Glenoid Failure after Total Shoulder Arthroplasty, cemented all-polyethylene versus metal-backed: A Systematic Review Protocol

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Protocol

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Abstract

Background

Anatomical Total Shoulder Arthroplasty (TSA) is an effective treatment adopted in patients with glenohumeral osteoarthritis. The glenoid component failure is the main risk that occurs in this therapeutic choice; however, doubts remain, regarding the selection of the best implant in order to avoid such complication.

Methods

A systematic review of randomized clinical trials (RCTs) or quasi will be carried out, applying the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) protocols, comparing polyethylene (keeled and pegged) versus metal back implants in adult patients with glenohumeral osteoarthritis.

Our search strategy will be carried out in the MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science. Data management and extraction will be performed using a data withdrawal form and by analyzing study method characteristics, participant characteristics, intervention characteristics, results, methodological domains.

The summaries of research evidence will be accessed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE). Shoulder function through functional scores such as Constant-Murley (CM) and American Shoulder and Elbow Surgeons (ASES), pain (Visual Analogue Scale), infection, procedure failure, radiograph radiolucency and loosening, are the selected outcomes. Another analysis such as subgroup, heterogeneity, sensitivity and statistical are going to be performed whenever possible.

Discussion

This systematic review aims to analyze how glenoidal implants behave in Total Shoulder Arthroplasties and therefore provide evidence concerning the best clinical practice to avoid complication.

Systematic review registration

PROSPERO, CRD 42018079537.

Background

Osteoarthritis (OA) of the glenohumeral joint is a common clinical condition that affects adult population [1], mainly in patients between 60 and 80 years old [2].

Total Shoulder Arthroplasty has been proved to be effective to treat this condition [3]. There has been an increase rate in these procedures between 300–400% for the last two decades (1990–2010), varying from 13.000 to 42.000 approximately, with an annual variation in the order of 10.6% [4, 5]. It was also

observed that approximately 24% of complications of this surgery were related to glenoid implant and 28.5% of those required surgical revision due to loosening. Loosening of the glenoid implant is the main cause of failure, followed by pain and decrease in range of motion after a TSA [6, 7, 8, 9]. This important complication compromises the function of the joint and can even lead need of reoperation.

This systematic review aims to evaluate the glenoid component by comparing the effectiveness of different types of implants, either with metal back or those exclusive in polyethylene (keeled or pegged), considering function of the shoulder and complications (persistence or worsening of pain, infection and failure of the surgery regarding glenoidal implants loosening in the glenohumeral joint).

Methods

Types of Studies and inclusion criteria:

This systematic review will follow recommendations proposed by the Cochrane Handbook of Interventions Reviews [10, 11] and PRISMA protocols [12, 13]. Our study will include only randomized or quasi-randomized controlled clinical trials, comparing metal-backed glenoid designs and polyethylene (keeled or pegged) design in Total Shoulder Arthroplasties.

Ethics Approval:

This study has been approved by the Research Ethics Committee of Universidade Federal de São Paulo (protocol 0725/2017, 2.157.415 and 70473017.5.0000.5505) (document attached).

Types Of Participants (inclusion And Exclusion Criteria):

The inclusion eligibility studies that assessed adults that underwent TSA due to idiopathic and inflammatory OA [14, 15, 16, 17]. The following exclusion criteria were adopted: Patients with previous surgery, neurological diseases (Charcot's Arthropathy, Parkinson's disease), Revision surgeries of arthroplasty and Reverse Total Arthroplasty.

Primary Outcomes:

Functional results, complications and failure represented by new surgical intervention, will be our main outcomes. We will consider the Constant-Murley (CM) [18], American Shoulder and Elbow Surgeons (ASES) [19] and University of California at Los Angeles (UCLA) [20] to measure function as a validated score. Complications like deep infection affecting prosthesis components, persistence or worsening of pain (Visual Analogue Scale - VAS) [21], loosening or breakage of implanted materials, dislocation, surgical revision.

Secondary Outcomes:

Clinical and radiographic outcomes will be assessed by range of motion (forward flexion, lateral and internal rotation) and indirect radiographic signs that evidence the loosening of the glenoid implant. The Lazarus classification for keeled components and Franklin classification for pegged components were the systems selected to assess radiolucency concerning those all-polyethylene components [22, 23].

Quality of life analysis validated short form scores 36 [24], will also be assessed.

Search Methods And Strategy:

The electronic search will be carried out in the MEDLINE (PubMed), Cochrane Central Register of Controlled Trials [25, 26], EMBASE, Web of Science, International Clinical Trials Registry Platform, ClinicalTrials.gov and Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS for randomized or quasi-randomized RCTs). The grey literature will also be searched through Google Scholar, OpenGrey and GreyNet [27].

We are going to use the following terms in different combinations and combinations for our search: “total shoulder arthroplasty”, “glenoid”, “keeled”, “pegged”, “loosening”, “metal-backed” and “radiolucency”. No restriction on language or publication status.

Data Collection And Analysis:

Two independent reviewers will access the selected studies, as well as the data extracted from these studies using EndNote X9, in order to facilitate collaboration among them during the selection process.

Two authors will select independently and analyze the eligible studies for this systematic review through the title and abstract. The selected studies will be entirely reviewed. Any disagreement will be resolved through discussion and, when necessary, will be judged by a third author in an attempt to resolve a possible conflict.

Data Extraction And Handling:

Data extraction will be performed by two reviewers will extract the data using an appropriate extraction form based on methodological characteristics, including design and duration, whether the protocol was published prior the recruitment of the patients, possible funding sources and study registration; characteristics of the participants including location, number of recruits, their evaluation, inclusion and exclusion criteria, age and classification relevant to the disease addressed; characteristics of the intervention like duration, surgery type and complications; results through time and loss of follow-up; methodological domains and risk of bias.

The extracted data will be also classified according to the time of follow-up into early and late, establishing 1 year as the cutoff for this division.

Access To Risk Of Bias:

Two authors will independently evaluate various aspects of methodological quality of the included studies using a modified version of the Cochrane Bone Joint and Muscle Trauma Group tool form [28]. Some items will be considered: random sequence generation, allocation concealment, participant blinding, outcome assessment blinding, selective reporting and potential influence of incomplete outcome data, in each trial, will also be carried out. After judgment and classification, these criteria will produce three levels of bias: low, high or unclear. Disagreements will be solved by the analysis of a third reviewer [29, 30].

Measures Of Treatment Effect:

The resulting dichotomous data will be analyzed with relative risk (RR) with a 95% confidence interval. When appropriate, we will express the estimated effects as numbers that need treatment (NNTs). Data on continuous outcomes will be expressed as an average difference of 95% in the confidence interval (CI). We intend to group the results with the mean difference (MD) if two or more trials reveal results from the same valid instrument of evolution (with the same units of measurement). If primary studies measure the same variables using different instruments (as well as different units of measurement), Cochrane Review Manager on its 5.3 version will be used for the statistical analyze.

Dealing With Missing Data:

We will perform an intention-to-treat analysis in order to include all randomized participants of any intervention. Insufficient information according to the estimated effects, as well as the number of participants, mean, uncertainty measurement (standard deviation or error) or number of events; we will contact the authors of the selected trials.

An analysis will be carried out independently of the lost data, submitting them to the worst and best scenarios.

Heterogeneity Analysis:

The heterogeneity of the estimated effects between the included studies will be evaluated through visual inspection of the forest plots and the statistical I^2 test (significant > 50%).

Data Synthesis:

The results of comparable tests will be grouped using the fixed-effect model and a 95% CI. However, the variable model will be used when there is a diversity in clinical or methodological characteristics.

Subgroup Analysis and Heterogeneity Investigation:

Where appropriate, subgroups will be analyzed in order to explore the difference in side effect related to the type of glenoid selected.

Confidence in Cumulative Evidence:

We will apply GRADE (www.gradepro.org) in order to describe and rate the quality of evidence and the strength of the recommendations, classifying them as *high*, *moderate*, *low* and *very low* [31, 32, 33].

Results:

Following this protocol publication, electronic searches will be carried out and the selected trials will be analyzed. By the time we get the final results, we are going to send this paper for publication. Our intention is to have it ready by the end of 2021.

Discussion:

We observe an increasing rate of TSA in the adult population and, therefore, complications also assume an increasingly important role in this particular treatment. The glenoid component is the main site of these complications in terms of pain, limiting range of motion, but also in worsening quality of life. These findings are correlated with loosening or even implant breakage [34]. There are some evidences that cemented all-polyethylene glenoid implant has a better loosening rate compared to the metal-backed design, but in terms of radiolucency, this statement is reversed [35, 36, 37, 38].

Nowadays we have several types of glenoid implants in both polyethylene and metal-backed designs, however searching the literature, there is a lack of systematic reviews. In fact, we found only one study including trials with low level of evidence such as nonrandomized and case series [39]. Further evaluation on this subject with better methodological quality should be carried out covering functional, clinical, and radiographic outcomes as well as complications.

We expect difficulty to find trials with adequate sample size, standardization in the functional scores, follow-up pattern and also methods of the results, promoting a possible limitation in our revision. The aim of this study is to provide support and scientific evidence for decision making in orthopedic clinical practice regarding the glenoid implant selection on TSA, serving as a guide for future trials with better methodological quality.

List Of Abbreviations

(ASES) American Shoulder and Elbow Surgeons

(CI) Confidence Interval

(CM) Constant-Murley

(GRADE) Grading of Recommendations Assessment, Development and Evaluation

(LILACS) Literatura Latino-Americana e do Caribe em Ciências da Saúde

(MD) Mean Difference

(NNTs) Numbers that Need Treatment

(OA) Osteoarthritis

(PRISMA) Preferred Reporting Items for Systematic Review and Meta-Analysis

(RCTs) Randomized Clinical Trials

(RR) Relative Risk

(SMD) Standard Mean Difference

(TSA) Total Shoulder Arthroplasty

(UCLA) University of California at Los Angeles

Declarations

Ethics approval and consent

Included.

Consent for publication

Not applicable.

Availability of data and materials

The datasets that will be used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The author(s) declare(s) that they have no competing interests.

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Contributions

RAZ is the guarantor of the review and drafted the manuscript. RAZ, FTM, JCB and MJST conceptualized the methods. RAZ and RFL contributed for the development of the eligibility criteria, and the data extraction items. RAZ, FTM and MJST designed the work. NAN helped with the electronic search and translation. All authors reviewed several drafts of the manuscript for critical content and also approved the final protocol.

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