CHAPTER 4
DATA ANALYSIS

GENERAL CONSIDERATIONS

The statistical analysis was focus on the detection of significant differences between the treatment and the control groups with respect to the maximum pain intensity during F/C as measured by 10-cm VAS.

Analyses of efficacy and adverse outcomes were based on per-protocol population.

All tests of hypotheses were conducted at the ***two-sided***, and ***0.05 level of significance***.

The statistical analysis was performed using SPSS for Windows, release11.0.1 (SPSS, Inc).

PLAN FOR STATISTICAL DATA ANALYSES

Baseline characteristics

The study groups were examined for comparability on their baseline characteristics. Statistical analysis was ***not*** applied to compare the baseline characteristics between the study groups. Owing to randomization, it was expected that the baseline characteristics of both groups would be comparable. However, if there was clinically significant difference between groups in some baseline variables that were potential to affect the primary outcome, these variables were planned to be statistically adjusted using multivariable analysis.

Efficacy analyses

Statistical analysis was performed to compare the outcomes between the two treatment groups. The statistical analysis was summarized in Table 4.1. Since the primary outcome (maximum pain score) was the continuous variable that was not normally distributed, non-parametric test was used primarily for the hypothesis testing. Because of small sample size, the ordinal data would be transformed to dichotomous data before statistical test was performed.

Safety analyses

The frequency of adverse events in both treatment and control groups were tabulated and presented with descriptive statistics. Test of statistical hypothesis was not applied because the adverse events were expected to occur in very low frequency.

Table 4.1 Summary of statistical analysis

Outcome	Statistical test
Primary efficacy variable	
▪ Maximum VAS pain score	Mann-Whitney U test
Secondary efficacy variables	
▪ Proportion of patients with maximum VAS pain score ≤ 4	Fisher's exact test
▪ Pain profile during the procedure	Unpaired t-test
▪ Proportion of patients requiring immediate post operative analgesic medication	Fisher's exact test
▪ Success rate of F/C	Fisher's exact test
▪ Patients' global satisfaction to treatment	Fisher's exact test
Safety variables	
▪ Adverse events	No statistical test