Conservative treatment of scaphoid fracture: Protocol for a systematic review

Tratamento conservador da fratura do escafóide: Protocolo para uma revisão sistemática

Conservative treatment of the scaphoid fracture: Protocol for a systematic review

Abstract
The scaphoid is the most commonly fractured carpal bone. Fractures affecting this bone affect young and active patients between 15 and 40 years of age. Stable scaphoid fractures are treated conservatively by plaster cast immobilization or other type of orthosis for an average period of four to 12 weeks. Failure to treat scaphoid fractures may result in avascular necrosis, nonunion, and early secondary osteoarthritis, which may result in significant economic and social impact due to the affected population, formed by young people of productive age. The management of this type of fracture varies significantly between different Institutions and orthopedic surgeons. This article describes a protocol for a systematic review that aims to evaluate the effects (benefits and harms) of conservative interventions in the treatment of scaphoid fractures in adults.

Keywords: Scaphoid bone; Fractures, bone; Fracture healing; Conservative treatment.

Resumo
O escafóide é o osso carpal mais comumente fraturado. As fraturas que afetam este osso acometem pacientes jovens e ativos entre os 15 e os 40 anos de idade. As fraturas estáveis do escafóide são tratadas de forma conservadora, mediante imobilização gessada ou outro tipo de órtese por período médio de quatro a 12 semanas. Falha no tratamento das fraturas do escafóide pode resultar em necrose avascular, não união e osteoartrite secundária precoce, podendo resultar em significativo impacto econômico e social por conta da população afetada, formada por jovens em idade produtiva. O manejo deste tipo de fratura varia significativamente entre diferentes instituições e cirurgiões ortopédicos. O presente artigo descreve protocolo para uma revisão sistemática que visa avaliar os efeitos (benefícios e malefícios) de intervenções conservadoras no tratamento de fraturas do escafóide em adultos.

Palavras-chave: Osso escafóide; Fraturas ósseas; Consolidação da fratura; Tratamento conservador.

Resumen
El escafoídes es el hueso carpiano más comúnmente fracturado, las fracturas que afectan a este hueso afectan a pacientes jóvenes y activos entre 15 y 40 años de edad. Las fracturas de escafoídes estables se tratan de manera conservadora mediante inmovilización enyesada u otro tipo de órtesis durante un período promedio de cuatro a 12 semanas. El fracaso en el tratamiento de las fracturas de escafoídes puede resultar en necrosis avascular, no unión y...
osteoarthritis secundaria temprana, lo que puede resultar en un impacto económico y social significativo debido a la población afectada, formada por jóvenes en edad productiva. El manejo de este tipo de fractura varía significativamente entre los diferentes Instituciones y cirujanos ortopédicos. Este artículo describe un protocolo para una revisión sistemática que tiene como objetivo evaluar los efectos (beneficiosos y perjudiciales) de las intervenciones conservadoras en el tratamiento de las fracturas de escafoides en adultos.

**Palabras clave:** Hueso escafoides; Curación de fractura; Fracturas óseas; Tratamiento conservador.

1. Introduction

1.1 Description of the Condition

The scaphoid is an obliquely oriented bone, located on the radial face of the wrist joint, and is the only one that extends through both carpal rows, serving as a bridge between proximal and distal bones, transferring compression loads from the hand to the forearm, being fundamental in maintaining carpal stability (Yang et al., 1994). It is divided into three regions: proximal pole, waist, and distal pole; has six surfaces, of which three are articular (Larsen et al., 1992).

The blood supply of the scaphoid is exercised mainly by the radial artery branches, which pass through the capsular insertion to the dorsal crest, reaching its proximal pole. The distal pole has direct blood supply, and the proximal pole is mainly supplied by intraosseous retrograde flow; for this reason, fractures that occur through the waist of the scaphoid can disrupt blood flow to the proximal pole of this bone (Larsen et al., 1992).

The scaphoid is the most fractured carpal bone, representing 2% to 6% of all skeletal fractures; usually occur in young and active patients between 15 and 40 years of age (Tiel-van Buul et al., 1993). The most common fracture mechanism is forced wrist hyperextension, usually due to fall on the outstretched hand. Thus, fractures of the middle third of the scaphoid are probably caused by wrist hyperextension with compression of the radial side of the palm (Weber & Chao, 1978). In addition, backfalls with the previously directed hand can also cause hyperextension of the wrist (Cockshott, 1980). Less commonly, direct trauma to the wrist can also cause fracture of this bone (Russe, 1960).

There are several classification systems for scaphoid fractures, considering fracture pattern, stability, consolidation stage and time of injury (Kalainov & Osterman, 2001). As for the time of injury, fractures can be considered acute (less than three weeks of evolution), with consolidation delay (four to six months of evolution) and with non-union or absence of consolidation (more than six months of evolution) (Simonian & Trumble, 1994). With respect to the fracture site, we may have lesions identified in the proximal pole or third, waist or middle third and distal pole or third. Scaphoid fracture instability is defined as displacement greater than 1 mm in any direction, intrascaphoid angulation greater than 35° in lateral view, substantial bone loss or comminution, perilunate dislocation, misalignment, and fracture of the proximal pole of the scaphoid with instability (Cooney et al., 1980).

The time for scaphoid fracture healing varies between six and 18 weeks, depending on the fracture location, the extent of dislocation and instability, as well as the chosen treatment method (Dias et al., 2005; Düppe et al., 1994; Schädel-Höpfner et al., 2000).

Failure to treat scaphoid fractures may result in avascular necrosis (up to 40% of cases), pseudarthrosis (up to 21% of cases) and early secondary osteoarthritis (up to 32% of cases) (Tiel-van Buul et al., 1993; Divelbiss & Adams, 2001; Rajagopalan et al., 1999; Raudasoja et al., 1999). The treatment of unstable fractures is associated with additional complications (Szabo & Manske, 1988). In addition, the late consolidation of scaphoid fractures leads to longer immobilization time and greater loss of function, resulting in significant economic and social consequences due to the affected population, composed mainly of young people in their most productive life phase - even uncomplicated healing leads to the average interruption of work of 21 weeks, and in those who evolve with pseudoarthrosis, this average increases to 42 weeks (van der Molen et al., 1999).
1.2 Description of the Intervention

Typically, stable scaphoid fractures are treated conservatively, with plaster cast immobilization or other type of orthosis for an average period of four to 12 weeks. This treatment can be performed in several ways, differing mainly regarding the inclusion or not of unaffected joints and the positioning of the wrist. The main immobilization options are:

- Antebrachiopalmar (from forearm to palm), not including thumb.
- Antebrachiopalmar, with inclusion of the thumb.
- Brachiopalmar (from arm to palm), not including thumb.
- Brachiopalmar, with inclusion of the thumb.
- Plaster cast immobilization with the wrist in flexion, extension or neutral position.

1.3 How the Intervention Might Work

The objectives of the treatment of scaphoid fractures are to achieve consolidation, functional recovery, and prevention of complications such as pseudarthrosis or vicious consolidation (Rhemrev et al., 2011).

The main treatment method for scaphoid fractures without or with minimal displacement, is plaster cast immobilization, usually successful, resulting in consolidation rates between 90% and 100% (Bhat et al., 2004; Gellman et al., 1989). However, the management of this type of fracture varies significantly between different institutions and orthopedic surgeons.

Something important in choosing immobilization is defining which joints need to be immobilized. Some authors have advocated the use of models that extend above the elbow (brachiopalmar immobilizations) as a means of achieving better consolidation rates, while others suggest that models below the elbow may result in movement at the fracture site, since normal rotation of the forearm is transmitted to the radiocarpal joint (Kuhlmann et al., 1987). Although the inclusion of the base of the proximal phalanx of the thumb in the so-called "scaphoid cast" may improve fracture healing through greater stabilization, the immobilization of any unaffected joint may result in increased morbidity, leading to joint stiffness (Clay et al., 1991; Karantana et al., 2006).

Another issue concerns the position in which the wrist is immobilized; if in flexion (Cooney et al., 1980; Yanni et al., 1991) or slight extension (Fisk, 1970; King et al., 1982).

There is a consensus among orthopedic surgeons that most stable scaphoid fractures take six to eight weeks to consolidate. However, if the lesion is not treated properly, there may be implications related to fracture consolidation, need for surgical treatment and recovery time. All types of immobilizations will restrict the function of the hand during treatment, demanding motor rehabilitation after removal. On the other hand, inadequate immobilization can increase the risk for pseudarthrosis in about one third of cases (Furunes & Vandvik, 2009; Langhoff & Andersen, 1988; Sjølin & Andersen, 1988). Thus, immobilization in acute scaphoid fractures seems justified.

Radiographic follow-up is important in these cases, and the change in management, with surgical indication, may be necessary, especially if there is deviation from the fracture. Consolidation is a continuous process and serial images are needed to evaluate their progression. The consolidation of scaphoid fractures may be difficult to evaluate by radiographs, and low interobserver agreement was found 12 weeks after the injury (Dias et al., 1988). Although other modalities, such as magnetic resonance imaging (MRI) and computed tomography (CT) are also used to evaluate fracture consolidation, there is variation in the way these tests are interpreted (Buijze et al., 2012; Kulkarni et al., 1999; McNally et al., 2000).

1.4 Objective

To evaluate the effects (benefits and harms) of conservative interventions in the treatment of scaphoid fractures in
2. Methods

The protocol will serve as a guide to conducting a review of the literature available with a detailed quantitative and qualitative data analysis. This systematic review will be conducted in accordance with the recommendations of Cochrane Handbook for Systematic Reviews of Intervention (Cumpston et al., 2019). The protocol was prospectively registered at the PROSPERO database (registration number CRD42021285510) and the reporting will be prepared following the PRISMA statement (Moher et al., 2010).

2.1 Criteria for Considering Studies for this Review

Types of Studies

We will include randomized clinical trials (RCTs) and randomized quasi clinical trials (in which the method of allocating participants for treatment is not strictly randomized (e.g., date of birth, hospital registration number, alternation), evaluating conservative interventions for the treatment of scaphoid fractures in adults.

Types of Participants

We will include adults with acute scaphoid fractures treated by conservative interventions. We will record the diagnostic method or its absence in the included studies and report it in the review, but we will not use it as an exclusion criterion.

Trials that include adolescents will be included, provided that the proportion of adolescents is less than 10% or has available separate data to them.

Types of Interventions

We will include studies comparing different conservative interventions used in the definitive treatment of scaphoid fractures, with a focus on the differences between the types of immobilizations, wrist positions, types of materials used and the immobilization time. The main guide for the selection of the experimental or intervention group will be the one that involves immobilization of a smaller number of joints (i.e., does not include joints that were not injured) than the control group.

The main comparisons will be:

- Antebrachiopalmar plaster cast immobilization without thumb inclusion versus antebrachiopalmar plaster cast immobilization, with inclusion of the thumb.
- Plaster cast immobilization below the elbow (antebrachiopalmar) versus plaster cast immobilization above the elbow (brachiopalmar).
- Plaster cast immobilization with the wrist in flexion position versus extension position versus neutral position.

We will exclude intervention trials aimed at accelerating fracture consolidation, such as ultrasound, a topic addressed in another systematic review (Griffin et al., 2012).

Types of Outcome Measures

Where possible, primary outcome measures will be presented for follow-up periods of up to one year, between one and three years, and from three years onwards.
Primary Outcomes

- Functional outcome based on upper member function scores reported by the patient, including DASH questionnaire score (Hudak et al., 1996) and by the Patient-Rated Wrist Evaluation (PWRE) (MacDermid et al., 1998).
- Major adverse effects, including symptomatic pseudarthrosis, vicious consolidation, avascular necrosis and complex regional painful syndrome, along with secondary treatment (e.g., other method of immobilization, surgery).

Secondary Outcomes

- Other composite measures or function scores of the upper limbs.
- Quality of life measures reported by the patient.
- Reduction of return time to previous activities.
- Complications with plaster cast immobilizations (e.g., ischemia, skin lesions, joint stiffness).
- Symptomatic pseudarthrosis and potential long-term consequences (determined in patient evaluation during follow-up).

We will also present data for other outcomes reported in the included studies, such as consolidation time and joint amplitude, but will not be presented in the abstracts of the main results of the review. The authors will also try to provide information, when possible, on how clinical trials determined fracture consolidation and the development of pseudarthrosis. Thus, we will try to verify if this evaluation was made by radiography (anteroposterior and lateral wrist incidences, or the scaphoid series), or other imaging methodologies, such as CT or MRI. We will also check whether CT or MRI were performed in all cases, or only in those in which there was uncertainty about the diagnosis.

We will collect socioeconomic data, such use of resources, number of hospital visits and time away from work.

2.2 Search Methods for Identification of Studies

Electronic Searches

We will search the Cochrane Central Register of Controlled Trials (Biblioteca Cochrane current edition), MEDLINE (1946 up to the present), LILACS e EMBASE (1980 up to the present).

We won't apply restrictions based on the language or status of the post. In MEDLINE, a specific strategy for the subject will be combined with the maximizing sensitivity version of search strategies for the Cochrane Central Register of Controlled Trials and EMBASE (Table 1).

See also the complete search strategy extended data in Figshare (de Santana Ribeiro de Mattos, E., 2022).
Table 1. Search strategy used in MEDLINE (Ovid online)

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| 1. | Scaphoid Bone/
| 2. | Carpal Bones/
| 3. | scaphoid.tw.
| 4. | (#1 OR #2 OR #3)
| 5. | exp Fractures, Bone/
| 6. | Fracture Healing/
| 7. | Wrist Injuries/
| 8. | fracture.tw.
| 9. | (#5 OR #6 OR #7 OR #8)
| 10. | (#4 AND #9)
| 11. | Randomized controlled trial.pt.
| 13. | randomized.ab.
| 14. | placebo.ab.
| 15. | Drug therapy.fs.
| 16. | randomly.ab.
| 17. | trial.ab.
| 18. | groups.ab.
| 19. | (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)
| 20. | exp Animals/ not Humans/
| 21. | (#19 NOT #20)
| 22. | (#10 AND #21)


2.3 Data Collection and Analysis

Selection of Studies

The authors (MVM, TRSOC, ESRM, LRL) will screen independent research results for potentially eligible studies. After obtaining the full articles of appropriate reports, the authors will select the studies independently, according to the inclusion criteria of the review. Any disagreement will be resolved through discussion or by experts (CKCS, AG) who will act as arbitrators.

2.4 Data Extraction and Management

Data will be extracted and verified for all studies using a data collection form based on the Consolidated Standards of Reporting Trials (CONSORT) checklist (Schulz et al., 2010). Baseline data characteristics will include age, gender and the interval between fracture and the beginning of definitive treatment. We will try to contact the study authors if there are incomplete details about the methods or data of the research. In addition to recording the diagnostic method used in the studies, we will collect and report information on the methods of evaluating results, including those for pseudarthrosis and vicious fracture consolidation.

2.5 Assessment of Risk of Bias in Included Studies

The authors will assess the bias risk of the included trials using the Cochrane Collaboration tool (Higgins & Green, 2011). This will include the following domains: random sequence generation, allocation hiding, participants and personnel blinding, results evaluation blinding, results data integrity, selective results reports, and any other bias sources.
Subjective results such as pain or post-treatment function will be analyzed separately from other results, such as fracture consolidation, when evaluating the evaluation result blindness and the data result integrity. We will try to contact the authors of the trials for clarification when the methodological details are unclear. We will resolve the differences through discussion. For each of the above domains, the authors will assign a bias risk judgment of as being low, high or unclear, according to the criteria summarized in the Cochrane Manual (Higgins & Green, 2011).

2.6 Measures of Treatment Effect

Risk rates with 95% confidence intervals will be calculated for dichotomous results. Average differences with 95% confidence intervals will be calculated for continuous data. When two or more studies present data derived from the same validated evaluation instrument (with the same units of measure), the data will be grouped as an average difference. When primary studies express the same variables using different instruments and different units of measure, the standardized mean difference will be used.

If data from time to event arise, they will be analyzed as dichotomous data, provided that the situation of all study participants is known at a fixed time point. The data will be analyzed over a period that reflects the time to union, the time to discharge, and the time to resolve symptoms. As the consolidation rate may be difficult to assess, and an interobserver agreement was identified for consolidation rates (Dias et al., 1988), no specific criteria will be defined to evaluate the short- and long-term benefit.

2.7 Unit of Analysis Issues

We predict that the randomization unit in the included studies will be the individual. Occasionally, when participants who have suffered bilateral injuries are included, the results may be presented in the form of fractures or limbs. Where such unit of analysis questions arise and appropriate corrections have not been made, and where the disparity between the analysis and randomization units is small, we will consider presenting the data for such trials. Where the data is grouped, we will perform sensitivity analysis to examine the effects of excluding the analysis from incorrectly reported trials.

2.8 Dealing with Missing Data

We will try to contact the authors of the studies to request missing data. Where appropriate, we will conduct analysis of intent to treat to include all randomized people for the intervention groups. If there is a discrepancy between the randomized participants and analyzed in each treatment group, we will calculate the percentage of follow-up loss in each group. Unless we can calculate lost standard deviations from standard errors, exact P values, or 95% confidence intervals, we will not impute them. Where data are not available because of the follow-up loss of participants, their results will remain unknown and therefore will not be available for inclusion in the review.

2.9 Assessment of Heterogeneity

The heterogeneity of the estimation effects among the included studies will be evaluated by visual inspection of the forest graph (analysis), together with the consideration of the Chi² test for heterogeneity and the I² statistic.

2.10 Assessment of Reporting Biases

We plan to reduce reporting bias through:

• Research of published, unpublished and ongoing trials.
• Not including language restrictions in the search strategy.
• Verification of multiple test reports of the same trial.
• Attempt to obtain the trial protocol or registration document.
• Contact the authors in cases where pre-specified primary results (favorable or adverse) are not reported.

2.11 Data Synthesis
When considered appropriate, the results of comparable groups of runs will be grouped using fixed and random effect models. The choice of the model to be reported will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors such as the number and size of the included studies. 95% confidence intervals will be used throughout the process. We will consider not grouping data where there is considerable heterogeneity ($\eta^2$ greater than 75%) that cannot be explained by the diversity of methodological or clinical characteristics between trials. If meta-analysis is not possible or appropriate, the data of these trials will be reported individually and presented in forest plots.

2.12 Subgroup Analysis and Investigation of Heterogeneity
The following subgroup analyses (guided by the expectation of large differences in fracture healing potential) will be considered:
• Fractures of the proximal pole versus fractures of the waist and distal pole of the scaphoid (the first group is likely to have worse results).
• Smokers versus nonsmokers (the first group is likely to have worse results). We will investigate whether the results of the subgroups differ significantly by inspecting the overlap of the confidence intervals and performing the test for differences in subgroups available in the Review Manager 5.2 software (RevMan 2012).

2.13 Sensitivity Analysis
If the data permit, sensitivity analyses will be carried out to explore aspects of the evaluation methodology, including exploring the effects of the lack of data; the inclusion of studies with high or uncertain risk of bias due to lack of concealment of allocation or blinding of the evaluator, or both; the selection of the statistical model (fixed effect versus random effects) for meta-analysis and the inclusion of studies reported only in conference summaries and studies with unclear diagnostic methods.

2.14 "Summary of Findings" Tables
If there is sufficient evidence to prepare “summary of findings” tables, we will develop them for the main comparations. We will use the GRADE approach to assess the quality of evidence related to each of the main results listed in the types of outcome measures (Higgins & Green, 2011).

3. Results and Discussion
Scaphoid fractures occur predominantly in young people of productive age (Rhemrev et al., 2011) and require several weeks of immobilization until fracture consolidation occurs, which leads to significant economic and social impact (Ibrahim et al., 2011).

There is considerable variation in conservative treatment in terms of the way these fractures are immobilized. Petheram et al. (2009) identified that 57% of surgeons treat these fractures with brachial immobilizations including the thumb, 40% treat with immobilizations below the elbow (antebrachiopalmar) and with free thumb and the remaining 3% varied the management between the two types of immobilizations; in relation to the position of the wrist, 68% of the surgeons put the wrist in a neutral position, 20% in extension and 12% in flexion position.
The importance of this lesion and the clear variation in the configuration of immobilizations used in conservative treatment endorse the need for a systematic review of the best evidence present in the literature, seeking to inform about the effects of the needless treatment of scaphoid fractures. Immobilization of the affected limb is a consensus for conservative treatment of scaphoid fractures. This method is beneficial for bone consolidation, but adverse effects may occur due to prolonged immobilization, such as joint contracture and muscle atrophy and bone demineralization.

It is fundamental for the advancement of science, and improvement of society that publications respect scientific integrity (Mesquita, 2017). Another contribution of this paper is to make clear the information on the conduct of this systematic review ensuring integrity, avoiding scientific fraud and discuss for the promotion of good practices in research.

We plan to present the results further in a final systematic review as described above in the Methods section.

4. Final Considerations

This review aims to evaluate the effects (benefit and harm) of conservative interventions in the treatment of scaphoid fracture in adults, based on RCTs available in the literature. We intend to contribute with better understanding of the treatment of these fractures provided by the best available research evidence.

This work is linked to the UniFTC Medicine Graduation Final paper with scientific, economic, and social repercussions. We expect this literature review to be updated periodically with the addition of relevant future researches.

References


