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Editorial Board Member of *World Journal of Orthopedics*, Farzin Halabchi, MD, Professor, Department of Sports and Exercise Medicine, Tehran University of Medical Sciences, Tehran 14395-578, Iran. fhalabchi@tums.ac.ir

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Role of platelet-rich plasma in the treatment of rotator cuff tendinopathy

Ausberto Velasquez Garcia, Liborio Ingala Martini, Andres Franco Abache, Glen Abdo

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Ausberto Velasquez Garcia, Department of Orthopedic Surgery, Clínica Universidad de los Andes, Santiago 7620157, Chile

Liborio Ingala Martini, Department of Orthopedic Surgery, Hospital IVSS Dr. Luis Ortega, Porlamar 6301, Venezuela

Liborio Ingala Martini, Department of Orthopedic Surgery, Hospital Clinicas del Este, Los Robles 6301, Venezuela

Andres Franco Abache, Department of Orthopedic Surgery, Hospital de Especialidades Guayaquil MSP, Guayaquil 090101, Ecuador

Glen Abdo, Department of Graduate Medical Education, Internal Medicine Residence Program, New York Medical College at St. Mary's and St. Clare's, Passaic, NJ 07055, United States

Corresponding author: Ausberto Velasquez Garcia, MD, Surgeon, Department of Orthopedic Surgery, Clínica Universidad de los Andes, Av. Plaza 2501, Las Condes, Santiago 7620157, Chile. ausbertovelasquez@hotmail.com

Abstract

Shoulder pain is a common musculoskeletal complaint, and rotator cuff (RC) pathologies are one of the main causes. The RC undergoes various tendinopathic and avascular changes during the aging process. Other degenerative changes affecting its healing potential make it an appealing target for biological agents. Platelet-rich plasma (PRP) has demonstrated the potential to deliver a high concentration of several growth factors and anti-inflammatory mediators, and its clinical use is mainly supported by experiments that demonstrated its positive effect on muscle, ligaments, and tendinous cells. This review aimed to specify the role of PRP and its future applications in RC tendinopathies based on the current clinical evidence. Due to the different characteristics and conflicting outcomes, clinicians should use PRP with moderate expectations until more consistent evidence is available. However, it is reasonable to consider PRP in patients with contraindications to corticosteroid injections or those with risk factors for inadequate healing. Its autologous origin makes it a safe treatment, and its characteristics make it a promising option for treating RC tendinopathy, but the efficacy has yet to be established.

Key Words: Rotator cuff; Tendinopathy; Platelet-rich plasma; Shoulder pain; Nonoperative

treatment; Injectables

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Core Tip: Platelet-rich plasma may be a promising treatment option for rotator cuff tendinopathy, but more consistent evidence is needed to establish its effectiveness. Therefore, clinicians should approach its use with moderate expectations and consider it a potential treatment option for patients who cannot receive corticosteroid injections or have risk factors for poor healing.

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INTRODUCTION

Shoulder pain and disability are common musculoskeletal complaints caused mainly by rotator cuff (RC) lesions[1]. Aging can promote the development of many tendinopathic and avascular changes in RC, altering its intrinsic healing capacity and increasing failure rates after surgical or non-surgical treatment[2]. RC lesions include a wide range of pathological states, beginning with acute tendinitis and progressing to tendinosis, degeneration, partial-thickness, and full-thickness tears[2,3]. Full-thickness RC tears represent the end stage of RC pathology and have an incidence of approximately 20% in adults. The prevalence of these tears increases to over 50% after the age of 60 years[4-6].

To ensure accurate management and effective communication among clinicians, it is necessary to establish a clear definition for tendinitis and tendinosis[7,8]. Tendinitis is associated with inflammation, stress, degeneration, and poor mechanics and is generally caused by overuse[9]. Tendinosis encompasses tendon degeneration with or without histological signs of inflammation, including impaired and disorganized collagen, increased vascularity, and cellularity[9, 10]. In general, tendinopathy is a term attributed to different tendons pathologies with various etiological factors, mainly caused by overuse, that can cause discomfort when the tissue does not regenerate[7,11].

New biological therapies aim to improve tendon healing as part of the ongoing development for the treatment of RC tendinopathy. These therapies include platelet-rich plasma (PRP) injections, growth factors, mesenchymal stem cells (MSCs), adipose-derived, and bone marrow aspirate concentrate. These have been proposed to speed up tendon recovery based on encouraging results from experimental models and clinical trials[12,13]. Therefore, a wide range of the states of RC tendinopathy may be effectively treated with nonoperative treatment, particularly in those where the structural integrity of the tendon has not been fully involved[14]. This review aimed to summarize the current evidence for the effectiveness of PRP as a non-surgical treatment method for RC tendinopathy.

ETIOLOGY AND SYMPTOMS OF RC TENDINOPATHY

Several theories have described possible pathophysiological routes for RC tendinopathy. Intrinsic and extrinsic mechanisms have traditionally been associated with the development of RC tendinopathy[2]. Widely studied, the intrinsic pathway describes degeneration due to hypoperfusion of the RC tendons, cell degeneration, and apoptosis, and some authors state that these create the main link in the establishment of tendinopathy[2]. Extrinsic factors are related to mechanical theories, in which microtears occur due to overuse or repetition[15]. Disorders associated with biomechanical causes, such as chronic impingement, superior humeral head translation, and overuse, have been associated with progressive degeneration of the RC tendons[2]. Since the underlying mechanism or tendon pathology cannot be determined in routine clinical practice, tendinopathy is a common term that involves many different clinical diagnoses [16].

RC tendinopathy, including partial-thickness tears, could cause limited shoulder motion, discomfort at rest, a painful arc of motion, and external rotation weakness. It is common to cause symptoms with painful overhead and positive special testing[16]. Furthermore, sleep disturbances may be characterized by discomfort in the mid-lateral region of the humerus or the anterolateral aspect of the acromion[7,8]. Indeed, partial tears are usually more painful than full-thickness [17].

TENDON HEALING

Regardless of the type of treatment applied, tendon healing occurs in three overlapping phases: Inflammatory, proliferative, and remodeling[18]. The inflammatory process produces cytokines near the injury site in the first 24 to 48 h,

attracting neutrophils, macrophages, and red blood cells. The healing process continues with hematoma formation and cellular invasion into the surrounding areas of the tendon. Growth factors, such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF- β), and vascular endothelial growth factor, are released by platelets during this phase[19-21].

During the proliferative phase, MSCs migrate and differentiate, influenced by PDGFs[18]. The cells involved in tissue repair, such as fibroblasts and MSCs, proliferate and synthesize extracellular matrix (ECM) proteins[19-23]. Fibroblasts that migrate during this phase generate type III collagen and glycosaminoglycans, which enhances the tissue's tensile strength, elasticity, and lubrication[24,25]. Tenocytes become the primary cell type responsible for producing and maintaining the ECM proteins that provide the necessary structure and mechanical properties to form new tissue[19].

Collagen cross-linking increases during the remodeling phase, and collagen type III is reabsorbed and replaced, resulting in an improved organization[25]. During this stage, tenocytes produce ECM proteins and other signaling molecules that amplify the upregulation of collagen type I gene expression and optimize the structure and function of the newly formed tissue[19,20,22,23]. However, complete tendon regeneration is not achieved, and the complex remodeling process usually leads to a steady decrease in tendon biomechanical strength[18,24]. **Figure 1** illustrates the role of PRP in different stages of tendon healing.

CLINICAL EVIDENCE OF PRP INJECTIONS

Overall, clinical findings suggest that PRP injections for musculoskeletal pathologies, including supraspinatus tendinopathy, are safe[26], cost-effective, and easily administered outpatient procedures providing promising results compared to other treatment options[3]. The efficacy of various types of PRP is currently being evaluated in the shoulder and other joints[27]. Previous reports have shown inconsistent outcomes, with superior results in the PRP-treated group compared to the control groups, while others have shown similar or even inferior results[28-31]. The variability in the preparation techniques for PRP may explain the wide range of effectiveness among various studies[32]. Furthermore, factors such as the number of platelets available and the presence of anticoagulants and activators can significantly impact the growth factors present in the final PRP composition. As a result, it is difficult to compare research studies that differ substantially in design and methodology[33-35]. Furthermore, the intrinsic heterogeneity in the final composition of PRP and the various elements involved have been recognized as the main limitation of PRP injections for their wide recommendation in clinical practice[36-40].

Since these studies used different procedures to obtain the final PRP and varied the concentration of platelets and other components, the clinical results are inconsistent. This compositional variation can affect the advantages of a hypothetical healing effect[41]. Furthermore, factors such as concurrent physical therapy, exercise programs, and the impact of needle stimulation can contribute to some bias, which could also affect outcomes[42].

PRP IN TENDINOPATHIES

Natural growth factors, cytokines, and anti-inflammatory mediators are used in orthopedics to treat and recover tissues involved in diseases. As a result, a significant increase in the use of biological agents to treat common musculoskeletal injuries has been observed in recent years[43]. Different disorders have been treated with PRP, MSCs obtained from bone marrow aspirates, and adipose tissue[43]. PRP has gained recent popularity for treating shoulder disorders in clinical practice and as a viable method to enhance the surgical treatment of RC tears[44]. However, due to conflicting results, clinicians are still skeptical about the actual benefit and optimal use of these treatments in common shoulder diseases[43].

The clinical use of PRP is mainly supported by *in vitro* experiments that demonstrated its positive effect on muscle and tendinous cells[45]. Tenocytes exhibit enhanced proliferation and ECM production, improving tendon recovery. Additionally, when exposed to PRP, stem cells are stimulated to differentiate into tenocytes[45-48]. These characteristics show that PRP might enhance human tenocyte healing through cell proliferation and encourage ECM production[49]. Consequently, PRP could be a highly appealing therapy option for RC tendinopathy[49].

Authors in recent years have encompassed a wide range of preparations, presentations, and formulations under the term PRP. From a bioanalytical point of view, PRP consists of a fraction of whole blood with a supraphysiological concentration of platelets and other components[44]. The PRP therapy preparation process involves the separation of platelets from whole blood by centrifugation. In addition, platelet-activating chemicals can be added to enhance the effectiveness of the therapy. The growth factors released from the platelet alpha granules, approximately 7-10 d after PRP administration, coincide with the inflammation and healing phases of the tendon, promoting cellular differentiation and the healing process[32,50,51].

Growth factors, inflammatory mediators, and proteins that promote stromal and MSCs growth, including those derived from tendons, multiply once activated and hinder the repair process by creating fibrous scar tissue instead of healthy tissue[44]. Studies have shown that PRP injections can improve the structure of the ECM of tendons in the short term when injected directly into the tissue and administered through a matrix scaffold. This tendon healing and regeneration mechanism may be responsible for the clinical and structural improvements of the tendons after PRP therapy[28,33,44,52].

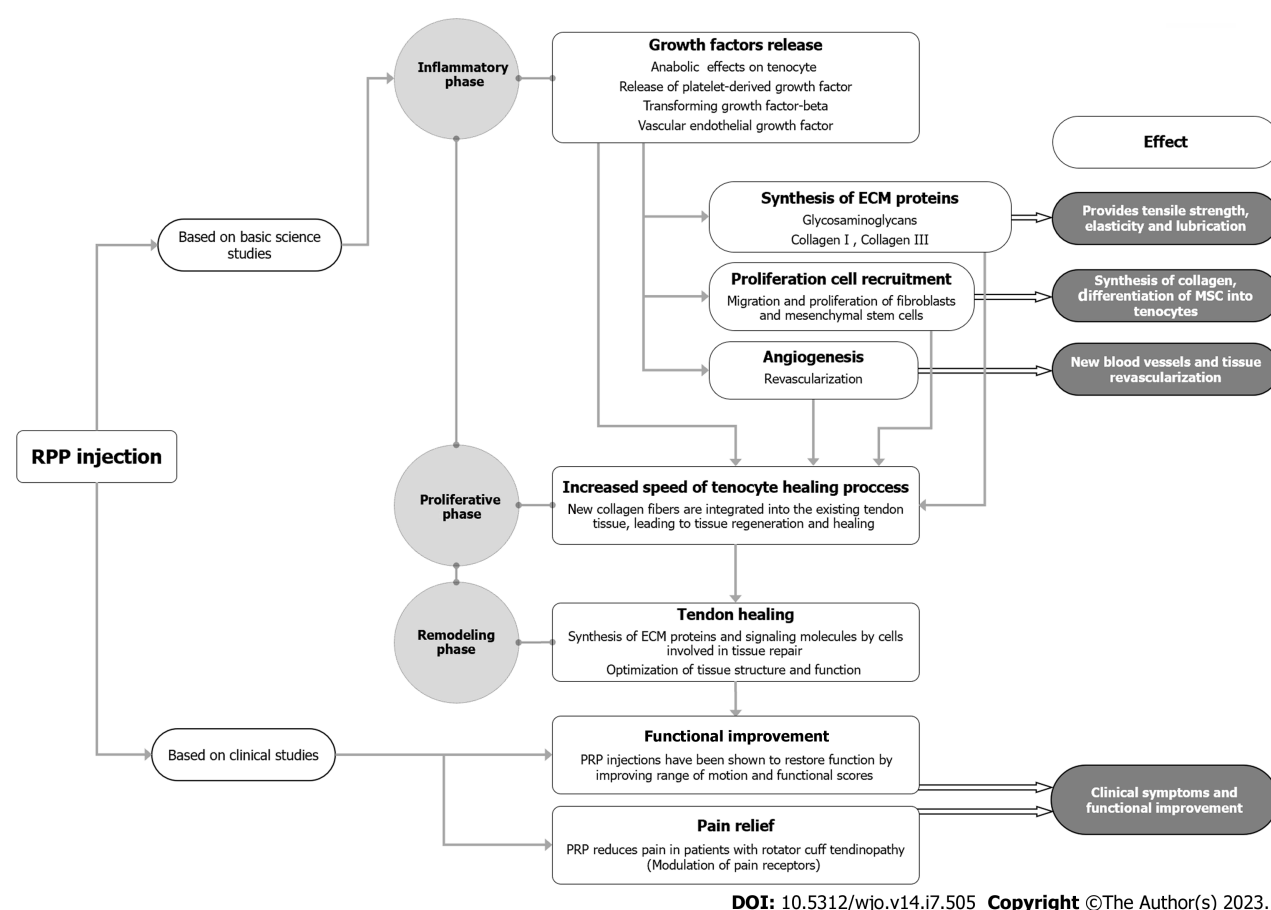


Figure 1 The potential role of platelet-rich plasma in different stages of tendon healing. PRP: Platelet-rich plasma; ECM: Extracellular matrix.

PRP FOR RC TENDINOPATHY

PRP vs placebo injections, dry needling, or exercise

The comparative clinical efficacy of PRP, placebo (saline), autologous whole blood, and dry needling for ligament and tendon injury is unclear (Table 1). Lin *et al*[53] conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) to investigate the effectiveness of PRP therapy in patients with RC tendinopathy compared to sham injection, no injection, or physical therapy alone. The study found that PRP therapy produced significant long-term pain relief (> 24 wk) but did not show significant differences in functional results compared to the control groups. Notably, the study included trials using various numbers of injections, ultrasound-guided and non-guided injection techniques, and different injection approaches, but it found no specific approach to be more effective than others.

Chen *et al*[26] conducted a systematic review and meta-analysis that evaluated the efficacy of PRP therapy in the healing of tendons and ligaments. The study analyzed 37 articles and included 1937 patients without restrictions on the tendons or ligaments studied. The authors found a wide variety of preparation methods used in the studies, and half of the studies did not use platelet activation or did not report the specific kit used. Despite this, the authors found no significant adverse events, highlighting the safety of PRP therapy. Overall, the PRP groups in the studies showed significantly less long-term pain than the control groups, particularly in lateral epicondylitis and RC injuries.

A randomized controlled study by Kesikburun *et al*[54] evaluated the effectiveness of PRP therapy in patients with RC tendinopathy who were treated with an exercise program. The study found that PRP was less effective than a placebo injection in several aspects, which can be attributed to leukocyte-rich PRP and shorter follow-up periods. However, another prospective open-label comparative trial compared a PRP group with an exercise group and found that PRP showed better American Shoulder and Elbow Surgeons Score (ASES) and Constant Murley Score (CMS) at 6 and 12 wk. However, at 24 wk, PRP was not superior to exercise. The PRP group had better rates of decreasing tendon thickness, but the concentration of leukocytes was not analyzed. Furthermore, the study found that higher levels of TGF- β 1 and interleukin-1 β growth factors were related to the clinical efficacy of PRP. This suggests that PRP provided more remarkable results than exercise alone, but exercise showed a cumulative positive effect in the long term, suggesting that more than a single injection may be necessary[55].

Wesner *et al*[56] reported results in a RCT that included 9 participants with RC tendinopathy receiving 4 mL of PRP injected into the supraspinatus or infraspinatus, and patients in the placebo group were injected with 4 mL of saline. All participants completed a 3-mo standardized home-based daily exercise program. The primary outcome measures were evaluated 3 and 6 mo after injection in RCT[56]. The study showed that patients who underwent PRP injections reported considerable improvements in pain and disability[56]. The authors concluded that intratendinous ultrasound-guided PRP

Table 1 Single or double-arms trials assessing effectiveness of platelet-rich plasma vs placebo injections, dry needling, or exercise

Ref.	Level of evidence	Design	Groups (n)	Injections/dosis	Outcomes measure	Follow-up	Conclusions
Kesikburun <i>et al</i> [54], 2013	I	Ultrasound-guided PRP injections <i>vs</i> saline injections	40 patients PRP (20), placebo (20)	1/5 mL	VAS, WORC, and SPADI	3, 6, 12, 24 wk, 1 yr	PRP is not more effective in improving shoulder quality of life, pain, disability, and range of motion than placebo
Rha <i>et al</i> [57], 2013	I	PRP injections <i>vs</i> dry needling	39 patients. PRP (20), dry needling (20)	1/3 mL	SPADI, passive ROM, global rating scale, ultrasound measurement	24 wk	PRP leads to a progressive reduction in pain and disability compared to dry needling
Scarpone <i>et al</i> [59], 2013	III	Ultrasound guided PRP injection at the lesion and surrounding tendon	18	1/3.5 mL	MRI, VAS and three-item patient satisfaction scale	8, 12, 52 wk	Improvement in MRI, pain and function with PRP
Lee <i>et al</i> [62], 2019	III	PRP injection <i>vs</i> exercise treatment; leukocyte-poor <i>vs</i> leukocyte-rich PRP	60. PRP (27), exercise (33)	1/1.5 mL	ASES, CMS, and NRS	12 wk, 24 wk	PRP is more effective than exercise therapy for the first 3 mo
Kim <i>et al</i> [55], 2019	II	PRP injection <i>vs</i> exercise treatment	30 patients. PRP (15), exercise (15)	1/2 mL	ASES, CMS, and NRS	12 wk, 24 wk	PRP had an advantage over exercise; improvement until 12 wk, slight decrease at 24 wk
Rossi <i>et al</i> [71], 2021	II	Subacromial PRP injections	50 patients	1/5 mL	ASES, CMS, and VAS	1 yr	PRP decreased pain, improved functional outcomes, and resolved sleep disturbances. Return to sports for most athletes
Oudelaar <i>et al</i> [77], 2021	I	NACD + PRP <i>vs</i> NACD + CI	88 patients. NACD + PRP (41), NACD + CI (47)	1/5 mL	VAS, CMS, DASH, OSS, EQ-5D	6 wk, 3 mo, 6 mo, 12 mo, 24 mo	NACD + PRP was worse at the 6-wk follow-up but better at the 6-mo follow-up. Comparable results at 12 and 24 mo

ASES: American Shoulder and Elbow Surgeons score; CMS: Constant Murley Score; CI: Corticosteroid injection; DASH: Disability of Arm-Hand-Shoulder score; PRP: Platelet-rich plasma; ROM: Range of motion; SPADI: Shoulder Pain and Disability Index; SST: Simple Shoulder Test; UCLA: University of California Los Angeles score; VAS: Visual analog scale; WORC: Western Ontario Rotator Cuff; MRI: Magnetic resonance imaging; NACD: Needle Aspiration of Calcific Deposits; OSS: Oxford Shoulder Score.

injection could improve tendon pathology as documented by magnetic resonance imaging (MRI). This finding provides information for future studies examining PRP effectiveness[56]. However, the study's limited sample size restricts the generalization of the results, and larger-scale studies are required to validate the findings.

A clinical trial compared the effectiveness of dry needling *vs* ultrasound-guided injection of PRP to treat RC tendinopathy[57]. The study found similar levels of effectiveness in reducing pain and improving function between dry needling and PRP injection. However, patients who received PRP injections experienced a steady decrease in pain and impairment six months after treatment, suggesting that PRP may have long-term benefits[57].

A recent systematic review and meta-analysis pooled the results of previous studies on the efficacy of PRP injections *vs* other treatments for patients with RC tendinopathy[58]. The study included 8 RCTs and found no significant differences between the PRP and control groups after three weeks of follow-up[58]. PRP was compared to saline injection in 4 trials, while rehabilitation programs and dry needling were control interventions in the other 4. PRP therapy's medium- and long-term outcomes were superior, except for the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. The most common adverse effect was mild and temporary pain[58].

In another long-term trial, 18 patients who had not responded to previous physical treatment but received a single 3.5 mL ultrasound-guided intralesional injection of PRP showed steady improvement on the Visual Analog Scale (VAS)[59]. At one year of follow-up, the median VAS dropped from 7.5 ± 0.3 before injection to 0.4 ± 0.2 , and MRI alterations and functional outcomes similarly improved[59].

PRP vs corticosteroid injections

Subacromial corticosteroid injections (CI) or PRP have both seen an increase in comparative investigations in recent years [60-63] (Table 2). Some evidence supports that PRP could be a suitable substitute for patients who cannot use CIs, as suggested in a RCT of 40 patients with symptomatic partial-thickness RC tears, where PRP injections and CI were compared for pain control and patient-reported outcomes (PROs)[60]. Although both groups showed a significant improvement over the pre-injection condition at 12 wk, the PRP group showed a statistically significant improvement in pain and PROs at 24 wk. MRI at 6 mo of follow-up did not show significant differences between groups[60].

Table 2 Randomized controlled trials comparing platelet-rich plasma vs corticosteroid injections for rotator cuff tendinopathy

Ref.	Level of evidence	Design	Groups (n)	Dosis/quantity	Outcomes measure	Follow-up	Conclusions
Barreto <i>et al</i> [66], 2019	I	Subacromial PRP injections <i>vs</i> CI	51 patients. PRP (26), CI (25)	1/about 3 mL	DASH, UCLA-SRS, CMS	3mo, 6 mo	No statistically significant differences
Dadgostar <i>et al</i> [63], 2021	I	Ultrasound guided PRP injections <i>vs</i> CI	58 patients. (30) PRP, (28) CI	1/3 mL intra-articular, 3 mL intratendinous	VAS, ROM, WORC, DASH, US supraspinatus thickness	3 mo	PRP with similar results to CI
Kwong <i>et al</i> [70], 2021	I	Ultrasound-guided leukocyte-poor PRP injection <i>vs</i> CI	99 patients. PRP (47), CI (52)	1/(3-5) mL intratendinous (non-specific) and the rest at the subacromial space	VAS, ASES score, and WORC	6, 12, 48 wk	The PRP group showed superior improvement in pain and function at short-term follow-up, without benefit at long-term follow-up
Ibrahim <i>et al</i> [68], 2019	I	Ultrasound guided subacromial PRP <i>vs</i> CI	30 patients. PRP (15), CI (15)	1/2 mL	VAS, SDQ, ROM Clinical tests, US findings	8 wk	Both groups showed significant improvement. PRP is safe and can be used for PRCT
Jo <i>et al</i> [78], 2020	I	Ultrasound guided allogenic PRP <i>vs</i> CI	60 patients. PRP (30), CI (30)	1/4 mL	VAS, CMS, ASES, DASH, RC strength, ROM	1, 4, 12, 24 wk	PRP reduced pain and improved overall function at 6 mo. DASH score, overall function, and external rotation were significantly better in the PRP group
Pasin <i>et al</i> [79], 2019	I	PRP <i>vs</i> CI <i>vs</i> exercise	60 patients. PRP (30), CI (30)	1/4 mL	VAS, quick DASH, UCLA SRS, SF-36	3, 8 wk	PRP had better scores than CI and Physical Therapy even in a long time
Sabaah <i>et al</i> [80], 2020	I	Prolotherapy <i>vs</i> CI and PRP	40 patients. PRP (20), CI (20)	2/5 mL	VAS, WORC-Index, ROM and US findings	12 wk	Prolotherapy was superior. PRP improve tendon healing
Sari <i>et al</i> [81], 2020	I	Ultrasound guided PRP <i>vs</i> CI, prolotherapy and lidocaine	60 patients. PRP (30), CI (30)	1/5 mL	VAS, ASES and WORC	3, 12, 24 wk	CI were better at 3 wk. NO difference at 12 wk. PRP had better outcomes at 24 mo
Thepsoparn <i>et al</i> [82], 2021	I	Ultrasound guided leukocyte-poor PRP <i>vs</i> CI	31 patients. PRP (15), CI (16)	1/5 mL	VAS and OSS	4, 24 wk	No difference at 4 wk. PRP had better results at 24 wk for PRCT. No complications

ASES: American Shoulder and Elbow Surgeons score; CMS: Constant Murley Score; CI: Corticosteroid injection; DASH: Disabilities of the Arm, Shoulder and Hand score; PRP: Platelet-rich plasma; ROM: Range of motion; SPADI: Shoulder Pain and Disability Index; SST: Simple Shoulder Test; UCLA: University of California Los Angeles score; UCLA-SRS: University of California Los Angeles Shoulder Rating Score; VAS: Visual analog scale; WORC: Western Ontario Rotator Cuff; MRI: Magnetic resonance imaging; SDQ: Shoulder Disability Questionnaire; PRCT: Partial rotator cuff tears; SF-36: Short Form 36; OSS: Oxford Shoulder Score.

PRP has proven advantages, such as the possibility of repeat injections if symptoms worsen. It could even be administered 1 to 6 mo before surgery due to its safety, which contrasts with CI, and its recognized risk of perioperative complications[64,65]. However, the cost-effectiveness of PRP has not been established. Other reports have shown similar effectiveness between PRP and CI. In a randomized, double-blind trial, patients were evaluated using the DASH score, the University of California Los Angeles (UCLA) shoulder rating scale, and CMS at baseline and 1, 3, and 6 mo after treatment. Results showed no statistically significant differences ($P < 0.05$) between the PRP and CI groups in any outcome measures at any time. Both groups showed a significant improvement in DASH and UCLA scores ($P < 0.05$) compared to baseline, but the CMS score 6 mo after corticosteroid treatment was lower than baseline. These findings suggest that PRP is a safe treatment option for RC impingement syndrome and may be a valuable alternative, as it was found to be equally effective as corticosteroids[66]. Similar results were found in a prospective study with 60 patients with RC tendinosis or partial tendon tear. The authors used 2.5 mL of activated PRP or 40 mg methylprednisolone during the trial. The CMS improved from 41 to 53 points at 6 mo in the PRP group and from 38 to 66 points in the CI group[67].

In a study of 30 patients with RC tendinopathy, two groups of 15 were randomly chosen to receive a subacromial ultrasound-guided injection of PRP or corticosteroids. Pain in patients was evaluated using the VAS, shoulder function using the Shoulder Disability Questionnaire, and range of motion (ROM) before and 8 wk after injection. The study found that PRP and CI were similarly effective in the treatment of RC tendinopathy, showing significant improvements in pain, function, and ROM. These results suggest that PRP is a safe alternative to CI, decreasing inflammation and improving

outcomes[68].

In another double-blind clinical trial, 58 patients with RC tendinitis were randomized to receive 3 mL of PRP or 1 mL of Depo-medrol 40 mg. The study found that both treatments resulted in similar significant improvements in pain, ROM, Western Ontario Rotator Cuff scores, DASH scores, and supraspinatus thickness during follow-ups[63]. A recent systematic review and meta-analysis of RCTs that included 639 patients revealed that at short-term follow-up, CI was more effective than PRP in the short term, but, in the mid-term, PRP was superior to CI in DASH and ASES scores. However, both treatments achieved minimal clinical important difference for each score, indicating no significant clinical differences between the two treatment modalities in managing RC disease[69].

A double-blind, randomized controlled study compared ultrasound-guided PRP injection with conventional CI in patients who had completed a detailed physical therapy protocol. Ninety-nine patients with MRI or ultrasound documented partial-thickness RC tears or tendinopathy were included. Patients treated with leukocyte-poor PRP ultrasound-guided injections showed superior improvement in pain and function at short-term follow-up. However, at 12 mo, there was no persistent effect of PRP over CI and no variations in the incidence of failure or conversion to surgery [70]. Ultrasound-guided injection of PRP potentially improves the precision and safety of the infiltration method, thus leading to improved effectiveness of the treatment[3,68]. However, the benefit has not been demonstrated extensively.

In contrast, a recent systematic review and meta-analysis of 12 RCTs have shown that while CI may have better short-term outcomes in treating RC tendinopathy, PRP therapy may have superior medium-term outcomes. These results suggest that while CI may provide faster pain relief, PRP therapy may be more effective in promoting long-term healing and tissue regeneration[69]. However, it should be noted that the studies included in the review had significant heterogeneity in their preparation of PRP (such as using the buffy-coat method *vs* the tube method and using one *vs* two centrifugation steps) and their treatment protocols after injection[69].

Similarly, a prospective cohort study included 50 patients with MRI-diagnosed tendinopathy, no tendon rupture, and 3 mo of failed conservative treatment. Two spin protocols were performed, and 5 mL of leukocyte-rich PRP was used to treat patients in combination with physical therapy. Results included pain relief, positive clinical results, and a return to sports at the pre-injury level at high rates[71].

FUTURE PERSPECTIVE

Kieb *et al*[72] introduced an innovative method to standardize PRP growth factor concentrations using allogeneic lyophilized PRP powder. This technique involves creating a powder using twelve pooled platelet concentrations from various donors and comparing the growth factor concentration achieved using this technique to that found in whole blood. Theoretically, this approach allows the precise composition of the PRP to be chosen to provide a specific amount of growth factors based on the treated pathology. This advantage may provide a more controlled and efficient way to use the benefits of PRP therapy.

In a separate study, 17 patients with RC tendinopathy were treated with an injection of allogeneic PRP, while a control group received CI. Both groups experienced a significant reduction in pain and improved outcomes, with the CI group showing a faster recovery. No adverse effects were reported. The results of this trial suggest that allogeneic PRP may be a safe and potentially beneficial treatment option for RC tendinopathy, but further research is needed to confirm these findings and establish its long-term effectiveness[73].

High-quality evidence supports the use of PRP after RC repair[74]. However, the clinical evidence on the benefits of PRP in the nonoperative treatment of RC disorders is inconsistent. This makes it difficult to draw firm conclusions about PRP's advantages in treating RC disorders. Although some *in vitro* studies have shown promising results for PRP, clinical studies have not consistently supported its therapeutic impact.

Additionally, the effectiveness of PRP can depend on the type and concentration of the specific components used. Therefore, more research is needed to fully understand PRP's potential benefits and limitations in treating RC disorders. This situation highlights the need for a detailed investigation to define the optimal composition, efficient dose, and mechanism of action of PRP[73,75,76].

CONCLUSION

PRP therapy has been proposed as a treatment option for RC tendinopathy, but the available evidence is conflicting due to variability in settings, indications, and clinical outcomes. As a result, clinicians should approach PRP therapy with moderate and realistic expectations until more reliable evidence is available. While the basic science literature supports the potential of PRP to manage RC tendinopathy, there is not yet enough clinical data to support its effectiveness. However, PRP therapy is considered a safe treatment option because it uses a patient's blood, decreasing the risk of allergic reactions or other complications associated with the use of foreign substances. Therefore, it is reasonable to consider PRP injections in patients with a contraindication to CI or patients with risk factors for inadequate healing as a promising treatment option for RC tendinopathy.

FOOTNOTES

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Country/Territory of origin: Chile

ORCID number: Ausberto Velasquez Garcia 0000-0002-4135-2235; Liborio Ingala Martini 0000-0001-6199-3577; Andres Franco Abache 0000-0002-7883-4035; Glen Abdo 0000-0002-1578-7593.

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Retrospective Cohort Study

Effectiveness of an early operating room start time in managing pediatric trauma

Dan Kym, Japsimran Kaur, Nicole Segovia Pham, Eric Klein, Joanna Lind Langner, Ellen Wang, John Schoeneman Vorhies

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Dan Kym, Japsimran Kaur, Nicole Segovia Pham, Joanna Lind Langner, John Schoeneman Vorhies, Department of Orthopaedic Surgery, Stanford University School of Medicine, Palo Alto, CA 94304, United States

Eric Klein, Lucile Packard Children's Hospital, Palo Alto, CA 94304, United States

Ellen Wang, Department of Anesthesiology, Pain and Perioperative Medicine, Stanford University School of Medicine, Palo Alto, CA 94304, United States

Corresponding author: John Schoeneman Vorhies, MD, Assistant Professor, Department of Orthopaedic Surgery, Stanford University School of Medicine, 453 Quarry Rd, 3rd Floor, MC 5658, Palo Alto, CA 94304, United States. john.vorhies@stanford.edu

Abstract

BACKGROUND

The timing of operative treatment for pediatric supracondylar humerus fractures (SCHF) and femoral shaft fractures (FSF) remains controversial. Many fractures previously considered to be surgical emergencies, such as SCHF and open fractures, are now commonly being treated the following day. When presented with an urgent fracture overnight needing operative treatment, the on-call surgeon must choose whether to mobilize resources for a late-night case or to add the case to an elective schedule of the following day.

AIM

To describe the effect of a program allowing an early operating room (OR) start for uncomplicated trauma prior to an elective day of surgery to decrease wait times for surgery for urgent fractures admitted overnight.

METHODS

Starting in October 2017, patients were eligible for the early slot in the OR at the discretion of the surgeon if they were admitted after 21:00 the previous night and before 05:00. We compared demographics and timing of treatment of SCHF and FSF treated one year before and after implementation as well as the survey responses from the surgical team.

RESULTS

Of the 44 SCHF meeting inclusion criteria, 16 received treatment before imple-

mentation while 28 were treated after. After implementation, the mean wait time for surgery decreased by 4.8 h or 35.4% (13.4 h vs 8.7 h; $P = 0.001$). There were no significant differences in the operative duration, time in the post anesthesia care unit, and wait time for discharge. Survey results demonstrated decreased popularity of the program among nurses and anesthesiologists relative to surgeons. Whereas 57% of the surgeons believed that the program was effective, only 9% of anesthesiologists and 16% of nurses agreed. The program was ultimately discontinued given the dissatisfaction.

CONCLUSION

Our findings demonstrate significantly reduced wait times for surgery for uncomplicated SCHF presenting overnight while discussing the importance of shared decision-making with the stakeholders. Although the program produced promising results, it also created new conflicts within the OR staff that led to its discontinuation at our institution. Future implementations of such programs should involve stakeholders early in the planning process to better address the needs of the OR staff.

Key Words: Pediatrics; Trauma; Supracondylar humerus fractures; Operating room

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Core Tip: This study describes the effect of a program allowing an early operating room start for uncomplicated trauma prior to an elective day of surgery to decrease wait times for surgery for urgent fractures admitted overnight. After implementation, the mean wait time for surgery decreased by 4.8 h or 35.4%. Survey results demonstrated decreased popularity of the program among nurses and anesthesiologists relative to surgeons. Our findings demonstrate significantly reduced wait times for surgery for uncomplicated pediatric supracondylar humerus fractures presenting overnight while discussing the importance of shared decision-making with the stakeholders.

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INTRODUCTION

The timing of operative care for pediatric orthopedic injuries is a subject of controversy. Recent studies comparing early vs delayed intervention for supracondylar humerus fractures (SCHF) in children have challenged the conventional wisdom that postponing cases leads to unsatisfactory results[1-3]. Many fractures that were previously considered to be surgical emergencies, such as SCHF and open fractures, are now commonly being treated the following day. This avoids potentially inefficient provision of care by an on-call team who may not be as well-rested or as familiar with pediatric orthopedic care as a day team[4,5]. Despite this shift away from overnight care, a safe and expeditious provision of care remains in the best interest of the patient and family. The timely provision of care for urgent fractures thus presents a logistical challenge to hospitals.

SCHF and femoral shaft fractures (FSF) are among the most common surgically treated pediatric fractures, with SCHF accounting for 60% of pediatric elbow fractures and FSF being the most common diaphyseal fracture in children[6-10]. Given their high incidences, the timeliness of their treatment continues to be a metric used for United States News and World Report's ranking of children's hospitals[8]. This presents a challenge for hospitals with moderate trauma volume that is insufficient to justify a daily trauma room. When presented with an urgent fracture overnight needing operative treatment, the on-call surgeon must choose whether to mobilize resources for a late-night case or to add the case to an elective schedule of the following day.

Here we describe the effect of the 6 AM start quality improvement program implemented at a suburban level I trauma center. This program was designed to decrease wait times for urgent trauma cases while minimizing surgeon fatigue, thereby increasing the efficiency of care and improving compliance with United States News and World Report's standard for timely management.

MATERIALS AND METHODS

Implemented at our facility in October 2017, the 6 AM start program allowed the orthopedic surgeon on call overnight to book an uncomplicated case for an early start in the operating room (OR) at 06:00 prior to the start of a typical elective surgery weekday (Monday through Friday, excluding holidays) at 07:30. Patients with SCHF and FSF were eligible if they were admitted to the ED after 21:00 the prior day and indicated for surgical treatment at the discretion of the surgeon.

Surgeon-controlled time in the OR also had to be projected at less than 75 min.

We received IRB approval (IRB #46989) which granted a waiver of consent and assent. We queried our electronic medical record system for all pediatric patients who underwent surgical fixation for closed isolated SCHF (CPT codes: 24538, 24545, 24546) or FSF (CPT codes: 27502, 27506, 27507) from October 2016 to October 2018. We included patients who were admitted to the ED between 19:00 and 05:00 as the program was often applied to patients technically admitted earlier than 21:00 who had a long wait for an orthopedic consult. Patients admitted on Friday or Saturday nights as well as on the eve of a holiday were excluded. Those over age 12 for SCHF and eight for FSF were excluded since they were more likely to have adult or transitional fracture patterns indicating fixation methods that exceed the projected-surgeon control time of 75 min. Complicated cases including open fractures, threatened vascular status, concurrent ipsilateral fractures, and pathological fractures were excluded.

Patient charts were screened for patient and fracture characteristics. The outcome measure of this study was the wait time for surgery, defined as the time between ED admittance and the patient's arrival at the OR. Balancing measures included the operative duration (time between start and end of the procedure), post anesthesia care unit (PACU) length-of-stay (LOS), time between arrival and departure from the PACU, and wait time for discharge (time between departure from the PACU and discharge). Cases were further classified as overnight cases, 6 AM start cases, and add-on cases based on their scheduled start time as more than 1.5 h prior, 1.5-1 h prior, and after the start of the elective surgery weekday, respectively. The percentage of eligible cases that utilized the 6 AM start program served as the process measure for this study.

For additional balancing measures, all OR staff received an anonymous electronic survey through the internal hospital distribution lists. The survey asked respondents to score their level of agreement on a Likert scale with five statements regarding the beneficiaries of the program and the effectiveness of the program. Additional text boxes allowed providers to explain their responses and provide general feedback.

Statistical analyses were performed with RStudio (Boston, MA) using a two-sided level of significance of 0.05. Baseline characteristics among groups were tested using two-sample *t*-tests, Mann-Whitney *U*-tests, and Fisher's exact tests. Wait time for surgery, operative duration, PACU LOS, and wait time for discharge were compared between patients admitted before and patients admitted after the implementation of the program using two-sample *t*-tests or Mann-Whitney *U*-tests. The same outcome variables were compared among patients whose surgeries were scheduled at the three aforementioned time points (overnight cases, 6 AM start cases, and add-on cases) using one-way ANOVA tests and Kruskal-Wallis tests, with Tukey-adjusted *P* values and Dunn's test for pairwise comparisons. For the survey analysis, responses to the five survey items were compared between various roles in the surgical team using one-way ANOVA tests with Bonferroni-adjusted *P* values for pairwise comparisons.

RESULTS

We initially identified 118 pediatric patients with SCHF and 23 with FSF treated during the study period. After applying the exclusion criteria, 44 SCHF and six FSF were included in the study (Figure 1). For SCHF, 16 patients received operative treatment before the program's implementation and the other 28 were treated after. There were no significant differences in patient and fracture characteristics between the two groups (Table 1). After the implementation of the 6 AM start program, the mean wait time for surgery for patients presenting overnight with uncomplicated SCHF decreased by 4.8 h or 35.4% (13.4 h *vs* 8.7 h; *P* = 0.001). There were no significant differences in the operative duration, PACU LOS, or wait time for discharge (Table 2). The before-implementation group for SCHF included one (6%) overnight case and 15 (94%) add-on cases. The after-implementation group was composed of four (14%) overnight cases, 14 (50%) 6 AM start cases, and 10 (36%) add-on cases. Other than the significantly decreased wait time for surgery, the three subgroups in the after-implementation group showed no differences in demographics and subsequent phases of patient care (Tables 3 and 4).

This study identified five FSF cases treated before the program's implementation and one case treated after. A case in the former group had an incorrectly recorded time of discharge and was thus excluded from the calculation for the wait time for discharge. All patients in the before-implementation group were add-on cases, while the one case in the after-implementation group was a 6 AM start case. Although sample size precludes a meaningful statistical analysis, the 6 AM start case had a shorter wait time for surgery by 4.2 h or 30.2% [13.9 (12.7-19.6) h *vs* 9.7 h] than the before-implementation group. Otherwise, it had a longer operative duration (61 ± 42 min *vs* 138 min), PACU LOS (1.6 ± 1.1 h *vs* 3.2 h), and wait time for discharge [12.4 (4.4-42.9) h *vs* 51.1 h].

There were a total of 24 survey respondents which was composed of 11 (46%) anesthesiologists, seven (29%) surgeons, and six (25%) nurses. 17 (70.8%) respondents directly participated in a 6 AM surgery while five (20.8%) respondents did not; two (8.4%) respondents did not answer the prompt. Since many of the OR staff are involved in scheduling cases without directly participating in the surgery or may have participated in other surgeries that were affected by the program's policy, all 24 respondents were included in the analysis.

Univariate analysis showed a significant difference in responses among anesthesiologists, nurses, and surgeons for all five survey questions. Further pairwise comparisons revealed that anesthesiologists reported more dissatisfaction than surgeons for all five items. Furthermore, nurses reported lower opinions on the program's benefit to the patient, ease of placing urgent trauma cases, and overall effectiveness than surgeons (Figure 2). Seven (29%) providers cited that the program benefited patient care because of the efficiency, stating that "patients received surgical care more quickly". However, four (17%) providers disagreed as they "felt that the timing of the 6 AM cases typically did not end at an appropriate time" and "caused delays for scheduled patients". Regarding the program's benefit to the staff, eight (33%)

Table 1 Demographics of uncomplicated supracondylar humerus fractures treated before and after implementation of the 6 AM start program

	Total (n = 44)	Before implementation (n = 16)	After implementation (n = 28)	P value
Female, % (n)	61 (27)	56 (9)	64 (18)	0.182
Age	5.1	5.1	5.1	0.912
Gartland classification, % (n)				0.686
Type I	0 (0)	0 (0)	0 (0)	
Type II	38.6 (17)	31.3 (5)	42.9 (12)	
Type III	52.2 (23)	56.3 (9)	50 (14)	
Type IV	9.09 (4)	12.5 (2)	7.14 (2)	
Reduction, % (n)				0.732
Closed	95.5 (42)	100 (16)	92.9 (26)	
Open	4.6 (2)	0 (0)	7.14 (2)	

Table 2 Length of time within phases of patient care for supracondylar humerus fractures

	Total (n = 44)	Before implementation (n = 16)	After implementation (n = 28)	P value
Wait time for surgery, h	10.4 ± 9.3	13.4 ± 8.6	8.6 ± 7.9	0.001
Operative duration, min	31.5 (24.5-35.3)	30.5 (21.5-37.5)	31.5 (24.5-35.3)	0.817
PACU LOS, h	1.34 (1.2-1.6)	2 ± 1.6	1.4 (1.2-1.6)	0.060
Wait time for discharge, h	4.96 (3.5-9.7)	3 (0.01-7.21)	5 (3.5-9.7)	0.924

PACU: Post anesthesia care unit; LOS: Length-of-stay.

Table 3 Demographics of supracondylar humerus fractures treated after the implementation of the 6 AM start program, stratified by scheduled surgery time

	Overnight cases (n = 4)	6 AM cases (n = 14)	Add-on cases (n=10)	P value
Female, % (n)	100 (4)	57.1 (8)	60 (6)	0.271
Age	6	4	6.3	0.310
Gartland classification, % (n)				0.514
Type I	0 (0)	0 (0)	0 (0)	
Type II	50 (2)	42.9 (6)	40 (4)	
Type III	25 (1)	50 (7)	60 (6)	
Type IV	25 (1)	7.1 (1)	0 (0)	
Reduction, % (n)				0.210
Closed	75 (3)	100 (14)	90 (9)	
Open	25 (1)	0 (0)	10 (1)	

providers commented that the early hours were an issue with reports of being “frustrated having to come back to the hospital for a 6 AM start” and concluding that it was “a horrible time to do a case”. In the feedback section, seven (29%) providers expressed their dislike of the program while seven (29%) providers liked the program as “it gave a time for patients to be scheduled in a timely manner” and “benefited patient care”. Six (25%) providers suggested that either “starting at 7:30 (or) having a bump room for quick ortho cases is preferred”. Regarding the program’s benefit to the hospital, while four (17%) providers believed that the program positively impacts the United States News and World Report scores, four (17%) staff members expressed that “the intangible negative effects on nursing and anesthesiologists far outweighed any USNWR points it got (the hospital)”.

Table 4 Length of time within phases of patient care for supracondylar humerus fractures, stratified by scheduled surgery time

	Night cases (n = 4)	6 AM cases (n = 14)	Add-on cases (n = 10)	P value
Wait time for surgery, h	2.3 ± 0.2	8.2 ± 2.4	11.8 ± 3.1	1.19e-06
Operative duration, min	30.5 (27.5-71.5)	33.5 ± 7.7	25.5 (19-35)	0.229
PACU LOS, h	1.2 ± 0.3	1.4 (1.2-1.6)	1.5 (1.1-1.6)	0.681
Wait time for discharge, h	8.9 ± 6.6	6.5 ± 3.6	3.6 (0.9-3.9)	0.410

PACU: Post anesthesia care unit; LOS: Length-of-stay.

DISCUSSION

The provision of consistent and timely pediatric orthopedic trauma care can present logistical challenges when available OR space and patient volumes render a daily trauma or add-on room inefficient. Our study evaluated the effectiveness of a program that made available an earlier slot in the OR for uncomplicated fractures presenting to the ED overnight, thus facilitating timely care without disrupting the daily elective schedule or mobilizing resources for an urgent case at night. Before the implementation of this program, it was not uncommon for an urgent case presenting overnight to wait until the end of a scheduled day of elective cases in the following afternoon or evening. Our findings suggest that the 6 AM start program facilitated more timely care for patients with uncomplicated fractures presenting overnight without significant consequences to subsequent phases of patient care.

The timeliness of operative treatment for SCHF and FSF continues to be in dispute in the medical community. Furthermore, studies use different standards for what is considered early and delayed intervention[11-13]. For the ranking of children's hospitals, United States News and World Report defines timely management as the treatment for SCHF and FSF within 18 h of presentation to the ED. For SCHF, hospitals receive one point for ≥ 75% and < 90% of cases that meet this definition and two points for ≥ 90%; for FSF, hospitals are awarded one point for ≥ 60% and < 80% of cases and two points for ≥ 80%[8]. A review of the literature calls into question the wisdom of rewarding hospitals for expedited care and in absence of literature support any improved patient outcomes with expedited care. For example, a study in Texas of 399 SCHF demonstrated that a delay in surgery of greater than 24 h did not result in increased rate of complications for type II SCHF[14].

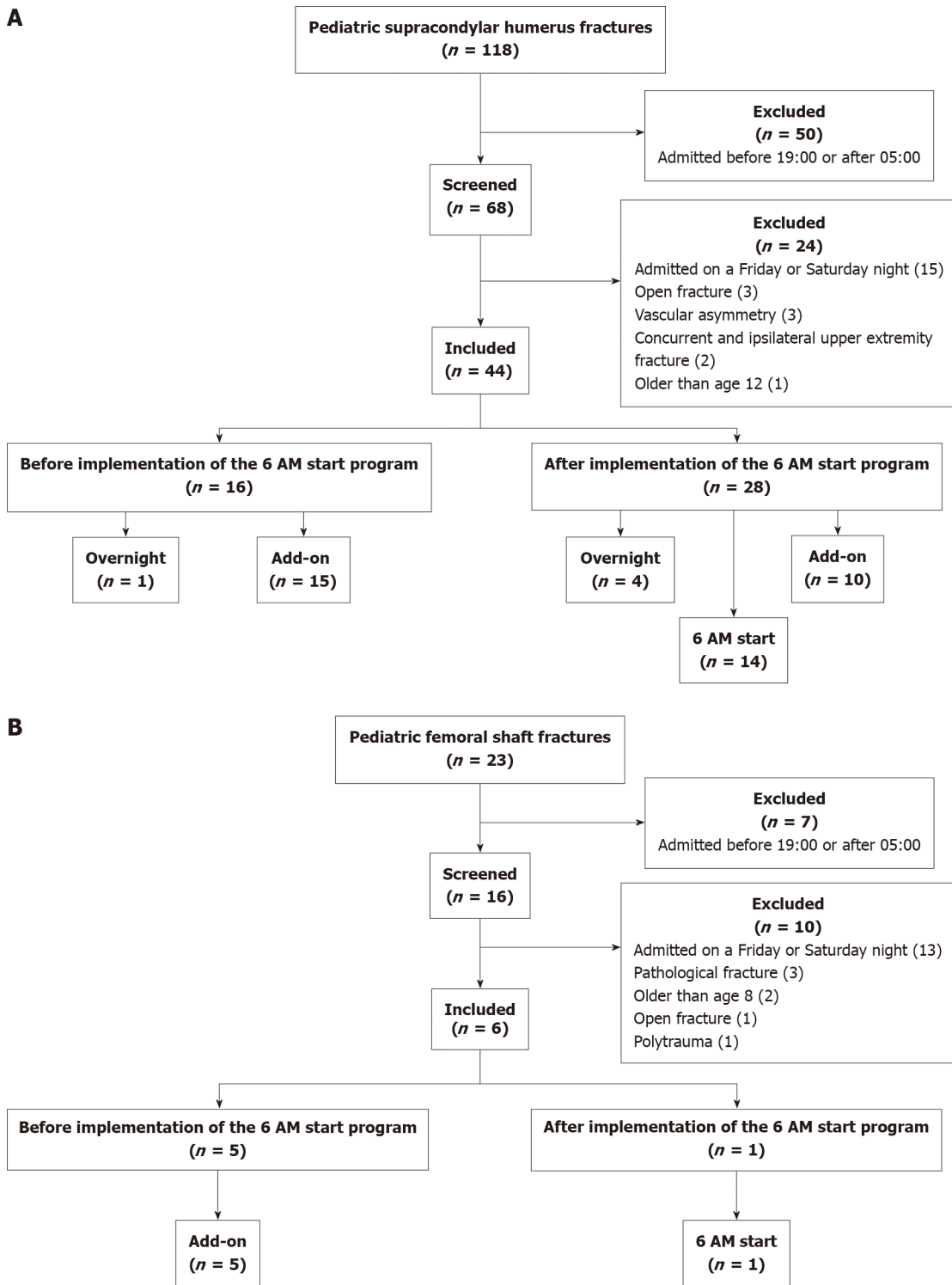
At our own institution we previously published a review of 153 patients with SCHF and we found no significant differences in outcomes among SCHF operated on overnight *vs* daytime surgery however surgery between midnight and 6 AM was associated with slightly a higher rate of malunion[15].

The treatment of type III SCHF is perhaps more controversial. A retrospective review of 172 patients spanning different severities of from the United Kingdom found no increasing complications when supracondylar fractures arriving after hours are managed the following day *vs* overnight[16].

Similarly, a recent report from Japan including 244 patients found that delaying treatment more than 12 h did not affect the rate of complications after surgery for Gartland type II or III SCHF[17]. A recent paper from Boston Children's Hospital demonstrated that at that institution 35% of type III and IV SCHF presenting overnight are operated on the night they presented while the remainder were treated the following day. No difference in complication rate was found based on timing of treatment. Based on their existing practice patterns they suggested that patients with potential neurovascular compromise or displacement of any cortex by greater than 25 mm should be considered for treatment overnight[18]. Despite the lack of any clinically demonstrable threshold for a delay in care that predicts poor outcomes, expediting care may have other benefits to families and patients. Furthermore timeliness of care continues to be a benchmark process metric of quality.

In this study, the percentage of cases with wait times for surgery within 18 h of ED admittance increased from 81% to 100% for SCHF and 56% to 100% for FSF after the implementation of the program. This translates to an additional award of two points to achieve the maximum of four points in this category. These findings support the 6 AM start program as an effective alternative to designated trauma rooms for reducing wait times for operative treatment for uncomplicated fractures, benefiting both patients and the institutions that do not have the OR space or trauma volume to render a trauma room cost-effective.

However, the survey responses highlight issues to address for future attempts at implementation of similar programs. The survey uncovered a significant disparity in opinions about the program amongst the staff, in particular those of surgeons *vs* those of anesthesiologists and nurses. This is partly attributed to the time of transition from overnight calls to daytime shifts at our institution. Surgeons typically take a home call followed by a clinic or OR day. In contrast, the on-call anesthesiologist has a 24-h shift from 07:00 to 07:00, making the 6 AM start case the 24th h of their shift. Nurses also change shifts at 07:00. Thus surgeons would take on the 06:00 fracture cases as their first or only surgery of the day while overnight anesthesiologists and nurses would have to either come in from home or stay until the last hour of their shift. This led nurses and anesthesiologists to feel that the program took advantage of OR staffing to facilitate the surgeon's schedule. Several nurses and anesthesiologists voiced concerns that the elective schedule was often delayed if the 06:00 case did not start on time or ran over the expected time. The nursing staff also felt that mobilizing for an urgent case at 06:00 was inefficient because the 06:00 h is typically spent preparing the following day's cases. Several nurses questioned the logic of waiting until 06:00 if the OR and staff were available to do the case sooner.

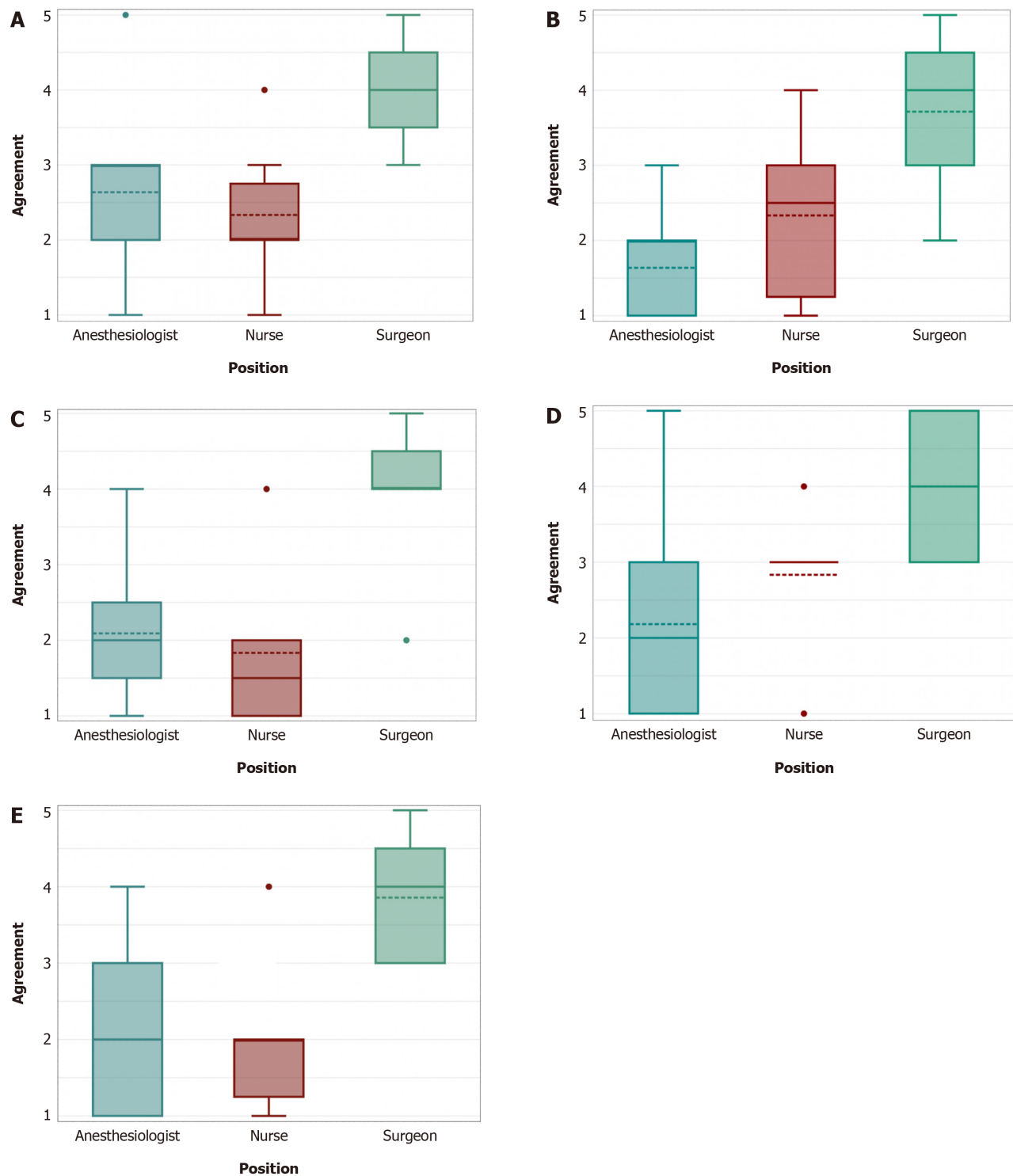


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Figure 1 Flow chart of the inclusion and exclusion criteria for supracondylar humerus fractures patients. A: Pediatric supracondylar humerus fractures; B: Pediatric femoral shaft fractures.

While the 6 AM start program was effective in reducing wait times for surgery, it was ultimately discontinued at our institution after one year, based in large part on the aforementioned inefficiencies and the extreme unpopularity of the program with non-surgeons. This outcome could potentially have been mitigated had anesthesiologists, nurses, and surgical technologists been invited earlier to plan and facilitate the implementation of the program. Many authors have stressed the importance of multidisciplinary teams in the success of quality improvement initiatives[19]. We recommend other institutions consider adopting similar programs to engage stakeholders early in the planning process to minimize the risks of unintended consequences and customize the program to best fit the structure of each institution.

With this study's retrospective design, we were also unable to ensure adherence to the protocol of scheduling eligible cases and starting the case on time which influenced the opinions of some OR staff. Factors other than the imple-



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Figure 2 Survey responses on 6 AM start program effectiveness. A: The 6 AM start program benefited patient care; B: The 6 AM start program benefited my service; C: The 6 AM start program made it easier to place urgent trauma cases; D: Supracondylar humerus fractures benefited from the 6 AM Start program; E: The 6 AM start program was an effective way to manage uncomplicated elbow and femur fractures presenting at night.

mentation of the early start time may influence the amount of time it takes for child to get to the OR. For example, individual decision making of attendings and residents on-call. By sampling patients for 1 year before and after we hope to have a good distribution of attendings and residents to eliminate individual decision making is a significant confounder. There are also large scale time variations that affect volume of these type of fractures. By using a sample size of 1 year before and 1 year after the implementation of the policy we hope to eliminate the effect of seasonal variation in volume and fracture type/severity on the timing of surgical treatment. This study is also limited by its smaller sample size, in particular, the FSF given that they are often complicated by polytrauma or pathology. The 6 AM start program was discontinued at our institution after a year, thus we were unable to expand the time window to capture more cases for the study.

CONCLUSION

We have demonstrated that our 6 AM start program was effective in reducing the wait time for operative treatment for uncomplicated SCHF presenting overnight. This is of interest and benefit to institutions as United States News and World Report uses timeliness of operative treatment for SCHF and FSF as a metric for ranking children's hospitals. Although the program produced promising results, it also created new conflicts within the OR staff that led to its discontinuation at our institution. This information may be useful to surgeons and hospital administrators as they undertake quality improvement programs to enhance the timeliness of care. Future implementations of such programs should involve stakeholders early in the planning process to better address the needs of the OR staff.

ARTICLE HIGHLIGHTS

Research background

This study describes the effect of a program allowing an early operating room (OR) start for uncomplicated trauma prior to an elective day of surgery to decrease wait times for surgery for urgent fractures admitted overnight.

Research motivation

The timing of operative treatment for pediatric supracondylar humerus fractures (SCHF) and femoral shaft fractures (FSF) remains controversial.

Research objectives

We present the impact of the quality improvement program initiated at a suburban level I trauma center, aiming to enhance the efficiency of care and adhere to United States News and World Report's standard for timely management. The program specifically focuses on reducing wait times for urgent trauma cases and mitigating surgeon fatigue by implementing a 6 AM start.

Research methods

From October 2017 onwards, patients admitted between 21:00 the previous night and 05:00 were considered for the early slot in the OR, subject to the surgeon's judgment. To evaluate the effects of this change, we analyzed the demographic characteristics and treatment timelines of patients with SCHF and FSF, comparing data from one year before and one year after the implementation. Additionally, we gathered survey responses from the surgical team for further insights.

Research results

Out of the 44 SCHF cases that met the inclusion criteria, 16 underwent treatment prior to the program's implementation, while 28 received treatment afterward. Following the implementation, the average wait time for surgery decreased by 4.8 h or 35.4% (from 13.4 h to 8.7 h; $P = 0.001$). However, no significant differences were observed in operative duration, post anesthesia care unit stay, or discharge wait time. Survey responses indicated a decline in the program's popularity among nurses and anesthesiologists compared to surgeons. While 57% of surgeons believed the program was effective, only 9% of anesthesiologists and 16% of nurses shared the same opinion. Due to the overall dissatisfaction, the program was eventually discontinued.

Research conclusions

The results of our study highlight a significant decrease in surgery wait times for uncomplicated SCHF cases admitted overnight. Additionally, we emphasize the significance of engaging stakeholders in shared decision-making. While the program yielded promising outcomes, it also gave rise to conflicts among the OR staff, ultimately leading to its discontinuation at our institution. Moving forward, it is essential to involve stakeholders early on during the planning phase of similar programs to effectively address the OR staff's requirements and concerns.

Research perspectives

Surgeons and hospital administrators engaging in quality improvement initiatives to improve the timeliness of care can find value in this information. It is recommended that future implementations of such programs involve stakeholders from the outset of the planning process to ensure better alignment with the needs of the OR staff.

FOOTNOTES

Author contributions: Kym D, Kaur J, Pham NS, Klein E, Langner JL, Wang E, and Vorhies JS contributed to the research, writing, and revision of the manuscript.

Institutional review board statement: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted an IRB waiver by the Ethics Committee of Stanford University (IRB No. 46989).

Informed consent statement: This project is not a randomized clinical trial. Per our Institutional Review Board, this study did not need signed consent from participants.

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Country/Territory of origin: United States

ORCID number: Dan Kym 0000000223618685; Joanna Lind Langner 0000-0002-5981-4733; John Schoeneman Vorhies 0000-0002-2526-4489.

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L-Editor: A

P-Editor: Ju JL

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Retrospective Cohort Study

Low risk of postoperative ulnar nerve affection in surgically treated distal humeral fractures when the nerve is released *in situ*

Mustafa Al-Gburi, Ali Al-Hamdani, Jeppe Vejlgard Rasmussen, Bo Sanderhoff Olsen

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Mustafa Al-Gburi, Ali Al-Hamdani, Jeppe Vejlgard Rasmussen, Bo Sanderhoff Olsen, Section for Shoulder and Elbow Surgery, Department of Orthopaedic Surgery, Herlev and Gentofte University Hospital, Hellerup 2900, Gentofte, Denmark

Corresponding author: Mustafa Al-Gburi, Doctor, MD, Doctor, Section for Shoulder and Elbow Surgery, Department of Orthopaedic Surgery, Herlev and Gentofte University Hospital, 12 Gentofte Hospitalsvej, Hellerup 2900, Gentofte, Denmark.

mustafa.hamid.hussein.al-gburi@regionh.dk

Abstract

BACKGROUND

Adult distal humeral fractures (DHF) comprise 2%-5% of all fractures and 30% of all elbow fractures. Treatment of DHF may be technically demanding due to fracture complexity and proximity of neurovascular structures. Open reduction and internal fixation (ORIF) are often the treatment of choice, but arthroplasty is considered in case of severe comminution or in elderly patients with poor bone quality. Ulnar nerve affection following surgical treatment of distal humerus fractures is a well-recognized complication.

AIM

To report the risk of ulnar nerve affection after surgery for acute DHFs.

METHODS

We retrospectively identified 239 consecutive adult patients with acute DHFs who underwent surgery with ORIF, elbow hemiarthroplasty (EHA) or total elbow arthroplasty (TEA) between January 2011 and December 2019. In all cases, the ulnar nerve was released *in situ* without anterior transposition. We used our institutional database to review patients' medical records for demographics, fracture morphology, type of surgery and ulnar nerve affection immediately; records were reviewed after surgery and at 2 wk and 12 wk of routine clinical outpatient follow-up. Twenty-nine percent patients were excluded due to pre- or postoperative conditions. Final follow-up examination was a telephone interview in which ulnar nerve affection was reported according to the McGowen Classification Score. A total of 210 patients were eligible for interview, but 13 patients declined participation and 17 patients failed to respond. Thus, 180 patients were included.

RESULTS

Mean age at surgery was 64 years (range 18-88 years); 121 (67.3%) patients were women; 59 (32.7%) were men. According to the AO/OTA classification system, we recorded 47 patients with type A3, 55 patients with type B and 78 patients with type C fractures. According to the McGowen Classification Score, mild ulnar nerve affection was reported in nine patients; severe affection, in two. A total of 69 patients were treated with ORIF of whom three had mild temporary ulnar nerve affection and one had severe ulnar nerve affection. In all, 111 patients were treated with arthroplasty (67 EHA, 44 TEA) of whom seven had mild ulnar nerve affection and one had severe persistent ulnar nerve affection. No further treatment was provided.

CONCLUSION

The risk of ulnar nerve affection after surgical treatment for acute DHF is low when the ulnar nerve is released *in situ* without nerve transposition, independently of the treatment provided.

Key Words: Humeral fracture; Arthroplasties; Internal fixation; Ulnar nerve affection; *In situ* release

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Core Tip: Ulnar nerve affection after surgery for distal humerus fractures (DHF) is a known complication. We retrospectively reviewed a consecutive series of 180 patients with acute DHF treated either with open reduction and internal fixation (ORIF), total elbow arthroplasty (TEA) or elbow hemiarthroplasty (EHA). According to the McGowan Classification Score, 11 patients reported ulnar nerve affection symptoms (nine patients with mild affection and two patients with severe affection). The risk of ulnar nerve affection after surgery for acute DHF is low when the ulnar nerve is released *in situ* without transposition, independently of the treatment provided (*i.e.*, ORIF, EHA, or TEA).

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INTRODUCTION

Adult distal humeral fractures (DHF) comprise approximately 2%-5% of all fractures and 30% of all elbow fractures[1,2]. Open reduction and internal fixation (ORIF) is often the treatment of choice, but arthroplasty [elbow hemiarthroplasty (EHA) or total elbow arthroplasty (TEA)] may be considered in case of severe comminution or in elderly patients with poor bone quality[3-5]. Ulnar nerve affection is a known complication associated with surgical treatment of distal humerus fractures[6]. The development of ulnar affection has many potential aetiologies[7]. The ulnar nerve may be contused or lacerated at the time of the initial trauma or at the time of the surgical intervention, particularly from excessive retraction during fracture exposure or fixation. Swelling in the immediate posttraumatic or postoperative setting may also contribute to ulnar nerve affection. Postoperatively, soft tissue scar formation, heterotopic ossification and prominent hardware may represent aetiological factors for ulnar nerve affection. During surgery, mobilisation of the ulnar nerve is often necessary for protection and to reduce and fixate the fracture or to perform a joint arthroplasty. Most injuries are described to give temporary paraesthesia without motoric affection[8,9]. In some rare cases, severe ulnar affections are seen with weakness and atrophy of one or more of the ulnar intrinsic muscles, leading to claw hand deformity, which compromises the outcome[10]. Some surgeons perform anterior transposition of the ulnar nerve, which has theoretical advantages including moving the nerve away from the implants, preventing kinking of an incompletely released nerve, avoiding subluxation over the medial epicondyle, limiting entrapment in scar tissue and allowing nerve-free excursion[11-13]. On the other hand, transposition requires further nerve dissection with a potential risk of additional trauma, devascularisation and prolonged operative time[12,14]. How the ulnar nerve is best protected during surgery is still debated[9].

This study aimed to report the risk of ulnar nerve affection after surgery for acute DHF with *in situ* release and protection of the ulnar nerve without anterior transposition. The secondary outcome was to investigate if the type of surgery performed is a risk factor for postoperative ulnar nerve affection.

MATERIALS AND METHODS

Study design

This was a retrospective study conducted within a consecutive cohort of patients surgically treated for distal humerus fracture. The study was conducted in accordance with the STROBE guidelines[15].

Study population

We used our institutional database to identify all adult patients surgically treated for acute DHF during the nine-year period from 2011 to 2019. A total of 239 patients were identified (Figure 1). Twenty-nine percent patients were excluded due to pre-operative nerve affection, postoperative infection and reoperation, other fractures adjacent to the elbow and pathological fractures. Additionally, we excluded patients whose data could not be retrieved due to immigration and cognitive impairment. Thus, 210 patients were eligible for the final telephone interview. In all, 13 patients opted out of participating, and 17 patients failed to respond to the phone calls. According to the medical records, four of these 30 patients had mild paraesthesia without motoric affection in the immediate postoperative period, which resolved spontaneously during the first 12 postoperative weeks. Thus, 180 patients were included in the study.

Participants included 121 (67.3%) women and 59 (32.7%) men. The mean age was 64 years (18-88 years). The mean follow-up was six years (3-11 years). According to the OTA/AO Classification, we recorded 47 patients with type A (7 type A2 and 40 type A3), 55 patients with type B (15 type B1, 18 type B2, and 22 type B3) and 78 patients with type C (19 type C1, 30 type C2, and 29 type C3). The fractures were classified by the first author using conventional X-rays supplied with computed tomography (CT) if available. A total of 69 patients were treated with ORIF, 67 with EHA and 44 with TEA.

Treatment, surgical technique and rehabilitation

According to our treatment algorithm, conservative treatment is indicated for non-displaced fractures and in patients with severe comorbidities where the risk of surgery outweighs its benefit. Arthroplasty is considered for comminuted intra-articular fractures unamenable for ORIF. EHA is preferred in active patients, whereas TEA is preferred in elderly and low-demanding patients and patients with radiographic signs of osteoarthritis. Conventional radiographs were performed in all cases, and CT was used for preoperative planning in selected cases.

All patients were operated in the lateral decubitus position with a standard posterior midline approach. All operations were performed in general anaesthesia. Tourniquets were used in all cases. All patients were operated within two weeks from their injury (range 2-14 d). The ulnar nerve was identified, released *in situ* and protected. The ulnar nerve was not transposed. All procedures were performed using a triceps split with a reverse Y-shaped incision in the triceps[16] except for OTA/AO type 13A fractures where a triceps-sparing approach with medial and/or lateral windows was adopted at the surgeon's discretion and the fracture comminution. In the ORIF group, all patients were operated with double plates [Synthes Locking Plate System (West Chester, PA, United States), VariAx Locking Plate System (Stryker, Kalamazoo, MI, United States), or Acumed Elbow Plating System (Hillsboro, OR, United States)]. The Latitude (WRIGHT, Memphis, TN, United States) was used as EHA and the Coonrad-Morrey elbow arthroplasty (Zimmer Biomet, Rochester, MN, United States) as TEA.

All patients performed oedema prophylactic exercises of the hand and fingers during the time of immobilisation. In ORIF and EHA groups, a posterior splint was used for two weeks. Passive exercises were allowed from week two to week six, and light weight bearing was permitted after six weeks. Full weight-bearing exercises were allowed after three months. In TEA, group mobilisation was initiated on the first postoperative day or as soon as discomfort allowed, with retention of the bulky dressing. Mobilisation was proceeded incrementally according to the patient's level of discomfort. Patients were instructed to keep the arm in a sling, except when they were exercising it. They were also instructed specifically to avoid resisted extension and lifting during the first six postoperative weeks. Thereafter, they were advised to stretch the elbow into full extension and full flexion daily, progressively increasing their level of activity as their discomfort decreased. They were advised to indefinitely refrain from strenuous manual activities such as carrying more than 5 kg loads with the treated arm.

Outcome

Medical records were reviewed for demographics, fracture morphology, type of surgery and ulnar nerve affection immediately after surgery and at 2 wk and 12 wk of routine clinical outpatient follow-up. All patients participated in a final telephone interview, and ulnar nerve conditions were reported. Ulnar nerve affection was categorised according to the McGowan Classification Score[17]. Mild affection was identified as paraesthesia in the 4th and 5th fingers aggravated by elbow flexion (grade 1). Paraesthesia with additional weakness and clumsiness of the interossei was graded as moderate (grade 2); and severe symptoms in form of interossei paralysis and marked hypoesthesia in the 4th and 5th fingers were identified as severe affection (grade 3). Routine electromyographic studies were not performed.

Statistical analysis

Descriptive statistics for continuous variables were presented as mean, minimum and maximum values. Categorical variables were presented by frequencies and percentages. A binary logistic regression model was used to compare the risk of ulnar nerve affection for different types of surgery. The results were presented as odds ratio (OR) with 95% confidence intervals (CI) and *P* values. The ORIF group was used as a reference. *P* values < 0.05 were considered statistically significant. The analyses were performed using SPSS software (version 25.0, IBM, Armonk, NY, United States).

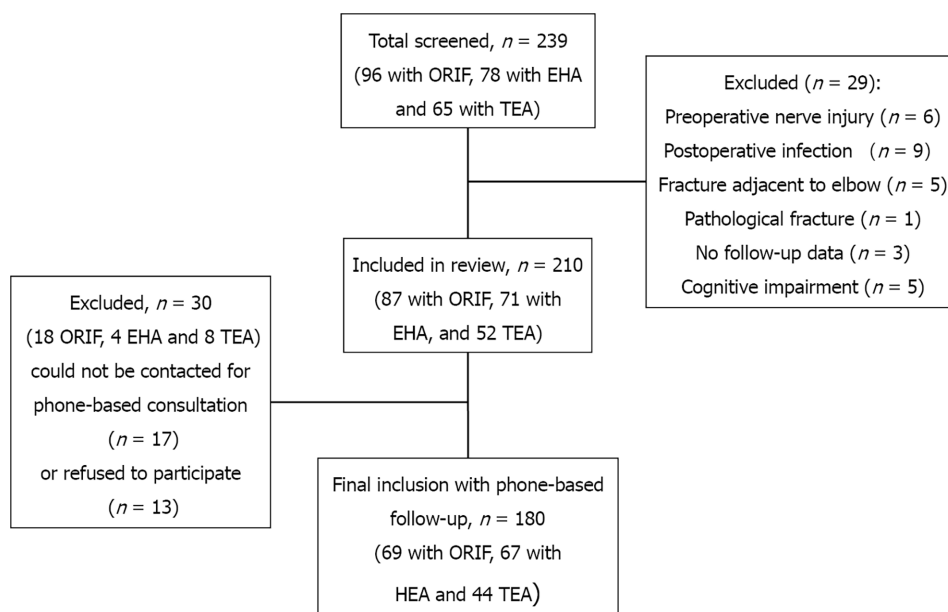
RESULTS

Eleven patients (6%) had post-operative ulnar nerve affection during the follow-up period; seven women and four men. Four of these patients were treated with ORIF, four with EHA and three with TEA (Table 1).

Table 1 List of patients with ulnar nerve affection

Patient number	AO fracture classification	Gender	Age at surgery	Surgery type	The onset of affection postoperatively	McGowan grade
1	A3	F	67	ORIF	Two weeks	3
2	C3	F	73	EHA	Two years	3
3	C3	F	63	EHA	Immediately	1
4	C2	M	61	EHA	Immediately	1
5	C3	F	70	TEA	Immediately	1
6	C2	F	79	EHA	Two weeks	1
7	C3	M	68	TEA	Two weeks	1
8	C1	F	66	ORIF	Immediately	1
9	A3	M	53	ORIF	Immediately	1
10	B1	M	48	ORIF	Two weeks	1
11	B3	F	82	TEA	Immediately	1

AO: Arbeitsgemeinschaft für osteosynthesefragen; ORIF: Open reduction and internal fixation; EHA: Elbow hemiarthroplasty; TEA: Total elbow arthroplasty.



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Figure 1 Study flowchart summarizing screening, inclusion, exclusion and final phone-based patient follow-up. ORIF: Open reduction and internal fixation; EHA: Elbow hemiarthroplasty; TEA: Total elbow arthroplasty.

Six patients had ulnar nerve affection immediately after surgery. The symptoms were mild paraesthesia in the 4th and 5th fingers (McGowan grade 1, which resolved spontaneously before the 12-wk follow-up examination).

Four patients had ulnar nerve affection with onset around the two-week follow-up. Three of these patients had mild symptoms with paraesthesia in the 4th and 5th fingers (McGowan grade 1), which resolved spontaneously before the 12-wk follow-up examination. The fourth patient had persistent severe symptoms in the form of interossei paralysis and marked hypoesthesia in the 4th and 5th fingers (McGowan grade 3).

One patient had persistent, severe symptoms (McGowan grade 3) in the form of interossei paralysis and marked hypoesthesia in the 4th and 5th fingers with onset during the second year.

No difference was observed in the risk of ulnar nerve affection between patients treated with ORIF or EHA (OR = 1.03, 95%CI: 0.25, 4.31, $P = 0.97$) or between patients treated with ORIF or TEA (OR = 1.19, 95%CI: 0.25, 5.59, $P = 0.83$).

DISCUSSION

In this study, 11 out of 180 patients (6%) had ulnar nerve affection after surgery for distal humerus fractures. However, only two patients (1%) had severe and persistent ulnar nerve affection (McGowan grade 3). Ulnar nerve affection may occur due to excessive retraction during exposure, or the nerve may become affected after surgery due to hardware irritation or scar tissue formation. This may explain the late symptom onset in some patients. In this study, we focused on per- and post-operative nerve affection. We excluded patients with pre-operative ulnar nerve affection and patients complicated by postoperative infection. Surgery of the ulnar nerve may consist of either subcutaneous anterior transposition or *in situ* release retaining the nerve in its original position. However, which method should be preferred is debatable. Several retrospective studies have reported a risk of ulnar nerve affection after surgery for DHF where the nerve was either anteriorly transposed or released *in situ*, but they have drawn different conclusions[6]. We used the McGowan Classification Score[17] to evaluate the postoperative ulnar nerve affection and to grade the severity of the nerve affection. We chose this classification system to ensure the comparability of our results to the results of those previously published studies.

However, the true prevalence of ulnar nerve affection after elbow injury remains unknown as studies have not successfully differentiated between acute injury-related, acute surgery-related and delayed (subacute or chronic) ulnar affections. Furthermore, in most of these retrospective case series, careful evaluation of ulnar nerve function was not reported[18].

Wiggers *et al*[19] retrospectively analysed a cohort of 107 consecutive adult patients with surgically treated distal humerus fractures to determine risk factors for development of ulnar affection. These risk factors included age, sex, implant over or below the medial epicondyle and total number of surgeries. They found that columnar fracture and application of a medial plate were the only potential risk factors for iatrogenic postoperative ulnar affection.

To identify factors related to ulnar nerve affection, Vazquez *et al*[20] retrospectively evaluated 69 DHF treated with or without ulnar nerve transposition. They reported 14 patients with documented ulnar nerve affection either in the immediate postoperative period or at the final evaluation; and the prevalence of post-operative affection reached 16%. They concluded that transposition of the nerve did not significantly decrease the risk of iatrogenic ulnar affection. However, the optimal handling of the ulnar nerve remains uncertain even though anterior transposition in the acute surgical treatment of displaced distal humerus fractures seems to be associated with a high risk of ulnar nerve affection [20].

Chen *et al*[21] retrospectively investigated the risk of ulnar nerve affection in 170 patients who underwent ORIF for acute distal humeral fracture. The study groups consisted of patients who did not undergo ulnar nerve transposition at the time of fracture fixation and a control group of patients who did undergo ulnar nerve transposition during fracture fixation. They reported that the risk of ulnar nerve affection was four times higher after transposition (33%) than (9%) in the *in situ* release group. They suggested three explanations for this observation. The first was devascularisation of the nerve during transposition, the second was iatrogenic compression resulting from an overlying tight transposition and the third was an inadequate proximal release of the arcade of Struthers or the medial intermuscular septum. The study was limited by selection bias that was potentially introduced by the surgeon's decision to perform a transposition. Even so, the decision to transpose was based on a best practice scenario.

Likewise, in a retrospective series of 83 total elbow arthroplasties, Dachs *et al*[22] observed a lower incidence of ulnar nerve affection when they used *in situ* release of the nerve than when they used transposition. They recommended that transposition of the nerve should be reserved for cases with marked limitation of preoperative elbow flexion or when deemed necessary at intraoperative assessment, like abnormal tracking or increased tension on the nerve after insertion of the prosthesis.

Ahmed *et al*[12] conducted a retrospective cohort study of 97 consecutive patients with distal humerus fractures who underwent ORIF where subcutaneous ulnar nerve anterior transposition was compared with no transposition at the time of ORIF. They found a five-fold increase in ulnar nerve affection following transposition (35.7% for transposition; 14.5% for no transposition). However, this study may suffer from selection bias because nerve transposition was not conducted systematically.

In the present study, we found that *in situ* release and protection of the ulnar nerve without transposition produced a low prevalence of postoperative ulnar nerve affection for both ORIF and arthroplasty surgery following distal humerus fracture. The potential advantage of *in situ* management of the ulnar nerve is less manipulation of the nerve and its vascularity. In contrast, the potential disadvantages of transposition are a higher risk of nerve affection, devascularisation and scar formation.

The present study is primarily limited by its retrospective design. Additionally, the data collection process depended on the accuracy of follow-up reports from the outpatient clinic during the initial follow-up period. Another limitation is that electromyographic examination was generally not used to confirm ulnar nerve affection. This may lead to information bias due to, *e.g.*, misclassification of ulnar nerve affection.

In addition, the study comprised initial follow-up examinations only at two and 12 wk, which makes it difficult to report the exact time of onset and when the symptoms resolved. Furthermore, we had no information about the length of tourniquet time, which may possibly have influenced ulnar nerve affection.

The main strength of this study is its large sample. Further strengths include that all eligible patients were reviewed, that the surgeries were performed by speciality-trained surgeons in a single centre, that the follow-up period was mean seven years and that an independent reviewer conducted the final telephone interview. In contrast to the previously published studies, we were able to compare the risk of ulnar nerve affection after ORIF, EHA, and TEA.

CONCLUSION

The risk of ulnar nerve affection after surgery for acute DHF is low when surgeons use *in situ* ulnar nerve release without nerve transposition, regardless of the treatment provided (*i.e.*, ORIF, EHA, or TEA).

ARTICLE HIGHLIGHTS

Research background

Ulnar nerve affection following surgical treatment of distal humerus fractures (DHF) is a well-recognized complication. Surgery of the ulnar nerve may consist of either subcutaneous anterior transposition or *in situ* release retaining the nerve in its original position. However, which method should be preferred is debatable. We believe that *in situ* release and protection of the ulnar nerve without transposition produced a low prevalence of postoperative ulnar nerve affection for both Open reduction and internal fixation (ORIF), Total elbow arthroplasty, (TEA) and elbow hemiarthroplasty (EHA) surgeries of distal humerus fracture. In contrast to the previously published studies, we were able to compare the risk of ulnar nerve affection after ORIF, EHA, and TEA.

Research motivation

Several retrospective studies have reported a risk of ulnar nerve affection subsequent to surgery for distal humeral fractures (DHF), where either the nerve was anteriorly transposed or released *in situ*. However, these studies have arrived at differing conclusions. As a result, we were motivated to conduct a detailed investigation into the prevalence of pre- and post-operative ulnar nerve affection when the nerve is released *in situ*. To this end, we excluded patients who were presented with pre-operative ulnar nerve affection, as well as those who were afflicted with postoperative infection.

Research objectives

To report the risk of ulnar nerve affection after surgeries (ORIF, TEA, and EHA) for acute DHF when the ulnar nerve is *in situ* released without transposition.

Research methods

We retrospectively reviewed a consecutive series of 180 patients with acute DHF treated either with ORIF, TEA, or EHA.

Research results

Our study found a low risk of ulnar nerve affection following surgical treatment for acute DHF when the ulnar nerve was released *in situ* without nerve transposition. Of the 180 patients included in the study, only nine reported mild ulnar nerve affection and two reported severe affection according to the McGowen Classification Score. The study also found that the type of surgery (ORIF, EHA, or TEA) did not significantly affect the risk of ulnar nerve affection. Three out of 69 patients treated with ORIF had mild temporary ulnar nerve affection, while seven out of 111 patients treated with arthroplasty (67 EHA, 44 TEA) had mild ulnar nerve affection and one had severe persistent affection.

Research conclusions

The findings of our study suggest that releasing the ulnar nerve *in situ* without transposition during surgical treatment of acute DHF may help minimize the risk of ulnar nerve affection, regardless of the type of surgery performed.

Research perspectives

Further research may be needed to confirm these results and explore other potential risk factors for ulnar nerve affection in DHF patients.

FOOTNOTES

Author contributions: Al-Gburi M, Al-Hamdani A, Rasmussen JV, and Olsen BS made substantial contributions to the conception and design, the analysis and interpretation of data, and the drafting and revising of the article; and all authors approved the final version of the manuscript for publishing.

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Informed consent statement: According to the local Danish medical law, the study did not require informed consent from the patients in such a quality control study.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

Data sharing statement: No additional data are available.

STROBE statement: The authors have read the STROBE Statement—checklist of items, and the manuscript was prepared and revised according to the STROBE Statement—checklist of items.

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Country/Territory of origin: Denmark

ORCID number: Mustafa Al-Gburi 0000-0002-3725-5416; Ali Al-Hamdani 0000-0001-5562-2737; Jeppe Vejlgard Rasmussen 0000-0001-5886-1629; Bo Sanderhoff Olsen 0000-0002-3509-0742.

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Retrospective Cohort Study

Excision of trochanteric bursa during total hip replacement: Does it reduce the incidence of post-operative trochanteric bursitis?

Wai-Huang Teng, Adeel Ditta, Jane Webber, Oliver Pearce

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Wai-Huang Teng, Adeel Ditta, Jane Webber, Oliver Pearce, Division of Trauma and Orthopaedics, Milton Keynes University Hospital, Milton Keynes MK6 5LD, United Kingdom

Corresponding author: Wai-Huang Teng, MBChB, Doctor, Surgeon, Division of Trauma and Orthopaedics, Milton Keynes University Hospital, Standing Way, Milton Keynes MK6 5LD, United Kingdom. waihuang0506@outlook.com

Abstract

BACKGROUND

Trochanteric bursitis is a common complication following total hip replacement (THR), and it is associated with high level of disability and poor quality of life. Excision of the trochanteric bursa prophylactically during THR could reduce the occurrence of post-operative trochanteric bursitis.

AIM

To evaluate whether synchronous trochanteric bursectomy at the time of THR affects the incidence of post-operative trochanteric bursitis.

METHODS

This retrospective cohort study was conducted in the secondary care setting at a large district general hospital. Between January 2010 and December 2020, 954 patients underwent elective primary THR by two contemporary arthroplasty surgeons, one excising the bursa and the other not (at the time of THR). All patients received the same post-operative rehabilitation and were followed up for 1 year. We reviewed all cases of trochanteric bursitis over this 11-year period to determine the incidence of post-THR bursitis. Two proportion Z-test was used to compare incidences of trochanteric bursitis between groups.

RESULTS

554 patients underwent synchronous trochanteric bursectomy at the time of THR whereas 400 patients did not. A total of 5 patients (incidence 0.5%) developed trochanteric bursitis following THR; 4 of whom had undergone bursectomy as part of their surgical approach, 1 who had not. There was no statistically significant difference between the two groups (Z value 1.00, 95%CI: -0.4% to 1.3%, $P = 0.32$). There were also 8 other patients who had both trochanteric bursitis and hip osteoarthritis prior to their THR; all of whom were treated with THR and synchronous trochanteric bursectomy, and 7 had resolution of their lateral buttock pains but 1 did not.

CONCLUSION

Synchronous trochanteric bursectomy during THR does not materially affect the incidence of post-operative bursitis. However, it is successful at treating patients with known trochanteric bursitis and osteoarthritis requiring THR.

Key Words: Total hip replacement; Trochanteric bursectomy; Trochanteric bursitis; Greater trochanteric pain syndrome

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Core Tip: We investigated a plausible theory of prophylactic trochanteric bursectomy at the time of total hip replacement (THR) to reduce the incidence of post-operative bursitis. Our retrospective study included 954 patients over an 11-year period operated by two contemporary surgeons, one excising the bursa and the other not. From our analysis, we found no significant difference in the incidence of post-THR bursitis between the two groups. However, our series did demonstrate that synchronous trochanteric bursectomy during THR is successful at treating the lateral buttock pain component for patients with known trochanteric bursitis and osteoarthritis requiring THR; and therefore, we recommend the procedure in these patients.

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INTRODUCTION

Hip osteoarthritis is a common painful condition of the groin and anteromedial thigh. It is one of the leading causes of elderly disability worldwide[1]. In fit patients, where medical treatment has been exhausted, total hip replacement (THR) offers the best chance of symptomatic relief and functional recovery. Trochanteric bursitis, on the other hand, is a condition of localised lateral buttock pain that can radiate down the lateral thigh, or into the posterior buttock, or both. Trochanteric bursitis is the most common cause of Greater Trochanteric Pain Syndrome (GTPS) in the literature. It is estimated to affect 17.6% of adults aged between 50-79 years[2], and associated with similar level of disability and poor quality of life as in severe osteoarthritis[3]. Trochanteric bursitis can occur primarily from repetitive stress or secondary to various hip, knee, or lower back pathologies. It is also common following THR, with an incidence of 4%-8%[4-8]. When sub-analysed according to surgical approach, several studies have reported lower incidence in those operated by posterior approach, as low as 1.2%[8], compared to anterior or lateral approaches[7-9].

For a decade, our lead author has performed trochanteric bursectomy as part of the surgical approach for all his THR. The rationale being that the bursa is likely to fibrose following surgery, losing its functional properties as friction buffer but still have the potential of developing bursitis at a later date. Therefore, its prophylactic excision seemed logical. This is a unique series based on a plausible supposition (that excision of the trochanteric bursa during THR would be preventative of later trochanteric bursitis) carried out by a single surgeon continuously for a decade and collecting outcome data contemporaneously. There are no similar papers in the literature.

This study compares the outcomes between patients who underwent THR with synchronous trochanteric bursectomy and those without (within the same department, and with the same post-operative rehabilitation protocol), looking in particular at the incidence of post-THR bursitis that required secondary care treatment. As part of the study, the overall incidence of trochanteric bursitis, the incidence of post-THR bursitis, and the incidence of symptomatic bursitis and hip osteoarthritis prior to THR were also investigated. In addition, for the latter subgroup (symptomatic bursitis and hip osteoarthritis), we assessed whether the bursectomy at the time of THR abolished the lateral buttock pains as well as the groin pains.

MATERIALS AND METHODS

Study population

This is a single-centre retrospective cohort study conducted within a secondary care setting. 954 consecutive patients who underwent elective primary THR by either of two consultant hip arthroplasty surgeons, one who performed THR with synchronous trochanteric bursectomy (Surgeon A) and the other without bursectomy (Surgeon B), between January 1, 2010 and December 31, 2020, were identified and included in the study. There are no exclusion criteria. Research ethics approval was not sought as the study was purely observational, and only included anonymised and non-sensitive data.

Total hip replacement

Both surgeons use the same posterior approach to the hip joint. Surgeon A routinely excises the trochanteric bursa as part of the surgical approach while Surgeon B does not. The bursa is left open at the end of the procedure without repair.

Both surgeons perform a curvilinear skin incision centred on the greater trochanter, followed by fascia lata incision in this line. At this point, Surgeon A excises the bursa using electrocautery and tension from forceps, whereas Surgeon B incises into the bursa to expose the trochanter and posterior structures to continue with the posterior approach to the hip. The remaining procedure follows the same logical sequence of a standard total hip replacement. Both surgeons perform a standard capsulotomy and detach the short external rotators to visualise the acetabulum, and femoral head and neck. The hip replacement is then performed. The short external rotators are re-attached using sutures, closing the capsule, and subsequent soft tissue structures closed in layers.

Anaesthesia and post-operative variables

Patients in the cohort had a combination of different anaesthetic techniques at the time of surgery, dependent on individual anaesthetist's decision-making-process. 70% of the patients received a spinal anaesthetic (with propofol or midazolam sedation) containing fentanyl with either a low dose diamorphine, or fentanyl as an adjunct. The remaining 30% had either both spinal and general anaesthetic (GA), or a straight GA in the form of Total Intravenous Anaesthesia. All patients had 0.125% Bupivacaine (no adrenaline) injected as Local Infiltration of Anaesthesia into the periarticular tissues, generally 100 mL, but a lower volume used for patients with a low body weight.

All patients were managed under the same enhanced recovery programme. Patients are mobilised either on the same day of surgery, or the following day, and are permitted full weight bearing. The mean length of stay has fallen over this 11-year period from 4.4 d to 2.5 d at the time of writing. The discharge criteria have not changed in this time. Patients must be able to independently walk 20 m on flat surface with crutches, safely get into and out of bed, safely get into and out of a chair, and pass the stairs test. A dry dressing is mandated before discharge. All patients were then followed up with the primary surgeon in an elective clinic 6 wk after the operation, and with the physiotherapist at 3 mo, 6 mo and 1 year. Any patients, at any stage, with problematic symptoms of hip or lateral buttock pain were booked back into the clinic of the operating surgeon as a matter of course.

Trochanteric bursitis

We used our institution's electronic patient records to identify any patient coded as having a diagnosis of trochanteric bursitis, injection into the trochanteric bursa, and/or trochanteric bursectomy. From this list, each patient's electronic patient record was reviewed to confirm the finding. The resulting list of confirmed cases of trochanteric bursitis (managed within the secondary care setting) was then compared with the list of total hip replacements by either of the two surgeons to generate a list of patients who had both a diagnosis of trochanteric bursitis and total hip replacement over the 11-year period. It also permitted the investigators to document the incidence of trochanteric bursitis independent of having a THR during this study period.

Statistical analysis

Data was collected and analysed in Microsoft Excel. Continuous variables with normal distribution were expressed in mean \pm SD. Two proportion Z-test was performed to compare the incidences of trochanteric bursitis between Surgeon A and Surgeon B. Continuity correction was not applied. Logistic regressions were carried out in R software v4.2.2. Results were considered statistically significant at $P \leq 0.05$.

RESULTS

From January 2010 to December 2020, 954 patients underwent primary total hip replacement by either of two consultant hip arthroplasty surgeons. Six patients underwent simultaneous bilateral uncemented THR, thus increasing the number of procedures to 960. Among these, 556 procedures had synchronous trochanteric bursectomy by Surgeon A as part of the surgical approach. Demographic and operative data are displayed in Table 1. 10.5% of patients did not turn up at their post-operative follow up with the primary surgeon, and hence were deemed lost to follow up. There is no significant difference in lost to follow up between surgeons ($P = 0.06$). The mean follow-up time for the entire cohort was 291 ± 115 d.

We identified a total of 152 cases of trochanteric bursitis at our institution over the 11-year period (independent of having hip osteoarthritis or THR, so the raw incidence). There were 16 patients who, on coding, had diagnoses of both THR and trochanteric bursitis. Of these 16 patients, 3 were for bursitis on the *contralateral* hip, 8 were pre-existing diagnosis of bursitis *prior* to THR, and 5 were identified to have developed bursitis *after* their THR (Table 2). The incidence of post-operative bursitis that required secondary care treatment in our series was therefore 0.5%. The mean interval between THR and diagnosis of bursitis was 412 days. Of these 5 patients; 4 patients had undergone a trochanteric bursectomy as part of the surgical approach (by Surgeon A), and 1 had not (by Surgeon B), corresponding to incidences of 0.72% and 0.25% respectively. Comparison using two proportion Z-test showed that there is no significant difference between the incidences of trochanteric bursitis following primary THR between Surgeon A and Surgeon B (Z value 1.00, 95%CI: -0.4% to 1.3%, $P = 0.32$).

There were 8 cases of trochanteric bursitis diagnosed prior to THR, all of which had synchronous trochanteric bursectomy by Surgeon A. Of them, 7 reported resolutions of symptoms following their hip procedures. But the 8th patient suffered a periprosthetic infection requiring staged revision surgery, confounding his outcome in the context of

Table 1 Patient demographic and operative data

Demographic	Surgeon A	Surgeon B
	Synchronous trochanteric bursectomy	Trochanteric bursa preserved
Number of patients	554	400
Age, mean \pm SD, yr	66 \pm 11.9	69 \pm 9.9
Gender		
Female	346	264
Male	208	136
Procedures		
Uncemented THR	329	195
Cemented THR	0	84
Hybrid THR (cemented femoral component)	227	125
Laterality		
Right	288	204
Left	264	192
Bilateral	2	4

Note that six patients underwent simultaneous bilateral total hip replacement, thus increasing the total number of procedures to 960. SD: Standard deviation; THR: Total hip replacement.

Table 2 Incidence of trochanteric bursitis

Trochanteric bursitis	Number of cases
Overall incidence (independent of osteoarthritis or THR)	152
Laterality	
Right	73
Left	53
Bilateral	26
Trochanteric bursitis <i>after</i> THR	
With synchronous trochanteric bursectomy	4
Trochanteric bursa preserved	1
Pre-existing diagnosis of bursitis <i>prior</i> to THR	
With synchronous trochanteric bursectomy	8
Trochanteric bursa preserved	0

THR: Total hip replacement.

this series.

DISCUSSION

Lateral buttock pain is a common presentation in orthopaedic practice. Historically, majority of these have been diagnosed as trochanteric bursitis. However, recent studies with use of modern imaging techniques have shown that not all had evidence of inflamed peri-trochanteric bursae[10,11]. Other diagnoses reported were abductor tendinosis, abductor tears, and thickened ilio-tibial bands. The overall diagnostic term for this cohort is Greater Trochanteric Pain Syndrome. GTPS is the current preferred term to describe tenderness over the greater trochanter, buttock, or lateral thigh. It is reported to affect between 10% and 25% of the general population[12], and 17.6% of adults aged between 50-79 years

[2].

Trochanteric bursitis, a subset of GTPS, is a common complication following primary total hip replacement. Our study reported an overall incidence of 0.5%, which is significantly lower than previous studies where incidences ranged from 4% to 8% [4-8]. However, it should be noted that the incidence of trochanteric bursitis varies with surgical approach. Vicar *et al* [5] and Schinsky *et al* [7] both reported highest incidence of post-THR bursitis with the historic trans-trochanteric approach. Iorio *et al* [8] compared direct lateral and posterior approaches, and found that the latter had lower incidence of post-THR bursitis, corresponding to 5.3% and 1.2% respectively. Interestingly, Shemesh *et al* [6] reported no significant difference in incidences of post-THR bursitis between direct anterior and posterior approaches. One study evaluated soft tissue changes following THR using magnetic resonance imaging and identified more frequent occurrence of fluid within the trochanteric bursa for direct lateral approach compared to anterior, anterolateral, and posterior approaches [13]. This may explain our low incidence of post-THR bursitis as the posterior approach appears to be 'protective' against trochanteric bursitis following THR.

Trochanteric bursectomy has been thoroughly examined in a recent systematic review [14]. Crutchfield *et al* [14] included 15 studies with a mean follow-up of at least 12 mo. Despite the variability in outcome measures, all reported outcomes indicate the same positive trend in post-operative improvement. Patient satisfactions were high at 95%, and rate of failure to improve pain were low, ranging from 0% to 8%. Among patients who underwent trochanteric bursectomy by arthroscopy, several studies [15-17], with minimum of 1 year follow-up, have reported similar positive outcomes ranging from 85% to 97%. In the study by Fox [17], one patient (3.7%) had recurrence of symptoms at 1 year and two additional patients (total 11%) had recurrence at 5 years. Van Hofwegen [18] evaluated arthroscopic bursectomy in 12 patients with trochanteric bursitis following THR and found significant improvement in pain scale. The positive outcomes of bursectomy were the reason that Surgeon A chose in 2010 to perform prophylactic trochanteric bursectomy, as part of the surgical approach, in all patients undergoing elective THR. The hypothesis being that without a trochanteric bursa, one would not go on to develop trochanteric bursitis later. This is a plausible hypothesis but would require large numbers in a consecutive series to demonstrate a difference given the low post-operative incidence of trochanteric bursitis.

In our series, trochanteric bursitis appeared to occur more frequently in patients who underwent THR with synchronous bursectomy (0.72%) compared to those without bursectomy (0.25%). This apparent difference is however not statistically significant. Even taking the confidence interval into account, we consider that the rates of trochanteric bursitis following THR is not materially different between the two groups. We therefore concluded that the procedure is unnecessary. Of note, however, our series did demonstrate that it is successful at treating the lateral buttock pain component for patients with known trochanteric bursitis and osteoarthritis requiring THR. We therefore recommend performing synchronous bursectomy in this specific patient group.

To check whether any differences in the two surgeons' bursitis rates were being masked by confounding by their cases having different characteristics, we carried out logistic regressions using the four factors in Table 1 (as covariates) and the identity of the surgeon as explanatory variables, and the outcome (post-THR bursitis) as the response. None of the logistic regression models, including possible combinations of these variables, had any statistically significant terms. This could be because there were too few post-THR bursitis cases to estimate the associations precisely enough, or it could be because in fact none of the covariates have an influence on the outcome.

There were a number of limitations to our study. This is a retrospective study where cases were identified using procedure codes. There is the potential for missed cases from uncoded diagnosis of trochanteric bursitis even though our lost to follow-up figures were only 10.5%. In addition, our study only included trochanteric bursitis managed within the secondary care setting. Patients who were solely managed in the primary care are not accounted for. The reported incidences in this series could therefore be underestimates, and the true incidence of post-THR bursitis may be higher than 0.5%. This study is also observational, and there may be other possible explanation for our conclusion as not all confounding factors have been accounted for, most notably confounding by surgeon. To improve on this, a prospective study randomising patients to bursectomy *vs* non-bursectomy at the time of planned THR, effectively a clinical trial, would be needed.

CONCLUSION

Synchronous trochanteric bursectomy at the time of THR does not materially affect the incidence of post-THR bursitis. It may therefore be considered unnecessary. However, our series did demonstrate that it is successful at treating the lateral buttock pain component for patients with known trochanteric bursitis and osteoarthritis requiring THR.

ARTICLE HIGHLIGHTS

Research background

Trochanteric bursitis is a common complication following total hip replacement (THR). It has a reported incidence of 4%-8% and is associated with high level of disability and poor quality of life.

Research motivation

For a decade, our lead author has performed prophylactic trochanteric bursectomy as part of the surgical approach for

THR. The rationale being that the bursa is likely to fibrose following THR, losing its functional properties as friction buffer but still have the potential of developing bursitis at a later date. The procedure, therefore, seems logical as it could reduce the occurrence of post-operative trochanteric bursitis.

Research objectives

The study was conducted to evaluate whether synchronous trochanteric bursectomy at the time of THR affects the incidence of post-operative trochanteric bursitis.

Research methods

This retrospective cohort study was conducted in the secondary care setting at a large district general hospital. Between January 2010 and December 2020, 954 patients underwent elective primary THR by two contemporary arthroplasty surgeons, one excising the bursa and the other not (at the time of THR). All patients received the same post-operative rehabilitation and were followed up for 1 year. We reviewed all cases of trochanteric bursitis over this 11-year period to determine the incidence of post-THR bursitis. Two proportion Z-test was used to compare incidences of trochanteric bursitis between groups.

Research results

554 patients underwent synchronous trochanteric bursectomy at the time of THR whereas 400 patients did not. A total of 5 patients (incidence 0.5%) developed trochanteric bursitis following THR; 4 of whom had undergone bursectomy as part of their surgical approach, 1 who had not. There was no statistically significant difference between the two groups (Z value 1.00, 95%CI: -0.4% to 1.3%, $P = 0.32$). There were also 8 other patients who had both trochanteric bursitis and hip osteoarthritis prior to their THR; all of whom were treated with THR and synchronous trochanteric bursectomy, and 7 had resolution of their lateral buttock pains but 1 did not.

Research conclusions

Synchronous trochanteric bursectomy at the time of THR does not materially affect the incidence of post-operative bursitis and may therefore be considered unnecessary. However, our series did show that it is successful at treating patients with known trochanteric bursitis and osteoarthritis requiring THR.

Research perspectives

Future research in the form of a clinical trial randomising patients to prophylactic trochanteric bursectomy *vs* non-bursectomy at the time of THR would be needed.

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FOOTNOTES

Author contributions: All authors have substantial contributions to this study; Teng WH, Webber J and Pearce O conceptualised and designed the research; Teng WH and Ditta A collected, analysed, and interpreted the data; Teng WH, Ditta A, Webber J and Pearce O contributed to writing of the manuscript.

Institutional review board statement: The study was registered with our institution's Research and Development Department. Following review, it was confirmed that NHS Research Ethics Committee approval is not required.

Informed consent statement: Informed written consent was not obtained from individual patients as the study was purely observational, and only included anonymised and non-sensitive data.

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Country/Territory of origin: United Kingdom

ORCID number: Wai-Huang Teng 0000-0002-9624-0257; Adeel Ditta 0000-0002-2251-2053; Oliver Pearce 0000-0001-9584-1395.

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Retrospective Study

Locking plates for distal fibula fractures in young and elderly patients: A retrospective study

Francesco Roberto Evola, Giovanni Francesco Di Fede, Giuseppe Evola, Martina Barchitta, Antonella Agodi, Gianfranco Longo

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Francesco Roberto Evola, Gianfranco Longo, Department of Surgery, Division of Orthopedics and Trauma Surgery, “Cannizzaro” Hospital, Catania 95100, Italy

Giovanni Francesco Di Fede, Department of Radiodiagnostics, Division of Radiology, “S. Marta and S. Venera” Hospital, Acireale 95024, Italy

Giuseppe Evola, Department of Surgery, Division of Surgery, “Garibaldi” Hospital, Catania 95100, Italy

Martina Barchitta, Antonella Agodi, Department of Medical and Surgical Sciences and Advanced Technologies “GF Ingrassia”, University of Catania, Catania 95100, Italy

Corresponding author: Francesco Roberto Evola, MD, PhD, Additional Professor, Department of Surgery, Division of Orthopedics and Trauma Surgery, “Cannizzaro” Hospital, MESSINA n° 829, Catania 95100, Italy. robertoevola@virgilio.it

Abstract

BACKGROUND

Ankle fractures are common injuries in the young and elderly populations. To prevent post-traumatic arthritis, an anatomic reconstruction of the ankle structure is mandatory. Open reduction and internal fixation is the treatment of choice among orthopaedics. Conventional plates allow stability of the fracture if bone quality is present. Locking plates might offer an advantage for the treatment of lateral malleolar fracture in patients with comminution, severe instability, distal fractures, or osteoporotic bone. Our hospital introduced a new locking plate for fracture of the distal fibula.

AIM

To evaluate locking plates in terms of outcomes and complications in young and elderly patients.

METHODS

We retrospectively reviewed a total of 67 patients treated for displaced distal fibula fractures. Demographic data, number of comorbidities, use of inter fragmentary screw, complication, time of fracture healing, partial or full weight bearing, and reoperation were recorded for all patients. Clinical outcome was assessed by the American Orthopedic Foot and Ankle Society clinical scoring

system. Radiographs were obtained at 4, 8, 12, 16, 20, and 24 wk until radiographic union was obtained.

RESULTS

All patients displayed complete bony union on radiographic assessment, and no patients developed any serious complications. We observed two superficial infections, one delayed wound healing, and two plate intolerances. Significant differences were observed between the two age groups in terms of radiographic healing (11.9 wk in younger patients *vs* 13.7 wk in older patients; $P = 0.011$) and in the American Orthopedic Foot and Ankle Society score at 6 mo after surgery (88.2 in younger patients *vs* 86.0 in older patients; $P = 0.001$) and at 12 mo after surgery (92.6 in younger patients *vs* 90.0 in older patients; $P = 0.000$).

CONCLUSION

Locking plates provide a stable and rigid fixation in multifragmentary and comminuted fractures or in the presence of poor bone quality.

Key Words: Ankle fracture; Locking plate; Distal fibula fracture; Outcome; Complications; Osteoporosis

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Core Tip: Ankle fractures are common injuries in the young and elderly populations. Fibula locking plate is used for the older population due to osteoporotic bone or for the younger population with multifragmentary and comminuted fractures. We introduced a new locking plate for fracture of the distal fibula and evaluated it for lateral malleolar fixation in terms of outcomes and complications in young and elderly patients. We were interested in determining whether the use of this locking plate would provide the same advantage and outcomes that were described in literature.

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INTRODUCTION

Ankle fractures are common injuries and represent 9% of all fractures[1,2]. These fractures, often due to low energy trauma, have an annual incidence of 122-184/100000 people[2,3] and represent the third most common fracture, after hip and wrist fractures[4]. The repair process of these fractures is classified into primary and secondary fracture healing. Primary healing is direct bone repair without cartilaginous callus formation where bone remodelling occurs with rigid fixation and no gap formation; secondary healing is typically characterised by callus formation due to the presence of movement at the fracture site. The key to the repair process is the appropriate stability of the fracture site to obtain a biological healing response.

Several fixation methods may be used including one-third tubular plate, dynamic compression plate, and locking plate. The treatment in the elderly population must consider the presence of osteoporosis as the decisive factor for the type of implant to be used. Conventional plates allow stability of the fracture if bone quality is present. Loosening or toggling of screws represent a failure of fixation due to loss of friction between the plate and the bone[1]. Locking plates might offer an advantage in patients with osteoporotic bone. The stability does not depend on bone-plate friction because the screw head locks into the threaded hole of the plate. These plates reduce periosteal compression and improve bone healing through increased blood supply[5]. Precontoured locking plates facilitate placement and fixation of fractures in elderly and young patients and must be reserved for distal fractures that have limited places available for distal screw insertion through multiple multidirectional metaphyseal locked screws. Unfortunately, locking plates form a stiffer screw-plate construct that can cause greater rigidity compared to conventional plates, affecting fracture healing and causing delayed union or non-union.

In February 2017, our unit introduced a new locking plate for the fracture of the distal fibula. The aim of this study was to evaluate the new locking plate for lateral malleolar fixation in terms of outcomes and complications in young and elderly patients. We were interested in determining whether the use of this locking plate would provide the same advantage and outcomes that were described in the literature.

MATERIALS AND METHODS

We retrospectively reviewed a consecutive cohort of patients admitted from February 2017 to September 2018 for fixation of a distal fibula fracture with a follow-up of 1 year. Permission for this study was obtained from our institutional ethics

committee for the use of patient data for publication purposes (n°161/2020/CA). The eligibility criteria were displaced distal fibula fractures classified as a Dannis-Weber type B or C after a low-energy trauma, minimum follow-up of 1 year, and patient ambulatory prior to injury. Open ankle fracture, pilon fracture, bilateral ankle fractures, pathologic fractures, paediatric fractures, previous malleolar fractures history, fracture treated temporarily with external fixator, fracture treated with syndesmotomic screws, patients with cognitive impairment, and polytrauma were excluded from study.

A total of 67 patients treated for displaced Dannis-Weber type B or C distal fibula fractures were included in this study. The implant used was a 3.0/3.5 mm precontoured anatomical locking plate for the distal fibula, manufactured by Hofer Medical Italy (Inteos plate). This implant provides a unicortical locking system to allow fixation in metaphyseal bone with 3.0 mm distal screws. The plate has a low profile and multiple smaller screws distally to obtain adequate distal fixation through multiple multidirectional locked screws. The use of a lag screw was left to the discretion of the surgeon, depending on the pattern of fracture.

Patients were divided into two groups based on age: Group 1 patients were under 60-years-old; and group 2 patients were aged 60 years and over. Demographic data (age, sex, type of fracture), number of comorbidities (diabetes, history of deep venous thrombosis or limb vascular disease), use of inter fragmentary screws, complications (superficial or deep infection, loss of reduction, loose screw, non-union, nerve injury, delayed wound healing, skin irritation), time of fracture healing, partial or full weight bearing, and reoperation were recorded for all patients.

Clinical outcome was assessed by the American Orthopedic Foot and Ankle Society (AOFAS), with clinical scoring at 6 and 12 mo after surgery. The AOFAS score has a maximum value of 100 points (50 points for function, 40 for pain, 10 for alignment). Complications were recorded at every clinical and radiographic follow-up. Radiographs of the anterior-posterior, lateral, and mortise view were obtained at 4 wk postoperatively and then at 8, 12, 16, 20, and 24 wk until radiographic union was obtained. Fracture healing was defined by the identification of three of the four cortices to be bridged by visible callus on X-ray exam, determined by a single radiologist that was not involved in this study, and full weight bearing without pain.

All patients received antibiotic prophylaxis with a single dose of 2 g of a second-generation cephalosporin. In case of allergy, the patients received teicoplanin or levofloxacin according to hospital protocol. All patients received low-molecular-weight heparin for thrombo prophylaxis from 6 h postoperatively and for the duration of immobilisation (30 d). Possible syndesmotomic injuries (talar tilt or increase in tibial medial space) were evaluated during the surgery with external rotation stress test under fluoroscopy. In the event of a syndesmotomic injury, the patient was excluded from the study. A short leg cast was applied for the first 2 wk, and then a brace for another 2 wk. Full weight bearing with a brace was allowed at 4 or 6 wk after surgery, depending on the radiographic result, while full weight bearing without a brace was allowed about 8 or 10 wk after surgery.

Statistical analysis was conducted using the IBM Statistical Package for Social Sciences, version 26. Descriptive statistics were calculated. Depending on the variable analysed, χ^2 test and *t*-test were used to compare the two age groups. All *P* values ≤ 0.05 were considered statistically significant.

RESULTS

A total of 67 patients (55.2% females), mean age 58.5 ± 16.2 years, were included in the study since their data were available for complete analysis and comparison. Among them, 43.3% of patients were in group 1 (< 60 -years-old), and 56.7% were in group 2 (≥ 60 -years-old). The majority of patients (79.1%) had a Dannis-Weber type B distal fibula fracture. In 9 patients (13.4 %), there was at least one comorbidity at the time of surgery.

All 67 patients displayed complete bony union on radiographic assessment. Radiographic union was obtained in 8 patients (11.9%) at 8 wk, in 40 patients (59.7%) at 12 wk, in 15 patients (22.4%) at 16 wk, and in 4 patients (6.0%) at 20 wk. Plates with a lag screw were used in 26 fractures (38.8%) and without in 41 fractures (61.2%), suggesting that these fractures frequently do not require a lag screw due to stabile fixation of locking plates. Full weight bearing with a brace was allowed at 4 wk after surgery in 54 patients and at 6 wk in 13 patients. Full weight bearing without a brace was allowed at 8 wk in 54 patients and at 10 wk in 13 patients. No patients developed any serious complications, including non-union, malunion, loss of fixation, loose screws, deep infection, peroneal tendinitis, nerve injury, and post-traumatic osteoarthritis. We observed two (3%) superficial infections (1 case in group 1, 1 case in group 2), which completely resolved after antibiotic treatment, one (1.5%) delayed wound healing (1 case in group 2), which was treated with medications, and two (3%) plate intolerances (1 case in group 1, 1 case in group 2) due to incorrect positioning that required removal of the implant. Patients with superficial infection or delayed wound healing had at least one comorbidity at the time of surgery.

Table 1 reports results of the comparison between group 1 and group 2. Significant differences were observed between the two age groups in terms of radiographic healing (11.9 wk in younger patients *vs* 13.7 wk in older patients; *P* = 0.011) and in the AOFAS score at 6 mo after surgery (88.2 in younger patients *vs* 86.0 in older patients; *P* = 0.001) and at 12 mo after surgery (92.6 in younger patients *vs* 90.0 in older patients; *P* = 0.000).

DISCUSSION

Fibula locking plate is used for the older population due to osteoporotic bone or for the younger population in multifragmentary and comminuted fractures. Biomechanical studies have shown that locking plates in an osteoporotic fibula have greater torque and axial and angle resistance at failure than conventional plates[6]. The use of two distal unicortical

Table 1 Comparison between group 1 and group 2 (mean \pm SD)

Feature	Total, <i>n</i> = 67	Group 1 < 60 yr, <i>n</i> = 29	Group 2 \geq 60 yr, <i>n</i> = 38	<i>P</i> value
Age in yr	58.5 \pm 16.2	42.4 \pm 11.7	70.7 \pm 2.9	NA
Female sex	55.2%	55.2%	55.3%	0.994
Weber classification				
B	79.1%	79.3%	78.9%	0.971
C	20.9%	20.7%	21.1%	
Radiographic healing in wk	12.9 \pm 2.9	11.9 \pm 3.1	13.7 \pm 2.6	0.011
Partial load with brace in wk	4.4 \pm 0.8	4.3 \pm 0.8	4.4 \pm 0.8	0.701
Total load without brace in wk	8.4 \pm 0.8	8.3 \pm 0.8	8.4 \pm 0.8	0.701
AOFAS score at 6 mo after surgery	86.9 \pm 2.8	88.2 \pm 1.9	86.0 \pm 3.0	0.001
AOFAS score at 12 mo after surgery	91.1 \pm 2.7	92.6 \pm 2.4	90.0 \pm 2.3	0.000

AOFAS: American Orthopedic Foot and Ankle Society; NA: Not assessed; SD: Standard deviation.

screws was mechanically equivalent to three distal cortical screws of standard plate[1,6,7]. In conventional devices, the plate-bone construct is dependent on bone mineral density, while in locking devices, bone quality does not influence the biomechanical resistance of the implant because the plate produces stability through a fixed-angle structure without the need for contact between the bone and the plate[8]. Locking plates do not offer an advantage in stable fractures with normal mineral density[9,10]. In addition, the fixation of the distal fibula could be inappropriate with a standard plate because it depends on the mechanical strength of a single cortex and cancellous bone of the distal fragment. The locking plates produce a fixed-angle structure without the need for anchorage of the screws on both cortices; therefore, these plates are useful in multifragmentary and distal fractures in young patients.

Wound infection, delayed wound healing, and skin irritation are common postoperative complications of ankle fixation and sometimes require revision or removal of metalwork[11,12]. Other postsurgical complications described in the literature are non-union, malunion, loss of fixation, loose screws, peroneal tendinitis, nerve injury, and post-traumatic osteoarthritis[5].

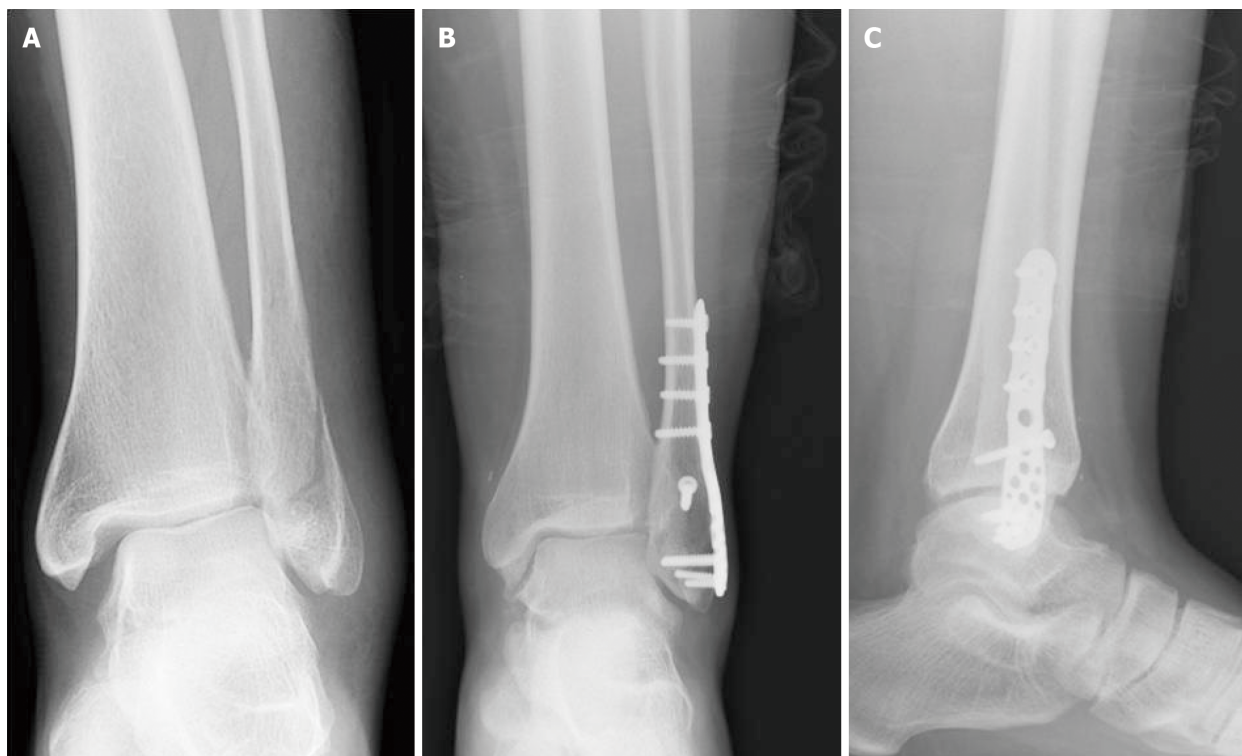
In the literature, there is a debate on clinical results, incidence of complications, and advantages on the use of locking plates. Generally, complications after locking plate osteosynthesis can reach 20%[1,13-15] and even 40% according to other authors[16]. Naumann *et al*[17] retrospectively reviewed 997 patients following surgery for ankle fractures and reported that 17.0% required implant removal and 2.6% required infection treatment. Lynde *et al*[18], through a retrospective study, found that there was no difference in the complication rates between locking *vs* non-locking plates used for distal fibula fracture. Lyle *et al*[1] and Tsukada *et al*[19] did not observe any clinical advantage in the use of locking plates and found no difference in complication rates between locking plates and conventional plates.

Huang *et al*[20] compared one-third tubular plates with locking compression plates and showed a higher functional score and less healing time in locking plates. Schepers *et al*[21], through a retrospective study, advised against the use of locking plates because of increased wound complication with respect to conventional plates (17.5% *vs* 5.5%). Herrera-Pérez *et al*[4] observed similar outcomes in both locking and conventional plates but recommended the use of locking plates in patients with concomitant soft tissue damage or who cannot tolerate prolonged immobilisation, as it reduces non-weight-bearing time. Takemoto *et al*[22] observed that in multifragmentary fractures, lag screws are used half as often with locking plates compared to conventional plates because locking plates provide the necessary fixation. Kim *et al* [7], using a biomechanical study, compared semitubular locking and non-locking plates and observed that both implants were similar. However, locking plates were independent of bone mineral density and were advantageous for elderly patients with osteoporosis.

In our study, we used locking plates in both young and elderly patients (Figures 1 and 2) and found no differences in the complication rates between the two groups. Moreover, the complication rates were in line with those found in the literature for the treatment of distal fibula fractures.

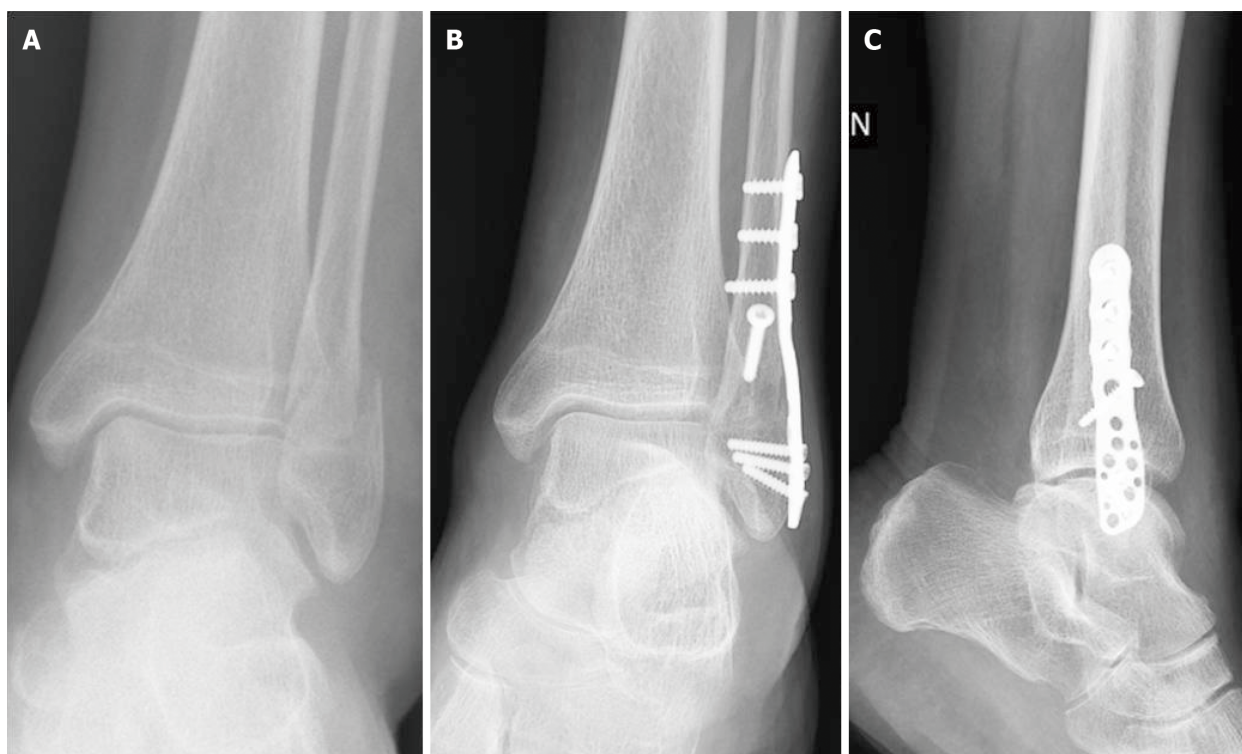
In this study, we observed a significant difference between the two groups in terms of radiographic healing (11.9 wk in younger patients *vs* 13.7 wk in older patients) and in the AOFAS score at 6 mo (88.2 in younger patients *vs* 86.0 in older patients) and at 12 mo (92.6 in younger patients *vs* 90.0 in older patients). Our findings indicated a high efficacy of these plates in lateral malleolar fixation. Therefore, in this study, locking plates seemed to offer an advantage in young patients with normal bone mineral density for the treatment of multifragmentary and comminuted fractures, permitting early rehabilitation and full weight bearing through a rigid fixation of the malleolar fracture. In elderly patients, this locking plate showed excellent results, as already known in the literature for the other devices.

The present retrospective study was limited because it was not randomised, did not have a control group, had a short follow-up, and had a limited sample of patients. Further studies, especially prospective, are needed to confirm clinical and radiological outcomes of locking plates in displaced malleolar fractures.



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Figure 1 Fixation of a lateral malleolus fracture with locking plate in a young patient. A: Preoperative X-ray; B: Anterior-posterior X-ray at follow-up; C: Lateral X-ray at follow-up.



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Figure 2 Fixation of a lateral malleolus fracture with locking plate in an elderly patient. A: Preoperative X-ray; B: Anterior-posterior X-ray at follow-up; C: Lateral X-ray at follow-up.

CONCLUSION

Locking plates provide a stable and rigid fixation in multifragmentary and comminuted fractures or in the presence of poor bone quality. The cost is greater than conventional plates but decreases the risk of displacement of fractures or further intervention of revisions in patients with osteoporotic bone or unstable fractures. In the young population, anatomical locking plates are useful to obtain stable fixation for distal fractures with comminution that have limited places available for distal screws. In the elderly population, locking plates offer an advantage in the presence of poor bone quality, avoiding screws loosening and subsequently coming out. Although locking plates have been associated with delayed union or non-union in the literature, we did not observe this in our study. However, the observation time was not very long and the overall included samples were limited. The locking plate utilised in this study showed few complications and complete bone union in all patients.

ARTICLE HIGHLIGHTS

Research background

Ankle fractures are common injuries in the young and elderly populations. Locking plates might offer an advantage for the treatment of these fractures in patients with comminution, severe instability, distal fractures, or osteoporotic bone.

Research motivation

The aim of this study was to evaluate our hospital's new locking plate for lateral malleolar fixation in terms of outcomes and complications in young and elderly patients.

Research objectives

We were interested in determining whether the use of a locking plate would provide the same advantage and outcomes that were described in literature.

Research methods

We retrospectively reviewed a consecutive cohort of patients for fixation of distal fibula fracture with a follow-up of 1 year.

Research results

Significant differences were observed between the two age groups in terms of radiographic healing and in the American Orthopedic Foot and Ankle Society score at 6 mo and at 12 mo after surgery.

Research conclusions

The locking plate utilized in this study showed few complications and complete bone union in all patients.

Research perspectives

Prospective studies with larger patient samples and longer follow-up are needed.

FOOTNOTES

Author contributions: All authors designed the study, acquired and interpreted the data, wrote the manuscript, and approved the final version of the article; Evola FR and Di Fede GF designed and performed the research; Evola FR and Evola G contributed to the literature research; Agodi A and Barchitta M analysed the data; Evola FR wrote the paper; Longo G revised the manuscript; All authors read and approved the final manuscript.

Institutional review board statement: The permission of this study was obtained from our Institutional Ethics Committee for the use of patient data for publication purpose (n°161/2020/CA).

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data obtained after each patient agreed to treatment by written consent.

Conflict-of-interest statement: The authors declare that they have no conflicts of interest.

Data sharing statement: No additional data are available.

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Country/Territory of origin: Italy

ORCID number: Francesco Roberto Evola 0000-0002-0470-8343; Giovanni Francesco Di Fede 0000-0001-6387-7377; Giuseppe Evola 0000-0002-3648-7063; Martina Barchitta 0000-0002-0905-5003; Antonella Agodi 0000-0002-4405-8162; Gianfranco Longo 0000-0003-4457-8405.

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Observational Study

Physiologic postoperative presepsin kinetics following primary cementless total hip arthroplasty: A prospective observational study

Davide Bizzoca, Andrea Piazzolla, Lorenzo Moretti, Giovanni Vicenti, Biagio Moretti, Giuseppe Solarino

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Davide Bizzoca, Andrea Piazzolla, Lorenzo Moretti, DAI Neuroscienze, Organi di Senso e Apparato Locomotore, AOU Consorziale Policlinico di Bari, Bari 70124, Italy

Giovanni Vicenti, Biagio Moretti, Giuseppe Solarino, Di Brain, University of Bari "Aldo Moro", Bari 70124, Italy

Corresponding author: Giuseppe Solarino, MD, PhD, Associate Professor, Di Brain, University of Bari "Aldo Moro", Piazza Giulio Cesare, 11, Bari 70124, Italy. giuseppe.solarino@uniba.it

Abstract

BACKGROUND

Presepsin is an emerging biomarker in the diagnosis of sepsis. In the field of orthopaedics, it could be useful in diagnosing and managing periprosthetic joint infections.

AIM

To define the normal postoperative presepsin plasmatic curve, in patients undergoing primary cementless total hip arthroplasty (THA).

METHODS

Patients undergoing primary cementless THA at our Institute were recruited. Inclusion criteria were: Primary osteoarthritis of the hip; urinary catheter time of permanence < 24 h; peripheral venous cannulation time of permanence < 24 h; no postoperative homologous blood transfusion administration and hospital stay ≤ 8 d. Exclusion criteria were: The presence of other articular prosthetic replacement or bone fixation devices; chronic inflammatory diseases; chronic kidney diseases; history of recurrent infections or malignant neoplasms; previous surgery in the preceding 12 mo; diabetes mellitus; immunosuppressive drug or corticosteroid assumption. All the patients received the same antibiotic prophylaxis. All the THA were performed by the same surgical and anaesthesia team; total operative time was defined as the time taken from skin incision to completion of skin closure. At enrollment, anthropometric data, smoking status, osteoarthritis stage according to Kellgren and Lawrence, Harris Hip Score, drugs assumption and comorbidities were recorded. All the patients underwent serial blood tests, including complete blood count, presepsin (PS) and C-reactive protein 24 h before arthroplasty and at 24, 48, 72 and 96 h postoperatively and at 3, 6 and 12-mo follow-up.

RESULTS

A total of 96 patients (51 female; 45 male; mean age = 65.74 ± 5.58) were recruited. The mean PS values were: 137.54 pg/mL at baseline, 192.08 pg/mL at 24 h post-op; 254.85 pg/mL at 48 h post-op; 259 pg/mL at 72 h post-op; 248.6 pg/mL at 96-h post-op; 140.52 pg/mL at 3-mo follow-up; 135.55 pg/mL at 6-mo follow-up and 130.11 pg/mL at 12-mo follow-up. In two patients (2.08%) a soft-tissue infection was observed; in these patients, higher levels (> 350 pg/mL) were recorded at 3-mo follow-up.

CONCLUSION

The dosage of plasmatic PS concentration is highly recommended in patients undergoing THA before surgery to exclude the presence of an unknown infection. The PS plasmatic concentration should be also assessed at 72 h post-operatively, evaluate the maximum postoperative PS value, and at 96 h post-operatively when a decrease of presepsin should be found. The lack of a presepsin decrease at 96 h post-operatively could be a predictive factor of infection.

Key Words: Presepsin; Periprosthetic joint infection; Total hip arthroplasty; Total hip replacement; Hip surgery; Postoperative care

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Core Tip: The dosage of plasmatic presepsin (PS) concentration is highly recommended in patients undergoing total hip arthroplasty before surgery to exclude the presence of an unknown infection. The PS plasmatic concentration should be also assessed at 72 h post-operatively, to evaluate the maximum postoperative PS value, and at 96 h post-operatively when a decrease of presepsin should be found. The lack of a presepsin decrease at 96 h post-operatively should be a predictive factor of infection.

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INTRODUCTION

Periprosthetic joint infections (PJIs) are a relevant cause of prosthetic surgery revision, accounting for 15% of failed total hip arthroplasties (THA)[1-3].

PJIs are fearsome complications in orthopaedics, as they might significantly affect the patient's quality of life. Therefore, in the last two decades, an increasing interest towards the prevention of these complications has developed[1-3]. In the meantime, several research groups have investigated the potential role of presepsin (PS) in this PJI prevention and diagnosis[1-3].

PS, from a molecular point of view, is the N-terminal fragment of the soluble cluster of differentiation 14-SubType[14]. It is released into circulation after the activation of defence mechanisms, mainly bacterial phagocytosis[4].

Yaegashi *et al*[5], in 2004, hypothesized for the first time that PS could be useful as a biomarker to predict clinical prognosis in septic conditions. In the following years, different studies have highlighted the potential of PS in several infectious diseases, including severe community-acquired pneumonia, severe acute pancreatitis, infections in patients with haematological malignancies, implantable cardioverter-defibrillator (ICD) pocket infections, neonatal sepsis, pacemaker and PJIs and surgical site infections (SSIs)[6-22].

Furthermore, PS has been also studied in the risk stratification in patients undergoing cardiac surgery and as a biomarker in the perioperative management of patients undergoing total knee arthroplasty (TKA) or THA[23-29].

In a previous preliminary study, our research group defined the normal perioperative plasmatic levels of presepsin at 96 h postoperatively in 50 patients undergoing primary cementless THA and primary cemented TKA[25].

The present study aims at depicting the normal postoperative PS plasmatic curve, in patients undergoing primary cementless THA, at 12-mo follow-up.

MATERIALS AND METHODS

Study population and data collection

Patients undergoing primary cementless THA at our Institute were recruited. Ethical clearance was obtained from our centre's Clinical Research Ethics Committee, as per the 1964 Declaration of Helsinki.

All the patients gave written informed consent before enrolment in the study. Inclusion criteria were: Primary osteoarthritis of the hip; urinary catheter time of permanence < 24 h; peripheral venous cannulation time of permanence < 24 h; no postoperative homologous blood transfusion administration and hospital stay \leq 8 d.

Exclusion criteria were: The presence of other articular prosthetic replacement or bone fixation devices; chronic inflammatory diseases; chronic kidney diseases; history of recurrent infections or malignant neoplasms; previous surgery in the preceding 12 mo; diabetes mellitus; immunosuppressive drug or corticosteroid assumption.

All the patients received the same antibiotic prophylaxis with cephazolin 2 g. All the THA were performed by the same surgical and anaesthesia team; total operative time was defined as the time taken from skin incision to completion of skin closure. At enrolment anthropometric data, smoking status, osteoarthritis stage according to Kellgren and Lawrence, Harris Hip Score, drugs assumption and comorbidities were recorded.

All the patients underwent serial blood tests, including complete blood count, PS and C-reactive protein (CRP) 24 h before arthroplasty and at 24, 48, 72 and 96 h postoperatively and at 3, 6 and 12-mo follow-up. The complication rate was recorded during the 12-mo follow-up.

Statistical analysis

Statistical analysis was performed with SPSS v25.0 (SPSS Inc, Chicago, IL, United States). The Shapiro-Wilk Test was conducted. Pearson correlation test was performed to assess any relationship between non-modifiable risk factors and preoperative PS values at baseline.

Compared to the baseline, the paired t-student test was performed to assess PS and CRP modifications at 3, 6 and 12-mo follow-ups. *P* values below 0.05 were considered significant.

RESULTS

A total of 96 patients (51 females; 45 males; mean age = 65.74 ± 5.58) were recruited in the present study. The main data of the study are summarized in [Table 1](#).

[Table 2](#) shows the correlation between non-modifiable risk factors and preoperative PS values at baseline; a significant correlation was observed between patients' age and preoperative PS levels. Notably, no correlation was found between preoperative creatinine and preoperative PS levels, since patients with chronic kidney disease were excluded from the present study.

[Figure 1](#) shows the mean postoperative PS levels ([Figure 1A](#)) and the mean PS levels at 12-mo follow-ups ([Figure 1B](#)). The PS plasmatic concentration showed an increasing trend until 72 h post-op and started decreasing 96 h after surgery. During the 12-mo follow-up, the plasmatic PS concentration showed a significant increase at the three-month follow-up, when three patients out of 96 (3.125%) reported a soft-tissues infection. Higher levels (> 350 pg/mL) were recorded in these three patients at a 3-mo follow-up. No PJIs were diagnosed during the 12-mo follow-up.

[Figure 2](#) shows plasmatic CRP kinetics after surgery ([Figure 2A](#)) and at 12-mo follow-up ([Figure 2B](#)). The plasmatic CRP curve still showed an increasing trend at 96 h after surgery. During the 12-mo follow-up, plasmatic CRP showed a reducing trend and it was not influenced by the presence of soft-tissue infections.

DISCUSSION

PJIs are an emerging complication in prosthetic surgery, accounting for a relevant percentage of revision surgeries[27,28].

The pursuit of a biomarker able to improve the diagnosis and management of PJI, together with clinical findings and imaging modalities, is currently playing a central role in orthopaedics and traumatology[1].

Presepsin is an emerging biomarker studied in a wide range of infective conditions, including severe acute pancreatitis, neonatal sepsis, severe community-acquired pneumonia, pacemaker and ICD pocket infections, infections in patients with haematological malignancies, SSIs and PJIs. The present paper aims at depicting the normal postoperative plasmatic PS trend, in patients undergoing primary cementless THA, at 12-mo follow-up, to further depict a presepsin cut-off level for hip PJIs.

Our data showed PS has an increasing trend until 72 h post-op after THA surgery and starts decreasing 96 h after surgery. Furthermore, during the 12-mo follow-up, the plasmatic PS concentration showed a significant increase at the three-month follow-up, when three patients reported a soft-tissues infection. Hence, in the present study, plasmatic PS values are more sensitive to soft-tissues infection, than CRP. Although the study sample is not so big and no cases of PJI have been observed in this trial, based on the study findings, the dosage of plasmatic PS concentration is recommended in patients undergoing THA before surgery, to exclude a concomitant unknown infection. However, future studies with a bigger sample size are needed to better define the limits of presepsin physiologic interval. The PS plasmatic concentration should be also assessed at 72 h after surgery, to assess the highest postoperative PS value, and at 96 h after surgery, when a decrease in plasmatic PS concentration is awaited. The lack of a plasmatic PS decrease, at 96 h after surgery could be a predictive factor of SSI or PJI.

These findings are consistent with the data reported by our research group in a preliminary report on perioperative presepsin levels in patients undergoing THA and TKA[25].

PS has been also studied in the assessment of PJIs by Marazzi *et al*[23], in a prospective multicentre study recruiting 100 patients who underwent revision surgery for aseptic loosening or PJI. These authors reported PS plasmatic levels were

Table 1 Main data of the study	
Characteristic	Values
Patients (n)	96
Gender, male, n (%)	45 (46.875)
Age, mean ± SD	65.74 ± 5.58
Range	54–77
BMI (kg/m ²), mean ± SD	26.34 ± 7.22
Total operative time (min), mean ± SD	86.54 ± 43.5
Hospital staying (d), mean ± SD	5.45 ± 1.76

Table 2 Non-modifiable risk factors and presepsin values at recruitment: Pearson correlation test		
	Presepsin	
	R	P value
Age	0.74	0.018 ^a
BMI (kg/m ²)	-0.259	0.734
Gender	0.19	0.44
KLS	0.287	0.16
HHS	-0.17	0.645
Creatinine	0.056	0.852

^a*P* < 0.005.
HHS: Harris Hip Score.

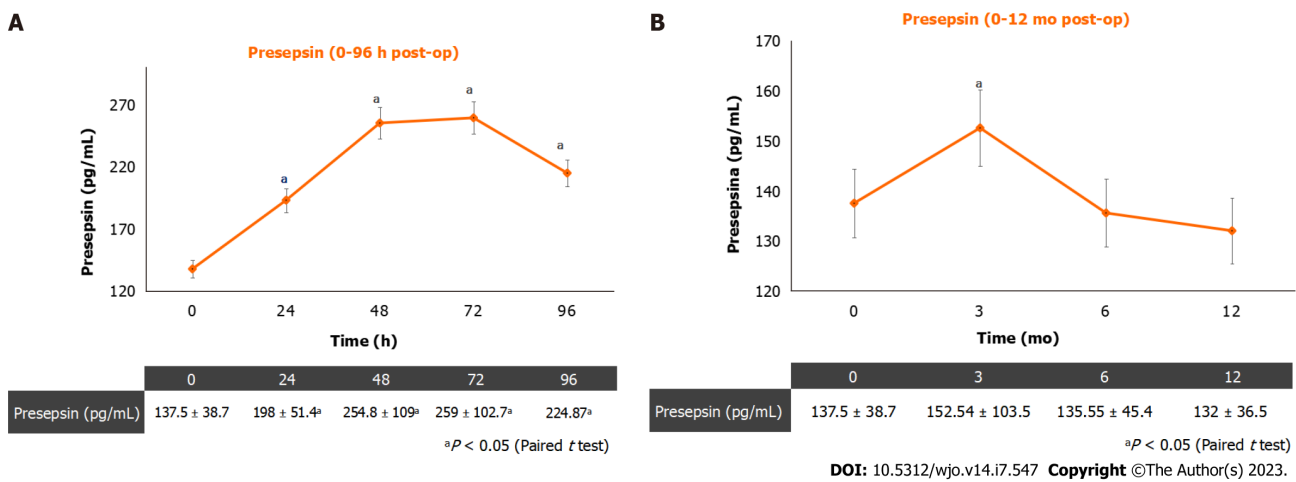


Figure 1 Presepsin levels. A: Presepsin postoperative plasmatic concentration (0-96 h after surgery); B: Presepsin plasmatic levels during the 12-mo follow-up.

higher in the PJI group compared to the aseptic loosening group[23].
Koakutsu *et al*[30] have recently investigated the potential of PS in SSIs in a prospective observational study recruiting 118 patients who underwent elective major spine surgical procedures. These authors depicted an SSI in 3 patients out of 118; in these patients, higher levels (*i.e.*, > 300 pg/mL) were depicted in the first postoperative week[30].
Imagama *et al*[31] recently evaluated synovial fluid and serum PS, together with procalcitonin (PCT) serum levels, in 28 patients affected by osteoarthritis (OA), compared with 18 patients suffering from septic arthritis (SA). These authors observed that synovial fluid, plasmatic PS and plasmatic PCT were significantly higher in the SA group compared with the OA group[31]. Hence, Imagama *et al*[31] concluded that synovial fluid PS could be a useful biomarker to differentiate SA from OA.

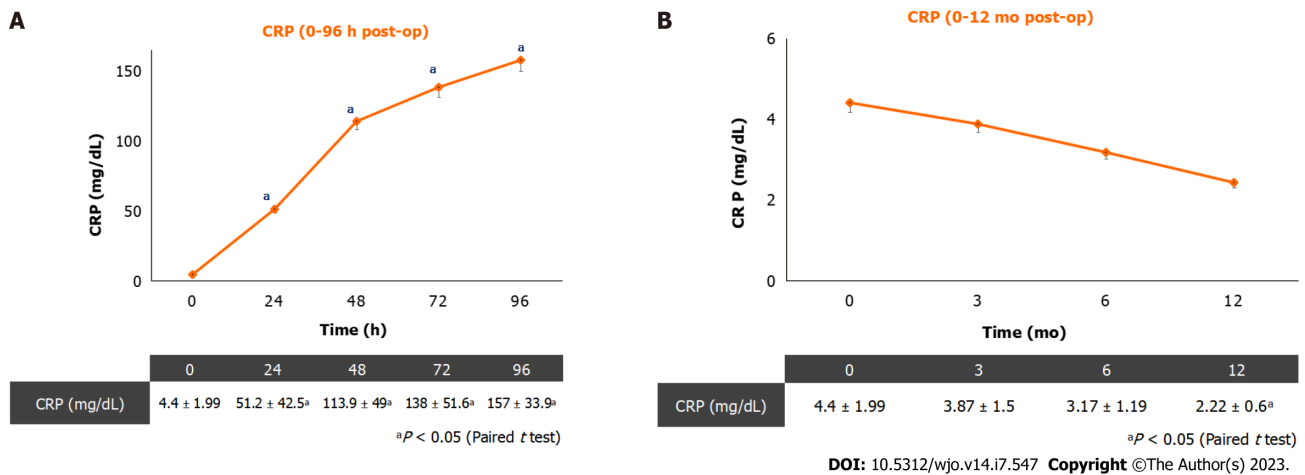


Figure 2 C-reactive protein levels. A: C-reactive protein postoperative plasmatic concentration (0-96 h after surgery); B: C-reactive protein plasmatic levels during the 12-mo follow-up. CRP: C-reactive protein.

On the other hand, Busch *et al*[32], in a prospective cohort study on 53 patients with aseptic painful total shoulder, knee and hip arthroplasty and 27 patients affected by PJI, reported synovial fluid PS was not significantly higher in the PJI group, compared with the aseptic group. Synovial fluid presepsin specificity was 51% and sensitivity was 29%, with a cut-off value above 0.06 ng/mL[32].

Considering the above-mentioned findings, further studies with larger samples are awaited to better define the potential of serum and synovial PS concentration in the diagnosis of PJI.

The present study has some limitations. First of all, the sample size is not so large and no cases of PJI were recorded in the recruited patients during follow-up, hence the findings of the present study should be validated in a study with a larger sample size. Moreover, no control group was included in the present study and presepsin accuracy was not compared to other emerging biomarkers.

CONCLUSION

The dosage of plasmatic PS concentration is highly recommended in patients undergoing THA, in the preoperative phase, to rule out any unknown infection.

The PS plasmatic concentration should be also assessed at 72 h after surgery, to assess the higher postoperative PS value, and at 96 h after surgery, when a PS decrease should be found. The lack of a presepsin decrease at 96 h after surgery might be a predictive factor of infection.

ARTICLE HIGHLIGHTS

Research background

Periprosthetic joint infections (PJIs) are a relevant cause of prosthetic surgery revision, accounting for 15% of failed total hip arthroplasties (THA).

Research Motivation

Presepsin (PS) is released into the circulation following bacterial phagocytosis and the activation of other innate defence mechanisms. In a previous preliminary study, our research group defined the normal perioperative plasmatic levels of presepsin at 96 h postoperatively in 50 patients undergoing primary cementless THA and primary cemented total knee arthroplasties.

Research objectives

This paper aims at depicting the normal postoperative PS plasmatic curve, in patients undergoing primary cementless THA, at 12-mo follow-up.

Research methods

Patients undergoing primary THA were prospectively recruited. All the procedures were performed by the same anaesthesia and surgical équipe. The recruited patients underwent serial blood tests, including complete blood count, PS and C-reactive protein 24 h before arthroplasty and at 24, 48, 72 and 96 h postoperatively and at 3, 6 and 12-mo follow-up.

Research results

Ninety-six patients (51 female; mean age = 65.74 years old) were included in the present study. The mean PS values were: 137.54 pg/mL before surgery, 192.08 pg/mL at 24 h post-op; 254.85 pg/mL at 48 h post-op; 259 pg/mL at 72 h post-op; 248.6 pg/mL at 96-h post-op; 140.52 pg/mL at 3-mo follow-up; 135.55 pg/mL at 6-mo follow-up and 130.11 pg/mL at 12-mo follow-up.

Research conclusions

The assessment of plasmatic PS concentration is highly recommended in patients undergoing THA in the preoperative phase, to rule out any unknown infection. The PS plasmatic concentration should be also assessed at 72 h after surgery, to quantify the higher postoperative PS value, and at 96 h after surgery, when a decrease in PS should be found. The lack of a presepsin decrease at 96 h after surgery might predict a local infection.

Research perspectives

Presepsin is an emerging biomarker in the diagnosis of PJIs. However, further studies with bigger samples are awaited to better define the role of serum and synovial PS in the diagnosis of PJI.

FOOTNOTES

Author contributions: Bizzoca D, Moretti B and Solarino G designed the research study; Bizzoca D and Vicenti G performed the research; Bizzoca D wrote the manuscript; Moretti L and Piazzolla A revised the manuscript; all authors have read and approved the final manuscript.

Institutional review board statement: The study was approved by the local Ethics Committee of AOU Policlinico di Bari (No. 6919).

Informed consent statement: Written informed consent was obtained from the patients.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at giuseppe.solarino@uniba.it.

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Country/Territory of origin: Italy

ORCID number: Davide Bizzoca 0000-0002-7516-2333; Andrea Piazzolla 0000-0003-2319-2108; Lorenzo Moretti 0000-0003-0106-6215; Giovanni Vicenti 0000-0002-7412-7990; Biagio Moretti 0000-0002-1234-8616; Giuseppe Solarino 0000-0001-6325-9691.

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Observational Study

Clinical outcome of open ankle fractures in patients above 70 years of age

Wajiha Zahra, Mina Seifo, Paul Cool, David Ford, Tosan Okoro

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Wajiha Zahra, Mina Seifo, David Ford, Tosan Okoro, Department of Trauma and Orthopedics, Royal Shrewsbury Hospital, Shrewsbury SY3 8XQ, United Kingdom

Paul Cool, David Ford, Tosan Okoro, Department of Trauma and Orthopedics, Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry SY10 7AG, United Kingdom

Paul Cool, Department of Trauma and Orthopedics, Keele University, Stafford ST5 5BG, United Kingdom

Corresponding author: Wajiha Zahra, MBBS, MSc, Doctor, Department of Trauma and Orthopedics, Royal Shrewsbury Hospital, Mytton Oak Road, Shrewsbury SY3 8XQ, United Kingdom. wajiha.zahra@nhs.net

Abstract

BACKGROUND

Open fractures of the ankle are complex injuries requiring multidisciplinary input and are associated with significant morbidity and mortality. However, data on the clinical outcomes of open ankle fracture management in patients older than 70 is minimal.

AIM

To evaluate the clinical outcomes following open ankle fracture management in patients older than 70. Our secondary aim is to look at predictors of poor outcomes.

METHODS

Following local research and audit department registration, 22 years of prospectively collated data from an electronic database in a district general hospital were assessed. All patients older than 70 years of age with an open ankle fracture requiring surgical intervention were identified. Demographic information, the nature, and the number of surgical interventions were collated. Complications, including surgical site infection (SSI), venous thromboembolic events (VTEs) during hospital stay, and mortality rate, were reviewed.

RESULTS

A total of 37 patients were identified (median age: 84 years, range: 70-98); $n = 30$ females median age: 84 years, range: 70-97; $n = 7$ males median age: 74 years,

range: 71-98)) who underwent surgical intervention after an open ankle fracture. Sixteen patients developed SSIs (43%). Superficial SSIs ($n = 8$) were managed without surgical intervention and treated with antibiotics and regular dressing changes. Deep SSIs ($n = 8$; 20%) required a median of 3 (range: 2-9) surgical interventions, with four patients requiring multiple washouts and one patient having metalwork removed. VTE incidence was 5% during the hospital stay. Eight patients died within 30 d, and mortality at one year was 19%. The 10-year mortality rate was 57%. The presence of a history of stroke, cancer, or prolonged inpatient stay was found to be predictive of lower survivorship in this population (log-rank test: cancer $P = 0.008$, stroke $P = 0.001$, length of stay > 33 d $P = 0.015$). The presence of a cardiac history was predictive of wound complications (logistic regression, $P = 0.045$). Age, number of operations, and diabetic history were found to be predictive of an increase in the length of stay (general linear model; age $P < 0.001$, number of operations $P < 0.001$, diabetes $P = 0.041$).

CONCLUSION

An open ankle fracture in a patient older than 70 years has at least a 20% chance of requiring repeated surgical intervention due to deep SSIs. The presence of a cardiac history appears to be the main predictor for wound complications.

Key Words: Fragility fracture; Open fracture; Clinical outcome; Mortality; Infection; Survival

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Core Tip: There is no standard consensus on management of open ankle fractures in patients above 70 years of age. Cardiac issues are the main predictors of poor outcome. 1 in 5 patients above 70 years of age develop deep infection requiring further surgical intervention. High infection increases length of stay in the hospital and mortality.

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INTRODUCTION

Open fractures are complex injuries requiring multidisciplinary input[1] and are associated with significant morbidity and mortality[2]. Open ankle fractures account for about 2% of all ankle fractures[3]. About 187 per 100000 adults sustain ankle fractures every year[4]. Ankle fractures can be caused by various modes of trauma, *e.g.*, twisting, impact, and crush injuries. The degree of bony comminution and soft tissue damage is directly related to the energy of trauma[5]. In older patients with unstable ankle fractures, surgical intervention *vs* application of a contact cast is reported to have an equivalent functional outcome at six months[6]. Surgical intervention is still the first line of management for the elderly with open fractures to minimize the risk of infection[7]. Among the elderly, an open ankle fracture can reduce quality of life by more than half, sharing a similar characteristic to a fragility fracture[8]. Typically, fractures of the hip, pelvis, spine, humerus, wrist, rib, clavicle, scapula, or sternum are described as osteoporotic fractures[9,10]. The incidence of ankle fractures does not increase with age, excluding them from the osteoporotic fracture class[11,12]. Minimal data on the clinical outcome of open ankle fracture management in patients older than 70 is available[13].

The primary aim of this study is to describe the clinical outcomes following an open ankle fracture in patients older than 70. Our secondary aim is to look at predictors of poor outcomes in this age group.

MATERIALS AND METHODS

Following local research and audit department registration, 22 years of prospectively collated data from an electronic database in a district general hospital (DGH) were reviewed. All patients older than 70 years with an open ankle fracture requiring surgical intervention were identified. Demographic information, the nature, and the number of surgical interventions were collated. All open fractures were classified according to the Gustilo and Anderson classification[14] and the number of malleoli involved[15].

Complications, including surgical site infection (SSI), venous thromboembolic events (VTE) during hospital stay, and mortality rate at 30 d and one year, were reviewed. The presence of comorbidities, including diabetes mellitus, a history of cancer, and previous thromboembolic disease, and their relationship to poor outcomes, were evaluated.

Statistical analysis was performed using R 4.2.2 (R foundation). With patient factors as explanatory variables, logistic regression was used to predict any wound complication. A general linear model was chosen to identify variables that are predictive of an increased length of hospital stay. Survival analysis was performed with follow up time from admission

and death due to any cause as endpoint. The log-rank test was used to compare variables influencing survival. For all statistical analyses, a P value $< 5\%$ was considered significant.

RESULTS

There were 37 patients older than 70 years who underwent surgical intervention after an open ankle fracture. The median age was 84 years (range: 70-98), with 30 females (median age: 84, range: 70-97 years) and seven males (median age: 74, range: 71-98 years).

Twenty-nine patients (78%) sustained bimalleolar ankle fractures; four patients had unimalleolar and another four had trimalleolar ankle fractures. An open wound over the medial malleolus was seen in 89% of the patients. Eight patients had a Gustilo-Anderson Type I fracture, and 24 patients had Type II, with the remaining five patients having Type III. The ankle joint was dislocated at initial assessment in 86% of cases (Table 1). There were no sex differences in the type of ankle fracture sustained or in the incidence of complications (Table 2).

Thirty-two patients (86%) had surgery within 24 h of injury, four underwent surgical intervention within 48 h, and one patient had surgery after six days due to a late presentation to the emergency department. Two patients were allowed to put partial weight on the surgical site following surgery.

The remaining 35 patients were advised to initially mobilize non-weight bearing on the operated site.

All 37 patients had wound washout and debridement at initial surgery. Twenty-one (57%) patients had primary closure, and 25 (68%) underwent definite fixation in the first sitting. Of the 37 patients, 16 wounds (43%) were left to heal by secondary intention. Of these, three patients later required a split skin graft, and seven required vacuum assisted closure (VAC) therapy application to achieve skin closure (Figures 1 and 2).

Out of 16 wound complications, eight were managed with regular dressing changes and antibiotics (superficial SSIs).

The other eight patients required further washout in the operating theatre (deep SSIs). Four patients with deep SSIs required multiple washouts. One of these patients needed to have the metalwork removed for the wound to heal. The maximum number of operations one patient had was nine (requiring washouts and VAC dressing changes). The median number of operations patients with deep SSIs had to undergo was three (range: 2-9). Table 3 describes the instances where either primary or secondary closure was chosen at the initial surgical intervention (Table 3).

The overall mortality rate in this study was 59%. Out of 37, seven (19%) patients died within one year of the open ankle injury. The 30-d mortality rate was 8%, with the 0-year mortality rate at 57%. The median length of stay in the hospital was 26 d (range: 3-84) (Table 4).

The overall mortality rate in this study was 59%. Out of 37, seven (19%) patients died within one year of the open ankle injury. The 30-d mortality rate was 8%, with the 0-year mortality rate at 57%. The median length of stay in the hospital was 26 d (range: 3-84) (Table 5).

DISCUSSION

This is a retrospective study that evaluates the outcome of patients older than 70 who had surgical treatment for an open ankle fracture. Previously, Schermann *et al*[16] looked at predisposing factors and associated mortality in patients older than 65 years with open ankle fractures. Wijendra *et al*[8] reviewed outcomes in low-energy open ankle fractures in patients aged 27-100 (mean: 73). We assessed the clinical outcome in this group of patients based on the rate of complications and the number of operations undertaken. Patients requiring multiple operations had a longer hospital stay (median: 26 d, range: 5-84 d). All these patients were initially managed per the BOA Standards for Trauma guidelines[7] for open fractures.

In our study, four out of five Type III open fractures required multiple operations due to wound complications. These results are similar to the meta-analysis by Kortram *et al*[17] who described the Gustilo-Anderson classification Type III open fracture as a statistically significant risk factor for developing infectious complications. Thangarajah *et al*[18] showed SSI after fixation to be higher in patients with bimalleolar fractures. However, our study did not show any such relationship. We found that two out of four trimalleolar ankle fractures had a primary closure at the initial operation, while three unimalleolar ankle fractures required multiple operations due to wound complications.

Forty-five percent of patients presenting with an open bimalleolar fracture had definite fixation and primary closure.

The outcome and complication rates after an open ankle fracture dislocation are multifactorial. Factors include multiple comorbidities, the patient's age, and wound contamination. These findings are similar to Frank *et al*'s work on dislocated ankles[19].

Comparing the clinical outcomes of patients who had primary closure *vs* delayed closure, none of the 21 patients with primary closure and definite fixation required a second operation. Eight patients in this group developed superficial wound infections that could be managed with antibiotics. All patients with external fixation as primary fixation required a split skin graft at a later setting. These patients had the longest length of stay in the hospital. Patients requiring VAC dressing to achieve skin closure were at high risk for deep infections and required multiple washouts in the operating theatre. These findings align with the work done by Ovaska *et al*[15] and Wijendra *et al*[8]. We did not find any influence of the fracture pattern or fixation type on clinical outcomes.

Mortality among patients who are older than 65 with open ankle fractures has been reported at about 23%-27% during the first year postoperatively[16]. The mortality rate in our study was 19% at 12 mo and 57% at 10 years. Patients with multiple comorbidities had poor survival. Patients on anticoagulants or antiplatelets medication or patients with a cardiac

Table 1 Description of clinical features of open ankle fractures in patients > 70 years old

Clinical feature	Number of patients, <i>n</i> (%)
1 Mechanism of injury	
Road traffic accident	4 (11)
Falls	33 (89)
2 Classification of ankle injuries[23]	
Unimalleolar	4 (11)
Bimalleolar	29 (78)
Trimalleolar	4 (11)
3 Site of open wound	
Medial	33 (89)
Lateral	1 (3)
Anterior	1 (5)
Medial + lateral + anterior	1 (3)
4 Gustilo-Anderson classification[24]	
Type I	8 (22)
Type II	24 (65)
Type III	5 (13)
5 Joint dislocation at initial assessment	
Yes	32 (86)
No	5 (13)

Table 2 Male vs female characteristics, *n* (%)

Gender	Number of patients (<i>n</i> = 37)	Open fracture classification	Number of operations	Complications
Male	7 (19)	Type I = 3; Type II = 3; Type III = 1	Range - 1 to 7; Median - 2	Superficial SSI - 2; Deep SSI - 3
Female	30 (81)	Type I = 21; Type II = 5; Type III = 4	Range - 1 to 9; Median - 2	Superficial SSI - 5; Deep SSI - 6

SSI: Surgical site infections.

Table 3 Type of wounds and joint congruency vs type of closure at initial surgical intervention

Type of wound	Total No. of patients (%)	Primary closure (%)	Secondary (%)	Closure
Gustilo-Anderson classification Type I	8 (22)	7 (87)	1 (13)	
Gustilo-Anderson classification Type II	24 (65)	13 (54)	11 (46)	
Gustilo-Anderson classification Type III	5 (13)	1 (20)	4 (80)	
Dislocated joint	32 (86)	20 (62)	12 (37)	
Congruent joint	5 (13)	1 (20)	4 (80)	
Medial wound	33 (89)	19 (57)	14 (42)	
Lateral wound	1 (3)	1 (100)	0	
Anterior wound	2 (5)	0	2 (100)	
Medial + lateral + anterior wound	1 (3)	1 (100)	0	

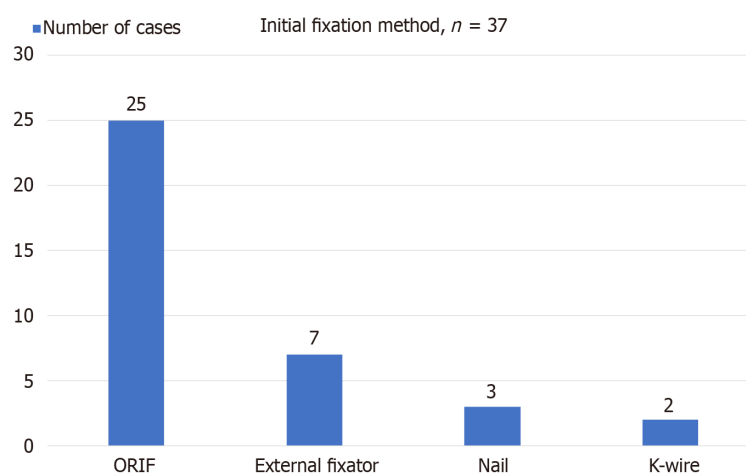
Table 4 Predictors of poor outcome in patients with open ankle fractures > 70 years old

No.	Predictors	Number of patients (%)	P value
1	Diabetes mellitus	9 (24)	0.041
2	Anticoagulants/Antiplatelets intake: Warfarin/ Apixaban; Aspirin/ Clopidogrel; Dual antiplatelet therapy	20 (54); 9 (45); 9 (45); 2 (10)	
3	Cardiac history (IHD, AF)	21 (57)	0.045
4	Chronic kidney disease	12 (32)	
5	Cancer history	8 (22)	0.008
6	History of thromboembolic disease	3 (8)	0.001
7	Steroids intake	9 (24)	0.75

IHD: Ischemic heart disease; AF: Atrial fibrillation.

Table 5 Male vs Female predictors of poor outcome (%)

Gender	Diabetes mellitus	Anticoagulants/Antiplatelets intake	Cardiac history	Chronic kidney disease	Cancer history	History of thromboembolic disease	Steroids intake
Male	2 (28)	3 (43)	3 (43)	1 (14)	4 (57)	0	0
Female	7 (23)	17 (57)	18 (60)	11 (37)	4 (13)	3 (10)	9 (30)



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Figure 1 Surgical Interventions performed in patients > 70 years old presenting with open ankle fractures.

history had a worse outcome. This is likely due to the poor blood supply to the limb, which disrupts the wound-healing process. In our study, 20 patients were on anticoagulation due to a history of ischemic heart disease or atrial fibrillation. Three patients had a history of pulmonary embolism or deep venous thrombosis. These outcomes are similar to the work done by Schermann *et al*[16] and Toole *et al*[20], who also concluded that ischemic heart disease, chronic kidney disease, diabetes, and peripheral vascular disease are variables for mortality in the elderly population. Deep infection (8%) and skin necrosis (14%) were the most common complications after immediate internal fixation in open ankle fractures. Minimal literature is available on the outcomes of definitive treatment in patients with open ankle fractures[16]. In our study, two patients had a thromboembolic event.

Our results are compatible with other studies that suggest that definite fixation in the initial operation is safe, has fewer complications, and leads to a shorter hospital stay[8,21,22]. An external fixator is best employed in patients with inadequate soft tissue coverage.

There are limitations to this study. First, the total number of patients is relatively small. We operated on nearly 2500 ankle fractures over this 22 year period. This is mainly because this study is undertaken in a DGH, not an orthoplastic center. Second, this study has some selection bias. The data was collected from a database, and medical notes were reviewed retrospectively. The database was used logistically in generating theatre lists and acted as an accurate source of data. However, the surgery description may not always have included an open wound, which could have led to underre-

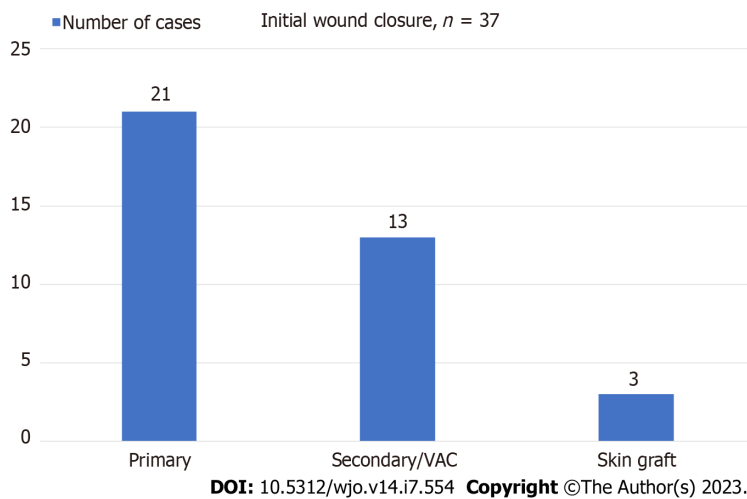


Figure 2 Soft tissue procedures performed in patients > 70 years old presenting with open ankle fractures. VAC: Vacuum assisted closure.

porting.

CONCLUSION

An open ankle fracture in a patient older than 70 years of age has at least a 20% chance of requiring repeated surgical intervention due to deep SSI. The presence of a cardiac history appears to be the main predictor for wound complications.

ARTICLE HIGHLIGHTS

Research background

There is no data on the clinical outcomes of patients older than 70 admitted with open ankle fractures. This study sets the foundation for future research trials in elderly population.

Research motivation

This is the only study looking at patients older than 70 with open ankle fractures. This study highlights the multiple factors which can predict the poor outcome in this age group with open ankle fractures. There is no consensus on the best management strategy for these injuries in this population.

Research objectives

The overall objective of this study is to look at the predictors of poor clinical outcome in patients older than 70 with open ankle fractures.

Research methods

This is a retrospective observational study performed on 22 years of prospectively collated data from an electronic database in a district general hospital. We used R 4.2.2 (R foundation) to perform statistical analysis.

Research results

We identified 37 patients above 70 years of age admitted over the period of 22 years with an open ankle fractures. Sixteen patients developed deep surgical site infections, with 4 requiring multiple wash outs. Eight patients developed superficial surgical site infections and were managed with antibiotics and regular dressing change. The 10 years mortality rate in this age group was 57%. The presence of a cardiac and stroke history, cancer, or prolonged inpatient stay were found to be the predictors of mortality.

Research conclusions

We concluded that there is a 20% risk of patients above 70 years of age with open ankle fracture requiring repeated surgical intervention. The need for repeated surgical interventions is mainly due to deep Surgical Site Infections. We identified multiple predictors for worse outcome. However, the presence of a cardiac history appears to be the main predictor for wound complications.

Research perspectives

This study sets the foundation for further research trials in patients above 70 years of age.

FOOTNOTES

Author contributions: Zahra W, Seifo M, and Cool P contributed to data collection; Zahra W and Cool P contributed to data analysis; Cool P and Ford D contributed to supervision; Ford D and Okoro T contributed to project idea; Zahra W contributed to writing the manuscript and literature review; Seifo M contributed to review the manuscript; Okoro T contributed to overall supervision.

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Informed consent statement: This study is registered with the local audit department and patients data has been used as per the local trust guidelines. This authorization has no expiration date.

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Data sharing statement: No additional data are available.

STROBE statement: The authors have read the STROBE Statement – checklist of items, and the manuscript was prepared and revised according to the STROBE Statement – checklist of items.

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Country/Territory of origin: United Kingdom

ORCID number: Wajiha Zahra 0000-0002-9813-0414; Paul Cool 0000-0002-4985-3085.

S-Editor: Liu JH

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P-Editor: Liu JH

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Prospective Study

Internal fixator vs external fixator in the management of unstable pelvic ring injuries: A prospective comparative cohort study

Mohamed Abo-Elsoud, Mostafa I Awad, Mahmoud Abdel Karim, Sherif Khaled, Mohamed Abdelmoneim

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Mohamed Abo-Elsoud, Mahmoud Abdel Karim, Sherif Khaled, Mohamed Abdelmoneim, Department of Orthopedics and Traumatology, Cairo University Hospitals, Cairo 11562, Egypt

Mostafa I Awad, Department of Trauma and Orthopedics, Mataria Teaching Hospital, Cairo 4540046, Egypt

Corresponding author: Mahmoud Abdel Karim, MD, PhD, Professor, Department of Orthopedics and Traumatology, Cairo University Hospitals, Kasr Al-Ainy Street, Cairo 11562, Egypt. mabdelkarim@hotmail.com

Abstract

BACKGROUND

Reconstruction of the pelvic ring anatomy in unstable anterior pelvic ring injuries is a significant step to reduce the mortality rate associated with these injuries efficiently. There is a debate on using either an anterior subcutaneous pelvis internal fixator (INFIX) or an anterior supra-acetabular external fixator (EXFIX) to manage an unstable anterior pelvic ring fracture.

AIM

To compare the functional and radiological outcomes and complications of INFIX vs EXFIX in managing unstable pelvic ring injuries.

METHODS

A prospective cohort study included 54 patients with unstable pelvic ring fractures. The patients were divided into two groups; the INFIX group, in which 30 cases were fixed by INFIX, and the EXFIX group, in which 24 patients were treated by EXFIX. The average age in the EXFIX group was 31.17 years (16-57 years), while in the INFIX group, it was 34.5 years (17-53 years). The study included 20 (66.7%) males and 10 (33.3%) females in the INFIX group and 10 (41.7%) males and 14 (58.3%) females in the EXFIX group. The radiological outcomes were evaluated using Matta and Tornetta's score, and the functional outcomes using the Majeed score.

RESULTS

The results revealed a statistically significant difference between both groups ($P = 0.013$) regarding radiological outcomes, according to Matta and Tornetta's score in favor of the INFIX group. Sitting, standing, and walking abilities were measured at a 3-mo follow-up visit using Majeed score modules. It was significantly better

among the INFIX group than the EXFIX group in all three modules. At the final follow-up, both groups had no statistically significant difference according to the Majeed score; 92.35 in the INFIX group and 90.99 in the EXFIX group ($P = 0.513$). A lower surgical site infection rate was noticed in the INFIX group ($P = 0.007$).

CONCLUSION

Anterior subcutaneous pelvis INFIX is associated with better radiological outcomes and a lower infection rate than anterior supra-acetabular EXFIX in managing patients with unstable anterior pelvic ring fractures.

Key Words: Internal fixator; External fixator; Unstable; Anterior; Pelvic; Injuries

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Core Tip: Reconstruction of the pelvic ring anatomy in unstable anterior pelvic ring injuries is considered to be a great step to efficiently reduce the mortality rate associated with these types of injuries. There is a debate on the use of either anterior subcutaneous pelvis internal fixator (INFIX) or anterior supra-acetabular external fixator (EXFIX) in the management of anterior unstable pelvic ring fracture. This study aimed to compare the functional, radiological outcomes as well as complications of INFIX vs EXFIX in management of unstable pelvic ring injuries. This study showed that anterior subcutaneous pelvis INFIX is associated with better radiological outcome and less rate of infection than anterior supra-acetabular EXFIX in management of patients with anterior unstable pelvic ring fractures.

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INTRODUCTION

Unstable pelvic fractures represent a complex pathology that is often life-threatening and associated with significant morbidity[1]. Although stabilization of the injured pelvis is sustained by posterior ring fixation, concurrent anterior stabilization significantly improves biomechanical stability as the anterior ring provides about 30% of the pelvic stability [2,3].

The management of anterior ring injuries is still a matter of debate. Open reduction and internal fixation using plates and screws have been traditionally prescribed. While this has proven biomechanically superior for pure ligamentous disruption of the symphysis[4], it has the disadvantage of extensive soft tissue dissection, particularly when used for proximal ramus fractures[5].

Percutaneous external fixation in unstable pelvic ring injuries has also been used as an emergency treatment and a method for definitive fixation, which can be left in place until the consolidation of the injuries. This technique aims to stabilize anterior injuries of the pelvic ring, with posterior lesions being treated as required[6,7].

The two primary technical modalities for external fixation of the anterior pelvic ring are the iliac crest and supra-acetabular routes.

The main advantage of choosing the iliac crest route is its fast application without fluoroscopic imaging. However, iliac crest frames are more likely to be associated with primary or secondary reduction failure, particularly in obese patients [8]. In contrast to the iliac crest frame, supra-acetabular pins provide a large corridor of excellent quality bone stock, which allows for a solid purchase of a single Schanz pin; however, it needs fluoroscopically guided pin placement. This technique requires high expertise to find the perfect corridor[8].

Anterior pelvic external fixator (EXFIX) has some disadvantages as it can limit patient mobilization, particularly hip flexion and side rolling, and has a high rate of pin-track infection, fixator loosening, and skin problems[9]. To avoid some of these disadvantages associated with traditional external fixation, a subcutaneous anterior pelvic internal fixator (INFIX) was described[10-12].

Technically, in the anterior pelvic INFIX, two pedicle screws are fixed into the ilium and connected to a curved subcutaneous rod. It had been reported that INFIX is associated with less pin tract infection and loosening than the anterior pelvic EXFIX, but transient neuropraxia of the lateral cutaneous nerve of the thigh and discomfort were reported as complications[11,13-15].

This study aimed to compare both fixation methods regarding the radiological quality of fracture reduction, functional outcomes, and rate of complications.

MATERIALS AND METHODS

From December 2018 to December 2021, a prospective comparative cohort study included skeletally mature patients presenting with rotationally and/or vertically unstable pelvic ring fractures (Tile-type B and C) at our level 1 trauma center.

The ethical committee approved the study on December 8, 2018 with the number "N-147-2023". Exclusion criteria included stable pelvic ring fractures (Tile-type A), fractures with anterior injuries in the form of pure ligamentous symphysis pubis injuries, and pathological fractures. Furthermore, patients aged < 16 or > 65 years and those with incomplete follow-up records were also excluded.

Fifty-four patients were divided into two groups: 30 had an INFIX for anterior pelvic stabilization (the INFIX group), while the remaining 24 were treated using a supra-acetabular EXFIX group.

Standard preoperative radiographic evaluation included anteroposterior, inlet, and outlet X-ray views and computed tomography scans of the pelvis with coronal and 3-D reconstruction. Prophylaxis against deep venous thrombosis using low-molecular-weight heparin was started upon admission, stopped 12 h before surgery, and resumed for 28 d post-operation.

Surgical technique

Proper fixation of the posterior pelvic ring injury was performed first, as dictated by the patho-anatomy of the fracture. For both techniques, patients were placed supine on a radiolucent table, and fluoroscopy was adjusted to identify the anterior inferior iliac spine (AIIS) as an osseous entry on the obturator outlet view (teardrop) before starting (Figure 1). In addition, fluoroscopy was used to obtain anteroposterior, inlet, outlet, iliac, and obturator inlet views.

A 3-cm longitudinal incision was then centered over the AIIS. The AIIS is not easily palpable in obese patients but generally lies 3 to 4 cm distal and 2 cm medial to the anterior superior iliac spine.

In the INFIX group, blunt dissection was performed medially to the sartorius and tensor fascia lata muscles to gain access to the AIIS. A starting awl was placed in the middle of the AIIS (the center of the teardrop) and used to open the cortex. Next, a pedicle finder was used to establish a bony tunnel toward the posterior superior iliac spine. The obturator inlet view was utilized to confirm that the tunnel had not penetrated the inner or outer tables of the iliac bone. The iliac oblique view was used to ensure the pedicle finder was clear of the hip joint and greater sciatic notch (Figure 1).

The 6.5-7.3 mm diameter and 70-100 mm length U-shaped-headed polyaxial pedicular screws (local manufacture; EgyFix spinal system: EgyFix, Cairo, Egypt) were inserted bilaterally in supra-acetabular bone. Screw heads were left proud at the level of the sartorial fascia to avoid compression of neuromuscular structures. A subcutaneous 6 mm diameter pre-contoured (short lateral transverse limbs and curved central parts with an anteroinferior bow) connecting rod was maneuvered into the screw heads to connect the screws. The screw caps were then fixed to retain the rod in place (Figure 2). Polyaxial screw heads greatly facilitate rod placement.

In the EXFIX group, a similar approach was used until the AIIS, with the difference of using the interval between the sartorius and tensor fascia lata muscles. 6 mm pins were inserted bilaterally in supra-acetabular bone with an extracorporeal connecting rod system (pins connected to each other by either one or two extracorporeal connecting rods with clamps) (Figure 3).

Reduction of the pelvis was achieved using C-rings, laminar spreaders, compression or distraction using pins in the ASIS, or even injured leg traction, according to the characteristics and morphology of the fracture. The final reduction and fixation device positions were checked with fluoroscopy.

Anteroposterior, inlet, and outlet X-ray views of the pelvis were obtained on the first postoperative day and used to grade reduction quality according to Matta and Tornetta's score[16].

Bed-to-chair mobilization was allowed from the first postoperative day, guided by the injury pattern and associated injuries. Moreover, touch weight-bearing was allowed immediately from the 2nd day up to the 6th week. Partial weight-bearing was allowed from the 6th week. After achieving full union, full-weight bearing was allowed.

Follow-up evaluations were performed at 2 and 6 wk, 3 and 6 mo, and then yearly after the operation. Sitting, standing, and walking abilities were measured at a 3-mo follow-up visit (before implant removal) using Majeed score modules[17]. The total Majeed score[17] was measured among the two groups using its six questionnaire parameters, starting at six months and at the final follow-up.

In both groups, implant removal was scheduled starting in the 12th postoperative week, guided by fracture union and a non-painful straight leg raising test. While removal of the EXFIX was usually an outpatient procedure performed in the clinic, removing the INFIX required a second anesthetic session to remove the implants. This was achieved using the same incisions as implantation.

Statistical analysis

Data were analyzed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp.). Qualitative data were described using frequency and percent. Furthermore, quantitative data were described using the range, mean, standard deviation, median, and interquartile range. The Kolmogorov-Smirnov test was used to verify the normality of the distribution. For comparing groups, quantitative variables were analyzed using a student *t*-test or Mann-Whitney test, as appropriate. Chi-square and Fisher's exact tests were used for categorical data. The significance of the obtained results was judged at the 5% level.

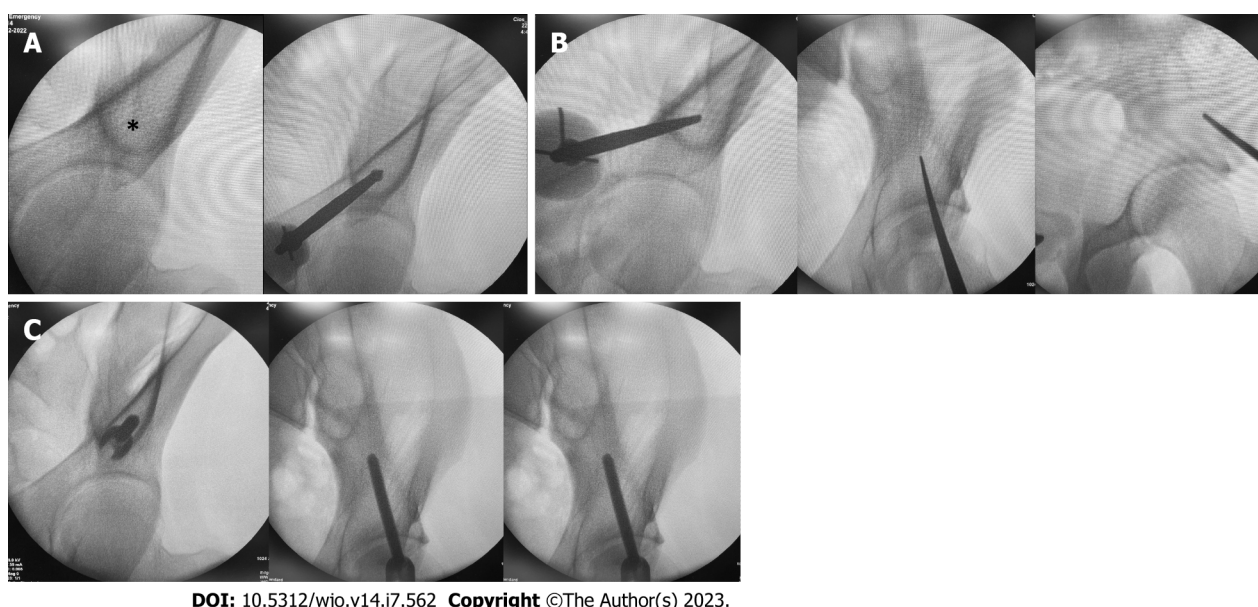


Figure 1 Intraoperative fluoroscopy images used to insert the internal fixator screws. A: Obturator outlet view showing the teardrop (*). A sharp starting awl was used to open the cortex for screw insertion; B: Pedicle finder was then used to establish the bony tunnel. Correct screw trajectory was checked in the obturator outlet, obturator inlet and iliac views; C: After screw insertion the three views checked again to ensure that the screw did not penetrate the cortex and was placed totally intraosseous.

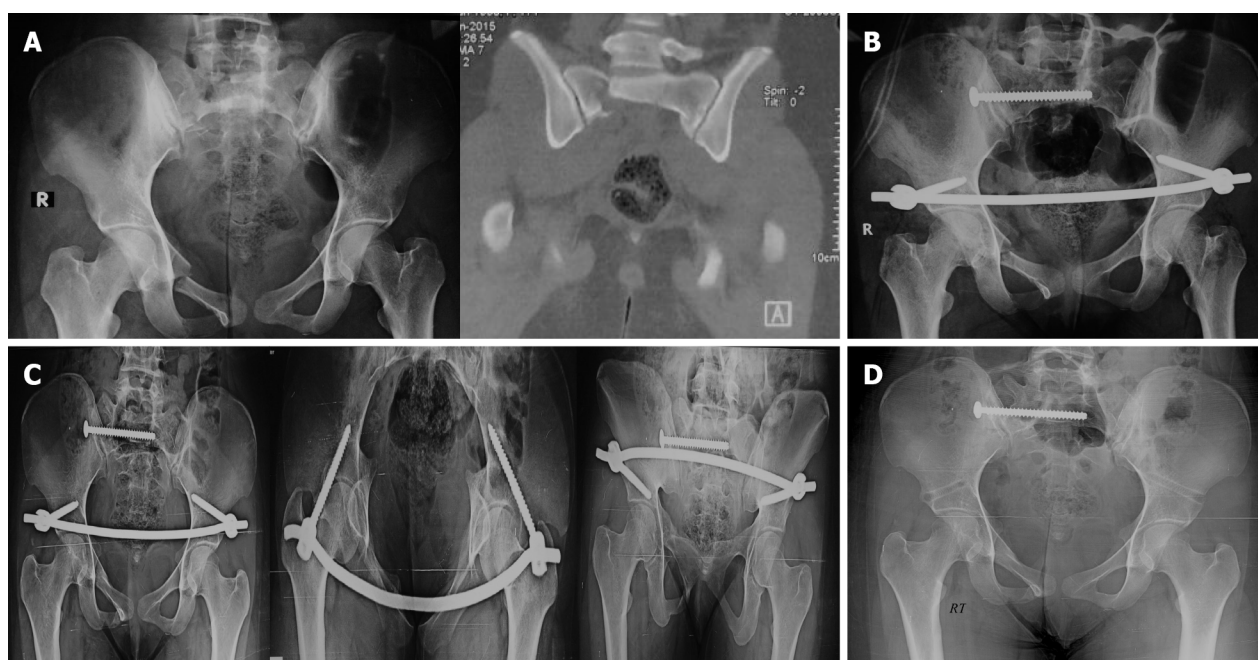


Figure 2 17-year-old girl sustained a Tile C type pelvic fracture after fall from a height of 6 m. A: Pelvis antero-posterior (AP) X-ray view and sagittal computed tomography scans showing sacral and ramus fractures on the Rt. Side; B: The pelvic fracture was fixed using a fully threaded sacroiliac screw and an internal fixator (INFIX); C: 3-mo follow-up pelvic X-ray (AP, inlet and outlet) views showing complete union. The INFIX was removed 2 mo later in the OR; D: One-year follow-up X-ray. The patient had excellent function with complete return to her prefracture activity level.

RESULTS

Fifty-nine patients were recruited for the study; five were lost during follow-up and were excluded. Fifty-four patients were left for analysis; 30 for the INFIX and 24 for the EXFIX groups. These were 30 (55.6%) males and 24 (44.4%) females with a mean follow-up of 15.4 mo (range: 12-20 mo). The average age in the INFIX group was 34.5 years (range: 17-53 years) while in the EXFIX group, it was 31.2 years (range: 16-57 years). Patients' demographics and fracture characteristics are shown in Table 1. No significant differences in age, gender, associated comorbidities, ASA score, injury mechanism, fracture classification, fracture side, preoperative displacement, operative delay and intra-operative blood loss were

Table 1 Patient's demographics and fracture characteristics

	EXFIX group (n = 24)	INFIX group (n = 30)	P value
Age (years, mean \pm SD)	31.2 \pm 10.95	34.5 \pm 8.35	0.205
Sex			0.066
M, n (%)	10 (41.7)	20 (66.7)	
F, n (%)	14 (58.3)	10 (33.3)	
Follow-up (months)			0.0468
Range	12-18	12-20	
mean \pm SD	14.8 \pm 0.8	15.9 \pm 2.4	
Mode of trauma			0.873
Falling from height	10	12	
Road traffic accident	13	17	
Train accident	1	0	
Heavy object	0	1	
Tile classification			0.650
B1	2	0	
B2	8	8	
B3	3	7	
C1	9	12	
C2	1	2	
C3	1	1	
ASA score			0.978
ASA1	13	17	
ASA2	7	8	
ASA 3	4	5	

SD: Standard deviation; ASA: American society of anesthesiologists; EXFIX: External fixator; INFIX: Internal fixator.

noticed between both groups. However, operative time was significantly shorter among the EXFIX group (mean = 20.9 \pm 2.6 min, range: 16-25 min) compared to the INFIX group (mean = 41.2 \pm 7.7 min, range: 28-60 min) ($P < 0.001$) (Table 2). The INFIX group had significantly better quality of fracture reduction scores with 93% of the patients having excellent to good reduction (compared to 70% in the EXFIX group) ($P = 0.022$). All fractures united by an average of 13 wk (range: 10-16 wk) with no significant difference among the two groups ($P = 0.536$). Implants were removed in both groups starting at 3 mo postoperatively. However, patients tended to retain INFIX for longer periods ($P < 0.001$) which was in-part related to better tolerance of the implant as well as logistics related to hospital surgical schedule. Moreover, 2 patients were even reluctant to remove the implant and had them retained for more than 18 mo. Lateral femoral cutaneous nerve (LFCN) injury (22%) and surgical site infection (11%) were the most common complications reported. LFCN injury was equally observed among both the INFIX and the EXFIX groups with a frequency of 23.3 and 20.8 % respectively ($P = 0.826$). There was a transient nerve irritation that usually improved after implant removal except for two patients (one in each group) that experienced no improvement of their symptoms. Nevertheless, these patients had mild to moderate symptoms that were medically controlled and required no further intervention. On the contrary, surgical site infection was significantly higher among the EXFIX group ($P = 0.007$). Eight (33.4%) patients experienced pin-track infections that were classified according to Meléndez and Colón system[18]. Fortunately, five of these were grade I infections that responded well to daily wound dressing. In addition, two patients had grade III infection that needed intravenous antibiotic therapy together with surgical wound debridement during removal of the implants after union was achieved. One patient had a severe surgical site infection (grade V) causing loosening of the pins and very early fixation failure after 2 wk. EXFIX had to be prematurely removed with wound debridement and intravenous antibiotics for two weeks. After infection clearance, revision fixation of the anterior ring fractures was done using a 3.5 mm reconstruction plate and screws. The fracture eventually united with good function at last follow-up. As regards the INFIX group, there was a single case (3.3%) of superficial surgical site infection that was treated by intravenous antibiotics and local wound dressing. No implant loosening, loss of reduction and/or fixation failures were noted for this group. In a trial to assess patients' function before implant removal, sitting, standing, and walking abilities were measured at the 3-mo follow-up

Table 2 Results

	EXFIX group	INFIX group	P value
Operative time (minutes)			< 0.001 ^a
Range	16-25	28-60	
mean ± SD	20.9 ± 2.6	41.2 ± 7.7	
Quality of reduction (Matta and Tormenta score)			
Excellent	10	14	0.022 ^a
Good	7	14	
Fair	6	0	
Poor	1	2	
Duration of fixation till removal (months)			< 0.001 ^a
Range	3-4	3-18	
Median (IQR)	3 (3-4)	5 (3-6)	
Function before removal			
Sitting abilities (n)			
Painful	0	0	< 0.001 ^a
Painful if prolonged or awkward	8	0	
Uncomfortable	15	29	
Free	0	1	
Standing abilities (n)			
Bedridden or almost	1	0	0.008 ^a
Wheelchair	1	0	
Two crutches	8	2	
Two sticks	4	2	
One stick	6	18	
No sticks	3	8	
Walking abilities (n)			
Cannot walk or almost	0	0	0.042 ^a
Shuffling small steps	9	4	
Gross limp	6	4	
Moderate limp	5	7	
Slight limp	2	8	
Normal	1	7	
Total Majeed score at the end of the follow-up			
Range	75-100	71-100	0.513
mean ± SD	91 ± 7.8	92.4 ± 7.2	
LFCN affection, n (%)	5 (20.8)	7 (23.3)	0.826
Surgical site infection, n (%)	8 (33.3)	1 (3.3)	0.007 ^a

^aP < 0.05, Statistically significant.

SD: Standard deviation; IQR: Interquartile range; LFCN: Lateral femoral cutaneous nerve; EXFIX: External fixator; INFIX: Internal fixator.

visit using Majeed score modules. INFIX group was found to have significantly better scores in all modules (Table 2). Nevertheless, patients' function at the time of final follow-up showed no significant difference between both groups. The total Majeed score had an average of 92.3 (range: 71-100) and 91 (range: 75-100) for the INFIX and the EXFIX groups, respectively.



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Figure 3 57-year-old male patient sustained a Tile B type pelvic fracture after fall from a 3 meter height on his Rt. side. A: Pelvis antero-posterior (AP) X-ray view and axial computed tomography cuts showing Rt. sacral and bilateral rami fractures. The patient has an associated Rt. pertrochanteric fracture; B: The pelvic fracture was fixed using a fully threaded sacroiliac screw and an external fixator (EXFIX). The pertrochanteric fracture was also fixed at the same session using a long femoral nail; C: 3-mo follow-up pelvic X-ray (AP, inlet and outlet) views showing complete union. The EXFIX was removed in the outpatient clinic on the same day; D: 9-mo follow-up X-ray showing consolidation of the fractures. The patient had excellent function with complete return to his prefracture activity level.

DISCUSSION

Injuries of the pelvic ring represent 3%-8% of all fractures and are usually associated with high-energy trauma[19,20]. Combined anterior and posterior fixation is usually needed to restore pelvic stability; anterior pelvic fixation adds stability and protects the posterior fixation[2,21,22]. Open reduction and plate fixation of anterior ring fractures usually require extension lateral to the hip joint with extensive soft tissue dissection and a high risk of damaging the neurovascular structures[5]. EXFIX and, more recently, INFIX have been used for less invasive surgical options for anterior pelvic fixation.

Both techniques have provided adequate fixation, high fracture union rates, and ultimate good functional recovery[2,5,11,12,23-25]. In our series, except for one early failure due to pin-track infection, all fractures united by an average of 13 wk, and patients had good functions at the final follow-up in both groups.

However, several authors have argued that INFIX has been better tolerated than EXFIX in the postoperative period, particularly in obese patients[12]. Patients could sit, stand, lie prone, and lie on their sides normally. In addition, Vaidya *et al*[11] reported that nursing care for INFIX patients was easier than for EXFIX patients, especially in the intensive care unit setting, with more patient independence.

Nevertheless, these have been largely subjective opinions of treating surgeons and intensive care unit nursing staff. We measured sitting, standing, and walking abilities using Majeed score modules at the 3-mo follow-up visit for a better and more objective assessment of the patients' early functional recovery. The INFIX group showed significantly better scores in all modules. Similarly, Gardner *et al*[12] assessed hip flexion before INFIX removal. They found the mean hip flexion among their patients to be 96° (range: 60-120°), with 60% of them achieving flexion of 90° or more.

Moreover, better implant tolerance is reflected in the fact that patients tended to keep the INFIX for longer periods after fracture union, with some of them even declining the removal surgery. Vaidya *et al*[13] even reported on a patient conceiving twice (she even had normal vaginal deliveries) with the device in place. This observation, however, should be taken cautiously, as INFIX (contrary to EXFIX) requires removal inside the operating room.

Owing to its extracorporeal location, the main disadvantage of EXFIX, besides being cumbersome and limiting patient mobility, is a very high incidence of infection[9,26,27]. This is especially evident in obese patients with larger surgical wounds and greater soft tissue mobility around the transcutaneous pins[11]. This is the main selling point for INFIX. Our study highlights this fact with a highly significant difference between study groups regarding infection rates. Besides, infection with EXFIX is often associated with pin loosening, which may even lead to premature fixation failure and loss of reduction[21,26].

Moreover, EXFIX stability is affected by the distance between the bar and the bone-pin interface. In this regard, INFIX benefits from its subcutaneous location, with improved biomechanics superior to EXFIX in overall stiffness[4]. This might partially explain the better reduction quality achieved with INFIX.

However, failures were reported with INFIX. These were mostly related to the posterior fixation (mostly iliosacral screws) rather than the INFIX[5]. Nevertheless, unfamiliarity with the INFIX technique with improperly secured screw caps was reported to result in a loss of reduction requiring revision[11].

LFCN injury is a known complication with EXFIX using supra-acetabular Schanz pins. However, its incidence is usually low. On the contrary, the reported incidence of cutaneous nerve affection with INFIX was usually higher, reaching up to 55%[5]. This could be explained by the increased nerve irritation caused by the subcutaneous location of the implants, particularly the screw-rod junction. Moreover, excessive lateral rod overhang may be another contributor to nerve irritation. Several authors recommended a more medial soft tissue dissection to protect the nerve[15,21,28]. We believe that the low incidence in our series (comparable between the two groups) could be explained by the technique we adopted using the intermuscular interval between the sartorius and psoas muscles.

Femoral nerve palsy is another devastating condition; however, rare complications were reported to occur after INFIX use for pelvic fractures. Patients usually complain of delayed quadriceps weakness with gait affection in addition to anterior thigh pain and altered sensations[29]. Nevertheless, acute cases of postoperative palsy, sometimes associated with vascular compression, were reported[21,29]. It is thought that this neural affection is usually the result of the too-deep insertion of the pedicle screw heads, leading to nerve compression within the psoas muscle fascia. Despite the more medial approach we used, we had no cases of femoral nerve affection, and we believe this highlights the importance of paying careful attention to the technique and leaving the screw heads and the screw-rod junctions above the sartorial fascia. We did not use routine postoperative sonographic examination. Nevertheless, there have been reports on the safety of the INFIX with no femoral vessel compression and up to 90 degrees of hip flexion[11,15].

One last point is that INFIX is a relatively time-consuming procedure (up to one hour in some reports) requiring full fluoroscopic control[12]. Although there is a learning curve with improvements in the INFIX operative time towards the end of our study, we still found EXFIX to be a significantly more rapid procedure. Similar results were reported by Bi *et al* [21] comparing EXFIX to a modified three-screw INFIX technique. Thus, we strongly recommend against INFIX use for hemodynamically unstable patients. EXFIX is still the recommended technique in emergencies to rapidly reduce pelvic volume and allow for hematoma stabilization. Strengths of the study include being prospective, utilizing a similar approach for all patients, and using the Majeed score to determine the function between fixation and implant removal. Limitations of the current study include a small sample size, heterogeneity of posterior pelvic ring fractures, which may affect the failure rate of the fixation, including cases from a single trauma center, and a lack of randomization of cases in each group.

CONCLUSION

Both INFIX and EXFIX can provide anterior pelvic ring fracture stability to achieve comparable good functional and radiological outcomes. This study suggests that the anterior subcutaneous pelvis INFIX is associated with better radiological outcomes and a lower infection rate than the anterior supra-acetabular EXFIX in the management of patients with unstable anterior pelvic ring fractures. Benefits of INFIX use include easiness of sitting, standing, and walking with the implant and a low incidence of surgical site infection. On the other hand, the operative time of EXFIX is shorter, making it more suitable for emergencies.

ARTICLE HIGHLIGHTS

Research background

Reconstruction of the pelvic ring anatomy in unstable anterior pelvic ring injuries is considered to be a great step to efficiently reduce the mortality rate associated with these types of injuries. There is a debate on the use of either anterior subcutaneous pelvis internal fixator (INFIX) or anterior supra-acetabular external fixator (EXFIX) in the management of anterior unstable pelvic ring fracture.

Research motivation

This is one of the very few studies comparing the INFIX vs EXFIX in management of unstable anterior pelvic ring injuries.

Research objectives

The objective of this study was to compare the functional, radiological outcomes as well as complications of INFIX vs EXFIX in management of unstable pelvic ring injuries.

Research methods

A prospective cohort study was carried including 54 patients with unstable pelvic ring fractures. The patients were divided into two groups: INFIX group in which 30 cases were fixed by INFIX and EXFIX group in which the 24 patients were treated by EXFIX. The average age in the EXFIX group was 31.17 years (16-57 years) while in the INFIX group, it was 34.5 years (17-53 years). The study included 20 (66.7%) males and 10 (33.3%) females in the INFIX group and 10 (41.7%) males and 14 (58.3%) females in the EXFIX group. Evaluation of the radiological outcomes was done using Matta and Tornetta score and functional outcomes using Majeed score.

Research results

Fifty nine patients were recruited for the study; five were lost during follow-up. Fifty-four patients were left; 30 for the INFIX and 24 for the EXFIX groups. Operative time was shorter among the EXFIX group compared to the INFIX group ($P < 0.001$). INFIX group had significantly better quality of fracture reduction scores ($P = 0.022$). All fractures united by an average of 13 wk (range; 10-16 wk) ($P = 0.536$). Implants were removed in both groups starting at 3 mo postoperatively. Lateral femoral cutaneous nerve injury and infection were the most common complications reported. Infection was significantly higher among the EXFIX group ($P = 0.007$). Eight (33.4%) patients experienced pin-track infections that were classified according to Meléndez and Colón system. One patient had a severe surgical site infection (grade V) causing loosening of the pins and fixation failure after 2 wk. As regards the INFIX group, there was a single case (3.3%) of superficial infection that was treated by intravenous antibiotics and wound dressing. INFIX group was found to have significantly better Majeed scores in all modules. The total Majeed score had an average of 92.3 and 91 for the INFIX and the EXFIX groups, respectively.

Research conclusions

This study suggests that anterior subcutaneous pelvis INFIX is associated with better radiological outcome and less rate of infection than anterior supra-acetabular EXFIX in management of patients with anterior unstable pelvic ring fractures. Benefits of INFIX use include easiness to sit, stand and walk with the implant and low incidence of surgical site infection. On the other hand, operative time of EXFIX is shorter which makes it more suitable for emergency situations.

Research perspectives

Further research studies that would have more sample size, and randomization of the patients (if feasible) are required.

FOOTNOTES

Author contributions: All authors have contributed to design of the study, surgical intervention, patients assessment and follow up, manuscript writing and editing.

Institutional review board statement: The study was approved by the ethical committee of faculty of medicine, Cairo university on 8/12/2018 with the number "N-147-2023".

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Country/Territory of origin: Egypt

ORCID number: Mahmoud Abdel Karim 0000-0002-3134-5402.

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Randomized Clinical Trial

Instrumented assisted soft tissue mobilization vs extracorporeal shock wave therapy in treatment of myofascial pain syndrome

Nourhan Elsayed Shamseldeen, Mohammed Moustafa Aldosouki Hegazy, Nadia Abdalazeem Fayaz, Nesreen Fawzy Mahmoud

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Nourhan Elsayed Shamseldeen, Mohammed Moustafa Aldosouki Hegazy, Nadia Abdalazeem Fayaz, Nesreen Fawzy Mahmoud, Department of Physical Therapy for Musculoskeletal Disorders & Its Surgery, Faculty of Physical Therapy, Cairo University, Cairo 14531, Egypt

Corresponding author: Nesreen Fawzy Mahmoud, MSc, PhD, Lecturer, Physiotherapist, Senior Research Fellow, Department of Physical Therapy for Musculoskeletal Disorders & Its Surgery, Faculty of Physical Therapy, Cairo University, Dokki, Giza, Cairo 14531, Egypt.
dr_nesreenfawzy@cu.edu.eg

Abstract

BACKGROUND

Active myofascial trigger points (TrPs) often occur in the upper region of the upper trapezius (UT) muscle. These TrPs can be a significant source of neck, shoulder, and upper back pain and headaches. These TrPs and their related pain and disability can adversely affect an individual's everyday routine functioning, work-related productivity, and general quality of life.

AIM

To investigate the effects of instrument assisted soft tissue mobilization (IASTM) vs extracorporeal shock wave therapy (ESWT) on the TrPs of the UT muscle.

METHODS

A randomized, single-blind, comparative clinical study was conducted at the Medical Center of the Egyptian Railway Station in Cairo. Forty patients (28 females and 12 males), aged between 20-years-old and 40-years-old, with active myofascial TrPs in the UT muscle were randomly assigned to two equal groups (A and B). Group A received IASTM, while group B received ESWT. Each group was treated twice weekly for 2 weeks. Both groups received muscle energy technique for the UT muscle. Patients were evaluated twice (pre- and post-treatment) for pain intensity using the visual analogue scale and for pain pressure threshold (PPT) using a pressure algometer.

RESULTS

Comparing the pre- and post-treatment mean values for all variables for group A, there were significant differences in pain intensity for TrP1 and TrP2 ($P = 0.0001$) and PPT for TrP1 ($P = 0.0002$) and TrP2 ($P = 0.0001$). Also, for group B, there were

significant differences between the pre- and post-treatment pain intensity for TrP1 and TrP2 and PPT for TrP1 and TrP2 ($P = 0.0001$). There were no significant differences between the two groups in the post-treatment mean values of pain intensity for TrP1 ($P = 0.9$) and TrP2 ($P = 0.76$) and PPT for TrP1 ($P = 0.09$) and for TrP2 ($P = 0.91$).

CONCLUSION

IASTM and ESWT are effective methods for improving pain and PPT in patients with UT muscle TrPs. There is no significant difference between either treatment method.

Key Words: Myofascial trigger points; Upper trapezius muscle; Instrument-assisted soft tissue mobilization; Extracorporeal shock wave therapy; Myofascial pain syndrome

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Core Tip: This is the first study to compare the effects of instrument-assisted soft tissue mobilization (IASTM) vs extracorporeal shock wave therapy (ESWT) on trigger points of the upper trapezius muscle in myofascial pain syndrome. The results of the current study revealed no statistically significant differences between the effect of IASTM and ESWT on pain intensity and pain pressure threshold of upper trapezius muscle trigger points. However, both IASTM and ESWT improved pain measures in both groups of patients suffering from myofascial pain syndrome. Based on these results, treatment methods can be selected based on availability, cost, therapist experience, and patient preference.

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INTRODUCTION

Myofascial pain syndrome (MPS) is a complex of sensory, motor, and autonomic symptoms that are caused by myofascial trigger points (MTrPs) “muscle knots”[1]. It is the most potent cause of persistent regional pain[2] that affects all ages[3]. MPS commonly affects the neck and shoulder muscles, with the upper trapezius (UT) being the most involved[4]. MTrPs are hypersensitive, palpable spots involving muscle fibers and fascia[5]. They are classified into two clinical types: active and latent. Active TrPs cause persistent pain at rest and referred pain patterns, while latent TrPs cause pain with direct pressure and movement limitation[1]. Patients with myofascial pain represent a large number of musculoskeletal patients. The estimated overall prevalence of active MTrPs is $46.1\% \pm 27.4\%$ [6]. It has been estimated that around 85% of patients visiting chronic pain clinics and 30% of patients visiting internal medicine clinics have myofascial pain[7].

MPS can be presented clinically after repetitive muscle microtrauma, while other patients have no precipitating factors. Pain onset of pain may be acute or gradual[8]. A physical examination can detect the existence and type of MTrPs by manual palpation[3,8]. The physical therapy for MPS might include stretching exercises, ultrasound[9], massage[10], kinesio tape[11], dry needling (an invasive technique)[12], and muscle energy technique (MET)[13].

Instrument-assisted soft tissue mobilization (IASTM) is one of the techniques used to treat MPS. After an injury, inflammation and proliferation of inflammatory cells occur, during which fibrosis and scar tissue formation in the injured soft tissue may occur[14]. These changes reduce tissue elasticity and cause adhesions, diminishing soft tissue function and pain[15]. In particular, scar tissue limits perfusion to the injured soft tissue, restricting oxygen and nutrients supply and interfering with collagen synthesis and tissue regeneration, which may then cause incomplete functional recovery[16,17] and increase the risk of reinjury[15]. IASTM creates microtrauma to scar tissue or myofascial adhesions using a specially designed instrument to reduce pain and improve range of motion and function. Additionally, it minimizes the stress on the practitioner’s hand and the effort he has to put forth[18].

Extracorporeal shock wave therapy (ESWT) produces mechanical energy through high-pressure air. The mechanical signal is converted into biochemical or molecular biological signals in the tissues by propagating as a longitudinal wave. This mechanism is called mechanotransduction. It has been proven that ESWT has a pain-relieving effect described in plantar fasciitis[19], calcifying tendinitis[20], and MPS[21,22]. ESWT has no serious side effects besides minimal pain, bruising, and swelling, which can be significant after treatment[23].

Currently, no study has compared the effects of IASTM and ESWT in treating myofascial TrPs of the UT muscle in patients with MPS. We hypothesized that there was no significant difference between the two methods on pain and pain pressure threshold (PPT).

MATERIALS AND METHODS

This study was conducted at the outpatient physical therapy clinic, Medical Center of the Egyptian Railway Station. It was registered at Cairo University and approved by the Faculty of Physical Therapy, Research Ethics Committee (P.T.REC/012/003180).

Study design

A single-blinded comparative clinical study.

Sample size calculation

The sample size was calculated using the MedCalc® version 12.3.0.0 program “Ostend, Belgium” and was 38 cases, according to a 95% confidence interval and the power of the study 80% with 5% error. Assuming a drop-out ratio of 5%, the sample size was 20 cases in each group.

Patients

Forty male and female patients were referred by orthopedic surgeons with a diagnosis of MPS in the neck with active TrPs of the UT muscle. Their ages ranged from 20 years to 40 years[24]. They were randomly assigned into two equal experimental groups, using a simple randomization method (patients enrolled consecutively in group A or B). Group A ($n = 20$) received IASTM on TrPs of the UT muscle (TrP1 and TrP2), and group B ($n = 20$) received ESWT on TrPs of the UT muscle (TrP1 and TrP2). Each patient signed an informed consent before starting the study.

All patients received four treatment sessions, twice per week over 2 weeks[25]. Both groups received a post isometric relaxation technique for the UT muscle. Patients were evaluated before treatment and 2 days after treatment for neck pain intensity and PPT of the UT TrPs (TrP1 and TrP2).

Patients were included if they had MTrPs of unilateral UT muscle (TrP1 and TrP2) that exhibit the following characteristics[26,27]: (1) A taut band within a muscle; (2) Extreme tenderness at a point within the taut band; (3) Reproduction of the patient's pain; (4) Referred pain; (5) Eliciting a localized twitch response; (6) Muscle weakness; (7) Limited range of motion; and (8) Autonomic signs (erythema, lacrimation, pilo-erection). To make a diagnosis, the first three characteristics must be present[26,27].

Patients with malignancy, cervical spine fractures, cervical radiculopathy, myelopathy, or vascular syndromes (such as vertebrobasilar insufficiency) were excluded[28]. Also, patients were excluded if they received any other treatment, in the form of physical therapy or medication, that would interfere with the results of this study and if they exhibited any contraindication for IASTM and ESWT[29].

Assessment procedures

All patients were evaluated before and 2 days after treatment by a research assistant who was unaware of the treatment program given to each patient. The patients were positioned comfortably in a prone position on a plinth with sufficient exposure to the UT muscle. The head was slightly tilted ipsilateral to the side being palpated. Using a pincer grasp, the free margin of the UT fibers was held firmly. Once the palpable band was located, it would be firmly rolled between fingers and thumb. Local tenderness and referral pattern were noted. The process was carried out for two points (TrP1 and TrP2). TrP1 was palpated in the angle between the neck and shoulder[30], while TrP2 was palpated halfway between the spinous processes of the C5/C6 vertebrae and the acromion process of the scapula using a small pincer grip[31]. Manual palpation of the muscle is the most reliable method of diagnosing a MTrP[32].

Assessment of pain intensity using the visual analogue scale

The visual analog scale (VAS) is a self-reported pain measurement scale. It consists of a 10 cm long line, and the extremes of the line are labeled as no pain and most severe pain. It is valid, reliable, and suitable for clinical practice[33]. The patient was asked to mark a point on the VAS, and then this number was taken for statistical analysis[34].

Assessment of PPT using pressure algometer

The pressure algometer is a valid and reliable tool to determine PPT. An algometer is a force gauge with a spring-operated plunger. The gauge is attached to a short metal pole with a round 1 cm rubber tip. The device is calibrated in kilograms of pressure per centimeter squared (kg/cm^2). The gauge has a range of 0 to 10 kg/cm^2 . Once a measurement was recorded, the device was reset to 0 to take another measurement[21,35].

The research assistant positioned the tip of the algometer (Greenwich, CT, United States) at the TrP and increased the pressure by 1 kg/s . When the patient indicated discomfort, the pressure value was recorded in kg/cm^2 . The procedure was repeated three times at 60 s intervals, and the mean of these measurements was taken for statistical analysis.

Treatment procedures

Treatment procedures for group A: This group of patients received IASTM with an M2T blade. Upon a table in front of the patient, his or her forehead resting on his or her forearm. Before treatment, a lubricant (petroleum jelly) was applied to the skin around the neck area, and the M2T blade was cleaned with an alcohol pad.

Following the localization of TrP1 and TrP2, the M2T blade was positioned at a 45° angle. For about 3 min, slow strokes were applied along the muscle from its origin to its insertion without discomfort or pain. The strokes were longitudinally parallel to the muscle fibers. If patients experienced burning sensations after the session, they were instructed to apply an ice pack to the treated area[24].

Treatment procedures for group B: Patients in this group received ESWT (Unify Elektromedizin, Germany, SN:3012095,2012). All aspects of the procedure were explained to the patient before treatment. The patients were informed that the shockwave machine produces intense pressure when applied and creates considerable noise. The patient requested to speak with the researcher if the intensity was too uncomfortable.

The patient was positioned on a plinth. The treatment area was sufficiently exposed, and a coupling gel was applied. The shockwave unit was calibrated to the correct therapeutic settings. For MTrPs, the settings were 2.0 bars at 15 Hz for 2000 pulses[22,36]. The handheld transmitter head was applied to the area to be treated. Slight pressure was applied with circular movements to treat the TrP sufficiently. The shockwave unit automatically stopped the treatment once all 2000 pulses were delivered. Any residue from the coupling gel was wiped off with a paper towel[22,36].

Post-isometric relaxation technique for UT muscle

All patients in both groups received the post-isometric relaxation technique for the UT muscle. The patient was instructed to lie in a supine position with the cervical spine in opposite lateral flexion to the affected side to lengthen the UT muscle fibers. Sub-maximal resistance was applied to the UT muscle for about 5 s, followed by 3 s of relaxation, and then stretching the UT muscle for 15-30 s to reach a new barrier. This maneuver was repeated four times in each session[37].

Statistical analysis

This study's data analysis used the SPSS version 26 for Windows (IBM Corp, Armonk, NY, United State). The data distribution was tested *via* the Shapiro-Wilk test. Independent *t*-test and χ^2 test were used to compare demographic data between both groups. A paired *t*-test was used to compare pre- and post-treatment mean values of all variables within both groups. For comparing all the dependent variables pre- and post-treatment between both groups we used an independent *t*-test. The significance level of a *P* value of ≤ 0.05 was considered statistically significant using 95% confidence intervals.

RESULTS

Descriptive statistics of demographic data for all patients in both groups

The data showed that each dependent variable was normally distributed and did not violate the parametric assumption. Using an independent *t*-test, there were no significant differences between patients in both groups in age ($P = 0.16$), weight ($P = 0.83$), height ($P = 0.8$), and body mass index ($P = 0.34$). The distribution of males and females in group A was 20% and 80%, respectively. In group B, there was 40% males and 60% females. Comparing the sex distribution for all patients in both groups using the χ^2 test, there were no significant differences ($P = 0.17$) (Table 1).

Pre-treatment between group comparisons of all variables in both groups

Comparing the pre-treatment mean values between both groups using the independent *t*-test, there were no significant differences in pain intensity for TrP1 ($P = 0.55$), pain intensity for TrP2 ($P = 0.94$), PPT for TrP1 ($P = 0.18$), and PPT for TrP2 ($P = 0.58$) (Table 2).

Post-treatment between group comparisons of all variables in both groups

Comparing the post-treatment mean values between both groups using an independent *t*-test, there were no significant differences in pain intensity for TrP1 ($P = 0.9$), pain intensity for TrP2 ($P = 0.76$), PPT for TrP1 ($P = 0.09$), and PPT for TrP2 ($P = 0.91$) (Table 2).

Within group pre-treatment and post-treatment comparison of all variables in group A

Comparing the pre-treatment and post-treatment mean values using paired *t*-test for all variables in group A, there were significant differences in pain intensity for TrP1 ($P = 0.0001$), pain intensity for TrP2 ($P = 0.0001$), PPT for TrP1 ($P = 0.0002$), and PPT for TrP2 ($P = 0.0001$) (Table 3).

Within group pre-treatment and post-treatment comparison of all variables in group B

Comparing the pre-treatment and post-treatment mean values using a paired *t*-test for all variables in group B, there were significant differences in pain intensity for TrP1 ($P = 0.0001$), pain intensity for TrP2 ($P = 0.0001$), PPT for TrP1 ($P = 0.0001$), and PPT for TrP2 ($P = 0.0001$) (Table 3).

DISCUSSION

This is the first study to compare the effects of IASTM vs ESWT on TrPs of the UT muscle in MPS. The current study revealed no statistical differences between IASTM and ESWT on pain intensity and PPT of UT muscle TrPs. However, IASTM or ESWT improved pain measures in both groups of patients suffering from MPS.

Table 1 Descriptive statistics for the mean values of age, weight, height, body mass index, and sex distribution of all patients in both groups

	Group A <i>n</i> = 20	Group B <i>n</i> = 20	<i>t</i> value	<i>P</i> value	Significance
Age in yr	31.20 ± 4.15	29.10 ± 5.12	1.43	0.16	NS
Weight	72.55 ± 7.65	73.35 ± 14.23	-0.22	0.83	NS
Height	168.40 ± 5.90	169.05 ± 9.83	-0.25	0.80	NS
BMI in kg/m ²	25.50 ± 2.25	24.80 ± 2.29	0.98	0.34	NS
Sex distribution	20% male and 80% female	40% male and 60% female	$\chi^2 = 1.91$	0.17	NS

NS: Non-significant; BMI: Body mass index. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

Table 2 Independent *t*-test for comparison of pre- and post-treatment mean values between both groups

Treatment period	Group A <i>n</i> = 20	Group B <i>n</i> = 20	<i>t</i> value	<i>P</i> value	Significance
Pre-treatment					
Pain intensity for TrP1	6.05 ± 1.90	6.38 ± 1.50	-0.61	0.55	NS
Pain intensity for TrP2	7.15 ± 1.90	7.20 ± 1.56	-0.08	0.94	NS
PPT for TrP1	17.08 ± 4.99	14.83 ± 5.31	1.38	0.18	NS
PPT for TrP2	15.72 ± 5.75	14.68 ± 6.13	0.55	0.58	NS
Post-treatment					
Pain intensity for TrP1	3.75 ± 1.69	3.82 ± 1.53	-0.13	0.9	NS
Pain intensity for TrP2	4.06 ± 1.45	3.93 ± 1.22	0.31	0.76	NS
PPT for TrP1	30.75 ± 18.12	22.82 ± 9.55	1.7	0.09	NS
PPT for TrP2	27.93 ± 9.90	28.29 ± 10.08	-0.11	0.91	NS

Data are presented as mean ± SD unless otherwise indicated. NS: Non-significant; PPT: Pressure pain threshold; TrP: Trigger point. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

Effects of IASTM on pain intensity and PPT

The results of the current study confirmed the results of previous studies. This proved the effectiveness of IASTM in decreasing pain intensity and increasing PPT in MTrP in the UT muscle. El-Hafez *et al*[25] showed a significant difference between pre-treatment and post-treatment within the group of patients treated with IASTM twice a week for 4 weeks, regarding pain intensity and PPT. In like manner, other studies showed that using IASTM twice a week for 2 weeks, significantly improved pain and PPT of active MTrPs of the UT muscle[38,39]. Also, IASTM induced thinning of the UT muscle when applied for six sessions at 1-day intervals[38].

Moreover, after one session, IASTM induced immediate significant results concerning decreasing the resting pain[40, 41] and increasing the pain threshold in the neck and lower back[40]. Erden *et al*[42] stated that adding IASTM to the conventional physical therapy program for 8 wk was superior to conventional physical therapy alone for patients with myofascial pain with upper and mid back TrPs in the improvement of pain intensity and PPT. The effect of IASTM on pain could be explained by increasing blood flow, which removes pain substrates[43-45]. Furthermore, IASTM stimulates the A-beta sensory fibers and blocks the A-delta and C-fibers. As for the “gate control theory”, this blocks substance P from pain receptors *via* presynaptic inhibition at the dorsal horn[46]. Also, it improves collagen fiber bundle formation and orientation, which decreases cell matrix adhesions within the MTrP, which explains the increased PPT after using IASTM[47].

Effect of ESWT on pain intensity and PPT

In the same manner, the group that received ESWT showed a significant improvement in pain and PPT after four sessions of treatment. This was in agreement with previous evidence investigating the effect of ESWT on MTrPs of the UT muscle in MPS cases.

Table 3 Paired t-test comparison for pre- and post-treatment mean values of all variables for all group (A and B) patients

Group	Pre-treatment	Post-treatment	t value	P value	Significance
	n = 20	n = 20			
Group A					
Pain intensity for TrP1	6.05 ± 1.90	3.75 ± 1.69	6.55	0.0001 ¹	HS
Pain intensity for TrP2	7.15 ± 1.90	4.06 ± 1.45	8.32	0.0001 ¹	HS
PPT for TrP1	17.08 ± 4.99	30.75 ± 18.12	-3.51	0.002 ¹	Sig
PPT for TrP2	15.72 ± 5.75	27.93 ± 9.90	-6.97	0.0001 ¹	HS
Group B					
Pain intensity for TrP1	6.38 ± 1.5	3.82 ± 1.53	9.56	0.0001 ¹	HS
Pain intensity for TrP2	7.20 ± 1.56	3.93 ± 1.22	12.82	0.0001 ¹	HS
PPT for TrP1	14.83 ± 5.31	22.82 ± 9.55	-5.86	0.0001 ¹	HS
PPT for TrP2	14.68 ± 6.13	28.29 ± 10.08	-7.03	0.0001 ¹	HS

Data are presented as mean ± SD unless otherwise indicated.

¹Statistically significant.

HS: Highly significant; PPT: Pressure pain threshold; Sig: Significance; TrP: Trigger point. Group A: Patients treated with instrument assisted soft tissue mobilization; Group B: Patients treated with extracorporeal shock wave therapy.

A recent systematic review and meta-analysis showed that ESWT significantly affects pain reduction compared with sham ESWT or ultrasound treatment. However, conventional treatments, such as dry needling, TrP injection, and laser therapy, have no significant differences in pain intensity and neck disability index[48]. Taheri *et al*[49] and Jeon *et al*[50] confirmed that three sessions of ESWT had a comparable effect with laser therapy[49], TENS, and TrP injection[50] for relieving pain in patients with MPS. Choi *et al*[51] reported that combining ESWT with the myofascial release technique improved in pain intensity and PPT more than myofascial release alone.

In addition, Lee and Han[52] compared the effects of ESWT, proprioceptive neuromuscular facilitation, and TrP injection on pain intensity and PPT in patients with UT muscle MPS. In line with the findings of the current study, VAS and PPT showed statistically significant differences among patients in the ESWT group. Ji *et al*[53] examined the VAS and PPT in the UT before and after 4 treatment sessions of ESWT. It showed a significant increase in PPT and a significant decrease in VAS. Moreover, in patients with non-specific neck pain, pain intensity and PPT were significantly improved after applying three ESWT sessions performed once a week for 3 weeks, on the UT muscle TrP[54]. On the other hand, Lee *et al*[55] revealed that two treatment sessions of ESWT in patients with MTrPs in the trapezius muscle significantly reduced the amount of pain, although there was no change in the PPT. Gür *et al*[56] reported that one session and three sessions once a week of low-energy ESWT revealed statistically significant improvements in pain, quality of life, and anxiety scores in patients with MPS. Additionally, the three sessions produced more substantial efficacy. Also, Király *et al* [23] proved the long-term effect of ESWT and reported improvement of resting pain and pain tolerance at the week 3 and week 15 follow-up in patients with MPS who received ESWT at the TrP of UT.

An analgesic effect of shock waves may be explained by increased blood and nutrients flow to the MTrPs, selective destruction of unmyelinated nerve fibers (C nerve fibers)[57], reduced substance P[58], and increased nitric oxide release [59]. The second possible mechanism is hyperstimulation, indicating that a shock wave triggers the release of endorphins and other analgesic molecules by activating the descending inhibitory system[60-62].

Recent studies on animal models focusing on the peripheral nervous system after ESWT application to the musculo-skeletal system *in vivo* pointed specifically to reducing two substances involved in pain perception: calcitonin gene-related peptide and substance P[58,63,64]. The results of these mechanisms of action have resulted in ESWT being well used in treating myofascial pain.

There were some limitations to this study because of the study design and nature of tools. There is no “placebo” group, and the evidence is insufficient to disprove that either the patient’s expectation or interaction with the physiotherapist is the cause of all the improvements after both treatments. In addition, this study did not include a follow-up assessment. IASTM and ESWT are performed with MET, which may influence the outcome. Future studies will be required to study the effect of applying IASTM and ESWT without other techniques that may influence the outcome.

CONCLUSION

Patients with MPS benefit from IASTM and ESWT combined with MET to reduce pain and improve PPT.

ARTICLE HIGHLIGHTS

Research background

Active myofascial trigger points (MTrPs), commonly occurring in the upper region of the upper trapezius (UT), can be a significant source of neck, shoulder, upper back, and headache pain. This can negatively impact daily routine functioning, work-related productivity, and overall quality of life. With the rising prevalence of musculoskeletal pain and disability, it is critical to identify the most effective interventions to improve patient outcomes. This will reduce the societal burden.

Research motivation

Instrument assisted soft tissue mobilization (IASTM) and extracorporeal shock wave therapy (ESWT) are two treatment methods for MTrPs. Each method was tested independently and compared to another modality. To the author's knowledge, this is the first study to compare IASTM *vs* ESWT on MTrPs of the UT.

Research objectives

This study compared the effects of IASTM *vs* ESWT in patients with UT MTrPs. These findings are critical in guiding the therapist in selecting treatment methods based on availability, cost, therapist experience, and patient preference.

Research methods

Forty patients (28 females and 12 males) with active TrP in the UT muscle were randomly assigned to one of two equal groups (A and B). Group A received IASTM, while group B received ESWT. Each group received treatment twice a week for 2 weeks. Both groups received muscle energy technique for the UT muscle. Patients were assessed twice (pre-treatment and post-treatment) for pain intensity using the visual analog scale and pain pressure threshold (PPT) using a pressure algometer. A paired *t*-test was used to compare the pre-treatment and post-treatment mean values of all variables within both groups. For comparing all the dependent variables pre-treatment and post-treatment between both groups, we used an independent *t*-test. The significance level of a *P* value of ≤ 0.05 was considered statistically significant with a 95% confidence interval.

Research results

In group A (treated with IASTM) as well as in group B (treated with ESWT), there were significant differences between pre-treatment and post-treatment for pain intensity of TrP1 and TrP2 ($P = 0.0001$) and PPT for TrP1 and TrP2 ($P = 0.0002$ and $P = 0.0001$, respectively). There were no significant differences for pain intensity for TrP1 ($P = 0.9$), pain intensity for TrP2 ($P = 0.76$), PPT for TrP1 ($P = 0.09$), and PPT for TrP2 ($P = 0.91$) when comparing the post-treatment mean values between both groups.

Research conclusions

IASTM and ESWT are effective methods for treating pain and PPT in patients with UT muscle TrPs. However, there is no statistically significant difference between the two methods.

Research perspectives

Future research will be required to investigate the effect of only using IASTM and ESWT without other techniques that may influence the outcome.

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FOOTNOTES

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Country/Territory of origin: Egypt

ORCID number: Nourhan Elsayed Shamseldeen 0000-0003-0704-7445; Mohammed Moustafa Aldosouki Hegazy 0000-0002-5725-3135; Nesreen Fawzy Mahmoud 0000-0002-2880-4639.

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Isolated lateral leg compartment syndrome: A case report

Majd M Alrayes, Mohammad Alqudah, Walaa Bani Hamad, Mohamed Sukeik

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Majd M Alrayes, Department of Trauma and Orthopedics, Dammam Medical Complex, Dammam 32210, Saudi Arabia

Mohammad Alqudah, Mohamed Sukeik, Department of Trauma and Orthopaedics, Dr. Sulaiman Al-Habib Hospital, Khobar 34423, Saudi Arabia

Walaa Bani Hamad, Department of Radiology, Dr. Sulaiman Al-Habib Hospital, Khobar 34423, Saudi Arabia

Corresponding author: Mohamed Sukeik, FRCS (Ed), MD, Surgeon, Department of Trauma and Orthopaedics, Dr. Sulaiman Al-Habib Hospital, King Salman Bin Abdulaziz Road, Khobar 34423, Saudi Arabia. msukeik@hotmail.com

Abstract

BACKGROUND

Acute leg compartment syndrome is a well-known orthopedic emergency associated with potentially devastating consequences if not treated immediately. Multiple compartments are usually involved with a clear history of trauma and classic symptoms and signs. However, isolated lateral leg compartment syndrome is relatively rare and is often misdiagnosed due to the atypical presentation of no trauma and the lack of pathognomonic signs.

CASE SUMMARY

A 31-year-old male patient presented to our emergency room with excruciating left calf pain and inability to mobilize one-day after participating in a football match despite no clear history of preceding trauma. The patient went to another hospital before presenting to us where he was diagnosed to have a soft tissue injury and was discharged home on simple analgesics. On clinical examination, the left leg showed a tense lateral compartment with severe tenderness. The pain was aggravated by dorsiflexion and ankle inversion. Neurovascular examination of the limb was normal. We suspected a compartment syndrome but as the presentation was atypical and an magnetic resonance imaging (MRI) was readily available in our institution, we immediately performed an MRI and this confirmed a large hematoma in the lateral compartment with a possible partial proximal peroneus longus muscle tear. The patient was taken immediately for an emergency open fasciotomy. The patient is now 18 mo postoperatively having recovered completely and engages fully in sports with no restrictions.

CONCLUSION

Atypical presentation due to the lack of pathognomonic signs makes the diagnosis of isolated lateral leg compartment syndrome difficult. Pain on passive inversion

and dorsiflexion and weak active eversion may be suggested as sensitive signs.

Key Words: Isolated; Lateral compartment; Peroneal compartment; Atraumatic compartment syndrome; Case report

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Core Tip: Atraumatic isolated lateral leg compartment syndrome is rare and constitutes a diagnostic challenge due to the atypical presentation and lack of pathognomonic signs. It should be considered even in the context of atraumatic events. Pain on passive inversion and dorsiflexion and weak active eversion may be suggested as sensitive signs. Drop foot is a delayed presentation as a result of deep peroneal nerve involvement. A high index of clinical suspicion is the key to early diagnosis and timely surgical intervention.

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INTRODUCTION

Compartment syndrome of the leg is a well-known orthopedic emergency. It usually involves the anterior compartment of the leg or multiple compartments. However, isolated lateral (also known as peroneal) leg compartment syndrome is rare and may be caused by a traumatic or atraumatic (exertional) event[1,2]. In these cases, the peroneus longus muscle is typically affected and the accompanying hematoma is presumed to be the reason for the intracompartmental pressure rise[3]. Early diagnosis can be challenging especially in atraumatic events due to the atypical presentation. Hereby, we present a case of an isolated lateral leg compartment syndrome in the context of an atraumatic event. Additionally, we performed a comprehensive review of all reported cases of acute atraumatic isolated lateral leg compartment syndrome.

CASE PRESENTATION

Chief complaints

A 31-year-old male patient with no past medical history presented to our emergency room (ER) with severe left calf pain and inability to walk after participating in a football game the preceding day despite no clear history of trauma.

History of present illness

The patient went to another hospital on the same day of the injury and was diagnosed to have a soft tissue injury and got reassured and discharged home on simple analgesics. The following day, the patient presented to our hospital as the pain was worsening and became intolerable.

Physical examination

On examination, the patient was in excruciating pain, his vitals were normal, and his left leg showed a tense lateral compartment with severe tenderness. The overlying skin was normal, and no bullae were seen. The pain was aggravated by dorsiflexion and ankle inversion. Distal pulses were intact, and the neurological status was normal.

Laboratory examinations

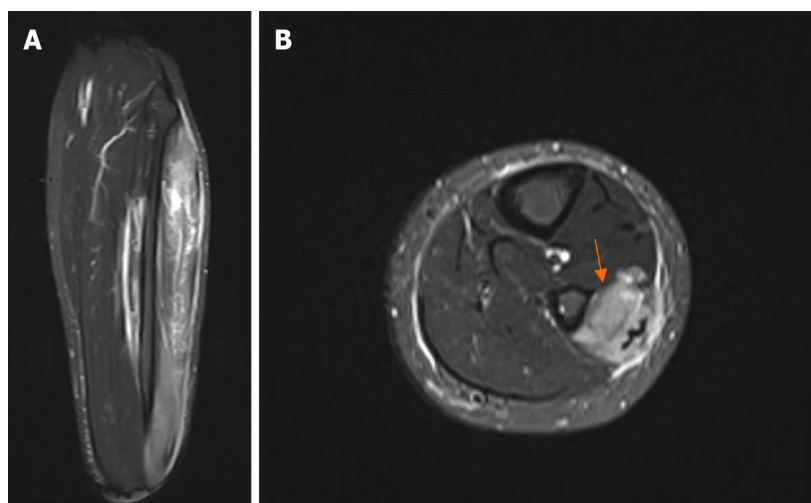
Laboratory tests were normal.

Imaging examinations

X-rays were normal. As magnetic resonance imaging (MRI) is readily available at our institution, it was performed immediately without any delay and showed diffuse abnormal signals over the lateral compartment indicating a large hematoma in the lateral compartment with a possible partial proximal peroneus longus muscle tear (Figure 1).

FINAL DIAGNOSIS

Acute isolated lateral leg compartment syndrome was diagnosed based on the clinical picture and the MRI findings which was further confirmed intraoperatively.



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Figure 1 Magnetic resonance imaging of the left leg. A: Coronal view demonstrating diffuse abnormal signals over the left lateral compartment; B: Axial view, showing possible proximal partial tear of the peroneal muscle as indicated by the orange arrow.

TREATMENT

The patient was taken directly to the operating room (OR) for an emergency open fasciotomy. In the OR, a longitudinal incision over the lateral compartment was made extending from the fibula down to the lateral malleolus. Immediate relief and bulging of the underlying muscles which were under significant pressure was noted. Most of the hematoma was seen at the proximal and distal thirds of the compartment and surrounding the peroneus longus muscle but there was no active bleeding seen. The entire compartment was successfully decompressed. The muscles appeared dusky in color and edematous and were slow to respond to stimulation with diathermy initially but towards the end of the operation, they recovered fully with no evidence of muscle damage or necrosis. A washout of the entire area was performed. As the skin was healthy and other compartments were not affected, the skin edges were approximated and the wound closed primarily but avoiding any tight closure. The patient recovered well and was discharged home the following day after the operation.

OUTCOME AND FOLLOW-UP

The patient is now 18 mo postoperatively having recovered completely and engages fully in sports with no restrictions.

DISCUSSION

Anterior or multiple compartments syndrome of the leg is common and well documented in the literature. However, acute isolated lateral leg compartment syndrome is rare with a variety of etiologies, presentations, symptoms, and signs reported in the literature. Hence, we performed a comprehensive literature review using PubMed to summarise all reported cases. The following keywords were searched: [(lateral compartment) OR (peroneal compartment)] AND (isolated compartment syndrome). The relevant literature was carefully studied and the results were summarized in Table 1. Forty-seven papers were identified but only 12 were relevant and thus included.

Acute compartment syndrome commonly occurs shortly after substantial trauma in long bone fractures[4,5]. However, it could also arise as a result of minimal trauma or atraumatic events[2]. Isolated lateral leg compartment syndrome has been linked to atraumatic events and atypical presentations in 12 papers reporting 14 cases. Two interesting cases have linked atypical events to the development of isolated lateral compartment syndrome of the leg; wearing high heels without any obvious history of trauma[6] and using excessively tight compression stockings for DVT prophylaxis during surgery[7]. Additionally, other preceding events reported include playing football[2,8-12], basketball[9], running[13], dancing[14], and forced marching[15]. Hypothetically, any reduction of the compartment volume or increase in the amount of fluid present inside the compartment will lead to an elevation of the osseofascial compartment pressure which may result in reduction of the perfusion gradient across tissue capillaries. This leads to cellular anoxia and muscle ischemia resulting in the development of compartment syndrome[4,16]. The incidence is believed to be greatest in young men who have a larger muscle mass at this age contained within the restricted fascia[5,17]. This goes along with what we found in our review in which the mean age of the cases at presentation was 27 years and most cases occurred in males, with a male to female ratio of 7:1.

Table 1 A summary of the 12 included papers reporting on 14 cases of atraumatic isolated lateral leg compartment syndrome

Ref.	Age	Gender	Site	Presentation	Preceding event	Comorbidities	Intercompartmental pressure	Management	Other
[6]	Mid 30s	F	R	Atraumatic, painless ankle swelling and footdrop 1 d prior to presentation	Wearing high heels, no history of trauma	Obese, bipolar on lithium	Lateral compartment pressure 92 mmHg	Anterior and lateral compartment fasciotomy; significant muscle necrosis lateral compartment	-
[7]	44	M	R	Severe pain lateral aspect of the lower extremity and loss of protective sensation over the dorsolateral aspect of the foot	Excessively tight compression stockings used for DVT prophylaxis post surgery	Obesity, atrial fibrillation, congestive heart failure, obstructive sleep apnea, and obesity	Lateral compartment pressure 122 mmHg	Lateral compartment fasciotomy and delayed closure with a split-thickness skin graft	-
[9]	21	M	R	Mild pain in the lower leg and drop foot	Basketball, no history of trauma	Medically free	Anterior compartment pressure 42; lateral compartment pressure 120 mmHg	Lateral compartment fasciotomy closed primarily then reopened next day due to recurrent pain and raised intercompartmental pressure underwent delayed closure after 14 d	Peroneus longus found completely detached from its proximal origin
	16	M	R	Swelling, pain and numbness in the leg	Football, no history of trauma	Medically free	Lateral compartment pressure 100 mmHg, anterior compartment pressure 42 mmHg	Lateral compartment fasciotomy, with delayed closure	Peroneus longus found completely detached from its proximal origin
[2]	34	M	R	Dorsal foot numbness and burning pain, excruciating lateral leg pain and persistent but not severe swelling of the leg	Football, no history of trauma	Medically free	Lateral compartment pressure 130 mmHg	Lateral compartment fasciotomy	Peroneus longus partially exhibited a burgundy discoloration
[13]	33	M	R	Excruciating lateral leg pain, numbness and tingling dorsum of the foot	Noncontact injury with forceful inversion of the ankle while running on uneven ground	Not reported	Lateral compartment pressure 120 mmHg	Lateral compartment fasciotomy with delayed closure	Hematoma at the musculotendinous junction of the peroneus longus
[1]	27	M	L	Pain and tightness along the lateral aspect of the leg and swelling; passive foot inversion produced significant pain in the ankle and lateral leg	Noncontact inversion ankle injury during practice	Not reported	Lateral compartment pressure 115 mmHg anterior compartment pressure 5 mmHg	Lateral compartment fasciotomy	Peroneus longus belly initially dusky in color and edematous but no evidence of muscle rupture or hematoma
[12]	25	M	L	Lateral ankle pain rapidly increasing in intensity and spreading to the leg, lateral malleolus edema and severe pain with foot inversion and weakness on foot eversion	Football, inversion ankle injury	Not reported	Lateral compartment pressure > 130 mmHg	Lateral compartment fasciotomy	Partial muscle necrosis with proximal rupture of the peroneus longus muscle
[15]	21	M	R	Severe lateral leg pain, decreased	Two-mile mark of a 12-	Not reported	Lateral compartment pressure > 130 mmHg	Lateral compartment fasciotomy with	-

				range of motion of the foot and paresthesias over the dorsum of the foot, peroneal pain on passive inversion of the subtalar joint	mile forced-march			delayed closure	
	24	M	L	Pain and tenderness over the lateral aspect of the leg, tense peroneal compartment and pain on passive stretch of the peroneal muscles with inversion of the foot. Reduced sensation to pin-prick in the first web space	18-km cross-country march	Not reported	Lateral compartment pressure 130-140 mmHg	Lateral compartment fasciotomy with delayed closure	-
[10]	17	M	R	Anterolateral leg pain, swelling and numbness in the lateral leg and dorsal foot	Football practice, no history of trauma	Medically free	Lateral compartment pressure 44 mmHg anterior compartment pressure 26 mmHg	Anterolateral fasciotomy; lateral compartment was under severe pressure, vac pump applied, returned to OR after 2 d	At 2 d, peroneus longus necrotic and noncontractile with tendon detachment proximally
[11]	29	M	R	Extreme pain, paresthesia and decreased sensation in the second web space with extreme tenderness over the proximal lateral compartment	Touch football, insignificant twisting of the knee while warming up	Not reported	Lateral compartment pressure 55 mmHg Anterior compartment pressure 20 mmHg	Lateral compartment fasciotomy with delayed closure	Ischemic muscles in the lateral compartment and small bleeding vessel in the mid portion of the muscle
[14]	25	F	R	Pain distal to the fibular head, difficulty to walk, calf swelling and spasms	Inversion ankle injury while dancing	Medically free	Lateral compartment pressure 70 mmHg	Lateral compartment fasciotomy with delayed closure	50% of the lateral compartment muscles necrotic
[8]	28	M	R	Pain and paresthesia, tense swelling in the lateral compartment with extreme pain to passive stretching of the compartment	Football, no history of injury	Medically free	Lateral compartment pressure 122 mmHg	Lateral compartment fasciotomy	-

DVP: Dose-volume parameter; OR: Operating room.

Acute compartment syndrome is usually diagnosed clinically with pain, pallor, paresthesia, paralysis, and pulselessness as classic symptoms and signs[4,18]. However, the diagnosis of acute isolated lateral leg compartment syndrome in specific is quite challenging due to the lack of characteristic clinical symptoms and signs. Thus, it is often missed or delayed[9]. Persistent or worsening pain following a minor injury or exertion is often described and the initial physical findings are usually nonspecific. A marked increase in pain with passive inversion, dorsiflexion, and weak active eversion of the ankle have been commonly reported among most cases and may be suggested as sensitive signs for the diagnosis of the lateral compartment syndrome of the leg. In cases that present late or where the diagnosis is initially missed, there is often common and/or deep peroneal nerve palsy which causes paresthesia or if severe enough leads to foot drop as reported by Hiramatsu *et al*[9].

The use of other diagnostic methods besides good history and physical examination such as intracompartmental pressure measurement may be beneficial when the physical exam is equivocal or in unconscious patients[4,18]. In our review, all authors have measured the compartmental pressures of the different compartments to confirm the diagnosis, and the lateral compartment pressure was particularly elevated with a mean pressure of 106 mmHg among the 14 cases. In our case, we did not measure the intracompartmental pressures as the clinical picture of the patient alongside the MRI report were sufficient to decide that surgery is warranted. However, we agree that measuring the pressures would have confirmed the diagnosis and this could be considered as a potential limitation in our workup despite no delays to surgery.

or resultant adverse outcomes.

Prompt diagnosis and immediate surgical decompression of compartment syndrome are necessary to prevent permanent impairment[19]. As seen in the majority of cases reviewed in the literature, partial or complete injury to the peroneus longus muscle and the subsequent hematoma were the culprit for the isolated elevation of the lateral compartment pressure of the leg[3]. Interestingly, none of the cases included in the literature review reported any history of trauma or direct injury[1,2,14,15,6-13]. Hence, we presume that the pathophysiological process causing the detachment of the proximal origin of the peroneus longus muscle is an overuse or repetitive extensive eccentric muscular contraction against the floor during inversion of the subtalar joint. Interestingly, despite the late presentation of our patient at 24 h after playing football, he recovered well with no residual deficit. This may be attributed to him developing gradual increased pressures at the time when he presented to the other hospital and over the following hours prior to attending our hospital but reaching the threshold to having significant compartment syndrome only recently prior to his presentation to our ER.

Other principles of acute compartment syndrome management can be applied in isolated lateral compartment syndrome as well such as debridement of all nonviable tissues, delayed surgical site closure if needed, close postoperative monitoring, and pain control.

CONCLUSION

Acute isolated lateral leg compartment syndrome is rare and constitutes a diagnostic challenge. It can be missed easily due to the atypical presentation and the lack of diagnostic symptoms and signs. It should be considered even in the context of atraumatic events. Pain on passive inversion and dorsiflexion and weak active eversion may be suggested as sensitive signs. Drop foot is a delayed presentation as a result of deep peroneal nerve involvement. A high index of clinical suspicion is the key to early diagnosis and timely surgical intervention.

FOOTNOTES

Author contributions: Alrayes MM and Alqudah M contributed to manuscript writing, and literature search; Bani Hamad W contributed by providing and reviewing the radiological content; Sukeik M was the primary surgeon of the case and contributed to scientific content, paper revision, editing, and overall supervision.

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Country/Territory of origin: Saudi Arabia

ORCID number: Mohamed Sukeik [0000-0001-9204-9757](https://orcid.org/0000-0001-9204-9757).

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