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Review Article

Intramedullary devices fixation versus plate fixation for adult displaced mid-shaft clavicle fractures: an update meta-analysis

Xiao Zhang[1,2*], Tao Geng[1,2,3*], Haitao Xue[4], Wenqiang Zhang[4], Yingchao Yin[1,2,3], Zhen Jiang[5], Zeqing Hu[6], Tong Luo[1,2], Guisheng Zhang[1], Yi Xu[1,2,3]

[1]Department of Orthopedic Surgery, The Third Hospital of Hebei Medical University, Shijiazhuang, P. R. China; [2]Key Laboratory of Biomechanics of Hebei Province, Shijiazhuang, P. R. China; [3]Orthopedic Research Institution of Hebei Province, Shijiazhuang, P. R. China; [4]Department of Orthopedic Surgery, The People's Hospital of Quzhou Country, Handan, P. R. China; [5]Department of Orthopedic Surgery, The Traditional Chinese Medicine Hospital of Hebei Province, Shijiazhuang, P. R. China; [6]Department of Emergency, The People's Hospital of Pingxiang Country, Xingtai, P. R. China. [*]Equal contributors.

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Abstract: Nowadays, the exact efficacy of intramedullary devices fixation and plate fixation for adult displaced mid-shaft clavicle fractures (DMCF) is still debated. This study aims to re-assess the functional outcomes and complications of the two optimal surgical approaches. Cochrane Central Register of Controlled Trials, EMABASE, and PubMed databases were searched for the literature that studied the efficacy of intramedullary devices fixation versus plate fixation for acute DMCF before August 2015. This meta-analysis focused on the Constant Shoulder Score, Oxford Shoulder Score and the incidence of infection, implant irritation, implant failure and nonunion. Revman 5.2 was used to analyze the difference between two approaches. Six trials altogether including 335 fractures were eligible, in which 163 clavicle fractures were treated with intramedullary repair and 172 with plates. The final results of our study indicate that the Constant Shoulder Score is significantly higher (MD, 2.64; 95% CI, 1.42 to 3.87; P<0.05) and the infection rate is slightly lower (RR, 0.25; 95% CI, 0.07 to 0.96; P<0.05) in intramedullary devices fixation group than the plate fixation group. And the occurrence of other adverse effects remains the same. The present meta-analysis indicates that intramedullary devices fixation could improve the functional recovery and reduce the infection rate. The intramedullary approach does not yield the irritation rate significantly.

Keywords: Intramedullary, plate, mid-shaft clavicle fractures, meta-analysis

Introduction

Clavicle is the only bony attachment of upper limbs to the thoracic cage. It plays an important role in the stability of shoulder girdle and allows the arm to perform a full range of movement [1]. Clavicle fractures account for 2.2% to 10% of adult fractures and most of them (approximately 80%) are located in the middle one-third [2-5]. The operative management is the most common treatment of the acute displaced mid-shaft clavicular fractures (DMCF) [6-12]. In terms of the operative fixation, there are multiple techniques. The plate fixation and intramedullary devices fixation are the two most widely applied treatments for DMCF. The plate fixation includes dynamic compression plate (DCP), limited contact dynamic compression plate (LC-DCP) and reconstruction plate. Though, they could provide anatomical reduction and rigid stabilization, the large incisions, extensive soft tissue and periosteum stripping at the fracture site are inevitable. The intramedullary devices, which include titanium elastic nail (TEN), Rockwood pin, Knowles pin and Smooth pin, could offer the integrity of periosteum and preservation of the soft tissue envelope. However, the intramedullary fixation might be associated with the risks of high mal-union and fixation looseness [13].

The exact efficacy of the two optimal surgical approaches, plate or intramedullary fixation, still remains debated. There have been few studies addressed the question that whether the open reduction and internal plate fixation is

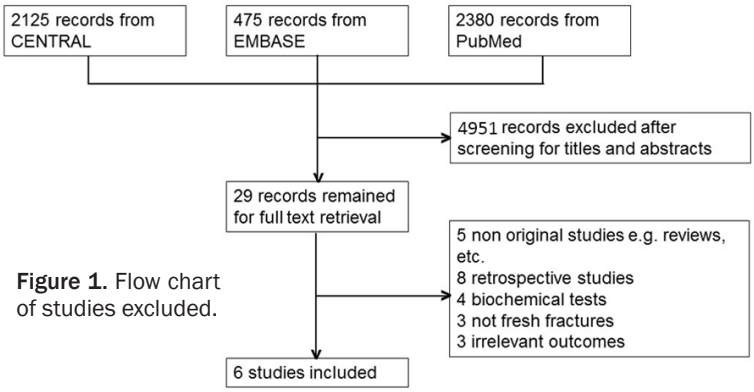

Figure 1. Flow chart of studies excluded.

superior to intramedullary pin fixation or not [11]. However, more new studies including randomized controlled studies (RCT) and clinical controlled studies (CCT) on the comparison of two treatments were conducted all over the world. It might produce a different and more reliable result when pool the added studies. The objective of this review is to compare the functional outcomes and complications of these two treatments performed on the patients with DMCF to provide an updated reference for clinical protocol making.

Patients and methods

Search strategy and criteria

To collect studies referring the treatments of plate fixation and intramedullary devices fixation in adult DMCF, two investigators (Y.Y. and J.Z.) searched the Cochrane Central Register of Controlled Trials (CENTRAL; Wiley Online Library, August 2015), EMABASE (1980 to August 2015), and PubMed (1950 to August 2015) independently using the following search terms: clavic* fractures AND nailing*; clavic* fractures AND pin*; clavic* fractures AND plate OR plating; clavic* fixation. There is no language restriction.

Studies were selected if they met the eligibility criteria: (1) the patients were more than 16 years old; (2) diagnosed as displaced mid-shaft clavicular fracture clearly; (3) the fracture was fresh or occurred within 4 weeks before operation; (4) the experimental design was RCT, qRCT or CCT; (5) the treatment methods were intramedullary fixation and plate fixation; (6) the year of study published or carried out was clear; (7) the sample size was stated; (8) data collection and analysis methods were scientific; (9) the results of the complications, such as infection, mal-union, nonunion, skin irritation and implant failure, were reported. The exclusion criteria were: (1) pathological, comminuted, open or nonunion fractures which suggested a strong tendency to the plate fixation; (2) the controls were not provided; (3) case reports, animal studies, biochemical tests and system reviews; (4) retrospective trials; (5) repeating literatures.

All the data of the articles were extracted carefully and separately after reviewing by two independent investigators. The following variables were evaluated and extracted from each study: publication year, the first author's name, periodical title, country, individual study design, characteristics, number of participants, results of the controls and cases. Contacted the authors of articles if there was any missing information or confuses about studies. The disagreements were settled by discussion and a consensus was reached for the final decisions.

Analyses

Meta-analysis was performed by RevMan 5.2 Software. Treatment effects were assessed using risk ratios (RR) with its 95% confidence intervals (CI) for dichotomous data (Constant Shoulder Score, Oxford Shoulder Score, Infection, Implant irritation, Implant failure and Nonunion) using the Mantel-Haenszel method. It was considered significantly different if $P<0.05$ and statistically heterogenous if $P<0.10$ which was tested by Q-test [14]. A random-effects model would be used to calculate pooled RRs only in the case of $P<0.10$ and I^2 statistics more than 30%, which indicated inconsistency. Otherwise, the fixed-effects model was chosen [15]. In our study, the fixed-effects model was applied in the analysis of Constant Shoulder Score, Oxford Shoulder Score, Infection, Implant irritation, Implant failure and Nonunion.

Results

Literature search results

The search strategy initially selected 4980 studies, 2125 from CENTRA, 475 from EMBASE and 2380 from PubMed. After excluding the

Table 1. Basic characteristics and quality assessment of included studies

Study	Published year	Published journal	Language	Interventions	Intramedullary group	Plate group	Total	Average time of follow-up (m)	Jadad score
Lee	2007	Orthopedics	English	KP vs DCP	32	30	62	13	4
Lee	2008	International Orthopaedics	English	KP vs Plate	56	32	88	6	2
Bohme	2010	Trauma	German	TEN vs DCP/LC-DCP/ Reconstruction plate	20	53	73	8	3
Ferran	2010	Journal of Shoulder and Elbow Surgery	English	RP vs LC-DCP	17	15	32	12	5
Qian	2010	Journal of Clinical Rehabilitative Tissue Engineering Research	Chinese	TEN vs Reconstruction plate	19	23	42	12	2
Assobhi	2011	Journal of Orthopaedics and Traumatology	English	TEN vs Reconstruction plate	19	19	38	12	5

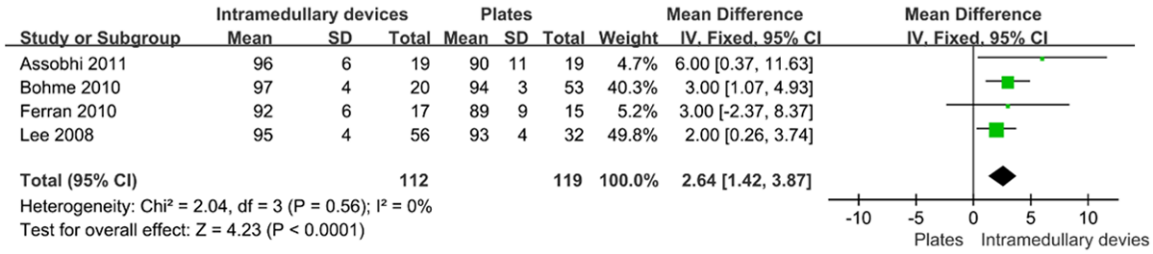

Figure 2. Meta-analysis results for the Constant Shoulder Score of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval; SD, standard deviation.

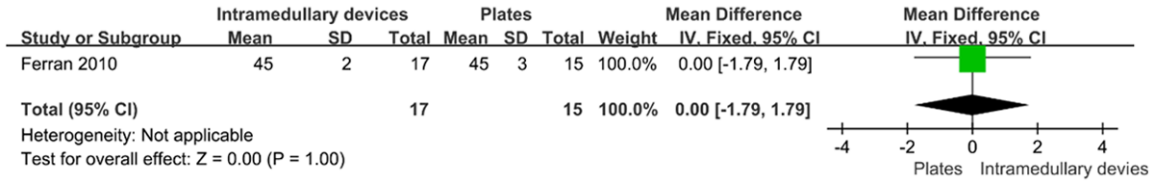

Figure 3. Meta-analysis results for the Oxford Shoulder Score of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval; SD, standard deviation.

duplicates and irrelevant references by examining titles and abstracts, we eventually identified 6 trials including 335 fractures, among which 163 clavicle fractures were treated with intramedullary repair and 172 with plate fixation (**Figure 1**) [13, 16-19]. In the 6 selected trails, the publication year ranged from 2007 to 2011 and the number of participants in each trail ranged from 32 to 73. The basic characteristics, the first author, publication year and journal, sample size, kinds of treatment, follow-up time, and jaded score, were summarized in **Table 1**.

Constant shoulder score

Five studies reported the Constant Shoulder Score of two groups. There are 112 fractures in intramedullary devices fixation group and 119 fractures in plate fixation group. The fixed-effects model was adopted to estimate pooled RRs for the evidence of homogeneity among the literatures (X^2 = 2.04, P = 0.56, I^2 = 0%). The Constant Shoulder Score was significantly higher in group with intramedullary devices fixation than in group with plate fixation (MD, 2.64; 95% CI, 1.42 to 3.87; **Figure 2**).

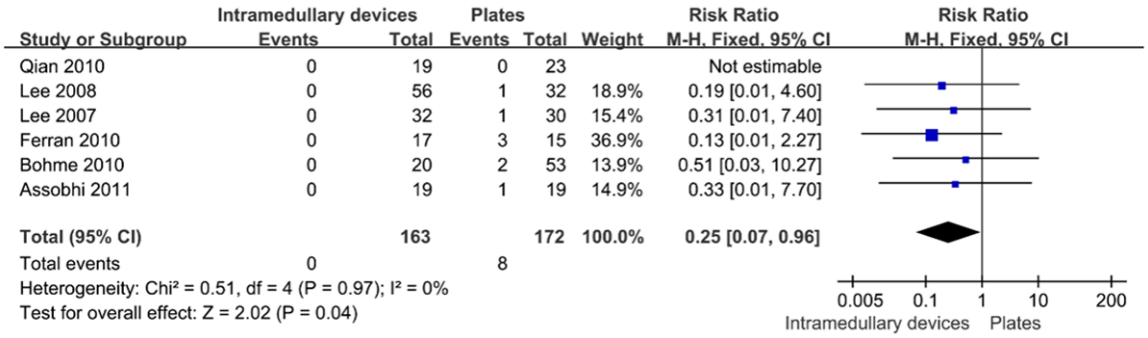

Figure 4. Meta-analysis results for the infection incidence rate of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval.

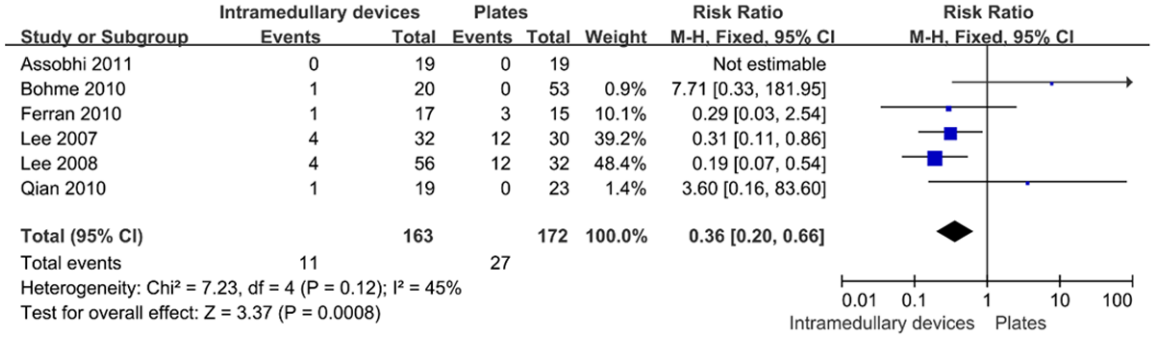

Figure 5. Meta-analysis results for the implant irritation incidence rate of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval.

Oxford shoulder score

The data on Oxford Shoulder Score was provided in only one study. The heterogeneity was not applicable and a fixed-effects model was used. No statistical differences of the Oxford Shoulder Score between intramedullary devices fixation group and the plate fixation group were identified (MD, 0.00; 95% CI, -1.79 to 1.79; **Figure 3**).

Infection

All 6 studies reported the incidence of postoperative infection between the intramedullary repair group (163 patients) and plate fixation group (172 patients). Because of the evidence of homogeneity in the studies, the fixed-effects model was performed to estimate the pooled RR (X^2 = 0.51, P = 0.97, I^2 = 0%). The test for overall effects showed that the difference of RR between two groups was statistical (RR, 0.25; 95% CI = 0.07-0.96; **Figure 4**).

Implant irritation

All six literatures investigated the incidence of skin irritation after the implant set. No heterogeneity was detected and the fixed-effects model was used (X^2 = 7.23, P = 0.12, I^2 = 45%). Results showed the incidence of implant irritation was similar between intramedullary devices fixation group and that in plate fixation group (RR, 0.36; 95% CI, 0.20 to 0.66; **Figure 5**).

Implant failure

The incidence of implant failure was available in all 6 studies. Fixed-effects model was adopted (X^2 = 1.94, P = 0.75, I^2 = 0%). No statistical differences of the incidence of implant failure were showed between these two groups (RR, 0.50; 95% CI, 0.16 to 1.55; **Figure 6**).

Nonunion

The Forest plot for the RR of nonunion between these two groups is shown in **Figure 6**. With no evidence of heterogeneity was detected among

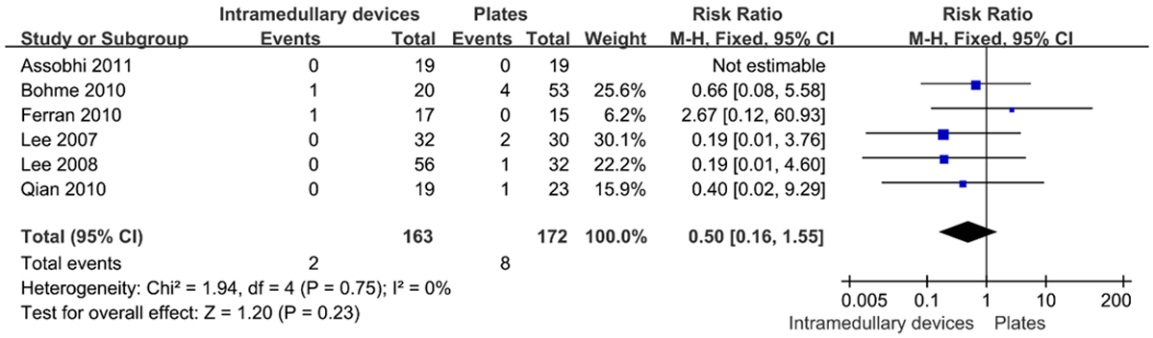

Figure 6. Meta-analysis results for the implant failure incidence rate of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval.

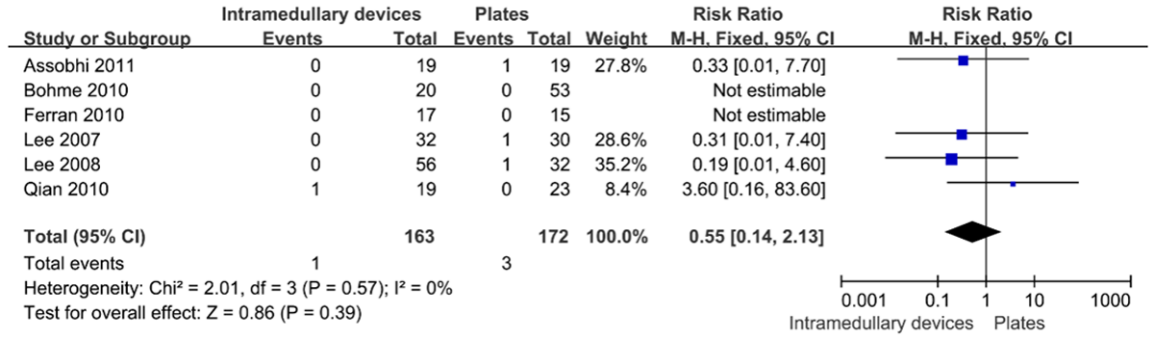

Figure 7. Meta-analysis results for the nonunion incidence of displaced mid-shaft clavicle fractures between the two managements. CI, confidence interval.

all 6 studies (X^2 = 2.01, P = 0.57, I^2 = 0%), a fixed-effects model was used, which revealed that the RR between the intramedullary repair group and plate fixation group were not significant (RR = 0.55, 95% CI, 0.14 to 2.13; **Figure 7**).

Discussion

There are several reviews on the comparison of shoulder functional outcomes and complication rates in adult displaced mid-shaft clavicle fractures with intramedullary devices fixation and plate fixation, with the conclusion that there were no significant difference between the results of those two managements [11, 20, 21]. However, given the limitation to the recall level and quality of studies included (no more than 1 high quality RCTs), they failed to make a more convincing conclusion about these questions. This meta-analysis aims to re-appraise the evidence on the comparison of the outcomes and complication rates between these two groups. In the present study, we added the latest literature, including 2 high quality RCTs, 1 qRCT and 1 CCT [4, 16, 18, 19]. We retrieved the literatures without language limitation to reduce the language bias to the minimum. All 6 studies we identified were respectively derived from China, Germany, United Kingdom and Egypt, and published in Chinese, German and English.

Our meta-analysis revealed that most of results, Oxford shoulder score, implant failure incidence rate, and nonunion incidence rate had no statistically significant differences between those two approaches and the irritation incidence rate in intramedullary devices group was significantly lower than it in plate group. All of them agreed with previous meta-analysis.

In terms of the Constant Shoulder Score, Duan *et al*. concluded that there was no difference in the results between the intramedullary repair group and the plate fixation group [11]. However, it only included one study. When the other three

RCTs or qRCT were added to analysis in our studies, we got a different result. The scores in the intramedullary repair group were significantly higher than those in the plate group ($P<0.05$), which indicated a superior functional outcome of the shoulder on the injury side.

In our study, we found the infection incidence rate in intramedullary devices group was statistically lower than it in the plate fixation group ($P<0.05$). The open reduction and internal fixation with plates was presented as a gold standard treatment for displaced mid-shaft clavicle fractures. It was inevitable to extend the exposed surface, periosteal stripping and, at the same time, increase the amount of blood loss and duration. All those factors contribution to an increased risk of infection.

There are several limitations of this meta-analysis. Only 1 trail including 32 patients on the aspect of Oxford Shoulder Score was selected in our studies and the conclusion of the analysis on this effect size might content a larger bias. On the other hand, the different age groups, genders, and exact degree of injury, which in- or directly influenced the results, were not reported in this study.

The present meta-analysis indicates that intramedullary devices fixation could improve the functional recovery and reduce the infection rate. The intramedullary approach does not yield the irritation rate significantly. The occurrence of other adverse effects remains the same.

Disclosure of conflict of interest

None.

Authors' contribution

X.Z., T.G. and Y.X. were responsible for conception and design, coordinated the study, and wrote the article. Y.Y. and Z.J. searched through the databases and extracted information. Z.H. and T.L. were involved in the performance of analysis. G.Z., Y.X., H.X. and W.Z. provided critical revisions. All authors have read and approved the final article.

Address correspondence to: Dr. Yi Xu, Department of Orthopedic Surgery, The 3rd Hospital, Hebei Medical University, 139 Ziqiang Road, Shijiazhuang 050051, P. R. China. Tel: 0086-311-8860-3629; Fax: 0086-311-8702-3626; E-mail: 390999745@qq.com

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