

CHAPTER III

RESEARCH METHODS

3.1 Research Design

This study employed a descriptive correlational research design with a cross-sectional approach. A cross-sectional approach means the research is conducted at a single point in time, where the study subjects are observed or assessed only once, with no intervention applied (Notoatmodjo, 2018). This study explains the factors influencing pain in patients on mechanical ventilators using the Critical Care Pain Observation Tool (CPOT) assessment in the ICU of RSUD Ngudi Waluyo Wlingi.

3.2 Population, Sample, and Sampling Technique

3.2.1 Population

A population refers to the entire set of objects that will be studied (Notoatmodjo, 2018). In this research, the population consists of all patients using ventilators in the ICU of Ngudi Waluyo Wlingi Regional Hospital. The size of the population used is based on the average number of patients using mechanical ventilators monthly in a similar hospital, dr. Sostroatmodjo Regional Hospital, which is 30 patients.

3.2.2 Sample

A sample is a subset of the population, or a representative portion of the population being studied, from which data is collected. It should be able to represent the entire population. A sample can also be defined as a part of the total number and characteristics possessed by the population (Jailani et al., 2023). This study utilized a sample of patients using mechanical ventilators in the ICU of Ngudi Waluyo Wlingi Regional General Hospital. Determining the sample size must involve calculating the number of samples required for a study, as this aims to facilitate the researcher's execution of the research (Setyawan, 2017).

The sample studied consisted of patients using mechanical ventilators in the ICU of Ngudi Waluyo Wlingi Regional General Hospital during June 2025. In this study, the researcher drew the sample using Slovin's formula, which is:

$$n = \frac{N}{1 + N(e)^2}$$

Keterangan:

n : Sample size

N : Population size

e : Tolerable margin of error for sampling (0.05 or 5%)

$$n = \frac{N}{1 + N(e)^2}$$

$$n = \frac{30}{1 + 30(0,05)^2}$$

$$n = \frac{30}{1 + 30 (0,0025)}$$

$$n = \frac{30}{1,075}$$

$$n = 27,9$$

Based on the sample calculation using Slovin's formula, the result was 27.9. For rounding purposes, the total sample size for this study will be 28 samples.

3.2.3 Sampling Technique

Sampling technique refers to methods of sample selection that consider only specific aspects of a population (Ulfa, 2021). This study utilized a non-probability sampling technique. The specific sampling method employed in this research was purposive sampling. Purposive sampling is a sampling technique where samples are selected based on certain considerations (Suryani et al., 2023).

3.2.4 Research Sample Criteria

In this study, the sample used consists of a portion of the population that meets specific inclusion and exclusion criteria. Below are the inclusion and exclusion criteria for the sample in this research:

1. Inclusion Criteria

Inclusion criteria are the characteristics that every member of the population must possess to be included in the sample (Notoatmodjo, 2018). The inclusion criteria for this study are:

- a. Adult patients aged ≥ 18 years old.

- b. Patients who have been on mechanical ventilation for > 24 hours in the ICU of Ngudi Waluyo Wlingi Regional General Hospital.

2. Exclusion Criteria

Exclusion criteria are characteristics that, if present in a research subject, would disqualify them from the study; subjects meeting these criteria must be removed from the research process (Prihatiningsih, 2022). The exclusion criteria for this study are:

- a. Patients with stroke
- b. Patients with cancer/tumors.
- c. Patients with deep sedation.
- d. Patients with semi-coma or coma levels of consciousness.

3.3 Research Variabel

A research variable is an attribute, characteristic, or value possessed by a person, object, organization, or activity that has specific variations, which are determined by the researcher to be studied and from which conclusions are drawn (Sugiyono, 2016).

3.3.1 Dependent Variable

The dependent variable, also known as the outcome variable, is defined as the variable that changes due to the influence of the independent variable (Dharma, 2015). In this study, the dependent variable is pain, which will be measured using the Critical Care Pain Observation Tool (CPOT) assessment.

3.3.2 Independent Variables

The independent variables, or free variables, are characteristics of the subject variables whose presence causes changes in other variables (Dharma, 2015). In this research, the independent variables are age, gender, disease complications, surgery, level of consciousness, and duration of endotracheal tube (ETT) use.

3.4 Definisi Operasional Variabel

Table 3. 1 Operational Definitions of Variables for Analyzing Factors Influencing Pain in Patients on Mechanical Ventilators Using the Critical Care Pain Observation Tool (CPOT)

Variables	Operational Definition	Parameter	Measuring Tools or Instruments	Measuring Scale	Measurement Results
Age	Age of patient on ventilator	Age includes years counted from birth	Observation	Ordinal	“1” 18-25 years old “2” 26-54 years “3” 55-74 years
Gender	Sexual identity of patients on ventilators	Differences between men and women	Observation	Nominal	“1” Male “2” Women
Disease	Number of diseases suffered by patients on ventilators	Number of diseases currently being suffered	Observation	Ordinal	“1” 1 type of disease “2” 2 types of disease “3” more than 2 types of disease
Post Operative	Recent post-operative history of patients on ventilators	There is a history of post-operative	Observation	Nominal	“0” No “1” Yes
Level of Consciousness	The state of consciousness of patients on a ventilator	<i>Glasgow Coma Scale</i> - Eye - Verbal - Motoric	Observation	Ordinal	“1” Stupor (5-6) “2” Somnolence (7-9)

Variables	Operational Definition	Parameter	Measuring Tools or Instruments	Measuring Scale	Measurement Results
					“3” Delirium (10-11) “4” Apathy (12-13) “5” Compos Mentis (14-15)
Duration of endotracheal tube use	Duration of use of endotracheal tube in patients with ventilators	Time (in days) calculated from the first intubation process until the assessment is carried out	Observation	Ordinal	“1” 1 day “2” 2 days “3” more than 2 days
Painful	Pain will be measured at least 1x24 hours after endotracheal tube insertion	CPOT (Critical Care Pain Observation Tools) - Facial expressions - Body movements - Ventilator suitability - Muscle tension	Observation	Ordinal	“0” No Pain (0) “1” Mild Pain (1-2) “2” Moderate Pain (3-4) “3” Severe pain (5-6) “4” Very severe pain (7-8)

3.5 Operational Framework

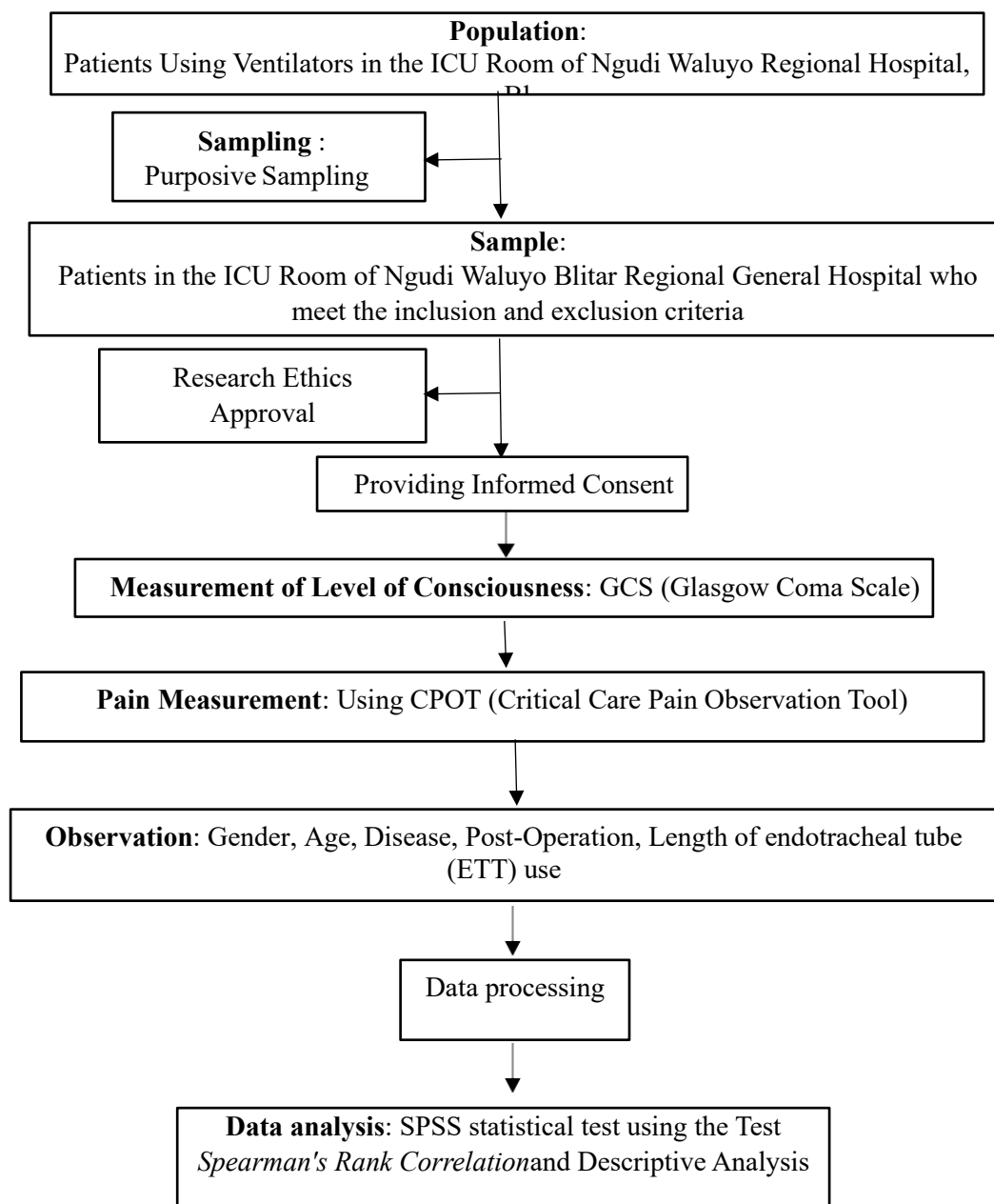


Figure 3. 1 Operational Framework for Analysis of Factors Influencing Pain in Patients on Ventilators Using Critical Care Pain Observation Tool (CPOT)

3.6 Research Instrument

In any research, collecting data that captures the facts or realities of life requires effective tools and methods to ensure the data gathered is valid, reliable, and current. An instrument is a measuring device used in research, adhering to principles of validity and reliability (Nursalam, 2014). For this study, the researcher will use an observation sheet comprising several research instruments, including:

1. Observation, this instrument will be used to gather data on age, gender, disease, and post-operative history. The observation used in this study is divided into:
 - a. Observation of respondent characteristics (name, age, and gender) through patient medical records
 - b. Observation of diseases suffered through medical record
 - c. Observation of post-operative history through patient medical record
 - d. Observation of the duration of endotracheal tube (ETT) use through patient medical records
2. Measurement of consciousness level using the Glasgow Coma Scale (GCS). The GCS has a sensitivity of 80% and a specificity of 77.8% (Oktarina & Simanjuntak, 2017).
3. Measurement of pain scores using the Critical Care Pain Observation Tool (CPOT). The CPOT has a sensitivity of 76.5% and a specificity of 70.8%, with an accuracy of 74.68% (Severgnini et al., 2016). The CPOT has a reasonably high sensitivity and lower specificity, meaning the instrument is

statistically weak but clinically significant, as shown by its good AUC (area under the curve) value, making it suitable for assessing pain in mechanically ventilated patients (Wahyuningsih, 2019).

3.7 Research Time and Place

3.7.1 Research Place

The research will be conducted in the ICU (Intensive Care Unit) of Ngudi Waluyo Wlingi Regional General Hospital

3.7.2 Research Time

The research will be carried out for 2 weeks, from June 9-21, 2025.

3.8 Data Collection Procedures

3.8.1 Administrative Procedures

1. Submit an introductory letter from the Applied Bachelor of Nursing Study Program in Malang to the Coordinator of Education and Training at Ngudi Waluyo Wlingi Regional General Hospital
2. Obtain research permission from the Coordinator of Education and Training at Ngudi Waluyo Wlingi Regional General Hospital

3.8.2 Technical Procedures

1. Prepare the research proposal
2. Conduct a proposal seminar and revise based on feedback from the examiners
3. Submit a research permit application to the Coordinator of Education and Training at Ngudi Waluyo Wlingi Regional General Hospital

3.8.3 Implementation Procedures

1. Identify research subjects and select them based on the established inclusion and exclusion criteria. This will involve reviewing their GCS scores, sedation history, diagnosed diseases, and ETT placement time from the daily observation sheets used by the ward
2. Record the patient's initials, age, gender, diseases, post-operative history, and duration of ETT use on the observation sheet prepared by the researcher
3. Conduct informed consent with the families of patients whose data will be used for the research
4. Perform data collection by measuring GCS and CPOT scores directly on the patients and recording them on the observation sheet.

3.9 Data Processing

After data collection, the obtained data will be organized in a way that facilitates presentation and analysis. The steps for data processing, according to (Notoatmodjo, 2018) include:

1. Editing (Data Editing)

The collected data from the observation sheets will undergo editing. This editing is done to check for any errors or deficiencies in the data gathered on the observation sheets.

2. Coding (Data Coding)

Once the data is collected, a coding process will be applied, converting words or sentences into numerical codes. This coding is used to simplify the process of data processing, analysis, and interpretation.

a. Age

- 1) 1 : 18-25 years old
- 2) 2 : 26-54 years old
- 3) 3 : 55-74 years old

b. Gender

- 1) 1 : Male
- 2) 2 : Female

c. Disease

- 1) 1 : 1 types of disease
- 2) 2 : 2 types of disease
- 3) 3 : more than 2 types of disease

d. Post Operative

- 1) 0 : No
- 2) 1 : Yes

e. Tingkat Kesadaran

- 1) 1 : Somnolence (5-6)
- 2) 2 : Stupor (7-9)
- 3) 3 : Derilium (10-11)
- 4) 4 : Apathy (12-13)
- 5) 5 : Compos Mentis (14-15)

f. Duration of endotracheal tube use

- 1) 1 : 1 day
- 2) 2 : 2 days
- 3) 3 : more than 2 days

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- 1) 0 : No pain (0)
- 2) 1 : Mild pain (1-2)
- 3) 2 : Moderate pain (3-4)
- 4) 3 : Severe pain (5-6)
- 5) 4 : Very severe pain (7-8)

3. Entry Data

After all the data obtained from the observation sheets have been coded, the next step is to enter the data into a computer system. The data entry process will be performed using SPSS.

4. Cleaning (Data Cleaning)

Cleaning is the process of reviewing the entered data. This involves checking for any missing data and examining the variations and consistency of the data.

3.10 Data Analysis and Presentation

3.10.1 Univariate Analysis

Univariate analysis aims to describe the characteristics of each variable (Notoatmodjo, 2018). This analysis will be performed to describe the respondent characteristics. In this study, univariate analysis will be used to

identify respondent characteristics, including patient age, gender, disease, surgery, level of consciousness, duration of endotracheal tube (ETT) use, and the frequency distribution of pain measured using CPOT.

Frequency distribution tables and percentages for each variable will be used to determine the respondent characteristics. The data analysis in this study will focus on the frequency analysis of each respondent characteristic. This analysis will be conducted after understanding the characteristics of the collected data, which are the observation results presented in frequency distribution tables. The interpretation of data results will be as follows (Sugiyono, 2019):

1. All: 100 %
2. Almost all : 76-99%
3. Most: 51-75%
4. Half : 50 %
5. Almost half: 26-49%
6. A small portion : 1-25 %
7. None : 0 %.

3.10.2 Bivariate Analysis

Bivariate analysis is data analysis performed to find correlations or influences between two or more variables under study (Sugiyono, 2019). In this research, bivariate analysis will be used to determine whether there is a relationship between the independent variables or factors and the dependent variable.

Table 3. 2 Bivariate Analysis

Independent Variable (X)	Dependent Variable (Y)	Bivariate Test
Age factor	Painful	<i>Spearman Rank</i>
Gender factors	Painful	<i>Spearman Rank</i>
Disease factors	Painful	<i>Spearman Rank</i>
Post-operative factors	Painful	<i>Spearman Rank</i>
Awareness level factor	Painful	<i>Spearman Rank</i>
Factors affecting the length of ETT (endotracheal tube) use	Painful	<i>Spearman Rank</i>

The correlation test applied in this study will be Spearman's Rank or Spearman's rho. In this research, bivariate analysis will be used to determine if there is a relationship between the existing factors and increased pain in the ICU (Intensive Care Unit) of Ngudi Waluyo Wlingi. Regional General Hospital.

Table 3. 3 Correlation Coefficient Value

Correlation Coefficient Value (r)	Connection
0.00-0.25	Very weak
0.26-0.50	Enough
0.51-0.75	Strong
0.76-0.99	Very strong
1.00	Perfect

The Sig value or p-value is used to determine whether the null hypothesis is accepted or rejected. A relationship is considered significant if the calculated Sig (2-tailed) value is less than 0.05. Conversely, if the Sig (2-tailed) value is greater than 0.05, the relationship between variables is considered not significant or meaningless.

To identify the most dominant factor among variables, the researcher will observe the highest correlation coefficient (r) value among them. The

highest coefficient value indicates that the independent variable has the greatest influence on the dependent variable.

3.10.3 Data Presentation

Data presentation refers to the way research findings are reported so they can be easily understood and analyzed according to the study's objectives. Data collected from respondents will be presented in crosstabulations, showing the relationships between variables and serving as a basis for drawing general conclusions in a narrative form.

3.11 Research Ethics

The researcher underwent an ethical review at the Health Research Ethics Committee of RSUD Ngudi Waluyo Wlingi and was declared ethically approved on June 10, 2025, with ethics number No. B/070/2275/409.52.4/2025. According to the Health Methodology Book (2023), research ethics are guidelines applicable to every activity involving researchers and research subjects, and researchers and the benefits of the research, ensuring that respondents benefit from the study. This research will adhere to ethical principles, specifically four core ethical tenets:

1. Respect for human dignity

When providing informed consent, researchers must respect the dignity and rights of respondents. In this study, the researcher will provide an informed consent form, if the respondent's family agrees to their family member being observed for the study, they will sign it. If they do not agree, the researcher will respect their right without coercion.

2. Respect for privacy and confidentiality

Data collection inherently involves disclosing individual information, including personal details, so researchers must protect these fundamental individual rights. In this study, the researcher will only record the initials of the respondents in the observations, not their full names or other personal data. Codes or sequential numbers will be used to differentiate data from respondents with the same name. The collected data will be used and processed solely for this research.

3. Respect for justice and inclusiveness

The principle of openness in research means that the research is conducted honestly, transparently, and professionally. The principle of justice means that the research should also provide benefits to the respondents. In this study, after observations are made and pain scores are obtained, this data can be used as an indicator for nurses to provide appropriate nursing care to patients.

4. Balancing harms and beneficence

The principle of balancing harms and beneficence means that researchers must consider the potential benefits and harms of their study. The researcher will conduct the study according to established procedures to obtain the maximum possible benefit for both the researcher and the respondents while minimizing any adverse impacts on the respondents. In this study, after observations are made and pain scores are obtained, this data can be used as an indicator for nurses to provide appropriate nursing care to patients.