**ABSTRACT**

**Background:** Systematic review (SR), as secondary research is in the context of Evidence-Based Healthcare (EBHC) classified as the most important and valuable type of publication within the level of evidence hierarchy. Hallux valgus (HV) is a common forefoot deformity. In the current literature, there is no SR which has reviewed the effect of HV surgery on gait, pain or function in the global evidence.

**Aim:** Main aim of this propedeutically focused paper was to highlight the importance of SR within EBHC approach and explain rigorous and systematic methods of its development by example of partial results of the SR focusing on evaluation of the effect of the hallux valgus surgery.

**Methods:** Firstly, we formulated an answerable review question and specified inclusion and exclusion criteria. Protocol of the SR was prepared using software developed by Joanna Briggs Institute for SR preparation. Systematic search of published and unpublished studies included three steps: 1. Initial search in Medline, Embase and Cinahl; 2. secondary search in 13 databases; 3. hand-search in the reference lists of relevant papers. We have searched randomized controlled trials (RCT) in any date and language.

**Results:** We found 2412 papers and deleted 767 duplicates. Then a paper retrieval according to inclusion and exclusion criteria and critical appraisal of methodological quality were done using standardized critical appraisal instruments JBI-MAStARI. 27 RCT were included into SR. Currently, we are extracting data using JBI MAStARI and preparing them for meta-analysis. Partial results showed heterogeneity of used method for evaluation of pain and patient satisfaction after HV surgery in included RCT.

**Conclusions:** SR is a very important link between scientific evidence and their implementation into clinical practice. Evidence-Based approach can be used in all areas with high quality of primary scientific evidence.

**KEY WORDS**

systematic review, Evidence-Based Healthcare, bunion, surgery, podiatry

**INTRODUCTION**

*Why is the systematic review so important in clinical practice?*

A systematic review (hereinafter SR), as secondary research represents the most important and valuable type of study within the level of scientific evidence, synthesized by the given SR in the context of the Evidence-Based Healthcare approach and philosophy (hereinafter EBHC). EBHC is a generally methodological approach, which combines the excellent clinical experience of healthcare professionals with the best available scientific evidence and patient preferences (1) (Figure 1).
One component is not sufficient without the other two in a comprehensive approach in patient care. Only in the Medline database is added approximately 20,000 new studies per year. So, it means that for an individual, it is not possible to examine all the new studies. Therefore, the EBHC approach in patient care plays a key role in the current modern medicine and healthcare. SR represents an important part of EBHC, systematically and rigorously assessing, analysing and synthesizing scientific evidence from primary studies (2).

In the case of SR, explicit and rigorous methods are used for search, selection and critical assessment of relevant studies, data extraction and their analysis and synthesis. The essence of SR development is based on the formulation of the answerable review question, transformed into a systematic search strategy. A team of experts independently retrieves, critically appraises and analyzes the data based on a rigorous methodology and finally brings a new scientific information. The basic premise of SRs creation is their reliability, where the different teams have to result in the same conclusions in case of the same review questions, inclusion and exclusion criteria. In practice, the SRs play a key role in the decision-making process of the healthcare professional, because they provide the highest level of scientific evidence, based on the best globally available scientific evidence. SRs reduce bias, which is more or less part of the primary studies and unsystematic and literature reviews, by development of the extend search strategy to find all the relevant studies and also by independent and standardized critical assessment of their methodological quality. Currently, the SRs are the basis for creation of clinical guidelines.

Why have we focused on evaluating the effect of hallux valgus surgery?

Hallux valgus (or bunion, hereinafter HV) is a complex progressive forefoot deformity, which is closely related to foot dysfunction according to Kozáková, Janura (3), i.e. to disruption of the basal support in standing, with an absorption and loading transmission during walking. HV is characterized by valgus deviation of the big toe, varosity of the first metatarsal and medial prominence on its head. Deformity develops slowly based on the interaction of internal and external factors. The most important of these are biomechanical factors, structural changes, systemic diseases, hereditary predisposition, and wearing of improper shoes (4, 5).

According to published SR, it is a very common deformity in population, especially among women and older people. However, the SR also highlighted the enormous differences in the results of primary studies, dealing with the HV prevalence (6). This deformity may not have any consequence or cause difficulties. However, the patients with HV complain about severe pain, in the first ray of the foot in many cases as well as difficulty in walking, problems with the choice of footwear due to the widening of the forefoot and often-painful exostosis in MTP joint of the hallux (3). Kozáková and Janura (7) found that HV deformity affects not only the biomechanics of the foot, but also the whole kinematic chain of lower limbs and pelvis. Nix and Vicenzino (8) confirmed biomechanical changes in walking performance in patients with HV by SR. It were mainly the physicians specializing in orthopaedics, who were dealing with HV deformity for last 80 years. Available sources describe more than 130 surgical procedures correcting the HV (9). Selection and course of treatment depends on the stage of deformity, extent and nature of patient’s complaints according to Kozáková, Janura (3). The key role plays an accurate and especially early diagnostic of HV, detecting a risk of dysfunction preferably before its development. Prevention is the best therapeutic approach. However, the patients unfortunately see an expert at an advanced stage of deformity in most cases. Possibilities of preventive as well as non-invasive conservative interventions are very limited at this time. In these cases, there is usually no other option than to perform a surgical correction. However, there is a recurrence of the deformity quite often even after successful with a pathophysiological loading of the foot at the same time.

Many primary studies evaluated the effect of therapy of HV deformity, though SRs dealing with the effect of surgical correction of HV on walking, quality of life, satisfaction and pain is missing in the accessible literature.

OBJECTIVE

The main objective was to highlight the importance of systematic review in the context of Evidence-Based Healthcare approach and to explain the rigorous and systematic methodology of its creation with an example of partial results of the systematic review focused on evaluation of the effect of hallux valgus surgery.
METHODOLOGY
We proceeded in accordance with rigorous methodology by Joanna Briggs Institute (hereinafter JBI), which is currently the global leader in the EBHC approach and creation of SR.

First, we defined the topic, formulated an answerable review question and specified the criteria for inclusion and exclusion of primary studies into the systematic review, concretely a group of patients according to instrument PICO, thus population (P), type of intervention (I), comparison (C) with another type of intervention and outcomes (O) (Table 1). The acronym PICO (population, intervention, comparison and outcomes) represents a very useful tool in the creation of SR. The title, along with the objectives and criteria for inclusion and exclusion of studies in a format of PICO was approved in a peer-review procedure by the JBI board and officially registered in JBI Library.

After the approval and registration of the topic, we created a protocol of SR, which is a key component of any SR and includes an accurate description all the steps of systematic and rigorous process of its creation. We elaborated the SR protocol in a JBI software CReMS v5.0.2 (JBI Comprehensive Review Management System), which was developed by JBI for creation of protocol as well as full SR, used as a guide for the development of SR at the same time. The CReMS software represents one part of SUMMARI software package (System for the Unified Management, Assessment and Review of Information), which contains further analytical modules designed for a critical assessment of the methodological quality of studies included in SR, to extract and process data and last but not least for the data synthesis (e.g. using meta-analysis). The SR protocol was peer-reviewed and accepted for publication in peer-reviewed journal JBI Library. (10).

Creation of search strategy was an important part of the SR protocol. Systematic search of published and unpublished primary studies involved three steps. The initial search was carried out in Medline, Embase and Cinahl databases. We verified our search strategy by the initial searching (Table 2). We performed the second phase of searching in the following databases: Medline (Ovid MEDLINE(R) 1946 to current), Cinahl (CINAHL® Plus with Full Text 1935 to current), Embase (1974 to current), Tripdatabase, Nursing ovid, Web of Science, Cochrane library, Pedro. This step included also search for unpublished studies or the so-called grey literature (GoogleScholar, ClinicalTrials.gov, The Grey Literature Report, Current Controlled Trials, Cos Conference Papers Index, and Scirus) and dissertation theses (ProQuest). The third and final step in the search included the examination of the reference lists of relevant studies identified in the previous step of searching. We searched for randomized controlled trials (RCT) without time limitation and in all languages (10).

PARTIAL RESULTS
We found 2412 studies in the above databases (Figure 2). All the studies found were imported into the EndNote software, which we use to work with scientific literature. First, we removed 767 duplicates. After removing the duplicates, we followed with the first phase of the evaluation of relevance of

Table 1 Criteria for inclusion and exclusion of studies in a systematic review based on relevance in a PICO format

| Population: | Adults (18 years or older) with hallux valgus deformity, excluding adults with neurological problems causing foot deformities e.g. cerebral palsy, neuropathy, stroke, MS |
| Intervention: | Any type of hallux valgus surgery |
| Comparison: | No surgery Conservative treatment (such as physical therapy, kinesio taping, orthosis, etc. Different types of hallux valgus surgeries |
| Outcomes: | Gait measures, quality of life, patient satisfaction, pain, adverse events (short-term: < 6 months after surgery, medium-term: 6-12 months after surgery, long-term: > 1 year after surgery) |

Table 2 Bases for search strategy

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<td>surg* OR operat* OR osteotom* OR arthrodes* OR arthroplas*</td>
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1645 studies according to defined inclusion criteria based on their titles and abstracts analysis. Primary and secondary reviewer conducted evaluation of relevance of the studies independently. This phase of the evaluation was completed by comparing the results of the two reviewers and discussing of potential differences. There were 62 studies retrieved based on the first phase of assessing their relevance. In the second stage, the primary and secondary reviewer independently assessed the relevance of studies on the full-texts basis. Comparison of the results of both reviewers and subsequent discussion was continued by consultation of three disputed studies with a third reviewer. We excluded 35 irrelevant studies in the second phase of assessing their relevance.

Critical assessment of methodological quality of included studies is another very important step in the systematic and rigorous process of SR creation. We assessed the methodological quality of included studies using a standardized assessment tool (Meta-analysis of Statistics Assessment and Review Instrument – JBI-MAStARI), which was specially developed by Joanna Briggs Institute for the creation of quantitative systematic review as a part of the already mentioned SUMMARI software package. We critically assessed the quality and performance of randomization, allocation, internal and external validity, reliability, objectivity and the presence of bias and confounding factors using JBI-MAStARI instrument (Figure 3). Primary and secondary reviewer independently assessed the methodological quality of included studies. This was followed by comparison of the results of both reviewers and discussion. No studies were excluded from the SR based on methodological quality assessment. There were 27 RCTs included in the systematic review based on the systematic and rigorous assessment process of relevance and their methodological quality (Figure 2).

We are currently extracting data from 27 studies included in the SR and preparation of data for meta-analysis. Data extraction is performed using a standardized JBI-MAStARI instrument. The extracted data contain information about the experimental group, used intervention, selected methods and results. Partial results showed inconsistencies in the methods used to evaluate pain and patient satisfaction after HV operation involved in RCT. The pain was assessed using a standardized visual analogue scale only in several studies. Some of the authors simply asked their patients only whether they felt pain or not and another group of authors described the pain only partially within the AOFAS scoring system (American Orthopaedic Foot and Ankle Society), modified for HV deformity – Hallux Metatarsophalangeus-Interphalangeus Scale. Patient satisfaction after HV operation was evaluated in several RCT using 6-point or 3-point scales. However, the authors have created their own rating scale in most RCTs.

The authors dealt with influence of HV operation on gait performance just in one RCT (11), showing no effect of HV operation on gait measures from the short-term or long-term point of view. Assessment of quality of life was included in the preoperative and postoperative examination in just few RCT, while there were the standardized questionnaires used in all cases (11–15).

Figure 2 Flowchart of systematic process of assessing the relevance and methodological quality of the identified studies (modified according to Moher, Liberati) (21)
DISCUSSION
SR is, according to Klugar (16), design of the study, in which a new knowledge is created from the existing forms of knowledge of science and research. It is a so-called secondary research. SR is often confused with nonsystematic or overview review (literature review, a simple review, review, etc.) in general public, but also in the wider professional one. However, literature review, unlike SR, does not bring a new knowledge/evidence. It provides only an overview, which is often very subjectively influenced by an author or a group of authors about a particular discourse to a specific issue. While the SR provides new insights, review paper is more or less an essay on a specific topic.

As mentioned above, SR uses a rigorous procedure, while its minimum is according to Liberati, Altman (17) established under recommendations of PRISMA, whose compliance reduces the risk of errors and biased results of SR. Currently, SR should form the basis for the creation of clinical guidelines. For example, clinical guidelines for diagnosis and treatment of Achilles Tendon Rupture (18) and clinical guidelines for the treatment of knee osteoarthritis (19) have been created on the basis of SR.

Methodology and the actual creation of SR is represented by two leading global organizations in EBHC area „The Cochrane Collaboration“ and „The Joanna Briggs Institute” (hereinafter, JBI); although, there are several other organizations and groups (Campbell Collaboration, Centre for Reviews and Dissemination, etc.) dealing with creation of SR. The Cochrane Collaboration, founded in 1992, has currently more than 39 collaborating centres. The Cochrane Collaboration is primarily focused on creating SRs of RCTs in medicine, while focus of the JBI, established four years later at Adelaide Royal Hospi-
tal (Australia), is much wider. The JBI comprehensively describes the methodology and the creation of both quantitative and qualitative SR, and allows synthesizing scientific evidences from different types and levels of scientific studies (1, 20). Currently there are more than 90 collaborating JBI centres.

However, studies of the highest quality, such as SRs, have certain limits. For example, the Cochrane Collaboration was criticized in the past, for synthesizing only randomized controlled studies, which significantly discriminated such fields of healthcare, in which these very time consuming and costly studies do not exist or is not possible to conduct. Further limitation might be that SR creation of is conditioned by the existence of primary studies, however, as we stated above, JBI philosophy and methodological approach allows to synthesize all levels of scientific evidence, because this organization emphasizes not only the creation of SRs, but also their implementation in clinical practice. Currently, the JBI completes a methodology for creation of SR from „expert opinion”, i.e. consensus or opinion of experts, because in case of absence of scientific evidence, the best evidence available in this case is, according to EBHC approach, an opinion or a consensus of experts. If 1,000 experts from various countries of the world have the same opinion on a clinical problem, it is the scientific evidence on which the practice, according to the philosophy of JBI in the absence of a higher level of scientific evidence may rely.

Although is not necessary to use a dedicated software, such as SUMARI or RevMan (software for creation of SR developed by the Cochrane Collaboration), for the creation of a systematic review, we highly recommend to use such software. Both of the above mentioned products, which are freely available, contain also statistical modules, enabling the reviewer to conduct, for example, a meta-analysis. Performance of meta-analysis without specialized software may be insurmountable problem for many authors. Although using other statistical software e.g. STATA, SAS, R, etc. might by a solution. The first Czech Centre for Evidence-Based Healthcare in the Czech Republic: affiliate centre of JBI was founded in December 2013. It focuses on the creation of SR, methodology and implementation EBHC approach of scientific evidence into clinical practice.

CONCLUSIONS
SRs represent a very important link between scientific evidence and their implementation into clinical practice. Evidence-Based approach can be used in all areas in which the primary quality scientific evidences are constituted. This propaedeutic paper aims, among other things, on example of SR partial results to point out the possibilities and need of Evidence-Based approach in Podiatry.

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