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Operative versus nonoperative treatment in the management of midshaft clavicular fractures: a meta-analysis of randomized controlled trials

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Background: There is no consensus on the effects of operative versus nonoperative treatment on the outcomes of midshaft clavicular fractures in adults. We conducted a meta-analysis of randomized clinical studies.

Materials and methods: We searched the literature and included studies that investigated the effects of operative versus nonoperative intervention on the outcome of midshaft clavicular fractures. Patient data were pooled by use of standard meta-analytic approaches. For the continuous variables, the weighted mean difference was used. For dichotomous data, the relative risk was calculated.

Results: Seven studies reported in 8 publications were eligible for data extraction. The pooled analyses showed that, compared with nonoperative treatment, operative treatment led to significantly lower incidences of nonunion and fewer symptomatic malunions. Subgroup analysis indicated that these advantages could be ascribed to plate fixation. Furthermore, surgery with plates resulted in significantly fewer complications. Patients undergoing surgery had better Disabilities of the Arm, Shoulder and Hand and Constant scores and lower dissatisfaction with their appearance.

Conclusion: In the management of midshaft clavicular fractures, surgery is superior to nonoperative treatment. Surgery with plates results in lower incidences of nonunion, fewer total complications, and fewer symptomatic malunions compared with nonoperative treatment.

Level of evidence: Level II, Meta-Analysis.

Keywords: Midshaft clavicular; plating; intramedullary fixation; nonoperative treatment; meta-analysis

Traditionally, midshaft clavicular fractures have been managed nonoperatively, even when substantially displaced.[7] Recent studies have shown a greater prevalence of nonunion, symptomatic malunion, and poor functional outcomes after nonsurgical management of displaced fractures. Although midshaft clavicular fractures have always been managed conservatively, surgery is becoming increasingly accepted as the optimal treatment method for displaced midshaft clavicular fractures.[2,10-12]

A few randomized controlled trials (RCTs) concerning surgical versus nonoperative treatment have been published in recent years. However, the relatively small sample size in

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each published study made the results inconclusive and controversial. Recently, a meta-analysis of RCTs compared operative versus nonoperative approaches for the treatment of midshaft clavicular fractures.[14] Regrettably, analysis of publication bias, which is an essential part of a meta-analysis, was not performed in that study, thereby making the conclusions questionable. Another meta-analysis, without assessment of publication bias, only included 4 RCTs.[24] Moreover, additional RCTs have been published since these earlier meta-analyses,[15,21] which makes the present meta-analysis a more precise estimation.

Materials and methods

Search strategy

This meta-analysis was carried out following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement, which was established to help authors report a wide array of systematic reviews to assess the benefits and disadvantages of health care interventions.[13] We performed a literature search without language restrictions on July 22, 2012, and an updated literature search was performed on February 12, 2013, using the phrase ''clavicular fractures'' with the limits ''randomized controlled trial.'' A second search was performed using the phrase ''clavicle fractures'' with the limits ''randomized controlled trial'' using PubMed (1949-2013), Ovid's Medline (1946-2013), and Medline's in-process and other non-indexed citations (updated up to February 12, 2013), as well as Web of Knowledge and Embase (1966-2013). Further searches using the same keywords and limitations did not identify any additional references.

We also conducted a search of the Cochrane Central Register of Controlled Trials. Reference lists of review articles were scanned to find additional publications. In addition, reference lists of all primary articles and previously published systematic reviews and meta-analyses were manually searched for additional eligible studies. Duplicates were removed. Information was carefully extracted from all eligible publications independently by 2 reviewers (J.X. [first author] and L.X.); disagreements were resolved by discussion between them. If a consensus could not be reached, a third investigator (W.X.) adjudicated the disagreements. The search results were then screened based on the following inclusion criteria: (1) the studies had to be RCTs on patients with midshaft clavicular fractures, (2) the studies had to compare operative with nonoperative treatment, and (3) the patients were aged at least 16 years. Exclusion criteria included (1) non-randomized trials, (2) studies concerning adolescent fractures, and (3) fracture in the proximal or distal third of the clavicle. The Jadad scale was used to assess the quality of included RCTs, where a score of less than 3 indicates low quality.[8]

Statistics

The primary outcome of our analysis was the incidence of nonunion, which is determined using radiographs or, in some cases, with additional computed tomography scans. The secondary outcome was the functional outcome, measured with the Disabilities of the Arm, Shoulder and Hand (DASH) score and the Constant score. Furthermore, data on complications and patient dissatisfaction were collected. We attempted to contact the authors of the studies included to obtain missing information. For studies that did not present standard deviations, the standard deviations were calculated from the *P* value or confidence interval (CI) following the guidance of the *Cochrane Handbook for Systematic Reviews of Interventions*.[6]

For the meta-analysis of continuous variables, the weighted mean difference with 95% CI was used. For dichotomous variables, the relative treatment effect was expressed as relative risk (RR) with 95% CI.[4] Statistical heterogeneity was investigated with the χ^2 test and quantified with the I^2 statistic. We anticipated the presence of clinical heterogeneity based on the findings that the fixation methods and implants used in surgery varied among the RCTs. Because the test for heterogeneity had low statistical power, we assumed the presence of heterogeneity a priori and used the random-effects model in all the analyses. Subgroup analyses of plate or intramedullary fixation were conducted when possible. A sensitivity analysis was performed by detecting the effect of each individual study on the pooled effect size. Funnel plots and Egger tests were used to assess possible publication bias. A funnel plot is a simple scatter plot of the intervention effect estimates from individual studies against some measure of each study's size or precision. It assumes that the largest studies will be near the mean and smaller studies will be spread on both sides of the mean. Variation from this assumption can indicate publication bias. $P < .05$ was considered statistically significant. Analyses were performed with the Stata/SE 10.0 program (StataCorp, College Station, TX, USA).

Results

Selected studies and characteristics

Potentially relevant citations were identified and screened, of which only 6 published RCTs[3,9,15,19,21,22] and 1 abstract[20] met the inclusion criteria and were selected for this meta-analysis (Fig. 1 and Table I). One study[17] provided 2-year follow-up data of the study by the Canadian Orthopaedic Trauma Society.[3] In this analysis, the 2 publications were considered as reports of 1 study and were combined. Among the RCTs, 4 compared plate fixation with nonoperative treatment[3,15,20,21] and 3 compared intramedullary fixation with nonoperative treatment.[9,19,22]

The level of evidence for each article was graded with a score from 1 to 3 according to the Jadad score.[8] A total of 471 patients were included in the analysis. Sample sizes of the studies ranged from 50 to 111 patients. Of the patients, 231 were randomized to receive surgery and 240 to nonoperative treatment. Among individuals treated surgically, 146 were treated with plate fixation and 94 with intramedullary fixation. One study was a multicenter RCT,[3] and the others were single-center RCTs.[2,9,19-22] Allocation concealment was reported in 5 trials[3,9,15,19,21] and not stated in the other trials.[20,22] Because of the obvious nature of the intervention, no trials were double blind.