

CHAPTER 4

RESULTS

4.1 Basic characteristics of patients

A total of 108 patients (preincisional group = 53 ; postincisional group = 55) were enrolled in this study. Two of the 53 patients who received preincisional morphine and 1 of the 55 patients who received postincisional morphine were excluded because of positive result on urine opiate test. One additional patient in postincisional group did not complete the study protocol due to the technical problem of PCA machine and was considered missing in primary outcome data.

The basic characteristics of patients are presented in Table 4.1. The demographic and baseline data were comparable in both groups.

The NRS reported at 6, 24 and 48 hours in each group were described as median and interquartile range (Table 4.2). The median

NRS was no more than 5 at each period of time. There was no significant differences of NRS demonstrated between pre- and postincisional groups.

Table 4.1 Demographic and baseline data

	Preincisional gr. n = 51	Postincisional gr. n = 54	p value
1. Age (yr)	47.69;11.38 ⁺	48.96;10.75 ⁺	0.556
2. Sex			
- female	27	28	0.911
- male	24	26	
3. Body weight(kg)	53.6;11.52 ⁺	55.76;11.65 ⁺	0.343
4. Physical status			
- ASA I	35	40	0.537
- ASA II	16	14	
5. Site of surgery			
- upper	19	19	0.969
- lower	16	18	
- upper+lower	16	17	
6. Duration of surgery (min)	190.35;89.58 ⁺	183.94;72.56 ⁺	0.687
7. Interval between first injection of morphine/ placebo and incision making.(min)	18(15-25)*	20(15-30)*	0.351

+ Values are expressed as mean ; SD

* Median with interquartile range in parentheses

Table 4.2 Comparison of NRS at 6, 24 and 48 hours

	Median, interquartile	Mean rank	P value
<u>NRS at 6 hr.</u>			
- Preincisional (n = 51)	5 (2-6)	50.25	.4428
- Postincisional (n = 53)	5 (4-6)	54.67	
<u>NRS at 24 hr.</u>			
- Preincisional	4 (2-5)	51.62	.7666
- Postincisional	4 (2-5)	53.35	
<u>NRS at 48 hr.</u>			
- Preincisional	2 (1-5)	50.64	.5317
- Postincisional	3 (2-4)	54.29	

Mann-Whitney “U” test

4.2 Primary outcome analysis

The mean analgesic consumption during the first 48 hours postoperatively were 45.94 (S.D. = 25.65) and 60.2 (S.D. = 33.05) mg. in preincisional and postincisional group respectively. The result was considered statistical significance (p value = .016). The reduction of

analgesic requirement in preincisional group was about 24 % which can also be considered as clinical significance.

In order to demonstrate trend of response and interaction between time and analgesic consumption, repeated measures analysis had been performed. The results indicated that there was no significant difference of morphine used during the 6-and 12-hr period whereas the morphine consumption at 24 and 48 hours were significantly reduced in preincisional group. (p value .046 and .016 respectively). The analgesic consumption in each period were shown in Fig 4.1.

4.3 Secondary outcome analysis

4.3.1 Pain-free period after surgery

The time to first requirement of analgesia was analysed by survival analysis. The survival curves in both group were shown in Fig 4.2. The median survival time in pre- and postincisional groups were 28.13 and 31.67 minutes respectively. Comparison of median survival times was carried out by calculating an approximate confidence interval for the

ratio of two independent median survival times using the formula introduced by Simon.⁽³⁴⁾

$$95\% \text{ confidence interval} = \frac{m_1 e^{-1.96 S}}{m_2} \text{ to } \frac{m_1 e^{+1.96 S}}{m_2}$$

where m_1 and m_2 = median survival times of two independent samples.

$$\begin{aligned} S &= \sqrt{\frac{1}{0_1} + \frac{1}{0_2}} \\ &= \sqrt{\frac{1}{51} + \frac{1}{54}} \\ &= 0.195 \end{aligned}$$

95 % confidence interval of $\frac{m_1}{m_2}$ is 0.61 to 1.30

Since there was no censored observations in this study, the standard non-parametric test can also be used to compare the time to first requirement of analgesia of each group. The result was shown in Table 4.3.

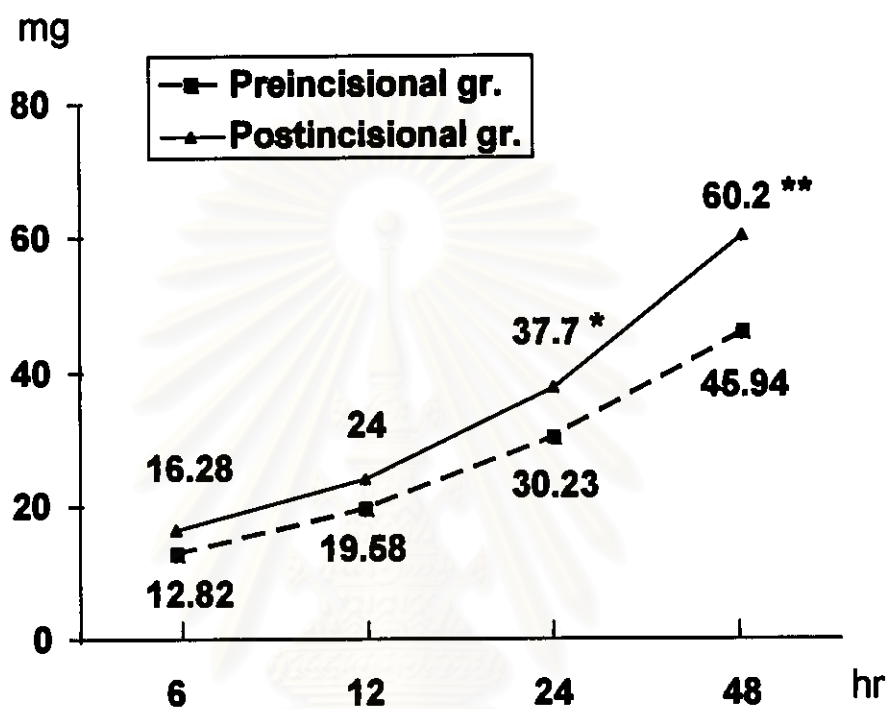


Fig 4.1 Comparison of mean value of analgesic consumption between pre- and postincisional groups
(* p value = .046 ; ** p value = .016)

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

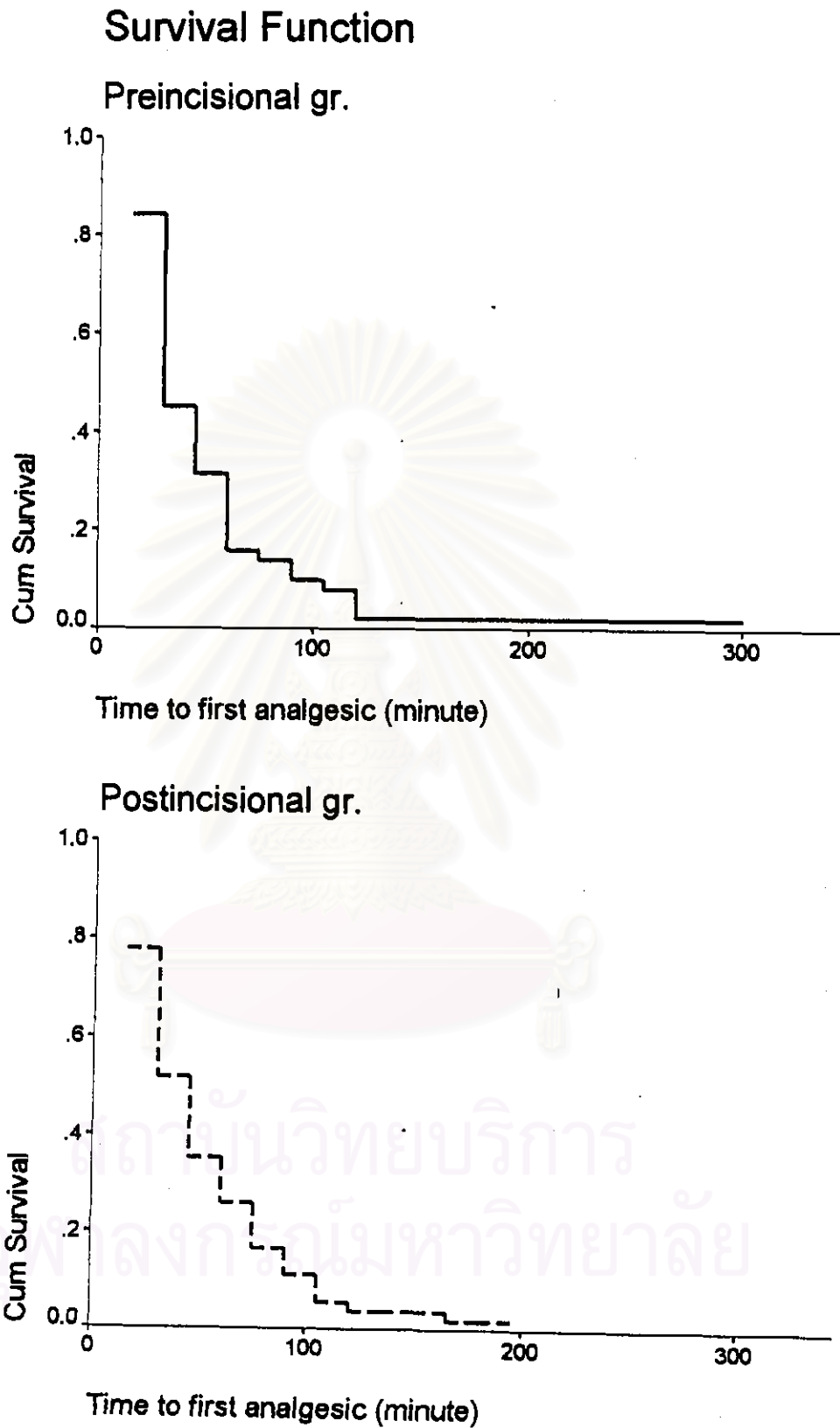


Fig. 4.2 Survival function of pre- and postincisional groups.

Table 4.3 Time to first requirement of analgesia in pre- and post-incisional groups.

	Median, interquartile	Mean Rank	p value
Preincisional (n = 51)	25 (15-45)	52.43	.852
Postincisional (n = 53)	30 (15-60.75)	53.54	

Mann-Whitney “U” test

We therefore concluded that the time to first requirement of analgesia in both groups were not significantly different.

4.3.2 The side effect rates

Three categories of side effects were compared between pre- and postincisional group by Chi-squared statistics. There were no statistically significant differences detected (Table 4.4).

Table 4.4 Side effects during immediate postoperative period

Side effects	Preincisional gr. n = 51	Postincisional gr. n = 54	p value
1. Nausea/vomiting	3 (5.9 %)	1 (1.9 %)	.354
2. Respiratory depression	0	0	
3. Others (eg. shivering, pain from urinary catheterization etc)	3 (5.9 %)	7 (13 %)	.217

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย