การศึกษาเปรียบเทียบการตรวจการนอนหลับในเวลากลางวันและกลางคืน
ในผู้ป่วยที่เสี่ยงต่อภาวะนอนกรนหยุดหายใจ

นายประสิทธิ์ มหากิจ

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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THE COMPARATIVE STUDY OF DAYTIME AND OVERNIGHT POLYSOMNOGRAPHY IN HIGH RISK SNORER

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A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Health Development
Faculty of Medicine
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Thesis Title	The comparative study of daytime (DPSG) and overnight polysomnogram (ONPSG) for high risk snorer
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พ.อ.ประสิทธิ์ มหากิจ: การศึกษาเปรียบเทียบผลการตรวจการนอนหลับในเวลากลางวันและการตรวจการนอนหลับในเวลากลางคืน เพื่อใช้เป็นเครื่องคัดกรองผู้ป่วยนอนกรนที่มีความเสี่ยงสูงต่อภาวะหยุดหายใจ (THE COMPARATIVE STUDY OF DAYTIME (DPSG) AND OVERNIGHT POLYSOMNOGRAM (ONPSG) FOR HIGH RISK SNORER) อาจารย์ที่ปรึกษา: ผศ.นพ.วินัย แวดวงธรรม, อาจารย์ที่ปรึกษาร่วม: รศ.นพ.สงวนศักดิ์ ธนาวิรัตนานิจ, 35 หน้า
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วัตถุประสงค์ : เพื่อเปรียบเทียบผลการตรวจการนอนหลับเวลากลางวันเป็นเวลา 2 ชั่วโมง กับผลการตรวจการนอนหลับเวลากลางคืน (ตลอดคืน) ในผู้ป่วยนอนกรนที่มีความเสี่ยงสูงในการเกิดภาวะนอนกรนหยุดหายใจ

วิธีการวิจัยศึกษา: การศึกษาแบบ พรรณนา (แบบทดสอบการวินิจฉัย)

สถานที่ทำการศึกษา: ศูนย์นอนกรน รพ. พระมงกุฎเกล้า

กลุ่มศึกษาและวิธีการศึกษา: การศึกษานี้ทำการวิจัยในผู้ป่วยที่มารับการรักษาที่ศูนย์นอนกรน รพ.พระมงกุฎเกล้า ตั้งแต่เดือนกันยายน 2548 – กุมภาพันธ์ 2549 โดยเป็นผู้ป่วยที่มีความเสี่ยงสูงต่อการเกิดภาวะนอนกรนหยุดหายใจ และจำเป็นต้องได้รับการตรวจวินิจฉัยด้วยการตรวจการนอนหลับวิธีมาตรฐานไม่เกิน 2 เดือน ก่อนการตรวจการนอนหลับเวลากลางวัน ซึ่งใช้เวลา 2 ชั่วโมง ทุกรายได้รับยา midazolam เป็นยาช่วยนอนหลับ ผู้ป่วยต้องมีค่าคะแนน Epworth Sleepiness Scale (ESS) $\geq$ 8 ใน 24 และ / หรือมีค่าดัชนีมวลกายมากกว่า 27.5 การศึกษานี้ได้แบ่งผู้ป่วยออกเป็น 2 กลุ่ม คือ กลุ่มที่มีค่า Apnea-hypopnea Index (AHI) $\geq$ 20 ครั้ง/ ชั่วโมง (กลุ่มเสี่ยงต่อการเกิดภาวะแทรกซ้อนสูง) และกลุ่มที่มีค่า AHI < 20 ครั้ง/ ชั่วโมง สำหรับความดังของเสียงกรนแบ่งเป็น 3 กลุ่ม คือ 1 = ดังเล็กน้อย, 2 = ดังปานกลาง และ 3 = ดังมาก

ผลการศึกษา: ผู้ป่วยที่เข้าร่วมโครงการมี 50 ราย อายุเฉลี่ย 48.3 $\pm$ 10.6 ปี เป็นเพศชาย 31 คน เพศหญิง 17 คน มีดัชนีมวลกายเฉลี่ย 27.7 $\pm$ 3.9 หน่วย (พิสัยอยู่ระหว่าง 22.5-36.9) ค่าคะแนน ESS มีค่าเฉลี่ย 10.6 $\pm$ 2.3 เมื่อแบ่งกลุ่มเป็นกลุ่มเสี่ยงสูงต่อการเกิดภาวะแทรกซ้อนสูง(AHI$\geq$ 20) และกลุ่มเสี่ยงต่ำ (AHI < 20) พบว่าผลการตรวจการนอนหลับเวลากลางวันมีความไวเท่ากับร้อยละ 92 ค่าความจำเพาะเท่ากับร้อยละ91.3 ค่าทำนายว่าผิดปกติเมื่อผลการตรวจการนอนหลับเวลากลางวันเป็นบวก (positive predictive value) ให้ค่าเท่ากับร้อยละ 92 และค่าทำนายว่าปกติเมื่อผลการตรวจการนอนหลับเวลากลางวันเป็นลบ (negative predictive value) เท่ากับร้อยละ 91 โดยมีค่าความสอดคล้องของเสียงกรนในกลางวันและเวลากลางคืน (kappa statistics) ให้ค่าสถิติแคปป้าเท่ากับ 0.72

สรุปการศึกษา: การศึกษานี้พบว่าการตรวจการนอนหลับเวลากลางวันมีความไว และ ความจำเพาะสูง ฉะนั้น การตรวจการนอนหลับในเวลากลางวัน น่าจะใช้แทนการตรวจการนอนหลับในเวลากลางคืนในแง่การคัดกรองผู้ป่วยและติดตามผลการผ่าตัดผู้ป่วยนอนกรนหยุดหายใจ

สาขาวิชา การพัฒนาสุขภาพ
ปีการศึกษา 2548

ลายมือชื่อนิสิต.....
ลายมือชื่ออาจารย์ที่ปรึกษา.....
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

4775004730: MAJOR HEALTH DEVELOPMENT

KEYWORD: DAYTIME PSG/ SNORING INTENSITY/ OVERNIGHT PSG/ MIDAZOLAM/ SLEEP DISORDER BREATHING

PRASIT MAHAKIT M.D., THE COMPARATIVE STUDY OF DAYTIME (DPSG) AND OVERNIGHT POLYSOMNOGRAPHY (ONPSG) FOR HIGH RISK SNORER THESIS ADVISOR: ASSOC. PROF. WINAI WADWONGTHAM, M.D., M.Sc., THESIS CO-ADVISOR: ASSOC.PROF.SANGUANSAK THANAVIRATANANICET, M.D., M.SCC., 35 pp

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Objective: To compare the results between 2-hour daytime polysomnography (PSG) and overnight PSG (as gold standard) to screen high risk snorers.

Study design: Descriptive study (Diagnostic test)

Setting: Snoring clinic, Phramongkutklao hospital

Method and material: This study included patients with high risk of obstructive sleep apnea and were scheduled for overnight PSG at the snoring clinic, Phramongkutklao Hospital between September 2005 and February 2006. Two-hour DPSG was conducted with midazolam induction. ONPSG was performed as the gold standard procedure within 2 months before DPSG.

These patients had to have Epworth Sleepiness Scale (ESS) $\geq$ 8/24 and/or BMI more than 27.5. Patients were categorized into high risk obstructive sleep apnea syndrome (OSAS) (AHI $\geq$20/ hr) and low risk OSAS (AHI < 20/hr). Regarding snoring sound, it was divided in 3 groups: 1 = mild, 2 = moderate, 3 = severe.

Results: Fifty patients, 31 Males and 17 Females were participated in this study with the mean age of 48.3$\pm$10.6 year (range 22-65), BMI of 27.7$\pm$3.9 (22.5-36.9) and ESS of 10.6$\pm$2.3. By categorized the patients into high risk OSAS and low risk OSAS, the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of DPSG comparing with ONPSG were 92% 91.3% 92.%and 91.3% The agreement (kappa statistics) of snoring sounds in daytime and night time was 0.72

Conclusion: This study revealed the DPSG had a high sensitivity and specificity. Therefore it should be used as a good screening test for high risk snorers and was very helpful to assess the outcomes of OSAS patients after surgical intervention.

Field of study Health Development

Academic year 2005

Student's signature.....

Advisor's signature .....

Co-advisor's signature.....

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Finally the two persons I can never forget to thank, are my wife, Ms.Sunantha and my lovely daughter, Ms.Nuttida, who provided superb environment for me to work and encouraged me to finish this thesis.

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CHAPTER I

IMTRODUCTION

Background and rationale

Sleep disordered breathing (SDB) is one of common medical problems leading to social annoyance, impaired cognitive and psychomotor performance,(1) loss of libido,(2) behavioral derangement, medical complication such as cardiovascular condition (3-4) or stroke (5) including increase mortality from accident in working place, traffic accident (6) and cardiovascular disease. (7)

Sleep disorder has a high prevalence in the general population, insomnia 10-15% (8) and sleep apnea syndrome 2-4% while snoring ranges between 12-30 % in middle age and 40-60% in elderly.(9-10) Snoring is thought to be the initial onset of the spectrum of disease process culminating in apnea caused by narrowing of airway especially in oropharynx.

There are 3 postulated risk factors for SDB leading to narrowing of oropharyngeal airway.

1) Unfavorable anatomical structure such as enlarged tonsils, adenoid, redundant soft palate and uvula, base of tongue enlargement.

2) Respiratory dilator muscle relaxation during deep sleep or under other condition(s) such as alcohol consumption, exhaust or ingest sleeping pill

3) Increased negative pressure in upper airway (nasal cavities) which creates sound (snoring) and collapse of small airway by Bernoulli's effect.

SDB is responsible for high cost investigations and treatment modalities. The investigations are usually performed in sleep laboratory at the expense of personal cost, time consuming, increasing in demand and long waiting list.

Overnight polysomnography (ONPSG) is accepted to be the gold standard to differentiate severe form of SDB (sleep Apnea syndrome) from mild form of SDB (simple snorer). Average expense for ONPSG in Europe is about 390 Euro per test, while ambulatory polysomnography (PSG) which has moderate to high sensitivity and specificity is only 30% ONPSG (120 Euro/test).(11) In Thailand it costs about 9000 baht for overnight PSG. For alternative method, Nap PSG or daytime PSG is another objective evaluation in daytime and consumes only a few

hours of staff and patient's time. This study created nighttime environment such as dark, quiet, cold temperature room, and induced sleepiness with Midazolam.

Midazolam has a rapid onset and prolong duration of sleep without any quantitative impairment of rapid eye movement stage (REM) sleep and has muscle relaxation properties. It is commonly used in pediatric and geriatric sedation before brief intervention such as laceration repair, or endoscopic examination. Regarding nasal blockage, which creates negative pressure in oropharyngx, there are various causes such as cold dry air of air conditioning room or house dust mite in bed room of patients with coexisting allergic rhinitis.

If the result of the study is comparable with overnight PSG, then daytime PSG may be an effective method to screen high risk snorer before undergoing for overnight PSG. It may be also accepted as a very effective method to follow up patients after surgical treatment which will save tremendous time, expense and sleep laboratory staff's time.

CHAPTER II

LITERATURE REVIEW

Search strategy

Using PubMed search engine between January 1966 and December 2005 to find published articles comparing between daytime PSG and overnight PSG in Medline database. The search terms were ("Daytime polysomnogra*" OR nap polysomnogra*") AND ("sleep apnea*" OR "sleep disorder breathing*") AND ("overnight polysomnogra*" OR "standard polypsomnogra*"

Literature review

Polysomnography (PSG) is a gold standard tool for diagnosis of sleep disordered breathing (SDB). The high cost, time consumption, high demand with limited resources (trained score reader, expensive equipment) lead to limit access to standard PSG. Therefore many procedures were introduced as screening tools for snorers before undergoing for standard PSG, such as excessive daytime sleepiness, Epworth sleepiness score (12) Sonography, Snap study, Quisi, Nap or daytime PSG, pulse oximetry including ambulatory PSG. (13-14)

Regarding Cochrane review, based on symptoms and questionnaire to estimate pretest probability of having sleep apnea syndrome (SAS), the assignment to high probability group could not be used with enough certainty to eliminate the need for PSG and assignment to a low probability group reduced the probability that a patient has SAS is between 0% and 17%. In general pretest probability of having SAS at least 70% which inturn give a sensitivity of about 30% and a specificity of about 90%. Tami et al. used body mass index (BMI) and in depth sleep questionnaire alone or in combination were low to recommend their use in lieu of a formal sleep study, level 3 ambulatory monitor devices may still be the most cost effective alterative for evaluating this high risk population. (15)

There were a few studies about the value of daytime polysomnography (DPSG) or nap PSG. Saeed et al retrospectively studied 143 children who were previous performed ONPSG and 1 hour nap PSG. They found that nap study had low sensitivity in predicting abnormal ONPSG but had high specificity and high positive predictive value.(16) Suzuki et al demonstrated that the

sleep latency and sleep time of two nap PSG did not differ among groups (normal control group, OSAS group and another sleep disorder group). In contrast, the frequency of micro-arousal and movement arousal was significantly higher in the OSAS group than in the other groups. They suggested that two nap PSG was useful for evaluating disturbance of sleep maintenance. (17) Mizuma et al compared three hours DPSG with ONPSG and demonstrated that there was no significant difference among apnea index and arterial oxygen saturation (SaO_2) but there was a significant positive correlation between DPSG and ONPSG. Therefore DPSG was useful not only for diagnosing sleep apnea syndrome (SAS) but also in evaluating its severity. (18)

Yoshiko et al also suggested that DPSG was a useful screening tool for SAS. (19) In contrary, Van Keimpema et al compared one-hour DPSG with ONPSG. The result showed that the sensitivity was 66% and specificity was 88% with the positive predictive value of 70% and the negative predictive value of 86% They concluded that one-hour PSG is not sufficient to diagnose or exclude SAS with certainty. (20) Most of the previous studies reported low sensitivity of daytime sleep test which might be due to one probable factor, the patient did not fall deep sleep enough during the daytime sleep test. Regarding recording time, one hour recording time may too short and three hours may too long because the normal sleep cycle is usually between 90-120 minutes. So two-hour recording time with creation of nighttime environment for DPSG may be appropriate and should be studied to compare with ONPSG.

CHAPTER III

RESEARCH METHODOLOGY

Research questions

Primary research question:

Is daytime PSG (DPSG) a good screening test to detect high risk snorer?

Secondary research question:

Is there a good agreement between snoring intensity (loudness) rating score between daytime and night time sleep?

Research objectives

Primary objective

To determine the sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio of DPSG to detect high risk snorer compare with ONPSG.

Secondary objective

To evaluate the agreement of snoring intensity rating between daytime and overnight sleep

Research hypothesis

The challenging daytime polysomnography is a good screening test for high risk snorer with the sensitivity of at least 90%

Statistical hypothesis

Null

Conceptual framework

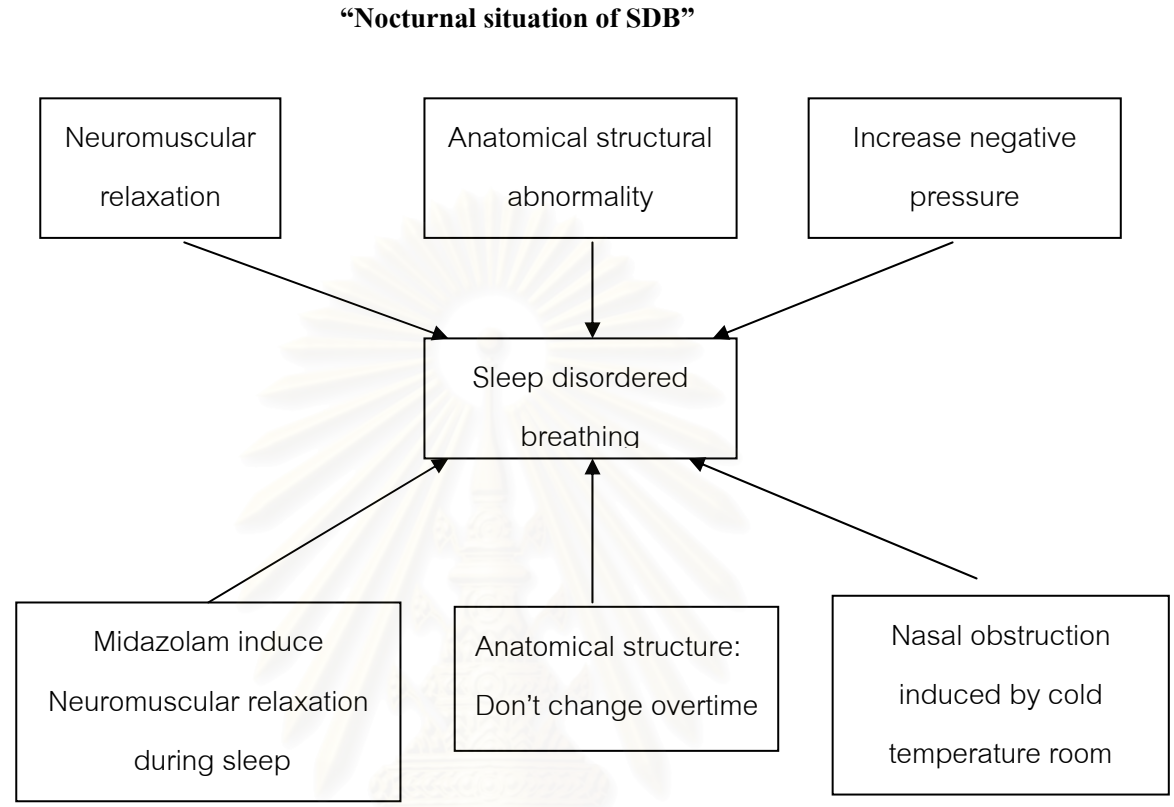

Figure 1: Illustration of conceptual framework of the study

Key word:

Daytime PSG, snoring intensity, overnight PSG, Midazolam, sleep disorder breathing.

Operational definition

Overnight PSG: Polysomnography performed in night time, record and score according to Rechtschaffen and Kales system. (21) The PSG in this study was performed by Meditel polysomnogram model EX 810

Daytime PSG: Polysomnography performed in daytime during 08.00-16.00 and record PSG for two hours during sleep.

Room environment for all sleep test: the room temperature was set at 25 degree celsius, keep the room quiet and dark as nighttime environment

Epworth sleepiness scale (ESS): a self administrated questionnaire, provided an subjective estimation of daytime sleepiness suffered by patients with OSA (ranging from 0-24)

High risk snorer before sleep test: a patient who had Epworth sleepiness scale 8 or more.(12)

Apnea index (AI) was defined as number of cessation of airflow >10 seconds per hour.

Hypopnea index (HI) was defined as number of decrease airflow >10 seconds with arousal and oxyhemoglobin desaturation >4% per hour.

Apnea hypopnea index (AHI) was defined as number of apnea and hypopnea index (22)

Apnea hypopnea index was categorized into 2 groups (after sleep test)

a) Low risk snorer (mild SAS) was defined as patient who had AHI less than 20/hour diagnosed by overnight PSG.

b) High risk snorer (moderate and severe SAS) was defined as patient who had AHI as least 20/hour diagnosed by overnight PSG. (7)

There were 3 reasons to define 20/hr as a cut off point for high or low risk group

1. Patient who had AHI 20 or more per hour had 9 times higher mortality rate than those who had AHI less than 20/hr. (7)

2. Criteria for surgical intervention (Uvulopalatopharyngoplasty) allowed for patient only those who had AHI less than 20/hr. (Riley-Powell-Stanford Surgical Protocol) (23)

3. Successful criteria for surgical intervention is defined as

a) AHI less than 20/hr.

b) AHI less than 50% of pre - treatment (22)

Snoring intensity (loudness): rating by 3 trained score raters was categorized into 3 groups as

Mild: In bed annoyance (~ 25 dB)

Moderate: Open door annoyance (~ 25-55dB)

Severe: Close door annoyance (~ >55dB)

The regulation of Minnesota pollution control agency (MPCA) limits maximal acceptable outdoor night time noise less than 55 dB.

Research design

Descriptive study (diagnostic test)

Research methodology

Patient selection

A consecutive sample of snorers who had risk for sleep apnea syndrome and had underwent or scheduled for overnight PSG within two months.

Target population

Snoring patients who had symptoms related to sleep disordered breathing.

Study population

All snorers in Snoring clinic, Phramongkutklao hospital who were or scheduled for or had underwent overnight PSG and volunteered to underwent a daytime PSG.

Inclusion criteria

1. Patient aged 19-65 year who had snoring problem(s)
2. Well cooperated patients and informed consent was signed

Exclusion criteria

1. Unstable medical condition which might be unable to do polysomnography such as congestive heart failure or chronic cough.
2. Epworth sleepiness scale less than 8 in 24 (less likely to have sleep apnea){Johns 1991 #130}
3. History of anaphylaxis.
4. History of sensitive or tolerant to sedative agent(s).
5. Structural abnormality in nasal cavity such as severe nasal deviation, nasal polyp, sinusitis
6. Patient who underwent overnight PSG more than 2 months before/after DPSG

Sample size calculation

Sample size estimation was based on 95% confidence interval of sensitivity of daytime PSG compared to overnight PSG as shown below

$$n = \frac{Z_{\alpha}^{2}.P.Q}{d^{2}}$$

Where n = Number of high risk snorers.

P = Expected sensitivity of daytime PSG.

Q = 1- P

d = Acceptable error.

α = Probability of type 2 error = 0.05 (2 sided)

If expected sensitivity (P) = 0.9

1 – P (Q) = 0.1

Accepted error (d) = 0.1

Thus $n = \frac{(1.96)^{2}(0.9x0.1)}{(0.1)^{2}} = 34.57$

Proportion of high risk snorers at snoring clinic, Phramongklao hospital was 70%

Sample size = n / Prevalence = $\frac{34.57}{0.7}$ = 49.4 cases

Thus the total sample size (number of snorers recruited) was 50 cases

Intervention;

1. All eligible patients who scheduled for overnight PSG had invited to join the study and completed by signing informed consent and sleep questionnaire.
2. Patients who had underwent overnight PSG within two months were asked to revisit and do a daytime PSG.
3. Daytime polysomnography was performed in the same room and same conditions as overnight polysomnography.

4. One tablet of Midazolam (15 mg) was taken to induce patient to sleep.
5. After patient felt asleep, PSG was recorded for two hours.
6. An average snoring intensity (loudness) was rated.

Recommendation before performing daytime PSG

1. It was necessary to have a relative or accompanying person to take patient back home safely after challenging daytime PSG.
2. No alcohol consumption or other sleeping pill was allowed in the night before performing daytime PSG.

The intervention was discontinued if

1. The patient was unable to fall sleep within 20 minutes
2. The patient developed adverse reactions during the study.

Outcome measurement

The following baseline variables were collected

Age

Gender

BMI (body mass index)

ESS (Epworth sleepiness scale)

Nasal symptoms

Co-morbidity condition such as hypertension, diabetes mellitus

Primary outcome variable

Severity of AHI (apnea hypopnea index) was measured as event(s) /hour and categorized into two groups (low risk and high risk groups). Interpretations of AHI from DPSG and ONPSG were performed independently and blinding to each other.

Secondary outcome variable

Snoring intensity rating was rated by trained personnels and was classified into 3 groups according to the operational definitions. The rating during day time and night time sleep was done independently and blinding to each other

Table 1 Summary of variable's measurement

Variables	Scale	Description of data
Baseline characteristics		
Age	Continuous	Mean ±SD
Gender	Dichotomous	Frequency
BMI	Continuous	Mean ±SD
ESS	Continuous	Mean ±SD
		(Score 0-24)
Nasal symptom(s)	Nominal/Ordinal	Frequency
		Mild
		Moderate
		Severe
Co morbidity	Nominal	Frequency
Primary outcome variable Severity of apnea		Binary
Frequency		
Secondary outcome variable		
Snoring intensity	Nominal	Frequency

Data collection and statistical analysis

General consideration

This study was designed to compare the sensitivity and specificity of daytime PSG to conventional overnight PSG. This study focused on the severity of snoring in terms of apnea index because the mode of treatment and prognosis depends on whether patient is in high or low risk group. The data analysis was based on the completeness of PSG record. Incompleted data were reported in percentage and the cause(s) were also reported.

Data Analysis

All data were analyzed by SPSS version 10.5.

Baseline characteristics including age, gender, BMI, Epworth sleepiness scale, nasal symptom(s), co morbidity condition(s).were analysed as descriptive statistics.

The primary outcome variable was categorized in two groups

1) High risk group (AHI at least 20/hr.)
2) Low risk group (AHI less than 20/hr.)

Analysis of PSG outcome ;

Main outcome was analyzed and reported in terms of sensitivity, specificity, positive predictive value, negative predictive value, accuracy and positive likelihood ratio.

Table 2: Two by two table for the result of low risk and high risk group of DPSG and ONPSG

Daytime or nap polysomnography	Gold standard (Overnight Polysomnography)	
	High risk group (AHI $\geq$ 20 /hr)	Low risk group (AHI < 20/hr)
High risk group (AHI$\geq$20 /hr)	a	b
Low risk group (AHI<20/hr)	c	d

Sensitivity = a / a+c

Specificity = d / b+d

95% CI for sensitivity = $a / (a+c) \pm 1.96 \sqrt{\frac{\{a/(a+c)\}\{c/(a+c)\}}{(a+c)}}$

95% CI for specificity = $d / (b+d) \pm 1.96 \sqrt{\frac{\{d/(b+d)\}\{b/(b+d)\}}{(b+d)}}$

Positive predictive value = a /(a+b)

Negative predictive value = d/ (d+c)

Accuracy = (a+d) / (a+b+c+d)

Positive likelihood ratio คือ= {a/(a+c)}/{b(b+d)}

Negative likelihood ratio คือ= {c/(a+c)}/{d/(b+d)}

Snoring intensity (loudness)

To assess agreement between daytime snore score vs. overnight snore score.

Kappa statistic was used for the test of agreement (24)

$$K = \frac{P_o - P_e}{1 - P_e}$$

P_o = Proportion of observed agreement

P_e = Chance agreement, proportion of agreement expected to occur by chance alone

$$\text{Chance agreement} = \frac{(Ao \times Ae) + (Bo \times Be) + (Co \times Ce)}{(\text{Total patients})^2}$$

$$\text{Observed agreement} = \frac{A+B+C}{\text{Total patients}}$$

Table 3. Dummy table for daytime and night time result of scoring for snoring loudness

Daytime scoring for snoring loudness	**Night time scoring for snoring loudness (level of annoyance)**			
	In bed	**Open door**	**Close door**	**Total**
In bed	A			Ae
Open door		B		Be
Close door			C	Ce
Total	Ao	Bo	Co	

Level of agreement (k-value) was followed according to Landis & Koch (25)

0.2	poor
>0.2 -0 4	fair
>0.4 - 0.6	moderate
>0.6 -0.8	good
>0.8	very good

Ethical considerations

This study was conducted according to the Declaration of Helsinki

1) Informations about detail of the study and potential adverse reaction were explained to patients before the consent signatures were requested.
2) Patients had the right to withdraw from the study anytime without further interfere with the regular optimal management.
3) The study was performed without any charge to the patient.
4) The research proposal had been submitted to the hospital ethic committee and the study started after IRB/EC approval.
5) Rescue kit was always available on-site during the study period and investigators were available to be contacted anytime during the study.

Rescue kit and safety procedure

1) Standard cardiopulmonary resuscitation (CPR) unit was available on-site during study.
2) Fumazenil was provided as an antidote for Midazolam .
3) The participants had to have a relative or accompanying person (age >18 years) with them in order to take the patients back home safely.
4) The trained staffs and investigators were available on-site during study.

Expected benefit from this study

The results might be able to answer the research question whether daytime PSG is a good screening test for high risk snorers. If the results provided a high sensitivity (>90%), it will save cost, time consumption of both trained score readers and patients during performing screen and follow up test. Especially, for follow up test, it will be easy and convenient to evaluate the outcome of treatment (medical or surgical intervention) in the same comparable unit (AHI) as the standard test. Moreover it will add marginal benefit of the equipment.

Limitation and possible obstacle

1) It was difficult for the patients to fall asleep in day time

2) The patient might be sensitive or tolerant to medication (Midazolam)

Time schedule of the study (in quarter,Q)

	2005				2006			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Protocol approval	→							
Data collection	→	→	→	→				
Data analysis					→			
Thesis writing					→			
Thesis defense						★		

CHAPTER IV

STUDY RESULTS

Results of the study

Demographic and baseline data

Fifty patients underwent daytime polysomnography (DPSG) and overnight polysomnography during 6-month period from September 2005 to February 2006 at Snoring center Phramongkutklao Hospital. Two cases were excluded from the study due to inadequate recording time of less than 2 hours

Average age of patients was 48.3 ± 10.64 (S.D.) years (ranged 26-65 years) , 31 males (68.9%) and 14 females (31.1%) , mean ± SD of body mass index and Epworth sleepiness scores were 27.87 ± 3.95 (ranged 22.5 – 36.9) and 10.56 ± 2.25 (ranged 8 – 16 in 24) respectively as shown in Table 4. Forty of forty eight patients (83%) had nasal symptoms, 20/48 (42%) had mild, 14/48 (29%) had moderate, 6/48 (13%) had severe nasal symptom. Thirty four of forty eight patients (71%) had hypertension and 18/48 (38%) had diabetes mellitus.

The means (± SD) of apnea index (AI) for ONPSG and DPSG were 24.31 (± 21.4) and 21.4 (± 20.4) respectively. Apnea and hypopnea index (AHI) for ONPSG and DPSG were 28.3 (± 21.4) and 25.3 (± 20.9) events per hour respectively. Difference in AHI between the DPSG and ONPSG for each individual patient was illustrated in figure 2. A positive value indicated an AHI of ONPSG recording and was depicted as an upward – extending bar. A negative value indicated an AHI of DPSG recording and was depicted as a downward extending bar. Statistical analysis of the two AI and AHI measurements demonstrated a good agreement with pearson correlation of 0.87 ($p<.01$) and 0.86.($p<.01$) .

To compare apnea index and Apnea hypopnea index between DPSG and ONPSG. There were no statistical differences between both groups as shown in Table 5 when categorized AHI into high risk (AHI $\geq$20 hr) and low risk group (AHI ‹ 20 / hr) (Table 5). The correlation of DPSG and ONPSG was high with kappa statistics of 0.88 ($p<.01$)

The following are the results of sensitivity, specificity, positive predictive value negative predictive value, accuracy, Likelihood Ratio.

$$\text{Sensitivity} = \frac{a}{a+c} = 0.92$$

$$\text{Specificity} = \frac{d}{b+d} = 0.913$$

$$\text{Positive Predictive Value} = \frac{a}{a+b} = 0.92$$

$$\text{Negative Predictive Value} = \frac{d}{d+c} = 0.913$$

$$95\%\ \text{CI for sensitivity} = a/(a+c) \pm 1.96\sqrt{\frac{\{a/(a+c)\}\{c/(a+c)\}}{(a+c)}}$$

$$= 0.92 \pm 1.96(0.01084)$$

$$= 0.92 \pm 0.021$$

$$= 0.899\text{-}0.941$$

$$95\%\ \text{CI for specificity} = d/(b+d) \pm 1.96\sqrt{\frac{\{d/(b+d)\}\{b/(b+d)\}}{(b+d)}}$$

$$= 0.913 \pm 1.96(0.0129)$$

$$= 0.913 \pm 0.0252$$

$$= 0.8878\text{-}0.9382$$

$$\text{Accuracy} = \frac{a+d}{a+b+c+d} = 0.80$$

$$\text{Positive likelihood ratio} = \{a/(a+c)\}/\{b(b+d)\}$$

$$= 10.57$$

$$\text{Negative likelihood ratio} = \{c/(a+c)\}/\{d/(b+d)\}$$

$$= 0.09$$

Regarding Snore Score

Underestimated daytime snoring sounds were found in 2/48 (4.2 %) when compared to the overnight snoring sounds while overestimated daytime snoring sounds were found in 5/48 (10.4%). The rest, 41/48 (85.4%) of daytime snoring sounds were the same score as overnight snoring sounds. Therefore the agreement (Kappa statistics) between daytime snoring sounds and overnight snoring sounds was 0.72 ($p<.01$) which was a good correlationto be between daytime and night time snore results.

Table 4: Demographic data of BMI & ESS of patients

	Minimum	Maximum	Mean	Std. Deviation
AGE	26.00	65.00	48.30	10.64
BMI	22.49	36.91	27.87	3.96
ESS	8.00	16.00	10.56	2.25

Figure 2: illustrated the AHI result of ONPSG- (upward bar) and DPSG (downward bar)

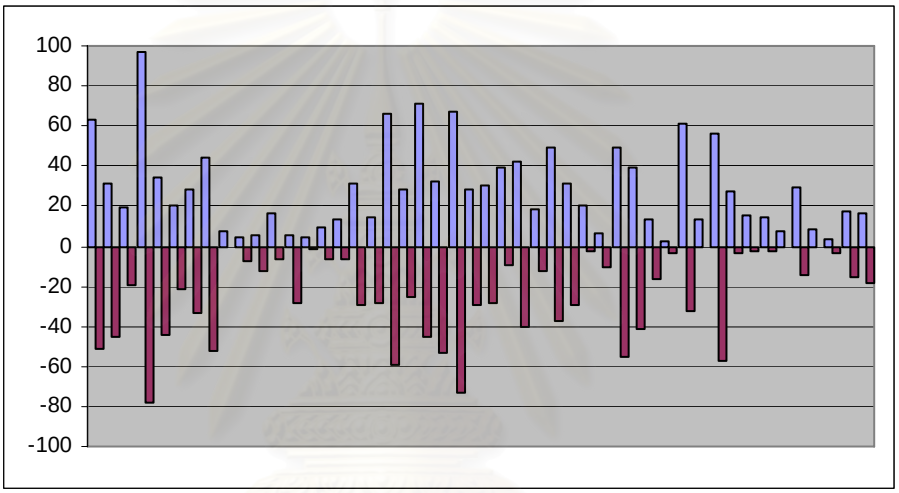

Table 5 Mean values for AI HI and AHI of DPSG and ONPSG

	Mean	Std. Deviation	95% CI	Sig. (2 tailed)
AI ONPSG	24.31	21.36		
DPSG	21.39	10.70		
ONPSG-DPSG	1.92	20.43	-1.18-5.03	0.22
HI ONPSG	3.99	4.69		
DPSG	2.91	4.36		
ONPSG-DPSG	1.08	6.51	-0.81-2.97	0.26
AHI ONPSG	28.29	21.44		
DPSG	25.30	20.91		
ONPSG-DPSG	3.00	11.12	-0.23-6.23	0.07

Table 6: Cross table of high risk and low risk (AHI ≥20 and AHI<20) between daytime and overnight polysomnography

		AHI ON PSG		Total
		≥20	<20	
AHI DPSG	≥20	23	2	25
		(92%)	(8.7%)	
	<20	2	21	23
		(8%)	(91.3%)	
Total		25	23	48

Fig 3 demonstrated snoring intensity of individual patient of night time (SN 1 or blue) and daytime (SN2 or red)

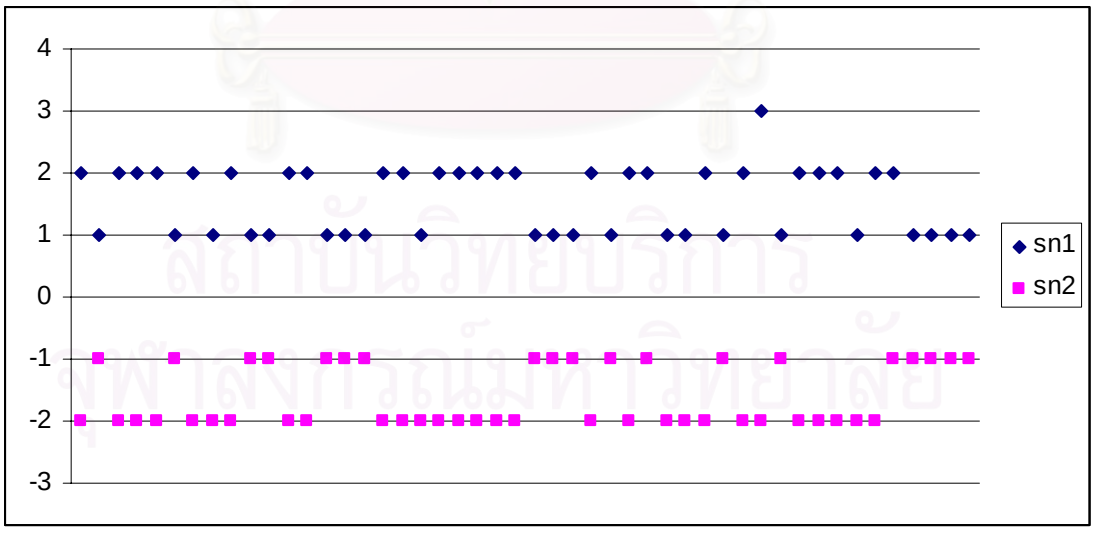

Table 7: Agreement of snoring intensity between daytime and night time assessment

Daytime	Night time			Total
	Mild	Moderate	severe	
Mild	17	5	0	22
	(35.4%)	(10.4%)		(45.8%)
Moderate	2	23	0	25
	(4.2%)	(47.9%)		(52.1%)
Severe	0	0	1	1
			(2.1%)	(2.1%)
Total	19	28	1	48
% of Total	(39.6%)	(58.3%)	(2.1%)	(100.0%)

CHAPTER V

DISCUSSION

Discussion

The purpose of this study is to compare the results of daytime polysomnography (DPSG) and overnight polysomnography (ONPSG) which are accepted as the gold standard for the diagnosis of patient with sleep apnea. Our result has shown that the apnea index (AI) and apnea hypopnea index (AHI) determined by DPSG had a good agreement with ONPSG. There were 2 cases which failed to undergo DPSG due to less than 2 hour PSG recording. One case was awakened by cell phone ringing and the other was awaked by full bladder .

ONPSG is the gold standard for the diagnosis of sleep disordered breathing, but it is expensive and time-consuming. So for screening or to assess an outcome of surgical intervention such as tongue base surgery, maxillo-mandibular advancement or somnoplasty, repeating ONPSG could burden patient's expense and adding more waiting list for sleep apnea patients. It will be helpful, if there is a comparative test for screening or to assess an outcome of surgical treatment which could minimize time consuming and expense.

DPSG has a great advantage over other alternative sleep study such as SNAP test, pulse oximetry, Quisi, Sonography or MESAM, even home monitor (ambulatory) PSG. The reasons are as followings

1. It is recorded by full-scale PSG which is a gold standard diagnostic tool so the result is comparable in terms of the same parameter
2. It could add more value for PSG because it can also be used during daytime.
3. It is recorded under closed monitor by well trained sleep test personnel.
4. It takes a relatively shorter time.

Saeed et al compared 1-hour DPSG with ONPSG. The finding of 59% and 66% of daytime or Nap polysomnography and ONPSG study were abnormal. No individual Nap study parameter had good sensitivity for predicting abnormal ONPSG, but most of them had good specificity and positive predictive value. One hour of Nap PSG recording may be too short to detect abnormality in terms of sensitivity. (16) In our study we recorded 2-hour DPSG which the sensitivity and specificity showed to be higher than Saeed's study.

Sergi et al. showed no difference in the AHI and mean oxygen saturation between DPSG and ONPSG. The sensitivity was 91% and specificity was 100%. A good correlation was found for AHI and oxygen desaturation index in two experimental conditions with r = 0.89 and r = 0.79 respectively. It also showed that daytime recording was accurate for sleep apnea diagnosis in the majority of patient with a clinical suspicion of sleep apnea syndrome .(26)

Urgeijo et al demonstrated that nap PSG is a technique for rapid diagnosis of sleep apnea-hypopnea syndrome (OSAHS) and found that 70% of NPSG were diagnosis on OSAS patients.(27) Suzuki et al had studied two nap sleep test as an easy objective sleepiness test in long distant driver comparing with ONPSG and found that there were no difference among both tests. (17)

Montero et al. reported sensitive and specificity for high risk group by used the cut off point of AHI $\geq$ 10/hr. were 73% and 83% respectively The positive predictive value of 93% and negative predictive value of 50% when compared with our study that raised the cut off point from AHI $\geq$ 10/hr to AHI $\geq$ 20/hr which we use as a cut off point for high risk and low risk groups in terms of cardio vascular consequences.(28) Regarding other sleep tests, such as pulse oximetry, which defines the severity of OSA as severe (AHI more than 25/hr), moderate OSA (AHI 16-25) and mild OSA (AHI 5-15)respectively. The sensitivity and specificity for severe OSA are found to be 100% and 75%respectively. The moderate severe OSA (15 -25/hr) are 86% and 80%. Finally mild OSA (5 –15/hr) are 60% and 95% for sensitivity and specificity. So the pulse oximetry is helpful only for severe OSA patients. Meanwhile White et al.. used sound recording and oxygen saturation in screening for OSA and showed that the sensitivity of oximetry increased as the threshold AHI used in the definition of OSA increased.(29)

Van Surell et al. studied ambulatory device as CID 102 in diagnosis OSA (RDI $\geq$ 5/hr), the sensitivity and specificity were only 73% and 62% respectively but positive predictive value of CID was 94%.(30)

Zucconi et al compared an alternative method, microdigitrappers and found that the sensitivity and specificity were 91% and 94% respectively, but the device could not predict the severity of OSA precisely enough.(31) Stoohs and Guilleminault found that sleep sonography had an overall impressive sensitivity of 96% but a low specificity of 27%. The sonography results correlated well to polysomnography with a pearson correlation coefficient of 0.88 ($P < 0.001$) and an accuracy of 85%. (32)

Liesching et al evaluated the accuracy of SNAP comparing with conventional PSG and found that overall agreement with K-Value of 0.23 (P = 0.008) which suggested that SNAP studies did not appear to accurately assess severity of OSA.(33)

Esnaola et al demonstrated MESAM (monitor breathing sound heart rate, arterial oxygen saturation and body position), a portable recording device in identifying obstructive sleep apnea (OSA) as an exclusion test. It reached a sensitivity of 98% and specificity of 78%, as confirmation test the value were 69% and 97% respectively.(34) Meanwhile Koziej found that the sensitivity and specificity of MESAM for oxygen desaturation index were 100% and 27%, heart rate variation index 81% and 74%. . For intermittent snore index were 92 % and 16%. It was a high sensitivity but low specificity diagnostic tool so it was good for only screening test. (35)

In conclusion, this study demonstrated that 2-hour daytime polysomnography had high sensitivity, specificity, positive predictive value and negative predictive value. So it should be accepted as a screening test and also using as assessment tool for outcome of surgical intervention, when compare with standard overnight polysomnography in high risk snorers.

Recommendation

Midazolam used in this study to induce patient fall sleep in daytime sleep test has some effect on sleep pattern as it improve sleep in the first part of night with sleep disruption and fragmentation in second part of the night because of withdrawal from tha medication. Its dosage also depends on patient history of sleeping pill usage. It may be get more acceptable to use other sleeping pill without effect on sleep pattern.

Because of limitation in budget

- Esophageal pressure monitoring was not included to detect respiratory afford arousal events. So this study reported only the results of AHI; not RDI.

References

1. Bassiri AG, Guilleminault C. Clinical features and evaluation of obstructive sleep apnea-hypopnea syndrome. In: Kryger MH, Roth T, Dement WC, Editors. Principles and Practice of Sleep Medicine. 3rd edition. Philadelphia: W.B. Saunders Company, 2000: 869-78.
2. Fanfulla F, Malaguti S, Montagna T et al. Erectile dysfunction in men with obstructive sleep apnea: an early sign of nerve involvement. Sleep 2000; 23(6):775-81.
3. Peppard PE, Young T, Palta M, Skatrud J. Prospective study of the association between sleep-disordered breathing and hypertension. N Engl J Med 2000; 342(19):1378-84.
4. Phillips BG, Somers VK. Sleep disordered breathing and risk factors for cardiovascular disease. Curr Opin Pulm Med 2002; 8(6):516-20.
5. Partinen M. Ischaemic stroke, snoring and obstructive sleep apnoea. J Sleep Res 1995; 4(S1):156-9.
6. Teran-Santos J, Jimenez-Gomez A, Cordero-Guevara J. The association between sleep apnea and the risk of traffic accidents. Cooperative Group Burgos-Santander. N Engl J Med 1999; 340(11):847-51.
7. He J, Kryger MH, Zorick FJ, Conway W, Roth T. Mortality and apnea index in obstructive sleep apnea. Experience in 385 male patients. Chest 1988; 94(1):9-14.
8. Ohayon MM, Caulet M, Guilleminault C. How a general population perceives its sleep and how this relates to the complaint of insomnia. Sleep 1997; 20(9):715-23.
9. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med 1993; 328(17):1230-5.
10. Gallup Organization. Sleep in America. Princeton, NJ.: The Gallup Organization, 1995.
11. Pelletier-Fleury N, Meslier N, Gagnadoux F et al. Economic arguments for the immediate management of moderate-to-severe obstructive sleep apnoea syndrome. Eur Respir J 2004; 23(1):53-60.
12. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep 1991; 14(6):540-5.
13. Kirk VG, Bohn SG, Flemons WW, Remmers JE. Comparison of home oximetry monitoring with laboratory polysomnography in children. Chest 2003; 124(5):1702-8.

14. Golpe R, Jimenez A, Carpizo R. Home sleep studies in the assessment of sleep apnea/hypopnea syndrome. Chest 2002; 122(4):1156-61.

15. Tami TA, Duncan HJ, Pfleger M. Identification of obstructive sleep apnea in patients who snore. Laryngoscope 1998; 108(4 Pt 1):508-13.

16. Saeed MM, Keens TG, Stabile MW, Bolokowicz J, Davidson Ward SL. Should children with suspected obstructive sleep apnea syndrome and normal nap sleep studies have overnight sleep studies? Chest 2000; 118(2):360-5.

17. Suzuki H, Moriguchi K, Matsuura M et al. Two nap sleep test: an easy objective sleepiness test. Psychiatry Clin Neurosci 2000; 54(3):285-6.

18. Mizuma H, Sonnenschein W, Meier-Ewert K. Diagnostic use of daytime polysomnography versus nocturnal polysomnography in sleep apnea syndrome. Psychiatry Clin Neurosci 1996; 50(4):211-6.

19. Yoshiko K, Okada T. [Screening of sleep apnea syndrome using daytime polysomnography--its usefulness and the characteristics of daytime sleep in the patients with sleep apnea syndrome]. Rinsho Byori 1993; 41(3):279-84.

20. Van Keimpema AR, Rutgers SR, Strijers RL. The value of one hour daytime sleep recording in the diagnosis of the sleep apnoea syndrome. J Sleep Res 1993; 2(4): 257-9.

21. Rechtscha en A., Kales A. A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects. Washington: U.S. Dept. Health, Education and Welfare, National Institute of Health Publ. No.204, 1968.

22. Guilleminault C, Abad VC. Obstructive sleep apnea syndromes. Med Clin North Am 2004; 88(3):611-30, viii.

23. Troell RJ, Riley RW, Powell NB, Li K. Surgical management of the hypopharyngeal airway in sleep disordered breathing. Otolaryngol Clin North Am 1998; 31(6):979-1012.

24. Szklo M, Nieto FJ. Quality assurance and control. Epidemiology: beyond the basics . Maryland: Aspen Publishers. Gaithersburg, MD, 343-404.

25. Altman DG. Practical statistical for medical research. London: Chapman and Hall, 1991.

26. Sergi M, Rizzi M, Greco M et al. Validity of diurnal sleep recording performed by an ambulatory device in the diagnosis of obstructive sleep apnoea. Respir Med 1998; 92(2):216-20.

27. Aguirregomoscorta Urquijo JI, Menendez Gastan I, Aparicio Abendano S, Quintana Lopez J, Capelastegui Saiz A, Urrutia Landa I. [Nap polysomnography: sufficient grounds for initiating CPAP treatment?]. Arch Bronconeumol 2001; 37(8):302-6.

28. Cordero Montero P, Marquez Perez FL, Rodriguez Blanco I, Inigo Naranjo P, Antona Gomez JM, Fuentes Otero F. [Abbreviated diurnal polysomnographic records in the diagnosis of sleep obstructive apnea syndrome]. Rev Clin Esp 1998; 198(6):351-5.

29. White JE, Smithson AJ, Close PR, Drinnan MJ, Prichard AJ, Gibson GJ. The use of sound recording and oxygen saturation in screening snorers for obstructive sleep apnoea. Clin Otolaryngol Allied Sci 1994; 19(3):218-21.

30. Van Surell C, Lemaigre D, Leroy M, Foucher A, Hagenmuller MP, Raffestin B. Evaluation of an ambulatory device, CID 102, in the diagnosis of obstructive sleep apnoea syndrome. Eur Respir J 1995; 8(5):795-800.

31. Zucconi M, Ferini-Strambi L, Castronovo V, Oldani A, Smirne S. An unattended device for sleep-related breathing disorders: validation study in suspected obstructive sleep apnoea syndrome. Eur Respir J 1996; 9(6):1251-6.

32. Stoohs R, Guilleminault C. MESAM 4: an ambulatory device for the detection of patients at risk for obstructive sleep apnea syndrome (OSAS). Chest 1992; 101(5):1221-7.

33. Liesching TN, Carlisle C, Marte A, Bonitati A, Millman RP. Evaluation of the accuracy of SNAP technology sleep sonography in detecting obstructive sleep apnea in adults compared to standard polysomnography. Chest 2004; 125(3):886-91.

34. Esnaola S, Duran J, Infante-Rivard C, Rubio R, Fernandez A. Diagnostic accuracy of a portable recording device (MESAM IV) in suspected obstructive sleep apnoea. Eur Respir J 1996; 9(12):2597-605.

35. Koziej M, Cieslicki JK,Gorzelak K, Sliwinski P,Zielinski J. Hand –scoring of MESAM 4 recordings is more accurate than automatic analysis in screening for obstructive sleep apnea Eur Respir J 1994;7(10):1771-5

Appendices

APPENDIX A

ใบยินยอมของผู้เข้าร่วมโครงการวิจัย

(Thai Consent Form)

ชื่อผู้ป่วย_____

ผู้ป่วยนอนกรนหยุดหายใจเป็นภาวะที่อันตรายมีผลกระทบในระยะสั้นต่อประสิทธิภาพการทำงานของสมอง เพิ่มอุบัติเหตุจากการทำงานและการขับขี่ยวดยาน และผลกระทบระยะยาวต่อระบบหัวใจและหลอดเลือด การตรวจการนอนหลับ (Polysomnography) เป็นวิธีมาตรฐานในการแยกผู้ป่วยนอนกรนทั่วไปจากผู้ป่วยที่มีภาวะนอนกรนหยุดหายใจ

การตรวจการนอนหลับเป็นวิธีที่มีค่าใช้จ่ายสูง (ประมาณ 9000 บาท) และใช้เวลา 1-2 คืน ทำให้ไม่สะดวกในการใช้เป็นวิธีการคัดกรองผู้ป่วยตลอดจนประเมินผลการรักษาผู้ป่วย โดยเฉพาะผู้ป่วยที่ได้รับการผ่าตัด หรือจี้ลดขนาดช่องคอด้วยคลื่นวิทยุความถี่สูง การตรวจการนอนหลับในเวลากลางวันจึงเป็นวิธีการหนึ่งที่เคยมีการศึกษาเพื่อใช้เป็นเครื่องคัดกรองและติดตามผล แต่ไม่มีข้อสรุปชัดเจนในวิธีการตรวจดังกล่าว ทางผู้วิจัยจึงได้กำหนดบรรทัดฐานชัดเจนในการทำวิจัย เพื่อเปรียบเทียบผลการตรวจการนอนหลับโดยวิธีมาตรฐานตอนกลางคืนกับการตรวจการนอนหลับในเวลากลางวัน ในผู้ป่วยที่มีความเสี่ยงต่อการเกิดภาวะนอนกรนหยุดหายใจ ซึ่งท่านเป็นผู้หนึ่งที่อยู่ในเกณฑ์ดังกล่าว โดยทางผู้วิจัยจะใช้ยานอนหลับหนึ่งเม็ด เพื่อให้ท่านนอนหลับซึ่งมีความปลอดภัย (เนื่องจากเป็นยาที่ใช้แพร่หลายก่อนทำหัตถการต่างๆ เช่น การส่องกล้องในทางเดินอาหาร และลำไส้ ทั้งในเด็กและผู้สูงอายุ) โดยจะมีการตรวจการนอนหลับประมาณ 2 ชั่วโมงในเวลากลางวัน แต่ไม่อนุญาตให้ท่านขับรถกลับบ้านเองเด็ดขาด ขณะตรวจดังกล่าวจะมีการเฝ้าสังเกตการเปลี่ยนแปลงตลอดเวลา โดยแพทย์และพยาบาล ข้อมูลทั้งหมดจะเก็บในฐานข้อมูลทางคอมพิวเตอร์ ข้อมูลดังกล่าวรวมทั้งการเผยแพร่ ผลการศึกษาครั้งนี้จะไม่มีระบุชื่อของท่าน

เพื่อให้การวิจัยสมบูรณ์ตามมาตรฐาน อาจมีการตรวจสอบความถูกต้องของข้อมูลจากบุคลากรภายนอก (external audit) ทั้งนี้จะกระทำภายใต้ความยินยอมของท่าน

ท่านสามารถเข้าร่วมโครงการนี้ โดยท่านจะไม่เสียค่าใช้จ่ายใดๆสำหรับการตรวจการนอนหลับในเวลากลางวัน ค่ายา รวมถึงค่าใช้จ่ายอันเป็นผลจากภาวะแทรกซ้อนจากการศึกษา หากท่านปฏิเสธเข้าร่วมโครงการนี้ ท่านยังคงได้รับการดูแลรักษาตามปกติที่ท่านควรได้รับ ท่าน

สามารถตัดสินใจเข้าร่วมโครงการหรือไม่ก็ได้โดยความสมัครใจ โดยจะไม่มีผลใดๆต่อการดูแลรักษาพยาบาล

ข้าพเจ้าได้อ่านข้อมูลข้างต้น รวมทั้งได้รับการอธิบายจากคณะผู้ทำวิจัย และสมัครใจเข้าร่วมโครงการ

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ชื่อผู้เข้าร่วมโครงการ	ชื่อแพทย์ผู้ทำวิจัย	ชื่อพยาน
----------	----------	----------
ลายเซ็น	ลายเซ็น	ลายเซ็น
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วันที่	วันที่	วันที่

แพทย์ผู้ทำวิจัย พันเอก น.พ.ประสิทธ์ มหากิจ
กองโสต ศอ นาสิกกรรม โรงพยาบาล พระมงกุฎเกล้า โทร. 05-0643478
หรือ โทร 02-3547600 ต่อ 93076 หรือ 93928

APPENDIX B

Patient initials_____ Patient number _____

Date _____

dd mm yy

The comparative study of daytime and overnight polysomnography for high risk snorers

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Case Record Form

Principle investigator ;

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Patient initials_____ Patient number _____

Date _____

dd mm yy

Epworth sleepiness scale

How likely are you to doze off or fall asleep in the following situations in contrast to just feeling tired?

Use the following scale to choose the most appropriate number for each situation

0 = would never doze

1 = slight chance of doze

2 = moderate chance of doze

3 = severe chance of doze

Situation	Chance of dozing
Sitting and reading	_____
Watching television	_____
Sitting in public place (e.g. a theatre, a meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when permit	_____
Sitting and talking to someone	_____
Sitting quietly after lunch with out alcohol	_____
In a car while stopped for few minute in the traffic	_____

Total score for ESS is _____/24

(If ESS score $\geq$ 8 in 24 is classified as risk group need to do PSG)

Patient initials_____ **Patient number**_____

Date _____

dd mm yy

Eligibility Criteria:

	No	Yes
Inclusion criteria :		
Written informed consent	☐	☐
Aged 15 – 65 years	☐	☐
Presence of snoring problem(s)	☐	☐
Exclusion criteria :		
Unstable medical condition	☐	☐
Epworth sleepiness scale less than 8/24	☐	☐
History of anaphylaxis	☐	☐
History of sensitive or tolerance to sedative agents	☐	☐
Structural abnormality in nasal cavity causes persistent obstruction	☐	☐
Patient who underwent overnight PSG > 2 months	☐	☐
Conclusion :		
Patient fulfils all inclusion criteria and none of an exclusion criteria	☐	☐

Patient initials_____ Patient number _____

Date _____

dd mm yy

Patient data

Date of birth _____

Weight _____kg. Height _____ cm BMI _____

Neck circumference (cricoid level) _____inch

	No	Yes
1. Do patient have chronic medical problem	☐	☐
2. Do patient daily take medication	☐	☐
3. Any history of allergy	☐	☐
4. Do patient smoke	☐	☐
5. Do patient drink	☐	☐

_____

Epworth sleepiness scale is _____/ 24

Physical examination

Blood pressure _____mmHg.

Specification of abnormality

	No	Yes
Face (maxilla,mandible)	☐	☐
Nasal cavity	☐	☐
Oral cavity		
Soft palate	☐	☐
Base of tongue	☐	☐
Tonsil and adenoid	☐	☐

Patient initials_____ Patient number _____

Date _____

dd mm yy

Diagnostic stage

	Overnight PSG	**Daytime PSG**
Starting time	_____	_____
Finish time	_____	_____
Total time	_____	_____
Apnea index	_____ / hr	_____/hr
Hypopnea index	_____/ hr	_____/hr
Apnea hypopnea index	_____ / hr	_____/hr
Lowest oxygen saturation	_____%	_____%
Mean oxygen saturation	_____%	_____%
Type of apnea		
Obstructive	_____	_____
Mixed	_____	_____
Central	_____	_____
Time spent for body position		
Left / right / supine / prone	__/__/__/___	___/__/__/___
Patient is classified as		
High risk group (AHI > 20)	_____	_____
Low risk group (AHI < 20)	_____	_____
Snoring loudness		
In bed annoyance	_____	_____
Open door annoyance	_____	_____
Close door annoyanc	_____	_____

Curriculum Vitae

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Member of Professional Association Fellow of Royal College of Otolaryngology Thailand

International Scientific Presentation;

1995 The study of indoor inhalant allergens by prick test. The second Asian Pacific Congress of Allergy and Clinical Immunology October 1995, Taipei, TAIWAN

1993 The preliminary study of mucociliary Transport in sinusitis ,allergic rhinitis and smoker

The twelfth international symposium on infectious and allergy of the nose November 1993, Seoul, KOREA

SCIENTIFIC PUBLICATION

1. Mahakit P, Pumhirun H. A preliminary study nasal mucociliary clearance in smokers, sinusitis and allergic rhinitis. Asian Pac J Allergy Immunol 1995; 13(2):119 -21.