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CLINICAL REPORT

Morbidity in Patients with or at High Risk for Obstructive Sleep Apnea after Ambulatory Laparoscopic Gastric Banding

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Abstract Considerable controversy exists about the perioperative management of patients at high risk for obstructive sleep apnea (OSA) in free-standing clinics. Eighty-eight percent of an American Society of Anesthesiologists expert panel felt that upper abdominal laparoscopic surgery could not be performed safely on an outpatient basis. We sought to review the incidence of major adverse events after outpatient laparoscopic adjustable gastric banding (LAGB) in a high risk population for OSA at a free-standing facility. Research Ethics Board approval was obtained and charts were reviewed retrospectively for 2,370 LAGB performed at a free-standing clinic between 2005 and 2009. In this observational cohort study, patients were classified as high risk for OSA if they received continuous positive airway pressure (CPAP) treatment for OSA pre-operatively or had a history of at least three STOP-BANG criteria. Follow-up was verified and adverse events reviewed, including death, unanticipated transfer or admission to hospital within 30 days. A total of 746 of the 2,370 patients (31%) met criteria for or were at high risk for OSA (357 received CPAP for OSA and 389 by STOP-BANG criteria). The incidence of transient desaturation to less than 93% was 39.5%. There were no deaths and no cases of respiratory failure or re-intubation. The 30-day mortality was zero and the 30-day anesthesia related morbidity was less than 0.5%. For patients at high risk for OSA after LAGB, the significance of transient oxygen desaturation and the need to develop monitoring and admission standards remain to be determined.

Keywords Sleep apnea · Obstructive · Ambulatory care facilities · Obesity

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Introduction

It has been estimated that between 2% and 25% of the general population suffers from obstructive sleep apnea (OSA) [1] which is associated with significant long-term health consequences [2]. OSA may lead to postoperative complications such as oxygen desaturation [3] and re-intubation or other respiratory support. Due to concerns regarding the perioperative morbidity and mortality of patients with OSA, the American Society of Anesthesiologists (ASA) convened an expert panel task force which published practice guidelines for the perioperative management of patients with OSA [4].

The panel determined that there was a lack of scientific evidence so that many of the guidelines for increased monitoring were based on expert opinion and open forum commentary. The task force recommended that patients with OSA be monitored for 3 h longer than their non-OSA

counterparts before discharge. A survey of the consultants showed that 88.1% of respondents felt that upper abdominal laparoscopic surgery could not be performed safely on an outpatient basis for patients with known or suspected OSA [4].

The incidence of obesity is steadily increasing in North America and there has been a dramatic increase in the number of bariatric surgical procedures worldwide [5]. Laparoscopic weight loss surgery is being performed on an outpatient basis [6, 7] and in keeping with the general growth of out-of-hospital procedures, increasingly in free-standing ambulatory surgery centers [8].

Obese patients have a markedly increased incidence of OSA [9]. Many of the patients presenting for weight loss surgery via upper abdominal laparoscopy have either known or suspected OSA. It is not clear whether the rate of postoperative complications, particularly oxygen desaturation, leads to a clinically relevant increase in perioperative morbidity and mortality.

Our hypothesis was that upper abdominal laparoscopic surgery could be performed safely on an outpatient basis for patients with known or suspected OSA. We thus sought to review the incidence of major, clinically relevant adverse events (defined as unexpected events that negatively affect the patient's health or quality of life for a minimum period of 2 weeks) occurring within 30 days after ambulatory laparoscopic adjustable gastric banding (LAGB) in a high-risk population for OSA at a free-standing non-hospital based facility.

Materials and Methods

Institutional Review Board approval was obtained from the primary author's base hospital (the free-standing clinic does not have their own REB) for a retrospective observational cohort study to review patient charts who had LAGB performed at a single free-standing clinic in Mississauga, Ontario (Canada) from February 2005 to December 2009 inclusive. This clinic is entirely free-standing and not associated with a hospital. Patients were excluded if they had previous bariatric surgery (total of 16 patients) or if they had surgery performed due to uncontrolled comorbidities (i.e., aortic stenosis, poorly controlled atrial fibrillation, myasthenia gravis) or anticipated technical difficulties at the local hospital (total of 92 patients) because of anticipated higher risk for admission due to surgical factors and different care protocol in the hospital (i.e., invasive monitoring, routinely prolonged observation, etc.).

Patients were subdivided into (1) those having OSA if they indicated during the history that they had been diagnosed with OSA and used CPAP or (2) were deemed to be at high risk for OSA if they had at least three of the STOP-BANG [10] criteria documented on the chart (i.e., age over 50, male sex, HTN, BMI over 35, neck circumference over 40 cm), and (3) all other patients.

Anesthetic management of patients for LAGB at the free-standing clinic as per practice by the anesthesia provider group is described in Table 1 with a random sample of approximately 5% of all charts (as well as the charts from all patients with adverse events) audited for compliance with the anesthetic management. Patient information was extracted from the patients' charts, recorded, and entered into a spreadsheet summarizing demographic data, clinical variables, and adverse events (see Table 2). Unexpected outcomes were tracked, including (but not limited to) oxygen desaturation in the OR (after extubation and until arrival in the PACU) and in the PACU (arbitrarily defined as documented $SpO_2<93\%$), delayed discharge from the PACU (defined as over 4 h), unanticipated transfer

Table 1 Anesthetic care

1. Oral premedication with 8 mg ondansetron, 600 mg gabapentin, and 200 mg celecoxib 1 h prior to the procedure
2. Intravenous (iv) premedication with midazolam 1–2 mg prn
3. Pre-oxygenation followed by iv induction with 200–300 mg propofol (PPF), 1–2 mcg/kg of fentanyl, and 50 mg rocuronium, ventilation to maintain $SpO_2\geq93\%$ and normocapnia
4. Intraoperative administration of iv 10–20 mg dexamethasone, iv 1–2 gm cefazolin, iv 60 mg ketorolac, subcutaneously 2,500 U Fragmin, intermittent venous compression devices and repeat dose of iv 4 mg ondansetron
5. Maintenance with PPF infusion at 100–150 mcg/kg/min and isoflurane (up to 0.5%) or sevoflurane (up to 1%) with 50% oxygen/nitrous oxide (no BIS monitor)
6. Insertion of a nasogastric tube
7. All patients had their neuromuscular blockade reversed and were extubated in the OR followed by administration of oxygen by facemask as needed
8. PACU pain medication included meperidine up to iv 50 mg, fentanyl up to iv 50 μg or po codeine for patients taking po fluids
9. Antiemetic treatment in the PACU consisted of prn prochlorperazine up to 10 mg, followed by repeat doses of dexamethasone and ondansetron
10. All patients received supplemental oxygen on arrival to the PACU and were encouraged to resume using their CPAP masks in the PACU (if applicable) for a $SpO_2<93\%$

Table 2 Data sample sheet

Patient ID	Numeric identifier
Age	Age in years
Gender	Female=0, Male=1
HTN	Treated hypertension=1, other=0
D.m. I	Treated D.m. I=1, other=0
D.m. II	Treated D.m. II=1, other=0
Sleep apnea	Diagnosed OSA on CPAP=1, other=0
Asthma	Diagnosed asthma=1, other=0
ASA status	ASA status numeric
Neck circumference	Documented over 40 cm=1, all others=0
Body mass index	Numeric value
Duration anesthesia	Time in minutes
Duration PACU stay	Time in minutes
Lowest SpO_2 (reviewer #1, comment #4) in OR (after extubation and until arrival to PACU)	Lowest documented O_2 saturation in percent
Lowest SpO_2 (reviewer #1, comment #4) in PACU	Lowest documented O_2 saturation in percent
Admission/transfer to hospital	Admission or transfer on day of surgery=1, all others=0
Admission/transfer to hospital	If admission/transfer=1, narrative description of details
Complication/follow-up	Other adverse events until day 30=1, all others=0
Complication/follow-up	If other adverse events until day 30=1, narrative description of details

on the day of surgery, hospital visit within 30 days, or death. Missing data were treated as blanks.

The primary outcomes of interest were death, respiratory failure or re-intubation, and admission or transfer anytime to a hospital within 30 days. The secondary outcome measures were incidence of desaturation, anesthetic time, and time in PACU.

Descriptive statistics were calculated for all variables of interest. Continuous measures were summarized using means and standard deviations, whereas categorical measures were summarized using counts and percentages. Confidence intervals (CI) (95%) were provided where appropriate. The sample was sufficient to provide 95% confidence intervals around estimates with less than 4% absolute margin of error for our outcome of interest. As over 90% of the data was complete, there were no concerns regarding missing data (missing data were restricted to secondary outcomes only and usually the result of illegible or incomplete charting). All analyses were carried out using SAS Version 9.1 (SAS Institute, Cary, NC, USA).

Results

Three patients did not have upper abdominal laparoscopic surgery and thus had to be excluded from the database (one patient, who could not be intubated, was transferred to the hospital, discharged and declined further surgery; two patients, who became hypotensive during induction presumably due to relative hypovolemia, were transferred to the hospital, discharged, and subsequently underwent uneventful inpatient LAGB). Ninety-three patients had elective in-hospital surgery at the local hospital due to uncontrolled comorbidities and had thus been excluded from the study also. A total of 2,370 patients met the study criteria and were included in the review. Of those patients, 746 (31%) were documented to be at high risk for OSA (357 with diagnosed OSA and 389 who had at least three of the STOP-BANG criteria documented on the chart, i.e., age over 50, male sex, HTN, BMI over 35, neck circumference over 40 cm). Information about snoring, tiredness, and observed apnea had not been routinely documented in the patients' charts. Demographics are listed in Table 3. The study investigators noticed that a number of patients had been classified as ASA 4 on the anesthesia records and reviewed the history of respective patients in greater detail (note: regulations to declare ASA 4 patients unsuitable for surgery in free-standing facilities only came into effect after December 2009). Even though there was no documentation that any of the comorbidities represented a constant threat to life, the decision was made not to change the ASA classification that was recorded on the chart.

Average anesthetic time was 85±22 min (mean±SD), and average time in the PACU (phase I and II) was 126± 31 min (mean±SD). Seven patients had a delayed discharge from the PACU (range 245–315 min, five patients due to drowsiness, one due to nausea, and one due to a delay with transportation home). Oxygen saturation in the OR after

Table 3 Demographic information

	All patients	Patients with documented OSA or at high risk for OSA (subgroup of all patients)
Number	*n*=2,370	*n*=746
Average age (mean±SD)	46±11	53±9
Male (%)	424 (18%)	284 (38%)
Female (%)	1,947 (82%)	462 (62%)
Average BMI (mean±SD)	42.7±7.7	44.9±7.6
Hypertension	732 (31%)	531 (71%)
Diabetes mellitus type 1 (reviewer#2 comment#21)	30 (1%)	25 (3%)
Diabetes mellitus type 2	306 (13%)	200 (27%)
Asthma	305 (13%)	106 (14%)
ASA I	129 (5%)	17 (2.2%)
ASA II	1426 (60%)	291 (39%)
ASA III	757 (32%)	423 (57%)
ASA IV	12 (0.5%)	10 (1.3%)

extubation or post-anesthesia care unit was less than 85% for 18 patients (2.4%, range 68–84%), 85–89% for 46 patients (6.1%), and 90–92% for 231 patients (30.9%). Overall, the incidence of transient desaturation after extubation to less than 93% was 39.5% (295 of 746 patients; 95% CI 35.9–43.1%). The incidence of desaturation to <93% occurred in approximately twice as many patients immediately after extubation as compared to during their PACU stay (290 patients versus 126 patients). Selected outcome variables are listed in Table 4.

All patients were followed-up by the surgical team and information about major adverse events were recorded on the patient's chart. There were no deaths and no cases of respiratory failure or re-intubation among the 746 patients who were documented to be at high risk for OSA. One patient was transferred to hospital because of severe nausea presumably caused by gastric obstruction due to swelling around the gastric band which resolved over 48 h. Four patients required hospital admission within 30 days of surgery, three for transient dysphagia, and one due to an infectious complication.

There were also no deaths and no cases of respiratory failure or re-intubation among the remaining 1,624 patients. A total of 15 of those patients experienced complications which resolved in all cases without long-term sequelae, and all those events except for two were surgery related. One patient had postoperative respiratory distress and was transferred to the hospital to be released the same day and another patient could not tolerate fluids the next day and required temporary admission for medical management, including IV fluids.

Discussion

Advances in clinical care have led clinicians to migrate away from tertiary care hospitals into smaller ambulatory care centers and ultimately free-standing clinics. This has been fueled by demand from both patients and health care providers alike [11]. As the incidence of obesity (and OSA) increases, anesthesiologists and surgeons are looking for clinical practice guidelines to assist in the management of

Table 4 Selected outcome variables

	All patients	Patients with documented OSA or at high risk for OSA (subgroup of all patients)
Number	*n*=2,370	*n*=746
Anesthetic time	83±23 min (mean±SD)	85±22 min (mean±SD)
Time in PACU (phase I and II)	127±31 min (mean±SD)	126±31 min (mean±SD)
Incidence of SpO_2<93%	29.8% (95%CI 27.0–31.7%)	39.5% (95%CI 35.9–43.1%)
Deaths	0	0
Respiratory failure or re-intubation	0	0
Readmission or transfer within 30 days	20	5

patients at high risk for OSA. Unfortunately, the current recommendations, including the ASA's Practice Guidelines, lack scientific support for their recommendations and thus are not evidence-based.

In our study, we found that the incidence of clinically significant morbidity and mortality among a patient population at high risk for OSA presenting for LAGB appears to be very low. The incidence of hypoxia in the OR (after extubation) or PACU (defined as SpO_2 less than 93%) in our study was high (39.5%) but consistent with other similar studies [3]. A higher incidence of desaturations occurred immediately after extubation (and despite oxygen administration), but this seemed to decrease with the patients' arrival to the PACU. Desaturations did not lead to any delay in discharge and do not seem to have been associated with any significant morbidity: the 30-day mortality was zero and the 30-day anesthesia related morbidity was less than 0.5% (one case of hospital transfer with nausea that was probably related to swelling around the gastric band).

There are limitations to our retrospective observational study. The charts recorded only the diagnosis of OSA (but not the severity). Therefore, it is theoretically possible that a large fraction of the patients in our sample could have had mild OSA and minimal implications for perioperative care. However, all those patients had been advised to use CPAP and thus it is likely their OSA was at least moderate in severity. Also, not all the items on the STOP-BANG questionnaire were documented in the chart (information about snoring, tiredness, and observed apnea). However, the STOP-BANG questionnaire has been validated and classifies patients with three or more items at high risk of OSA, so that regardless of the findings for the other criteria, the risk classification for these patients would not change. The lack of information about the other items did not allow us to draw conclusions about the remainder of the patients, as they may or may not meet the STOP-BANG criteria for being at high risk of OSA.

Since the STOP-BANG questionnaire has high sensitivity, but only limited specificity [12], it is possible that the majority of the patients in this study who were deemed at high risk for OSA based solely on their STOP-BANG score, did not have significant OSA. However this is unlikely, as other studies have shown the prevalence of OSA in morbidly obese patients alone, scheduled to undergo bariatric surgery, to be as high as 68% (mean BMI 49, with a mean AHI 31 [13].

Due to the sample size, this study may lack the power to detect rare, but catastrophic adverse events and also the findings in this study may not be applicable to other patient populations with OSA, as this patient cohort may represent a sub-population of unusually motivated patients.

We conclude that the incidence of clinically significant morbidity and mortality among a patient population at high risk for OSA presenting for LAGB appears to be very low. The long-term significance of transient oxygen desaturation in patients at high risk for OSA after LAGB and the implication for developing monitoring and admission standards for this patient population remains to be determined.

Further studies utilizing clinical data rather than expert opinion are required to identify factors that must be considered when developing perioperative guidelines for patients at risk for OSA.

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