CHAPTER 3

MATERIALS AND METHODS

3.1 Research design

This study was a prospective simple randomized, double blind cross-over design. This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Chiang Mai University (Appendix A).

3.2 Materials

- Portable nitrous oxide/oxygen machine (MDM®, MDS matrx, USA)
- Nitrous oxide and oxygen gas
- Nasal hood (Matrx®, MDS matrx, USA)
- Blood pressure and heart rate meter (Microlife® model BP 3BZ1-3, Switzerland)
- Pulse oximetry (Criticare System Inc. model 504/504P, USA)
- Stopwatch

3.3 Research populations and samples groups

3.3.1 Study populations

All subjects in this study were recruited from the fourth to sixth-year undergraduate dental students who were studying at the Faculty of Dentistry, Chiang Mai University and had attended the course DPED 414481 that contains the theoretical section of N_2O/O_2 inhalation sedation in dentistry. All subjects who volunteer to participate in this study were screened by the following inclusion and exclusion criteria.

3.3.1.1 Inclusion criteria

- The volunteers were from the fourth to sixth-year undergraduate dental students at the Faculty of Dentistry, Chiang Mai University who were attending or had attended the course DPED 414481
- Healthy
- Not medically compromised
- Not contraindicated for the use of N_2O/O_2 inhalation sedation

The contraindications for the use of N_2O/O_2 inhalation sedation were as follows: [4]

- Compulsive personality
- Claustrophobia
- Upper respiratory tract infection
- Pregnancy
- Abnormal respiratory system such as nasal septum deviation and nasal polyp.

- Chronic obstructive pulmonary disease (COPD)

3.3.1.2 Exclusion criteria

- The volunteers who did not want to participate in this study
- The volunteers who were contraindication for the use of N_2O/O_2 inhalation sedation

3.3.2 Sample size

40 volunteers were recruited. Each volunteer received both of administrative techniques of N_2O/O_2 inhalation sedation, slow titration and rapid induction techniques. Thus, 80 sessions of N_2O/O_2 inhalation sedation were performed in this study.

3.3.3 Random sampling

For the first N_2O/O_2 administration, all volunteers were equally randomly assigned to either slow or rapid administration techniques using random number table. After 1 week of the first administration, the volunteers then were crossover assigned to another administrative technique (Figure1).

3.4 Calibration

Prior to the study, two postgraduate dentists had done the pilot study. During the pilot study, objective signs, subjective symptoms, and the ideal stage of sedation were calibrated between the observers and confirmed by the experienced clinician who is the advisor of this thesis.

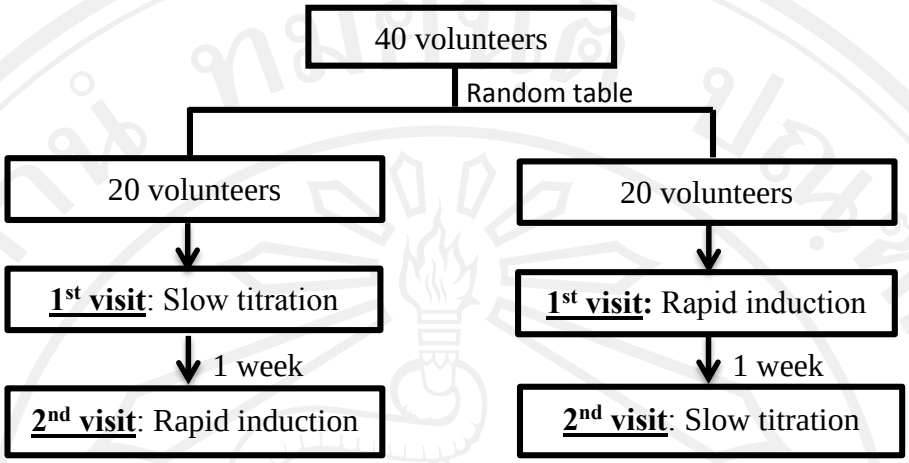

Figure 1 Sequence of N_2O/O_2 administration

3.5 N_2O/O_2 administration protocol

The administrative techniques compose of

1. Slow titration: this technique started with 20% N_2O and 10% of N_2O was incrementally increased every 1 minute until the volunteer achieved the ideal stage of sedation [4].
2. Rapid induction: this technique started with 50% N_2O and this concentration was maintained or minimally adjusted to suit the patient's need [6].

All steps of N_2O/O_2 administrations were performed by two postgraduate students in pediatric dentistry who had been attended both theoretical and practical sections in the use of N_2O/O_2 inhalation sedation under supervision of an experienced lecturer in this area. Two postgraduate students were dentist A and B. Dentist A was the person who adjusted N_2O concentration and recorded physiologic parameters (blood pressure, heart rate and oxygen saturation). N_2O/O_2 delivery machine was

placed behind the scene so that dentist B and volunteers were blinded from the technique of administration and N_2O concentration delivered. The objective signs, subjective symptoms and time that signs and symptoms of ideal sedation appear were recorded by dentist B. At the end of procedure, before discharged, the volunteer was asked by dentist B to determine satisfaction using VAS.

The objective sign was defined as the sign that was observed from the volunteer and subjective symptom was defined as the feeling which the volunteer reported during N_2O/O_2 administration.

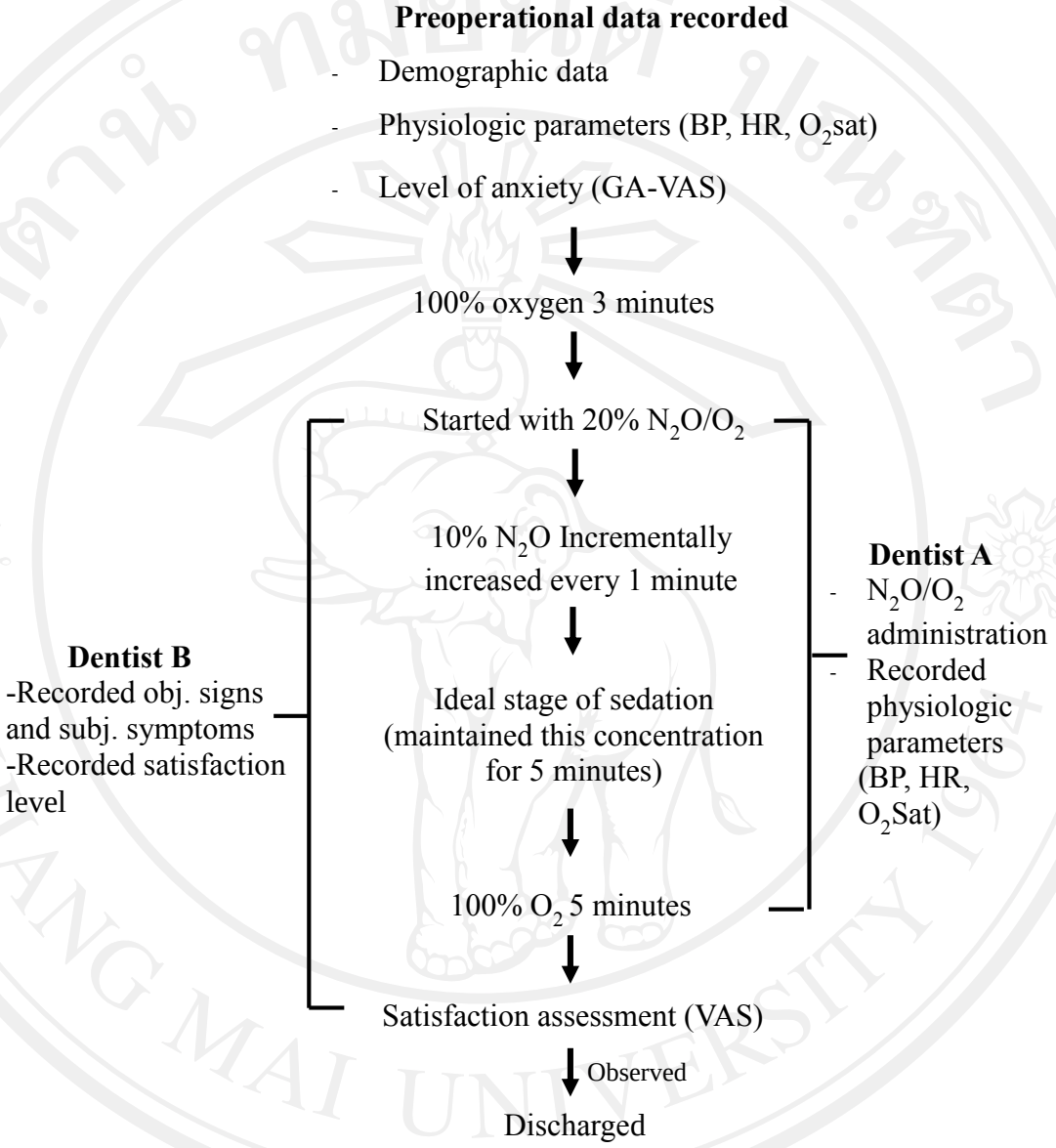

Figure 2 Clinical procedure for $N_20/0_2$ administration by *'slow titration'* technique

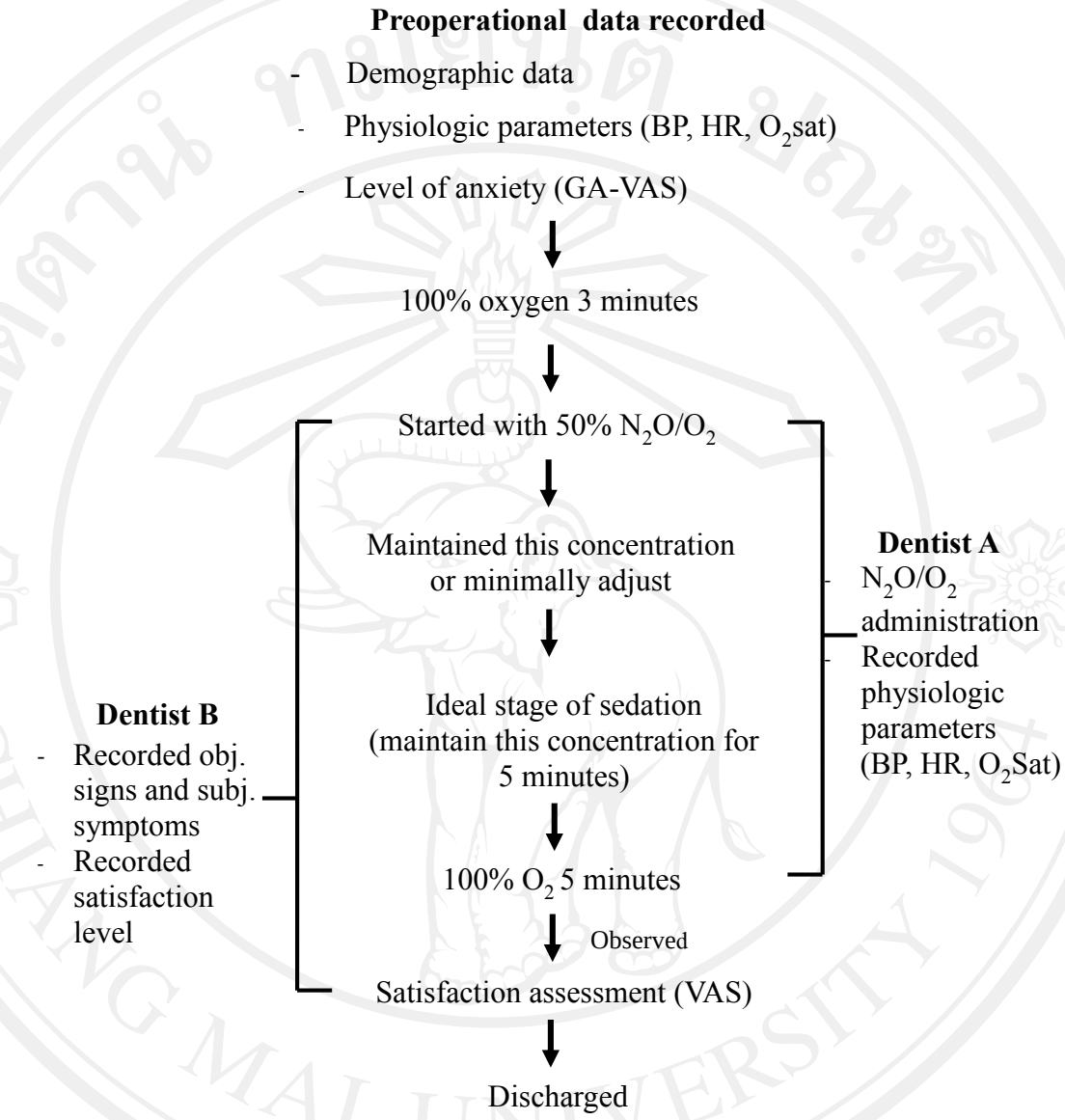

Figure 3 Clinical procedure for $N_20/0_2$ administration by *'rapid induction'* technique

3.6 Clinical procedure of N_2O/O_2 administration

3.6.1 Before N_2O/O_2 administration

(All data collection forms were presented in appendix B)

- Demographic data including age, sex, weight, height and health status were recorded prior to N_2O/O_2 inhalation sedation.
- Anxiety level was measured by using Global Anxiety-Visual Analog Scale (GA-VAS)
- Physiologic parameters (blood pressure, heart rate and oxygen saturation) were obtained as the baseline values, preoperatively.

3.6.2 N_2O/O_2 administration

A. N_2O/O_2 machine (MDM® portable N_2O/O_2 machine, MDS Matrx, USA), an automatic adjustment, was checked for proper functioning. Then, tubes and elbows were checked that they were in the correct position to prevent the gas leakage.

B. The volunteer, then, sat in semi-supine position in dental chair and the pulse probe was attached to the great thumb of the volunteer's left foot and blood pressure cuff was placed on the volunteer's left upper arm.

C. Appropriate size of scavenging nasal hood in relation to the morphology of volunteer's nose was selected.

D. The procedure started with 100% oxygen at 6 liter/min. Then nasal hood was placed on the volunteer's nose and ensure that it was fit to the volunteer's nose; a piece of gauze was placed between nasal hood and nose to minimize

gas leakage. Then volunteer was asked to breathe through his/her nose. The flow rate was adjusted to meet the volunteer's need. The appropriate flow rate was determined by observing the size of reservoir bag that it was not too inflated or deflated. The proper flow rate (liter/min) was recorded. After the suitable flow rate of oxygen was achieved, volunteer was maintained at this step for 3 minutes.

E. N_2O/O_2 administrative techniques were as follows:

3.6.2.1 Slow titration technique

20% N_2O was initiated and physiologic parameters were recorded (blood pressure, heart rate and oxygen saturation). Thereafter, 10% N_2O concentration was incrementally increased every 1 minute. While dentist A was administrating N_2O and recording physiologic parameters, dentist B observed objective signs and asked the volunteer with open-ended questions to determine subjective symptoms. Time that these signs and symptoms emerged was recorded. N_2O concentration was adjusted until the volunteer achieved the *ideal stage* of sedation. The ideal stage of sedation was considered from objective signs and subjective symptoms as well as answers to indicate that the volunteers were comfortable, relaxed, and ready to be treated if they were patients. However, concentration of N_2O was not over 50%. Time and concentration of N_2O that the volunteer achieved the ideal stage of sedation was recorded. While the N_2O concentration was maintained at this step for 5 minutes, objective signs, subjective symptoms together with oxygen saturation and heart rate were recorded periodically at every 1 minute. Blood pressure was recorded at the beginning of oxygen administration, at the fifth minute of the ideal stage of sedation

and at the fifth minute after N_2O termination. Sequence of N_2O/O_2 administration by the slow titration technique was shown in figure 2.

3.6.2.2 Rapid induction technique

50% N_2O was initiated and constantly maintained for 5 minutes. Physiologic parameters including heart rate and oxygen saturation were recorded every 1 minute while blood pressure was recorded at the beginning of oxygen saturation, at fifth minute of the ideal stage of sedation and at fifth minute after nitrous oxide termination. The volunteer's objective signs and subjective symptoms were observed until the ideal stage of sedation was achieved and the N_2O concentration and time at this stage were recorded. If the volunteer presented any signs or symptoms of oversedation, nitrous oxide concentration was decreased immediately and concentration used to create the ideal stage of sedation was recorded. Sequence of N_2O/O_2 administration by the rapid induction technique was shown in figure 3.

3.7 Criteria for the ideal stage of sedation

The criteria for determination that the volunteer achieved *the ideal stage of sedation* composed of objective signs and subjective symptoms

Objective signs indicating the ideal stage of sedation were the comfortable and relaxed in manner such as open the palm of hand, abducted feet or limp legs. The volunteer was conscious and responded normally or purposefully to verbal command and tactile stimulation [4, 6].

Subjective symptoms observed in the ideal stage are abnormal sensation area of head, abdomen, fingers and toes such as lightheadedness, tingling sensation, paresthesia or numbness, feeling of lightness, heaviness, warmth or floating [4].

The volunteer who reported and presented signs of relaxation and comfort together with the presentation of 3 or more subjective symptoms as mentioned above was identified that he/she achieved the ideal stage of sedation.

Two operators in this study had to agree with each other that the volunteer achieved the ideal stage of sedation then the volunteer was judged to be in the ideal stage of sedation.

3.8 Criteria for oversedation[4]

- The volunteer complained of nausea and feel uncomfortable.
- The volunteer became sleepy.
- The volunteer spoke incoherently or dreams.
- The volunteer became uncooperative.

The volunteer who presented only one sign or symptom as mentioned above was defined to be oversedation.

F. After 5 minutes of N_2O/O_2 administration at the ideal stage of sedation, N_2O was discontinued and 100% oxygen was delivered to the volunteer for 5 minutes postoperatively.

G. Then, the volunteer was taken to the recovery room and physiologic parameters (blood pressure, heart rate and oxygen saturation) were monitored

and recorded. The volunteer was monitored until he/she returned to presedation level and met the discharge criteria

H. After the volunteer returned to presedation level, he/she was asked of the satisfaction level by using Visual Analog Scale (Figure 4). Each of volunteer was asked the question 'if you were the patient and have to be treated under N_2O/O_2 inhalation sedation with this administrative technique, please score your satisfaction on this line'

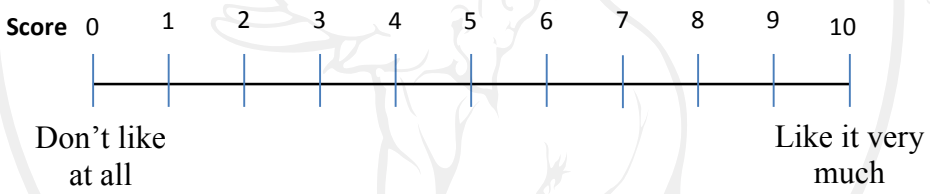

Figure 4 Visual Analog Scale

3.9 Criteria for discharge

- Volunteer returned to the presedation level of responsiveness and consciousness.
- Normal cardiopulmonary function was presented.

According to Malamed [4], ranges of variation that were acceptable were as follows:

- Blood pressure: ± 20 mm Hg/ 10 mm Hg from baseline.
- Heart rate: ± 15 beats/min from baseline
- Oxygen saturation is more than 95%.

3.10 Data analysis

The software SPSS (Statistic Package for the Social Science, Chicago, III) version 17.0 was used for statistical analysis as follows:

- Descriptive analysis was used to describe demographic data.
- Objective signs, subjective symptoms, N_2O concentration and complications between the slow titration and rapid induction techniques were analyzed by Pearson Chi-square with 95% confidence level.
- The changes of blood pressure and heart rate from the baseline within the same administrative technique were analyzed by One-Way ANOVA with 95% confidence level.
- The changes of blood pressure and heart rate from the baseline between the slow titration and rapid induction technique were analyzed by Independent Sample T-test with 95% confidence level.
- Level of anxiety, time to achieve the ideal stage of sedation and level of satisfaction between the slow titration and rapid induction techniques were analyzed by Paired T-test with 95% confidence level.