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Original Article / Orijinal Araştırma

Comparison of Analgesic Efficacy of Cooling Spray and Saline Spray in Wrist Trauma; Randomized Controlled Double Blind Study

Bilek Travmasında Serinletici Sprey ve Salin Spreyin Analjezik Etkinliğinin Karşılaştırılması; Randomize Kontrollü Çift Kör Çalışma

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Abstract

Aim: Cooling spray application is commonly used in sports injuries to manage acute pain and reduce tissue edema. However, its effectiveness in treating acute trauma in the emergency department remains understudied. This prospective randomized controlled trial assessed the efficacy of cooling spray for pain management in patients with wrist injuries.

Material and Method: A randomized trial was conducted in a tertiary care hospital's trauma department. Patients with wrist trauma were assigned to cooling spray or placebo (saline spray) groups. The cooling spray was Cryos®Spray (Phyto Performance, Italy), while the placebo was chilled saline in an identical bottle. Pain scores and radiographic images were evaluated.

Results: In 131 patients (mean age: 35.60±19.58 years, 26.7% fractures), cooling spray (n=73) yielded a delta pain score of 1.74±1.88, while saline (n=58) had 0.84±1.54 (p=0.003). Cooling spray's delta score for fracture patients was 2.26±1.88, compared to saline's 0.0±0.96 (<0.001). Non-fracture patients showed similar efficacy between cooling spray (1.55±1.85) and saline (1.16±1.60, p=0.258). Logistic regression indicated that cooling spray reduced pain 1.174 times more effectively than saline.

Conclusions: Cooling sprays demonstrated superior acute pain control, notably in fractures, outperforming the placebo. Similar efficacy was observed in non-fracture cases.

Keywords: Cooling spray, wrist trauma, analgesic

Öz

Amaç: Soğutma spreyi uygulaması akut ağrıyı kontrol etmek ve doku ödemi ile başa çıkmak için genellikle spor yaralanmalarında kullanılır. Ancak, acil serviste akut travmanın tedavisindeki etkinliği yetersiz bir şekilde araştırılmıştır. Bu prospektif randomize kontrollü çalışma, bilek yaralanması olan hastalarda ağrı yönetiminde soğutma spreyinin etkinliğini değerlendirdi.

Gereç ve Yöntem: Bir üçüncü basamak hastanenin travma bölümünde randomize bir deneme yapıldı. Bilek travması olan hastalar soğutma spreyi veya plasebo (salin spreyi) gruplarına ayrıldı. Soğutma spreyi Cryos®Spray (Phyto Performance, İtalya) olarak kullanıldı, plasebo ise aynı görünüme sahip soğutulmuş bir salin şişesiydi. Ağrı skorları ve radyografik görüntüler değerlendirildi.

Bulgular: 131 hastada (ortalama yaş: 35.60±19.58 yıl, %26.7 kırık), soğutma spreyi (n=73) 1.74±1.88 delta ağrı skoru üretirken, salin (n=58) 0.84±1.54 (p=0.003) değerini verdi. Kırık hastalar için soğutma spreyinin delta skoru 2.26±1.88 iken salin grubunda 0.0±0.96 olarak saptandı (<0.001). Kırık olmayan hastalarda soğutma spreyinin (1.55±1.85) ve salinin (1.16±1.60, p=0.258) benzer etkinlik gösterdiği görüldü. Lojistik regresyon, soğutma spreyinin ağrıyı salin grubuna göre 1.174 kat daha etkili bir şekilde azalttığını gösterdi.

Sonuç: Soğutma spreyleri plaseboyu aşan akut ağrı kontrolü sağladı, özellikle kırıklarda daha başarılı oldu. Kırık olmayan vakalarda benzer etkinlik gözlendi.

Anahtar Kelimeler: Soğutma spreyi, el bileği travması, ağrı

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INTRODUCTION

Musculoskeletal injuries are one of the most common causes of emergency department visits. These injuries occur during daily activities or due to sports accidents and account for 20% of emergency department admissions.[1] One of the problems of musculoskeletal injuries in emergency department management is pain and limitation of movement during examination and imaging procedures. Therefore, saving the patient from uncomfortable pain sensations during diagnostic procedures is realized with successful pain control by emergency physicians.[2]

Cryotherapy is a therapeutic cold application procedure for relieving pain and discomfort caused by injury. Cooling sprays have become the first treatment choice for all musculoskeletal injuries, mainly due to their ease of application, repetitive use, and use on all body surfaces. In addition to reducing pain and edema, cooling sprays provide local anesthesia for up to 30 minutes with their effect on nerve conduction. Therefore, they can relieve spasms caused by trauma.[3] Therefore, cryotherapy is one of the most recommended methods for pain control. The literature has studies on cooling sprays for different body parts.[4-6] However, there are few studies on using cooling spray in the emergency department.

This study aimed to determine the efficacy of cooling spray application for pain control in patients admitted to emergency departments with isolated wrist trauma. Our secondary objective was to compare the efficacy of fractured and nonfractured patients.

MATERIAL AND METHOD

The study was carried out with the permission of Izmir Katip Çelebi University Clinical Research Ethics Committee (Date: 24/02/2022, Decision No: 0063). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Study Design and Setting

This prospective randomized, controlled, double-blind study was conducted in the trauma area of a university hospital emergency medicine clinic over six months between March and September 2022. Patients were admitted to the study during working hours when the study team was available. This hospital operates as a trauma center accepting referrals from 6 districts in the metropolitan area and serves a population of approximately 1.5 million. The emergency department trauma area has six beds with vital monitoring facilities, four mechanical ventilators, one portable, and two handheld ultrasound devices. All trauma patients brought to the emergency department by ambulance or outpatients are admitted to this area. Signed informed consent was obtained from the relatives of all patients included in the study.

Study Population

All adult patients over 18 years of age who presented to the hospital's trauma department with wrist trauma alone and who agreed to participate were included in the study. Patients with primary acute trauma were included in the study, and patients who presented after 24 hours of trauma, those who did not give voluntary consent, patients under 18 years of age, pregnant women, and patients with trauma elsewhere other than the wrist that may affect pain perception were excluded from the study.

Study protocol

Before the start of the study, a 2-person study team consisting of an emergency department faculty member and a senior resident was formed, and patients were accepted to the study when one of these teams was on duty. Patients were assigned to the SF or Cold spray groups by simple randomization with probability. According to the examination findings, patients with fracture expectations (shape deformity, severe tenderness and edema, and bruising) were sub-randomized and distributed to the study groups.

The cold spray cooling spray (Cryos ®Spray, Phyto Performance, Italy) and +4 C* SF bottles to be applied were set in the same view and numbered 1 and 2. Bottle numbers were changed at random time intervals under the supervision of a non-team faculty member. The physician and the patient were blinded to the content in which number. Randomization and sub-randomization groups were formed according to the numbers on the bottle. The randomization groups were rearranged each time a non-team member changed the number.

After the patient was accepted to the study, Numerical Rating Scale (NRS) (10) pain score was measured and recorded. Then, cold spray or SF was applied according to the randomization order. The application method was the same for both sprays spraying from a distance of 20 cm from the injured area for 5-10 seconds, as recommended by the manufacturer for cooling spray. Patients were directed to the imaging unit for radiographic imaging 10 minutes after spray application. The emergency medicine specialist finalized the radiographs based on the results reported by radiology. After the necessary imaging and interventions were performed, the NRS pain scale was measured 10 minutes later and recorded. Patients were asked if they needed any additional painkillers. Additional pain relief was administered to those who felt the need. Demographic characteristics, vital signs, X-ray results, and the need for additional analgesics were recorded on the data recording form. The images were re-evaluated with the orthopedic specialist in the study from the hospital system to classify the fractures, if any, and the fracture classification was made according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) (**Figure 1**).

Patients were grouped according to whether there was a fracture, and those with fractures were grouped according to the fracture scale. In this way, pain scores of each group and subgroup were obtained on arrival and after emergency department management. The obtained data were processed daily by the team leader, who had the content information in the bottle numbers. Demographic information, diagnoses, and treatments administered in the emergency department or inpatient hospitalization were recorded after all examinations.

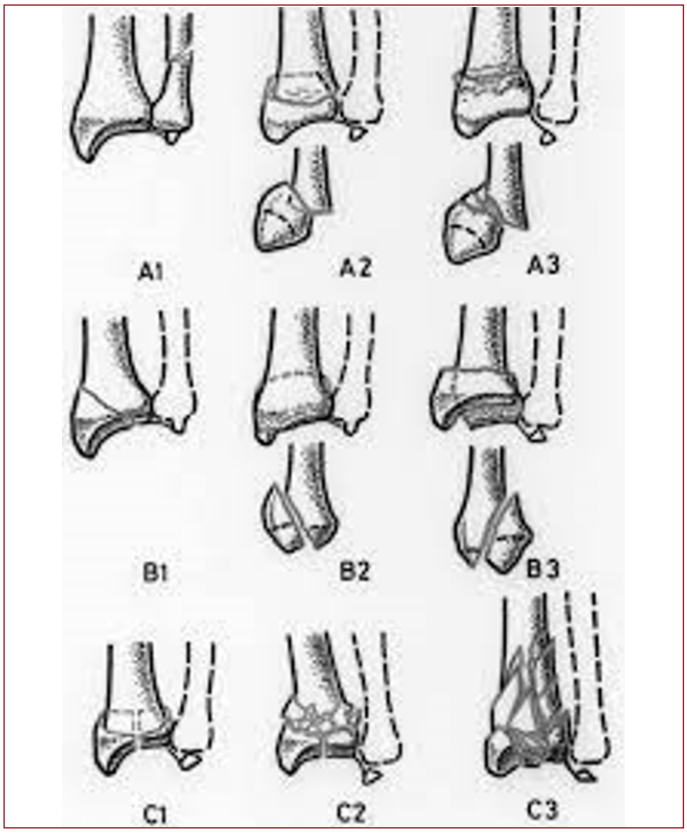

Figure 1. Working Group for Osteosynthesis Issues (AO) sınıflaması

Outcome Measures

The primary outcome measure of this study was the change in patients' pain scores with cold spray and SF administration. For this purpose, the difference between the patient's pain scores on arrival and after examinations/interventions were calculated and analyzed to see if there was a difference between cold spray and placebo. Secondarily, cold spray and placebo were compared between the fracture and non-fracture groups. Thus, whether cold spray made a difference between the fracture and non-fracture groups was calculated.

Statistical Analysis

Descriptive statistics were obtained, including frequency, percentage, mean, standard deviation, median, minimum, and maximum values. Number and percentage were calculated for categorical variables, and mean, standard deviation, minimum and maximum values, and interquartile range (IQR) were calculated for numerical variables. Histogram curves, kurtosis, skewness values, and the Shapiro-Wilks test were used to test whether continuous variables were normally distributed. Student's t-test was used when parametric test prerequisites were met, and Mann Whitney - U test was used when not met. Group regression analysis of the effects of cooling spray and cold saline was performed.

Statistical calculations were performed with SPSS 24.0 software, and all calculations were performed with a 95% confidence interval. $P<0.05$ was considered statistically significant.

RESULTS

789 patients were admitted with wrist trauma during the study period, and 131 patients who met the study criteria were included. The distribution of patients accepted and included in the study was shown in the consort diagram (**Figure 2**).

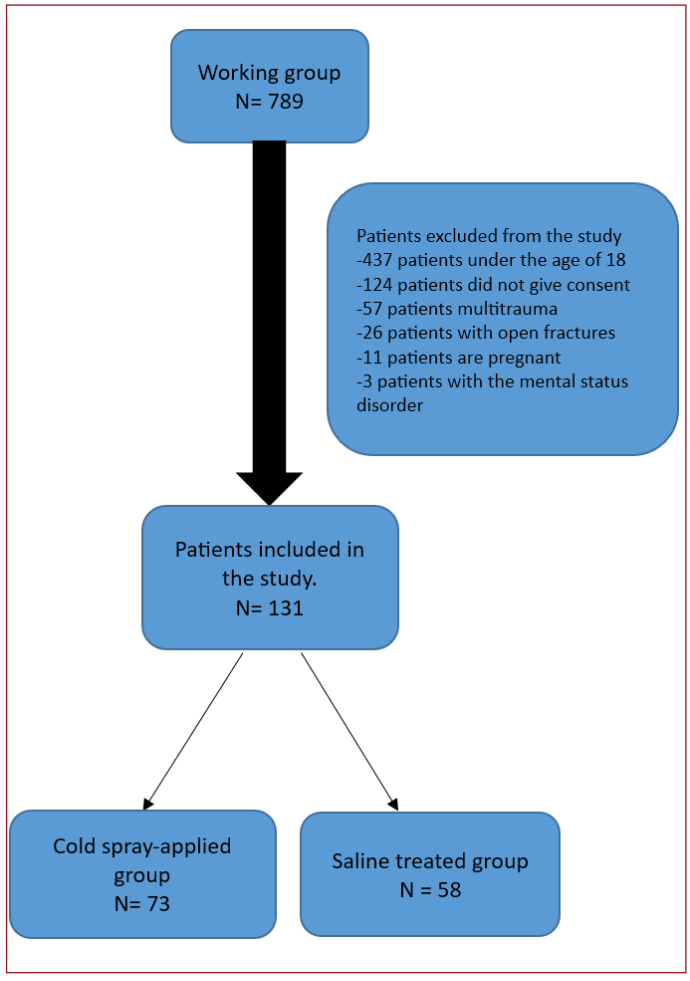

Figure 2. Consort Diagram

Of the patients included in the study, 56 were female, and 75 were male. The mean age was calculated as 35.60±19.58 years. 96 patients (73.3%) had isolated musculoskeletal injuries, and 35 (26.7%) had fractures. Fracture classification was evaluated according to the AO classification, and the most common injury type was A2 type with 15 (42.9%) patients. Regarding the side of injury, left-sided injuries were slightly more common than right-sided injuries, with 67 (51.1%). The radial region was the most common site of tenderness, with 38.9% of the patients.

The sprays' distribution was cold spray in 73 (55.7%) patients and saline in 58 (44.3%) patients. No additional analgesia was administered in 121 (92.4%) patients, while 10 (7.6%) patients received additional analgesia. Descriptive statistics and AO classification distribution of the patients are shown in **Table 1**.

Table 1: Descriptive statistics

Variables	Statistics
Gender, (%)	
Woman	56 (42.7)
Male	75 (57.3)
Age	
x̄± hs	35.60±19.58
M (min-max)	31.5 (9-92)
Spray Applied, (%)	
Cold Spray	73 (55.7)
Serum Physiological	58 (44.3)
Wrist Direction, (%)	
Right	64 (48.9)
Left	67 (51.1)
Sensitivity Zone, (%)	
radial	51 (38.9)
ulnar	40 (30.5)
Radial+Ulnar	30 (22.9)
Phalanx	10 (7.6)
Analgesia in the Emergency Department, (%)	
Not Implemented	121 (92.4)
Done	10 (7.6)
Fracture, (%)	
None	96 (73.3)
Exist	35 (26.7)
Fracture Classification	**N (%)**
A1	2 (5.7)
A2	15 (42.9)
A3	5 (14.3)
B2	3 (8.6)
B3	1 (2.9)
C1	2 (5.7)
C2	3 (8.6)
C3	4 (11.4)

The difference between the pre-treatment pain score, defined as delta pain, and the post-treatment pain score was 1.34±1.78 for the whole group. There was a statistically significant difference in the delta pain score between patients treated with cold spray and patients treated with saline (p=0.003). No statistically significant difference was found in terms of analgesia administration in the emergency department, presence of fracture, and fracture classification (p<0.05) (**Table 2**)

Table 2: Distribution of descriptive data by delta pain

	Delta Agri		Test Statistics	
	x̄± hs	M (min-max)	Test Value	p value
Delta Pain	1.34±1.78	1 ((-2)-6)		
Spray Applied				
Cold Spray	1.74±1.88	1.48 ((-2)-6)	z=2,940	0.003
Serum Physiological	0.84±1.54	0.54 ((-2)-6)		
Analgesia in the emergency department				
Not Implemented	1.34±1.79	0.92 ((-2)-6)	z =0.005	0.996
Done	1.40±1.90	0.80 ((-1)-4)		
Broken				
None	1.39±1.76	0.98 ((-2)-6)	z=0.519	0.604
Exist	1.23±1.90	0.75 ((-2)-6)		
Fracture Classification				
A1	2.0±2.83	2 (0-4)		
A2	0.93±1.75	0.56 ((-2)-5)		
A3	2.20±0.84	2.25 (1-3)		
B2	0.67±1.15	-0.67 ((-2)-0)	H=9,341	0.223
B3	0.0±0.0	0 (0-0)		
C1	3.0±2.83	3 (1-5)		
C2	2.0±3.46	2 (0-6)		
C3	1.0±1.41	0.67 (0-3)		

Logistic regression analysis is shown in **Table 3**. According to this, cold spray application is 1.174 times more likely to reduce pain than saline application.

Table 3: Evaluation of Before-After Pain Scores according to application types

	B	SE	Wald	df	p	OR ¥
Delta Agri	0.161	0.113	7,614	one	0.006	1,174
Constant	-0.311	0.223	0.518	one	0.472	0.733

¥ Logistic Regression

In subgroup analyses, there was no difference between the type of spray applied and the need for analgesia in the emergency department when the variables were compared according to the presence or absence of fracture (p>0.05). When the pre-application pain score and post-application pain score were analyzed, the pain score was calculated as 8.0±2.11 in the group with fracture and 6.88±1.83 in the group without fracture, and the difference was statistically significant (p=0.002). Accordingly, the pain score before and after the application was 6.77±2.34 in the fracture group and 5.54±2.34 in the non-fracture group, and the difference between them was significant (p=0.017). Cryotherapy to be applied after the injury was found to be effective in reducing the pain of the patients (**Table 4**).

Table 4: Comparison of variables according to the presence of fracture

	Broken		Test Statistics	
	None	There is	Test value	p-value
Spray Applied				
Cold spray	54 (74.0)	19 (26.0)	0.040	0.841
Serum physiological	42 (72.4)	16 (27.6)		
Pre-Application Pain Score				
x̄± hs	6.88±1.83	8.0±2.11	3,047	0.002
M (min-max)	7 (2-11)	8 (2-10)		
Post-Application Pain Score				
x̄± hs	5.54±2.34	6.77±2.34	2,394	0.017
M (min-max)	6 (1-10)	7 (2-10)		
Analgesia in the Emergency Department				
Not Implemented	91 (75.2)	30 (24.8)	2,997	0.083
Done	5 (50.0)	5 (50.0)		

In the comparison made according to the type of application, cold spray application was more effective than saline use in patients with fractures, and this effect was statistically significant (**Table 5**).

Table 5: Comparison of fracture cases according to application types

	APPLICATION		Test Statistics	
	Cold Spray	Serum Physiological	z value	p-value
	x̄± hs	x̄± hs		
Broken				
None	1.55±1.85	1.16±1.60	1,131	0.258
Exist	2.26±1.88	0.0±0.96	3,632	<0.001

Retrospective Power Analysis

No previous studies used similar data and our research perspective; therefore, we evaluated our findings to describe the radiographic scoring. If both patient groups included at least 55 patients, the power of the test was estimated at 0.90 and the type 1 error at 0.01.

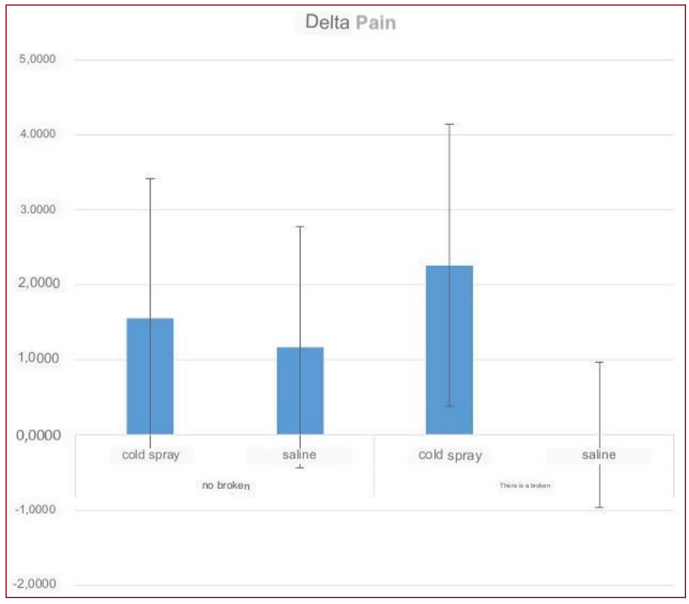

Figure 3: Comparison of fracture phenomenon according to application types

DISCUSSION

Trauma-related injuries are among the most common causes of admission to emergency departments. In the emergency department management of traumatic injuries, it is aimed to facilitate the preferred radiologic interventions, increase patient comfort, and rapidly reduce the intensity of the emergency department. A large proportion of musculoskeletal traumas are superficial mechanism injuries [7] These patients should be evaluated rapidly, and investigations and treatment procedures should be completed. It aims to facilitate the diagnostic procedures and simultaneously start the treatment with the patient's comfort to be obtained by relieving the pain due to the injury. Cryotherapy is one of the most practical and effective options among these methods. Especially compared to standard cryotherapy, cooling sprays are compelling thanks to their ease of application and reproducibility. It increases patient satisfaction by reducing pain, muscle spasms, and edema. It allows the emergency department's planned examination and imaging processes to be completed effectively and quickly. They have few side effects and form part of the treatment.

The use of cooling sprays in injuries caused by daily activities is widespread, and many studies show successful results in sports injuries [3,8] . However, their use in emergency departments has remained limited. Our study was planned based on evaluating the effect of cooling sprays on patient comfort in emergency departments. It was aimed to ensure patient comfort for an easy examination and examination process. Imaging results and patient pain severity were evaluated separately for the study. Since pain is a subjective finding and independent of injury, the Numerical Rating Scale (NRS-10) was used, and the results were analyzed. This study is one of the first studies regarding its design and use in emergency departments.

Cooling sprays are not limited to sports injuries and are becoming increasingly widespread. In a recent study, it has been reported that they can be used effectively in reducing pain and edema after subcutaneous ejections (9). The role of cooling sprays in coastal injuries occurring in geriatric patient groups was studied, and pain control was reported to be highly effective in the acute period [10] It was shown that patients' diagnosis and treatment processes were completed more rapidly by reducing acute pain. In a similar study, Gür et al. reported successful results in reducing pain and providing patient comfort in acute ankle injuries with a cooling spray [11] Park et al. reported that it could be used for pain control in the preoperative period, but its efficacy in controlling long-term pain and reducing edema is limited [3] In parallel with previous studies, this study evaluated that the use of cooling spray in emergency departments was effective in acute pain control in emergency departments.

Our study analyzed patients presenting to emergency departments with wrist injuries. The cooling spray was applied to these patients before the necessary examinations and imaging for diagnosis, and pain scores were analyzed. The results were compared with a placebo. As a result, cooling sprays were effective in controlling acute pain. The effectiveness of these sprays was at least as successful in controlling the pain needed in patients with fractures as in patients without fractures. However, no additional pain control was required in patients without fractures who received cooling sprays in the emergency department. When all these results are evaluated together, using cooling sprays may be beneficial in increasing patient comfort and faster circulation in emergency departments with high workloads.

Limitation

The fact that our study is a single-center study limits generalization due to the limited number of patients included.

CONCLUSION

This study found that acute pain in patients admitted to emergency departments with wrist trauma and fractures could be controlled more successfully with cooling sprays than placebo. Cooling sprays may comfort patients during uncomfortable procedures such as physical examination and radiologic imaging in emergency departments. As a secondary result, cold spray application in the emergency department limits the use of analgesics during pain control. Therefore, cold spray applications should be used as a valuable practice because they form a practical part of the treatment, provide patient comfort, and speed up the operation of the emergency department.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Izmir Katip Çelebi University Clinical Research Ethics Committee (Date: 24/02/2022, Decision No: 0063).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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