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The Comparative Efficacy of Intravenous Ibuprofen 400 mg and 800 mg in Acute Mechanical Low Back Pain: A Prospective, Randomized, Double-Blind Clinical Study

Acil Serviste Akut Mekanik Bel Ağrılarında Ibuprofen 400 Mg and 800 Mg Intravenöz Formlarının Analjezik Etkilerinin Karşılaştırılması: Prospektif, Randomize Klinik ve Çift Kör Çalışma

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ABSTRACT

Objective: This study aimed to compare the analgesic efficacy of intravenous (IV) ibuprofen at doses of 400 mg and 800 mg for acute mechanical low back pain.
Methods: A Prospective, randomized, double-blind controlled clinical trial design was employed. Patients with moderate to severe acute low back pain were recruited from emergency departments. Ethical approval was obtained, and patients provided written consent. The study adhered to ethical guidelines and Good Clinical Practice principles.
Results: Of the 144 patients, demographic characteristics were similar between groups. The 800 mg IV ibuprofen group demonstrated superior analgesic efficacy compared to the 400 mg group, with no significant adverse effects reported.
Conclusion: The study concludes that the 800 mg IV dose of ibuprofen was more effective in providing analgesia control for patients with acute mechanical low back pain at all time intervals except for the 30th minute.
Keywords: Acute low back pain, ibuprofen, intravenous, analgesic efficacy, randomized controlled trial

ÖZ

Amaç: Bu çalışmanın amacı, akut mekanik bel ağrısı için intravenöz (IV) ibuprofenin 400 mg ve 800 mg dozlarının analjezik etkinliğini karşılaştırmaktı.
Yöntemler: Orospektif, randomize, çift-kör kontrollü klinik bir çalışma tasarımı kullanıldı. Orta ila şiddetli akut bel ağrısı olan hastalar çalışmaya dahil edildi. Etik onay alındı ve hastalar yazılı onay verdiler. Çalışma etik kurallara ve İyi Klinik Uygulama prensiplerine uygun olarak yürütüldü.
Bulgular: 144 hastadan, demografik özellikler gruplar arasında benzerdi. 800 mg IV ibuprofen grubu, 400 mg grubuna göre üstün analjezik etkinlik gösterdi ve önemli bir yan etki rapor edilmedi.
Sonuç: Çalışma, akut mekanik bel ağrısı olan hastalarda 800 mg IV ibuprofen dozunun, 30. dakika hariç tüm zaman aralıklarında analjezi kontrolü sağlamada daha etkili olduğunu sonuçlandırdı.
Anahtar Kelimeler: Akut bel ağrısı, ibuprofen, intravenöz, analjezik etkinlik, randomize kontrollü çalışma

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Introduction

Low back pain is a common ailment affecting a significant portion of the population at some point in their lives, with mechanical factors often being the underlying cause. This condition tends to be more prevalent among women and becomes increasingly frequent after the age of 40 (Dogan et al., 2022). Recent data over the past five years highlights low back pain as a leading cause of physical impairment on a global scale. In fact, it ranks as the second most common reason for hospital admissions, following upper respiratory tract infections such as colds (Traeger et al., 2019).

Patients grappling with acute low back pain can regain their regular daily activities through a combination of medical interventions and supportive care (Dixit, 2013). Analgesic medications play a pivotal role in alleviating the pain experienced by individuals with lumbalgia, enabling them to maintain their normal routines. These analgesics may include oral, intravenous (IV), and topical non-steroidal anti-inflammatory drugs (NSAIDs)(Sullivan et al., 2007). In clinical practice, patients admitted to hospitals with low back pain have been treated with various agents, including acetaminophen and nimesulide, in addition to ibuprofen (Ibu)(Friedman et al., 2020; Ostojic et al., 2017; Pohjolainen et al., 2000). The mechanism underlying the analgesic effects of these non-selective NSAIDs involves the inhibition of both the COX-1 and COX-2 pathways, which ultimately leads to a reduction in the release of prostaglandin precursors. This, in turn, mitigates the cellular response to pathological and physiological stimuli, providing pain relief (French, 2005).

Both 400 mg and 800 mg IV forms of ibuprofen are approved for use in cases of low back pain. However, this study represents a recent examination comparing the analgesic efficacy of these two IV doses of ibuprofen against the backdrop of earlier literature on low back pain. The primary objective of this study is to assess and compare the analgesic efficacy of 400 mg and 800 mg IV ibuprofen doses in managing moderate and severe pain in patients experiencing acute low back pain.

Methods

Study Design and Setting: The study followed a multicenter, prospective, randomized, double-blind controlled clinical trial design. The study included patients with moderate to severe acute low back pain, characterized by Numeric Rating Scale (NRS) scores greater than 4 and Rolland Morris Disability Questionnaire (RMDQ) scores exceeding 5. Patient recruitment took place in the emergency departments of two tertiary-level hospitals. Ethical approval for the study was granted by the Clinical Research Ethics Committee of Atatürk University Hospital (Ethics Committee No: B.30.2.ATA.0.01.00/681). This study was also registered via Clinical Trials.gov (NCT06064175).

Before participating in the study, all patients were provided with detailed information about the objectives and procedures of the study, and written consent was obtained. This study adheres to the principles of the Helsinki Declaration and follows the Good Clinical Practice principles. The study was conducted in accordance with the CONSORT guidelines.

Patient Selection: Patients presenting to both emergency departments with complaints of acute low back pain and having RMDQ> 5 were included in the study. Patients between the ages of 18 and 65, hemodynamically stable, without additional diseases, providing an NRS (Numeric Rating Scale)> 4 pain score, having no history of adverse reactions to the study drugs, conscious, fully oriented, cooperative, not considering different differential diagnoses, willing to be discharged home, and agreeing to participate in the study were enrolled.

Exclusion criteria involved patients who were not willing to participate in the study, pregnant or lactating, allergic to any of the drug groups under investigation, having any contraindications to the use of these drugs, having other pre-existing diagnoses, not suitable for home discharge, having additional diseases (such as hypertension, kidney failure, liver disease, COPD, heart failure, diabetes, etc.), using analgesic drugs within the last 6 hours, mentally retarded or uncooperative, hearing impaired, and those with underlying organic neurological and psychiatric disorders.

Sample Size: The sample size was determined using G-Power 3.1 software, and a power analysis was conducted, referencing the study by Tuzun et al. (2009), which involved patients with acute low back pain. To ensure 80% statistical power and a 5% type-1 error rate, the number of patients to be included in each group was calculated to be at least 28, with a ,5 effect size. Taking into account potential data losses and dropouts during follow-up, a total of 160 patients were planned to be enrolled in the study, with 80 patients in each group.

Intervention: The randomization process was overseen by the principal investigator and involved the creation of a randomization table using the website https://www.randomizer.org/. Each code, along with the corresponding dose of Ibuprofen (Ibu), was documented on paper within opaque envelopes. These envelopes were numbered sequentially to indicate the order of opening. The entire procedure was closely monitored by SD and E.T.

Once an eligible patient was enrolled, a comprehensive medical history was obtained, and their admission vital signs were reviewed and documented. Additionally, their pain intensity was assessed using the 11-point Numeric Rating Scale (NRS), ranging from "no pain" (0) to "worst possible pain" (10) at both ends.

Study nurses, who were unaware of the study's protocol and instructed not to reveal the Ibuprofen dose, opened the sealed envelopes. They then added the prescribed Ibuprofen dose to 100 ml of saline solution and handed it to the attending nurse before leaving the area. The prepared treatment was administered to the patient as a rapid infusion, ensuring it did not exceed 5 minutes. Consequently, neither the patient, the treating physician, nor the nurse administering the drug at that moment were aware of the treatment dose.

The remaining 120 minutes of the work period were completed, during which time the rescue drug treatment protocol was initiated. This involved adding 100 mg of tramadol hydrochloride to 500 ml of saline solution for patients whose pain score did not show improvement at 30 minutes or those with an NRS score greater than 4 at 60 minutes. Vital signs, NRS scores, and any occurrences of side effects were meticulously recorded at baseline (0), 15, 30, 60, and 120 minutes.

Definition: The Roland Morris Disability Questionnaire (RMDQ) is a tool employed to assess patients' low back pain. It comprises 24 items, with a scoring range of 0 to 24. A score of 0 signifies no impairment, while a score of 24 indicates the highest level of impairment (Friedman et al., 2020).

The Numeric Rating Scale (NRS) is a pain assessment scale that assigns numerical ratings to pain levels, using a scale from 0 to 10. On this scale, "0" represents the absence of pain, while "10" represents the most intense and severe pain (Firdous et al., 2017).

Outcomes: As a result, the case report forms recorded age, gender, presence of chronic diseases, vital signs, presenting complaint, duration of complaint, pain localization, pain radiation, RMDQ score, previous analgesic use, timing of analgesic use if applicable, administered treatment, NRS pain scores at 0, 15, 30, 60, and 120 minutes, whether rescue medication was used, and the presence of side effects. The primary outcomes included pain scores at 15-30-60-120 minutes and the degree of pain score reduction during the 0-15, 0-30, 0-60, and 0-120 minute periods. Secondary outcomes, such as the need for rescue analgesics and drug-related side effects, were evaluated. Comparative analysis of these data was conducted between the two groups.

Statistical Analysis: The statistical analysis was conducted using IBM SPSS for Windows 16.0 software. To compare categorical data, Pearson Chi-Square and Fisher's Exact tests were employed in the study. For continuous data, a distribution analysis was carried out using the Shapiro-Wilk test. When data did not follow a normal distribution, the Mann Whitney-U test was utilized to compare medians between the two groups. The results of this analysis are presented as medians and interquartile ranges. Furthermore, the Kruskal Wallis test was applied when comparing data that did not exhibit a normal distribution among more than two groups. The level of statistical significance was set at $P< .05$.

Results

Of the 144 patients participating in the study, 71 (49.3%) patients received a dose of 800 mg ibuprofen, while 73 (50.7%) patients received 400 mg ibuprofen. Demographic characteristics during follow-up (gender, age, height and weight, body mass index, analgesic use, hours ago last analgesic use, Rolland Morris Disability Questionnaire, side effects, need for rescue medication) were consistently equally distributed between the two groups (Table -1). Remarkably, only one patient in the Ibu 400 mg group reported experiencing side effects manifesting as nausea. In Table 2, the characteristic features (agitation) that can be seen and occur secondary to pain and the findings describing the characteristics of the pain itself (time of onset of symptoms, localization, radition of pain, NRS values at the time of measurement) are given. It was observed that the data were normally distributed and there was no statistical difference between the groups. The comparison of the groups based on body mass index (BMI) revealed that baseline pain scores were also homogeneously distributed (Table 3). However, as shown in Table 4 and Figure 1, according to the change in pain scores at different time intervals according to the arrival NRS scores, statistically significant differences were observed in favor of the 800 mg group, except for the 0-30 minute interval(0-15 min [p = .04], 0-30 min [p = .1], 0-60 min [p = .007], 0-120 min [p = .008]).

Discussion

This study is the first clinical trial to compare two different doses of ibuprofen (400-800 mg) in the treatment of lower back pain, employing a randomized, double-blind clinical study.

Table 1.
Demographics And Baseline Statistics

Variables		Main groups				
		800 mg		400 mg		p-value
		n (%)	Median (IQR)	n (%)	Median (IQR)	
Gender	Male	46 (64.8)		40 (54.8)		.222*
	Female	25 (35.2)		33 (45.2)		
Age- year			39 (30-50)		39 (32-46)	.892†
Height- cm			171 (163-177)		168 (163-174)	.238†
Weight- kg			77 (67-86)		75 (66-85)	.426†
BMI groups	...-24.9	23 (32.4)		25 (34.2)		.973*
	25-29.9	33 (46.5)		33 (45.2)		
	30-...	15 (21.1)		15 (20.5)		
BMI			25.9 (24.1-29.7)		26.6 (24.0-29.3)	.962†
Symptom time- hours			48 (24-118)		28 (12-96)	.092†
Agitation		14 (19.7)		16 (21.9)		.745*
Localization	Right	17 (23.9)		15 (20.5)		.601*
	Middle	26 (36.6)		33 (45.2)		
	Left	20 (28.2)		15 (20.5)		
	Bilateral	8 (11.3)		10 (13.7)		
Pain radiation	None	29 (40.8)		27 (37.0)		.163*
	Right	18 (25.4)		10 (13.7)		
	Left	14 (19.7)		18 (24.7)		
	Bilateral	10 (14.1)		18 (24.7)		
Analgesic use		30 (42.3)		37 (50.7)		.311*
Analgesic use- hours before			10 (8-20)		10 (8-16)	.563†
RMDQ			16 (11-21)		16 (11-21)	.911†
NRS-0			8 (7-10)		8 (7-9)	.477†
NRS-15			6 (5-7)		7 (4-8)	.380†
NRS-30			5 (3-6)		5 (3-7)	.499†
NRS-60			2 (1-4)		3 (2-5)	.081†
NRS-120			1 (1-3)		2 (1-3)	.111†
Side effect		0 (0.0)		1 (1.4)		1.000‡
Rescue drug		13 (18.3)		25 (34.2)		.030*

* Pearson Chi-square test
† Mann Witney-U test
‡ Fisher's Exact test

Table-2.
Body Mass İndex And Pain Scale

Variables		Median (IQR)	p-value
Initial NRS in BMI groups	...-24.9	8 (7-10)	.833
	25-29.9	8 (7-9)	
	30-...	8 (7-9)	
Kruskal Wallis test			

Table 3.
NRS Differences in Two Main Groups

Numerical rating scale	Main groups				
	800 mg		400 mg		p-value
	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	
Difference of 0-15 minute	2 (1-3)	2.4 (1.4)	2 (0-3)	1.9 (1.7)	.043
Difference of 0-30 minute	4 (2-5)	3.6 (1.8)	3 (2-4)	3.1 (2.0)	.103
Difference of 0-60 minute	6 (4-6)	5.3 (1.8)	5 (3-6)	4.4 (2.1)	.007
Difference of 0-120 minute	6 (6-8)	6.6 (1.5)	6 (5-7)	6.0 (1.4)	.008
Mann Whitney-U test					

Lower back pain is a prevalent issue experienced by many individuals at some point in their lives, making it one of the most common problems among people(Hoy et al., 2010). While one study reported the highest incidence of lower back pain in the third decade of life, another cohort study indicated that it was most frequent between the ages of 35 and 44(Hoy et al., 2010; Skovron, 1992). In contrast to these findings, our study observed the highest frequency of acute lower back pain in individuals in their forties, showing both agreement and disagreement with existing literature. Additionally, while some studies have suggested a higher prevalence of lower back pain among women compared to men, our study yielded the opposite result(Dogan et al, 2020). We attribute this difference to socio-cultural factors, regional variations, and the fact that our study was conducted in proximity to workplaces.

The association between an increase in body mass index (BMI) and the frequency of lower back pain has been previously documented(Skovron, 1992). Consistent with this, our study identified a positive correlation between a higher BMI and the incidence of lower back pain, with approximately 66% of patients having a BMI of 25 or above.

In a study comparing diclofenac 50 mg and ketorolac 10 mg to 600 mg ibuprofen tablets (tb), pain scores and Roland Morris Disability Questionnaire (RMDQ) values were assessed at the time of emergency department admission and on the fifth day. The results indicated no significant differences between these medications in terms of pain relief, RMDQ values, or side effect profiles (Irizarry et al., 2021). Similarly, another study by Doğan et al. involved 210 patients and compared paracetamol 100 mg, ibuprofen 400 mg, and dexketoprofen 50 mg in intravenous forms. This study found no statistically significant differences in pain relief among these medications (Dogan et al., 2020). In a separate study comparing ibuprofen-acetaminophen tablet combinations to the use of ibuprofen tablets with a placebo, no significant differences were observed between the two groups when patients were reassessed on the 2nd and 7th days (Dixit, 2013). However, in another study comparing ibuprofen 400 mg tablets to a combination of ibuprofen 200 mg and acetaminophen 325 mg tablets, the combination therapy was reported to provide more effective pain relief (Ostojic et al., 2017). Additionally, a study comparing ibuprofen 400 mg tablets to ketorolac 30 mg IV administration for pain control after laparoscopic cholecystectomy revealed that ibuprofen had lower analgesic efficacy and a higher need for rescue medication (Lee et al., 2022). Conversely, in a similar study comparing IV doses of ibuprofen 800 mg and ketorolac 30 mg after arthroscopic knee surgery, ibuprofen demonstrated better analgesic efficacy and a reduced need for rescue medication (Uribe et al., 2018). A study involving patients with migraine headaches compared IV doses of ibuprofen at 200 mg and 400 mg, and both doses were found to be superior to placebo with similar efficacy (Codispoti et al., 2001). In another placebo-controlled study for postoperative pain control, IV doses of ibuprofen at 400 mg and 800 mg were shown to have significant and comparable efficacy compared to placebo (Southworth et al., 2009). Moreover, in a review conducted by Derry et al., it was reported that the use of increasing doses of ibuprofen in the treatment of pain, such as after dental operations, showed a proportional relationship in pain control, with higher doses resulting in more significant efficacy (Derry et al., 2009).

In the context of the present study focusing on acute low back pain, it was found that ibuprofen at a dose of 800 mg provided more effective pain relief. Importantly, no side effects were reported with either dose of the drug. This suggests that increasing the dose of ibuprofen or combining it with other drugs can enhance its analgesic effectiveness.

Study Limitations: The number of patients in the study could have been higher. In this case, it could have further increased the power of the study. Additionally, since it was a study conducted in the emergency department, patient follow-up periods could not be extended further once the patient was relieved.

Conclusion

When considering the NRS, BMI, RMDQ values, and demographic characteristics of our patients, it was observed that the baseline values were statistically similar. This allowed us to obtain more accurate results regarding the effectiveness of medication doses in the study. As a result, it was statistically determined that the 800 mg IV dose was more effective in providing analgesia control for patients with acute mechanical low back pain at all time intervals except for the 30th minute.

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Genişletilmiş Özet

Bel ağrısı, hayatlarının bir noktasında insanların büyük bir kısmını etkileyen yaygın bir rahatsızlıktır ve genellikle mekanik faktörler bu durumun altında yatar. Son beş yıllık veriler, bel ağrısının dünya genelinde fiziksel yetenek kaybının önde gelen nedenlerinden biri olduğunu göstermektedir. Üst solunum yolu enfeksiyonlarından sonra hastaneye başvuruların ikinci en yaygın nedeni olarak bel ağrısı öne çıkmaktadır. Akut bel ağrısı yaşayan hastalar, tıbbi müdahaleler ve destekleyici bakımla günlük aktivitelerine geri dönebilirler. Analjezik ilaçlar, lumbalji yaşayan bireylerin ağrısını hafifleterek günlük rutinlerini sürdürmelerine olanak tanır. Bu analjezikler arasında oral, intravenöz (IV) ve topikal nonsteroid antiinflamatuvar ilaçlar (NSAİİ'ler) bulunur. Klinik uygulamada, hastanelere bel ağrısı şikayetiyle başvuran hastalar, ibuprofen (Ibu) dışında parasetamol ve nimesulid gibi çeşitli ajanlarla tedavi edilmiştir. Bu non-selektif NSAİİ'lerin analjezik etkilerinin altında yatan mekanizma, hem COX-1 hem de COX-2 yolaklarının inhibisyonunu içerir, bu da prostaglandin öncüllerinin salınımının azalmasına yol açar. Bu, hücresel yanıtın patolojik ve fizyolojik uyarıcılara karşı hafiflemesini sağlar ve ağrıyı dindirir.

400 mg ve 800 mg IV ibuprofen formları, bel ağrısı vakalarında kullanımı onaylanmıştır. Ancak, bu çalışma, bel ağrısı üzerine önceki literatürle karşılaştırıldığında bu iki IV ibuprofen dozunun analjezik etkinliğini değerlendiren yakın tarihli bir incelemeyi temsil etmektedir. Bu çalışmanın birincil amacı, akut bel ağrısı yaşayan hastalarda 400 mg ve 800 mg IV ibuprofen dozlarının analjezik etkinliğini değerlendirmek ve karşılaştırmaktır.

Çalışma, prospektif, randomize, çift kör kontrollü bir klinik çalışma tasarımına sahiptir. Çalışma, Numerik Derecelendirme Ölçeği (NRS) skorları 4'ün üzerinde ve Rolland Morris Disability Questionnaire (RMDQ) skorları 5'in üzerinde olan orta ve şiddetli akut bel ağrısı olan hastaları içermektedir. Hasta alımı, iki üçüncü basamak hastanenin acil servislerinde gerçekleştirilmiştir. Çalışma için etik onay, Atatürk Üniversitesi Tıp Fakültesi Klinik Araştırmalar Etik Kurulu tarafından verilmiştir.

Çalışmaya katılmadan önce tüm hastalara çalışmanın amacı ve prosedürleri hakkında ayrıntılı bilgi verilmiş ve yazılı onay alınmıştır. Her iki acil servise akut bel ağrısı şikayetiyle başvuran ve RMDQ > 5 olan hastalar çalışmaya dahil edilmiştir. 18-65 yaş arası, hemodinamik olarak stabil, ek hastalığı olmayan, NRS > 4 ağrı skoru sağlayan, çalışılan ilaçlara karşı advers reaksiyon öyküsü olmayan, bilinçli, tam yönelimli, işbirlikçi, farklı ayırıcı tanılar düşünmeyen, evde taburculuk talep eden ve çalışmaya katılmayı kabul eden hastalar çalışmaya alınmıştır.

Örneklem büyüklüğü, G-Power 3.1 yazılımı kullanılarak belirlenmiş ve güce dayalı bir analiz yapılmıştır. Tuzun ve ark. çalışmasına referansla %80 istatistiksel güç ve %5 tip-1 hata oranı sağlamak için her gruba dahil edilecek hasta sayısı en az 28 olarak hesaplanmıştır. Takip sırasında olası veri kayıpları ve düşüşleri dikkate alarak, çalışmaya toplam 160 hastanın alınması planlanmış, her grupta 80 hasta bulunmuştur.Randomizasyon süreci, baş araştırmacı tarafından yönetilmiş ve randomizasyon tablosu bir web sitesi kullanılarak oluşturulmuştur. Her bir kod ve karşılık gelen ibuprofen dozu, opak zarfların içine yazılmıştır. Bu zarflar, açılma sırasını gösterecek şekilde ardışık olarak numaralandırılmıştır. Prosedür, SD ve E.T. tarafından yakından izlenmiştir. Uygun bir hasta kaydedildikten sonra, kapsamlı bir tıbbi öykü alınmış ve kabul vital bulguları gözden geçirilip belgelenmiştir. Ayrıca, ağrı yoğunluğu 11 puanlık Numerik Derecelendirme Ölçeği (NRS) kullanılarak değerlendirilmiştir. Çalışma protokolünü bilmeyen ve ibuprofen dozunu açıklamaması talimatı verilen çalışma hemşireleri, kapalı zarfları açmış ve belirlenen ibuprofen dozunu 100 ml salin çözeltisine eklemişlerdir. Hazırlanan tedavi, hastaya hızlı bir infüzyon olarak uygulanmış ve 5 dakikayı geçmemiştir. Roland Morris Disability Questionnaire (RMDQ), hastaların bel ağrısını değerlendirmek için kullanılan bir araçtır ve 24 maddeden oluşur. Skor aralığı 0 ile 24 arasındadır; 0, hiç bozukluk olmadığını, 24 ise en yüksek bozukluk düzeyini belirtir. Numerik Derecelendirme Ölçeği (NRS), ağrı seviyelerine sayısal dereceler veren bir ağrı değerlendirme ölçeğidir ve 0'dan 10'a kadar bir ölçek kullanır. Bu ölçekte "0" ağrı olmadığını, "10" ise en yoğun ve şiddetli ağrıyı temsil eder.Çalışmaya katılan 144 hastadan 71'i 800 mg ibuprofen dozu alırken, 73'ü 400 mg ibuprofen dozu almıştır. Takip sırasında demografik özellikler iki grup arasında eşit olarak dağıtılmıştır. Sadece bir hasta Ibu 400 mg grubunda bulantı şeklinde yan etki bildirmiştir. Ağrıya ikincil olarak görülebilen özellikler ve ağrının kendine özgü özelliklerini tanımlayan bulgular normal dağılım göstermiştir ve gruplar arasında istatistiksel fark olmadığı gözlemlenmiştir. Gruplar arasında vücut kitle indeksi (BMI) bazında karşılaştırma yapıldığında, başlangıç ağrı skorlarının homojen olarak dağıldığı belirlenmiştir. Ancak, başlangıç NRS skorlarına göre farklı zaman aralıklarındaki ağrı skoru değişikliklerine göre 800 mg grubunun lehine istatistiksel olarak anlamlı farklar gözlemlenmiştir. Bu çalışma, akut bel ağrısı tedavisinde iki farklı ibuprofen dozunu (400-800 mg) karşılaştıran ilk klinik çalışmadır. Çalışmada elde edilen bulgular, 800 mg IV ibuprofen dozunun 400 mg dozuna kıyasla daha etkili olduğunu göstermektedir. Bu sonuç, akut bel ağrısı olan hastalarda daha yüksek dozlarda veya kombine tedavilerin analjezik etkinliği artırabileceğini göstermektedir. Çalışmanın bazı sınırlamaları arasında, hasta sayısının daha yüksek olmasının çalışmanın gücünü artırabileceği ve acil serviste gerçekleştirildiği için hasta takip sürelerinin daha uzun olamayacağı bulunmaktadır. Sonuç olarak, akut mekanik bel ağrısı olan hastalarda, başlangıç NRS, BMI, RMDQ değerleri ve demografik özellikler dikkate alındığında, 800 mg IV dozunun 400 mg IV dozuna kıyasla daha etkili olduğu belirlenmiştir.