

## CHAPTER IV

### RESULTS

#### 4.1 Demographic and baseline data

A total of thirty-six patients who underwent unilateral total knee arthroplasty under spinal anesthesia who already presented in Postanesthetic Care Unit were enrolled in the study and were randomized to placebo (n = 15) or parecoxib sodium (n=21). The physical characteristics of the patients in both groups were comparable except age in study group was significantly higher than the control group; most patients were female (30). Regarding sex, body weight, height, ASA physical status, duration of tourniquet and duration of surgery, there were no significant differences between groups (Table 1).

Table 4.1 Demographic Characteristics, and Surgical Times of the two Study Groups

|   | Control<br>(N=15)  | Parecoxib<br>(N=21) |
|---|--------------------|---------------------|
| Sex (male/female)                             | 2/13               | 4/17                |
| Age (yr) ( Mean $\pm$ SD)                     | 65.40 $\pm$ 7.55   | 69.43 $\pm$ 4.43    |
| Height (cm) ( Mean $\pm$ SD)                  | 160 $\pm$ 5.8      | 159.24 $\pm$ 6.5    |
| Body weight (kg) ( Mean $\pm$ SD)             | 67.53 $\pm$ 13.3   | 60.52 $\pm$ 9.7     |
| ASA 1 (%)                                     | 5(33.3)            | 1(48)               |
| ASA 2 (%)                                     | 10(66.7)           | 20(95.2)            |
| Duration of Tourniquet (min) ( Mean $\pm$ SD) | 101.33 $\pm$ 16.95 | 96.43 $\pm$ 16.06   |
| Duration of Surgery (min) ( Mean $\pm$ SD)    | 112.33 $\pm$ 18.7  | 110.24 $\pm$ 18.5   |

#### 4.2 Primary outcome analysis

##### Morphine consumption

There were no significant differences in morphine consumption between study groups. Mean cumulative amounts of morphine consumed over 24 h were 27.67  $\pm$  14.72 mg in the placebo group, and 20.57  $\pm$  9.44 mg in the parecoxib sodium group (Table 4.2).

Table 4.2 Morphine consumption

|                                 | Control<br>(N=15) | Parecoxib<br>(N=21) | P-value | Mean<br>difference | 95%CI           |
|---------------------------------|-------------------|---------------------|---------|--------------------|-----------------|
| PCA 24 hrs morphine consumption | 27.67 ± 14.72     | 20.57 ± 9.44        | 0.115   | 7.1                | -1.865 – 16.055 |

#### 4.3 Secondary outcome analysis

##### 4.3.1 Pain intensity

Parecoxib sodium administered with morphine provided equal pain relief as morphine alone. There were no significant differences in pain intensity between the two groups at 24 hours end point (Table 4.3).

Table 4.3 Visual Analog Scale Pain Scores

|                       | Control<br>(N=15) | Parecoxib<br>(N=21) | P-value | Mean<br>difference | 95%CI           |
|-----------------------|-------------------|---------------------|---------|--------------------|-----------------|
| Pain scores at 24 Hrs | 36 ± 14.09        | 28.81 ± 11.94       | 0.108   | 7.19               | -1.653 – 16.034 |

##### 4.3.2 Adverse effects

The overall incidence of opioid-type side-effects between the two groups was similar. Incidences of nausea in both group was 33.3%. But an incidence of vomiting in study group was 4.8 % and control group was 13.3 %. There were no significant differences in vomiting between the two groups (Table 4). There were no other side effects detected.

Table 4.4 Postoperative Side Effects

|              | Control<br>(N=15) | Parecoxib<br>(N=21) | P-value |
|--------------|-------------------|---------------------|---------|
| Nausea (%)   | 5(33.3)           | 7(33.3)             | > 0.05  |
| Vomiting (%) | 2(13.3)           | 1(4.8)              | 0.559   |

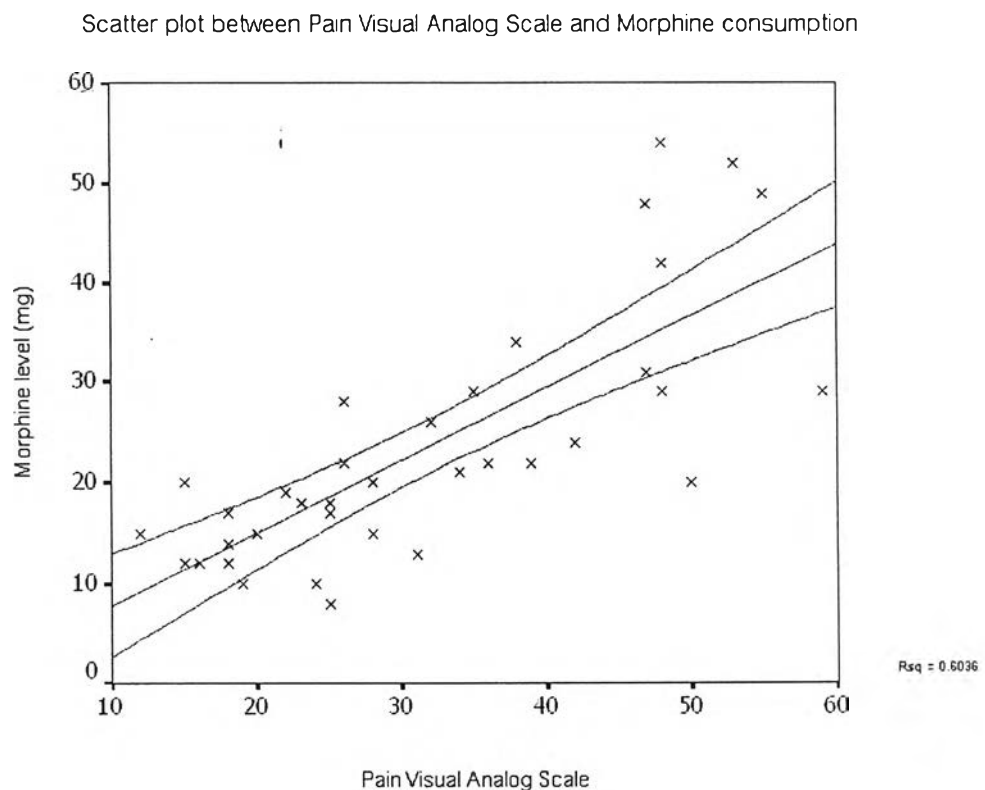
#### 4.3.3 Correlation coefficient between Pain Visual Analog Scales and Morphine level

Table 4.5 Correlation coefficient between Pain Visual Analog Scale and Morphine level

| Variables | Statistics  | MORPHINE |
|-----------|-------------|----------|
| PAINVAS   | Pearson     | .777(**) |
|           | Correlation |          |
|           | p-value     | <0.001   |
|           | N           | 36       |

\*\* Correlation is significant at the 0.01 level (2-tailed).

Figure. 4 Scatter plot between Pain Visual Analog Scale and Morphine Consumption



The relationship between visual analog scale and morphine consumption per day of the patients in this study showed a significant positive correlation at  $R^2$  equaled to 0.78 (p-value < 0.001).

The visual analog scale could be used to predict the level of morphine consumption per day with the equation of

$$\text{Morphine level} = 0.72X (\text{Pain Visual Analog scale}) + 0.57$$