

CHEPTER V

RESULTS

Results. The following results was based on analysis of 84 laparoscopic cholecystectomy, 42 patients in each group. The analysis was based on intention to treat basis

5.1 Baseline data

Table 5.1 Baseline data.

		TPC (n =42)	AWL (n=42)
Age	mean , SD	53.45,13.61	55.93,10.84
Sex	M	9	9
	F	33	33
Weight	mean, SD(kg)	57.61,9.90	62.1,11.36
Associated Disease		22	20
Hx. of Ac. Cholecystitis		5	4
Previous abdominal operation		9	8

The baseline characteristics of the two groups were comparable. Mean age of the TPC and AWL groups were 53.5 and 55.9 kg. respectively. Weight in the AWL group was higher than the TPC group. The presenting symptoms of the two groups were similar as shown in Table 5.2

Table 5.2 Presenting symptoms

	Group I (TPC)	Group II (AWL)
Asymptomatic	3	3
Dyspepsia	2	5
Biliary colic	4	5
H x % biliary colic	25	25
Hx of acute cholecystitis	5	4
Cholangitis	2	

5.2 Success of the operations

Table 5.3 Two by two table of success of the operations.

		GROUP		Total
		TPC	AWL	
Success	yes	40	28	68
	no	2	14	16
Total		42	42	84

Table 5.4 Chi-square tests for Success of the Operations.

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	11.118 ^b	1	.001		
Continuity Correction	9.342	1	.002		

The success rate of the TPC group was 95.2 per cent and the success rate of the AWL group was 66.7 percent. There was a statistical significant difference between the 2 groups, $p = 0.001$.

5.3 Operative time:

Table 5.5 Descriptive Statistics of Operative Time

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
Total operative	TPC	40	64.60	24.11	3.81
	AWL	38	104.03	32.19	5.22
Prepare time	TPC	35	12.23	6.71	1.13
	AWL	31	23.00	7.85	1.41
Dissection time	TPC	35	39.94	21.33	3.61
	AWL	31	61.94	34.46	6.19
Closure time	TPC	35	10.37	3.03	.51
	AWL	31	14.52	4.15	.75

Operative time was divided into 3 phases

1. preparation time was counted at beginning of the incision until starting dissection of the gallbladder
2. dissection time was counted from starting dissection of the gallbladder to the gallbladder was extracted out of the abdominal cavity
3. closure time was time used for closure the puncture sites

The total operative time and time in each phase were show in Table 5.5. Time used in the open cholecystectomy was not included in the calculation.

After evaluation with a non-parametric statistics (Mann-Whitney U test), the operative times in all 3 phases of the TPC group were shorter than the AWL group, $p = 0.001$ or $p < 0.001$, as shown in Table 5.6

Table 5.6 Mann-Whitney U test and Wilcoxon rank sum test for operation time

	Total operative time	Prepare time	Dissection time	Closure time
Mann-Whitney U	233.000	87.500	292.500	241.000
Wilcoxon W	1053.000	717.500	922.500	871.000
Z	-5.277	-6.032	-3.229	-4.222
Asymp. Sig. (2-tailed)	.000	.000	.001	.000

5.4 Complication rate

The complication rate in both groups is equal. Two patients in TPC group (4.8 per cent) had intraoperative complications. A patient had a sidewall injury of the CBD during clipping a short cystic duct. Primary repair of the sidewall injury was performed by open surgery. The other patient had bronchospasm during the operation and was treated successfully with bronchodilator.

There were 2 postoperative complications in AWL group (4.8 percent). One patient had a wound infection after open cholecystectomy for a failed LC. The other patient had pneumonia and was treated by antibiotics. She recovered well and was discharged within 5 postoperative days.

There was no difference in complication rate between the 2 groups.

5.5 End tidal CO₂ and cardiac arrhythmia rate

Table 5.7 Descriptive statistics of end tidal CO₂.

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
End tidal CO ₂	TPC	37	31.692	2.804	.461
	AWL	34	29.185	3.247	.557

Table 5.8 Result of t-test for end tidal CO₂

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Mean	
									Lower	Upper
End tidal CO ₂	Equal variances assumed	.598	.442	3.489	69	.001	2.507	.718	1.073	3.940
	Equal variances not assumed			3.467	65.525	.001	2.507	.723	1.063	3.950

ET CO₂ levels of the TPC and AWL groups were 31.7 ± 2.8 and 29.2 ± 3.3 mm. Hg. respectively. There was a statistically significant difference between the two groups, $p = 0.001$. (Table 5.7 and 5.8)

However there was no difference in cardiac arrhythmia rate between the two groups. Four patients in each group (9.5 percent) had PVC and were treated by intravenous administration of Cardipine or Xylocard. Surprisingly, at the time of PVC occurrences the ETCO₂ levels were not higher than a normal range.

5.6 Postoperative pain score

Table 5.9 Descriptive statistics on postoperative pain score

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
pain at 6 hour	TPC	40	51.38	27.48	4.34
	AWL	37	53.78	25.29	4.16
pain at 24 hour	TPC	40	29.38	22.74	3.59
	AWL	37	33.24	21.83	3.59

Table 5.10 Tests of Within-Subjects Effects of Postoperative Pain

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power ^a
PAIN	391.899	1	391.899	89.868	.000	89.868	1.000
PAIN * RANDOM	20.470	1	20.470	.106	.746	.106	.062
Error(PAIN)	514.595	75	193.528				

Table 5.11 Test of Between-Subjects Effects on Postoperative Pain

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power ^a
Intercept	270524.1	1	270524.1	269.535	.000	269.535	1.000
RANDOM	378.660	1	378.660	.377	.541	.377	.093
Error	5275.236	75	1003.670				

Postoperative pain score were evaluated by repeated measure ANOVA statistics. The mean pain score at 6 hour were 51.83 ± 27.48 in TPC group and 53.78 ± 25.29 in AWL group. The mean pain score at 24 hours postoperative period were 29.38 ± 22.74 and 33.24 ± 21.83 respectively. There was a significant difference of the pain score at 6 hour and at 24-hour postoperative period (within subject factor) $p < 0.001$. But there was no significant difference of the pain score between TPC and AWL patients (Between subject), $p = 0.541$

5.7 Shoulder Pain

Table 5.12 Number of patients with shoulder pain

		GROUP		Total
		TPC	AWL	
Shoulder pain	yes	13	9	22
	no	27	26	53
Total		40	35	75

Table 5.13 Chi-square test for shoulder pain

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.415 ^b	1	.520		
Continuity ^a Correction	.152	1	.697		

The shoulder pain was recorded in proportion and was compared by Chi-square test. Thirteen out of 40 patients in TPC group and 9 out of 35 patients in the AWL group had shoulder pain. The patients who were converted to open cholecystectomy were not included in the calculation. There was no statistically significant difference between the 2 groups.

5.8 Post operative hospital stay

Table 5.14 postoperative hospital stay.

GROUP	N	Mean	Std. Deviation	Std. Error Mean
Postoperative TPC	40	2.63	.90	.14
stay AWL	37	3.14	1.23	.20

Post operative hospital stay of the TPC group was 2.63 ± 0.9 days, and the AWL group was 3.14 ± 1.23 days. (open cases were excluded). There was no statistical ly significant difference as compare by Mann-Whitney-U test, $p= 0.057$. The total hospital stay was not evaluated because there were many factors, which affected the pre-operative period.

5.9 Costs.

1. Patient's perspective	Group I (TPC)	Group II (AWL)
1. Direct cost		
Medical		
Operation fee	210,000	210,000
Anesthesia fee	126,000	126,000
Medication	118,000	150,000
OPD medication	8,400	8,400
Non medical		
Room fee	243,300	195,400
Diet fee	53,750	47,050
2. Indirect cost		
Taxi	12,600	12,600
Accompanying person	49,000	53,400
3. Intangible cost	-	-
Total	821,050	802,850

Cost /1 success case = 20,526.25

28,673.21

For the patient's perspective the expense per one successful case of TPC group is less than that-of AWL group.

2. Provider's Perspective

Costs of performing laparoscopic cholecystectomy were evaluated. The detailed calculation for operative room expenses (Provider's perspective) is in the Appendix III.

1. Capital cost Land and Equipment. Baht/hr/bed

Anesthesia	96.6
Operative room (Land)	803.8
OR Equipments + Instruments	798.99

2. Labour cost

anesthesiologists + team	909.08
surgeons + team	803.81
OR nurses	952.65

1+2 4,364.93

3. Maternal cost

- Anesthetics	690.00	Baht/hr/bed
- Material cost for LC (TPC)	8770	Baht/case
- Material cost for LC (AWL)	5020	Baht/case
- Estimated material cost for conversion (open) = 5000		Baht/case
- Estimated material cost for conversion to gas = 6000		Baht/case

	TPC group	AWL group
Operative time (hr)	47.8	79.0
1. Capital +Labour costs	208643.65	344829.47
2. Material cost: OR	368340.00	210840.00
Anesthetics	32982.00	54510.00
3. Cost for conversion	10000.00	79000.00
Total costs	619965.65	689179.47
Cost/1 successful case	15,499.14	24,613.55

For the provider's perspective the expense of the hospital per one successful case of TPC group is less than that-of AWL group.

5.10 A summary of the results.

Table 5.15 A summary of the results.

	TPC	AWL	Significant
Success rate*	40/42	28/42	p = 0.001
Operative time* min	64.6+24.1	104.0+32.2	p < 0.001
Complication rate	4.8%	4.8%	NS.
ETCO ₂ *	31.7+2.8	29.2+3.3	p = 0.001
Cardiac arrhythmia	9.5%	9.5%	NS
Post op pain 6hr	51.4+27.5	53.8+25.3	NS
24hr.	29.4+22.7	33.2+21.8	NS
shoulder pain	13/40	9/35	NS
Post op stay	2.63+0.9	3.14+1.2	NS
Cost/success case**			
Patient's perspective Bant	20,526.25	28,673.21	
Provider's perspective Baht	15,499.14	24,613.55	

* statistical significant difference

** difference