RESEARCH ARTICLE

Respiratory events in patients undergoing laparoscopic gastric bypass surgery [version 1; peer review: 1 approved, 1 approved with reservations, 1 not approved]

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Abstract

Background: The incidence of morbid obesity is increasing and has led to an increase in bariatric procedures and previous studies have shown that 71% of these patients suffer from obstructive sleep apnea (OSA). Patients with OSA have a higher rate of postoperative complications. We investigated if patients with OSA undergoing laparoscopic gastric bypass surgery have an increased risk of postoperative respiratory events. In this observational study we examined the data of 89 consecutive patients undergoing gastric bypass surgery.

Methods: All patients scheduled for gastric bypass surgery between 7/28/2010 and 02/15/2011 were enrolled and managed according to our routine clinical protocol (48 with OSA / 41 without OSA (NOSA)). Depending on the patient's preoperative compliance with CPAP therapy, they were further assigned into a compliant (OSAc) and noncompliant (OSAn) group. A respiratory event was defined as a deviation from the regular postoperative management.

Results: Both OSA and NOSA groups were similar based on clinical characteristics and narcotic consumption. Fourteen patients (29.2%) suffered from a respiratory event in the OSA group and 8 patients (19.5%) in the NOSA group ($p=0.29$). Patients compliant with continuous positive airway pressure CPAP had a similar complication rate to patients without OSA ($p=0.96$). 53.8% of patients with OSA that were noncompliant with CPAP therapy (OSAn) had a respiratory event in the direct postoperative period. This is statistically significant in comparison to patients diagnosed with OSA that are compliant with CPAP (OSAc) ($p=0.03$).

Conclusion: It may be beneficial to encourage OSA patients to use CPAP preoperatively to reduce postoperative respiratory events.

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Any reports and responses or comments on the article can be found at the end of the article.

Furthermore, adequately treated OSA may not be an independent risk factor for postoperative respiratory events.

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Editorial note:

Please note that the refereeing status of this article was changed from "indexed" to "[v1; ref status: approved 1, approved with reservations 1, not approved 1]".

When this article was first published, *F1000Research* was still in its beta phase; during this period articles that received any two of "Approved" or "Approved with Reservations" statuses from the reviewers were labelled as "indexed". When the journal was formally launched in January 2013, the requirements for indexing were tightened, and only articles that are given either two "Approved" or one "Approved" plus two "Approved with Reservations" statuses by the reviewers are labelled "indexed". The new criteria for "indexing" can still be met in the future if a new revised version receives the necessary approval status from the reviewers.

Introduction

The incidence of morbid obesity is increasing and has led to an increase in bariatric procedures¹. The incidence of obstructive sleep apnea (OSA) amongst patients undergoing bariatric surgery has been shown previously to be 71%². The prevalence of moderate OSA (apnea hypopnea index – AHI $\geq$ 15) in obese patients with a body mass index (BMI) of >40 kg/m² is 42–55% in men and 16–24% in women³. Patients with OSA have a higher rate of postoperative complications^{4,5}.

We investigated if patients with OSA undergoing laparoscopic gastric bypass surgery have an increased risk of postoperative respiratory events and desaturations in the first postoperative night. In this observational study we examined the data of $n=89$ consecutive patients undergoing gastric bypass surgery.

Patients and methods

After Institutional Review Board (IRB) approval was obtained, data on all patients undergoing gastric bypass surgery in a community hospital was collected between 7/2010 and 2/2011. All patients scheduled for gastric bypass surgery were enrolled and managed according to our routine clinical protocol. The need for consent was waived by our IRB due to the entirely observational nature of our study.

The clinical protocol includes a simplified [Berlin questionnaire](#) to detect sleep disordered breathing preoperatively. If patients were determined to be at risk for OSA they were evaluated by a pulmonologist to determine if a sleep study is indicated and continuous positive airway pressure CPAP therapy necessary.

Patients with known OSA were encouraged to bring their CPAP equipment for perioperative use. Patients that used their CPAP device preoperatively were considered to be compliant (OSAc). Patients that were not using their CPAP device preoperatively were considered noncompliant (OSAn). All patients received oxygen via nasal cannula (2–4 l/min) and were monitored with continuous pulse oximetry and EKG after PACU discharge. Desaturations were defined as a pulse oximetry reading $<90\%$. Time spent with an oxygen saturation below 90% during the monitoring period was defined as T90%. If patients showed frequent desaturations the oxygen flow

was increased. If this was insufficient to resolve hypoxemia a mask or CPAP with oxygen was applied to increase the inspired fraction of oxygen and resolve possible obstruction.

The monitoring time started on the day of operation between 21:00–22:00 and ended between 07:00–07:30 the following morning. Pain was managed with intravenous hydromorphone PCA with standard settings (hydromorphone 0.2mg q 6min, 4h lockout 6mg, no basal rate). Hydromorphone consumption was recorded intraoperatively and during the monitoring period. Narcotics given after PACU discharge and before the monitoring time were not recorded.

All respiratory events were counted during the immediate postoperative period starting in PACU until the following morning. A respiratory event was defined as a deviation from the standard management protocol as described above. Application of an oral airway, oxygen mask or CPAP, prolonged postoperative ventilation and unplanned admission to the intensive care unit were considered respiratory events. CPAP is not routinely started in PACU in our institution. The administration of naloxone was considered a respiratory event as it is administered in patients that are considered to be hypoventilating. For all details please see [Table 7](#).

The initial data was entered in an EXCEL spreadsheet and later transferred to a SAS data set for analysis. The categorical data was analyzed with the chi square test for independence. For small subsets for which there was insufficient data for the chi square test to be valid, data analysis was done with the two-tailed Fisher's Exact Test.

Results

89 patients, 63 (70.8%) female and 26 (29.2%) male, underwent gastric bypass surgery. Patients were grouped according to the diagnosis OSA (OSA/ $n=48$) and no diagnosis of OSA (NOSA/ $n=41$). In the OSA group 29 (60.4%) patients were female and 19 (39.6%) male. In the NOSA group 34 (82.9%) patients were female and 7 (17.1%) male. The gender distribution is significantly different in both groups ($p=0.02$).

Raw data - Respiratory events in patients undergoing laparoscopic gastric bypass surgery

1 Data File

<http://dx.doi.org/10.6084/m9.figshare.97066>

The BMI of patients in both groups was statistically not significantly different. Both groups had a similar number of smokers and patients on pain medication. In the OSA group significantly more patients were using antidepressants and anxiolytics. Patients who had OSA also had a significantly higher number of comorbidities ([Table 1](#)).

Both groups (OSA vs. NOSA) received similar amounts of midazolam (2.25mg vs. 2.20mg; $p=0.802$), fentanyl (198 μ g vs. 207 μ g; $p=0.59$) and hydromorphone (1.07mg vs. 0.85mg; $p=0.344$) intraoperatively (mean doses; p value). One patient in the OSA group

Table 1. Clinical characteristics of patients with and without obstructive sleep apnea (OSA/NOSA).

Variable (SD)	OSA (n=48)	NOSA (n=41)	P
Gender f/m (%)	29/19 (60.4%/39.6%)	34/7 (82.9%/17.1%)	0.02
Age	53.25 (11.1)	50.9 (12.9)	0.36 (NS)
Height (cm)	165.48 (10.10)	163.34 (9.49)	0.32 (NS)
Weight (kg)	128.6 (30.4)	127.3 (24.7)	0.09 (NS)
BMI	45.84 (9.29)	43.70 (6.57)	0.14 (NS)
Smoker	7 (14.6%)	4 (9.8%)	0.49 (NS)
Pain Medication	15 (31.3%)	11 (28.8%)	0.65 (NS)
Antidepressants/Anxiolytics	29 (60.4%)	16 (39.0%)	0.04
Comorbidities	4.83 (2.0)	3.65 (2.48)	0.01

SD – standard deviation.
NS – non significant ($p>0.05$).

and 2 patients in the NOSA group received ketamine intraoperatively. Two patients in the OSA group and one the NOSA group received morphine intraoperatively.

Patients were monitored during the first postoperative night with continuous pulse oximetry and EKG. Data was collected at a central monitoring unit. The monitoring time did not differ significantly between groups (Table 2). Patients were monitored for an average of 9.67 hours (9.71 hours in the OSA group/9.62 hours in the NOSA group).

Data was unavailable for 5 patients: 3 patients in the OSA group and two patients in the NOSA group.

The hydromorphone consumption during the monitoring time did not differ significantly between the two groups (Table 3). Patients undergoing gastric bypass surgery required on average 2.13mg hydromorphone during the first night.

Data was unavailable for 6 patients: one patient in the OSA group and 5 patients in the NOSA group.

Two patients in the OSA group received extra analgesic medication. One received 30mg ketorolac intravenous and the other received his home dose of gabapentin (300mg) at night.

Table 2. Total monitoring time during the first postoperative night between patients with and without obstructive sleep apnea (OSA/NOSA).

	OSA (n=45)	NOSA (n=39)	Total (n=84)	P
Average (SD) monitoring time (h)	9.7 (0.56)	9.6 (0.53)	9.67 (0.55)	0.40 (NS)

SD – standard deviation.
NS – non significant ($p>0.05$).

Table 3. Hydromorphone consumption during first postoperative night between patients with and without obstructive sleep apnea (OSA/NOSA).

	OSA (n=47)	NOSA (n=36)	Total (n=83)	P
Hydromorphone (mg) (SD)	2.09 (1.40)	2.16 (1.49)	2.13 (1.59)	0.84 (NS)

SD – standard deviation.
NS – non significant ($p>0.05$).

The total number of desaturations were compared in all groups. A desaturation was defined as oxygen saturation $<90\%$. Patients noncompliant with CPAP showed significantly more desaturations than patients without OSA (NOSA). The other comparisons did not show statistical significance (see Table 4).

Patients who presented with an oxygen desaturation below 90% during the monitoring time did not use more hydromorphone (2.2mg vs 2.0mg; $p=0.66$).

T90% is defined as the time an oxygen saturation below 90% was measured during the monitoring time. The T90% was not significantly different in patients with OSA compared to patients that didn't have a diagnosis of OSA. Patients that were compliant with using CPAP (OSAc) had a similar T90% compared to patients that didn't have OSA (NOSA). Patients that were noncompliant with using CPAP (OSAn) showed a higher T90% than patients that were compliant with CPAP (OSAc) ($p=0.19$), but this finding was not statistically significant. This indicates that patients in all groups had similar T90% (Table 5).

Data was unavailable for 3 patients: one patient in the OSA group and two patients in the NOSA group.

Using a chi square test, there was no statistically significant difference in the incidence of respiratory events in patients in the OSA group compared with in the NOSA group ($p=0.29$) (Table 6). Patients compliant with using CPAP (OSAc) had a similar incidence of respiratory events to patients without OSA (NOSA) ($p=0.96$). Patients noncompliant with using CPAP (OSAn) presented a

Table 4. Comparison of overnight oxygen desaturation $<90\%$ between patients with obstructive sleep apnea in general (OSA), patients compliant or non-compliant with CPAP therapy (OSAc/OSAn) and patients without sleep apnea (NOSA). * chi-square test.

Group	Group	p
NOSA	OSA	NS*
NOSA	OSAn	0.04#
NOSA	OSAc	NS#
OSAc	OSAn	NS#

NS – non significant ($p>0.05$).
Fisher's Exact test.

Table 5. Time of oxygen concentration <90% during monitoring time in percent (T90%) between patients with and without obstructive sleep apnea (OSA/NOSA). * Significance between OSA and NOSA (Chi-square Analysis).

	OSA (n=47)	NOSA (n=39)	p(*)	OSAc (n=35)	OSAn (n=12)	p(\$)	Total (n=80)
Average (SD) in %	5.13 (7.37)	5.14 (10.36)	0.69	5.25% (6.91)	8.30% (8.56)	0.19	5.36 (8.84)

SD – standard deviation.

NS – non significant (p>0.05).

\$: significance between OSAc and OSAn (two-tailed Fisher's Exact Test).

Table 6. Respiratory events in patients after gastric bypass surgery between patients with obstructive sleep apnea in general (OSA), patients compliant or non-compliant with CPAP therapy (OSAc/OSAn) and patients without sleep apnea (NOSA). * Significance between OSA and NOSA (Chi-square Analysis).

	OSA (n=48)	NOSA (n=41)	p(*)	OSAc (n=35)	OSAn (n=13)	p(\$)	Total (n=89)
n	14	8	0.29	7	7	0.03	22
Percent	29.2%	19.5%	(NS)	20.0%	53.8%		24.7%

SD – standard deviation.

NS – non significant (p>0.05).

\$: significance between OSAc and OSAn (two-tailed Fisher's Exact Test).

statistically significant increased risk of suffering a respiratory event compared to patients compliant with CPAP (OSAc) (p=0.03).

We considered assisted or prolonged ventilation, administration of naloxone and unplanned admission to the SICU as serious events. There were 5 serious respiratory events in the OSA group and 2 in the NOSA group (patients 70, 107, 149, 69, 97 and 96, 129). For all details please see [Table 7](#).

Discussion

We prospectively collected data on 89 consecutive patients undergoing gastric bypass surgery between 7/28/2010 and 2/15/2011. 48 patients were previously diagnosed with OSA. Sleep apnea in the surgical population is an independent risk factor for pulmonary complications⁶. This study was not controlled for BMI. Morbidly obese patients seem to have an increased risk of postoperative mortality⁷. It is unclear in the literature if bariatric patients with OSA have a higher incidence of postoperative complications⁵.

Hwang *et al.* found that sleep-disordered breathing (SDB) is associated with an increased risk of postoperative complications. The authors screened patients preoperatively. If patients showed clinical features suggestive of OSA they were selected for home nocturnal oximetry testing. They measured the number of episodes per hour of oxygen desaturation (oxygen desaturation index – ODI) of $\geq 4\%$ (ODI4%) and the percentage of the study time spent with an oxygen saturation of <90% (T90%). A total of 172 patients aged 27 to 85 years were enrolled. They could show that an ODI4% ≥ 5 and a T90% were associated with an increased risk of postoperative complications^{5,8,9}.

These findings are consistent with Liao *et al.*, who reported in their retrospective study, that patients with OSA have an increased incidence of postoperative complications compared to matched controls⁹.

In contrast to the above findings there was no statistical difference in our study in respiratory events in the OSA compared to the NOSA group (p=0.29). In our study 29.2% (14/48) of patients with OSA had a respiratory event compared to 19.5% (8/41) in the group of patients without OSA (NOSA). Patients in both studies had a lower BMI than in our study and patients underwent a variety of different surgical procedures^{5,9}. Interestingly the two patients with an ODI4% <5 in one study that suffered a complication were morbidly obese⁵. In the other study complications included mild and severe desaturations⁹. OSA is defined as a reduction or cessation of airflow with respiratory effort during sleep leading to oxygen desaturations¹⁰. It would be therefore anticipated to find a higher incidence of desaturations in the OSA group as compared to the control group. It is difficult to determine if mild desaturations with an oxygen saturation greater than 90% but less than 95% pose a significant immediate health risk and can therefore be counted as a complication, and it is unclear if the number of total respiratory “complications” in this study would have reached clinical significance⁹.

Jensen *et al.* reported that CPAP and bilevel positive airway pressure (BiPAP) use can be safely omitted after laparoscopic gastric bypass operation. The authors reported data on 1095 patients undergoing gastric bypass surgery. Out of 284 patients with a diagnosis of OSA, 144 used CPAP/BiPAP and 140 did not use CPAP/BiPAP.

Table 7. Narrative of patients having respiratory events.

Roux-en-Y operation	Compliance	Patient ID	Description of respiratory event
OSA (n=48)	c	11	Preoperative nebulizer, intraoperative steroids, inhalers first night
	c	70	Prolonged intubation: on T-piece in PACU after 0.3mg naloxone, hypoventilation, sedated with propofol and mechanically ventilated, extubated 1.5h after the end of surgery
	c	50	OAW in PACU
	c	75	CPAP in PACU
	c	124	Wheezing and UAW obstruction, CPAP and nebulizer treatment in PACU
	c	23	Oxygen mask overnight, no CPAP
	c	22	Subjective "hot and suffocating", normal clinical exam, normal vitals, improvement after nebulizer
	n	87	UAW obstruction, started CPAP first night
	n	141	Requiring oxygen on PACU discharge
	n	107	Intraoperative bronchospasm, facemask in PACU then weaned to 4l/min, apnea first night, naloxone 0.3mg given
	n	149	Bag-mask ventilation on PACU arrival, CPAP started in PACU, unable to wean from CPAP
	n	57	Mild wheezing in PACU, inhalers and CPAP first night
	n	69	UAW obstruction in PACU, BiPAP started, unplanned admission to SICU
	n	97	Severe UAW obstruction, BiPAP applied, unplanned admission to SICU
NOSA (n=41)		96	Apnea during first night, naloxone 0.3mg
		29	OAW in PACU
		58	UAW obstruction, started CPAP first night
		102	UAW obstruction, started CPAP first night
		109	UAW obstruction, started CPAP first night
		62	UAW obstruction, started CPAP first night
		65	UAW obstruction, started CPAP first night
		129	Bag-mask ventilation in PACU, BiPAP started, prolonged PACU stay

OAW – oral airway, UAW – upper airway, PACU – post anesthesia care unit, SICU – surgical intensive care unit, c – compliant with CPAP, n – noncompliant with CPAP.

Patients received supplemental oxygen 2–4 l/min using a nasal cannula postoperatively. CPAP/BiPAP was not used after surgery and patients were instructed not to use it after discharge. The authors defined a respiratory complication as respiratory distress, pneumonia or reintubation within 30 days after gastric bypass operation. Data on overnight oxygen saturations were not published⁸. None of our patients required reintubation, developed pneumonia or respiratory distress postoperatively during the first 24h. CPAP treatment is primarily indicated to treat upper airway obstruction in patients with OSA during deep stages of sleep to prevent hypoxemia¹¹. It can also be used to prevent reintubation in patients developing hypoxemia after surgery. In a randomized controlled trial the use of CPAP with oxygen to treat postoperative hypoxemia after abdominal surgery compared to oxygen alone decreased the need for reintubation and mechanical ventilation and appeared to be safe. As

secondary endpoints, CPAP helped to prevent pneumonia, infection and sepsis but in this study, patients with sleep disorders or BMI>40 kg/m² were excluded¹².

In the literature only 25.8–50% of patients with OSA undergoing bariatric surgery are compliant with CPAP¹³. Patients with OSA who are noncompliant with CPAP seem to have a higher rate of complications compared to patients with OSA who are using CPAP⁹. OSA was shown to be a risk factor in adverse outcome in bariatric surgery¹⁴. In the present study 35 patients (72.9%) were using their CPAP and only 13 patients (27.1%) were noncompliant. 53% of patients with OSA that were noncompliant with CPAP therapy (OSAn) had a respiratory event in the direct postoperative period. This is statistically significant in comparison to patients diagnosed with OSA that are compliant with CPAP (OSAc) (p=0.03).

In the present study patients compliant with CPAP (OSAc) have a similar complication rate compared to patients that don't have OSA (NOSA) ($p=0.96$). In the study by Liao *et al.* patients with OSA that were compliant with CPAP had a higher rate of complication than the control group. Patients in the OSA group had a higher BMI⁹ and this may have influenced the results. Morbidly obese patients are at greater risk of desaturations¹⁵. Obesity is an independent risk factor for sleep-disordered breathing (SDB) and the development of OSA¹⁶. In our study both groups had a similar BMI and were using similar amounts of opioids during the monitoring time. The mean BMI in two large multicenter studies was 46.9–47.0 kg/m²^{14,17}. The average BMI in our study was 47.1 kg/m².

Opioid consumption has a profound effect on SDB and affects sleep architecture.

Anesthetic and analgesic agents used during the perioperative period can decrease pharyngeal tone, and depress ventilatory response to hypoxia and hypercapnia¹⁸. Midazolam and narcotic consumption during surgery and the monitoring period were similar in the OSA group and in the NOSA group. Narcotic consumption may lead to hypoventilation, hypercarbia and hypoxemia. By increasing the inspired concentration of oxygen hypercarbia induced hypoxemia can be prevented. All but one patient received oxygen via a nasal cannula with a flow to up to 4l/min. Incentive spirometry was also encouraged. 3 patients had to be treated with naloxone due to opioid induced hypoventilation (two patients in the OSA group and one in the NOSA group).

In a study by Ahmad *et al.*, 40 patients underwent bariatric surgery. There was no difference in hypoxemic episodes in the group of patients diagnosed with OSA versus patients without OSA. 29 patients underwent gastric bypass surgery and 11 gastric banding. Surgical time for gastric bypass surgery compared to gastric band was longer (150–180min versus 116–125min), more invasive and more painful. Patients required higher doses of narcotic medication intra- and postoperatively (remifentanyl 1060–1520µg vs 525–737µg; morphine 22–25.5mg vs 2–5.4mg). Patients undergoing gastric bypass surgery had a longer hospital stay than patients having gastric banding (60–73h versus 28–29h, respectively). The authors state in their discussion “the lack of a uniform surgical procedure could have affected the results”¹¹. In other words the differences in surgical stress and narcotic consumption could have affected sleep architecture¹⁹. In our study, all patients underwent gastric bypass surgery by one of the two coauthors, (either J. Koppman or R. Marema).

In the study by Ahmad *et al.* oxygen saturation was measured for the first 24h following PACU discharge¹. OSA is a sleep related disorder and may not influence daytime, awake oxygen saturation. Therefore differences that may be found at night may become insignificant when calculating long periods of wakefulness into a data set. This reduced the percent of time spent <90% saturation to 0.2–0.6%. The total monitoring time in our study was exclusively at night when one would expect the most desaturations. The patients in the present study showed the percentage time spent <90% saturation (T90%) of 6.05% in the OSA group and 5.14% in the NOSA group.

Ahmad *et al.* defined an ODI4% as a “hypoxemic” episode. The ODI showed a correlation to apnea-hypopnea-index (AHI) in the polysomnogram (PSG) which helped to determine the severity of OSA²⁰. We defined clinically relevant hypoxemia as oxygen saturation <90%. The T90% was greater in patients who experienced complications compared to those without a complication (20.8% vs 9.9%). Patients in the ODI4% ≥5 group had significantly higher BMI, more comorbidities and underwent a variety of surgical procedures⁵. These factors may have influenced the results.

The small difference in desaturation (T90%) in the present study may be explained by the fact that we failed to identify patients with OSA in the NOSA group. Frey *et al.* found that the incidence of OSA is present in 71% of patients that have been evaluated for bariatric surgery². In a multicenter study the incidence of OSA in patients undergoing gastric bypass surgery was 47%¹⁷. Application of CPAP or BiPAP was considered a respiratory event. 13 patients required CPAP/BiPAP postoperatively [7 (14.6%) patients in the OSA group and 6 (14.6%) patients in the NOSA group]. The STOP-BANG assessment has a high sensitivity (>90%) in detecting patients at risk for obstructive sleep apnea²¹. We did not screen the patients in this study with the STOP-BANG index. We collected only four of the 8 variables available (history of hypertension (HTN), BMI, gender and age). In the group of patients without OSA (NOSA, n=41) 27 (65.9%) patients had at least 3 positive answers. The number of patients with at least three positive answers would most likely be greater if we would have screened for all parameters of the STOP-BANG index. This may make it not very useful in identifying patients at risk for OSA in the bariatric population.

Also the application of oxygen may have prevented more desaturations in the first postoperative night. In the OSA group an average oxygen flow of 3.33l/min was administered. In the NOSA group an average oxygen flow of 2.75l/min was administered. We did not measure inspired oxygen concentration or oxygen flow provided overnight. Patients in one group could have been treated with higher oxygen concentration during the monitoring time influencing the results in this study.

Also the unequal gender distribution may have affected our results. In our study 70.8% of patients were female and 29.2% male. In the literature 77.5–83% of patients that undergo bariatric surgery are female^{1,2,14,17} whereas more male patients have OSA than female² and we did indeed observe a higher percentage of male patients in the OSA group as compared to the NOSA (39.6% vs. 17.1%) group.

In the study by Ahmad *et al.* 74.2% in the OSA group were female and 25.8% male patients. In the NOSA group; all patients were female¹.

Conclusion

The results in the present study suggest that morbidly obese patients with OSA have a similar rate of respiratory complications and desaturations compared to patients without OSA (NOSA) undergoing laparoscopic gastric bypass surgery. Patients with OSA that are noncompliant with CPAP (OSAn) have a statistically

significant increase in respiratory complications compared to patients with OSA that are compliant in the use of CPAP (OSAc). The significant increase in desaturations and T90% in the OSA group simply confirms the diagnosis of OSA. Our study suggest that it may be beneficial to educate and encourage patients with OSA in the use of CPAP to reduce postoperative respiratory events and that adequately treated OSA is not an independent risk factor for respiratory events^{22,23}.

Author contributions

Patrick Ziemann-Gimmel helped design the study, conduct the study, enter and analyze the data and write the manuscript. Pricilla Hensel helped analyze the data and write the manuscript. Salam Abdo helped design the study, analyze the data and write the

manuscript. John Koppman helped design and conduct the study, analyze the data and write the manuscript. Robert Marema helped design and conduct the study, analyze the data and write the manuscript. All authors approved the final manuscript.

Competing interests

Patrick Ziemann-Gimmel received honoraria from Cadence and Baxter and is a shareholder in Cadence and Johnson & Johnson.

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Rob Basner

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Although the subject matter is of great interest, there are many scientific concerns regarding the methodology, which greatly limit any clinical or scientific relevant conclusions to be made. Among these concerns is that the three groups are unbalanced regarding co-morbidities, and the documentation of type of anesthesia other than sedation and narcotic medications, and indeed specification of the type of surgery each patient underwent is lacking. For example, did any patients receive general anesthesia? Was there pre-operative intubation?

In addition, there is also no analysis offered to determine power in order to assess significant differences among groups and similarly, no simultaneous comparison (e.g., ANOVA) among the 3 groups of interest; OSA, OSA (compliant and non compliant). Patient selection for CPAP was apparently not standardized, nor was the use of PAP post-operatively standardized or protocolized. It is also not clear from the study description how much O₂ supplementation was provided and under what conditions (e.g., awake, sleep) was it allowed prior to considering a "deviation from the standard protocol". Overall, there is a lack of standardization of the approach immediately, preoperatively, perioperatively, and post operatively emerging from the study description. Furthermore, there is no clear physiologic or clinical rationale regarding the use of CPAP pre-surgery being protective in this setting, a crucial consideration and an important conclusion one might have made given the gist of these results, particularly since the "no OSA" group likely contained OSA patients. "Compliance" itself was not documented either subjectively or objectively and many upper airway obstruction events were seen even in the "non OSA" group. Additionally, there was no apparent standardization of approach pre-surgically for the identification and treatment of OSA or for any other pulmonary co-morbidities.

Therefore, there is no clear imperative here from which to draw conclusions regarding post operative complication risk, as the overall non-standardization of the methodology and the allowance of clinical bias and design unbalance compromises the scientific validity of such data. Thus, while the subject is of great interest and importance, adjudication regarding the importance of identification and pre-, peri-, and post- operative treatment of OSA in obese patients undergoing the

particular bariatric procedure these patients underwent continues to warrant randomized clinical trials rather than retrospective data.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 15 Nov 2012

Patrick Zeimann-Gimmel, Coastal Anesthesiology, USA

I thank Dr. Basner for his comments and criticism.

All patients underwent one single type of surgery: laparoscopic gastric bypass also known as Roux-en-Y. All patients undergo general anesthesia with endotracheal intubation. One of the reasons for general anesthesia with endotracheal tube is that the abdominal cavity is insufflated to a pressure of 15-20cm H₂O with CO₂. This creates a "cavity" so the surgeon has visibility and room to perform the procedure. So there is uniformity of surgical procedure and type of anesthesia.

We agree completely with Dr. Basner, that a power analysis and possibly other statistical test could be applied to determine sample size or to improve statistical validity. In order to perform a valid power analysis one need to be able to estimate or "best guess" the difference that seems to be relevant. This becomes difficult when there is insufficient data available to guide this "best guess".

We agree that a standardized algorithmic approach to utilization of resources improves homogeneity of the results. Here a clinical approach was used: A patient becomes hypoxemic at any time during the hospital stay. Now interventions are initiated, as described in the methodology, in escalating order to resolve hypoxemia. We made the conscious decision to use a clinical approach to reflect clinical reality.

Patients come treated and optimized by multiple different physicians with multiple different approaches to clinical problems eg. OSA and CPAP initiation. It is correct that potentially some patients were not diagnosed with OSA preoperatively and therefore were being "assigned" to the NOSA group. This could have influenced the results. Patients were screened of being at risk for OSA by a simplified Berlin questionnaire in the surgeon's office. The awareness is very high that bariatric patients suffer from OSA and the threshold very low to refer a patient to a pulmonologist. The pulmonologist then determined if further testing eg. a polysomnogram is indicated. The surgery is delayed until the pulmonologist then optimized the patient's medical condition and "clears" the patient for surgery.

In science randomized clinical trials are base on and designed according to data gathered from studies of lower level of evidence eg. observational, retrospective or case-control studies. This study can serve as a starting point in the field of perioperative medicine taking care of a growing number of morbidly obese patients.

There are certain ethical limitations that need to be considered, also, in the design of prospective randomized trials. Patients with a diagnosis of OSA should be treated accordingly even though there is limited evidence that preoperative CPAP therapy influences outcome.

So how did we change our clinical practice? We continued with the screening process (high awareness/low threshold for referral) and if patients were newly diagnosed with OSA surgery was delayed so patients could get used to the CPAP therapy for 4-6 weeks. We also strongly emphasize to patients the importance of being compliant with CPAP preoperatively early on during the first info sessions.

Competing Interests: No competing interests were disclosed.

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Sairam Parthasarathy

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This is an interesting study with important findings regarding the increased risk for respiratory events in obstructive sleep apnea (OSA) patients who were not adherent to continuous positive airway pressure (CPAP) therapy.

There are, however, limitations to this study in that the decision-makers were not blinded to the purpose of the study and the definition of "respiratory events" was all encompassing and included initiation of nasal CPAP for oxygen desaturations that failed to respond to O₂ alone. Conceivably, due to the nature of the OSA and its treatment, it may have been prudent to have included only the following; application of an oral airway, prolonged postoperative ventilation, unplanned admission to the intensive care unit, post-operative pneumonia, and respiratory failure/re-intubation. Furthermore, Cox-proportional hazards analysis with time-to-event and adjustment for covariates could have increased the power and have adjusted for known confounders (such as anxiolytics) in this observational study.

Lastly, a caveat for the finding that there was no difference in respiratory events between OSA and non-OSA group should be that there may not have been sufficient power to detect any differences. A power analysis for such comparison if performed prior to study initiation could have been helpful.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 13 Nov 2012

Patrick Zeimann-Gimmel, Coastal Anesthesiology, USA

Thank you Dr. Parthasarathy for your comments and criticism.

The idea for this study was to determine if a OSA increases the postoperative risk for a respiratory event. In the current literature there is either a too broad definition of "complication" e.g. only pneumonia or re-intubation or patients were undergoing a variety of procedures with different narcotic requirements and different degrees of inflammation. We used a homogenous group of patients (gastric bypass) and decided to use a clinical approach. A deviation from the routine clinical protocol implies that health care providers spend more time treating patients who for example desaturate despite having an oxygen mask and have to then "fit" a CPAP in the middle of the night.

Secondly, as you pointed out correctly, severe adverse outcomes such as pneumonia could have been included. Typically those develop later in the clinical course unless there would be direct evidence of aspiration in the perioperative period. Our goal was to collect data in the immediate postoperative "first night" where we believe sleep and its related breathing disorders are affected the most due to the degree of inflammation and higher narcotic requirements, anticipating the greatest difference in both groups. It is still a matter of discussion if there is a "REM rebound" on the third postoperative day leading to an increase in the apnea-hypopnea index.

I completely agree that blinding increases the validity of results but this would be a difficult task in an observational study. Also a prior power analysis is clearly helpful to determine group size and to increase the validity of results. Unfortunately the data available is unclear in what the anticipated relative risk difference/reduction is in patients with OSA or without OSA. I also agree that a bigger sample size would have helped to validate the results but this in turn poses an ethical problem. The PI observes more respiratory events in patients non-compliant with CPAP. I saw it as my responsibility to improve patient care as soon as I saw a difference and we changed our clinical approach accordingly. This is the drawback of an observational study that protocols may change during the observational period. Also, only a few weeks after concluding the initial data acquisition we decided to change our postoperative analgesic treatment to a multimodal approach reducing significantly the narcotics. This would therefore have made a comparison difficult.

Again thank you very much Dr. Parthasarathy for your comments.

Competing Interests: No competing interests were disclosed.

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Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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