WHIOCE PUBLISHING PTE. LTD.
PROVIDING
FIRST-CLASS SCIENTIFIC INFORMATION
FOR TOP SCHOLARS

2025 Volume 10, Issue 3
Journal of Medicines Development Sciences
ISSN: 2382-6371(Online) ISSN: 2382-6363(Print)

The Efficacy of Ultrasound-guided Drug Delivery of Diclofenac Diethylamine Emulsion Combined with Rehabilitation Training in the Treatment of Elbow Ossifying Myositis

Huiping Zhang*
Civil Aviation General Hospital, Beijing 100123, China

***Corresponding author:** *Huiping Zhang, 438879316@qq.com*

Abstract: *Objective:* To explore the clinical efficacy of ultrasound-guided drug delivery of diclofenac diethylamine emulsion combined with rehabilitation training in the treatment of elbow ossifying myositis (EOM), and to provide evidence-based support for clinical treatment. *Methods:* 86 patients with elbow ossifying myositis admitted to the orthopedics department of our hospital from January 2022 to December 2023 were selected as the study subjects. They were divided into a control group (43 cases) and an observation group (43 cases) using a random number table method. The control group received rehabilitation training only, while the observation group received ultrasound-guided drug delivery of diclofenac diethylamine emulsion in addition to the rehabilitation training. Both groups were treated continuously for 8 weeks. The range of motion (ROM), visual analogue scale (VAS) for pain, and Mayo Elbow Performance Score (MEPS) were compared between the two groups before and after treatment, and adverse reactions were recorded. *Results:* Before treatment, there were no statistically significant differences in elbow ROM (flexion, extension, pronation, and supination angles), VAS score, and MEPS score between the two groups (P>0.05). After 8 weeks of treatment, the observation group had significantly better elbow flexion angle (115.23±10.56)°, extension angle (-5.12±2.34)°, pronation angle (78.45±8.12)°, and supination angle (75.36±7.89)° compared to the control group's (92.67±9.87)°, (-12.34±3.12)°, (65.78±7.56)°, and (62.13±6.98)°, respectively (P<0.05). The VAS score of the observation group (1.23±0.56) was significantly lower than that of the control group (3.56±0.89) (P<0.05). The excellent and good rate of the observation group was significantly higher than that of the control group (P<0.05). There was no statistically significant difference in the incidence of adverse reactions between the observation group (4.65%) and the control group (6.98%) (P>0.05). *Conclusion:* Ultrasound-guided drug delivery of diclofenac diethylamine emulsion combined with rehabilitation training can effectively improve joint mobility, reduce pain, and enhance elbow function in patients with elbow ossifying myositis. This treatment approach is safe and worthy of clinical promotion and application.

Keywords: elbow osteomyelitis; ultrasonic drug delivery; diclofenac diethylamine emulsion; rehabilitation training; range of joint motion; pain score

Online publication: September 26, 2025

1. Introduction

Elbow osteomyelitis is a common chronic progressive disease in orthopedic clinics, mostly caused by abnormal ossification of local muscles, tendons, and fascial tissues after elbow trauma, surgery, or inflammation. The main symptoms include elbow pain and limited range of motion. In severe cases, it can lead to joint stiffness and dysfunction, greatly affecting patients' daily life and work quality [1]. Currently, there are various clinical treatments for elbow osteomyelitis, including drug therapy, physical therapy, rehabilitation training, and surgical treatment. Among them, rehabilitation training is a basic treatment method that can delay the progression of ossification and improve joint function through joint range of motion training and muscle strength training. However, when applied alone, it has a slower onset and poor pain relief effect [2]. As a non-steroidal anti-inflammatory drug, diclofenac diethylamine emulsion has anti-inflammatory and analgesic effects, which can effectively relieve local inflammatory reactions and pain symptoms. However, under the traditional external application method, the drug penetration depth is limited, and the bioavailability is low [3]. Ultrasonic drug delivery technology is a new drug delivery method that utilizes the mechanical vibration and thermal effects of ultrasonic waves to break the skin stratum corneum barrier, promote the directional penetration of drug molecules, increase the drug concentration in local tissues, and enhance the efficacy [4]. Based on this, this study combined ultrasonic drug delivery of diclofenac diethylamine emulsion with rehabilitation training for patients with elbow osteomyelitis to explore its clinical efficacy and safety. The report is as follows.

2. Materials and Methods

2.1. General Information

Eighty-six patients with elbow ossifying myositis admitted to the orthopedic department of our hospital from January 2022 to December 2023 were selected as the study subjects. Inclusion criteria were: (1) meeting the diagnostic criteria for elbow ossifying myositis in "Orthopedics" [5], confirmed by X-ray, CT, or MRI examination to have ossification foci around the elbow joint; (2) significant elbow pain with a VAS score ≥ 4; (3) limited elbow joint mobility, with a flexion angle < 100° or extension limitation > 10°; (4) disease duration of 3 months to 1 year; (5) informed consent from the patient and their family members, with signed informed consent forms. Exclusion criteria were: (1) severe cardiac, liver, kidney, or other organ dysfunction; (2) allergy to diclofenac diethylamine emulsion or ultrasound therapy; (3) damaged, infected, or open wounds on the skin of the elbow joint; (4) unhealed fractures, dislocations, or other joint diseases; (5) pregnant or breastfeeding women; (6) patients with mental illness unable to cooperate with treatment and follow-up. The patients were divided into a control group and an observation group using a random number table method, with 43 cases in each group. In the control group, there were 25 males and 18 females, aged between 22 and 58 years old, with an average age of (38.56±8.23) years. The disease duration ranged from 3 to 12 months, with an average of (6.89±2.15) months. Injury types included 20 cases of elbow fracture surgery, 12 cases of elbow dislocation, and 11 cases of soft tissue injury. In the observation group, there were 24 males and 19 females, aged between 23 and 59 years old, with an average age of (39.12±8.56) years. The disease duration ranged from 3 to 11 months, with an average of (6.78±2.03) months. Injury types included 19 cases of elbow fracture surgery, 13 cases of elbow dislocation, and 11 cases of soft tissue injury. There were no statistically significant differences in general information such as gender, age, disease duration, and injury type between the two groups (P>0.05), indicating comparability. This study was approved by the Medical Ethics Committee of our hospital.

2.2. Treatment Methods

2.2.1. Control Group: Rehabilitation Training Only

A personalized rehabilitation training program will be developed by a professional rehabilitation therapist, consisting of 8 consecutive weeks of treatment, with 5 training sessions per week, each lasting 40-60 minutes. The specific contents are as follows:

(1) Joint Range of Motion Training: ① Passive Movement Training: The therapist assists the patient in performing

slow passive movements of elbow flexion, extension, pronation, and supination. Each movement is maintained for 10-15 seconds and repeated 10-15 times, depending on the patient's tolerance and absence of significant pain. ② Active-Assisted Movement Training: With the assistance of the therapist or elastic bands, the patient actively performs elbow movements, gradually increasing the range of motion. Each training session lasts 20 minutes. ③ Stretching Training: Static stretching is used to stretch the muscles around the elbow (such as the biceps, triceps, and forearm flexors). Each area is stretched for 15-20 seconds and repeated 5-8 times.

(2) Muscle Strength Training: ① Isometric Contraction Training: The patient sits or lies down, with the elbow joint maintained in a neutral position or at a specific angle, performing isometric muscle contractions. Each contraction lasts 10-15 seconds, followed by a 10-second rest, and repeated 10-15 times. The contraction intensity is gradually increased. ② Isotonic Contraction Training: Depending on the patient's muscle strength, 1-2 kg dumbbells or elastic bands are used for isotonic contraction training of elbow flexion, extension, pronation, and supination. Each movement is repeated 10-15 times in 3 sets. The load is adjusted weekly based on the patient's tolerance.

(3) Physical Factor Therapy: Low-frequency pulsed electrotherapy (Beijing Hengkang Kailin Medical Instrument Co., Ltd., Neuromuscular Rehabilitation Instrument Model NMR-1) is used. Electrode pads are placed on the painful areas of the elbow, with a frequency of 50 Hz. The current intensity is adjusted until the patient feels a slight soreness and numbness. Each treatment lasts 20 minutes, 5 times a week.

2.2.2. Observation Group: Rehabilitation Training Combined with Ultrasonic Drug Delivery of Diclofenac Diethylamine Emulsion

The rehabilitation training program for the observation group was the same as that for the control group, but with the addition of ultrasonic drug delivery treatment. The specific operations were as follows:

(1) Instrumentation and Medication: An ultrasonic drug delivery device (DS-UCMF2B, Nanjing Dingshi Ultrasonic Electro-conductive Targeted Drug Delivery System) with a probe frequency of 1MHz was used. The medication selected was diclofenac diethylamine emulsion (produced by Sino-American Tianjin SmithKline & French Laboratories Limited, National Medical Approval Number HJ20181225, specification: 20g/tube).

(2) Operation Method: The patient was positioned in a comfortable posture, exposing the treatment site of the elbow joint. After cleaning the skin, the diclofenac diethylamine emulsion was evenly applied to the skin around the painful and ossified areas of the elbow joint, with a thickness of about 1-2mm and an area covering the size of the probe (approximately 5cm×5cm). After applying coupling agent to the ultrasonic probe, it was placed closely on the drug-applied area. The instrument parameters were adjusted as follows: output power of 0.8-1.2W/cm², continuous wave mode, treatment duration of 30 minutes per session, 5 sessions per week, synchronized with rehabilitation training, and continuous treatment for 8 weeks.

2.3. Observation Indicators

(1) Elbow Range of Motion (ROM): Before treatment and after 8 weeks of treatment, a goniometer was used to measure the flexion, extension, pronation, and supination angles of the patient's elbow joint. Flexion angle: the maximum angle of elbow flexion from the extended position; Extension angle: full extension of the elbow joint was considered as 0°, and limited extension was recorded as a negative value; Pronation and supination angles: with the elbow joint close to the body side and the forearm in a neutral position as 0°, pronation was the angle of palm rotation downward, and supination was the angle of palm rotation upward.

(2) Pain Score: The Visual Analog Scale (VAS) was used to evaluate the patient's pain level, with a scoring range of 0-10. A score of 0 indicated no pain, while a score of 10 indicated severe pain. Patients marked their scores on the scale based on their own pain perception, and measurements were taken before treatment and after 8 weeks of treatment.

(3) Elbow Joint Function Score: The Mayo Elbow Performance Score (MEPS) was used to evaluate patients' elbow

joint function, including pain (40 points), range of motion (20 points), muscle strength (20 points), and daily activities (20 points), with a total score ranging from 0-100. A higher score indicates better elbow joint function, where 90-100 is excellent, 75-89 is good, 60-74 is average, and <60 is poor. Evaluations were conducted before treatment and 8 weeks after treatment, and the excellence rate (excellent + good) was calculated.

(4) Adverse Reactions: Adverse reactions such as skin redness and swelling, itching, rash, and local tingling that occurred in both groups during treatment were recorded, and the incidence of adverse reactions was calculated.

2.4. Statistical Methods

Data analysis was performed using SPSS 26.0 statistical software. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$). Paired t-tests were used for comparisons before and after treatment within the group, and independent sample t-tests were used for comparisons between groups. Count data were expressed as rates (%), and comparisons were made using the χ^2 test. A P-value < 0.05 was considered statistically significant, and all data were rounded to two decimal places.

3. Results

3.1. Comparison of Elbow ROM Before and After Treatment in Both Groups

Before treatment, there was no statistically significant difference in elbow flexion, extension, pronation, and supination angles between the two groups (P > 0.05). After 8 weeks of treatment, the above ROM indicators in both groups were significantly improved compared to before treatment (P < 0.05), and the improvement in the observation group was significantly better than that in the control group, with a statistically significant difference (P < 0.05). See **Table 1** for details.

Table 1. Comparison of Elbow ROM Before and After Treatment in Both Groups (mean ± standard deviation, °)

Indicator	Group	BeforeTreatment	AfterTreatment	t-value	P-value
Flexion Angle	Control (n=43)	75.34 ± 9.12	92.67 ± 9.87	8.560	<0.05
	Observation (n=43)	76.12 ± 8.98	115.23 ± 10.56	15.890	<0.05
	t-value	0.403	10.823	-	-
	P-value	>0.05	<0.05	-	-
Extension Angle	Control (n=43)	-18.56 ± 3.89	-12.34 ± 3.12	8.230	<0.05
	Observation (n=43)	-17.98 ± 3.67	-5.12 ± 2.34	18.760	<0.05
	t-value	0.723	12.772	-	-
	P-value	>0.05	<0.05	-	-
Pronation Angle	Control (n=43)	52.34 ± 7.23	65.78 ± 7.56	8.900	<0.05
	Observation (n=43)	53.12 ± 7.01	78.45 ± 8.12	14.560	<0.05
	t-value	0.513	7.855	-	-
	P-value	>0.05	<0.05	-	-
Supination Angle	Control (n=43)	49.87 ± 6.89	62.13 ± 6.98	7.890	<0.05
	Observation (n=43)	50.23 ± 6.78	75.36 ± 7.89	13.240	<0.05
	t-value	0.247	8.627	-	-
	P-value	>0.05	<0.05	-	-

3.2. Comparison of VAS scores before and after treatment between the two groups

Before treatment, the VAS score of the control group was (6.89±1.23) points, and that of the observation group was (6.78±1.15) points. There was no statistically significant difference between the two groups (t=0.428, P>0.05). After 8 weeks of treatment, the VAS score of the control group was (3.56±0.89) points, and that of the observation group was (1.23±0.56) points. Both groups showed significant reductions compared to before treatment (control group t=14.383, observation group t=28.453, P<0.05), and the observation group had significantly lower scores than the control group (t=14.530, P<0.05).

3.3. Comparison of MEPS scores before and after treatment between the two groups

After 8 weeks of treatment, the excellent and good rate of MEPS in the control group was 65.12% (28/43), including 8 excellent cases, 20 good cases, 10 average cases, and 5 poor cases. The excellent and good rate in the observation group was 90.70% (39/43), including 20 excellent cases, 19 good cases, 3 average cases, and 1 poor case. The excellent and good rate in the observation group was significantly higher than that in the control group (P<0.05). See **Table 2** for details.

Table 2. Comparison of MEPS score grades after treatment between the two groups (n, %)

Group	n	Excellent	Good	Fair	Poor	Excellent-Good Rate
Control	43	8 (18.60)	20 (46.51)	10 (23.26)	5 (11.63)	28 (65.12)
Observation	43	20 (46.51)	19 (44.19)	3 (6.98)	1 (2.33)	39 (90.70)
χ^2 value						8.174
P value						<0.05

3.4. Comparison of adverse reactions between the two groups

During the treatment period, there were 2 cases of skin itching and 1 case of local tingling in the control group, with an adverse reaction rate of 6.98% (3/43). In the observation group, there were 1 case of skin redness and swelling and 1 case of itching, with an adverse reaction rate of 4.65% (2/43). There was no statistically significant difference in the incidence of adverse reactions between the two groups (χ^2=0.000, P>0.05). All adverse reactions were relieved after suspending treatment for 1-2 days or applying calamine lotion locally, without affecting subsequent treatment.

4. Discussion

The pathogenesis of elbow ossifying myositis is not fully understood, but it is currently believed to be related to local bleeding, inflammatory response, abnormal proliferation and differentiation of fibroblasts, and abnormal expression of bone morphogenetic protein (BMP) after elbow injury [6]. After injury, local tissue hypoxia and ischemia can activate inflammatory cells to release inflammatory factors (such as IL-1 and TNF-α), promoting the transformation of fibroblasts into osteoblasts, which leads to ectopic ossification, compressing surrounding nerves, blood vessels, and soft tissues, causing pain and limited joint movement [7]. Therefore, the key to clinical treatment lies in reducing local inflammatory response, inhibiting the progression of ossification, and improving joint range of motion and function. Rehabilitation training is a basic treatment for elbow ossifying myositis. Joint range of motion training can break the adhesion of surrounding tissues and delay the further maturation of ossification foci; muscle strength training can enhance the muscle strength around the elbow joint, improve joint stability, and reduce joint load; low-frequency pulsed electrotherapy can promote local blood circulation through electrical stimulation, relieve muscle spasms, and reduce pain [8]. In this study, the control group received simple rehabilitation training, and the elbow joint ROM, VAS score, and MEPS score were all improved compared with those before treatment, confirming the effectiveness of rehabilitation

training, but there is still room for improvement in the overall efficacy.

The main component of diclofenac diethylamine emulsion is diclofenac diethylamine, which can exert anti-inflammatory and analgesic effects by inhibiting the activity of cyclooxygenase (COX-1, COX-2) and reducing prostaglandin synthesis. However, when applied externally in the traditional way, the drug needs to pass through the skin stratum corneum barrier, and the penetration efficiency is low, making it difficult for the local drug concentration to meet the treatment demand, thus affecting the efficacy. Ultrasonic drug delivery technology utilizes the "cavitation effect", "mechanical vibration effect", and "thermal effect" of ultrasonic waves to destroy the lipid structure of the stratum corneum, forming temporary pores, and simultaneously promoting local tissue blood circulation, accelerating drug molecule diffusion and penetration, increasing local tissue drug concentration, and enhancing anti-inflammatory and analgesic effects. In addition, ultrasonic waves can directly act on the surrounding tissues of ossification foci, softening fibrous tissues, relieving tissue adhesion, and creating favorable conditions for rehabilitation training to improve joint range of motion.

The results of this study showed that the observation group had significantly better elbow ROM (flexion, extension, pronation, and supination angles) than the control group after treatment. The VAS score was significantly lower in the observation group, while the MEPS score and excellent rate were significantly higher than those in the control group ($P<0.05$). This suggests that the combined therapy has more pronounced advantages in improving joint range of motion, reducing pain, and enhancing elbow function. The reasons for this can be analyzed as follows: On one hand, rehabilitation training can improve joint range of motion and enhance muscle strength through active and passive activities; on the other hand, ultrasound-guided drug delivery can increase the local drug concentration of diclofenac diethylamine emulsion, more effectively inhibiting inflammatory responses and reducing pain, thus providing support for the smooth implementation of rehabilitation training. These two approaches form a synergistic effect, further enhancing the treatment effect.

In terms of safety, there was no statistically significant difference in the incidence of adverse reactions between the two groups ($P>0.05$), and the adverse reactions were minor and resolved after symptomatic treatment. This indicates that ultrasound-guided drug delivery of diclofenac diethylamine emulsion has high safety. This may be related to the precise control of drug penetration depth achieved by ultrasound-guided drug delivery, which reduces systemic drug absorption and lowers the risk of adverse reactions such as gastrointestinal and cardiovascular events that may be caused by oral nonsteroidal anti-inflammatory drugs.

This study has certain limitations: the sample size is small, and it is a single-center study, so the results may be biased; the follow-up time is short, and the long-term efficacy of combined therapy and the progression of ossification foci have not been observed. Future studies need to expand the sample size, conduct multi-center, long-term follow-up studies, further verify the efficacy and safety of combined therapy, and explore the effects of different ultrasound parameters and drug dosages on the efficacy, providing more evidence for the optimization of clinical treatment plans.

In summary, the combination of ultrasonic drug delivery of diclofenac diethylamine emulsion and rehabilitation training for the treatment of elbow ossifying myositis can effectively improve patients' elbow range of motion, reduce pain symptoms, enhance elbow function, and has few adverse reactions and high safety. It is an efficient and safe treatment plan worthy of clinical promotion and application in orthopedics.

Disclosure statement

The author declares no conflict of interest.

References

[1] Wang J, 2024, Meta-analysis of integrated traditional Chinese and western medicine treatment for traumatic ossifying

myositis of the elbow joint. Shanxi Medical University.

[2] Qin J B, Zhuang X P, Zhang L H, 2021, Observation on the efficacy of ultrasound-guided drug delivery of diclofenac diethylamine emulsion combined with rehabilitation training in the treatment of ossifying myositis of the elbow joint. Massage and Rehabilitation Medicine, 12(12): 45-47.

[3] Wang B, Sun J P, Wu Yongtao, et al., 2021, Analysis of clinical treatment strategies for post-traumatic ossifying myositis of the elbow joint in children. Chinese Journal of Bone and Joint, 10(03): 175-180.

[4] Hou C J, Li J, Zhang Z J, 2020, Observation on the preventive effect of external application of Huoxue Ruanjian Powder on ossifying myositis after elbow joint injury. Traditional Chinese Medicine and Technology, 27(06): 900-902.

[5] Shao Y G, Zhu Z K, Shen Z W, et al., 2020, Treatment of 34 cases of ossifying myositis after elbow joint injury surgery with Xugu Huoxue Decoction. Zhejiang Journal of Traditional Chinese Medicine, 55(02): 108-109.

[6] Wang J, 2019, Treatment of 39 cases of ossifying myositis of the elbow with traditional Chinese medicine combined with small needle knife. Journal of Practical Traditional Chinese Medicine, 35(03): 290-291.

[7] Liang G G, 2018, Observation on the efficacy of oral administration of Ruanjian Decoction combined with traditional Chinese medicine scalding therapy in the treatment of ossifying myositis of the elbow joint in adults. Clinical Research of Traditional Chinese Medicine, 10(27): 65-67.

[8] Luo L, Zeng W B, 2018, Clinical observation on the treatment of early traumatic ossifying myositis of the elbow joint with milli-fire needle combined with manipulation. Chinese Ethnic Medicine, 27(06): 94-95+98.