CHAPTER IV

DATA MANAGEMENT

4.1 Observation and Measurements.

The clinical outcomes were observed, measured and recorded in details.

1. Successful operation: The surgeon recorded the result.
2. Cardiac arrhythmia : Cardiac arrhythmia was measured by detection of PVC by EKG monitoring during the operation and was recorded by an anesthesiologist.

End-tidal CO_2: End-tidal CO_2 was measured with the same machine in every patients and was recorded by an anesthesiologist.

3. Complications : All complications were detected and recorded by residents and surgeons during the current admission and follow-up period.
4. Post operative pain : Postoperative pain was measured by one independent evaluator (a research nurse) at 6 and 24 hour after the operation.

5. Shoulder pain shoulder pain will be asked after postoperative pain evaluation at 24 th postoperative hour with non-leading questions

All clinical outcomes were recorded in a case report form (Appendix I).

4.1.1 The variables were:

1. Baseline variables

Baseline data, age, sex, weight, past history and associated diseases, were recorded and evaluated to show the distribution between the two groups.

4.1.2. Outcome variables

The outcome variables were measured and recorded as foilow:

1. Successful operation	Yes or No	nominal scale
2. Operative time	Minutes	ratio scale
3. Postoperative stay	Days	ratio scale
4. Cardiac arrhythmia	Yes or No	nominal scale
5. Post operative pain score by visual analog pain scale	Pain score	ordinal scale
6. Shoulder pain	Yes or No	nominal scale
7. Complications	(descriptive)	
8. Cost	Baht	

4.2 Validity of measurement

Validity: The criteria or operational definitions of each outcome were discussed among surgeons and an evaluator. Most of the clinical outcomes were hard outcomes : success rate, operative time, post operative stay, cardiac arrhythmia and complication. Pain score was evaluated by a research nurse. The pain scores correlated well with analgesic requirement. (recorded in the medical records)

4.3 Data collection

The data was collected in a case report form (Appendix I). The analog pain score was evaluated by an research nurse who is independent and the results were kept until the end of the study. The data were entered into the SPSS statistical program and missing value was corrected by searching the result from the hospital medical records and case report forms.

4.4 Data Analysis

Data analysis was evaluated on the intention to treat basis by using SPSS statistical program. (SPSS for Windows Version 7.52, SPSS Inc.)

Baseline data were evaluated and presented by descriptive statistics as follow:

Variables	Statistic
Age	mean, SD
Sex	M : F
Weight	mean, SD
Pt. with associated diseases	descriptive
Past Hx. of cholecystitis	descriptive

Outcome variables were evaluated by :

Variables	Statistic
1. Successful operation	Chi-square test
2. Operative times	Mann-Whitney U test
3. Complication rate	Fisher's exact's test
4. End tidal CO_2	Independent t-test
5. Cardiac arrhythmia	Fisher's exact's test
6. Postoperative pain score	repeated measure ANOVA
7. Shoulder pain	Chi-square test
8. Costs	Estimation, calculation

The success of operation and shoulder pain were recorded as proportion and were evaluated by chi-square test. The other proportional outcomes: complication rate and rate of cardiac arrhythmia were evaluated by Fisher is exact test because the expected value in one cell is less than 5.

Postoperative pain score was plotted in a histogram and found to be a normal distribution and was evaluated using repeated measure ANOVA, because it was repeatedly measured at 6 and 24 hours after the operation.

Operative time was plotted in a histogram and the distribution was not a normal curve. It was evaluated by a non-parametric statistic, Mann - Whitney U test.

4.5 Cost effectiveness analysis

Cost effectiveness analysis will be analyzed using both patient's perspective and provider's perspective.

Patient's perspective

Costs in the patient 's perspective were divided into

1. Direct costs, which included direct medical costs and direct non medical costs which were calculated from the actual cost of each patient in each group.
2. Indirect costs were estimated and used for all patients.
3. Intangible costs were not included in this study, because operative wound pain and cosmesis were similar in both groups.

Provider's perspective

Costs in the provider's perspective were evaluated for capital, labors and material costs of the operation. The costs that occurred at the operative room were evaluated and compared. Costs at wards were not evaluated in the study because it was not our main interest. The details of the costs summarized in Table 4.1

Table 4.1 Costs in provider's perspective.

	What to measure	How	Source	Remark
1. Capital cost.	Land and building	Estimate from rental cost per month.	Secondary	Rental cost at the same area in the 1999
	Equipments	Calculation	Primary	Annuity factor was used
2. Labour cost.	Labour cost of all personnels	Survey the opportunity cost	Private hospitals	260 days/yr., 8 working hour/day
3. Material cos	Medications	Estimation	Secondary source	
	Surgical materials	Estimation	Secondary source	
	Trochars	Estimation	Secondary source	Re-sterilization 2 times
	Cleaning + sterilization	Estimation	Secondary source	
	Electricity + water supply cost	Calculation and estimation	Hospital's engineer	
	Patient's diet	Estimation	Secondary source	
Cost of Consequences	Complications	Estimation from treatments for each complication	Secondary source	