Study protocol with Statistical analysis plan

Title: The Effectiveness of Cancer Pain Management in Tertiary Hospital Outpatient in Thailand: Prospective observational study.

NCT: 03474406

Date of document: October 18th, 2020

Faculty location:

Pain Clinic, Department of Anesthesiology, Faculty of Medicine, Siriraj Hospital Mahidol University

2 Wang Lang Rd, Bangkok Noi, Bangkok, Thailand 10700

Study Protocol

With approval from the Siriraj Institutional Review Board (Number Si 622/2017) and registered ClinicalTrials.gov (NCT03474406), we conducted a prospective observational study of patients 18 years and older who received a new consult for cancer pain at the Siriraj Pain Clinic from January to December 2018. Written informed consent was obtained from all patients. We excluded patients who had difficulties with listening, reading, and writing Thai and those who were unable to interpret the evaluation form/questionnaires.

All patients enrolled in the study received standard care by pain specialists in the clinic. The WHO analgesic guidelines, selective consideration of pain interventions, and nurse-directed analgesic rescue program were implemented. Additionally, patients received a phone call as a reminder to attend follow-up visits. Patients were followed every 2-4 weeks based on physician judgment and pain severity.

Data collection and outcome measures

The primary outcome of this study was the percentage of patients defined as "pain responders" by either 30% reduction in pain intensity rating or pain intensity less than 4 at the third follow-up visit (FU3). Secondary outcomes included pain interference, other symptom scores, side effects, and analgesic prescribing and consumption.

Data were collected at baseline and at three follow-up times (FU1, FU2, FU3). Patients' baseline demographic data (age, gender, marital status, and education) and clinical characteristics (Cancer status, stage, and sites of involvement) were recorded. Pain severity, performance status, pain interference, other symptoms, side effects, pharmacological treatments and dosage, and patient satisfaction were recorded at every visit. We retrospectively reviewed palliative care medical records for additional data related to pain intensity, performance status, opioid

consumption, date of first palliative care visit, and dates of death, if applicable. Data were collected by research assistants, nurses, and physicians and entered into Case Report Forms.

Statistical analysis Plan

Analyses were performed using SPSS statistical package 21.0 (SPSS, Inc., Chicago, IL). Categorical data are reported as numbers and percentages, and continuous data are reported as median (IQR). Repeated measures designs used Friedman tests for continuous data and Cochran's Q for dichotomous data, with post-hoc comparisons at each time point using the Wilcoxon matched-pairs signed rank test for continuous variables, McNemar tests for dichotomous variables, and the Marginal Homogeneity test for a categorical variable with 3 or more values. Comparison of continuous variables between two independent populations was assessed using the Mann-Whitney test. Comparison between more than two independent populations was assessed using the Kruskal-Wallis test, with post-hoc Dunn's Bonferroni tests between groups. Variables with p-value<0.1 in the bivariable analyses were considered for entry in subsequent multivariable analyses. A significance level of 0.02 was chosen to account for repeated comparisons across 3 time points.