CHAPTER 3

MATERIALS AND METHODS

3.1 Research design

This study was a prospective stratified randomized design. This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Chiang Mai University (Appendix A).

3.2 Research populations and samples

3.2.1 Study populations

Subjects in this study were selected from the fourth to the sixth year undergraduate dental students at the Faculty of Dentistry, Chiang Mai University who have studied DPED 414481 which has theoretical section about N_2O /O_2 inhalation sedation and interested in participating in this study. All volunteers that wanted to participate in this study were screened according to inclusion and exclusion criteria as follows:

3.2.1.1 Inclusion criteria

The volunteers were from the fourth to the sixth year undergraduate dental students at the Faculty of Dentistry, Chiang Mai University who was taking or had taken course DPED 414481. Only healthy volunteer or American Society of Anesthesiologists (ASA) classification I, not taking medications and without

contraindications for the use of N_2O/O_2 inhalation sedation were selected as subject. Volunteers were able to communicate by verbal and nonverbal and willing to participate in this study.

3.2.1.2 exclusion criteria

Contraindications for the use of N_2O/O_2 inhalation sedation were the following [6, 9, 24]:

- The volunteers who had systemic diseases that were contraindications to the use of N_2O /O_2 sedation such as upper airway infections and inflammation, chronic obstructive pulmonary disease, acute respiratory infections.
- The volunteers who had abnormal anatomy of respiratory tract such as nasal polyps or nasal septum deviation.
- The volunteers who had claustrophobia that was intolerance to the use of the apparatus, pregnancy, latex allergy, schizophrenia, severe personality disorders and bipolar disorder.
- The volunteers that were not willing to participate in this study

3.2.2 Sample size

In this study, sample size of each group was 28 sessions. Therefore, there were 112 sessions (112 volunteers) in a total of 4 experimental groups.

3.2.3 Random sampling

Each volunteer was randomized to receive nitrous oxide with four different administrative and ending techniques by random numbers table (Figure 7)**.**

1. Administrative techniques of N_2O /O_2 composed of

   S: Slow titration technique

   R: Rapid induction technique

2. At the completion of procedure, ending techniques composed of

   O: N_2O was discontinued and 100% O_2 was provided for 5 minutes

   R: N_2O was discontinued and volunteers breathed with room air for 5 minutes

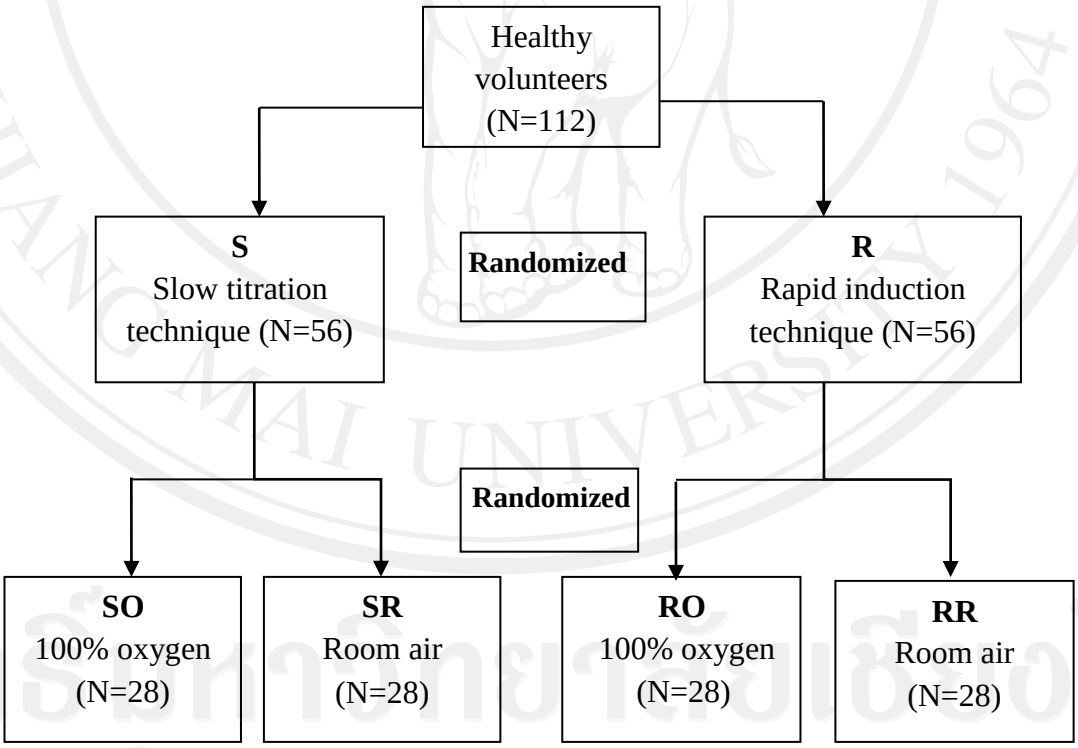

Figure 7 Sequence of administrative and ending techniques of N_2O/O_2

Four different administrative and ending techniques composed of

SO group: Started with the slow titration technique of N_2O/O_2 and completed with 100% O_2 after N_2O was discontinued

SR group: Started with the slow titration technique of N_2O/O_2 and completed with room air after N_2O was discontinued

RO group: Started with the rapid induction technique of N_2O/O_2 and completed with 100% O_2 after N_2O was discontinued

RR group: Started with the rapid induction technique of N_2O/O_2 and completed with room air after N_2O was discontinued

3.3 Calibration

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

3.4 Treatment protocol

Every step in this study was operated by two postgraduate dental students in pediatric dentistry who had attended the theoretical and practical sections in the use of N_2O/O_2 inhalation sedation under supervision of experienced faculty at the Faculty of Dentistry, Chiang Mai University. N_2O concentration was adjusted behind the scene by Dentist A so dentist B was blinded of N_2O /O_2 administrative technique.

3.4.1 Before nitrous oxide administration

1. Each volunteer was asked to sign the informed consent (Appendix B) and received pre-sedation instructions.
2. Demographic data including age, sex, weight, height, ASA classification and any medications were recorded (Appendix C).
3. Pre-sedation anxiety level was evaluated by the Global-Anxiety Visual Analog Scale (GA-VAS) (Figure 8) before N_2O/O_2 administration. This step was explained by dentist B. The test was performed using the form showed in Appendix C: Form 1 while volunteer was sitting on the chair in front of the desk.

Figure 8 The Global-Anxiety Visual Analog Scale (GA-VAS) [71]

4. Volunteer's blood pressure and heart rate were recorded by blood pressure and heart rate meter (Microlife®, model BP 3BZ1-3, Switzerland) and oxygen saturation were measured by pulse oximeter (Criticare ®, model 504/504P, Criticare System Inc., USA) for the baseline data (Appendix C: Form 1).
5. Psychomotor performance was evaluated by the Trieger test (Figure 9). Missed dots and time to complete the test were recorded at the preoperative period as the baseline value using Appendix C: Form 1.

Figure 9 The Trieger test [62]

3.4.2 Nitrous oxide administration

1. All parts of automatic adjustment N_2O/O_2 machine and scavenging nasal mask (Quantiflex MDM®, Matrx Medical Inc., USA) were checked and prepared for use.
2. Volunteer sat in recline position on dental chair. The pulp oximeter was placed on the toe of right foot.
3. The patient was initially administered 6 L/min of O_2. Nasal hood was placed on volunteer's nose. The leakage of gas was prevented by placing gauze on space between nasal hood and bridge of nose.

4. The flow rate of 100% O_2 was adjusted to the level that volunteer could breathe comfortably, determined by asking volunteer and observing the size of reservoir bag that should not be too inflated or deflated. The proper O_2 flow rate (L/min) was recorded using Appendix C: Form 2 and this step was maintained for 3 minutes.
5. The administrative technique was randomized using the random numbers table.

3.4.2.1 Administrative techniques

3.4.2.1.1 Slow titration technique

- Administrative with 20% N_2O/O_2 was begun. Volunteer's blood pressure, heart rate and SaO_2 were monitored and recorded by dentist A using Appendix C: Form 2.
- N_2O concentration was increased 10% incrementally in 60 seconds intervals. Dentist A adjusted N_2O/O_2 concentration and monitored physiologic parameters at the beginning of 100% O_2 administration, at the fifth minute of the ideal stage of sedation and at the fifth minute after N_2O termination.
- N_2O/O_2 concentration was adjusted until volunteer reached the ideal stage of sedation by observing volunteer's objective signs and subjective symptoms. However, N_2O/O_2 concentration must not exceed 50%. Time and level of N_2O /O_2 at ideal sedation were recorded using Appendix C: Form 2 and this level was maintained for 5 minutes.

3.4.2.1.2 Rapid induction technique

- Administrative with 50% N_2O /O_2 was begun. Dentist A monitored and recorded volunteer's blood pressure, heart rate and SaO_2 at the beginning of 100% O_2

administration, at the fifth minute of the ideal stage of sedation and at the fifth minute after N_2O termination using Appendix C: Form 2.

- If volunteer presented signs and symptoms of oversedation, N_2O /O_2 concentration was decreased until the state of ideal sedation was reached. Time and concentration of N_2O /O_2 were recorded using Appendix C: Form 2 and this level was maintained for 5 minutes.

3.4.2.2 Criteria for the state of ideal sedation

Volunteer felt comfortable and relaxed and showed objective signs such as open hand, limp legs, abduction of feet. Volunteers had full cooperation together with the following symptoms: warmth, floating, light headedness, heaviness of body, tingling sensation of hands and feet and numbness [8, 27].

3.4.2.3 Criteria of oversedation

Volunteer complained of at least one of the following symptoms: nausea and vomiting, dreaming and hallucinating, inability to move or communicate, sluggish, laugh or cry, delayed response and uncooperation [8, 27].

3.4.2.4 Ending techniques

After 5 minutes of ideal stage of sedation of both N_2O/O_2 administrative techniques, volunteer was randomized for the ending technique using the random numbers table.

3.4.2.4.1 N_2O was discontinued and 100% O_2 was given for 5 minutes.

- Volunteer's blood pressure, heart rate and SaO_2 were monitored and recorded by dentist A using Appendix C: Form 2.
- Objective signs and subjective symptoms were monitored and recorded at any time when signs and symptoms were occurred using Appendix C: Form 3.
- Psychomotor performance was evaluated with the Trieger test every 3 minutes interval by dentist B using Appendix C: Form 4. Missed dots and time to complete Trieger test were recorded.

3.4.2.4.2 N_2O was discontinued and volunteers breathed room air for 5 minutes.

- Volunteer's blood pressure, heart rate and SaO_2 were monitored and recorded by dentist A using Appendix C: Form 2.
- Objective signs and subjective symptoms were monitored and recorded at any time when signs and symptoms occurred using Appendix C: Form 3
- Psychomotor performance was evaluated by the Trieger test every 3 minutes interval by dentist B using Appendix C: Form 4. Missed dots and time to complete the Trieger test were recorded.

3.4.2.5 Criteria of diffusion hypoxia

Volunteer complained of at least one of the following symptoms: headache, lethargy, nausea, dizziness together with less than 95% of oxygen saturation [50].

3.4.3 Recovery period

1. After the procedure was completed, volunteer was taken to the recovery room. Physiologic parameters (blood pressure, heart rate and SaO_2), objective signs, subjective symptoms and recovery time were recorded using Appendix C: Form 5. Psychomotor performance was evaluated again by the Trieger test at the recovery period using Appendix C: Form 5.
2. The satisfaction of each technique was tested by the Visual Analog Scale (VAS) (Figure 10) before volunteer was discharged. This step was explained by dentist B. The test was performed using Appendix C: Form 5 while volunteer was sitting on the chair in front of the desk.
3. Volunteers were assessed for full recovery before they were discharged.

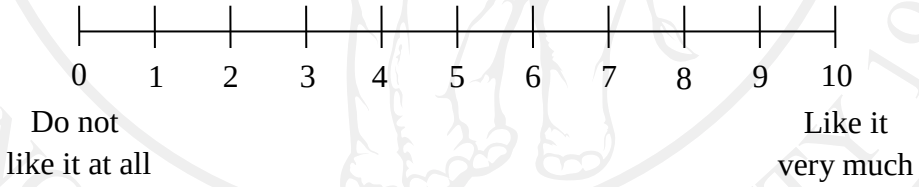

Figure 10 The Visual Analog Scale (VAS)

3.4.3.1 Criteria for discharge

3.4.3.1.1 Physiologic parameters

Physiologic parameters such as blood pressure and heart rate returned to close to baseline and SaO_2 was not less than 95%. Malamed [1] recommended the acceptable ranges of parameters as follows:

- Blood pressure: ±20 mmHg/10 mmHg from the baseline.
- Heart rate: ±15 beats/min from the baseline.

3.4.3.1.2 Objective signs

Objective signs of volunteers before they were discharged are as follows [10, 27, 65]:

- Level of consciousness and protective reflex of volunteer's returned to pre-sedation level.
- Volunteer's verbal and nonverbal communication were normal.
- Volunteer be able to sit up or walk without assistance.
- No post-operative complications.

3.4.3.1.3 Subjective symptoms

Volunteer did not complain of the following symptoms: lethargy, headache, dizziness, confusion, nausea and vomiting [10].

3.4.3.1.4 Psychomotor performance

The result from psychomotor test was normal when compared with the baseline test.

3.5 Data analysis

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

- Descriptive statistics were used to describe and summarize the distribution of data obtained in this study such as gender, N_2O/O_2 concentration and post-sedation complications by Chi-square test and Fisher Exact test with 95% confidence level.

- The data obtained including age, physiologic parameters and level of satisfaction were analyzed by the One-way ANOVA analysis at 95% confidence level to compare the difference of each group.
- The data obtained including of pre-sedation anxiety level, length of procedure, phychomotor performance and recovery time were analyzed by Kruskal-Wallis test at 95% confidence level to compare the difference of each group.