

## Determination of the Effects of Change in Anxiety Level on Pain Perception in Patients who Present to Emergency Department due to Acute Pain: A Double Blind, Randomized, Controlled Trial

*Acil Servise Akut Ağrı Sebebiyle Başvuran Hastalarda Anksiyete Düzeyindeki Değişimin Ağrı Algısı Üzerindeki Etkisinin Saptanması: Randomize Kontrollü, Çift kör Çalışma*

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### ABSTRACT

**Aim:** The aim of this study is to determine the level of pain and anxiety, and to investigate the effect of standard analgesic treatment and additional anxiolytic treatment on pain and anxiety in patients who presented to the emergency department due to acute pain.

**Material and Methods:** This is a prospective, randomized, controlled, double-blind study. As the study group received dexketoprofen trometamol plus midazolam, the control group received dexketoprofen trometamol alone. At 0<sup>th</sup>, 30<sup>th</sup>, 60<sup>th</sup> and 120<sup>th</sup> minutes of treatment, patients' pain and anxiety levels were measured. Patients' overall anxiety levels were measured. The primary outcome measure was the comparison of pain and anxiety change at 0-30 minutes.

**Results:** The study was conducted with 90 patients in each group. The median pain change was 33.5 (IQR, 38) for the control group and 30 (IQR, 33) for the study group, and the mean difference was 3.5 (95% CI; -7.2 to 14.2). The median anxiety change was 9.5 (IQR, 41) for the control group and 20 (IQR, 40) for the study group, and the mean difference was -10.5 (95% CI; -24.37 to 3.37). The rescue therapy needed, treatment satisfaction and preference to the same treatment in the future were similar between the control and the study group, respectively (26.7% vs 40%, p=0.058; 64% vs 57%, p=0.770; 90% vs 89%, p=0.802).

**Conclusion:** In patients who present to the emergency department due to an acute pain complaint, adding anxiolytic treatment to the analgesic treatment does not contribute to a reduction of pain and anxiety.

**Keywords:** Acute pain, anxiety, emergency department, pain management

### ÖZ

**Amaç:** Çalışmanın amacı, acil servise akut ağrı sebebiyle başvuran hastaların ağrı ve anksiyete düzeylerini belirleyip standart ağrı kesici tedaviye ek olarak anksiyolitik tedavi vermenin ağrı ve anksiyete düzeyleri üzerindeki etkisini araştırmaktır.

**Gereç ve Yöntemler:** Bu çalışma prospektif, randomize, çift kör bir klinik çalışmadır. Çalışma grubuna deksketoprofen trometamol ve midazolam verilirken, kontrol grubuna sadece deksketoprofen trometamol verildi. Tedavinin 0, 30, 60 ve 120. dakikalarında hastanın ağrı ve anksiyete düzeyleri ölçüldü. Hastaların genel anksiyete düzeyleri ölçüldü. Birincil sonuç ölçümü hastaların 0-30. dakikalardaki ağrı değişimidir.

**Bulgular:** Çalışmada her gruba 90 hasta dahil edildi. Çalışma grubunda ağrı değişim medyanı 30 (IQR, 33), kontrol grubunda 33.5 (IQR, 38) tespit edildi. Ortalama değişim 3.5 (95% CI; -7.2 - 14.2) olarak saptandı. Çalışma grubunda anksiyete değişim medyanı 20 (IQR, 40), kontrol grubunda 9.5 (IQR, 41) tespit edildi. Ortalama değişim -10.5 (95% CI; -24.37 to 3.37) olarak saptandı. Kurtarıcı tedavi ihtiyacı, tedavi memnuniyeti ve uygulanan tedaviyi gelecekte de isteme oranları gruplar arasında benzerdi (26.7% vs 40%, p=0.058; 64% vs 57%, p=0.770; 90% vs 89%, p=0.802).

**Sonuç:** Acil servise akut ağrı şikayetiyle başvuran hastalarda ağrı kesici tedaviye anksiyolitik tedavi eklemek ağrı ve anksiyete düzeylerinin azalmasına katkı sağlamamaktadır.

**Anahtar Kelimeler:** Akut ağrı, anksiyete, acil tıp, ağrı yönetimi

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## Introduction

Pain is a common health problem; it accounts for 78-84% of emergency department (ED) visits (1,2). Since pain is one of the major reasons for presentation to the ED, emergency physicians must focus on pain relief, detection of the cause of the pain, and prevention of pain dominance to evaluate the patient objectively. Pain sensation is also an obstacle for proper history taking and physical examination. As the pain is relieved, better patient care will be provided. Unrelieved pain prolongs the stress response, adversely affecting the patient's recovery (3). Anxiety is frequently observed together with pain. Approximately 60% of patients in the ED demonstrate pain-related anxiety (4). Previous non-ED clinical studies show that as the anxiety reduces, the chronic pain or post-operative pain perception reduces (5). Analgesics and sedatives are integral for the relief of pain and anxiety in critically ill patients (6). In addition, anxiety and pain relationship in the patients who present to the ED with acute pain remains controversial. Some studies reported that higher anxiety levels were related to higher pain scores whereas, some reported that adding anxiolytics to analgesics offers no advantage to the standard treatment (4,7).

The aim of this study is to determine the level of pain and anxiety in patients who present to the ED with acute pain, and to investigate the effect of the standard analgesic treatment and an additional anxiolytic treatment on pain and anxiety.

## Material and Methods:

### Study Design

This was a single centre, prospective, randomised, double-blind study. This centre was an academic ED with 35000 ED visits per year. The study was approved by the local ethics committee (KOU KAEK 2013/147). Written consent was obtained from each participant.

### Study Order and Population

The study was conducted with the patients who presented consecutively to the ED with acute pain between June 2013 and December 2013. Acute pain is defined as pain that started in the last 12 weeks (8).

### Inclusion criteria

The patients who presented to the ED with acute pain (headache, flank pain or musculoskeletal pain)  
Who accepted to include the study  
Who were older than 18 years old

### Exclusion criteria

History of allergy to any of the study drugs  
Pregnancy  
Chronic pain  
Antidepressant or anxiolytic drug use  
Advanced kidney or liver failure  
Use of analgesics within 6 hours before presentation

### Study Protocol

After triage, each acute pain patient who qualified for the study was asked for consent. Written informed consent was obtained from all patients who were eligible for the study. After obtaining written informed consent, demographic and clinical data were collected and recorded by the attending physician. Our study consisted of two parallel groups.

Participants were randomly assigned into two groups with a 1:1 allocation following simple randomization procedures by a program ([www.randomization.com](http://www.randomization.com)) generating an online random number. The study group was given analgesic plus anxiolytic, dexketoprofen trometamol (Arveles®, UFSA ILAC SANAYI VE TICARET AS, Istanbul, Turkiye) plus midazolam (Dormicum® DEVA ILAC SANAYI VE TICARET AS, Istanbul, Turkey) and the control group was given only the same dose of the analgesic drug dexketoprofen trometamol. Both groups received the study drugs in 100 mL of normal saline within 5 minutes. The dexketoprofen trometamol dose was 50 mg, and the midazolam dose was 1 mg. The study was double-blind. Sequenced study medications were prepared by a nurse, and another nurse administered the medications. In patients with an insufficient improvement of pain after 60 minutes, fentanyl (TALINAT®, VEM ILAC SANAYI VE TICARET LTD STI Istanbul, Turkiye) 1 mcg/kg IV was administered as a rescue medication.

Pain and anxiety in patients were measured at 0, 30, 60 and 120 minutes using the standard 100 mm horizontal visual analogue scale (VAS). The patient's general anxiety states were measured with the Turkish adopted version of the Hospital Anxiety and Depression Scale (HADS) which contains seven questions to determine general anxiety level of the patient in anxiety scale and each question on the questionnaire is scored from 0 to 3. Therefore, HADS scale might be scored between 0 to 21 points range. Patients who have greater than 10 points are assumed anxious (9). Depression part of the HADS scale was not used in the study. The HADS and VAS scores were measured and recorded to the database by the researcher. At the time of discharge, patient satisfaction with treatment was evaluated by asking two questions with the 5-step Likert scale. The questions were, "I am satisfied with the applied treatment", and "I would like the same treatment applied again". Patient answers were, "1-I strongly disagree", "2-I disagree", "3-I am not sure", "4-I agree", and "5-I strongly agree".

### Outcome Measures

The primary outcome measure was determined as the change in pain levels between groups on the visual analogue scale at 0-30<sup>th</sup> minutes. The secondary outcome measures were the change in anxiety levels between groups on the visual analogue scale at 0-30<sup>th</sup> minutes, general anxiety levels according to the HADS scale, the need for rescue treatment at 60<sup>th</sup> minute and at 120<sup>th</sup> minute the rate of the request for the same treatment again on the Likert scale, and the comparison of the pain and anxiety change on the visual analogue scale in patients who have a greater anxiety score.

### Statistical Analysis

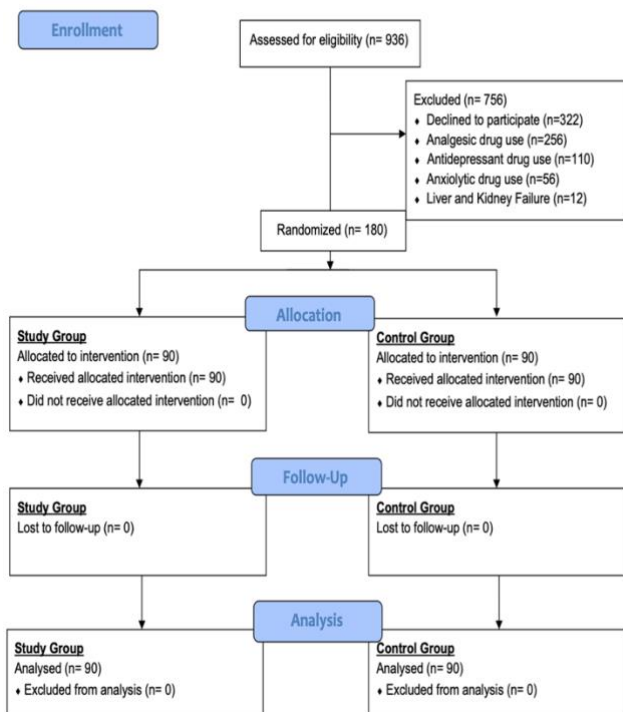
Data were analysed using SPSS version 13.0 (SPSS Inc. Chicago, USA). The normality of the distribution of the data was assessed with the Kolmogorov-Smirnov test. The continuous variables were analysed using a range between median and quartiles, and the categorical variables were analysed with percentages. The Chi-square test was used to compare the rate of independent groups. The Mann Whitney U test was used for comparison between the groups. Owing to the skewed distribution of the response variable, the median of the changes in this study would be more meaningful than the mean of the changes. Therefore, the mean of the changes between the treatment groups was

calculated with the confidence interval of the medians description by Bonnet & Price (10). The Spearman correlation test was performed to determine the relationship of pain and anxiety between the groups.  $p < 0.05$  was considered statistically significant. The number of subjects required for the study was calculated with the G\*Power program (G\*Power 3.1.3, Franz Faul, Kiel University, Kiel, Germany). We determined the sample size 80 for each group to achieve 0.90 power,  $\alpha = 0.05$  and a standard deviation of 25 for 15 mm VAS (visual analogue scale) difference.

**Results**

During the study period, 936 patients presented with complaints of acute pain. 756 patients were excluded from the study for various reasons, and the study was conducted with 180 patients (Figure 1).

**Consort Flow Diagram**



**Figure 1.** Consort flow diagram

The demographic characteristics of the patients in both groups were similar (Table 1). The patients who had anxiety were 34 (38%) in the study group and 35 (39%) in the control group. The proportion of those diagnosed with renal colic at discharge was not similar between the two groups ( $p = 0.006$ ).

The median value of the pain score at the baseline was 70 (IQR, 27) in the study group and 73.5 (IQR, 33) in the control group. The median pain score at 30 minutes was 32 (IQR, 45) in the study group and 25.5 (IQR, 40) in the control group (Figure 2). The mean of the changes in the pain levels among the treatment groups was -3.5 (95% CI; 14.2 to -7.2) (Table 2).

The median anxiety score at the baseline was 52 (IQR, 58) in study group and 52.5 (IQR, 79) in control group.

Characteristics	Study (n=90)	Control (n=90)	p values
Age (median, IQR)	35 (24-44)	35.5 (24-49)	0.78
Male (%)	45 (50)	46 (51.1)	0.88
Education (%)			0.47
Primary School	30 (33.3)	39 (43.8)	
Junior High School	12 (13.3)	9 (10.1)	
Senior High School	17 (18.9)	12 (13.5)	
University	31 (34.4)	29 (32.6)	
Comorbidity (%)			
Hypertension	14 (15.6)	13 (14.4)	0.83
Diabetes Mellitus	1 (1.1)	3 (3.3)	0.62
CAD	2 (2.2)	2 (2.2)	
Migraine	4 (4.4)	1 (1.1)	0.36
Kidney stone	3 (3.3)	3 (3.3)	
Other	2 (2.2)	9 (10)	0.019
Clinical Findings			
HADS (median, IQR)	7.5 (5-12)	7.5 (5-11)	0.92
Discharge Diagnosis (%)			
Headache	39 (43.3%)	44 (48.9%)	0.45
Renal colic	23 (25.6%)	9 (10%)	0.006
Muscle-skeletal Pain	28 (31.1%)	34 (37.8%)	0.34
Other	0 (0%)	3 (3.3%)	0.24

IQR=interquartile range; CAD=coroner artery disease; HADS=hospital anxiety and depression scale

**Table 1:** Demographic data of study patients

The median anxiety score at 30 minutes was 13.5 (IQR, 42) in study group and 20 (IQR, 49) in control group (Figure 3). The mean of the changes in the anxiety levels among the treatment groups was 10.5 (95% CI; 3.37 to -24.37) (Table 2).

	Study	Control	Mean of the changes
<b>Pain change (median, IQR)</b>	30 (33)	33.5 (38)	-3.5 (95% CI, 14.2 to -7.2)
<b>Anxiety change (median, IQR)</b>	20 (40)	9.5 (41)	10.5 (95% CI, 3.37 to -24.37)

IQR=interquartile range

**Table 2:** Pain and anxiety change (delta) values of groups at 0 – 30<sup>th</sup> minutes

The patients who were assumed as anxious since their HADS score were greater than 10 points were analysed separately. A total of 69 (38.3%) anxious patients included to the analysis. There were 34 patients (38%) in the study group and 35 patients (39%) in the control group. The median pain change was found to be 31.5 (IQR, 30) in the study group and 35 (IQR, 39) in the control group. The mean of the changes in the pain levels between the treatment groups was -3.5 (95% CI, 19 to -12) in the anxious patients. The median anxiety change was found to be 24.5 (IQR, 36) in the study group and 14 (IQR, 54) in the control group. The mean of the changes in the anxiety levels between the treatment groups was 10.5 (95% CI, 11.38 to -32.38) in the anxious patients.

Change in anxiety level on pain perception

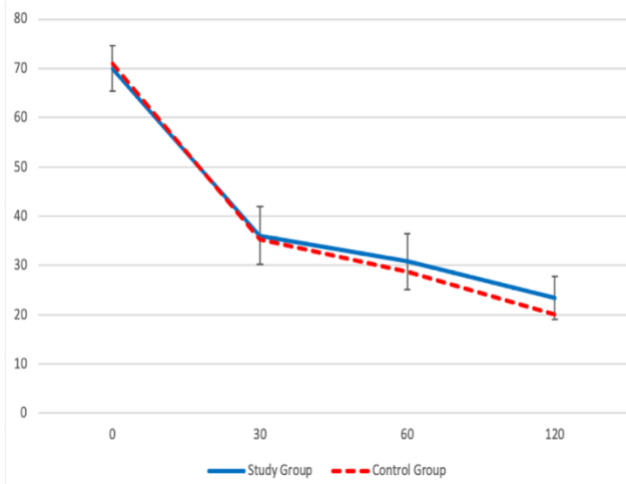


Figure 2. Study and control group pain change graph

In order to determine the relationship between pain and anxiety, the intra-group correlation of changes in pain and anxiety was evaluated. There was a positive correlation between the pain and anxiety levels in the study group (Rho: 0.599;  $p < 0.001$ ). There was no correlation between the pain and anxiety changes in the control group (Rho: 0.274;  $p = 0.144$ ).

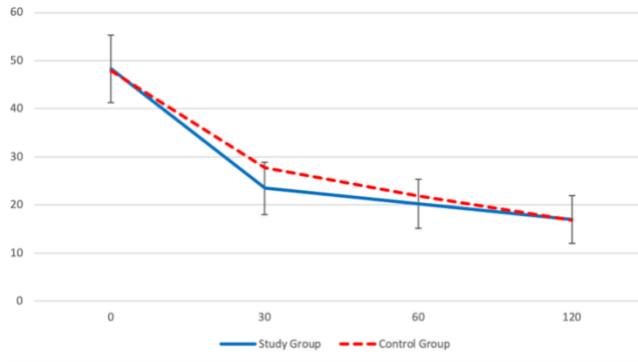


Figure 3. Study and control group anxiety change graph

There were no serious adverse events with the study drugs. After the fentanyl implementation, a symptomatic hypotension occurred in one of the patients. After a fluid resuscitation, the symptoms improved.

The rate of need for additional treatment at the 60<sup>th</sup> minute was 40% in the study group and 26.7% in the control group ( $p = 0.058$ ). 57% of the patients in the study group and 64% of the patients in control group stated that they were very satisfied with the treatment ( $p = 0.770$ ). 89% of the patients in the study group and 90% of the patients in the control group stated that they would prefer the same treatment in the next emergency visit ( $p = 0.802$ ).

**Discussion**

This prospective, randomized double-blind study failed to show the presence of any statistically significant difference in VAS of pain between study groups when treating patients with acute pain in the ED. The VAS of anxiety also did not differ between the groups. HADS scores, the rate of need for additional treatment and the mean of the changes in the pain and anxiety levels in patients who have a greater anxiety score were similar between two groups.

There was no statistically significant difference in the pain perception between the two groups. The relationship

	Study Group Level of Pain Measured by VAS	Control group Level of Pain Measured by VAS	P values
Baseline (median, IQR)	70 (58-85)	73 (56-89)	0.60
30 <sup>th</sup> minute (median, IQR)	32 (14-58)	25 (12-52)	0.68
60 <sup>th</sup> minute (median, IQR)	29 (14-64)	24 (0-73)	0.40
120 <sup>th</sup> minute (median, IQR)	24 (0-48)	3 (0-29)	0.05
	Study Group Level of Anxiety Measured by VAS	Control group Level of Anxiety Measured by VAS	P values
Baseline (median, IQR)	52 (18-76)	52 (0-79)	0.97
30 <sup>th</sup> minute (median, IQR)	13 (0-42)	20 (0-49)	0.53
60 <sup>th</sup> minute (median, IQR)	18 (0-46)	14 (0-56)	0.99
120 <sup>th</sup> minute (median, IQR)	5 (0-38)	8 (0-25)	0.71

IQR=interquartile range; VAS=Visual Analog Scale

Table 3: Pain and anxiety levels of the patients at 0, 30<sup>th</sup>, 60<sup>th</sup>, and 120<sup>th</sup> minutes

between acute pain and anxiety is unclear. There are few studies conducted on this issue, specifically in the ED. Previous studies have shown differing effects of anxiety on pain perception. Craven et al. reported that higher anxiety scores were found to be related to higher pain scores (4). In accordance with the Craven et al.'s findings Kapoor et al. reported that pain intensity was associated with the state anxiety (11). In contrast, Behrbalk et al. reported that an anxiolytic adjunct to morphine analgesia for acute low back pain relief in the ED showed no advantage over morphine alone (7).

In our study, 51.6% of the patients who were assessed with the HADS scale were anxious. Similarly, previous studies identified a general anxiety rate of the Turkish population as 55.6% (12). The general anxiety level in the patients of this study was consistent with this data. According to the U.S. National Institute of Mental Health, the anxiety rate in women is 60% higher than the rate in men (13). In our study, the general anxiety rate in women was also higher than the rate in men. Our study also demonstrated that acute anxiety is a common problem in patients presenting to the ED due to pain. This result is consistent with previous studies (14).

In previous studies, Shillington et al. evaluated that whether a therapeutic conversation with an ED nurse was effective on patient satisfaction who was on acute pain and found that this has no effect on pain management (15). The underlying reason of these results might be that pain perception may be affected by many factors and a therapeutic conversation is the only one dimension of these factors during the pain management. In contrast, Lefebvre et al. found that mood changes directly affect the experience of acute pain (16).



Mocha Chai et al. reported that in patients with acute low back pain, anxiety levels are associated with pain levels (17). Oktay et al. evaluated pain and anxiety during the IM diclofenac administration and proposed that anxiety is associated with pain. However, they did not evaluate the relationship between instant anxiety and pain (18). Craven et al. evaluated pain and anxiety scores with the VAS and found a relationship between anxiety and pain in the ED; however, this study included patients with diagnoses of anxiety disorders and chronic pain (4). In our study, we excluded the patients with diagnoses of anxiety disorders and chronic pain, and we examined the relationship between instant anxiety and pain.

We examined whether or not the patients without anxiety affected the study results. A subgroup analysis was performed for the anxious patients. There was no significant difference on pain perception and anxiety levels between the two groups.

As a result of our study, there is no difference in terms of analgesic efficacy between analgesics alone and the use of an anxiolytic with analgesic in the patients who presented to the emergency service with acute pain. More randomized controlled studies on this subject are needed in the future.

Our study has several limitations. Since this study was conducted in a single academic ED, the results cannot be generalized. Pain types were classified in the study, but the primary etiological factor causing the pain was not specified. Types of pain were not evaluated independently. For example, migraine or tension-type pain may respond differently to therapy. We expect our study to be a beginning point for studies to evaluate the efficiency of combination of NSAIDs and benzodiazepines in particular pain types.

In this study, the pain and anxiety scores of the patients were measured at the baseline, 30, 60 and 120 minutes. After the treatment, for those patients who stated that they wanted to leave the emergency medical service, changes in the pain and anxiety at 0-30 minutes were evaluated. The anxiety and pain scores of these patients were not measured separately. Patients' complaints, such as headache and low back pain, may be caused by different reasons. In this study, symptomatic treatment was conducted in order to reduce pain but not according to etiology. Study patients were patients with an acute pain complaint in different features, and a single analgesic treatment was dispensed to patients with different characteristics. However, since there was a significant reduction in pain in all subgroups, it is thought that the results are affected by the application of the same analgesic to pain in different regions. In this study, pain levels of the patients were not classified as mild, moderate and severe. Since patients with severe pain were given the same NSAID treatment, the reduction in the pain level might have been insufficient. However, there was no significant difference in the rate of patients with severe pain, and patients' pain in both groups was significantly reduced with the NSAID treatment. The patients in our study were consistently medicated with 1 mg of midazolam according to the recommended initial IV dose for anxiolysis but if this dose is not enough, supplemental IV doses is recommended to achieve and maintain the desired effect so for some patients 1 mg midazolam might not be enough to reach the desired anxiolysis. In this study, midazolam and

dexketoprofen trometamol were delivered in same saline solution; it was administered in this way because there is no known drug interaction. Patients evaluated pain and anxiety subjectively. Even patients without a significant reduction in pain evaluated their satisfaction as "I strongly agree". Since this was not the aim of the study, there is no evaluation of these results.

## Conclusion

In conclusion anxiety is frequently observed in patients who present to the ED with an acute pain complaint. However, additional anxiolytic treatment to analgesic treatment does not contribute to the treatment of pain and anxiety in these patients.

**Conflict of Interest:** The authors declare no conflict of interest regarding this study.

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**Authors' Contribution:** AEO, and MP conceived the study, designed the trial, and supervised the conduct of the trial and data collection. AT and HA collected the data. MP and UT provided statistical advice on study design and analyzed the data. AEO and MP drafted the manuscript, and all authors contributed substantially to its revision. AEO takes responsibility for the paper as a whole.

**Ethical Statement:** The study was approved by the local ethics committee (KOU KA EK 2013/147). Also this study was registered to Clinical Trials with NCT03420911 ID number. All authors declared that they follow the rules of Research and Publication Ethics.

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