SSPCRC Proposal Cover Sheet

Title: Comparison of patient characteristics and perioperative outcomes of patients with a formal diagnosis, preoperative bedside diagnosis or no diagnosis of obstructive sleep apnea

Principle Investigator:
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Co-Investigators:
Ken Bullard, BS
Leslie Jameson, MD Associate Professor
Others as appropriate

Primary Hypothesis: Using the STOP-BANG* score, patients diagnosed in the preoperative care unit as "at risk" for obstructive sleep apnea (dosOSA) exhibit the same incidence of intraoperative and postoperative care unit adverse respiratory events (ARE) as patients presenting with an established diagnosis of OSA (estOSA).
Secondary Hypothesis: OSA groups have increased ARE when compared to patients who do not meet the STOP-BANG criteria for possible OSA (noOSA).

Number of Patients/Participants: Current Preliminary at UCo: 18,531 patients with 3.1% FormalSA, 15.7% BedsideSA, and 81.2% NoSA

Power Analysis: Not performed.

Proposed statistical test/analysis:
A bivariate analysis will be performed to compare patients diagnosed with STOP-BANG criteria to patients with an established diagnosis. Chi square and Fisher's Exact tests will be used to examine the difference in proportions of the ARE categorical variables between the two groups. T-tests and the nonparametric Wilcoxon Rank Sum test will be used to examine the difference in means for any continuous ARV outcome variables. P-values will be adjusted to account for multiple comparisons. To examine differences in patients diagnosed with OSA either by STOP-BANG score or through an established diagnosis to patients without an OSA diagnosis, Chi square test or Fisher's exact (categorical variables) and t-tests or Wilcoxon Rank

Sum test (continuous variables) test will be performed. P-values will be adjusted for multiple comparisons. *(Provided by Angela Moss of ACCORD (formerly COHO)*

Resources (Brief summary of resources for data collection, personnel, financial):
Ken Bullard, Sean Clifford –for IT component.

Introduction

What is the significance of the clinical problem being addressed?

Sleep apnea (SA) is an under-diagnosed disease that is estimated to affect about 1 in 4 men and 1 in 10 women totaling 70 million people in the US[1-3]. This is a crude estimate since the availability of a definitive diagnosis by polysomnography is limited due medical resource availability. Primary care physicians frequently make an office-based diagnosis and prescribe therapy based solely on validated clinical criteria. The most widely accepted clinical evaluation tool, STOP-BANG*, has been compared to the polysomnography criteria. [4,5] When STOP-BANG score was between 3 and 7/8, Chung et.al. confirmed by polysomnography that OSA was present in 68.4% of patients. The severity of polysomongrphay diagnosed OSA increased from mild to severe as the STOP-Bang score increased. The predicted probabilities for moderate/severe OSA increased from 0.36 to 0.60 as the STOP-Bang score increased from 3 to $\leq$7.[6] Thus, STOP-Bang is an effective physician screening tool to diagnose SA. It has also been suggested that adding elevated HCO_3 (HCO3 $\geq$ 28 mmol/L) increases the probability of dosOSA to 80%.[7]

Table 1. *STOP-Bang Questionnaire*

S = Snoring. Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?
T = Tiredness. Do you often feel tired, fatigued, or sleepy during daytime?
O = Observed apnea. Has anyone observed you stop breathing during your sleep?
P = Pressure. Do you or are you being treated for high blood pressure?
B = BMI > 35 kg/m^2
A = Age > 50 y
N = Neck circumference >40 cm
G = Male sex (gender)

High risk of obstructive sleep apnea is considered if answering yes to ≥3 for STOP-Bang questionnaire.
Adapted from Chung et al.[34]

Table 2. *Odds Ratio of Different STOP-Bang Scores*

	Odds Ratio for OSA at Different AHI Cutoffs		
STOP-Bang Score	Mild OSA (AHI > 5)	Moderate/Severe OSA (AHI > 15)	Severe OSA (AHI > 30)
Score 3 vs. score 0-2	3.01	2.59	3.56
Score 4 vs. score 0-2	3.15	3.33	5.33
Score 5 vs. score 0-2	3.98	4.75	10.39
Score 6 vs. score 0-2	4.52	6.29	11.55
Score 7 and 8 vs. score 0-2	7.04	6.88	14.86

AHI indicates Apnea Hyponea Index; OSA, obstructive sleep apnea.
Adapted from Chung et al.[35]

All OSA patients experience numerous nocturnal episodes of hypoxemia and hypercarbia[3,8,9] that produce increased oxidative stress, systemic inflammation and decreased immune response[10-12]. Preoperative co-morbid conditions that are associated with chronic physiologic stress include systemic and pulmonary hypertension, arrhythmias, coronary artery disease, congestive heart failure, cerebrovascular disease and diabetes or hyperglycemia. Anesthetic management of these chronic and possibly preventable chronic medical illnesses have substantial impact on perioperative anesthesia and surgical care. Large population studies have established that an estOSA increases the incidence of perioperative pulmonary complications, including aspiration pneumonia, mechanical ventilation reintubation and acute respiratory distress syndrome (ARDS)[13-17] plus cardiovascular complications (eg hypertension, myocardial ischemia, atrial fibrilation) [18-21]. Simply put the incidence of postoperative desaturation, respiratory failure, postoperative cardiac events, and ICU transfers are higher in patients with estOSA.[22]

What current gaps exist in the understanding of this problem?

Up to 90% of patients who have OSA are undiagnosed at the time of surgery[23] which prevents use of perioperative interventions specifically designed for patients with estOSA. These interventions have been shown to reduce at ARE[24]. Multiple studies have established that the long term medical complications associated with OSA[25-28] and that the immediate postoperative complications of OSA can be modified by preoperative medical management. It is however assumed that estOSA is associated with intraoperative complications such as difficult initial intubation, hypoxemic events in the operating room and the postanesthesia care unit (PACU). Only 2 papers have addressed this issue. Kim et.al. compared 90 estOSA patients to a control. The estOSA patients had a significantly greater frequency of difficult intubation but other factors including desaturation, and length of stay in PACU were similar to the control group[29] A similar assessment by Stierer et.al. found that 75% of the patients at high risk for OSA (self reported or high STOP-Bang score) had increased likelihood of a difficult intubation, administration of intraoperative pressers, and postoperative desaturation in the PACU[30].

It has not been conclusively established in a large outcome study that either self identified (estOSA) or dosOSA patients are at a similar risk for difficult airway management, intraoperative desaturation, postoperative desaturation or inadequate postoperative pain management. They have also not been shown to have an increased risk over noOSA patients. Establishing the validity of dosOSA could mean the OSA treatment could be more readily prescribed and could improve short and long term health outcomes.

How will this project address this gap and advance clinical care and/or research knowledge?

Current expected adverse intraoperative events associated with OSA are rare events. Establishing the details of the airway risk and the risk of desaturation and pain management will provide the first objective comparisons that dosOSA and estOSA are associated with significant additional anesthetic risk in comparison to patients without STOP-Bang

Methods

Previously established institutional review board (IRB) exemption (University of Michigan, Ann Arbor, MI HUM00033894) and University of Colorado School of Medicine IRB exemption was obtained for this observational study of de-identified data. If MPOG and University of Co data is combined, the U of Co IRB requires a statement of use.

Study type

Retrospective observational comparison

Cross sectional study

Primary outcome

estOSA patients and dosOSA patients will have a same frequency of respiratory adverse events

- Difficult airway management events
    - excess of 3 intubation attempts
    - use of a specialized airway device (CMac, Glidescope, fiberoptic intbation)
    - Difficulty mask airway
    - Episodes of intraoperative desaturation
        - SPO2 below 90%, 85%, 80% (defined as three consecutive values below the threshold) during
            - Intubation
            - Extubation
            - procedure lasted more than 5 minutes
    - PACU data
        - SPO2 below 85%, below 75% (defined as any value entered below the threshold)
        - Oxygen supplementation
        - Pain Score

Patient inclusion criteria

- All adult patients (age≥18 years) undergoing inpatient anesthesia care.
    - Underwent orthopedic, general surgery, major gynecologic procedure
- Requires the preoperative assessment for OSA that
    - Uses STOP-Bang criteria and identifies preprocedure diagnosis
    - Patient BMI, demographics, surgical service
    - Mask ventilation with grading system
    - Intubation with grading system that includes number of attempts, view, blade, stylet use
    - Use of SPO2

Patient exclusion criteria

- Patient <18 years
  - Undergoing Neurosurgery, Spine, AirwayENT procedure
- All patients where STOPBANG score and demographic data is not available

Data source--preliminary

- The Epic Clarity database was queried for all anesthesia cases preformed at University of Colorado Hospital (prior to UCHealth (3 system consortium)) between 1-24-20012 and 2-1-13

Statistical analysis

A bivariate analysis will be performed to compare patients diagnosed with STOP-BANG criteria to patients with an established diagnosis. Chi square and Fisher's Exact tests will be used to examine the difference in proportions of the ARE categorical variables between the two groups. T-tests and the nonparametric Wilcoxon Rank Sum test will be used to examine the difference in means for any continuous ARV outcome variables. P-values will be adjusted to account for multiple comparisons. To examine differences in patients diagnosed with OSA either by STOP-BANG score or through an established diagnosis to patients without an OSA diagnosis, Chi square test or Fisher's exact (categorical variables) and t-tests or Wilcoxon Rank Sum test (continuous variables) test will be performed. P-values will be adjusted for multiple comparisons. (Provided by Angela Moss of ACCORD (formerly COHO)

Power analysis

NA

Discussion

Major liability is there is no independent measure of OSA for either group or for the control group. However, this is the information most anesthesiologist must model their care from. Major liabilities in this study are the accuracy and consistency in recognizing and charting the SPO2 in PACU (validated or entered by nursing), STOP-Bang assessment. The issue with the STOP-Bang assessment can be over come if the other locations have access to a screening tool administered by nursing were anesthesiology and nursing responses to the same questionnaire can be verified.

Variables to be collected

Table:

Source	Data Column	Data type and range	MPOG source table, column, and MPOG concept ID
AIMS	Age in years	Numeric, 18 –100	Aims_intraopcaseinfo.AIMS_age_in_years
	Gender	Character	Aims_patients.AIMS_sex
	First BP	numeric	70211,70212, 71122
	First HR	numeric	70210
	Preop SPO2	Numeric 0-100	70214
	Weight (kg)	Numeric, 30-300	70264
	Height (cm)	Numeric, 135-225	70257
	Body Mass Index	Numeric, 0-100	70253
	Sleep apnea	Character	70122
	OSA, SA or sleep apnea established	Character Yes/no	200?
	Use CPAP	Yes/no*	
	Snoring	Character	100
	Tired	Character	???
	Observed apnea	Character	
	Diagnosed Hypertension	Character	70031
	Neck>16in	Character	
	Serum HCO3	Lab Value	

Variables to be included in the query

Source	Data Column	Data type	MPOG source table, column, and MPOG concept ID
MPOG intraop data	Surgery type General, ortho joint, GYN, Urology	Character	Aims_intraopcaseinfo.aims_actual_procedure_text
	Hospital location	NA as a variable	De-identified but classified as higher or lower altitude?? Or just Denver vs non-Denver?
	Lowest SpO2—series of 3	Numeric, 0-100	Induction to incision
Co- Morbid conditions	Cardiac Disease To include CAD, CHF, Other	Character	AIMS_Preop, MPOG Concept ID 70027, 70026,70034
	COPD	Character	AIMS_Preop, MPOG Concept ID 70115
	Smoker	Character	Current smoker?
	Pulmonary - Asthma	Character	AIMS_Preop, MPOG Concept ID 70117
	Renal disease	Character	AIMS_Preop, MPOG Concept ID 70060
	Liver disease	Character	AIMS_Preop, MPOG Concept ID 70052
	Diabetes	Character	AIMS_Preop, MPOG Concept ID 70046
	Case length in minutes (patient in room to patient out of room)	Numeric, 0 – 1000	AIMS_IntraopNotes, MPOG Concept ID 3281/3289; used to calculate the number of 10 minute epochs
MPOG intraop data	Lowest SpO2	Numeric, 0-100	Number of episodes
	Lowest SpO2—series of 3 determinations	Numeric, 0-100	Induction to incision
	Lowest SpO2—series of 3 determinations	Numeric, 0-100	Incision to extubation
	Lowest SpO2—	Numeric, 0-100	Extubation to out of room

	series of 3 determinations		
	Mask ventilation difficulty	Character	50113, 50114
	Laryngoscopy view	Character	50119, 50100
	Intubation technique	Character Laryngoscope, videoscope, Eschmann, fiberoptic scope- may be excluded	50123, 50115, 50120
	LMA difficulty rescue	character	50143
	Anesthesia Technique	Character: General	50395, tracheal tube
MPOG PACU data	Lowest SpO2	Single report Data—categorical 90-89, 80-76,75	50452? For duration of PACU stay
		89-76	
		<76	
	Oxygen administration First 30 minutes	Character-mask, nasal cannula, intubated, none CPAP. BIPAP	Order-
	Pain Score highest		
	Pain Score discharge		
	DischargeNursing Discharge score		

Proposed Additions

- Pain Score in PACU
    - Highest
    - Discharge
- Discharge Nursing Score
- Discharged location
- Order for respiratory therapy (O2, BiPAP)
- Serum HCO3
    - Attempt to validate recent suggestion that HCO3 increases accuracy by a factor of 2.

Management of missing data

PACU SPO2, OSA –diagnosis, Gender, BMI or Height/weight, Airway management, Operative SPO2, BP preop or first in OR, surgical service, Preliminary Outcome

Results-2 3+ STOPBANG Criteria

- estOSA and dosOSA different but both very different from the noOSA group.

	Any Sleep Apnea	Formal SA	Bedside Sleep Apnea)	No Sleep Apnea
Patients, n(%)	3491 (18.8%)	580 (16.7%)	2911 (83.3%)	15040 (88.1%)
Age, Mn(SD)	57.0 (+13.5)#	55.1(+14.4)*	57.4(+13.4)*^	50.8 + 17.4
Gender, n(%)				
Male	2056 (58.8%)#	344 (59.3%)*	1712 (58.8%)*	6217 (41.4%)
Female	1436 (41.1%)	236 (40.7%)	1199 (41.1)	8827 (58.7%)
BMI, Mean(SD)	33.9 (+9.9)#	37.4(+6.0)*	33.4(+10.3)*	26.6 (+5.4)
STOP BANG criteria, n(%)				
S = (S)noring		Not recorded	1131 (89.5%)	Not recorded
T = (T)ired		Not recorded	365 (12.5%)	Not recorded
O = (O)bserved Apnea		Not recorded	441 (15.1%)	Not recorded
P = Hy(P)ertension	1937 (55.4%)#	519 (89.5%)*	1418 (48.7%)*^	3266 (21.7%)
B = (B)MI > 35kg/m^2	1398 (40.0%)#	417 (71.9%)*	981 (33.0%)*^	1006 (6.7%)
A = (A)ge > 50 years	2090 (59.0%)#	390 (67.2%)*	2090 (71.8%)*^	8232 (54.7%)
N = (N)eck > 16 in	1304 (37.3%)#	455 (78.4%)*	849 (29.2%)*^	456 (3.0%)
G = (G)ender Male	2056 (58.8%)	344 (59.3%)*	1712 (58.8%)*	6217 (41.4%)

Results—Airway Management

	Any Sleep Apnea	Formal SA	Bedside Sleep Apnea)	No Sleep Apnea
Mask ventilation--Difficult	308 (13.9%)	69 (16.3%)	239 (13.3%)	408 (4.6%)
Difficult	301 (98.6%)#	65(94.2%)*	236(98.7%)*^	400(98.1%)
Not possible	7(1.4%)	3(5.8%)	4(1.3%)	8(1.9%)

Results—Airway Management

	Any Sleep Apnea	Formal SA	Bedside Sleep Apnea)	No Sleep Apnea
AIRWAY Management				
Intubation technique N (%)	2220 (63.6%)	424 (73.1%)	1796 (61.7%)	8836 (58.8%)
Direct Laryngoscopy	1455 (65.5%)#	258(60.8%)*	1197(66.6%)*	7606(86.1%)
Videolaryngoscopy	632 (28.4%)#	135(31.8%)*	497(27.7%)*^	818 (9.3%)
Eschmann	133 (6.0%)#	31(7.3%)*	102(5.7%)*^	350(4.0%)
Laryngoscopy view				
	2091	386	1705	8604
I	647(70.9%)	261 (67.6%)	1223 (71.7%)	6881 (80.0%)
II	493 (23.5%)	107(27.7%)*	386 (22.6%)	1458 (16.9%)
III, IV	116 (5.5%)#	20(5.2%)*	96 (5.6 %)*	260 (3.0%)

Results Oxygenation

Saturation	3492	580	2911	15040
Incidence Sat<%, n(%)				
OR Sat <70%	60 (1.7%)#	18(3.1%)*	42(1.4%)*^	151 (1.0%)
<80%	262 (7.5%)#	56(9.7%)*	206(7.1%)*	640(4.3%)
PACU Sat <75%	6 (0.1%)#	1(.2%)*	5(.2%)^	18 (.1%)
<80%	23(.7%)	5(.8%)	18(.6%)	50(.3%)
<90%	244 (7.0%)#	44 (7.6%)*	200(6.9%)*^	488(3.2%)

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