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REVIEW PROTOCOL

Efficacy and safety of electrophysical agents in tibial lengthening by the Ilizarov method: a protocol of systematic review

Eficácia e segurança de agentes eletrofísicos no alongamento tibial pelo método Ilizarov: um protocolo de revisão sistemática

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Abstract

Introduction: The Ilizarov method, a circular external fixator, is the most commonly used approach to assist in bone union for tibial fractures. Electrophysical agents play a crucial role in rehabilitation, offering significant benefits in speeding up the recovery process and reducing treatment time. Objective: To evaluate the efficacy and safety of using electrophysical agents as adjunct treatment in the rehabilitation of tibial lengthening with the Ilizarov method. Methods: A systematic review of

randomized clinical trials (RCTs) will be conducted. The review protocol has been registered on the PROSPERO platform (CRD42023432698). Adults aged 18 years and older undergoing tibial lengthening using the Ilizarov method will be included. Searches will be performed in the following databases: Medical Literature Analysis and Retrieval System Online (Medline) via PubMed, Brazil Scientific Eletrononic Library Online (SciElo), Latin American and Caribbean Health Sciences Literature (LILACS) via Virtual Health Library, Physiotherapy Evidence Database (PEDro), Web Of Science, Sciverse Scopus and Excerpta Medica dataBASE (Embase) via Elsevier, with no language or publication year restrictions. The methodological rigor and certainty of evidence of the included studies will be assessed using the Risk of Bias tool and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, respectively. Study selection, data extraction, and methodological quality assessment will be conducted by two independent researchers. Expected outcomes: To provide robust information on how rehabilitation through electrophysical agents can impact bone lengthening using the Ilizarov method.
Keywords: Ilizarov Technique; Rehabilitation; Systematic Review.

Resumo

Introdução: O método Ilizarov, fixador rígido circular, é o método mais utilizado para auxiliar na reunião óssea de fratura de tíbia. Os agentes eletrofísicos desempenham um papel crucial na reabilitação, oferecendo benefícios significativos na aceleração do processo de recuperação e na redução do tempo de tratamento. Objetivo: Avaliar a eficácia e segurança do uso dos agentes eletrofísicos como tratamento coadjuvante na reabilitação do alongamento tibial com método Ilizarov. Métodos: Será realizada uma revisão sistemática, de ensaios clínicos randomizados (ECR). O protocolo de revisão foi registrado na plataforma PROSPERO (CRD42023432698). Serão incluídos adultos com idade maior igual a 18 anos, submetidos ao alongamento tibial pelo método de Ilizarov. As buscas serão realizadas nas bases de dados: Medical Literature Analysis and Retrieval System Online (Medline) via PubMed, Brazil Scientific Eletrononic Library Online (SciElo), Latin American and Caribbean Health Sciences Literature (LILACS) via Virtual Health Library, Physiotherapy Evidence Database (PEDro), Web Of Science, Sciverse Scopus and Excerpta Medica dataBASE (Embase) via Elsevier, sem restrição de idioma ou ano de publicação. Será realizada a avaliação do rigor metodológico e a certeza da evidência dos estudos incluídos utilizando a ferramenta Risco de Viés e a abordagem Grading of Recommendations Assessment, Devellopment and Evalution (GRADE), respectivamente. A seleção dos estudos, extração de dados e avaliação da qualidade metodológica será realizada por dois pesquisadores independentes. Resultados esperados: Fornecer informações robustas de como a reabilitação através dos agentes eletrofísicos podem atuar no alongamento ósseo com utilização do método ilizarov.
Palavras-chave: Técnica de Ilizarov; Reabilitação; Revisão Sistemática.

Introduction

The Ilizarov method, a circular external fixator, is the most commonly used technique to assist in the bone union of tibial fractures, allowing controlled and gradual displacement referred to as bone lengthening [5]. The global incidence of tibial shaft fractures was 16.9 per 100,000 per year [1]. Tibial bone lengthening, due to its extended duration, causes gastrocnemius muscle contracture resulting in 'equinus foot' with joint stiffness. Moreover, one of the major issues associated with bone distraction is the prolonged treatment duration using a complicated external fixation structure, leading to subsequent socio-economic and psychological disadvantages, as well as an increased risk of complications such as pin tract infections and soft tissue contractures [12,11]. Therefore, reducing the treatment time, especially the maturation period, would decrease costs, complications, and burdens on the patient [4].

Electrophysical agents play a crucial role in rehabilitation, offering significant benefits in accelerating the recovery process and reducing treatment duration [2,14,15]. These therapeutic modalities, including various forms of energy such as shock waves, ultrasound, and electric currents [2,3,9], have shown efficacy in promoting healing, decreasing treatment time, and stimulating osteogenesis [2,3,9,10]. By appropriately applying electrophysical agents, healthcare professionals can optimize the body's physiological response, facilitating the restoration of compromised functions [2,10]. Furthermore, these agents' ability to act on specific cellular and tissue levels contributes to a more targeted and efficient approach, enabling patients to recover more quickly and effectively [10].

Studies demonstrate that ultrasound stimulation can accelerate callus formation rate and regenerated bone maturation in distraction osteogenesis, allowing earlier removal of the external fixator, shortened treatment periods, reduced complications, and quicker return to daily activities for patients [2,14,15]. Similarly, studies have shown the benefits of Low-Intensity Pulsed Ultrasound (LIPUS) in enhancing bone consolidation after recent fractures, as well as in cases with delayed or non-union [4,14,15], with accelerated fracture healing by 24% - 42% and a high success rate in treating delayed fractures, significantly reporting nearly a twofold increase in union rate associated with electrical stimulation [3].

However, despite detailed descriptions in the literature of surgical methods for tibial lengthening using the Ilizarov technique, there is a noticeable scarcity of studies addressing rehabilitation techniques with electrophysical agents and their influence on functional and musculoskeletal outcomes of patients undergoing tibial distraction. Additionally, information regarding the quality of life of these individuals is limited. Given this scenario, it becomes necessary to identify in the literature the primary electrophysical means used in this condition and understand the results of these physiotherapeutic interventions concerning patients who underwent tibial lengthening using the Ilizarov method.

Objective

To assess the effectiveness and safety of using electrophysical agents as adjuvant treatment in the rehabilitation of tibial lengthening using the Ilizarov method.

Methods

Type of study

A systematic review will be conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for protocol (PRISMA-P).

Ethical aspects and research location

The review protocol has been registered on the PROSPERO platform (CRD42023432698). This study will be conducted at the Federal University of Amapá (UNIFAP) within the undergraduate Physiotherapy program, Department of Biological and Health Sciences.

Eligibility criteria

Types of included studies

Randomized clinical trials will be accepted without language or publication year restrictions.

Types of participants

Adults aged 18 years and older undergoing tibial lengthening using the Ilizarov method.

Types of interventions

Electrophysical agents such as ultrasound, low-intensity laser, or any type of electric current.

Types of comparisons

Any treatment using electrophysical agents versus -sham; electrophysical agents versus any control group; any treatment using electrophysical agents versus another treatment using electrophysical agents.

Evaluated Outcomes

Primary Outcome:

- **Bone consolidation:** Assessed through X-rays or any other recognized and validated instrument.
- **Adverse events:** Defined by the WHO (2009) as an incident resulting in harm to a patient. Harm includes impairment of body structure or function and/or any resulting exclusion effects.

- **Secondary Outcomes:**
- **Pain:** Can be assessed using a visual analog scale; dichotomous responses (yes or no); and/or ordinal scales.
- **Functional capacity:** Validated measures for specific patient conditions (e.g., Western Ontario and McMaster Universities Arthritis Index [WOMAC], Lysholm Knee Scale score, Health Assessment Questionnaire [HAQ], or any other validated instrument).
- **Quality of Life:** Assessed using SF-36, GHQ-28, or any other validated instrument.

Collection procedure

Literature search strategy

The search strategy will be tailored for each database and conducted in the following sources: Medical Literature Analysis and Retrieval System Online (Medline) via PubMed, Brazil Scientific Eletrononic Library Online (SciElo), Latin American and Caribbean Health Sciences Literature (LILACS) via Virtual Health Library, Physiotherapy Evidence Database (PEDro), Web Of Science, Sciverse Scopus and Excerpta Medica dataBASE (Embase) via Elsevier. To identify additional studies, we will also search the Clinical Trials Registry (www.clinicaltrials.gov) and reference lists of included studies. Grey literature searches will also be performed to ensure the inclusion of potentially

relevant studies. No language or date restrictions will be applied in our eligibility criteria."

Study selection

The study inclusion will be conducted by two independent authors (GCSA; ASAT). Title screening, removal of duplicates, abstract assessment, and when necessary, full-text reading will be performed. To optimize the screening and selection process, the Rayyan app (https://www.rayyan.ai/) will be utilized. Disagreements will be resolved by a third author (INLA).

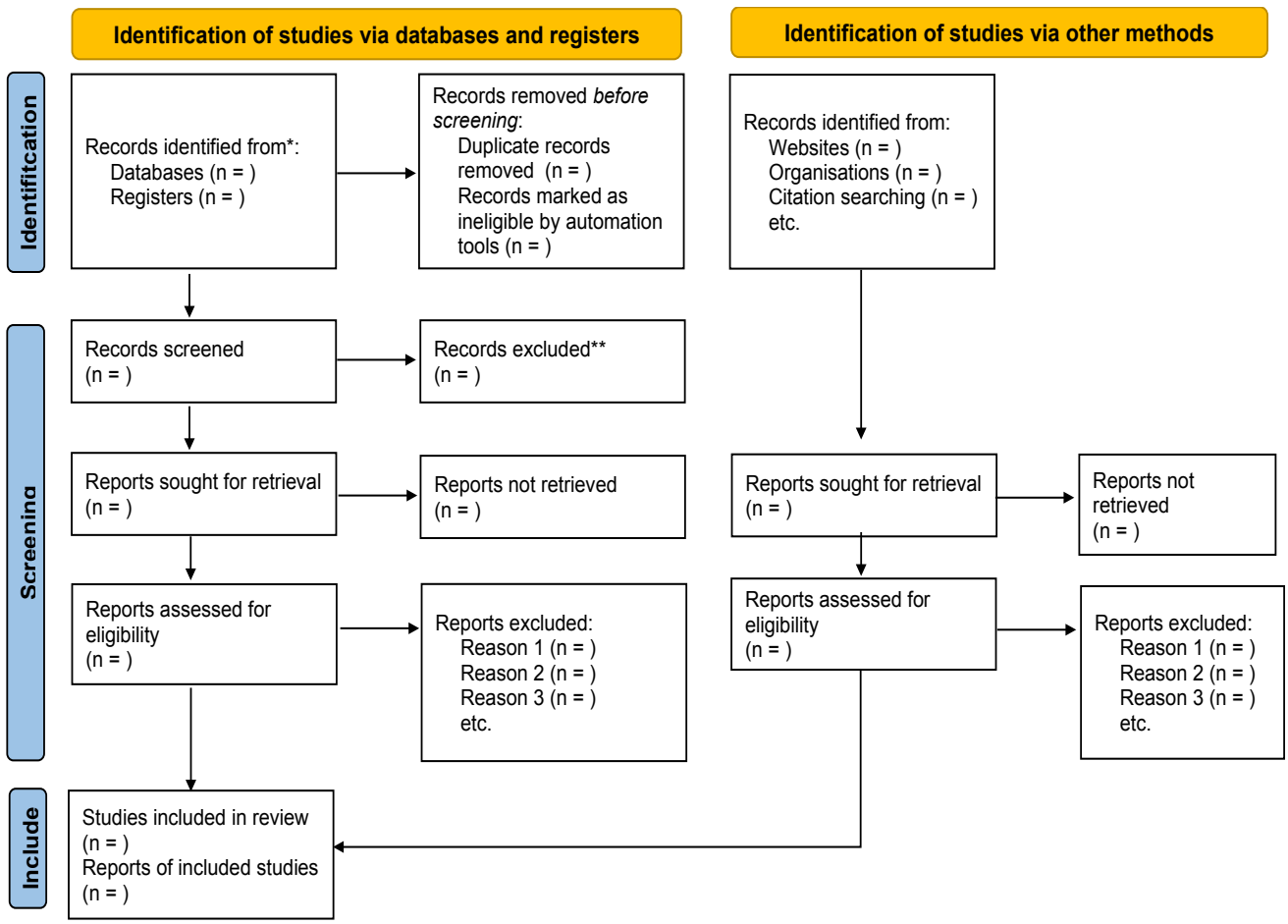

Figure 1: *Systematic Review Flowchart.*

Evaluation of Study Bias and Evidence Certainty

The Cochrane Risk of Bias Tool or RoB 2.0 (Risk of Bias), developed by the Cochrane Collaboration, will be used to assess the bias in the included studies' quality of individual clinical trials. To evaluate the certainty of the evidence set, the GRADE (Grading of Recommendations Assessment, Development and Evaluation) will be utilized [6], which should be sequentially applied in a systematic review to these tools, using the available evidence set [7].

Discrepancies will be resolved through consensus. The following domains will be analyzed: bias due to deviations from intended interventions, bias due to missing outcome data, bias in outcome measurement, bias in selection of the reported result, and overall study bias. Each bias risk domain will be graded according to GRADE, into four levels:

very low, low, moderate, and high. We will reach out to study authors to clarify any unclear or missing information regarding the assessed domains.

Data Synthesis and Analysis

If at least two studies demonstrate sufficient homogeneity concerning participants, interventions, and assessed outcomes, the results will be combined into a meta-analysis. Trials will be grouped based on intervention similarity. We will group different electrophysical agents and different comparators separately into meta-analyses, depending on the clinical and methodological heterogeneity of the included studies, making comparisons as follows:

- Any electrophysical agent versus Control;
- Therapeutic ultrasound versus sham;
- Low-intensity laser versus sham;
- Transcutaneous electrical nerve stimulation (TENS) versus Sham.

If the data is inadequate for inclusion in the meta-analysis, study authors will be contacted to request additional data. If even after this contact the data remains insufficient, the results will be summarized in a narrative synthesis.

When conducting meta-analyses is feasible, data will be aggregated using the inverse variance method and the random-effects model in Review Manager 5.4 software. Continuous variables will be summarized, whenever possible, using the difference (post and pre-intervention, when applicable) with a 95% confidence interval. In the case of studies using different measurement instruments to evaluate continuous outcomes, data will be pooled and reported as standardized mean differences. If adjusted data are available (e.g., ANCOVA or ANOVA), priority will be given to using this data.

Assessment of Heterogeneity

Statistical heterogeneity will be assessed using the I^2 statistic. The I^2 statistic, as defined in the Cochrane Handbook, is categorized as follows:

- 0% to 40%: might not be important;
- 30% to 60%: might represent moderate heterogeneity;
- 50% to 90%: might represent substantial heterogeneity;
- 75% to 100%: specific heterogeneity.

In the case of significant heterogeneity detection ($I^2 > 50\%$), we will proceed to investigate sources of heterogeneity through subgroup analyses and sensitivity analyses, following the guidelines established in the Cochrane Handbook for Systematic Reviews of Interventions. These analyses will be conducted to explore the impact of bias risk classification on intervention effects. If it's not feasible to combine results due to heterogeneity, the results will be presented in a narrative format.

Expected outcomes

This study aims to provide robust insights into how rehabilitation using electrophysical agents can impact bone lengthening with the Ilizarov method, investigating which physiotherapeutic interventions exhibit greater efficacy in restoring patient function. Additionally, it seeks to enhance treatment protocols involving pulsed ultrasound therapy and electrical stimulation concerning the parameters to be used, treatment duration, and application site. Thus, the goal is to structure a study addressing the effectiveness of rehabilitation and how physiotherapy can influence the recovery period in cases of tibial distraction using an external fixator.

Impacts and expected results

Through the conduct of this study, we aim to: Gain a comprehensive understanding of how rehabilitation using electrophysical agents can influence bone lengthening with the Ilizarov method. Investigate which physiotherapy interventions are most effective in restoring the patient's functional capacity. Refine treatment protocols for pulsed ultrasound therapy and electrical stimulation, including the parameters to be used, treatment duration, and application site. Structure a study to assess the effectiveness of rehabilitation and the impact of physiotherapy on the recovery period in cases of tibial distraction using an external fixator.

Conflicts of interest

We declare no conflicts of interest.

Funding sources

No funding sources was received.

Authors contribution

Conception and design of the research: Iosimuta NCR, Pinto ACPN, Alves, INL; Data collection: Anjos, GCS, Távora ASA; Data analysis and interpretation: Anjos, GCS, Távora ASA; Statistical analysis: Iosimuta NCR, Pinto ACPN; Manuscript writing: Anjos, GCS, Távora ASA; Critical revision of the manuscript for important intellectual content: Alves INL, Iosimuta NCR, Pinto ACPN.

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