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ABOUT COVER

Editorial Board Member of *World Journal of Orthopedics*, Maciej Płaszewski, MEd, PT, PhD, is a university professor and Head of the Department of Rehabilitation, Faculty in Biała Podlaska, Józef Piłsudski University of Physical Education, Warsaw, Poland. He has a background in physiotherapy and health policy, and also in physical education and occupational therapy. His research interests are primarily focused on evidence-based practice, secondary research and research synthesis methods. He has been engaged in research synthesis studies addressing management and recommendations for school screening and treatment interventions for people with idiopathic scoliosis, as well as other, especially physiotherapeutic, interventions, including physical modalities and pulmonary physiotherapy. Currently, he is leading an international project from the Polish Ministry of Science and Higher Education, focusing on the implementation and dissemination of evidence-based physiotherapy practice in Poland. (L-Editor: Filipodia)

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Anterior glenohumeral instability: Current review with technical pearls and pitfalls of arthroscopic soft-tissue stabilization

John M Apostolakos, Joshua Wright-Chisem, Lawrence V Gulotta, Samuel A Taylor, Joshua S Dines

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Abstract

The glenohumeral joint (GHJ) allows for a wide range of motion, but is also particularly vulnerable to episodes of instability. Anterior GHJ instability is especially frequent among young, athletic populations during contact sporting events. Many first time dislocators can be managed non-operatively with a period of immobilization and rehabilitation, however certain patient populations are at higher risk for recurrent instability and may require surgical intervention for adequate stabilization. Determination of the optimal treatment strategy should be made on a case-by-case basis while weighing both patient specific factors and injury patterns (*i.e.*, bone loss). The purpose of this review is to describe the relevant anatomical stabilizers of the GHJ, risk factors for recurrent instability including bony lesions, indications for arthroscopic *vs* open surgical management, clinical history and physical examination techniques, imaging modalities, and pearls/pitfalls of arthroscopic soft-tissue stabilization for anterior glenohumeral instability.

Key Words: Arthroscopic; Soft-tissue; Anterior instability; Glenohumeral; Functional anatomy; Recurrent instability

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Core Tip: Management of the patient with anterior shoulder instability is a common yet complex condition for the orthopaedic clinician. To optimize the evaluation and management of these patients the clinician must ensure a detailed and thorough clinical and radiographic workup, have a thorough understanding of the dynamic, static, and bony stabilizers of the glenohumeral joint, and understand the common causes of failed surgical intervention in order to address these concerns when appropriate. This review describes the current evidence on anterior glenohumeral instability including functional anatomy, risk factors for recurrent instability, clinical history and physical examination techniques, imaging modalities, and operative pearls and pitfalls.

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INTRODUCTION

The unique structure of the glenohumeral joint (GHJ) allows for a wide range of motion, but also makes the joint particularly vulnerable to episodes of instability[1]. Anterior instability is the most common form, accounting for 80%-98% of all GHJ instability events among young, athletic populations particularly during contact sporting events with the shoulder in the abducted and externally rotated position [2-10]. In 2018, the MOON Shoulder Instability Study reported on the descriptive epidemiology of 863 patients who underwent surgical intervention for GHJ instability[11]. They found the mean age for the cohort was 24 years with males representing 82% of all patients. The primary direction of instability was most commonly anterior for male (74%) and female (73%) patients with football (24%) and basketball (13%) the most common sports during which the injury occurred. The etiology of instability events ranges from ligamentous laxity to traumatic dislocation events, with the latter being the most common with an overall incidence of 1.7% [7,12].

Many first time dislocators can be managed non-operatively with a period of immobilization and rehabilitation, however, certain patient populations are at higher risk for recurrent instability which can lead to substantial time loss from active participation/training and may require surgical intervention for adequate stabilization[4,13,14]. Operative techniques aimed at addressing GHJ instability are variable and range from arthroscopic soft-tissue stabilization, open soft-tissue stabilization, as well as techniques aimed at addressing bone loss such as the Latarjet procedure, autologous bone graft transfer, and allograft bone transfers. Determination of the optimal treatment strategy should be made on a case-by-case basis while weighing patient specific factors such as age, activity/sport/working status, goals, and previous history of instability events. Additionally, injury specific factors should also be considered such as acuity of injury and the degree of bone loss which will be discussed in more detail later in this text.

The purpose of this review is to describe the relevant anatomical stabilizers of the GHJ, risk factors for recurrent instability including bony lesions, indications for arthroscopic *vs* open surgical management, clinical history and physical examination techniques, imaging modalities, and pearls/pitfalls of arthroscopic soft-tissue stabilization for anterior glenohumeral instability.

FUNCTIONAL ANATOMY

GHJ stability is provided through a complex interplay of passive and dynamic stabilizers[1,15-19]. Passive stabilizers include the rotator interval [superior glenohumeral ligament (SGHL), coracohumeral ligament, and joint capsule], the middle glenohumeral ligament (MGHL), and most importantly the inferior glenohumeral ligament complex (IGHL)[20]. The glenoid labrum runs circumferentially along the glenoid rim and serves as the point of insertion for all of the GH ligaments[1]. The SGHL prevents inferior translation of the adducted shoulder, the MGHL resists anterior translation in the externally rotated shoulder in abduction up to 45 degrees, and the IGHL can be broken down into the anterior band which is the major restraint to anteroinferior translation in external rotation with abduction > 45 degrees and the posterior band which resists posterior translation in the flexed and internally rotated shoulder[1,20-25]. The labrum deepens the glenoid socket and acts as a physiologic bumper to prevent GHJ instability[1]. Furthermore, the fibrocartilaginous labrum which circumferentially surrounds the glenoid and provides stabilization to the GHJ is tight in its anteroinferior attachment and loose in the superior attachment with a great deal of anatomic variation[1,21]. Acting in accordance with these

ligamentous and capsular stabilizers are surrounding muscles providing dynamic stabilization which include the deltoid, biceps brachii, and the rotator cuff muscles. The basis for dynamic stability is the theory that instability occurs at end-range positions which place the GHJ at its maximum vulnerability in regards to dislocation. Muscular activity acts to compress the humeral head against the center of the glenoid fossa thereby stabilizing during these end-range motions[15,17-19,26].

While there are several ligamentous and muscular components to stability, the glenoid and humeral head add an additional osseous component for stabilization. Therefore, in the evaluation of GHJ instability a proper understanding of the bony anatomy and pathoanatomy is critical to determine an accurate diagnosis and treatment plan. When considering the size of the glenoid in comparison to the humeral head it is clear that even a small bony lesion can lead to significant instability by altering the bony articulation of the glenoid and humeral head[21,27-29]. The glenoid is a pear shaped bone which is widest in the inferior half and is tilted anteriorly[1,26]. Wide variability in the size and inclination of the glenoid make bony lesions related to instability especially challenging to treat. The articulation between the glenoid and humeral head is important to consider in the patient with recurrent anterior instability. Burkhart and Danaceau[30] described the “articular arc” between these bones and determined that defects in this arc could lead to engaging lesions and instability events.

A proper understanding of the anatomy related to the GHJ is critical to properly evaluate, diagnose, and treat anterior GHJ instability. The surgeon needs to have a precise understanding of both the normal and variant anatomy of the capsulolabral complex as well as the dynamic muscular stabilizers to properly evaluate and surgically manage injury. Additionally, an understanding of the bony anatomy of the glenoid and humeral head come into play as the clinician needs to thoroughly evaluate and manage these defects. These challenges will be described further in later sections of this text.

RISK FACTORS FOR RECURRENT GLENOHUMERAL INSTABILITY

Although GHJ instability is considered a relatively common event in young athletes and physically active patient populations, oftentimes first-time dislocators can be effectively managed non-operatively [3-6,31]. However, several proposed risk factors associated with recurrent instability events have been described. Of these reported risk factors, the most closely associated with recurrence include a history of instability events, age at the time of initial injury, contact sports, overhead athletes, and those with ligamentous laxity[4,7,21,32-36]. In addition, the most challenging injuries to treat are those with concomitant bony pathologies. During an anterior GHJ instability event there can be bony injury to the glenoid (referred to as a bony Bankart lesion), the humeral head (referred to as a Hill-Sachs lesions), or to both structures (bipolar lesions). Several studies have reported on the relationship between GHJ instability and bony deficits with recurrent instability rates in correlation with the size of the bony lesion [34,37]. In the past these injuries were managed with isolated soft tissue repairs, however growing evidence of recurrent instability raised questions as to the appropriate management of these injuries. An investigation performed by Burkhart *et al*[29] reported on 194 consecutive arthroscopic Bankart cases and found recurrence rates of 4% in those without significant bone defects as compared to 67% in those with humeral and/or glenoid lesions. These findings added evidence to the recurrent instability in those with untreated bony lesions and increased the awareness and treatment of these pathologies. In the management of patients with anterior GHJ instability it is important to think about the bony risk factors for recurrent instability and to modify these risk factors when possible to improve clinical results. Some of these potential risk factors related to bony defects have been researched in the literature and include.

Glenoid defects: The bony Bankart

Glenoid lesions have been reported to occur in 22%-41% of first time dislocation events and up to 86% of recurrent events[28,32,38,39]. Bony Bankart lesions occur during anterior GHJ instability as the dislocation of the humeral head creates a bony lesion on the anteroinferior aspect of the glenoid in addition to avulsion of the anteroinferior labrum. Burkhart *et al*[29] described the normal glenoid to appear pear shaped with a wider diameter in the inferior aspect as compared to the superior aspect. They went on to describe the “inverted pear” phenomenon which was in reference to the pathologic appearance of the glenoid resulting from a bony Bankart injury where the superior aspect of the glenoid appeared wider in diameter as compared to the inferior aspect. This change disrupts the arc of motion while the arm is abducted and externally which places the GHJ at a higher risk of redislocation. This theory was then confirmed by the biomechanical work of Gerber *et al*[40] who reported that increasing loss of the anteroinferior glenoid arc was associated with decreased resistance to dislocation. Bigliani *et al*[28] further categorized glenoid lesions and provided prognostic factors as follows: Type 1 Lesions involve a non-displaced anterior glenoid fragment, type 2 Lesions involve a small anterior fragment detached from the labrum, type 3a lesions involve < 25% anterior glenoid deficiency, and type 3b lesions involve > 25% anterior glenoid deficiency.

Humeral head defects: The Hill-Sachs lesion

In addition to glenoid sided lesions, a bony lesion to the posterolateral aspect of the humeral head is

referred to as a “Hill-Sachs” lesion and can also lead to GHJ instability. These bony defects following first time GHJ dislocation have been reported to be found in up to 70% of patients[32,41]. In their review of 91 patients, Boileau *et al*[35] found Hill-Sachs lesions to be significantly related to failure. The failures resulting from Hill-Sachs lesions are theorized to result secondary to the articular arc defect which causes engagement of the humerus against the anterior glenoid rim referred to as the “engaging Hill-Sachs” lesion[29,35]. In their investigation, Burkhart *et al*[29] reported recurrent anterior GHJ instability in 100% ($n = 3$) of patients found to have an “engaging” Hill-Sachs lesion treated with arthroscopic Bankart repairs for traumatic anteroinferior instability. Although the clinical correlation between humeral defects and recurrent dislocation has been reported, there is a lack of current information regarding the size of the defect and relation to instability.

The combined bony Bankart and Hill-Sachs injury

While bony Bankart and Hill-Sachs lesions can occur in isolation, these injuries may also occur concurrently. A recent cadaveric study by Arciero *et al*[42] reported on these combined injuries. The study developed models for bony lesions based on computed tomography (CT) scans from 142 consecutive patients presenting with GHJ instability. The authors found that combined glenoid and humeral lesions displayed an additive and negative effect on GHJ stability. More specifically, they found that in patients with moderate sized Hill-Sachs lesions (defined as 50th percentile within the population of 142 consecutive patients), a glenoid lesion as small as 2 mm significantly compromised the stability of a soft tissue Bankart repair. These findings led to the conclusion that combined glenoid and humeral head defects have an additive and negative effect on glenohumeral stability.

The “glenoid track” concept

This description of the zone of contact between the glenoid and humeral head during elevation of the arm is termed the “glenoid track”[43]. This concept was initially described by Yamamoto *et al*[43] in a cadaveric study focused on the location and width of this “glenoid track” during various degrees of abduction while maintaining maximum external rotation and horizontal extension. The investigators found that the zone of contact shifted from the inferomedial to the superolateral portion aspect of the humeral head. They determined the width of the track from the rotator cuff attachment site of the greater tuberosity to be $84\% \pm 14\%$ of the width of the glenoid (assuming no bone injury to the glenoid) and used this concept to determine the risk of a Hill-Sachs lesion engaging the glenoid rim in cases with and without bony injury. If the bony injury to the humeral head is located within the width of the glenoid track then there is no opportunity for the Hill-Sachs lesion to over-ride the glenoid creating a potential instability event. However, in cases where the Hill-Sachs lesion extends beyond the width of the glenoid track this creates an opportunity for instability. Another important aspect of this concept is that the width of the glenoid track is determined solely on the width of the glenoid meaning that a bony Bankart directly correlates with a decrease in width of the glenoid track. This concept was not the first to describe bony lesions as they relate to anterior glenohumeral instability, however this provided a new concept to evaluate both humeral and glenoid sided lesions simultaneously as the authors concluded that if the medial margin of a Hill-Sachs lesion is more medial than the glenoid track then standard stabilization techniques are unlikely to adequately address the bony sources of instability. Several investigations have identified “off-track” lesions to be at higher risk for recurrent instability[44-48]. Most recently, in a 2020 investigation by Yian *et al*[36] the authors reported on 540 patients undergoing primary arthroscopic Bankart repair and found “off-track” glenoid lesions to be statistically significantly associated with higher rates of recurrent instability (odds ratio, OR 2.86).

INDICATIONS FOR ARTHROSCOPIC VS OPEN SURGICAL MANAGEMENT

The purpose of surgical management of anteroinferior labral injuries is to reduce the risk of recurrent instability events. Historically, the rate of recurrent glenohumeral dislocations following open surgical repair have been lower (5%-9%)[49-51] as compared to arthroscopic interventions (5%-33%)[52-54]. Traditionally, open Bankart repair performed simultaneously with a capsular shift was considered the preferred management option, however improvements in arthroscopic techniques and implants have resulted in arthroscopic stabilization becoming the currently preferred technique for management of recurrent anterior GHJ instability[55-57]. One of the major advantages of the arthroscopic technique is that it does not violate the subscapularis which could potentially lead to functional deficits in external rotation[49]. Several high level investigations have reported similar rates of recurrent instability following arthroscopic *vs* open surgical intervention[53,55,58,59]. While these investigations found similar outcomes in results following both arthroscopic and open stabilization procedures, only short term outcomes were reported. Others have argued that outcomes between arthroscopic and open stabilization cannot be established in 2-3 years of followup[56]. Supporting this argument, longer-term studies have found much higher rates of recurrent shoulder instability following arthroscopic repair ranging from 17%-35% at 5-10 years[60-63]. This is in comparison to longer-term studies reporting on outcomes of open Bankart repairs with recurrence rates of 15%-17.5% at 10-20 years[61,62,64]. Although

it may seem reasonable to utilize an open Bankart repair following initial failure of an arthroscopic technique, the current literature shows inferior outcomes in patients undergoing revision open Bankart compared to primary open Bankart[65-67]. Despite the abundance of clinical outcomes on this topic, indications for primary open Bankart repair remain controversial[56]. Some advocate for open Bankart repair in the setting of male collision athletes younger than 20 years, patients with subcritical (10%-20%) glenoid bone loss, patients with 10 or more shoulder dislocations, patients who have failed arthroscopic Bankart repair with less than 20% glenoid bone loss, and those with poor capsulolabral tissue[56].

When considering operative intervention it is also critical to evaluate associated bony injuries as discussed in previous sections of this manuscript. Amounts of bone loss initially thought to be adequately treated with Bankart repair is shrinking. Historically, anteroinferior glenoid bone loss of $\geq 25\%$ of the inferior glenoid diameter is managed with glenoid bone grafting with a coracoid autograft (Latarjet), iliac autograft, or allograft[29,35,40,54,68-71]. Cadaveric investigations have shown that bone loss of $> 21\%$ has resulted in residual instability, resulting in some advocating for a threshold of 20% glenoid bone defect to be an indication for bony stabilization[54,72]. A 2015 investigation by Shaha *et al* [73] reported increased shoulder pain and decreased function in patients after arthroscopic Bankart repair with bone loss of 13.5%-19.8% of the inferior glenoid which they termed "subcritical" bone loss. This investigation led to the potential role of bony augmentation in patients with this "subcritical" bone loss of the glenoid. More recently, Pickett and Svoboda[54] reported their threshold for a Latarjet procedure to be 20% glenoid bone loss while also considering the procedure in contact athletes with "subcritical" (13%-19%) glenoid bone loss.

The clinical implications of Hill-Sachs lesions is not completely understood, original thought was that lesions $> 16\%$ of the humeral head diameter, those whose volume exceed 1000 mm^3 , or patients who experienced a clunking sensation with the arm in 90 degrees of abduction and 90 degrees of external rotation required operative intervention[54,74]. Others advocated that defects $> 20\%$ - 25% of the humeral head diameter required management with an allograft[54,75]. These investigations preceded the concept of the glenoid track by Yamamoto *et al*[43] which was discussed earlier in this text.

While many investigations have reported on glenoid or humeral sided bone lesions, in practice these injuries can occur concurrently. Di Giacomo *et al*[68] proposed an algorithm in patients with bipolar lesions with varying degrees of glenoid and humeral head involvement. The authors broke patients down into the following four groups with their associated treatment: (1) Group 1: $< 25\%$ glenoid bone loss and on-track Hill-Sachs defect can be treated with an arthroscopic Bankart repair; (2) Group 2: $< 25\%$ glenoid bone loss and off-track Hill-Sachs defect can be treated with an arthroscopic Bankart repair and remplissage; (3) Group 3: $> 25\%$ glenoid bone loss and on-track Hill-Sachs defect require a Latarjet procedure; and (4) Group 4: $> 25\%$ glenoid bone loss and off-track Hill-Sachs defect require a Latarjet procedure and may need an additional bony procedure to address the humeral head.

It would seem practical to utilize the glenoid track concept to assist in surgical planning as it incorporates bony lesions to both the glenoid and humeral head. Due to the fact that this initial concept was described *in vitro*, some theorized it may not represent true conditions of recurrent instability due to its lack of including factors such as laxity of the capsulolabral complex. In theory, this could lead to a smaller sized Hill-Sachs lesion facilitating an engaging bipolar lesion causing recurrent instability[44, 76]. However, there is growing evidence supporting clinical outcomes using the glenoid track concept while lowering the threshold for glenoid bone loss[48,77]. More specifically, Metzger *et al*[77] reported on 205 patients with recurrent anterior shoulder instability. The patients had a mean glenoid bone loss of 7.6% (range 0%-29%) with 22% of patients engaging on clinical exam under anesthesia (EUA). When comparing clinical EUA findings with radiographic findings, 84.5% of patients with radiographic findings suggestive of an engaging lesion displayed clinical evidence of an engaging lesion on EUA while only 12.4% clinically engaged during EUA without radiographic evidence of engagement ($P < 0.001$). The investigation demonstrated that gleno-humeral engagement was well predicted based on preoperative glenoid and humeral head bone loss measurements using the glenoid track concept. Supporting these findings, a 2016 investigation by Shaha *et al*[48] reported on 57 shoulders over a two year period treated with a primary arthroscopic Bankart reconstruction. The authors reported 10 instability recurrences (18%) with 4 (8%) failures in the on-track patients as compared to 6 (75%) in the off-track group ($P = 0.0001$). Importantly, they reported the positive predictive value (PPV) of an off-track measurement was 75% compared to a 44% PPV in those with glenoid bone loss of $> 20\%$. They concluded that the application of the glenoid track concept was superior to using glenoid bone loss alone when predicting post-operative stability.

More recently, a 2018 Yang *et al*[76] investigated the relationship between the Hill-Sachs interval and the glenoid track. The investigators retrospectively reviewed 160 patients who underwent an arthroscopic Bankart repair with a minimum of 24 mo follow up. They reported that a Hill-Sachs interval to glenoid track width ratio (H/G ratio) of ≥ 0.7 was a significant predictor of higher risk for recurrent instability. This value was validated by the recent findings of Chen *et al*[44] who found the H/G ratio of ≥ 0.7 to be comparable to the instability severity index score (ISIS) for predicting an increased risk of recurrent instability after arthroscopic Bankart repair. The ISIS was initially developed by Balg *et al*[78] and utilizes a combination of clinical characteristics and radiographic findings to predict risk for recurrent instability. It has been validated by several studies as a useful tool in predicting recurrent instability[44,79-83].

CLINICAL HISTORY AND PHYSICAL EXAM

The history of injury should include a description of the position of the arm, force applied, and point of force[84]. The typical mechanism for an anterior GHJ dislocation is a force to an extended, abducted, and externally rotated upper extremity[84]. Clinical history elicited during the initial encounter should also include evaluation of other sources of instability such as connective tissue disorders or generalized joint laxity. Connective tissue disorders such as Ehlers Danlos or Marfan's syndrome should be ruled out by inspecting for skin hyper-extensibility, widened atrophic scarring, family history, personal history of instability events, and evaluation of joint hypermobility utilizing the Beighton criteria when clinically appropriate[85]. Evaluation should always include comparison to the contralateral shoulder.

Examination of the shoulder should include evaluation of the cervical spine, visualization of bilateral shoulders for evidence of muscular atrophy or deformities, active and passive range of motion, and a neurovascular exam with careful evaluation of the axillary nerve[32]. Finally, evaluation should include specific laxity and instability testing. It is important for the clinician to differentiate GHJ instability which is described as symptomatic and reproducible dislocation of the joint as compared to generalized joint laxity which is characterized by loose ligamentous tissue causing chronic pain and instability during minor events.

Tests specific to joint laxity include the load and shift test and the sulcus test. In the load and shift test an axial load is placed on the shoulder to center the humeral head onto the glenoid cavity and the examiner stabilizes the shoulder girdle with one hand while applying an anterior or posterior load to the proximal humerus with the other hand[32]. Increased translation in the anterior or posterior directions indicates joint laxity in that plane. The sulcus test is performed while the patient stands with their arm at the side while the examiner places a downward force onto the arm. It can be indicative of inferior laxity if a sulcus, or hollowing, occurs inferior to the acromion. Both of these tests should be performed in comparison to the contralateral side. In regards to testing for joint stability the clinician may perform the apprehension test and the jerk test. The apprehension test is performed with the patient in a supine or standing position. The arm is held in 90 degrees of abduction and in external rotation. The examiner places one hand behind the scapula for stabilization while simultaneously pulling back on the wrist putting the patient into further external rotation. The patient with anterior instability becomes apprehensive during this maneuver[84]. The jerk test is performed with the patient in internal rotation and flexed to 90 degrees. With one hand stabilizing the scapula the examiner grasps the elbow and places an axial load onto the humerus while simultaneously moving the arm horizontally across the body. The clinician is evaluating for a sudden "jerk" of the humeral head sliding off of the posterior glenoid followed by a "clunk" when the arm is brought back to the original positioning[84]. A positive jerk test is indicative of posterior instability.

Imaging

Initial radiographic workup of GHJ dislocation should include plain radiographs with anteroposterior (AP), infraspinal outlet, and axillary views to evaluate for bony pathology and the version of the glenoid. Angled views such as the apical oblique view, Stryker notch view, and the West Point view could also be obtained to better visualize bony defects to the glenoid and posterolateral humeral head [84]. If there is further clinical or radiographic concern for bony pathology, or in cases of recurrent episodes of instability, computed tomography (CT) imaging with 3D reconstruction remains the gold standard for evaluation of bony injury[28,32]. In addition to evaluation of bony deficits, magnetic resonance imaging (MRI) is the preferred method for evaluation of the soft tissues of the shoulder joint, specifically for evaluation of the glenoid labrum and rotator cuff. Based on its location, the GHJ is inherently difficult to image and the best positioning is with the arm in a neutral or externally rotated position as internal rotation of the shoulder can cause labral and/or anteroinferior capsule redundancy which obscures tears[1,86]. In general, several consecutive images should be reviewed when evaluating an MRI and MR arthrography may also be utilized to increase visualization[1,87].

OPERATIVE PEARLS AND PITFALLS OF ARTHROSCOPIC BANKART REPAIR

Patient positioning

Based on the importance of the inferior anchor placement the clinician should consider the benefits and disadvantages of beach chair *vs* lateral decubitus positions. In regards to the beach chair positioning the benefits include easier conversion from arthroscopic to open, anatomic orientation of the joint, rotational control of the shoulder, and optimal visualization of the subacromial joint. Despite these advantages, the major difficulty with beach chair orientation is decreased visualization of the inferior aspects of the joint. In comparison, the lateral decubitus positioning allows for increased joint space as traction can be applied in addition to improved access and visualization to the inferior GHJ. Despite this advantage it's important to note that the disadvantages of lateral decubitus positioning include non-anatomic orientation, difficult conversion from arthroscopic to open, challenging positioning for the anesthesia team, and the possibility of traction related injury.

In regards to the optimized visualization/access to the inferior joint, a systematic review with meta-regression analysis conducted by Frank *et al*[88] on outcomes of arthroscopic anterior shoulder instability cases in beach chair *vs* lateral positioning. The study reported on 64 studies including 3668 shoulders and found the overall recurrent instability rates were 14.65% in the beach chair positioning patients as compared to 8.5% in the lateral decubitus positioning. Although the study reported decreased recurrence rates within the lateral decubitus group the differences in range of motion, return to activity, and Rowe scores between groups were not significant. Although patient positioning may be related to recurrent instability events it is important to recognize that these results do not necessarily suggest a more or less successful surgery as clinical outcome scores were similar and the fact that recurrence is a difficult measure of operative success based on the wide spectrum inherent to the term "instability."

Portal placement

Optimal portal placement is crucial during the operative management of GHJ instability. With incorrect or inadequate portal placement the visualization into the joint can be severely compromised and can also dramatically increase the technical difficulty. Ideal placement of the portals allows for adequate visualization for proper diagnostic arthroscopy and eases the technical demands of anchor placement. Initial portal placement begins with standard posterior portal located roughly 2 cm inferior and 1 cm medial to the posterolateral corner of the acromion. Next, the anterosuperior (AS) portal is placed anterolateral to the edge of the acromion and lateral to the coracoid under direct visualization. Ideal intraarticular placement of this portal is just posterior to the insertion of the long head of the biceps. The primary purpose of the AS portal is to visualize the inferior, anterior, and posterior capsule while allowing for a thorough diagnostic scope to evaluate and recognize the anatomy of the shoulder. During this stage of the procedure the surgeon will evaluate the capsular volume, biceps tendon, glenohumeral ligaments, rotator cuff, and the anterior, posterior, and inferior labrum. Next, the anterior and posterior working portals can be created under direct visualization. During creation of these portals an "outside in" technique is utilized meaning a spinal needle is used to ensure ideal placement. For the anterior portal the needle should be placed between the acromioclavicular joint and the lateral coracoid. Intra-articularly the needle will ideally pierce the capsule just superior to the subscapularis tendon directly parallel to the surface of the glenoid. The posterior portal is created slightly inferior to the arch of the acromion and directed towards the coracoid process. Proper placement of these portals will allow the surgeon to visually appreciate the entire capsulolabral complex.

Labrum and glenoid preparation

Adequate labral preparation is a critical component of anterior GHJ instability repairs as error during this step may lead to recurrent instability due to inadequate capsulolabral plication. An elevator device can be used during this step to peel the labrum off the glenoid surface. After elevating the labrum from the glenoid neck a small shaver can be used to prepare the surface of the glenoid for anchor placement. Preparation of the labrum should be completed prior to preparation of the glenoid surface and anchor placement.

Anchor placement

Ideal anchor placement is below the 3 o'clock position placed 2-3 mm from the glenoid rim at a 45 degree angle relative to the anterior glenoid rim[21]. Anchors can then be placed approximately 7 mm apart. Based on the study performed by Boileau *et al*[35] at least 4 suture anchors should be utilized as 3 or fewer were found to be at higher risk for recurrent instability. During this stage of the procedure it is critical to achieve inferior anchor placement onto the glenoid. There are several portal positions and guides available to the surgeon to achieve this low placement however there remains no perfect option. A biomechanical study by Frank *et al*[89] reported on inferior anchor placement in 30 cadavers which were randomized into 3 test groups based on portal location and drill guide. The study found that there was no significant difference in ultimate load to failure among anchors placed *via* the 3 techniques. However, the authors did conclude that midglenoid portal anchors drilled with a straight or curved guide placed at the 5 o'clock position displayed significantly increased risk of opposite cortex perforation. Although the clinical applicability of these findings remained unclear, the study prompted discussion regarding ideal patient positioning in order to visualize the inferior glenoid in order to place the inferior anchor.

Rehabilitation

The authors prefer an abduction sling post-operatively in order to keep the shoulder in neutral positioning. Physical therapy then begins 7-10 d post-operatively with passive and active range of motion (ROM) for 4 wk (forward flexion to 130 degrees, external rotation to 30 degrees), ROM progression from 4-6 wk (forward flexion to 180 degrees, external rotation to 60 degrees), followed by resistive strengthening from 8-12 wk, and return to full sports and activities at 4-6 mo[21].

CONCLUSION

Management of the patient with anterior shoulder instability is a common yet complex condition for the orthopaedic surgeon. To optimize the evaluation and management of these patients the provider must ensure a detailed and thorough clinical and radiographic workup, have a thorough understanding of the dynamic, static, and bony stabilizers of the GHJ, and understand the common causes of failed surgical intervention in order to address these concerns when appropriate.

FOOTNOTES

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Observational Study

Ceramic-on-ceramic vs ceramic-on-polyethylene, a comparative study with 10-year follow-up

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Abstract

BACKGROUND

In press-fit total hip arthroplasty (THA) ceramic-on-ceramic (CoC) bearings are a potential for overcoming the wear that is seen in ceramic-on-polyethylene (CoPE) bearings, and can lead to wear-induced osteolysis, resulting in loosening of the implant. However, CoC bearings show disadvantages as well, such as squeaking sounds and being more fragile, which can cause ceramic head or liner fracture. Because comparative long-term studies are limited, the objective of this study was to determine the long-term difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, and evaluate clinical functioning and complications between these bearings.

AIM

To determine 10-year differences in wear, predictive factors for wear, and investigate radiological findings and clinical functioning between CoC and CoPE.

METHODS

This observational prospective single-center cohort study with a 10-year follow-up includes a documented series of elective THAs. Primary outcome was wear measured by anteroposterior (AP) radiographs. Secondary outcomes were potential predictive factors for wear, complications during follow-up, Harris hip

score (HHS), and radiological findings such as presence of radiolucency, osteolysis, atrophy, and hypertrophy around the cup. Due to the absence of wear in the CoC group, stratified analysis to identify risk factors for wear was only performed in the CoPE group by use of univariate linear regression analysis. HHS was expressed as a change from baseline and the association with bearing type was assessed by use of multivariate linear regression analysis, adjusted for potential confounders.

RESULTS

A total of 17 CoPE (63.0%) and 25 CoC (73.5%) cases were available for follow-up and showed a linear wear of respectively 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005), which was significant ($P < 0.001$) between both groups. Wear always occurred in the cranial direction. Cup inclination was the only predictive factor for polyethylene (PE) wear. No dislocations, ceramic head, or liner fractures were seen. The HHS showed a mean change from baseline of 37.1 points (SD 18.5) in the CoPE group and 43.9 (SD 17.0) in the CoC group. This crude difference of 6.8 (range -5.2; 18.7) in favor of the CoC group was not significant ($P = 0.26$) and was not significant when adjusted for age, gender, and diagnosis either ($P = 0.99$). No significant differences in complications and radiological findings were seen between groups.

CONCLUSION

CoC bearing shows lower wear rates compared to CoPE at 10-year follow-up with cup inclination as a predictive factor for wear and no differences in complications, HHS, and radiological findings.

Key Words: Total hip arthroplasty; Press-fit; Bearing; Ceramic-on-ceramic; Ceramic-on-polyethylene; Wear

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Core Tip: Polyethylene wear of the acetabular insert can cause osteolysis and aseptic loosening of the implant in total hip arthroplasty. Ceramic-on-ceramic (CoC) bearing can overcome this problem, but comparative long-term data between ceramic-on-polyethylene (CoPE) and CoC are limited. This 10-year follow-up study showed higher wear rates in CoPE with cup inclination as a predictive factor for wear. No differences in complications, radiological findings, and clinical scores were seen. To confirm the potential benefits of CoC bearing focusing on wear and survival rates of the implant, more long-term data are needed.

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INTRODUCTION

Total hip arthroplasty (THA) is considered the operation of the century, but the search for the ideal articulation is still a point of discussion[1]. Several bearing surfaces have been developed in the past to reduce causes for revision. Polyethylene (PE) or highly cross-linked PE (HXLPE) inlay combined with a ceramic head still remains the option of choice[2]. Therefore, the use of a ceramic-on-polyethylene (CoPE) articulation increased with almost 20% in the last decade up to 63.4% of all THAs as seen in the Dutch Arthroplasty Register in 2019[3].

Wear rates of PE are widely investigated, since wear-induced osteolysis resulting in aseptic loosening still remains one of the main causes of late revision[4,5]. The threshold of 0.05 mm/year was eventually stated to eliminate osteolysis, but recent long-term results showed that even wear rates below this threshold in both PE and HXLPE are associated with osteolysis[6,7]. Ceramic-on-ceramic (CoC) bearings are a potential to overcome this problem, with lower wear rates and incidence of osteolysis than CoPE [8]. However, CoC bearings show disadvantages as well, such as a squeaking sound and being more fragile, which can cause fracture of both the head and the inlay and makes revision THA challenging[9, 10].

Comparative long-term studies are needed to confirm if the aforementioned disadvantages of both bearings will be reflected in accompanying revision rates, clinical functioning, and radiological findings over time. Recent systematic reviews have shown that more data and especially more research focused on long-term are required to clarify clinical advantages of both bearings[11,12].

The objective of this study was to determine the long-term difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, and evaluate clinical functioning and complications between CoC bearing *vs* CoPE in THA when using the same implants with a 10 years follow-up.

Our hypotheses were that CoPE would show higher wear rates than CoC and no differences would be observed in radiological findings, clinical functioning and complications.

MATERIALS AND METHODS

Ethical approval/registration

No ethical approval was needed for this observational prospective cohort study because this documented series was part of the normal follow-up of elective THAs. Reporting was done in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement. This research was conducted according to the Declaration of Helsinki.

Study design

This observational prospective single center cohort study with 10-year follow-up included a documented series of elective THAs performed between December 2003 and December 2004 comparing the EP-FIT PLUS press-fit cup system with ceramic insert (BIOLOX delta, Smith and Nephew) to standard PE acetabular inserts (Standard REXPOL, Smith and Nephew) with similar ceramic head (BIOLOX delta, Smith and Nephew) articulation. No randomization was performed in this study. The choice between PE or ceramic insert depended on patient characteristics and the experienced orthopedic surgeons' preferences. All patients included were seen in a standard follow-up scheme with X-rays at baseline, 3, 12, 36, 60, and 120 mo post-operatively. After surgery, a standard postoperative rehabilitation protocol under guidance of a physical therapist consisted of immediate weightbearing and crutches for 6 wk. All outcomes were analyzed by a reviewer and checked by a second researcher who were both not involved in the selection, surgery, and follow-up process.

Eligibility

All indications for THA included in this study were primary osteoarthritis (OA), degeneration due to rheumatoid arthritis or other inflammatory arthritis, avascular necrosis and hip dysplasia. Patients were included after completing verbal informed consent. Patients with secondary OA due to trauma, infection of the hip, osteoporosis or a prior osteotomy or arthroplasty were excluded from this study. No a priori power analysis was performed.

Surgical procedure

All THAs were performed at Slotervaart Medical Center by experienced orthopedic surgeons using a straight lateral approach under standard antibiotic prophylaxis. The surgical approach was according to the surgical technique described by the manufacturer of the implants. The same uncemented acetabular cup (EP-FIT PLUS, Smith and Nephew) was used in all patients. This cup is an equatorial flattened press-fit cup design with an open porous titanium vacuum plasma coating to increase roughness, with initial fixation by 2%-3% oversizing. A non-cemented Zweymuller titanium rectangular tapered shape femoral stem (SL-PLUS, Smith and Nephew) was used as femur component in all cases in combination with a ceramic head articulation (BIOLOX delta, Smith and Nephew). A 32 mm and 28 mm head were respectively used in CoC and CoPE bearing. The liner being used was either a ceramic insert (BIOLOX delta, Smith and Nephew) or a standard PE acetabular insert (Standard PE, Smith and Nephew). Both the ceramic head and liner are made of a zirconia toughened alumina ceramic alloy, a fourth-generation ceramic material. The aimed leg length and femoral offset was measured accordingly to be identical to the contralateral side.

Outcomes

Patient demographics were recorded at baseline, including age, gender, body mass index (BMI), indication for surgery (primary OA or other diagnosis), and operation side. Information regarding the operation was recorded as well including articulation, head size, and cup inclination in degrees on direct post-operative radiographs. Perioperative and complications during follow-up like ceramic articulation fractures, squeaking and dislocations were directly registered.

The primary outcome was wear in mm/year measured by an independent orthopedic surgeon, by consecutive radiography using standard weightbearing anterior-posterior radiographs. By using the penetration and the size of the head, the thickness of the inlay was calculated. The method being used as demonstrated in [Figure 1](#), is widely used and first described and validated by Charnley *et al*[13]. The width of the narrowest part of the inlay in the proximal weightbearing region (B) was subtracted from the widest part in the distal non-weightbearing area (A) and halved. With this formula, wear = (A - B)/2, wear was calculated as cranial migration in mm. These outcomes were used to calculate linear

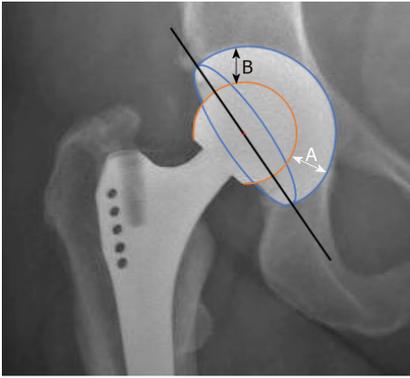


Figure 1 Method of wear measurement with center of rotation (red), boundaries of the cup (blue) and head (orange) and line for measurement of inclination angle (black). A: Widest distal part of inlay; B: Narrowest proximal part of the inlay.

wear rates in mm/year. As an example, if no wear occurs, the thickness of the inlay is the same in all directions. Hereby the difference between the measurement of A and B is zero, meaning that there is no cranial migration and hereby no wear. If wear increases and more cranial migration is seen, the measurement of B will become lower and A will increase due to a wider distal part, resulting in a greater difference between both values (Figure 1). As a secondary outcome, potential predictive factors for wear such as gender, age, operation side, BMI, diagnosis (primary OA *vs* other), cup size, and cup inclination were determined. The Harris hip score (HHS) was used as a clinical questionnaire to measure patient reported outcomes[14]. Radiographs were evaluated by two researchers to determine presence of radiolucency, osteolysis, atrophy, and hypertrophy around the cup in Zones I-III according to DeLee *et al*[15].

Statistical analysis

Statistical analyses were performed with Statistical Package for Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, New York, United States). Normally distributed continuous variables are stated as mean with standard deviation (SD) and tested by use of Student's *t*-test. In case of non-normality medians with interquartile ranges are presented and a Mann-Whitney *U* test was used to assess for significant differences between both groups. Categorical data were compared by use of chi-squared tests. Due to the absence of wear in the CoC group, stratified analysis to identify risk factors for wear was only performed in the CoPE group by use of univariate linear regression analyses. HHS was expressed as a change from baseline and the association with bearing type was assessed by use of multivariate linear regression analysis, adjusted for potential confounders (*i.e.* age, sex, and diagnosis). Differences were stated significant if *P* values were less than 0.05. Complications and radiological findings were expressed as frequencies with percentage. All statistical methods in this study were done by a biomedical statistical expert (Inger N Sierevelt).

RESULTS

A total of 61 patients receiving THAs were included in this study at baseline (Figure 2). A significant difference in age and distribution of diagnosis (primary OA *vs* other) between both groups was observed (Table 1). A total of 17 CoPE (63.0%) and 25 CoC (73.5%) cases were available for 10-year follow-up. Intra-operative trochanteric fracture occurred in one case (4%) in the CoPE group and two (6%) in the CoC group, and were treated with a trochanteric wire. Delayed wound healing was seen in two (8%) and four (13%) patients in the CoPE and CoC group, respectively. Temporary peroneal nerve injury was observed in the CoPE group in two cases (7.4%). During follow-up, one periprosthetic joint infection (3%) was seen in the CoC group, which was initially treated with lavage and antibiotics; however, removal of the implant was done elsewhere after 3 years of follow-up. Femoral component loosening was the reason for one revision in both groups, treated by revision of the stem and inlay elsewhere in the CoC case and in our clinic in the CoPE patient. No dislocations, squeaking, and fracture of the ceramic liner were observed. A total of two revisions were planned in the CoPE group after the 10-year follow-up due to complaints combined with excessive wear. All complications showed no significant differences between both groups.

Primary outcome

After 10 years of follow-up, the median linear wear of CoPE and CoC bearing was 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005), respectively. Wear always occurred in the

Table 1 Baseline characteristics and operation information

| | CoPE, n = 27 (100%) | CoC, n = 34 (100%) | P value |
|---------------------------------------|---------------------|--------------------|---------|
| Female gender, n (%) | 21 (78%) | 22 (65%) | 0.27 |
| Right side, n (%) | 19 (76%) | 17 (50%) | 0.11 |
| Diagnosis, n (%) | | | 0.01 |
| Primary OA | 23 (85%) | 19 (56%) | |
| Other | 4 (15%) | 15 (44%) | |
| Age, in years, mean (SD) | 64.2 (5.3) | 55.7 (8.5) | < 0.001 |
| BMI, in kg/m ² mean (SD) | 27.6 (4.1) | 26.9 (4.1) | 0.52 |
| Cup size in mm, mean (SD) | 52.1 (3.4) | 53.6 (3.5) | 0.10 |
| Inclination cup in degrees, mean (SD) | 46.8 (6.7) | 44.6 (5.0) | 0.22 |
| HHS, mean (SD) | 50.2 (13.3) | 47.5 (13.4) | 0.44 |

BMI: Body mass index; CoPE: Ceramic-on-polyethylene; CoC: Ceramic-on-ceramic; HHS: Harris hip score; OA: Osteoarthritis; SD: Standard deviation.

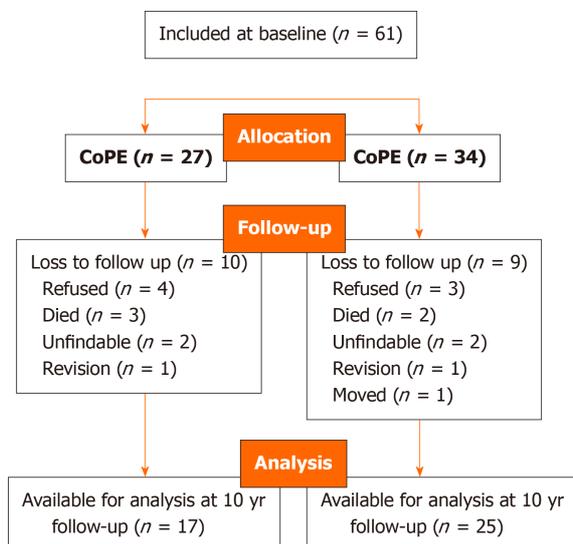


Figure 2 Flowchart of 10-year follow-up.

cranial direction. In two patients in the CoC group, wear of 0.05 mm was measured, in all other cases, no wear was observed. The difference in wear between both groups was significant ($P < 0.001$).

Secondary outcomes

The results of the stratified analysis to identify risk factors for wear in the CoPE group are shown in Table 2. Increased cup inclination was the only predictive factor for PE wear in CoPE bearing.

The HHS score showed a mean change from baseline of 37.1 points (SD 18.5) in the CoPE group and 43.9 (SD 17.0) in the CoC group. This crude difference of 6.8 (range -5.2; 18.7) in favor of the CoC group was not significant ($P = 0.26$). When adjusted for age, gender, and diagnosis (primary OA vs other), a mean difference of -0.02 (range -14.7; 14.7) was seen, which was not significant either ($P = 0.99$).

The radiological findings in the periacetabular cup zones are shown in Table 3. These outcomes showed no significant differences between both groups.

DISCUSSION

The main finding of this observational prospective cohort study of 61 THAs with 17 CoPE and 25 CoC cases available for 10-year follow-up was a significantly different degree of wear between the CoPE and CoC, with values of 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005),

Table 2 Potential predictive values for polyethylene wear in beta-coefficient (range)

| Potential predictive factors for PE wear | Beta-coefficient (95%CI) | P value |
|--|--------------------------|---------|
| Gender | 0.06 (-1.18; 1.29) | 0.93 |
| Age | -0.01 (-0.10; 0.08) | 0.82 |
| Operation side | -0.40 (-1.53; 0.73) | 0.46 |
| BMI | -0.05 (-0.20; 0.10) | 0.46 |
| Diagnosis, primary OA vs other | 1.10 (-0.42; 2.61) | 0.14 |
| Cup size | -0.06 (-0.23; 0.12) | 0.52 |
| Cup inclination | 0.08 (0.02; 0.15) | 0.02 |

BMI: Body mass index; CI: Confidence interval; OA: Osteoarthritis; PE: Polyethylene.

Table 3 Radiological findings in DeLee and Charnley zones I, II and III at 10-yr

| Zones | CoPE, n = 17 | | | CoC, n = 25 | | |
|-------------------|--------------|---------|-----|-------------|---------|-----|
| | I | II | III | I | II | III |
| Radiolucent lines | 0 | 0 | 0 | 0 | 0 | 0 |
| Osteolysis cup | 0 | 1 (6%) | 0 | 2 (8%) | 3 (12%) | 0 |
| Atrophy | 2 (12%) | 3 (18%) | 0 | 5 (19%) | 5 (19%) | 0 |
| Hypertrophy | 0 | 0 | 0 | 0 | 0 | 0 |

CoPE: Ceramic-on-polyethylene; CoC: Ceramic-on-ceramic.

respectively in the cranial direction. Comparable significant differences in wear rates were seen in the literature in both the short and long-term[8,16]. Conventional PE inlays have been improved by cross-linking to improve wear rates, but CoC bearings still show the lowest wear rates[17-19]. Therefore, long-term follow-up is required to assess whether differences in wear will result in different survival rates. Although survival was not the focus of our study, to the best of our knowledge, the literature has only one comparative study with 12.6 years of follow-up showing no differences between CoC and CoHXLPE[18]. Studies that only focused on CoPE and CoHXLPE showed long-term survival rates of 86% and 100%, respectively, at 13 years and 88.3% and 93.8%, respectively, at 16 years[20,21]. Long-term studies that focused only on CoC showed divergent survival rates, with a 15-year follow-up study showing a survival rate of 92%, whereas another 20 years of follow-up showed a survival rate of 99.7% [22,23]. Our wear rate results combined with the revision rates in the literature indicated a possible advantage of ceramic coupling over PE, which needs to be confirmed with longer follow-up studies of at least 20 years.

The low wear and revision rates of CoC in the longer term become highly relevant since a rise in prevalence of THA and a shift to younger age is seen over the last decades[24]. Moreover, our study shows that patients receiving CoC articulation were significantly younger. Since life expectancy is still increasing worldwide, further research is needed to show if CoC can improve the longevity of THAs [25].

Our study showed that a higher inclination angle of the cup is a significant risk factor for wear. The same results are seen in the literature, with inclination angles above 45 degrees[26-28]. Since the mean angle of CoPE in our group was above this angle, it supports that acetabular positioning is highly important to reduce wear of CoPE.

In addition, inclination angles above 45 degrees are related to the higher incidence of squeaking in CoC[29,30]. In the literature, the incidence of squeaking is significantly higher in CoC than CoPE and varies between 0.5% and 20% and can influence the satisfaction of patients[11,12,31]. Although the mean angle of inclination in CoC in our study was just below the 45 degrees, no squeaking was reported.

Since the introduction of CoC, fracture of the ceramic, which was seen more often than in CoPE, was one of the greatest concerns against using this articulation[11,12]. A recent long-term meta-analysis showed that improvement of the ceramic over time led to lower fracture rates[32]. Additionally, in the literature, fourth-generation ceramic bearings showed no ceramic fracture when compared to third-generation CoC[33]. Since we used a fourth-generation ceramic bearing, this might be a reason that no head or liner fractures occurred in our study[32,33].

Another complication that influences long-term outcomes is dislocation, which can be caused by wear and malpositioning[34,35]. In the literature, a trend is seen in favor of CoC over CoPE[11,12]. Although no dislocations were seen in our study, the higher wear rate and wider angles of inclination presented in CoPE can indicate an increased risk of dislocation, which might become significant in the longer term.

In our study, no differences in radiological findings such as osteolysis were seen, which was supported by recent systematic reviews comparing CoC and CoPE[11,12]. Longer follow-up is needed to see if differences in osteolysis will occur over time.

No significant differences in clinical outcomes on the HHS were seen in our study. Since comparable scores on the HHS were seen in systematic reviews, there is no preference for one of the bearings based on functioning[11,12].

Finally, ceramic inserts are more expensive than PE, which might be an important issue in decision making in modern healthcare systems with an increasing focus on healthcare costs. Beaupre *et al*[36] stated that the costs of ceramic inserts were three times higher. To the best of our knowledge, no cost-analyses are performed in the literature between CoC and Co(HXL)PE. Long-term analysis needs to clarify if differences in outcomes, complication, and revision rates are cost-effective to the costs of both bearings.

A strength of our study is that we provided comparative results of a fourth-generation ceramic bearing, which are limited in the literature including wear, clinical, and radiological results. A limitation of our study was that no randomization was performed, which can have consequences for the comparability of the groups and might give indication bias. Moreover, a high loss to follow-up was seen in this study. Wear measurements were done using standard AP radiographs, which is a valid method, but is subsidiary to radiostereometric analysis (RSA)[37]. For example, we measured wear in two cases of CoC, which might be an error. Finally, no HXLPE was used, which is currently preferred when using a CoPE bearing.

CONCLUSION

In this study, higher wear rates were observed in CoPE compared to CoC bearing in THA at the 10-year follow-up, with cup inclination as a predictive factor for wear for CoPE bearing, and no differences in complications, HHS, and radiological findings. More long-term comparative studies are needed to confirm potential benefits of CoC bearing, which might be the preference in THA focused on wear and survival rates, especially in younger patients.

ARTICLE HIGHLIGHTS

Research background

Ceramic-on-ceramic (CoC) bearing in total hip arthroplasty (THA) is presumed to give lower wear rates *in vivo*, compared to ceramic-on-polyethylene (CoPE).

Research motivation

More *in vivo* long-term studies are needed in literature, to confirm potential benefits or disadvantages of CoC over CoPE.

Research objectives

The objective of this study was to determine the 10-year difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, evaluate clinical functioning and complications between CoC bearing *vs* CoPE when using the same implants.

Research methods

An observational prospective single-center cohort study with 10-year follow-up of a documented series of elective THAs was performed with either a ceramic (BIOLOX delta, Smith and Nephew) or a standard PE acetabular insert (Standard REXPOL, Smith and Nephew) with a similar ceramic head (BIOLOX delta, Smith and Nephew) articulation.

Research results

Higher wear rates were observed in CoPE compared to CoC bearing after 10-year follow-up with cup inclination as a predictive factor for wear for CoPE bearing, and no differences in complications, Harris hip score, and radiological findings.

Research conclusions

The potential benefit of CoC over CoPE at the 10-year follow-up is less wear with cup inclination as a

predictive factor for wear, without differences in clinical or radiological outcomes.

Research perspectives

Further investigation of wear, revision, and complication rates between CoC and CoPE, especially in the long-term, should be done, to confirm potential benefits of CoC over CoPE and to prove if it can improve the longevity of THAs. In addition, long-term analysis needs to clarify if differences in outcomes, complication, and revision rates are cost-effective to the costs of both bearings.

FOOTNOTES

Author contributions: All authors contributed to the study conception and design; Haverkamp D, Hoornenborg D, and van der Vis HM were involved in the follow-up after the surgical procedures; van Loon J and Sierevelt IN performed the data collection and analyses; van Loon J wrote the first draft of the manuscript; All authors read and approved the final manuscript.

Institutional review board statement: This observational prospective single-center cohort study with a 10-year follow-up was part of the normal follow-up of a documented series of elective THAs. Therefore, no ethical approval was needed for this study. Moreover, the analysis used anonymous data that were obtained after each patient agreed to the operation by written consent.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent for the operation.

Conflict-of-interest statement: The authors declare that there is no conflict of interest.

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Observational Study

Hello, can you hear me? Orthopaedic clinic telephone consultations in the COVID-19 era- a patient and clinician perspective

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The coronavirus disease 2019 (COVID-19) pandemic has resulted in seismic changes in healthcare delivery. As a result of this, hospital footfall required to be reduced due to increased risk of transmission of infection. To ensure patients can safely access healthcare, we introduced orthopaedic clinic telephone consultations in our busy district general hospital.

AIM

To investigate patients' and clinicians' perspective of telephone consultations during COVID-19, and whether this method of consultation could be a viable option in the post- pandemic future.

METHODS

This is a single centre, prospective study conducted in a busy National Health Service district general hospital. In May 2020, 100 non- consecutive adult patients were contacted by independent investigators within 48 h of their orthopaedic clinic telephone consultation to complete a telephone satisfaction questionnaire. The questions assessed satisfaction regarding various aspects of the consultation including overall satisfaction and willingness to use this approach long term. Satisfaction and perspective of 25 clinicians conducting these telephone consultations was also assessed *via* an online survey tool.

RESULTS

93% of patients were overall satisfied with telephone consultations and 79% were willing to continue this method of consultation post- pandemic. Patients found telephone consultations to reduce personal cost and inconvenience associated with attending a hospital appointment. 72% of clinicians reported overall

satisfaction with this service and 80% agreed that telephone consultations should be used in the future. The majority found it less laborious in time and administration in comparison to face to face consultations. Patients and clinicians expressed their desire for video consultations as a method of further improving their experience with remote consultations.

CONCLUSION

Our study has shown that telephone consultations are a safe and rapid method of adaptation to the COVID-19 pandemic, achieving the aim of reducing hospital footfall. This method of consultation has resulted in immense clinician and patient satisfaction. Our findings suggest that this tool has benefits in post pandemic healthcare delivery. It has also highlighted that telephone consultations can act as a steppingstone to the introduction of the more complex platform of video consulting.

Key Words: COVID-19; Telephone consultation; Orthopaedic clinic; Patient satisfaction; Patient perspective; Clinician perspective

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Core Tip: Telephone consultations are a safe and rapid method of adaptation to the coronavirus disease 2019 pandemic, achieving the aim of reducing hospital footfall. This method of consultation has resulted in immense patient and clinician satisfaction, suggesting that this tool has benefits in the post pandemic healthcare delivery. Telephone consultations can also act as a steppingstone to the safe introduction of the more complex platform of video consulting.

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INTRODUCTION

Severe acute respiratory syndrome coronavirus disease 2019 (COVID-19) was declared as a pandemic on 11th March 2020 by the World Health Organization and has had a profound effect on trauma and orthopaedic services in the National Health Service (NHS). Public Health England reported the burden of coronavirus in England as 157074 Lab- confirmed cases with 37266 confirmed deaths as of June 15, 2020[1]. In response to the rapidly spreading infection, the UK public were placed in lockdown on March 23, 2020.

The NHS England and NHS Improvement released clinical guidelines in delivering remote consultations in secondary care during the coronavirus pandemic to reduce the transmission of disease [2]. The British Orthopaedic Association also supported a pragmatic approach in dealing with trauma and orthopaedic patients in these extraordinary circumstances advocating conservative management for a wide range of injuries that may have been considered for operative management weeks' before[3].

Trauma and Orthopaedic clinics are one of the busiest clinical environments with each clinician seeing 15-20 patients on average per clinic session. With the high volume and rapid turnover of patient attendance, running these clinics with appropriate social distancing to reduce spread of infection was deemed challenging. Therefore, our trauma and orthopaedic department set up telephone consultations as a way of rapidly adapting to the new guidance provided to reduce hospital footfall and ensuring to deliver high quality patient care.

In the United Kingdom, telephone consultations are not a new concept and are used for primary care triage and have shown to reduce face to face (F2F) consultations[4,5]. In the last decade, digital health technologies have developed that allow virtual medical consultations such as GP at Hand by Babylon Health that is currently trialled as a virtual GP practise in NHS Hammersmith and Fulham Clinical Commissioning Group[6]. There is a long-term plan for digital services within the NHS in the future[7].

Telemedicine is well established within orthopaedics worldwide, especially useful for clinical management in remote locations. An American hospital followed up their trauma patients remotely when discharged from a level 1 trauma centre with high levels of satisfaction[8]. In elective orthopaedics, telemedicine has been used for elective paediatrics in Australia for their rural population [9] and also in American paediatric fracture management[10]. Post-operative carpal tunnel care has been

conducted using telemedicine with good satisfaction and financial savings[11]. One prospective study found no difference in satisfaction between F2F consultations and telemedicine[12]. In the United Kingdom, the virtual fracture clinic is a common form of telemedicine used in orthopaedics, but the pandemic meant that there needed to be a rapid shift to telephone consultations without a pre-existing United Kingdom model to follow.

There are proven positive models of telemedicine consultations, however particularly in orthopaedics, limitations include the inability to carry out a thorough clinical assessment by physically examining a patient. This can be frustrating for both patients and clinicians. The purpose of this study was to assess patients' and clinicians' perspective of telephone consultations during COVID-19, and whether this could be a viable option in the post pandemic future.

MATERIALS AND METHODS

Study population and data collection

This is a single centre, prospective study at a busy NHS district general hospital in the United Kingdom. Telephone clinics were rapidly implemented at the start of the pandemic. In May 2020, 100 non-consecutive adult patients were contacted after their orthopaedic clinic telephone consultation by independent investigators (orthopaedic clinic healthcare professionals) and completed a telephone satisfaction questionnaire (Supplementary material 1) within 48 h of the consultation. We contacted new and follow-up patients from fracture and elective clinics across all trauma and orthopaedic subspecialties to avoid selection bias. Inclusion and exclusion criteria are summarised in Table 1.

These clinics were consultant-led clinics, with additional specialty registrar and core surgical trainee support. To assess suitability for telephone consultations, each patient was screened by a clinician, by reviewing their emergency department notes, or previous clinic letters and imaging. Any patients that required a wound check, plaster cast care or physical examination were deemed unsuitable for a telephone consultation and a F2F appointment was made.

We assessed the satisfaction and perspective of clinicians conducting the telephone consultations *via* an online questionnaire tool (Supplementary material 1). All clinicians who conducted the telephone consultation were included and were consultant or specialty registrar level.

The questionnaires for both clinicians and patients were designed by the authors and used a Likert scale. The questions aimed to assess satisfaction regarding various aspects of the consultation including overall satisfaction and willingness to use this approach long term. We broke down the telephone consultation into 3 sections and analysed satisfaction with each: (1) Satisfaction with the explanation of patient condition/ injury; (2) Satisfaction with the outcome received from the consultation; and (3) Satisfaction with the answers received to patient questions during the consultation.

Statistical analysis

Cronbach's Alpha coefficient of internal consistency was used as a measure of reliability for the results from the Likert scale used for questions 2 to 6 of the patient satisfaction questionnaire. Analysis was performed on SPSS Statistics version 27.

Fisher's exact test was used to assess differences in the level of patient satisfaction for age, gender and diagnosis of upper/lower limb injuries. A statistically significant level of $P < 0.05$ was set. Statistical analysis was performed on GraphPad Prism version 8.3.

RESULTS

Telephone satisfaction questionnaires were carried out from May 5, 2020 to May 20, 2020, equating to 12 working days. 23 clinics were held during this time with a total of 262 patients reviewed. Of these, 125 patients (47.7%) had a telephone consultation, and 100 patients were surveyed giving us a capture rate of 80%.

This was compared with the same time period 1 year prior (May 5, 2019 to May 20, 2019) which equated to a total of 10 working days. 36 clinics were held during this time with a total of 617 patients reviewed F2F. There were no telephone consultations taking place within the department prior to the pandemic.

There were 49 males and 51 females, capturing a wide age demographic from 18 to 85+, with the largest cohort (29%) 45-54 years of age. There was a total of 100 injuries in 100 patients. 50% of these were upper limb injuries, 44% lower limb injuries, 1% spine and 5% did not have a diagnosis recorded on the questionnaire.

Patient perspective

90 out of the 100 patients were happy to be reviewed *via* telephone consultation. 93% of patients were overall satisfied with telephone consultations with 91% of patients satisfied with the explanation of their

Table 1 Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--|--|
| Adult patients aged ≥ 18 years of age | Patients aged < 18 yr of age |
| Received orthopaedic clinic telephone consultation | If other members of the family responded on patient's behalf |
| Satisfaction questionnaire completed within 48 h from telephone consultation | Unable to consent to complete satisfaction questionnaire |
| | Communication difficulties (verbal or auditory) as stated in patient clinical notes |
| | Cognitive impairment as stated in patient clinical notes |
| | If patients did not answer their telephone on two occasions to complete the satisfaction questionnaire |

condition and answers received to all their questions during the consultation. 79% of the patients were willing to continue this method of consultation in the future. Table 2 is a detailed summary of the level of patient satisfaction with each question. The results of the Likert scale used (very satisfied, satisfied, neutral, dissatisfied and very dissatisfied) for questions 2 to 6 in the patient satisfaction questionnaire revealed satisfactory reliability as shown by Cronbach's alpha coefficient of internal consistency 0.763.

Patients had the opportunity to provide free text comments at the end of their questionnaires. Table 3 is a summary of quotations which highlight both positive and negative feedback on telephone consultations. Positive comments were broadly categorized into convenience and efficiency, avoidance of hospital attendance during COVID-19 and mannerisms of the doctors. Negative comments included lack of visual feedback, inability to review images and non-adherence to appointment times.

We found no statistically significant difference ($P < 0.05$) in the level of satisfaction between age groups, gender and diagnosis of upper or lower limb injuries (Table 4). There was also no statistically significant difference between willingness for telephone consultations during the current pandemic and willingness for telephone consultations in the future.

Clinician perspective

The level of satisfaction of all orthopaedic surgeons carrying out telephone consultations within the department (17 consultants and 8 specialty registrars) was assessed. 72% of clinicians reported overall satisfaction with the use of telephone consultations during the pandemic, with 80% agreeing to continue this method in the future. Figures 1 and 2 compare patient and clinician satisfaction with telephone consultations and their willingness to continue this method of consultation in the future.

Clinicians did not find telephone consultations overly laborious. 80% stated that it took the same amount of time or shorter than traditional face to face consultations and 84% felt telephone consultations required the same or less amount of preparation compared to F2F.

In regard to the effectiveness of telephone consultations, 68% reported them as less comprehensive a medium to F2F consultations. However, the process of explaining the diagnosis and management plan, with subsequent patient questioning fared better. 60% found it the same or easy to explain the diagnosis and management over the telephone and 76% were satisfied with opportunities for patient questions.

Clinicians were also given an opportunity to provide free text suggestions at the end of their questionnaires (Table 5). The overarching suggestions included the need for video consultations which would help with the process of virtual examination, show patients their imaging so as to improve the overall understanding of their condition and subsequent management plan. Additionally, a notable point from a spinal consultant which can be extrapolated across specialties. ("It has to be noted that the public are currently accepting phone consultation as the best available option. This view may change if it carries on for too long. In spine clinics many patients may find it difficult to be convinced that their cases are not suitable for surgical intervention without "hands on" clinic assessment").

DISCUSSION

This study investigated patient and clinician satisfaction with orthopaedic clinic telephone consultations. 93% of patients were overall satisfied with telephone consultations. Gilbert *et al*[13], recently published a quality improvement study which focused on the process involved in the implementation of virtual clinics in response to the COVID-19 pandemic. A secondary outcome from their study assessed patient satisfaction with telephone consultations using a single summative question, which resulted in a mean satisfaction score of 90 out of 100, which was similar to our study findings[13]. From our literature review, no previous United Kingdom based study assessed level of patient satisfaction with the various aspects involved in a telephone consultation. We divided the telephone consultation into 3 sections and analysed satisfaction with each: (1) satisfaction with the

Table 2 Summary of patient satisfaction levels (%)

| Scale | Explanation of condition | Outcome of consultation | Answers received to all questions | Overall satisfaction | Willingness for future telephone consultations |
|-------------------|--------------------------|-------------------------|-----------------------------------|----------------------|--|
| Very satisfied | 51 | 47 | 46 | 56 | 44 |
| Satisfied | 40 | 45 | 45 | 37 | 35 |
| Neutral | 6 | 6 | 4 | 2 | 10 |
| Dissatisfied | 3 | 2 | 3 | 4 | 3 |
| Very dissatisfied | 0 | 0 | 2 | 1 | 8 |

Table 3 Free text feedback from patients

| Positives | | Negatives | |
|-----------------------|---|-------------------------|---|
| Logistical advantages | A better way to avoid coming to hospital during COVID-19 Good and efficient way to receive results Great service to be seen at home | Lack of visual feedback | More explanation of X-ray required as I could not see it Video conferencing would be an improvement <i>e.g.</i> , Skype/Zoom Prefer F2F to show doctor the deformity |
| | Telephone consultations made the process quicker than attending the hospital for an appointment | Consultation timings | Was not expecting telephone consultation, a pre-warning text message may have helped |
| Overall Satisfaction | Very satisfied - doctor really listened and able to ask questions Very clear and precise Doctor was very helpful Doctor very friendly Pleasant doctor | Patient confidence | No specific time given, better to have one hour slots or "window" Would prefer F2F for first appointment Prefer F2F for more support with condition Needed to guess whether exercises were being done correctly With elderly patients important to advise to have someone accompany them on the telephone call on loudspeaker |

Table 4 P values for Fisher's exact test in level of satisfaction between age, gender and diagnosis of upper or lower limb injuries

| P value (≤ 0.05) | | | | |
|------------------|--|--------|--------|---|
| | | Age | Gender | Diagnosis of upper or lower limb injuries |
| Question 1 | Willingness for telephone consultation in the current pandemic | 0.31 | 0.32 | > 0.99 |
| Question 2 | Explanation of condition | > 0.99 | 0.09 | 0.25 |
| Question 3 | Outcome of consultation | 0.71 | 0.48 | 0.25 |
| Question 4 | Answers received to all questions | > 0.99 | 0.31 | 0.14 |
| Question 5 | Overall satisfaction | > 0.99 | 0.11 | 0.41 |
| Question 6 | Willingness for future telephone consultations | 0.81 | 0.33 | 0.43 |

explanation of patient condition/ injury; (2) satisfaction with the outcome received from the consultation; and (3) satisfaction with the answers received to patient questions during the consultation. Greater than 90% of patients were satisfied with each of the three areas within the consultation.

79% of patients agreed to future follow ups using this form of telemedicine. Patients felt they were able to obtain the required information from the comfort of their own home, avoiding exposure/spread of COVID-19 and reducing personal cost and inconvenience associated with attending a hospital appointment. In 2014, a study comparing web- based follow up to face to face consultations following joint arthroplasty found that patients in the web-based group incurred lower associated costs[14].

Remote consultations theoretically may be more cost-effective for the NHS. In our department, the average cost per appointment for all trauma and orthopaedic clinics (fracture and elective) are £206 for first time appointment and £165 for follow up appointments[15]. 80% of clinicians in our study found

Table 5 Free text suggestions from clinicians

| Suggestions |
|---|
| Lack of visual feedback |
| Visual consultations would be a great improvement and improve quality of consultation |
| Video software that will also allow sharing of clinicians' screen would be more informative as imaging can be shown |
| Workload |
| Dedicated administrator for telephone consultation preparation would be useful |
| Lack of examination |
| Difficult to examine patients. Often reliant on family or patient's own interpretation of examination |
| Could be limited to follow ups only |
| Difficult to build rapport or trust |

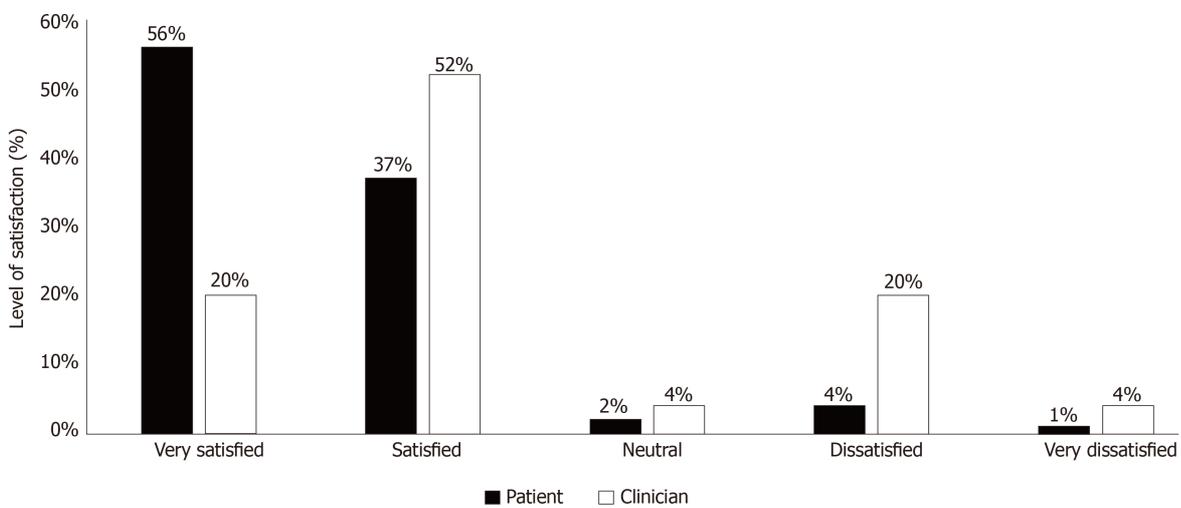


Figure 1 Compares patient and clinician overall satisfaction with telephone consultations.

that telephone consultations took the same amount of time or less compared to F2F consultations. Unfortunately, at present, we are unable to comment on the cost-effectiveness of this new telephone consultation service because costing returns are carried out every 3 months. The main cost for an outpatient department is staff payroll. During the pandemic, staff base has not changed because many clinicians were deployed to carry out COVID related duties. Therefore, the base staff cost remained static. Marsh *et al*[16] in 2014, carried out an economic evaluation of web-based (\$98 per patient) compared with in- person follow up (\$162 per patient) and showed that service costs were significantly lower in the web-based group[16]. In the near future, if clinicians are back to their normal duties and telephone consultations continue then the average cost per appointment may reduce because more appointments will be carried out per clinician *via* the telephone and fewer staff may be required to review the same number of patients. This aspect of remote consultations is worthwhile to investigate to ascertain its costing benefits as the NHS is constantly under pressure to provide a cost- effective service but at the same time respond to the rising needs and demands of the population.

72% of clinicians were overall satisfied with telephone consultations. 80% agreed with continuing this method of consultation after the pandemic. Our findings were in contrast with a recent study published in Madrid where only 37.5% of clinicians agreed with continuing telephone consultations in the future because they felt this method of consultation may have limitations for first clinical appointments[17]. Even though our study did not differentiate between first and follow up appointments we had high satisfaction rates to continue this form of telemedicine consultation in the post pandemic era. We recognise that there is a need for further research in identifying the challenges related to first and follow up telephone consultation appointments.

Patients in our study highlighted the importance of clinician punctuality with appointment times. As a new method of consultation, there were wide variations in adherence to appointment times with some clinics being carried out earlier or later than scheduled. In most cases, patients were called by the administrative team in regard to their new date and time of appointment. To ensure future adherence to

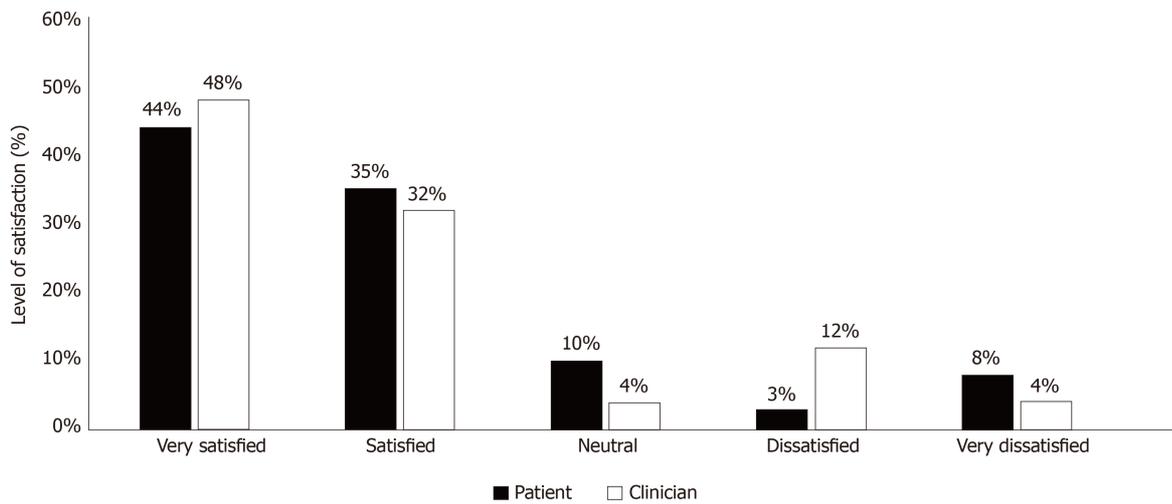


Figure 2 Compares patient and clinician willingness to continue this method of consultation in the post pandemic era.

appointment times and better communication with patients in regard to changes to their appointments a patient text messaging service could be implemented[18].

We are aware that telephone consultations have limitations from both patient and clinician perspectives. They may not be suitable for all conditions but can be a useful tool to stratify risk for each patient. It will help identify those who can be provided advice over the telephone and signposted to resources online. But it will also help identify a clinical situation that necessitates a face to face consultation.

Both patients and clinicians report a lack of visual feedback with telephone consultations. Patients were frustrated that they were unable to visually demonstrate areas of pain or deformity and they could not confirm whether the rehabilitation exercises given to them were being carried out correctly. They also expressed wishes to be able to view their imaging to have a better understanding of their condition. These concerns were also echoed by the clinicians in our study. 68% felt that telephone consultations were not as comprehensive as face to face consultations and this may be due to the inability to examine the patient, review images with patients to explain their conditions and subsequent management in more detail.

Telephone consultations require a very different skill set in comparison to F2F consultations. Clinicians carrying out telephone consultations may adequately assess patients but inadequately reassure them due to the lack of visual cues. This may mean that clinicians may need to quickly adapt specific skills for effective telephone consultations.

In our study, due to the rapid implementation of telephone consultations, clinicians did not receive any formal training, yet, 91% of patients were satisfied with the explanation of their condition and 91% found that all their questions were appropriately answered during the consultation. A number of articles have been published providing guidance on effective telephone consultations, which have also stressed the importance of accurate documentation and stated that clinic letters that are normally sent to GPs should also be sent to patients to reinforce what was discussed and avoid misunderstandings[19, 20]. It would be beneficial to review these articles by those carrying out this form of consultation.

Both patients and clinicians in our study suggested the need for video consultations to further improve their experience with remote consultations. A systematic review by Gilbert *et al*[21] in 2018, showed that patients preferred video consultations to telephone because they had visual feedback from their clinician. This increased their confidence with the information received during the consultation thus increasing their adherence to the medical advice given. They also found video consultations useful for those who have difficulty with verbal descriptions, and it was a good medium to receive rehabilitation as their exercises can be shown to them[21].

Video consultations can help overcome many challenges associated with telephone consultations. But it is important to recognise that implementation of a video consulting platform is a complex process which is resource heavy and requires the involvement of both national and local strategic leads[22]. The execution of a video consultation service requires a team of experts to install new software, adequately train clinicians and administration staff, set up videoconferencing programmes and equipment in patient’s homes and be available for any technical issues that may occur. This process is difficult, requiring a lot of planning and if implemented at speed, service failure may occur.

During our study period in the midst of the pandemic, the number of trauma and orthopaedic clinics held was 1.5 times less (23 clinics *vs* 36 clinics) and the volume of patients reviewed in these clinics was approximately twice as less compared to the same time period in 2019 (262 patients *vs* 617 patients). The reduction in the volume of patients in our clinics is likely a reflection of a change in people’s behaviour

in response to COVID-19 and the nationwide lockdown. It would be important to assess whether satisfaction levels of telephone consultations amongst our patients remain high when we revert back to running clinics at the pre-pandemic capacity as there would be increased time pressure amongst the clinicians.

Due to the unforeseen circumstances of the COVID-19 pandemic, we had to introduce a safe alternative to F2F consultations quickly. Telephone consultations were easy to implement rapidly in a department with no pre-existing remote consultation model. They were found to be an acceptable method of communication irrespective of age, gender and diagnosis. A similar finding was found in a study carried out at 5 GP practices in South Yorkshire in the United Kingdom[23].

Telephone consultations act as a steppingstone to the introduction of the more complex platform of video consulting. Our department is currently in the process of introducing a video consultation service in a planned and safe manner to ensure a more effective and interactive healthcare service delivery to our patients in the post pandemic future.

Strengths and limitations

This study has several strengths. Firstly, it has shown that telephone consultations have been well received by both clinicians and patients across all ages. Patients had high satisfaction with the opportunity to discuss their condition and have had all their questions answered to an acceptable standard. Telephone consultations have shown to be a safe and quick adaptation to the pandemic, achieving the aim of reducing hospital footfall. This study has also identified the need to further improve remote consultations by introducing video consultation services.

The rapid implementation of this method of remote consultation service within our department has resulted in this study having limitations. We were unable to put our patient and clinician questionnaires through the validation process, but we used a validated Likert scale[24] to assess satisfaction to reduce measurement error and we demonstrated satisfactory reliability of the results obtained as shown by Cronbach's alpha coefficient. Due to the time critical nature of this study, we were unable to compare satisfaction levels of telephone consultations with F2F consultations and we did not differentiate between first time and follow up clinic appointments, even though overall satisfaction amongst our patients was high. Our clinicians did not receive any specific training prior to carrying out telephone consultations but patients were satisfied with the information provided and subsequent management as a result of these consultations.

CONCLUSION

We are aware that telemedicine is not a novel approach in trauma and orthopaedics, but our study is a snapshot of patient and clinician satisfaction with the rapid implementation of telephone consultations in the midst of a pandemic. We understand that more detailed work needs to be completed to analyse the effectiveness and acceptability of telephone consultations as a form of safe healthcare delivery in the long term. But for now, it has proved an effective alternative in providing high quality healthcare during these unprecedented times.

ARTICLE HIGHLIGHTS

Research background

The coronavirus disease 2019 (COVID-19) pandemic resulted in seismic changes in healthcare delivery. Due to the high transmission risk of this infection, hospital footfall required to be reduced rapidly. Trauma and Orthopaedic clinics are one of the busiest clinical environments with high volume and rapid turnover of patient attendance. Running these clinics with appropriate social distancing to reduce the spread of infection was deemed challenging. To ensure patients can continue to safely access healthcare, we introduced orthopaedic clinic telephone consultations within our department in a busy district general hospital in England.

Research motivation

Telephone consultations were rapidly implemented within a department with no pre-existing remote consultation model in order to adapt to the COVID-19 pandemic. But in order to ensure patients received high quality care it was vital to obtain patient and clinician satisfaction with this method of remote consultation.

Research objectives

This study aimed to investigate patient and clinician perspective of telephone consultations during the COVID-19 pandemic, and whether this method of remote consultation could be a viable option in the

post- pandemic future.

Research methods

This is a single centre, prospective study conducted in a busy National Health Service district general hospital. 100 non- consecutive adult patients were contacted within 48 h of their telephone consultation to complete a patient satisfaction questionnaire which assessed satisfaction with various aspects of the consultation including willingness to continue this method of consultation in the long term. Clinician perspective and satisfaction with conducting these telephone consultations was also sought.

Research results

93% of patients were overall satisfied with telephone consultations and 79% were willing to continue this method of consultation post- pandemic. Patients found telephone consultations to reduce personal cost and inconvenience associated with attending a hospital appointment. 72% of clinicians reported overall satisfaction with this service and 80% agreed that telephone consultations should be used in the future. The majority found it less laborious in time and administration in comparison to face to face consultations. There was no statistically significant difference ($P < 0.05$) in the level of satisfaction between age groups, gender and diagnosis of upper or lower limb injuries. There was also no statistically significant difference between willingness for telephone consultations during the current pandemic and willingness for telephone consultations in the future.

Research conclusions

This study has proved that telephone consultations are an effective alternative that can be implemented rapidly to provide high quality healthcare during these unprecedented times. This method of consultation has resulted in immense clinician and patient satisfaction. Our findings suggest that this tool has benefits in the post-pandemic healthcare delivery.

Research perspectives

Although the number of patients and clinicians included was relatively small, this study provided a snapshot of patient and clinician satisfaction with the rapid implementation of telephone consultations, achieving the aim of reducing hospital footfall in response to the COVID-19 pandemic. It also highlighted the need to further improve patient experience of remote consultations with the safe and planned introduction of the more complex platform of video consultation services.

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Author contributions: Vusirikala A and Ensor D performed a literature search, created the data collection proformas, collected the data, wrote the manuscript; Asokan AK collected the data, interpreted the data and wrote the results section; Lee AJX performed statistical analysis on the data; Ray R and Tsekis D edited the manuscript; Edwin J designed the study, provided guidance on data collection proformas, edited the manuscript; all authors provided final approval for the paper to be published.

Institutional review board statement: This study was reviewed by the Research and Ethics Committee at the Basildon and Thurrock University Hospitals NHS Foundation Trust who felt this study did not require ethical approval.

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Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at anuhya.vusirikala@nhs.net. Participants consent was not obtained but the presented data are anonymized and risk of identification is low.

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Thirty-day mortality of patients with hip fracture during COVID-19 pandemic and pre-pandemic periods: A systematic review and meta-analysis

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Abstract

BACKGROUND

Timely intervention in hip fracture is essential to decrease the risks of perioperative morbidity and mortality. However, limitations of the resources, risk of disease transmission and redirection of medical attention to a more severe infective health problem during coronavirus disease 2019 (COVID-19) pandemic period have affected the quality of care even in a surgical emergency.

AIM

To compare the 30-d mortality rate and complications of hip fracture patients treated during COVID-19 pandemic and pre-pandemic times.

METHODS

The search of electronic databases on 1st August 2020 revealed 45 studies related to

mortality of hip fracture during the COVID-19 pandemic and pre-pandemic times. After careful screening, eight studies were eligible for quantitative and qualitative analysis of data.

RESULTS

The pooled data of eight studies ($n = 1586$) revealed no significant difference in 30-d mortality rate between the hip fracture patients treated during the pandemic and pre-pandemic periods [9.63% *vs* 6.33%; odds ratio (OR), 0.62; 95%CI, 0.33, 1.17; $P = 0.14$]. Even the 30-d mortality rate was not different between COVID-19 non-infected patients who were treated during the pandemic time, and all hip fracture patients treated during the pre-pandemic period (OR, 1.03; 95%CI, 0.61, 1.75; $P = 0.91$). A significant difference in mortality rate was observed between COVID-19 positive and COVID-19 negative patients (OR, 6.99; 95%CI, 3.45, 14.16; $P < 0.00001$). There was no difference in the duration of hospital stay (OR, -1.52, 95%CI, -3.85, 0.81; $P = 0.20$), overall complications (OR, 1.62; $P = 0.15$) and incidence of pulmonary complications (OR, 1.46; $P = 0.38$) in these two-time frames. Nevertheless, the preoperative morbidity was more severe, and there was less use of general anesthesia during the pandemic time.

CONCLUSION

There was no difference in 30-d mortality rate between hip fracture patients treated during the pandemic and pre-pandemic periods. However, the mortality risk was higher in COVID-19 positive patients compared to COVID-19 negative patients. There was no difference in time to surgery, complications and hospitalization time between these two time periods.

Key Words: Hip fracture; Femur neck fracture; Trochanter fracture; Mortality; Pandemic; COVID-19

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Core Tip: Timely intervention in hip fracture is essential to decrease the risks of perioperative morbidity and mortality. However, limitations of the resources, risk of disease transmission and redirection of medical attention to a more severe infective health problem during coronavirus disease 2019 (COVID-19) pandemic period have affected the quality of care even in a surgical emergency. This meta-analysis and systematic review compared the 30-d mortality rate and complications of hip fracture patients treated during COVID-19 pandemic and pre-pandemic times. The findings of the meta-analysis revealed whether the delay in surgery for hip fracture patients affected the outcome or not.

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INTRODUCTION

The health care delivery systems of most of the nations have been affected by the outbreak of coronavirus disease 2019 (COVID-19)[1]. In order to prevent the spread of the disease and to provide essential care to infected patients, many elective surgical procedures were postponed. Even emergency surgical procedures also got delayed because of the lack of human resources and operation theatre. Optimization of the patients before surgery also took a long time. Hip fracture is a surgical emergency. Despite mandatory lockdown during COVID-19 pandemic, hip fracture incidence has remained unaltered[2-5].

The most worrisome problem is that majority of these patients are elderly individuals with numerous comorbidities[6-10]. Management of such fractures in these vulnerable immunocompromised patients during COVID-19 pandemic time is a big challenge[11-29]. With the best possible care, the incidence of 30-d mortality in hip fracture has been reported between 9%-13% in the literature[14,15]. Those who survive usually have a poor functional outcome and quality of life[14,15]. During the pandemic time, when the entire medical services have focused on COVID-19 treatment, delaying of hip fracture surgery might cause increased complication and perioperative mortality. Although it was believed that COVID-19 infected patients with hip fracture might have more incidences of pulmonary complications, pneumonia and perioperative mortality, few studies reported similar mortality rates in both COVID-19 infected and non-infected patients[18,24]. The observational study by the Spanish HIP-COVID group

reported a 10% incidence of in-hospital death among fracture patients who were negative for COVID-19 [16]. Similar observations were reported by Kayani *et al*[18], who had a similar incidence of mortality in hip fracture among the COVID-19 infected and non-infected patients. Several cohort studies reported no significant difference in delay in surgery, treatment methods, complications, and 30-d mortality in the hip fracture between the pandemic and the pre-pandemic period[24,27]. Because of the small cohort of hip fracture patients during the pandemic time, such conclusion should be interpreted judiciously as it seems there is no ill-effect of COVID-19 infection *per se* on the patient and probably there is no severe consequence of slight treatment delay. Therefore, this systematic review and meta-analysis were designed to look for: (1) The 30-d mortality in hip fracture during the pandemic time *vs* the pre-pandemic time; and (2) the 30-d mortality rate between COVID-19 negative hip fracture patients and pre-pandemic era hip fracture patients. Similarly, delay in surgery, the length of hospital stay, and overall complication in the hip fracture patients in these two-time frames will be compared. We hypothesized that the 30-d mortality rate in hip fracture patients treated during the pandemic time is more than the pre-pandemic time.

MATERIALS AND METHODS

The recommendations of Preferred Reporting Items for Systematic Reviews and Meta-analyses was followed for reporting this systematic review/meta-analysis[30] (Figure 1). It was registered in PROSPERO (Regd. No.: CRD42020203581) before the data extraction and analysis.

Literature search strategy

A literature search was performed on 1st of August 2020 by two authors (Tripathy SK and Varghese P) to identify studies that have evaluated hip fractures during COVID-19 pandemic and pre-pandemic period. PubMed/Medline, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched using the keywords “COVID”, “COVID-19”, “pandemic”, “hip fracture”, “trochanter fracture” and “femur neck fracture”. The Boolean operators “and” or “or” was used with different combinations of the keywords. The search was not time-bound but limited to the English literature and human being. The exact search strategy of Medline database has been provided in Table 1. The title and abstract of the retrieved articles were assessed carefully for possible inclusion in this review. The references of the relevant articles and reviews were also searched to get more studies related to the topic. The opinion of a third author (Panda BB) was sought when there was any disagreement/ discrepancy between the two authors (Figure 1).

Study selection

Any randomized controlled trial or observational prospective/retrospective study that mentioned the 30-d mortality rate of hip fracture patients (age > 18 years) in both pandemic and pre-pandemic periods were selected for this systematic review/meta-analysis. Studies that reported on open fracture or pathological fracture were not considered. If any study reported the 30-d mortality of hip fracture only for the pandemic period, it was excluded.

The hip fracture in this review included both intracapsular (neck femur fracture) and extracapsular fracture (intertrochanteric and subtrochanteric fracture). Patients who had clinical symptoms/signs of COVID-19 with reverse transcriptase-polymerase chain reaction positive nose or throat swab for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were considered as COVID-19 infected (COVID-19 +). Asymptomatic patient with negative throat and nose swabs were considered as COVID-19 non-infected (COVID-19 -). In cases where there was strong clinical suspicion, it was labelled as COVID suspect even though the swab tests were negative. For data analysis, all suspect patients were included in the COVID-19 + group. Similarly, patients who were not tested, and there was no clinical suspicion, were categorized as COVID-19 -.

Data extraction

The data from the included studies were extracted by two authors (Tripathy SK and Varghese P). The details (author, year of publication, study design, demographic properties, surgical details, follow-up, 30-d mortality, and complications) were filled up in a Microsoft Excel sheet for subsequent analysis. The opinion of a third author (Panda BB) was sought in case of disagreement.

The primary objective of this study was to look for the 30-d mortality of hip fracture in COVID-19 pandemic period and pre-pandemic period. The secondary objective was to compare 30-d mortality of hip fracture among COVID-19 negative patients and pre-pandemic hip fracture patients. The duration of hospital stay, complications and preoperative morbidity among the hip fracture patients during these two-time frames were compared.

Methodological quality and risk of bias assessment

The methodological quality and risk of bias of the observational studies were evaluated by two authors (Tripathy SK and Varghese P) using the Newcastle-Ottawa scale (NOS)[31]. The NOS evaluates a study

Table 1 Search strategy of Medline database

| Keyword | Search strategy | No. of hits |
|---|---|-------------|
| COVID, COVID-19, Pandemic, Hip fracture, Trochanter fracture, Femur neck fracture | ((("COVID"[All Fields] AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR "ncov"[All Fields] OR "2019 ncov"[All Fields] OR "covid 19"[All Fields] OR "sars cov 2"[All Fields] OR ("coronavirus"[All Fields] OR "cov"[All Fields]) AND 2019/11/01:3000/12/31[Date - Publication])) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) AND (((("hip fractures"[MeSH Terms] OR ("hip"[All Fields] AND "fractures"[All Fields]) OR "hip fractures"[All Fields] OR ("hip"[All Fields] AND "fracture"[All Fields]) OR "hip fracture"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("femur"[MeSH Terms] OR "femur"[All Fields] OR "trochanter"[All Fields] OR "trochanters"[All Fields]) AND ("fractur"[All Fields] OR "fractural"[All Fields] OR "fracture s"[All Fields] OR "fractures, bone"[MeSH Terms] OR ("fractures"[All Fields] AND "bone"[All Fields]) OR "bone fractures"[All Fields] OR "fracture"[All Fields] OR "fractured"[All Fields] OR "fractures"[All Fields] OR "fracturing"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("femoral neck fractures"[MeSH Terms] OR "femoral"[All Fields] AND "neck"[All Fields] AND "fractures"[All Fields]) OR "femoral neck fractures"[All Fields] OR "femur"[All Fields] AND "neck"[All Fields] AND "fracture"[All Fields]) OR "femur neck fracture"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) | 24 |

COVID-19: Coronavirus disease 2019.

in three domains (8 items with maximum score 9): Study group selection, comparability of the groups, and determining the outcome of interest for case-control and cohort studies[31]. A score of more than six was considered as a high-quality study. In case of disagreement between the authors, the opinion of a third author (Naik MA) was sought.

Statistical analysis

The Review Manager (RevMan) V.5.3 was used for data analysis[32]. Few studies provided the median value and interquartile range (IQR). The mean and SD value was calculated from the median and IQR as per the recommendation of Luo *et al*[33] and Wan *et al*[34]. The study, providing the previous two years of data (pre-pandemic) were evaluated jointly, and the mean (SD) was calculated using the RevMan calculator. Whenever feasible, data were pooled for analysis. For the comparison of binary data, the odds ratio (OR) and a 95% confidence interval (CI) were calculated. Similarly, the mean difference (MD) and 95%CI were estimated for continuous data. The *P* value of < 0.05 was considered as statistically significant. The heterogeneity among the cohort studies was evaluated by Cochrane's Q ($\chi^2 P < 0.10$) and quantified by *I*²-Higgins test. The *I*² value of 25%, 50% and 75% were considered as low, moderate, and high grade of heterogeneity, respectively[35,36]. The random-effects model was applied to address the high grade of heterogeneity (*I*² > 50%)[37].

RESULTS

Selection of the study, quality assessment, and patient demographics

A total of 45 studies were retrieved after the search of electronic databases using the keywords; of which, eight studies were eligible for review after screening[9,19,20,27-29,38,39] (Figure 1). There were three prospective studies and five retrospective comparative studies. The inclusion and exclusion criteria were well defined in all studies. Assessment of quality of the studies using NOS revealed a low risk of bias in one study and moderate risk of bias in the remaining seven studies (Table 2). The data of 901 hip fracture patients who were treated during the pre-pandemic period (similar time in 2018 and 2019) was evaluated, and it was compared to 685 hip fracture patients treated during the pandemic period. There were 77 COVID-19 + patients and 608 COVID-19 – patients (Table 2). The mean/median age of the patients in all studies was above 75 years during both pre-pandemic and pandemic periods. The female patients had more incidences of hip fracture during both the time periods. The study by Macey *et al*[9] had age- and sex-matched hip fracture patient cohort from the pre-pandemic time. The body mass index and domicile status during both time periods have been provided in Table 2.

Table 2 Demographic properties, fracture type and surgical techniques in hip fractured patients treated during coronavirus disease 2019 and pre-coronavirus disease 2019 times (2020)

| Study/country | Macey <i>et al</i> [9]/United Kingdom | Malik-Tabassum <i>et al</i> [38] /United Kingdom | Segarra <i>et al</i> [27]/Spain | Thakrar <i>et al</i> [19] /United Kingdom | Egol <i>et al</i> [20]/United States | Williams <i>et al</i> [28]/United Kingdom | Slullitel <i>et al</i> [39] /Argentina | Karayiannis <i>et al</i> [29] /United Kingdom | |
|--------------------------|--|---|--|--|---|---|--|--|---|
| Study design | Retrospective study with prospective data collection | Retrospective observational studies | Longitudinal prospective cohort study | Prospective cohort study | Prospective cohort study | Retrospective observational study | Retrospective case-control study | Retrospective case-control study, multicentre | |
| Sample size/ duration | Pre-COVID | 76 (20 th March 2019-24 th April 2019) | 174 [90 (23 rd March 2018-11 th May 2018); 84 (23 rd March 2019-11 th May 2019)] | 70 (1 st February 2019-15 th April 2019) | 99 [51 (15 th March 2018-15 th April 2018); 48 (15 th March 2019-15 th April 2019)] | 115 (1 st February 2019-15 th April 2019) | 15 (January 2020) | 86 (1 st December 2019-19 th March 2020) | 266 (18 th March 2019-27 th April 2019) |
| | COVID | 76 (20 th March 2020-24 th April 2020) | 68 (23 rd March 2020-11 th May 2020) | 68 (1 st February 2020-15 th April 2020) | 43 (15 th March 2020-15 th April 2020) | 138 (1 st February 2020-15 th April 2020) | 15 (March 2020) | 74 (20 th March 2020-31 st May 2020) | 203 (18 th March 2020-27 th April 2020) |
| | COVID + | 10 (13.16%) | 1 (1%) | 2 (2.94%) | 12 (27.9%) | 31 (22.5%) | 0 | 0 | 21 (10.35%) |
| | COVID - | 66 (86.84%) | 67 (99%) | 66 (97%) | 31 (72.1%) | 107 (77.5%) | 15 (100%) | 74 (100%) | 182 (89.65%) |
| NOS | 8 (moderate risk) | 8 (moderate risk) | 7 (moderate risk) | 8 (moderate risk) | 9 (low risk) | 7 (moderate risk) | 8 (moderate risk) | 7 (moderate risk) | |
| Age (yr) | Pre-COVID | Median: 83 (IQR, 74-88) | 2018: 82.9 ± 9.9; 2019: 83.8 ± 7.7 | 84 ± 7.8 | 2018: 81.6 ± 12.3; 2019: 84.0 ± 8.7 | 81.5 ± 10.7 | 86.6 | Median: 86 (IQR, 78-90) | 78.0 ± 12.8 |
| | COVID | Median: 83 (73-87) | 84.3 ± 8.9 | 82.4 ± 7.4 | 81.6 ± 11.3 | 83.0 ± 10.2 | 81.5 | Median: 86 (IQR, 80-91) | 81.3 ± 9.7 |
| Sex, M:F | Pre-COVID | 58:18 | 37:137 | 18:52 | 25:74 | 34:81 | 2:13 | 19:67 | 79:187 |
| | COVID | 58:18 | 25:43 | 21:47 | 23:20 | 50:88 | 3:12 | 9:65 | 65:138 |
| BMI (kg/m ²) | Pre-COVID | NM | NM | NM | NM | 24.6 ± 5.2 | NM | Median 24 (IQR, 21.7-26.6) | NM |
| | COVID | NM | NM | NM | NM | 24.4 ± 5.1 | NM | Median 24.5 (IQR, 22.3-27.3) | NM |
| Domicile status | Pre-COVID | Home: 58 (79.45%); residential care: 10 (13.69%); hospital: 5 (6.84%) | Nursing care: 14 (8.04%); own home/sheltered housing: 135 (77.58%); residential care: 25 (14.36%) | NM | NM | NM | NM | NM | NM |
| | COVID | Home: 61 (80.2%); residential care: 11 (14.47%); hospital: 4 (5.26%) | Nursing care: 8 (11.8%); own home/sheltered housing: 52 (76.5%); residential care: 8 (11.8%) | NM | NM | NM | NM | NM | NM |

| | | | | | | | | | |
|---------------------|-----------|--|--|---|---|---|--|--|--|
| ASA grade | Pre-COVID | 1:2 (2.6%); 2:18 (24%); 3:42 (56.3%); 4:13 (17.3%); 5:0 (0%) | 1:4 (2.29%); 2:53 (30.4%); 3:98 (56.3%); 4:19 (10.9%) | 1:0; 2:22 (31.4%); 3:48 (68.6%); 4:0 | NM | NM | NM | 1 and 2: 22 (25.6%); 3 and 4: 64 (74.4%) | 1 and 2: 66 (25.3%); 3, 4 and 5: 195 (74.7%) |
| | COVID | 1:2 (2.6%); 2:12 (15.7%); 3:51 (67%); 4:9 (11.8%); 5:2 (2.6%); | 1:0 (0.0%); 2:17 (25.0%); 3:47 (69.1%); 4:4 (5.9%); | 1:0; 2: 29 (42.7%); 3:37 (54.4%); 4:2 (2.9%) | NM | NM | NM | 1 and 2: 12 (16.2%); 3 and 4: 62 (84%) | 1 and 2: 35 (17.2%); 3, 4 and 5: 168 (82.8%) |
| Anesthesia | Pre-COVID | GA: 51 (69.8%); SA: 22 (30.1%) | NM | NM | NM | GA: 78 (70.3%); SA: 33 (29.7%) | NM | NM | GA: 76 (29.1%); SA/nerve block: 185 (70.9%) |
| | COVID | GA: 36 (50%); SA: 36 (50%) | NM | NM | NM | GA: 82 (61.2%); SA: 52 (38.8%) | NM | NM | GA: 37 (18.2%); SA/nerve block: 166 (81.8%) |
| Time to surgery (h) | Pre-COVID | Median: 20 (IQR, 16-25); ¹ mean: 20.35 ± 6.80 | 2018: 26.5 ± 18.7; 2019: 28.2 ± 51.7 | 36 ± 38.4 | NM | 33.6 ± 19.2 | 21.8 (range, 8-48) | Median: 16.5 (IQR, 9-30); ¹ mean 18.61 ± 15.83 | < 24 h: 56 (21.4%); 24-48 h: 85 (32.6%); > 48 h: 120 (46.0%) |
| | COVID | Median: 23 (IQR, 18-30); ¹ mean: 23.7 ± 9.06 | 21.8 ± 12.1 | 43.2 ± 31.2 | 51.2 | 33.6 ± 36 | 35.8 (range, 8.5-79) | Median: 24 (IQR, 24-48); ¹ mean: 32.46 ± 18.14 | < 24 h: 78 (38.4%); 24-48 h: 92 (45.3%); > 48 h: 33 (16.3%) |
| Fracture type | Pre-COVID | FN: 45 (59.2%); IT: 31 (40.7%) | FN: 101 (58.0%); IT: 66 (37.9%); ST: 7 (4.02%) | NM | NM | FN: 43 (37.4%); IT: 69 (60.0%); ST: 3 (2.6%) | NM | IT: 45 (52.33%); FN: 41 (47.67%) | FN: 266 |
| | COVID | FN: 51 (67.1%); IT: 25 (32.8%) | FN: 44 (64.7%); IT: 21 (30.8%); ST: 3(4.41%) | NM | NM | FN: 71 (51.4%); IT: 60 (43.5%); ST: 7 (5.1%) | NM | FN: 33 (44.59%); IT: 41 (55.41%) | FN: 203 |
| Surgical techniques | Pre-COVID | Nonoperative: 3 (3.9%); DHS: 26 (34.2%); IMN: 9 (11.8%); Hemi A: 31 (40.7%); THA: 7 (9.2%); CRPP: 0 (0%) | THA: 12 (6.8%); Hemi A: 77 (44.2%); CCS: 4 (2.29%); DHS: 48 (27.5%); IMN: 31 (17.8%); Nonoperative: 2 (1.14%) | Operative: 67 (95.7%); nonoperative: 3 (4.3%) | NM | IMN: 61 (54.9%); Hemi A: 22 (19.8%); THA: 10 (9.0%); DHS: 10 (9.0%); CRPP: 8 (7.2%); nonoperative: 4 (3.5%) | All operative (15) | CS: 11 (12.8%); Hemi A: 14 (16.3%); THA: 19 (22.1%); Girdlestone: 1 (1.1%); IMN: 41 (47.7%); nonoperative: 0 | Hemi A: 115 (44.1%); DHS: 68 (26%); IMN: 43 (16.5%); THA: 35 (13.4%); conservative: 5 (1.9%) |
| | COVID | Nonoperative: 3 (3.9%); CRPP: 1 (1.31%); DHS: 14 (18.4%); IMN: 13 (17.1%); Hemi A: 42 (55.2%); THA: 3 (3.9%) | Nonoperative: 2 (2.94%); CCS: 3 (4.41%); DHS: 12 (17.64%); IMN: 11 (16.17%); Hemi A: 39 (57.35%); THA: 1 (1.47%) | Operative: 64 (94.1%); nonoperative: 4 (5.9%) | DHS: -7 (16.27%); CS: 3 (6.9%); Hemi A: 15 (34.8%); IMN: 13 (30.2%); THA: 1 (2.3%); Rev THA: 4 (9.3%) | IMN: 64 (46.3%); Hemi A: 42 (31.3%); THA: 6 (4.5%); DHS: 7 (5.2%); CRPP: 15 (11.2%); nonoperative: 4 (2.9%) | Operative:14; 1 patient expired before surgery | CS: 2 (2.75%); Hemi A: 20 (27%); THA: 10 (13.5%); Girdlestone: 0; IMN: 41 (55.4%); nonoperative: 1 (1.35%) | Hemi A:113 (55.7); DHS: 47 (23.1%); IMN: 36 (17.7%); THA: 7 (3.4%); conservative: 0 |

¹Indicates that the mean has been calculated from the median value and interquartile range/range. NOS: Newcastle-Ottawa scale; M: Male; F: Female; ASA: American Society of Anesthesiologists Classification; COVID: Coronavirus disease 2019; IQR: Interquartile range; NM: Not mentioned; GA: General anesthesia; SA: Spinal anesthesia; FN: Femoral neck fracture; IT: Intertrochanteric fracture; DHS: Dynamic hip screw; IMN: Intramedullary nail; Hemi A: Hemiarthroplasty; THA: Total hip arthroplasty; CRPP: Closed reduction percutaneous pinning; ST: Subtrochanteric fracture; CS: Cannulated screw; CCS: Cannulated compression screw; Rev THA: Revision total hip Arthroplasty.

Preoperative morbidity, time to surgery and type of anesthesia

The preoperative morbidity status of the patients in both pandemic and pre-pandemic periods were compared using the American Society of Anesthesiologists (ASA) classification. Pooled analysis of five studies ($n = 1159$) revealed significantly increased number of severely morbid (ASA grade > 3) hip fracture patients who were treated during the pandemic period (OR, 1.43; 95% CI, 1.08, 1.89; $P = 0.01$)[9, 27,29,38,39]. Egol *et al*[20] (2020) did not observe a significant difference in preoperative morbidity using

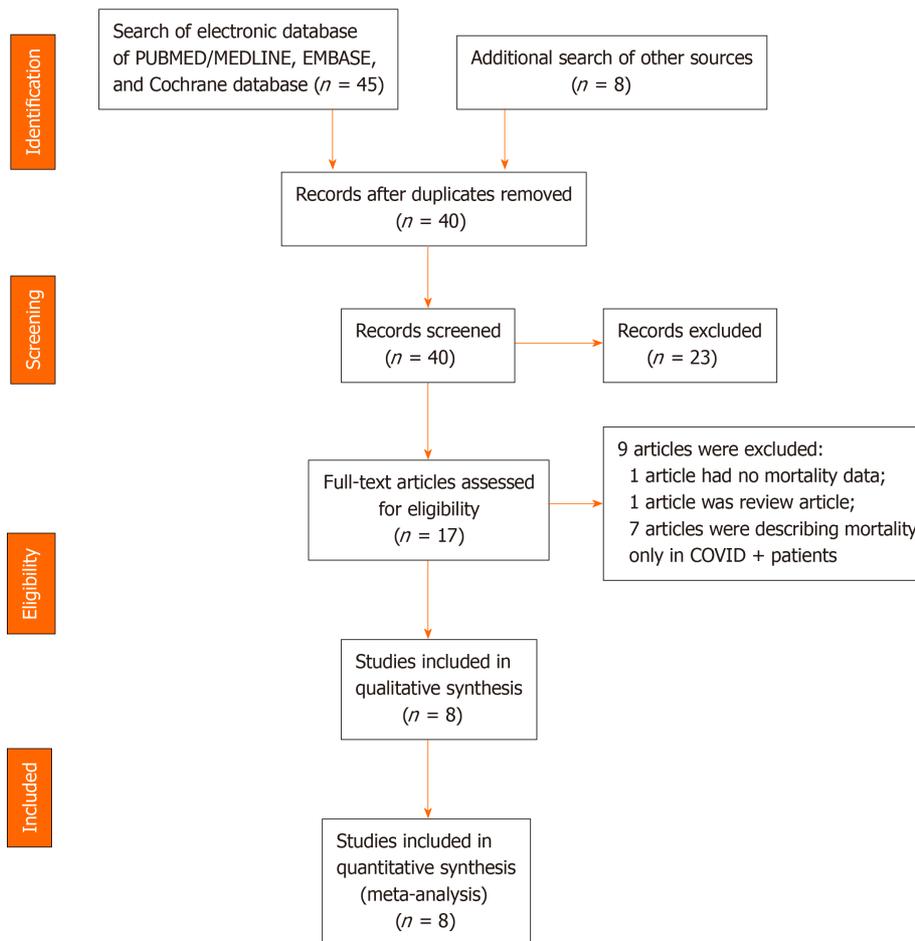


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram showing methods of study recruitment. COVID-19 +: Coronavirus disease 2019 infected.

the Charlson Co-morbidity index between 2020 hip fracture cohort and 2019 hip fracture cohort.

After pooling of the data from five studies [9,20,27,38,39], it was observed that there was no difference in time to surgery following the injury (MD, 6.57; 95%CI, -0.25, 13.39; $P = 0.06$). The high grade of heterogeneity ($I^2 = 88\%$) among the studies was addressed by the random effect model (Figure 2).

Only three studies ($n = 874$) had provided details about the type anesthesia (regional *vs* general anesthesia) used during surgery [9,20,29]. There was significantly less use of general anesthesia during the pandemic period (37.17% *vs* 44.86%; OR, 0.57; 95%CI, 0.42, 0.77; $P = 0.0003$) (Figure 2).

Mortality, length of hospital stay, complications

Pooled analysis of 30-d mortality from the eight studies ($n = 1586$) revealed a significantly increased death among hip fracture patients during the pandemic time (9.63% *vs* 6.33%; OR, 0.62; 95%CI, 0.33, 1.17; $P = 0.14$) (Table 3, Figure 3) [9,19,20,27-29,38,39]. There was no difference in 30-d mortality rate between COVID-19 negative patients who were treated during the pandemic time and all hip fractured patients treated during the pre-pandemic period (6.44% *vs* 5.74%; OR, 1.03; 95%CI, 0.61, 1.75; $P = 0.91$) [9,19,20,29,38]. However, a significant difference in mortality rate was observed between COVID-19 + and COVID-19 - patients with an OR of 6.99 (29.33% *vs* 5.73%; 95%CI, 3.45, 14.16; $P < 0.00001$) (Table 3, Figure 3) [9,19,20,29,38].

There was no difference in length of hospital stay among hip fracture patients treated during pandemic and pre-pandemic periods (OR, -1.52; 95%CI, -3.85, 0.81; $P = 0.20$) [9,20,38,39]. Similarly, major complications (17.98% *vs* 10.64%; OR, 1.62; $P = 0.15$) and the incidence of pulmonary complications (9.09% *vs* 6.78%; OR, 1.46; $P = 0.38$) among the hip fracture patients during these two-time frames were not different (Table 3, Figure 4) [9,20,38,39].

DISCUSSION

The main finding of the meta-analysis was that there was no difference in 30-d mortality in hip fracture patients between the pandemic and pre-pandemic periods. Even, the mortality risk was not different

Table 3 Mortality and complications in hip-fractured patients treated during coronavirus disease 2019 and pre-coronavirus disease 2019 times (2020)

| Study/country | | Macey <i>et al</i> [9] /United Kingdom | Malik-Tabassum <i>et al</i> [38] /United Kingdom | Segarra <i>et al</i> [27] /Spain | Thakrar <i>et al</i> [19] /United Kingdom | Egol <i>et al</i> [20] /United States | Williams <i>et al</i> [28] /United Kingdom | Slullitel <i>et al</i> [39] /Argentina | Karayiannis <i>et al</i> [29] /United Kingdom |
|---|-----------|---|---|-------------------------------------|--|--|---|--|--|
| 30-d mortality | Pre-COVID | 10 (13%) | 12 (6.89%) | 9 (12.9%) | 6 (6.06%) | 3 (2.7%) | 1 (6.6%) | 0 | 16 (6%) |
| | COVID | 11 (14%) | 6 (8.8%) | 8 (11.8%) | 7 (16.3%) | 17 (12.3%) | 2 (13.3%) | 8 (10.8%) | 7 (3.4%) |
| | COVID + | 2 (20%) | 1 (100%) | NM | 4 (33%) | 9 (52.9%) + 2 (14.3%); Total-11 (35.4%) | NM | NM | 4 (57.14%) |
| | COVID - | 9 (13.6%) | 5 (7.4%) | NM | 3 (9.6%) | 6 (5.6%) | NM | NM | 3 (42.86%) |
| In-patient mortality | Pre-COVID | NM | 11 (6.32%) | NM | NM | 1 (0.9%) | NM | NM | NM |
| | COVID | NM | 4 (5.9%) | NM | NM | 8 (5.8%) | NM | NM | NM |
| Length of hospital stay (d) | Pre-COVID | Median: 12 (range, 7-26); ¹ mean: 14.25 ± 3.17 | 2018: 15.8 ± 11.4; 2019: 16.3 ± 11.4 | NM | NM | 5.8 ± 3.7 | 11.7 | Median: 5 (IQR, 4-7); ¹ mean: 5.35 ± 2.26 | NM |
| | COVID | Median: 11.5 (range, 6-22); ¹ mean: 12.75 ± 2.67 | 8.6 ± 4.6 | NM | NM | 5.8 ± 3.8 | 6.2 | Median: 6 (IQR, 5-8); ¹ mean: 6.35 ± 2.26 | NM |
| Major complications | Pre-COVID | 11 (14.5%) | 17 (9.7%) | NM | NM | 10 (8.7%) | NM | 10 (11.6%) | NM |
| | COVID | 17 (22.4%) | 3 (4.5%) | NM | NM | 28 (20.3%) | NM | 16 (21.6%) | NM |
| Pulmonary complications/pneumonia/respiratory infection | Pre-COVID | 8 (10.95%) | NM | NM | NM | NM | 2 (13.3%) | 2 (2.32%) | NM |
| | COVID | 15 (20.54%) | NM | NM | NM | NM | 0 | 0 | NM |
| Deep vein thrombus/pulmonary embolism | Pre-COVID | 1 (1.36%) | 2 (1.14%) | NM | NM | NM | NM | 0 | NM |
| | COVID | 0 | 1 (1.47%) | NM | NM | NM | NM | 5 (6.75%) | NM |

¹Indicates that the mean has been calculated from the median value and interquartile range/range. COVID: Coronavirus disease 2019; COVID +: Coronavirus disease 2019 infected; COVID -: Coronavirus disease 2019 non-infected; NM: Not mentioned; IQR: Interquartile range.

among the COVID-19 – patients of pandemic time and all hip fracture patients of pre-pandemic time. However, significantly increased 30-d mortality rate was observed in COVID-19 + patients. There was less use of general anesthesia during the pandemic period and patients with hip fracture treated during this time were severely morbid.

Early intervention in hip fracture reduces morbidity and mortality. A shorter hospital stay and minimal respiratory complications have been reported if the hip fracture surgery is stabilized within 24 h of admission[40,41]. During the pandemic, there was difficulty in treating these patients within the stipulated time[42,43]. Accordingly, a high incidence of 30-d mortality was expected, but the pooled analysis of the studies did not observe a significant difference in mortality among the hip fracture patients treated during the pandemic and pre-pandemic periods. However, the difference in the mortality was limited to the COVID-19 + patients as the analysis failed to notice a difference between COVID-19 – patients and pre-pandemic hip fracture patients. The respiratory compromise because of the COVID-19 infection in the perioperative period acts as a second hit phenomenon as the cytokines are already flared up by the traumatic hip fracture[18,20,24]. Prolonged recumbency, poor immunity and multiple comorbidities in the elderly individuals are also detrimental[43,44]. Nevertheless, asymptomatic COVID-19 – patients are not different from the typical elderly cohort. Accordingly,

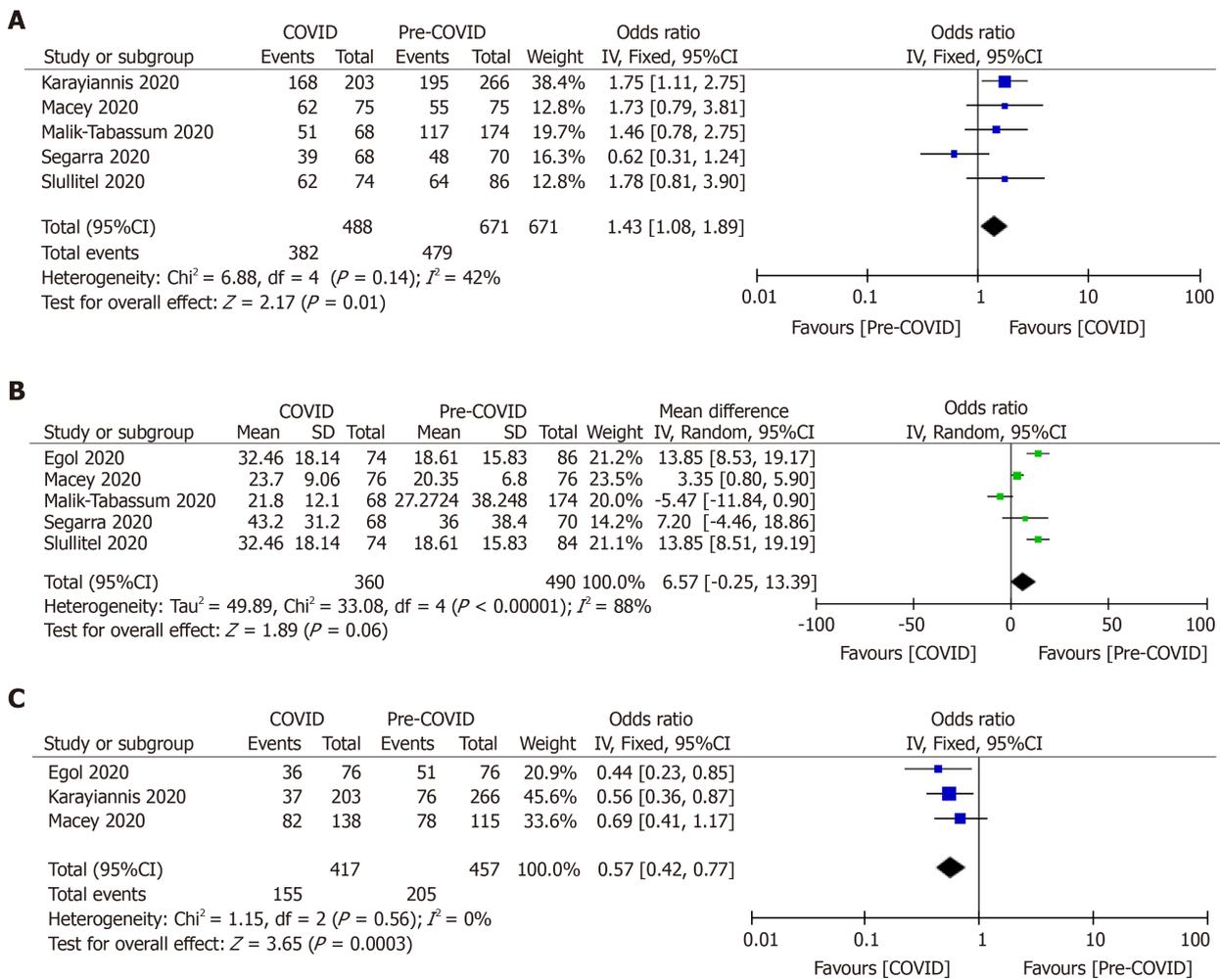


Figure 2 Forest-plot diagram showing preoperative morbidity, time to surgery and use of general anesthesia among hip-fractured patients during the pandemic and pre-pandemic periods. A: Preoperative morbidity (American Society of Anesthesiologists grade); B: Time to surgery; C: General anesthesia. COVID: Coronavirus disease 2019.

segregations of the hip fracture patients into the COVID-19 positive site or the negative site will minimize cross-infection, and it will help in early delivery of medical care to the non-infected patients [24,27]. The patient may be temporarily held up in a transition zone till COVID-19 test result is available.

The importance of patient segregation into two different sites has been evaluated by Chui *et al*[24] and Segarra *et al*[27]. Chui and his associate did not notice a significant difference in mortality between COVID-19 infected and non-infected patients as they could operate 61% of hip fractured patients within 36 h[24]. It has been reported that the respiratory symptoms have improved after femur fracture stabilization[23]. Catellani *et al*[23] advocated that the patients could be mobilized after surgery with general patient comfort, and there was an improvement in physiological ventilation. Few studies reported a slight delay (48-72 h) in providing care to the COVID-19 infected compared to non-infected patients because of the need for medical optimization of these patients[18,20,24]. Whether this delay was responsible for increased mortality in the COVID-19 positive patients is unknown. Overall, there was no significant delay in time to surgery during this epidemic. It indicates the promptness of medical health care professionals in understanding the timely delivery of emergency care. Despite understanding the risk of disease transmission, the orthopedic surgeons have given priority to the patients' health and safety. In order to evaluate the impact of COVID-19 infection in the hip fracture patients, the mortality rate of these patients was compared with the national average mortality rate of the corresponding country that has been related to COVID-19 infection. The national statistics bulletin report of United Kingdom stated that 13.7% of all deaths that occurred in England (45439 deaths) between January and July 2020 was COVID-19 related and it was 10.8% in Wales (2274 deaths) for the same period. The age-standardized mortality rates for deaths due to COVID-19, per 100000 persons, in England for March, April and May 2020 (for the period under consideration in this meta-analysis), were 33.8, 623.2 and 244.8 respectively[45,46]. It is quite apparent that the death rate of hip fracture patients with the SARS-CoV-2 infection is very high (29.33% as per the current meta-analysis) compared to the national average

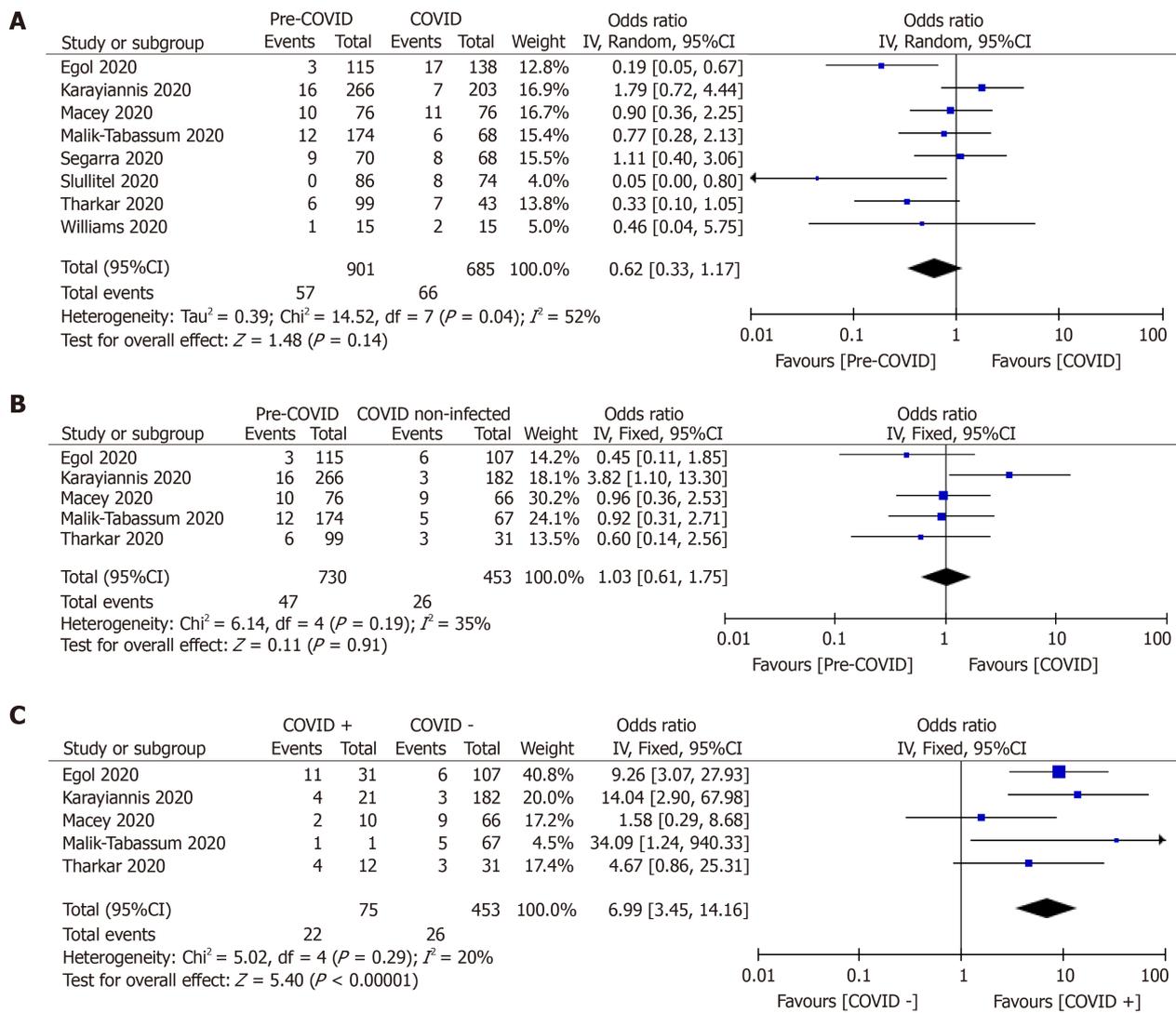


Figure 3 Forest-plot diagram showing 30-d mortality among hip-fractured patients in these two time frames. A: Thirty-day mortality rate in hip-fractured patient during pre-coronavirus disease 2019 (COVID-19) and COVID-19 periods; B: Thirty-day mortality rate in hip-fractured patient managed during pre-COVID-19 time vs COVID-19 non-infected hip-fractured patients managed during COVID-19 time; C: Thirty-day mortality rate in COVID-19 infected and COVID-19 non-infected hip-fractured patients managed during COVID-19 pandemic time. COVID: Coronavirus disease 2019; COVID +: COVID-19 infected; COVID -: COVID-19 non-infected.

death due to COVID-19 infection (13.7%, five studies are from the United Kingdom).

Previous literature revealed that COVID-19 patients with multiple associated comorbidities had an increased risk of death when admitted to the critical care service[18,20,24,45]. Deng *et al*[47] compared the clinical characteristics, blood parameters and morbidity of 109 COVID-19 + patients who died during hospitalization with 116 recovered patients. The risk of mortality increased from 41.5% to 72.5% (P < 0.01) in patients with associated pre-existing comorbidities[45]. The national statistics bulletin of England and Wales reported 50335 deaths involving COVID-19 between March and June 2020. About 91% of these patients had at least one pre-existing disease, and the remaining 9% had no associated comorbidity[45,46]. The average number of comorbidities for COVID-19 related death was 2.1 for patients of 0-69 years of age, and it was 2.3 for patients aged > 70 years[45,46]. Center for Disease Control and Prevention reported that 8 out of 10 COVID-19 deaths in the United States have been in the older individuals of age > 65 years[48]. Poor immunological status and multiple chronic pre-existing disease conditions such as hypertension, diabetes mellitus and chronic cardiorespiratory disorders were attributed for this high death rate[18,20,24,47,48]. The preoperative comorbidities, as reported using ASA grading system, showed increased pre-morbid patients during the pandemic time in this review. These patients had probably poor systemic baseline function and their physiological capability to endure the surgical procedure was limited[18,20,24]. The concomitant use of angiotensin-converting enzyme (ACE) inhibitors that up-regulates the expression of ACE-2 receptors hypothetically might have increased the virus-cell binding and thereby increased the virus transmission into the cell in the COVID-19 patients. The resultant increased viral load explains the increased rate of mortality[49]. Regarding the

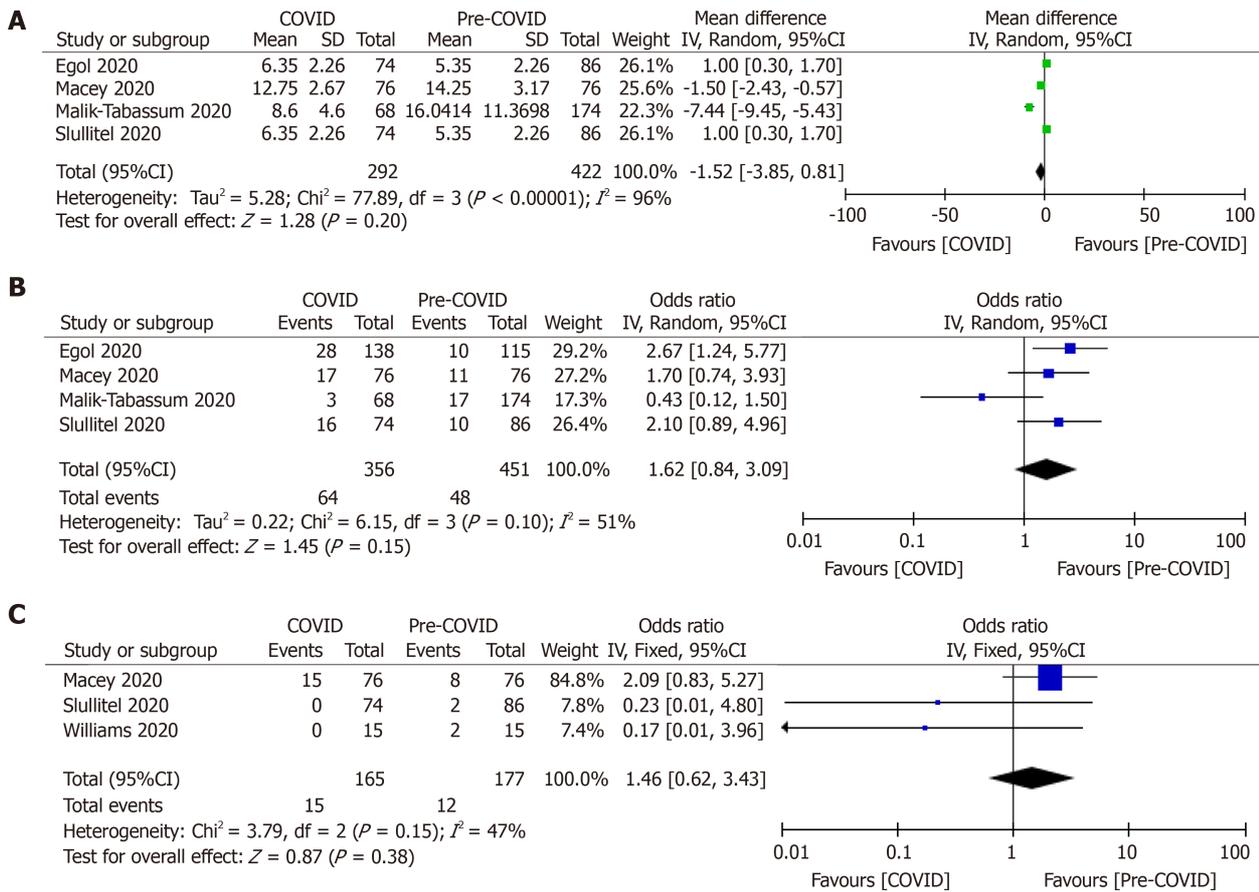


Figure 4 Forest-plot diagram showing length of hospital stay, overall complications, and respiratory complications among hip-fractured patients during the pandemic and pre-pandemic periods. A: Length of hospital stay; B: Major complications; C: Pulmonary complications. COVID: Coronavirus disease 2019.

increased numbers of pre-morbid patients during the pandemic time, we believe that most of these old patients had not performed their regular check-up for chronic illnesses because of lockdown, and restriction of medical service for regular care. Despite the poorly controlled chronic disease conditions among all hip fracture patients, the increased mortality was selectively observed in the COVID-19 + patients.

General anesthesia increases the risk of aerosol exposure among health care workers and hence increases the chance of infection in them [16,18,20]. Besides, the general anesthesia also augments an inflammatory reaction within the lung parenchyma of the patients. Consequently, there was significantly less use of general anesthesia during the pandemic time compared to the pre-pandemic period. Despite the recommendation of regional anesthesia, Kayani *et al* [18] noted no difference in types of anesthesia between COVID-19 infected and non-infected patients in their series.

Many researchers reported increased early mortality, increased length of hospital stay, a higher incidence of major complications, and a greater incidence of respiratory complications in COVID-19 infected compared to the non-infected patients [16,18,20]. However, this meta-analysis did not perceive a significant difference in major complications, length of hospital stay and respiratory complication among hip fracture patients managed during the pandemic and pre-pandemic times. Probably the higher proportion of COVID-19 – patients (89%) in the evaluation controlled the result or, most of the COVID-19 + patients were probably asymptomatic or minimally affected by the infection.

There were certain limitations to this meta-analysis. All these studies are from developed nations where the health care sectors are streamlined and protocol-based; hence it cannot be generalized to all nations. Only 30-d follow up has been studied in this review, so the outcome after one month is unknown. The retrospective study design and small patient cohort are also the main limitations for this meta-analysis. Despite that, this meta-analysis is first of its kind comparing the mortality and morbidity among hip fracture patients during the pandemic and pre-pandemic periods.

CONCLUSION

To conclude, there was no difference in 30-d mortality rate among hip fracture patients treated during the COVID-19 pandemic and pre-pandemic periods. The mortality risk was significantly high among COVID-19 + patients as compared to non-infected patients. With the development of better drug and better treatment protocol of COVID-19, the interpretation of this meta-analysis might change.

ARTICLE HIGHLIGHTS

Research background

During the coronavirus disease 2019 (COVID-19) pandemic time, the attention of the whole of the medical fraternity was diverted to the infective viral severe acute respiratory syndrome coronavirus-2 infection. There was a huge risk of infection among the medical staffs and patients coming to the hospital for other serious problems. Limitations of the operation theatre and medical staff were other hurdles in tackling life-threatening emergency surgeries. Although the mandatory lockdown policy might have reduced the incidence of the road traffic accident, the incidence of fragility fractures remained unaltered. Hip fracture is a surgical emergency and needs urgent surgical intervention to reduce morbidity and mortality. The impact of the COVID-19 infection on hip fracture management has been studied by a few researchers.

Research motivation

This systematic review and meta-analysis were designed to look for the impact of COVID-19 infection on hip fracture management and outcome.

Research objectives

The objectives of this meta-analysis were to compare the 30-d mortality and complications of hip fracture management during COVID-19 pandemic time and pre-pandemic time.

Research methods

The search of electronic databases was performed to retrieve studies related to hip fracture management during COVID-19 pandemic and pre-pandemic times. A total of 45 studies were identified, of which eight studies were eligible for quantitative and qualitative analysis of data.

Research results

The pooled data of eight studies with 1586 patients showed no significant difference in 30-d mortality rate between the hip fracture patients treated during the pandemic and pre-pandemic periods [9.63% *vs* 6.33%; odds ratio (OR), 0.62; 95%CI, 0.33, 1.17; $P = 0.14$]. Even there was no difference in the 30-d mortality rate between COVID-19 – patients managed during the pandemic time *vs* all hip fracture patients managed during the pre-pandemic period (OR, 1.03; 95%CI, 0.61, 1.75; $P = 0.91$). A significant difference in mortality rate was observed between COVID-19 positive and COVID-19 negative patients (OR, 6.99; 95%CI, 3.45, 14.16; $P < 0.00001$). There was no difference in the duration of hospital stay (OR, -1.52; 95%CI, -3.85, 0.81; $P = 0.20$), overall complications (OR, 1.62; $P = 0.15$) and pulmonary complications (OR, 1.46; $P = 0.38$) in these two-time frames. Nevertheless, the preoperative morbidity was more severe, and there was less use of general anesthesia during the pandemic time.

Research conclusions

There was no difference in 30-d mortality rate between hip fracture patients treated during the pandemic and pre-pandemic periods. However, the mortality risk was higher in COVID-19 positive patients compared to COVID-19 negative patients. There was no difference in time to surgery, complications and hospitalization time between these two time periods.

Research perspectives

This meta-analysis showed that the COVID-19 infected patients with a hip fracture had a higher mortality rate, but the non-infected patients received the same level of care and they had similar mortality to that of hip fracture patient managed during the pre-pandemic period. The orthopedic trauma surgeons have learnt the ways to tackle the orthopedic emergency during the epidemic time.

FOOTNOTES

Author contributions: Tripathy SK, Varghese P, Panigrahi S and Panda BB designed the study, searched the literature and screened the articles; Tripathy SK, Panda BB, Velagada S and Naik MA assessed the quality of the studies and

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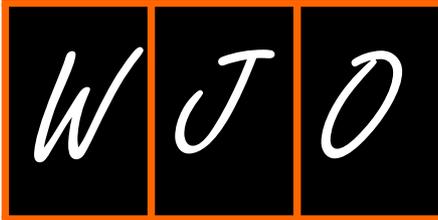
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Hallux rigidus treated with adipose-derived mesenchymal stem cells: A case report

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Abstract

BACKGROUND

First metatarsophalangeal joint arthritis (FMTPA), also known as hallux rigidus, is the most frequent degenerative disease of the foot. Diagnosis is made through both clinical and radiological evaluation. Regenerative medicine showed promising results in the treatment of early osteoarthritis. The aim of the present study was to report the results of a case of FMTPA treated with the injection of autologous adipose-derived mesenchymal stem cells.

CASE SUMMARY

A gentleman of 50 years of age presented with a painful hallux rigidus grade 2 resistant to any previous conservative treatment (including nonsteroidal anti-inflammatory drugs and hyaluronic acid injections). An injection of autologous adipose-derived mesenchymal stem cells into the first metatarsophalangeal joint was performed. No adverse events were reported, and both function and pain scales improved after 9 mo of follow-up.

CONCLUSION

The FMTP joint injection of mesenchymal stem cells improved symptoms and function in our patient with FMTPA at 9 mo of follow-up.

Key Words: First metatarsophalangeal joint arthritis; Hallux rigidus; Stem cells; Regenerative medicine; Early osteoarthritis; Adipose derived-mesenchymal stem cells; Case report

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Core Tip: Recently, the use of intra-articular injections of stem cells has been proposed as a promising treatment in early osteoarthritis. In particular, autologous adipose-derived stem cells (aASCs) have attracted considerable attention, considering the easy access to fat tissue and the absence of adverse events registered. These characteristics make aASCs one of the most promising cell types used in regenerative medicine. Hallux rigidus, is the most frequent degenerative disease of the foot. Patients with hallux rigidus present a history of pain, gait discomfort, articular effusion, and a reduction in range of motion. Different types of treatment are available, both conservative and operative, but both are often ineffective. aASCs might overcome the gap between these two methods of treatment.

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INTRODUCTION

First metatarsophalangeal joint arthritis (FMTPA), also known as hallux rigidus, is the most frequent degenerative arthritis disease of the foot[1]. Depending on the severity of the disease, the symptoms in the case of FMTPA are pain, gait discomfort, articular effusion, and a reduction in range of motion. The diagnosis is generally completed by observing the typical findings of osteoarthritis (OA) revealed by X-rays. Coughlin and Shurnas proposed a classification for FMTPA based on both clinical features and imaging[2] (Table 1).

Different types of treatments had been proposed, both conservative [*i.e.*, orthosis, nonsteroidal anti-inflammatory drugs, hyaluronic acid (HA) injections] and operative (*i.e.*, cheilectomy, arthroplasty, arthrodesis)[3].

Recently, emerging evidence has supported the use of autologous adipose-derived mesenchymal stem cells (aAMSCs) for the treatment of early OA[4-7].

The aim of the present study was to report the clinical results of a case of FMTPA treated with the injection of aAMSCs.

CASE PRESENTATION

Chief complaints

A gentleman of 50 years of age presented with a painful FMTP joint in the left foot.

History of present illness

His symptoms were resistant to both nonsteroidal anti-inflammatory drugs and HA injections.

History of past illness

The patient was already scheduled for an aAMSCs injection due to right knee Kellgren-Lawrence grade 2 OA.

Personal and family history

Personal and family history were negative for foot pathologies.

Physical examination

The clinical examination showed a positive axial grind test and joint pain, exacerbated by the dorsiflexion that impaired the patient's ability to walk.

Laboratory examinations

Laboratory tests did not support the final diagnosis.

Imaging examinations

Antero-posterior and latero-lateral standard X-rays showed FMTPA stage 2.

Table 1 Coughlin and Shurnas clinical and radiographic classification of hallux rigidus

| Grade | Dorsiflexion | Radiographs | Clinical |
|-------|--------------|---|--|
| 0 | 40°-60° | Normal | No pain, stiffness with loss of motion |
| 1 | 30°-40° | Dorsal osteophytes; Minimal narrowing; Minimal flattening | Mild pain and stiffness pain with maximum dorsiflexion/plantar flexion |
| 2 | 10°-30° | Global osteophytes, mild/moderate narrowing | Moderate to severe pain and stiffness relatively constant, pain near extreme ROM |
| 3 | < 10° | Cystic changes | Nearly constant pain and stiffness, no midrange pain |
| 4 | < 10° | Same as grade 3 | Grade 3 + midrange pain |

FINAL DIAGNOSIS

FMTPA stage 2 was diagnosed.

TREATMENT

The patient was already scheduled for an aAMSCs injection due to right knee Kellgren-Lawrence grade 2 OA, and therefore a similar injection was proposed to treat the hallux rigidus.

Concentrated aAMSCs were obtained from the abdomen, filtered as previously reported[5], and then injected into the FMTP joint after its distraction (Figure 1).

Protected weight bearing was prescribed during the first week after the procedure.

OUTCOME AND FOLLOW-UP

The patient was followed up at regular intervals. The clinical evaluation was completed using both the American Orthopedic Foot and Ankle Society (AOFAS) for hallux metatarsophalangeal-interphalangeal scale and the Visual Analog Scale (VAS).

No adverse effects were reported, excluding a transient pain in the FMPT joint in the first week after surgery. During the entire follow-up, an improvement in both VAS and AOFAS scales were observed (Table 2), leading to a final VAS scale of 0 and an AOFAS of 78 at 9 mo of follow-up.

DISCUSSION

Recently, the use of regenerative medicine principles has been proposed for various applications in both trauma and orthopedics, and especially for the treatment of early OA[4-6,8-11]. While conventional therapies for early OA (*i.e.* physical therapy, glucosamine and chondroitin sulfate supplementation) showed little benefits, regenerative medicine was demonstrated to be a promising option, due to the paracrine, anti-apoptotic, anti-inflammatory, and anti-aging effects of stem cells[12,13].

aAMSCs showed some theoretical advantages over other sources of stem cells. In fact, aAMSCs are easy to harvest, because of the wide availability of adipose tissue, and their sampling is generally associated with minimal discomfort, considering that it can be carried out using local anesthesia[7]. Moreover, aAMSCs demonstrated a high capacity for proliferation and fibroblastic differentiation[14]. Hass *et al*[15] showed that adipose tissue should be considered a primary source of cells for regenerative medicine as it contains 500 times more MSCs than the same volume of bone marrow.

Emerging literature has underlined the role of aAMSCs in the treatment of early OA. Schiavone Panni *et al*[5] conducted a study of 52 patients with early knee OA treated with arthroscopic debridement and aAMSCs injection, and showed improvement in both function and pain at an average of 15.3 mo of follow-up. Similarly, Song *et al*[16] reported the amelioration of pain, function and cartilage volume of the knee after multiple injections of aAMSCs. The efficacy of aAMSCs in OA was recently confirmed in a systematic review conducted by McIntyre *et al*[17].

FMTPA is a degenerative disease with an incidence of 2.5% in patients over 50 years of age. Its treatment might be frustrating for both the orthopedic and the patient, considering the conflicting outcomes reported after conservative treatment, including HA injections. Petrella *et al*[18] in their study of 47 patients with FTMPA, described the long-term improvement in both pain and function after multiple HA injections; however, Munteanu *et al*[19] in their randomized controlled trial did not observe any differences when HA was compared with placebo.

Table 2 American Orthopedic Foot and Ankle Society and Visual Analog Scale scores

| | Pre-operatively | 6-mo follow-up | 9-mo follow-up |
|-------------|-----------------|----------------|----------------|
| AOFAS score | | | |
| Pain | 30 | 30 | 30 |
| Function | 35 | 40 | 40 |
| Alignment | 8 | 8 | 8 |
| Total score | 73 | 78 | 78 |
| VAS | 7 | 5 | 0 |

AOFAS: American Orthopedic Foot and Ankle Society; VAS: Visual analog scale.



Figure 1 Intraoperative picture showing the autologous adipose-derived mesenchymal stem cells injection into the first metatarsophalangeal joint.

Pons *et al*[20] in a randomized study compared the use of sodium hyaluronate with triamcinolone acetonide in FMTPA, and reported an improvement in pain relief and function at 3 mo after the injections. However, a high percentage of patients in both groups required subsequent surgery after 1 year of follow-up, due to further progression of the disease with worsening of both pain and function.

To the best of our knowledge, this is the first report on the use of aAMSCs for FMTPA. A single injection was effective in treating FMTPA, improving both the AOFAS and VAS score at 9 mo of follow-up.

CONCLUSION

The present case report indicates that the injection of aAMSCs might be a promising treatment for FMTPA. Obviously, larger cohorts and longer follow-up studies are needed to confirm these findings.

FOOTNOTES

Author contributions: Braile A, Toro G, and Panni AS conceived the study; Cecere AB, and De Cicco AD collected clinical data; Cecere AB, De Cicco AD, and Zanchini F interpreted the obtained data; Braile A and Toro G wrote the article; Panni AS supervised the entire process; all authors revised and approved the final version of the manuscript.

Informed consent statement: As routinely performed, the patient signed a written informed consent in which he authorized the surgical procedure and data collection for research and audit purposes. According to Italian law no formal ethical approval is required for this type of study as it includes routinely performed clinical evaluations.

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