School of Lifesciences and Education: Professional Doctorate in Healthcare Sciences

Title: Key concepts for intra-articular corticosteroid injections for pathology of the first metatarsophalangeal joint: a scoping review protocol

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ABSTRACT

Background: The two most common diseases affecting the first metatarsophalangeal joint (1st MTP jt) of the foot are hallux limitus/rigidus (osteoarthritis) and hallux valgus (bunion), but other pathologies also affect the region. There are a range of treatments for these conditions: one treatment option is intra articular injection therapy, and this is one of the most common therapeutic interventions in musculoskeletal healthcare. Therapeutic injections of corticosteroids provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, in those in whom conservative treatment has failed or for those awaiting surgery. They are accepted as an important treatment modality, but currently there are no evidenced-based guidelines about administration technique or regimen of the 1st MTP jt. This is a scoping review protocol for the study to identify key concepts in intra-articular corticosteroid injections for pathology of the first metatarsophalangeal joint.

Methods and analysis: Scoping reviews are used to assess and understand the extent of the knowledge in an emerging field or to identify, map, report, or discuss the characteristics or concepts in that field. The Joanna Briggs Institute (JBI) is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide. The JBI develops and delivers evidence-based information, software, education, and training and its guidance is widely cited across a range of disciplines, academic fields, and professional backgrounds. This scoping review will follow the JBI process who recommend the PCC framework ('Population–Concept–Context') to frame the research question. The 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews' will be used to guide the reporting of this protocol and will also subsequently be used to structure the reporting of the full review (PRISMA-ScR).

Dissemination: Findings will be presented to explore speciality-specific and profession-specific commonalities and differences. The scoping review results will be disseminated via publication in peer-reviewed journals (it is envisaged that at least two publications will be developed) and presentation at national/international conferences.

INTRODUCTION

Injection therapy

A needle is inserted into a joint for two main indications: aspiration of fluid (arthrocentesis) for diagnosis or for relief of pressure, or injection of medications (Roberts, 2020). Injection therapy for the treatment of joint pain has been performed since the 1930's. The introduction of cortisone revolutionized the treatment of several medical diseases and injections of glucocorticoids for the relief of vertebrogenic, arthritic and radiculopathic pain are widely accepted (Anitescu et al., 2013). Diarthrodial joints are well suited to intra-articular injection and the local delivery of therapeutics in this fashion brings several potential advantages to the treatment of a wide range of arthropathies (Evans et al., 2014). As well as eliminating many patient-compliance issues, this route of administration overcomes potential problems of bioavailability, uncontrollable drug dosing and the effects of drug binding to systemic molecules that can all limit the efficacy of a substance administered via enteral delivery.

The first metatarsophalangeal joint

The first metatarsophalangeal (great toe) joint (1st MTP jt) is a condyloid synovial juncture (McSweeney, 2016). The metatarso-sesamoid complex consists of the head of the first metatarsal, the base of the proximal phalanx, six muscles, eight ligaments and two sesamoid bones. The base of the proximal phalanx is concave and has a large base to receive its muscular and ligamentous attachments (Percival, 2001). The six muscles are abductor and (the two heads of) adductor hallucis, flexor hallucis longus and brevis, and extensor hallucis longus and brevis. The ligaments of the joint are the joint capsule, the medial and lateral collateral ligaments, the medial and lateral sesamoid ligaments, the plantar transverse metatarsal ligament, the inter-sesamoid ligament, and the hood ligament (Alvarez et al., 1984). It differs from the lesser MTP joints by its sesamoid mechanism: a single dominant fibrocartilaginous capsular thickening does not exist at the 1st MTP jt in contradistinction to the lesser MTP jts (Hallinan et al., 2020).

Pathology

The two most common diseases affecting the 1st MTP jt of the foot are hallux limitus/rigidus (osteoarthritis [OA]) and hallux valgus (bunion) (Ajwani et al., 2018; Mann, 1995). Other common pathologies include rheumatoid arthritis, gout and

sesamoiditis (Tallia & Cardone, 2003). There are a range of treatments for these conditions: one treatment option is intra articular (IA) injection therapy. Therapeutic injections - especially corticosteroid mixed with anaesthetic - provide a treatment option for patients with joint or peri-articular pain, those who are not surgical candidates, in those in whom conservative treatment has failed or those that are awaiting surgery (Chow & Brandser, 1998). They are accepted as an important treatment modality, but currently there are no evidenced-based guidelines about administration technique or regimen of the 1st MTP jt.

Reilly et al (2020) performed a systematic review of injectable corticosteroid for OA of the 1st MTP jt (Reilly et al, 2020). The aim of their review was to determine if good quality research exists to enable clinicians to adopt an evidenced based approach to corticosteroid injection (CSI) of the jt. They undertook a review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. A search of electronic databases identified 111 studies for possible inclusion. 64 duplicates were excluded, and 47 titles and abstracts were assessed. Titles and abstracts were assessed and evaluated against their aims. 36 articles were rejected, and 11 full text articles were retrieved for assessment against the selection criteria. One randomised control trial and one systematic review were identified for inclusion in their review. The authors concluded that despite the frequency of use, no high-quality studies support the use of IA CSI of the 1st MTP jt in osteoarthritis.

The planned coping review will take a wider approach to gathering data for the use of IA CSI for all 1st MTP jt pathologies to chart themes and identify gaps in the evidence base.

METHODS

Scoping reviews

All literature review methods offer a set of tools that researchers need to use appropriately. The method adopted for identifying literature for this review needs to achieve in-depth and broad results regardless of study design. In 2009, Grant and Booth identified 14 different types of literature reviews (Grant and Booth, 2009), one of which was the ‘scoping review’. Scoping reviews are used to assess and understand the extent of the knowledge in an emerging field or to identify, map, report, or discuss the characteristics or concepts in that field. (Peters, 2020a). A scoping review is commonly used for ‘reconnaissance’ of an area; to map out and clarify working definitions and conceptual boundaries of a topic or field (Davis et al, 2009). It is a form of knowledge synthesis that addresses an exploratory research question and maps the key concepts underpinning a research area by systematically searching, selecting, and synthesizing existing knowledge (Arksey & O’Malley, 2005; Colquhoun et al., 2014). They are useful when a body of literature has not yet been comprehensively reviewed, or exhibits a large, complex, or heterogeneous nature that is not amenable to a more precise systematic review (Peters et al, 2015).

Munn et al (Munn et al, 2018) listed the indications for scoping reviews:

- As a precursor to a systematic review,
- To identify the types of available evidence in a given field,
- To identify and analyse knowledge gaps,
- To clarify key concepts/ definitions in the literature,
- To examine how research is conducted on a certain topic or field,
- To identify key characteristics or factors related to a concept.

With the review by Reilly et al (2020) failing to produce strong evidence for the IA CSI of 1st MTP jt OA, a scoping review was therefore considered to be the most suitable approach to answer the research question looking at the wider themes about injection therapy of this jt.

Scoping review design

A scoping review methodological framework was first proposed by Arksey and O'Malley and Colquhoun (Arksey & O'Malley, 2005; Colquhoun et al., 2014) and amended by Levac et al (Levac et al., 2010). The six stages of the frameworks they produced for conducting a scoping study were:

- Stage 1: identifying the research question
- Stage 2: identifying relevant studies
- Stage 3: study selection
- Stage 4: charting the data
- Stage 5: collating, summarizing, and reporting the results
- Stage 6: consultation

The Joanna Briggs Institute (JBI) is an international research organisation based in the Faculty of Health and Medical Sciences at the University of Adelaide (Pearson et al, 2005). The JBI develops and delivers evidence-based information, software, education, and training and its guidance is widely cited across a range of disciplines, academic fields, and professional backgrounds (Khalil et al, 2020). This scoping review will follow the JBI process, which provides for the review to be rigorously conducted, transparent, and trustworthy (Peters, 2020b). Building on the guidance developed by Arksey and O'Malley (2005) and Levac et al (2010), the JBI framework (Peters, 2020a) recommends organising the review process into nine stages:

1. Defining and aligning the review objectives and questions,
2. Developing the inclusion criteria with the objective and questions,
3. Describing the planned approach to evidence searching, selection, extraction, and charting,
4. Searching for the evidence,
5. Selecting the evidence,
6. Extracting the evidence,
7. Charting the evidence,
8. Summarising the evidence in relation to the objectives and questions.
9. Consultation.

The JBI framework informs the overall conduct of the scoping review. The 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

extension for Scoping Reviews' (Tricco et al, 2018) will be used to guide the reporting of this protocol and will also subsequently be used to structure the reporting of the full review (PRISMA-ScR).

Protocol

The JBI recommend that an *a-priori* protocol must be developed before undertaking the scoping review (Peters, 2020a). A scoping review protocol is important as it pre-defines the objectives and methods of the scoping review. It is a systematic approach to the conduct and reporting of the review and allows transparency of process. The objectives, inclusion criteria and methods for this scoping review are specified in advance and documented in this protocol.

1. Defining and aligning the review objectives and questions.

Scoping study research questions are broad in nature as the focus is on summarizing the breadth of evidence. Arksey and O'Malley (Arksey & O'Malley, 2005) suggest an iterative process for developing research questions, i.e., the process is not linear and requires researchers to engage with each stage in a reflexive way and, where necessary, repeat steps to ensure that the literature is covered comprehensively. The scoping review question guides and directs the development of the specific inclusion criteria for the scoping review. Clarity of the review question assists in developing the protocol, facilitates effectiveness in the literature search, and provides a clear structure for the development of the scoping review (Peters et al, 2020).

2. Developing the inclusion criteria with the objective and questions

Aim

To establish what is known about intra-articular cortico-steroid injection therapy for pathology of the 1st MTP jt.

Objectives

1. To establish the key concepts about IA CSI therapy for pathology of the 1st MTP jt.,
2. To map or chart the data obtained to identify themes,
3. To identify key gaps in the existing evidence base and suggest the most urgent questions for future research.

The JBI recommends the PCC framework ('Population–Concept–Context') for scoping reviews to identify the main concepts in review questions (Peters et al, 2020a), see table 1.

Inclusion criteria	Rationale for inclusion and exclusion
Population	Human subjects (patients)
Concept	This scoping review will consider literature that provides information related to treatment with an intra-articular (IA) CSI
Context	IA CSI for pathology of the 1st MTP jt
Types of evidence to be included:	<p>Published papers or published conference abstracts reporting empirical or qualitative data from primary research or service evaluations. All research designs pertaining to the scoping review objectives will be considered</p> <p>Grey literature will be excluded for primary searching as published sources will be most useful and appropriate – and likely more rigorous. This is also to limit the number of hits as there are an unmanageable number of grey articles/websites. Selected sources found through secondary reference lists may be considered.</p> <p>To ensure a wide-ranging review, as per JBI guidelines, there will be no date or language restrictions.</p> <p>Studies that do not use IA (e.g., peri-articular, or systemic) CSI for the 1st MTP jt, or for which the original manuscript could not be retrieved, will be excluded.</p>

Table 1: PCC inclusion and exclusion criteria

3. Describing the planned approach to evidence searching, selection, extraction, and charting

The search strategy for a scoping review should ideally aim to be as comprehensive as possible within the constraints of time and resources to identify appropriate literature. To achieve the research aim, a strategy that involves searching for research evidence via the following different sources will be adopted:

- a) Electronic databases
- b) Google scholar
- c) Reference lists

4. Searching for the evidence

Step 1: The following databases will be searched via the NHS Healthcare Advanced Database Search (HDAS) search engines using MeSh terms/free text:

- CINHAL (Cumulative Index to Nursing and Allied Health Lit.: 1981 - 2021)
- EMBASE (Excerpta Medica Database: 1974 - 2021)
- MEDLINE (Medical Literature Analysis and Retrieval Online: 1946 - 2021)

Search terms

"((GLUCOCORTICOIDS/ OR (Steroid*).ti,ab OR (glucocorticoid*).ti,ab) AND ("INJECTIONS, INTRA-ARTICULAR"/ OR (Injection*).ti,ab)) AND (HALLUX/ OR (hallux).ti,ab OR ("big toe").ti,ab OR ("great toe").ti,ab OR (arthrofibrosis).ti,ab OR (gout).ti,ab OR (sesamoid*).ti,ab)"

Step 2: Google Scholar will be searched using key words identified from an analysis of the text words contained in the title and abstract of retrieved papers, and these key words used to search for articles.

Step 3: Examination of reference lists of all identified sources from step 1 and 2.

5. Selecting the evidence

Following the execution of the search strategy, the identified records will be retrieved and included or excluded according to the inclusion and exclusion criteria listed above. To support the greater breadth for scoping reviews, a variety of study designs will be included: scoping reviews are designed to provide an overview of the existing evidence base regardless of research quality and therefore a formal assessment of the methodological quality of the included studies is generally not performed.

6. Extracting the evidence

Following retrieval (database and snowball referencing), charting and sorting of material according into key issues and themes will be performed. A data extraction instrument for study details, characteristics and results extraction is provided in Appendix 1, adapted from the template provided by Peters et al (2020a):

- a) Author(s), source, and year of publication,
- b) Type of evidence,
- c) Origin/country of origin (where the study was published or conducted),
- d) Profession,
- e) Population,
- f) Concept,
- g) Context,
- h) Aims,
- i) Methodology,

- j) Intervention,
- k) Outcomes,
- l) Key findings that relate to the scoping review question.

7. Charting the evidence

The themes will be tabulated and summarized to present a narrative account of the existing literature. Data synthesis is not normally undertaken in scoping reviews because of the heterogeneity of the data (Peters et al, 2015).

8. Summarising the evidence in relation to the objectives and questions

Due to the heterogeneity of data, scoping reviews do not synthesize the results/outcomes of included sources of evidence as this is more appropriately done within the conduct of a systematic review (Peters et al, 2020a). The results of this scoping review will be presented as a map of the data extracted from the included literature in a tabular form and in a narrative descriptive summary that aligns with the objectives of the review. It is expected that the evidence will be further refined toward the end of the review when there is greater awareness of the contents of the included studies.

9. Consultation

This review will be registered with Open Science Framework and be available as a preprint. Findings will be presented to explore speciality-specific and profession-specific commonalities and differences. The scoping review results will be disseminated via publication in peer-reviewed journals (it is envisaged that at least two publications will be developed) and presentation at national/international conferences.

DECLARATIONS

Declaration of interest: The author confirms that he has no competing interests. This scoping review has been developed as part of the requirements toward completion of a doctoral degree in healthcare science at the University of Staffordshire.

Funding: This research did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

Patient and public involvement: Patients and/or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication: Not required.

ORCID ID

<https://orcid.org/0000-0002-2786-5739>.

OPEN SCIENCE FRAMEWORK

Reilly, I. N. (2021, September 10). Key concepts for intra-articular corticosteroid injections for pathology of the first metatarsophalangeal joint: a scoping review protocol. Retrieved from osf.io/kjc3u.

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APPENDIX 1:

Study details, characteristics, and results extraction instrument

Adapted from JBI template source of evidence details, characteristics and results extraction instrument (Peters et al, 2020a)

Template

Evidence source details and characteristics	
Citation (author/s, date, title, journal, volume, issue, pages)	
Type of evidence source	
Country/Profession	
Inclusion/exclusion criteria	
Population	
Concept	
Context	
Details/results extracted from source of evidence (in relation to the concept of the scoping review)	
Aims: Methodology: Intervention: Outcomes:	

<https://wiki.jbi.global/display/MANUAL/Appendix+11.1+JBI+template+source+of+evidence+details%2C+characteristics+and+results+extraction+instrument>