CHAPTER III

RESEARCH DESIGN AND METHODOLOGY

3.1 Research question

Primary research question

Does local perianal nerve block with 0.25 percent bupivacaine provide less pain at 6 and 24 hours after closed hemorrhoidectomy compared with spinal anesthesia?

Secondary research question

Does local perianal nerve block with 0.25 percent bupivacaine provide fewer postoperative complications compared with spinal anesthesia?

What is the level of satisfaction among subjects in local anesthetic group?

What is the level of satisfaction among subjects in spinal anesthetic group?

3.2 Objectives

To compare closed hemorrhoidectomy under local perianal block with spinal anesthesia regarding to pain control and complications after surgery

3.3 Research Hypothesis

Null hypothesis: There is no difference in pain measured by visual analogue score at 6 and 24 hours after surgery in local anesthetic group compared to spinal anesthetic group.

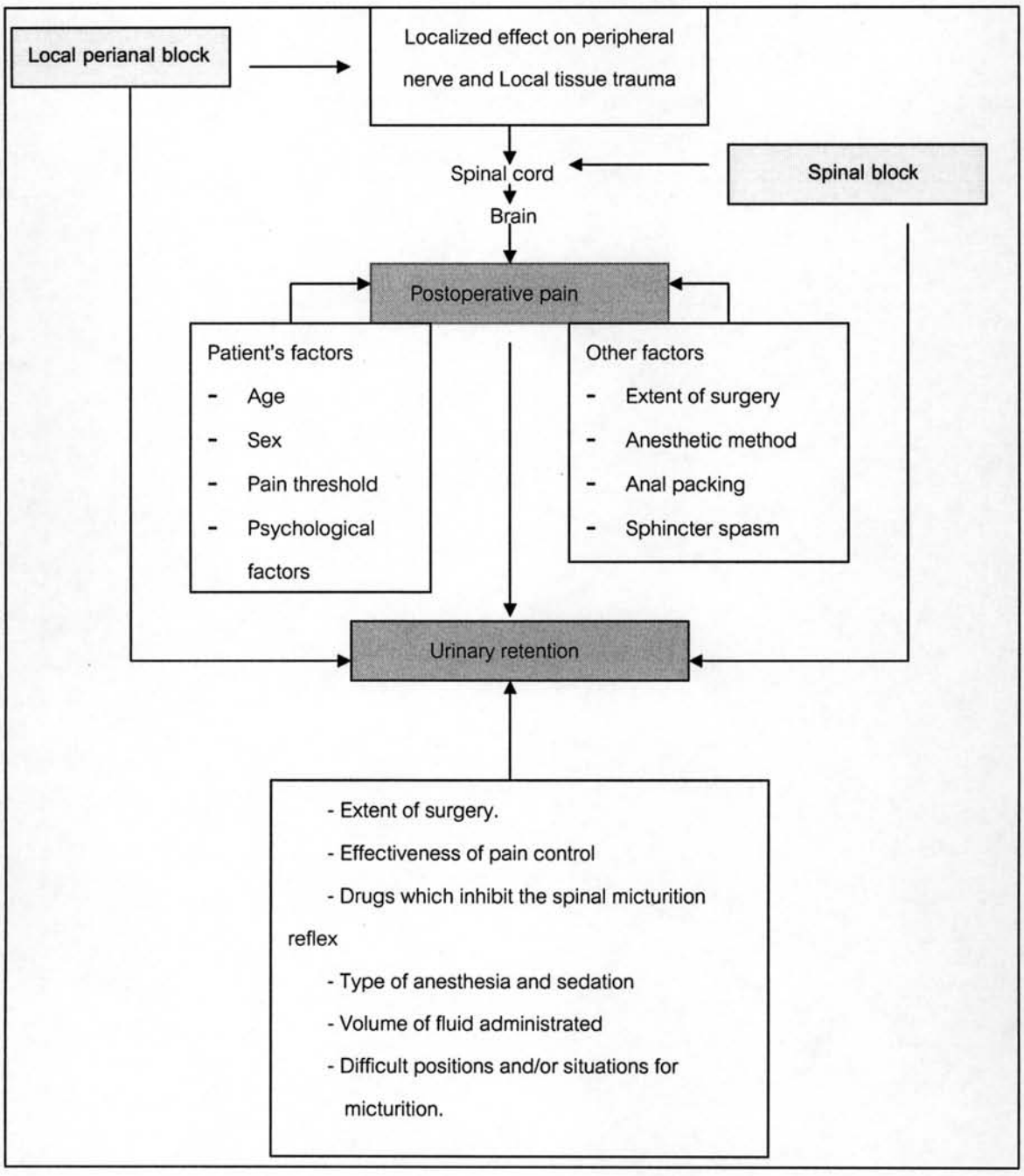
Alternative hypothesis: There is difference in pain measured by visual analogue score at 6 and 24 hours after surgery in local anesthetic group compared to spinal anesthetic group.

3.4 Statistic hypothesis: $H_0 = \mu_{LA} = \mu_{SA}$ $H_A = \mu_{LA} \neq \mu_{SA}$

where μ_{LA} = median of pain score in the local anesthetic group

μ_{SA} = median of pain score in the spinal anesthetic group

3.5 Conceptual framework



3.6 Keyword: Hemorrhoidectomy, Hemorrhoid surgery, Bupivacaine, Pain, Spinal anesthesia, Local anesthesia, Perianal block

3.7 Operational definition

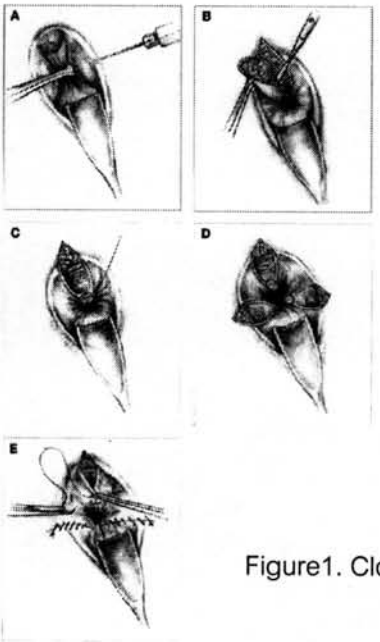
Surgical classification of hemorrhoids

First degree: bleed but do not prolapse outside of the anal canal

Second degree: prolapse outside of the anal canal, usually upon defecation, but retract spontaneously.

Third degree: require manual placement back inside of the anal canal after prolapsing.

Fourth degree: consist of prolapsed tissue that cannot be manually replaced and is usually strangulated or thromboses. The area where the rectal mucous membrane meets the anal skin (the dentate line) is positioned almost outside the anal canal, and the rectal mucous membrane permanently occupies the muscular anal canal



Closed Hemorrhoidectomy : An elliptical excision is begin at the perianal skin to include external and internal hemodrrhoids and the dissection is carried up to a level approximately 1 –2 cm cephalad to the dentate line ended at anorectal ring. The entire wound is closed with running absorbable suture

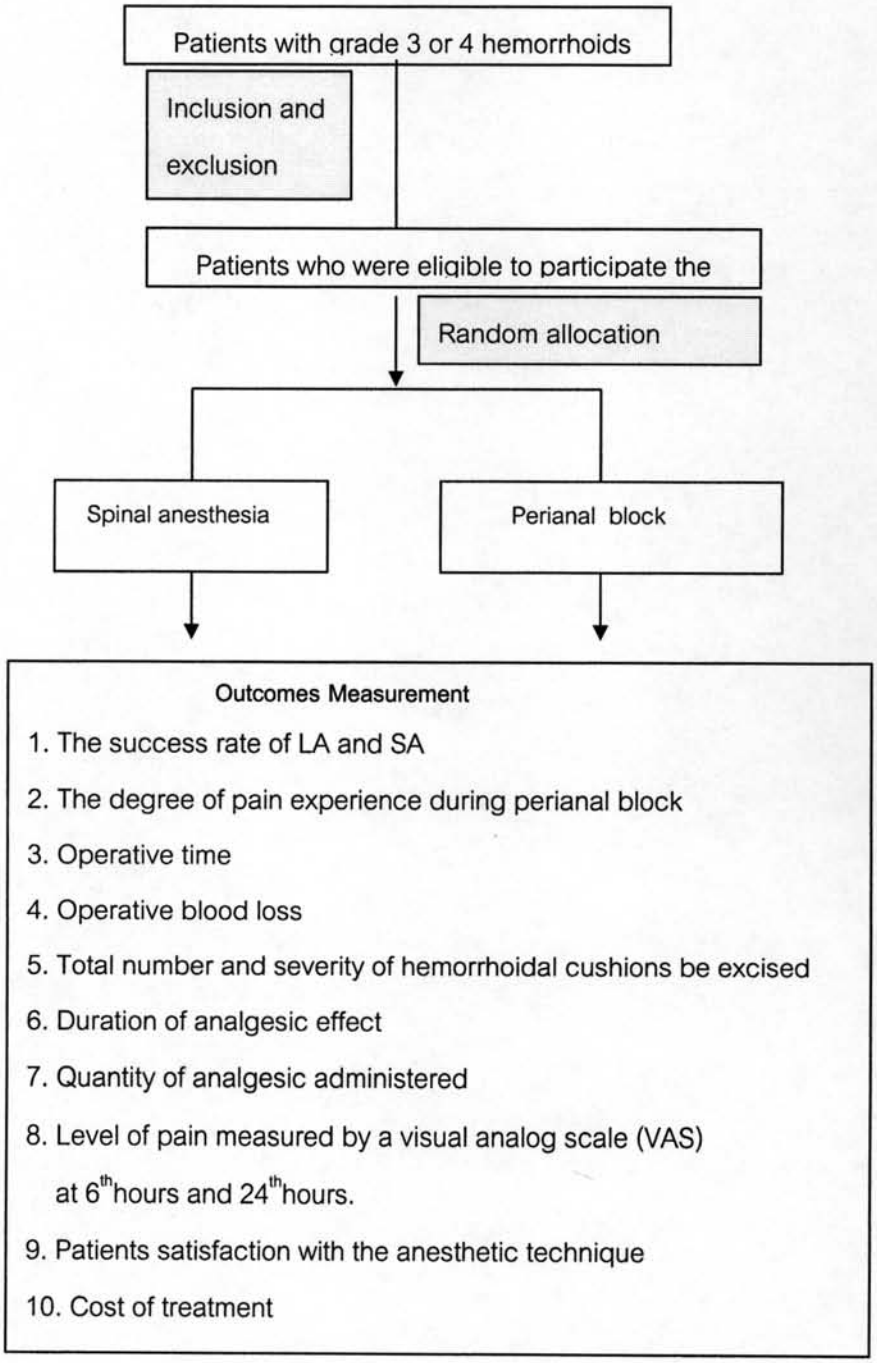
Figure1. Closed hemorrhoidectomy

Visual analogue score: VAS is usually a horizontal line, 100 mm in length. The patient marks on the line the point that they feel represents their perception of their current

state. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks.

No pain **Unbearable pain**

3.8 Study protocol



3.9 Research design

The research was carried out as a prospective randomized controlled trial.

3.10 Research methodology

3.10.1 Population and sample

Target population: Patients with grade 3 or 4 hemorrhoidal disease who required elective surgery.

Sample population: Patients aged between 18-60 years old with grade 3 or 4 hemorrhoidal disease who visited colorectal surgical unit, Phramongkutklao hospital and require elective surgery.

3.10.2 Inclusion criteria

1. Patients aged between 18 and 60 years with grade 3 or 4 hemorrhoid.
2. Had no history of bupivacaine allergy.

3.10.3 Exclusion criteria

1. Complicated hemorrhoid e.g. prolapsed or incarcerated hemorrhoid, gangrenous hemorrhoid.
2. Associated anorectal disease.
3. Patients whose characteristics of his/her buttock were difficult to gained adequate exposure when performing surgery under local anesthesia such as the mounds of his/her buttock is very high and rise almost straight up from the anal verge.
4. Patient was unfit for surgery e.g. heart disease, liver cirrhosis, or coagulopathy.
5. Patients who had symptoms of benign prostatic hypertrophy or bladder neck obstruction.
6. Pregnancy.
7. Patients with neuropsychotic problems.
8. Did not agree to participate this study

3.10.4 Outcomes

The primary outcome: The degree of pain measured by visual analogue scale at 6 and 24 hrs after surgery.

The secondary outcome: Patients' satisfaction with the anesthetic techniques, postoperative voiding complications, and other complications

3.10.5 Allocation procedure

The patients who were eligible to participate in this study were allocated into two groups.

LA group: Perianal nerve block by infiltration with 0.25% Bupivacaine

SA group: Spinal anesthesia with 0.5% Bupivacaine.

The patients were stratified by gender in order to have the same proportion of male and female between groups. The two separate lists of randomized blocks of four were prepared.

3.10.6 Sample size

Sample size calculation was based on comparison of median of maximum postoperative pain scale in first 24 hrs between two independent groups.

Statistical hypotheses:

H_0 =There was no difference in pain score between LA and SA group

H_A =There was a difference in pain score between LA and SA group

Previous study by Kim J [11] revealed a maximum visual analogue pain score during first 24 hours in SA of 5.2. It was expected that LA should provide magnitude of pain relief at least 30% lower than SA during first 24 hours postoperatively, so expected maximum postoperative pain in LA was 3.64

The sample size for this study was calculated using the **nQuery Advisor** program for non-parametric test (Mann- Whitney U test) with reference to Noether G E [13].

Where α = probability of Type I error = 0.05 (two-sided)

β = probability of Type II error = 0.2

σ = standard deviation of maximum VAS pain score during first 24 hours = 2.1

r = n2/n1 = 1

The estimated required sample size per group was 33

3.10.7 Outcome measurement

1. The success rate of anesthetic techniques, operative time, operative blood loss and total number and severity of hemorrhoidal cushions be excised were recorded.

2. In LA group, the degree of pain experience during injection of local anesthetic, introduction of proctoscope and the surgery itself were graded by patient as mild, moderate, severe and unbearable.

3. Duration from finishing injection of the anesthetics to first sensation of pain was recorded.

4. Quantity of analgesic administered was recorded.

5 Any voiding difficulty was recorded and Foley catheterizations were performed in those patients who could not void at all. Number of patient with voiding difficulty and who urinary catheterization had been performed in both groups were record.

6. The total cost of treatment was recorded.

7. Level of pain during early postoperative period was measured with a visual analog scale (VAS) at the 6 and 24 hours.

8. Patients were asked to rate their satisfaction with the pain relief by using verbal rating scale (0 -100).

3.11 Intervention and Methods

All patients had been encouraged to void before going to the operative theatre. Fluid intake was restricted; however, 5 percent Dextrose in NSS/2 was administered at rate 2 ml/kg/hr two hours before surgery, which continued until two hour after surgery. The type of anesthesia was determined by the list of randomized blocks of four which stratified by gender of the patient. Total amount of intravenous fluid given during and after surgery was recorded.

The SA group were received a subarachnoid block with 2.0 -2.5 ml of 0.5% bupivacaine. The LA group was performed local perianal block by using 0.5% bupivacaine 20 ml diluted with sterile water in equal amounts (2.5 mg per ml). The maximum dose of bupivacaine hydrochloride for each patient had been calculated and prepared before starting of surgery (2.5 mg per kilogram body weight not to exceed 175 mg). The patients were placed in the jackknife position, and a long 25 gauge needle

was used for the deep infiltration of the anesthetics to perianal region. This injection scheme targets the terminal nerve branches of the anus rather than blocking the trunk of major nerves. The solution was injected, starting at ischiorectal fossa infiltrations were made bilaterally just lateral to the anus, then infiltrates at behind the anus and anterior aspect of anus was the last point. Each 10 ml of anesthetic solution was injected perisphincteric in the pattern that mention above deep enough to reach the infralevator space. This blocked all terminal nerve endings of the sphincters and anus. No need to target or block a specific nerve structure. The blockade affected all of the perisphincteric infralevator space and blocked branches to the sphincter and anal canal from the internal pudendal nerves, the inferior haemorrhoidal nerves and the anococcygeal nerves. Some bupivacaine was infiltrated subcutaneously on the hemorrhoidal pedicle in LA group.

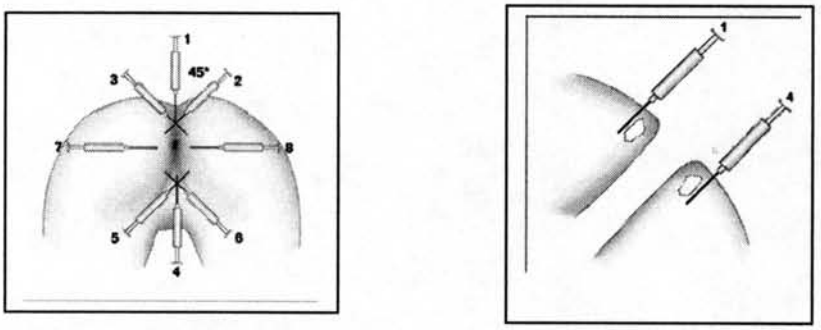


Figure 2. Perianal four-field block

The closed Ferguson technique hemorrhoidectomy was used in this study. All operations were done by single surgeon. In LA group, the degree of pain experience during injection of local anesthetic, introduction of proctoscope and the surgery itself were graded by patients as mild, moderate, severe and unbearable. No anal packing after finishing the surgery. All patients were closed monitored in recovery area of the operative theatre for one hour before returned to ward. All patients were kept lining flat on bed until 4 hours after finishing anesthetic injection. Patients were asked to inform the time at which their first sensation of pain occur. Then the elapsed time in minutes was calculated and recorded from finishing anesthetic injection to first feeling of pain. At 6 and 24 hours after surgery pain intensity was measured by the evaluator who unknown

to what anesthetic technique had been performed. Patients were not allowed to warm sitz bath until the end of 24 hours after surgery. Paracetamol (15-20 mg/kg) was prescribed orally every 6 hrs when VAS $\geq$ 3. In case of pain could not relieved after one hour after taking paracetamol, the pain rescue medication were given with pethidine (0.5-1 mg/kg) intramuscular injection every 4 hours. All postoperative complications were recorded. Before discharge all patients were asked to rating their satisfaction by using verbal rating scale.

3.12 Data collection

Demographic data, operative blood loss, the number of subjects to whom the anesthetic method failed to provided adequate relaxation of sphincter and pain control for surgery was recorded. The degree of pain experience graded by patient during each step of procedure, operative time, number and grading of hemorrhoidal tuffs those be excised, duration of the onset of postoperative pain from finishing injection of anesthesia, pain measurement with VAS at 6 and 24 hours, Quantity of analgesic medication administered were recorded, Number of patient with voiding difficulty and who urinary catheterization had performed in both group were recorded. All postoperative complications were recorded. A verbal rating scale was used to assess patient's satisfaction with the anesthetic technique.

3.13 Data analysis

Patient demographic data were compared between two groups using the **independent t-test** for continuous data and **Chi-squared test** for categorical data. All continuous data were tested for normality with **Kolmogorov-Smirnov (KS) test.** Intraoperative blood loss, operative time, total number of excised hemorrhoids, number of grade 3 and 4 hemorrhoidal cushion to be excised, amount of analgesic pill in first twenty-four hour, postoperative pain at 6 and 24 hours ,and total amount of intravenous fluid administrated were compared between two groups using a **two-sample *t*-test.** Duration of surgery, satisfaction score and total number of analgesic injection were compared between two groups using a **Mann-Whitney U test** due to non-normal distribution of the data. To compare time of the onset of first feeling of pain after finishing

of anesthesia between two groups, Kaplan-Meier survival curve was constructed with the use of **Tarone-Ware method** to compare two survival curves.

3.14 Ethical consideration

In general practice hemorrhoidectomy is treatment of choice for patient with grade 3 or 4. This procedure is able to be done by spinal or local anesthesia. Both anesthetic techniques can successfully block for surgery after administering the anesthesia. Although spinal anesthesia provide more complete relaxation of anal sphincter and puborectalis muscle however, using local anesthesia does not cause trouble or limit the surgical exposure. There is acceptable mild pain or discomfort during the intradermal infiltration of local anesthetic. Regarding to treatment results is comparable for both types of anesthetic. This study have been reviewed and approved by institutional review board and ethical committee of Phramongkutklao Hospital and Faculty of Medicine, Chulalongkorn University. Patients who enrolled to the study have been clearly explained about the risks and benefits. The potential complication of both types of anesthesia has been explained to the patients in detail before consent. Patients with complication from either procedure have been given proper management immediately. Patients have signed a consent form before entering to the study. They were free to withdraw from the study at any time. All data were used for study purpose only and it will be kept confidentially.

3.15 Limitation

Patients who the mounds of the buttock are high and rise almost straight up from the anal verge this type is really difficult to do surgery with local anesthesia since unable to provide adequate exposure.

3.16 Expected benefit and application

If this study demonstrates that the local anesthesia provides adequate pain control after surgery without increasing morbidity. This procedure may hold out prospective benefits by reducing postoperative discomfort and reducing the cost of treatment. Furthermore, in some remote area, where anesthesiologist is not available this mode of anesthesia will be an alternative for hemorrhoidectomy in an emergency situation such as severe bleeding. Fewer postoperative complications lead to better postoperative care and reduce number of hospitalization day and cost for the patients. This also makes bed available for others undergoing major surgical procedures. This would be of great benefit both for patients and society in general. In addition, this study will be conducted as a randomized control trial in order to enhance the quality of evidence base concerning anesthetic methods for hemorrhoid surgery. The results from this study can be used for conducting further study with regard to hemorrhoid surgery in the future.