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REVIEW

Septic arthritis of the hand: Current issues of etiology, pathogenesis, diagnosis, treatment

Konstantin V Lipatov, Arthur Asatryan, George Melkonyan, Aleksandr D Kazantcev, Ekaterina I Solov'eva, Urii E Cherkasov

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Abstract

Septic arthritis of the hand is a serious disease that often results in dysfunction of the joint or even the need to perform amputation of the finger. They rank second in the frequency of occurrence after lesions of the knee joint. Many points concerning the etiology, the timing of the development of cartilage destruction and the development of osteomyelitis, approaches to surgical treatment, the duration of antibiotic therapy, and the start of rehabilitation measures remain the subject of numerous discussions. Based on a search in the PubMed, Web of Science and Google Scholar databases down to 1990-2021, publications on septic arthritis of the hand were found and analyzed. The following inclusion criteria were used in our review: (1) Septic arthritis of the hand; (2) Published in a peer review journal; (3) Written in English; and (4) Full text version available. Studies were excluded if they met any of the following criteria: (1) Letters; (2) Articles published in abstract form only; and (3) Cadaveric studies. Septic arthritis of the hand was characterized by the most frequent damage to the joints of the index and middle fingers (> 50% of cases). Up to 90% of cases, the infection enters the joint as a result of penetrating trauma, animal bites, *etc.* Staphylococcus aureus became the most frequently isolated microorganism (30%-55%), and its polyanti-

biotic-resistant form Methicillin-resistant Staphylococcus aureus was found, according to various sources, from 0% to 73% among all isolated Staphylococcus aureus. In arthritis, Pasteurella multocida (6%-11%) is often isolated as a result of animal bites. Articular cartilage destruction in the experiment developed within 24-48 h after infection. In clinical studies, the development of osteomyelitis was noted when treatment was delayed by more than 10 d. X-ray data during the first two weeks were uninformative. Priority of surgical treatment of septic arthritis. Drainage and surgical treatment, and with the development of osteomyelitis, the implementation of arthrodesis. Antibacterial therapy for 2-4 wk and early start of rehabilitation measures. Timely surgical treatment in combination with antibiotic therapy and rehabilitation makes it possible to obtain a positive result in the treatment of septic arthritis of the hand.

Key Words: Septic arthritis; Hand; Staphylococcus aureus; Metacarpophalangeal joint; Interphalangeal joint; Rehabilitation

Core Tip: Septic arthritis of the hand often occurs as a result of penetrating wounds. The most common causative agent is Staphylococcus aureus, often characterized by high antibiotic resistance. Delayed treatment of septic arthritis can lead to cartilage destruction and osteomyelitis. To achieve a positive result in the treatment of septic arthritis of the hand, timely surgery, adequate antibiotic therapy and early rehabilitation are necessary.

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INTRODUCTION

The hand is a unique anatomical formation of the human body, that determines its authenticity and individuality. Injuries and diseases of the hand can have the most tragic consequences, depriving the victims of the opportunity to continue their professional activities, causing irreparable cosmetic damage, and often causing disability[1,2]. Among the infectious pathologies of the hand, septic arthritis of the metacarpophalangeal and interphalangeal joints is characterized by particular severity. Delayed or inadequate treatment of these diseases can lead to loss of joint function or even to the need for finger amputation[3,4]. In addition, persistent infection, impaired function, and chronic pain after septic arthritis may warrant arthrodesis or amputation in 50%-75% of patients[1].

PREVALENCE AND CAUSES

The incidence of purulent arthritis of the hand joints is characterized by significant regional differences and ranges from 2 to 12 cases per 100000 people per year[5]. They rank second in prevalence (15%-20%) among purulent arthritis of other locations in adults after lesions of the knee joint[3]. However, according to other data, they are much less common than 5% among septic arthritis patients[6]. Among all hand infections, the proportion of bone and joint lesions ranges from 5% to 18%[3].

The joints of the index and middle fingers are most often affected (more than 50% of cases). Information about the involvement in the inflammatory process of the distal (DIP), proximal (PIP) interphalangeal joints and metacarpophalangeal (MCP) joints is contradictory according to various authors. Some of them indicate a higher frequency of DIP lesions, while others, on the contrary, indicate a more frequent involvement of PIP or MCP in the inflammatory process[2,6,7]. At the same time, it should be noted that the judgments of most authors are based on little clinical material.

As a rule, (85%-90% of all cases) the infection entered the joint directly as a result of tissue damage as a result of a domestic or industrial injury, animal or human bites, or medical manipulations[2]. Cat bites are significantly more likely than dog bites to cause infectious complications. This is due to differences in anatomy and bite mechanism. Dog bites are characterized by a crushing and tearing mechanism associated with naturally blunt dog teeth. The sharp teeth of cats, piercing tissues, leave behind a bacterial trail like an injection needle. This mechanism is characterized by slight tissue damage, contributing to the retention of bacteria in the deep layers, which leads to severe infectious complic-

ations[8]. Quite typical is the development of purulent arthritis of the metacarpophalangeal joint in traumatic injury, called clenched fist injury. It is dangerous not only because of tissue contamination with pathogenic microflora from the oral cavity, but also due to possible damage to the extensor tendon, MCP capsule, and metacarpal head[9]. It is possible to spread the infection to the joint with the development of septic arthritis from the surrounding soft tissues with felon, and pyogenic flexor tenosynovitis[10].

Much rare (up to 10%-12%) is the hematogenous route of infection penetration into the joint, and the source in most cases remains unidentified[2,4]. When trauma is not evident, the differential diagnosis should include degenerative arthritis, inflammatory arthritis, crystalline arthropathy, cellulitis and soft tissue abscess[11,12].

MICROBIOLOGY

The microbiology of causative agents of septic arthritis of the hand has not been studied in sufficient detail. Data have been published that among the isolated microorganisms in septic arthritis, Staphylococcus aureus prevailed (30%-55%), and among its strains, the methicillin-resistant form was often found[7,13-15] (Figure 1). Various types of Streptococcus were also often isolated (up to 15%), including the most pathogenic Streptococcus pyogenes[16]. The level of gram-negative microorganisms remained relatively high (up to 13%)[3,16]. A feature of the microbial landscape of septic arthritis of the hand was the fairly frequent release of Pasteurella multocida (up to 6%-11%), the causative agent of zoonotic infections, which usually enter tissues with animal bites[7]. With septic arthritis of the fingers, monoinfection prevailed, although cases of isolation of associations of microorganisms (up to 5%-19%) were not uncommon[13,17]. The importance of identifying pathogens was not only in conducting scientific analysis, but also in the possibility of antibacterial therapy, taking into account the sensitivity of the isolated microflora. However, according to researchers, successful isolation of microorganisms in purulent arthritis of the hand occurred in only 50%-70% of cases[2,7,18].

PATHOGENESIS

Pathogenic microorganisms that have penetrated into the joint produce substances that promote their adhesion and protection from humoral and cellular immunity factors. The multiplication of bacteria leads to the spread of infection. In the initial stage of the immune response of the macroorganism, a cell wall is formed, including macrophages and polymorphonuclear leukocytes. The production of proinflammatory cytokines (interleukin 1-β, interleukin-6, tumor necrosis factor-α, *etc.*) begins along with the activation of the complement system. If it is impossible to eliminate the infection, the immunological response continues to develop with the formation of byproducts that lead to the release of matrix proteinases and lysosomal enzymes. They, in combination with bacterial toxins, cause the degradation of host collagen. The formed articular effusion disrupts the nutrition of chondrocytes, contributing to the occurrence of cartilage destruction[19-22]. Experimental studies have shown that cartilage surface erosion, degeneration and necrosis of chondrocytes appear starting from 24 h after intra-articular injection of bacteria[23,24]. An *in vivo* study showed the death of chondrocytes within 48 h of interaction with pathogenic microflora (S. aureus, E. coli)[23,25,26]. Clinical studies indicate that delaying treatment by more than 10 days leads to the development of osteomyelitis[4,27,28]. Other authors note even later periods of osteomyelitis − 1 mo or more after injury[3,29]. Undoubtedly, timely treatment is the most important factor preventing the occurrence of osteochondral destruction in purulent arthritis, which was proven by a study in which, with an average treatment delay of 5.4 d, osteomyelitis was not detected in any case[2]. Similar data are given by M. Sinha *et al*[10] (2006), who observed 26 patients with hand arthritis. The maximum treatment delay was up to 6 days. At the same time, cartilage destruction was not detected in any case.

CLASSIFICATION

Currently, a specialized classification of purulent arthritis of the hand has not been proposed, which would reflect important parameters such as the destruction of bone and cartilage structures, the tendons of the flexor and extensor of the finger, the presence of paraarticular wounds and fistulas. Septic arthritis of the fingers found some reflection in the classification of hand infections Brown[30] (1978). It includes such forms as: cellulitis, necrotizing fasciitis, paronychia, felon, pyogenic flexor tenosynovitis, deep space infections, septic arthritis, and osteomyelitis. The classification presents only two variants of purulent arthritis, one of which is accompanied by the development of osteomyelitis. Along with this, there is no information about the condition of the surrounding soft tissues, the patient's immune status, or clinical data. The generally accepted and recommended practice is to use the classifications

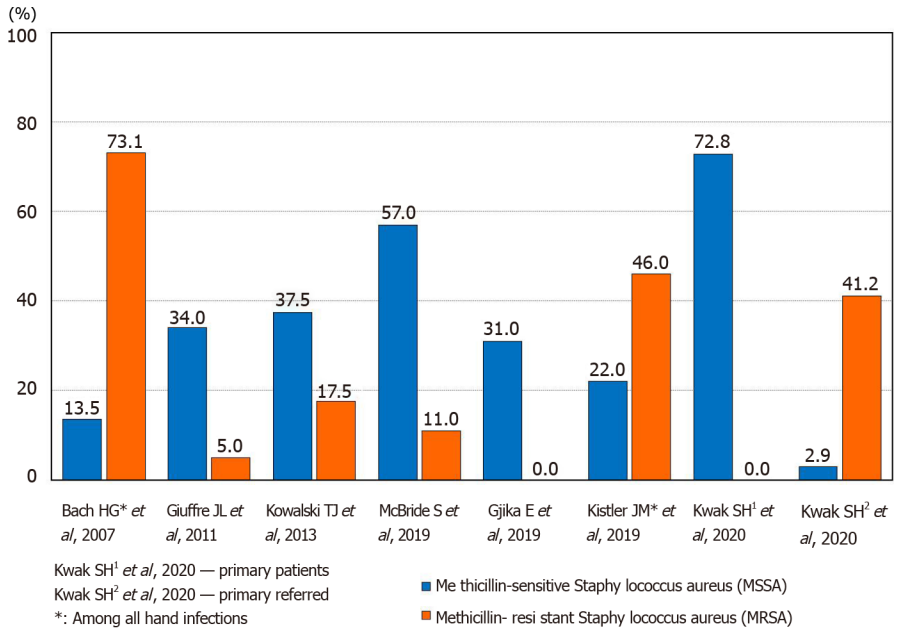

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Figure 1 The frequency of isolated microorganisms of Methicillin-sensitive Staphylococcus aureus and methicillin-resistant staphylococcus aureus.

developed for purulent arthritis of large joints. One of the most successful for clinical use is the classification by Tan *et al*[31] (1998), which includes a number of important parameters:

Joint name

Anatomic type: I: Periarticular soft-tissue infection without pyarthrosis; II: Isolated septic arthritis; III: Septic arthritis with soft-tissue extension, but no osteomyelitis; IV: Septic arthritis with contiguous osteomyelitis.

Host class: A: Normal immune system; B: Compromised system, B_L: Local tissue compromise, B_S: Systemic immune compromise; C: Risk associated with aggressive treatment unwarranted.

Clinical setting

(1) Less than 5 d of symptoms and nonvirulent organism; and (2) Symptoms for 5 d or more, or a virulent organism.

Clinical stage for the septic joint

Anatomic type + host class + clinical setting = stage.

DIAGNOSTICS

The diagnosis of septic arthritis of the hand is based on a set of clinical, instrumental and laboratory research methods. Among the clinical manifestations, there are symptoms such as pain, swelling, skin hyperemia, dysfunction of the joint, and signs of fluid accumulation in the joint cavity[13]. The severity of clinical symptoms may differ significantly depending on the acute or chronic course of the disease. A number of authors, extrapolating the data used in the classification of periprosthetic infections of large joints, highlight the acute or chronic course of arthritis of the hand. The acute course is associated with a duration of symptoms of < 3 wk with a hematogenous route of infection or < 4 wk with an exogenous source. In a chronic course, symptoms persist for ≥ 3 wk with a hematogenous route of infection of the joint or ≥ 4 wk with a nonhematogenous route[32].

Instrumental diagnostics may include radiography, ultrasound, computed tomography (CT) and magnetic resonance tomography (MRI). X-ray data are usually uninformative in the early stages, which can lead to diagnostic errors[1,3]. Less than 5% of acute cases of osteomyelitis of the hand are recognized on radiographs[33]. Signs characteristic of osteomyelitis, such as osteolysis (70%), osteopenia (10%), osteosclerosis (10%), periosteal reaction (10%), and sequestration (5%), appear on radiographs 2-3 wk after the onset of the disease[8]. Technetium-, gallium-, and indium-labeled white blood cell scans are helpful in identifying acute osteomyelitis before the aforementioned changes can be detected on

plain radiographs[33]. Ultrasound examination makes it possible to detect intra-articular effusion, and is also useful for pointing the needle when puncturing small joints of the hand[5,34,35]. MRI is a useful diagnostic tool to visualize joint effusion, its distribution, and the destruction of soft tissues and osteochondral structures of the joint. However, MRI is expensive and usually accompanied by a significant time delay and therefore can only be used in an acute situation to a limited extent[36,37]. CT makes it possible to examine bone structures in more detail than MRI, losing the visualization of soft tissues[5,38]. Both methods are necessary in the chronic course of the inflammatory process[39]. Laboratory diagnostics consisted of conducting a microbiological and cytological study of the articular effusion. Identification of the pathogen and determination of its sensitivity to antibiotics makes it possible to conduct effective antibiotic therapy[2,10,40].

TREATMENT

Recommendations for the treatment of patients with septic arthritis of the small joints of the hand are based on data from retrospective studies and expert opinion. The choice of sanitation method depends on the nature and severity of pathological changes and may include: repeated punctures, arthroscopic drainage and open sanitation[13,41]. Puncture treatment is effective only at the earliest stages of the disease, and arthroscopic sanitation of small joints of the hand is very difficult, so open sanitation of the joint is the most frequently performed surgical intervention[4,42]. In the absence of osteochondral destruction, the concept of continuous catheter irrigation, described by Wright[43] (1943) in the treatment of tendon sheath infections. Timely continuous irrigation of the joint cavity made it possible to prevent the destruction of cartilaginous tissue that accompanies septic arthritis. The authors noted such obligatory moments during irrigation as: axial traction along with passive flexion and extension of the joint[42]. The catheter was removed after the disappearance of edema and other clinical manifestations of inflammation, usually after 2-5 d. The start of rehabilitation was critical to joint function. Another treatment option has also been described: After surgical debridement, a collagen sponge with gentamicin was installed in the joint, and immobilization was performed for a period of 4 wk[44,45].

If signs of infection persist, a second operation is recommended within 24-48 h after the first operation[4,5,12]. There is only fragmentary information regarding the frequency of reoperations for septic arthritis of the hand. A number of authors report that in most cases (up to 80%) patients underwent 2 or more surgical interventions. The most common of these was surgical debridement[2,16,44]. Often, this was associated with suppuration of the paraarticular soft tissues and destruction of the flexor and extensor tendons of the finger[46]. Progression of the infection, despite surgical debridement and antibiotic therapy, may require amputation[1]. Along with this, data on the treatment of septic arthritis of the hand in two hospitals in Switzerland were published, where the number of surgical interventions in 1 patient was 1. At the same time, the average delay in surgical treatment from the onset of the disease was no more than 2-3 d[47].

In cases of detection of destruction of the articular cartilage and osteomyelitis, arthrodesis is recommended to prevent the formation of painful arthrosis or contracture in a functionally disadvantageous position[6,48]. Most of the experts prefer primary arthrodesis of the interphalangeal joints, while others favor secondary arthrodesis 4−6 wk after the primary revision with immobilization with an external fixator and the introduction of a cement spacer with gentamicin[4,13,16,45]. Single reports concern the possibility of using the Masquelet technique in the treatment of septic arthritis of the interphalangeal joints[38,49]. However, given the risk of purulent complications and rejection of the bone autograft, the expediency of such an operation may be questionable.

The course of septic arthritis of the hand in patients with diabetes mellitus is especially severe[9,50]. Published data indicate that the need for arthrodesis increased by 1.7 times. The risk of finger amputation increased even more, by 2.1 times[13]. Stiffness of the interphalangeal joints after purulent arthritis in patients with diabetes mellitus developed in more than 50% of cases, despite early activation and manual therapy started 24 h after surgery[13].

Antibacterial therapy, along with surgical treatment, is an essential component in purulent arthritis of the hand. Taking into account the data obtained in the study of the microbial landscape of purulent arthritis, the main antibacterial drugs used in their treatment are: amoxicillin/clavulanate, clindamycin, levofloxacin, vancomycin, cefazolin, and ceftriaxone[51,52]. Correction of empirical antibiotic therapy is carried out taking into account the results of microbiological studies. Based on an extensive systematic review evaluating the role of antimicrobials in the treatment of bone and joint infections, it was concluded that there is no evidence that any drug is superior to others[53]. However, if the nature of antibiotic therapy in general does not cause controversy among researchers, then its duration remains the subject of numerous discussions. A frequently encountered opinion of experts indicates the need for a course of antibiotic therapy for septic arthritis of the hand lasting approximately 1 mo[16]. As a rule, both the initial parenteral and subsequent oral routes of drug administration are included here[54]. On the other hand, Gjika *et al*[18] (2019) conducted a prospective randomized study (154 cases), which compared the effectiveness of 2 and 4 wk of antibiotic therapy after surgical treatment of septic arthritis of the hand in adults. The conclusion made proved the absence of any advantages of a 4-wk course over

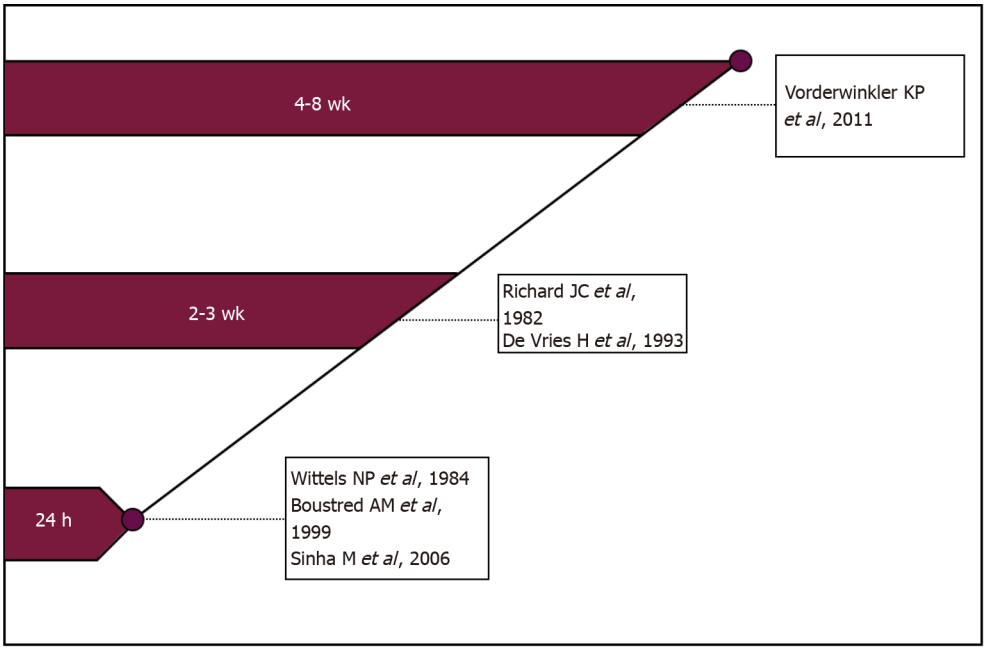

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Figure 2 Review of beginning postoperative mobilisation of patients with the hand or wrist septic arthritis.

a 2-wk course. According to Kowalski *et al*[7] (2014) found that the combination of surgical treatment of a purulent focus with parenteral (less than 1 wk) and subsequent oral (2-3 wk) administration of antibacterial drugs is optimal. To date, a combined scheme (parenterally and then orally) for the administration of antibacterial drugs in the treatment of septic arthritis of the hand is optimal, since it is designed for both inpatient and outpatient treatment of patients[18,54].

REHABILITATION

It is known that one of the negative consequences of septic arthritis of the hand is stiffness of the joints [16]. In this regard, the question of the timing of the start of rehabilitation of patients who underwent surgery for septic arthritis of the metacarpophalangeal or interphalangeal joint remains important and controversial[5,7,42]. The duration of postoperative immobilization depends on the presence of articular cartilage destruction and is the subject of numerous discussions. The concept of supporters of early rehabilitation is that it contributes to the restoration of range of motion after inflammation. It is believed that "ideal" rehabilitation should begin 24 h after surgery[10]. Along with these, there is an opinion that it is advisable to apply a splint for several days or external fixation devices for 2-4 wk[4,44] (Figure 2).

The most important component in evaluating the results of treatment of septic arthritis of the hand is not only the elimination of the infection but also the restoration of the function of the affected joint, as well as the hand as a whole. Among the currently existing questionnaires and scales, Disabilities of the Arm, Shoulder, and Hand (DASH) and total active motion (TAM) are the most widely used in assessing hand function. Originally published in 1996 in the American Journal of Industrial Medicine, the DASH was a collaborative initiative between the American Academy of Orthopedic Surgeons, the Council of Musculoskeletal Specialty Societies, and the Institute for Work and Health. This outcome measure was designed to be a standardized assessment of the impact on function of a variety of musculoskeletal diseases and injuries in the upper extremities. The DASH is a 30-item self-report questionnaire in which the response options are presented on 5-point Likert scales. Scores range from 0 (no disability) to 100 (most severe disability). This score was designed to be useful in patients with any musculoskeletal disorder of the upper limb[55]. However, this questionnaire is characterized by a significant degree of subjectivity and reflects the function of the hand as a whole to a greater extent than a specific joint or finger.

TAM is described by the American Society for Surgery of the Hand as the sum of active MCP, PIP and DIP arc of motion in degrees of an individual digit. This calculation can then be compared to the TAM of the contralateral hand[56]. The TAM scale is objective and with high accuracy makes it possible to assess the degree of dysfunction of a particular finger. Complementing each other, DASH and TAM make it possible to obtain maximum information characterizing the functional result of the treatment of septic arthritis.

CONCLUSION

Thus, septic arthritis of the hand is a serious disease that can lead to the destruction of articular cartilage and the development of osteomyelitis, which, in turn, leads to loss of joint function or even the need for amputation of the finger. Even isolated septic arthritis is often accompanied by joint stiffness, which negatively affects the function of the hand as a whole. In the treatment of this disease, timely surgical treatment is of decisive importance, which, along with antibacterial therapy and a complex of rehabilitation measures, makes it possible to achieve a positive result.

FOOTNOTES

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ORIGINAL ARTICLE

Retrospective Cohort Study

Outcomes after arthroscopic repair of rotator cuff tears in the setting of mild to moderate glenohumeral osteoarthritis

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Abstract

BACKGROUND

Rotator cuff pathology is a very common source of shoulder pain. Similarly, osteoarthritis of the glenohumeral joint can cause shoulder pain and produce similar symptoms. Surgical management can be indicated for both pathologies, however, outcomes data is limited when examining rotator cuff repair (RCR) in the setting of glenohumeral arthritis (GHOA). Thus, this study sought to determine outcomes for patients who undergo RCR in the setting of GHOA.

AIM

To evaluate if a relationship exists between outcomes of RCR in the setting of GHOA.

METHODS

This was a retrospective analysis of patients who underwent arthroscopic rotator cuff repair with concurrent glenohumeral osteoarthritis between 2010-2017.

Patients were stratified based on rotator cuff tear size and glenohumeral osteoarthritis severity. Cohorts were paired 1:1 with patients without glenohumeral osteoarthritis. Patients included had a minimum two year follow-up. Rate of conversion to total shoulder arthroplasty, complication rates following initial surgery, and patient-reported outcome measures were collected.

RESULTS

A total of 142 patients were included. The number of patients that required total shoulder arthroplasty within two years after index surgery was low. 2/71 (2.8%) patients with GHOA, and 1/71 (1.4%) without GHOA. Following rotator cuff repair, both groups showed favorable patient-reported outcomes.

CONCLUSION

Patients with glenohumeral osteoarthritis who underwent arthroscopic rotator cuff repair showed comparable outcomes to patients without glenohumeral osteoarthritis.

Key Words: Rotator cuff repair; Rotator cuff tear; Glenohumeral osteoarthritis; Shoulder; Arthroscopic; Outcomes

Core Tip: We evaluated a cohort of patients with mild to moderate glenohumeral arthritis who underwent rotator cuff repair. We retrospectively reviewed 71 patients with glenohumeral osteoarthritis (GHOA) (Glenohumeral Arthritis) who underwent concomitant rotator cuff repair, and matched these patients to 71 patients who underwent rotator cuff repair without GHOA. We evaluated patient reported outcomes and demographic information for both cohorts.

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INTRODUCTION

Rotator cuff pathology is a common source of shoulder pain. A significant proportion of individuals have rotator cuff tears with increasing age and can become disabled[1-3]. In older patients, onset of new symptoms correlate to the progression of rotator cuff tear size and increasing morbidity[3].

Like rotator cuff pathology, glenohumeral osteoarthritis (GHOA) is related to advancing age and is estimated to affect 16%-20% of adults over age 65[4,5]. It can be debilitating and a source of shoulder dysfunction, pain, and loss of motion[6,7].

Although rotator cuff pathology and GHOA are two prevalent shoulder pathologies, there are limited studies evaluating the relationship of GHOA to outcomes after rotator cuff repair (RCR)[8-11]. Cases of severe GHOA accompanied by rotator cuff pathology are most appropriately managed with either reverse total shoulder arthroplasty (RTSA) or total SA (TSA) with RCR. However, a recent study by Jeong *et al*[8] suggests that patients with mild GHOA and repair of large rotator cuff tears fare similarly to their counterparts without GHOA in terms of clinical outcomes and progression to GHOA. In contrast, another study found that GHOA was associated with lower outcome scores after RCR at 1-year follow-up[10].

Studies have shown that patients with concomitant GHOA and rotator cuff tears can range from 13%-27% of patients treated for rotator cuff tears; to our knowledge, the outcomes of these patients after RCR are lacking within literature[12,13]. This study evaluated the effect of the presence or absence of GHOA on short and mid-term clinical outcomes after arthroscopic repair of small to large rotator cuff tears, comparing the rates of conversion to shoulder arthroplasty (TSA or RTSA) as well as PROM's at follow-up > 2 years from their RCR surgery. We hypothesized there would be no significant differences in clinical outcomes or rates of subsequent conversion to shoulder arthroplasty in patients with small to large rotator cuff tears undergoing arthroscopic repair with or without concurrent GHOA.

MATERIALS AND METHODS

Following International Review Board approval, patients who underwent arthroscopic RCR of small (< 1 cm), medium (1-3 cm), or large (3-5 cm) rotator cuff tears with GHOA were identified at a large single-center academic orthopedic group. All patients treated between January 2010 and June 2017 were identified using Current Procedural Terminology code 29827 for "arthroscopy, shoulder, surgical, with rotator cuff repair." Patients with GHOA were initially identified and paired with patients without GHOA. The three criteria for matching the patients involved: Age ± 3 years, clinical follow-up ± 1 year, and same sex (Figure 1A).

Inclusion criteria consisted of patients who: (1) Were 18 years old at the time of index surgery; (2) Had a rotator cuff tear measuring 0-5 cm; (3) Had a preoperative plain radiograph; (4) Had a preoperative magnetic resonance imaging (MRI); and (5) Had a minimum of 2 year follow-up after their index RCR procedure. Patients were excluded if they had any of the following: (1) Open physes; (2) Post-traumatic osteoarthritis; (3) Post-dislocation glenohumeral arthropathy; (4) Avascular necrosis; (5) Prior surgical intervention on the ipsilateral shoulder; and/or (6) Autoimmune conditions such as rheumatoid arthritis. The data was collected and stored using REDCap electronic data capture tools hosted at OrthoCarolina Research Institute[4].

The primary outcome variable was the rate of conversion to TSA or RTSA within 2 years from the index surgery. Secondary outcomes were clinical patient-reported outcome measures (PROs) including American Shoulder and Elbow Surgeons (ASES) score, Single Assessment Numeric Evaluation (SANE), VAS for pain, and Veterans RAND 12-Item Health Survey (VR-12).

Demographical information such as age, sex, body mass index (BMI), smoking history, diabetes, and injury mechanism (ultra-low *vs* low *vs* high energy) where applicable was obtained. Using preoperative plain radiographs and MRI, the Samilson-Priesto Classification (Figure 2**)**, Goutallier classification, and Warner atrophy grade were obtained to assess GHOA severity, fatty degeneration of rotator cuff muscles, and muscle atrophy, respectively. Each patient was classified based on the presence of GHOA in the setting of a small, medium, or large rotator cuff tear (Figure 3**)**. The different rotator cuff tear sizes, largely based on level of retraction, were determined by two independent fellowship trained sports medicine and shoulder orthopedic surgeons using MRI imaging. Coronal oblique images were obtained and used to identify the tears, and were classified as either small (< 1 cm) medium (1-3 cm) and massive (< 5 cm).

The procedural variables captured using operative notes included: surgical technique, fixation technique, and concomitant procedures (*e.g.*, distal clavicle excision, subacromial decompression, capsular release, debridement, chondroplasty, biceps tenotomy, and/or biceps tenodesis). Postoperative variables were measured: complications, re-operation (s) and the type of secondary procedure. PROs following surgery were collected during routine clinical follow-up at 2 or more years. Patients without the standard of care 2-year follow-up were contacted *via* phone or email to answer questions regarding PROs, subsequent rotator cuff re-tear, or re-operation outside of our institution.

Statistical analysis

All data underwent descriptive statistical analysis using SAS version 9.4 (SAS Institute, Cary, NC; http://www.sas.com/software/sas9). Two groups were defined based on presence or absence of primary GHOA and stratified based on rotator cuff tear size. For normally distributed continuous data, mean and standard deviation, were reported. For non-parametric continuous data, median and interquartile range were reported. Frequencies and proportions were reported for categorical variables. A Wilcoxon rank sum test was used for non-parametric continuous variables and a two-sample t test was used for normally distributed data. For categorical variables, a chi-square test (or Fisher's exact test, where appropriate) was used for comparisons between groups. Significance was determined by an alpha level of 0.05.

RESULTS

Between January 2010 and June 2017, 71 patients were identified that underwent arthroscopic RCR of small to large tears with the presence of GHOA. These patients were subsequently matched with 71 patients without GHOA that underwent the same procedure.

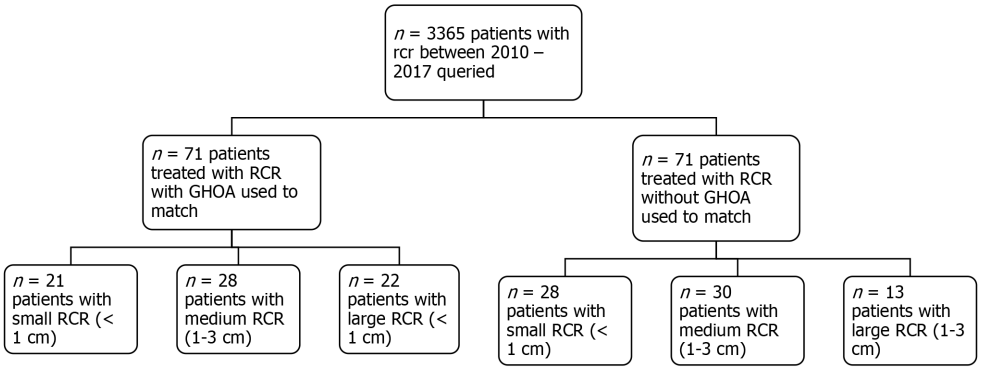
The demographics of the comparison study groups can be found in Table 1. The median age at time of rotator cuff repair was 64 years (IQR 60, 70) for patients in both groups. They had an exact match by sex and 57.7% (41/71) of repairs were performed in males in each respective group. Median BMI at the time of repair was 29.8 (IQR 26.7, 33.2) and 28.5 (IQR 25.5, 31) respectively. In patients with GHOA, 57.7% (41/71) reported having never smoked tobacco products, 40.8% (29/71) have smoked previously and 1.4% (1/71) were actively smoking. In patients without GHOA, 60.6% (43/71) reported having never smoked tobacco products, 33.8% (24/71) have smoked previously and 5.6% (4/71) were actively smoking.

Table 1 Demographic information

		With GHOA				Without GHOA			
		Tear size group				Tear size group			
	Overall (*n* = 142)	Case overall (*n* = 71)	Small (0-1 cm) (*n* = 21)	Medium (1-3 cm) (*n* = 28)	Large (3-5 cm) (*n* = 22)	Control overall (*n* = 71)	Small (0-1 cm) (*n* = 28)	Medium (1-3 cm) (*n* = 30)	Large (3-5 cm) (*n* = 13)
Age (in yr) at surgery, median (IQR)	64 (60, 70)	64 (60, 70)	63 (62, 67)	63 (58, 67.5)	66 (62, 71)	64 (60, 70)	63 (59.5, 68.5)	65 (61, 70)	63 (61, 69)
BMI, median (IQR)	29.2 (25.8, 32.9)	29.8 (26.7, 33.2)	32.9 (29.4, 35.9)	28.1 (24.5, 30.8)	29 (27.3, 33.2)	28.5 (25.5, 31)	29.9 (27, 31)	27.2 (24.5, 30.4)	27.5 (24.7, 32.1)
Time (in yr) since DOS, median (IQR)	8.1 (6.9, 9.3)	8.2 (6.9, 9.3)	8 (7.1, 9.4)	8 (6.4, 9.3)	8.3 (7.1, 8.9)	8.1 (6.8, 9.3)	8.3 (6.8, 9.6)	8 (7.5, 8.8)	7.8 (6.9, 9.3)
Tear size, median (IQR)	2 (1, 3)	2 (1, 3.5)	1 (1, 1)	2 (1.7, 2.6)	4 (3.5, 4)	1.5 (1, 2.5)	.5 (.5, 1)	2 (1.5, 2.5)	4 (3.7, 4.3)
Male	82 (57.7)	41 (57.7)	10 (47.6)	13 (46.4)	18 (81.8)	41 (57.7)	13 (46.4)	19 (63.3)	9 (69.2)
Sex, *n* (%)									
Female	60 (42.3)	30 (42.3)	11 (52.4)	15 (53.6)	4 (18.2)	30 (42.3)	15 (53.6)	11 (36.7)	4 (30.8)
Smoking, *n* (%)									
Never	84 (59.2)	41 (57.7)	16 (76.2)	14 (50.0)	11 (50.0)	43 (60.6)	19 (67.9)	19 (63.3)	5 (38.5)
Previous	53 (37.3)	29 (40.8)	5 (23.8)	13 (46.4)	11 (50.0)	24 (33.8)	7 (25.0)	10 (33.3)	7 (53.8)
Current	5 (3.5)	1 (1.4)	0 (0)	1 (3.6)	0 (0)	4 (5.6)	2 (7.1)	1 (3.3)	1 (7.7)
Diabetes, *n* (%)									
No	115 (81.0)	57 (80.3)	18 (85.7)	24 (85.7)	15 (68.2)	58 (81.7)	22 (78.6)	27 (90.0)	9 (69.2)
Yes	27 (19.0)	14 (19.7)	3 (14.3)	4 (14.3)	7 (31.8)	13 (18.3)	6 (21.4)	3 (10.0)	4 (30.8)
Preoperative samilson-prieto score, *n* (%)									
None	71 (50.0)	1 (1.4)	0 (0)	1 (3.6)	0 (0)	70 (98.6)	28 (100.0)	29 (96.7)	13 (100.0)
Mild (< 3 mm)	62 (43.7)	61 (85.9)	18 (85.7)	27 (96.4)	16 (72.7)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Moderate (3 mm-7 mm)	9 (6.3)	9 (12.7)	3 (14.3)	0 (0)	6 (27.3)	0 (0)	0 (0)	0 (0)	0 (0)
Goutallier classification, *n* (%)									
Grade 0 (normal muscle)	95 (66.9)	47 (66.2)	18 (85.7)	19 (67.9)	10 (45.5)	48 (67.6)	23 (82.1)	20 (66.7)	5 (38.5)
Grade 1 (some fattys-treaks)	36 (25.4)	18 (25.4)	2 (9.5)	7 (25.0)	9 (40.9)	18 (25.4)	5 (17.9)	8 (26.7)	5 (38.5)
Grade 2 (< 50% fattymuscle atrophy)	11 (7.7)	6 (8.5)	1 (4.8)	2 (7.1)	3 (13.6)	5 (7.0)	0 (0)	2 (6.7)	3 (23.1)
Muscle atrophy (warner grading system), *n* (%)									0 (0)
None	107 (75.4)	50 (70.4)	18 (85.7)	21 (75.0)	11 (50.0)	57 (80.3)	24 (85.7)	24 (80.0)	9 (69.2)
Mild	29 (20.4)	17 (23.9)	2 (9.5)	5 (17.9)	10 (45.5)	12 (16.9)	4 (14.3)	5 (16.7)	3 (23.1)
Moderate	6 (4.2)	4 (5.6)	1 (4.8)	2 (7.1)	1 (4.5)	2 (2.8)	0 (0)	1 (3.3)	1 (7.7)
Primary GHOA, *n* (%)									
No	71 (50.0)	0 (0)	0 (0)	0 (0)	0 (0)	71 (100.0)	28 (100.0)	30 (100.0)	13 (100.0)
Yes	71 (50.0)	71 (100.0)	21 (100.0)	28 (100.0)	22 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)

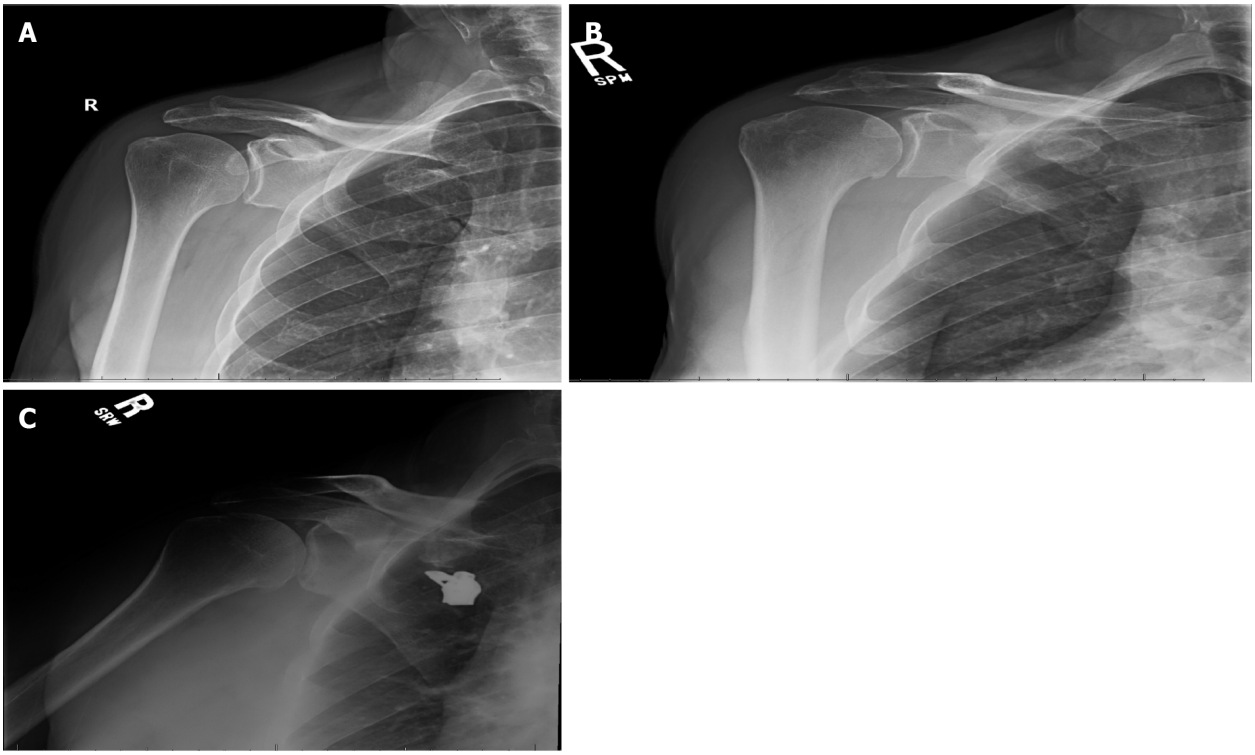
GHOA: Glenohumeral osteoarthritis; BMI: Body mass index; DOS: Date of surgery.

Using the Samilson-Prieto classification to grade GHOA severity, 85.9% (61/71) had a grade of 1 (mild or < 3 mm), and 12.7% (9/71) had a grade of 2 (moderate or 3 mm - 7 mm). Goutallier classification of the rotator cuff revealed that patients with GHOA: 66.2% (47/71) had a grade of 0 (normal muscle), 25.4% (18/71) had a grade of 1 (some fatty streaks), and 8.5% (6/71) had a grade of 2 (less than



DOI: 10.5312/wjo.v13.i7.631

Figure 1 CONSORT flow diagram of patients included in study. RCR: Rotator cuff repair; GHOA: Glenohumeral osteoarthritis.



DOI: 10.5312/wjo.v13.i7.631

Figure 2 Anteroposterior radiograph. A: Anteroposterior radiograph of right shoulder demonstrating Samilson-Prieto grade 0 (normal); B: Anteroposterior radiograph of right shoulder demonstrating Samilson-Prieto grade 1 (mild); C: Anteroposterior radiograph of right shoulder demonstating Samilson-Prieto grade 2 (moderate).

50% fatty muscle atrophy). In comparison, the Goutallier classification of the rotator cuff for patients without GHOA revealed: 67.6% (48/71) with grade of 0, 25.4% (18/71) with a grade of 1, and 7.0% (5/71) with a grade of 2. Finally, in patients with GHOA the Warner grading system for muscle atrophy revealed: 70.4% (50/71) with no atrophy, 23.9% (17/71) with mild atrophy, and 5.6% (4/71) with moderate atrophy. For patients without GHOA, the Warner grading system for muscle atrophy revealed: 80.3% (57/71) with no atrophy, 16.9% (12/71) with mild atrophy, and 2.8% (2/71) with moderate atrophy.

Detailed data regarding RCR surgical technique, type of anchors used, fixation method and concurrent procedures for patients with or without GHOA stratified by rotator cuff tear size can be found in Table 2.

The re-operation rate was 15.5% (11/71) and 8.5% (6/71) in patients with GHOA and without GHOA respectively. The mean follow-up period for both groups was 12.45 mo, with a range from 0-104 mo for the GHOA group, and 0-94 mo for the patients without GHOA. Within two years after rotator cuff repair, 2.8% (2/71) patients with GHOA underwent TSA or RTSA in the ipsilateral shoulder compared to 1.4% (1/71) patients without GHOA. Both patients developed rotator cuff arthropathy and pain with range of motion, and eventually underwent RTSA. The non GHOA patient eventually underwent an

Table 2 Operative data and type of operation

	With GHOA				Without GHOA			
		Tear size group				Tear size group		
	Overall (*n* = 142)	Overall Case (*n* = 71)	Small (0-1 cm) (*n* = 21)	Medium (1-3 cm) (*n* = 28)	Large (3-5 cm) (*n* = 22)	Overall Control (*n* = 71)	Small (0-1 cm) (*n* = 28)	Medium (1-3 cm) (*n* = 30)	Large (3-5 cm) (*n* = 13)
Single row, *n* (%)									
No	124 (87.3)	60 (84.5)	16 (76.2)	24 (85.7)	20 (90.9)	64 (90.1)	26 (92.9)	26 (86.7)	12 (92.3)
Yes	18 (12.7)	11 (15.5)	5 (23.8)	4 (14.3)	2 (9.1)	7 (9.9)	2 (7.1)	4 (13.3)	1 (7.7)
Double row, *n* (%)									
Yes	122 (85.9)	60 (84.5)	17 (81.0)	23 (82.1)	20 (90.9)	62 (87.3)	24 (85.7)	26 (86.7)	12 (92.3)
No	20 (14.1)	11 (15.5)	4 (19.0)	5 (17.9)	2 (9.1)	9 (12.7)	4 (14.3)	4 (13.3)	1 (7.7)
Medial row, *n* (%)									
Yes	138 (97.2)	69 (97.2)	19 (90.5)	28 (100.0)	22 (100.0)	69 (97.2)	28 (100.0)	28 (93.3)	13 (100.0)
No	4 (2.8)	2 (2.8)	2 (9.5)	0 (0)	0 (0)	2 (2.8)	0 (0)	2 (6.7)	0 (0)
Lateral row, *n* (%)									
Yes	120 (84.5)	61 (85.9)	18 (85.7)	23 (82.1)	20 (90.9)	59 (83.1)	24 (85.7)	24 (80.0)	11 (84.6)
No	22 (15.5)	10 (14.1)	3 (14.3)	5 (17.9)	2 (9.1)	12 (16.9)	4 (14.3)	6 (20.0)	2 (15.4)
Arthrotunneler, *n* (%)									
No	139 (97.9)	71 (100.0)	21 (100.0)	28 (100.0)	22 (100.0)	71 (100.0)	28 (100.0)	28 (93.3)	12 (92.3)
Yes	3 (2.1)		0 (0)	0 (0)	0 (0)		0 (0)	2 (6.7)	1 (7.7)
Medial row fixation type, *n* (%)									
Missing for 6 patients									
Suture tied	135 (95.1)	67 (94.4)	19 (90.5)	26 (92.9)	22 (100.0)	68 (95.8)	28 (100.0)	28 (93.3)	12 (92.3)
Knotless	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
Medial row anchor type, *n* (%)									
Missing for 11 patients									
PEEK	86 (60.6)	53 (74.6)	16 (76.2)	21 (75.0)	16 (72.7)	33 (46.5)	16 (57.1)	12 (40.0)	5 (38.5)
Knotted	35 (24.6)	10 (14.1)	2 (9.5)	5 (17.9)	3 (13.6)	25 (35.2)	10 (35.7)	11 (36.7)	4 (30.8)
Knotless	7 (4.9)	0 (0)	0 (0)	0 (0)	0 (0)	7 (9.9)	1 (3.6)	5 (16.7)	1 (7.7)
Plastic	3 (2.1)	3 (4.2)	1 (4.8)	0 (0)	2 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)
Lateral row fixation type, *n* (%)									
Missing for 23 patients									
Knotless	90 (63.4)	46 (64.8)	13 (61.9)	16 (57.1)	17 (77.3)	44 (62.0)	20 (71.4)	18 (60.0)	6 (46.2)
Suture tied	29 (20.4)	15 (21.1)	5 (23.8)	7 (25.0)	3 (13.6)	14 (19.7)	4 (14.3)	6 (20.0)	4 (30.8)
Lateral row anchor type, n (%)									
Missing for 29 patients									
PEEK	70 (49.3)	28 (39.4)	12 (57.1)	8 (28.6)	8 (36.4)	42 (59.2)	21 (75.0)	15 (50.0)	6 (46.2)
Plastic	20 (14.1)	20 (28.2)	3 (14.3)	8 (28.6)	9 (40.9)	0 (0)	0 (0)	0 (0)	0 (0)
Knotted	17 (12.0)	6 (8.5)	1 (4.8)	4 (14.3)	1 (4.5)	11 (15.5)	3 (10.7)	4 (13.3)	4 (30.8)

Knotless	6 (4.2)	3 (4.2)	1 (4.8)	1 (3.6)	1 (4.5)	3 (4.2)	0 (0)	3 (10.0)	0 (0)
Concurrent procedures									
Distal clavicle excision, *n* (%)									
Yes	79 (55.6)	41 (57.7)	15 (71.4)	16 (57.1)	10 (45.5)	38 (53.5)	16 (57.1)	17 (56.7)	5 (38.5)
No	63 (44.4)	30 (42.3)	6 (28.6)	12 (42.9)	12 (54.5)	33 (46.5)	12 (42.9)	13 (43.3)	8 (61.5)
Subacromial decompression, *n* (%)									
Yes	142 (100.0)	71 (100.0)	21 (100.0)	28 (100.0)	22 (100.0)	71 (100.0)	28 (100.0)	30 (100.0)	13 (100.0)
Capsular release, *n* (%)									
No	133 (93.7)	66 (93.0)	20 (95.2)	25 (89.3)	21 (95.5)	67 (94.4)	26 (92.9)	30 (100.0)	11 (84.6)
Yes	9 (6.3)	5 (7.0)	1 (4.8)	3 (10.7)	1 (4.5)	4 (5.6)	2 (7.1)	0 (0)	2 (15.4)
Labral debridement, *n* (%)									
No	125 (88.0)	63 (88.7)	20 (95.2)	24 (85.7)	19 (86.4)	62 (87.3)	24 (85.7)	26 (86.7)	12 (92.3)
Yes	17 (12.0)	8 (11.3)	1 (4.8)	4 (14.3)	3 (13.6)	9 (12.7)	4 (14.3)	4 (13.3)	1 (7.7)
Chondroplasty, *n* (%)									
No	120 (84.5)	54 (76.1)	14 (66.7)	20 (71.4)	20 (90.9)	66 (93.0)	25 (89.3)	28 (93.3)	13 (100.0)
Yes	22 (15.5)	17 (23.9)	7 (33.3)	8 (28.6)	2 (9.1)	5 (7.0)	3 (10.7)	2 (6.7)	0 (0)
Biceps tenotomy, *n* (%)									
No	92 (64.8)	44 (62.0)	11 (52.4)	20 (71.4)	13 (59.1)	48 (67.6)	18 (64.3)	23 (76.7)	7 (53.8)
Yes	50 (35.2)	27 (38.0)	10 (47.6)	8 (28.6)	9 (40.9)	23 (32.4)	10 (35.7)	7 (23.3)	6 (46.2)
Biceps tenodesis, *n* (%)									
No	99 (69.7)	54 (76.1)	20 (95.2)	19 (67.9)	15 (68.2)	45 (63.4)	18 (64.3)	17 (56.7)	10 (76.9)
Yes	43 (30.3)	17 (23.9)	1 (4.8)	9 (32.1)	7 (31.8)	26 (36.6)	10 (35.7)	13 (43.3)	3 (23.1)
If biceps tenodesis, *n* (%)									
Suprapectoral	37 (26.1)	11 (15.5)	0 (0)	5 (17.9)	6 (27.3)	26 (36.6)	10 (35.7)	13 (43.3)	3 (23.1)
Subpectoral	6 (4.2)	6 (8.5)	1 (4.8)	4 (14.3)	1 (4.5)	0 (0)	0 (0)	0 (0)	0 (0)

GHOA: Glenohumeral osteoarthritis; PEEK: Polyether ether ketone.

RTSA for rotator cuff arthropathy. Beyond the two year follow-up 4 patients with GHOA and 2 patients without GHOA underwent the conversion to TSA or RTSA. Complication rates after initial rotator cuff repair was 23.9% (17/71) and 18.3% (13/71) for patients with GHOA and without GHOA respectively and 12.7% (9/71) of patients with GHOA experienced rotator cuff re-tear after RCR compared to 11.3% (8/71) of patients without GHOA as determined by post op MRI or intra-operative findings (Table 3).

The Median VR-12 mental health component summary scores were 58.3 (IQR 44.8, 61.3) and 56.5 (IQR 47.5, 61.7) and the median VR-12 physical health component summary scores were 49.6 (IQR 40.2, 52.4) and 47.6 (IQR 36.6, 53.7) in patients with and without GHOA respectively. The overall median ASES score for the right shoulder was 98.3 (IQR 93.3, 100) in patients with or without GHOA; overall median ASES score for the left shoulders were 100 (IQR 91.7, 100) and 96.7 (86.7, 100) respectively. Finally, the overall median SANE score was 95 (IQR 90, 100) and 95 (IQR 85, 100) in patients with or without GHOA respectively. PROs did not show any significant difference according to rotator cuff tear size when patients with GHOA were compared with patients without GHOA (Table 4).

Table 3 Postoperative complications

	With GHOA					Without GHOA			
		Tear size group				Tear size group			
	Overall (*n* = 142)	Case Overall (*n* = 71)	Small (0-1cm) (*n* = 21)	Medium (1-3cm) (*n* = 28)	Large (3-5cm) (*n* = 22)	Control Overall (*n* = 71)	Small (0-1cm) (*n* = 28)	Medium (1-3cm) (*n* = 30)	Large (3-5cm) (*n* = 13)
Reoperation post RCR, *n* (%)									
No	125 (88.0)	60 (84.5)	19 (90.5)	23 (82.1)	18 (81.8)	65 (91.5)	26 (92.9)	28 (93.3)	11 (84.6)
Yes	17 (12.0)	11 (15.5)	2 (9.5)	5 (17.9)	4 (18.2)	6 (8.5)	2 (7.1)	2 (6.7)	2 (15.4)
Complications, *n* (%)									
Missing for 1 patient									
No	111 (78.2)	53 (74.6)	16 (76.2)	22 (78.6)	15 (68.2)	58 (81.7)	22 (78.6)	24 (80.0)	12 (92.3)
Yes	30 (21.1)	17 (23.9)	4 (19.0)	6 (21.4)	7 (31.8)	13 (18.3)	6 (21.4)	6 (20.0)	1 (7.7)
Wound issues, *n* (%)									
Missing for 131 patients									
No	11 (7.7)	9 (12.7)	2 (9.5)	3 (10.7)	4 (18.2)	2 (2.8)	0 (0)	2 (6.7)	0 (0)
Infection, *n* (%)									
Missing for 131 patients									
No	11 (7.7)	9 (12.7)	2 (9.5)	3 (10.7)	4 (18.2)	2 (2.8)	0 (0)	2 (6.7)	0 (0)
Stiffness, *n* (%)									
Missing for 126 patients									
Yes	8 (5.6)	5 (7.0)	3 (14.3)	1 (3.6)	1 (4.5)	3 (4.2)	1 (3.6)	2 (6.7)	0 (0)
No	8 (5.6)	7 (9.9)	0 (0)	3 (10.7)	4 (18.2)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Rotator cuff retear, *n* (%)									
Missing for 122 patients									
Yes	17 (12.0)	9 (12.7)	0 (0)	4 (14.3)	5 (22.7)	8 (11.3)	3 (10.7)	4 (13.3)	1 (7.7)
No	3 (2.1)	2 (2.8)	2 (9.5)	0 (0)	0 (0)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Other complication, *n* (%)									
Missing for 128 patients									
No	8 (5.6)	4 (5.6)	1 (4.8)	2 (7.1)	1 (4.5)	4 (5.6)	1 (3.6)	2 (6.7)	1 (7.7)
Yes	6 (4.2)	3 (4.2)	1 (4.8)	1 (3.6)	1 (4.5)	3 (4.2)	2 (7.1)	1 (3.3)	0 (0)
Other complication description, *n* (%)									
Pain	1 (0.7)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Block related neuropraxia	1 (0.7)	1 (1.4)	0 (0)	1 (3.6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Weakness	1 (0.7)	1 (1.4)	0 (0)	0 (0)	1 (4.5)	0 (0)	0 (0)	0 (0)	0 (0)
Median nerve neuropathy	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	1 (3.6)	0 (0)	0 (0)
Greater tuberosity fx	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	1 (3.6)	0 (0)	0 (0)
Heterotopic ossification	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
1st reoperation diagnosis, *n* (%)									
Other	13 (9.2)	9 (12.7)	2 (9.5)	4 (14.3)	3 (13.6)	4 (5.6)	1 (3.6)	1 (3.3)	2 (15.4)
Stiffness	3 (2.1)	2 (2.8)	0 (0)	1 (3.6)	1 (4.5)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Hardware pain	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	1 (3.6)	0 (0)	0 (0)
1st reoperation other diagnosis, *n*									

(%)									
Rotator cuff arthropathy	4 (2.8)	3 (4.2)	0 (0)	2 (7.1)	1 (4.5)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
Rotator cuff retear	4 (2.8)	3 (4.2)	0 (0)	2 (7.1)	1 (4.5)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Inflammatory arthritis	1 (0.7)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Glenohumeral arthritis	1 (0.7)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Retear RTC, rotator cuffarthropathy	1 (0.7)	1 (1.4)	0 (0)	0 (0)	1 (4.5)	0 (0)	0 (0)	0 (0)	0 (0)
Greater tuberosity fracture	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	1 (3.6)	0 (0)	0 (0)
Rotator cuff arthropathy	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
1st reoperation procedure, *n* (%)									
Conversion to RTSA	8 (5.6)	5 (7.0)	1 (4.8)	2 (7.1)	2 (9.1)	3 (4.2)	1 (3.6)	0 (0)	2 (15.4)
Other	6 (4.2)	3 (4.2)	0 (0)	2 (7.1)	1 (4.5)	3 (4.2)	1 (3.6)	2 (6.7)	0 (0)
Lysis of adhesions	2 (1.4)	2 (2.8)	0 (0)	1 (3.6)	1 (4.5)	0 (0)	0 (0)	0 (0)	0 (0)
Conversion to TSA	1 (0.7)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
1st reoperation other procedure, *n* (%)									
Revision rotator cuff repair	4 (2.8)	3 (4.2)	0 (0)	2 (7.1)	1 (4.5)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Removal of heterotopicossification	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	0 (0)	1 (3.3)	0 (0)
Removal of hardware, RTC debridement	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	1 (3.6)	0 (0)	0 (0)
2nd reoperation post RCR, *n* (%)									
Missing for 1 patient									
No	14 (9.9)	10 (14.1)	1 (4.8)	5 (17.9)	4 (18.2)	4 (5.6)	1 (3.6)	2 (6.7)	1 (7.7)
Yes	2 (1.4)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
2nd reoperation diagnosis, *n* (%)									
Other	2 (1.4)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
2nd reoperation other diagnosis, *n* (%)									
Insufficiency due to subscapularis failure	1 (0.7)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Instability	1 (0.7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
2nd reoperation procedure, *n* (%)									
Other	2 (1.4)	1 (1.4)	1 (4.8)	0 (0)	0 (0)	1 (1.4)	0 (0)	0 (0)	1 (7.7)
Conversion to TSA/RTSA within 2 yr post index DOS, *n* (%)									
No	139 (97.9)	69 (97.2)	20 (95.2)	28 (100.0)	21 (95.5)	70 (98.6)	28 (100.0)	30 (100.0)	12 (92.3)
Yes	3 (2.1)	2 (2.8)	1 (4.8)	0 (0)	1 (4.5)	1 (1.4)	0 (0)	0 (0)	1 (7.7)

GHOA: Glenohumeral osteoarthritis; RCR: Rotator cuff repair; RTSA: Reverse tota shoulder arthroplasty; TSA: Total shoulder arthroplasty.

DISCUSSION

The results demonstrate the conversion to shoulder arthroplasty, patient-reported clinical outcome scores, and rates of re-operation were no different when comparing RCR done in the setting of GHOA *vs* without GHOA in short-term follow-up. Our results indicate that the presence of GHOA at the time of RCR did not seem to influence the progression of GHOA. There is general agreement within literature that severe primary GHOA is an appropriate indication for TSA or RTSA[14,15]. Additionally, rotator cuff tear arthropathy, rotator cuff insufficiency, and superior migration of humeral head - is considered another indication for RTSA[14-16]. While GHOA and rotator cuff tears both contribute to morbidity due to decreased shoulder function, there are limited studies evaluating the outcomes of

Table 4 Patient-reported outcomes

	Overall (*n* = 142)	With GHOA, Small tear (0-1 cm) (*n* = 21)	Without GHOA, Small tear (0-1 cm) (*n* = 28)	*P* value	With GHOA, Medium tear (1-3 cm) (*n* = 28)	Without GHOA, Medium tear (1-3 cm) (*n* = 30)	*P* value	With GHOA, Large tear (3-5 cm) (*n* = 22)	Without GHOA, Large tear (3-5 cm) (*n* = 13)	*P* value
MCS, median (IQR)	57.1 (46.5, 61.6)	60.9 (37.6, 64.1)	56.3 (44.4, 61.5)	> 0.99	59.3 (44.6, 61.3)	58.3 (50, 62.8)	> 0.99	54.4 (48, 57.9)	51 (47.3, 60.2)	> 0.99
PCS, median (IQR)	49.1 (40, 52.6)	40.2 (29.6, 49.1)	51.4 (42.4, 55)	0.148	50 (44.9, 51.8)	46.4 (35.1, 50.8)	> 0.99	52.7 (49.7, 55.4)	41.8 (34.4, 53.3)	> 0.99
VAS pain, median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	> 0.99	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	> 0.99	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	> 0.99
VAS instability, median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	> 0.99	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	-	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	-
ASES shoulder right, median (IQR)	98.3 (93.3, 100)	100 (95, 100)	99.2 (95, 100)	> 0.99	98.3 (91.7, 100)	95 (91.7, 100)	> 0.99	98.3 (93.3, 98.3)	100 (95, 100)	> 0.99
ASES shoulder left, median (IQR)	98.3 (90, 100)	100 (85, 100)	98.3 (91.7, 100)	> 0.99	100 (93.3, 100)	95.8 (87.5, 100)	> 0.99	100 (91.7, 100)	90 (66.7, 100)	> 0.99
SANE, median (IQR)	95 (85, 100)	96.5 (90, 100)	100 (92.5, 100)	> 0.99	100 (95, 100)	95 (80, 100)	> 0.99	90 (85, 95)	85 (50, 100)	> 0.99

MCS: Veterans RAND 12-Item Health Survey mental health component summary scores; PCS: Veterans RAND 12-Item Health Survey physical health component summary score; VAS: Visual analogue scale; ASES: American shoulder and elbow surgeons score; SANE: Single assessment numeric evaluation.

joint-preserving treatment *via* RCR in the setting of GHOA.

A recent study by Jeong *et al*[8] retrospectively evaluated the clinical outcomes of large to massive RCR in patients with and without mild GHOA. The authors found that preoperative and postoperative variables (VAS scores, ROM, muscle strength, University of California, Los Angeles (UCLA) scores, and Constant scores) at final follow-up (2 years) showed no significant differences between the two groups. Our study also included VAS and similarly did not show any significant difference between groups at final follow up period of 2 years. Jeong *et al*[8] reported mean VAS scores in patients with large to massive tears with mild GHOA and without mild GHOA to be 0.3 ± 0.7 and 0.3 ± 0.8, respectively which are similar to our overall median VAS score of 0.0 (IQR 0.0, 0.0). These combined results indicate that patients with small to large rotator cuff repairs in the setting of mild to moderate GHOA can expect to have a pain score close to 0 after a minimum of 2 years after RCR.

A study by Kukkonen *et al*[10] evaluated outcomes using Constant scores in patients with or without GHOA after undergoing supraspinatus tendon repair with tear sizes ranging from 0.5 cm to 2.5 cm. Both pre and post-operative Constant scores were significantly lower in patients with GHOA. These results differ from ours and Jeong *et al*'s which showed no difference in PROs in patients with or without GHOA[8]. Kukkonen *et al*'s study only included males, had final follow-up of 1 year, and used the Kellgren-Lawrence classification to determine GHOA severity and status[10]. In contrast, our study and the study by Jeong *et al*[8] included males and females with a follow-up of 2 years and used the Samilson-Priesto classification for GHOA grading. A study of radiographic classifications of GHOA found that the Kellgren-Lawrence provided inferior inter-observer agreement in diagnosis of GHOA compared to Samilson-Priesto due to the challenge of identifying minor joint space narrowing in the non-weight bearing shoulder joint[17]. The aforementioned finding may limit comparative value of studies using different radiographic classification methods.

Overall, the results of our PROs after a short to medium term follow-up period show favorable results in VR-12, VAS, ASES, and SANE regardless of tear size or presence of GHOA. In patients with mild to moderate GHOA, there were no significant differences in all categories of PROs when comparing to patients without GHOA stratified by small to large rotator cuff tears. The minimal clinical important difference (MCID) was established to define minimum difference in PROs that is required to provide a clinically relevant benefit for patients rather than relying on statistically significant differences. The MCID for VR-12 PCS, MCS, VAS pain, ASES, and SANE following RCR has been reported to be 4.94, 5.99, 1.4, 21.0, and 11.80 respectively[18,19]. VR-12 PCS was the only PROs that showed MCID when patients with small or large rotator cuff tears were compared by presence or absence of GHOA. Surprisingly, patients with mild to moderate GHOA and small RCR had worse VR-

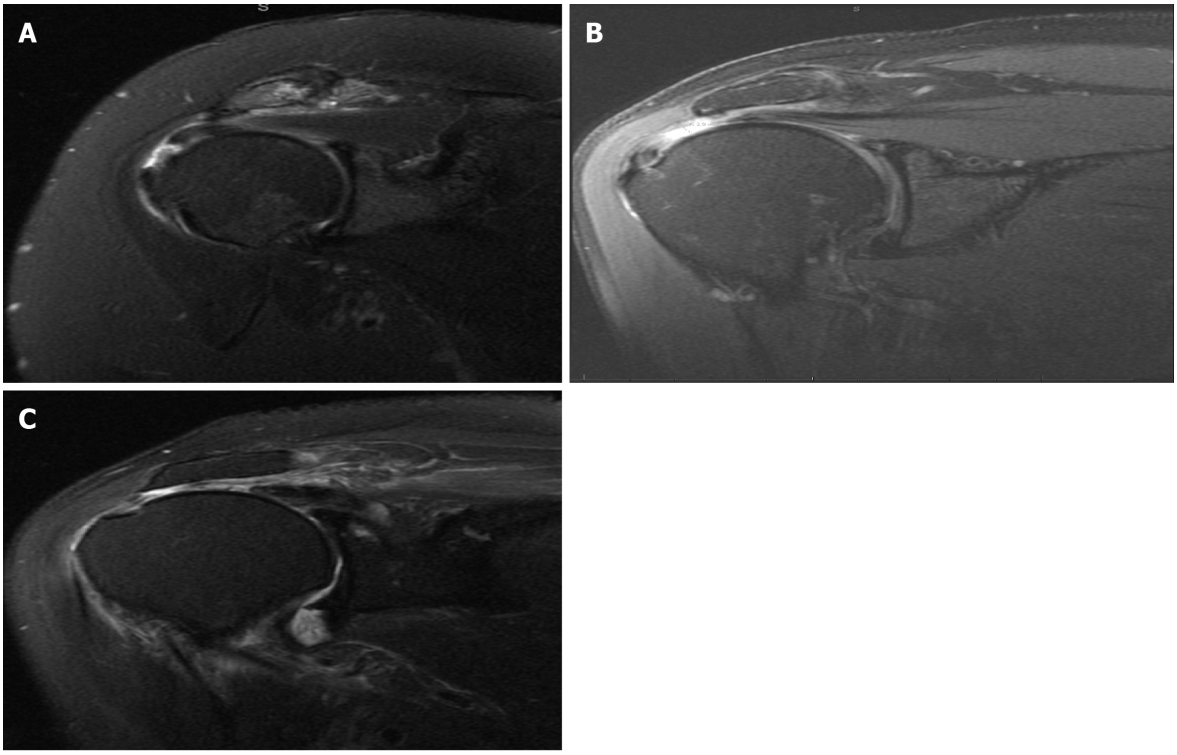


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Figure 3 Magnetic resonance imaging. A: Magnetic resonance imaging demonstrating small (0-1 cm) tear of rotator cuff; B: Magnetic resonance imaging demonstrating medium (1-3 cm) tear of rotator cuff; C: Magnetic resonance imaging demonstrating large (3-5 cm) tear of rotator cuff.

12 PCS scores. A literature review of histopathology of rotator cuff tears showed that inflammatory cell infiltrate and number of blood vessels are inversely correlated with tear size[20]. Immunochemistry has also shown torn rotator cuff tendons with lower vascularity have fewer new nerve fibers and is linked to lower chronic pain[21].

The rate of conversion to TSA or RTSA within 2 years after RCR were low for patients with and without GHOA at 2.8% (2/71) and 1.4% (1/71), respectively. This is the first study to report conversion to TSA or RTSA as an outcome variable while comparing outcomes following RCR in patients with or without GHOA. Results of previous studies, which showed that the progression of GHOA did not negatively affect PROs at final follow-up in patients who underwent RCR or arthroscopic debridement of massive irreparable rotator cuff tears[8,22,23], led us to hypothesize patients with GHOA would have conversion rate to TSA or RTSA are comparable with patients without GHOA. The results of our study report good PROs and very low conversion rates to shoulder arthroplasty after RCR with concomitant GHOA.

Due to the retrospective design, there are aspects to patient selection and classification that may introduce confounding biases. The heterogeneous nature of the patients with regard to demographics, surgical technique, and being treated by multiple surgeons at a single academic institution may limit the ability to make accurate comparisons between groups. Furthermore, no preoperative PROs were obtained which may have served as a baseline measure to observe any improvements or exacerbations following RCR. Our follow-up period may be reflective of short- term outcomes with a lack of findings for longer-term outcomes (greater than 5 years or 10 years). However, a recent study by Manderle *et al* [24] showed that the vast majority of RCR patients achieve MCID, substantial clinical benefit and patient acceptable symptomatic state for various PROs within 1 year. Therefore, our minimum 2-year follow-up period may be sufficient to evaluate and make comparisons of the postoperative PROs following RCR in this patient population.

CONCLUSION

This study reveals comparable outcomes in patients following small, medium, and large RCR with or without GHOA. Within a clinical follow-up period of 2 years, there were low rates of conversion to TSA or RTSA and no significant statistical differences found in PROs between patients with and without GHOA. In patients with mild to moderate GHOA and small to large rotator cuff tears, RCR is an effective means of surgical intervention that allows for joint-preservation and satisfactory PROs at short and medium-term follow-up.

ARTICLE HIGHLIGHTS

Research background

This study showed that patient reported outcomes in patients that have undergone a rotator cuff repair procedure, in the setting of Glenohumeral Osteoarthritis (GHOA) are favorable at short term (IE less than 2 year) follow-up. The rate of conversion to arthroplasty for these patients was also very low, indicating satisfaction with their outcomes.

Research motivation

There is a paucity of literature surrounding this topic, rotator cuff repair (RCR) in the setting of GHOA, so we felt it necessary to add to the literature with our own set of data in hopes of providing clinicians with more data surrounding this topic.

Research objectives

To determine patient report outcomes and rate of conversion to arthroplasty for patients with GHOA after undergoing a rotator cuff repair procedure. With favorable outcomes, and low conversion rates to arthroplasty, these objectives were realized in our data set.

Research methods

This was a retrospective cohort study with patient follow-up *via* questionnaire by phone, email, or in person *via* clinic visits.

Research results

Our results showed a low rate of conversion to arthroplasty in both subgroups after undergoing RCR. Patient reported outcomes using standardized scales were also quite favorable in both subgroups.

Research conclusions

Our study showed favorable outcomes with regards to patient reported outcomes. A low conversion rate to arthroplasty was also noted in the short term follow-up.

Research perspectives

The future direction of our research will include longer term patient follow-up (IE greater than 5-10 years) to ascertain data on conversion to arthroplasty in the GHOA patient.

FOOTNOTES

Author contributions: Saltzman BM, Fleischli JE, Connor PM and Hamid N developed the idea for the project; Hong IS, Rao AJ, CarlLee TL, and Meade JD contributed to formulating, writing, and revising the documents; Hurwit DJ, Scarola G, Trofa DP, and Schiffern SC contributed to development of the data analysis, manuscript revisions and formulation of project; all authors have agreed to be responsible for the final version of the manuscript.

Institutional review board statement: This study was reviewed and approved by Atrium Health Institutional Review Board, Charlotte NC. File #11-19-20E.

Informed consent statement: All study participants or their legal guardian provided informed written consent about personal and medical data collection prior to study enrolment.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Association between tourniquet use and intraoperative blood loss during below-knee amputation

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Abstract

BACKGROUND

Despite over 150000 amputations of lower limbs annually, there remains a wide variation in tourniquet practice patterns and no consensus on their necessity, especially among orthopedic patient populations. The purpose of this study was to determine whether tourniquet use in orthopedic patients undergoing below knee amputation (BKA) was associated with a difference in calculated blood loss relative to no tourniquet use.

AIM

To determine if tourniquet use in orthopedic patients undergoing BKA was associated with a difference in calculated blood loss relative to no tourniquet use.

METHODS

We performed a retrospective review of consecutive patients undergoing BKA by orthopedic surgeons at a tertiary care hospital from 2008 through 2018. Blood loss was calculated using a combination of the Nadler equation for preoperative blood volume and a novel formula utilizing preoperative and postoperative hemoglobin levels and transfusions. Univariate and forwards step-wise multivariate linear regressions were performed to determine the association between tourniquet use and blood loss. A Wilcoxon was used to determine the univariate relationship between tourniquet use and blood loss for in the restricted subgroups of patients who underwent BKA for trauma, tumor, and infection.

RESULTS

Of 97 eligible patients identified, 67 underwent surgery with a tourniquet and 30 did not. In multivariate regression, tourniquet use was associated with a 488 mL decrease in calculated blood loss (CI 119-857, P = 0.01). In subgroup analysis, no

individual group showed a statistically significant decrease in blood loss with tourniquet use. There was no significant association between tourniquet use and either postoperative transfusions or reoperation at one year.

CONCLUSION

We found that tourniquet use during BKA is associated with decreased calculated intraoperative blood loss. We recommend that surgeons performing this procedure use a tourniquet to minimize blood loss.

Key Words: Amputation; Tourniquet; Blood loss; Hemostasis

Core Tip: We retrospectively evaluated 138 patients who underwent a below knee amputation by an orthopedic surgeon and compared the calculated intraoperative blood loss between patients who received or did not receive a tourniquet. We found that patients who did receive a tourniquet had significantly lower blood loss than those who did not.

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INTRODUCTION

Since its 2nd century introduction to amputation surgery by Heliodorus, the tourniquet has been nearly as enduring as the knife itself[1,2]. Yet despite the amputation of over 150000 Lower limbs annually in the United States, there are wide variations in tourniquet practice patterns and no consensus on their necessity during limb removal[3].

Tourniquet application during limb amputation is controversial. Historically, the high rate of mortality associated with early amputations was attributed to both delayed septicemia and immediate blood loss, leading surgeons such as Esmarch, Lister, and Cushing to improve upon early designs during the 19th and 20th centuries[2]. Today, tourniquet use is associated with decreased intraoperative blood loss and fewer transfusions in below knee amputations performed primarily in vascular surgery settings[4,5]. However, this has hardly settled the question of whether they should be used routinely for hemorrhage control during orthopedic limb removal. Throughout the dissection, use of a tourniquet may provide a drier surgical field by slowing intraoperative bleeding, but at the same time may limit the palpation of neurovascular structures[6-8]. Additionally, blood loss continues beyond the intraoperative period, and application of a tourniquet may prevent the surgeon from identifying damage to small vessels that continue to ooze postoperatively. There is also a theoretical risk of damaging fragile atherosclerotic vessels as pneumatic pressure increases, leading to swelling and blood loss in the perioperative period after the tourniquet has been removed[9]. This may explain studies finding no difference in total blood loss or transfusions with tourniquet use in studies of both below knee amputation and total knee arthroplasty[9-12].

There is a paucity of literature describing the association between tourniquet use and blood loss during below knee amputation in orthopedic populations, which include patients undergoing surgery for neoplastic disease, trauma, and infection[11]. Furthermore, blood loss in prior studies has typically been recorded using surgeon estimation, which is subjective, imprecise, and does not account for perioperative "hidden" blood loss that continues after closure of the wound[10,13,14].

The primary purpose of this study was to determine whether tourniquet use in orthopedic patients undergoing below knee amputation was associated with a difference in calculated blood loss relative to no tourniquet use. Secondarily, we assessed whether tourniquet application was associated with postoperative transfusions during the inpatient stay or reoperation within one year. We hypothesized that tourniquet use would not be associated with decreased blood loss, postoperative transfusions, or reoperation within one year.

Table 1 Demographic characteristics of patients undergoing below knee amputation with and without tourniquet

	No tourniquet	Tourniquet	*P* value
n	30	67	
Age, mean (SD)	43.31 (18.53)	56.05 (14.02)	< 0.001
Gender = M (%)	19 (63.3)	43 (64.2)	1
Height (mean (SD))	1.73 (0.10)	1.75 (0.10)	0.423
Weight (mean (SD))	90.63 (31.57)	98.78 (32.46)	0.252
BMI (mean (SD))	29.96 (9.62)	32.12 (9.81)	0.315
Diabetes (%)	7 (23.3)	27 (40.3)	0.165
Hepatitis C (%)	0 (0.0)	4 (6.0)	0.415
Smoking (%)	6 (20.0)	26 (38.8)	0.112
IV drug use (%)	1 (3.3)	5 (7.5)	0.746
Alcoholism (%)	2 (6.7)	10 (14.9)	0.419
Outside hospital transfer (%)	3 (10.0)	13 (19.4)	0.391
ASA score (%)			0.433
1	1 (3.3)	0 (0.0)	
2	12 (40.0)	20 (29.9)	
3	15 (50.0)	40 (59.7)	
4	2 (6.7)	6 (9.0)	
5	0 (0.0)	1 (1.5)	
Homeless (%)	0 (0.0)	1 (1.5)	1
Preoperative hemoglobin (mean (SD))	11.91 (2.64)	11.78 (2.74)	0.82
Platelets (mean (SD))	270.83 (153.50)	315.09 (114.02)	0.117
Indication for surgery (%)			< 0.001
Infection	14 (46.7)	53 (79.1)	
Trauma	2 (6.7)	9 (13.4)	
Tumor	14 (46.7)	5 (7.5)	

BMI: Body mass index.

MATERIALS AND METHODS

With Institutional Review of Board approval, we retrospectively reviewed consecutive patients undergoing below knee amputation by orthopedic surgeons at a single academic institution over a ten-year period from January 1, 2008 to December 31, 2018. The hospital is a tertiary referral center for soft tissue sarcomas and a Level 1 trauma center. This study was conducted following STROBE guidelines [15].

Patients were identified by CPT code for below-knee amputation. To prevent confounding by other sources of bleeding, patients were excluded if the indication for below-knee amputation was a trauma that had occurred within one week, if they had active gastrointestinal bleeding, or if they had a diagnosed bleeding disorder. We excluded patients with through-knee amputations.

Data for identified patients was collected from chart review including demographic characteristics (*e.g.*, age, sex), known or potential modifiers of blood loss (*e.g.*, kidney dysfunction, platelet count), and surgical data (*e.g.*, indication for surgery, intraoperative transfusions). A full list of variables that were collected can be found in Supplementary Table 1. Tourniquet use and tourniquet time were taken from surgeon operative reports. Post-operative hemoglobin and hematocrit results were taken within 72 h of the operation. We used the first post-operative hemoglobin in blood loss calculations.

Blood loss was determined using a series of calculations. Preoperative blood volume was calculated using patient height, weight, and gender by the Nadler formula[16]:

Table 2 Results of multivariate regression modeling

Variable	Estimate (95%CI)	*P* value
Tourniquet use	-488 mL (-857, -119)	0.01
Indication (*vs* infection)		
Trauma	12 mL (-474, 498)	0.96
Tumor	-190 mL (-624, 245)	0.39

CI: Confidence interval.

Blood volume (Male) = $0.3669 \times H^3 + 0.03219 \times W + 0.6041$.

Blood volume (Female) = $0.3561 \times H^3 + 0.03308 \times W + 0.1833$.

Total blood loss was then determined using calculated blood volume, change in hemoglobin concentration, and the mass of hemoglobin transfused intraoperatively, based on modification of the formula by Wied *et al*[10]: Total mass of Hgb lost = Blood volume (L) × (Hgb preop - Hgb postop) × 10 + mass of transfused Hgb. Where mass of transfused Hgb = 61.25g × intraoperative units transfused[16]. Blood loss (L)= total mass of Hgb lost/ (Hgb preop × 10).

We excluded five variables with > 5% data missingness (functional capacity, erythrocyte sedimentation rate, C-reactive protein, A1c, and albumin). The only remaining variable with missing data (creatinine, 2%) was included in regression analysis. Characteristics of patients undergoing below knee amputation with and without tourniquet were compared using t tests or chi square tests as appropriate.

For our primary outcome, we performed a univariate linear regression to determine the association between tourniquet use and blood loss. We also ran subgroup analyses by indication for surgery, using a Wilcoxon due to the non-parametric distribution of blood loss and the low number of observations in each subgroup. We then performed a forward stepwise regression with potential modifiers of the association between tourniquet use and blood loss, sequentially retaining variables that changed the estimation of the association by greater than 10 percent. We excluded the surgeon as a variable from this analysis as it was thought to lie on a causal pathway between indication and blood loss and was not generalizable. We also excluded operative time due to the directionality of its association with tourniquet use and because it likely lies along the causal pathway between tourniquet use and blood loss[11]. To avoid spurious associations, we only included variables that were logically associated tourniquet use and blood loss, and limited the variables tested to 10% of the number of observations. We included interaction terms for variables of interest.

We then performed two logistic regressions in a similar fashion using postoperative transfusion and reoperation in one year as outcomes. Postoperative transfusions were only included if administered during the immediate inpatient stay. Reoperations included stump revisions, revision to a higher-level amputation (*e.g.*, above-the-knee), and irrigation and debridement.

All statistical analysis was performed using R version 3.6.3 including the packages tableone, dplyr, ggplot2, and chest. Statistical significance was determined at 0.05. The study was reviewed by our statistician Dr. Erik Woelber.

RESULTS

138 patients undergoing below knee amputation were identified by chart review. 41 patients were excluded because they sustained a trauma within the prior week, leaving 97 patients for analysis. Of the patients identified, 67 underwent surgery with a tourniquet and 30 did not. Indications included infection (69%, $n = 67$), trauma (11%, $n = 11$), and tumor (20%, $n = 19$). Demographic characteristics are shown in Table 1. The tourniquet group was older (56 *vs* 43 years, $P < 0.001$) and had categorical differences in indication for surgery ($P < 0.001$).

In simple linear regression, tourniquet use was associated with significantly decreased blood loss (-0.41 Liters, SE 0.17, $P = 0.01$) (Figure 1). The calculation allowed for negative blood loss values to occur for 6 patients (6%). The plots reveal a right-skewed distribution of calculated blood loss for both tourniquet and non-tourniquet patients. In the analysis of restricted subgroups, no individual group showed a statistically significant decrease in blood loss with tourniquet use (Figure 2).

Results of multivariate regression are shown in Table 2. Of the tested variables, only the indication for surgery modified the association between tourniquet use and blood loss above the 10% threshold for inclusion. Though it differed significantly between tourniquet and non-tourniquet groups, age did not significantly modify the association between tourniquet use and blood loss. Two patients with missing data for creatinine were excluded from stepwise regression modelling but were included in the final multivariate model. The interaction term between tourniquet use and indication for surgery was not

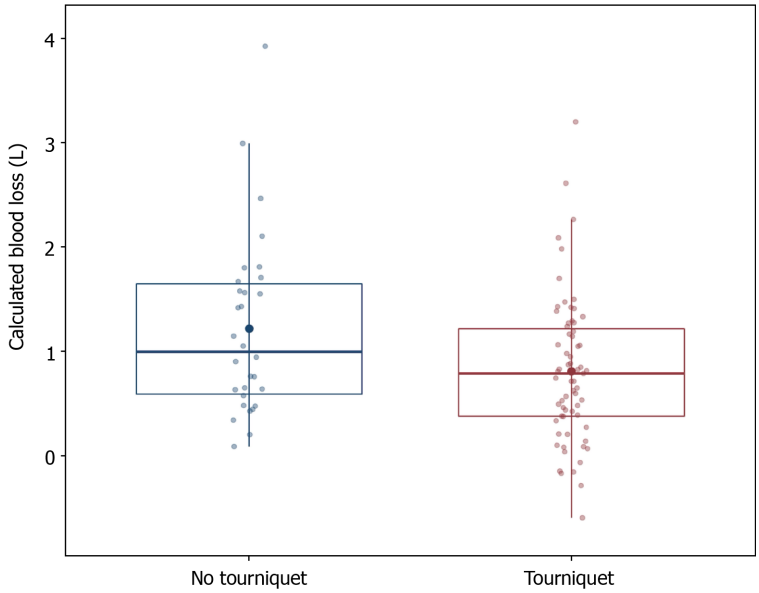

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Figure 1 Tourniquet use was associated with significantly decreased blood loss.

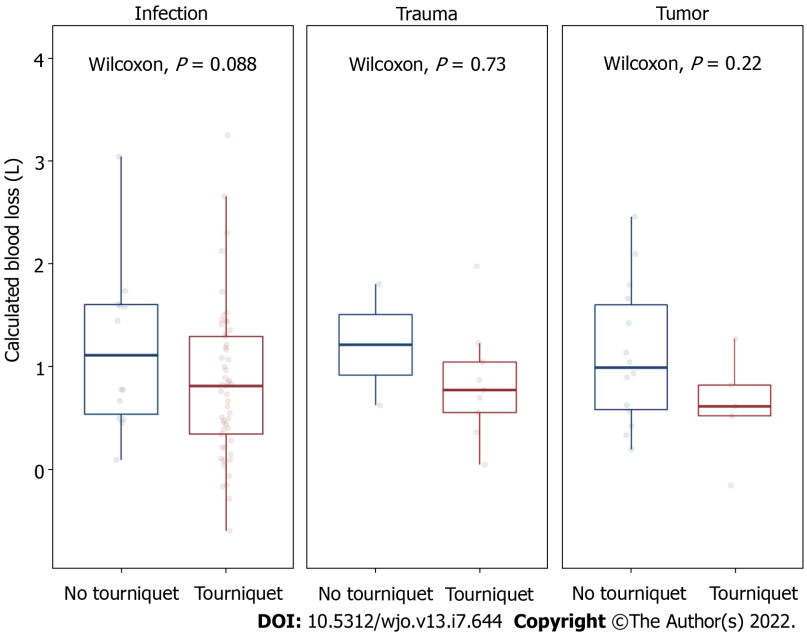

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Figure 2 No individual group showed a statistically significant decrease in blood loss with tourniquet use.

significant (P = 0.84 for trauma and P = 0.99 for tumor, relative to infection).

Thirteen patients in the tourniquet group (19%) and six patients in the non-tourniquet group (20%) received a postoperative transfusion. Twenty patients in the tourniquet group (30%) and 13 patients in the non-tourniquet group (43%) underwent an unplanned reoperation within one year of the index surgery. Adjusted secondary analyses showed no statistically significant association between tourniquet use and either inpatient blood transfusion after the first postoperative lab draw (OR 0.83, CI 0.25-2.72, P = 0.75) or reoperation at one year (OR 0.84, CI 0.26-2.79, P = 0.78).

DISCUSSION

Our results indicate that tourniquet use during below knee amputations performed on orthopedic surgery patients is associated with significantly decreased surgical blood loss. The magnitude of the as

sociation is noteworthy, as a 488 mL decrease with use of a tourniquet equates to an approximately ten percent difference in total blood volume lost.

Our findings are consistent with the results of prior studies in non-orthopedic populations. A non-randomized study found that tourniquet use in vascular patients undergoing below-knee amputation is associated with decreased surgical blood loss, fewer postoperative transfusions, and fewer complications[4]. Similarly, a prospective, randomized, blinded study found that tourniquet use in peripheral arterial disease patients is associated with less intraoperative blood loss, a smaller perioperative drop in hemoglobin, fewer transfusions, and similar complication rates[5].

Our secondary analysis did not demonstrate a statistically significant association between tourniquet use and inpatient postoperative transfusions. A prior study found that as much blood is lost following above-knee amputations postoperatively as during the procedure, which could explain this result[10]. Another study echoed the finding that tourniquet use during BKA is associated with less intraoperative blood loss, but no difference in total blood loss (including the postoperative period)[11]. In the joint arthroplasty literature, tourniquet use is not associated with a difference in transfusions or total blood loss[12]. In our study, it is also possible that we did not have adequate power to detect a difference in transfusions due to their rarity.

Our secondary analysis also did not demonstrate a statistically significant association between tourniquet use and reoperations at one year. At least one study comparing reoperation rates with and without a tourniquet found no difference in the rate of conversion to a higher-level amputation at 30 days[11].

This study had multiple limitations. First, the calculation of intraoperative blood loss relies on several assumptions: It assumes that all patients are adequately resuscitated following their operation at the time of their first postoperative blood draw (and thus may have underestimated total blood loss), and it does not account for changes in intravascular volume cause by vasoconstriction or fluid shifts. The calculation also does not account for any blood volume in the amputated limb. In theory, the equation overestimates blood loss because it is based off of a pre-operative patient weight, but this impact is negligible and should be equal in both groups. Patients taking anticoagulation or antiplatelet medications could also have increased blood loss and this was not taken into account in our analysis. However, patients are usually instructed to stop such medications before an operation. These calculations impose rigid mathematical formulas on patients representing a range of body compositions and physiologic responses to surgery that are dynamic and idiosyncratic. This may be particularly relevant in tertiary referral centers that see a non-representative range of body habitus and patients with impaired compensatory responses to hemorrhage. However, calculated blood loss has several advantages over surgeon estimation, including its standardization and immunity to the bias of a surgeon's visual assessment. It is also easily replicable at other centers and avoids the logistical hassles of alternative methods such as weighing surgical drapes and sponges.

A second limitation is that our patient population was heterogenous and derived from an academic center, and therefore potentially less generalizable. This fact is offset by our study being the first to approach this question in an orthopedic patient population, which differs from the more commonly studied general surgery population in terms of indications and patient characteristics. Second, the patients underwent procedures by a diverse group of surgeons employing a range of surgical techniques, increasing the external validity of our results.

Another limitation is that in the patients with an infectious etiology, which was primarily due to diabetes, the presence of peripheral vascular disease was not taken into account, which could affect blood loss.

Our study found no evidence of effect modification by the indication for surgery, indicating that use of a tourniquet does not have a variable effect on blood loss in oncology, infection, and trauma patients. However, the subgroup analysis was not powered to detect a difference in blood loss; comparisons within these groups were affected by small sample sizes, particularly in the group undergoing amputation due to trauma (n = 11). Thus, both the individual subgroup analyses and the lack of evidence for effect modification should be interpreted with caution.

CONCLUSION

We found that tourniquet use during below knee amputation is associated with decreased calculated intraoperative blood loss. The decision to use a tourniquet depends on multiple factors related to the individual patient, the underlying pathology being treated, and surgeon preferences. However, based on these results, we recommend that surgeons performing this procedure use a tourniquet if they wish to minimize blood loss. Analysis of a larger database may provide supporting evidence for tourniquet use in specific patient subgroups including patients with malignant tumors and those who sustained acute traumatic injury.

ARTICLE HIGHLIGHTS

Research background

Below-knee amputation (BKA) is common procedure in the orthopedic population. Etiology for patients requiring this surgery are primarily trauma, infection, and neoplastic disease. There is currently no consensus among orthopedic surgeons regarding the use of a tourniquet in these patients.

Research motivation

The motivation behind this study is to determine a possible method to minimize blood loss in BKA operations.

Research objectives

To compare blood loss between patients who received a tourniquet during their BKA procedure and those who did not.

Research methods

We performed a retrospective cohort study on consecutive patients who underwent BKA over a ten-year period at a tertiary care hospital. Blood loss was estimated using the Nadler equation for preoperative blood volume and a novel formula that utilizes preoperative and postoperative hemoglobin levels and transfusions. Univariate and forwards stepwise multivariate linear regression were utilized to determine an association between tourniquet use and blood loss.

Research results

We found that patients undergoing a BKA operation with tourniquet use were associated with a 488 mL decrease in calculated blood loss. This is significant for orthopedic surgeons wanting to minimize blood loss in BKA operations.

Research conclusions

This study utilized a calculated blood loss rather than the commonly utilized estimated blood loss, and proposes that a tourniquet should be used if orthopedic surgeons wish to minimize blood loss in BKA operation.

Research perspectives

Research should be conducted on a larger population across multiple centers to determine a stronger association and increase external validity.

FOOTNOTES

Author contributions: Woelber E, Meeker J and Working Z contributed the study conception and design; Wyland AE, Wong LH and Arakawa J contributed the generation, collection of the data; Wyland AE and Woelber E contributed the assembly, analysis and/or interpretation of the data; Wyland A, Woelber E, Meeker J and Working Z contributed to drafting and revising the manuscript.

Institutional review board statement: This study was approved by the Institutional Review Board (STUDY00020406).

Informed consent statement: All study participants or their legal guardian provided informed written consent about personal and medical data collection prior to study enrolment.

Conflict-of-interest statement: Each author certifies that he or she has no commercial associations (*e.g.*, consultancies, stock ownership, equity interest, patent/Licensing arrangements, *etc.*) that might pose a conflict of interest in connection with the submitted article.

Data sharing statement: Data and study materials are available upon reasonable request from the corresponding author at meekerj@ohsu.edu. Consent was not obtained, but the data are anonymous and the risk of identification is low.

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ORIGINAL ARTICLE

Randomized Controlled Trial

Does orthotics use improve comfort, speed and injury rate during running? Preliminary analysis of a randomised control trial

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Abstract

BACKGROUND

Evidence regarding the effectiveness of using orthotics in improving comfort, increasing running speed and helping to reduce injury rate during running is limited and mixed. Alongside the increasing popularity of running is the increasing rate of running-related injuries (RRIs). Further research into whether orthotics could be used to help reduce RRIs would be highly beneficial for those affected. Additionally, there is a need to clarify whether orthotics use increases comfort during running and helps improve running speed.

AIM

To investigate whether running with Aetrex Orthotics improves comfort and performance and reduces injury whilst running.

METHODS

Runners were recruited on a voluntary basis if they were 18 or older with no serious health conditions, ongoing foot pain or deformity, previous foot surgery in their lifetime or any surgery in the past 6 mo. Participants were randomly assigned to either an intervention group or a control group. All participants were asked to complete runs and provide quantitative data regarding comfort during running, running time and distance, and any RRIs over an 8-wk study period. Participants in the intervention group ran with Aetrex L700 Speed Orthotics, whilst participants in the control group ran without orthotics. Other than the addition of orthotics for participants in the intervention group, all participants were asked to run as they usually would. This report presents preliminary data from the first 47 participants recruited for this study. Running speed was calculated from running distance and time and given in miles per hour. For each outcome variable, the mean for each group, effect size and 95% confidence

interval were calculated, and a t-test was performed to determine if between-group differences were statistically significant.

RESULTS

Data for all three primary outcomes was provided from a total of 254 runs by the 23 participants in the intervention group and a total of 289 runs by the 24 participants in the control group. Participants in the intervention group reported higher comfort scores (8.00 ± 1.41 *vs* 6.96 ± 2.03, $P \leq 0.0001$), faster running speeds (6.27 ± 1.03 *vs* 6.00 ± 1.54, $P = 0.013$), and lower RRI rates (0.70 ± 1.01 *vs* 1.21 ± 1.53, $P = 0.18$) than those in the control group. These findings were statistically significant for comfort and running speed but not for RRI rate, with statistical significance considered if $P < 0.05$. No adjustments were made for group differences in age, gender, tendency for RRIs or usual running speed.

CONCLUSION

This preliminary report provides evidence for orthotics use in increasing comfort levels and running speed, but no significant difference in RRI rate.

Key Words: Running; Foot orthoses; Running related injuries; Pain; Patient comfort; Athletic performance

Core Tip: Running-related injuries are becoming increasingly prevalent due to the increasing popularity of this sport. Foot orthotics have been suggested to increase comfort and speed whilst running, as well as reduce injury rate. However, current evidence is limited and mixed. This article, presenting preliminary randomised control trial data, finds significant evidence that running with Aetrex L700 Speed Orthotics, compared to running with no orthotics, in 'participants' regular running shoes, improves comfort and running speed. Participants running with Aetrex L700 Speed Orthotics, on average, reported lower injury rates than those running without orthotics. However, this difference was not significant.

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INTRODUCTION

Running is becoming an increasingly popular sport, likely due to it being easily accessible, low cost and having multiple physical and mental health benefits. However, alongside this, there is also an increase in running-related injuries (RRIs). These usually affect the lower limb, the most common site being the knee, with almost half of RRIs occurring here[1-5]. Other common areas include the lower leg, ankle and foot due to injuries such as Achilles Tendonitis, Plantar Fasciitis and Tibial Stress Syndrome[3]. RRIs result in pain and discomfort and often cause individuals to take time off running. Reported rates of RRIs vary between 19.4% to 79.3% - partly due to the variation in the definition for RRI used by different studies, and therefore, it is important that studies clarify which definition they use. The risk of RRIs when running, alongside the rising popularity of the sport, necessitates research to find ways to prevent injury.

For many years foot orthotics have been used by runners to correct the alignment of the lower leg, improve arch support and increase cushioning of the foot. Orthotics are inserts which fit into the shoe in place of the removable insole. There are many different types, including off-the-shelf and custom-made. Previous research into the use of orthotics has found that they can improve comfort, provide better arch support and decrease the incidence of certain lower limb injuries such as stress fractures[6-9]. However, some studies have found no statistically significant difference in the Incidence of certain RRIs, such as soft-tissue injuries, when comparing the use of orthotics to no orthotics[9,10]. One study suggested that orthotics were a risk factor for RRIs, although the runners using orthotics in this study may have been more prone to injury than those who were not[5].

Previous research into the impact that orthotics have on running performance is limited and gives no clear conclusion. Some studies have shown a small significant increase in running economy with cushioned shoes[11], whereas others have found orthotics to have a negative impact on running economy[12]. Whether or not an improvement in running economy leads to a subsequent increase in performance is also unclear[13].

Overall, previous research regarding the effect of orthotics on running comfort, RRI rate and running performance is not clear. There are conflicting issues creating a lack of guidance for both professional and amateur runners concerning whether orthotics should or should not be used. Further research is required to clarify the effectiveness of orthotics in increasing comfort during running, improving running performance and preventing RRIs. The aim of this study is to assess comfort during running, running performance and RRI rate for recreational runners using prefabricated Aetrex[14] Orthotics compared to recreational runners not using orthotics. The results from this study will add to the existing knowledge surrounding the effect of orthotics on running and may provide evidence of a useful tool to prevent RRIs.

This article presents preliminary data from this study, followed by a discussion of how this data confers, conflicts with, and expands the current evidence base.

MATERIALS AND METHODS

This is a randomised control trial. The primary objective is to investigate whether inserting prefabricated orthotics into running shoes will increase comfort and speed and help decrease injury during recreational running as compared to running shoes without orthotics.

Recruitment

Participants were recruited on a voluntary basis through local running clubs and social media advertisements. Posters were distributed containing contact details for the Principal Investigator. Participants who got in contact were provided with the participant information sheet *via* email or post by a member of the research team. Potential participants were asked to read the information sheet fully and given time for consideration. Subsequently, all participants had either a phone or Zoom call, depending on their preference, with the Principal Investigator to discuss any queries they had about the study. Once participants had understood all the information and were happy to proceed, written informed consent was obtained, either online *via* legalesign.com or by post.

To be eligible, participants had to be aged 18 or over and be used to completing runs of at least 5km distance during the last 1 year. Participants were excluded if they were using prescription orthotics, had any ongoing pain or deformity in the foot or any serious health condition which has led to a doctor advising them not to exercise. They were also excluded if they had undergone any surgery in the last 6 months or any surgery to the feet during their lifetime. Participants were informed of their ability to withdraw from the study at any time if they wished, without needing to give a reason.

Randomisation

Once recruited, participants were randomised into one of two groups: an intervention group, who ran with Aetrex[14] L700 Speed Orthotics in their usual running shoes (Group A), and a control group, who ran with no orthotics (Group B). The Aetrex[14] L700 Speed Orthotics are pictured in Figure 1. Group allocation occurred by the opening of pre-filled and sealed envelopes containing notes to assign them either to Group A or to Group B. These envelopes were shuffled, and an individual independent of the study picked an envelope at random to assign a participant to a group. There was no blinding of either participants or researchers to group allocations following randomisation.

Those in Group A received Aetrex[14] L700 Speed Orthotics *via* post, according to their shoe size, along with an instruction sheet on how to use the orthotics. Participants in Group B were asked to run as they usually would, with no adjustments made to their regular running shoes.

Data collection

Basic demographic information was collected from participants upon recruitment to the study. All participants were asked to complete runs and provide quantitative data over an 8-wk data collection period. Participants provided data remotely *via* an online or paper survey, depending on their preference. Other than the addition of orthotics for participants in Group A, all participants were asked to run without altering their regular running routine, thereby keeping confounding variables to a minimum.

The following data was collected by participants immediately after each run: (1) Comfort - collected on a self-report visual analogue scale (VAS) of 0 to 10, where 0 is "No comfort" and 10 is "Maximum comfort"[15]; and (2) Running duration (measured in hours and minutes) and running distance (measured in miles) – used to calculate running speed.

Once per week, participants were asked to provide data relating to any RRIs experienced in the previous seven days *via* a self-report 'fill me in' section of the survey. The consensus definition for an RRI presented by Yamato and co-workers[16] was used in this study which is: "Running-related musculoskeletal pain in the lower limbs that causes a restriction or stoppage of running (distance, speed, duration, or training) for at least 7 d or 3 consecutive scheduled training sessions, or that which requires the runner to consult a physician or other health professional." Participants were provided with an RRI information sheet to inform them of this definition, and the common sites, symptoms and causes

Figure 1 Image of Aetrex L700 Speed Orthotics.

of RRIs, to help them provide accurate, consistent data relating to the injury.

Weeks 1 and 2 of data collection were an 'acclimatisation period', and weeks 7 and 8 were a 'de-acclimatisation period'; during these weeks, only injury data was collected. Comfort during running, running time and running distance data was collected during weeks 3, 4, 5 and 6.

The preliminary data presented in this article relates to the first 47 participants recruited for the study. However, recruitment is still ongoing in order to obtain a larger study cohort of 106 participants to maximise the reliability and reproducibility of results. This number is based on a sample size calculation performed using a target significance level of 5%, target power of 80% and allowing for a 20% dropout rate.

Statistical analysis

Once collected, data was stored appropriately, and statistical testing was performed[17]. The standard deviations, effect size (mean difference) and 95% confidence interval for each outcome variable were calculated to determine the direction and strength of any correlations in the results. An unpaired two-tailed t-test was performed from the data for each outcome variable to determine if between-group differences were statistically significant. Standard deviations differed between the two groups, and so all *t*-tests used Welch's correction to adjust for this.

The statistical methods of this study were reviewed by Steven Lane from the Department of Biostatistics, University of Liverpool.

The full trial protocol can be accessed at: https://clinicaltrials.gov/ct2/show/NCT04901442?term=orthotic%2C+running+related+injury%2C+comfort&cntry=GB&draw=2&rank=1.

RESULTS

This article presents preliminary data from the first 47 participants recruited to this randomised control trial (intervention group = 23, control group = 24). The details of participant flow, including numbers of participants recruited, randomly allocated to a group, and included in analysis, as well as withdrawals, are provided in Figure 2.

Recruitment began in July 2021 and is planned to finish in October 2022. Participants ranged in age from 19 to 67 years old (mean age = 39.9 years old). Participants in the intervention group were, on average, older than participants in the control group, with a mean age of 42.2 and 37.8 years old, respectively. 61.7% of study participants were male, and both groups contained more males than females. Basic demographic data and clinical characteristics for the 47 participants included in the preliminary analysis are provided in Table 1.

All participants were analysed within their original assigned groups, and all participants in the intervention group ran with the orthotics for the entire study period. Data for all three primary outcomes were provided from a total of 254 runs by the 23 participants in the intervention group (an average of 11 runs per participant) and a total of 289 runs by the 24 participants in the control group (an average of 12 runs per participant). Results for each primary outcome in each group are provided in Table 2, along with the mean difference and its precision. Results show positive effects between the use of Aetrex[14] Orthotics and comfort and running speed compared with using no orthotic. The effect size for the use of the orthotics on comfort was 1.10 (95%CI 0.81-1.40), larger than for running speed, which showed an effect size of 0.28 (95%CI 0.06–0.50). These differences in comfort and running speed are statistically significant, with P values of < 0.0001 and 0.013, respectively.

Table 1 Basic demographic information for participants included in preliminary analysis

	Orthotic group (%)	Control (no orthotic) group (%)	Total (%)
Sex			
Male	13 (56.5)	16 (66.7)	29 (61.7)
Female	10 (43.5)	8 (33.4)	18 (38.3)
Age (years)			
< 20	1 (4.3)	0 (0)	1 (2.1)
20-29	1 (4.3)	3 (12.5)	4 (8.5)
30-39	6 (26)	9 (37.5)	15 (31.9)
40-49	10 (43.5)	10 (41.7)	20 (42.6)
50-59	3 (13)	1 (4.2)	4 (8.5)
60-69	2 (8.7)	1 (4.2)	3 (6.4)
Total	23	24	47

Table 2 Data on all primary outcomes for both groups

	Intervention group	Control group	Mean difference (95%CI)	*P* value
Comfort	8.06 ± 1.41	6.96 ± 2.03	1.10 (0.81 to 1.40)	< 0.0001
Injury rate	0.70 ± 1.01	1.21 ± 1.53	-0.51 (-1.28 to 0.25)	0.18
Running speed (miles per hour)	6.27 ± 1.03	6.00 ± 1.54	0.28 (0.06 to 0.50)	0.013

Values for the intervention group and control group are expressed as mean ± standard deviation. Statistical analysis used *P* values from unpaired two-tailed t-tests with Welch's correction. Significant difference was considered if $P < 0.05$. CI: Confidence interval. Injury rate: Number of injuries reported per participant over the 8-wk study period.

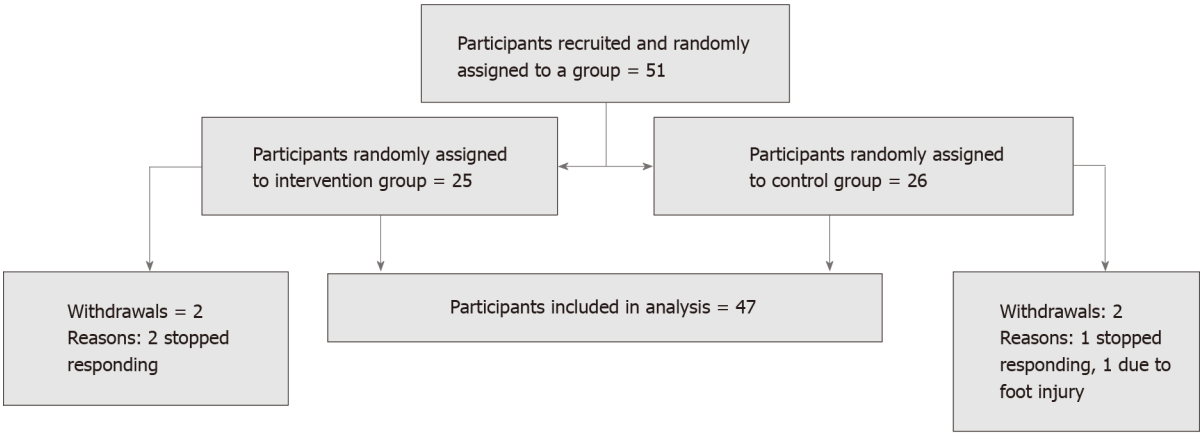

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Figure 2 Participant flow, including randomised group assignment and any withdrawals.

Participants in the intervention group reported a lower RRI rate than the control group, with an average of 0.70 injuries per participant running with the orthotics during the study period, compared to 1.21 injuries per participant running with no orthotics. This corresponds to a negative effect of -0.51 (95%CI -1.28 to 0.25) for RRI rate with the orthotics compared with no orthotics. This difference, however, is not statistically significant ($P = 0.18$).

Table 2 also shows standard deviations for each mean value. These are generally large relative to mean values, demonstrating widespread data. As a result, 95% confidence intervals for effect sizes are also wide. Interestingly, standard deviations and confidence intervals for all outcome measures data were larger for the control group, indicating that the intervention group generally produced more consistent data.

Despite injury being measured in the study, it was ensured that no participants experienced any additional harm or injury as a result of taking part by asking all participants to run as they normally would, without changing their running frequency, duration or speed. The only intervention was the addition of orthotics in the running shoes of participants in the intervention group, which demonstrated a lower RRI rate than the control group. One participant withdrew from the study due to injury. However, they were assigned to the control group meaning their injury was not due to the study intervention. This participant did not require any medical intervention other than cessation of running.

DISCUSSION

This article presents preliminary results from a randomised control trial study investigating the impact of running with Aetrex[14] Orthotics inserted into normal running shoes on comfort, running speed and RRI rate compared with running in normal running shoes with no orthotics. It finds that participants who ran with Aetrex[14] Orthotics reported higher comfort scores and running speeds and lower RRI rates than those who ran with no orthotics. This confers with other studies that have tested prefabricated orthotics[8,9] and adds to the current evidence for orthotics improving these parameters. The working principle of orthotics in benefitting comfort and reducing injury relates to their function in distributing pressure across the soles of the feet and decreasing overpronation. This subsequently reduces the internal rotation of the lower limb joints, which in turn reduces the risk of pressure- and overpronation-associated lower limb injuries[18-20]. This working principle is illustrated in Figures 3 and 4.

In this preliminary report, the relationship between improved comfort during running with Aetrex [14] Orthotics showed the largest effect size, whereas improvements in running speed and reductions in RRI rate showed smaller effects. Improvements in comfort and running speed when running with the orthotics were statistically significant in this study. This is relevant and advances current evidence for orthotics in improving these parameters, as many previous studies have been unable to find significant improvements[9,10]. In contrast, the reduction in RRI rate with orthotics in this study was not significant. These findings suggest that orthotics may be a cost-benefit. However, a full cost analysis will be provided in the final study report.

The spread of data was high for all outcome measures; this may be partly due to the nature of the variables, as running speed varies greatly between different runners, likewise tendency for injury. This may partly explain why many previous studies have found benefits in comfort, running performance and injury reduction with orthotics use[17,21], but that was not statistically significant, and additionally why the reduction in RRI rate with orthotics in this study was not significant.

Strengths and limitations

A limitation of the data in this preliminary report is the small number of participants. Further analysis, once the study has recruited its target sample size (106 participants), will provide more reliable and reproducible results. Another limitation is the lack of blinding of participants following group assignment due to the nature of the study. Some improvements in comfort and performance reported by participants who were provided with an orthotic may have been due to the placebo effect if participants had expectations that the orthotic would improve these parameters. VAS was selected for comfort scoring as it has been shown to have high inter-session reliability when used for a comfort rating of footwear[15], but it is still a subjective measurement, creating the potential for bias.

The study sample demonstrates a wide range of ages (19 to 67 years old), adding to the generalisability of the results. It also reflects the 2017 Sport England Active Lives Survey[22] estimate of the characteristics of the UK running population, in that it contains a greater number of men than women, adding to the validity of the results. However, the voluntary nature of recruitment in this study means that its sample cannot be said to be representative of the general population.

No adjustments were made for group differences in certain variables, such as tendency to become injured and usual running speed, and these may have had confounding effects on the results. One way to improve reliability in this study could be to collect quantitative data from participants for normal injury tendency (e.g. number of weeks spent injured, or number of RRIs in the past one year) and running speed (e.g., average running speed overall runs in the past six months) and adjust for group differences in these parameters.

CONCLUSION

This preliminary report of randomised control trial data provides evidence that using Aetrex[14] Orthotics in normal running shoes increases comfort levels and speed during running and decreases RRI rates, with the relationship between orthotics use and improved comfort showing the largest effect size. However, only improvements in comfort and running performance were significant. The sample

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Figure 3 Internal rotation of lower limb joints and opposing external rotation of the patella caused by overpronation during running, which can lead to injuries.

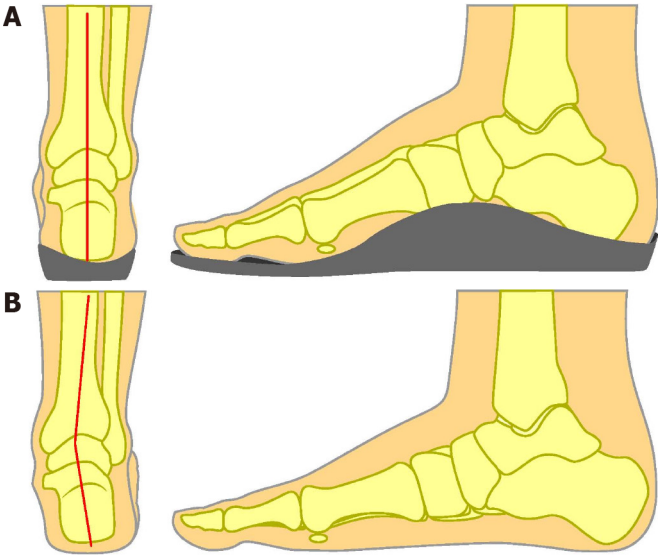

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Figure 4 Working principle of orthotics. A: The correction of lower limb alignment by orthotics, by reducing overpronation; B: Compared to the lower limb misalignment present without orthotics, due to overpronation.

size included in this preliminary analysis is small (n = 47). Further analysis, once recruitment and data collection in this study is complete, will expand on the findings given in this report and provide a full analysis of the cost-benefit.

ARTICLE HIGHLIGHTS

Research background

There is currently mixed and limited evidence regarding the effectiveness of orthotics use in increasing comfort and speed and reducing injury rate during running.

Research motivation

Further research into the effect of orthotics use on running-related injury (RRI) rates would be helpful for the ever-growing population of runners, who frequently suffer from RRIs. Additionally, there is a need to clarify whether orthotics use increases comfort during running and helps improve running speed.

Research objectives

To investigate whether running with Aetrex Orthotics improves comfort and performance and reduces injury whilst running.

Research methods

A randomised control trial study design was used. Participants were regular runners over 18 with no serious health conditions, ongoing foot pain or deformity, previous foot surgery in their lifetime or any surgery in the past 6 months, recruited on a voluntary basis through local running clubs and social media advertisements. Participants were randomly assigned to either an intervention group or a control group. Participants in the intervention group ran with Aetrex orthotics inserted into their normal running shoes, whilst participants in the control group ran in their normal running shoes with no orthotics. All participants were asked to complete runs as they usually would and provide data regarding comfort during running, running time and distance, and any RRIs over an 8-wk study period. For each outcome variable, the mean for each group, effect size and 95% confidence interval were calculated, and a t-test was performed to determine if between-group differences were statistically significant.

Research results

This article presents the interim results from the first 47 participants recruited to this study (intervention group = 23, control group = 24), who provided data for all three primary outcomes from a total of 543 runs. Participants in the intervention group reported higher comfort scores (8.00 ± 1.41 *vs* 6.96 ± 2.03, $P \leq 0.0001$), faster running speeds (6.27 ± 1.03 *vs* 6.00 ± 1.54, $P = 0.013$), and lower RRI rates (0.70 ± 1.01 *vs* 1.21 ± 1.53, $P = 0.18$) than participants in the control group. Statistical significance was considered if $P < 0.05$. The findings were statistically significant for comfort and running speed but not for RRI rate.

Research conclusions

This interim report finds that using Aetrex Orthotics whilst running significantly increases comfort and speed. Using Aetrex Orthotics also reduces the rate of RRIs. However, this was not significant.

Research perspectives

Further analysis, once recruitment and data collection in this study is complete, is needed to expand on the findings given in this report and provide a full analysis of the cost-benefit of using orthotics for running.

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FOOTNOTES

Author contributions: Fortune AE, Sims JMG, Rhodes SJ, and Ampat G contributed equally to the study; Fortune AE, Sims JMG and Ampat G designed the research study; Sims JMG and Rhodes SJ were involved in recruitment and data collection; Ampat G performed telephone consultations with all participants on enrolment to the study; Fortune AE analysed the data and wrote the manuscript; all authors have read and approved the final manuscript.

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Conflict-of-interest statement: George Ampat, Jonathan M G Sims and Samantha J Rhodes are Directors/employees of Talita Cumi Ltd. Talita Cumi Ltd has a commercial relationship with Aetrex, Inc. 414 Alfred Avenue Teaneck, NJ 07666, USA. Alice E Fortune has no conflict of interest.

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SYSTEMATIC REVIEWS

Clinical and mechanical outcomes in isolated anterior cruciate ligament reconstruction *vs* additional lateral extra-articular tenodesis or anterolateral ligament reconstruction

Nikhil Agarwal, Jaibaji Monketh, Andrea Volpin

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Abstract

BACKGROUND

Anterior cruciate ligament (ACL) reconstruction has been a successful treatment for ACL rupture. However ongoing rotational instability can be an issue. Several surgical techniques have been recommended to overcome this including lateral extra-articular tenodesis (LET) and more recently anterolateral ligament reconstruction (ALLR).

AIM

To compare the clinical outcomes following ACL reconstruction (ACLR) alone or ACLR with either LET or ALLR.

METHODS

A systematic review was conducted by means of four databases (MEDLINE, EMBASE, Cochrane and Clinical.Trials.Gov), and the *Reference Citaion Analysis* (https://www.referencecitationanalysis.com/) to identify all studies investigating either or both of LET and ALLR. The Critical Appraisal Skills Programme checklist for cohort studies was employed for critical appraisal and evaluation of all twenty-four studies which met the inclusion criteria.

RESULTS

Pooled meta-analyses illustrated that ACLR with additional LET or ALLR results in improved pivot shift test scores, compared to isolated ACLR. There was no statistically significant difference in International Knee Documentation Committee (IKDC) clinical scores with addition of either LET or ALLR. ACL re-rupture

rates were compared between LET and ALLR techniques. There was a statistically significant difference between techniques, with a 1.14% rupture rate in ACLR +ALLR, and 4.03% rupture rate in ACLR + LET. Isolated ACLR re-rupture rates were 12.59%, significantly higher than when augmented with either ALLR or LET ($P < 0.0001$ for both groups). There were no statistical differences in pivot shift test or IKDC scores between LET and ALLR techniques.

CONCLUSION

This meta-analysis has found that use of either LET or ALLR in addition to ACLR results in improved mechanical outcomes suggesting surgeons should consider augmenting ACLR with an extra-articular procedure in patients with rotatory instability. Furthermore, both anterolateral extra articular procedures in addition to ACLR lead to reduced ACL re-rupture rates compared to isolated ACLR. Moreover, ALLR results in reduced ACL re-rupture rates, compared to LET. More research is needed to compare the two respective extra-articular procedures.

Key Words: Anterior cruciate ligament; Knee; Systematic review; Lateral extra tenodesis; Anterolateral ligament; Knee surgery

Core Tip: Either lateral extra-articular tenodesis (LET) or anterolateral ligament reconstruction (ALLR) should be utilized with anterior cruciate ligament (ACL) reconstruction (ACLR) in patients with rotational instability, to confer greater stability. Either technique, together with ACLR, leads to superior mechanical outcomes, in comparison to ACLR alone. Both techniques reduce risk of ACL re-rupture, compared to isolated ACLR, with ALLR having lower rates than LET.

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INTRODUCTION

Rupture of the anterior cruciate ligament (ACL) is one of the most common sporting injuries affecting the knee joint. In the United Kingdom, the National Ligament Registry has noted over 15304 cases of ACL rupture between 2012 and 2019[1].

Those with symptomatic instability have traditionally been treated with arthroscopic ACL reconstruction (ACLR). Numerous studies demonstrate excellent short term functional outcomes however some questions remain regarding this treatment[2,3]. ACLR has demonstrated to be effective in restoring translational stability, however the capacity to restore rotational stability is limited[4,5]. Patient reported outcome measures tend to correlate with improvements in translational rather than rotational stability. Moreover, rotational instability has been implicated in the development of knee osteoarthritis. Despite technical improvements, such as single or double bundle reconstructions and more accurate tunnel placement, the rates of positive pivot-shift test remain unacceptably high.

The role of the anterolateral soft tissue restraints (including the anterolateral ligament (ALL)) in rotational stability are increasingly being recognized[6,7]. Historically, several anterolateral extra articular procedures (AEAP) had been developed to tackle anterolateral instability, including lateral extra-articular tenodesis (LET), originally described by Lemaire[8]. There is conflicting evidence in the literature surrounding LET. Some studies have shown that LET provides no additional benefit when performed in combination with ACLR, compared to isolated ACLR[9,10]. Other studies have found that in high-risk patients, such as those with additional laxity, LET results in reduced graft rupture and reduces rotatory laxity[11,12]. More recently, with the newfound understanding of biomechanics and anatomy, another procedure, anterolateral ligament reconstruction (ALLR) has been developed. Biomechanical studies have shown variable restoration of knee kinematics in addition to concerns that the technique may lead to over constraint of the lateral compartment; thus, actually accelerating degenerative changes[13,14].

The aim of this systematic review and meta-analysis was to firstly compare the clinical effectiveness of ACLR combined with LET or ALLR, to ACLR alone. Secondly, to compare the clinical and mechanical outcomes of the two AEAPs discussed.

MATERIALS AND METHODS

Database and inclusion criteria

A systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRSIMA) was conducted[15]. Using the PICO model, inclusion and exclusion criteria were set[16]. Only randomized control trials (RCTs) cohort, cross-sectional studies and case control studies were included. Reviews, conference abstracts, case series, case reports and editorials were excluded. Only studies which investigated either ACL reconstruction with additional ALLR or LET were included. Studies which investigated revision ACLR were excluded. The references of the final studies were checked for any additional studies that would meet the inclusion criteria.

A literature search was carried out by A. N. Four databases were searched for studies which were relevant to this systematic review: MEDLINE (2000 to Week 4 November 2021), EMBASE (2000 to 29 November 2021), Cochrane library (2000 to November 2021) and clinical trials.gov (2000 to November 2021). The *Reference Citaion Analysis* (https://www.referencecitationanalysis.com/) software was also utilized to identify any additional studies.

A comprehensive strategy was developed, upon which the databases were searched. This was designed on the basis of the guidelines provided by the Cochrane Highly Sensitive Search Strategy[17]. This included but was not restricted to the following MeSH terms: "Anterior Cruciate Ligament", or "tenodesis" or "iliotibial band" or "extra articular" and "reconstruction" or "Anterior Cruciate Ligament Reconstruction". Full MeSH terms used can be found in Appendix 1 (Supplementary material). Only *in vivo* studies were included. In addition, it was decided that only studies from 2000 onwards should be included, since studies before this time could be considered outdated, considering the novel developments in orthopaedic surgery. The authors only wanted to examine novel techniques which are currently in use in clinical practice. The overall results of the comprehensive search are shown in Figure 1. The structure of this table was incorporated from Page *et al*[18].

Quality assessment

All studies included in this review were independently appraised by two authors A. N and J. M. The critical appraisal was conducted by the Critical Appraisal Skills Programme (CASP) checklists for randomized controlled trials, cohort studies and case control studies[19]. The appraisals for each RCT can be found in Table 1 and appraisals for cohort studies can be found in Table 2. One study was of case control study design. This was assessed accordingly by the CASP checklist for case control studies. The questions in each of the checklists are listed in Appendix 2 (Supplementary material). Any disagreements were solved by discussion.

Data extraction

The following study characteristics were extracted from each study after full text analysis: study design, number of patients included in the study, country of origin, mean follow up time, type of AEAP investigated, outcomes measured, and year published.

Statistical analysis

All statistical analysis was conducted using JASP (version 0.16, University of Amsterdam). A restricted maximum likelihood random effects model was used to generate a pooled estimate of the odds ratio of an "event" for analysis of post-operative pivot shift test and International Knee Documentation Committee (IKDC) score. I^2 test was used as a measure of between study heterogeneity. The pivot shift test is a validated tool to assess rotatory instability, is highly sensitive and specific for ACL rupture and the presence of a positive results does correlate well with clinical outcomes[20]. The IKDC score has also been shown to have a high criterion validity in assessment of treatment outcome and is widely used [21]. As these two measures could be recorded as categorical variables they were selected for meta-analysis. For the purpose of the analysis and in line with previous published literature we considered a pivot shift test grades 1, 2 or 3 was defined as an event[22]. For the IKDC score an overall grade C (abnormal) or D (severely abnormal) was considered an event. Statistical analysis on categorical data was performed using cross tabulation and Chi squared testing for categorical data, or Fisher's exact test if the sample size did not permit Chi Squared testing. A P value of < 0.05 was considered statistically significant.

RESULTS

Study characteristics

Table 3 displays the study characteristics of all 24 studies encompassed in this review. Most studies were cohort studies, with 6 retrospective, 5 prospective and 2 matched cohort studies (n = 2). Ten studies were RCTs. One study was a case control study.

Table 1 Critical appraisal of randomised control trials, using Critical Appraisal Skills Programme checklist for randomised control trials, *n* = 10

Ref.	Q1	Q2	Q3	Q4a	Q4b	Q4c	Q5	Q6	Q7	Q8	Q9	Q10	Q11
Chiba *et al*[23]	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Getgood *et al*[12]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hamido *et al*[39]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ibrahim *et al*[40]	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Mogoş *et al*[24]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Porter *et al*[41]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sonnery-Cottet *et al*[25]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stensbirk *et al*[42]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trichine *et al*[43]	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Vadalà *et al*[44]	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 2 Critical appraisal of cohort studies, using Critical Appraisal Skills Programme checklist for cohort studies, *n* = 13: Questions 7, 8 and 12 were left out of the table due to the fact they are not yes/no questions

Ref.	Q1	Q2	Q3	Q4	Q5a	Q5b	Q6a	Q6b	Q9	Q10	Q11
Ahn *et al*[45]	Yes	Yes	Yes	Yes	No	Can't tell	Yes	Yes	Yes	Yes	Yes
Dejour *et al*[46]	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	No	Yes	Yes	Yes
Erden *et al*[47]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Ferretti *et al*[33]	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Giraud *et al*[48]	Yes	Yes	Yes	Yes	No	Can't tell	Yes	No	Yes	Yes	Yes
Goncharov *et al*[49]	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes
Lee *et al*[50]	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	No	Yes	Yes	Yes
Mahmoud *et al*[11]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Rowan *et al*[51]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Sonnery-Cottet *et al*[52]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Sonnery-Cottet *et al*[53]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Sonnery-Cottet *et al*[36]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ventura *et al*[54]	Yes	Yes	Yes	Yes	No	Can't tell	Yes	Yes	Yes	Yes	Yes

Thirteen studies compared ACLR to ACLR + LET. The remaining 11 were studies which compared ACLR to ACLR + ALLR.

The most common range of follow up times was 37-60 mo (*n* = 7). Six studies had a follow up time between 13 and 24 mo. Only 5 of studies used follow up times greater than 60 mo. Thirteen of the studies included in this review, had a follow up duration time less than 37 mo.

Upon critical appraisal of the studies included in this review, using the appropriate CASP tools, it was established that very few RCTs included in this review were blinded. This was however, recognized by most studies, who considered it unfeasible to blind the patients, and impractical to blind the surgeons. Some of the cohort studies included in this review did not account for or did not mention confounding variables, which could have led to unforeseen biases. Three of the studies also were deemed to have short follow up (< 24 mo). While it was recognized the reliably of the meta-analysis would be improved by only including studies with longer follow up (> 24 mo), it was the consensus of the authors that the large number of patients and the overall quality of the studies meant the data present in these three studies would add robustness to the meta-analysis as such they were included[23-25]. Overall, the quality of all studies included in this review was high. Tables 1 and 2 demonstrate the full methodological quality assessment of the included studies.

Table 3 Characteristics of the studies included in the review, *n* = 24

Study characteristic	*n* (%)
Study design	
Randomised controlled trial	10 (42)
Prospective cohort study	5 (21)
Retrospective cohort study	6 (25)
Matched cohort study	2 (8)
Case control study	1 (4)
Country of origin	
France	6 (25)
Italy	4 (17)
Australia	2 (8)
South Korea	2 (8)
United States	1 (4)
Kuwait	2 (8)
Turkey	1 (4)
United Kingdom	1 (4)
Brazil	1 (4)
Russia	1 (4)
Canada	1 (4)
Denmark	1 (4)
Algeria	1 (4)
Year published	
2006	1 (4)
2012	1 (4)
2013	1 (4)
2014	2 (8)
2016	1 (4)
2017	2 (8)
2018	1 (8)
2019	4 (17)
2020	4 (17)
2021	7 (29)
Number of patients	
< 50	2 (8)
50-100	10 (42)
100-250	8 (33)
250-500	2 (8)
> 500	2 (8)
Mean follow-up time	
1-12 mo	2 (8)
13 -24 mo	6 (25)
25-36 mo	4 (17)

37-60 mo	7 (29)
61-120 mo	4 (17)
> 120 mo	1 (4)
Type of AEAP	
LET	13 (54)
ALLR	11 (46)

AEAP: Anterolateral extra articular procedures; LET: Lateral extra articular tenodesis; ALLR: Anterolateral ligament reconstruction.

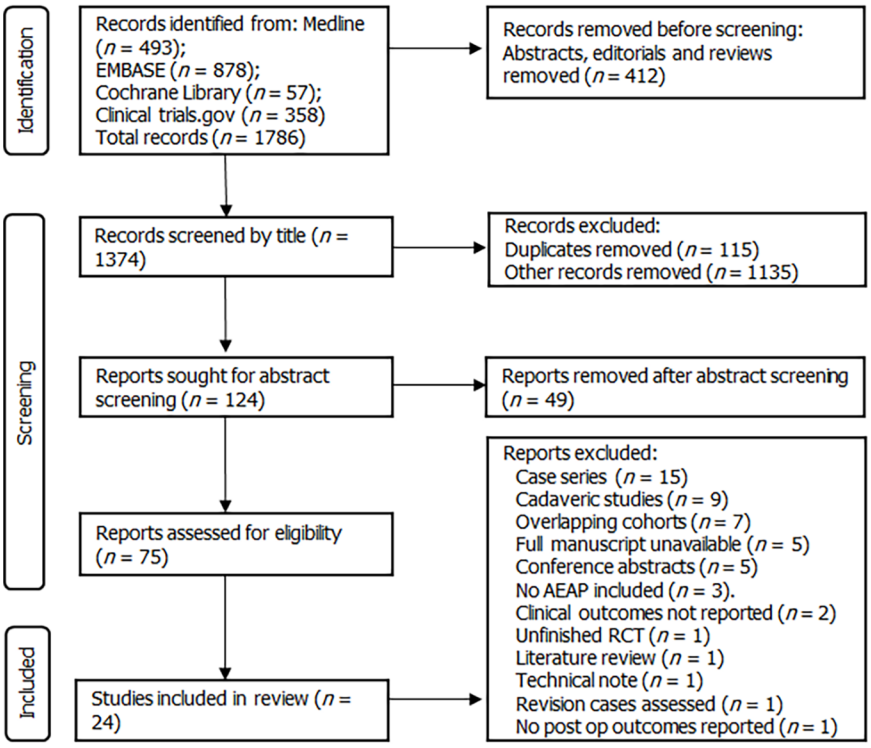

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Figure 1 Results from the comprehensive literature search.

Clinical outcomes

Table 4 summarizes the main characteristics of all the studies included in this systematic review.

Forest plots were created to analyze clinical and mechanical outcomes most utilized by all studies in ACLR only patient groups *vs* ACLR + AEAP patient groups (Figure 2).

Figure 2A shows analysis of all nine studies which used pivot shift test scores to analyze mechanical outcomes in ACLR only patient groups *vs* ACLR + AEAP patient groups. The nine studies that could be used in analysis encompassed 961 knees. Six of the nine studies demonstrated a statistically significant difference in pivot shift test scores between ACLR only patient groups and ACLR + AEAP patient groups. The pooled estimates of odds ratio were -1.54 (95%CI -2.02 to -1.06, $P < 0.001$) in favor of ACLR + AEAP. This suggests that the addition of AEAP to ACLR results in statistically significantly better pivot shift test scores and therefore greater rotational stability.

Comparison of clinical outcomes between ACLR only and ACLR + AEAP patient groups was conducted using IKDC scores. Five studies were eligible for pooled analysis, which encompassed 878 knees (Figure 2B). There was no statistically significant difference in IKDC scores between the ACLR only and ACLR + AEAP patient groups in any of the five studies. The pooled estimates of log ratio were -0.34 (95%CI -1.04 to 0.37). This demonstrated that the addition of AEAP to ACLR did not result in any statistically significant improvement in IKDC clinical scores ($Z = -0.938$, $P = 0.348$).

Following statistical analysis of ACLR alone *vs* ACLR + AEAP, analysis was then conducted to determine whether there was a difference in clinical and mechanical outcomes between the two AEAPs included: LET and ALLR. The chi squared test was performed which demonstrated that there was no statistically significant difference in pivot shift tests between ACLR + LET and ACLR + ALLR groups ($P = 0.39$). The chi squared test also showed that there was no statistically significant difference in IKDC

Table 4 Main characteristics of studies included in this systematic review, *n* = 24

Ref.	Design of study	AEAP used	Number of patients involved	Mean follow up	Outcome measures used	Technique favoured
Ahn *et al*[45]	Retrospective cohort study	LET	171	49.7 ± 5.7 mo	IKDC, KL grade, graft maturation score and revision rates	ACLR with LET favoured over ACLR alone
Chiba *et al*[23]	RCT	LET	18	12 mo	Anterior tibial translation, KOOS, tibial rotation relative to the femur	ACLR with LET is not superior to ACLR alone
Dejour *et al*[46]	Prospective cohort study	LET	75	25 mo	Anterior tibial translation, IKDC, pivot shift grading	ACLR with LET favoured over ACLR alone
Erden *et al*[47]	Retrospective cohort study	ALLR	63	24 mo	Cincinnati knee score, IKDC, Lysholm scores, graft rupture rate, anterior tibial translation, pivot shift test	ACLR with ALLR is not superior to ACLR alone
Ferretti *et al*[33]	Retrospective cohort study	LET	140	120 mo	Lysholm score, IKDC, Tegner score, anterior tibial translation	ACLR with LET favoured over ACLR alone
Getgood *et al*[12]	RCT	LET	618	24 mo	P4, KOOS, Marx Activity Rating scale, IKDC, ACL QOL	ACLR with LET favoured over ACLR alone
Giraud *et al*[48]	Prospective cohort study	LET	63	84 mo	IKDC, anterior tibial translation, radiological medial and lateral compartment laxity	ACLR with LET is not superior to ACLR alone
Goncharov *et al*[49]	Prospective cohort study	ALLR	50	24 mo	Tegner Lysholm score, IKDC, Lachmann test, Pivot shift test	ACLR with ALLR is not superior to ACLR alone
Hamido *et al*[39]	RCT	ALLR	107	60 mo	IKDC, anterior tibial translation, Tegner score, Lysholm score	ACLR with ALLR favoured over ACLR alone
Helito *et al*[55]	Case control study	ALLR	90	29.6 ± 6.2 mo for group 1; 28.1 ± mo for group 2	Anterior tibial translation, IKDC, Lysholm, Tegner score Pivot shift test, rupture rates	ACLR with ALLR favoured over ACLR alone
Ibrahim *et al*[40]	RCT	ALLR	103	27 mo	Anterior tibial translation, IKDC, Lysholm score, Tegner score, Pivot shift test	ACLR with ALLR is not superior to ACLR alone
Lee *et al*[50]	Retrospective cohort study	ALLR	87	36 mo	ACL-RSI, Anterior tibial translation, IKDC, Lysholm score, Tegner score	ACLR with ALLR is not superior to ACLR alone
Mahmoud *et al*[11]	Matched cohort study	LET	144	120 mo	IKDC, Lysholm score, OKS, Tegner score	ACLR with LET favoured over ACLR alone
Mogoş *et al*[24]	RCT	ALLR	57	12 mo	IKDC, Lysholm score, Pivot shift test, Rolimeter test, Tegner score	ACLR with ALLR favoured over ACLR alone
Porter *et al*[41]	RCT	LET	55	24 mo	IKDC, Lysholm score, KOOS, Tegner score	ACLR with LET favoured over ACLR alone
Rowan *et al*[51]	Prospective cohort study	LET	273	52 mo	Lysholm score, Tegner score	ACLR with LET favoured over ACLR alone
Sonnery-Cottet *et al*[52]	Prospective cohort study	ALLR	502	38.4 ± 8.5 mo	IKDC, Lysholm score, Side to side laxity, Tegner score	ACLR with ALLR favoured over ACLR alone
Sonnery-Cottet *et al*[53]	Retrospective cohort study	ALLR	383	37.4 mo	Lysholm score, Side to side laxity, Tegner score	ACLR with ALLR favoured over ACLR alone
Sonnery-Cottet *et al*[25]	RCT	ALLR	224	12.3 ± 1.9 mo	IKDC, Lysholm score, KOOS, Range of motion, Tegner score	ACLR with ALLR favoured over ACLR alone

Sonnery-Cottet *et al*[36]	Matched cohort study	ALLR	172	104.33 ± 3.74 mo	IKDC, Lysholm score, KOOS, Side to side laxity, Tegner score	ACLR with ALLR favoured over ACLR alone
Stensbirk *et al* [42]	RCT	LET	60	180 mo	AKP questionnaire, Lysholm score, Tegner score	ACLR with LET is not superior to ACLR alone
Trichine *et al*[43]	Single blinded RCT	LET	120	24 mo	IKDC, Objective laxity	Inconclusive
Vadalà *et al*[44]	RCT	LET	60	44.6 mo	Anterior tibial translation, IKDC, Lysholm score, Tegner score, VAS	ACLR with LET favoured over ACLR only
Ventura *et al*[54]	Retrospective cohort study	LET	24	54 mo	Anterior tibial translation, IKDC, Lysholm score, Tegner score	ACLR with LET favoured over ACLR alone

AEAP: Anterolateral extra articular procedures; ACL-RSI: Anterior cruciate ligament – return to sport after injury; ALLR: Anterolateral ligament reconstruction; AKP: Anterior knee pain; IKDC: International Knee Documentation Committee; KOOS: Knee injury and Osteoarthritis Outcome Score; LET: Lateral extra articular tenodesis; OKS: Oxford Knee Score; RCT: Randomised controlled trial; VAS: Visual analogue scale.

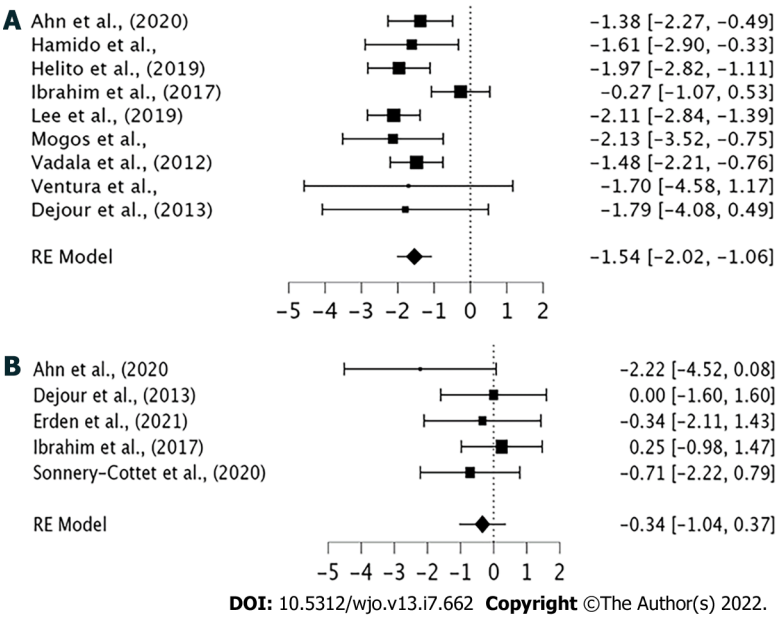

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Figure 2 Forest plot. A: The effect size of pivot shift test scores in patients who underwent anterolateral extra articular procedures (AEAP) in addition to anterior cruciate ligament reconstruction (ACLR), compared to ACLR alone. I^2 = 47.192; B: The effect size of International Knee Documentation Committee scores in patients who underwent AEAP in addition to ACLR, compared to ACLR alone. I^2 = 6.432e-6. RE: Random effects.

scores between ACLR + LET and ACLR + ALLR groups (P = 0.90). This indicates that there are no differences in rotational stability or clinical outcomes with regards to the specific AEAP (LET or ALLR) utilized with ACLR.

ACL re rupture rates were also compared between ACLR + LET and ACLR + ALLR techniques. There was a statistically significant difference between techniques, with a 1.14% re rupture rate in ACLR + ALLR, and 4.03% re rupture rate in ACLR + LET (P = 0.015). This indicated that ACL re-rupture rates were higher in ACLR + LET compared ACLR + ALLR. The re-rupture rate for ACLR alone across all studies was 12.59%, significantly higher than when augmented with either ALLR or LET (P < 0.0001 for both groups).

DISCUSSION

ACLR has shown excellent results in restoring translational stability. The capacity to restore rotational stability, however, remains an issue. This review has focused on the clinical and mechanical outcomes which follow treatment of primary ACL injuries with AEAPs, in addition to ACLR. The supplementation of an AEAP does appear to improve mechanical outcomes compared to ACLR alone. This suggests that patients with rotatory instability should be offered an AEAP with the ACLR

reconstruction. However, there appears to be no difference in mechanical outcomes between AEAPs, which suggests that either LET or ALLR can be used with ACLR to reduce rotational instability. Our results did not show any benefits in clinical outcomes with the addition of AEAP to ACLR. An important consideration to note is that, since we have demonstrated there may not necessarily be direct clinical benefit in all patients, the challenge will be to identify patients where the risk-benefit analysis would favour AEAP. Both LET and ALLR can cause issue over constraint with poor graft placement which may worsen patient outcomes.

The most common mechanical outcome measured in the studies included in this review was the pivot shift test scores. Other mechanical outcomes investigated by studies included; KT 1000/-2000 arthrometry side to side laxity, anterior tibial translation, Lachmann test, Rolimeter test scores and radiological medial and lateral compartment laxities. Analysis of instability using the latter techniques mentioned was not conducted due to the inconsistent use of these scoring systems between studies, and the small number of studies which employed each. The combined analyses of pivot shift test scores demonstrated that use of AEAP in addition to ACLR results in better pivot shift test scores, compared to ACLR alone. However, upon comparison of the ACLR + LET *vs* ACLR + ALLR there is no statistically significant difference in mechanical outcomes between these two groups. This suggests that though ACLR + AEAPs confers greater rotational stability than ACLR alone, neither technique confers more rotational stability than the other.

Studies have shown that poorer pivot shift test scores correlate to poorer clinical outcomes and patient satisfaction following ACLR[26,27]. Moreover, recent cadaveric studies have demonstrated that ACLR alone does not restore normal knee kinematics, and that an AEAP is required to restore anterior tibial translation and tibiofemoral motion[28,29].

The most common clinical outcome utilized by studies was IKDC scores. Other clinical scores used were: Lysholm score, Tegner score, KOOS score and Cincinnati knee score. Analysis of clinical outcomes, using these latter scoring systems was not conducted due to the small number of studies which employed each one. The pooled analyses of the IKDC scores demonstrated that use of an AEAP with ACLR does not result in any statistical improvements in outcomes. There are several possibilities for this. There may be a ceiling effect to IKDC score making it insensitive in detecting improvements in rotatory stability. We also utilized overall scores and dichotomized the outcomes; this may have also reduced the sensitivity of the analysis.

When directly comparing ALLR with LET, re-rupture rates were higher with LET (1.14% *vs* 4.03%, $P = 0.015$). The re-rupture rate for ACLR alone across all studies was 12.59%, significantly higher than when augmented with either ALLR or LET ($P < 0.0001$ for both groups). Studies that evaluated ACLR + LET were then compared with studies which assessed ACLR + ALLR. Direct analysis shows that ACL re-rupture rates were higher in ACLR + LET than with ACLR + ALLR. This suggests that LET techniques have a higher ACL re rupture rate. However, existing literature suggests that ACL re-rupture rates are higher in ACLR alone compared with ACLR with AEAPs. A study conducted by Marom *et al*[30], found that the addition of LET to ACLR reduces stress on the graft, by transferring loads to the LET. In addition, this reduces anterior tibial translation when pivoting loads are applied [30]. The reduced strain on the graft would explain why AEAPs lead to reduced re-rupture rates.

There were no studies in the literature which directly compared LET with ALLR. This is understandable given the recent growing interest in ALLR. Certainly, randomized controlled trials are required to assess the two techniques. As ALLR becomes more common practice in the future this will likely become feasible. Ra *et al*[31] did compare the studies using ACLR + LET with ACLR + ALLR in 2020. Their meta-analysis of non-comparative could not demonstrate a significant difference in rotational stability between ALLR and LET.

There are risks associated with LET procedure. LET is a non-anatomical reconstructive procedure potentially giving it inherent disadvantages over ALLR. While there is evidence to suggest it does help restore normal knee kinematics following ACL injury, there are concerns in the literature that the knee may become over constrained[28,32]. Biomechanical studies have investigated the effects of over constraining[28,32]. Several studies reporting on LET have recommended the graft be fixed with the knee in extension. This could interfere with the "screw home" mechanism of the knee by acting as a restraint to tibial internal rotation[28]. Tibiofemoral contact pressures could increase, thus accelerating the development of osteoarthritis. In addition, this would increase tensile forces the knee is subjected to through the action of the extensor mechanism, potentially increasing the risk of graft rupture. This could explain why our date shows increased risk of graft rupture in LET compared to ALLR. However, these same studies have noted that if the graft is tensioned in neutral, risk of overstraining decreases and there is little risk of accelerated osteoarthritis[28,32]. The study by Ferretti *et al*[33] demonstrated that at a 10 year follow up, ACLR with LET did not result in increased osteoarthritic rates. This perhaps underscores the importance of sound surgical technique, as more experience is gained with LET, we may see improved outcomes with respect to over constraining of the lateral compartment. Longer term follow-up studies are needed to examine the risk of osteoarthritis further.

Similar concerns have been voiced for ALLR techniques. A recent cadaveric study demonstrated that over constraining is possible with ALLR[34]. A separate study by Neri *et al*[35] illustrated that ALLR does not lead to increased contact pressures in the lateral compartment. Sonnery-Cottet *et al*[36] commented that they considered the reason that ALLR avoids over constraint is because the grafts are

fixed such that they behave an isometrically. In their technique they identify an isometric point close to the lateral femoral condyle. This point is drilled in an outside-in technique. The tunnel is used for both the ACL reconstruction and ALLR. Once the ACL reconstruction is completed the remaining strand of the graft is used to complete the ALLR by tunnelling it under the ilio-tibial band but superficial to the fibular collateral ligament. The graft is then passed though the tibial tunnel and then brought back proximally towards the femur. This creates an inverted Y shaped acting as a double bundle graft. Whether this behaves isometrically has yet to be proven.

LET is also associated with donor site cosmesis problems[37,38]. It is possible this can be overcome with new minimally invasive techniques which involve tunnelling the grafts deeper.

The strengths of this review include the breadth of studies included. Studies from 13 countries were included in this review. Multiple languages were included, meaning we were less likely to miss relevant datasets. To the best of our knowledge this first meta-analysis to include randomized control studies and case-control studies ALLR with ACLR and the largest to include ALLR.

There were limitations to this review. There was significant heterogeneity amongst the studies included in this review, and thus several studies could not be included in the pooled analysis. This is a common problem encountered when attempting to conduct a meta-analysis. Moreover, there was a wide variation in the techniques used for each procedure of ACLR, ALLR and LET. Regarding extra articular procedures, no consensus has been reached regarding the optimal graft type, location of fixation or the fixation angle.

Another limitation was that only studies conducted after 2000 were included in this review. The reason for this was we wanted to examine novel techniques that were currently in use. However, we acknowledge that this may bias the outcomes of this review. Moreover, this analysis did not search the grey literature, and so there are potentially other studies which are relevant but were not included in this review.

There were also limitations of the studies included in this review. The mean follow duration was 50.8 mo across all studies. The mean follow-up for LET studies was 62.2 mo, compared with 36.8 mo for ALLR. As a result, these studies could not effectively compare rates of osteoarthritis between techniques. Though as previously mentioned, Ferretti *et al*[33] which conducted a 10-year follow up study, found no increases in osteoarthritic rates with ACLR with LET. Since ALLR is a relatively new technique, it is possible that more studies with longer follow up times may be available over the coming years. While it was recognized the reliably of the meta-analysis would be improved by only including studies with longer follow up (> 24 mo). We did include three studies that had a mean follow up period of approximately 12 mo[23-25]. It was the consensus of the authors that the large number of patients and the overall quality of the studies meant the data present in these two studies would add robustness to the meta-analysis as such they were included. The authors also felt it would be of value to the reader for the review to be more comprehensive to make the reader aware of the breadth of evidence available on the subject matter. This strengthened the consensus for the inclusion of these studies.

CONCLUSION

The addition of AEAPs to primary ACLR appears to result in improved rates of rotatory stability when comparing pivot shift test results, however it remains unclear whether this translates to improved functional outcomes. Our results suggest that surgeons should consider offering AEAPs in patients with rotatory instability following ACL rupture. More work is needed to identify patients who would benefit most. Both techniques appear to result in reduced rates of graft failure, compared to isolated ACLR, though ALLR has lower re-rupture rates than LET. Mechanical outcomes appear equivocal between the two AEAPs. A randomized controlled trial comparing the two techniques would be of value.

ARTICLE HIGHLIGHTS

Research background

Anterior cruciate ligament (ACL) reconstruction surgery has shown excellent outcomes, however the restoration of rotational stability remains limited. The role of the reconstruction of the lateral soft tissue restraints or the supplement of the ACL reconstruction with a lateral extra-articular tenodesis have gain popularity and they are now routinely procedures following an ACL reconstruction.

Research motivation

The research motivation of this systematic review and meta-analysis was to clarify how ACL reconstruction surgery combined with lateral extra-articular tenodesis (LET) or anterolateral ligament reconstruction (ALLR) can improve rotational stability and how this can prevent possible failure and instability symptoms.

Research objectives

The aim of this review article was to compare the clinical effectiveness of ACL reconstruction surgery combined with LET or ALLR to ACLR alone.

Research methods

A systematic review to include all the studies investigation either or both of LET and ALLR was conducted. A literature search was carried out on 4 databases for studies from 2000 to November 2021. All studies included in this review were independently appraised by two authors. The critical appraisal was conducted by the Critical Appraisal Skills Programme. Statistical analysis was performed on the collected data.

Research results

Thirteen studies compared ACLR to ACLR + LET. The remaining eleven were studies which compared ACLR to ACLR + ALLR.The nine studies that could be used in analysis encompassed 961 knees. Six of the nine studies demonstrated a statistically significant difference in pivot shift test scores between ACLR only patient groups and ACLR + AEAP patient groups.

Research conclusions

This systematic review has demonstrated that the use of either LET or ALLR in addition to ACLR results in improved mechanical outcomes suggesting surgeons should consider augmenting ACLR with an extra-articular procedure in patients with rotatory instability.

Research perspectives

A randomized controlled trial comparing the two techniques would be of value for clarifying which technique would give the better outcomes regarding the rotational stability following an ACL reconstruction surgery.

FOOTNOTES

Author contributions: Monketh J and Agarwal N analyzed the data and wrote the manuscript; Volpin A designed the research study and reviewed the manuscript; and All authors have read and approve the final manuscript.

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LETTER TO THE EDITOR

Risk of methicillin-resistant *Staphylococcus aureus* prosthetic joint infection in elective total hip and knee arthroplasty following eradication therapy

Jayaweera Arachchige Asela Sampath Jayaweera

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Abstract

Re-screening following methicillin-resistant *Staphylococcus aureus* (MRSA) decolonization will be helpful to minimize the development of prosthetic joint infection among MRSA colonizers.

Key Words: Methicillin-resistant *Staphylococcus aureus* colonization; MRSA decolonization; Prosthetic joint implantation; Prosthetic joint infections

Core Tip: Patients with methicillin-resistant *Staphylococcus aureus* (MRSA) colonization have a high risk of contracting prosthetic joint infections, and MRSA screening and decolonization are essential to minimize the development of prosthetic joint infection. However, studies showed that re-screening following MRSA decolonization is important before planned prosthetic joint surgery to minimize infections.

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TO THE EDITOR

I read the important retrospective study by Kapur *et al*[1] on the risk of methicillin-resistant *Staphylococcus aureus* (MRSA) prosthetic joint infection in elective total hip and knee arthroplasty following eradication therapy. MRSA is a virulent pathogen that causes infections among healthy and immunocompromised individuals. The spectrum of MRSA infection varies from cellulitis, necrotizing fasciitis, bone and joint infections, bacteremia, and infective endocarditis to pneumonia[2].

That article provides a crucial insight into the importance of screening and re-screening following eradication of MRSA prior to prosthetic joint implant in orthopedic surgery. The authors have compared the incidence of prosthetic joint infection (PJI) among MRSA colonizers and non-colonizers, and following follow-up, found that PJI risk is high among MRSA colonizers. As we know, the associated financial burden following PJI is substantial.

The authors have mentioned the method of MRSA decolonization and some practice instead of prontoderm nasal spray and octenisan for 4% chlorhexidine and mupirocin ointment. The IDSA guidelines explain the importance of the latter regime, but different formulae have similar decolonization ability and differ in cost as the latter is cheaper[3]. Use of povidone-iodine and rifampin has shown efficient and low cost MRSA decolonization. Simor *et al*[4] showed that the use of topical germicide and antibiotic plus oral agents and rifampin achieved a 92% eradication rate for MRSA. Moreover, the duration of decolonization was given as 5-10 d of mupirocin and 5-14 d of 4% chlorhexidine body wash. Here the authors have discussed the mupirocin use.

The authors mentioned the use of teicoplanin prophylaxis among MRSA positive patients. In emergency surgery, the advice is to provide vancomycin or teicoplanin prophylactically while replacing cefuroxime. However, routine use of anti-MRSA antibiotic prophylaxis for MRSA positives following decolonization is questionable. The expectation would be to minimize the occurrence of MRSA bacteremia. Most studies have discussed the failure of the MRSA decolonization procedure. Almost all prosthetic joint implantation is done as a planned procedure; this would signify the importance of employing the re-screening strategy following decolonization prior to the surgery[5].

A study conducted by Garvey *et al*[6] showed the possibility of having MRSA colonization following decolonization. Following repeated decolonization, the MRSA colonization has been reduced from 7.2% to 4.7%. Several methods were employed by different research groups for MRSA screening. In addition to molecular methods, the use of chromogenic agar is also costly, but the use of mannitol salt agar and swabs into 7.5% NaCl in brain-heart infusion broth and phenotypic detection including tube and slide coagulase testing is cost effective to isolate MRSA[2]. Over the period, I have seen many patients with repeated MRSA colonization following MRSA decolonization. However, almost all isolates were mupirocin susceptible. Therefore, it may be associated with a lack of compliance and a lack of highlighting the importance of decolonization to the patient or the family. Since most patients are morbid and probably have mobility problems, adherence to a 5-d regular body wash and nasal spraying is questionable[7].

The authors have highlighted the importance of re-screening while relating the financial and social burden following PJI. Another thing is that, if possible, re-screening following MRSA eradication would minimize the prophylactic use of teicoplanin.

Re-screening following MRSA decolonization will be helpful to minimize the development of PJI among MRSA colonizers.

FOOTNOTES

Author contributions: Sampath Jayaweera JAA designed the study, analyzed the data, and wrote the manuscript.

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