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Original Article

Observational study of ropivacaine and compound betamethasone mixture for analgesia after triangular fibrocartilage complex repair under wrist arthroscopy: A single-center randomized double-blind controlled trial

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ABSTRACT

Background: The purpose of this study was to investigate the clinical effect of an intra-articular and local infiltration injection of a compound analgesic mixture of ropivacaine and compound betamethasone on the repair of the triangular fibrocartilage complex under wrist arthroscopy.

Methods: This prospective, double-blind, randomized study involved 20 patients with Atzei type 2 or 3 injuries of the triangular fibrocartilage complex who underwent repair under wrist arthroscopy. Patients were divided into two groups (n = 10) according to the systematic random sampling method. The test group was injected with a "cocktail" mixture for pain relief. The control group was injected with normal saline. The visual analog scale (VAS) pain score, pinch force, wrist joint mobility, wrist joint function score (PRWE score), occurrence of adverse reactions and dosage of analgesic drugs were evaluated before and after the operation in the two groups.

Results: The resting pain of the patients in the test group was less severe than that of the control group at 12 h, 24 h and 48 h after the operation ($P < 0.05$), and the pinch force of the patients in the test group was significantly greater than that of the control group at 1 d, 2 d and 3 d after the operation ($P < 0.01$). The amount of postoperative analgesics used in the test group was significantly lower than that in the control group ($P < 0.01$), and the patient satisfaction rate in the test group was higher than that in the control group ($P < 0.05$). There were no postoperative adverse effects in either group.

Conclusion: An intra-articular and local infiltration injection of a "cocktail" analgesic mixture in the repair of triangular fibrocartilage complex under wrist arthroscopy can provide good pain control in the early postoperative period and reduce the amount of postoperative analgesic drugs administered, thus improving clinical safety.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study.

1. Introduction

Poor postoperative pain control in the wrist is an important, current clinical problem that requires further study. If postoperative pain is not treated in time, it will affect wound healing, increase the chance of cerebral thrombosis or cardiovascular accidents, and cause atelectasis and lung infection, which is not conducive to early functional recovery, thus prolonging the hospital stay and eventually leading to long-term chronic pain that reduces the patient's quality of life [1–5]. In recent years, a "cocktail" analgesic mixture has been administered postoperatively as an important supplement to multimodal analgesia in clinical orthopedic surgery, and the analgesic effect is obvious. The cocktail analgesic is administered via local infiltration. Usually, a mixture of cortisol, nonsteroid anti-inflammatory drugs, local anesthetics, and

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opioids is injected around the joint at the surgical site [6]. Many studies have shown that an intra-articular and infiltration injection of analgesic mixtures can effectively relieve pain, improve early postoperative joint movement, shorten the hospital stay and improve patient satisfaction with hip and knee replacement surgery or hip, knee and shoulder arthroscopy [7–11].

Although the "cocktail" analgesic model has been confirmed to be effective in hip, knee and shoulder arthroscopic procedures, the clinical application and efficacy of the "cocktail" analgesic model after wrist surgery has not been confirmed [9,12]. Wrist arthroscopy technology has rapidly improved in recent decades. Compared with conventional examination and open procedures, wrist arthroscopy has higher diagnostic accuracy, causes less soft tissue trauma and is associated with a faster postoperative recovery. Wrist arthroscopy has been widely used in the treatment of TFCC injuries and has achieved good clinical outcomes [13]. In this study, the authors describe a prospective randomized, double-blind, controlled trial that was performed to study the clinical effects of an intra-articular and local infiltration injection of a "cocktail" mixture of ropivacaine and compound betamethasone for analgesia on the arthroscopic repair of TFCC.

2. Materials and methods

2.1. Study participants

From October 2019 to January 2022, the clinical data of 20 patients who were diagnosed with a TFCC injury and treated under wrist arthroscopy in the authors' department were prospectively collected. Patients were randomly divided into a test group of "cocktail" analgesic mixture injection and a control group of normal saline injection, with 10 cases in each group, by using a random-number table. Clinical data collectors and patients were unaware of the grouping.

2.2. Inclusion criteria

(1) Adult patients over 18 years old; (2) Patients with Atzei type 2 or 3 TFCC injuries diagnosed by MRI and wrist arthroscopy.

2.3. Exclusion criteria

(1) Patients with mental illness who cannot cooperate with treatment; (2) Long-term opioid use for chronic pain; (3) Patients who are allergic to the drug in this study; (4) Patients with neurosensory abnormalities or motor impairments of the affected limb.

2.4. Ethics approval and consent to participate

This prospective randomized double-blind controlled trial was conducted from October 2019 to January 2022 in the authors' department. This study was approved by the institutional review board of the authors' affiliated institutions.

2.5. Study design

2.5.1. Perioperative management

(1) All the admitted patients underwent preoperative examinations, such as routine blood, blood type, urine, liver and kidney function, coagulation function, and immunity tests; (2) All the patients received patient education material upon admission, were informed about the operation method and risk of postoperative complications and signed the informed consent form.

2.5.2. Surgical procedure

The patients underwent the operation under brachial plexus block anesthesia. A 3/4 and 6R portals were established using a standard technique under vertical traction. Atzei type 2 or 3 injuries to the TFCC were finally diagnosed under distal radioulnar (DRU) arthroscopy, and fibrous tissues at the foveal footprint were debrided aggressively. The foveal avulsion was reinserted through a transverse bone tunnel at the distal ulna. First, we approached the distal ulna through a 20-mm longitudinal ulnar incision that was created along the ulnar border of the ulnar styloid. The osseous suture hole was horizontally established outside the joint capsule below the ulnar fovea using a 1.2 mm Kirschner needle from the ulnar incision. Two needles were then inserted, each loaded with looped sutures (2.0 PDS suture; Ethicon) through the dorsal and volar faces of the ulnar styloid base. The needles were then pushed to penetrate the ulnar margin of the TFCC avulsion under arthroscopic guidance. Both sutures were pulled through the 6R portal with a mosquito clamp. Once the suture was pulled on the outside, one loop of the suture was prepared as a single suture and then passed through the other loop. Then, the loop was pulled out. After passing the dorsal suture to the volar side through the bone hole, the suture was tied into knots. Operations in both groups were completed by one surgeon, a highly experienced specialist in the management of TFCC injuries [14].

(1) Test group: Four milliliters of 1 % ropivacaine and 0.2 mL of 0.7 % compound betamethasone was mixed in normal saline to make 10 mL of the "cocktail" analgesic mixture. Before the incision was sutured, 2 mL of a "cocktail" analgesic mixture was locally infiltrated and injected into the subcutaneous tissues around the incision, the periosteum around the bone tunnel and the soft tissue. After suturing the incision, a 4 mL "cocktail" analgesic mixture was injected into the wrist joint cavity and around the joint capsule under arthroscopy.
(2) Control group: The same volume of normal saline was injected according to the injection method used in the test group.

2.5.3. Precautions after operation

The affected limb was immobilized with above elbow (long arm) plaster casts after the surgery, with the elbow flexed at 90° and the forearm supination at 45–60° for 3 weeks. The below elbow (short arm) plaster casts were then worn for another 3 weeks. After the plaster casts were removed, the patient was instructed to perform functional exercises.

2.5.4. Observation index

Data collection and analysis were performed by an independent examiner (a hand surgery doctor). The examiner was blinded to the group allocation and the identity of the surgeon.

Main outcome measures: (1) Pain degree: resting VAS (visual analog scale) score. The resting pain of each patient was evaluated and recorded at 5 time points, including preoperatively and 12, 24, 48, and 72 h postoperatively. (2) Pinch force: the pinch force between the thumb and index finger of the patient before the operation and 1 d, 2 d, and 3 d after the operation. (3) Satisfaction with analgesia: Before discharge, patients were asked about their satisfaction with the effect of analgesia on the affected side, which was divided into 3 levels: satisfactory, average, and unsatisfactory. (4) The use of analgesic drugs: patients in the two groups did not routinely use analgesic drugs after surgery. If they felt pain after surgery, they could take oral paracetamol and dihydrocodeine tartrate tablets for pain relief, and the applied dose was recorded. (5) Postoperative adverse reactions: Changes in the blood

circulation of the skin around the incision, wound healing, urinary retention, respiratory depression, drug allergy, nausea, and vomiting were recorded. The number of cases of the above adverse reactions in the test group and the control group before discharge were recorded. (6) Wrist joint range of motion measurement: the range of motion of the patient's wrist joint was measured before and after surgery. (7) Wrist joint function evaluation: the wrist joint function of the patients was evaluated by the patient-rated wrist evaluation (PRWE) score before the operation and 1 year after the operation.

2.5.5. Sample size and statistical analysis

The sample size was calculated by online Power and Sample Size Program software. Previous studies have suggested that a change in pain score of 1–1.3 points is clinically significant [15]. The preexperimental results showed a 1.2-point decline in the VAS score in the test group at 24 h after the operation. A sample size of 7 patients in each group was calculated by using a power of 0.8 and a type-I error of 5 %. After considering the number of patients likely to be lost to follow-up, we enrolled 10 patients in each group.

The data were analyzed and processed by SPSS 26.0 statistical software. The measurement data of normal distribution were expressed by $\overline{x} \pm s$, and the comparison between groups was by independent sample *t*-test; the measurement data of nonnormal distribution were expressed by M (IQR), and the comparison between groups was used for the Mann–Whitney U rank-sum test; the Fisher exact probability method was used for the comparison of unordered count data, and the Mann–Whitney U rank-sum test was used for the comparison of ordered count data. $P < 0.05$ indicated that the difference was statistically significant.

3. Results

An intention-to-treat analysis was performed for all the participants in the study. All 20 patients were included in the result analysis, and no patient dropped out of the treatment. The experimental flowchart describing the study design is shown in Fig. 1.

(1) Comparison of general information between the two groups: There was no difference in the basic information of the two groups (sex, age, height, weight, body mass index), preoperative pain degree, preoperative pinch force, preoperative wrist flexion and extension range of motion, ulnar deviation and radial deviation range of motion, forearm rotation range of motion, preoperative wrist joint function and operative time ($p > 0.05$, Table 1). (2) Comparison of postoperative resting VAS scores between the two groups: The resting pain scores of the test group at 12 h, 24 h and 48 h after the operation were lower than those of the control group, and the difference was statistically significant ($P < 0.05$, Table 4). There was no difference in the pain scores at 72 h postoperatively between the two groups ($P > 0.05$, Table 4). (3) Comparison of postoperative pinch force between the two groups: the pinch force of the affected side in the experimental group was significantly greater than that in the control group at 1 d, 2 d and 3 d postoperatively, and the difference was statistically significant ($P < 0.01$, Table 3). (4) Comparison of postoperative oral analgesic consumption between the two groups: postoperative oral analgesic consumption in the control group was significantly higher than that in the test group, and the difference was statistically significant ($P < 0.01$, Table 2). Although there was no statistically significant difference in the number of patients taking analgesics between the two groups postoperatively ($P > 0.05$, Table 2), 90 % of the patients in the control group took oral analgesic drugs after the operation, while only 50 % of the patients in the test group took oral analgesic drugs. (5) Comparison of postoperative analgesic satisfaction between the two groups: The survey of patients on postoperative analgesic satisfaction showed that the analgesic satisfaction of the test group was higher than that of the control group, and the difference was statistically significant ($P < 0.05$, Table 2). The satisfaction rate of the test group was 70 %, while that of the control group was only 40 %. (6) Comparison of wrist joint range of motion and wrist joint function between the two groups 1Y after surgery: 1Y after surgery, the wrist joint range of motion and wrist joint function were evaluated. There was no significant difference in wrist flexion and extension, ulnar deviation and radial deviation, forearm rotation or PRWE evaluation of wrist joint function between the two groups ($P > 0.05$, Table 2). (7) Comparison of the general conditions of the two groups after the operation: There was no redness, swelling or cracking of the incision in the two groups of patients after the operation, and all of the patients had excellent healing. Postoperative adverse reactions such as urinary retention, respiratory depression, drug allergy, nausea, and vomiting did not occur in the two groups of patients.

4. Discussion

At present, wrist arthroscopy is often used to repair such injuries in clinical practice, and good results have been achieved [13]. For wrist arthroscopic surgery, the efficacy of the analgesic regimen after wrist surgery is the key to wrist rehabilitation and patient satisfaction. The “cocktail” analgesic mode has been used in arthroscopy and has achieved good analgesic effects. In hip arthroscopy, Sean et al. [7] applied an intra-articular injection of a cocktail mixture for analgesia after hip arthroscopic surgery in patients under general anesthesia. Compared with preoperative femoral nerve block anesthesia, an intra-articular injection of a “cocktail” mixture also effectively controlled postoperative pain in patients who underwent hip arthroscopic surgery. In knee arthroscopy, Koh et al. [16] found that in the comparison of analgesic effects after arthroscopic anterior cruciate ligament repair, a knee periarticular injection combined with an intra-articular injection had the best analgesic effect. Knee periarticular injections of the cocktail mixture are better than intra-articular injections of the cocktail mixture. Therefore, to achieve better analgesia, anesthetics must be injected not only in the wrist joint cavity but also around the wrist joint. Based on the reported research results, it was found that the main components of the cocktail mixture used in arthroscopic surgery are local anesthetics, glucocorticoids, nonsteroidal anti-inflammatory drugs, and opioids.

Local anesthetics, particularly bupivacaine and ropivacaine, are commonly used in “cocktail” mixtures. Ropivacaine is pharmacologically similar to bupivacaine but causes less cardiac and central nervous system toxicity, which allows patients to tolerate higher doses [17]. Therefore, our research group chose ropivacaine as the local anesthetic component. None of the patients reported tinnitus, tingling sensations, perioral numbness, or other toxicity symptoms related to local anesthetics after surgery.

Glucocorticoids are another main component of the “cocktail” mixture, which can inhibit inflammation at surgical sites and reduce pain signals. Dexamethasone and compound betamethasone are commonly used [18–20]. However, some studies have found that high-dose glucocorticoids can cause serious postoperative complications, such as new-onset diabetes, hypertension, osteoporosis, growth retardation, and hyperlipidemia [21]. Compound betamethasone has a longer effective time due to its ingredients. Therefore, a low-dose compound betamethasone injection was used in the study.

NSAIDs may be associated with adverse effects such as kidney disease, gastrointestinal bleeding, and epidural hematoma [22]. Opioids may be associated with adverse effects such as constipation, nausea, itching, and respiratory depression [23].

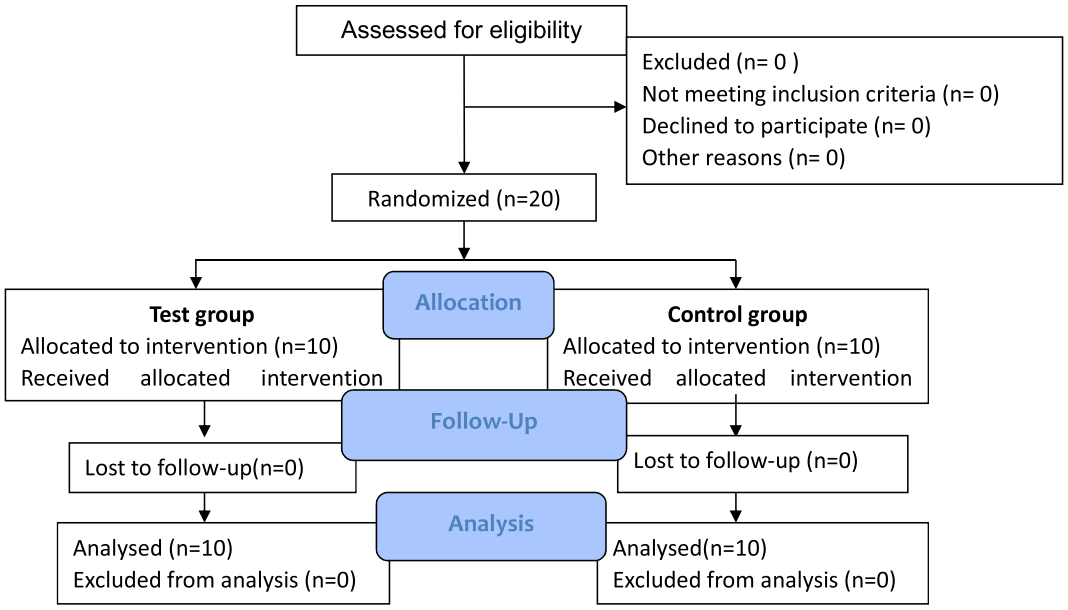

Fig. 1. Consort flow diagram describing the study design.

Table 1
Comparison of general data in two groups.

Variables	Test group	Control group	Statistics	*P*-value
Sex (Male/Female, n)	7/3	6/4		1.000
Age ($\bar{x} \pm s$, year)	29.80 ± 7.02	31.70 ± 9.67	t = 0.50	0.621
Height ($\bar{x} \pm s$, m)	1.71 ± 0.09	1.73 ± 0.11	t = 0.41	0.686
Weight ($\bar{x} \pm s$, kg)	66.30 ± 10.88	66.00 ± 10.26	t = −0.06	0.950
BMI ($\bar{x} \pm s$, kg/m^2)	22.66 ± 2.87	22.13 ± 2.60	t = −0.43	0.672
Preoperative resting VAS	1.80 ± 0.92	1.40 ± 0.97	t = −0.95	0.355
Preoperative pinch force, Operated side/Nonoperated side, ($\bar{x} \pm s$, %)	92.87 ± 14.24	99.37 ± 18.90	t = 0.87	0.397
Preoperative wrist joint range of motion ($\bar{x} \pm s$, °)				
Flexion and extension	125.50 ± 17.55	122.00 ± 18.74	t = −0.43	0.672
Forearm rotation	148.00 ± 20.84	148.5 ± 19.87	t = 0.06	0.957
Ulnar and radial deviation	56.50 ± 15.64	57.00 ± 13.98	t = 0.08	0.941
Preoperative PRWE score	31.95 ± 10.55	33.85 ± 15.39	t = 0.32	0.751
Operation time ($\bar{x} \pm s$, min)	94.50 ± 19.73	93.00 ± 21.65	t = −0.16	0.873

Table 2
Comparison of clinical data in two groups.

Variables	Test group	Control group	Statistics	*P*-value
Postoperative oral analgesic consumption (M(IQR), mg)	255.00 (1020.00)	2040.00 (1020.00)	Z = −3.309	0.001
The number of patients taking analgesics postoperatively (taken/not taken, no. of patients)	5/5	9/1		0.141
Satisfaction with analgesia (no. of patients (%))			Z = −1.99	0.047
satisfactory	7 (70 %)	4 (40 %)		
average	2 (20 %)	3 (30 %)		
unsatisfactory	1 (10 %)	3 (30 %)		
Wirsit joint range of motion joint 1 year after the operation ($\bar{x} \pm s$, °)				
Flexion and extension	132.00 ± 14.76	129.00 ± 14.49	t = −0.46	0.652
Forearm rotation	161.00 ± 6.99	160.50 ± 11.65	t = −0.12	0.909
Ulnar and radial deviation	62.00 ± 10.85	60.50 ± 8.32	t = −0.35	0.733
PRWE score at 1 year after the operation	9.20 ± 3.75	9.25 ± 4.42	t = 0.03	0.979
Adverse reactions after the operation (no. of paients with adverse reactions/no. of paients without adverse reactions)	0/10	0/10		

Moreover, our study found that no patient in the test group or control group had severe pain after surgery. Therefore, we voluntarily removed nonsteroidal anti-inflammatory drugs and opioids from inclusion in the “cocktail” mixture and instead instructed patients to take paracetamol and dihydrocodeine tartrate tablets for pain relief. Our study found that the application of the “cocktail” mixture can significantly reduce the consumption of analgesic drugs. Relevant studies have shown that adrenaline has a vasoconstrictive effect, which can prolong the effective time of the “cocktail” mixture, but the vasoconstrictive effect of adrenaline may cause skin to become ischemic and necrotic, so it is not suitable for subcutaneous injection [24]. Therefore, epinephrine was not

Table 3
Comparision of operated side/nonoperated side pinch force in two groups ($\bar{x} \pm s$, %).

Variables	Test group	Control group	Statistics	*P*-value
1 day after the operation	47.65 ± 10.09	12.87 ± 12.84	t = −6.74	0.000
2 days after the operation	55.37 ± 17.58	20.97 ± 13.97	t = −4.85	0.000
3 days after the operation	64.83 ± 9.42	36.24 ± 13.46	t = −5.50	0.000

Table 4
Comparison of resting VAS in two groups (M(IQR), n = 10).

Variables	Test group	Control group	Statistics	*P*-value
12 h after the operation	3.00 (2.00)	4.50 (2.00)	Z = −2.24	0.025
24 h after the operation	3.00 (1.00)	4.00 (2.00)	Z = −2.85	0.004
48 h after the operation	2.00 (0.00)	3.00 (2.00)	Z = −2.00	0.046
72 h after the operation	2.00 (1.00)	2.00 (2.00)	Z = −1.15	0.250

used in this study. Incision redness, swelling and cracking, urinary retention, respiratory depression, drug allergy, nausea and vomiting were not found in either group after the operation. This shows that the formula used in this research is safe and reliable, and no adverse reactions occurred.

Bhattacharjee et al. [18] showed that an intra-articular injection of a "cocktail" mixture composed of dexamethasone and bupivacaine alone after knee arthroscopic surgery can improve the postoperative analgesic effect and prolong the postoperative analgesic time. Moreover, considering the side effects of nonsteroidal anti-inflammatory drugs, opioids and epinephrine, we only selected local anesthetics and glucocorticoids for inclusion in the "cocktail" formula in this study. This analgesic formula has a particularly significant analgesic effect within 48 h after surgery. Postoperative short-term pain relief reduces postoperative oral analgesic consumption, accelerates the recovery of pinch force, and increases patient satisfaction. All of these results will increase patients' confidence in treatment, which is more conducive to their later recovery. This is consistent with the enhanced recovery after surgery (ERAS) protocol to reduce postoperative stress and promote early mobilization [25]. Due to the patient's need for plaster fixation of the affected limb to the metacarpophalangeal joint after surgery, only the fingers could move. Therefore, we chose pinch force as an indicator to evaluate postoperative recovery. The improvement in early postoperative pinch force indicates that patients can exercise their metacarpophalangeal and interphalangeal joints in the early postoperative period, and the evaluation of the TFCC repair effect through pinch force has also been reported in other studies [26,27]. Although the effectiveness of the "cocktail" analgesic formula is only confirmed in arthroscopic repair of the TFCC, the ingredients and dosage used in the "cocktail" are safe, so it can be used in other wrist surgeries and is not limited to arthroscopic surgery.

4.1. Limitations of this study

There are several limitations to our study. First, the sample size is relatively small. Further studies on larger patient groups are required to validate our findings. The follow-up period was 1 year after surgery, which was relatively short in terms of clinical evaluation. Second, although the definition of the VAS score is clear, scoring is still subjective. We minimized bias as much as possible, ensuring that all procedures and scorings were performed by the same surgeon.

5. Conclusion

In summary, the "cocktail" analgesic formula used in this study is a mixture of ropivacaine and compound betamethasone, which is injected into the joint cavity and locally infiltrated in the repair of the triangular fibrocartilage complex under wrist arthroscopy. It can achieve a good analgesic effect in the early postoperative period, reduce the amount of analgesics used, and promote the early functional recovery of the small joints beyond the wrist joint, with no postoperative adverse reactions. This formula is safe and reliable, and it is worthy of clinical application.

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Declaration of competing interest

All the authors of this article make a joint statement, and this article has no relevant conflicts of interest.

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