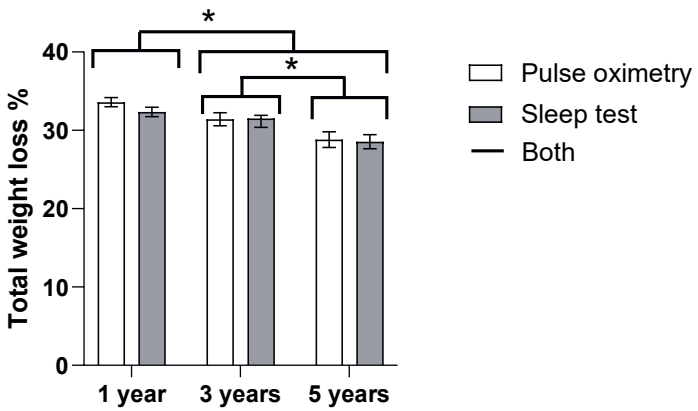

Figure 5. Estimated marginal mean percentage of total weight loss 1, 3 and 5 years after metabolic and bariatric surgery for the pulse oximetry and sleep test strategy. *Significant improvement of the score within the group (pulse oximetry or sleep test) compared to pre-operative (p<.001).

Discussion

The aim of this study was to compare two perioperative strategies for OSA (pulse oximetry versus sleep test strategy) on post-operative EDS, the impact of sleepiness on daily functioning, HRQoL and TWL until 5 years after MBS. The postoperative courses were comparable between the strategies for all outcomes up to five years after MBS, except for the RAND-36 category 'energy/fatigue.' Although a significant difference in the postoperative course was found for this category, post-hoc comparisons revealed no significant differences at any time point between groups suggesting that the observed difference is unlikely to be clinically relevant. The most favorable scores for all outcomes were observed one year after MBS, with all outcomes remaining significantly improved up to five years post-MBS, except for the RAND-36 category 'role limitations due to emotional problems,' where an improvement was observed, but it was not statistically significant.

In our study, both the EDS (ESS) and the impact of sleepiness on daily functioning (FOSQ-10) did not meet the minimum clinically important difference (MCID) of 2 - 3 points for the ESS and 1.8 - 2.2 points for the FOSQ-10 [22-24]. The MCID for both the ESS and FOSQ-10 were probably not met 5 years after MBS, because MCID was based upon the improvement of patients with OSA, while our study included both patients with and without OSA. Additionally, with relatively low preoperative ESS scores (pulse oximetry: 6.5 [95% CI: 6.1 to 6.9], sleep test: 6.4 [95% CI: 6.0 to 6.8]) and high preoperative FOSQ-10 scores (pulse oximetry 17.3 [95% CI: 17.1 to 17.5], sleep test 17.2 [95% CI: 17.0 to 17.4]) a difference of 2 - 3 or 1.8 - 2.2 points is relatively large. A recent systemic review evaluated the effect of MBS on EDS [24]. In this systematic review, 27 studies reported on ESS scores after MBS and all studies found postoperative improvement of ESS scores. However, in most

of these studies, the follow-up period was relatively short (ranging from 3 to 24 months post-MBS), and only one study reported a follow-up until 5 years after MBS [26].

The impact of sleepiness on daily life (as measured by the FOSQ-10) after MBS was assessed in one other study, six months post-MBS [27]. Therefore, no comparison with the literature could be made regarding the impact of sleepiness on daily functioning five years after MBS.

Preoperative ESS scores of our study were comparable with those of a retrospective cohort study assessing preoperative EDS and its impact on daily functioning of participants scheduled for MBS [28]. This retrospective cohort study found, on the contrary of wat is expected, a low mean ESS score (6.3 ±4.8), despite a prevalence of 58.3% of moderate to severe OSA (AHI>15 events hour). The explanation of the authors from this retrospective cohort was, that patients may be unaware of their EDS, because patients with obesity may experience other weight-related symptoms (e.g., gastroesophageal reflux, depression, joint pain) that are more noticeable or bothersome than EDS. Additionally, not all patients diagnosed with OSA report EDS [29].

An explanation for the absence of a difference in EDS between the pulse oximetry and sleep test strategies could be that the EDS caused by obesity is more pronounced than the EDS caused by OSA. A cross-sectional study found BMI to be independently associated with EDS, as depression and metabolic factors (such as obesity) were more strongly associated with EDS than sleep disordered breathing or sleep disturbances [30].

In the current study, similar outcomes for HRQoL were found between the pulse oximetry and sleep test strategy. Therefore, similar to EDS and the impact of sleepiness on daily life, the effect of obesity on HRQoL appears to be greater than that of OSA. Although the effect of treating obesity (with MBS) versus OSA (with CPAP) on HRQoL has never been directly compared, some studies suggest a greater improvement in HRQoL following MBS. As the increase in RAND-36 scores was more pronounced after MBS than after OSA treatment [31-33]. The finding in our study that HRQoL is best one year after MBS is comparable with a systematic review which found that HRQoL increases until 1to 2 years after MBS after which it decreases. In our study, HRQoL remained significantly improved 5 years after MBS when compared to preoperative levels, except for the category "role limitations due to emotional problems" in which the score was increased five years after MBS, but not statistically significant.

The reported TWL of ± 28% in both the pulse oximetry and sleep test strategy was higher than previous research reporting a TWL of 16-22% [34, 35]. As this higher TWL was observed in both strategies, it unlikely that weight loss is associated with a specific OSA management strategy.

A major strength of this study is that it is the first to evaluate EDS, its impact of sleepiness on daily functioning and HRQoL until 5 years after MBS, which are all factors important for the patients' wellbeing. Another strength of this study was that participating centers followed their own protocols, resulting in real-world data that accurately reflect daily practice. In addition, the study had few exclusion criteria and a large study population.

However, there are some limitations that should be acknowledged. First, this was an observational study and not a randomized trial. While this is advantageous in representing real-world data, it also has limitations, such as the baseline groups not being fully comparable, potentially introducing selection bias. The difference in baseline characteristics is probably due to the fact that in the pulse oximetry patients with treated OSA were excluded, as the differences in baseline characteristics align with the known risk factors or associated comorbidities for OSA (male, higher age, hypertension, dyslipidemia) [36]. However, this is no longer the case at the 5-year follow-up time point, as the groups become comparable at that stage.

Second, despite all effort requesting patients to fill out questionnaires, we experienced a relatively high loss to follow up rate of 74% during the study period. High drop-out rates are often described in bariatric care with up to 50% lost to follow-up at 5 years post-MBS [37, 38]. The high loss to follow-up may therefore have introduced some bias, as it is likely that more motivated patients were included, while those who were less motivated or potentially less satisfied may have dropped out. However, the remaining number of 362 participants is still substantial, and more importantly, the groups were comparable regarding preoperative patient characteristics. Third, the preoperative OSA prevalence in the pulse oximetry group and the postoperative prevalence of OSA in the total group was unknown. This precluded the possibility of performing sub-analyses between participants with and without OSA, which would have been both interesting and potentially contributory in distinguishing the effects of OSA treatment and weight reduction. However, the comparisons as they have been conducted are reflective of real-world practice, which provides valuable insights into both strategies.

Conclusion

The present study found similar outcomes for EDS, impact of sleepiness on daily functioning, HRQoL and TWL until five years after MBS, between the pulse oximetry and sleep test strategy. Taking into account that the pulse oximetry strategy was previously proven to be more cost-effective and equally safe, these longer-term results lend further support for the pulse oximetry strategy as the best available strategy for perioperative management of OSA in patients undergoing MBS.

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Supplementary table 1. Estimated marginal scores and number of patients that completed the ESS questionnaire at baseline and 1, 3, and 5 years after MBS

Follow-up	Pulse oximetry		Sleep test	
	n (%)	EMM [95% CI]	n (%)	EMM [95% CI]
Baseline	671 (96.3)	6.5 [6.1 to 6.9]	675 (97.7)	6.4 [6.0 to 6.8]
1 year	577 (82.8)	3.8 [3.4 to 4.1]	537 (77.7)	3.3 [3.0 to 3.6]
3 years	180 (25.8)	4.2 [3.6 to 4.7]	229 (33.1)	4.2 [3.7 to 4.7]
5 years	154 (22.1)	4.3 [3.7 to 4.9]	191 (27.6)	4.7 [4.2 to 5.3]

ESS: Epworth sleepiness scale, MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval.

Supplementary table 2. Estimated marginal mean scores and number of patients that completed the FOSQ-10 questionnaire at baseline and 1, 3, and 5 year after MBS

Follow-up	Pulse oximetry		Sleep test	
	n (%)	EMM [95% CI]	n (%)	EMM [95% CI]
Baseline	676 (97.0)	17.3 [17.1 to 17.5]	666 (96.4)	17.2 [17.0 to 17.4]
1 year	556 (79.8)	18.3 [18.1 to 18.5]	521 (75.4)	18.4 [18.2 to 18.6]
3 years	183 (26.3)	18.1 [17.8 to 18.4]	221 (32.0)	17.9 [17.6 to 18.2]
5 years	153 (22.0)	18.1 [17.7 to 18.4]	188 (27.2)	17.8 [17.5 to 18.1]

MFOSQ-10: functional outcome of sleep questionnaire, MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval.

Supplementary table 3. Mean scores and numbers of patients that completed the questionnaire per category of the RAND-36 questionnaire at baseline and 1, 3, and 5 year after MBS

Follow-up	Pulse oximetry		Sleep test	
	n (%)	EMM [95% CI]	n (%)	EMM [95% CI]
Physical functioning				
Baseline				
1 year	665 (95.4)	57.5 [55.9 to 59.3]	654 (94.6)	58.4 [56.7 to 60.1]
3 years	573 (82.2)	86.6 [84.4 to 88.4]	529 (76.6)	87.3 [85.5 to 89.2]
5 years	185 (26.5)	85.2 [82.2 to 88.3]	230 (33.3)	83.3 [80.5 to 86.0]
	154 (22.1)	83.0 [79.6 to 86.3]	195 (28.2)	79.0 [75.9 to 82.0]
Role functioning emotional				
Baseline	656 (94.1)	91.3 [89.7 to 92.8]	657 (95.1)	90.9 [89.3 to 92.4]
1 year	568 (81.5)	96.1 [94.8 to 97.2]	529 (76.6)	95.6 [94.2 to 96.7]
3 years	187 (26.8)	94.1 [91.6 to 96.2]	237 (34.3)	92.9 [90.5 to 95.0]
5 years	156 (22.4)	95.0 [92.5 to 97.2]	196 (28.4)	91.7 [88.9 to 94.1]

Supplementary table 3. Mean scores and numbers of patients that completed the questionnaire per category of the RAND-36 questionnaire at baseline and 1, 3, and 5 year after MBS (continued)

Follow-up	Pulse oximetry		Sleep test	
	n (%)	EMM [95% CI]	n (%)	EMM [95% CI]
Physical functioning				
Baseline				
1 year	665 (95.4)	57.5 [55.9 to 59.3]	654 (94.6)	58.4 [56.7 to 60.1]
3 years	573 (82.2)	86.6 [84.4 to 88.4]	529 (76.6)	87.3 [85.5 to 89.2]
5 years	185 (26.5)	85.2 [82.2 to 88.3]	230 (33.3)	83.3 [80.5 to 86.0]
	154 (22.1)	83.0 [79.6 to 86.3]	195 (28.2)	79.0 [75.9 to 82.0]
Role functioning emotional				
Baseline	656 (94.1)	91.3 [89.7 to 92.8]	657 (95.1)	90.9 [89.3 to 92.4]
1 year	568 (81.5)	96.1 [94.8 to 97.2]	529 (76.6)	95.6 [94.2 to 96.7]
3 years	187 (26.8)	94.1 [91.6 to 96.2]	237 (34.3)	92.9 [90.5 to 95.0]
5 years	156 (22.4)	95.0 [92.5 to 97.2]	196 (28.4)	91.7 [88.9 to 94.1]
Role functioning physical				
Baseline	659 (94.5)	51.7 [48.9 to 54.7]	654 (94.6)	51.6 [48.7 to 54.5]
1 year	565 (81.1)	83.4 [80.3 to 86.5]	527 (76.3)	83.3 [80.1 to 86.5]
3 years	189 (27.1)	78.6 [73.5 to 83.3]	235 (34.0)	78.3 [73.6 to 83.0]
5 years	156 (22.4)	78.7 [72.9 to 84.4]	193 (27.9)	69.3 [64.2 to 74.5]
Energy/fatigue				
Baseline	672 (96.4)	52.1 [50.7 to 53.6]	671 (97.1)	51.8 [50.4 to 53.2]
1 year	583 (83.6)	68.5 [67.0 to 70.0]	551 (79.7)	69.2 [67.7 to 70.8]
3 years	185 (26.5)	64.1 [61.6 to 66.6]	232 (33.6)	66.7 [64.4 to 68.9]
5 years	165 (23.7)	71.1 [58.4 to 85.2]	196 (28.4)	68.1 [53.2 to 69.9]
Emotional well-being				
Baseline				
1 year	681 (97.7)	75.3 [73.9 to 76.7]	668 (96.7)	76.0 [74.6 to 77.3]
3 years	584 (83.8)	84.9 [83.7 to 86.1]	552 (79.9)	84.8 [83.6 to 86.0]
5 years	184 (26.4)	80.9 [78.7 to 83.0]	235 (34.0)	82.4 [80.6 to 84.3]
	156 (22.4)	81.2 [81.3 to 85.3]	196 (28.4)	79.2 [76.9 to 81.3]
Social functioning				
Baseline				
1 year	656 (94.1)	77.7 [75.8 to 79.5]	657 (95.1)	77.8 [75.9 to 79.6]
3 years	555 (79.6)	93.2 [92.0 to 94.2]	525 (76.0)	92.9 [91.7 to 94.0]
5 years	183 (26.3)	90.2 [87.9 to 92.3]	231 (33.4)	90.2 [88.2 to 92.1]
	156 (22.4)	89.4 [86.8 to 91.7]	196 (28.4)	85.3 [82.6 to 87.7]
Pain				
Baseline	661 (94.8)	64.9 [63.2 to 66.6]	661 (95.7)	63.6 [61.9 to 65.2]
1 year	567 (81.3)	83.2 [81.4 to 85.0]	532 (77.0)	81.8 [80.0 to 83.6]
3 years	190 (27.3)	78.8 [76.0 to 81.7]	236 (34.2)	80.0 [77.4 to 82.5]
5 years	153 (22.0)	76.2 [73.0 to 79.3]	198 (28.7)	74.1 [71.3 to 77.0]
General Health				
Baseline	676 (97.0)	50.3 [48.9 to 51.8]	664	50.5 [49.1 to 51.9]
1 year	579 (83.1)	73.7 [72.2 to 75.2]	549	74.4 [72.8 to 75.9]
3 years	180 (25.8)	69.4 [66.9 to 71.9]	228	69.9 [67.7 to 72.2]
5 years	158 (22.7)	64.2 [61.5 to 66.9]	195	63.2 [61.2 to 66.2]

Supplementary table 3. Mean scores and numbers of patients that completed the questionnaire per category of the RAND-36 questionnaire at baseline and 1, 3, and 5 year after MBS (continued)

Follow-up	Pulse oximetry		Sleep test	
	n (%)	EMM [95% CI]	n (%)	EMM [95% CI]
Health change				
Baseline	693 (99.4)	41.6 [40.1 to 43.1]	687 (99.4)	43.8 [42.2 to 45.3]
1 year	595 (85.4)	90.9 [89.3 to 92.6]	559 (80.9)	91.5 [89.8 to 93.2]
3 years	188 (27.0)	57.9 [55.0 to 60.9]	236 (34.2)	58.7 [56.1 to 61.3]
5 years	156 (22.4)	53.1 [50.0 to 56.4]	198 (28.7)	52.2 [49.3 to 55.1]

MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval.

Supplementary Table 4. The p-values between each timpoint (preoperative, 1, 3 and 5 years after metabolic and bariatric surgery) for the pulse oximetry and sleep test strategy

	Pre-1 year	Pre-3 years	Pre 5years	1 year-3years	1 year-5 years	3 years-5 years
			Pulse oximetry			
ESS	<.001	<.001	<.001	.70	.53	1.0
FOSQ10	<.001	<.001	<.001	1.0	1.0	1.0
TWL	<.001	<.001	<.001	<.001	<.001	<.001
RAND-36						
PF	<.001	<.001	<.001	1.0	.319	1.00
RLE	<.001	.262	.066	.601	1.00	1.00
RPH	<.001	<.001	<.001	.53	.81	1.0
EN	<.001	<.001	<.001	.003	.701	.810
EWB	<.001	<.001	<.001	<.001	.010	1.00
SF	<.001	<.001	<.001	.042	.012	1.0
Pain	<.001	<.001	<.001	.024	<.001	.857
GH	<.001	<.001	<.001	.005	<.001	.003
HC	<.001	<.001	<.001	<.001	<.001	.147
			Sleep test			
ESS	<.001	<.001	<.001	<.001	<.001	.398
FOSQ10	<.001	<.001	.006	.003	.001	1.0
TWL	<.001	<.001	<.001	<.001	<.001	<.001
RAND-36						
PF	<.001	<.001	<.001	.048	<.001	.112
RLE	<.001	.837	1.00	.115	.018	1.00
RPH	<.001	<.001	<.001	.328	<.001	.021
EN	<.001	<.001	.049	.092	<.001	.037
EWB	<.001	<.001	1.00	.051	<.001	.024
SF	<.001	<.001	<.001	.040	<.001	.002
Pain	<.001	<.001	<.001	1.00	<.001	.002

Supplementary Table 4. The p-values between each timpoint (preoperative, 1, 3 and 5 years after metabolic and bariatric surgery) for the pulse oximetry and sleep test strategy (continued)

	Pre- 1 year	Pre- 3 years	Pre 5years	1 year- 3years	1 year- 5 years	3 years- 5 years
GH	<.001	<.001	<.001	<.001	<.001	<.001
HC	<.001	<.001	<.001	<.001	<.001	.004

ESS: Epworth sleepiness scale, FOSQ-10: functional outcomes of sleep questionnaire, short form , TWL: total weight loss, RAND-36: Research and Development 36-item Health Survey, PF: RAND-36 category: physical functioning, RLE: RAND-36 category: role limitations due to emotional problems, RPH: RAND-36 category: role limitations due to physical health, EN: RAND-36 category: energy/fatigue, EWB: RAND-36 category: emotional well-being, SF: RAND-36 category: social functioning, GH: RAND-36 category: general health, HC: RAND-36 category: health change.

Supplementary Table 5. Mean scores and number of patients with TWL 1, 3, and 5 years after MBS

TWL	**pulse oximetry** n (%)	**EMM** **[95% CI]**	**sleep test** n (%)	**EMM** **[95% CI]**
1 year	690 (99.0)	33.6 [33.0 to 34.2]	662 (95.8)	32.4 [31.8 to 32.9]
3 years	191 (27.4)	31.5 [30.6 to 32.3]	240 (34.7)	31.1 [30.4 to 31.9]
5 years	158 (22.7)	28.8 [27.8 to 29.8]	203 (29.4)	28.6 [27.7 to 29.5]

TWL: total weight loss, MBS: metabolic and bariatric surgery, EMM: estimated marginal mean, CI: confidence interval.

Supplementary Material 1. Version of the FOSQ-10 used in the POPCORN study (Dutch version as used in the POPCORN study and the English translation).

Dutch

FOSQ-10: Kwaliteit van leven met slaperigheid

De komende vragen gaan over de relatie tussen de neiging om in slaap te vallen en de invloed daarvan op uw dagelijks leven.

Wij willen vragen om in de komende 10 situaties een score te geven wat het beste past bij uw leven.

Kies het getal dat het best past bij uw toestand in die situatie.
0= Ja, heel erg
1= Ja, behoorlijk
2= Ja, een beetje
3= Nee

	0	1	2	3
Heeft u moeite met het concentreren op alledaagse activiteiten omdat u moe of slaperig bent?				
Heeft u moeite met dingen onthouden omdat u moe of slaperig bent?				
Heeft u moeite met het autorijden van korte afstanden (minder dan 160 km) omdat u dan slaperig wordt?				
Heeft u moeite met het autorijden van lange afstanden (meer dan 160 km) omdat u dan slaperig wordt?				
Heeft u moeite met op bezoek gaan bij familie of vrienden omdat u moe of slaperig wordt?				
Is uw relatie met familieleden, vrienden of collega's veranderd doordat u moe of slaperig bent?				
Heeft u moeite met het kijken van een film omdat u slaperig of moe wordt?				
Heeft u moeite om 's avonds net zo actief te zijn als u graag zou willen, omdat u slaperig of moe bent?				
Heeft u moeite om 's ochtends net zo actief te zijn als u graag zou willen, omdat u slaperig of moe bent?				
Wordt uw stemming beïnvloedt doordat u slaperig of vermoeid bent?				

English (translated)

FOSQ-10: Quality of Life with Sleepiness

The following questions are about the relationship between the tendency to fall asleep and its impact on your daily life.

We would like to ask you to give a score for the next 10 situations that best fits your life.

Please choose the number that best describes your condition in that situation.
0 = Yes, very much
1 = Yes, quite a bit
2 = Yes, a little
3 = No

	0	1	2	3
Do you have difficulty concentrating on the things you do because you are sleepy or tired?				
Do you have trouble remembering things because you are tired or sleepy?				
Do you have trouble driving short distances (less than 160 km) because you become sleepy?				
Do you have trouble driving long distances (more than 160 km) because you become sleepy?				
Do you have trouble visiting family or friends because you become tired or sleepy?				
Has your relationship with family members, friends, or colleagues changed because you are tired or sleepy?				
Do you have trouble watching a movie because you become sleepy or tired?				
Do you have trouble being as active in the evening as you would like because you are sleepy or tired?				
Do you have trouble being as active in the morning as you would like because you are sleepy or tired?				
Is your mood affected because you are sleepy or tired?				

Chapter 4

First-night desaturations and nursing interventions in patients undergoing metabolic and bariatric surgery with unknown obstructive sleep apnea status

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Submitted

Abstract

Background: The pulse oximetry strategy is a is a safe and cost-effective perioperative strategy to manage obstructive sleep apnea (OSA) in patients undergoing metabolic and bariatric surgery (MBS). In this strategy patients with an unknown OSA status are postoperatively monitored with pulse oximetry and receive supplemental oxygen therapy (2L/min) during postoperative night one. However, the desaturation rate and the associated workload for the nursing staff is unknown. This study aimed to characterize the desaturation and nursing intervention rate and identify patient-related risk factors for developing desaturations.

Methods: An observational study in 385 participants undergoing primary MBS with the pulse oximetry strategy as perioperative OSA management. During postoperative night one, desaturations (SpO_2 <90%), SpO_2 (10 min interval) and nursing interventions (e.g. waking up patient, increasing oxygen flow) were collected. Binary logistic regression was used to estimate risk factors for developing desaturations.

Results: Desaturation occurred in 86 (22%) participants (median: 3.0 [1.8-6.0] desaturations per participant), and nursing interventions in 54 participants (14%). The odds ratio (OR) for desaturations was higher in men (OR 2.8, 95% confidence interval [CI]: 1.5-5.1), current smokers (OR 2.6, 95% CI: 1.2-5.3) older age (OR 1.5 per decade, 95% CI: 1.1-1.7) and higher BMI (OR: 1.4 per 5 BMI points, 95% CI: 1.1-1.7).

Conclusion: The pulse oximetry strategy does not impose a high workload for the nursing staff, with low desaturation and nursing intervention rates. Future research comparing patients with and without supplemental oxygen is needed to assess the value of supplemental oxygen in patients undergoing MBS.

Introduction

Obesity is a major health issue worldwide with one in eight people living with obesity in 2022. Metabolic and bariatric surgery (MBS) has proven to be an effective and durable treatment against obesity. In 2022, more than 450,000 MBS procedures were performed globally, with the sleeve gastrectomy (SG) being the most common procedure, followed by the Roux-en-Y Gastric Bypass (RYGB) [1]. Of all patients undergoing MBS, 35-94% have obstructive sleep apnea (OSA) [2]. Despite this high incidence of OSA, the best perioperative strategy remains unclear. Recently, a large non-inferiority trial (n=1390) compared two perioperative OSA strategies. The sleep test strategy: with preoperative poly(somno)graphy with subsequent treatment with continuous positive airway pressure (CPAP) in case of OSA diagnosis versus pulse oximetry strategy: not preoperatively testing for OSA but postoperative continuous monitoring using pulse oximetry and administering two liters of supplemental oxygen therapy [3]. This study found that complication and readmission rates were comparable between the two strategies, and that the pulse oximetry strategy is more cost-efficient [3]. Yet, it is unknown if supplemental oxygen has additional value during the first postoperative night after MBS in a population potentially suffering from OSA. Patients frequently complain about the discomfort of the nasal canula. Additionally, administration of supplemental oxygen leads to additional costs and environmental carbon dioxide emission [4]. A first step in determining if supplemental oxygen therapy has added value in this population, is by characterizing if and how often desaturations occur, and if supplemental oxygen therapy is needed in all patients, or just those with specific risk factors. Besides, it is unknown whether this strategy creates a higher workload for nurses, as it is unknown if and how many nursing interventions are required due to or to prevent desaturations. Therefore, the primary aim of this study was to characterize the number of desaturations and nursing interventions in patients with a (largely) unknown OSA status receiving supplemental oxygen therapy during the first night after MBS. The secondary aim was to identify patient-related risk factors for developing desaturations.

Methods

Study design and population

This was a single center prospective observational cohort study, strengthening the reporting of observational studies in epidemiology (STROBE) guidelines were used to ensure complete and transparent reporting [5]. This study was approved by the institutional review board of Rijnstate hospital (study number: 2022-2107, approved September 2022) and retrospectively registered in the clinicaltrial.gov database (NCT07174674). All participants gave their written informed consent.

All adult patients scheduled for MBS between September 2022 and October 2023 at a large teaching hospital (Rijnstate hospital Arnhem, the Netherlands) were screened for eligibility. Patients undergoing primary MBS with an unknown OSA status or OSA without treatment (e.g. CPAP, mandibular advancement devices) were included. Preoperative exclusion criteria were: patients who underwent secondary or revisional MBS, patients who were diagnosed with OSA and received treatment or had chronic obstructive pulmonary disease. Potential same-day discharge (based on preoperative criteria) was not an exclusion criterium preoperatively, because same-day discharge was relatively new during the study period and the majority of these patients eventually had an overnight hospital stay. Participants who did have same-day discharge were postoperatively excluded. All participants received standard care, including no routine testing for OSA preoperatively, and receiving 3L/min of supplemental oxygen in the post-anesthesia care unit and subsequently 2L/min of supplemental oxygen therapy at the nursing ward while being continuously monitored. MBS was performed under general anesthesia. General anesthesia was induced with intravenous propofol (1-2 mg/kg), sufentanil (10 mcg) and rocuronium (0.2-0.5 mg/kg), and maintained with sevoflurane 0.8-1.0 minimum alveolar concentration and intravenous remifentanil (12.5 mcg/kg ideal body weight/h). Additional intraoperative analgesia included intravenous morphine (5 mg), paracetamol (1000 mg) and metamizole (1000 mg). For postoperative analgesia on the post-anesthesia care unit and nursing ward paracetamol (1000 mg four times a day), tramadol (as needed, 50 mg 3 times a day), or subcutaneous morphine or piritramide (as needed, 7.5-10 mg four times a day) was used.

Nurses were trained to correctly connect and interpret the vital signs measured during continuous monitoring. Postoperatively, saturation was monitored continuously using a pulse oximeter attached to the index finger and saved every 10 minutes until 6 A.M. the next morning with the IntelliVue-MX100 (Philips, the Netherlands). A central dashboard provided an overview of the real-time saturation for all patients in the ward. If a patient desaturated peripheral oxygen saturation [SpO_2] <90% an alarm went off. In case of persistent desaturations, nurses intervened by waking up the patient, putting the nasal cannula back in place or increasing the oxygen flow (non-invasive nursing interventions). Nurses were specifically trained to perform airway maneuvers (jaw trust, chin lift), which were classified as invasive nursing interventions. If these nursing interventions were insufficient, the attending physician was consulted.

Outcomes

The primary outcome was the number of desaturations and nursing interventions. The secondary outcome was to identify participant-related risk factors for developing desaturations.

Data collection

The follow up of this study was until 6 A.M. on the first postoperative day. The following data was extracted from the electronic patient records: age, sex, body mass index (BMI), smoking status, medical history, medication use, surgery details (e.g. date, duration, type of surgery, perioperative complications) intraoperative and postoperative opioid use, neuromuscular blocking drug dose (NMBD; rocuronium) and reversal agent use (sugammadex), esketamine and benzodiazepine dose on the day of surgery. To calculate the total intraoperative and postoperative opioid dosage, opioids (parenteral morphine, piritramide, sufentanil, oral tramadol) were converted to their oral morphine milligram equivalent (MME) [6, 7].

Oxygen saturation registered with a 10-minute interval and all desaturations (SpO_2 <90%, time, value) between 11 P.M and 6.A.M. were collected. Participants with ≥50% of the 10-minute saturation missing were excluded. The nurses had an intervention form, on which they filled out if and how often they had to intervene and what kind of intervention was performed (i.e. waking up patient, increasing oxygen flow, airway maneuvers).

Sample size calculation

A population proportion sample size was used, with a confidence interval of 95%, margin of error 5% and a proportion of 0.50 as the exact proportion of patients with desaturations was unknown. This resulted in a required sample size of 385 patients.

Statistical analysis

Continuous data were expressed as median with [25th percentile (Q1) - 75th percentile (Q3)] and categorical data as frequencies (percentage). For the comparison of SpO_2 and nursing interventions (number, types of intervention) between participants with desaturation (≥1 desaturation, SpO_2 <90%) and without desaturations, a Mann Whitney U test was used for continuous data, and the Fisher's exact test for categorical data.

Binary logistic regression was used to estimate the risk for developing desaturations, displayed as odds ratio (OR) with a 95% confidence interval (CI). Within this logistic regression model, the effect on desaturations was tested for sex (refence = female), age (per decade), BMI (per 5 points), smoking status (reference = non-smoker), chronic benzodiazepines use (reference = no use), the presence of obesity related comorbidities (hypertension, dyslipidemia, diabetes mellitus type 2; reference = not present), operating time, intraoperative dose of rocuronium, sugammadex use, intraoperative MME, postoperative MME and postoperative benzodiazepine use.

A sub analysis in participants with postoperative opioid use was performed, to determine if the effect of opioids on desaturations was different between opioid naïve (=reference) and opioid tolerant participants (participants with or without opioid use at home).

For the statistical analysis, SPSS Statistics (v.29.1, IBM, New York, United States) was used. A p-value of <.05 was considered statistically significant.

Results

A total of 563 participants signed informed consent before undergoing MBS, of whom 178 were excluded postoperatively, this resulted in a final study population for analysis of 385 patients (Figure 1). The majority of the study population was female (83.6%), with a median age of 42 [31-51] years, and a median BMI of 42.0 [39.2-46.0] kg/m^2. The most performed type of surgery was the RYGB (74.0%) (Table 1). No perioperative complications occurred.

Desaturations

A total of 456 desaturations in 86 participants (22.3%) were measured, with a median SpO_2 during desaturation of 88% [85-89%], and a lowest saturation of 68% (Table 2). Most participants had 1-3 desaturations (61.6%), and the maximum number of desaturations was 55.

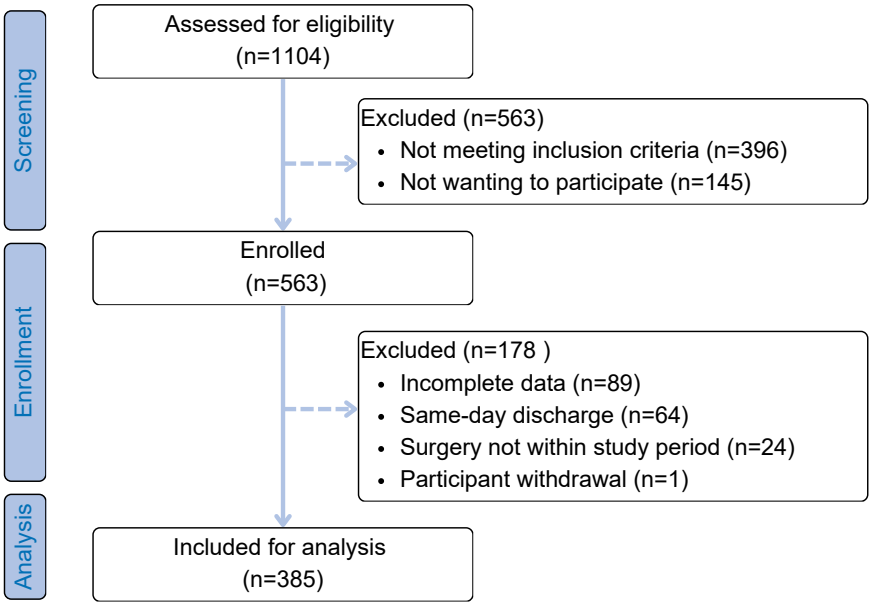

Figure 1. Flowchart for enrollment and subsequent inclusion for analysis

Table 1. Participant characteristics before undergoing MBS

Characteristic	Total study population n=385
Sex (female)	322 (83.6)
Age (years)	42 [31-51]
BMI (kg/m^2)	42.0 [39.2-46.0]
Obesity related comorbidities	
Hypertension	128 (33.2)
Dyslipidemia	25 (6.5)
Diabetes mellitus type 2	41 (10.6)
OSA without treatment	2 (5.7)
Smoking status (non-smoker)	344 (89.4)
Type of surgery	
RYGB	285 (74.0)
SG	100 (26.0)

Data is presented as number (percentage), median [Q1-Q3]. MBS: metabolic and bariatric surgery, BMI: body mass index, OSA: obstructive sleep apnea, RYGB: Roux-en-Y gastric bypass, SG: sleeve gastrectomy.

Nursing interventions

Nursing interventions were needed in 54 participants (14%), of which 42 with and 12 without desaturation (p=<.001, Table 2). A median of 3.0 [1.8 - 6.0] interventions were performed for participants with desaturation(s). In total, 76 nursing interventions were performed, which consisted of putting back the nasal canula (39.5%), waking up the patient (38.2%), increasing oxygen flow (21.0 %) and putting the patient in upright position (1.3%; Table 2). In 8 of the 12 patients with a nursing intervention without a desaturation, the intervention was putting back the nasal canula. In the remaining 4 patients oxygen flow was increased, in 3 because of a low saturation (mean ranging 94.3 - 94.8%) and in 1 patient the reason for increasing the oxygen flow is unknown, as the nurse provided no explanation and the 10-minute saturation levels were never below 96%. Additionally, no airway maneuvers were performed on any of the participants, attending physicians were never consulted and no escalation of care (e.g. intervention rapid response team, transfer to intensive care unit) was needed.

Table 2. Desaturation and nursing interventions for participants with and without desaturation

	Total study population n=385	Without desaturation n=299	With desaturation n=86	p-value
SpO_2	98 [97-99][1]	98 [97-99]	97 [95-98][2]	<.001[a]
SpO_2 during desaturation			88 [85-89]	
Number of desaturations (per patient)			3.0 [1.8-6.0]	
Participants needing a nursing intervention	54 (14.0)	12 (4.0)	42 (48.8)	<.001[b]
Type of nursing intervention				.52[b]
Waking up patient	29 (38.2)	4 (25.0)	25 (41.7)	
Putting back nasal canula	30 (39.5)	7 (43.8)	23 (38.3)	
Increasing oxygen flow	16 (21.0)	5 (31.2)	11 (18.3)	
Patient placed in upright position	1 (1.3)	0 (0.0)	1 (1.7)	

Data are presented as median [Q1-Q3] or number (percentage). [1]n=384, [2]n=85. [a] Mann Whitney U test, [b] Fisher's exact test, SpO_2: peripheral capillary oxygen saturation

Risk for desaturation

The risk of developing desaturations during the first night after MBS, while receiving supplemental oxygen therapy was significantly higher in men (OR 2.8, 95% CI: 1.4 to 5.3) and smokers (OR 2.8, 95% CI: 1.2 to 5.5, Table 3). Furthermore, a significant higher risk was found with older age (OR 1.5 per decade, 95% CI: 1.1 to 1.9) and higher BMI (OR: 1.4 per 5 BMI points, 95% CI: 1.1 to 1.8). Intra and postoperative opioid use (both OR 1.0, 95% CI 1.0 to 1.0), intraoperative dosage of rocuronium and use of sugammadex (OR 1.0, 95% CI 0.8 to 1.0; OR 1.1, 95% CI 0.6 to 2.4) were not associated with an increased risk of desaturation. Additionally, in the sub analysis in participants with postoperative opioid use (n=96) there was no increased risk of developing desaturations in opioid naive participants compared to opioid tolerant participants (OR 0.7; 95% CI 0.77 to 6.3).

Table 3. Risk factors for developing desaturations in 385 participants undergoing MBS

	Odds ratio	95% CI	p-value
Sex[#]	2.8	1.4 to 5.3	.003*
Age (per decade)	1.5	1.1 to 1.9	.004*
BMI (kg/m^2, per 5 BMI points)	1.4	1.1 to 1.8	.002*
Smoking status[†]	2.8	1.2 to 5.5	.01*
Chronic benzodiazepine use	2.1	0.7 to 6.6	.19
DM type 2[‡]	0.8	0.4 to 1.9	.64
Hypertension[‡]	1.1	0.6 to 2.0	.80
Dyslipidemia[‡]	1.9	0.7 to 5.0	.20
Operating time	1.0	1.0 to 1.0	.53
MME postoperatively	1.0	1.0 to 1.0	.73
MME intraoperatively	1.0	1.0 to 1.0	.23

Table 3. Risk factors for developing desaturations in 385 participants undergoing MBS (continued)

	Odds ratio	95% CI	p-value
Rocuronium (per 5mg)	1.0	0.8 to 1.1	.54
Sugammadex‡	1.2	0.6 to 2.4	.19

The odds ratio with 95% CI and p-value was estimated using a binary logistic regression. #Female = 0, male = 1, †non smoker = 0, smoker=1, ‡no = 0, yes = 1. BMI: body mass index; DM: diabetes mellitus, CI: confidence interval, MME: morphine milligram equivalent. *Statistically significant

Discussion

The primary aim of this study was to characterize the incidence of desaturations and nursing interventions in participants with a largely unknown OSA status receiving supplemental oxygen therapy during the first night after MBS. We found that the minority of participants (22%) had desaturations, of which the majority (62%) only had 1-3 desaturations. Additionally, the number of participants in need of nursing interventions was low (14%), and only non-invasive nursing interventions (e.g. waking up the patient, putting back nasal canula) were sufficient as the attending physician was never consulted and escalation of care was never needed. Further analysis showed that male sex, higher age, higher BMI and smoking were risk factors for developing postoperative desaturations during the first night after MBS.

A systematic review investigating the effects of oxygen therapy on OSA found that oxygen therapy significantly improves the AHI and oxygen saturation, but the duration of apnea and hypopnea episodes were longer in patients with oxygen therapy [8]. Nevertheless, it is questionable if this population is comparable to our postoperative population with an unknown OSA status, as the population from the systematic review included participants (n=359) that did not tolerated CPAP therapy, and oxygen therapy was used as an alternative treatment.

A trial in which participants (n=123) were randomly assigned to receive supplemental oxygen (3L/min) or no supplemental oxygen during the first three postoperative nights, found that the group with supplementary oxygen had a significantly higher saturation [9]. However, this was only measured during postoperative night three, when a peak of AHI and potentially desaturations is expected, while we are interested in postoperative night one [10].

The literature regarding desaturations specific for patients after MBS is scarce and is only described in one other study (n=40) [11]. This study reported frequent postoperative oxygen desaturations in patients with and without OSA (number of desaturations: with OSA 129 [26-204], without OSA: 53 [31-149]) during the first 24 hours after MBS, while

receiving 3L of supplemental oxygen therapy. These desaturation numbers were during day and night, so a fair comparison with our data with only measurements during the night could not be made. That same study reported that after discontinuation of oxygen therapy, the median SpO_2 decreased from 97% to 94% in both patients with and without OSA. Unfortunately, the number of desaturations after discontinuation of oxygen therapy was not described, therefore no conclusions could be drawn about the effect of oxygen on preventing desaturation after MBS. In another study including patients after abdominal surgery receiving 4L of supplemental oxygen, the number of desaturations was higher (27.8 ± 30.7) compared to our study (3.0 [1.8-6.0]) [12]. However, this was in a small study population (n=29), providing highly variable data with a standard deviation higher than the mean. Another study comparing general surgery patients with and without supplemental oxygen therapy after surgery (n=67), found no clinically relevant difference in mean SpO_2 in patients without (93.8%, 95%CI:92.7 to 94.9%) and patients with oxygen therapy (95.8%; 95% CI:94.8 to 96.8%:) [13]. Additionally, no significant difference in the proportion of time during the night in desaturation state was found between the groups with O_2 (18.6% of time ± 3.4%) versus without O_2 (27.1 of time % ±3.0%, p=.06) and the proportion of time in recovery state after desaturation was comparable (4.0% ±1.1% versus 8.4% ±2.1%, p=.08). Although this could indicate that supplemental oxygen therapy does not have clinical added value, it is questionable if these results can be extrapolated to patients after MBS with an increased incidence of OSA.

The additional workload for nurses when continuously monitoring seems limited with only 14% of participants needing a total of 76 non-invasive interventions. The percentage of participants with a nursing intervention because of a desaturation in our study was 49%, this is lower than in an orthopedic population without an increased risk of OSA where only part of the population received supplemental oxygen and 66% had an intervention [14]. In accordance with our results only non-invasive nursing interventions were needed, and no escalation of care or a rapid response team call was needed. Therefore, there is no reason to assume that our strategy increases the risk of non-invasive and invasive nursing interventions.

Male sex, higher age, higher BMI and smoking were risk factors for developing postoperative desaturations in our study, which is in line with previous research. In a general surgery population (n=1064) age (OR 1.04; 95% CI 1.03 to 1.06), BMI (OR 1.12; 95% CI 1.06 to 1.18) and current smoking (OR 1.91; 95% CI 1.12 to 3.42) were significant risk factors for desaturation [15]. In elective surgical patients (n=298) the following factors were associated with hypoxemia: age greater than 55 years (OR <55 years 0.28, 95%CI 0.14 to 0.56) preoperative saturation below 95% (OR 4.1, 95%CI 2.2 to 7.2) and postoperative pain score (OR 0.12, 95%CI 0.06 to 0.26) [16]. In a study in patients undergoing upper abdominal procedures (n=206), factors that correlated with postoperative desaturation were BMI >25 kg/m^2 (OR 3.07, 95%CI 1.49 to 6.32) and subcostal incision (OR 2.68, 95%CI

1.41 to 5.07) [17]. Based on these studies, the reoccurring risk factors for developing postoperative desaturations are BMI, age and smoking status. This raises the question if solely patients with these risk factors should be monitored continuously or given supplemental oxygen, but to answer this question further research is needed.

A strength of this study is that data of continuous SpO_2 monitoring was used instead of intermittent measurements, reducing the chance of missing events. Another strength is that, next to SpO_2 data, nursing interventions were also analyzed, providing valuable insight into the clinical relevance and workload. However, limitations must be acknowledged as well. First, although the anesthetic procedures were largely standardized, they were not uniformized, which potentially could influence the desaturation incidence. However, we tested for intraoperatively used opioids, rocuronium and sugammadex and no increased risk for desaturations was found. Second, both participants undergoing RYGB and SG were enrolled, this may have biased the results as pain and thereby analgesic requirements differ between RYGB and SG. Nevertheless, this bias appears to be limited as we found that intra and postoperative increased use of opioids were not associated with an increased risk of developing desaturations. Third, even though our study population is relatively large, the study was not powered to assess risk factors for desaturation.

In conclusion, supplemental oxygen therapy with continuous monitoring does not seem to impose a high workload for the nursing staff, with a low incidence of desaturations requiring a limited number of non-invasive nursing interventions during the first night after MBS. The nursing interventions appeared effective as no physician was consulted or escalation of care was needed for desaturations. In this population, the risk of desaturations was higher in men, and patients with older age, higher BMI and current smoking status. No increased risk was found for intra and postoperative opioid use, intraoperative dosage of rocuronium and use of sugammadex. Future research, preferably a randomized controlled trial, comparing participants with and without supplemental oxygen therapy during the first night after MBS in a population with unknown OSA status, is needed to assess the value of supplemental oxygen therapy in this specific population.

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Chapter 5

Routine oxygen supplementation as part of a perioperative obstructive sleep apnea strategy in metabolic and bariatric surgery: is it beneficial?

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Submitted

Abstract

Introduction: Pulse oximetry monitoring with supplemental oxygen during the first night after metabolic and bariatric surgery (MBS) is a safe and cost-effective alternative to preoperative obstructive sleep apnea (OSA) testing. The value of supplemental oxygen is unknown. This study aimed to evaluate if omitting supplemental oxygen is non-inferior to administering oxygen during the first night after MBS.

Methods: Randomized non-inferiority trial including patients undergoing primary MBS with unknown OSA status or untreated OSA. Apnea-hypopnea index (AHI; primary outcome), oxygen desaturation index (ODI), and respiratory disturbance index (RDI) were compared between participants without (non-O_2) and with supplemental oxygen (O_2), using a non-inferiority margin (NIM) for the mean difference of 11 events/hour (e/h). Additionally, saturation, sleep architecture and clinical outcomes (nursing intervention rate, 30-day complication rate) were compared.

Results: In 140 participants (non-O_2 n=68, O_2 n=72), the 95%CI of the mean difference for AHI and RDI remained below the NIM, the ODI partially exceeded the NIM (95%CI: AHI: 2.7-9.9, ODI: 2.3-17.3, RDI: 0.6-8.5 e/h). The median AHI and desaturation rate were higher in the non-O_2 group (AHI: 5.8 [2.4-17.0] versus 2.2 [0.8-5.4], desaturations: 61.5 [31.0-140.8] versus 17.0 [7.3-52.0]). Sleep architecture and clinical outcomes were similar between groups.

Conclusion: In this population with potentially untreated OSA, omitting supplemental oxygen was non-inferior to administering oxygen regarding AHI. The increased desaturation rate and inferiority of ODI appears not to be clinically relevant with low absolute AHI values and similar clinical outcomes between groups, although this study was not powered to detect differences in clinical outcomes.

Introduction

Obstructive sleep apnea (OSA), is the most common form of sleep-disordered breathing (SDB) and is more prevalent in individuals with obesity [1]. The reported prevalence of OSA in patients undergoing metabolic and bariatric surgery (MBS) is high (35-94%), and mostly undiagnosed and therefore untreated [2]. Patients with OSA might be at increased risk for developing postoperative cardiovascular and respiratory complications [3]. Despite this potential increased complication risk, the optimal perioperative strategy to manage OSA in MBS remains unclear. Recently, a study compared two perioperative OSA strategies in 1390 patients undergoing MBS [4]. In the first strategy, the sleep test strategy, all patients were preoperatively tested for OSA with poly(somno)graphy (P(S)G) and subsequently treated with continuous positive airway pressure (CPAP) if OSA was diagnosed. In the second strategy, the pulse oximetry strategy, patients were not routinely tested for OSA but were postoperatively given supplemental oxygen therapy (2L/min) and were continuously monitored with pulse oximetry. Although patients in the second strategy potentially had untreated OSA, complication rate and emergency intensive care unit admission rate were comparable. Moreover, the second strategy was found to be more cost effective [4].

Supplemental oxygen therapy alone is not recommended as a treatment for OSA, because it may improve oxygen saturation, but does not improve the upper airway obstruction [5]. In contrast, CPAP does maintain patency of the upper airway and is therefore the treatment of choice for OSA [6]. This is supported by the fact that in most patients the apnea-hypopnea index (AHI) and sleep architecture improve with CPAP, but not with supplemental oxygen therapy alone [5]. Conversely, supplemental oxygen therapy may prolong the duration of apneas and worsen hypercapnia, particularly in patients with concurrent chronic hypercapnia, such as patients with obesity hypoventilation syndrome or chronic obstructive pulmonary disease [5, 7, 8]. Especially patients after surgery could be at risk for hypercapnia, as the use of sedatives and opioids can lead to blunted hypercapnic and hypoxic ventilatory responses [9-11].

However, in a subset of patients, presumably with a reduced collapsibility of the airway and greater respiratory compensation mechanisms, AHI does improve with supplemental oxygen therapy alone, compared to room air [5, 12, 13]. This raises the question if patients after MBS, with a high risk for OSA, benefit from supplemental oxygen therapy during the first postoperative night.

Therefore, this study aimed to evaluate if omitting supplemental oxygen is non-inferior to administering supplemental oxygen during the first postoperative night after MBS with regard to AHI, in a population with potentially untreated OSA. This was assessed by comparing SDB indices, saturations measures, sleep architecture, and clinical outcomes

between participants with and without supplemental oxygen therapy. We hypothesized that omission of supplemental oxygen is non-inferior to oxygen therapy, as supplemental oxygen therapy alone does not prevent collapse of the upper airway.

Methods

Study design and population

This randomized non-inferiority trial (OXYBAR trial), was conducted in a in a large teaching hospital (Rijnstate Hospital, the Netherlands), patients were screened for eligibility between May 2024 and February 2025. Inclusion criteria were: undergoing primary MBS (Roux-en-Y gastric bypass [RYGB] or sleeve gastrectomy [SG]) and a unknown OSA status or diagnosed OSA without receiving treatment (in accordance with the institution protocol, patients were not routinely tested for OSA preoperatively, but some had previously undergone P(S)G). Exclusion criteria were: same-day discharge, undergoing secondary or revisional MBS, diagnosed OSA with treatment (e.g. CPAP, mandibular advancement devices), use of alpha blockers, being a professional driver and having a pacemaker.

This study was approved by the medical ethics review committee Oost-Nederland (NL84729.091.23, approved November 2023), was registered at clinicaltrials.gov (NCT06432933, April 2024) and reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines [14]. All participants gave their written informed consent.

Treatment of participants

Preoperatively, all participants filled out the Epworth sleepiness scale and STOP BANG questionnaire. As part of standard care, all participants underwent screening at the preoperative clinic under supervision of the anesthesiologist. Preoperative risk estimation and management occurred according to relevant guidelines [15, 16]. MBS was performed under general anesthesia in all participants. General anesthesia was induced with intravenous propofol (1-2 mg/kg), sufentanil (10 mcg) and rocuronium (0.2-0.5 mg/kg), and maintained with sevoflurane 0.8-1.0 minimum alveolar concentration and intravenous remifentanil (12.5 mcg/kg ideal body weight/h). Further intraoperative analgesia included intravenous morphine (5 mg), paracetamol (1000 mg) and metamizole (1000 mg). For postoperative analgesia on the post anesthesia care unit and nursing ward paracetamol (1000 mg four times a day), tramadol (as needed, 50 mg three times a day), or subcutaneous morphine or piritramide (as needed, 7.5-10 mg four times a day) was used.

Postoperatively, all participants were continuously monitored using pulse oximetry and received 2 liters of supplemental oxygen therapy until 10 P.M. In the O_2 group (standard of care), supplemental oxygen therapy was continued overnight, while in the non-O_2 group

(intervention) the supplemental oxygen therapy was discontinued from 10 P.M. onwards. As part of the study, all participants underwent a sleep test with the WatchPAT® 300 (ZOLL Itamar) during the first postoperative night. To ensure equal treatment of participants, criteria for nursing interventions in case of desaturation were defined as follows: 1) wake up patient in case of a desaturation with a peripheral oxygen saturation (SpO_2) ≤75% for more than 60 seconds, 2) start or increase oxygen administration if the patient has to be woken up more than 10 times, or if the patient experiences a desaturation with a SpO_2 <90% for ≥10 min. Nurses filled out a questionnaire to document if they had to perform an intervention, and if so, which intervention and how often.

Outcomes

The primary outcome was the difference in AHI (events/hour [e/h]) between the groups. Secondary outcomes were: differences in other SDB indices (ODI and RDI), saturation measures (mean saturation, nadir mean saturation, number of desaturations [decrease of at least 3% from baseline], SpO_2 <90% for >10% of sleep), sleep architecture (total sleep time [min], percentage of rapid eye movement [REM] sleep, deep sleep, light sleep, wakefulness after sleep onset [WASO, min]). Tertiary outcomes were number and type of nursing interventions and 30-day complication rate. The 30-day complication rate was graded according to the Clavien-Dindo classification: grade I: any deviation from the normal postoperative course, grade II requiring pharmacological treatment, grade III: requiring surgical, endoscopic or radiological intervention, grade IV: life-threating complication, grade V: death of a patient [17].

Data collection

The following preoperative data were extracted from the electronic patient records: age, sex, body mass index (BMI), smoking status, medical history and medication use. Moreover, surgery details (e.g. date, type of surgery, perioperative complications) and complications until 30 days postoperative were collected. Scores of the preoperatively administered Epworth sleepiness scale and STOPBANG were collected. From the postoperative sleep test with the WatchPAT® 300, data regarding sleep disordered breathing parameters, saturation measures and sleep architecture were collected. Manual review of the raw data of all sleep tests was conducted to identify and correct potential misclassifications by the algorithm.

Randomization

After inclusion, participants were randomly allocated to omitting supplemental oxygen therapy (non-O_2 group, intervention) or receiving supplemental oxygen (O_2 group, control). Randomization was performed using Research Manager (V.7.1.) with stratified block randomization (block size 10) for sex, age (≤ 50 or > 50 years), neck circumference (≤ 40 or > 40 cm) and BMI (≤ 43 or >43 kg/m^2). Blinding of participants or health care providers was not possible, as it was clearly visible if participants received supplemental oxygen.

The manual review of the raw sleep test data and the collection of the 30-day complication rate were semi-blinded by performing these tasks in bulk, with the group allocation not being directly visible. The entry of the (reviewed) sleep test data was performed by an external researcher using pseudonymized reports, without access to the group allocation.

Sample size calculation

The sample size was calculated using the software program Power Analysis & Sample Size 2021 (PASS 2021, v.21.0.3). Mean and standard deviation (SD) of the AHI was based on a previous study population within our research group, who all underwent a PG preoperatively [4, 18]. In this bariatric population, the mean AHI of 833 participants (both with and without OSA) was 22 e/h (SD: 24). As this data was not normally distributed, we used the Mann-Whitney U test for non-inferiority. The non-inferiority limit was set to a mean difference of 11 e/h, as a difference in AHI of more than 50% was deemed clinically relevant. Together with a power of 0.8 and an alpha of 0.05, resulted in a sample size of 126 participants. We adjusted the sample size for a dropout rate of 20% which gave a total sample size of 152 participants, 76 per arm.

Statistical analysis

Continuous data were expressed as mean ± standard deviation in case of a normal distribution and as median with [25th percentile (Q1) - 75th percentile (Q3)] for a non-normal distribution. Categorical data were expressed as frequencies (percentage). Participant characteristics between the intervention and control group were compared using standardized mean differences (SMDs) [19]. Effect sizes were interpreted using conventional thresholds: 0.2 indicating a small effect, 0.5 a medium effect, and 0.8 a large effect [20].

For the non-inferiority analysis, we have applied a log-normal distribution, as the SBD indices (AHI, ODI, RDI) did not follow a normal distribution. The arithmetic means, their variance and 95% confidence interval (CI) were obtained using generalized pivotal confidence intervals, as described by Ledolter et al. (Equation 4) [21]. The difference in (arithmetic) means and the 95% CI were compared to the preset non-inferiority limit of 11 e/h. For saturation and sleep architecture measures, differences in continuous outcomes between the groups were analyzed using an independent samples T-test (normal distribution) or Mann Whitney U test (non-normal distribution). Differences in categorical outcomes were analyzed using Fisher's exact tests. To correct for multiple comparisons, the Benjamini-Hochberg procedure was applied to control the false discovery rate [22]. An intention-to-treat (ITT) analysis was used as the primary analysis. Additionally, per protocol (PP) analysis was conducted as a sensitivity analysis to assess the effect of the intervention (omitting oxygen) in patients who adhered strictly to the study protocol, excluding those in the intervention group who required oxygen during the study. All statistical analyses were performed using SPSS Statistics (v.29.1, IBM, New York, United States). A p-value of $<.05$ was considered statistically significant.

Results

A total of 153 participants were included, of whom 75 were allocated to the non-O_2 group and 78 to the O_2 group (Figure 1). Thirteen participants were excluded, because the sleep test failed (non-O_2: n=7, O_2: n=6), resulting in 140 included participants for analysis. In the non-O_2 group, five participants needed oxygen during the night because of persistent desaturations (SpO_2 <90% >10 minutes). The characteristics of both groups were similar, except that in the non-O_2 group relatively more participants underwent RYGB (92.6% versus 81.9%, SMD: 0.3) and less patients had an obesity-related comorbidity (51.5% versus 61.1%, SMD: 0.2; Table 1). Participants were predominately female (84.3%) with a mean age of 43.8 ± 11.7 years, median BMI of 41.4 [38.5 – 44.8] kg/m^2, STOP BANG score of 3 [2 - 4], ESS of 4 [2 – 6], and hypertension was the most common comorbidity (30.7%). Postoperative opioid use was similar between the groups (non-O_2 group: 30.6%, O_2 group: 32.4%; p=.86).

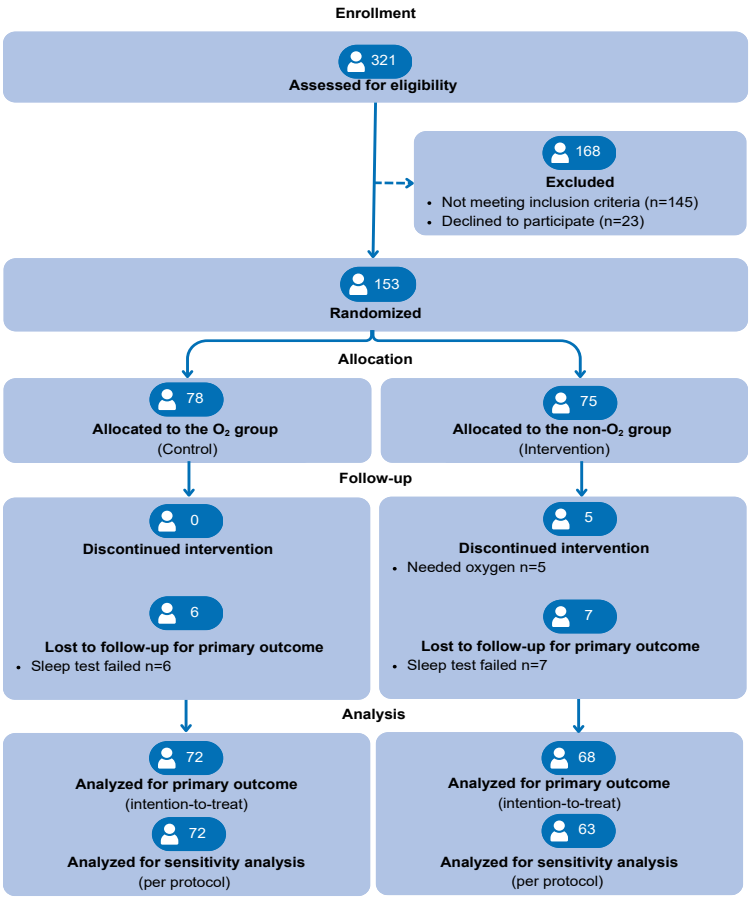

Figure 1. CONSORT flow diagram of inclusion for analysis [14]

The five participants in the non-O_2 group who required additional oxygen were older (55.0 [45.0-60.0] years), had a higher BMI (44.2 [36.7 – 52.7] kg/m^2), and all had hypertension (Supplementary Table 1).

Table 1. Participant characteristics before undergoing MBS in the intervention and control group

	Total population n=140	Without supplemental oxygen (intervention) n=68	With supplemental oxygen (control) n=72	SMD
Sex (female)	118 (84.3)	59 (86.8)	59 (81.9)	.13
Age (years)	43.8 ± 11.7	44.1 ± 10.8	43.5 ± 12.6	.13
BMI (kg/m^2)	41.4 [38.5 – 44.8]	41.5 [38.2 – 44.5]	41.3 [38.9 – 45.1]	.01
Neck circumference	40.4 [38.0 – 43.9]	40.0 [38.0 – 43.0]	40.8 [38.0 – 44.0]	.01
STOP BANG score	3 [2 – 4]	3 [2 – 4]	3 [3 – 4]	.03
ESS	4 [2 – 6]	4 [2 – 6]	4 [2 – 6]	.00
obesity-related comorbidities				
None	79 (56.4)	35 (51.5)	44 (61.1)	.20
Hypertension	43 (30.7)	22 (32.4)	21 (29.2)	.07
Dyslipidemia	22 (15.7)	11 (16.2)	11 (15.3)	.02
DM type 2	18 (12.9)	10 (14.7)	8 (11.1)	.11
Smoking status				
Non-smoker	66 (47.1)	29 (42.6)	37 (51.4)	.18
Former smoker	59 (42.1)	32 (47.1)	27 (37.5)	.19
Current smoker	15 (10.7)	7 (10.3)	8 (11.1)	.03
Type of surgery				
RYGB	122 (87.1)	63 (92.6)	59 (81.9)	.33
SG	18 (12.9)	5 (7.4)	13 (18.1)	.33

Data are presented as number (percentage), mean ± standard deviation, median [Q1-Q3]. MBS: metabolic and bariatric surgery, SMD: Standard mean difference, BMI: Body mass index, STOP BANG: snoring, tiredness, observed apneas, blood pressure, age, neck circumference, gender, ESS: Epworth sleepiness scale, DM: diabetes mellitus, RYGB: Roux-en-Y gastric bypass, SG: sleeve gastrectomy.

Sleep disordered breathing indices

Mean difference in AHI was 6.3 e/h (95% CI: 2.7 to 9.9 e /h). The upper limit of the CI remained below the predefined non-inferiority margin of 11 e/h, indicating non-inferiority of omitting oxygen (Figure 2). The median AHI was higher in the non-O_2 group compared to the O_2 group (5.8 [2.4 - 17.0] versus 2.2 [0.8 - 5.4] e/h).

Median ODI and RDI were also higher in the non-O_2 group: ODI 10.6 [5.8 - 27.8] versus 3.7 [1.6 - 9.4] e/h; RDI 9.9 [5.7 - 23.1] versus 6.6 [4.1- 13.2] e/h. The 95% CI of the mean difference did partially (ODI: 11.3, 95% CI: 2.3 to 17.3 e/h) or did not (RDI:4.6 95% CI: 0.6 to 8.5) exceed the non-inferiority limit (Figure 2).

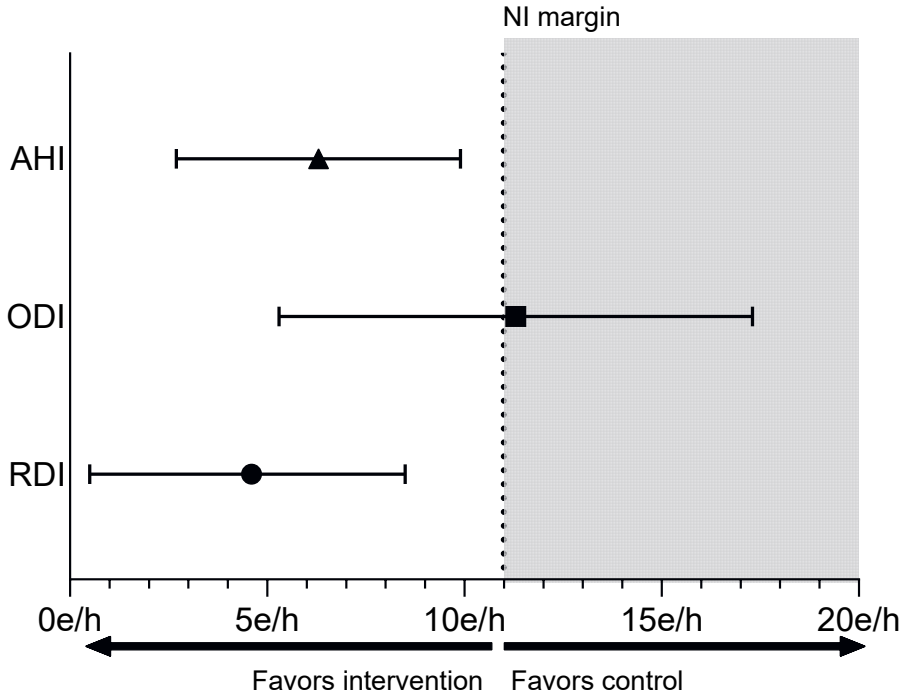

Figure 2. Mean difference with 95% confidence intervals between the non-O_2 (intervention) and O_2 group (control) for AHI, ODI and RDI relative to the non-inferiority margin of 11 e/h for the intention to treat analysis (n=140). AHI: apnea-hypopnea index, ODI: oxygen desaturation index, NI margin: non-inferiority margin, RDI: respiratory disturbance index

Saturation

The mean SpO_2 was lower in the non-O_2 group (92.7% ± 1.7 versus 95.6% ± 1.4; p= <.001) and the number of desaturations was higher (61.5 [31.0 - 140.8] versus 17 [7.25 - 52.0], p= <.001) than in the O_2 group (Table 2). In both groups, only desaturations of 3-9% lower than baseline were found. A SpO_2 below 90% for more than 10% of sleep time, was only observed in the non-O_2 group (n= 9, 13.2%). In these participants, the sleep time with a SpO_2 below 90% ranged from 11.6 - 49.7%, with the number of desaturations ranging from 62 - 347 per participant. Two of these participants received oxygen.

Sleep architecture

The total sleep duration was comparable between the non-O_2 group and O_2 group (5.7 [5.2 - 6.5] hrs versus 5.5 [4.9 - 6.0] hrs; p=.24; Table 2). In both groups, light sleep accounted for the largest proportion of total sleep, followed by deep sleep and REM sleep (Table 2).

Similar results for sleep disordered breathing indices, saturation and sleep architecture were found in the PP analysis (Supplementary Figure 1 and Table 2).

Table 2. Comparison of saturation measures and sleep architecture between the non-O_2 and O_2 group during the first night after MBS.

	Non-O_2 (intervention) n=68	O_2 group (control) n=72	p-value
Received oxygen	5 (7.4)	72 (100.0)	
Saturation measures			
Mean (SpO_2)	92.7 ± 1.7	95.6 ±1.4	<.001*
Mean of nadirs (SpO_2)	91.3 ±2.0	93.7 ±1.5	<.001*
Total number of desaturations	61.5 [31.0 - 140.8]	17.0 [7.3- 52.0]	<.001*
SpO_2 <90% in >10% of sleep time (n of participants)	9 (13.2)	0 (0.0)	.001*
Sleep architecture			
Sleep duration (hrs)	5.7 [5.2 - 6.5]	5.5 [4.9 - 6.0]	.24
% REM sleep	5.5 [2.0 - 9.7]	4.0 [1.6 - 7.2]	.18
% light sleep	79.9 [70.3 - 85.4]	79.5 [74.8 - 84.9]	.39
% deep sleep	15.1 [11.6 - 19.6]	15.1 [11.6 - 19.6]	.81
WASO (min)	92.0 [60.0 - 117.0]	104.5 [69.5 - 152.5]	.40
Pulse rate (bpm)	74 ± 13	73 ± 11	.39

Data are presented as number (percentage), median [Q1-Q3], mean ± standard deviation.

*Significant after Benjamini-Hochberg correction [22]. MBS: metabolic and bariatric surgery, SpO_2: peripheral capillary oxygen saturation, REM: rapid eye movement, WASO: wakefulness after sleep onset

Nursing interventions

Nursing intervention rate was comparable between the groups (p=.77). In the non-O_2 group, supplemental oxygen therapy was started because of a SpO_2 <90% for >10 min (n=5). In the O_2 group, nursing intervention were performed in seven participants: increasing oxygen flow (n=4), waking up the participant (n=2) and putting back the nasal canula (n=1). One participant was woken up twice, all other participants received one nursing intervention each.

Thirty-day complication rate

The thirty-day complication rate tended to be lower in the non-O_2 group (4.4% versus 13.9%), but this difference was not statistically significant (p=.08; Table 3). The majority of complications were graded as Clavien-Dindo grade II, and no grade IV and V occurred. None of the complications were related to OSA or cardiorespiratory conditions.

Table 3. Thirty-day complication rate after MBS for the non-O_2 and O_2 group, graded with the Clavien-Dindo classification

	Non-O_2 (intervention) n=68	O_2 group (control) n=72	p-value
With complication	3 (4.4)	10 (13.9)	.079
I: any deviation normal postoperative course	**1 (1.5)**	**2 (2.8)[1]**	
Nausea and insufficient oral intake	0	1 (1.4)	
Postoperative fever	0	1 (1.4)	
Obstructing ureteral stone	1 (1.5)	0	
II: pharmacological treatment	**1 (1.5)**	**6 (8.3)**	
Gastrointestinal bleeding	0	3 (4.2)	
Gastroesophageal reflux	0	1 (1.4)	
Allergic reaction to per operative antibiotics	0	1 (1.4)	
Urinary retention	0	1 (1.4)	
Abdominal pain	1 (1.5)		
III a: intervention not under general anesthesia	**1 (1.5)**	**0**	
Obstructing ureteral stone	1 (1.5)	0	
III b: intervention under general anesthesia	**0**	**2 (2.8)[2]**	
Postoperative bleeding	0	1 (1.5)	
Abdominal pain	0	1 (1.5)	

[1]=one patient with a grade IIB complication also had a grade I complication, [2]= one patient with a grade II complication also had a grade I complication.

Discussion

This study aimed to evaluate if omitting supplemental oxygen is non-inferior to administering supplemental oxygen during the first postoperative night after MBS in a population with potentially untreated OSA. Our results show, in line with our hypothesis, that omitting supplemental oxygen, based on the difference in mean AHI, is non-inferior to administering oxygen. Additionally, the RDI showed non-inferiority, and supplemental oxygen did not appear to affect sleep architecture, the nursing intervention rate and the 30-day complication rate, as these were similar between groups. In contrast, the 95% CI of the mean difference in ODI partially exceeded the non-inferiority limit and more desaturations occurred in the non-O_2 group.

In accordance with our results, two previous studies also found lower AHI and ODI in patients receiving supplemental oxygen therapy after surgery (not MBS). The first is a prospective observational study by Chung et al. (n=56), which found a lower AHI in participants with OSA and supplemental oxygen therapy compared to the group without oxygen, but this difference was not significant (p=.39) [9]. The ODI in participants with OSA and supplemental oxygen therapy was significantly lower compared to without supplemental oxygen (p=0.004). Second, a randomized controlled trial (RCT) by Liao et al. compared participants (n=123) with untreated OSA after surgery with or without

supplemental oxygen therapy [23]. Participants in the intervention group (with oxygen) were given oxygen (3L/min) during the first three postoperative nights, and all participants underwent a PSG during postoperative night three, which showed a lower AHI in participants receiving supplemental oxygen. In both studies, the absolute AHI was higher than in our study, which could be explained by three factors. First, all participants in these studies had OSA while our population is a combination of participants with and without OSA. Second, reports show that the AHI increases postoperatively with a peak AHI during postoperative night three [9, 24]. The sleep test in our study was performed during postoperative night one, whereas the PSG of Liao et al. was performed during postoperative night three, when a higher AHI is expected. Third, the raw sleep test data was manually reviewed, which predominantly led to a lower AHI. However, this is in line with previous research that found peripheral arterial tonometry, which is used by the WatchPAT®300, to overestimate the AHI compared to polysomnography [25-29].

Interestingly, Liao et al. found a comparable mean respiratory event duration between participants with and without supplemental oxygen therapy, while other studies found that oxygen therapy in participants with OSA increased the apnea duration [13, 30]. Unfortunately, the mean duration of respiratory events was not available from our sleep reports, therefore we are unable to draw conclusions about the effect of supplemental oxygen therapy on the duration of respiratory events in our study population. During the first postoperative night, residual anesthetics and opioids may aggravate respiratory event duration through blunted hypercapnic and hypoxic ventilatory responses [9-11]. However, in our study population, this does not appear to be a factor, as opioid use was similar between the groups.

Another breathing disorder to consider is obesity hypoventilation syndrome (OHS), with an estimated prevalence 15-18% in the MBS population [31, 32]. A randomized cross-over study found that in participants with mild untreated OHS, supplemental oxygen therapy increased CO_2 enough to induce acidemia [33]. Taken together, patients after MBS might be at increased risk for developing hypercapnia if supplemental oxygen is administered, because of an increased prevalence of both OSA and OHS. This could be a reason to administer supplemental oxygen with caution in this population.

In the present study, sleep architecture parameters were similar between participants with and without supplemental oxygen. This is in contrast with the findings of the aforementioned observational study by Chung et al., who found a significantly decreased REM-sleep in patients with supplemental oxygen [9]. Of note, these patients were potentially in a worse clinical state, as supplemental oxygen was solely administered if indicated, which could explain the decreased REM-sleep.

Nursing intervention rates were similar between groups, while the non-O_2 group experienced significantly more desaturations, and the 95% CI of the mean difference of the ODI partially exceeded the non-inferiority limit. This indicates that although more desaturations occurred, these were not severe enough to meet criteria for a nursing intervention. Additionally, the 30-day complication rate was similar between groups, making it questionable if a higher AHI and more desaturations during the first postoperative night is clinically relevant. Especially, as a narrative review found that postoperative complications are more likely to occur in patients with moderate to severe OSA (AHI≥15 e/h), and the median AHI in the non-O_2 group in our study was 5.8 [2.4 - 17.0] [34]. However, this current study was not powered to compare 30-day complication rates between groups. In addition, OSA-related critical postoperative events are rare, but a study from the "OSA Death and Near Miss Registry" found that death and brain damage were more likely to occur in patients that were not respiratory monitored, did not receive supplemental oxygen therapy, and with coadministration of opioid and sedatives [35].

A major strength of this study is the homogenous study population, including only patients with MBS performed according to a standardized general anesthesia protocol, using prespecified criteria for nursing interventions and performing the sleep test under the same conditions. This is in contrast with previous research in which patients with several types of surgery were compared, and sleep tests were carried out in varying settings (both home and hospital settings). A second strength is that nursing interventions were also analyzed, providing valuable insight into the clinical workload when supplemental oxygen therapy is withdrawn. Despite its strengths, this study has some notable limitations. First, no preoperative sleep test was performed. We believe this reflects clinical practice, as patients are not preoperatively tested for OSA in our hospital and some other Dutch bariatric centers. Second, while reporting 30-day complication rate is insightful, no definite conclusions could be drawn as this study was not powered for assessment of the complication rate. Third, the majority of participants is female, however this is a representative sample as the average female proportion undergoing MBS is approximately 80% [36]. Fourth, the participants and healthcare providers were not blinded and the manual reviewer of the raw sleep test data was only semi-blinded, which potentially introduced observer bias. Fifth, with the available software the raw data of the sleep test could only be reviewed once by one reviewer. Although we consider the effect of this to be minimal, as we have assessed the difference between the groups and all data were assessed in the same manner by the same reviewer, it could still potentially impact the absolute AHI values.

In conclusion, in the MBS population with potentially untreated OSA, omitting supplemental oxygen during the first post-operative night was non-inferior to administering oxygen based on AHI. The increased number of desaturations and inferiority of the ODI did not appear to be clinically relevant with relatively low absolute AHI values and

comparable clinical outcomes (i.e. nursing intervention rate, 30-day complication rate) between the O_2 and non-O_2 group, although the current study was not powered to detect differences in clinical outcomes.

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Supplementary table 1. Participant characteristics before undergoing MBS of participants in the intervention group (non-O_2 group) that received oxygen.

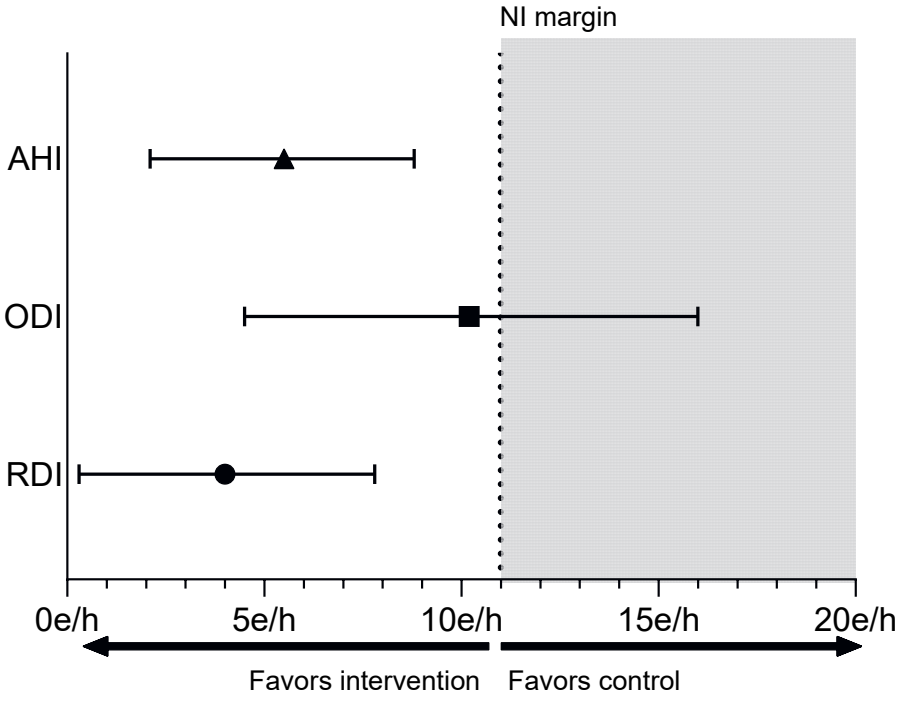
	n=5
Sex (female)	3 (60)
Age (years)	55 [45 - 60]
Body Mass Index (kg/m^2)	44.2 [36.7 - 52.7]
Neck circumference	43.5 [37.0 - 47.0]
STOP BANG score	5.0 [4.0 - 6.5]
ESS	4 [2.5 - 5.0]
Obesity related comorbidities	
None	0.0 (0)
Hypertension	5 (100)
Dyslipidemia	1 (20)
Diabetes mellitus type 2	2 (40)
OSA without treatment	1 (20)
Smoking status	
Non-smoker	2 (40)
Former smoker	2 (40)
Current smoker	1 (20)
Type of surgery	
RYGB	3 (60)
SG	2 (40)

Data are presented as number (percentage), median [Q1-Q3]. MBS: metabolic and bariatric surgery STOP BANG: snoring, tiredness, observed apneas, blood pressure, age, neck circumference, gender, ESS: Epworth sleepiness scale, OSA: obstructive sleep apnea, RYGB: Roux-en-Y gastric bypass, SG: sleeve gastrectomy.

Supplementary table 2. Comparison in the per protocol analysis of saturation measures and sleep architecture between the non-O_2 and O_2 group during the first night after MBS

	Non-O_2 (intervention) (n=63)	O_2 group (control) (n=72)	p-value
Received oxygen	0 (0)	72 (100)	
Saturation			
Mean (%)	92.8 (1.7)	95.6 (1.7)	<.001
Mean of nadirs (%)	91.4 (1.9)	93.7 (1.5)	<.001
Total number of desaturations	61.0 [31.0 – 137.0]	17.0 [7.25 – 52.0]	<.001
Desaturation 3-9%	62.0 [31.0 – 137]	18.5 [9.0 – 53.5]	<.001
SpO_2 <90% in >10% of sleep time (n of participants)	7 (11)	0 (0)	.004
Sleep			
Sleep duration (hrs)	5.5 [4.9 – 6.0]	5.7 [5.2 – 6.3]	.27
% REM sleep	5.1 [2.0 – 9.5]	4.0 [1.6 – 7.2]	.44
% light sleep	79.3 [70.6 – 85.4]	79.5 [74.8 – 84.9]	.49
% deep sleep	15.1 [9.3- 21.4]	15.1 [11.6 – 19.6]	.84
WASO	92.0 [60.0 - 117.0]	104.5 [69.5 – 152.5]	.34
Pulse rate (bpm)	73.6 (12.3)	72.6 (11.0)	.62

Data is presented as number (percentage), mean ± standard deviation, median [Q1-Q3]. MBS: metabolic and bariatric surgery SpO_2: peripheral capillary oxygen saturation, REM: rapid eye movement, WASO: wakefulness after sleep onset.



Supplementary figure 1. Mean difference with 95% confidence intervals between the non-O_2 (intervention) and O_2 group (control) for AHI, ODI and RDI relative to the non-inferiority margin of 11 e/h for the per protocol analysis (n=135). AHI: apnea-hypopnea index, ODI: oxygen desaturation index, NI margin: non-inferiority margin, RDI: respiratory disturbance index

Chapter 6

Postoperative course of sleep-disordered breathing, oxygen saturation and sleep architecture after same-day discharge metabolic and bariatric surgery

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Submitted

Abstract

Purpose: Obstructive sleep apnea (OSA) is known to temporarily deteriorate after surgery, therefore untreated OSA could be a contra-indication for same-day discharge (SDD) metabolic and bariatric surgery (MBS). However, a study in the general surgery population found a peak in apnea hypopnea (AHI) during postoperative night 3 (postN3), when both inpatient and SDD patients already sleep at home. It is unknown if this same pattern occurs in the MBS population.

Methods: In a prospective, observational cohort study (n=38), the postoperative course of sleep disordered breathing, oxygen saturation and sleep architecture in SDD-MBS was assessed. Participants underwent a home sleep apnea test preoperatively (preN), and during postoperative night one (postN1) and postN3.

Results: The highest AHI was found during postN3 (7.5 [3.5-14.8] events/hour (e/h), preN (6.0 [1.9-9.8]), postN1 (6.0 [2.2-15.9]). Sleep duration was comparable over time, the percentage of REM sleep changed over time (preN: 21.9%± 6.6, postN1:12.3% ±6.5, postN3: 21.8% ±7.5). A sub analysis in participants with untreated OSA (n=21), found the highest AHI during postN1: 11.9 e/h [6.5-21.7] (preN (9.7 e/h [6.3-14.7]), postN3: 8.7 [7.4-17.3]). No OSA related postoperative complications occurred.

Conclusion: Based on this study, there is no reason to consider OSA a strict contra-indication for same-day discharge in MBS. The highest AHI was found during postoperative night 3 when both inpatient and same-day discharge patients already sleep at home. However, this must be confirmed in future research because the effect of untreated OSA on the postoperative course of AHI could not be conclusively established.

Introduction

Metabolic and bariatric surgery (MBS) has proven to be a highly effective and sustainable treatment against severe obesity [1]. Same-day discharge after MBS is becoming more common, as accommodating high numbers of MBS is challenging with shortages of medical personnel, and same-day discharge could contribute to increasing efficiency in the use of hospital capacity. Same-day discharge MBS, with proper patient selection and discharge criteria, has proven to be safe with over 50,000 surgeries performed globally [2-4]. Currently, there are no evidence based same-day patient selection and discharge criteria for MBS, which could result in conservative and hospital-specific criteria. In particular, patient selection criteria for obstructive sleep apnea (OSA) diverge between hospitals. In some hospitals, having (untreated) OSA is considered a contraindication for same-day discharge MBS. However, patients are not always routinely screened for OSA preoperatively and the distinction between patients with or without OSA cannot be made.

The reluctance for same-day discharge MBS in patients with untreated OSA is probably because it is known that OSA may worsen after surgery, which could result in an increased risk for respiratory and cardiopulmonary complications. Additionally, although very rare, cases of anoxic brain injuries and unexpected deaths are reported in patients with OSA receiving opioids in the postoperative period [5]. A deterioration of OSA may be reflected by a higher apnea hypopnea index (AHI). Previous research in a population without obesity did find a postoperative increase in AHI, but the highest AHI was documented during the third postoperative night in both participants with and without OSA [6]. We hypothesize that this peak during the third postoperative night is probably due to rebound Rapid Eye Movement (REM) sleep, as a consequence of a decrease in REM sleep during the first postoperative night [7]. However, during this third postoperative night MBS patients (either same-day discharge or inpatient) with a normal postoperative course will already sleep at home. This raises the question whether having (untreated) OSA should be a contraindication for same-day discharge MBS. It is unknown if the same postoperative changes in AHI (and other sleep disordered breathing parameters) and sleep architecture observed in the general surgical population also occur in patients undergoing same-day discharge MBS. Therefore, the aim of this study was to assess the postoperative course of sleep disordered breathing, oxygen saturation and sleep architecture in patients after same-day discharge MBS, and the effect of OSA status and opioid use.

Methods

Study design and population

In this single center prospective, observational cohort study (DAGBAR study), all patients scheduled for primary MBS (Roux-en-Y gastric bypass [RYGB] or sleeve gastrectomy [SG]) with same-day discharge between July 2024 and July 2025 at a large teaching hospital (Rijnstate hospital Arnhem, the Netherlands) were screened for eligibility.

This study was approved by the regional medical ethics review committee (NL86035.091.23, approved March 2024), was registered at clinicaltrials.gov (NCT06452784, June 2024) and reported in accordance with the STROBE (strengthening the reporting of observational studies in epidemiology) guidelines [8]. All participants gave their written informed consent. The preoperative institutional selection criteria for same-day discharge were: having an adult caregiver present during the first postoperative night, reside within a 60-minute radius of the hospital during the first postoperative night, no insulin dependent diabetes, no active implants (e.g. pacemaker), not using a beta-blocker, and not having diagnosed OSA without treatment.

Exclusion criteria for the study were: no same-day discharge, undergoing secondary or revisional MBS, diagnosed OSA with treatment (e.g. continuous positive airway pressure, mandibular advancement devices), use of alpha blockers and being a professional driver. The distinction between treated and untreated OSA could not be made for the majority of the study population, as routine preoperative screening was not performed. Consequently, a portion of the study population likely had undiagnosed and therefore untreated OSA.

The timeline of study measurements can be found in Figure 1. Participants underwent a home sleep apnea test (HSAT) preoperatively (± seven days before surgery), and during the first and third postoperative night with a WatchPAT® ONE (ZOLL Itamar). Manual assessment of the raw data of all HSAT was conducted to identify and correct potential misclassifications by the algorithm. Participants that were preoperatively eligible for same-day discharge, could be excluded postoperatively if same-day discharge was not feasible because postoperative institutional same-day discharge criteria were not met (temperature <38.5°C, heart rate: 50-100 bpm, respiratory rate: 5-25/min, oxygen saturation >94%, no vomiting, able to mobilize independently, numeric pain rating scale <4, minimum fluid intake of 150mL orally and 1500mL intravenously, <1 mmol/L decrease of hemoglobin compared to preoperative measure, and no parenteral administration of piritramide or morphine in the 6 hours before discharge). Additionally, participants were excluded if one of the HSAT failed or was not performed.

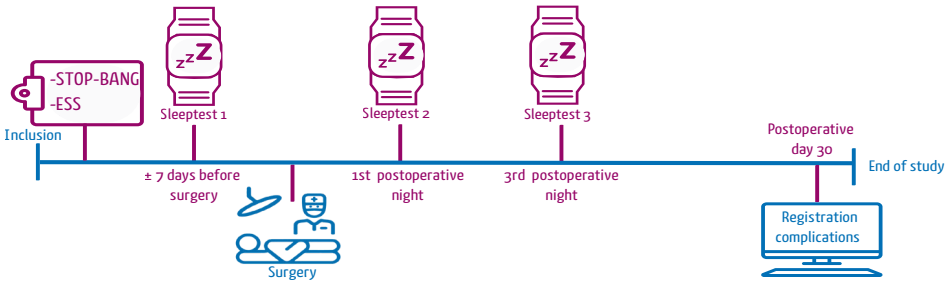

Figure 1. Timeline of the DAGBAR study

All participants underwent MBS under general anesthesia. General anesthesia was induced with intravenous propofol (1-2 mg/kg), sufentanil (10 mcg) and rocuronium (0.2-0.5 mg/kg), and maintained with sevoflurane 0.8-1.0 minimum alveolar concentration and intravenous remifentanil (12.5 mcg/kg ideal body weight/h). Further intraoperative analgesia included intravenous morphine (5 mg), paracetamol (1000 mg) and metamizole (1000 mg). For postoperative analgesia on the post anesthesia care unit and nursing ward paracetamol (1000 mg 4 times a day), tramadol (as needed, 50 mg 3 times a day), or subcutaneous morphine or piritramide (as needed, 7.5-10 mg 4 times a day) was used. At discharge tramadol (as needed, 50 mg maximum 3 times a day) was prescribed for pain management if paracetamol (as needed, 1000 mg maximum of 4 times a day) was not sufficient.

Outcomes

The primary outcome was the difference in AHI over time (preoperative night [PreN], postoperative night one [postN1] and three [postN3]). Secondary outcomes were differences over time in: other sleep disordered breathing parameters (oxygen desaturation index [ODI] and respiratory disturbance index [RDI]), oxygen saturation measures, sleep architecture and the effect of opioids on AHI, effect of OSA status on the postoperative course of AHI, and the 30-day complication rate.

Data collection

The following preoperative data were extracted from the electronic patient records: age, sex, body mass index (BMI), smoking status, medical history and medication use. Moreover, surgery details (e.g. date, duration, type of surgery, perioperative complications), total dose of preoperative and postoperative used opioids, and complications until 30 days postoperative were collected. The complication rate was graded according to the Clavien-Dindo classification: grade I: any deviation from the normal postoperative course, II requiring pharmacological treatment, III: requiring surgical, endoscopic or radiological intervention, IV: life-threating complication, V: death of a patient [9].

To calculate the total intraoperative and postoperative opioid dosage, opioids (parenteral morphine, piritramide, sufentanil, oral tramadol [both used in hospital or at home]) were converted to their oral morphine milligram equivalent (MME) [10, 11].

From the HSAT, the following data were collected: sleep disordered breathing parameters: AHI (3% decrease of SpO_2 from baseline), ODI , RDI; oxygen saturation measures: mean saturation, nadir mean saturation, number of desaturations, peripheral oxygen saturation (SpO_2) <90% for >10% of sleep; sleep architecture: total sleep time (min), percentage of REM sleep, deep sleep and light sleep, wake after sleep onset (WASO, min). Additionally, all participants filled out the Epworth sleepiness scale and STOP BANG questionnaire preoperatively [12, 13].

Sample size

The sample size was calculated using multivariate analysis of variance (repeated measures, within factors) in G-power (v.3.1) [14]. The effect size was calculated by dividing the expected effect by the standard deviation (SD). To calculate the expected effect, we used the smallest difference in AHI we wanted to detect, using data from Chung et al. [6].We used a weighted mean AHI (0.7 AHI patients with OSA, 0.3 without OSA), to better match our population. The smallest difference in weighted AHI was during postoperative night 2 and 3 and was 9.56% [6]. Mean and standard deviation of AHI was based on a previous study within our research group [15]. A log transformation of the AHI was performed, because the AHI was not normally distributed, resulting in a mean of 1.14 and a SD of 0.46. To calculate the expected effect, we took 9.56% of this mean (0.11) and divided by the SD (0.46). This gave an effect size of 0.24. There is no information about the correlation between repeated measures, so we estimated a correlation of 0.2. An effect size of 0.24, correlation of 0.2 together with an α of 0.05 and a power of 0.80, gave a sample size of 48 patients. Due to the high and fluctuating number of patients who were not eligible for same-day discharge after surgery, dropped out patients were replaced until the sample size, or the maximum of 192 HSAT measurements was reached, whichever occurred first, constrained by the study budget.

Statistical analysis

Continuous data were expressed as mean ± standard deviation in case of a normal distribution and as median with [25th percentile (Q1) - 75th percentile (Q3)] for a non-normal distribution. Categorical data were expressed as frequencies (percentage).

Differences of the HSAT parameters (sleep disordered breathing, oxygen saturation and sleep architecture) were analyzed using a repeated measures analysis of variance (normal distribution) or Friedman test (non-normal distribution). The Benjamini-Hochberg correction was used to correct for multiple comparisons. If a significant difference was found, post hoc pairwise comparisons were performed. To assess whether opioid use (MME)

affected the AHI, a linear regression analysis was performed using the relative difference (%) of the AHI between preN and postN1 and preN and postN3. For HSAT parameters a descriptive subgroup analysis was performed for participants with (AHI>5 e/h) or without OSA (AHI ≤5 e/h), based on the preoperative HSAT.

All statistical analyses were performed using SPSS Statistics (v.29.1, IBM, New York, United States). A two-sided p-value of <.05 was considered statistically significant.

Results

A total of 103 participants were enrolled, of whom 38 completed the study and were included for analysis (Figure 2). Participant enrollment was prematurely closed, because the predefined maximum of 192 HSATs was reached. Participants were predominately female (86.8%) with a median age of 40.0 [30.8 - 46.8] years, median BMI of 40.6 [38.1 – 44.6] kg/m^2, STOP BANG score of 3.0 [2.0 – 4.3] and mean ESS of 3.0 ± 2.2 (Table 1). The majority of participants had no obesity-related comorbidities (71.1%), and the most common comorbidity was hypertension (23.7%). The most performed surgical procedure was the RYGB (81.6%).

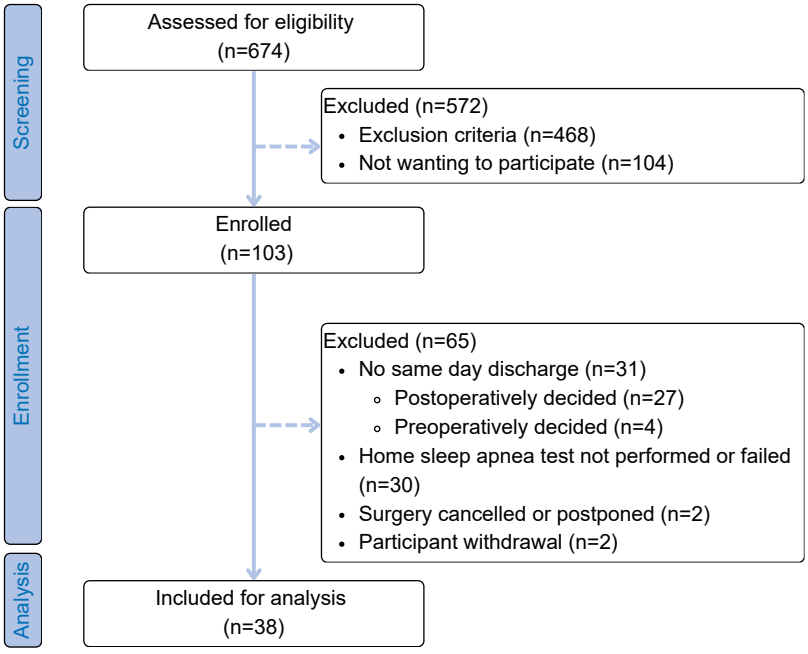

Figure 2. Flowchart for DAGBAR study for participants enrollment and inclusion for analysis

Table 1. Participant characteristics before undergoing MBS

Characteristic	Total population n= 38
Sex (female)	33 (86.8)
Age (years)	40.0 [30.8 - 48.0]
Body Mass Index (kg/m^2)	40.6 [38.1 - 44.6]
Neck circumference (cm)	41.2 ± 3.6
STOP BANG score	3.0 [2.0 - 4.3]
ESS	3.9 ± 2.2
obesity-related comorbidities	
None	27 (71.1)
Hypertension	9 (23.7)
Dyslipidemia	3 (7.9)
Diabetes mellitus type 2	4 (10.5)
Smoking status	
Non-smoker	20 (52.6)
Former smoker	14 (36.9)
Current smoker	4 (10.5)
Type of surgery	
RYGB	31 (81.6)
SG	7 (18.4)

Data are presented as number (percentage), mean ± standard deviation, median [Q1-Q3]. MBS: metabolic and bariatric surgery. STOP BANG: snoring, tiredness, observed apneas, blood pressure, age, neck circumference, gender, ESS: Epworth sleepiness scale, RYGB: Roux-en-Y gastric bypass, SG: sleeve gastrectomy,

Sleep disordered breathing

The median AHI increased over time (Figure and, Table 2), with a significant increase between the preN and postN3 (6.0 [1.9 - 9.8] e/h versus 7.5 [3.5 - 14.8] e/h, p=.003). Median ODI and RDI also increased over time, with a significant difference between preN and postN3 for both ODI (8.6 [3.8 - 18.7] e/h versus 11.6 [6.1 - 18.3] e/h, p=.004) and RDI (9.6 [5.0 - 15.0] versus 12.0 [8.6 - 17.3] e/h, p=.007). For ODI, there was also a significant increase between postN1 and postN3 (6.6 [4.0 - 23.9] e/h versus 11.6 [6.1 - 18.3] e/h, p=.02). Opioid use did not affect the AHI of postN1 (β = 3.7, 95% CI: -0.3 to 7.7) or postN3 (β = 1.8, 95% CI: -0.8 to 11.5).

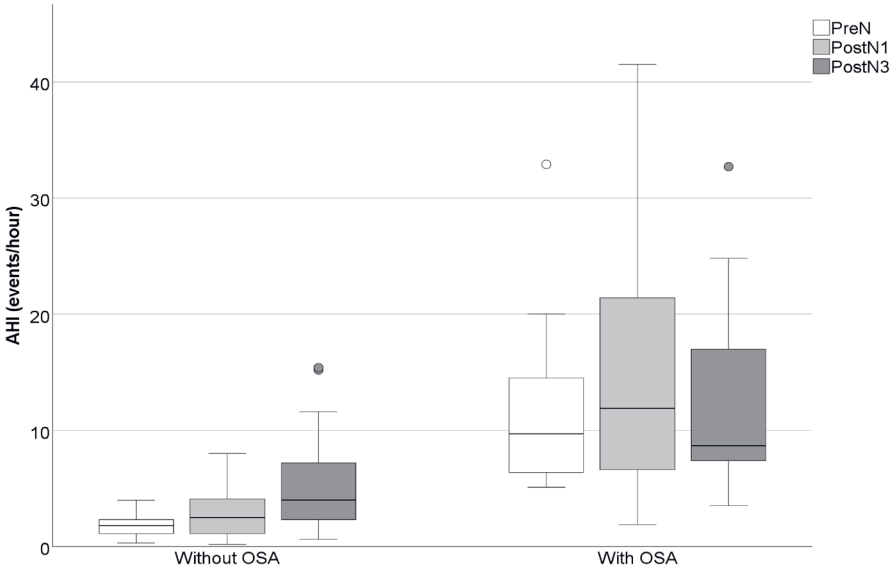

Figure 3. Events per hour of AHI, ODI and RDI over time (preoperative, postoperative night 1 and 3) in 38 participants. AHI: apnea-hypopnea index, ODI: oxygen desaturation index, PostN1: postoperative night 1, PostN3: postoperative night 3, PreN: preoperative night, RDI: respiratory disturbance index.

Table 2. Comparison of sleep disordered breathing parameters, saturation measures and sleep architecture over time (preoperative, postoperative night 1 and 3) in 38 participants undergoing same-day discharge MBS.

	Preoperative night	Postoperative night 1	Postoperative night 3	Effect size			Pairwise comparisons		
				Kendall's W	Partial η^2	p-value	PreN-postN1	PreN-postN3	postN1-postN3
SDB parameters									
$AHI_{3\%}$ (events/hour)	6.0 [1.9 - 9.8]	6.0 [2.2 - 15.9]	7.5 [3.5 - 14.8]	.11		.01*		.003	
$ODI_{3\%}$ (events/hour)	8.6 [3.8 - 18.7]	6.6 [4.0 - 23.9]	11.6 [6.1 - 18.3]	.12		.01*		.004	.02
RDI (events/hour)	9.6 [5.0 - 15.0]	11.1 [4.4 - 18.4]	12.0 [8.6 - 17.3]	.10		.03*		.007	
Saturation									
Mean SpO_2 (%)	94.4 ± 1.2	93.9 ± 1.5	93.7 ±1.6		.18	<.001*	.009	<.001	
Mean SpO_2 nadirs (%)	92.6 ± 1.3	92.3 ±1.6	92.0 ±1.3		.11	.01*		.002	
N of desaturations	58.0 [27.0 - 94.0]	43.0 [16.0 - 43.0]	72.5 [38.5 - 112.8]	.15		.003*		.005	.02
Sleep									
Sleep duration (hrs)	6.2 ± 1.0	5.9 ± 1.5	6.2 ± 1.2		.02	.44			
% REM sleep	21.9 ± 6.6	12.3 ± 6.5	21.8 ± 7.5		.45	<.001*	<.001		<.001
% light sleep	57.1 ± 7.4	70.4 ± 8.9	58.1 ± 9.4		.44	<.001*	<.001		<.001
% deep sleep	21.1 ± 5.3	17.3 ±5.6	20.1 ± 5.7		.126	.007*	.005		.02
WASO (min)	61.5 [41.0 - 87.5]	96.0 [65.0 - 133.8]	61.5 [47.0- 81.5]	.16		.002*	.006		.01

Data are presented as median [Q1-Q3], mean ± standard deviation. * Significant after Benjamini-Hochberg correction. Metabolic and bariatric surgery. postN1: postoperative night 1, postN3: postoperative night 3, preN: preoperative night, SDB: sleep disordered breathing, AHI: apnea-hypopnea index, ODI: oxygen desaturation index, RDI: respiratory disturbance index, SpO_2: peripheral capillary oxygen saturation, REM: rapid eye movement, WASO: wakefulness after sleep onset.

Oxygen saturation measures

Both the mean SpO_2 and the mean SpO_2 of nadirs decreased over time (Table 2), with a significant difference between preN and postN3 (SpO_2: 94.4% ± 1.2 versus 93.7% ± 1.6, p<.001; SpO_2 nadir: 92.6% ± 1.3 versus 92.0% ±1.3, p=.002), and for mean SpO_2 also for preN and postN1 (94.4% ± 1.2 versus 93.9% ±1.5, p=.009). A SpO_2 below 90% for more than 10% of sleep time, was only observed during postN1 in two (5.3%) participants, with 11.1% and 15.1% of SpO_2 <90%, and with mean SpO_2 of 92% and 93% and mean nadir SpO_2 of 90% and 91.%.

Sleep architecture

Duration of sleep was comparable over the three nights, whereas percentage of REM, light and deep sleep differed over these nights (Table 2). Percentage of REM sleep and deep sleep both decreased during postN1 and increased to values comparable with pre-operative during postN3. Percentage of light sleep followed an opposite pattern with an increase during postN1, after which values comparable with preoperative were reached during postN3.

OSA versus non-OSA

Of the 38 participants, 21 (55.3%) had untreated OSA based on the preoperative HSAT (AHI > 5e/h). Highest median AHI was found during postN1 for participants with OSA, and during postN3 in participants without OSA (Table 3, Figure 4). On individual level, 11 (52.3%) participants with OSA had the highest AHI during postN3 compared to 13 (75.5%) in participants without OSA (Supplementary Figure 1 and Figure 2). The number of desaturations followed this same pattern. Mean SpO_2 and mean SpO_2 of nadirs were comparable between participants with and without OSA. The two participants with a SpO_2 <90% for >10% of sleep time during both had OSA. There were no differences in sleep architecture between participants with and without OSA.

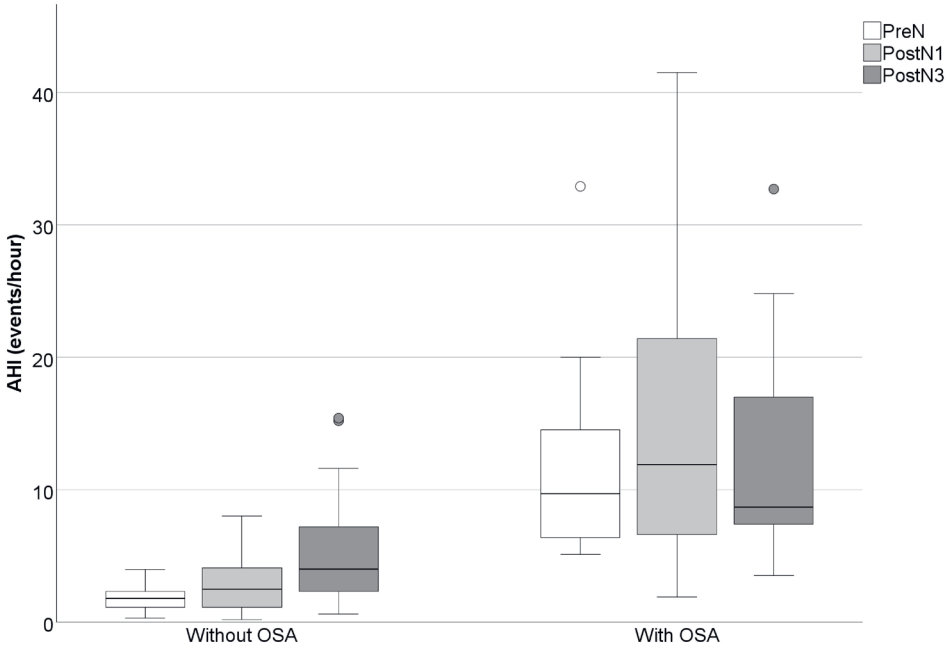

Figure 4. Events per hour of AHI (preoperative, postoperative night 1 and 3) in participants without (n=17) and with OSA (n=21), based upon preoperative AHI (≤5 or >5 events/ hour).
AHI: apnea-hypopnea index , ODI: oxygen desaturation index, PostN1: postoperative night 1, PostN3: postoperateive night 3, PreN: preoperative night.

Thirty-day complication rate

No perioperative complications occurred. Two patients experienced postoperative complications within 30 days after surgery (1 with and 1 without OSA). The first being a Clavien Dindo grade I, with vaginal blood loss, probably due to the weight loss which induced increased estrogen, and not requiring treatment. The second being a Clavien Dindo grade II, with abdominal pain that was treated with an increased dosage of proton pump inhibitors for two weeks, after which pain was resolved.

Table 3. Sleep disordered breathing parameters, saturation measures and sleep architecture stratified for patients with and without OSA

	With OSA n=21			Without OSA n=17		
	Preoperative night	Postoperative night 1	Postoperative night 3	Preoperative night	Postoperative night 1	Postoperative night 3
SDB parameters						
$AHI_{3\%}$ (events/h	9.7 [6.3 - 14.7]	11.9 [6.5 - 21.7]	8.7 [7.4 - 17.3]	1.8 [1.0 - 2.5]	2.5 [0.8 - 4.4]	4.0 [2.2 - 7.8]
$ODI_{3\%}$ (events/	18.1 [11.1 - 23.7]	15.6 [10.9 - 33.8]	15.5 [10.5 - 32.5]	3.6 [1.5 - 4.7]	4.0 [1.0 - 5.7]	6.3 [3.9 - 13.7]
RDI (events/ho	14.7 [12.9 - 18.5]	15.2 [9.1 - 31.9]	14.1 [10.7 - 23.3]	4.9 [3.1 - 6.1]	5.5 [3.1 - 10.5]	9.3 [6.2 - 13.3]
Saturation						
Mean SpO_2 (%)	93.7 ± 1.0	93.3 ± 1.6	93.3 ± 1.2	93.7 ± 1.0	93.3 ± 1.6	93.3 ± 1.2
Mean SpO_2 nadirs (%)	92.1 ± 1.2	91.8 ± 1.7	91.6 ±1.2	92.1 ± 1.2	91.8 ± 1.7	91.6 ± 1.2
N of desaturations	82.0 [68.5 - 144.0]	96.0 [35.0 -165.0]	87.0 [66.5 - 153.5]	27.0 [9.0 - 30.0]	30.0 [7.0 - 38.0]	39.0 [22.5 - 80.5]
Sleep						
Sleep duration (hrs)	6.0 ± 1.1	5.8 ± 1.3	6.0 ± 1.3	6.4 ± 0.8	6.0 ± 1.7	6.3 ± 1.1
% REM sleep	22.3 ± 7.6	13.8 ± 7.0	20.3 ± 7.1	21.4 ± 5.3	10.4 ± 5.4	23.6 ± 7.8
% light sleep	57.7 ± 7.5	69.1 ±10.3	59.3 ± 8.0	56.3 ± 7.4	72.0 ± 6.9	56.5 ±11.0
% deep sleep	20.0 ±4.0	17.1 ± 6.4	20.3 ± 6.1	22.3 ± 6.4	17.6 ± 4.6	19.9 ± 5.4
WASO (min)	55.0 [39.5 - 90.5]	86.0 [58.5 - 122.5]	64.0 [43.5 - 90.0]	68.0 [41.5 - 83.0]	103.0 [75.0 - 142.5]	57.0 [48.5 - 70.0]

Data presented as median [Q1-Q3], mean ± standard deviation. OSA: obstructive sleep apnea, SDB: sleep disordered breathing, AHI: apnea-hypopnea index, ODI: oxygen desaturation index , RDI: respiratory disturbance index, SpO_2: peripheral capillary oxygen saturation, REM: rapid eye movement, WASO: wakefulness after sleep onset.

Discussion

This study aimed to assess the postoperative course of sleep disordered breathing, oxygen saturation and sleep architecture in patients after same-day discharge MBS. In the total study population (irrespective of OSA status), we found that all sleep disordered breathing parameters (AHI, ODI, RDI) and number of desaturations were highest during postN3, compared to the preN and postN1. Sleep duration was comparable over time, but percentage of REM sleep significantly changed over time and in line with the hypothesis decreased during postN1 and increased during postN3. However, in a subgroup with untreated OSA, the median AHI peaked during postN1, while the percentage of REM sleep remained highest during postN3.

This is in contrast with another prospective observational study (n=58) of Chung et al. that found the highest AHI during postoperative night three in both patients with and without OSA [6]. It must be noted that the population of Chung et al. was very heterogeneous. Participants underwent different kind of surgeries varying from ophthalmic to orthopedic surgery under different types of anesthesia (general, spinal and regional). Additionally, sleep tests were performed both at home and in hospitals settings and some patients received supplemental oxygen therapy during one or more nights, which may affect sleep disordered breathing parameters [16]. In contrast, our population is more homogeneous as all participants underwent MBS with a standardized general anesthesia protocol and all sleep tests being performed at home. Nonetheless, it must be acknowledged that our study may be subject to small sample size bias, particularly in the subgroup analyses of patients with and without OSA.

However, even if AHI in patients with untreated OSA peaks during postN1, the clinical relevance is questionable, as the median AHI remains well below 15e/h and a narrative review found that postoperative complications are more likely to occur in patients with moderate to severe OSA (AHI≥15 e/h) [17].

Opioid use could be reason for a higher AHI, as previous research found that opioid use is a risk factor for developing respiratory events [18]. Yet, our linear regression found that the dose of opioids did not affect the AHI in postN1 and postN3 in the total study population. Unfortunately, due to the small study population, it was not feasible to conduct a linear regression analysis that was stratified by OSA status, leaving it uncertain what the effect of opioids in participants with untreated OSA was. An alternative that eliminates the potential effect of opioids on respiratory events is opioid-free anesthesia, which has proven to be effective and reduce postoperative opioid consumption in patients undergoing MBS [19, 20].

When evaluating the saturation measures, we did find a decrease in mean SpO_2 and mean SpO_2 of nadirs over time. However, these small differences of respectively 94.4% to 93.7% and 92.6% to 92.0% are not clinically relevant. Additionally, these measures seem comparable between participants with and without OSA, and only two participants had SpO_2 <90% for >10% of sleep time.

The 30-day complication rate was low, with only two participants (5.3%) with a complication, one with and one without OSA. More importantly, these complications were not OSA or cardiorespiratory related. However, the overall cardiorespiratory complication rate after MBS is low (0.4-1.2%), therefore due to the limited size of our population caution is warranted in drawing definitive conclusions from these results [21].

A strength of this study is the aforementioned homogeneous population. Another strength is that only data of participants who completed all three HSAT was analyzed. In this way, a fair comparison over time could be made, in contrast to previous research in which the majority of participants did not complete all sleep tests. A third strength is that this is the first study to characterize postoperative sleep-disordered breathing in a home setting among participants at high risk for OSA, offering new insights. However, some limitations must be acknowledged as well. First, the required sample size of 48 patients was not reached due to a high dropout rate, mainly because HSAT was not carried out by participants or participants were not found eligible for same-day discharge postoperatively. Second, the population is too small to draw definite conclusions about the 30-day complication rate, the effect of opioid use on the AHI and effect of OSA status on the postoperative course of AHI.

In conclusion, in this population (irrespective of OSA status) undergoing same-day discharge MBS, the highest AHI was found during postoperative night 3 compared to preoperative and postoperative night 1. During postoperative night 3, according to regular clinical practice, both inpatient and same-day discharge patients already sleep at home. However, in a subgroup with untreated OSA, the median AHI peaked during postoperative night one. The clinical relevance of this relatively low peak AHI is questionable. Nevertheless, due to the small size of the study population the effect of untreated OSA on the postoperative course of AHI and its clinical consequences could not be conclusively established. Future research in a comparable population powered to assess the difference in postoperative AHI in participants with and without OSA, preferably with non-opioid anesthesia, is needed to draw definite conclusions.

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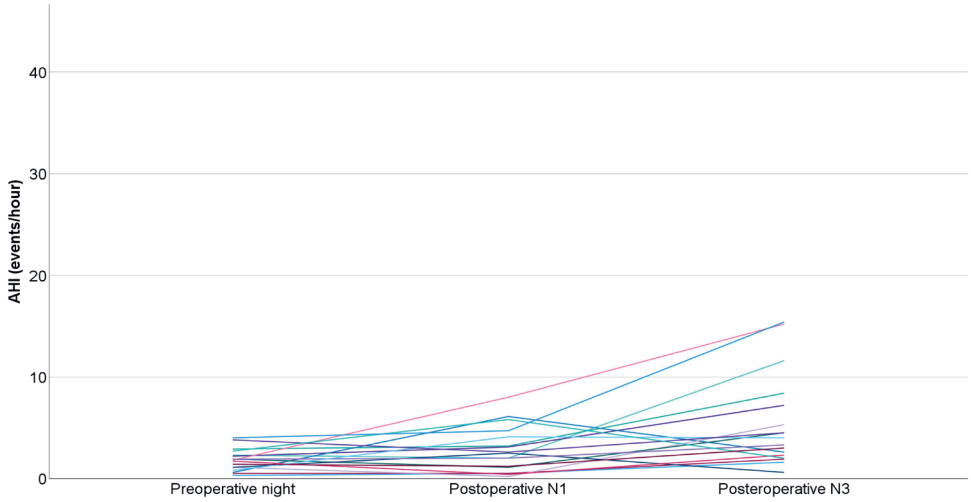
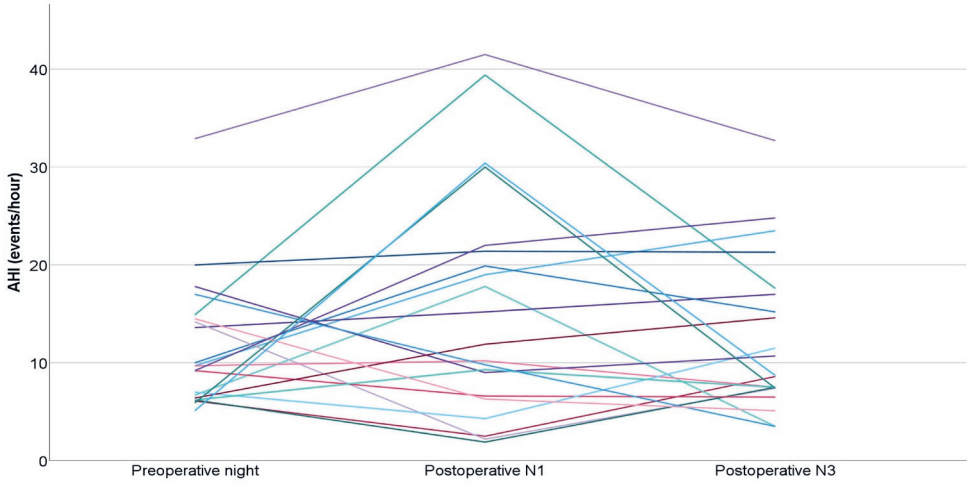


Supplementary Figure 1. The individual postoperative course of the AHI in 17 participants without OSA AHI: apnea-hypopnea index, OSA: Obstructive sleep apnea



Supplementary Figure 2. The individual postoperative course of the AHI in 21 participants with OSA AHI: apnea hypopnea index, OSA: obstructive sleep apnea

Chapter 7

General discussion and future perspectives

The aim of this dissertation was to evaluate and improve perioperative strategies for the management of obstructive sleep apnea (OSA) in metabolic and bariatric surgery (MBS) in both the inpatient and same-day discharge setting, with particular attention to minimizing excessive OSA diagnostics and treatment.

There is a need to evaluate and improve perioperative OSA strategies, as the currently best available evidence is a consensus guideline [1]. This consensus guideline recommends the "sleep test strategy", in which all patients are tested for OSA with poly(somno)graphy before undergoing MBS, and if indicated treatment with continuous positive airway pressure (CPAP) is initiated. However, the added value of this OSA testing and treatment regime is questionable considering that surgically induced weight loss will lead to OSA improvement, and therefore CPAP is often applied for only a short treatment period [2, 3]. A currently used perioperative OSA strategy that minimizes diagnostics and subsequent treatment is the "pulse oximetry strategy". In this strategy, patients are not routinely tested for OSA preoperatively but are postoperatively continuously monitored with pulse oximetry and receive supplemental oxygen therapy (2L/min) until the next morning. This strategy relies on postoperative weight loss as a concomitant treatment for OSA, while perioperative safety is maintained by continuous monitoring and oxygen supplementation [2-4]. A large prospective cohort study (POPCORN study) found the pulse oximetry strategy to be more cost-effective and equally safe compared to the sleep test strategy [4]. Building upon this, this dissertation further explored the feasibility of the pulse oximetry strategy as strategy of choice by comparing the patient-reported outcomes for sleepiness and health related quality of life (HRQoL) between the sleep test strategy and pulse oximetry strategy in the POPCORN study (Figure 1). The additional value of supplemental oxygen therapy within the pulse oximetry strategy was questioned, because oxygen therapy alone does not prevent apneas. This could lead to frequent desaturations requiring nursing interventions generating a high workload for the nursing staff. Therefore, the desaturation rate and nursing intervention rate was characterized in the SATBAR study (Figure 1). Thereafter, as part of improving the pulse oximetry strategy, the value of supplemental oxygen therapy was evaluated in the OXYBAR study. Lastly, the postoperative course of sleep disordered breathing in patients undergoing MBS with same-day discharge who were not preoperatively tested or treated for OSA was assessed in the DAGBAR study. Considering that there are no evidence based same-day patient selection and discharge criteria, and therefore it is unknown if untreated OSA should be contra-indicated for same-day discharge, because OSA may worsen for at least the first week after surgery [5].

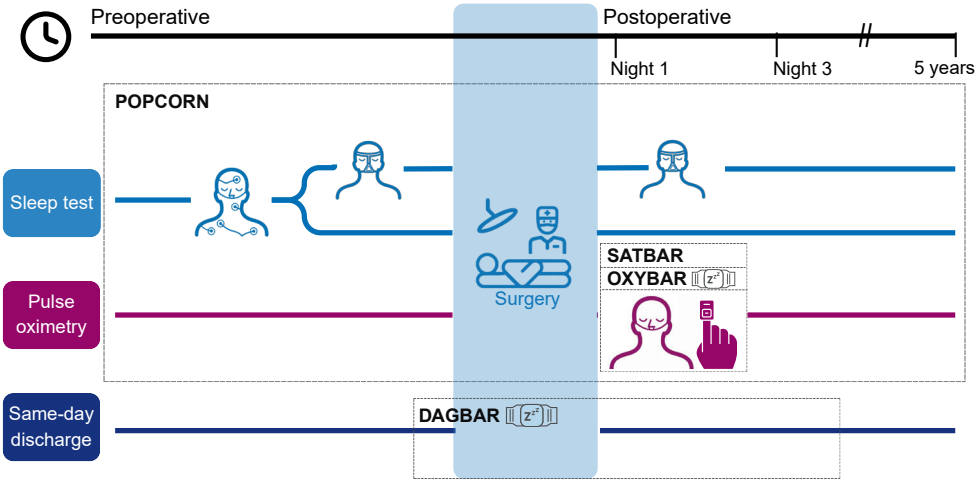


Figure 1. Overview and timeline of the assessed perioperative OSA management strategies and studies performed within this thesis, indicating the timing and specific strategy evaluated in each study

Patient-reported outcomes in the pulse oximetry strategy

As the pulse oximetry strategy does not include preoperative OSA testing, patients with obesity-related OSA may have untreated OSA during the first months after MBS. During this period, it is unknown whether these patients experience more excess daytime sleepiness (EDS), which consequently could impact their daily activities and HRQoL. Additionally, reduced sleep quality and EDS are known to impair weight loss after MBS [2, 6]. Given that OSA is accompanied with reduced sleep quality, it can be postulated that untreated OSA may impair early postoperative weight loss in the pulse oximetry group [6-8]. Therefore, in **Chapter 2** and **Chapter 3,** patients-reported outcomes for EDS, the impact of sleepiness on daily functioning, HRQoL and total weight loss (TWL) were compared between the pulse oximetry and sleep test strategy in the POPCORN study population until 1 and 5 years after MBS. In **Chapter 2** no differences between the strategies were found in EDS, the impact of sleepiness on daily functioning and HRQoL until 1 year postoperative (measured preoperatively and at 1, 3, 6 and 12 months after MBS). The postoperative course of TWL significantly differed between the 2 strategies, but with a maximum difference of 1.6% between the strategies, which was not considered clinically relevant. However, a follow up of 1 year is relatively short, as the median time to reach maximum weight loss is 2 years, and recurrent weight gain occurs in approximately 20-30% of patients after reaching nadir weight, which consequently can affect the severity of OSA [9, 10]. Therefore, in **Chapter 3,** the follow-up was extended until 5 years after MBS. Consistent with the findings up to 1 year after MBS, EDS and the impact of sleepi-

ness on daily functioning were comparable between the two strategies. No clinically relevant differences in HRQoL were found. While in **Chapter 2** a difference in TWL was observed during the 1 year follow up, TWL was comparable during the five year follow up period (measured preoperatively and at 1, 3 and 5 years after MBS). The absence of clinically relevant differences in EDS and its impact on daily functioning can be attributed to the fact that EDS and HRQoL are more strongly associated with obesity than with OSA. A cross-sectional study found BMI to be independently associated with EDS, and metabolic factors (such as obesity) were more strongly associated with EDS than sleep disordered breathing [11]. In addition, even though not directly compared, the increase in HRQoL was more pronounced after MBS than after OSA treatment [2, 12, 13].

Sleep test strategy versus pulse oximetry strategy

In summary, the POPCORN study found that besides being more cost-effective and equally safe, the pulse oximetry strategy is comparable regarding TWL and patient-reported outcomes for sleepiness and HRQoL when compared to the sleep test strategy. The main rationale for pre-operatively testing and treating OSA is because of a supposed increased postoperative complication risk in patients with OSA. However, this increased risk in MBS patients with OSA is questionable. A large retrospective study (n=2872) in patients undergoing MBS found a low rate of (potential) OSA-related complications (0.8%) and this number did not differ between OSA severity classes [14]. Additionally, in the POPCORN study a comparable overall postoperative complication rate was found between the pulse oximetry and sleep test strategy (pulse oximetry: 5.9%, sleep test: 7.9%, p=0.18). On the contrary, a systematic review and meta-analysis published in 2023, did find an increased complication risk in patients with OSA undergoing MBS compared to patients without OSA (RR = 1.23 [CI: 1.01 to 1.5 p = 0.04), which were mostly cardiac complications (RR = 2.44 [CI: 1.26 to 4.76] p = 0.009) [15]. Remarkably, only 1 (n=830) out of 9 studies (total n=4865) included in this systematic review found an increased complication risk in OSA patients. This inconclusive evidence tends to suggest that there is no increased risk of postoperative complications in MBS patients with OSA.

In addition, a recent study showed that 6 months after MBS, patients who were preoperatively newly diagnosed with OSA used CPAP adequately in only 27%, compared to 61% in patients with pre-existent OSA [16]. CPAP adherence is a known challenge in OSA treatment with adherence rates ranging from 17% to 85% [17]. Factors attributing to poor CPAP adherence include mask discomfort, air leaks, nasal congestion, abdominal bloating and difficulty tolerating the positive pressure [17]. Additionally, it is known that in asymptomatic patients CPAP adherence is even lower, because the discomfort outweighs the benefits [18]. Therefore, it can be postulated that a majority of the patients in the sleep test strategy who are newly diagnosed with OSA as part of routine pre-operative

testing and not because of symptoms, do not carry a significant symptomatic burden of their OSA. This could explain the low CPAP adherence in patients who are preoperatively newly diagnosed with OSA. Considering the poor CPAP adherence and inconclusive evidence regarding the postoperative complication rate in MBS patients with OSA, one could argue that the focus should shift towards using a more cost-effective strategy for OSA management. If the pulse oximetry strategy would be implemented as the standard in bariatric care, it could substantially reduce the number of sleep tests, thereby increasing sleep laboratory capacity for patients who actually have symptoms caused by sleep disordered breathing conditions. In addition, if solely the pulse oximetry strategy was used in bariatric care it could save an estimated €2.7 to €3 million per year in the Netherlands [4]. This could be an important cost saving, with rising healthcare costs leading to concerns about maintaining the Dutch healthcare affordable. The comparable clinical and patient-reported outcomes of the pulse oximetry and sleep test strategy, together with potentially low CPAP adherence in the sleep test strategy, and the pulse oximetry being more cost-effective, advocate for the pulse oximetry as the strategy of choice in bariatric care.

Desaturation and nursing intervention rate in the pulse oximetry strategy

Patients in the pulse oximetry strategy may have untreated OSA. The oxygen administered in the pulse oximetry strategy may improve baseline saturation, but does not prevent collapse of the upper airway, which could cause apneas with desaturations in untreated OSA patients [16, 17]. These desaturations might may require nursing interventions, such as waking up a patient or increasing oxygen flow. This could impose a high workload for the nursing staff, especially considering that these desaturations occur during the night, when nursing staff level is reduced. This does not apply for the sleep test strategy in which patients with OSA will continue using their CPAP mask in the hospital during the first postoperative night, as they do at home. In this way, desaturations in OSA patients are prevented, while patients without OSA are considered not to have an increased desaturation risk. Therefore, both patients with and without OSA in the sleep test strategy are not continuously monitored, thus even if desaturations occur, the nursing staff will not know and therefore can not intervene. However, the desaturation rate and its consequences for the workload of the nursing staff in the pulse oximetry strategy are unknown. Therefore in **Chapter 4**, the number of desaturations and nursing interventions in the pulse oximetry strategy during the first night after MBS were characterized in a prospective observational study (SATBAR study, n=385). Additionally, patient-related risk factors for developing desaturations while receiving supplemental oxygen were documented. The results from the SATBAR study showed that 22% of participants had a median of 3 [2 - 6] desaturations during the first postoperative night, and 14% of participants needed

nursing interventions (median of 1 [1 – 2)]. All nursing interventions were noninvasive (e.g. waking up the patient, putting back the nasal canula, increasing oxygen flow). The relatively low desaturation rate was unexpected in this population with an expected high prevalence of participants with untreated OSA. Especially, since supplemental oxygen alone does not prevent apneas and desaturations occur in the majority of apneic events, and more than 5 apneas and/or hypopneas per hour are required for an OSA diagnosis [19, 20]. The low desaturation rate measured in the SATBAR study might be explained by a reduced sleep quality and quantity in hospitalized patients [21]. Another explanation could be the definition for desaturation used in the SATBAR study, where a desaturation was scored if a patient had a saturation of peripheral oxygen (SpO_2) <90%. This deviates from the definition used in sleep tests in which a desaturation is defined as a decrease of ≥3% from baseline SpO_2. The saturation in the SATBAR was high (98% [97-99]) presumably due to the administered oxygen, consequently a decrease of 8% is required for desaturation to be scored. This is a relatively large decrease that is less likely to occur because a SpO_2 of 96-100% is positioned further to the right on the dissociation curve and therefore a greater amount of oxygen must be consumed to achieve a desaturation compared to a SpO_2 of 90% [22].

The nursing intervention rate of 14% can be considered relatively low, and shows that not every patient with a desaturation requires a nursing intervention. Regrettably, only the intervention rate per patient was registered, and not the total intervention rate per night. As a result, the exact nursing intervention rate per night, and consequently the workload per night remains unclear. However, it can be estimated that with a maximum of six bariatric procedures performed per day fewer than one (14% of 6: 0.84) desaturation-related nursing intervention per night is expected. This illustrates that the pulse oximetry does not provide a high workload for nurses. Secondary analysis of the data from the SATBAR study showed that male sex, higher age, higher BMI and smoking were risk factors for developing desaturations. This is largely consistent with previous research in the general surgery population, with reoccurring risk factors being BMI, age and current smoking [23-25]. Remarkably, male sex was not found to be a reoccurring risk factor for desaturation in previous research. This is probably due to the fact that in two of the three studies patients with OSA were excluded. Risk factors found in the SATBAR study indicate that patients with OSA are prone to developing postoperative desaturations even with supplemental oxygen suppletion, as male gender, higher age and BMI are well known OSA-related risk factors [26]. Which is in line with the assumption that oxygen therapy alone does not prevent apneas in patients with OSA. Supplemental oxygen therapy is administered in the pulse oximetry strategy to prevent desaturations in those with potentially undiagnosed OSA. However, based on the risk factors found in the SATBAR study one could postulate that particularly patients with OSA continue to experience desaturations, questioning the added value of supplemental oxygen in the pulse oximetry strategy.

Based on the outcomes of the POPCORN and SATBAR study, we can conclude that the pulse oximetry is a viable option as OSA strategy of choice in bariatric care. The pulse oximetry strategy minimizes OSA diagnostics and treatment and therefore is found to be more cost-effective, with comparable complication rate, TWL, and patient-reported outcomes for sleepiness, daily functioning and HRQoL when compared to the sleep test strategy without imposing a high workload for the nursing staff. However, there might be room for further optimization of the pulse oximetry strategy by evaluating the value of supplemental oxygen therapy in this strategy.

The value of supplemental oxygen therapy in the pulse oximetry strategy

To assess the value of supplemental oxygen therapy within the pulse oximetry strategy, in **Chapter 5** a randomized non-inferiority trial (OXYBAR trial) was conducted. The OXYBAR trial aimed to evaluate if omitting supplemental oxygen is non-inferior to administering oxygen during the first night after MBS, by allocating participants to have supplemental oxygen therapy administered or not (O_2 group versus non-O_2 group), while undergoing a sleep test (WatchPAT®300). The results from the OXYBAR trial indicated that omitting supplemental oxygen therapy, based on the difference in mean AHI, is non-inferior to administering oxygen, as the 95% confidence interval ([CI]; 95% CI: 2.7 to 9.9 events/hour [e/h])) remains below the predefined non-inferiority margin of 11e/h. Additionally, low absolute median AHI values in both groups were found (non-O_2: 5.8 [2.4 - 17.0] versus O_2: 2.2 [0.8 - 5.4] e/h) and sleep architecture, nursing intervention rate and 30-day complication rate were comparable between the O_2 and non-O_2 group. In contrast, significantly more desaturations were observed in the non-O_2 group (61.5 [31.0 -140.8] vs 17.0 [7.3 - 52.0]) and the oxygen desaturation index (ODI) of the pulse oximetry strategy was inferior compared to the sleep test strategy. The fact that the nursing intervention rate was comparable between the two groups, indicates that the desaturations that occurred were not severe, long or frequent enough for the nurses to intervene. Which is probably due to the fact that in a sleep test a 3% difference of baseline saturation of peripheral oxygen (SpO_2) is defined as desaturation. While only a SpO_2 decrease of 3% is generally of limited clinical relevance, as an intervention within the pulse oximetry strategy is indicated when SpO_2 falls below 90%. This is confirmed by the mean SpO_2 found in the OXYBAR study, which for both groups was around 93% or above (non-O_2 group; 92.7% ± 1.7, O_2-group 95.6% ±1.4). In the OXYBAR trial, strict criteria for nursing interventions were used to ensure equal treatment of participants. These criteria were designed to minimize interventions, while pursuing patient safety. Theoretically, nursing intervention rates could be understated and desaturation rates could be overstated, as nurses might intervene earlier in clinical practice without these criteria. Although the OXYBAR trial was not powered to assess the complication rate, the observed median AHI supports the low 30-day compli-

cation rate, as postoperative complications are generally more common in patients with moderate to severe OSA (AHI≥15 e/h) and the median AHI in the non-O_2 group was below 15 e/h [27]. However, the 75th percentile was slightly above this threshold with 17.0 e/h, indicating that part of the non-O_2group may be at an increased postoperative risk. Nonetheless, there may be an increased risk of hypercapnia in patients receiving supplemental oxygen due to general anesthesia and opioid use, particularly given the relatively high prevalence of obesity hypoventilation syndrome (15-68%) in patients undergoing MBS [28-31]. Furthermore, administration of supplemental oxygen leads to additional costs and environmental carbon dioxide emission, and patients frequently complain about the discomfort of the nasal canula [32]. Lastly, previous research showed that the AHI increases after general surgery but peaked during the third postoperative night, in both participants with and without OSA [5]. During this third postoperative night, MBS patients with a normal postoperative course will already sleep at home, without supplemental oxygen therapy.

Therefore, based on these results, it can be concluded that omission of routine supplemental oxygen therapy during the first postoperative night is justified, as the benefits of omitting supplemental oxygen therapy outweigh the potential drawbacks.

Perioperative management of OSA in same-day discharge MBS

In the last section of this dissertation, same-day discharge after MBS in a population with unknown OSA status was studied. Same-day discharge after MBS is the most recent development in perioperative MBS care and has proven to be safe if proper patient selection and discharge criteria are used [33-35]. However, there is no consensus whether untreated OSA should be regarded as a contra-indication for same-day discharge after MBS, as evidence regarding this subject is unavailable. At Rijnstate hospital, where the pulse oximetry strategy is used, the distinction between patients with and without OSA cannot be made for all patients, as patients are not routinely preoperatively tested for OSA. Both preoperatively and postoperatively strict criteria for same-day discharge are applied, to minimize the (cardiopulmonary) complication risks. The pre-operative criteria including: having an adult caregiver present during the first postoperative night, reside within a 60-minute radius of the hospital during, no insulin-dependent diabetes, no active implants (e.g. pacemaker), not using a beta-blocker, and not having diagnosed OSA without treatment. Postoperative same-day discharge criteria include a respiratory rate of 5-25/min, oxygen saturation of >94% and no opioid use in the six hours before discharge. According to a study in patients undergoing general surgery, the median AHI does not peak during the first, but during the third postoperative night in both patients with and without OSA [5].The hypothesis is that this peak is due to rebound rapid eye movement (REM)

sleep during the third postoperative night, as a consequence of decreased REM sleep during the first postoperative night [5, 36]. Interestingly, this peak in AHI during the third postoperative night has never been assessed in the MBS population. Moreover, MBS patients with an uneventful postoperative course will sleep at home on postoperative night three as they are usually discharged on the same day or the following day. Therefore, the aim of the prospective cohort study (DAGBAR study), described in **Chapter 6,** was to gain knowledge for evidence-based discharge criteria in patients undergoing same-day MBS by assessing the postoperative course of sleep disordered breathing, oxygen saturation and sleep architecture. Participants in the DAGBAR study underwent a home sleep apnea test, using peripheral arterial tonometry (PAT) for its measurements (WatchpatONE®), approximately one week prior to surgery and during postoperative night 1 and 3. The results of the DAGBAR study showed that all sleep disordered breathing parameters (AHI, oxygen desaturation index [ODI], RDI) and number of desaturations were highest during postoperative night 3, compared to preoperative and postoperative night 1. In line with the hypothesis, the percentage of REM sleep decreased during postoperative night 1 and increased during postoperative night 3. The 30-day overall complication rate was 5.3%, of which none were cardiorespiratory related.

However, in a sub-analysis involving only participants with a preoperative AHI >5 e/h, the median AHI peaked during postoperative night 1 instead of 3 (Night 1: 11.9 e/h [6.5 - 21.7], night 3: 8.7 e/h [7.4 - 17.3], while the percentage of REM sleep remained highest during postoperative night 3. This is in contrast with the prospective observational study by Chung et al. who found the highest AHI during postoperative night 3 in both patients with and without OSA [5]. This difference in findings might be attributable to several causes. First, the population of Chung et al. was very heterogeneous, participants underwent different types of surgeries varying from ophthalmic to orthopedic surgery under different types of anesthesia (general, spinal and regional). Second, the sleep tests were performed both at home and in hospitals settings, which can impact the results as it is known that sleep quality and quantity is reduced in hospitalized patients [21]. Third, some patients received supplemental oxygen therapy during one or more postoperative nights, which is likely to affect sleep disordered breathing parameters [37]. In contrast to the study by Chung et al., our study population was more homogeneous and all sleep tests were performed at home. Another difference was the type of sleep test used. Chung et al. used polysomnography, and in our study PAT was used. In PAT, unlike polysomnography, airflow is not directly measured. Instead, an algorithm uses peripheral arterial volume changes (measured by a finger-mounted plethysmograph), oxygen saturation, heart rate and actigraphy to determine if a respiratory event occurred [38]. Although polysomnography is considered the gold standard in the diagnosis of OSA, PAT has been approved by the American Academy of Sleep Medicine. The literature is inconclusive regarding the correlation between polysomnography and PAT outcomes, but the overall conclusion tends to be that PAT overestimates AHI compared to polysomnography [38-

42]. The reason PAT was the sleep test of choice for the DAGBAR (and OXYBAR) study, was because it is less invasive, easier to conduct, and less expensive. Considering that the PAT measurements were compared over time and that the raw sleep test data were manually reviewed resulting mainly in a lower AHI, the potential for overestimation was not considered an issue within the study design. Another reason for the AHI peak during postoperative night 1in the sub-analysis among participants with a preoperative AHI >5 e/h, could be a post-anesthetic effect, as all patients in the DAGBAR study underwent surgery with general anesthesia. However, a prospective observational study (part of the aforementioned study by Chung et al.), comparing postoperative AHI after general and regional anesthesia in participants, found no difference between anesthesia method for both participants with and without OSA [43]. This prospective study by Chung et al. did find 72-h opioid use to be positively associated with postoperative AHI, however in the DAGBAR study opioid use was not found to affect the postoperative AHI. Therefore, we have no theoretical explanation for the peak in AHI during the first postoperative night while REM sleep remains highest during postoperative night 3, in participants with a preoperative AHI >5 e/h, aside from a small sample size bias. This small sample size bias is supported by the fact that the DAGBAR study was not powered for a sub analysis and the intended sample size of 48 was not met due to a high drop-out rate (n=38 instead of n=48).

In both the OXYBAR study and DAGBAR study all median AHI values remained below 15 e/h. This could explain why MBS patients with OSA do not appear to have an increased postoperative complication risk, because postoperative OSA-associated complications are more likely to occur with an AHI ≥15 e/h [27]. However, it must be considered that even though low median AHI values were found, a small part of the participants did exhibit a AHI ≥15 e/h, some even reaching up to 40 e/h. These participants are more likely to be at increased risk of postoperative complications. However, even if a small subset of patients has an increased postoperative complication risk, the clinical consequences for same-day discharge are questionable. As aforementioned patients must adhere to strict preoperative and postoperative criteria to be eligible for same-day discharge, with the aim to reduce the (cardiopulmonary) complication risk. Even if a complication occurs, the discharge criteria require that an adult caregiver is present and that the patient resides within 60 minutes of the hospital, thereby ensuring timely access to treatment under normal circumstances.

Patients with same-day discharge do not receive supplemental oxygen therapy, nonetheless this does no appear to be an issue. Based on the results from the OXYBAR study we can conclude that supplemental oxygen therapy should be administered selectively and not routinely. Which is addressed by the discharge criteria, which specify that only patients with a oxygen saturation >94% are eligible for same-day discharge.

In summary, these findings suggest that there is no strict reason to consider OSA a contra-indication for same-day discharge in the general bariatric population, as the highest AHI was observed during postoperative night 3, when all patients (inpatient and same-day discharge) with a normal postoperative course will be at home. In addition, the median AHI during all postoperative nights was low. A small subset of patients with a AHI≥ 15 e/h might be at an increased postoperative complication risk, however the same-day discharge criteria, under normal conditions, ensure timely hospital access even in the event of a complication.

Conclusions and future perspectives

Based on the outcomes of this dissertation combined with knowledge from the available literature, there should be a shift towards a more pragmatic approach of perioperative OSA management for both inpatient and same-day discharge MBS. This approach should no longer include routine pre-operative OSA testing. Unfortunately, the studies in this dissertation were not powered to draw conclusion regarding the complication rate, as large sample sizes are needed and this was not practically feasible. However, a small subset of participants had a postoperative AHI ≥15 e/h, which may increase their post-operative complication risk. From a pragmatic perspective, it would be irrational to keep routinely testing all patients preoperatively, for only a small subset of patients with an presumably increased complication risk. Ideally, a tool or score should be developed that preoperatively predicts which patients have an increased OSA-associated postoperative complication risk and would benefit from OSA treatment. But similarly, to develop such a tool extensive research with large sample sizes are required, and only a small part of the MBS population would benefit. Therefore, future research should be directed towards reducing the postoperative deterioration of OSA in perioperative OSA management strategies without preoperative OSA testing, for example by assessing the effect of opioid free anesthesia and postoperative pain management. Instead of focusing on assessing the exact complication risk. This way all patients undergoing MBS will benefit and not only those with (severe) OSA. Although in this dissertation (**Chapter 4** and **6**) no correlation between AHI and opioid use was found, previous research have shown that patients with OSA have an increased risk for opioid-induced respiratory depression which could consequently worsen OSA postoperatively [44]. Opioid-free anesthesia is a method to avoid these opioid-induced respiratory depressions. A meta-analysis found that opioid-free anesthesia in MBS decreases postoperative pain and morphine use [45]. This was confirmed by a recent randomized controlled trial comparing opioid-free and opioid-based anesthesia in MBS, which in addition found an increased patient satisfaction rate [46]. However, the effect of opioid-free anesthesia on the postoperative course of sleep disordered breathing in patients with OSA has not been assessed in the MBS population. In addition to opioid-free anesthesia, it is interesting to assess the effect of

opioid free postoperative pain management. This is challenging as nonsteroidal anti-inflammatory drugs (NSAIDs) are contra-indicated after MBS because of an increased risk of anastomotic ulcerations, perforations, and leaks [47]. However, this applies particularly to chronic use, as NSAID use in the early postoperative period (day 0-3) after MBS is found to sufficiently reduce pain without increasing postoperative complication rate [47-49]. Nevertheless, it can be confusing for patients to have NSAID prescribed upon discharge, while it is contra-indicated after this early postoperative period. However, with the right counseling NSAIDs instead of opioids in the early postoperative period should be a feasible measure.

In conclusion, the pulse oximetry strategy is a viable option for perioperative OSA management in patients undergoing MBS. It avoids excessive OSA diagnosis and subsequent treatment and is therefore more cost-effective. In addition, it offers comparable outcomes regarding safety, total weight loss and patient-reported outcomes for excess daytime sleepiness, impact of sleepiness on daily functioning and health-related quality of life until 5 years after MBS without imposing a high workload for the nursing staff. The pulse oximetry strategy can be further optimized by administering oxygen selectively, as no clinically relevant difference in AHI and comparable sleep architecture, nursing intervention rate and 30-day complication rate were found between the non-O_2 and O_2 group. Besides cost savings and less inconvenience for the patient, this may also mitigate the risk of hypercapnia associated with oxygen supplementation in the MBS population. The current trend towards same-day discharge in MBS should not pose a barrier to widespread adoption of the pulse oximetry strategy, as there appears to be no strict reason to consider OSA a contraindication for same-day discharge in the general bariatric population. Future research should be directed towards reducing the postoperative deterioration of OSA in perioperative OSA management strategies without preoperative OSA testing, for example by assessing the effect of opioid free anesthesia and postoperative pain management.

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Summary

English summary

The prevalence of (obesity-related) obstructive sleep apnea (OSA) is high (70-94%) in patients undergoing metabolic and bariatric surgery (MBS). Patients with OSA may have an increased risk of postoperative complications, although evidence in the MBS population remains inconclusive. Currently, the best available evidence for the perioperative management of OSA in MBS is a consensus guideline from 2017, which may be outdated as practices such as same-day discharge were not yet widely adopted at that time.

Therefore, the aim of this dissertation was to evaluate and improve perioperative strategies for the management of OSA in MBS, in both the inpatient and same-day discharge setting, with particular attention to minimizing excessive OSA diagnostics and treatment.

In the Netherlands, there are two strategies that are mainly used:

1. "Sleep test strategy", in which all patients are preoperatively tested for OSA with poly(somno)graphy, and subsequently treated with continuous positive airway pressure (CPAP) if indicated.
2. "Pulse oximetry strategy", in which patients are not preoperatively tested for OSA, but are postoperatively continuously monitored with pulse oximetry and receive supplemental oxygen therapy (2L/min) until the next morning.

The consensus guideline recommends using the sleep test strategy, while the added value of OSA testing and subsequent treatment is questionable. Considering that surgically induced weight loss will lead to OSA improvement, subsequent CPAP therapy is often applied for only a short treatment period. The pulse oximetry strategy might be a viable alternative, as it minimizes OSA diagnostics and treatment. A large prospective cohort study (POPCORN study, n=1390) compared the sleep test strategy and the pulse oximetry strategy and found the pulse oximetry strategy to be more cost-effective and equally safe.

Elaborating on this, in **Chapter 2** and **Chapter 3** of this dissertation, total weight loss and patient-reported outcomes for sleepiness and health related quality of life were found to be comparable between the sleep test strategy and pulse oximetry strategy in the POPCORN study population until 1 year (**Chapter 2**) and 5 years (**Chapter 3**) after MBS.

In **Chapter 4,** the desaturation rate and nursing intervention rate during the first postoperative night was characterized in the pulse oximetry strategy in a prospective observational study (SATBAR study). Though the oxygen administered in the pulse oximetry strategy may improve baseline saturation, it does not prevent collapse of the upper airway in untreated OSA patients. This collapse of the airway could lead to desaturations, which may require nursing interventions and potentially result in a high workload for the

nursing staff. The results of the SATBAR study showed a relatively low desaturation rate (22%) and nursing intervention rate (14%), and that male sex, higher age, higher BMI and smoking were risk factors for developing postoperative desaturations. These findings indicate that the pulse oximetry does not impose a high workload for the nursing staff. Furthermore, it can be postulated that desaturations presumably occur more frequently in patients with (undiagnosed) OSA as risk factors for desaturation largely correspond with risk factors for OSA, which is in line with the assumption that oxygen therapy alone does not prevent apneas.

To evaluate if omitting supplemental oxygen is non-inferior to administering oxygen during the first night after MBS, a randomized non-inferiority trial (OXYBAR trial) was performed in **Chapter 5.** The results of the sleep test (WatchPat300®) showed that based on the apnea-hypopnea index (AHI), omitting supplemental oxygen was non-inferior to administering supplemental oxygen therapy. The increased desaturation rate and inferiority of oxygen desaturation index (ODI) appear not to be clinically relevant with low absolute AHI values and similar outcomes for sleep architecture, 30-day complication rate and nursing intervention rate.

In **Chapter 6,** the postoperative course of sleep disordered breathing (including AHI), oxygen saturation and sleep architecture were assessed in same-day discharge after MBS in a population with an unknown OSA status. In order to gain knowledge for evidence-based patient selection and discharge criteria for patients undergoing same-day MBS. This was assessed in a prospective observational study (DAGBAR study), in which patients underwent a sleep test (WatchpatONE®) at home, approximately 1 week prior to MBS and during postoperative night 1 and 3. The DAGBAR study showed that all sleep disordered breathing parameters (AHI, ODI, RDI) and number of desaturations were highest during postoperative night 3, compared to preoperative and postoperative night 1. In line with the hypothesis, the percentage of rapid eye movement sleep decreased during post-operative night one and increased during postoperative night three. The 30-day overall complication rate was 5.3%, of which none were cardiorespiratory related.

In conclusion, the pulse oximetry strategy in optimized version without routine post-operative oxygen suppletion is a viable option for perioperative OSA management in MBS. The pulse oximetry strategy minimizes diagnostics and treatment while being more cost-effective and equally safe and with comparable total weight loss and patient-reported outcomes for sleepiness, daily functioning and health-related quality of life. The trend towards same-day discharge in MBS should not pose a barrier to the widespread adoption of the pulse oximetry strategy, as there appears to be no strict reason to consider OSA a contraindication for same-day discharge in the general bariatric population. Future research should be directed toward reducing the postoperative deterioration of OSA in perioperative OSA management strategies without preoperative OSA testing, for

example by assessing the effect of opioid free anesthesia and opioid free postoperative pain management.

Nederlandse samenvatting

Bij patiënten die een maagverkleinende operatie, ook wel metabole en bariatrische chirurgie genoemd, ondergaan heeft 70-94% obstructief slaapapneu. Bij obstructief slaapapneu stoppen patiënten tijdens het slapen meerdere keren per uur met ademhalen door het samenvallen van de bovenste luchtweg. Patiënten met slaapapneu kunnen een verhoogd risico hebben op het ontwikkelen van complicaties na de operatie, maar het is onduidelijk of dit ook geldt voor patiënten die een maagverkleinende operatie ondergaan. Momenteel is er alleen een richtlijn uit 2017 beschikbaar waarin adviezen worden gegeven over hoe om te gaan met slaapapneu rondom maagverkleinende operaties. Deze richtlijn is mogelijk wat verouderd, omdat er sindsdien nieuwe ontwikkelingen zijn, zoals het uitvoeren van maagverkleinende operaties in dagbehandeling.

Het doel van dit proefschrift was om verschillende strategieën voor het omgaan met slaapapneu rondom maagverkleinende operaties te evalueren en te verbeteren, met de nadruk op het verminderen van overmatige slaapapneu diagnostiek en behandeling.

In Nederland worden er overwegend twee strategieën gebruikt:

1. De "Slaaptest strategie", waarin alle patiënten voor de operatie worden getest op slaapapneu met een slaaptest (poly(somno)grafie) en vervolgens worden behandeld met een masker dat met druk een continue luchtstroom in de bovenste luchtwegen blaast.
2. De "Pulsoximetrie strategie", waarin patiënten niet voor de operatie getest worden op slaapapneu, maar na de operatie continu worden gemonitord met pulsoximetrie (een meter aan de vinger die zuurstof en hartslag meet) en zuurstof krijgen toegediend tot de ochtend na de operatie.

In de richtlijn uit 2017 wordt de slaaptest strategie aanbevolen, terwijl de toegevoegde waarde van het vóór de operatie testen op slaapapneu en het vervolgens behandelen hiervan grotendeels onduidelijk is. Daarnaast zal het gewichtsverlies na de maagverkleinende operatie zorgen voor een verbetering van de slaapapneu, waardoor er meestal maar relatief kort behandeling voor slaapapneu nodig is. De pulsoximetrie strategie zou een goed alternatief kunnen zijn, omdat deze tot minder diagnostiek en dus mogelijk onnodige behandeling van slaapapneu leidt. In een grote studie met 1390 deelnemers (POPCORN studie) werd de slaaptest strategie met de pulsoximetrie strategie vergeleken en bleek dat de pulsoximetrie strategie kosteneffectiever en even veilig is.

Hierop voortbordurend bleek uit de resultaten van **hoofdstuk 2** en **hoofdstuk 3** van dit proefschrift dat het gewichtsverlies, de slaperigheid en de aan gezondheid gerelateerde kwaliteit van leven vergelijkbaar zijn tussen de slaaptest strategie en de pulsoximetrie

strategie in de deelnemers van de POPCORN studie tot één jaar (**hoofdstuk 2**) en vijf jaar (**hoofdstuk 3**) na de maagverkleinende operatie.

In **hoofdstuk 4** werd het optreden van zuurstofdalingen (desaturaties) en van verpleegkundige interventies, zoals het wakker maken van patiënten of het ophogen van de zuurstof tijdens de eerste nacht na de maagverkleinende operatie in kaart gebracht in SATBAR studie. Hoewel het toedienen van zuurstof in de pulsoximetrie strategie het zuurstofgehalte waarschijnlijk verhoogd, wordt het samenvallen van de bovenste luchtweg hier niet mee voorkomen. Het zuurstof wordt namelijk niet met druk de luchtweg in geblazen. Het samenvallen van de bovenste luchtweg kan leiden tot ademstops en daarmee tot zuurstofdalingen, waarbij vervolgens een verpleegkundige interventie nodig kan zijn. Als er veel interventies moeten worden gedaan, zou dit kunnen leiden tot een hoge werkdruk voor de verpleegkundigen. De resultaten van de SATBAR studie lieten een relatief lage frequentie van patiënten met zuurstofdalingen (22%) en verpleegkundige interventies (14%) zien. Daarnaast bleken het mannelijk geslacht, hogere leeftijd, hogere body mass index en roken risicofactoren voor het ontwikkelen van zuurstofdalingen in de SATBAR studie. De resultaten van de SATBAR studie laten zien dat de pulsoximetrie strategie niet leidt tot een hoge werkdruk voor de verpleegkundigen. Daarnaast is het waarschijnlijk dat zuurstofdalingen vooral voorkomen in patiënten met (ongediagnosticeerd) slaapapneu, omdat de gevonden risicofactoren voor het ontwikkelen van zuurstofdalingen grotendeels overeenkomen met de risicofactoren voor slaapapneu. Dit komt overeen met de veronderstelling dat het geven van alleen zuurstof alléén geen ademstops voorkomt.

Om te evalueren of het weglaten van zuurstof net zo goed is als het wel toedienen van zuurstof tijdens de eerste nacht na een maagverkleinende operatie, werd dit onderzocht in de OXYBAR studie in **hoofdstuk 5** van dit proefschrift. In deze studie werden patiënten willekeuring ingedeeld in de groep met of zonder zuurstof therapie. Ondanks dat er meer zuurstofdalingen voorkwamen bij patiënten die geen zuurstof therapie kregen, lieten de resultaten van de slaaptest (WatchPat300®) zien dat gebaseerd op het aantal ademstops per uur het weglaten van zuurstof therapie gelijk is aan het wel geven van zuurstof therapie. Ook bleek de slaapstructuur van slaapstadia, de complicaties binnen 30-dagen en de frequentie van verpleegkundige interventies gelijk tussen de groepen met en zonder zuurstof therapie

In **hoofdstuk 6** werd het beloop van slaapgerelateerde ademhalingsstoornissen, zuurstofgehalte en de slaapstructuur geobserveerd in patiënten waarvan niet bekend was of ze slaapapneu hadden en die een maagverkleinende operatie in dagbehandeling ondergingen. Dit werd gedaan om te onderzoeken of (onbehandelde) slaapapneu een contra-indicatie voor dagbehandeling zou moeten zijn. Hiervoor ondergingen patiënten in de DAGBAR studie thuis een slaaptest (WatchpatONE®) één week voor en tijdens de eerste en derde nacht na de maagverkleinende operatie. De resultaten van de DAGBAR

studie lieten zien dat alle waardes voor slaapgerelateerde ademhalingsstoornissen en het aantal zuurstofdalingen het hoogst waren tijdens de derde nacht na de operatie. Hieruit kan geconcludeerd worden dat slaapapneu geen contra-indicatie voor dagbehandeling hoeft te zijn, omdat slaapapneu het ergst is tijdens de derde nacht na de operatie, wanneer alle patiënten (ook die de operatie niet in dagbehandeling ondergaan) thuis slapen. Het percentage complicaties binnen 30 dagen was 5.3%, waarvan geen enkele gerelateerd was aan slaapapneu.

Samenvattend is de geoptimaliseerde versie van de pulsoximetrie strategie zonder routinematige toediening van zuurstof een goed alternatief voor het omgaan met slaapapneu rondom maagverkleinende operaties. Deze strategie geeft een vermindering in de diagnostiek en behandeling van slaapapneu en is hierdoor kosteneffectiever dan de slaaptest strategie. Daarnaast is de pulsoximetrie strategie even veilig en is het gewichtsverlies, de slaperigheid, dagelijks functioneren en de aan gezondheid gerelateerde kwaliteit van leven vergelijkbaar met de slaaptest strategie. De recente invoering van maagverkleinende operaties in dagbehandeling zou dan ook geen belemmering moeten vormen voor het op grote schaal toepassen van de pulsoximetrie strategie, aangezien er geen reden is om slaapapneu als strikte contra-indicatie te zien voor maagverkleinende operaties in dagbehandeling. Vervolgonderzoek zou zich kunnen richten op het verder verbeteren van pulsoximetrie strategie met als focus het verminderen van slaapapneu na de operatie door het effect van morfinevrije anesthesie en morfinevrije pijnstilling na de maagverkleinende operatie te onderzoeken.

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Ook mijn vriendinnen uit mijn geneeskundetijd zijn allemaal op hun eigen manier belangrijk voor mij. **Linda,** we go way back. Van guppies in de collegebanken en zeven weken samen door Thailand reizen tot waar we nu staan, jij bent een bijzondere vriendin voor mij. Mijn lieve goudvis, ook al vergeet je soms van alles, onze vriendschap is er gelukkig één om nooit te vergeten. **Hannah**, wij spreken elkaar door alle drukte en de kinderen minder vaak dan we zouden willen, maar we weten elkaar altijd weer te vinden wanneer dat nodig is. Die vanzelfsprekendheid en vertrouwdheid in onze vriendschap is mij heel dierbaar. **Ingrid**, helaas zien ook wij elkaar minder vaak dan we zouden willen, maar jouw betrokkenheid, of dat nu met een telefoontje of een lief kaartje is, is voor mij heel waardevol. **Isabella**, door ons gesprek aan de keukentafel begon ik mij te realiseren dat ik misschien toch huisarts wilde worden. Wie weet waar ik zonder dat gesprek terecht was gekomen. **Marit**, ook al heeft het leven ons inmiddels letterlijk wat verder uit elkaar gebracht en zijn we allebei druk met onze opleidingen, jij hoort voor mij nog altijd bij de vriendinnen met wie ik zo'n belangrijke periode van mijn leven heb gedeeld.

Yvonne en **Matthijs,** samen zijn we heel wat kilo's kwijtgeraakt en zweetdruppels verloren. Wat begon als samen sporten, is inmiddels uitgegroeid tot een mooie vriendschap. Ik hoop dan ook dat er nog vele sportmomenten én gezellige diners samen zullen volgen.

Stephan en **Marloes,** onze etentjes, spelletjesavonden en de nodige feestjes waren altijd momenten om naar uit te kijken. We begonnen met z'n vieren en ondertussen zijn we met z'n zessen. Ik hoop dat we nog veel mijlpalen samen mogen vieren.

Dan eindig ik natuurlijk met de twee belangrijkste personen uit mijn leven.

Lieve **Cas**, mijn schatje patatje, wat ben ik onbeschrijfelijk dankbaar en trots dat ik jouw moeder mag zijn. Jij hebt mij een titel gegeven die geen enkele andere titel ooit zal overtreffen, namelijk die van mama. Jij hebt mij beter dan wie dan ook leren relativeren, want mijn promotietraject kende de nodige tegenslagen. Maar als ik dan na een rotdag thuiskwam en jij enthousiast op mij af kwam rennen, met jouw armpjes gespreid, terwijl je "MAMAAA!" riep, was ik alles meteen weer vergeten. Dat ik veel met mijn proefschrift bezig ben geweest, bleek wel toen je laatst tijdens een weekendje weg in een boekje aan het tekenen was en zei: "Ik ben even mijn proefschrift aan het afschrijven." Gelukkig is die tijd nu voorbij, dus op naar allemaal mooie avonturen en tijd samen. Ik hou van jou tot de maan en weer terug.

Lieve **Mark**, mijn rots in de branding, al vanaf het allereerste begin toen ik begon met studeren. Als je dit leest, is mijn proefschrift écht af. Niet wéér 's avonds of in het weekend een stuk herschrijven of een analyse opnieuw doen. Nee, het is echt klaar. Wat heb jij een lange adem moeten hebben, want vooral toen ik het schrijven van mijn proefschrift moest combineren met de huisartsenopleiding, was het pittig. Elk vrij moment zat ik boven te schrijven. Ik ben je ontzettend dankbaar dat je mij daar alle ruimte voor gaf, maar ook dat je mij af en toe terechtwees en zei dat het nu wel even genoeg was en dat jij en Cas er ook nog waren. Hierdoor hield ik de balans en werd ik niet helemaal opgeslokt door mijn proefschrift. Maar die tijd is nu voorbij, dus op naar vele vrije avonden en weekenden samen. Al zal je misschien soms met enige weemoed terugdenken aan deze tijd waarin je wél op je gemak in je eentje een voetbalwedstrijd kon kijken op de bank.

About the author

Curriculum Vitae



Claudia Berends was born in 1992 and grew up in Eerbeek, a small village in the Netherlands. After completing her secondary education, she studied Biomedical Sciences for one year at the University of Antwerp, followed by one year at Vrije Universiteit Amsterdam. In 2012, she was accepted into Medical School at the University of Amsterdam, fulfilling her long-held ambition of becoming a physician.

After obtaining her medical degree in 2019, Claudia began working as a resident physician in the Department of Surgery at St. Jansdal Hospital in Harderwijk. In 2021, she started her PhD trajectory at Vitalys (part of Rijnstate hospital) in collaboration with Wageningen University & Research (Division of Human Nutrition and Health), under the supervision of Professor E.J. Hazebroek, Dr. L. Heusschen, and Dr. T.M. Fabius.

During her PhD trajectory, Claudia initiated and conducted multiple studies focusing on the perioperative management of obstructive sleep apnea in patients undergoing metabolic and bariatric surgery. She also conducted research on perioperative anticoagulation and on postoperative monitoring. Her work resulted in several peer-reviewed publications and presentations at both national and international scientific conferences. In 2025, she received the award for best presentation at the annual conference of the Dutch Society for Metabolic and Bariatric Surgery. In addition to her research activities, she served on the editorial board of the scientific magazine of Rijnstate Hospital and was an active member of the Rijnstate PhD Committee.

In September 2025, Claudia began her Family Medicine residency training. She is passionate about both patient care and scientific research and aims to combine clinical practice with research throughout her career.

List of publications

This thesis

C. Berends, L. Heusschen, S. L. van Veldhuisen, S. M. M. de Castro, R. N. van Veen, M. J. Wiezer, R. S. L. Liem, F. M. H. van Dielen, A. Demirkiran, E. G. Boerma, T. M. Fabius and E. J. Hazebroek (2026). "Excess daytime sleepiness, daily functioning and health-related quality of life during the first year after metabolic and bariatric surgery in patients with a known and unknown obstructive sleep apnea status." *Sleep Breath 30(4).*

C. Berends, L. Heusschen, S. L. van Veldhuisen, S. M. M. de Castro, R. N. van Veen, M. J. Wiezer, R. S. L. Liem, F. M. H. van Dielen, A. Demirkiran, E. G. Boerma, T. M. Fabius and E. J. Hazebroek. "Five-year follow-up of a nation-wide prospective cohort study comparing two perioperative obstructive sleep apnea strategies for metabolic and bariatric surgery." *Submitted to Sleep and Breathing*

C.Berends, L. Heusschen, A. Hofboer, N.J. Koning, T.M. Fabius, E.J. Hazebroek. "Desaturations and nursing interventions in patients receiving supplemental oxygen therapy after metabolic and bariatric surgery: a prospective observational cohort study" *Submitted to Obesity Research & Clinical Practice*

C.Berends, L. Heusschen, A. Hofboer, N.J. Koning, T.M. Fabius, E.J. Hazebroek. "Oxygen therapy as perioperative obstructive sleep apnea strategy in metabolic and bariatric surgery, is it beneficial? " *Submitted to Obesity Surgery*

C.Berends, L. Heusschen, A. Hofboer, N.J. Koning, T.M. Fabius, E.J. Hazebroek. "Postoperative course of sleep-disordered breathing, oxygen saturation and sleep architecture after same-day discharge metabolic and bariatric surgery" *Submitted to Sleep and Breathing*

Other publications

C. Berends, C. Lau, L. Heusschen, M. Hovens, B. Witteman, E. Hazebroek and H. Monajemi (2025). "Absorption of apixaban following metabolic and bariatric surgery: is reluctance still warranted?" *J Thromb Haemost 23(11): 3648-3653.*

Jansen, A. S., C. Berends, S. H. Garssen, L. N. Deden, L. Kooij, W. H. van Harten, E. J. Hazebroek and C. J. M. Doggen (2026). "The value of Continuous Remote Monitoring in Clinical Decision Making After Same-day Discharge Metabolic Bariatric Surgery." *Obes Surg 36(7): 3521-3534.*

Overview of completed training activities

Discipline specific activities	Organizer (location)	Year
Conferences		
IFSO European Chapter	IFSO (Prague, CZ)	2021
Frankfurter meeting	DGAV IFSO (Frankfurt, DE)	2021
DSMBS Congress	DSMBS (Veenendaal, NL)	2021
IFSO European Chapter	IFSO (Zurich, CH)	2023
IFSO 2023 World Congress	IFSO (Napoli, IT)	2023
DSMBS Congress	DSMBS (Veenendaal, NL)	2023
Rijnstate wetenschapssymposium	Rijnstate hospital (Arnhem, NL)	2023
DSMBS Congress	DSMBS (Veenendaal, NL)	2024
IFSO European Chapter	IFSO (Vienna, AT)	2024
V&VN Recovery congres	V&VN (Ede, NL)	2024
FNT Nascholingsdag	FNT (Apeldoorn, NL)	2024
European Congress on Obesity	EASO (Malaga, SP)	2025
DSMBS Congress	DSMBS (Veenendaal, NL)	2025
Sleep and Breathing Conference	ERS (Antwerp, BE)	2025
DSMBS Congress	DSMBS (Veenendaal, NL)	2026
General Courses	**Organizer (location)**	**Year**
Good clinical practice	TAPAS/EWMO (Online)	2021
Basic methods and reasoning in biostatistics	Boerhaave nascholing LUMC (online)	2022
Scientific writing	WGS (Online)	2023
Efficient writing strategies	WGS (Wageningen, NL)	2023
Project and time management	WGS (Online)	2023
Adobe InDesign course	WGS (Online)	2025
Teaching activities		**Year**
Klinische les calcium metabolisme		2023
Klinische les interpreteren laboratorium waarden		2023
Supervision Bsc and Msc students		2021-2023
Other activities	**Organizer (location)**	**Year**
Preparation of research proposal	HNH (Wageningen, NL)	2021
PhD students committee Rijnstate	Rijnstate hospital (Arnhem, Nijmegen)	2021-2022
Member of the Editorial Board of "Rijnstate research en innovatie"	Rijnstate hospital (Arnhem, Nijmegen)	2023-2025

Discipline specific activities	Organizer (location)	Year
Presentations		
Oral presentations		
Perioperative strategy for bariatric patients with potentially undiagnosed sleep apnea does not affect complication- and ICU admission rate	IFSO (Prague, CZ)	2021
Perioperative strategy for bariatric patients with potentially undiagnosed sleep apnea does not affect post-operative recovery and sleepiness	IFSO (Zurich, CH)	2023
Slaapapneu strategie en postoperatieve slaperigheid en welzijn	DSMBS (Veenendaal, NL)	2023
Efficacy and safety of apixaban and rivaroxaban in 152 patients after bariatric surgery	IFSO (Vienna, AT)	2024
Characteristics associated with desaturations in patients receiving preventive oxygen therapy during the first postoperative night after bariatric surgery	IFSO (Vienna, AT)	2024
Perioperatief management van slaapapneu in metabole en bariatische chirurgie	V&VN (Ede, NL)	2024
Antistolling na metabole en bariatrische chirurgie	FNT (Apeldoorn, NL)	2024
Absorptie van apixaban na metabole bariatrische chirurgie: is terughoudendheid nog steeds nodig?	DSMBS (Veenendaal, NL)	2025
Vijfjaarsuitkomsten van een landelijke prospectieve cohortstudie naar twee perioperatieve strategieën voor slaapapneu bij metabole en bariatrische chirurgie	DSMBS (Veenendaal, NL)	2026
Poster presentations		
Sleep apnea strategy does not affect post-operative wellbeing and sleepiness	Rijnstate hospital (Arnhem, NL)	2023
Apnea-Hypopnea Index in patients with or without oxygen therapy after bariatric surgery, results of a randomized non-inferiority trial (OXYBAR trial)	EASO (Malaga, SP)	2025
Absorption of apixaban following metabolic and bariatric surgery: is reluctance still warranted?	EASO (Malaga, SP)	2025
Apnea-Hypopnea Index in patients with or without oxygen therapy after bariatric surgery, results of a randomized non-inferiority trial (OXYBAR trial)	ERS (Antwerp, BE)	2025

Authorship statement

Chapter 1: General introduction
The general research question was proposed by my promotor. I delineated the research question, described how it fits in the current scientific literature and its clinical relevance. I wrote the first draft, which was revised several times after comments of my promotor and co-promotors.

Chapter 2:
I contributed to the completion of data collection at the twelve month follow-up. Additionally, I performed the statistical analysis and designed the tables and figures. I wrote the first draft of the manuscript, which I revised several times after comments of my promotor, co-promotors, co-authors and peer reviewers.

Chapter 3:
I wrote the protocol amendment and obtained the local approval to extent the follow-up period from one to five years. I conducted the data collection during this extension together with a research nurse. I performed the statistical analysis and designed the tables and figures. I wrote the first draft of the manuscript, which I revised several times after comments of my promotor, co-promotors and co-authors.

Chapter 4, chapter 5 and chapter 6:
I was responsible for the study conception and design, protocol development, ethical and regulatory approvals, statistical analyses, data collection (in collaboration with a research nurse), design of tables and figures. I wrote the first draft of the manuscripts, which I revised several times after comments of my promotor, co-promotors and co-authors.

Chapter 7: General discussion
I wrote the first draft of the text. I subsequently revised this draft several times after both comments on paper as oral discussion with my promotor and co-promotors.

Colophon

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