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Peri-operative and long-term outcomes of patients with severe obstructive sleep apnea after Nissen-Sleeve and matched Sleeve-gastrectomy: a cohort study

Matthias Guillemot

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UNIVERSITE DE MONTPELLIER
FACULTE DE MEDECINE MONTPELLIER-NIMES

THESE

Pour obtenir le titre de
DOCTEUR EN MEDECINE

Présentée et soutenue publiquement
Par
Matthias GUILLEMOT

le 6/12/2021

Peri-operative and long-term outcomes of patients with severe obstructive sleep apnea after Nissen-Sleeve and matched Sleeve-gastrectomy : a cohort study

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Aux membres du Jury :

Professeur Samir Jaber

Vous me faites l'honneur de présider ce jury et je vous en remercie. Veuillez trouver ici le témoignage de mon plus grand respect pour vos enseignements et vos valeurs. L'accueil dans votre équipe à Saint-Eloi a été exemplaire.

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Merci de m'avoir permis de travailler sur cette cohorte. Plus forte encore est la gratitude que ces patients expriment des années après et dont j'ai été témoin, mon regard sur la chirurgie bariatrique en sera marqué. Egalement, une pensée pour vous ponctuera mes venues au port de Sète.

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A mes Maîtres dans l'Art,
comme on disait dans l'temps

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Tous mes meilleurs amis d'un temps

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Brou, depuis depuis que tu as été porté disparu et retrouvé une semaine plus tard échoué sur notre canapé, je dois te compter dans les coloc, pas le choix. Ravi de pas t'avoir perdu !

Alexis, je sais pas si j'ai apprécié notre cohabitation, je pense qu'on devrait retenter le coup juste pour être sûr.

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Nico, j'ai pas les mots. Je les ai perdus, ou peut-être oublié quelque part... c'était sur un bout de papier, je sais plus ce que j'avais écrit, mais ça parlait de loukoum et de froissartage en milieu hostile il me semble, ça paraît insensé dit comme ça mais c'était un texte fluide avec des beaux passages sur l'amitié au grand air. Non, rien de sexuel, non. Dommage que j'ai perdu les mots ça t'aurai ému.

Et les derniers coloc : Toute la **Communauté Belleau**, une belle somme d'individus excentriques qui donne un tableau vraiment pas triste.

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Marie, j'allais écrire une connerie avec un second degré mal amené, mais c'est l'heure de la sincérité, alors sache que ces sous-colles à tes côtés ont été un calvaire. C'est simple tu m'as ralenti. Et ce **Paul** que tu ramènes depuis peu il n'est pas très fréquentable. Et attache moi ces cheveux t'as l'air d'une hippie comme ça.

Ondine, tiens : compliment, compliment, compliment, compliment. T'en veux plus ? Compliment. Encore ? Compliment. Toi, on voit que t'aimes les compliments, hain ? Tiens mange-moi bien tous ces compliments. Fais comme si c'était des chips. Voilà... compliment.

Paulin : Je voulais être le premier à te citer, mais **Gary** l'a fait avant moi (toujours à se faire remarquer celui-là, s'il n'était pas un type formidable je le claquerais). Alors tant pis, tu auras tes

remerciements quand tu sauras aligner trois mots. Dernièrement c'est que du bruit, on comprend rien. Grandis un peu.

Xav : Quand tu auras fini tes tours du monde de service d'urgence, tu reviendras te poser sur mon canap' comme tu savais bien y faire.

Benben : Pam,palapam,palapam,palapam et cætera... C'est pourtant pas compliqué.

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Lilian, tap' sur l'épaule droite. Tu t'y attendais pas hain. On règlera ce problème de flemme, demain sans faute.

Ianis, du bist über Alles man !

Les co-interne qui m'en voudront pas : Jade, Yasmina, Jacques, Thomas, aussi les autres.

Julie, Sacha, Martin, Maëlle, Ambro, Elea, Alex et la petite **Charlie**, je vous adore mais il faut vraiment que j'imprime là, c'est plus le moment de trainer alors peut être que je ne vous dirai pas à quel po... Bises.

Donc ceux qui liront ces lignes que j'ai eu le culot de ne point citer, je vous attends à la sortie et on règle ça entre hommes.

Mais aussi,

à m'amie, la mère-grand de nos petits-enfants,

à l'aventure...

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I. Introduction

Obesity is a rising public health challenge of the past decades.⁽¹⁻⁴⁾ Far from being a condition controlled by individual choices and caused only by environmental factors, obesity involves multiple biological systems that are in a constant fight to protect us from losing body weight. Obesity is defined as excess accumulation of body fat (estimated by the Body Mass Index (BMI), which is weight in kilograms divided by height in meters squared). Above an optimal BMI comprised between 22.5 and 25 kg/m², each 5 kg/m² higher BMI is on average associated with 30% higher overall mortality.⁽⁵⁾ In France, 47.3% of the global population is overweight (Body Mass Index [25-30] kg/m²), and 17% suffers from obesity (BMI > 30 kg/m²).⁽⁶⁾

The accumulation of fatty tissues in the neck narrows the upper respiratory tract, that is more likely to collapse in the supine position during sleep.⁽⁷⁾ This phenomenon leads to an obstructive sleep breathing disorder strongly associated with obesity: obstructive sleep apnea.⁽⁸⁾ Obstructive episodes lead to hypopnea, apnea and intermittent hypoxia (with acute drop of oxygen saturation)⁽⁹⁾, often followed by transient brain arousal and awakenings that have multiple acute and chronic adverse consequences: excessive daytime sleepiness, car accidents, deterioration in quality of life and chronic sympathetic activation resulting in premature mortality by cardio-vascular events.⁽¹⁰⁾

In the peri-operative setting, obstructive sleep apnea and obesity are now recognized as independent risk factors of respiratory complications: difficult mask ventilation, difficult intubation and related complications, postoperative pulmonary complications including atelectasis, pneumonia, acute respiratory distress syndrome and intensive care unit admission.⁽¹¹⁻²⁰⁾

Continuous Positive-Airway-Pressure (CPAP) therapy, with a device that provides a continuous jet of air to the airway as the person breathes, helps to keep the throat from

narrowing during sleep. This device is considered the first-line therapy for severe obstructive sleep apnea. ^(11,21,22) However, adherence to treatment is challenging : about two thirds of patients report bad adherence.⁽²³⁾

The key to obstructive sleep apnea resolution among patients with obesity is weight-loss.^(24,25) Surgical procedures are more effective than medical procedures to achieve a sustainable weight loss.⁽²⁶⁾ Weight loss by non-surgical means is non-satisfactory and non-sustainable, while bariatric surgery has been proven to be the most effective mean for durable weight loss. In addition to weight loss, bariatric surgery results in cure or improvement of obstructive sleep apnea in a significant proportion of patients.⁽²⁷⁻²⁹⁾ Rate of use of Sleeve gastrectomy has increased regularly and represented 61.1% of all bariatric operations in 2018, taking the share of adjustable gastric banding.⁽³⁰⁾ The middle and long-term benefits obtained with Sleeve gastrectomy regarding excessive weight-loss and resolution of comorbidities including obstructive sleep apneas result in a postoperative shift from high risk to lower risk in the American Society of Anesthesiologists (ASA) risk category.⁽³¹⁻⁴²⁾ This decrease in the ASA risk category is especially relevant for anesthesiologists, meaning a decrease in postoperative complications when the patient will experience other surgeries, months or years following the bariatric surgery.

An issue remains, as about half of patients experience de novo-gastroesophageal reflux symptoms after sleeve gastrectomy, leading to heartburn and regurgitation symptoms, chronic esophagitis, metaplasia and neoplasia, and proton-pump inhibitor dependence.⁽⁴³⁻⁴⁸⁾ An alternative to sleeve gastrectomy with concomitant anti-reflux fundoplication (Nissen-Sleeve Gastrectomy) has recently emerged as a new valid option to treat preexisting gastroesophageal reflux disease or prevent de novo-gastroesophageal reflux apparition after sleeve gastrectomy.⁽⁴⁹⁻⁵¹⁾

The relationship between gastroesophageal reflux and sleep apnea is often overlooked. Peri-operative and long-term respiratory outcomes of patients with severe sleep obstructive sleep apneas following Nissen-sleeve have never been studied yet. The aim of this study was to investigate if the Nissen-Sleeve was associated with higher rate of CPAP discontinuation at 3 years after surgery, in comparison with Sleeve gastrectomy. The secondary objectives were to investigate if the Nissen-Sleeve was associated with a decrease in the rate of patients reporting gastroesophageal reflux symptoms and post-operative surgical and respiratory complications. We made the hypothesis that the Nissen-Sleeve would be associated with a decrease of CPAP requirement at 3 years after surgery, in comparison with Sleeve gastrectomy.

II. Materials and methods

Study design & setting

This single center, observational, historic-prospective cohort-based study was carried out at the University Hospital of Saint-Eloi, Montpellier, France.

Patients Selection

All consecutive patients who underwent Nissen-Sleeve gastrectomy or Sleeve gastrectomy as part of routine clinical care from 1st January 2018 to January 2019 were assessed for eligibility. Patients with unknown obstructive sleep apneas status or no indication for CPAP-therapy were not included.

The year 2018 to include patients was chosen as the indications of adding a Nissen-fundoplication to standard Sleeve gastrectomy evolved in our institution from patients with preoperative gastroesophageal reflux disease only to a less restrictive indication. This resulted in about a half/half distribution between Nissen-Sleeve and Sleeve gastrectomy during this year.

Data collection & variables

Data were collected prospectively through an observational cohort including all patients having a bariatric procedure in our institution. The study project has been approved by the appropriate ethics committee 'Comité-de-Protection-des-Personnes (N° ID-RCB : 2011-A01324-37). The need for informed consent was waived by the ethics committee. The cohort was registered on clinicaltrials.gov "NCT02310178". The data were collected

during systematic pre and post-operative check-in by a multidisciplinary medical and paramedical team dedicated to bariatric surgical patients. The patients who did not fulfill their check-ins and whose personal data was outdated were tracked. They were contacted privately by phone call conducted by a single medical assistant, blinded from the type of surgery, at 3-years follow-up between January and June 2021. Missing baseline characteristics were completed retrospectively using the patient's medical record.

All patients were screened for obstructive sleep apnea before surgery by either intra-hospital or ambulatory nocturnal polygraphic assessment. Obstructive sleep apnea status and apnea-hypopnea index values were evaluated by patient's chosen sleep-physicist using his routine definition criteria. The demographic profile and comorbidities were collected during multidisciplinary (surgeon, endocrinologist, anesthesiologist) medical consultation conducted between 1 week and 3 months before surgery. Ideal body weight (kg) and excess body weight (kg) were calculated using Devine formula.

Per-operative data were collected through the anesthetic per-operative and post-anesthesia care unit (PACU) report file: surgery duration (from incision to closure), positive pressure pre-oxygenation, rapid sequence induction, type of neuromuscular blocker used, difficult mask ventilation, Cormack score, minimal post-induction oxygen saturation, minimal mean non-invasive arterial pressure, per-operative surgical complication, Sequential Acute Physiologic Score II (SAPS-II) on monitored care unit admission, in PACU: CPAP use, oxygen support and length of stay. Post-operative complications were collected prospectively and retrospectively based on medical record (DxCare®).

Long-term outcomes were collected on systematic post-operative ambulatory one-day-hospitalization visit proposed yearly for each patient. Missing variables were collected during a private phone-teleconsultation conducted by a physicist blinded to the type of surgery. Patients were asked about CPAP discontinuation, if they undergo sleep study before discontinuation, about self-reported CPAP adherence, about residual obstructive sleep apnea manifestation (American Association of Sleep Medicine, International Classification of Sleep Disorder-3 criteria and STOP-BANG questionnaire without neck circumference as this data was not collected), about current sleep-physicist follow-up, current weight, nadir weight, physical activity habits (Short-Form-36 quality of life questionnaire physical activity assessment and resulting metabolic equivalent (eqMET) categorization), gastroesophageal reflux symptoms (occasional or daily heartburn or regurgitation) and anti-acid intake (occasional or daily), insulin or oral antidiabetic discontinuation and if their antihypertensive treatment was lightened or discontinued.

The primary endpoint was self-reported CPAP discontinuation. The main secondary endpoint was self-reported gastroesophageal reflux symptoms. The other secondary endpoints were long-term and peri-operative criteria. Long-term endpoints collected were: Nocturnal polygraphy before discontinuation, post-operative apnea-hypopnea index, self-reported sleep disturbance, high residual obstructive sleep apnea syndrome probability, medical sleep follow-up, proton-pump-inhibitor intake, Short-form health survey (SF-36) physical activity score, metabolic equivalent category, Insulin or oral antidiabetic discontinuation, anti-hypertensive medication discontinuation, underwent an other surgery under general anesthesia since bariatric procedure, excess body-weight. Peri-operative endpoints were: Surgery duration, intraoperative surgical complication, SAPS II, PACU CPAP use, PACU morphine titration, PACU length of stay, PACU oxygen therapy, intra-hospital postoperative complication, intra-hospital length of stay.

Statistical analysis

Expecting a difference of first-attempt success of 35% between Sleeve gastrectomy and Nissen-Sleeve groups (from 45% to 80%),⁽²⁹⁾ we calculated the sample size as 29 per group, using a χ^2 test, with an α level of 0.05 and a power of 0.80. We decided to include at least 40 surgeries per period (total of 80 surgeries) to compensate for missing data and matching procedure and calculated that the one-year period of 2018 would allow to include at least the required number of surgeries.

All quantitative variables were described with median and interquartile range (25th-75th percentile) and compared with non-parametric test (Wilcoxon/Mann-Whitney). Qualitative variables were described with percentage (%) and compared with χ^2 or exact Fisher test as appropriate. In case of missing values, the number of available values was clearly stated for each variable.

A matching procedure was performed to form two groups with equivalent baseline characteristics and limit selection bias between Nissen-Sleeve and Sleeve-gastrectomy groups. Patients with Nissen Sleeve were matched to patients with Sleeve gastrectomy, according to the following three criteria: gender, gastroesophageal reflux symptoms and body mass index $\pm 5\%$.

Main and secondary outcomes were evaluated in all matched patients except those whom data was either not found in medical report file and patients were unreachable by e-mail or phone. For the main outcome and the main secondary outcome, a χ^2 test was used to compare Nissen-sleeve and Sleeve-gastrectomy groups. Odds ratio with corresponding 95% confidence interval were computed. For the other outcomes, a χ^2 test, exact Fisher test or Mann-Whitney test was used according to the type of outcome (qualitative or quantitative).

The statistical analysis was performed with the help of statistical software: SAS version 9.3, SAS Institute; Cary, NC). P value <0.05 was considered statistically significant.

III. Results

Study participants

Two-hundred and twenty-three patients underwent bariatric surgery between 1st January 2018 and 31th December 2018. Seven patients underwent other bariatric procedure than Nissen-Sleeve or Sleeve-Gastrectomy (1 gastric bypass, 4 Toupet-Sleeve and 2 unspecified other bariatric interventions). Twelve patients had missing preoperative data about obstructive sleep apnea and were not included, 118 patients had no severe obstructive sleep apnea requiring CPAP.

Baseline characteristics of the 46 Nissen-Sleeve and 40 Sleeve gastrectomy eligible for analysis are presented in Table 1.

Thirty-three Nissen-Sleeve patients were matched with 33 Sleeve Gastrectomy patients. The matching procedures was performed on variables that were statistically different between groups before matching (Table 1): gender, gastroesophageal reflux symptoms and BMI. The effectiveness of matching was 81% on gender category, 70% on gastroesophageal reflux symptoms and 100% on BMI ($\pm 5\%$). Flow chart of the study participants is presented in Figure 1.

Baseline characteristics of the matched cohort

Baseline characteristics of the matched cohort are reported in Table 2 and peri-operative characteristics of the matched cohort are reported in Table 3.

Median age at the time of surgery was 51 (44-58) years, 74% were classified ASA III and 26% ASA II. Their median BMI was 42 (38-46) kg/m² preoperatively, corresponding to a median excess body weight of 56 (46-69) kg. The two groups were clinically comparable after matching. There was no difference of baseline excess body weight between groups (Figure 2).

Main primary outcome

At 3 years follow-up, CPAP therapy status was known for 63 patients. Among them, 43/63 (68%) had discontinued their CPAP therapy: 25/31 (81%) and 18/32 (56%) in the Nissen-Sleeve and Sleeve Gastrectomy group respectively ($p=0.038$, odds ratio 3.24 95%CI(1.04-10.05)). Results on the main-primary outcome are shown in Figure 3.

Main secondary outcome

In the Nissen-Sleeve group, 30 (91%) patients did not report any gastroesophageal reflux symptoms, 3 (9%) reported symptoms. In the Sleeve gastrectomy group, 14 (42%) did not report any gastroesophageal reflux symptoms, 19 (47%) reported symptoms. The difference was statistically significant ($p<0.001$, odds ratio 13.6 95% CI (3.4-53.6)). Results on the main secondary outcome are shown in Figure 4.

Other long-term secondary outcomes

Before CPAP discontinuation, 13/43 (30%) did not undergo nocturnal polygraphy (7/25 and 6/18 patients in Nissen-Sleeve and Sleeve Gastrectomy groups respectively, $p=0.202$). Post-operative apnea-hypopnea index were available for 13 patients, median apnea-hypopnea index was 21 (7.4-32), 17.5 (7.4-22), 40.2 (5.6-68) in overall, Nissen-

Sleeve and Sleeve Gastrectomy groups respectively ($p=0.091$). The results on long-term outcomes are shown in Table 4. There was no difference of excess body weight between groups 6 months, 1 year and 3 years following surgery (Figure 2).

Peri-operative secondary outcomes

Median Surgery duration was 105 minutes (89-130) in the Nissen-Sleeve and 95 minutes (70-110) in the Sleeve Gastrectomy groups ($p=0.070$). Non-invasive positive pressure pre-oxygenation was performed in 10 (15%) of patients, rapid sequence induction in 12% of cases. Difficult mask ventilation occurred in 6/62 (11%) cases. Thirteen (20%) cases were scored Cormack 3 or 4. Twenty-four (36%) received Morphine during PACU stay, 2 (3%) had CPAP-therapy during PACU. Fifty-six (85%) required oxygen during the first post-operative night. The median length of stay in monitored care unit and hospital was 1 (1-1) and 4 (4-4) nights respectively. There was no difference between groups. The results on secondary outcomes are shown in Table 5.

IV. Discussion

For the first time, we reported in this matched historic-prospective cohort study, that the rate of CPAP discontinuation was higher in the Nissen-Sleeve group than in the Sleeve gastrectomy group: 25/31 (81%) and 18/32 (56%) respectively ($p=0.038$) (Figure 2, Table 4), despite similar baseline characteristics. Meanwhile, the rate of gastroesophageal reflux symptoms was thirteen times lower in the Nissen-Sleeve group than in the Sleeve-gastrectomy group, with no difference on other long-term respiratory outcomes or peri-operative outcomes.

Other studies that investigated this outcome after bariatric surgery owed almost similar rates of CPAP discontinuation. In these studies, factors including younger age, lower pre-procedure weight and greater weight loss were found to positively predict self-reported obstructive sleep apnea remission.^(52–55) Those variables were equivalent between the two groups assessed in the present study, Nissen-Sleeve and Sleeve gastrectomy groups. Of the 43 CPAP discontinuations, 30 (70%) patients underwent nocturnal polygraphy, however in the other 13 cases (30%) no objective measure of sleep events like apnea-hypopnea index was performed. While CPAP is considered a valuable patient-centered endpoint to evaluate improvements in obstructive sleep apnea, CPAP discontinuation might likely be inappropriate, as potentially in relation with a subjective feeling of obstructive sleep apnea resolution consecutive to weight loss. In a meta-analysis by Greenburg et al.⁽⁵⁶⁾, of twelve studies including 342 patients who underwent bariatric surgery, mean body-mass-index dropped from 55.3 to 37.7 kg/m² while the mean apnea-hypopnea index dropped from 54.7 event/h to 15.8 events/h. They conclude that despite improvement of apnea-hypopnea index values in nearly all cases after surgery, residual obstructive sleep apnea might persist in mild or moderate forms in the vast majority of cases.^(56,57) In the present study, median baseline apnea-hypopnea index was 48 (39.0-60.9) event per hour, and dropped to 21 (7.4-32) in a small sample of 13 post-

operative apnea-hypopnea index values available, which is consistent with moderately severe persisting obstructive sleep apnea (Table 4). Nastalek et al.⁽⁵⁸⁾ recently studied modification of obstructive sleep apnea severity and CPAP compliance around bariatric surgery in a prospective study. One third of the original sample underwent postoperative polysomnography, with residual obstructive sleep apnea in most cases. Compliance to CPAP rate was less than 50%. Two thirds of the original sample did not undergo postoperative polysomnography.⁽⁵⁸⁾ In the present study, at 3 years follow-up, 60% of patients with previous severe obstructive sleep apnea had no regular sleep follow-up, whereas 71% had high probability of residual obstructive sleep apnea (STOP-BANG > 2, with limitations regarding neck-circumference measurement in the setting of phone consultation, or more than 2 AASM diagnosis criteria, Table 5). These results highlight the need for more frequent and probably more effectively enforced follow-up visits after bariatric surgery. This could be accompanied by CPAP compliance analysis and identification of possible issues influencing CPAP therapy (value of pressure, mask fit, psychosocial factors affecting CPAP use).⁽⁵⁹⁾ Failing to recognize or treat persistent obstructive sleep apnea may significantly impact health and quality of life, leading to ensuing weight gain and increased cardiovascular risks.⁽⁶⁰⁾

Our main secondary outcome was self-reported gastroesophageal reflux. As expected, self-reported gastroesophageal reflux was significantly lower after Nissen-Sleeve (3 patients, 9%) than after Sleeve-gastrectomy (19 patients, 58%). Those results are consistent with previous studies.^(46,61) De novo reflux might impact patients' quality of life, requiring lifelong proton pump inhibitor medication, increases the risk of esophagitis and formation of Barrett's metaplasia. Gastroesophageal reflux disease is one the most common reason for conversion to gastric bypass. For the same reason, preoperative reflux is still considered a relative contra-indication to Sleeve-gastrectomy, and hinders its widespread.⁽⁶²⁾

In the present study, peri-operative surgical complications occurred in only 2 cases: one intraoperative minor bleeding of the splenic artery and one major hemorrhagic shock that occurred in PACU following a Nissen-Sleeve gastrectomy. No symptomatic respiratory complication occurred. The 3 patients with respiratory complications (Table 5) were asymptomatic pleural effusion and atelectasis. These observations are consistent with previous studies about post-operative complications after bariatric surgery. In a multi-center prospective database from the American College of Surgeons,⁽⁶³⁾ respiratory complications occurred in 0.6% for post-operative pneumonia and 0.6% for postoperative respiratory failure. In the sample of 66 patients reported in the present study, post-operative pulmonary complications were unlikely to happen in any group. As expected, no pulmonary embolism was reported.

The most dreadful post-operative complication of this procedure is gastric leak, which implies a long hospital stay, interventions, morbidities and sometime mortality. The International Sleeve Gastrectomy Expert Panel Consensus Statement 2011, reported a leak rate of 1.06%,⁽⁶⁴⁾ but it can vary between 1% and 3%.⁽⁶⁵⁾ The present study sample is small and no gastric leak or perforation occurred. Increased risk of post-operative respiratory or surgical complication when associating fundoplication remains of debate as no comparative study still exists.^(51,66)

Besides these limitations, the strength of the current study is that it's the first to investigate potential respiratory benefits of combining fundoplication to standard Sleeve gastrectomy.

Recent researches have reported that obstructive sleep apnea and gastroesophageal reflux symptoms are closely related. However, the exact causative relationship between them remains contradictory.^(67,68) Obstructive sleep apnea and gastroesophageal reflux disease are common chronic diseases among patients with obesity and share several similar risk factors. The prevalence of gastroesophageal reflux in obstructive sleep apnea

patients is significantly higher than in the general population; however, no temporal or causal relationship has ever been demonstrated between gastroesophageal reflux and obstructive sleep apnea.⁽⁶⁹⁾ One recent study found that gastroesophageal reflux is independently associated with obstructive sleep apnea, even while controlling for potentially related conditions. The strongest relationship was seen when using the strictest definitions of gastroesophageal reflux disease and obstructive sleep apnea in a study that was performed by 24h-pH monitoring and nocturnal polysomnography.⁽⁷⁰⁾

However, gastroesophageal reflux and obstructive sleep apnea might be related because of the positive effects that result from their treatment, although pathogenesis could not reveal the exact causal associations. The causal relationship of CPAP treatment on nocturnal gastroesophageal reflux symptoms resolution is well established. In the study of Tawk et al,⁽⁷¹⁾ one-week CPAP use seemed to be effective in obstructive sleep apnea patients with heartburn symptoms. The underlying mechanism might be negative mediastinal pressure during obstructive events favoring gastroesophageal reflux episodes, thus mitigated by positive airway pressure therapy.^(71–74)

It would be controversial to say whether treatment of gastroesophageal reflux could improve obstructive sleep apnea. Treatment of gastroesophageal reflux disease in obstructive sleep apnea patients improves sleep quality, but only few studies found significant difference in obstructive events.^(75–77) Effective treatment of gastroesophageal reflux disease could improve subjective sleep parameters, such as sleep duration and sleep quality regardless of any effect of apnea/hypopnea events. Out of the bariatric setting, Nissen fundoplication was found improving patient's perception of their sleep quality, with polysomnographic modifications of sleep architecture.⁽⁷⁸⁾

The strengths of this study is that it is the first study to investigate obstructive sleep apnea after Nissen-Sleeve. The 3 years assessment of the main outcome was blinded to the

type of surgery and there was few missing data. The potential selection bias was mitigated by a matching procedure to ensure comparability. The major weaknesses are, on one hand, that the study sample is too small to evaluate the post-operative complications rate that are uncommon. On the other hand, a systematic polysomnography would have been useful to quantitatively evaluate sleep events and obstructive apnea resolution.

V. Conclusion

This study showed a higher rate of CPAP discontinuation 3 years after Nissen-sleeve than after Sleeve-gastrectomy. Self-reported post-operative gastroesophageal reflux symptoms were also significantly reduced. A causal association between those two endpoints remains to be further investigated.

Tables:

Table 1: Main Characteristics of the 86 patients with CPAP before Matching procedure

	Overall (N=86)	Nissen- Sleeve (n=46)	Sleeve Gastrectomy (n=40)	p value
Age at the time of surgery, years				0.744
Median	50.5 (44.5-56)	51.5 (45-56)	49 (42.5-57)	
Range	16-76	16-71	16-76	
ASA category, n (%)				0.541
I	0 (0%)	0 (0%)	0 (0%)	
II	22 (26%)	13 (28%)	9 (23%)	
III	64 (74%)	33 (72%)	31 (78%)	
IV	0 (0%)	0 (0%)	0 (0%)	
Body mass index, kg/m²				0.020
Median	41.5 (38-46)	40.5 (38-44)	43.5 (39-47.5)	
Range	34-64	34-61	34-64	
Gender, n (%)				0.022
Female	54 (63%)	34 (74%)	20 (50%)	
Male	32 (37%)	12 (26%)	20 (50%)	
Diabetes, n (%)				0.344
No	54 (63%)	31 (67%)	23 (58%)	
Yes	32 (37%)	15 (33%)	17 (42%)	
Hypertension, n (%)				0.181
No	30 (35%)	17 (37%)	13 (33%)	
Yes	56 (65%)	29 (63%)	27 (67%)	
Self-reported CPAP adherence n, (%)				0.539
No	24/81 (30%)	14/33 (33%)	10/38 (36%)	
Yes	57/81 (70%)	29/33 (67%)	28/38 (74%)	
Apnea-Hypopnea-Index, event/hour*				0.205
Median	48 (37-60.9)	48 (32-58)	48 (40-70)	
Range	9.8-108	9.8-108	20-103	
Gastroesophageal reflux symptoms , n (%)				0.014
No	45 (52%)	18 (39%)	27 (68%)	
Yes	41 (48%)	28 (61%)	13 (32%)	
Proton-pump-inhibitor intake, n (%)				0.041
No	50 (58%)	21 (46%)	29 (73%)	
Yes	36 (42%)	25 (54%)	11 (27%)	

Abbreviations: ASA = American Society of Anesthesiologists; CPAP = Continuous Positive Airway Pressure

* Apnea-Hypopnea-Index was available for 29 patients in the group Nissen-Sleeve and 23 patients in the group Sleeve gastrectomy.

Quantitative variables are presented as median and interquartile range (25th percentile -75th percentile) and Range (minimal and maximal value). Qualitative variables are expressed in numbers and %.

Table 2: Baseline characteristics of the 66 patients with CPAP after matching procedure

	Overall (N=66)	Nissen-Sleeve (n=33)	Sleeve Gastrectomy (n=33)	p value
Age at the time of surgery, years				0.938
Median	51 (44-58)	52 (44-55)	50 (43-60)	
Range	16-76	16-71	16-76	
ASA category, n (%)				0.778
I	0 (0%)	0 (0%)	0 (0%)	
II	17 (26%)	8 (24%)	9 (27%)	
III	49 (74%)	25 (76%)	24 (73%)	
IV	0 (0%)	0 (0%)	0 (0%)	
Body mass index, kg/m²				0.884
Median	42 (38-46)	42 (38-45)	42 (34-46)	
Range	34-64	34-61	34-64	
Body mass index category, n (%)				0.792
30-40	21 (32%)	11 (33%)	10 (30)	
40-50	39 (59%)	19 (58%)	20 (61%)	
>50	6 (9%)	3 (9%)	3 (9%)	
Excess Body Weight, kg				0.899
Median	56 (46-69)	56 (45-68)	56 (48-70)	
Range	43-84	37-109	38-126	
Gender, n (%)				0.215
Female	37 (56%)	21 (64%)	16 (48%)	
Male	29 (44%)	12 (36%)	17 (52%)	
Diabetes, n (%)				0.211
No	39 (59%)	22 (67%)	17 (42%)	
Yes	27 (41%)	11 (33%)	16 (48%)	
Hypertension, n (%)				0.181
No	25 (38%)	16 (48%)	9 (32%)	
Yes	41 (62%)	17 (52%)	24 (68%)s	
Respiratory disease, n (%)				0.682
Asthma	6 (18%)	2 (6%)	4 (12%)	
Chronic obstructive pulmonary disease	2 (6%)	1 (3%)	1 (3%)	
Pulmonary embolism	2 (6%)	2 (6%)	0 (0%)	
Self-reported CPAP adherence n, (%)				0.637
No	18/65 (28%)	10/32 (33%)	11 (39%)	
Yes	47/65 (72%)	23/32 (72%)	24 (72%)	
Apnea-Hypopnea-Index, event/hour*				0.264
Median	34.6-61.9	44.5 (32-58.5)	46.8 (39.5-70)	
Range (min-max)	9.8-108	9.8-108.0	20.0-103.0	
Gastroesophageal reflux symptoms , n (%)				0.618
No	38 (58%)	18 (55%)	20 (61%)	
Yes	28 (42%)	15 (45%)	13 (39%)	
Occasional	8 (12%)	1 (3%)	7 (21%)	
Daily	20 (30%)	14 (42%)	6 (18%)	
Proton-pump-inhibitor intake, n (%)				0.306
No	42 (64%)	19 (58%)	23 (70%)	
Yes	24 (36%)	14 (42%)	10 (30%)	
Occasional	6 (9%)	4 (12%)	2 (6%)	
Daily	18 (27%)	10 (30%)	8 (24%)	

Abbreviations: ASA = American Society of Anesthesiologists; CPAP = Continuous Positive Airway Pressure

* Apnea-Hypopnea-Index was available for 24 patients in the group Nissen-Sleeve and 20 patients in the group Sleeve-gastrectomy.

Quantitative variables are presented as median and interquartile range (25th percentile -75th percentile) and Range (minimal and maximal value). Qualitative variables are expressed in numbers and %.

Table 3: Peri-operative characteristics of the study population after matching procedure

	Overall (N=66)	Nissen-Sleeve (n=33)	Sleeve Gastrectomy (n=33)	p value
Positive pressure pre-oxygenation, n (%)				0.492
No	56 (85%)	29 (88%)	27 (82%)	
Yes	10 (15%)	4 (12%)	6 (18%)	
Rapid sequence induction, n (%)				0.425
No	51/58 (88%)	25/30 (83%)	26/28 (93%)	
Yes	7/58 (12%)	5/30 (17%)	2/28 (7%)	
Mask ventilation, n (%)				0.513
Not performed	6/55 (11%)	5/30 (14%)	2/26 (8%)	
Easy	43/55 (78%)	23/30 (79%)	20/26 (77%)	
Difficult	6/55 (11%)	2/30 (7%)	4/26 (15%)	
Neuromuscular blocking agent, n (%)				1.000
Cisatracurium	49/50 (98%)	26/27 (96%)	23/23 (100%)	
Suxamethonium	1/50 (2%)	1/27 (34%)	0/23 (0%)	
Cormack score, n (%)				0.757
1-2	53 (80%)	27 (82%)	26 (79%)	
3-4	13 (20%)	6 (18%)	7 (21%)	
Yes	45 (78%)	25 (83%)	20 (71%)	
Minimal SpO₂, %*				0.223
Median	94 (90-97)	95 (91-97)	93 (89-95)	
Range	57-100	83-100	57-100	
Minimal mean arterial pressure, mmHg**				0.313
Median	62 (55-70)	62 (55-68)	62 (58-71)	
Range	34-97	34-84	47-97	

Abbreviations: SpO₂ = pulsed oxygen saturation (%)

* Minimal SpO₂ was available for 26 patients in the group Nissen-Sleeve and 26 patients in the group Sleeve gastrectomy.

** Minimal mean arterial pressure was available for 26 patients in the group Nissen-Sleeve and 26 patients in the group Sleeve gastrectomy.

Quantitative variables are presented as median and interquartile range (25th percentile -75th percentile) and Range (minimal and maximal value). Qualitative variables are expressed in numbers and %.

Table 4: Long term outcomes (3 years after surgery) after matching procedure

	Overall (N=66)	Nissen- Sleeve (n=33)	Sleeve Gastrectomy (n=33)	p value
<i>Obstructive sleep apnea related outcomes</i>				
CPAP discontinuation, n (%)				0.038
No	20/63 (32%)	6/33 (19%)	14/32 (44%)	
Yes	43/63 (68%)	25/33 (81%)	18/32 (56%)	
Nocturnal polygraphy before discontinuation, n (%)				0.202
No	13/43 (30%)	6/25 (24%)	7/18 (39%)	
Yes	30/43 (70%)	19/25 (76%)	11/18 (61%)	
Post-operative apnea-hypopnea index, event/hour*				0.091
Median	21 (7.4, 32)	17.5 (7.4, 22)	40.2 (5.6, 68)	
Range	7.4-97	2-32	5-97	
Self-reported sleep disturbance, n (%)				0.430
No	39/62 (63%)	21/31 (68%)	18/31 (58%)	
Yes	23/62 (37%)	10/31 (32%)	13/31 (42%)	
High residual OSAS probability, n (%)				
STOP-BANG > 2	44/62 (71%)	22/31 (71%)	22/31 (71%)	1.000
AASM clinical criteria > 2	46/62 (74%)	23/31 (74%)	23/31 (74%)	0.836
Medical sleep follow-up, n (%)				0.196
No	37/62 (60%)	21/31 (68%)	16/31 (52%)	
Yes	25/62 (40%)	10/31 (32%)	15/31 (48%)	
<i>Gastroesophageal reflux disease related outcomes</i>				
Gastroesophageal reflux symptoms , n (%)				<0.001
No	44 (67%)	30 (91%)	14 (42%)	
Yes	22 (33%)	3 (9%)	19 (58%)	
Proton-pump-inhibitor intake, n (%)				<0.001
No	46 (70%)	30 (91%)	16 (48%)	
Yes	20 (30%)	3 (9%)	17 (52%)	
<i>Other outcomes</i>				
SF-36 physical activity score (/30)***				0.369
Median	28 (26-29)	28 (26-29)	27 (26-29)	
Range	10-30	17-30	10-30	
Metabolic equivalent category, n (%)				0.826
≤ 4	8/60 (13%)	3/30 (10%)	5/30 (17%)	
> 4	52/60 (87%)	27/30 (90%)	25/30 (83%)	
4-7	26/60 (43%)	13/30 (43%)	13/30 (43%)	
≥ 7	26/60 (43%)	14/30 (47%)	12/30 (40%)	
Insulin or oral antidiabetic discontinuation, n (%)				0.687
No	10/27 (37%)	5/11 (45%)	5/16 (31%)	
Yes	17/27 (63%)	6/11 (55%)	11/16 (69%)	
Anti-hypertensive medication discontinuation, n (%)				0.965
No	25/41 (61%)	10/17 (59%)	15/24 (62%)	
Yes	16/41 (39%)	7/17 (41%)	9/24 (38%)	
Underwent an other surgery under general anesthesia since bariatric procedure, n (%)				0,921
No	21/39 (54%)	9/17 (53%)	12/22 (55%)	
Yes	18/39 (46%)	8/17 (47%)	10/22 (45%)	

Abbreviation: PACU = Post-Anesthesia Care Unit Abbreviations; SAPS II: Sequential Acute Physiologic Score II 2; SF: Short-Form; OSAS: Obstructive Sleep Apnea Syndrome

* Post-operative Apnea-Hypopnea-Index was available for 7 patients in the group Nissen-Sleeve and 6 patients in the group Sleeve gastrectomy.

**STOP-BANG Score: 1 point per item, loud snoring, sleepiness, remarked obstructive events, hypertension, BMI > 35, Male gender and age above 50 years. Neck-circumference was not available.

*** SF-36 physical activity score was available for 30 patients the group Nissen-Sleeve and 31 patients in the group Sleeve gastrectomy. 10 item, Score varies between 10 (extremely limited physical activity) and 30 (no limitation in daily physical activity)

Quantitative variables are presented as median and interquartile range (25th percentile -75th percentile) and Range (minimal and maximal value). Qualitative variables are expressed in numbers and %.

Table 5: Peri-operative outcomes after matching procedure

	Overall (N=66)	Nissen-Sleeve (n=33)	Sleeve Gastrectomy (n=33)	p value
Surgery duration, minutes*				0.070
Median	101 (81-120)	105 (89-130)	95 (70-110)	
Range	36-183	53-180	36-183	
Intraoperative surgical complication, n (%)				1.000
Hemorrhage	2 (3%)	1 (1.5%)	1 (1.5%)	
Other	0 (0%)	0 (0%)	0 (0%)	
Sequential Acute Physiologic Score II**				0.880
Median	13 (11-18)	13 (10.5-18)	13 (11-18)	
Range	6-40	6-40	6-29	
PACU CPAP use, n (%)				1.000
No	62/64 (97%)	31/32 (97%)	31/32 (97%)	
Yes	2/64 (3%)	1/32 (3%)	1/32 (3%)	
PACU morphine titration, n (%)				
No	42 (64%)	19 (58%)	23(70%)	
Yes	24 (36%)	14 (42%)	10 (30%)	
Dose, mg	7 (4-10)	8 (4-10)	6 (5-8)	0.280
PACU length of stay, number of nights				0.320
Median (25th,75th %-ile)	1 (1-1)	1 (1-1)	1 (1-1)	
Range (min-max)	1-7	1-7	1-2	
PACU oxygen therapy, n (%)				0.608
No	10 (15%)	4 (12%)	6 (18%)	
Yes	56 (85%)	29 (88%)	27 (82%)	
Intra-hospital postoperative complication, n (%)				1.000
Respiratory	3 (5%)	1 (3%)	2 (6%)	
Atelectasis	1 (2%)	0 (0%)	1 (3%)	
Pleural effusion	2 (3%)	1 (3%)	1 (3%)	
Hemorrhage	1 (2%)	1 (3%)	0 (0%)	
Intra-hospital length of stay, number of nights				0.725
Median	4 (4-4)	4 (4-4)	4 (4-4)	
Range	3-10	3-10	3-5	

Abbreviation: PACU = Post-Anesthesia Care Unit Abbreviations

* Surgery duration was available for 31 patients in the group Nissen-Sleeve and 33 patients in the group Sleeve gastrectomy.

** Sequential Acute Physiologic Score II was available for 28 patients in the group Nissen-Sleeve and 23 patients in the group Sleeve gastrectomy.

Quantitative variables are presented as median and interquartile range (25th percentile -75th percentile) and Range (minimal and maximal value). Qualitative variables are expressed in numbers and %.

Figures:

Figure 1: Flow diagram of Study Participants

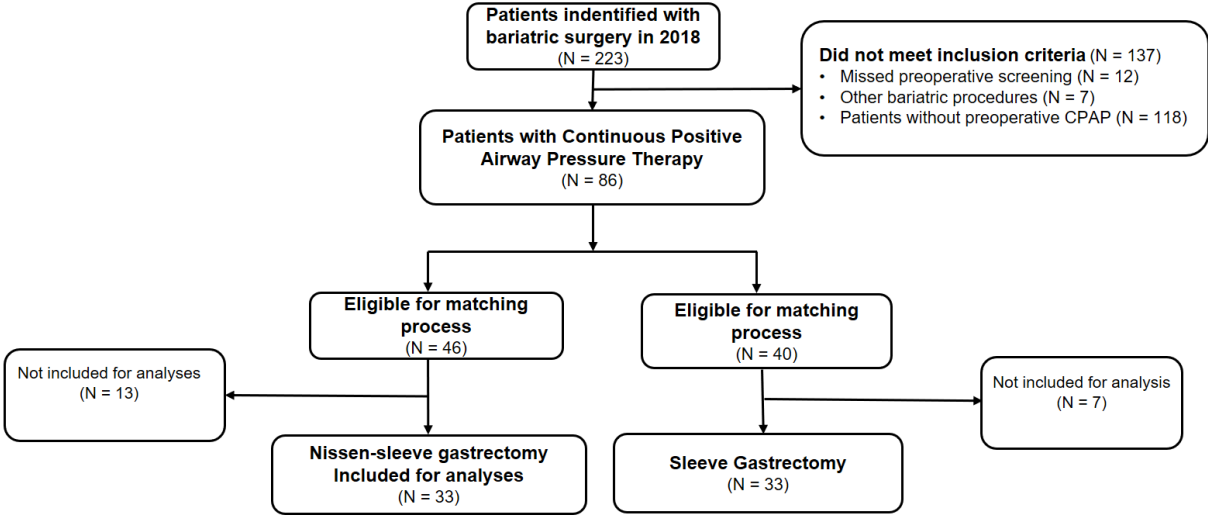


Figure 1 : Flow Diagram of Study Participant.

Figure 2. Excess body weight loss, in kilograms, at preoperative assessment (n=66), 6 months (n=44), 1 year (n=65), 3 years (n=66). P values at each time-point were not significant.

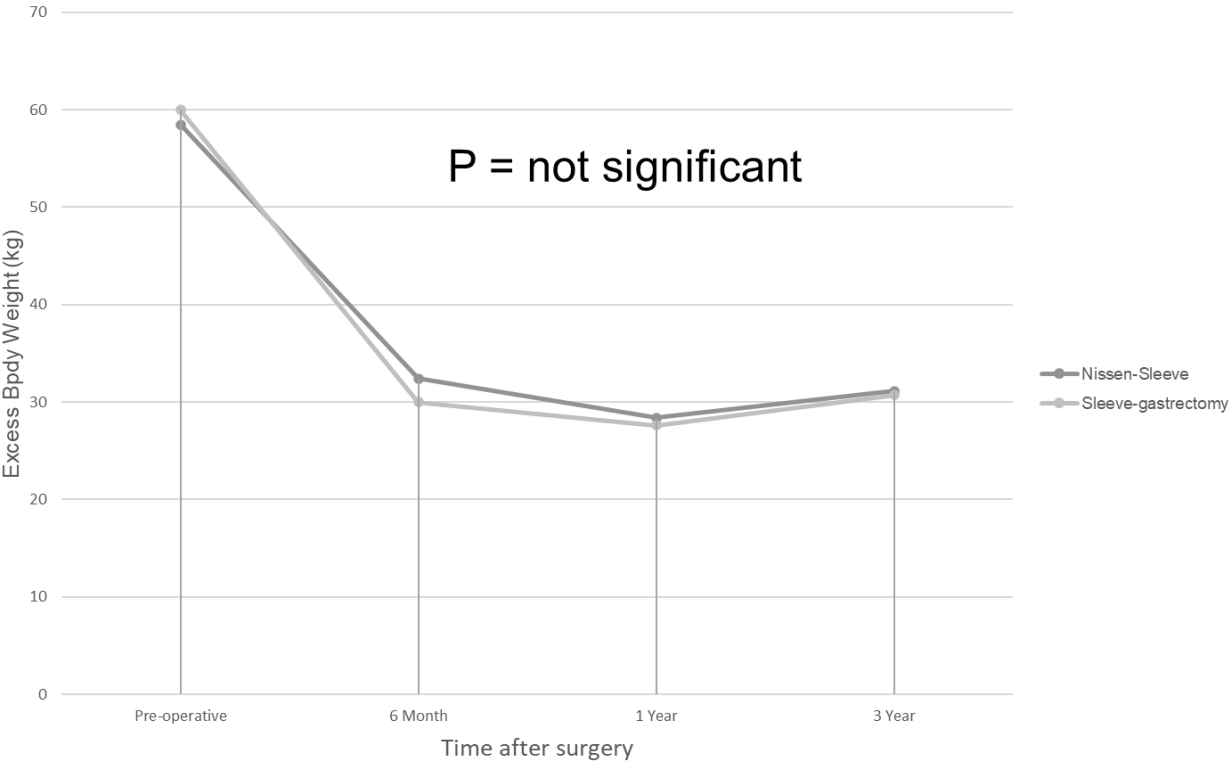


Figure 3: Percentage of patients who discontinued their CPAP at 3 years follow-up after Nissen-Sleeve or Sleeve-Gastreotomy.

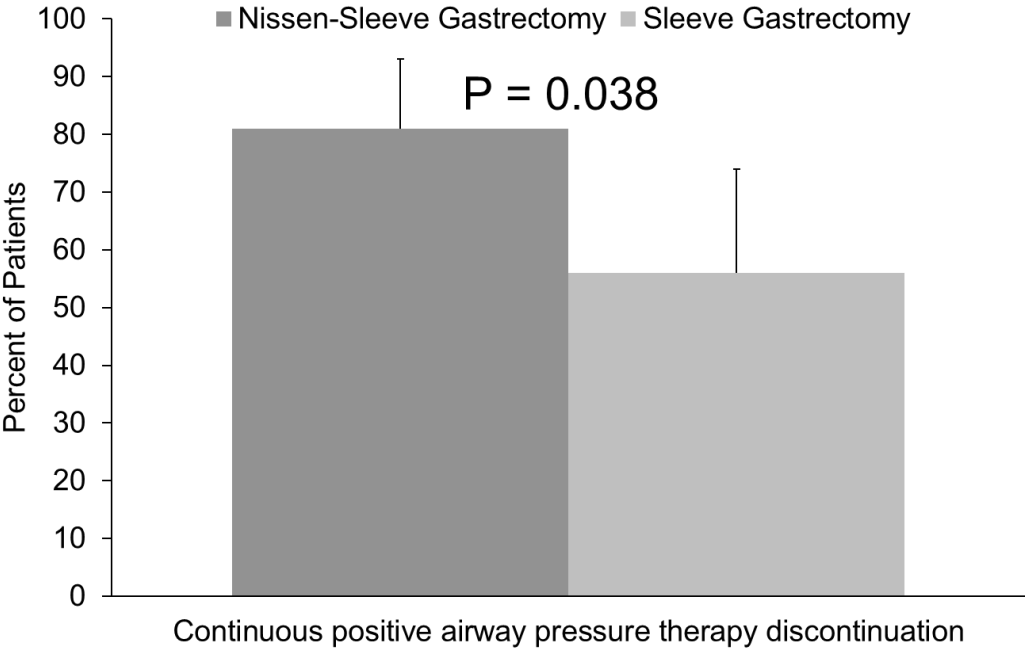
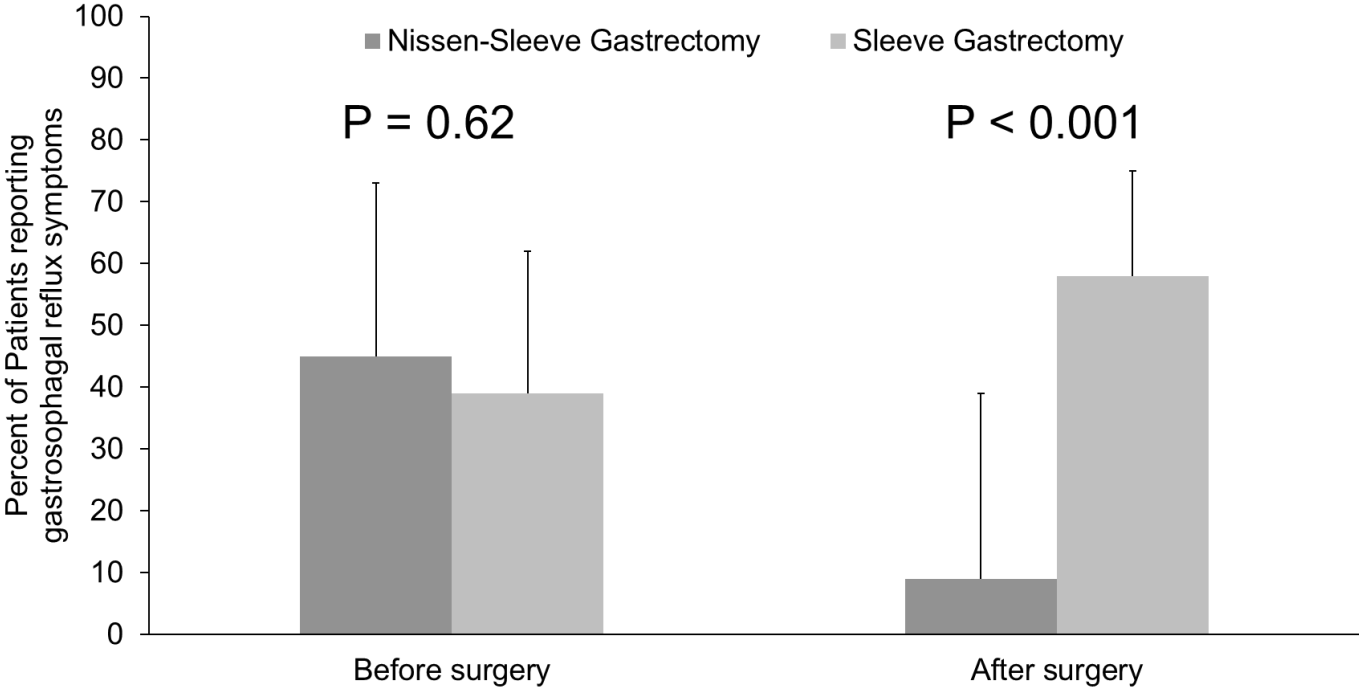


Figure 4: Percentage of patients reporting gastroesophageal reflux symptoms before and after (3 years) surgery.



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SERMENT

En présence des Maîtres de cette école, de mes chers condisciples et devant l'effigie d'Hippocrate, je promets et je jure, au nom de l'Être suprême, d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la médecine.

Je donnerai mes soins gratuits à l'indigent et n'exigerai jamais un salaire au-dessus de mon travail.

Admis dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés. Mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.

Respectueux et reconnaissant envers mes Maîtresses et Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les Hommes et Femmes m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'opprobre et méprisé de mes confrères et consœurs si j'y manque.

Résumé

Introduction : La clé de la rémission du syndrome d'apnée obstructive du sommeil (SAOS) chez les patients avec obésité est la perte de poids. La Sleeve-gastrectomie est un moyen efficace pour perdre l'excès de poids, améliorer le SAOS et diminuer les recours à la pression positive continue (PPC). Une fundoplicature de Nissen concomitante a récemment été proposée pour diminuer le reflux gastroœsophagien (RGO) post-opératoire. L'objectif de cette étude était d'évaluer le taux d'arrêt du traitement par PPC ainsi que le devenir post-opératoire des patients après une Nissen-Sleeve, en comparaison avec une Sleeve gastrectomie.

Méthodes : Dans cette étude monocentrique rétrospective, les patients appareillés par PPC opérés d'une Nissen-sleeve ou d'une Sleeve-gastrectomie au CHU de Montpellier en 2018 ont été inclus. Chaque Nissen-sleeve a été appariée à une Sleeve-gastrectomie selon le sexe, les symptômes de RGO et l'indice de masse corporelle.. Le critère de jugement principal était l'arrêt de la PPC après 3 ans de suivi. Le critère de jugement secondaire principal était la symptomatologie de RGO. Les complications postopératoires respiratoires et chirurgicales ont aussi été évaluées.

Résultats : Quarante-vingt-six patients ont répondu aux critères d'inclusion. Trente-trois patients opérés de Nissen-Sleeve ont été appariés avec 33 patients opérés de Sleeve-gastrectomie. L'arrêt de l'appareillage par PPC était significativement plus élevé dans le groupe Nissen-Sleeve (25/31, 81%) par rapport au groupe Sleeve-gastrectomie (18/32, 56%, $p=0,038$). Le nombre de patients présentant des symptômes de RGO à 3 ans était significativement plus bas après Nissen-Sleeve (3/33, 9 %) qu'après Sleeve-gastrectomie (19/33, 58 %, $p<0,0001$). Aucune différence significative n'a été rapportée concernant les complications postopératoires respiratoires et chirurgicales.

Conclusion : Chez les patients avec SAOS appareillé, la Nissen-Sleeve était associée à plus d'arrêt de l'appareillage par PPC à 3 ans, par rapport à une Sleeve-gastrectomie.

Mots clés : chirurgie bariatrique # Nissen-Sleeve # syndrome d'apnées obstructive du sommeil # Pression positive continue # fundoplicature # obésité # reflux gastro-oesophagien # péri-opératoire.