Systematic Review and Meta-Analysis

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The effectiveness and safety of plaster splint and splints for distal radius fractures

A systematic review and meta-analysis of randomized controlled trials

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Abstract

Background: To assess the efficacy and safety of plaster splint vs splints in the treatment of distal radius fractures (DRFs).

Methods: For a more comprehensive collection of original study, we mainly searched 9 electronic databases including the PubMed, Web of Science, EMBASE, Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), Clinical Trials.gov, the Chinese National Knowledge Infrastructure Database (CNKI), Wanfang Database, and VIP Database. The retrieval date of all databases is from the establishment to January 2019. In the aspect of assessing the quality of original research methodology, we mainly rely on the Cochrane risk bias assessment tool and GRADE assessment method. Revman 5.3 is used for statistical analysis.

Results: A total of 8 studies involving 717 participants were included. The results showed that effective rate (RR = 0.99, 95%CI 0.91 to 1.07, $P = .83$), reduction rate (RR = 1.00, 95%CI 0.93 to 1.07, $P = .98$), and complication rate of the plaster splint had no significant difference with the splint. In addition, for the excellent rate of treatment, subgroup analysis based on the included studies found that when the intervention period was 4 weeks, the plaster splint was better than the splint, and when the intervention period was more than 4 weeks, there was no significant difference between them.

Conclusions: There is no sufficient evidence that plaster splint is superior to splint. However, according to current evidence, plaster splint is more effective than splint when the intervention period is shorter (4 weeks), and its advantage disappears when the intervention period is longer (> 4 weeks). It should be noted that the results of this study were influenced by the sample size and the quality of the included studies. More high-quality and well-controlled RCTs are needed to draw better conclusions in further study.

Abbreviations: CENTRAL = Cochrane Central Register of Controlled Trials, CI = confidence intervals, CNKI = Chinese National Knowledge Infrastructure Database, DRFs = distal radius fractures, GRADE = Grading of Recommendations Assessment, Development, and Evaluation, MD = mean difference, PRISMA = Preferred Reporting Items for Systematic Review and Meta-analysis, RCTs = randomized controlled trials, RR = risk ratio.

Keywords: distal radius fractures, plaster splint, splints, systematic review

1. Introduction

Distal radial fractures (DRFs) are one of the most common wrist injuries,[1] accounting for one-sixth of the total number of visits in the emergency department[2] and 26% to 46% of all fractures observed in primary health care institutions.[3] In Western countries, 6% of women will have a DRF by the age of 80.[4] Recently, the incidence of DRFs has increased in all age groups around the world.[5,6] As the population grows in size and age, the number of patients with DRFs who require treatment will continue to increase. The exact cause of this upward trend is not yet clear. Some theories suggest it could be lifestyle effects (differences between urban and rural lifestyles), childhood obesity, or osteoporosis.[7–9] The most common reason is that people over 50 fall from standing height or lower, landing on their hands.[10] Every year 30% of people over 65 will fall and the rates rise with increasing age.[11] DRFs are characterized by a low-energy fracture, which mainly occurs about 2 cm above the articular surface of the distal radius, where the junction of cortical bone and cancellous bone is located.[12] The treatment of DRFs is mainly divided into conservative treatment and surgical treatment.[13] But surgery may bring pain and financial burden to

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XC, LL, and HZ contributed equally to this work and are co-first authors.

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the patient. Conservative treatment, reduction plus external fixation, is generally adopted for most of these fractures.[14] In conservative treatment, some studies[17,18,21–24] on the use of plaster splint or splint for DRFs have not been determined, which brings difficulties to clinical decision-making. As far as we can know, a systematic review and meta-analysis on this topic has not been retrieved. This study includes integrated multiple existing RCT studies to evaluate the clinical efficacy and safety of plaster splint and splint in the treatment of DRFs, with a view to providing reference for clinical application.

2. Methods

2.1. Search strategy

This systematic review is conducted according to the PRISMA statement.[15] For a more comprehensive collection of original study, we mainly searched 9 electronic databases including the PubMed, Web of Science, EMBASE, Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), Clinical Trials.gov, the Chinese National Knowledge Infrastructure Database (CNKI), Wanfang Database, and VIP Database. The retrieval date of all databases is from the establishment to January 2019. No limits were imposed on study dates or publication language, type, and status. The key terms used in these searches were: "splint," "plintlet," "splintlet," "splintage," "small plywood," "wood splint," "static splints," "static splinting," "dynamic splints," "dynamic splinting," "static orthose," "dynamic orthoses," "plaster splint," "cast," "radius fractures," "Colles fracture," "Smith fracture," "Barton fracture." Considering different language habits, we used different search strategies for Chinese and foreign databases. Additionally, published references on systematic review on plaster splint and splints were manually searched for better research.

This study is a systematic review and meta-analysis based on existing RCTs, which belongs to literature research. Thus, it does not require ethical approval and patient consent.

2.2. Inclusion criteria

(1) The type of studies included were RCTs.
(2) The participants included in the study were those who were definitely diagnosed as DRFs, not limited by age, race, nationality, primary disease, or clinical stage.
(3) Intervention measures: The experimental group is treated with manual reduction combined with external fixation of plaster splint, while the control group is treated with manual reduction combined with splint external fixation. (reduction + plaster splint vs reduction + splint).
(4) Main outcome is excellent rate, and secondary outcomes are effective rate, reduction rate, and complications.

2.3. Exclusion criteria

We will exclude those literatures that are not available in the full text and those that are republished.

2.4. Literature screening

The retrieved literature was screened by 2 independent reviewers to evaluate eligibility, and any discrepancies were settled by discussion and consensus. First, the titles and abstracts of searched studies were screened. Furthermore, we read carefully the full text to identify the studies that need to be included. When multiple time points were reported either in 1 particular report of a study or over the course of several articles from the same study, the longest follow-up period on treatment was considered in our article.

2.5. Data extraction

According to the established literature information table, the 2 reviewers independently extracted data from the included literature. When there is a disagreement, it will be resolved through group discussion with the third reviewer. The data extraction content are study characteristics, intervention, duration of treatment and follow-up, outcome, and other information.

2.6. Quality assessment

The methodological quality of the included studies is assessed according to the "risk of bias table" of the Cochrane Collaboration,[16] including:

1. Random sequence generation (selection bias);
2. Allocation concealment (selection bias);
3. Blinding of participants and personnel (performance bias);
4. Blinding of outcome assessment (detection bias);
5. Incomplete outcome data (attrition bias);
6. Selective reporting (reporting bias);
7. other bias.

The assessment degree of each item is divided into 3 levels: low risk, high risk, and unclear risk. According to the above items, the specific conditions included in the literature are assessed. If 2 reviewers have different opinions, discuss and solve the problem first. If there are still differences, a third party will join the discussion.

2.7. Grading the quality of evidence

To assess the quality of evidence for each outcome of meta-analysis, we used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method, which recommended that the quality of evidence can be classified into 4 levels: high (++++), moderate (+++), low (++), and very low (+). We can assess it on this website: https://gradepro.org/.

2.8. Statistical analysis

Revman 5.3 software is used for meta-analysis. For dichotomous variable, risk ratio (RR) and 95% confidence interval (95%CI) are used. For continuous variables, mean difference (MD) and 95%CI are used. The Cochrane's Q test and I^2 statistic are used for accessing heterogeneity across all included studies. When statistical homogeneity existed between studies ($P > .10$, $I^2 < 50\%$), fixed effect model is used for meta-analysis. Otherwise, the random effect model shall be used for meta-analysis. Also, in order to evaluate the sensitivity of the meta-analysis, articles will be excluded one by one, and the differences of the combining effects before and after exclusion will be compared, and if the pooled outcomes are found to have been reversed after the exclusions, the outcomes may be unstable.

3. Results

3.1. Result of literature retrieval and screening

Based on the preliminary search of the search terms, 683 related literatures were retrieved. Gray literature such as related conference papers and academic papers were also included in the retrieval scope. First, Endnote X8.0 software was adopted to check the duplicate literature. After that, 211 duplicate articles were excluded. The remaining 53 papers were selected by reading the title and abstract. Then, after reading the full text, 8 studies were finally included. The screening process of the included literature is shown in Figure 1.

3.2. Characteristics of included studies

All 8 of the included studies were RCTs conducted in China,[17–24] and the final results were published in China. The sample size

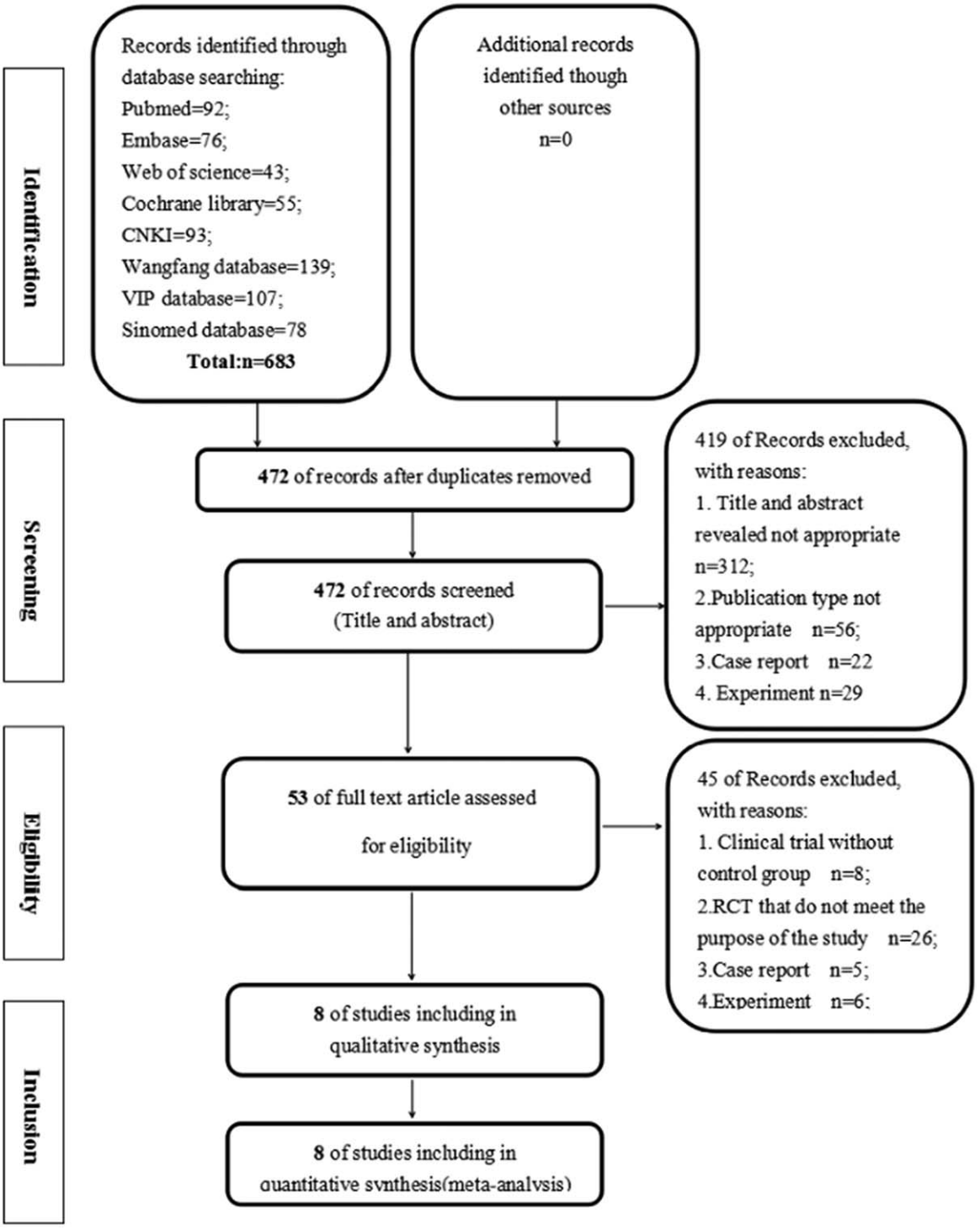

Figure 1. Flow diagram of literature search.

Table 1

Basic characteristics of the included trials.

Study ID	Sample size E/C (M/F)	Age (yr) E/C	Intervention		Time to intervention	Follow-up	Main outcomes
			Experiment group	Control group			
Wei 2018[17] China	E:32 (19/13) C:32 (20/12)	E:69.5±1.5 C:70.5±1.2	manual reduction + plaster splint	manual reduction + splints	4 wk	-	Effective rate (function), Reduction rate
Wu 2016[18] China	E:10 C:10	32∼68 (Mean: 47.2)	drug therapy + manual reduction + plaster splint	drug therapy + manual reduction + splints	6 wk	6 mo	Effective rate (function), Reduction rate
Cui 2015[19] China	E:80 (37/43) C:80 (39/41)	E:32.6±8.5 C:32.5±8.8	manual reduction + plaster splint + exercise	manual reduction + splints + exercise	4 wk	-	Excellent rate
Lv 2015[20] China	E:53 (26/27) C:52 (25/27)	E:57.5±4.3 C:56.4±4.9	manual reduction + plaster splint	manual reduction + splints	4 wk	18 wk	Excellent rate
Fang 2011[21] China	E:60 C:60	Mean: 66.4	manual reduction + plaster splint	manual reduction + splints	4–6 wk	6–26 mo	Excellent rate
Wu 2010[22] China	E:32 (14/18) C:32 (15/17)	E:(Mean: 32) C:(Mean: 30)	manual reduction + plaster splint+external washing of Chinese herbs	manual reduction + splints+external washing of Chinese herbs	4–6 wk	-	Excellent rate, Effective rate (function), Complication rate
Zeng 2010[23] China	E:39 (12/27) C:37 (10/27)	E:(Mean: 53.5) C:(Mean: 55.5)	manual reduction + plaster splint	manual reduction + splints	4–6 wk	5–18 mo	Effective rate (function), Reduction rate
Li 2012[24] China	E:45 (18/27) C:63 (27/36)	E:24∼61 (Mean: 50.5); C:21∼66 (Mean: 53.3)	manual reduction + plaster splint	manual reduction + splints	4–6 wk	6–36 mo	Excellent rate

E/C = experiment group/control group, M/F = male/female.

ranged from 20 to 160, with an average sample size of 90. All participants varied from 15 to 81 years in age. The duration of intervention ranged from 4 to 6 weeks. The interventions in all the 8 studies were manual reduction combined with plaster splint external fixation vs manual reduction combined with splint external fixation. On this basis, Wu's 2016[18] study added drug therapy in both experimental group and control group, Cui 2015[19] added exercise, and Wu 2010[22] added external use of Chinese herbs. A total of 717 participants were included in 8 studies, involving 351 in the experimental group and 366 in the control group. The basic information and characteristics of the 8 included literature are shown in Table 1.

3.3. Methodological assessment

Among the 8 studies, 2 were grouped by random number table,[17,19] 1 by lottery,[20] and 5 referred to "randomization" did not describe how to randomize in detail.[18,22,24] No allocation concealment was mentioned in all studies. One of the studies referred blind method,[23] while the others did not mention the blind method. All the outcomes of the 8 studies were completely reported, and no participant was lost to follow-up. Since no original protocol for the 8 studies has been obtained, it is not clear whether there is a selective publication bias. Other sources of bias in the 4 studies were low risk, as shown in Figure 2.

3.4. Excellent rate

Five studies[19–22,24] reported and analyzed the excellent rate of patients with DRFs. There were 270 participants in the experimental group and 287 participants in the control group. According to the sub-group analysis of the intervention period, 2 studies[19,20] had a 4-week intervention period, and the results

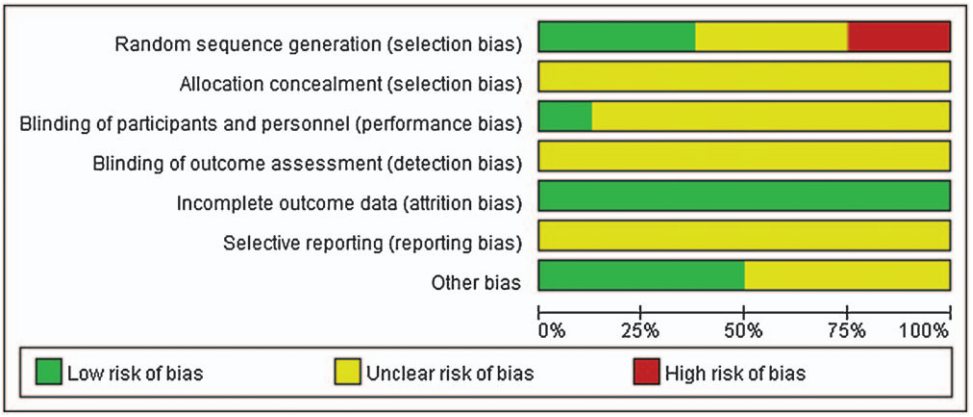

Figure 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

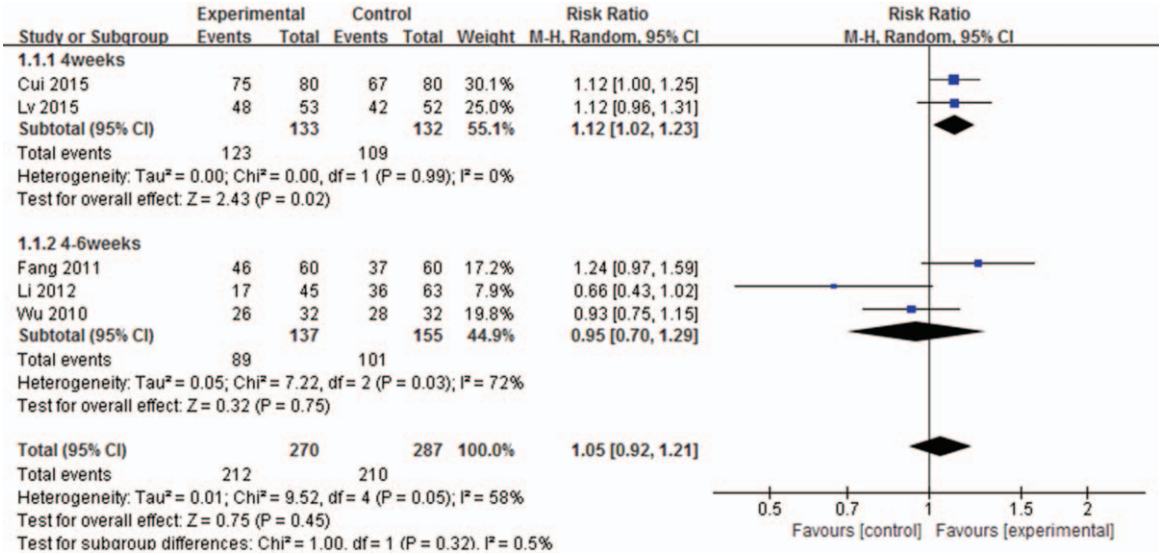

Figure 3. Excellent rate comparison.

showed that the excellent rate of external fixation with plaster splint might be better than that with splints [$I^2=0\%$, $P=.99$, RR = 1.12, 95%CI (1.02, 1.23), $P=.02$]. Three studies[21,22,24] had a 4- to 6-week intervention period, and the results showed no statistically significant difference between the 2 arms in the excellent rate [$I^2=72\%$, $P=.03$, RR = 0.95, 95%CI (0.70, 1.29), $P=.75$], as shown in Figure 3.

3.5. Effective rate

Four studies[17,18,22,23] reported effective rate of patients with DRFs. Heterogeneity test was conducted and the result showed $I^2=0\%$, $P=.59$. So fixed effect model was used for analysis. There was no significant difference [RR = 0.99, 95%CI (0.91, 1.07), $P=.83$] between the 2 groups, which cannot conclude that plaster splint external fixation therapy in improving effective rate is better than splints external fixation therapy, as shown in Figure 4.

3.6. Reduction rate

Three studies[17,18,23] involved reduction rate. There were 81 cases in the experimental group and 79 cases in the control group. The result showed that $I^2=90\%$, $P<.0001$; random effect model was adopted. There was no significant difference between the 2 groups [RR = 0.89, 95%CI (0.66, 1.20), $P=.45$], as shown in Figure 5. Besides, sensitivity analysis was conducted due to high heterogeneity. When Wei 2018[17] was excluded, heterogeneity

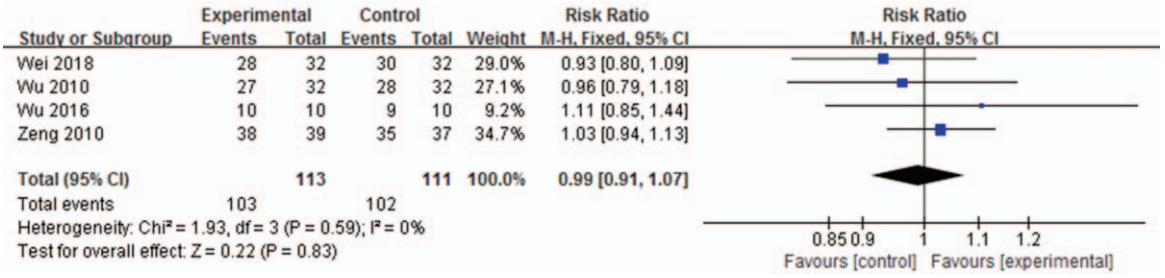

Figure 4. Effective rate comparison.

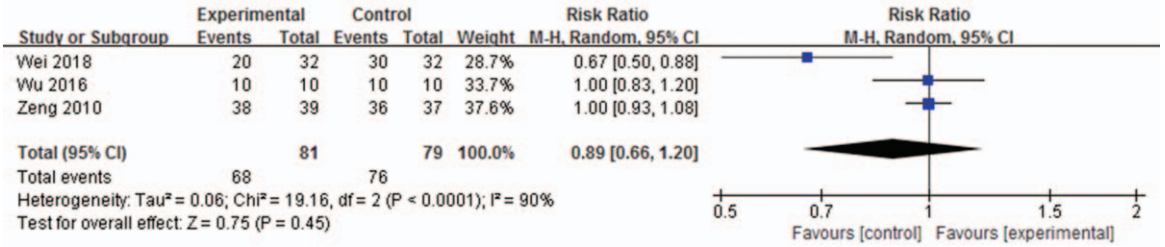

Figure 5. Reduction rate comparison.

Figure 6. Sensitivity analysis of reduction rate.

Table 2

Complication rate in each group (n = 32).

	Plaster splint	Splints
Complication rate	8/32	6/32

was significantly decreased, and the results remained unchanged [$I^2 = 0\%$, $P = .99$, RR = 1.00, 95%CI (0.93, 1.07, $P = .98$], as shown in Figure 6. The source of heterogeneity may be the intervention period. Therefore, the result of the statistical analysis was robust.

3.7. Complication rate

The incidence of complications was reported in 1 study.[22] There were 8 complications in the experimental group and 6 in the control group. The main complication was restricted range of motion of wrist joint, as shown in Table 2.

3.8. Publication bias

Publication bias was analyzed by excellent rate which included most studies, and a funnel plot was drawn. As shown in Figure 7, the symmetry of the plot indicated that publication bias was not obvious.

3.9. GRADE

The GRADE level of evidence is moderate for effective rate and complication rate but low for excellent rate and reduction rate. Table 3 shows the summary of evidence by GRADE. The main causes for the low quality of evidence are risk of bias and imprecision.

4. Discussion

We used excellent rate to evaluate the effect of plaster splint and splints on DRFs. Meanwhile, the effective rate was used to assess the functional recovery of the fracture. After the systematic review and meta-analysis was performed, we found that there was no statistically significant difference between the 2 groups for effective rate and reduction rate. Besides, the number of complications in the experimental group was higher than that in the control group.

However, as for intervention period of 4 weeks, plaster splint therapy is better than splints therapy about excellent rate based on current evidence. It may be that:

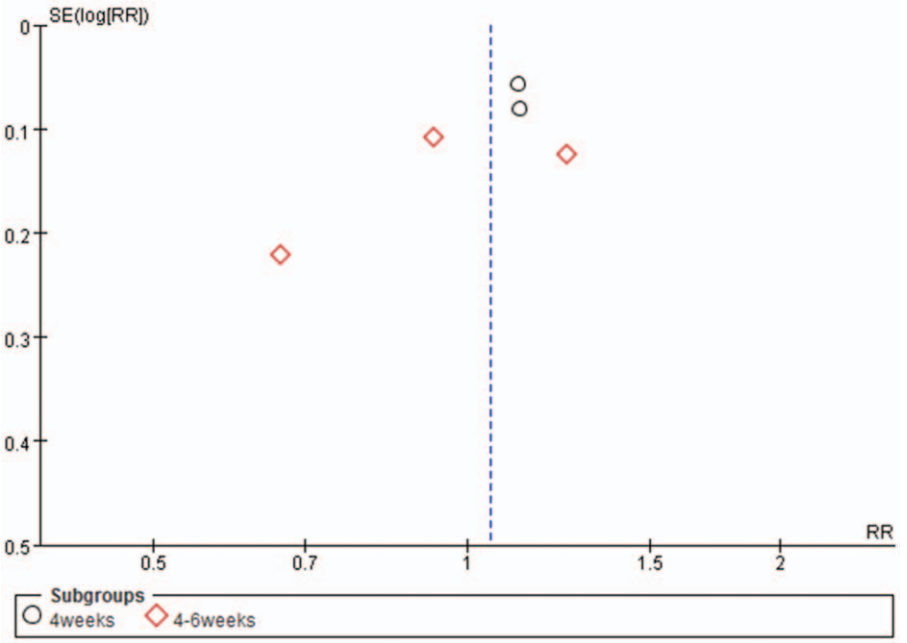

Figure 7. Funnel plot of excellent rate.

Table 3

Summery of the evidence for each outcome.

Certainty assessment						No. of patients		Effect		
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Plaster splint	splints	Relative (95% CI)	Absolute (95% CI)	Certainty
Excellent rate										
5	randomized trials	serious	not serious	not serious	serious*	212/270 (78.5%)	210/287 (73.2%)	**RR 1.05** (0.92 to 1.21)	**4 more per 100** (from 6 fewer to 15 more)	⊕⊕◯◯ LOW
Effective rate										
4	randomized trials	not serious	not serious	not serious	serious†	103/113 (91.2%)	102/111 (91.9%)	**RR 0.99** (0.91 to 1.07)	**9 fewer per 1000** (from 83 fewer to 64 more)	⊕⊕⊕◯ MODERATE
Reduction rate										
3	randomized trials	serious*	not serious	not serious	serious†	68/81 (84.0%)	76/79 (96.2%)	**RR 0.89** (0.66 to 1.20)	**106 fewer per 1000** (from 327 fewer to 192 more)	⊕⊕◯◯ LOW
Complication rate										
1	randomized trials	serious‡	not serious	not serious	not serious	8/32 (25.0%)	6/32 (18.8%)	not estimable	not estimable	⊕⊕⊕◯ MODERATE

CI = confidence interval, RR = risk ratio.
* High heterogeneity.
† Small sample size.
‡ Unclear methodological expression.

1. Plaster splint can better restrict the movement of fracture and keep wrist joint stretching.
2. Plaster splint fixation can balance the tension of flexor and extensor tendon in the wrist, maintain the stability of the fracture, and avoid the re-displacement of the fracture.
3. Plaster splint fixation is conducive to patients' early movement of interphalangeal and metacarpophalangeal joint, which effectively prevents wrist dysfunction caused by tense extensor tendon.
4. The treatment of DRFs with plaster splint fixation can stretch the injured bone until the plaster is completely hardened, which ensures that the wrist joint is in traction for a long term and is beneficial to the recovery of the radius length.

When the intervening period was more than 4 weeks, there was no significant difference between the experimental group and the control group, and the advantage of plaster splint disappeared. This may be due to the long-term fixation of wrist joint, restricting its movement, and then affecting the recovery of wrist joint function.

This study is the first systematic review of the efficacy and safety of plaster splint and splints in the treatment of DRFs, which integrates the latest and most comprehensive clinical evidence in this field. At the same time, the GRADE evidence grading assessment is more conducive to clinical decision-making and guideline transformation. Subgroup analysis was made on the excellent rate of treatment, and it was found that the intervening period may have an effect on the therapeutic effect. For the reduction rate, we did a sensitivity analysis, excluding the heterogeneous studies, and the results remained unchanged.

The results of this study are limited by the quality of the original study, and there are some biases, such as the implementation of unreported allocation concealment and blind method. In addition, as the studies included in the systematic review and meta-analysis are all Chinese literature, which may lead to the generation of some regional bias. We hope that this study not only can inspire more researchers around the world to carry out clinical studies in this field, but also can promote the formulation and updating of related guidelines.

It is suggested that future clinical researchers should pay attention to scientific and rational top-level design of research projects. Simultaneously, this demonstrates the need for systematic large-scale approaches to further support these findings.

5. Conclusion

In this systematic review and meta-analysis, there is no sufficient evidence that plaster splint is superior to splint. However, according to current evidence, plaster splint is more effective than splint when the intervention period is shorter (4 weeks), and its advantage disappears when the intervention period is longer (> 4 weeks). In addition, splints have fewer complications than plaster splint. It should be noted that the results of this study were influenced by the sample size and the quality of the included studies.

Author contributions

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