#### CHAPTER III

#### RESULTS

#### 3.1 Patient's characteristics and baseline data

Fifty patients were included in this study. All these following data were recorded as baseline data: age (yrs), sex, underlying disease of the patients, type of fistula in ano, and fistula length (cm). The surgical procedures allocated to each patient were successfully performed without intraoperative complication (Table 4).

All patients had good recovery in early postoperative period except 2 patients in fistulotomy group who developed urinary retention and they was successfully managed by intermittent catheterization, 1 patient in this group also developed transient fever (38 c) which was treated by paracetamol ingestion.

Table 4. Demographics and Patient's characteristics

Parameter	Fistulotomy alone (n = 25)	Fistulotomy with marsupialization $(n = 25)$
Age (yrs) <sup>a</sup>	43.20 (13.67)	40.60 (10.75)
Sex (M:F)	23:2	20 : 5
Underlying disease	4	3
- DM	3	1
- HT	1	2
Fistula type	9:16	8 : 17
(Intersphincteric: Low transphincteric)		
Fistula length (cm) <sup>a</sup>	2.21 (0.81)	2.56 (0.87)

<sup>&</sup>lt;sup>a</sup> Value are express as mean (SD)

The patients were informed to evaluate the pain score in the postoperative day 1, 3, 5, 7, and 14. The self report form was returned when they came back for postoperative check up as an outpatient in 2 weeks. None of the patients reported serious wound complication. Only minor postoperative bleeding was occurred in 2

patients in fistulotomy group and they were successfully managed by conservative means.

## 3.2 Primary outcome analysis.

## Postoperative pain score (VAS)

For the sample of 50 patients, the repeated measurement was operated for measuring the pain score in the postoperative day 1, 3, 5, 7, and 14. The descriptive statistics of postoperative pain score in each group was showed as mean and SD. (Table 5)

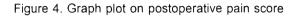
Table 5. Descriptive Statistics on postoperative pain score

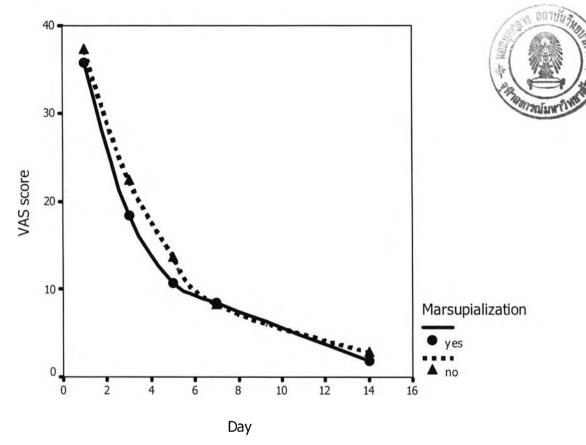
	MARSUPIAª	Mean	Std. Deviation	N
VAS <sup>b</sup> day1	no	37.20	24.157	25
	yes	35.76	21.799	25
	Total	36.48	22.784	50
VAS day3	no	22.36	14.835	25
	yes	18.48	14.618	25
	Total	20.42	14.707	50
VAS day5	no	13.60	10.124	25
	yes	10.72	8.687	25
	Total	12.16	9.449	50
VAS day7	no	8.12	6.766	25
	yes	8.36	10.688	25
	Total	8.24	8.854	50
VAS day14	no	2.80	3.969	25
	yes	1.80	3.440	25
	Total	2.30	3.710	50

<sup>&</sup>lt;sup>a</sup> Marsupialization

<sup>&</sup>lt;sup>b</sup>Visual analogue score

Graph plot on postoperative pain score showed the reduction of pain score while the postoperative day increased. (Figure 4)





For the repeat measurement of postoperative pain score (VAS), the Mauchly's test of sphericity was done and it showed that the error covariance matrix of the orthonormalized transformed dependent variable was not proportional to an identify matrix. (Table 6) The Greenhouse-Geisser was then selected to test the within subject effect and it revealed that the overall pain score in each postoperative day were significantly different (p=0.000) while there was no interaction between the postoperative pain score and the allocated treatment group (p=0.767). (Table 7)

## Table 6. Mauchly's Test of Sphericity(b)

Measure: postoperative pain (VAS)

Within	Mauchly's W	Approx. Chi-	df Sig.	Epsilon(a)			
Subjects Effect	Mauchiy S VV	Square	ui	Sig.	Greenhouse- Geisser	Huynh- Feldt	Lower- bound
PAIN	.142	90.679	9	.000	.479	.509	.250

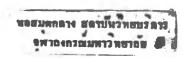
Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

Table 7. Tests of Within-Subjects Effects

Measure: postoperative pain (VAS)

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
PAIN	Greenhouse- Geisser	35079.400	1.916	18305.940	68.311	.000
PAIN * MARSUPIAª	Greenhouse- Geisser	130.296	1.916	67.994	.254	.767
Error(PAIN)	Greenhouse- Geisser	24649.104	91.982	267.978		

<sup>&</sup>lt;sup>a</sup> Marsupialization



a May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b Design: Intercept+MARSUPIA Within Subjects Design: PAIN

To test the effect of treatment group (fistulotomy alone and fistulotomy with marsupialization), test of between subject effect was done and it revealed that the difference between group was not significantly different (p=0.490). (table 8)

Table 8. Tests of Between-Subjects Effects

Measure: postoperative pain (VAS) Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	63361.600	1	63361.600	152.488	.000
MARSUPIA	200.704	1	200.704	.483	.490
Error	19944.896	48	415.519		

<sup>&</sup>lt;sup>a</sup> Marsupialization

Table 9. Postoperative pain/ wound condition/ complication and incontinence.

Parameter	Fistulotomy alone (n = 25)	Fistulotomy with marsupialization $(n = 25)$	P- value
VAS on the first defecation <sup>a</sup>	37.44( 22.15)	36.80( 23.67)	0.922 <sup>†</sup>
Number of patient requiring pethidine injection	13	4	0.017 <sup>§</sup>
Time to first pethidine injection (hrs) <sup>a</sup>	7.80 (4.36)	6.88 (0.56)	0.690 <sup>†</sup>
Number of Paracetamol ingestion in 7days after discharge (tablet) b	6 (0 – 24)	4 (0 - 18)	0.694 "
Wound condition at 2 weeks (no inflammation: inflammation)	19 : 6	22 : 3	0.463 <sup>‡</sup>
Complication	5	0	0.0501‡
- urinary retention	2	0	
- fever	1	0	
- bleeding	2	0	
Incontinence	0	0	-

<sup>&</sup>lt;sup>a</sup> Value are express as mean (SD)

<sup>&</sup>lt;sup>b</sup> Value are express as median (min - max)

<sup>†</sup> Student's t-test

μ Mann-Whitney U test

<sup>&</sup>lt;sup>‡</sup> Fisher exact test

 $<sup>^{\</sup>rm \$}$  Pearson  $\chi$   $^{\rm 2}$  test (continuity correction)

#### 3.3 Secondary outcome analysis

#### 3.3.1 Post operative pain score (VAS) on the first defecation (Table 9).

There was no statistically significant difference of pain score on the first defecation (p=0.922, student's T test) between the fistulotomy groups  $(37.44\pm22.15)$  and fistulotomy with marsupialization group  $(36.80\pm23.67)$ .

### 3.3.2 Number of patients requiring pethidine injection (Table 9).

For the sample of 50 patients, the Chi Squared test revealed that the number of patients requiring pethidine injection and the treatment groups (13 patients in fistulotomy and 4 patients in fistulotomy with marsupialization) was significant different (p=0.017, Pearson  $\chi^2$  test with continuity correction). Time to the first pethidine injection was also tested and no significant difference was found (p=0.690, student's T test) between the fistulotomy groups (7.80±4.36 hrs) and fistulotomy with marsupialization group (6.88±0.56 hrs)

# 3.3.3 Number of paracetamol ingestion in 7 days postoperative period (Table 9).

There was no statistically significant difference of the total number of paracetamol ingestion in 7 days postoperatively (p=0.694, Mann Whitney U test) between the fistulotomy groups (6 tablets) and fistulotomy with marsupialization group (4 tablets).

#### 3.3.4 Wound condition at 2 weeks (Table 9).

Wound condition was evaluated in the follow up clinic at 2 weeks after the operation. Wound inflammation was occurred in some patients (6 patients in fistulotomy and 3 patients in fistulotomy with marsupialization), and the Chi squared test revealed that the treatment group and wound condition was not statistical significant (p=0.463, Fisher exact test).

### 3.3.5 Complication (Table 9).

Five patients developed postoperative complication (2 patients with urinary retention, 1 patient with fever, and 2 patients with bleeding) and all of them were in the fistulotomy group. For the sample of 50 patients, the Chi squared test revealed that the complication and the treatment group was not statistically different (p=0.0501, Fisher exact test).

## 3.3.6 Incontinence (Table 9).

None of the patient in each group developed anal incontinence after the surgery.