Original article

Complications following open reduction and internal fixation versus external fixation in treating unstable distal radius fractures: Grading the evidence through a meta-analysis

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A B S T R A C T

Background: The common fixation techniques for unstable distal radius fractures include open reduction and internal fixation (ORIF) with plates and closed reduction and external fixation (EF). There is controversy over the choice of surgical approach in treating unstable distal radius fractures.

Hypothesis: This meta-analysis was performed to compare complication rates in patients treated with ORIF or EF for unstable distal radius fractures and to develop GRADE (grading of recommendations, assessment, development, and evaluation)-based recommendations for using the procedures to treat unstable distal radius fracture.

Materials and methods: A systematic search of all the studies published was conducted using the Pubmed, ScienceDirect, Embase, BIOSIS, Springer, Cochrane Library databases. The randomized controlled trials (RCTs) that compared ORIF with EF in treating adult patients with unstable distal radius fractures and provided data regarding the complication were identified. The demographic characteristics and adverse events were manually extracted from all of the included studies. RevMan 5.1 was used for data analysis. PRISMA guidelines were followed.

Results: Sixteen studies that included a total of 1280 patients met the inclusion criteria. Compared with ORIF, EF results in higher incidence of total complications, infection and malunion. The overall GRADE system evidence quality was very low, which reduces our confidence in the recommendations of this system.

Discussion: This meta-analysis indicates that ORIF and EF are both effective procedures for treating unstable distal radius fractures. ORIF may be superior to EF in the treatment of unstable distal radius fractures. Because of the low quality evidence currently available, high-quality RCTs are required.

Level of evidence: Level II: low-powered prospective randomized trial meta-analysis.

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1. Introduction

Distal radius fractures are a common injury and with an ageing population the incidence is rising, accounting for more than 17\% of all bony injuries seen in the emergency department \cite{1}, with an annual incidence of 31 per 10\(^4\) persons per year \cite{2}. Two thirds of these fractures are displaced and require reduction \cite{3}. Therefore, accurate anatomic reduction and adequate fixation are crucial for the successful treatment of distal radius fractures \cite{4}.

The common fixation techniques for unstable distal radius fractures include open reduction and internal fixation (ORIF) with plates and closed reduction and external fixation (EF). ORIF is an increasingly popular treatment for distal radius fractures. Johnson et al. \cite{5} reported volar locking plates were devised to allow direct reduction, solid fixation and early mobilisation of wrist fractures. The fixed angle construct provide a strong fixation in osteoporotic bone and comminuted fractures. And studies reported ORIF is associated with a low risk of complications postoperated \cite{6–15}. External fixation has been traditionally employed in the treatment of unstable distal radius fractures because of its ease of application and minimal surgical exposure \cite{16}. Mellstrand et al. \cite{10} reported EF is associated with a low risk of complications, and if health care expenses are considered, one can use percutaneous methods as an...
alternative to the more expensive volar plates for most dorsally dislocated distal radius fractures \[15,18\]. Although there are 39 studies that have been published by World Health Organization, there is controversy over which of the two procedures leads to lower risk of complications. There is no consensus as to whether ORIF or EF is the optimal treatment.

The purpose of this meta-analysis is to evaluate the evidence from the randomized controlled trial (RCT) studies that compared the complications of ORIF and EF for treating patients with unstable distal radius fractures and to develop GRADE (grading of recommendations, assessment, development, and evaluation)-based recommendations for using the procedures to treat distal radius fractures \[19,20\].

2. Materials and methods

PRISMA guidelines were followed in this meta-analysis.

2.1. Search strategy

A systematic search of all studies published was conducted using the Pubmed, ScienceDirect, Embase, BIOSIS, Springer, Cochrane Library databases from their inception to December 2016. Other internet databases were also performed to identify trials according to the Cochrane Collaboration guidelines. The following search terms were used to maximize the search specificity: distal radial fracture, plate fixation, external fixation (EF), open reduction and internal fixation (ORIF), randomized controlled trial (RCT). The reference lists of all the full-text papers were examined to identify any initially omitted studies. We made no restrictions on the publication language.

2.2. Inclusion criteria

The following inclusion criteria were applied:

- study design: interventional studies (RCTs);
- population: adult patients (>16 or older) with unstable distal radius fractures (axial shortening of >2 mm or a dorsal angulation >10°);
- intervention: EF (dynamic external fixation or static external fixation etc.);
- comparator: ORIF (dorsal and/or volar plates etc.)
- case series: study of >10 cases
- outcomes: reported at least one of the complications: total complications, infection, reoperation, nonunion, malunion, complex regional pain syndrome (CRPS), carpal tunnel syndrome (CTS), tendon rupture (TR), tendinitis, transient neurapraxia (TN), sustained neurapraxia (SN), skin scar (SS) and painful retained hardware (PRH).

2.3. Exclusion criteria

The following exclusion criteria were applied:

- non-RCTs;
- pathological fractures/metastatic malignant disease;
- case series <10 cases;
- review articles or experimental studies.

2.4. Study selection

Two reviewers (ZZY and ZY) independently screened the titles and abstracts for the eligibility criteria. Subsequently, the full-text of the studies that potentially met the inclusion criteria were read and the literature was reviewed to determine the final inclusion. We resolved disagreements by reaching a consensus through discussion.

2.5. Data extraction

Two of the authors (ZZY and ZY) independently extracted the relevant data from each full-text report using a standard data extraction form. The data extracted from studies included the title, authors, year of publication, study design, sample size, population, age, gender, type of interventions, surgical procedures, duration of follow-up and outcomes parameters. The corresponding authors of the included studies were contacted to obtain any required information that was missing. The extracted data were verified by ZY.

2.6. Outcomes

The clinical outcomes included: total complications, infection, reoperation, nonunion, malunion, complex regional pain syndrome (CRPS), carpal tunnel syndrome (CTS), tendon rupture (TR), tendinitis, transient neurapraxia (TN), sustained neurapraxia (SN), skin scar (SS) and painful retained hardware (PRH).

2.7. Assessment of methodological quality

According to Cochrane Handbook for Systematic Reviews of Interventions 5.0, the risk of bias of the included studies was assessed by two authors (ZZY and ZY) independently. Disagreements were resolved by discussion. A third author (QL) was the adjudicator when no consensus was achieved. We applied the “assessing the risk of bias” table, which include the following key domains: adequate sequence generation, allocation of concealment, blinding, incomplete outcome data, free of selective reporting and free of other bias.

2.8. Data analysis and statistical methods

The meta-analysis was undertaken using RevMan 5.1 for Windows (The Cochrane Collaboration, Oxford, United Kingdom). We assessed statistical heterogeneity for each study with the use of a standard Chi² test (for heterogeneity, a level of P<0.1 was considered significant) and the I² statistic. An I² statistic value of 50% was considered to indicate substantial heterogeneity. In comparing trials showing heterogeneity, pooled data were meta-analyzed using a random-effects model. Otherwise, a fixed-effects model was used for the analysis. Risk ratio (RR) and 95% confidence intervals (CIs) were calculated for dichotomous outcomes and mean differences (MDs) and 95% CIs for continuous outcomes. A P-value <0.05 was considered statistically significant.

Publication bias was assessed visually using a funnel plot and statistically using Begg funnel plots and Egger’s bias test using STATA 14.0 software (Statcorp, college station, Tex), which measures the degree of funnel plot asymmetry. The Begg adjusted rank correlation test was used to assess the correlation between the test accuracy estimates and their variances. The deviation of Spearman’s rho values from zero provides an estimate of the funnel plot asymmetry. Positive values indicate a trend towards higher levels of test accuracy in studies with smaller sample sizes. Egger’s bias test detects funnel plot asymmetry by determining whether the intercept deviates significantly from zero in a regression of the standardized effect estimates against their precision values.

2.9. Evidence synthesis

The evidence grade was determined using the guidelines of the GRADE (grading of recommendations, assessment,
3. Results

3.1. Search results

A total of 2187 titles and abstracts were preliminarily reviewed, of which 16 studies eventually satisfied the eligibility criteria [8,10–15,21–28] (Fig. 1). All of the included studies were RCTs compared ORIF and EF in the treatment of unstable distal radius fractures.

3.2. Quality assessment

Among the 16 included studies, the methods of randomization of 12 RCTs were clear. Ten studies describes the process of allocation concealment. None of the included studies reported blinding to the surgeons, participants or assessors. All studies had reported the expected the outcomes completely. Six studies had a high risk of bias, 10 studies had a moderate risk of bias. The methodological quality of the included studies is presented in Fig. 2. Judgments regarding each risk of bias item are presented as percentages across all the included studies in Fig. 3.

3.3. Demographic characteristics

The demographic characteristics of the studies included are summarized in Table 1. In total, 16 RCTs with 1280 total patients were eligible for inclusion. The individual sample sizes ranged from 12 to 91 patients. A total of 626 patients underwent ORIF, and the other 654 patients received a EF. There were 3 studies performed in the USA, 3 in Canada, 3 in Sweden, and 1 each in France, India, UK, Taiwan, Scotland, Norway, and Singapore. The follow-up period ranged from 6 to 48 months.

3.4. Outcome measure reporting

The reported outcomes of the included studies are summarized in Table 2. All 16 studies evaluated complications, however, the rate of total complications was evaluated in 14 studies. 13 evaluated rate of infection, 8 studies evaluated rate of reoperation, 2 evaluated rate of nonunion, 4 evaluated rate of malunion, 9 evaluated rate of CRPS, 7 evaluated rate of CTS, 6 evaluated rate of TR, 6 evaluated...
rate of tendonitis, 4 evaluated rate of TN, 8 evaluated rate of SN, 3 evaluated rate of SS and 3 evaluated rate of PRH.

3.5. Meta-analysis results

3.5.1. Total complications

Fourteen studies reported the total complications. The pooled results of the studies showed that external fixation treatment did increase the risk of total complications. (RR = 0.76, 95% CI: 0.64 to 0.90, P = 0.001). There was no significant heterogeneity (Z = 3.23, df = 13, I² = 11%, P = 0.33; Fig. 4). A fixed-effects model was used.

3.5.2. Infection

Thirteen studies reported infection. The pooled results of the studies showed that external fixation treatment did increase the risk of infection. (RR = 0.26, 95% CI: 0.15 to 0.44, P < 0.0001). There was no significant heterogeneity (Z = 5.01, df = 12, I² = 0%, P = 0.89; Fig. 5). A fixed-effects effects model was used.

3.5.3. Malunion

Four studies reported malunion. The pooled results of the studies showed that open reduction with internal fixation treatment did increase the risk of malunion (RR = 0.26, 95% CI: 0.07 to 0.89, P = 0.03). There was no significant heterogeneity (Z = 0.45, df = 3, I² = 0%, P = 0.93; Fig. 6). A fixed-effects effects model was used.

3.5.4. The rest complications

The rest of the complications were not significantly different between the two groups, which included reoperation, nonunion, CRPS, CTS, TR, tendonitis, TN, SN, SS and PRH (Table 3).

3.5.5. Publication bias

The publication bias test was performed for the most populations by the incidence of total complications. No significant publication bias was shown for the most populations by the Begg rank correlation method (P = 0.274) and Egger weighted regression method (P = 0.401).

3.5.6. Quality of the evidence and recommendation strengths

Thirteen outcomes in this meta-analysis were evaluated using the GRADE system. The following 11 outcomes were important: total complications, infection, reoperation, nonunion, malunion, CRPS, CTS, TR, tendonitis, SN and PRH. The evidence quality of 7 outcomes was very low, 6 outcomes was low (Table 4). We agreed that the overall evidence quality was very low.

4. Discussion

There were three kinds of complications undergoing ORIF and EF treatment for unstable distal radius fractures [8]. Most complications were minor (minor complications), such as transient CTS not requiring surgery, SS, tendonitis not requiring surgery, TN, and superficial infections not requiring antibiotics. There were also moderate complications, which with a need for further intervention such as surgery or antibiotic treatment, but not affecting the final outcome, for example, PRH and SN. Major complications, which may influence the final outcome, such as the nonunion and malunion requiring additional surgery and CRPS. In our study,
reoperation, nonunion, CRPS, CTS, TR, tendinitis, TN, SN, SS and PRH were found to be not significantly different between the two treatment groups.

Our meta-analysis suggests that patients undergoing ORIF with plate fixation for distal radius fractures had lower incidence of total complications. The incidence of total complications with ORIF treatment is 25.98%, in comparison with EF group 33.67%. Advantages of ORIF treatment include a biomechanically stable fixation, allowing early mobilisation and return of wrist function [29,30]. Studies reported a high rate of complications with EF treatment, but most were minor and transient [31,32]. Mellstrand et al reported that external fixation is associated with a low risk of
complications in dorsally displaced distal radius fractures, in particular, for low-energy fractures [13].

Infection as the primary outcome revealed that, compared with EF, distal radial fractures with treatment of ORIF led to a superior performance in subjective outcome. Pin tract infections were the most common infection in the external fixation group [33] and occurred at a rate of 10.33% in our study. Infection occurred at a rate of only 2.24% in the ORIF group. Most pin site infections, however, were relatively minor and resolved with antibiotic therapy and/or removal of the external fixator [34].

Malunion rate as an important index for distal radial fractures was evaluated, in our study an obvious trend that ORIF led to a lower malunion rate could be detected. Malunion defined as one of the follows [35]: radial inclination, less than 15° on posteroanterior view; radial length, more than 5 mm shortening on posteroanterior view; radial tilt, more than 15° dorsal or 20° volar tilt on lateral view; articular incongruity, more than to 2 mm of step-off. IF restored volar tilt and radial inclination significantly better than EF, with independent analysis concerning IF using volar locking plates supporting this conclusion [36,37].

In our meta-analysis, there were not significantly different in the incidence of TN. There were a mean time to tendon rupture of 10 months with ORIF treatment [38,39]. Some extensor tendon ruptures had screws that penetrated the dorsal cortex [40,41], others could be attributed to the sharp edges of the screws and volar plate [41,42].

Christina et al. reported median nerve dysfunction was the most common complication occurring in nine patients (9%) [39]. Median nerve symptoms can be caused by the original trauma and not related to any specific surgical technique. Wilcke et al. suggested by omitting the pins, the risk of radial nerve and skin complications is reduced [26]. CTS is a well-known complication after wrist fracture, which may occur early or late independent of the treatment method. Other studies have reported an incidence of CTS following volar plating of up to 14% [5]. But in our meta-analysis, neurapraxia (transient and sustained) and CTS were found to be not significantly different between the two treatment groups.
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>No. of studies</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
<th>ORIF</th>
<th>EF</th>
<th>Relative (95% CI)</th>
<th>Absolute</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total complications</td>
<td>14</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>152/585</td>
<td>199/591</td>
<td>OR 0.76 (0.64–0.9)</td>
<td>81 fewer per 1000 (34 fewer to 121 fewer) 71 fewer per 1000 (29 fewer to 106 fewer)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Infection</td>
<td>13</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>13/584</td>
<td>60/581</td>
<td>OR 0.26 (0.15–0.44)</td>
<td>76 fewer per 1000 (58 fewer to 88 fewer) 75 fewer per 1000 (57 fewer to 87 fewer)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Malunion</td>
<td>4</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>None</td>
<td>2/127</td>
<td>10/120</td>
<td>OR 0.26 (0.07–0.89)</td>
<td>62 fewer per 1000 (9 fewer to 77 fewer) 44 fewer per 1000 (7 fewer to 56 fewer)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Tendon rupture</td>
<td>7</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>11/355</td>
<td>2/341</td>
<td>OR 2.7 (0.98–7.4)</td>
<td>10 more per 1000 (0 fewer to 38 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Reoperation</td>
<td>8</td>
<td>Very serious</td>
<td>Serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>23/423</td>
<td>24/416</td>
<td>OR 0.96 (0.56–1.65)</td>
<td>2 fewer per 1000 (25 fewer to 37 more) 2 fewer per 1000 (26 fewer to 38 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Nonunion</td>
<td>2</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>2/109</td>
<td>3/112</td>
<td>OR 0.73 (0.14–3.71)</td>
<td>7 fewer per 1000 (25 fewer to 37 more) 5 fewer per 1000 (17 fewer to 54 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>CRPS</td>
<td>9</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>13/387</td>
<td>12/392</td>
<td>OR 1.1 (0.54–2.25)</td>
<td>3 fewer per 1000 (14 fewer to 38 more) 3 more per 1000 (15 fewer to 41 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>CTS</td>
<td>7</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>13/346</td>
<td>21/346</td>
<td>OR 0.63 (0.32–1.21)</td>
<td>22 fewer per 1000 (41 fewer to 13 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Tendonitis</td>
<td>6</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>7/221</td>
<td>2/223</td>
<td>OR 2.13 (0.71–6.36)</td>
<td>10 more per 1000 (3 fewer to 48 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>TN</td>
<td>4</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>None</td>
<td>41/194</td>
<td>29/183</td>
<td>OR 2.13 (0.71–6.36)</td>
<td>52 more per 1000 (21 fewer to 166 more) 48 more per 1000 (19 fewer to 152 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>SN</td>
<td>8</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>19/327</td>
<td>11/322</td>
<td>OR 1.57 (0.8–3.08)</td>
<td>19 more per 1000 (7 fewer to 71 more) 17 more per 1000 (6 fewer to 62 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>Scar</td>
<td>3</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>0/111</td>
<td>4/113</td>
<td>OR 0.27 (0.05–1.64)</td>
<td>26 fewer per 1000 (34 fewer to 23 more) 25 fewer per 1000 (32 fewer to 22 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
<tr>
<td>PRH</td>
<td>3</td>
<td>Very serious</td>
<td>None</td>
<td>None</td>
<td>Serious</td>
<td>None</td>
<td>4/131</td>
<td>4/113</td>
<td>OR 0.6 (0.2–1.78)</td>
<td>22 fewer per 1000 (44 fewer to 43 more) 22 fewer per 1000 (38 fewer to 37 more)</td>
<td>⬤ ⬤ ⬤</td>
<td>Important</td>
</tr>
</tbody>
</table>
There are several potential limitations of this meta-analysis. The sample sizes of included studies were relatively small, which may have affected our conclusions. The follow-up period of patients in some trials was short. This may have resulted in underreporting. The type of fracture of included studies were inconsistent, which may have an impact on the conclusions. The existence of a publication bias also affects the analysis; it is a limitation in all meta-analysis. The overall GRADE quality of evidence was very low, which lowers confidence in any subsequent recommendations. Therefore, the conclusions obtained in this meta-analysis should be treated with caution.

This meta-analysis demonstrates that ORIF and EF are both effective procedures for treating unstable distal radius fractures. But compared with ORIF, EF results in higher incidence of total complications, infection and malunion, which could negatively affect EF utilization. The overall evidence quality was very low; therefore, high-quality RCTs are required.

**Author contributions**

Conceived and designed the experiments: ZZY and ZY. Performed the experiments: ZZY and ZY. Analyzed the data: QL and YML. Contributed reagents/materials/analysis tools: ZZY and ZY. Wrote the paper: ZZY and ZY.

**Disclosure of interest**

The authors declare that they have no competing interest.

**Supporting information**

None.

**Acknowledgments**

None.

**References**


[27] Wilcke MK, Abbaszadegan H, Adolphson PY. Wrist function recovers more rapidly after volar locked plating than after external fixation but the outcomes are similar after 1 year. Acta Orthop 2011;82:76–81.


