CHAPTER 2

RESEARCH DESIGN

RESEARCH QUESTIONS

Primary research question

Was the maximum pain score during F/C measured by 10-cm visual analogue scale in the patients receiving PCB plus IUA lower than the score in those receiving PCB alone for at least 2 cm?

Secondary research questions

1. Did the two treatment groups have different proportion of the patients who had maximum pain score ≤ 4?
2. Was the pain profile during F/C in the patients receiving PCB plus IUA different from the pain profile in those receiving PCB alone?
3. Did the two treatment groups have different proportion of the patients who require immediate postoperative analgesic medication?
4. Did the two treatment groups rate the patients' global satisfaction score differently?
5. Was there difference in the success rate of F/C between the two treatment groups?
6. Did the gynecologists performing F/C rate the difficulty score in the two treatment groups differently?
7. What were the adverse events and how often do they occur in each treatment group?

OBJECTIVES

Primary objective

To compare the effectiveness of PCB plus IUA and PCB alone for the reduction of maximum pain score during F/C.

Secondary objectives

To compare the two anesthetic methods in the following outcomes:

1. Proportion of patients having pain score ≤ 4
2. Pain profile during F/C
3. Proportion of patients requiring immediate post operative analgesic medication
4. Patients' global satisfaction to the treatment
5. Success rate of F/C
6. Difficulty of performing F/C
7. Types and incidence of adverse events

RESEARCH HYPOTHESIS

The maximum pain score during F/C measured by 10-cm visual analogue scale in the treatment group receiving PCB plus IUA was significantly different from the score in the control group receiving PCB alone.

Null hypothesis:

$$Ho: \mu_1 = \mu_2$$

Alternative hypothesis:

$$Ha: \mu_1 \neq \mu_2$$

where

μ_1 = mean of maximum pain score in the patients receiving PCB alone

μ_2 = mean of maximum pain score in the patients receiving PCB plus IUA

CONCEPTUAL FRAMEWORK

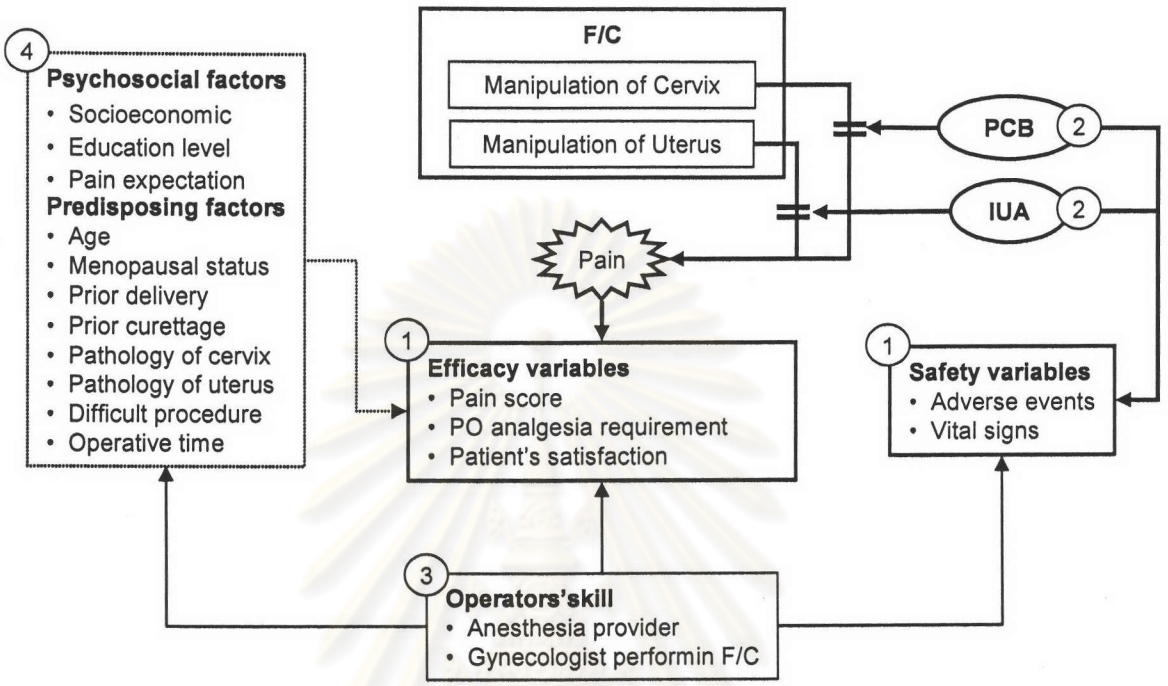

Figure 2.1 Conceptual framework demonstrates factors influencing pain elicited from fractional curettage procedure: ① = outcomes of interest; ② = independent variables, PCB = paracervical block, IUA = intrauterine anesthesia; ③ = covariates that are controlled in this study; ④ = covariates that are expected to be comparable between study groups due to randomization

OPERATIONAL DEFINITION

Pain

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[31]

Fractional curettage (F/C)

Fractional curettage is an operative procedure to obtain endocervical and endometrial tissue differentially. The operation comprises 2 major steps, i.e. endocervical curettage (ECC) and uterine curettage (UC).

1. ECC is performed by inserting a Sims curette no 00 (5 mm in the greatest diameter) through cervical canal up to internal os level and then drag out against the wall of cervical canal to external os level. The step is repeated for a few times to obtain tissue in anterior, posterior, and lateral walls of the endocervical canal.

2. UC is performed in similar manner, except that the curette is inserted to fundus and drag out to internal os level.

Steps of F/C are as the following: a single-toothed tenaculum is placed on the anterior lip of the cervix; ECC is performed; cervix is dilated to Hegar no 5 if necessary; uterine sound length is measured by inserting a metal uterine sound through the cervix; UC is performed using the same curette.

Paracervical block (PCB)

PCB is a local anesthetic method to block paracervical nerve plexus (uterovaginal plexus, Frankenhauser's plexus), which conveys nerve impulse to spinal segments T10-L1 and S2-S4. PCB is performed by injection of local anesthesia into posterior cervicovaginal reflexion for 2-4 sites (e.g. 3, 5, 7, 9; or 3, 9; or 4, 8 o'clock), at

approximate depth of 0.5 to 1 cm.[32] In this study the injection is made with a 23-gauge spinal needle at 3 and 9 o'clock, 1 cm deep. The anesthesia is 1% lidocaine in a total volume of 10 ml, or 5 ml at each injection site.

Intrauterine anesthesia (IUA)

IUA is a local anesthetic method to block nerve endings in uterine corpus and fundus, the nerve impulses of which convey through paracervical nerve plexus and other route to spinal segment T10-L1. IUA is performed by instillation of local anesthesia into uterine cavity. In this study 5 ml of 2% lidocaine is instilled into uterine cavity via 18-gauge venous catheter. The catheter, which is 2 inches long, is inserted through the cervical canal until connector of the catheter plugs the external cervical os. The anesthetic agent is instilled into the uterine cavity in a very gentle manner in order to minimize patient's discomfort. The catheter is left in that position for 3 minutes after instillation, to prevent back flow of the instilled solution, and to allow 3-minute contact time for the anesthesia to take action. In this study, IUA is performed immediately after PCB.

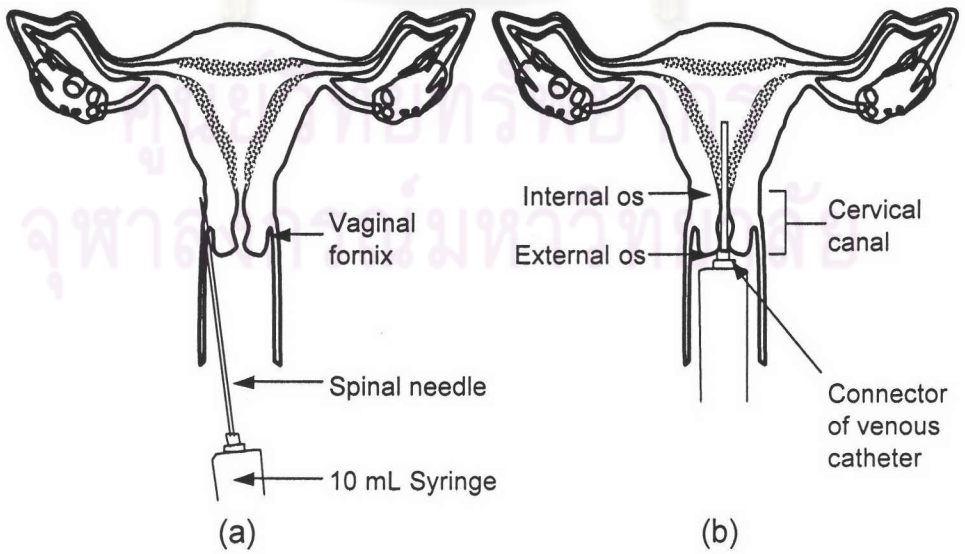

Figure 2.2 Anesthetic methods: (a) paracervical block; (b) intrauterine anesthesia

Menopausal status

Women are considered to be menopause if she is in late reproductive age group (i.e. older than 40 years) and her last episode of menstruation was at least 12 months prior to the recruitment of this study.

Operative time

The operative time is the duration from the beginning of PCB to the end of F/C.

RESEARCH DESIGN

This study is carried out as a double blind randomized placebo-controlled trial to answer the primary research question.