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Review

Management options for proximal humerus fractures – A systematic review & network meta-analysis of randomized control trials

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A B S T R A C T

Aims: The purpose of this study is to systematically review the randomized controlled trials on the various treatment options that can be utilized in the management of displaced proximal humerus fractures.
Materials & Methods: Based on the PRISMA guidelines, three independent reviewers performed a systematic review of the literature. Randomized control trials (RCTs) focusing on the outcomes of the following interventions in the management of PHFs were considered for inclusion; (1) non-operative or conservative (NOC) management, (2) open reduction and internal fixation (ORIF), (3) intra-medullary nailing (IMN), (4) shoulder hemi-arthroplasty (HA), and (5) reverse shoulder arthroplasty (RSA). Network meta-analyses were performed using R and studies were ranked according to their P-score.
Results: Our study included 13 RCTs. RSA had improvements in abduction, constant score, flexion, as well as lowest rates of malunion and osteonecrosis when compared to other management modalities (P-Score = 0.9786, P-Score = 0.9998, P-Score = 0.9909, P-Score = 0.9590 and P-Score = 0.8042 respectively). HA was found to have improvements in health-related quality of life scores when compared to other management modalities (P-Score = 0.9672). ORIF had the highest improvement in quick disability of arm, shoulder and hand scores and visual analogue scale scores (P-Score = 0.8209 and P-Score = 0.7155 respectively). NOC was found to have the lowest rate of conversion to surgical intervention, with RSA having the lowest rate of surgical interventions (P-Score = 0.9186 and P-Score = 0.7497 respectively).
Discussion & Conclusion: RSA offers satisfactory improvements in clinical and functional outcomes when compared to other non-operative and operative treatment options in the management of carefully selected proximal humerus fractures, with a minimal revision rate when compared to other surgical management modalities.
Level of Evidence: I - Systematic Review & Meta-Analysis of Randomized Control Trials
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Introduction

Proximal humerus fractures (PHFs) are common injuries in the elderly population, accounting for approximately 5% of all fractures [1]. In the past two decades, PHFs have become the 3rd most commonly seen fragility fracture, and therefore are a cause of significant morbidity in many of the osteoporotic patients in our aging population [2]. PHFs most commonly occur secondary to a low-energy fall in the osteoporotic patient, resulting in predominantly non-displaced two-part fracture that are often managed conservatively with sling immobilization with satisfactory clinical results [3].

In cases of displaced PHFs, discrepancies in opinion exist in relation to surgical versus conservative management. Although the 'ProFHER trial' demonstrated that satisfactory results can be achieved when these fractures are managed non-operatively, many surgeons have a preference for surgical management of displaced PHFs, particularly of more complex three or four part fractures [4]. The most widely used surgical modalities include open reduction and internal fixation (ORIF) with plates, intra-medullary nailing (IMN), shoulder hemi-arthroplasty (HA), and reverse shoulder arthroplasty (RSA).

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Du et al. [5]. published a systematic review and network meta-analysis of clinical outcomes for non-operative or conservative management (NOC), ORIF, RSA and HA in treating displaced three and four part PHFs. However, as many new randomized control trials (RCTs) have since been published on the topic, an up-dated systematic review and network meta-analysis which focuses on outcomes of all displaced PHFs, including analysis of IMN is warranted. Therefore, the purpose of this study was to systematically review the randomized control trials on the various treatment options that can be utilized in the management of displaced proximal humerus fractures. Our hypothesis was that the use of RSA would result in improved patient-reported outcomes, with a low revision rate when compared to other treatment options in the management of PHFs.

Materials and methods

Search strategy & study selection

Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a systematic search of the literature was performed by three independent reviewers (S.C., C.O.T. and J.K.). The PUBMED, EMBASE, and The Cochrane Library databases were queried in April 2020, using the following search terms: ((proximal) AND (humerus OR humeral)) AND ((surgical OR surgery OR operative) OR (nail OR nailing) OR (plate OR plating OR orif OR fixation) OR (non-operative OR conservative) OR (reverse shoulder OR total OR arthroplasty OR hemiarthroplasty)). The authors agreed not have a set time limit in respect to publication date. The search results were reviewed independently and compared by all three reviewers, with one of the senior authors (L.P.) agreeing to arbitrate in cases of disagreement. Following review of the abstracts of all search results, full texts of potentially eligible studies were evaluated by all reviewers, followed by screening of the reference lists of the included studies and literature reviews to obtain additional articles for inclusion.

Eligibility criteria

Only RCTs comparing and evaluating two or more different treatment modalities for the management of PHFs were considered. The research question is outlined in the PICO below:

PICO

Population: Patients included in RCTs who have undergone management of PHFs.

Intervention: Management of PHFs with one of the following: (1) non-operative or conservative management, (2) open reduction and internal fixation by plating, (3) intra-medullary nailing, (4) shoulder hemi-arthroplasty, and (5) reverse total shoulder arthroplasty.

Comparison: Network meta-analysis comparing functional outcomes, complication rates and revision rates between patients with PHFs managed with one of the aforementioned treatment options.

Outcomes: Compare the reported functional outcomes (including range of motion as well as VAS, ASES, HQRoL and Constant scores), the overall rate of complications (including infection, nonunion, osteonecrosis, malunion and dislocation) and the rate of revisions (or for non-operative or conservative management; conversion to surgical intervention) between patients who have been treated with one of the aforementioned treatment options for PHFs patients with PHFs managed with one of the aforementioned treatment options.

The exclusion criteria included studies which; (1) compared two different forms of the same management modality, (2) failed to report clinical outcomes, (3) were not prospective RCTs, (4) were not published in English, and (5) were not published in peer-reviewed journal.

Data extraction/analysis

The same three independent reviewers collected data in relation to study characteristics including study design level of evidence (LOE), methodological quality of evidence (MQOE), patient population, and outcome measures using a predetermined data sheet. The same senior author was available for arbitration in cases of discrepancies in opinion.

For each study, the LOE was evaluated based on the criteria of Wright et al. [6]. The MQOE and risk of bias was evaluated using the Cochrane Collaboration risk of bias tool [7].

Statistics

Network meta-analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). A frequentist approach to network meta-analysis with a random effects model was performed using the *netmeta* package version 0.9–6 in R[8]. Heterogeneity was quantified using the I^2 statistic [9]. To rank the treatments, we used the frequentist analogue to the surface under the cumulative ranking (SUCRA) probabilities called the P-score [8,10]. Studies were ranked according to their P-score. Meta-analysis was performed using *Review Manager ((RevMan)* [*Macintosh]. Version 5.3*. Copenhagen: The Nordic Cochrane centre, The Cochrane Collaboration, 2014.). A p-value of < 0.05 was considered to be statistically significant. Additionally, Qualitative analysis was performed for each study.

Results

Literature search

Our initial search found 12,103 studies, of which 3485 were duplicates leaving 8613 studies of outcomes following treatment of PHF. The PRISMA Study Selection Flow Diagram is illustrated in Fig. 1.

Patients demographics & study characteristics

Overall, 13 RCTs [11–23] (all level I evidence) satisfied our inclusion criteria. This included 836 patients (83.3% females) with a mean age of 72.7 years (58–92), who were followed up for a mean 21.6 months (12–36). A summary of these findings is further illustrated in Table 1.

Range of motion & patient reported outcomes

Across 12 studies, RSA had the highest improved constant scores (P-Score = 0.9998). Over 7 studies, RSA had the greatest range of flexion (P-Score = 0.9786), whereas 6 studies found that RSA had the greatest range of abduction (P-Score = 0.9909 respectively). ORIF had the lowest visual analogues scale (VAS) scores (P-Score = 0.7155) and the highest quick disability of shoulder, arm and hand (QDASH) scores over 8 studies (P-Score = 0.8042). Across 6 studies, HA had the highest health-related quality of life (HQRoL) score, whereas 2 studies found NOC to have highest American Shoulder & Elbow Surgeons (ASES) scores (P-Score = 0.9672 and P-Score = 0.7823 respectively). A summary of range of motion and patient-reported outcomes from the network meta-analysis is illustrated in Table 2. Forest plots illustrating results for Constant, VAS and QDASH scores are shown in Figs. 2, 3 and 4 respectively.

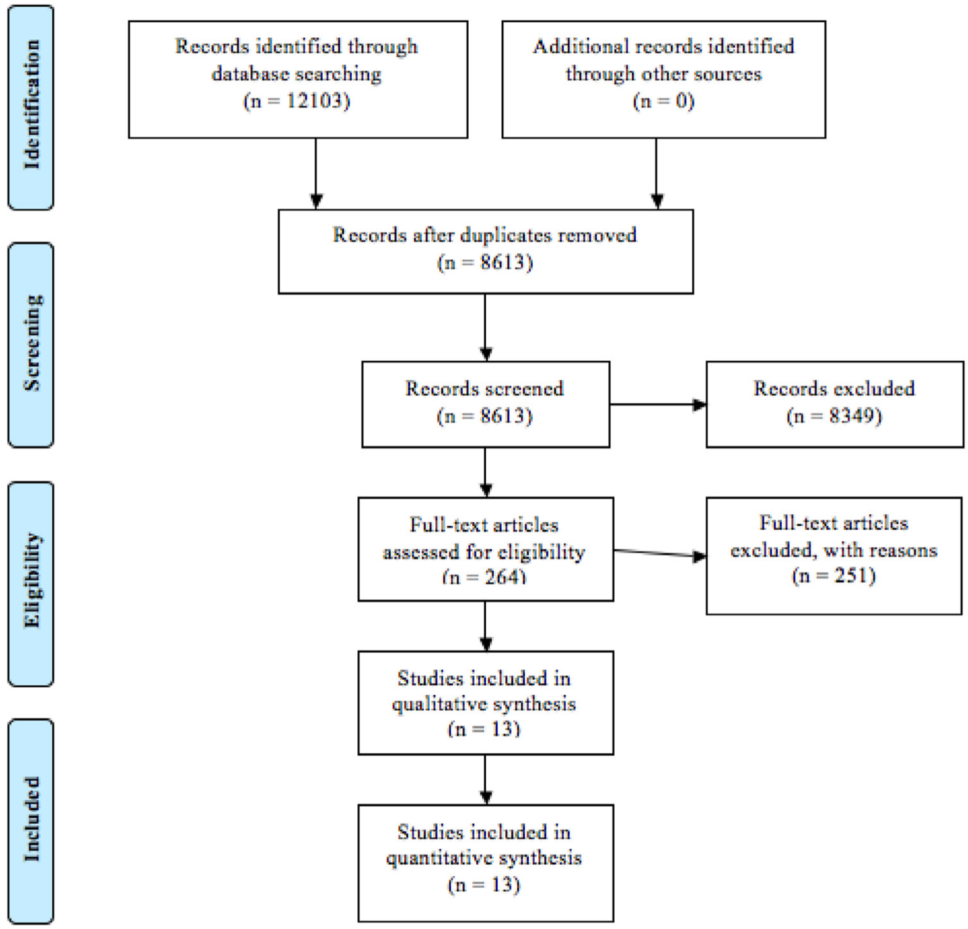

Fig. 1. PRISMA flow chart.

Table 1
Patient demographics & study characteristsics.

Authors	LOE	Fracture Pattern	Intervention 1	N 1	Intervention 2	N 2	Age (Yrs)	F/U (Mo)
Boons et al. [12]	I	4	HA	25	NO	25	78.2	12
Cai et al. [11]	I	4	ORIF	13	HA	19	71.8	24
Fjalestad et al. [13]	I	*B2/C2	ORIF	25	NO	25	72.6	24
Forcada et al. [14]	I	3,4	RTSA	31	HA	31	74	28.5
Fraser et al. [15]	I	*B2/C2	RTSA	64	ORIF	60	75.2	24
Gracitelli et al. [16]	I	2,3	IMN	36	ORIF	36	65.5	12
Launonen et al. [18]	I	2	ORIF	44	NO	44	72.5	24
Leighton et al. [17]	I	3	ORIF	30	NO	29	NR	24
Lopiz et al. [19]	I	3,4	RTSA	29	NO	30	83.5	12
Olerud et al. [20]	I	3	ORIF	30	NO	30	73.9	24
Olerud et al. [21]	I	4	HA	27	NO	28	76.6	24
Plath et al. [22]	I	3	IMN	36	ORIF	32	74.1	12
Zhu et al. [23]	I	2	IMN	28	ORIF	29	52.7	36

HA; Hemi-Arthroplasty, IMN; Intramedullary Nail, LOE; Level of Evidence, Mo; Month, N; Number, NO; Non-Operative, N/R; Not Reported, ORIF; Open Reduction & Internal Fixation, RSTA; Reverse Total Shoulder Arthroplasty, Yrs; Years.
* All fractures classified using Neer Classification, except those denoted with * indicating AO Classification.

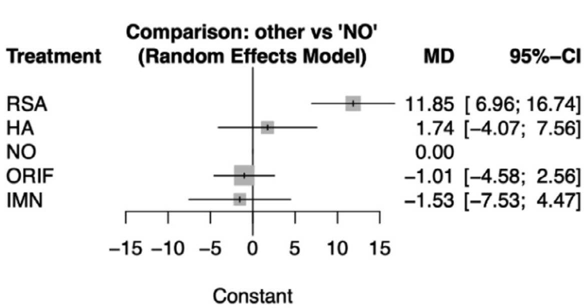

Fig. 2. Network meta-analysis by intervention for constant scores.

Complications & revisions

Across studies overall, NOC was found to have the lowest rate of conversion to surgical intervention, with RSA having the lowest rate of the surgical interventions (P-Score = 0.9186 and P-Score = 0.7497 respectively). RSA had the lowest rates of nonunion, osteonecrosis, malunion and dislocation (P-Score = 0.7676, P-Score = 0.9590, P-Score = 0.8209 and P-Score = 0.6588 respectively). Over 5 studies, ORIF had the highest rates of infection (P-Score = 0.6395). A summary of complications and revisions from the network meta-analysis is illustrated in Table 3. A forest plot illustrating results for revisions are shown in Fig. 5.

Table 2
Network meta-analysis: range of motion & patient-reported outcomes.

Outcome Measures			P Scores by Intervention				
Outcome	N Studies	N Treatments	HA	IMN	NO	ORIF	RTSA
ASES Score	2	3	N/R	0.0247	0.7823	0.6930	N/R
Abduction	6	5	0.4328	0.3341	0.3984	0.3561	0.9786
Constant Score	12	5	0.5844	0.2315	0.4199	0.2644	0.9998
Flexion	7	5	0.4980	0.3610	0.3025	0.3476	0.9909
HRQoL Score	6	4	0.9672	N/R	0.1952	0.3479	0.4897
QDASH Score	8	5	0.2936	0.6651	0.7311	0.8042	0.0061
VAS Scores	9	5	0.1171	0.5759	0.4043	0.7155	0.6873

ASES; American Shoulder & Elbow Surgeons, HA; Hemi-Arthroplasty, HRQoL; Health Related Quality of Life, IMN; Intramedullary Nail, N; Number, N/R; Not Reported, NO; Non-Operative,ORIF; Open Reduction & Internal Fixation, QDASH; Quick Disability of Arm, Shoulder & Hand, RSA; ReverseShoulder Arthroplasty, VAS; Visual Analogue Scale.

Table 3
Network meta-analysis: complications & revisions.

Outcome Measures			P Scores by Intervention				
Outcome	N Studies	N Treatments	HA	IMN	NO	ORIF	RSA
AVN	3	3	0.9291	N/R	0.5581	0.4622	N/R
Dislocation	3	4	0.3527	N/R	0.3445	0.6441	0.6588
Infection	5	5	0.3287	0.3429	0.8957	0.6395	0.2932
Malunion	5	4	0.5236	N/R	0.2861	0.3694	0.8209
Nonunion	7	4	0.6559	N/R	0.2211	0.3555	0.7676
Osteonecrosis	5	5	0.5424	0.3075	0.1914	0.4998	0.9589
Revisions	12	5	0.3659	0.3247	0.9186	0.1411	0.7497

HA; Hemi-Arthroplasty, IMN; Intramedullary Nail, N; Number, N/R; Not Reported, NO; Non-Operative,ORIF; Open Reduction & Internal Fixation, RSA; Reverse Shoulder Arthroplasty.

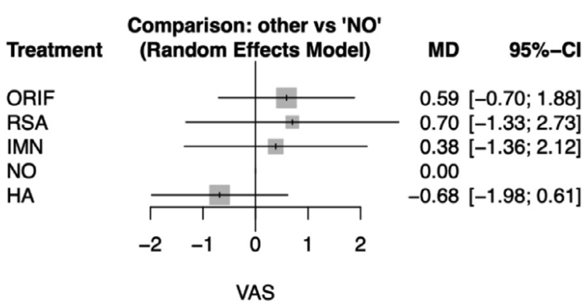

Fig. 3. Network meta-analysis by intervention for VAS scores.

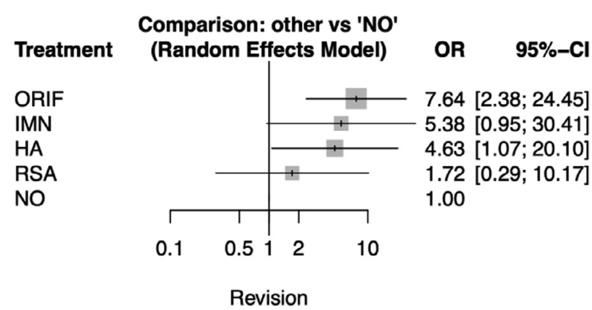

Fig. 5. Network meta-analysis by intervention for revisions.

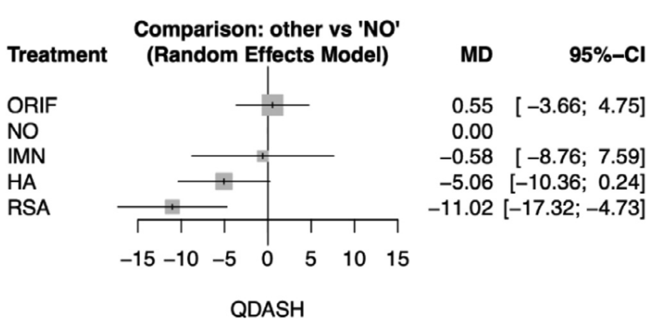

Fig. 4. Network meta-analysis by intervention for QDASH scores.

Discussion

The most important finding of this study was that when managing displaced PHFs, RSA offers patients the greatest range of motion and lowest rates of complications, with comparable patient-reported outcomes post-operatively when contrasted to other management modalities.

Controversy continues to exist when selecting treatment options for these fracture patterns, as RSA is often deemed a final operative measure, whereas ORIF and IMN may be revised more readily with comparable clinical outcomes. When treating the patient with a PHF, one must ultimately consider the indications for each intervention [24]. Non-operative or conservative management is often utilized in simple two-part PHFs that are non-displaced, whilst IMN tends to be predominantly utilized in the management of simple two- and three- part fractures [25]. Additionally, ORIF is favoured in cases of more complex three- and four-part PHFs with major displacement [26,27]. RSA is often reserved as a salvage technique in cases of severely comminuted PHFs, when other options are deemed unsuitable, or have failed previously [28–30]. Therefore, consideration of an initial trial period of non-operative treatment is often recommended in the literature, prior to ultimate decision for RSA or other surgical options without compromising functional outcomes at medium-term follow-up [31]. Our study showed that RSA results in the best combination of satisfactory functional outcomes, greatest range of motion, and lowest complication and revision rates in patients with PHF. However, correct patient selection is essential as many individual factors such as a patient's suitability for surgical intervention and demands on the arm have to be considered for optimal outcomes and risk management.

Patient-reported outcomes are a commonly utilized measure of treatment success by surgeons [32]. A previous RCT by Rangan et al. [4], the 'ProFHER trial', compared non-operative management of PHFs to many differing surgical interventions, demonstrating that no significant differences in patient-reported outcomes were reported between both groups, therefore favoring non-operative management for these fracture types. However, this trial not only pooled all surgical interventions together as one intervention, but also excluded patients with PHFs that the authors deemed surgical management to be an absolute necessity, therefore limiting their findings. Our review found superior ASES scores reported at short-term follow-up with NOC management of PHFs, when compared to other management modalities. Despite this, superior overall functional results were found in patients treated with RSA in this recent review of high-level studies. Therefore, although the ProFHER trial credits non-operative management of PHFs with excellent functional outcomes, caution must be used when electing for such management with complex, multi-fragment fractures as the lingering selection bias reported in the ProFHER trial limits the validity of its findings [4].

The results of this study found that patients who had PHFs managed by RSA had satisfactory functional outcomes, with superior constant scores compared to other management options. Similarly, a previous network meta-analysis by Du et al. [5] recommended the use of RSA as an optimum treatment method for the elderly patient with 3- or 4-part PHFs, with satisfactory ranges of motion reported in their study. Additionally, our study further supports such reporting as the use RSA in the treatment of PHFs results in excellent ranges of motion, with patients with RSA in this study reporting up to 40° more flexion and abduction than other treatment modalities. Therefore, although one of the more invasive interventions for PHFs, our study recommends RSA as the optimal management option to restore excellent functional outcomes in patients presenting with PHFs and satisfactory deltoid muscle function.

IMN in PHFs has been previously shown to minimize not only overall complication rates, but also blood loss, operative times, nonunion and osteonecrosis rates whilst preserving blood supply [25,33]. Despite this, our study reported lower complication rates in cases when RSA was utilized. As performing a RSA relies on osteotomy of an often-fractured humeral head, this modality has been shown to result in reliable pain relief alongside improvements in shoulder function. Our study found that with RSA complications could be reduced by avoiding issues mainly related to the humeral head, such as malunion, osteonecrosis or progressive arthritis. Thus, the superior outcomes with RSA can be attributed in large parts to the avoidance of many problems directly or indirectly related to preserving the damaged, native anatomy [34]. Nonetheless, RSA is primarily dependent on a strong, intact deltoid muscle in order to maximize post-operative function and should be best kept in reserve for irreparable PHFs in older patients, as longterm implant survival in young, active patients could become an issue [35,36].

Our study found that those who underwent NOC management of PHFs had lower conversion to surgical intervention when compared to the revision rates of all operative modalities. Although non-operative measures have previously demonstrated to result in lower conversion to surgery rates when compared to surgical management of PHFs [37], patients with many co-morbidities often are managed non-operatively in an effort to reduce peri–operative complications [38]. This therefore poses the question as to whether patient selection ultimately biases such outcomes. Beside the non-operative treatment group, this study further supports previous reports [39–44] that fewer surgical revisions are reported following RSA when compared to the other surgical interventions available to surgeons.

Limitations

Although this study evaluated the best available evidence in relation to various accepted management modalities in treating PHFs, it is not without its limitations. As a systematic review, a major limiting factor is the discrepancies between the data available from the included studies, as well as the heterogeneity of fracture patterns described in the included studies. Similarly, discrepancies exist in reported outcome measures as follow-up was obtained at various points during the post-operative period. In the included pooled analyses, the standardization of reporting limited our analysis. Similarly, for the purpose of simplicity in this study all revision intervention were pooled as 'revision surgeries'. However, we mitigated the heterogeneity by random effects models to control for this. Additionally, the outcomes following other accepted treatment options including Kirschner wire or external fixation methods were not considered for network meta-analysis in this study, as a lack of RCTs report on these topics. Finally, the ProFHER trial by Rangan et al. [4] which included 250 patients who were treated for PHFs, was excluded from the current analysis as it failed to clearly identify which surgical options were used in their experimental 'surgery' arm.

Conclusion

RSA offers satisfactory improvements in clinical and functional outcomes when compared to other non-operative and operative treatment options in the management of carefully selected proximal humerus fractures, with a minimal revision rate when compared to other surgical management modalities.

Declaration of Competing Interest

None.

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