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### **RESEARCH ARTICLE**



# COMPARISON OF THERAPY EFFECTS BETWEEN A SINGLE NON-STEROIDAL ANTI-INFLAMMATORY DRUG AND THE COMBINATION WITH MUSCLE RELAXANT ON THE DEGREE OF LOWER BACK PAIN

Santo Fitriantoro\*, Betty Soedaly

**\*Correspondence:** toroe.one@gmail.com Department of Neurology, HM Ryacudu General Hospital, Kotabumi, Lampung, Indonesia

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#### ABSTRACT

**Background**: Lower back pain often results from poor ergonomic practice, characterized by localized discomfort between the costal border and lower gluteus folds, lasting more than one day. Possible factors contributing to this condition include age, gender, body mass index, ergonomics, load, work life, smoking habits, physical activity, or sports habits.

**Objective**: This study aimed to examine the difference in therapy effects between a single non-steroidal anti-inflammatory drug (NSAID) (sodium diclofenac) and the combination of muscle relaxants (diazepam) against the severity of lower back pain. The degree of pain was assessed using the Alternative Method of Quantitative Pain Assessment (MAPKN) at HM Ryacudu Hospital, North Lampung. The sample consisted of 40 patients receiving medications at the Neurology Polyclinic.

Methods: A quantitative method was used with a descriptive comparative approach.

**Results**: The results showed that statistical analysis obtained a significance level of 0.737, indicating a normal data distribution. A paired sample t-test had a significance level of 0.000, which suggested a rejection of Ho and an acceptance of Ha.

**Conclusion**: Based on the results, the combination therapy of NSAID (sodium diclofenac) and muscle relaxant (diazepam) was more effective in reducing lower back pain than using only an anti-inflammatory drug.

Keywords: lower back pain, MAPKN, muscle relaxant, non-steroidal anti-inflammatory drug



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## Introduction

Lower back pain is a prevalent complaint often associated with work and physical activities. According to Kusumaningrum1, this condition often becomes an occupational health disorder that can affect an individual's productivity and quality of life. Lower back pain can stem from various factors, including problems with the spine, muscles, nerves, and other structures associated with support and mobility.<sup>2</sup> Long sitting posture can cause complaints of lower back pain. Poor sitting habits lead to muscle tension, increasing the risk of pain.<sup>3</sup> This problem is not only limited to old age but is also often experienced by young or adult individuals who live a less active lifestyle or spend a lot of time sitting.<sup>4</sup>

Excessive tension in lower back muscles causes damage to the surrounding tissue, triggering pain.<sup>5</sup> Therefore, it is essential to understand the risk factors associated with lower back pain and adopt appropriate preventive measures, such as maintaining good posture, exercising regularly, and avoiding uncomfortable or prolonged sitting positions.

People of all age categories, including productive adults, not only experience lower back pain but also complain about the condition. According to a study in the United States, middle-aged adults (30-60 years) are particularly vulnerable, with one in three adults under 65 years of age experiencing lower back pain each year.<sup>6</sup>

Incorrect ergonomics practices are a leading cause of lower back pain, defined as pain between the costal border and the inferior gluteal fold lasting more than one day. Factors include age, gender, body mass index, ergonomics, load, work period, smoking, and physical activities or sports habits.<sup>7</sup>

Pain can be a warning of actual or potential threats to the body. Pain indicates an actual or potential threat to the body, significantly impacting patients' biological, psychological, sociological, and economic conditions.<sup>8</sup> This leads to patients requesting treatment from various available clinical management options, with the majority focused on pharmacological therapy, one of which is the use of non-steroidal antiinflammatory drugs (NSAID).

The use of NSAID is the main focus in pain management by many medical practitioners. These drugs have been proven effective in reducing inflammation and pain, leading to frequent prescriptions to treat various types of pain, including lower back pain.9 NSAID use significantly assists patients in reducing pain symptoms and improving quality of life.<sup>10</sup> However, it is essential to realize that the use of NSAID is not without risk. Long-term use or in high doses can cause serious side effects, such as digestive tract disorders and kidney damage. The selection and use should be executed carefully according to individual needs and with appropriate medical supervision.

NSAIDs are the most common pain relievers used by more than 30 million people daily for chronic health problems such as rheumatoid, arthritis, osteoarthritis, and lupus. These drugs can also reduce inflammation, fever, swelling, and redness.<sup>10</sup>

A muscle relaxant reduces spasms, although limited evidence supports its efficacy in mitigating back pain or improving the patient's condition. The role remains controversial, with some references suggesting the combination of muscle relaxants and NSAIDs for mitigating lower back pain.

Various simple methods, including the Visual Analog Scale (VAS), Numerical Rating Scale (NRS), or Verbal Rating Scale (VRS), can be used to assess pain, but these methods remain very subjective. Validation test results of pain assessment method developed by Pain Working Group, Makassar, known as the "Alternative Method of Quantitative Pain Assessment (MAPKN)." The method offers a quantitative and objective pain evaluation, relying on the clinician's judgment rather than solely on the patient's report.<sup>11</sup>

In general, investigations on the therapeutic effect of a single NSAID (diclofenac sodium) and combination with muscle relaxant (diazepam) on the degree of lower back pain is a fascinating subject in the medical world. Lower back pain is one of the common complaints experienced by many individuals worldwide. Diclofenac sodium reduces inflammation and pain, while diazepam helps reduce muscle stiffness and relieve pain.

MAPKN method is often used to evaluate the therapeutic effect of the two drugs on the degree of lower back pain.<sup>12</sup> This quantitative approach allows the attainment of more accurate and measurable data regarding the level of pain felt by subjects.

This study provides a more profound understanding regarding the effectiveness of using a single NSAID compared to the combination with muscle relaxants in managing lower back pain. The combination offers a more optimal and individualized therapeutic approach for patients who experience complaints. The results are expected to significantly contribute to clinical practice in lower back pain management.<sup>13</sup> Furthermore, the information obtained can help health professionals select the most effective and safest treatment strategies for patients and minimize the risk of possible side effects.

The results offer a basis for further studies in developing a more innovative and effective therapy for treating lower back pain. Moreover, understanding the mechanisms and interactions between drugs will provide the best solutions to improve the quality of life.

## Methods

This study used a quantitative method with a descriptive and comparative approach. In general, a quantitative data analysis aims to test hypotheses established by individuals. The study was carried out at HM Ryacudu Hospital, North Lampung, on subjects receiving treatment at the Neurology Polyclinic. The samples comprised 40 individuals suffering from pain and receiving medication at the polyclinic, thereby providing sufficient representation for a more in-depth analysis regarding the therapeutic effects of combining NSAIDs with muscle relaxants.

As a retrospective study, data were collected from the medical records of patients to evaluate the therapeutic effects of using NSAID in combination with muscle relaxant (diazepam) on the degree of lower back pain. The quantitative assessment of pain method (MAPKN) was used to analyze existing data, allowing the evaluation of therapy effectiveness based on documented information. This retrospective study did not require the prospective collection of new data. Still, it relied on historical records to perform analyses and draw conclusions about the clinical outcomes of both treatment methods.

The use of statistical analysis in comparative studies is essential for several reasons. Statistical analysis allows for objective data assessment, reducing subjective data interpretation bias. It also validates the results by determining whether the observed differences between therapy groups are statistically significant, taking into account the variability of the data.

Statistical analysis supports evidence-based decision-making, helping to determine the effectiveness of interventions more clearly. This method also allows the generalization of results to a broader population and controls for confounding variables, ensuring that the observed effects are due to the intervention being tested. Statistical analysis also ensures that results can be reproduced, supporting verification and validation.

Data analysis was conducted through descriptive statistics, which were used to describe the characteristics of the study object based on sample or population data without performing analysis or drawing applicable conclusions for the general population. Furthermore, descriptive statistics include measures of mean, median, minimum, and maximum values, as well as standard deviation, following the methodology outlined by Sugiyono.<sup>14</sup> These statistics help to describe the distribution of data and variability, thereby allowing a better understanding of subjects' characteristics.<sup>15</sup>

The normality of data was tested using the Kolmogorov-Smirnov Test. At the same time, hypothesis testing was performed with the Paired Sample T-test, which is suitable for comparing the averages of two paired groups. This method allowed statistical evaluation of significant differences between the two groups.

## Results

#### 1. Descriptive Statistics Analysis

Table 1 presents the distribution of pain scores on the scale, with the minimum value recorded at 4 and the maximum value at 10. Additionally, the mean pain

Table 1. Descriptive Statistics Analysis Results for Class A

score for the group of patients who received only NSAIDs was 7.43, indicating the average pain level experienced by this group.

Descriptive Statistics								
Ν	Minimum	Maxim	num	Sum	Mean	Std. Deviation	Variance	
Scale Painful	40	4	10	297	7.43	1,448	2,097	
Valid N (listwise)	40							

Table 2 showed that the minimum and maximum pain scores on the scale were 3 and 9, respectively. The mean pain score for patients who received NSAIDs with muscle relaxants was 5.78. Upon conducting a

 Table 2. Descriptive Statistics Analysis Results for Class B

descriptive analysis of the two groups, a noticeable decrease in the degree of pain was observed, with both the minimum and maximum values reflecting a reduction in pain levels after treatment.

Descriptive Statistics									
Ν	Minimum	Maximum	Sum		Mean	Std. Deviation	Variance		
Scale Painful	40	3	9	231	5.78	1,423	2,025		
Valid N (listwise)	40								

#### 2. Kolmogorov Smirnov Normality Test

The normality of the data was assessed using the Kolmogorov-Smirnov Test, a statistical method commonly utilized to evaluate the distribution of data or to compare two samples, particularly when the data is in an ordinal form. This test is designed to determine whether the data significantly deviates from a normal distribution. The decision-making criteria for the Kolmogorov-Smirnov Test are outlined as follows:

- a. When the significance value (Asymp. Sig) is more significant than 0.05, the data is usually distributed.
- b. When the significance value (Asymp. Sig) is less than 0.05, the data is not normally distributed.

Table 3 showed that the significance value of 0.737 was more significant than 0.05, suggesting the data was normally distributed.

#### Table 3. Normality Test

One-Sample	Unstandardizeded Residuals			
Kolmogorov-Smirnov To	est			
Ν	40			
Normal Parameter	·S			
a,b				
Mean	0.0000000			
Std. Deviation	1.00623210			
Most Extreme Differen	nces			
Absolute	0.108			
Positive	0.108			
Negative	-0.077			
Kolmogorov-Smirno	<b>v Z</b> 0.684			
Asymp. Sig. (2-taile	<b>d)</b> 0.737			
Note: a. Test distribution	on is			
normal				
b. Calculated from da	ata			

#### 3. Paired Sample T-test

The paired sample t-test is a parametric statistical analysis method. This test aimed to determine whether there was a mean difference between two samples (two groups) of a mutual pair or related.

Hypothesis:

- a. Ha: There is a difference in therapeutic effects between a single NSAID (sodium diclofenac) and the combination with relaxant muscle (diazepam)
- b. Ho: There is no there is a difference in therapeutic effects between a single NSAID (sodium diclofenac) and the combination with relaxant muscle (diazepam)

Table 4 showed that the significance value was more significant than 0,000 and less than 0.05. Hence, Ha was accepted, and Ho was rejected. Therefore, it was concluded that there was a difference in therapy effects among samples who used relaxant muscle and those who did not.

Table 4. Sample T-test

Paired Samples Correlations						
		Ν	Correlation	Sig.		
Pair 1	Class A and Class B	40	0,707	0,000		

The decision-making criteria for the paired sample ttest are as follows:

a. When the significance value (Asymp. Sig) is more significant than 0.05, Ha is rejected, and Ho is accepted.

b. When the significance value (Asymp. Sig) is less than 0.05, Ha is accepted, and Ho is rejected.

## **Discussion**

This study was conducted at HM Ryacudu Hospital, North Lampung, with a sample of 40 people, namely 22 women and 18 men. The objective was to determine the difference in therapy effects between the use of a single NSAID and the combination with muscle relaxants in the treatment of lower back pain.<sup>17</sup> By incorporating a representative sample, this study aimed to provide a deeper understanding of the effectiveness of these two types of therapy in relieving lower back pain and the potential differences in effects between women and men.

The analysis showed that the group given only NSAID obtained a mean value of 7.43. Meanwhile, the group given the combination with muscle relaxant obtained a mean of 5.78. This difference shows a decrease in the degree of pain observed from minimum to maximum.<sup>16</sup>

In the combination therapy group, the degree of pain decreased from the minimum value, which decreased from 4 to 3, and the maximum value, which decreased from 10 to 9. These results show the potential for increasing therapeutic effectiveness when NSAID was combined with relaxant.

Further analysis was conducted using the Kolmogorov-Smirnov test to determine the normality of the data. Based on the results, a significance value of 0.737 was obtained, more significant than 0.05. Therefore, the data were considered normally distributed.

The results prove that the data used has a distribution close to normal. This allowed various parametric statistical methods that require assuming a normal distribution, thereby ensuring a more precise and accurate data analysis.<sup>18</sup> Following the confirmation of normal data distribution, the paired sample t-test was conducted to determine the possibility of a significant mean difference between the two groups. Based on the results in table 4, a significant value of 0.000 was obtained, which was less than 0.05. This shows that there is a significant difference between the two groups in terms of therapeutic effects.

The alternative hypothesis (Ha) was accepted, while the null hypothesis (Ho) was rejected. In other words, the therapeutic effect differed between the group that only used NSAID and the group that used a combination of muscle relaxants.<sup>19</sup> These results provide a deeper understanding of the potential benefits of combination therapies in managing lower back pain, which may aid in more effective clinical decision-making for patients.<sup>20</sup>

## Conclusion

In conclusion, this study found that samples who used NSAID (sodium diclofenac) and muscle relaxant (diazepam) experienced reduced pain compared to those who only used an anti-inflammatory drug. This result was proven with the paired sample t-test, which yielded a significance value of 0.000. Given that the significance value was less than 0.05, the alternative hypothesis (Ha) was accepted, while the null hypothesis (Ho) was rejected. In other words, the two groups significantly differed regarding therapy's effect on lower back pain.

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