CHAPTER 6
RESULTS OF THE STUDY

FLOW OF STUDY PARTICIPANTS

Figure 6.1 demonstrated flow of study participants. Fifty-seven eligible patients were randomized. Thirty patients were assigned to the control group (PCB alone) but 3 cases were excluded (1 case due to protocol violation, 1 case due to spillage of anesthetic agent, and 1 case due to pyometra). Twenty-seven cases were assigned to the treatment group (PCB plus IUA) but 2 cases were excluded (1 case due to protocol violation, and 1 case due to spillage of anesthetic agent). Characteristics of all 5 excluded cases were similar to those of included cases. Therefore, data of 52 cases were finally included in the analysis.

BASELINE AND DEMOGRAPHIC DATA

Table 6.1 demonstrated baseline and demographic data of the patients. Data of the control and the treatment groups were examined for comparability on their baseline characteristics without using statistical analysis. It was found that some baseline variables were comparable but some did not.

The comparable variables between the control and the treatment groups were age (44.2 ± 10.8 vs. 42.4 ± 6.3 yr), years of education (≤12 yr: 70.4% vs. 68.0%), economic status (not enough: 18.5% vs. 12.0%), history of vaginal delivery (66.7% vs. 60.0%), menopausal status (menopause: 11.1% vs. 8.0%), body mass index (25.0 ± 3.8 vs. 23.0 ± 2.9 kg/m2), and uterine sound length (8.0 ± 1.3 vs. 7.7 ± 0.8 cm).

The baseline variables that were different between the control and the treatment groups included history of curettage (18.5% vs. 32.0%), procedure with cervical dilatation (3.7% vs. 12.0%), and operative time longer than 10 minutes (14.8% vs. 24.0%).

EFFICACY OUTCOME

The histogram of maximum VAS pain score during fractional curettage (Figure 6.2) revealed non-normal distribution, which was confirmed by Kolomogorov-Smironov test (P = 0.004 and 0.200 for the treatment and the control group, respectively). Therefore, the comparison of maximum pain between the control and the treatment groups was performed by non-parametric test (Mann Whitney U-test).

Effectiveness of the treatment was demonstrated in Table 6.2. The maximum VAS pain score during F/C in the control group was significantly higher than that in the treatment group (4.7 vs. 2.3 cm, P = 0.033). Proportion of the patients with pain score $\leq$ 4 cm was higher in the treatment group (64.0%) than in the control group (40.7%) but the difference did not reach statistical significance. The requirement of immediate postoperative analgesic medication, the success rate of F/C, and the patient's global satisfaction index were not different between the 2 groups. There was only one case who did not satisfy the procedure. She was in the control group and gave maximum VAS pain score of 5.5 cm.

Pain profile during the procedures was demonstrated in Table 6.3 and Figure 6.3. Since the maximum VAS pain scores were not normally distributed and the time intervals between the consecutive measurements were not equal, analysis of repeated measured could not be applied. The maximum VAS pain score at each time point in the control and the treatment group were then compared using Mann Whitney U-test. Only the maximum VAS pain score during F/C was statistically significantly different between the 2 groups.

SAFETY OUTCOME

Mean arterial blood pressure (MABP), pulse rate (PR), and oxygen saturation (OS) during the procedures were demonstrated in Table 6.4 and Figure 6.4. The profiles of these parameters of the control and the treatment groups were similar. The MABP and OS during the operation and the 60 minutes post operative period did

not change from the baseline. PR slightly increased during administration of anesthesia, then decreased to lower than baseline at 60 minute post operation. None of the patients had PR slower than 60 beats/min.

Adverse events were demonstrated in Table 6.5. The incidence of adverse events in the control (29.6%) and in the treatment groups (32.0%) was not different. The adverse events included lightheadedness, sensation of hot or numbness in head, tinnitus, palpitation, increased in blood pressure, and numbness in right leg. Serious adverse event did not occur in this study.

Cost of IUA was demonstrated in Table 6.6. The total cost was 128 bath which included costs of 2% lidocaine (1 bottle), 1 drawing needle, 1 disposable syringe, and 1 venous catheter.

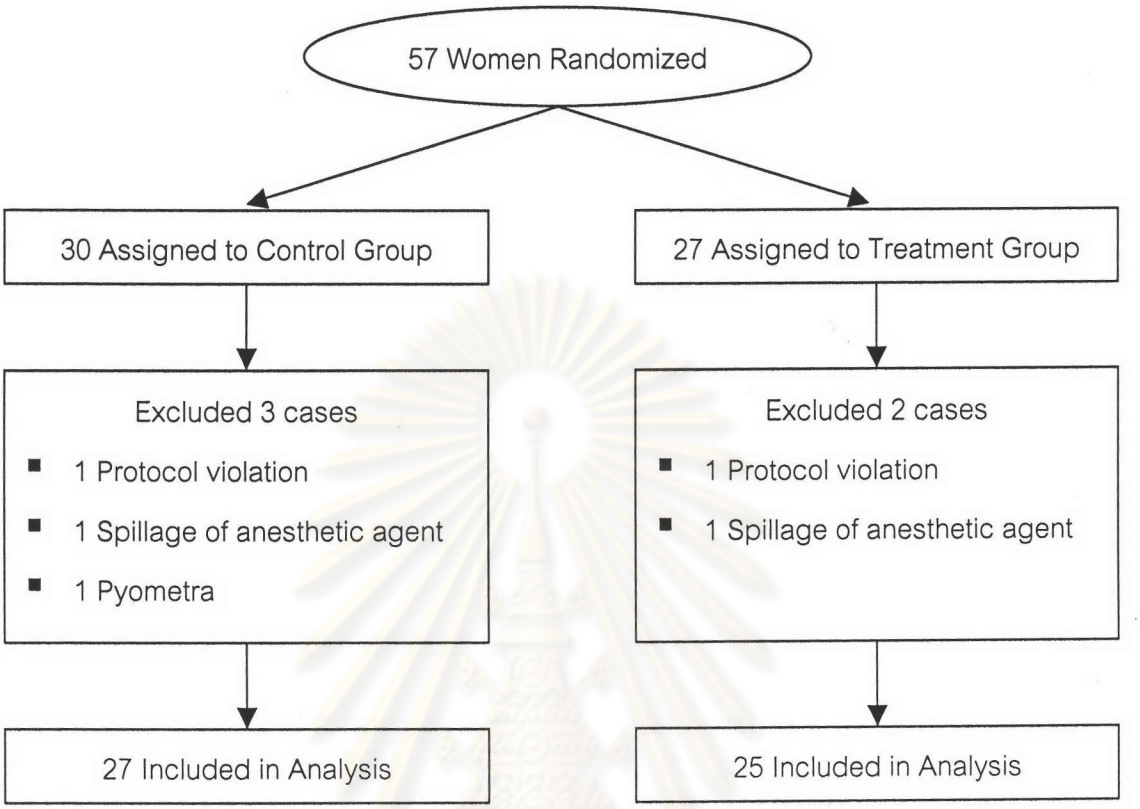

Figure 6.1 Flow of study participants

Table 6.1 Baseline characteristics in the control and the treatment groups

Characteristics	Control (n = 27)	Treatment (n = 25)
Age (yr)	44.2 ± 10.8	42.4 ± 6.3
Years of education		
■ ≤12 years	19 (70.4%)	17 (68.0%)
■ >12 years	8 (29.6%)	8 (32.0%)
Economic status		
■ Not enough	5 (18.5%)	3 (12.0%)
■ Enough	22 (81.5%)	22 (88.0%)
Vaginal delivery	18 (66.7%)	15 (60.0%)
Prior curettage	5 (18.5%)	8 (32.0%)
Menopause	3 (11.1%)	2 (8.0%)
Body mass index (kg/m^2)	25.0±3.8	23.0±2.9
Procedure with cervical dilatation	1 (3.7%)	3 (12.0%)
Uterine sound length (cm)	8.0±1.3	7.7±0.8
Operative time longer than 10 min	4 (14.8%)	6 (24.0%)

Note Data were mean ± SD or n (%) otherwise specified

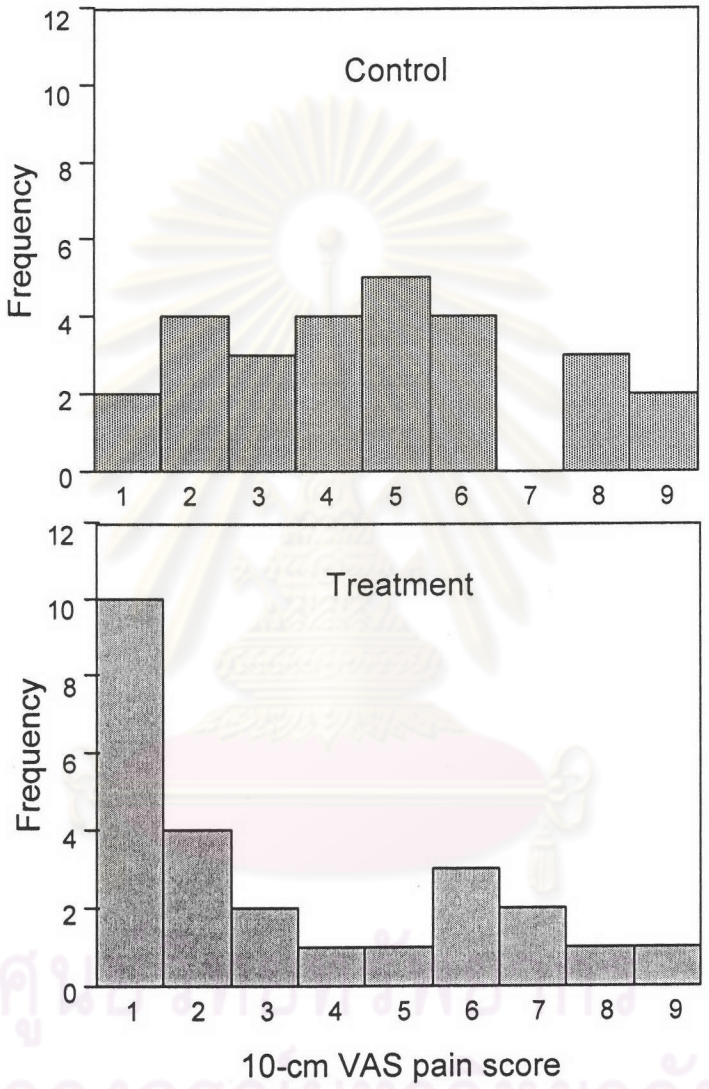

Figure 6.2 Histogram of maximum VAS pain score during fractional curettage

Table 6.2 Efficacy of treatment

Efficacy variables	**Control (n = 27)**	**Treatment (n = 25)**	**P-value[a]**
Median of maximum VAS pain score (cm)	4.7 (0.8-9.2)	2.3 (0.5-9.2)	0.033
Patients with pain score ≤ 4 cm	11 (40.7%)	16 (64.0%)	0.093
Requirement of immediate PO analgesic medication	0 (0%)	0 (0%)	1.000
Success rate of F/C	27 (100%)	25 (100%)	1.000
Patient's global satisfaction index			
■ Unsatisfied	1 (3.7%)	0 (0%)	1.000
■ Satisfied	26 (96.3%)	25 (100%)	

Note: Data were median (95% central value) or n (%)

(a) Fisher's exact test for qualitative data and Mann-Whitney U test for VAS pain score

Table 6.3 Pain profile during the procedures

Steps of procedure	VAS (cm) : Median (95% central value)		P-value[(a)]
	Control (n = 27)	Treatment (n = 25)	
Retractor insertion	1.0 (0-5.4)	0.9 (0.2-5.3)	.826
During F/C	4.7 (0.8-9.2)	2.3 (0.5-9.2)	.033
15 min PO	0.9 (0-7.8)	0.4 (0-8.8)	.446
30 min PO	0.8 (0-7.3)	0.4 (0-6.9)	.211
60 min PO	0.5 (0-2.6)	0.3 (0-2.3)	.418

Note: (a) Mann Whitney U-test.

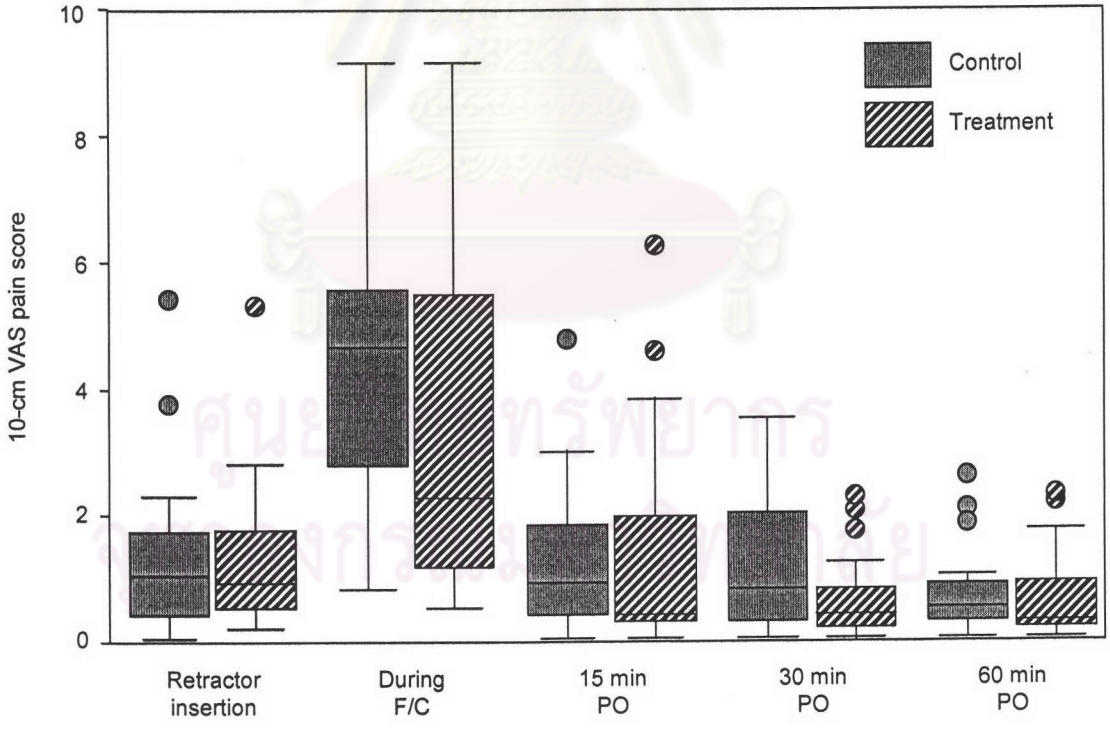

Figure 6.3 Pain profile during the procedures

(Box represented 25th, 50th, and 75th percentiles)

Table 6.4 Blood pressure, pulse and oxygen saturation during the procedures

Parameters	Control		Treatment		P-value[a]
	n	X±SD	n	X±SD	
Mean arterial blood pressure (mmHg)					
■ Before operation	27	96.5±9.7	25	92.0±9.1	.091
■ Immediately after anesthesia	27	96.9±13.5	25	92.5±12.0	.214
■ Immediately after F/C	27	94.1±11.9	25	91.4±9.7	.367
■ 15 min PO	26	90.2±10.2	25	87.8±9.3	.386
■ 30 min PO	27	89.2±10.2	23	85.6±11.6	.242
■ 60 min PO	25	90.8±10.2	23	86.3±10.7	.147
Pulse (beats/min)					
■ Before operation	27	83.6±13.3	25	88.0±13.0	.232
■ Immediately after anesthesia	27	88.4±15.9	25	93.2±15.0	.279
■ Immediately after F/C	27	84.±14.6	25	88.4±11.4	.280
■ 15 min PO	26	81.4±12.7	25	87.2±10.0	.075
■ 30 min PO	25	80.1±11.5	24	82.4±9.2	.445
■ 60 min PO	23	75.4±10.0	22	78.8±9.6	.247
Oxygen saturation (%)					
■ Before operation	27	97.4±1.8	24	97.9±0.9	.246
■ Immediately after anesthesia	25	97.6±1.0	23	98.1±0.9	.077
■ Immediately after F/C	26	98.0±0.9	23	97.8±0.8	.403
■ 15 min PO	24	97.6±0.9	24	97.5±0.8	.863
■ 30 min PO	21	97.6±0.8	16	97.8±0.8	.382
■ 60 min PO	18	97.6±1.0	14	97.6±0.7	.793

Note: (a) Unpaired t-test

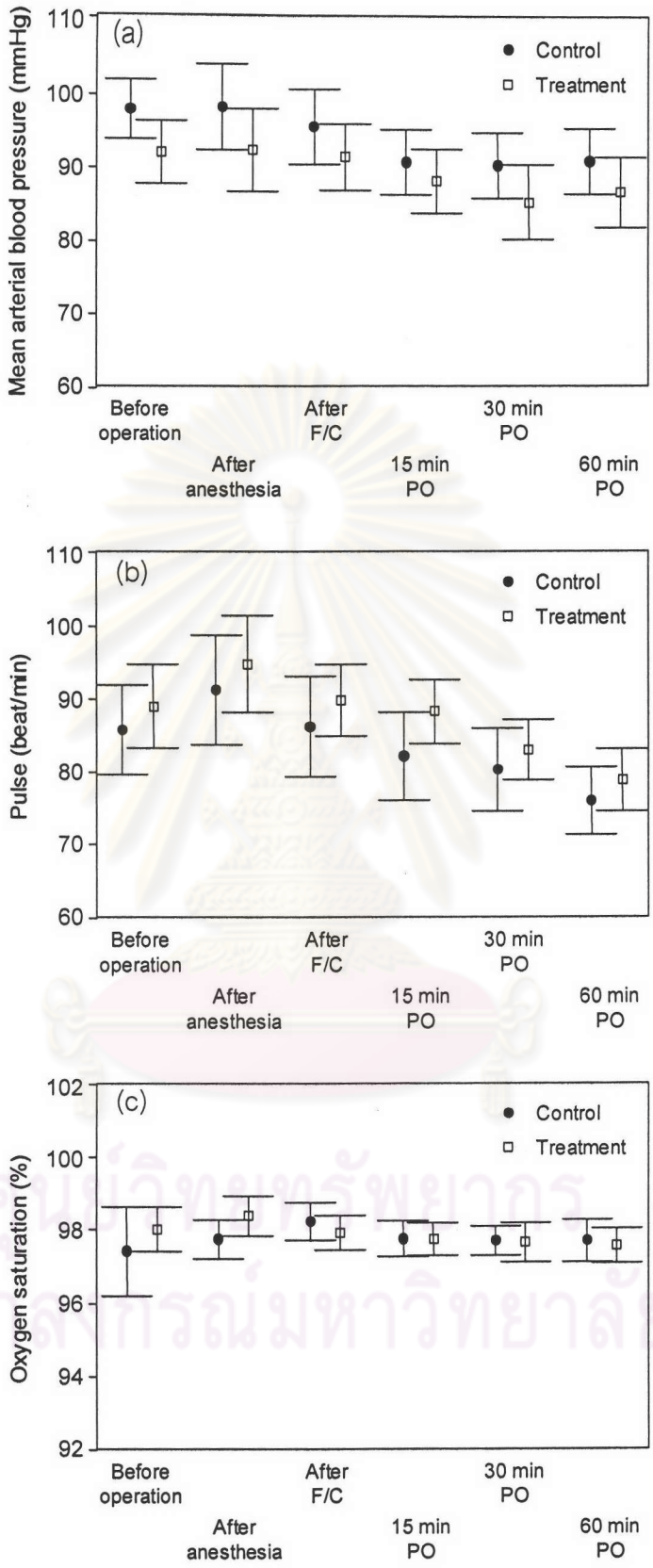

Figure 6.4 Profiles of blood pressure, pulse and oxygen saturation during the procedures (Data represented mean and SD)

Table 6.5 Adverse events

Variables	Control (n = 27)	Treatment (n = 25)	P-value[(a)]
Adverse events	8 (29.6%)	8 (32.0%)	1.000
■ Central nervous system			
○ Lightheadedness	1	1	
○ Sensation of hot or numbness in head	2	0	
○ Tinnitus	2	3	
■ Cardiovascular system			
○ Palpitation	3	5	
○ Increase BP	2	1	
■ Others			
○ Numbness in right leg	2	1	
○ Pelvic cramp	1	1	

Note Some patients experienced more than one adverse event.

(a) Fisher's exact test.

Table 6.6 Cost of intrauterine anesthesia (IUA)

Supplies	**Cost (baht)**
2% Lidocaine (20 mL)	62
Disposable syringe (5 mL)	4
Needle (no 20)	1
Venous catheter (no 18, 2 inches long)	61
Total cost	128

Source of data: The pharmacy of Outpatient Department at Siriraj Hospital