Evaluation of obstructive sleep apnea (OSA) management in obesity surgery.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21420

Source
NTR

Brief title
POPCORN

Health condition

The population of our study consists of morbidly obese patients scheduled to undergo bariatric surgery (gastric bypass or sleeve gastrectomy), selected following the criteria of the International Federation of Obesity Surgery (IFSO) for bariatric surgery, such as body mass index (BMI) > 40 kg/m2 or BMI > 35 kg/m2 with significant, obesity related comorbidity. OSA is defined as periodic reduction (hypopnea) or cessation (apnea) of breathing, caused by partial or complete occlusion of the upper airway during sleep. In the obese population, this occlusion is thought to be caused by an increased tissue mass. The severity of OSA is defined by the number of apneas and hypopneas per hour, as defined by the apnea-hypopnea-index (AHI). An AHI of 0-5/hour is no OSA, 5-15/hour represents mild OSA, 15-30/hour moderate OSA and more than 30/hour is severe OSA.

Sponsors and support

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Source(s) of monetary or material Support: ZonMw (The Netherlands Organisation for Health Research and Development), the Hague, the Netherlands

Intervention

Outcome measures

Primary outcome

Cost-effectiveness measured by:

- Quality-adjusted-life-years (QALY¡¯s) calculated with the European Quality of Life-5 Dimensions (EQ-5D)

- Productivity cost questionnaire (PCQ)

- Use of health care resources.

Secondary outcome

Pulmonary/cardiac/neurovascular complications

Length of hospital stay

Morbidity

Mortality

Generic quality of life: RAND-36

OSA-related quality of life: FOSQ-10 questionnaires

CPAP compliance

Resolution of OSA symptoms: Epworth Sleepiness Scale ¡°ESS¡±

Weight loss

Postoperative hypoxemic episodes during the first night after bariatric surgery:

- Mean SpO2

-Number of episodes SpO2 < 90%

-Number of episodes SpO2 4% below baseline saturation

-Duration of desaturations

-Lowest SpO2

Study description

Background summary

Obstructive sleep apnea (OSA) is a sleep breathing disorder commonly encountered in bariatric surgical patients. Its prevalence may be as high as 70% in high-risk populations such as patients undergoing bariatric surgery. Bariatric surgery itself has shown a reduction or even resolution of OSA. However, perioperative management of OSA remains a challenge since serious cardiopulmonary complications have been reported, such as desaturations/hypoxia, respiratory failure, cardiac arrest and death. Among the different treatment options for OSA, CPAP is an internationally used and efficacious modality. As diagnosing OSA and providing perioperative CPAP therapy for patients with moderately and severe disease may be effective interventions to reduce the incidence of post-operative adverse outcomes, routine OSA screening and subsequent instalment of CPAP in bariatric surgical patients has been advocated. However, a recent review of the US Preventive Services Task Force showed that the current evidence is insufficient to assess the balance of benefits and harms of screening for OSA in asymptomatic patients.

OSA is defined as periodic reduction (hypopnea) or cessation (apnea) of breathing, caused by partial or complete occlusion of the upper airway during sleep. In the obese population, this occlusion is thought to be caused by an increased tissue mass. OSA is clinically defined as 30% reduction of airflow when compared to baseline, lasting for at least ten seconds and resulting in 4% or more oxygen desaturation. Although several questionnaires, such as the Berlin and STOP-Bang questionnaires are used to screen OSA, the existing evidence regarding the accuracy of OSA questionnaires is associated with inconsistent results. High sensitivities go along with low specificities and the other way around. Currently, the gold standard for OSA diagnosis is poly(somno)graphy (P(S)G), providing amongst other things the number of apneas and hypopneas per hour, as defined by the apnea-hypopnea-index (AHI). An AHI of 0-5/hour is no OSA, 5-15/hour represents mild OSA, 15-30/hour moderate OSA and more than 30/hour is severe OSA.

The American Society of Anesthesiologists published a practice guideline recommending screening to identify undiagnosed OSA, preoperative initiation of CPAP if possible, and postoperative monitoring of patients with OSA. Especially in the US, perioperative

complications related to OSA are increasingly linked to malpractice lawsuits with severe financial penalties. However, the lack of evidence behind guideline recommendations and significant costs of guideline implementation create a dilemma between potentially improved postoperative adverse events, outcome and increased healthcare resource utilization.

Some centers have implemented a protocol of routine OSA screening by overnight polygraphy in all patients scheduled for bariatric surgery, with subsequent CPAP treatment during the perioperative period in a large subset of patients. Other bariatric centers utilize a more pragmatic approach in which monitoring by continuous pulse oximetry of all bariatric patients regardless of OSA severity is considered safe and sufficient and therefore PG screening could be omitted. The adagium in these hospitals is: 1) weight loss surgery itself is one of the most effective methods to cure OSA. 2) Regarding perioperative management: every morbid obese patient could be a potential OSA patient, therefore monitoring will be applied to every patient having a bariatric operation. In case desaturations occur post-operatively, instant appropriate measures can be taken to prevent adverse events.

Moreover, in recent years most bariatric centers have successfully implemented enhanced recovery after bariatric surgery (ERABS) protocols: early post-operative mobilization and minimizing opioid use in the perioperative period have led to a further decrease in cardiopulmonary morbidity. Therefore, OSA related mortality will be zero in most bariatric centers.

This leads to the question whether pulsoximetry can be a safe and cost-effective modality for peri-operative management compared to preoperative OSA screening and subsequent CPAP treatment.

Study objective

Patients with obesity face many health issues such as obstructive sleep apnea (OSA). Prevalence of OSA may be as high as 70% in high-risk populations such as morbidly obese patients undergoing bariatric surgery. Although bariatric surgery itself has shown a reduction or even resolution of OSA due to subsequent weight loss, the perioperative management of OSA remains challenging because of the risk of cardiopulmonary complications. Currently, there is a large clinical variation in perioperative monitoring protocols for bariatric surgical patients. Some centers have implemented a protocol of routine OSA screening by overnight poly(somno)graphy (which is the gold standard to diagnose OSA) in all patients scheduled for bariatric surgery. When OSA is diagnosed, CPAP treatment can be installed during the perioperative period. Other bariatric centers utilize a more pragmatic approach in which monitoring by continuous pulse oximetry of all bariatric patients regardless of OSA severity is considered safe and sufficient, and therefore polygraphy (PG) screening could be omitted. In case desaturations occur post-operatively, instant appropriate measures can be taken to

prevent adverse events. In absence of conclusive evidence, we aim to identify which strategies to prevent post-operative adverse outcomes are safe and cost-effective.
We hypothesize that postoperative monitoring of bariatric patients with continuous pulse oximetry leads to similar quality of life, but substantial cost savings when compared to pre-operative OSA screening by PG and subsequent application of CPAP.

Study design

Primary outcomes

EQ-5D: baseline, 1/3/6/12 months postoperatively

PCQ: baseline, 3/12 months postoperatively

Use of resources: 12 months postoperatively

Secondary outcomes

Pulmonary/cardiac/neurovascular complications: within 30 days of bariatric surgery

Length of hospital stay in days

Morbidity: within 30 days of bariatric surgery

Mortality: within 30 days of bariatric surgery & 1 year postoperatively

Generic quality of life (RAND-36): baseline & 1,3,6,12 months postoperatively

OSA-related quality of life (FOSQ-10): baseline & 1,3,6,12 months postoperatively

CPAP compliance: baseline & 1,3,6,12 months postoperatively

Resolution of OSA (ESS): baseline & 1,3,6,12 months postoperatively

Weight loss: baseline & 1,3,6,12 months postoperatively

Postoperative hypoxemic episodes during the first night after bariatric surgery:

- Mean SpO2

-Number of episodes SpO2 < 90%

-Number of episodes SpO2 4% below baseline saturation

-Duration of desaturations

-Lowest SpO2

Intervention

Morbid obese patients undergoing bariatric surgery will be monitored by continuous pulse oximetry 24h post-operatively (Intervention). This perioperative management of OSA will be compared to pre-operative OSA assessment by overnight PG and subsequent application of pre- and post-operative CPAP (Comparator).

Contacts

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Eligibility criteria

Inclusion criteria

- Scheduled for gastric bypass or sleeve gastrectomy

- BMI ≥ 35 kg/m2 (IFSO criteria for bariatric surgery)

- Age: 18-65 years

Exclusion criteria

- BMI < 35 kg/m2

- < 18 years or > 65 years

- Previous bariatric surgery

- Unable to speak or read the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	1380
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6805
NTR-old	NTR6991
Other	1) ZonMw, 2) Medical Research Ethics Committees United : 1) 843004110, 2) W17.050

Study results