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Original Article

Therapeutic effect analysis of closed reduction and intra-medullary nail fixation for treatment of middle clavicular fracture

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Abstract: Objective: This study aimed to analyze the therapeutic effect of closed reduction and intra-medullary nail fixation for the treatment of middle clavicle fracture. Methods: Seventy-four patients with middle clavicle fracture in our hospital for an operation were randomly divided into a research group and a control group, with 37 cases in each group. The research group was treated with closed reduction and intra-medullary nail fixation, while the control group was treated with open reduction and plate fixation. The therapeutic effect, operation time, perioperative bleeding volume, hospital stay, fracture healing time, and Constant-Murley (CM) scores of the shoulder before and after operation, Neer scores of the healthy side as well as the affected side after operation, and the occurrence of complications were compared. Results: There was no remarkable difference in therapeutic effect, CM scores and Neer scores between the two groups ($P > 0.05$). The operative time and perioperative bleeding volume of the research group were lower than those of the control group ($P < 0.05$); the hospital stay, and fracture healing time of the research group were lower than those of the control group ($P < 0.05$). The incidence of complications in the control group surpassed that in the research group with a statistical difference ($P < 0.05$). Conclusion: There is no obvious difference between closed reduction and intra-medullary nail fixation and traditional open reduction and plate fixation in the treatment of middle clavicle fracture. However, the former can better promote the healing of fracture, and has fewer complications with higher safety; which is worthy of clinical promotion.

Keywords: Closed reduction and intra-medullary nail fixation, treatment, middle clavicle fracture, complications

Introduction

The clavicle is located in a superficial part of the human body, so it is prone to fracture under external factors. Clavicle fracture is one of the most common fracture types in adults, and most fractures occur in the middle clavicle [1, 2]. In the past, conservative treatment was often used for clavicular fracture. But due to complications such as fracture displacement, the external fixation needs to be adjusted repeatedly, which increases the pain of patients [3]. Therefore, at present, surgical treatment of clavicular fracture is mainly adopted in clinic, but there is still much controversy about the surgical treatment of middle clavicular fracture [4].

At present, traditional open reduction and plate fixation, and closed reduction and intra-medullary nail fixation are the main surgical procedures for a middle clavicular fracture with obvious displacement [5]. Some studies [6] have suggested that the traditional open reduction and plate fixation had the advantages of good reduction effect and reliable fixation, and biomechanics showed that it can provide better internal fixation strength than intra-medullary nail fixation, which was conducive to early functional exercise. But some studies [7] have pointed out that the traditional open reduction and plate fixation not only can cause obvious surgical scaring to affect the appearance, but also can increase the surgical risk and economic burden of patients with secondary operation for the removal of the internal fixation plate. In recent years, with the development of minimally invasive technology, intra-medullary nail fixation has been widely applied in clinic due to its advantages of minimal invasion and elastic fixa-

tion [8]. However, due to the high technical requirements of closed reduction and intramedullary nail fixation, previous studies mostly reported the cases of failure of closed reduction and intra-medullary nail fixation and replacement with open reduction and fixation [9, 10].

Therefore, the therapeutic effect of closed reduction and intra-medullary nail fixation and open reduction and plate fixation were compared to explore the therapeutic effect of the former on the middle clavicle fracture and provide a theoretical basis for the clinical application and technical popularization of closed reduction and intra-medullary nail fixation.

Materials and methods

General data

Seventy-four patients with middle clavicular fracture were selected for operation in our hospital, including 41 males and 33 females. The average age of all patients was (35.82 ± 10.37) years. Among them, 17 patients were injured from falling, 18 from a tumble, 28 from a traffic accident, and 11 from an injury by heavy objects. The patients were randomly divided into a research group and a control group with 37 cases in each group. The research group was treated with a closed reduction and intra-medullary nail fixation for treatment, while the control group was treated with an open reduction and plate fixation for treatment. Exclusion and inclusion criteria: Inclusion criteria: patients diagnosed with middle clavicular fracture by imaging examination. Exclusion criteria: patients without indications for surgical fixation; patients with other open fracture injuries; patients with coagulation dysfunction; patients with severe immune system diseases; patients with severe liver and kidney dysfunction; patients with cognitive and communication disorders; patients who did not cooperate with the experiment. All patients and their families agreed to join the experiment and signed the informed consent. This experiment was approved by the Wendeng Osteopathic Hospital Ethics Committee.

Operative methods

The control group was treated with plate fixation: The patients in the control group were treated with plate fixation. Patients were put in a supine position and anesthetized with brachiplex nerve block. After routine disinfection and paving sterile sheet, an incision of about 8-12 cm in length was cut along the longitudinal axis of the clavicle at the center of the fracture. The skin, subcutaneous tissue and fascia were cut layer by layer, and the hemostasis was performed by electrocoagulation. Then the hematoma and fragments of the fracture broken end were cleared, and the reduction of fracture end was performed. The plate was fixed above the clavicle and the fixation screws were placed. Then the reduction and fixation of the fracture end were observed by C-arm machine. After observing everything in order, the wound was washed, and covered and closed by sterile dressing.

The research group was treated with closed reduction and intra-medullary nail fixation: The patients in the research group were treated with closed reduction and intra-medullary nail fixation. The patients were anesthetized with brachiplex nerve block. Patients were placed in the beach chair position, with an elevated scapular region in the affected side. After routine disinfection and paving sterile sheet, the fracture sections of the patients was identified, and the intra-medullary nail was placed through the upper edge skin of the scapula at about 2 cm outside the fracture broken end. Then the intramedullary nail was rotated reversely along the medullary cavity, and pulled in front of the proximal segment of the clavicle. After confirming that the intra-medullary nail had been thoroughly rotated into the medullary cavity, the clavicle was clamped with towel clip through both sides of the fracture broken end, and the rotary reduction of fracture was carried out under the observation of C-arm machine. The intra-medullary nail was rotated along the proximal medullary cavity of fracture. When the intra-medullary nail penetrated the cortex of the distal clavicle, the rotation was stopped. Then the intra-medullary nail was cut and embedded under the skin. Finally, the wound was dressed with sterile dressing.

All patients received routine antibiotic anti-infective therapy and clavicular band fixation for 2-week suspension after the operation, and functional exercise 3 weeks after operation.

Outcome measures: (1) Comparing the excellent and good therapeutic effect rate 3 months after treatment, the patients in the two groups

Table 1. Comparison of general data

Project	Research group n = 37	Control group n = 37	t/X^2	P
Gender			0.055	0.815
Male	20 (54.05)	21 (56.76)		
Female	17 (45.95)	16 (43.24)		
Age			0.054	0.816
≥ 35	18 (48.65)	17 (45.95)		
< 35	19 (51.35)	20 (54.05)		
BMI			0.057	0.812
≥ 23	22 (59.46)	23 (62.16)		
< 23	15 (40.54)	14 (37.84)		
Cause of injury			0.515	0.916
High fall	9 (24.32)	8 (21.62)		
Fall down	8 (21.62)	10 (27.03)		
Traffic accident	15 (40.54)	13 (35.14)		
Heavy impact	5 (13.51)	6 (16.22)		
Coagulation function				
APTT s	27.34 ± 2.56	27.45 ± 2.48	0.188	0.852
PT s	12.21 ± 1.13	12.23 ± 1.15	0.940	0.075
FIB g/l	3.54 ± 0.15	3.55 ± 0.14	0.297	0.768
TT s	14.32 ± 1.12	14.38 ± 1.13	0.229	0.819
Nutritional status			0.069	0.967
Well	25 (67.57)	24 (64.86)		
Moderate	10 (27.02)	11 (29.73)		
Poor	2 (5.41)	2 (5.41)		
Renal function index (μmol/L)				
Creatinine	60.33 ± 4.45	61.02 ± 4.47	0.665	0.508
Urea	5.12 ± 0.33	5.14 ± 0.37	0.245	0.867
Uric acid	276.38 ± 10.65	278.55 ± 10.71	0.874	0.385

were divided into three grades: excellent, good and poor. The specific evaluation criteria [11] were that excellent: clavicular fracture had no deformity, and X-ray showed the wound healed well and shoulder joint activity was normal; good: X-ray showed that the clavicle was displaced slightly, but the wound still healed well and shoulder joint function was normal; poor: there was malunion of fracture, and there was a serious obstacle to shoulder joint activity. Excellent and good rate = (excellent number + good number)/total number × 100%. (2) The operation duration and blood loss during the operation were recorded and compared between the two groups. (3) The hospital stay and fracture healing time of the two groups were recorded and compared. (4) Constant-Murley (CM) [12] shoulder joint function score was utilized to evaluate the shoulder function of the two groups before and 3 months after operation. The higher the score, the better the shoulder function. (5) Neer [13] score was applied to compare the shoulder joint function of the affected side and the healthy side of the two groups 3 months after operation. (6) A comparison was made between the two groups in the complications within the first 3 months after the operation. The complications included wound infection, malunion of fracture, breakage of internal fixation, and nerve injury.

Statistical methods

SPSS 19.0 software (Bi Insight (Beijing) Information Technology Co., Ltd.) was utilized for statistical analysis. The count data were expressed in the form of percentage and compared between the two groups by the chi-square test. The measurement data were expressed by mean ± standard deviation. The independent t-test was used for analyzing the comparison between the two groups. The paired t-test was applied for comparison before and after operation. $P < 0.05$ indicated that there is a statistical difference.

Results

General data comparison

There were no marked differences in gender, age, BMI and the cause of injury between the two groups ($P > 0.05$), which were comparable (**Table 1**).

The excellent and good therapeutic effect rate in the two groups 3 months after operation

Twenty-one patients had excellent therapeutic effect, 15 patients had good therapeutic effect

Table 2. The excellent and good therapeutic effect rate in the two groups 3 months after operation [n,(%)]

Project	Research group n = 37	Control group n = 37	X^2	P
Excellent	21 (56.76)	20 (54.05)	0.055	0.815
Good	15 (40.54)	15 (40.54)	-	-
Poor	1 (2.70)	2 (5.41)	0.347	0.556
Excellent and good therapeutic effect rate	36 (97.30)	35 (94.59)	0.347	0.556

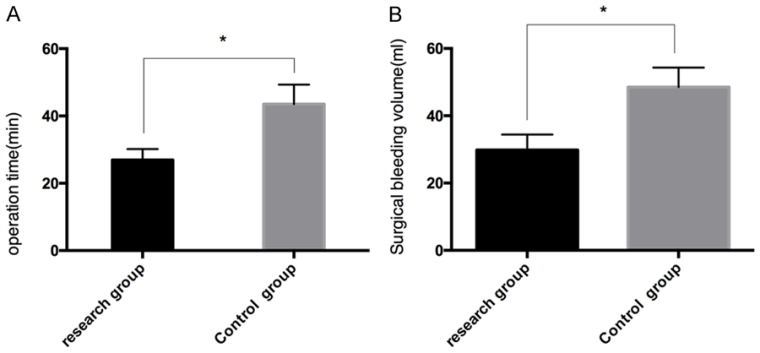

Figure 1. Comparison of operation time and perioperative bleeding volume in the two groups. The operation time and perioperative bleeding volume in the research group were lower than those in the control group (P < 0.05). Note: * represents P < 0.05.

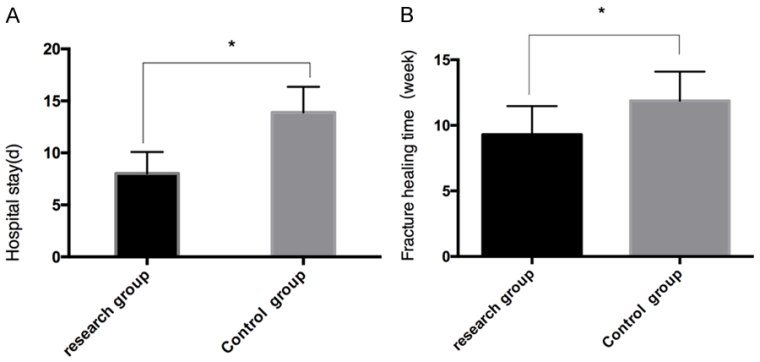

Figure 2. Comparison of hospital stay and fracture healing time in the two groups. The hospital stay and fracture healing time of the research group were lower than those of the control group (P < 0.05). Note: * represents P < 0.05.

and 1 patient had poor therapeutic effect in the research group 3 months after operation. The rate of excellent and good therapeutic effect in the research group reached 97.30%. Twenty patients had excellent therapeutic effect, 15 patients had good therapeutic effect, and 2 patients had poor therapeutic effect in the control group 3 months after operation. The rate of excellent and good therapeutic effect in the control group reached 94.59%. There was statistical difference in the surgical therapeutic effect (P > 0.05) (**Table 2**).

Comparison of operative time and perioperative bleeding volume

The operative time and perioperative bleeding volume in the research group were (26.91 ± 3.26) min and (29.82 ± 4.61) ml. The operative time and perioperative bleeding volume in the control group were (43.52 ± 5.79) min and (48.37 ± 5.15) ml. The operative time and perioperative bleeding volume in the research group were lower than those in the control group (P < 0.05) (**Figure 1**).

Comparison of hospital stay and fracture healing time

The hospital stay and fracture healing time in the control group were (13.90 ± 2.46) days and (11.87 ± 2.22) weeks. The hospital stay and fracture healing time in the research group were (8.03 ± 2.06) days and (9.29 ± 2.18) weeks. The hospital stay and fracture healing time in the research group were lower than those in the control group (P < 0.05) (**Figure 2**).

CM scores before and 3 months after operation

The CM scores of the research group before and 3 months after operation were (65.31 ± 12.35) and (97.26 ± 13.68), respectively. The

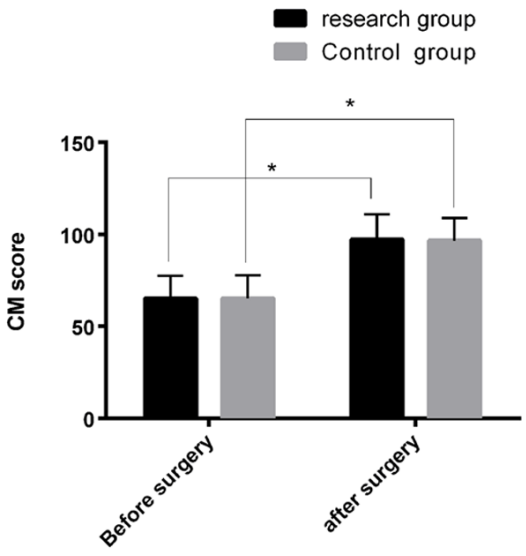

Figure 3. CM scores of the two groups before and 3 months after operation. CM scores of the two groups 3 months after operation were higher than those before operation ($P < 0.05$). Note: * represents $P < 0.05$.

CM scores of the control group before and 3 months after operation were (65.36 ± 12.39) and (96.67 ± 12.28), respectively. There was no remarkable difference between the two groups before and 3 months after operation ($P > 0.05$). The CM scores at 3 months after operation were higher than those before operation ($P < 0.05$) (**Figure 3**).

Neer scores of the affected side and the healthy side 3 months after operation

The NEER scores of the affected side and the healthy side in the research group were (98.81 ± 2.33) and (97.92 ± 2.35) 3 months after operation. The NEER scores of the affected side and the healthy side in the control group were (98.17 ± 2.29) and (97.32 ± 2.05) 3 months after operation. There was no remarkable difference in the NEER scores of the healthy side between the two groups ($P > 0.05$). There was no remarkable difference in the NEER scores of the affected side between the two groups ($P > 0.05$) (**Table 3**).

Incidence of complications

Within 3 months after operation, the number of patients with wound infection, malunion of fracture, breakage of internal fixation, and nerve injury in the research group was 1, 0, 0 and 1 patient, respectively. The incidence of complications was 5.41% in the research group. The number of patients with wound infection, malunion of fracture, breakage of internal fixation, and nerve injury in the control group was 3, 3, 2 and 1 patient, respectively. The incidence of complications was 24.32% in the control group. The incidence of complications in the control group surpassed that in the research group with a statistical difference ($P < 0.05$) (**Table 4**).

Discussions

The clavicle is a fragile bone segment due to its small diameter and little attachment of surrounding muscles and ligaments. When the clavicle is subjected to direct or indirect force, it is very vulnerable to fracture. Most clavicular fractures occur in the middle of the clavicle, and most of the middle clavicle fractures will have displacement [14]. When the clavicle fracture occurs, it will cause shoulder joint dysfunction, which has a serious impact on the daily life of patients. Therefore, how to effectively treat a middle clavicle fracture has important clinical significance [15, 16].

In our study, the therapeutic effects of open reduction and plate fixation and closed reduction and intra-medullary nail fixation on the treatment of middle clavicular fracture were analyzed. At present, these two methods are mostly used to treat clavicular fracture [17]. First, the surgical therapeutic effects of the two groups were compared. The results revealed that there was no obvious difference in the surgical therapeutic effects and CM and Neer scores between the two groups. It was suggested that open reduction and plate fixation, versus closed reduction and intra-medullary nail fixation for clavicular fracture, had a better therapeutic effect. The open reduction and plate fixation can be applied for reduction and fixation of clavicular fracture with plate under direct observation, and it had a good biomechanics environment and a good effect on maintaining the fixation strength after operation [18]. The intra-medullary nail fixation also has a high biomechanical stability, and less tissue dissection, which could reduce the surgical scaring [19]. These studies have shown that open reduction and plate fixation, and closed reduction and intra-medullary nail fixation have

Table 3. Neer scores of the affected side and the healthy side 3 months after operation

Project	Research group n = 37	Control group n = 37	t	P
Healthy side	98.81 ± 2.33	98.17 ± 2.29	1.192	0.237
Affected side	97.92 ± 2.35	97.32 ± 2.05	1.170	0.246
t	1.636	1.682	-	-
P	0.106	0.100	-	-

Table 4. Incidence of complications in the two groups [n,(%)]

Project	Research group n = 37	Control group n = 37	X^2	P
Wound infection	1 (2.70)	3 (8.11)	1.057	0.304
Malunion of fracture	0	3 (8.11)	3.127	0.078
Breakage of internal fixation	0	2 (5.41)	2.056	0.152
Nerve injury	1 (2.70)	1 (2.70)	-	-
Complication rate	2 (5.41)	9 (24.32)	5.232	0.022

better therapeutic effects on clavicular fracture, which are consistent with our conclusion. Subsequently, the operation time, perioperative bleeding volume, hospital stay, and fracture healing time of the two groups were compared to further compare the two treatment methods. The results suggested that the operation time, perioperative bleeding volume, hospital stay, and fracture healing time of the research group were lower than those of the control group, indicating that closed reduction and intra-medullary nail fixation for clavicular fracture has less trauma and faster healing than open reduction and plate fixation. It has been pointed out [20] that the intra-medullary nail, as an elastic fixation method, had less stress shielding, which could promote callus formation at fracture broken ends, thereby promoting fracture healing. Other studies [21, 22] suggested that the intra-medullary nail fixation had the advantages of light trauma, short operation time, and the periosteal tissue around the fracture preserved as much as possible. It could reduce the impact on the blood supply of the bone, which was conducive to the healing of the fracture. All of these confirmed our experimental conclusion. According to the records of complications, the incidence of complications in the control group surpassed that in the research group with a statistical difference. It was suggested that although both methods had good therapeutic effect, it was obvious that the intra-medullary nail fixation was safer for patients. Some studies [23] revealed that when an open incision was used for clavicle fracture surgery, there was a larger incision than closed surgery, which will cause greater injury to patients, affect the blood supply of patients at the fracture site, and increase the risk of postoperative infection. Other studies [24] clearly indicated that in the treatment of middle clavicle fracture with a plate, although the stability of the fracture broken end could be maintained well, the periosteum at both ends of the fracture needed to be peeled off, which will reduce the blood supply of the fracture end and further lead to slow healing of the fracture and other complications. Technically, when the intra-medullary nail was used for fixation, the nail was inserted at about 2 cm outside the fracture broken end. On one hand, this area could be implemented in the middle of clavicle; on the other hand, there are no more important vascular nerves in this area, which can reduce the occurrence of nerve injury [25, 26]. All the above studies confirmed our conclusion.

In summary, there was no remarkable difference between closed reduction and intra-medullary nail fixation and traditional open reduction and plate fixation in the treatment of middle clavicle fracture. However, closed reduction and intra-medullary nail fixation can better promote the healing of fracture and has fewer complications and higher safety. It is worth popularizing in clinical practice. However, there are some deficiencies in this study. For example, the therapeutic effect of open reduction and intra-medullary nail fixation was not explored. Although it is mostly performed after the failure of closed reduction and intra-medullary nail fixation, it is also an important treatment method. In addition, our sample size is relatively small. Therefore, the sample size will be further increased in subsequent experiments, and a more comprehensive comparison of treatment methods will be carried out.

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Disclosure of conflict of interest

None.

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