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Evaluation of surgical and non-surgical interventions for clavicle fractures

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Objective: The aim of this study was to review all systematic reviews and meta-analyses and provide an overview of the evidence of efficacy of interventions for clavicle fractures.

Methods: The Cochrane Library, PubMed, MEDLINE, Chinese Biomedicine database, China Academic Journals Full-text Database, VIP Chinese Science and Technology Periodicals Database and Wanfang Database were searched for eligible studies using keywords related to clavicle fractures. The methodological quality of included studies was assessed using the AMSTAR assessment tool. Direct evidence was analyzed narratively. Randomized controlled trials were pooled again for meta-analysis. The GRADE approach was used in summary conclusions.

Results: The result of pooled data showed that while operative treatment had lower nonunion and malunion rates and higher patient satisfaction than non-operative treatment modalities [RR=6.57, 95% CI (3.01, 14.35), RR=6.93, 95% CI (2.99, 16.09); RR=0.68, 95% CI (0.51, 0.90)], these 3 outcomes were based on low-quality evidence. There was no difference between dissimilar operative and dissimilar non-operative treatments.

Conclusion: Operative treatment is more effective than non-operative treatment in terms of nonunion and malunion rates and patient satisfaction. As the quality of evidence comparing efficacy between intervention methods is generally low, further original studies are needed.

Key words: Clavicle fracture; GRADE; non-operative treatment; operative treatment; overview of reviews; systematic review.

Clavicle fractures are among the most common fractures in adults, comprising 2.6 to 10% of all fractures.[1] They are commonly seen following a direct blow on the shoulder, such as a fall onto an outstretched hand.[2] Diagnosis is usually straightforward, with symptoms of shoulder deformity and bruising. Conventional radiographs are considered the gold standard for diagnosis. Due to its anatomy, the mid-shaft is the most common location for these fractures and accounts for 76.2 to 81.3% of all clavicle fractures.[1,3]

Treatment options for clavicle fractures currently include non-operative and operative treatment modalities. In terms of conservative treatment, a sling or figure-of-eight bandage is most commonly applied. Despite

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high union rates and good clinical results in most cases, malunion is commonly seen after non-operative treatment for displaced proximal and distal bone fragments.[4,5] Following the development of a theoretical base for fibular internal fixation, interest in operative treatment options, including internal fixation with screws, pins, or plates, has increased.[6,7] Unfortunately, as the majority of operative treatments require a second operation for surgical implant removal, the optimal treatment for clavicle fracture remains controversial.[8]

Systematic reviews are often considered the least biased source of evidence for the evaluation of the value of a particular intervention in evidence-based medicine. Overviews of reviews are designed to compile evidence from multiple systematic reviews of interventions into one accessible and usable document.

The aim of this study was to review all systematic reviews and meta-analyses and provide an overview of the evidence of efficacy of interventions for clavicle fractures.

Materials and methods

This study was conducted and reported according to the recommendations of The Cochrane Collaboration.

Both Cochrane reviews and non-Cochrane reviews comparing different interventions for clavicle fractures were included. The primary outcomes were nonunion rates and functional scores and secondary outcomes were malunion rates and patient satisfaction.

The Cochrane Library (2012, 3 issues), PubMed (1966 to September 2012), MEDLINE (1966 to September 2012), Chinese Biomedicine database (1978 to September 2012), China Academic Journals Full-text Database (1979 to September 2012), VIP Chinese Science and Technology Periodicals Database (1989 to September 2012) and Wanfang Database (1977 to September 2012) were searched. The search strategy outlined here was used to search PubMed, and a similar search strategy was employed in other databases. Search terms used in the Chinese database are given in Fig. 1. There were no restrictions on the publication language. In addition, references cited in the articles were checked manually to identify further eligible studies.

Search strategy in PubMed:

#1 "Clavicle" [Mesh]

#2 calvicle

#3 clavicle

#4 clavicular

#5 clavic*

#6 collarbone

#7 OR/#1-#6

#8 fracture

#9 fractures

#10 fracture*

#11 "Fractures, Bone" [Mesh]

#12 OR/#8-#11

#13 "Review" [Publication Type]

#14 systematic review

#15 systematic overview

#16 systematic evaluation

#17 evidence-based review

#18 evidence based evaluation

#19 meta analysis

#20 meta-analysis

#21 meta analyses

#22 meta-analyses

#23 metaanalysis

#24 metaanalyses

#25 OR/#13-#24

#26 #7 AND #12 AND #25

Two review authors independently scanned the titles, abstract sections and keywords of every record to determine studies to be assessed further according to the inclusion criteria. The full articles were then inspected to determine whether they met the review criteria. Disagreements were resolved through discussion.

Two reviewers independently extracted data using a standard form and a cross-check was performed to ensure validity. The data extraction consisted of study characteristics and the main results.

((锁骨 AND 骨折) OR 锁骨骨折) AND (系统评价 OR 系统评估 OR 系统综述 OR 循证评价 OR 循证评估 OR Meta 分析 OR 荟萃分析 OR 梅塔分析 OR 定量分析 OR 元分析)

Fig. 1. Search terms used in Chinese database.

Table 1. The characteristics and methodology quality of the included studies.

Study ID	Country	Update	No. of studies	Population	No. of RCTs	Interventions†	Outcomes‡	AMSTAR§
Zlowodzki et al.[15] (2005)	Canada	NO	22	2144	3	a, b, c	d, g	C/C/Y/C/N/N/N/Y/NA/N/N§§
Gu et al.[16] (2009)	China	NO	4	270	1	a	d, e, g	C/Y/N/N/N/N/N/Y/Y/Y/N
Lenza et al.[17] (2009)	Brazil	NO	3	354	3	b	d, e	Y/Y/Y/Y/Y/Y/Y/Y/NA/Y/Y
Lenza et al.[18] (2009)	Brazil	NO	3	238	3	c	d, e	Y/Y/Y/Y/Y/Y/Y/Y/NA/Y/Y
Virtannen et al.[14] (2009)	Finland	NO	11	1595	2	a, b	d, e, f	C/Y/N/Y/N/N/Y/Y/NA/N/N
Zhen et al.[19] (2010)	China	NO	4	307	4	a	d, f, g	C/Y/Y/Y/N/N/Y/Y/Y/N/N
Duan et al.[20] (2011)	China	NO	4	305	3	a, c	d, e, g	C/Y/Y/Y/Y/Y/Y/Y/Y/N/Y
Oh et al.[21] (2011)	Korea	NO	21	425	0	a, c	d	C/C/Y/Y/Y/Y/N/Y/NA/N/Y
Wang et al.[22] (2011)	China	NO	8	519	5	a	d, e, f, g	C/Y/N/C/N/N/Y/Y/Y/Y/N
Ban et al.[23] (2012)	Denmark	NO	5	365	4	a, c	d, e, f	C/Y/N/Y/N/Y/N/Y/NA/N/Y
Houwert 2012[24] (2012)	Netherlands	NO	4	311	1	a, c	d, e, f	C/Y/N/Y/Y/Y/Y/Y/NA/N/Y
McKee et al.[25] (2012)	Canada	NO	6	412	6	a	d, e, f	C/Y/Y/Y/N/Y/Y/Y/Y/Y/Y
Virtannen et al.[26] (2012)	Finland	NO	14	1190	6	a, b, c	d, e, f	Y/Y/Y/Y/N/Y/Y/Y/NA/N/Y
Wijdicks et al.[27] (2012)	USA	NO	11	NR*	3	a, c	d, f	C/C/Y/Y/N/Y/Y/Y/NA/N/Y
Xiong et al.[28] (2012)	China	NO	4	301	3	a	d, f	C/Y/Y/C/Y/Y/Y/Y/Y/Y/N

*NR: no report. †a: non-operative vs. operative; b: non-operative vs. non-operative; c: operative vs. operative. ‡d: nonunion rates; e: functional scores; f: malunion rates; g: satisfaction of patients. §AMSTAR items: (1) Was an "a priori" design provided? (2) Was there duplicate study selection and data extraction? (3) Was a comprehensive literature search performed? (4) Was the status of publication used as an inclusion criterion? (5) Was a list of studies (included and excluded) provided? (6) Were the characteristics of the included studies provided? (7) Was the scientific quality of the included studies assessed and documented? (8) Was the scientific quality of the included studies used appropriately in formulating conclusions? (9) Were the methods used to combine the findings of studies appropriate? (10) Was the likelihood of publication bias assessed? (11) Was the conflict of interest stated? §§Y: yes; N: no; C: can't answer; NA: not applicable.

Methodological quality and quality of the evidence were evaluated by 2 reviewers independently. The methodological quality of included studies was assessed with the AMSTAR assessment tool, an 11-item questionnaire with answers of 'yes', 'no', 'can't answer' or 'not applicable' (Table 1). The quality of the evidence was evaluated using the GRADE system.[9] The quality of evidence is presented in the footnote of Table 2.

Data was reorganized and re-extracted from the included reviews, and reported in tables or figures. When there was no evidence on direct comparison of both the included reviews and other known studies, but all other factors (except for the comparable factors) were similar, we considered whether it was feasible to undertake indirect comparisons across reviews. Since indirect comparisons are not randomized comparisons, caution was taken in interpreting the results.

Results

The search identified 376 references. Of these, 358 were excluded because they were duplicates, non-systematic reviews or inconsistent with the study objectives. The remaining 18 references were retrieved for further assessment and an additional 3 references were excluded because they were protocol, translation or a repeated report.[10-12] One article was listed as a study awaiting classification because it was written in German and the authors could not extract the data.[13] Additionally, one article obtained from the references cited in articles met the inclusion criteria.[14] Finally, a total of 15 systematic reviews met the eligibility criteria (Fig. 2).[14-28] Of these, 2 were Cochrane reviews[17,18] and 13 were non-Cochrane reviews.[14-16,19-28]

The characteristics and methodological quality of the included studies are given in Table 1. Based on the AMSTAR assessment, only 3 systematic reviews mentioned the protocols before conducting the review,[17,18,26] 6 provided a list of included and excluded studies[17,18,20,21,24,28] and 9 did not assess the likelihood of publication bias.[14,15,19-21,23,24,26,27] A total of 17 randomized controlled trials (RCT) were included in the 15 reviews.

Of the 15 included reviews, 13 compared non-operative treatment with operative treatment,[14-16,19-28] 5 of which reported the operation method as plate fixation or intramedullary pin fixation.[15,20,21,24,27] Others mentioned "comparing operative with non-operative treatment" or other similar parlance.[14,16,19,22,23,25,26,28,29]

Approximately 50% performed a meta-analysis, and the pooled results showed that operative treatment was better than non-operative treatment in terms of nonunion rates, malunion rates and patient satisfaction.[16,19,20,22,25,28] Because most trials were repeated in dif-

Table 2. The quality of the evidence.

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Operative	Non-operative				
Nonunion rates	Study population		RO 6.57	659	⊕⊕⊖⊖	
	14 per 1000	95 per 1000 (43 to 207)	(3.01 to 14.35)	(9 studies)	low†,‡	
	Moderate					
	0 per 1000	0 per 1000 (0 to 0)				
Malunion rates	Study population		RO 6.93	381	⊕⊕⊖⊖	
	20 per 1000	140 per 1000 (60 to 325)	(2.99 to 16.09)	(5 studies)	low†,‡	
	Moderate					
	0 per 1000	0 per 1000 (0 to 0)				
Satisfaction of patients	Study population		RO 0.68	251	⊕⊕⊖⊖	
	909 per 1000	618 per 1000 (464 to 818)	(0.51 to 0.9)	(3 studies)	low†,§	
	Moderate					
	900 per 1000	612 per 1000 (459 to 810)				

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio. GRADE Working Group grades of evidence: High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate. †The drop-out rate was no described or unacceptable. ‡The effect of volume estimates has a wide CI. §The sample size is too small.

ferent reviews, the results of 9 RCTs were pooled again. There was no statistical heterogeneity between trials ($p=0.44$, $I^2=0\%$). The result of pooled data showed that operative treatment had lower nonunion rates compared to non-operative treatment [RR=6.57, 95 %CI (3.01, 14.35)] (Fig. 3). The results were the same for malunion rates and patient satisfaction [RR=6.93, 95% CI (2.99, 16.09); RR=0.68, 95% CI (0.51, 0.90)]. However, the 3 outcomes were based on low-quality evidence (Table 2). Functional scores were reported in 8 reviews.[14,16,20,22-26] One meta-analysis of 3 trials and one of 2 trials revealed no statistical difference between groups. Other descriptive reviews reported better outcomes with operative treatment.

Of the 15 included reviews, 4 compared non-operative treatment with operative treatment.[14,15,17,26] Two RCTs were repeated in 4 reviews. Reviewers agreed that there was no difference in union or function in fractures treated with rucksack bandage or mitella.

About half of the 15 included reviews reported a comparison among different operation methods.[15,18,20,21,23,24,26,27] One was based on 2 RCTs and compared plating with intramedullary nailing.[20] Another reported 3 different comparisons; between low-contact dynamic compression plate (LCDCP) and dynamic compression plate (DCP), between Knowles pin and DCP, and between three-dimensional plate and superior-positioned plate.[18] Reviewers held the view that there were no differences in union or function in fractures treated with different operative methods.

Discussion

The evidence from the systematic reviews demonstrated that operative treatment was superior to non-operative treatment in terms of nonunion rates, malunion rates and patient satisfaction. There was no difference between dissimilar operative treatments or dissimilar non-operative treatments. However, as this finding was based

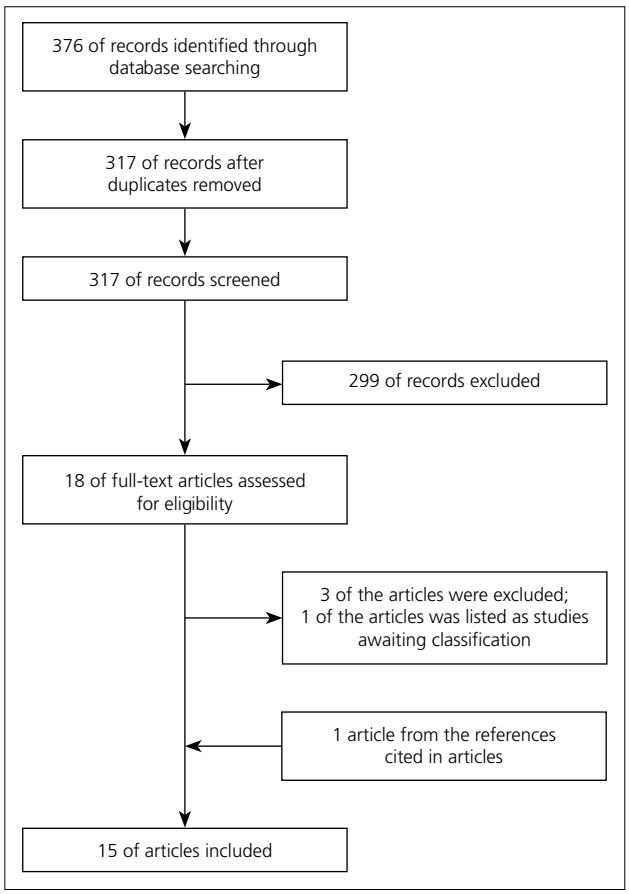

Fig. 2. The flowchart of literature screening.

on low-quality evidence, further research is likely to have an important impact on our confidence to estimate the effect and likely to change this estimate. The evidence regarding the efficacy between different treatments may not be powerful enough as it was mostly drawn from a few numbers of RCTs.

A number of recently published reviews provided useful supplementary information to this overview. To our knowledge, this was the first evidence-based overview of reviews on clavicle fracture intervention. An exhaustive and contemporaneous search strategy was employed to ensure all eligible systematic reviews were included. Study selection, data extraction and quality assessment were carried out independently by 2 authors to ensure validity. Additionally, both methodological quality of the included systematic reviews and quality of the evidence on outcomes were evaluated to provide a more comprehensive evidence-based review.

Limitations of this systematic review mainly arise from the quality of the included systematic reviews and the original trials included in the reviews. Systematic review results may be influenced by selection bias and publication bias through the results of quality assessment. Furthermore, as only 3 reviews mentioned an "a priori" design, such as a protocol, most authors spent a lot of time doing the same work. As a suggestion, it is necessary to pay attention to the protocol of study by researchers.

In conclusion, this overview provides an important significance for both clinical practice and research. The findings indicated that operative treatment is more effective than non-operative treatment in terms of nonunion rates, malunion rates and patient satisfaction. However, there was no difference between dissimilar operative treatments or dissimilar non-operative treatments. Further original studies are needed, as the quality of evidence regarding the efficacy between different interventions is generally low.

Study ro Subgroup	Non-operative Events	Total	Operative Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Smith 2000	12	50	0	50	7.5%	25.00 [1.52, 411.09]	2000
Judd 2005	1	29	1	29	15.1%	1.00 [0.07, 15.24]	2005
Jubel 2005	2	27	0	26	7.7%	4.82 [0.24, 95.88]	2005
Witzel 2007	0	33	0	35		Not estimable	2007
COTS 2007	7	49	2	62	26.6%	4.43 [0.96, 20.37]	2007
Figueiredo 2008	2	20	1	20	15.1%	2.00 [0.20, 20.33]	2008
Smekal 2009	6	52	0	60	7.0%	14.96 [0.86, 259.39]	2009
Judd 2009	1	28	1	29	14.8%	1.04 [0.07, 15.77]	2009
Virtanen 2010	8	25	0	35	6.3%	23.54 [1.42, 389.88]	2010
Total (95% CI)		313		346	100.0%	6.57 [3.01, 14.35]	
Total Events	39		5				

Heterogemneity Chi² = 6.90, df= 7 (P=0.44): I² = 0%

Test for overall effect: Z = 4.72 (P<0.00001)

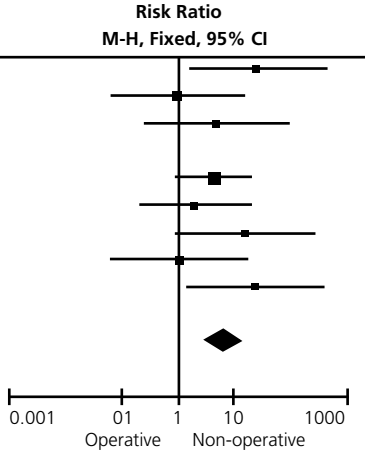

Fig. 3. Non-operative vs. operative results for nonunion.

Conflicts of Interest: No conflicts declared.

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