CHAPTER 3

RESEARCH METHODOLOGY

Research Design

This is a descriptive correlational study. The purposes of this study were to identify the pain intensity level, the anxiety level, and coping strategies of cancer patients in dealing with cancer-related pain patients, and to examine the magnitude of relationships among pain intensity, state anxiety, and coping strategies in cancer patients.

Population and Setting

The population of this study was all cancer patients attending the gynecological, radiology, surgical, and ENT (ear, nose, throat) wards of Dr. Kariadi Hospital between mid July and the third week of August 2004, who reported experiencing pain over the previous week and during the past 24 hours. Dr. Kariadi Hospital in Semarang, Central Java, Indonesia was purposively selected in this study to be a target setting for the following reasons:

1. It was the biggest hospital in Province of Central Java.
2. It had a high level of case referrals among all public hospitals in Central Java, that allowed the researcher to collect data from a number of patients that satisfied the minimum sample size needed for this study.

Sample

1. Sample Size

The sample size of this study was based on the sample size estimated by using power analysis (Polit & Hungler, 1999). The estimated sample size was calculated for an accepted minimum level of significance (α) of .05, an expected power of .80 ($1-\beta$) as the accepted minimum level of power of the test, and an estimated population effect size of .30 (γ) as the medium effect size used in most nursing studies. The effect size also could be estimated based on previous related studies, which had the same or similar problem (Polit & Hungler, 1999). Analyzing results from previous studies that examined the relationships between pain and coping in patients with phantom limb pain found $r = .33$ ($p < .01$) (Hill, 1993). One study that examined the correlation between anxiety and coping in patients with breast cancer scheduled for autotransplantation found $r = .22$ ($p < .05$) (Gaston-Johansson et al., 1999). Another study that examined the relationships between pain and anxiety in patients with breast cancer autologous bone marrow transplantation found $r = .43$ ($p < .001$) (Gaston-Johansson et al., 2000). Therefore, the researcher used the medium effect size of .30. To examine the relationships between two variables using Pearson r or Pearson correlation coefficient (r), the approximated sample size with the medium effect size should not be less than 88 patients (Polit & Hungler, 1999). Therefore, the actual number of the subjects involved in this study was 93 patients that had satisfied the minimum sample size determined by using power analysis to examine the magnitude of relationships among pain, anxiety, and coping strategies of cancer-related pain patients.

2. Sampling Technique

The sample consisted of 93 patients who were selected by convenience sampling from Dr. Kariadi Hospital, and to control the homogeneity of patients recruited for the study, the inclusion criteria were as follows:

2.1 Be adult cancer patients aged 35 years or above.

2.2 Be diagnosed of cancer disease.

2.3 Experienced pain during the past week and reporting having pain during the past 24 hours.

2.4 Be fully conscious.

2.5 Be able to communicate in Indonesian language.

Instrumentation

1. Instruments

Instruments used in this study were (1) Demographic Data and Disease-Related Form, (2) Pain Numeric Rating Scale, (3) State-Trait Anxiety Inventory (STAI), (4) Coping Strategies Questionnaires (CSQ), and (5) Interview Guide.

1.1 Part 1: Demographic Data and Disease-Related Form

This instrument was designed by the researcher to assess the demographic data of patients, such as age, gender, religion, level of education, marital status, occupation, income, diagnosis, stage of cancer, cancer treatments, site of pain, pain experience, prescribed pain medications, and pain medication used during the past 24 hours.

1.2 Part 2: Pain Numeric Rating Scale

Pain Numeric Rating scale was used to measure pain intensity. A number was

designed to the intensity of pain on a scale of 0 to 10, where 0 is "no pain" and 10 is "the worst pain possible" (Fitzgibbon & Chapman, 2001). The patients were asked to report their pain during the past 24 hours to what extent the pain was at its "worst", "least", and "average". They were also asked to rate their pain at the time of responding to the questionnaire (current pain). The "average" and "worst" pain score during the past 24 hours was used in the correlational analysis because one study found that the average pain has an adequate stability coefficient of scale in chronic pain patients (Jensen & McFarland, 1993), and the worst pain item has good reliability and validity to measure pain intensity in cancer patients (Lin, 1995 as cited in Petpichetchian, 2001).

1.3 Part 3: State-Trait Anxiety Inventory (STAI)

The STAI consists of separate self-report scales designed to measure A-State and A-Trait (Spielberger, 1983). The state form of the scale consisted of 20 items designed to measure how the subject felt at a particular moment. Scores indicate the level of transitory anxiety characterized by feelings of apprehension, tension, and autonomic nervous system induced symptoms: nervousness, worry, and apprehension. Meanwhile, the trait form of the scale consists of 20 items. It was designed to measure anxiety as a personality characteristic or stable enduring trait or to assess the individuals' predisposition to judge situations as dangerous or threatening and to respond with increased levels of state anxiety.

In scoring of STAI, each item is given a weighted score of 1 to 4. Patients rated themselves in relation to each statement on a Likert-type scale, with score: 1 = not at all, 2 = somewhat, 3 = moderately so, and 4 = very much so for A-State. For A-Trait, subjects rated the frequency of 20 T-Anxiety symptoms on the following a

Likert-type scale: 1 = almost never, 2 = sometimes, 3 = often, and 4 = almost always. A rating of 4 indicates the presence of high level of anxiety for ten A-State items and eleven A-Trait items (anxiety-present items). A high rating indicated the absence of anxiety for the remaining ten A-State items and nine A-Trait items (anxiety-absent items). The scoring weights for the anxiety-present items were the same as the rating scores of the test form. The scoring weights for the anxiety-absent items were reversed, i.e., responses marked 1, 2, 3, or 4 were scored 4, 3, 2, or 1, respectively. The anxiety-absent items for which the scoring weights were reversed on the A-State scales were 1, 2, 5, 8, 10, 11, 15, 16, 19, 20, and the A-Trait scales were 21, 23, 26, 27, 30, 33, 34, 36, and 39. The total score in each instrument (SAI or TAI) was the sum of all responses, with 20-39 = low anxiety, 40-59 = moderate anxiety, and 60-80 = high anxiety for State Anxiety scores (Spielberger, 1983).

1.4 Part 4: Coping Strategies Questionnaire (CSQ)

Pain coping strategies were measured using the CSQ developed originally by Rosensteil and Keefe (1983, as cited in Swartzman et al., 1994). The measurement consisted of 48 items that yielded scores on six cognitive coping strategy subscales: (1) Diverting Attention; (2) Re-interpreting Pain Sensations; (3) Ignoring Pain Sensations; (4) Coping Self-statements; (5) Praying and Hoping; (6) Catastrophizing; and two behavioral coping strategy subscales: (7) Increasing Pain Coping Behavior; and (8) Increasing Behavioral Activities. For each category of coping strategies, six items were listed on the CSQ, with possible total scores ranging from 0 to 36. Each item was rated on a 7-point scale (0 = never; 1 = almost never; 2 = rarely; 3 = sometimes; 4 = often; 5 = almost always; 6 = always) to indicate how often the strategy was used to cope with pain during the past week.

Cognitive coping strategies (CCS) consisted of 6 subscales including diverting attention, re-interpreting pain sensations, ignoring pain sensations, coping self-statements, praying and hoping, and catastrophizing with 6 items in each subscale. The researcher computed the CCS by averaging the score from each subscale, except for catastrophizing characterized by negative self-statements and thinking. In the present study, the researcher scored the catastrophizing items as negative coping strategies, but it was scored by reversing from the responses marked 0, 1, 2, 3, 4, 5, or 6 to 6, 5, 4, 3, 2, 1, or 0, respectively, when catastrophizing was computed in scoring of CCS; so, the higher score of CCS, the higher the frequency of using cognitive coping strategies.

The behavioral coping strategies (BCS) consisted of 2 subscales including increasing pain coping behavior and increasing behavioral activities, with 12 items. The BCS was scored by using the average score of the 2 subscales. The higher score of the BCS indicates the more frequent use of behavioral coping strategies.

The level of coping strategies was identified by using range order in low, moderate, and high level. The scores of cognitive coping strategies (CCS) were from 0 to 216, with 0-72 = low level, 73-144 = moderate level, and 145-216 = high level of CCS. The scores of behavioral coping strategies (BCS) were from 0 to 72, with 0-24 = low level, 25-48 = moderate level, and 49-72 = high level of BCS. The scores of each subscale of coping strategies were from 0 to 36, with 0-12 = low level, 13-24 = moderate level, and 25-36 = high level of coping strategies.

1.5 Part 5: Additional Questions (Interview Guide)

The additional questions consisted of 3 open-ended questions regarding the meaning of pain, and how the patients responded to their pain. These questions were

used to guide the researcher in interviewing the cancer patients with pain in relation to the culture. The results of interview were used to support the results of relationships among pain, anxiety, and coping strategies used by Indonesian cancer patients with pain.

2. *Validity and Reliability*

2.1 The Validity of Instruments

Prior to testing the validity and reliability of instrument, the original instrument had been translated into Indonesian language by using back translation technique. The content validity of STAI developed by Spielberger (1983) and CSQ developed by Rosensteil and Keefe (1983) were analyzed by five experts in pain, anxiety and coping before data collection. They comprised three experts, an anesthesiologist and a psychiatrist from Dr. Kariadi Hospital and a member of the Nursing Educational Program of Health Polytechnic in Semarang, Indonesia, and two experts from Prince of Songkla University, Thailand. The experts were asked to evaluate individual items. The issues in such an evaluation were whether individual items were relevant and appropriate in terms of the construct and whether the items adequately measured all dimensions of the construct. The researcher changed some items of Indonesian instruments to make it easier for the subjects' understanding based on the Indonesian experts' recommendations, without changing the meaning of the original English version.

2.2 The Reliability of Instruments

The STAI and CSQ translated into Indonesian language were analyzed for internal consistency reliability using Cronbach's alpha. The researcher conducted a

pilot study with 20 subjects who had the same characteristics as the population in this study. The coefficient reliability of STAI: the state anxiety was .94 and .89 for trait anxiety. A coefficient alpha of .95 was obtained for the total scale of CSQ, with coefficient alpha of .82 for cognitive coping strategies and .89 for behavioral coping strategies. The alpha coefficient of cognitive coping strategies subscales was .82, .89, .90, .86, .74, and .74 for diverting attention, re-interpreting pain sensations, ignoring pain sensations, coping self-statements, praying and hoping, and catastrophizing, respectively. While alpha coefficient of behavioral coping strategies subscales was .84 for increasing pain behavior and .69 for increasing behavioral activities. From these results, the alpha coefficients of the STAI and CSQ indicated that the instruments had good internal consistency. Furthermore, a significant correlation has been found in test retest reliability of trait anxiety; it was .89 over a day period in a sample of 20 cancer patients. This showed that the instrument of trait anxiety is presumably a fairly stable attribute that does not change markedly from one day to the next day (Polit & Hungler, 1999).

3. Translation of Instruments

The original instruments were developed in the English language. For this study, the English version of the instruments was translated into Indonesian language. The method of translation was back translation techniques and decentering. The back translation techniques and decentering are a translation process which ensures accuracy and a culturally equivalent version of an instrument translated to another language (Brislin, 1980).

The English version of the STAI and CSQ instruments that had been validated for content was translated into Indonesian version. Three bilingual translators who had ability in both English and Indonesian translated the instruments to obtain the accuracy of the translation and identify discrepancies between two versions (Burns & Grove, 2001). The process of back translation was conducted as follows:

1. The first bilingual translator translated the instruments from English version into Indonesian version.

2. The second bilingual translator did back translated of instrument from Indonesian version into English version.

3. The third bilingual translator then clarified and identified the discrepancies in some items between the two versions. Discrepancies in some items between two versions were overcome by changing, modifying, or adding words in translation process in order to convey the same meaning as the English version.

Protection of Human Rights

Permission for data collection was obtained from Ethical Committee of Nursing Faculty, Prince of Songkla University, Thailand and from Director of Dr. Kariadi Hospital in Semarang, Indonesia. The subjects who were willing to participate in this study were approached by the researcher and the subjects gave verbal consent to the researcher. The researcher explained to the subjects that they might withdraw at any time with no consequences to their nursing care. Then, the subjects were assured that the data would be kept confidential. The researcher protected the subjects' privacy through anonymity. The researcher used the coding system to identify the subjects. Anonymity and confidentiality of the subjects were protected at all times.

Data Collection

Data were collected after the research proposal was approved by the committee of Faculty of Nursing, Prince of Songkla University (PSU), Thailand, and the Director of Dr. Kariadi Hospital Semarang, Indonesia, where the study took place, agreed to data collection. The researcher informed to the head nurse of gynecology, radiology, surgery, and ENT wards about the objectives of this study and their participation during data collection. Review of the patients' medical records was carried out to obtain the information regarding patients' profiles related to their disease. Subjects who met the eligibility criteria were approached to participate in the study. The researcher explained to the subjects regarding the objectives, the outcomes of this study, and subjects' right. Then, patients who agreed to participate were required to give verbal consent and the researcher explained how to complete the questionnaires. First of all, the researcher assessed pain intensity (worst, least, average, current) of the patients who were reporting having pain during the past 24 hours, then asked them to complete the questionnaires of Demographic and Disease-Related Data Form, State-Trait Anxiety Inventory (STAI) and Coping Strategies Questionnaires (CSQ). After the patients finished answering the questionnaires, the researcher checked the questionnaires for incomplete answers. After that, the researcher continued to interview the patients about the meaning of cancer pain and how they responded to pain. The total time of data collection was approximately one hour per subject.

Data Analysis

The data were analyzed with Statistical Package for Social Science (SPSS) for version 10. The analysis included descriptive statistics and inferential statistics.

1. Descriptive Statistics

Descriptive statistics were used for presenting of the subject's demographics and disease-related data, pain, anxiety, and coping strategies of cancer patients. These were described in terms of frequency, percentage, mean, standard deviation (*SD*), and range.

2. Inferential Statistics

The assumptions of correlational analysis were conducted initially to test for normality and linearity, prior to running the parametric test. The Pearson's Product-Moment Correlation Coefficient (r) was used to test hypotheses concerning population correlation among the average and worst pain intensity, Anxiety-State, and coping strategies of cancer patients.

As Anxiety-Trait might confound the correlation coefficients being estimated, partial correlations of these variables (pain, Anxiety-State, Anxiety-Trait, and coping) were analyzed. Also, as pain medication taken by patients in the past 24 hours could be a confounder, it was carefully revised to examine whether it could contribute to the results of the correlational analysis. The subjects in this study received comparable pain medication, mostly non-opioids for pain relief. Therefore, no effort had been made to use the pain medication as a control variable.