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Surgical Versus Conservative Treatments for Displaced Midshaft Clavicular Fractures

A Systematic Review of Overlapping Meta-Analyses

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Abstract: Multiple meta-analyses have been performed to compare surgical and conservative interventions for treating displaced midshaft clavicular fractures. But conclusions are discordant.

The purposes of current study were (1) to conduct a systematic review of meta-analyses comparing surgical and conservative interventions for the treatment of displaced midshaft clavicular fractures, (2) to help decision makers interpret and choose among discordant meta-analyses, and (3) to provide treatment recommendations through the best available evidence.

We searched the Cochrane library, PubMed, and EMBASE databases to identify meta-analyses comparing surgical and conservative treatments for the displaced midshaft clavicular fractures. Two investigators independently scanned titles and abstracts to exclude irrelevant articles and identify meta-analyses that met the eligibility criteria. The methodological quality of the meta-analysis was independently assessed by the two investigators using the Oxford Centre for Evidence-based Medicine Levels of Evidence and the Assessment of Multiple Systematic Reviews (AMSTAR) tool. The Jadad decision algorithm was applied to determine which of the included studies provided the best available evidence.

Six meta-analyses met the eligibility criteria in this systematic review. AMSTAR scores ranged from 5 to 10. The Jadad decision-making tool suggests that the highest quality review should be selected based on the publication characteristics of the primary trials, the methodology of the primary trials, the language restrictions, and whether analysis of data on individual patients was included in the study. As a result, we selected a high-quality Cochrane review.

This systematic review of overlapping meta-analyses comparing surgical and conservative treatments suggests that surgical treatment provides a lower rate of overall treatment failure and a better functional outcome, but is associated with more implant-related complications. Hence, treatment should be individualized, with careful consideration of the advantages and disadvantages of each treatment method and of patient preferences.

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Abbreviations: AMSTAR = Assessment of Multiple Systematic Reviews, RCT = Randomized clinical trial.

INTRODUCTION

Clavicle fractures are common, with an overall incidence of 36.5 – 64 per 100,000 people every year.[1,2] The most common site of fracture is the midshaft of the clavicle, which accounts for 80% of all clavicle fractures. Conservative treatments are widely used and are recommended for midshaft clavicular fractures, with rates ranging from 0.03% to 5.9%.[1,3] However, the outcome of conservative treatment is not as favorable as once thought and there has been a growing trend to treat these fractures surgically.[4] The best treatment for displaced midshaft clavicle fractures remains a topic of debate.

Numerous clinical studies, including many prospective, randomized controlled trials (RCTs), have been published to compare surgical and conservative treatments.[5–9] On the basis of the proliferation of clinical studies, multiple authors have conducted systematic reviews and meta-analyses comparing surgical and conservative treatments.[10–16] However, the results of the overlapping meta-analyses have been discordant in their findings regarding the postoperative outcomes. For example, a meta-analysis by Kong et al[17] showed surgical treatment leads to a higher risk of postoperative complications. However, McKee et al[11] and Xu et al[16] concluded that both operative and conservative treatments can achieve a similar incidence of complications.

The purposes of this systematic review were: (1) to conduct a systematic review of meta-analyses comparing surgical and conservative interventions for the treatment of displaced midshaft clavicular fractures, (2) to help decision-makers interpret and choose among discordant systematic reviews, and (3) to provide treatment recommendations through the best available evidence.

MATERIALS AND METHODS

Literature Search

We searched the PubMed, Cochrane library, and EMBASE databases up to February 2015. The following key words were used for the searches: meta-analysis or systematic review; clavicle or clavicular; fracture. The references for each of these citations were also manually screened to ensure that no studies were missed.

Eligibility Criteria

We aimed to identify all meta-analyses or systematic review comparing surgical and conservative treatments for

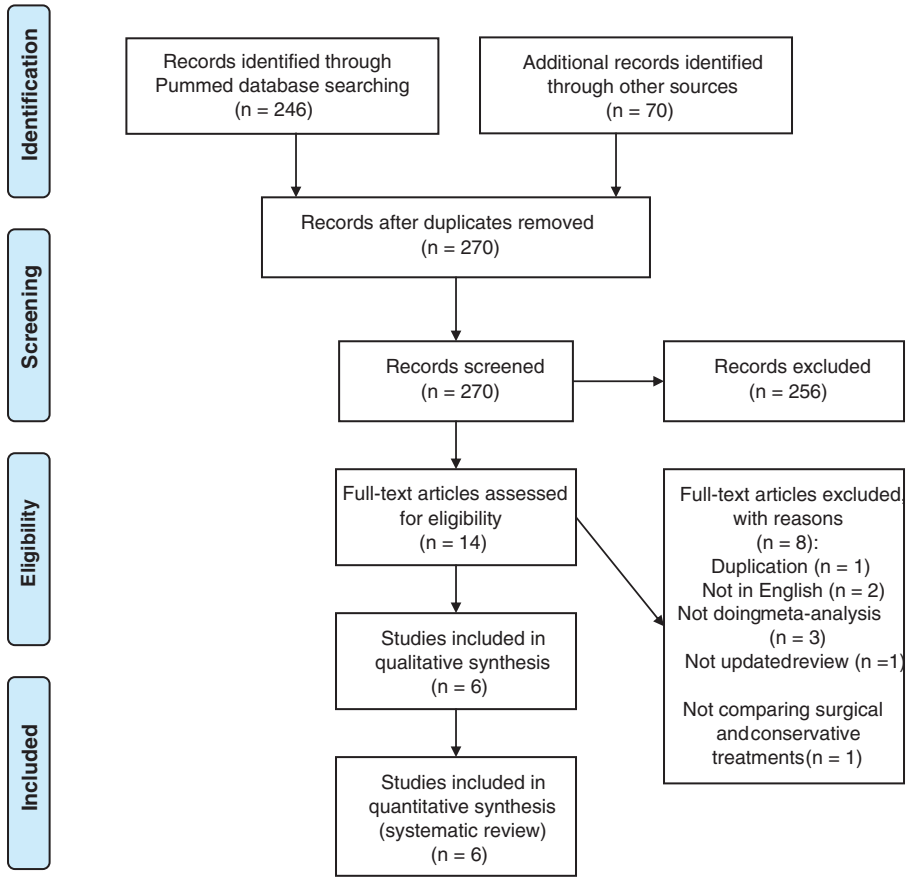

FIGURE 1. Flow diagram summarizing the selection process of meta-analyses.

displaced midshaft clavicular fractures. The exclusion criteria were: (1) non-English language articles; (2) meta-analysis was not performed; and (3) meetings abstract.

Selection of Studies

Two investigators independently scanned titles and abstracts to exclude irrelevant articles and identify meta-analyses that met the eligibility criteria. We resolved discrepancies between investigators by consulting a third review investigators. Then two authors independently extracted data for the included meta-analyses. The following information relating to key characteristics of the meta-analyses were extracted: date of literature search, search database, date of publication, number of included trials, design of included studies, software use, and I^2 statistic value.

Assessment of Methodological Quality

Two investigators independently assessed the methodological quality of the included meta-analyses using the Oxford Centre for Evidence-based Medicine Levels of Evidence[18] and the Assessment of Multiple Systematic Reviews (AMSTAR) tool.[19] AMSTAR was chosen because of its reported inter-rater reliability, construct validity and feasibility. AMSTAR uses 11 items to assess which review methods are unbiased[19,20] and are extensively applied.[21,22] Then the total scores for every article were calculated.

Application of Jadad Decision Algorithm

The Jadad decision algorithm was used to guide interpretation of discordant meta-analyses.[21] Discordance among meta-analyses as described by Jadad et al[21] derive from the following six reasons: clinical question, study selection and inclusion, data extraction, assessment of study quality, assessment of the ability to combine studies, and statistical methods for data synthesis.[23] It was independently applied by two authors, whose results were compared to most robustly determine which of the included meta-analyses proposed a guide through the currently best available evidence.

RESULTS

Search Results

The initial search found 316 abstracts. Six meta-analyses met the eligibility criteria in this systematic review (Figure 1).[10–12,16,17,24] These studies were published between 2012 and 2014, with all six studies performing a meta-analysis. All studies reported no conflict of interest in their studies. The included studies recruited from 321 patients[10] to 633 patients[24] (Table 1). The number of primary studies varied widely from 4 to 8 (Table 2).[5,6,8,25–32]

Search Methodology

Only one study[17] reported the publication language was restricted as English, and no language restriction were applied

TABLE 1. General Description of the Characteristics of Each Meta-Analysis

Authors	Journal	Date of Last Literature Search	Date of Publication	No. of Included Studies	No. of Included RCTs
McKee et al 2012	Journal of Bone and Joint Surgery Am	2010	April, 2012	6	6
Lenza et al 2013	Cochrane Database of Systematic Reviews	December, 2012	June, 2013	8	8
Liu et al 2013	International Orthopaedics	December, 2011	August, 2013	8	5
Xu et al 2013	European Journal of Orthopaedic Surgery and Traumatology	June, 2012	August, 2013	4	4
Kong et al 2014	Archives of orthopaedic and trauma surgery	January, 2014	November, 2014	6	6
Xu et al 2014	Journal of Shoulder and Elbow Surgery	February, 2013	February, 2014	7	7

TABLE 2. Primary Studies Included in Meta-Analyses

Authors	Smith 2000	COTS 2007	Witzel 2007	Figueiredo 2008	Koch 2008	Judd 2009	Smekal 2009	Chen 2011	Mirzatolooei 2011	Virtanen 2012	Robinson 2013
McKee et al 2012	+	+	+			+	+			+	
Lenza et al 2013		+		+	+	+	+	+	+	+	
Liu et al 2013	+	+				+	+			+	
Xu et al 2013	+	+					+		+		
Kong et al 2014		+				+	+		+	+	+
Xu et al 2014	+	+	+			+	+		+	+	

in other studies.[10–12,16,24] Most studies comprehensively searched databases. All of the included studies searched Medline or PubMed. There was heterogeneity as to whether meta-analyses also included searches of Embase, Cochrane library, OVID, and Google scholar (Table 3).

Study Quality and Validity

Only one meta-analysis[11] specially included Level I evidence; four studies[10,12,16,17] included evidence of Levels I to II; and one study[24] included evidence of Levels I and III (Table 4). One Cochrane review[12] reported the GRADE was used in their article. AMSTAR scores were assessed for each study and ranged from 5 to 10, with a median of 7.2 (Table 5). The Cochrane review by Lenza et al[12] was assessed as the most highest quality study.

Heterogeneity Assessment

All meta-analyses performed statistical heterogeneity analysis and reported I^2 statistic value. Of the six meta-analyses, three meta-analyses performed subgroup analyses based on the surgical method (Table 4).[10,12,16] Table 6 summarized the I^2

TABLE 3. Search Methodology Used by Each Study

			Search Database						
Authors	Restriction of Publication Language	Restriction of Publication Status	PubMed	Medline	Embase	Cochrane Library	OVID	Google scholar	Others
McKee et al 2012	No	NA		+					+
Lenza et al 2013	No	No		+	+	+			+
Liu et al 2013	No	NA	+	+	+	+		+	
Xu et al 2013	No	NA		+	+	+	+		+
Kong et al 2014	Yes	NA	+		+	+			+
Xu et al 2014	No	NA	+	+	+	+	+		+

NA = Not Available.

TABLE 4. Methodological Information for Each Included Study

Authors	Design of Included Studies	Level of Evidence	Software	GRADE Use	Subgroup Analysis
McKee et al 2012	RCT	Level I	Revman	No	No
Lenza et al 2013	RCT	Level II	Revman	Yes	Yes
Liu et al 2013	RCT or CCT	Level III	Revman	No	No
Xu et al 2013	RCT	Level II	Revman	No	Yes
Kong et al 2014	RCT	Level II	Revman	No	No
Xu et al 2014	RCT	Level II	Stata	No	Yes

CCT = controlled clinical trial, RCT = Randomized clinical trial.

statistic value for each outcome of included meta-analyses. Heterogeneities for the majority of outcomes were acceptable.

Results of Jadad Decision Algorithm

The Jadad decision algorithm was applied to determine which of the six included studies provided the best available evidence.[23] Figure 2 showed the all outcomes of included meta-analyses. Given that the selection criteria were not accordant among included meta-analyses, the Jadad algorithm suggests that the highest-quality review should be selected based on the publication characteristics of the primary trials, the methodology of the primary trials, the language restrictions, and whether analysis of data on individual patients was included in the study. As a result, we selected a high-quality Cochrane review (Figure 3).[12] This Cochrane review concluded that 'Limited evidence is available from randomised controlled trials on the relative effectiveness of surgical versus conservative treatment for acute middle third clavicle fractures. Treatment options must be chosen on an individual patient basis, after careful consideration of the relative benefits and harms of each intervention and of patient preferences.'

DISCUSSION

Although several meta-analyses have been published for the treatment of displaced midshaft clavicular fractures, they still reached different conclusions. Such discordance causes difficulties for decision makers (including clinicians, policy-makers, researchers and patients, depending on the context) who rely on these meta-analyses to help them make choices among alternative interventions when experts and the results of trials disagree. Jadad et al[23] summarized the potential sources of discordance among meta-analyses and provided a decision tool which summarizes the process for identifying and resolving causes of discordance.

According to the Jadad model, the Cochrane review by Lenza et al[12] was selected in this systematic review. Lenza et al[12] found that that surgical intervention was superior to conservative treatment in DASH questionnaire, constant score, symptomatic malunion, overall treatment failure, deformity and/or asymmetry, asymptomatic malunion, stiffness/restricted of range of shoulder movement, number of patients return to sport activities, and time to return to previous activities. There were no differences between surgical and conservative

TABLE 5. AMSTAR Criteria for Each Included Study

Items	McKee et al 2012	Lenza et al 2013	Liu et al 2013	Xu et al 2013	Kong et al 2014	Xu et al 2014
1. Was an a priori design provided?	0	1	0	0	0	0
2. Was there duplicate study selection and data extraction?	1	1	1	1	1	1
3. Was a comprehensive literature search performed?	0	1	1	1	1	1
4. Was the status of publication (ie grey literature) used as an inclusion criterion?	1	1	1	0	0	1
5. Was a list of studies (included and excluded) provided?	0	1	0	0	0	0
6. Were the characteristics of the included studies provided?	1	1	1	1	1	1
7. Was the scientific quality of the included studies assessed and documented?	1	1	0	1	1	1
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	1	1	0	0	1	0
9. Were the methods used to combine the findings of studies appropriate?	1	1	0	1	1	1
10. Was the likelihood of publication bias assessed?	0	0	0	0	0	1
11. Was the conflict of interest stated?	1	1	1	1	1	1
Total scores	7	10	5	6	7	8

TABLE 6. I^2 Statistic Value of Each Variable in Each Meta-Analysis

Items	McKee 2012	Lenza 2013	Liu 2013	Xu 2013	Kong 2014	Xu 2014
Function		85%				
DASH questionnaire		80%			91%	–
Constant score		72%		–	67 %	–
UCLA score		–				
SANE score		–				
L'Insalata score		–				
Pain		–				
Nonunion	0%		0 %	0%	0%	0%
Symptomatic nonunion		0%				
Malunion			0 %	0%	0%	
Symptomatic malunion		0%				–
Nonunion and symptomatic malunion	0%					
Delayed union			29 %			–
Early mechanical failure		0%				
Overall treatment failure		21%				
Deformity and/or asymmetry		0%				
Hardware irritation and/or prominence		0%				
Unsightly scar		0%				
Total of cosmetic problems		74%				
Asymptomatic nonunion		42%				
Asymptomatic malunion		0%				
Infection and/or dehiscence		0%				–
Hardware irritation requiring removal		0%				
Skin and nerve problems (incisional numbness)		57%				
Neurological complication			28 %	40%		
Stiffness/restricted of range of shoulder movement		0%				
Refracture		0%				
Refractures or implant failure						–
Surgery intervention						–
Total of adverse events	69%	82%		0%	0%	35.5%
Dissatisfaction				0%		
Outcomes dissatisfaction						48.8%
Appearance dissatisfaction						0%
Number of patients return to sport activities		–				
Time to return to previous activities		–				

treatments in function, UCLA score, pain, symptomatic nonunion, early mechanical failure, unsightly scar, total of cosmetic problems, asymptomatic nonunion, skin and nerve problems (incisional numbness), refracture, and total of adverse events. Conservative treatment was superior to surgical intervention in hardware irritation and/or prominence, infection and/or dehiscence, and hardware irritation requiring removal. However, because these results were based on evidence from the RCTs with high risk of bias, Lenza et al[12] concluded that the evidence is insufficient to indicate whether surgical or conservative treatment is best for treating displaced midshaft clavicular fractures. Treatment should be individualized, with careful consideration of the relative advantages and disadvantages of each intervention and of patient preferences.

This conclusion is consistent with the finding by Robinson et al.[5] They performed a multicenter RCT involving 200 patients and do not support the routine use of primary surgical fixation for displaced midshaft clavicular fractures in adults. Robinson et al[5] found that open reduction and plate fixation provides a lower rate of nonunion and a better functional outcome, but increased implant-related complications. When comparing with nonoperative treatment, routine primary surgical treatment not only exposed an unacceptably high number of patients to the risks of surgery, but also increased economic burden of hospital costs.[33] They think treatment should be chosen based on an individual patient, after consideration of expectations of treatment, each patient's age, and activity level.[5]

There are limitations to our study. First, we only included English language studies. Although we searched for as many meta-analyses as possible, it is possible that we have omitted non-English language trials. Second, meta-analyses included and analyzed lower quality RCTs. The evidence was of low quality overall as the result of methodological flaws including lack of adequate allocation concealment and failure to blind the outcome assessor in the majority of trials.

FIGURE 2. Results of each included meta-analysis.

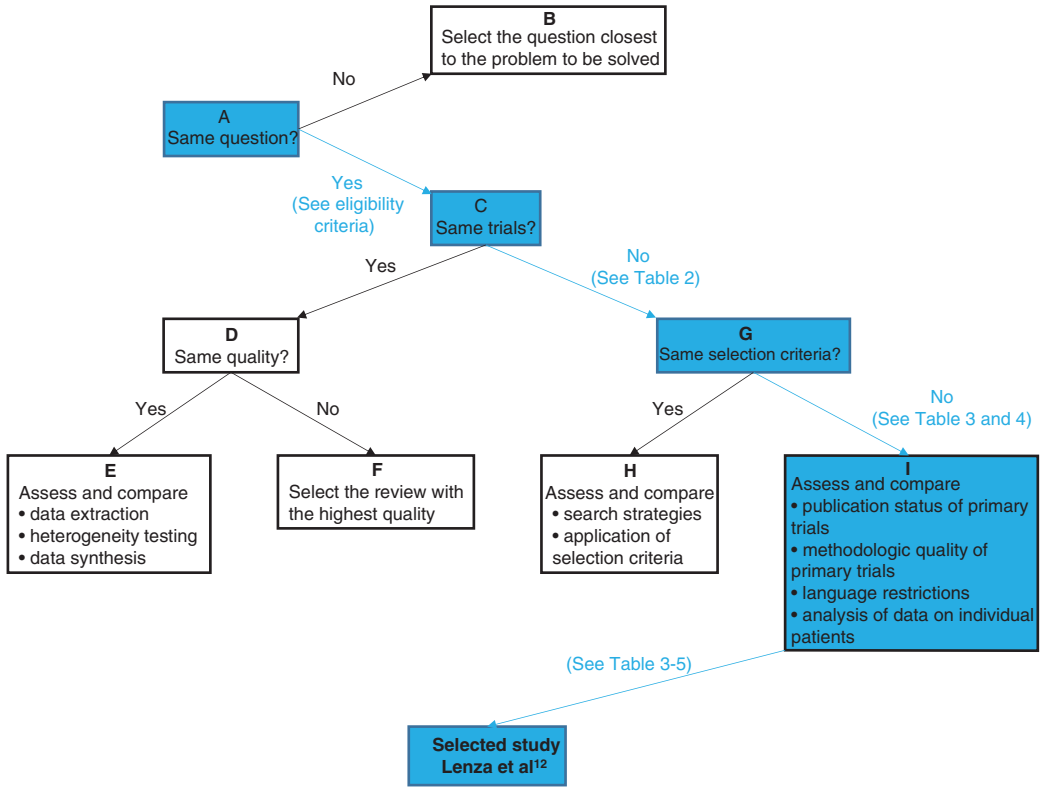

FIGURE 3. Flow diagram of Jadad decision algorithm.

CONCLUSIONS

This systematic review of overlapping meta-analyses comparing surgical and conservative treatments suggests that surgical treatment provides a lower rate of overall treatment failure and a better functional outcome, but is associated with more implant-related complications that are not seen in association with conservative treatment. Hence, treatment should be individualized, with careful consideration of the advantages and disadvantages of each treatment method and of patient preferences.

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