MATERIAL AND METHODS

A prospective, randomised and double blind study was undertaken in Indian surgical patients of either sex after obtaining approval for the study from the hospital ethics committee. Informed consent was obtained from each subject.

The study was planned as follows:

1. Duration
2. Selection of patients
3. Exclusion criteria
4. Diagnosis of obstructive sleep apnoea syndrome
5. Designing of study

Duration of the Study

It was planned to spread the duration of the study over 5-6 years (1998 – 2003) so that large number of cases can be enrolled for the study.

Selection of the Patients

Two thousand and eight hundreds surgical adult patients referred for pre anaesthetic evaluations for any surgery were enrolled for the study. The demographic features of all patients are shown in table 1 and 2.

TABLE – 1

DEMOGRAPHIC DATA

S.NO.	AGE RANGE (YEARS)	TOTAL NO. OF PATIENTS	MALES	FEMALES
1.	20 – 40	250	150	100
2.	41 – 50	1300	1100	200
3.	51 – 60	1000	700	300
4.	61 – 70	250	210	40
	TOTAL	**2800**	**2160**	**640**

Note- Table showing age and sex distribution. 70.83% of patients were in the age range of 41–60 years. Males (75%), Females (25%).

TABLE – 2

DEMOGRAPHIC DATA

S.NO.	WEIGHT RANGE (KG)	TOTAL NO. OF PATIENTS	MALES	FEMALES
1.	20 – 40	100	70	30
2.	41 – 50	600	400	200
3.	51 – 60	700	560	140
4.	61 – 70	900	750	150
5.	71 – 80	400	300	100
6.	> 80	100	80	20
	TOTAL	**2800**	**2160**	**640**

Note- Table showing weight range. (Weight 61 – 80 Kg) in 50% of patients. More than 80 Kg in 16.6 % of patients

All patients were handed over the printed Proforma (Appendix-A shown at the end of this chapter) containing questionnaire pertaining to sleep apnoea. The qualification criteria to enter into further study were followed as per Appendix-B (shown following Appendix A). Those who qualified, based upon clinical criteria, were enrolled for further study (Table 3).

TABLE – 3

DIAGNOSIS OF OBSTRUCTIVE SLEEP APNOEA BASED ON CLINICAL CRITERIA OUT OF 2800 SURGICAL PATIENTS

S.NO.	SEX	NO. OF PATIENTS	PERCENTAGE OUT OF 392	PERCENTAGE OUT OF 2800
1.	Male	290	73.97	10.37
2.	Female	102	26.02	3.64
	TOTAL	**392**		**13.9**

Note-Table showing number of patients sex wise qualifying for night polysomnography. Males have more incidence of obstructive sleep apnoea than females which was statistically significant (P<0.001)

Exclusion Criteria

- Patients on tranquillisers, sedatives, antidepressant.
- Patients with known cases of bronchial asthma, COPD, congestive heart failure.
- Patients with any psychiatric illness.
- Patients with hypothyroidism.
- Patients ASA grade III and above.

All patients were classified as per their sex, age, weight, dietary habits, socio-economic status, craniofacial/ upper airway abnormality and history of associated medical diseases. The obesity was defined when body mass index (bodyweight kg/M2) was 30 or above. Socio-economic status was defined as poor if income per month was less than Rs 10,000, middle class if income Rs 10,001- 20,000, rich if income was more than Rs 20,000 per month. The craniofacial upper airway abnormality was defined as having short chin or large tongue or uvula, short neck or any obvious abnormality of bony structure of face or head and neck as isolated finding or part of any congenital

syndrome. Associated medical diseases like hypertension, diabetic mellitus, acromegaly, psychiatric illness were noted and recorded. The record of medications, patients were on, was made and they were allowed to continue their medication unless contraindicated as per predetermined protocol. Patients after being screened for obstructive sleep apnoea based on clinical criteria were subjected directly to night polysomnography. They were not subjected to clinical morphometric model or indigenous night polysomnography as was done during pilot study. This change was made to avoid false positive cases.

Diagnosis of Sleep apnoea syndrome

The following protocol for night polysomnography was followed:

1. Procedure was explained in detail to patients and their relatives.

2. Patients were asked to abstain from alcohol, any sedative drugs or smoking at last 48 hours before test.

3. Continue same level of daily physical activity.

4. Stop caffeinated beverages 4 hrs prior to study.

5. They were asked to have normal meal in the evening and report to sleep lab by 2100 hours.

6. Patients were made comfortable after coming to the sleep lab and preparation of patients for fixing various electrodes for EEG, ECG, EMG, EOG, oro-nasal thermistor, tracheal snoring detecting sensor, pulse oximeter and thoracic and abdominal strain gauze (for detecting thoracic abdominal movements and body position) was started 15-20 minute before study time.

7. After fixing electrodes and all gadgets, connections of leads and computer, calibration was done as per set protocol for PSG study.

a) All channels on same sensitivity (50 μV).

b) All channels at filter setting at high frequency 35 Hz and low frequency at 03 Hz.

c) 60 Hz notch filter off. A signal of 50 μV is fed; this allows an electrical check on each channel.

d) Physiological calibration done.

i) Looking straight for 30 seconds.

ii) Looking left, right, up & down and repeats once.

iii) Keeping head still, blink five times.

iv) Grind teeth, clench jaw, and check chin, EMG amplitude and EMG signal quality.

v) Inhale & exhale three breaths, hold breath for 10 seconds.

vi) Check oro-nasal flow channel.

e) Start study at 2200 hours and switch off lights.

f) Seven hours study is carried out.

g) The number, duration, type of apnoea, heart rate, SaO_2, position of body were recorded simultaneously automatically by the computer.

h) Validation of data was done in the morning after completion of study and type and severity of sleep apnoea was diagnosed.

Polysomnographic Criteria for Diagnosis of Obstructive Sleep Apnoea

1. Duration of apnoea > 10 seconds
2. Minimum number of episodes per night 30 over 07 hours of sleep time.
3. Apnoea must occur in both repetitive eye movement and non-repetitive eye movement sleep.
4. Graphic evidence of diaphragmatic activity when no airflow as detected by nasal thermistor sensor.
5. Fall of arterial oxygen saturation > 4% of base line during apnoea.
6. Apnoea index of 5 or more. (Apnoea index was defined as minimum of 5 apnoea per hour.

In patients in whom the diagnosis of obstructive sleep apnoea was confirmed by night polysomnography, are shown in table 4.

TABLE – 4

DIAGNOSIS OF OBSTRUCTIVE SLEEP APNOEA BASED ON NIGHT POLYSOMNOGRAPHY OUT OF 960 PATIENTS

S.NO.	SEX	NO. OF PATIENTS	PERCENTAGE OUT OF 150	PERCENTAGE OUT OF 392	PERCENTAGE OUT OF 2800
1.	Male	100	66.6	25.5	3.57
2.	Female	50	33.3	12.7	1.78
	TOTAL	**150**		**38.26**	**5.35**

Note-Table showing number of patients sex wise confirmed with diagnosis of obstructive sleep apnoea, males 66.6%, females 33.3%. The disease more prevalent among males and difference is statistically significant (P=0.02)

Patients were identified of their age, sex and weight (table- 5).

TABLE – 5

AGE, SEX AND WEIGHT OF 150 PATIENTS

S.NO.	AGE RANGE (YEARS)	WEIGHT RANGE (KG)	SEX M/F
1.	30 – 40	50 ± 8	15/5
2.	41 – 50	52 ± 10	30/15
3.	51 – 60	65 ± 17	28/17
4.	Above 60	60 ± 12	27/13
TOTAL	**150**		**100/50**

Note-Table showing age, sex and weight distribution among 150 patients finally listed for the study. There was no statistically significant difference between males and females in their weight distribution (P= 0.792)

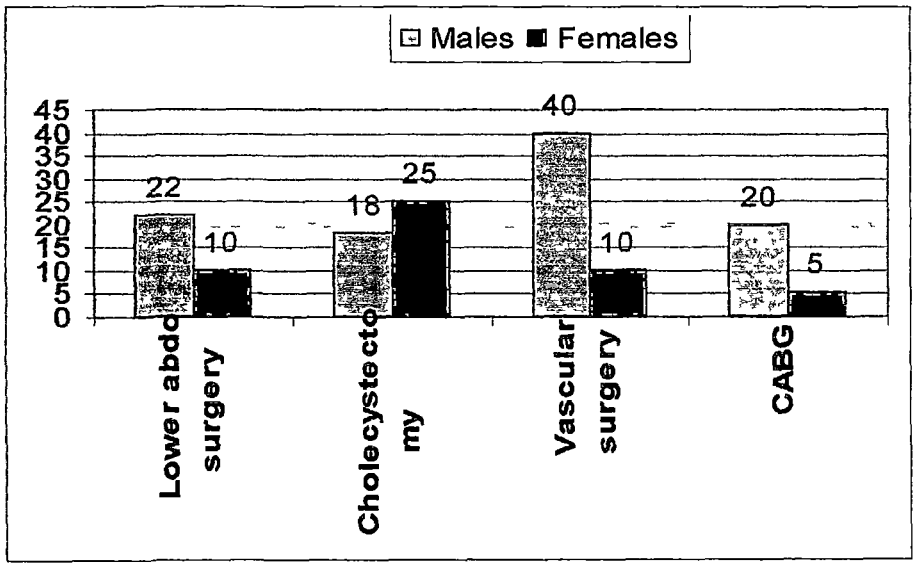
Type of surgery they underwent was also recorded shown in Table 6 and histogram.

TABLE – 6

PATIENTS AND TYPE OF SURGERY (150 PATIENTS)

S.NO.	TYPE OF SURGERY	TOTAL NO. OF PATIENTS	MALES	FEMALES
1.	Lower Abdominal Surgery	40	22	10
2.	Cholecystectomy	60	18	25
3.	Vascular Surgery	30	40	10
4.	Coronary Artery Bypass	20	20	5
	TOTAL	**150**	**100**	**50**

Note-Table showing Coronary Artery Bypass and Vascular Surgery dominating in male patients (60%) where Cholecystectomy among female patients.



The type and severity of obstructive sleep apnoea as confirmed by night polysomnography was recorded. Obesity pattern in the confirmed cases of obstructive sleep apnoea was recorded in all patients. Number of patients having craniofacial

The type and severity of obstructive sleep apnoea as confirmed by night polysomnography was recorded. Obesity pattern in the confirmed cases of obstructive sleep apnoea was recorded in all patients. Number of patients having craniofacial abnormality and type of abnormalities were identified and recorded. The dietary habits of patients were recorded.

The associated diseases like hypertension, diabetes mellitus or ischemic heart disease was noted and their incidence was recorded.

Study Protocol

The study was double blind. Neither the patient was told what premedication is given to the patient nor did the observer know what premedication administered.

All patients of obstructive sleep apnoea after the diagnosis was confirmed by night polysomnography were divided randomly into three groups. Control group consisted of 50 cases and study group 100 patients who were further divided into two subgroups S1 and S2 consisting 50 patients in each group. Patients on the day of surgery were given premedication by resident doctor in the operation theatre either Inj Ketorolac 30 mg intramuscularly in the control group or Inj Morphine sulphate 0.1 mg/ Kg or 0.15 mg/Kg intramuscularly in S1 and S2 group respectively 2 hours before surgery. Before premedication, they were connected with ECG monitor, pulse oximetry and non-invasive blood pressure monitor. Monitoring and observation was done by one of faculty member of Anaesthesiology volunteered to help in carrying out the study. Faculty member did not know about type of premedication patient received. Base line heart rate, SaO_2, respiratory rate were recorded .After premedication patients were monitored continuously for two hours for any alternation in the level of consciousness, degree of sedation, snoring, respiratory rate, change in SaO_2 and corresponding heart rate and blood pressure . Readings were recorded at 10 minutes interval.

The resuscitation kit was kept at hand to provide any support patient might need due to undue respiratory depression or cardiac arrhythmias. Ramsay sedation scale was applied to judge the severity of sedation in the study (Appendix C, shown at the end of

this chapter). Patient was diagnosed to have respiratory depression if respiratory rate dropped to 8 per minute or below and or drop in SaO2 below 90 % or 4% below the base line value. Respiratory support was provided whenever oxygen saturation dropped below 90% and or 4% below the base line value as it was graded as hypoxic event. Respiratory support was provided by anterior mandibular displacement, encouraging the patient to take deep breaths or application of nasal continuous positive airway pressure with or without oxygen depending upon the severity of the hypoxia.

The data were analysed by comparing values obtained following administration of drugs in the control and study groups to baseline values by applying χ^2 test of proportion, Fisher exact test Two way Anova test (one tail) was used to determine the significance of changes in respiratory variables. All reported values are mean with standard deviation. A statistical confidence interval of 0.05 was considered significant. The services of a qualified statistician were utilised to analyse the data by applying appropriate statistical methods.

Appendix – A

SLEEP DISORDER CENTRE

DEPARTMENT OF ANAESTHESIOLOGY AND CRITICAL CARE MEDICINE

ARMY HOSPITAL (R & R) DELHI CANTT

NAME		AGE		SEX :	MALE/ FEMALE
RESIDENTIAL ADDRESS					

S. NO.	QUESTIONNAIRE FOR SLEEP APNOEA SYNDROME (SCORE)	1 NO	2 OCCAS	3 OFTEN
1.	Do you experience excessive sleepiness during the day?			
2.	Do you suffer from sleep disturbance (Restless sleep)?			
3.	Do you have breathing difficulty, i.e. choking during sleep?			
4.	Do you snore?			
5.	Does your spouse notice you have			

S. NO.	QUESTIONNAIRE FOR SLEEP APNOEA SYNDROME (SCORE)	1	2	3
		NO	OCCAS	OFTEN
	long stops in breathing during night?			
6.	Do you feel tired in the morning, i.e. un-refreshing sleep?			
7.	Do you often suffer from headache and pains in the neck on waking up?			
8.	Do you suffer from high blood pressure?			
9.	Do you have pain in the chest?			
10.	Do you have to get up to pass urine during the night?			
11.	Do you take sleeping pills/ sedatives? If yes, details.			
12.	Do you consume alcohol before going to bed?			
13.	Do you smoke?			
	TOTAL SCORE			

14.	Are there any personality changes?	Yes	No
15.	Any history of nocturnal changes?	Yes	No
16.	Is there history suggestive of oesophageal reflux?	Yes	No
	IN CASE OF EXCESSIVE DAY-TIME SLEEPINESS (EDS)		
1.	Have you ever had an unusual muscular experience?		
	CATAPLEXY/ WEAKNESS DURING EXCITEMENT	Yes	No

2.	Do you snore? REGULARLY/ IRREGULARLY	Yes	No
3.	Do your legs feel restless when you relax?	Yes	No
4.	Do you sleep much longer on weekends?	Yes	No

	MISCELLANEOUS INFORMATION		
1.	Life Style Factors	:	Domestic, Occupational, Interpersonal
2.	General Medical Factors	:	Physical ailments, Psychiatric ailments, Prescribed drugs
3.	Specific Medical Factors	:	
	❖ Hypnotic drugs		
	❖ Illicit drugs		
	❖ Other sleep disorders		

	CLINICAL EXAMINATION						
1.	Pulse	/ Minute		2.	Height	cm	
3.	Blood Pressure			4.	Weight	Kg	
a)	Supine	mm Hg		5.	BMI	Kg/m^2	
	Erect	mm Hg		6.	Pallor	Yes / No	
7.	Temperature	^0C		8.	Icterus	Yes / No	

9.	Respiratory Rate	/ Minute		10.	Cyanosis	Yes / No	
11.	Clubbing	Yes / No		12.	Oedema	Yes / No	
13.	Koilo/ Platynychia	Yes / No		14.	Lymphadenopathy	Yes / No	

	UPPER RESPIRATORY TRACT		
15.	Nasal Examination		
			Deviated Nasal Septum
			Chronically Stuffy Nose
16.	Oropharynx		
			Enlarged Tonsils
			Large Tongue
			Large Uvula
17.	Short Neck		Yes / No
18.	Neck Size : Height Ratio		
19.	Respiratory System		
20.	Cardiovascular System		
21.	Neurological System		
22.	Endocrine System		

	Investigations						
	Routine Inv.						
		Hb	:		PCV	:	
		TLC	:		DLC	:	
		Urine RE	:		Blood Sugar	:	
		Blood Urea	:		Serum. Cholesterol	:	
		C X R	:				
	Special Inv.						
		PFT	:				
		Thyroid Function Test	:				
		Others	:				

Appendix – B

QUALIFICATION CRITERIA FOR DIAGNOSIS OF OBSTRUCTIVE SLEEP APNOEA BASED ON CLINICAL PROFILE

1. History of habitual snoring* during sleep confirmed by room/ bed partner.

2. History of cessation of breathing (apnoea) during sleeps occurring in both non-repetitive and repetitive eye movement sleep.

3. History of excessive daytime sleeping (EDS).

4. Associated symptoms: morning headache, fatigue, lack of concentration.

5. First three criteria were mandatory for the diagnosis of obstructive sleep apnoea.

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* Habitual snoring was defined as having snoring every night irrespective of provocative factors like alcohol consumption or taking sedative drugs.

Appendix – C

RAMSAY SEDATION SCALE

1. Patient anxious, agitated, or restless.
2. Patient cooperative, oriented, and tranquil.
3. Patient responds to commands only.
4. Brisk response to glabellar tap or loud auditory stimulus.
5. Sluggish response to glabellar tap or loud auditory stimulus.
6. No response to glabellar tap or loud stimulus.