Research Article
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Routine ward admission of the postoperative bariatric surgical patient with obstructive sleep apnoea as a safe alternative to level II critical care: a retrospective non-inferiority cohort study

Abstract

Objective: Determine if managing post-operative bariatric patients with obstructive sleep apnoea (OSA) in a ward environment is non-inferior to level II critical care/high dependency care unit (HDU) monitoring.

Design: A retrospective, non-inferiority, cohort study

Setting: Joondalup Health Campus, a 650 bed hospital located in Perth, Western Australia and the state's centre for bariatric surgery

Participants: All publicly insured patients who underwent uncomplicated bariatric surgery, confirmed or suspected of having OSA.

Intervention: A pre-planned change in hospital practice to routine post-operative admission to the ward based specialised nursing unit, instead of the HDU from July 2015.

Main outcomes/measures: Patient's records were reviewed to note the occurrence of the following outcomes; presence of hypoxia, hypoxic events, apnoea, use of supplemental oxygen, use of non-invasive ventilation, need for medical review, upgrade of care and presence of major clinical events including those related to OSA. Data underwent statistical analysis using Agresti-Caffo confidence intervals to determine non-inferiority at a tolerance level of 10%.

Results: 112 patients admitted to HDU (between February 2014 and June 2015) were compared to 100 patients admitted to the special nursing unit (between July 2015 and June 2016). In both cohorts, no patients experienced adverse clinical outcomes related to OSA. Ward care was established as non-inferior to HDU care for all outcomes except for the number of patients receiving supplemental oxygen. No patient on the ward suffered a major clinical event compared to two in HDU.

Conclusion: Post-operative ward-based management of OSA in the bariatric surgical patient is both safe and consumes less critical care resources, without negatively affecting patient outcomes.

Keywords: bariatric surgery, obstructive sleep apnoea, obesity, intensive care medicine, anaesthesia, perioperative medicine

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Introduction

Obstructive sleep apnoea (OSA) is a condition associated with the collapse of the oropharyngeal airway during sleep resulting in obstruction of airflow despite respiratory efforts.[1] As a result, patients exhibit episodes of apnoea, hypoxia, snoring and fragmented sleep leading to daytime somnolence. OSA has been linked to cognitive deficits, motor vehicle accidents, increased cardiovascular disease, metabolic syndrome and increased perioperative morbidity independently from obesity.[2,3] Obesity is a major risk factor for OSA. Large amounts of adipose tissue can exacerbate the collapse of pharyngeal soft tissue and reduce lung volumes. The prevalence of OSA in the general adult population is thought to range between 9 to 38%,[4] with OSA occurring in 70-90% of the bariatric population.[5,6] OSA is of special concern to the anaesthetist, with these patients having an increased risk of respiratory depression, apnoeic episodes and cardiac events during the post-operative period. Patients with BMI greater than 27 were 2.8 times more likely to suffer from pulmonary complications post operatively than those with a lower BMI.[7] There is also additional concern regarding the use of opioids post operatively due to the risk of profound respiratory depression.

These concerns often prompt routine patient admission to high dependence (level II critical care) units.[8] Several guidelines recommend the use of continuous pulse oximetry in this patient cohort, with additional monitoring of haemodynamic, respiratory rate and end tidal CO_2 in high risk patients.[9,10] In 2014, the American College of Anaesthesiologists acknowledged that there remains limited data on whether these patients require admission to a critical care unit.[9] In the last decade there have been a handful of studies demonstrating a lack of benefit of routine admission to the intensive care unit. In 2010, Grover et al compared post-operative outcomes of gastric bypass patients with OSA compared to those without OSA when managed on a surgical ward.[11] They found no significant difference in

postoperative mortality or pulmonary complications between the two groups, concluding there was no benefit of routine ICU admission for these patients. Shearer et al. established that patients with OSA, post laparoscopic bariatric surgery did not require routine admission to ICU and could be safely monitored in a surgical high dependency unit (HDU) on the ward.[12] No studies have yet directly compared or have established non-inferiority with regards to postoperative morbidity of patients with OSA managed on the ward against management in HDU. In the 2014-2015 period the number of bariatric weight control surgeries in Australia reached 22 700, more than double that of the 2005-6 period.[13] As bariatric surgeries become more frequent, the escalating use of critical care beds for OSA monitoring will have a tremendous impact on costing and resource allocation for hospitals. This study aims to determine if managing post-operative bariatric patients with OSA in a ward environment is safe and non-inferior to high dependency care monitoring.

Methods

Joondalup Health Campus (JHC) is a 650 bed hospital located in Perth, Western Australia and is the state centre for bariatric surgery. Prior to 2015, all patients undergoing bariatric surgery with OSA (either suspected or proven) were admitted to the HDU. In 2015, a specialised nursing unit on the surgical ward was developed to provide continuous oxygen saturation measurement and closer monitoring of post-surgical bariatric patients. All uncomplicated bariatric surgical patients were then admitted to the surgical ward rather than HDU. The treating anaesthetist could however request a post-operative HDU review if there were clinical concerns; such patients were then omitted from the surgical ward cohort. This study was approved by Joondalup Health Campus' Human Research Ethics Committee. Patients were enrolled by retrospective review of admission logs. Between February 2014 to June 2015 patients admitted to HDU fitting the below clinical criteria were included in the study. Comparative cohort data was collected from July 2015 to June 2016 in patients with identical inclusion criteria admitted to the special nursing unit.

Inclusion criteria for patient selection:

1. Publicly insured patients undergoing bariatric surgery, defined as one of the following:
   a. Gastric band
   b. Removal of a gastric band
   c. Gastric sleeve
   d. Removal of gastric band with conversion to sleeve
   e. Gastric bypass
2. Formal diagnosis of OSA based on a sleep study or suspected of having obstructive sleep apnoea by anaesthetic assessment using a STOPBANG[1],14
3. Undergoing general anaesthetic: Patients were excluded if undergoing bariatric surgery in conjunction with another surgery or if admitted privately (nursed on separate ward).

Standards of care

High dependency unit

Patients admitted to the HDU were nursed on a 2:1 nurse patient ratio. Patients underwent continuous electrocardiogram recording, pulse oximetry measurements and hourly monitoring of observations. Apnoeas were identified using *impedance* plethysmography. Routine alarmed monitoring systems were in place in the HDU to alert nursing staff to desaturations (SpO_2<90%) or apnoeic episodes. The HDU was staffed 24 hours a day by a junior medical officer, with access to an intensive care registrar and consultant.

Surgical ward

Standard of care for patients admitted to the special nursing unit on the ward included hourly observations for 24 hours, progressing to two hourly observations thereafter. Patients were nursed as a 5:1 patient nurse ratio. Continuous pulse oximetry was in place from the post-operative recovery bay until at least 24 hours post operation when it was ceased at the discretion of the consultant Anaesthetist. Apnoea monitoring was reliant on nursing staff observing apnoeic episodes.

Outcomes and analysis

Patient's records were reviewed retrospectively to note the occurrence of any of the below over whole duration of their admission in either unit.

1. Episodes of hypoxia (oxygen saturations below 90%)
2. Number of hypoxic events
3. Presence and number of apnoeas (defined as temporary cessation of breaths for greater than 10 seconds)
4. Use of supplemental oxygen overnight to maintain oxygen saturations above 90%
5. Use of non-invasive ventilation
6. Requirement of nursing review and/or medical review
7. Requirement of upgrade of care from post-operative recovery bay (e.g. to HDU instead of ward or ICU instead of HDU)
8. Presence of major clinical incident (defined as return to theatre, intubation or resuscitation)
9. Presence of adverse clinical outcomes deemed to be related to OSA

Once collated, the data underwent statistical analysis aimed at determining non-inferiority, with HDU acting as the control and the special nursing ward representing the experimental design. Using Stata (v.14) 90% confidence intervals were calculated for the risk differences between the two independent proportions using the Agresti-Caffo method. For the trial, the tolerance level was set to 10% determined by clinical reasoning, considering the severity of each outcome and the advantages of pure ward-based care such as financial benefits and judicious use of resources.

Results

112 HDU patients and 100 ward patients were identified as fulfilling the inclusion criteria detailed above. Baseline characteristics (Table 1) between the two cohorts were comparable except for minor differences in the presence of additional comorbidities, current smoking status and formal diagnosis of OSA. The HDU cohort had a marginally higher rate of COPD and current smoking status. A formal diagnosis of OSA was more prevalent in the HDU patient cohort than the ward cohort. HDU patients were also more likely to have documented severe OSA. Prevalence of clinical outcomes is documented in Table 2. In both

[1]STOPBANG is a questionnaire developed by Chung et al in 2008 which screens for OSA. It has been validated in various studies and settings.[14]

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cohorts, no patients experienced adverse clinical outcomes related to OSA. Two HDU patients experienced post-operative intra-abdominal haemorrhages following gastric sleeve, unrelated to OSA. There were no major clinical events in the ward cohort of 100 patients.

Table 1 Baseline characteristics of bariatric surgical patients included in HDU and Ward cohorts

Characteristic	HDU patients		Ward patients	
N (total number of patients)	112		100	
Average age (years)	45.5		42.4	
Males	38	-33.90%	31	-31.00%
Females	74	-66.10%	69	-69.00%
Average BMI male (kg/m2)	44.7		43.6	
Average BMI female (kg/m2)	52		47.1	
TYPE OF SURGERY				
Gastric band	35	-31.30%	30	-30.00%
Gastric sleeve	62	-55.40%	55	-55.00%
Gastric bypass	7	-6.30%	9	-9.00%
Removal of gastric band	6	-5.40%	6	-6.00%
Removal of gastric band and gastric sleeve	2	-1.80%	0	0.00%
Current smoker	27	-24.10%	18	-18.00%
Average cigarettes (if smoker)	16.4		11	
Formal diagnosis of OSA	72	-64.30%	35	-35.00%
Mild OSA (AHI 5-15)	2	-1.80%	9	-9.00%
Moderate OSA (AHI 16-30)	3	-2.70%	1	-1.00%
Severe OSA (AHI> 30)	23	-20.50%	8	-8.00%
Severity not documented	44	-39.30%	20	-20.00%
Using NIV at home	41	-36.60%	11	-11.00%
Prescribed regular opioids post operatively	36	(32.1%)	37	(37.0%)
Comorbidities: Asthma	31	-27.70%	28	-28.00%
Comorbidities: COPD	4	-3.60%	1	-1.00%

Table 2 Prevalence of outcomes in HDU and Ward cohorts

Outcome	HDU patients (n%)		Ward patients (n%)	
N (total number of patients)	112		100	
Unplanned admission to ICU (HDU listed patient)	1	-0.90%		
Unplanned admission to HDU (ward listed patient)			1	-1.00%
Post-operative hypoxia	27	-24.10%	21	-21.00%
Number of hypoxic events (total)	69		78	
Patients receiving supplemental O2	64	(57.1%)	69	(69.0%)
Patients having apnoeas	14	(12.5%)	7	(7.0%)
Use of NIV	38	-33.90%	19	-19.00%
Hospital's NIV machine used	29		10	
Patient's NIV machine used	9		9	
Required medical review for OSA	2	-1.80%	2	-2.00%
Required nursing review for OSA	32	-28.60%	24	-24.00%

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Table Continued....

Outcome	HDU patients (n%)		Ward patients (n%)	
Average HDU stay	1.2 days			
Required HDU stay >1 day	14	(12.5%)		
Delayed due to bed block	10	(8.93%)		
Delayed due to OSA requiring further NIV	2			
Major clinical event	2	-1.78%	0	0%
Major clinical event related to OSA	0	0%	0	0%
Discharged to ward	48	-42.90%		
Discharged directly home	64	-57.10%	100	-100.00%
Average length of Hospital admission	2.2 days		1.85 days	

From the post-operative recovery unit, one patient was admitted to HDU instead of the ward due to persistent apnoeas and sedation. Two ward patients and two HDU patients required medical review and intervention for OSA. These two HDU patients required CPAP for frequent apnoeas. One ward patient required medical review due to inability to maintain oxygen saturations with NIV alone, requiring the addition of supplemental oxygen. The second ward patient had a malfunctioning home CPAP machine and required supplemental oxygen to maintain saturations. Neither required upgrading to HDU level care. Where nursing review was required, staff mainly provided supplemental oxygen to maintain prescribed saturations, without a need for medical review.

On average, patients spent 1.2 days in HDU post operatively (14 of 112 stayed more than one day), 10 of the 14 patients who stayed for more than one day, remained in HDU due to hospital bed block. 2 patients were unable to be weaned off NIV on day one, and two patients developed intra-abdominal haemorrhages necessitating a return to theatre. Non-inferiority testing was not carried out for the outcomes of major clinical events and major clinical events related to OSA as no events occurred either on the ward and/or HDU, so a comparator could not be processed. Ward care was established as non-inferior to HDU care for all remaining outcomes excluding number of patients receiving supplemental oxygen, in which the number of HDU patients was statistically significantly less. 90% confidence intervals for risk difference for each outcome proportion are shown below in Figure 1 against the pre-determined tolerance level of 10%.

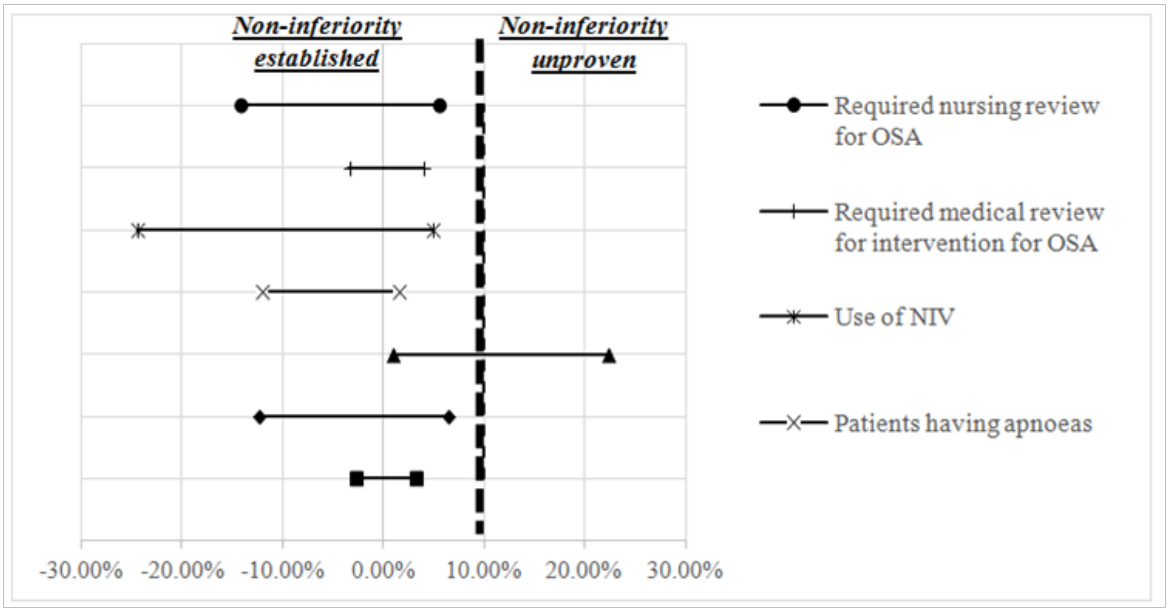

Figure 1 Agresti-Caffo 90% confidence intervals for outcomes plotted against tolerance level of 10%.

The routine use of high dependency units for post bariatric surgical patients has received scrutiny over the past few years due to concerns about judicious use of limited resources, funding and the increased number of bariatric surgical procedures being performed.[15] This study was aimed to answer the question "can post-operative bariatric surgery patients with OSA be safely managed in a ward environment?" Overall, our study found that there were no significant differences in any outcome when post-operative bariatric patients were cared for on a ward compared to HDU. No patients suffered major complications related to OSA in either group.

Our trial should reassure clinicians that uncomplicated bariatric surgical patients with confirmed or suspected OSA can be managed safely in a ward setting with continuous oxygen saturation monitoring under the care of nursing staff. Despite a statistically significant greater use of supplemental oxygen used on the ward than on HDU,

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this difference did not translate into an increased number of OSA related adverse clinical events or requirement for medical review when compared to HDU.

Unnecessary use of HDU beds for these patients has flow on effects for other healthcare users. 8.9% of patients were unable to be discharged from HDU to the ward due to hospital bed block, and 57.1% of patients were discharged directly home from HDU. Having such patients directly admitted to the ward would free precious critical care beds for sicker patients allowing for fairer resource allocation. These results complement a growing body of literature that does not advocate routine admission of post bariatric surgery patients with OSA into a critical care setting. Kadam et al.[16] discussed a similar concept in 2015 when 173 patients with mild OSA (determined by clinical assessment) were placed in a ward with 5:1 nursing care and continual oxygen saturation monitoring instead of HDU.[16] They established comparable rates of hypoxic events (19-28%) and only one patient suffered a major adverse outcome. The feasibility of managing OSA in the ward is not limited to patients with mild disease. Goucham et al. 2015 sited no major adverse outcomes in their cohort of 151 ICU patients with severe OSA who had undergone bariatric surgery, 17.4% of whom of patients experienced desaturations[15] which was similar to our rates of 21-24%. They concluded that these patients represent a low clinical risk and questioned the necessity of routine critical care admission even in this traditionally considered higher risk group.

Our study incorporated a broad range of OSA severities, 75% of ward patients did not have a formal diagnosis of OSA making our results highly generalizable to the standard bariatric patient, the majority of who do not have a known diagnosis of OSA. Additionally, whilst previous literature has suggested the need for both continue ECG monitoring and pulse oximetry for safe monitoring of these patients on the ward, our study did not utilise ECG monitoring forward patients.[12] The absence of arrhythmias in the monitored HDU group and the lack of adverse events in the ward cohort suggests that continuous pulse oximetry may be all that is required. There are several important limitations to this study, the most significant being the study design. Ideally a prospective blinded randomised control trial would best be used to establish non-inferiority. A selection bias exists as patients who were considered high risk by anaesthetist could still be admitted to HDU if requested. The HDU cohort has a much larger proportion of patients with formally diagnosed OSA, severe OSA and COPD compared to the ward patients. This may have skewered the ward results as they could be argued to be a "healthier" population than those in the HDU cohort.

Whilst this may be considered a weakness, this is a pragmatic trial and was designed to reflect a transition of care that occurred in our hospital, that is, a movement from routine HDU care to ward based care, with patients clinically determined as high risk in the perioperative assessment still being admitted to HDU. In this way, our study is more applicable to real life practice as has established that this change in standard of care is warranted and will not jeopardize patient outcomes. A small sample size resulted in a lower powered study and, in several cases, the inability to conduct inferiority testing due to lack of events. The reliability of the analysis also waivers for outcomes with low prevalence such as requirement for medical review and unplanned admission from recovery to escalated care. To minimize error from the above, the risk difference confidence intervals were calculated instead of conventional Wald confidence intervals, as they are more robust in small sized samples. Finally, double the amount of apnoeas for HDU patients were observed as compared to ward, whilst this did not correlate with any substantial disparity in adverse outcomes, the difference is noteworthy. It can likely be attributed to the way the apnoeas were observed. In HDU resistance plethysmography monitoring was used, whilst on the ward it was reliant on the nursing staff to observe apnoeas and record them. Apnoeas may have gone unnoticed on the ward introducing an observer bias to the data. This did not translate into a major difference in hypoxic events, a measure electronically derived.

Conclusion

Within the limitations of this study, we can conclude that post-operative ward based management of OSA in the bariatric surgical patient is both safe and consumes less critical care resources, without negatively affecting patient recovery. Routine admission to a critical care setting is not necessary in this cohort. The implications of this are numerous, with increasing rates of obesity and rising utilisation of bariatric surgery, the cost and logistics of providing post-operative HDU beds is fast becoming impractical.

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Conflicts of interests

Authors declare that there is no conflict of interest.

References

1. Strohl K. Overview of obstructive sleep apnea in adults. In: Collop N, Finlay G, editors. *UpToDate,* Waltham MA; 2017.
2. Young T, Palta M, Dempsey J, et al. Burden of sleep apnea: rationale, design, and major findings of the Wisconsin Sleep Cohort study. *WMJ.* 2009;108(5):246−249.
3. Shin CH, Zaremba S, Devine S, et al. Effects of obstructive sleep apnoea risk on postoperative respiratory complications: protocol for a hospital-based registry study. *BMJ Open.* 2016;6(1):e008436.
4. Senaratna CV, Perret JL, Lodge CJ, et al. Prevalence of obstructive sleep apnea in the general population: A systematic review. *Sleep Med Rev.* 2017;34:70−81.
5. Frey WC, Pilcher J. Obstructive sleep-related breathing disorders in patients evaluated for bariatric surgery. *Obes Surg.* 2003;13(5):676−683.
6. Hallowell PT, Stellato TA, Schuster M, et al. Potentially life-threatening sleep apnea is unrecognized without aggressive evaluation. *Am J Surg.* 2007;193(3):364−367.
7. Brooks-Brunn JA. Predictors of postoperative pulmonary complications following abdominal surgery. *Chest.* 1997;111(3):564−571.
8. Herder CD, Schmeck J, Appelboom DJK, et al. Risks of general anaesthesia in people with obstructive sleep apnoea. *BMJ.* 2004;329(7472):955−959.
9. American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. *Anesthesiology.* 2014;120(2):268−286.
10. de Raaff CAL, Gorter-Stam MAW, de Vries N, et al. Perioperative management of obstructive sleep apnea in bariatric surgery: a consensus guideline. *Surg Obes Relat Dis.* 2017;13(7):1095−1109.

11. Grover BT, Priem DM, Mathiason MA, et al. Intensive care unit stay not required for patients with obstructive sleep apnea after laparoscopic Roux-en-Y gastric bypass. *Surg Obes Relat Dis*. 2010;6(2):165−170.
12. Shearer E, Magee CJ, Lacasia C, et al. Obstructive sleep apnea can be safely managed in a level 2 critical care setting after laparoscopic bariatric surgery. *Surg Obes Relat Dis*. 2013;9(6):845−849.
13. Australian Institute of Health and Welfare. Weight loss surgery in Australia 2014–15: Australian hospital statistics. *AIHW*. 2017.
14. Chung F, Yegneswaran B, Liao P, et al. STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology*. 2008;108(5):812−821.
15. Goucham AB, Coblijn UK, Hart-Sweet HB, et al. Routine Postoperative Monitoring after Bariatric Surgery in Morbidly Obese Patients with Severe Obstructive Sleep Apnea: ICU Admission is not Necessary. *Obes Surg*. 2016;26(4):737−742.
16. Kadam VR, Markman P, Neumann S, et al. Risk stratification for obstructive sleep apnoea and optimal post-operative monitoring in an overnight stay ward. *Australian Journal of Advanced Nursing*. 2015;33(2):13.

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