CHAPTER 3

Materials and methods

3.1 Research design

This study was a descriptive study. Permanent mandibular molars with deep caries that met clinical and radiographic inclusion criteria were recruited. This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Chiang Mai University (Appendix A). The flow chart (Figure 3.1 and Figure 3.2) shows the overall experimental procedure in this study.

3.2 Research populations and samples

3.2.1 Study populations

All subjects participating in this study were recruited from healthy 6-20 years old patients attending the Dental Hospital, Chiang Mai University. All subjects had at least one permanent mandibular molar with deep carious lesions diagnosed as a normal pulp, reversible pulpitis or irreversible pulpitis.

3.2.2 Sample groups

All permanent mandibular molars were screened clinically and radiographically according to inclusion and exclusion criteria as follows:

Inclusion criteria

A. Subject inclusion criteria

-Healthy 6-20 years old patients with no systemic diseases and not taking any medications (including pain medications) on the day of treatment.

-Patients had no hypersensitivity to articaine or any components of anesthetic agent (i.e., epinephrine).

-The legal guardians allowed the subject who was younger than 18 years old to participate in the study and signed the informed consent (Appendix B) and the subject who was 18 years old or older were willing to participate in this study and signed his/her own informed consent.

- Patients were well co-operated and able to communicate with the operators.

B. The mandibular molars inclusion criteria

a. Preoperative clinical criteria

-Absence of clinical swelling, pus exudates/fistula of soft tissues and periodontal tissues

-Absence of abnormal tooth mobility

-The teeth were restorable

-The recruited mandibular molars must respond to the Endo-Ice® cold test showing the vitality of the tooth

b. Preoperative radiographic criteria

<u>From a preoperative posterior bitewing radiograph</u>

- The extension of the dental caries radiolucency penetrated into three fourths or more of the entire dentin thickness

From a preoperative periapical radiograph

- Absence of widening periodontal ligament space

- Absence of radiolucencies at periapical regions

- Absence of radiolucencies at furcation area

- Absence of internal and/or pathologic external root resorption

c. Intraoperative clinical criteria

- When pulp was exposed, it must be vital judging from its red color and hemostasis could be achieved within 10 minutes.

Exclusion criteria

A. Subject exclusion criteria

-Patients who had systemic disease and were taking medications (including pain medications) on the day of treatment.

-Patients who had hypersensitivity to articaine or any components of anesthetic agent (i.e., epinephrine).

-The legal guardians did not allow the child who was younger than 18 years old to participate in the study or patients who were 18 years old or older were not willing to participate in the study.

- Patients can not co-operate and/or were not able to communicate with the operators.

B. The mandibular molars exclusion criteria

a. Preoperative clinical criteria

-Presence of clinical swelling, pus exudates/fistula of soft tissues and periodontal tissues

-Presence of abnormal tooth mobility

-The teeth were unrestorable

-The recruited mandibular molars were non-vital tooth, judging from no response to the Endo-Ice® cold test

b. Preoperative radiographic criteria

From a pre-operative posterior bitewing radiograph

-The extension of the dental caries radiolucency penetrated into less than three fourths of the entire dentin thickness

From a pre-operative periapical radiograph

-Presence of widening periodontal ligament space

-Presence of radiolucencies at periapical regions

-Presence of radiolucencies at furcation area

-Presence of internal and/or pathologic external root resorption

c. Intra-operative clinical criteria

-When pulp was exposed, it was non-vital or hemostasis could not be achieved within 10 minutes.

Clinical symptom and Endo-Ice® cold test were used to separate the samples into three groups with different pulpal diagnoses (Table 3.1).

Table 3.1 The diagnosis criteria of each sample group

Sample groups	Clinical symptom	Endo-Ice® cold test
Normal pulp	Patients did not exhibit any symptoms	Moderate response to cold but disappeared immediately after removal of cold
Reversible pulpitis	Patients had uncomfortable symptom only with stimulation and the symptom reversed quickly after the stimulation had been removed	Sharp/immediate response to cold but subsided quickly after the cold stimulation had been removed
Irreversible pulpitis	Patient exhibited intermittent or spontaneous pain and had prolonged episodes of pain even after the thermal stimuli had been removed	Sharp/immediate response to cold and prolonged duration even after the cold stimulation had been removed

If clinical symptom and cold test did not correlate, the more severe diagnosis was chosen.

3.3 Operators

The masters students and advisor from the Division of Pediatric Dentistry, Chiang Mai University were the operators of this study. The same protocol was used under supervision of one advisor.

3.4 Treatment protocol

1. Before beginning of the treatment, anxiety level of each subject was measured using FIS (Appendix C). The FIS consists of 5 figures of faces from very happy face to very unhappy face. The subjects were asked to choose the figure that matched their feelings.

2. Maximum dosage of 4% articaine with 1: 100,000 epinephrine was calculated from the body weight of subjects.

3. Cold test with refrigerant spray (Green Endo-Ice®; Coltene Whaledent; Cuyahoga Falls, Ohio) was used to test **the vitality** leading to diagnosis of these following teeth:

-The control tooth: the contralateral permanent mandibular molar was the first choice for control. If the contralateral permanent mandibular molar also had deep caries or was non-vital, the vitality test of another sound, small carious and small restoration tooth in the contralateral side was evaluated.

-The studied tooth: the carious permanent mandibular molar that met the inclusion criteria.

The Green Endo-Ice® was sprayed on a large cotton pellet held with cotton tweezers. The cold pellet held was then placed on the control and the studied teeth respectively. Patient may respond as follows:

-Patient had no response to Endo-Ice® cold test meant that the tooth was non-vital and was further excluded from the study.

-Patient had response to Endo-Ice® cold test and the tested tooth was categorized according to different pulpal diagnoses (Table 3.1).

4. IANB with 4% articaine with 1:100,000 epinephrine (Septanest SP; Septodont; Saint-Maur-des-FassesCedex, France) was administered in all patients by using 27-gauge short needle (Terumo Dental Needle; Terumo corporation: Tokyo, Japan) and 1.5 ml of anesthetic agent was deposited.

Inferior alveolar nerve block injections (Halstead approach)

The patient opened his/her mouth widely and the ramus was held between the operator's thumb and index finger. The syringe was introduced across the premolars of the opposite side. The point of entry was midway between the internal oblique ridge and pterygomandibular raphe and the height was 10 mm above the occlusal plane.

The needle was advanced through tissue until bony contact was made which was approximately 15 mm of penetration and 1.5 ml of solution was slowly deposited.

5. After 10 minutes, soft tissue anesthesia (i.e., lip and tongue numbness) was tested. To test lip numbness, the patient was asked if his/her lip was numb. To test tongue numbness, the tongue was stuck by sharp explore.

-If lip and tongue were numb, IANB was considered successful. The next step was preceeded.

-If lip and tongue were not numb, waited for 5 minutes and tested again.

-After waiting for 5 minutes, if lip and tongue were still not numb, IANB was repeated using 1.5 ml of 4% articaine with 1:100,000 epinephrine. Wait for another 10 minutes and then soft tissue anesthesia was retested.

6. Cold test (Green Endo-Ice®; Coltene Whaledent; Cuyahoga Falls, Ohio) and EPT (Kerr Vitality Scanner; SybronEndo; Glendora, California) were used to test for **pulpal anesthesia** on the studied tooth.

Criteria of pulpal anesthesia success

-If patient had two consecutive negative responses to both Endo-Ice® cold test and EPT, pulpal anesthesia was successful. The next step was proceeded.

-If patient still had a positive response to either the Endo-Ice® cold test or EPT at least one time of two consecutive testings, pulpal anesthesia was considered as failure.

In both pulpal anesthetic failure and success cases, the next step of the procedure will invade buccal soft tissue; therefore, long buccal nerve block anesthesia was used to anesthetize the buccal soft tissue.

Long buccal nerve block

The needle was inserted 1-2 mm into the distobuccal area of the last mandibular tooth, 0.3 ml of anesthetic solution was deposited.

Sensibility tests were used to evaluate the pulpal anesthesia of the eight teeth with failure in the pilot study to confirm the effect of the long buccal nerve block administration on the pulpal anesthesia before going to the next step.

In the cases of pulpal anesthetic failure, IL injection with 0.4 ml of 4% articaine with 1:100,000 epinephrine was then added. The specialised syringe (Ergoject Intralig Syring; Anthogyr, France) was used in this step.

Intraligamentary injection technique

The needle was inserted at the mesiobuccal and distobuccal aspects of the roots at 30 degrees to the long axis of the tooth and the bevel of the needle was directed away from the tooth and toward the crestal bone. The needle was advanced to maximum penetration until it was wedged between the tooth and the alveolar crest. The solution was injected under the back pressure, 0.2 ml for each root. In this study, one click of the specialised syringe used in this study equals 0.2 ml of anesthetic solution and the injection time was about 20 seconds for one click. The needle was remained in this position for 10 seconds to prevent the solution leakage into the oral cavity (34).

And then, pulpal anesthesia was tested again.

If pulpal anesthesia was successful, the next step was proceeded.

If pulpal anesthesia failed, IL injection was once again added. Then, pulpal anesthesia was again tested.

The IL injection was allowed to be administered to the maximum of three injections.

7. Rubber dam was placed.

8. High speed round diamond bur was used to open the access. Low speed round carbide bur and spoon excavator were used to remove caries. Caries was removed from the lateral wall to the nearest point to pulp.

9. Wong-Baker Faces Pain Rating Scale (WBFPS) was used to test the success rate of pulpal anesthesia intra-operately. If the subject had intra-operative pain, he/she can ask the operator to stop. Then, subject was asked to score WBFPS matching his/her feeling.

The WBFPS (Appendix D) is a horizontal scale of 6 hand-drawn faces from smiling face to a crying face. The scores in WBFPS are as follows:

0: subject was very happy because he/she didn't hurt at all.

2: subject hurt just a little bit.

4: subject hurt a little more.

6: subject hurt even more

8: subject hurt a whole more.

10: subject hurt as much as he/she can imagine.

Criteria of intra-operative success

-If the subject scored 4 or less than 4, pulpal anesthesia was successful. The treatment was continued.

-If the subject scored 6 or more than 6, pulpal anesthesia failed. The procedure was stopped. IL injection with 0.4 ml of 4% articaine with 1:100,000 epinephrine was added.

10. Dental caries removal was continued. If subject still had intra-operative pain, he/she can ask the operator to stop and scored WBFPS (See 9). When the patients scored 6 or more of WBFPS, suitable supplementary injection, such as intrapulpal injection, IL injection, was added. However, the anesthetic solutions must not exceed the calculated maximum dosage (See 2).

11. When pulpal anesthesia was successful, the treatment was proceeded as follows:

-If there was no pulp exposure after removing dental caries, $Ca(OH)_2$ or Biodentine was used as a liner. The tooth was then restored with amalgam, composite or stainless steel crown.

-If there was pulp exposure pulpal after removing dental caries, vital pulp treatment was considered as direct pulp capping or partial pulpotomy with MTA or Biodentine.

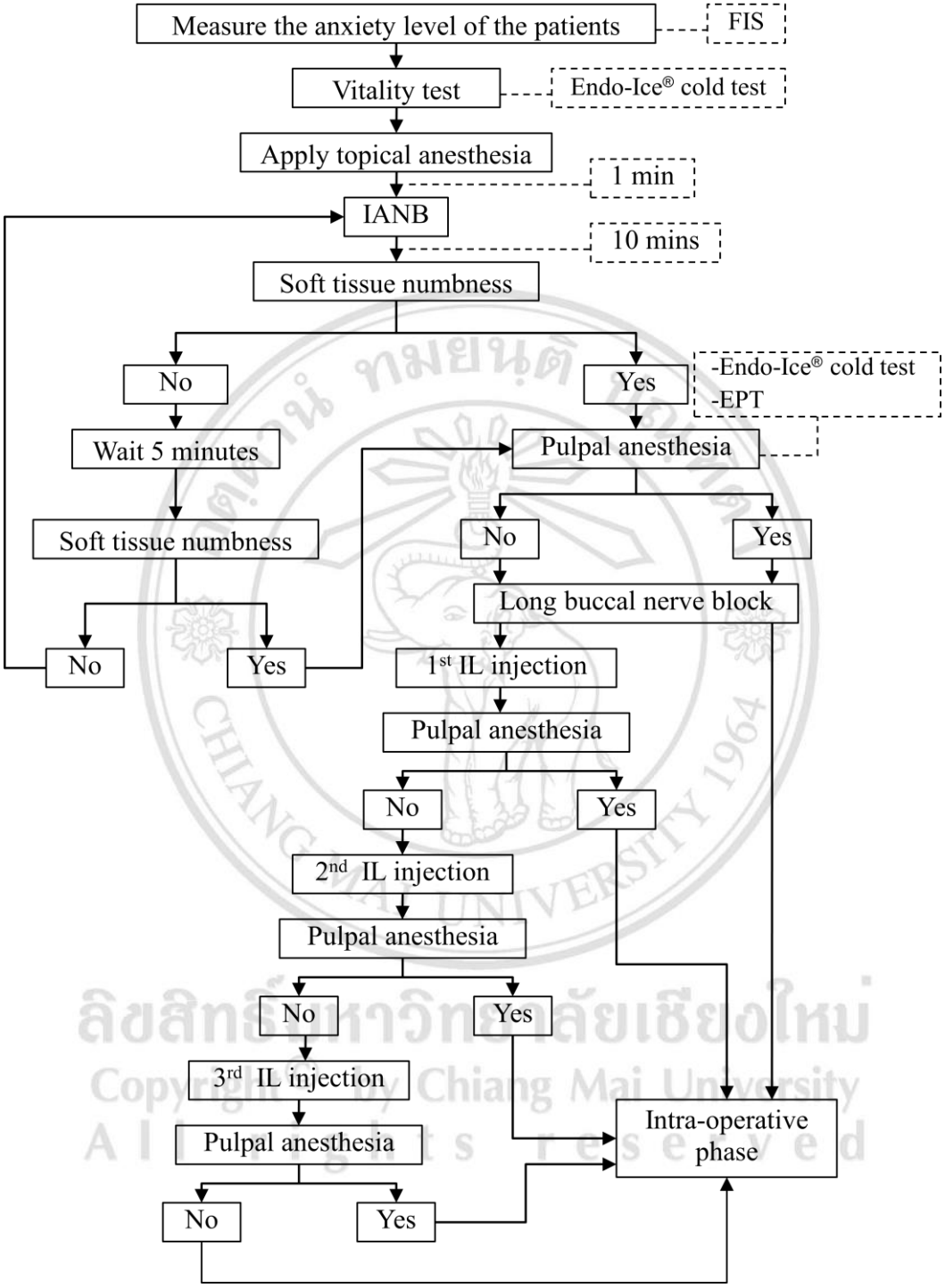

Figure 3.1 Flow chart of the experimental procedure (Pre-operative phase)

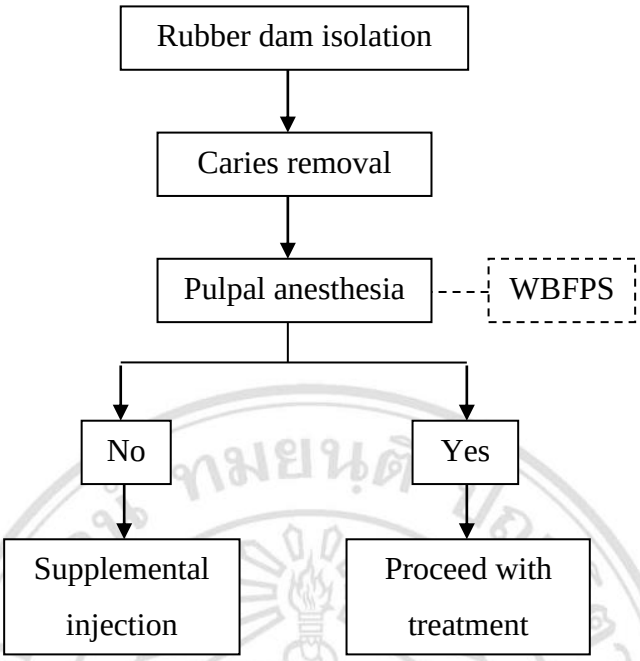

Figure 3.2 Flow chart of the experimental procedure (Intra-operative phase)

3.5 Data collection (Figure 3.3)

All data was recorded in the data collection form (Appendix E).

The subjects were divided into 3 groups as follows:

Group 1 permanent mandibular molars with deep caries diagnosed as normal pulp

Group 2 permanent mandibular molars with deep caries diagnosed as reversible pulpitis

Group 3 permanent mandibular molars with deep caries diagnosed as irreversible pulpitis

Collected data were divided into 4 parts as follows:

IANB-PO: success rate of pulpal anesthesia by IANB pre-operatively evaluated by Endo-Ice® cold test and EPT.

IANB-IO: success rate of pulpal anesthesia by IANB intra-operatively evaluated by WBFPS.

+IL-PO: success rate of pulpal anesthesia by supplemental IL injection pre-operatively evaluated by Endo-Ice® cold test and EPT.

+IL-IO: success rate of pulpal anesthesia by supplemental IL injection intra-operatively evaluated by WBFPS.

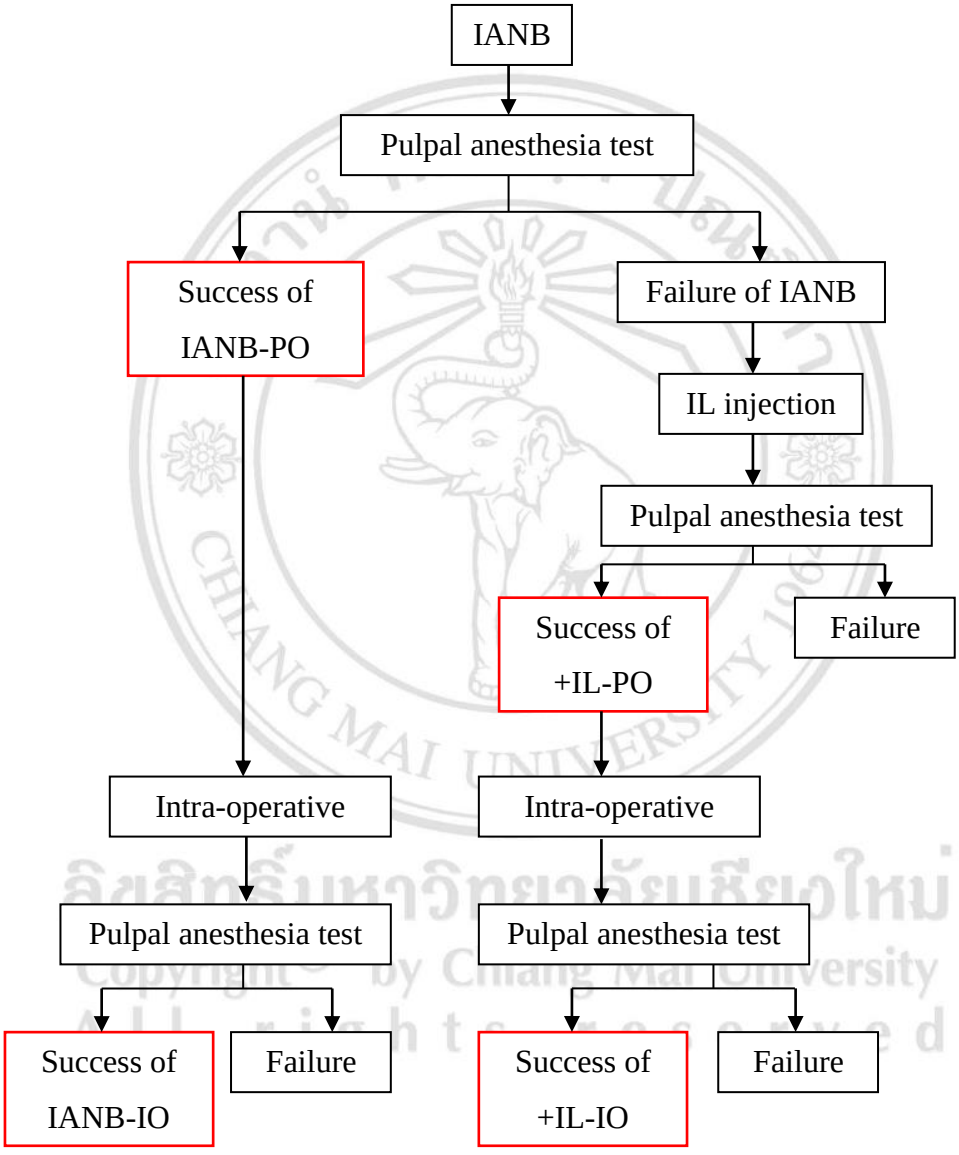

Figure 3.3 Data collection

3.6 Data analysis

The software used for these analyses was SPSS 17.0 (SPSS Inc., Chicago, IL). The success rate of pulpal anesthesia by IANB alone and supplement by IL injection in both pre-operative and intra-operative phases (Figure 3.3) were calculated into percentage. To compare the success rate of pulpal anesthesia between different diagnoses, Pearson Chi-square and Fisher's exact test were used.