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PROJECT COMPLETION REPORT

1. **Project Number :** **5341**

2. **Title of the Project** : **Can cardiovascular patients with obstructive sleep apnea have adverse perioperative outcomes?-a prospective study.**

3. **Funding Agency Name** : **RESMED Foundation,California**

4. **Project Reference Number provided by the Funding Agency**:

5. **Principal Investigator (Name & Address) :**
   Sapna Erat Sreedharan,
   Professor of Neurology,
   SCTIMST,TVM-11

6. **Co-Investigators (Name & Address):**
   - **i.** Dr Unnikrishnan K P,
     Professor of Anaesthesiology,SCTIMST,TVM-11
   - **ii.** Dr Suneel P R,
     Professor of Anaesthesiology,SCTIMST,TVM-11
   - **iii.** Dr Vivek Pillai,
     Professor of CVTS,SCTIMST,TVM-11

7. **Implementing Institution** : SCTIMST

7. **Collaborating Institutions** : None

8. **Date of Commencement** : 1.08.2017

9. **Duration** : 2 years

10. **Date of Completion** : 31.07.2019

11. Objectives as approved :

To study the prevalence of OSA in patients undergoing cardiovascular surgery using STOP-BANG questionnaire.

For validation of the questionnaire-To perform ambulatory polysomnography in the a quarter of the screened subjects before surgery,to understand sensitivity,specificity,positive and negative predictive value of the questionnaire in detecting OSA in cardiovascular patients.

To compare perioperative and postoperative adverse events,length of ventilation,ICU stay and outcome in the subjects with and without OSA.

12. Deviation made from original objectives if any, while implementing the project and reasons there of :

None

13. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs :

Clinical details,including vascular risk factors and their duration,sleep complaints were extracted as per proforma appended.We also completed 2 questionnaires STOP-BANG and Epworth Sleepiness scale for all recruited patients to extract degree of excessive day time sleepiness and screening for OSA respectively.

25% of the subjects were subjected to ambulatory Level 3 polysomnography(Apnea-link ,Resmed) and subjects were grouped into no OSA(Apnea hypopnea index <5) versus OSA(AHI >=5) and further divided into mild(AHI 5-15) versus moderate to severe OSA(AHI >15).

Also details on peri and postoperative adverse events using the second part of proforma.

14. Detailed anaylsis of results :

We had 120 patients, predominantly men (M: F 103:17) with a median age of 60 (±11.5) years. Baseline characteristics of those undergoing PSG did not differ from those who did not undergo overnight study, other than BMI which was higherin the sleep study group. The majority of our patients had mild-moderate upper airway narrowing.Around 86 patients (69%) had STOP-BANG scores ≥3 in our cohort (median 3 [interquartile range = IQR 2]) while 53 patients underwent overnight sleep study of which 28 (52.8%) had OSA (apnea-hypopnea index = AHI 5 or above per hour) and 14 (26.4%) had moderate OSA (AHI 15 or above). Median AHI was 5.6.Bivariate analysis showed that nocturnal arousals with respiratory difficulty, abnormal neck circumference(≥40 cm in male and ≥37 cm in female) `n male and ≥37 cm), and higher grades of tonsillar hypertrophy had a statistically significant correlation with OSA. Subgroup analysis showed a narrow upper airway by Mallampatti score and tobacco smoking as having a significant association with moderate to severe OSA.

At cut-off score 3 or above, STOP-BANG has a high sensitivity of 77.4%, albeit low specificity, making it a good screening tool for OSA in cardiovascular patients as well . Raising cutoff scores to 4 or above

improved specificity to 59.7% at the expense of sensitivity. Receiver operating characteristic (ROC) curve plotted for sensitivity and specificity of STOP-BANG scores showed an area under the curve of 0.8403 again highlighting the same property of the screening tool as mentioned above.

The predictive value of STOP-BANG increases with higher scores, while a score of less than 3 has a negative predictive value of 66.7% for ruling out OSA.

15. Summary sheet of not more than 2 pages under following heads :
(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

Attached

16. Contributions made towards increasing the state of knowledge in the subject :

The study added to the understanding of utility of STOP BANG for perioperative screening of OSA in Indian subjects with cardiovascular disease awaiting CABG.
The findings were presented in World Sleep conference 2019 and as an original article in Annals of Cardiac Anaesthesia Journal .

17. Conclusions summarising the achievements and indication of scope for future work :

Our study shows that the prevalence of OSA is high in our cohort of patients undergoing cardiovascular surgery. In cardiovascular patients less symptomatic for sleep complaints, the STOP-BANG questionnaire performs well as a screening tool for OSA detection. Assessment of neck circumference and airway narrowing preoperatively can predict patients at risk of OSA.
These findings can be tested in larger populations using multicentre studies ,which will add to our understanding on OSA in Indian subjects with cardiovascular diseases

18. Science and Technology benefits accrued :

a. List of research publications with complete details :

Erat Sreedharan S, Mitta N, Unnikrishnan KP,Paul R, Pillai V. Preoperative screening for obstructive sleep apnea in cardiovascular patients – How useful is STOP-BANG questionnaire in the Indian context? Ann Card Anaesth 2021;24:308-12.

b. Manpower trained on the project :

i.	**Research Scientists or Research Fellows**	**none**	
ii.	**No. of PhD's produced**	**:**	**none**
iii.	**Other Technical Personnel trained**	**:**	**none**
c.	**Patents taken, if any**	**:**	**none**
d.	**Products developed, if any**	**:**	**none**

20. Abstract: (In 300 words for possible publication in ..... Bulletin)

a. Background:

Obstructive sleep apnea (OSA) is reported in a high proportion of cardiac surgical patients, up to 73%. STOP-BANG is a validated questionnaire for screening of outpatients for OSA with high sensitivity. There is sparse literature from India regarding the prevalence of OSA in preoperative cardiovascular patients and the utility of screening tools.

Aims: We sought to study the utility of the STOP-BANG questionnaire as a screening tool for OSA in cardiovascular patients validating it with ambulatory level 3 polysomnography.

Materials and Methods: It was a prospective study where consecutive patients getting admitted for coronary artery bypass surgery (CABG) from August 2017–February 2019 were recruited. All the patients were screened with the STOP-BANG questionnaire. 53 patients underwent overnight level 3 polysomnography using Apnea-Link. Correlations were made between clinical symptoms, STOP-BANG score, and OSA severity, measured using Apnea hypopnea index (AHI).

Results: We had 120 patients(103 males) with a mean age 60 years. Snoring was the most common sleep complaint. Our cohort had a high prevalence of vascular risk factors (DM 72.3%, hypertension 59.2%, dyslipidemia 60%) and 11.7% were obese (BMI >30). The median STOP-BANG score was 3 (IQR 2) with 83 having scores ≥3. Median AHI was 5.6 with AHI ≥5 in 28 patients and AHI 15 or above in 14 patients.

Among the clinical parameters, arousals with respiratory difficulty at night, higher neck circumference, and tonsillar hypertrophy showed a significant association with PSG-proven OSA.STOP-BANG scores 3 or above had a sensitivity of 75% in predicting OSA.

Conclusions: Our study shows that in cardiovascular patients less symptomatic for sleep complaints, the STOP-BANG questionnaire is a useful screening tool for OSA in outpatient settings. Among clinical parameters, airway narrowing and neck circumference can predict OSA.

21. Procurement/Usage of Equipment:None

a. Details of Equipment:

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown

b. Suggestions for disposal of equipment(s):not applicable

25.11.2023

(Name and Signature of PIs with date)

Routing: *Signed copy of "Project completion Report" by PI → root@sctimst.ac.in, rpc@sctimst.ac.in*

Summary sheet of not more than 2 pages under following heads :

Title: Can cardiovascular patients with obstructive sleep apnea have adverse perioperative outcomes?-a prospective study.

Introduction

Obstructive sleep apnea (OSA) is a serious condition characterized by repeated episodes of complete or partial obstruction of the upper airway. These episodes are accompanied by varying degrees of arterial oxygen desaturation and sympathetic activation. They are usually terminated by brief cortical arousals or, occasionally, awakenings. Resultant sleep disruption is responsible for the commonly associated symptom of excessive daytime sleepiness. Habitual snoring usually coexists. Apart from these symptoms, which can be very intrusive, OSA can lead to adverse health outcomes, including cerebrovascular disease, cardiovascular disorders (eg, hypertension, ischemic heart disease, arrhythmias, pulmonary hypertension, and congestive heart failure), metabolic syndrome, depression, and increased risk of accidents(1–8).

Up to 90% of individuals with moderate-to-severe OSA may remain undiagnosed(9,10). Importantly, OSA is common in patients who present for surgery, with estimates ranging from the prevalence of the general population to as high as 70% in select populations like bariatric surgical patients(11,12). Similar to the general population, most patients with OSA remain undiagnosed at the time of surgery(13,14).

Literature regarding outcomes after cardiac surgery in patients with OSA is sparse, and little is known about the impact of OSA on postoperative outcomes(15,16). Results from large databases that included cardiac surgery among other surgeries have reported adverse postoperative outcomes, including emergent intubation, respiratory failure, cardiac complications, and ICU transfer(17,18).

There are various clinical screening tools for OSA detection. STOP-BANG score is a widely used one,which is an 8 point questionnaire,with scores above 3 or more is highly suggestive of OSA(19). In a recently published metaanalysis on STOP –BANG questionnaire,in the sleep clinic population,the sensitivity of the questionnaire for detecting any OSA(AHI>5),moderate-severe OSA(AHI>15) and severe OSA(AHI>30) was 90%,94% and 96% respectively with corresponding NPV was 46%,75%and 90% respectively(20).STOP-BANG questionnaire has also been found useful in perioperative OSA screening in surgical populations as well ,but there is scanty literature about its utility in cardiovascular surgical patients.Also large scale validation studies of STOP-Bang screening tool in cardiovascular patients are limited.

Rationale and Objectives

To study the prevalence of OSA in patients undergoing cardiovascular surgery using STOP-BANG questionnaire.

For validation of the questionnaire-To perform ambulatory polysomnography in the a quarter of the screened subjects before surgery,to understand sensitivity,specificity,positive and negative predictive value of the questionnaire in detecting OSA in cardiovascular patients.

To compare perioperative and postoperative adverse events,length of ventilation,ICU stay and outcome in the subjects with and without OSA.

Methodology

The study was performed at Sree Chitra Tirunal Institute for Medical Sciences and Technology,Trivandrum, India.The study design was prospective, where consecutive patients getting admitted for CABG electively were screened for sleep and other medical complaints using a structured proforma, and the STOP-BANG questionnaire was administered after getting informed consent. Recruitment period was-from August 2017 till February 2019. The conduct of the study was approved by the Institutional Ethics Committee (IEC/SCT/998/DEC 2016) and was funded by grant from ResMed Foundation, California, USA.
Among the subjects screened, those consenting underwe n t ove r n i g h t ambul a to r y Leve l 3 PSG (ApneaLink Air-ResMed Inc) 2 days before the surgery date. During the ambulatory sleep study, physiological parameters recorded were nasal airflow, pulse rate, and blood O2 saturation using a pulse oximeter, chest belt for recording chest excursions during respiration and snoring. Only studies with a minimum of 4 h of sleep record were analyzed, manually reviewed by sleep medicine specialists and report generated. Apneas and hypopneas were defined as per standard American Academy of
Sleep Medicine (AASM) guidelines for the scoring of sleep-related respiratory events.

Results

We had 120 patients, predominantly men (M: F 103:17) with a median age of 60 (±11.5) years.

Baseline characteristics of those undergoing PSG did not differ from those who did not

undergo overnight study, other than BMI which was higherin the sleep study group. The majority of our patients had mild-moderate upper airway narrowing.Around 86 patients (69%) had STOP-BANG scores ≥3 in our cohort (median 3 [interquartile range = IQR 2]) while 53 patients underwent overnight sleep study of which 28 (52.8%) had OSA (apnea-hypopnea index = AHI 5 or above per hour) and 14 (26.4%) had moderate OSA (AHI 15 or above). Median AHI was 5.6.Bivariate analysis showed that nocturnal arousals w i t h r e s p i r a t o r y d i f f i c u l t y, a b n o r m a l n e c k circumference(≥40 cm in male and ≥37 cm in female) `n male and ≥37 cm), and higher grades of tonsillar hypertrophy had a statistically significant correlation with OSA. Subgroup analysis showed a narrow upper airway by Mallampatti score and tobacco smoking as having a significant association with moderate to severe OSA.

At cut-off score 3 or above, STOP-BANG has a high sensitivity of 77.4%, albeit low specificity, making it a good screening tool for OSA in cardiovascular patients as well . Raising cutoff scores to 4 or above

improved specificity to 59.7% at the expense of sensitivity. Receiver operating characteristic (ROC) curve plotted for sensitivity and specificity of STOP-BANG scores showed an area under the curve of 0.8403 again highlighting the same property of the screening tool as mentioned

above.

The predictive value of STOP-BANG increases with higher scores, while a score of less than

3 has a negative predictive value of 66.7% for ruling out OSA.

Translational Potential

The study adds to our understanding on utility of STOP-BANG questionnaire in screening for OSA in perioperative subjects with cardiovascular diseases and its limitations.