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Xiu-Xia Song, Vice Director
World Journal of Orthopedics
Room 903, Building D, Ocean International Center,
No. 62 Dongsihuan Zhonglu, Chaoyang District,
Beijing 100025, China
Telephone: +86-10-59080039
Fax: +86-10-85381893
E-mail: editorialoffice@wjgnet.com
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EDITORIAL

Lateral elbow tendinopathy: Evidence of physiotherapy management

Stasinopoulos Dimitrios

Stasinopoulos Dimitrios, Physiotherapy Program, Department Health Sciences, School of Sciences, European University of Cyprus, 1516 Nicosia, Cyprus

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Correspondence to: Dr. Stasinopoulos Dimitrios, PhD, Physiotherapy Program, Department Health Sciences, School of Sciences, European University of Cyprus, 6, Diogenes Str. Engomi, 1516 Nicosia, Cyprus. d.stassinopoulos@euc.ac.cy
Telephone: +357-22-713044

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Abstract

Lateral elbow tendinopathy (LET) is a common musculoskeletal/sports injury. A plethora of physiotherapy techniques has been proposed in the management of LET. The exercise programme is the most common treatment in the management of LET. The optimal protocol of exercise programme is still unknown. The effectiveness of the exercise programme is low when it is applied as monotherapy. Therefore, exercise programme is combined with other physiotherapy modalities such as soft tissue techniques, external support, acupuncture, manual therapy and electrotherapy, in the treatment of LET. Future research is needed to determine which treatment strategy combined with exercise programme will provide the best results in LET rehabilitation.

Key words: Tennis elbow; Isometric exercises; Physical therapy; Electrotherapeutic modalities; Eccentric training; Stretching; Physical modalities; Manipulation; Lateral epicondylitis; Lateral elbow tendinopathy

Core tip: An effective treatment approach in the management of lateral elbow tendinopathy (LET) is an exercise programme. Exercise programme improves patients' symptoms but the ideal exercise protocol for the management of LET is still under investigation. Exercise programme as a sole treatment approach does not respond positively in many patients with LET. Thus, physiotherapists combine exercise programme with other physiotherapy techniques like electrotherapy, manual therapy, taping/bracing and acupuncture. Research to determine which treatment approach combined with exercise programme will provide the best results in the management of LET is needed.

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Lateral epicondylalgia, lateral epicondylosis, tennis elbow and/or lateral epicondylitis are inappropriate

clinical diagnostic terms due to pathophysiological, anatomical aetiological and factors[1]. Therefore, lateral elbow tendinopathy (LET) is the most appropriate clinical diagnostic term. LET is related to sport or arm work pain disorder. It is defined as a cause of pain in the lateral epicondyle[2] that failed healing tendon response rather than inflammatory or may be degenerative[3]. LET is characterized by the absence of inflammatory cells, glycosaminoglycans and proteoglycans, disorganized and immature collagen vascular hyperplasia, the increased presence of fibroblasts[4]. The most commonly affected structure is the origin of the extensor carpi radialis brevis[4]. LET is common between 30 and 60 years of age, the disorder appears to be more severe and of longer duration in females[3,5] and the most commonly affected arm is the dominant arm[2,6].

The main complaints of LET patients are decreased function and pain[2,3]. Both symptoms affect daily activities. Pain can be reproduced with one of the following ways: (1) palpation on the facet of the lateral epicondyle; (2) with the elbow in extension, resisted wrist extension and/or resisted middle-finger extension; and (3) gripping activities[2,3,7]. The Patient-Rated Tennis Elbow Evaluation questionnaire has been translated and culturally adapted into German[8], Italian[9], Swedish[10] and Greek[11] and provides a quick, standardized, and easy quantitative description of functional disability and pain in LET patients[8].

Although the diagnosis of LET is not difficult, the proper management is unknown. Physiotherapy is usually recommended for the management of LET[7,12]. A plethora of physiotherapy techniques, electrotherapeutic and non-electrotherapeutic modalities, has been recommended for the management of LET[2,3,7,12-15]. The aim of these treatments is the same, improving function and reducing pain, but the theoretical mechanism of action of these treatments is different. Therefore, more research is needed to find out the most effective treatment approach in LET patients since this variety of treatment techniques suggests that the most proper treatment technique is not known[2,3].

One of the most common physiotherapy treatments for LET is a supervised or in clinic exercise programme[2,3,7,12,14]. Malliaras *et al*[16] concluded that instead of eccentric loading in lower limb tendinopathy, clinicians should consider eccentric-concentric loading alongside. A Heavy Slow Resistance (HSR) program is recommended in the management of lower limb tendinopathy for young active people[17,18]. There are not similar studies for the upper limb. A similar loading program may be beneficial for the management of LET[2,3,7,12,14].

Alfredson *et al*[19] were first proposed the eccentric training of the injured tendon, the most commonly used conservative technique in the management of tendinopathy. Systematic review[20,21] and RCT[22] favor eccentric over other types of contractions in the management of LET, but using only eccentric training of the injured tendon is not effective treatment approach for some patients with upper and lower limb tendinopathies[23]. Thus, eccentric contractions of the injured tendon is combined with stretching exercises, especially static, of the injured tendon in the rehabilitation of tendinopathies as it was proposed by Stanish *et al*[24]. The patients in the Stanish exercise program, perform a five-steps program. A general, whole-body warm-up exercise is the first step. Static stretching exercises for the injured tendon are carried out in the second step. Next, the eccentric training is carried out once daily (3 sets of 10 repetitions) for six weeks and after six weeks, the patients are carried out three times per week for six more weeks 3 sets of 10 repetitions. Discomfort, or pain, is experienced in the last set of 10 repetitions. The eccentric training is described in detailed in the Stanish *et al*[24] article. Every treatment ends with the same stretching exercise as described in the second step. Ice on the «injured » tendon for about 5-10 min after the program is used by the patients. There are not studies to support the efficacy of the Stanish exercise protocol in LET patients.

It was stated by Martinez-Silvestrini *et al*[25] that isometric contraction, which would be more beneficial than eccentric contraction in LET because it is often related to forceful grip activities. Recently, isometric training has been recommended to decrease and manage the pain of tendon increasing the strength at the angle of contraction without producing inflammatory signs[26]. Forty five second isometric mid-range quadriceps exercise reduced the pain of patellar tendon for 45 min post exercise[26]. The dosage of isometric contractions in the present is based on clinical experience[26-28] and their effect on LET pain requires further research. Therefore, it was hypothesized that the simultaneous use of these two kinds of contractions (isotonic and isometric) and static stretching exercises will further enhance the analgesic effect of contractions in the treatment of LET, increasing the arm function[29]. However, the optimal protocol of exercise training needs to be investigated although the supervised exercise program is more effective than the home exercise program[30].

Exercise program is rarely delivered as a treatment in isolation in the management of LET[2]. An exercise program is usually combined with a range of physical therapy modalities. Furthermore, many manual therapies for the management of LET have been advocated, but the evidence to support the effectiveness of manual therapy in the management of tendinopathy is minimal[31]. The most common manipulative techniques for the treatment of LET are Cyriax manual technique, Mulligan manipulation, mobilization of the neck, manipulation of the wrist and radial neural mobilization are[32]. Manual therapy may increase grip strength and reduce pain immediately following treatment, but the evidence of any long-term clinical effects for manual therapy alone is insufficient[2,3,7,12,14].

Treatment focusing on trigger points reduces pain and improves function in LET patients[33]. A solid

conclusion will be formulated when high and large quality RCTs are carried out[2]. Myofascial pain management methods such as deep transverse friction, low level laser, dry needling, *etc.*, should also be evaluated[2]. The additional effect of myofascial methods, it would be interesting to determine on exercise program or other treatment methods used in management of LET[2,12,14].

Electrotherapeutic modalities such as low level laser, transcutaneous electrical nerve stimulation, extracorporeal shockwave therapy, pulsed electromagnetic field therapy therapeutic, ultrasound and iontophoresis are commonly used to manage LET[7,12,14,15,29,34]. Well-conducted trials are needed to determine the effectiveness of the above reported modalities in the management of LET. It is believed that the exercise training alone in the rehabilitation of LET is less effective therapeutic approach than the combination of exercise training with electrotherapeutic modality/ies[2,3,7,12,14,15].

External support such as bracing/taping is recommended for the management of LET[2]. The evidence for the effectiveness of bracing/taping in the improvement of function and reduction of pain is conflicted[35]. There was no compelling evidence that any one kind of bracing/any type of taping is superior to another in the short term, or that adding an external support to another treatment provides any additional benefit[7,12].

At the end of the treatment and/or at the short-term follow up acupuncture is an effective LET treatment[2,7,12]. The pathology of tendinopathy does not reverse using acupuncture, but it improves the signs of LET, reducing pain and increasing the function, but it[36]. To draw definite conclusions about the effectiveness of acupuncture, more research with well - designed clinical trials are needed.

Finally, the most promising treatment approach in the management of LET is the exercise training but more research is needed to investigate the optimal protocol of exercise training. When the exercise program is applied as part of the rehabilitation process its effectiveness is higher than it is applied as monotherapy[2,7,12,37]. More research to find out which treatment approach combined with exercises is needed to provide the best results in the management of LET.

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ORIGINAL ARTICLE

Basic Study

Antibiotic-loaded phosphatidylcholine inhibits staphylococcal bone infection

Jessica Amber Jennings, Karen E Beenken, Robert A Skinner, Daniel G Meeker, Mark S Smeltzer, Warren O Haggard, Karen S Troxel

Jessica Amber Jennings, Warren O Haggard, Department of Biomedical Engineering, University of Memphis, Memphis, TN 38152, United States

Karen E Beenken, Daniel G Meeker, Mark S Smeltzer, Department of Microbiology and Immunology, University of Arkansas Medical Sciences, Little Rock, AR 72205, United States

Robert A Skinner, Jamesport, NY 11947, United States

Karen S Troxel, Zimmer Biomet, Warsaw, IN 46581, United States

Author contributions: Jennings JA planned and performed the majority of experiments and analyzed the data; Beenken KE and Smeltzer MS planned and assisted with animal experiments; Skinner RA and Meeker DG performed surgical procedures; Skinner RA assisted with histological analysis; Haggard WO and Troxel KS assisted with materials formulation and planning experiments.

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Animal care and use statement: Study protocols were approved by the University of Arkansas for Medical Sciences IACUC and all appropriate measures were taken to minimize pain and discomfort.

Conflict-of-interest statement: Studies were funded and by Biomet, LLC. Karen S Troxel, PhD, is an employee of Zimmer Biomet.

Data sharing statement: Technical appendix, statistical analysis, and dataset available from the corresponding author at jjnnings@memphis.edu.

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Correspondence to: Jessica Amber Jennings, PhD, Assistant Professor, Department of Biomedical Engineering, University of Memphis, 330 Engineering Technology Building, Memphis, TN 38152, United States. jjnnings@memphis.edu
Telephone: +1-901-6782283
Fax: +1-901-6785281

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Abstract

AIM: To test antibiotic-loaded coating for efficacy in reducing bacterial biofilm and development of osteomyelitis in an orthopaedic model of implant infection.

METHODS: Phosphatidylcholine coatings loaded with 25% vancomycin were applied to washed and sterilized titanium wires 20 mm in length. A 10 mm segment was removed from rabbit radius (total = 9; 5 coated, 4 uncoated), and the segment was injected with 1×10^6 colony forming units (CFUs) of *Staphylococcus aureus* (UAMS-1 strain). Titanium wires were inserted through

the intramedullary canal of the removed segment and into the proximal radial segment and the segment was placed back into the defect. After 7 d, limbs were removed, X-rayed, swabbed for tissue contamination. Wires were removed and processed to determine attached CFUs. Tissue was swabbed and streaked on agar plates to determine bacteriological score.

RESULTS: Antibiotic-loaded coatings resulted in significantly reduced biofilm formation (4.7 fold reduction in CFUs; $P < 0.001$) on titanium wires and reduced bacteriological score in surrounding tissue (4.0 ± 0 for uncoated, 1.25 ± 0.5 for coated; $P = 0.01$). Swelling and pus formation was evident in uncoated controls at the 7 d time point both visually and radiographically, but not in antibiotic-loaded coatings.

CONCLUSION: Active antibiotic was released from coated implants and significantly reduced signs of osteomyelitic symptoms. Implant coatings were well tolerated in bone. Further studies with additional control groups and longer time periods are warranted. Antibiotic-loaded phosphatidylcholine coatings applied at the point of care could prevent implant-associated infection in orthopaedic defects.

Key words: Biofilm; Implant; Drug delivery coating; Antibiotic; Orthopaedic infection

Core tip: We report infection preventative results of a novel antibiotic-loaded coating in a severe contaminated model of orthopaedic infection. Phosphatidylcholine coatings loaded with 25% vancomycin, which can be applied to implants immediately prior to implantation, significantly reduced staphylococcal adherence to intramedullary titanium wires in rabbits. Reduction in bacterial load on implants and in tissue for antibiotic-loaded coatings accompanied reduction in swelling and pus formation. Mild inflammatory responses were noted with coated implants compared to uncoated infected controls. This preliminary short term study demonstrates the clinical potential of these broadly applicable coatings and the need for further characterization and development.

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INTRODUCTION

Biofilm formation on implants continues to be a cause of orthopaedic infection[1,2]. While the rate of infection in some orthopaedic implants has been reported to range from 1%-10%, in some complex orthopaedic trauma requiring percutaneous devices the rate of infection may approach 30%[3-5]. Protection of orthopaedic implants from contamination may be more successful through prevention of biofilm formation. Because microbial cells within a biofilm are less metabolically active and shielded to some degree by exopolymeric substance, there is a high concentration of persister cells with resistance to commonly used antibiotics within biofilm[6-9]. Standard treatment practices of prophylactic systemic administration of antibiotics may not be sufficient to inhibit or treat biofilm-based infections partly due to poor vascularity in injured tissue and partly due to the increased concentrations of antimicrobials required for elimination of biofilm[7,10,11].

Local delivery devices have been developed to achieve high concentrations of antibiotic within the potentially contaminated tissue to target biofilm[12-14]. However, some have limitations in degradability, implant coverage, and antibiotic loading, including non-degradable polymethylmethacrylate bone cement beads[15], degradable calcium sulfate beads[16], sponge devices[17], and injectable hydrogels[18]. Local delivery coatings directly on the implant can protect the biomaterial from biofilm formation[19-21], but may require extensive prefabrication steps.

We previously described the biofilm inhibitory nature of phosphatidylcholine coatings loaded with antibiotics, both *in vitro* and *in vivo*[22]. When loaded with antibiotics, this coating applied at the point-of-care just prior to implantation was shown to reduce biofilm formation of *Staphylococcus aureus* (*S. aureus*) and *Pseudomonas aeruginosa*, as well as prevent biofilm formation in a polymicrobial model of contamination with both microorganisms. While proof of principle was established in a soft-tissue dorsal model of implant infection, for this study our primary question was whether antibiotic-loaded coatings could successfully prevent infection in a contaminated orthopaedic model.

MATERIALS AND METHODS

Study design

Coatings were fabricated by mixing 6 g of purified phosphatidylcholine (Phospholipon 90G, Lipoid GMB, Germany) with 2 g of vancomycin through a previously described process of warming and kneading powdered antibiotics until the mixture was uniform[22]. The mixture was loaded into open-ended syringes and sterilized by low dose (25 kGy) gamma irradiation.

Titanium wire 0.81 mm in diameter (Mcmaster Carr) was trimmed to 15 cm in length. Titanium wire was cleaned by washing with dish detergent, after which it was soaked in 20% nitric acid for 1 h. Wire was rinsed thoroughly in ultrapure water, sonicated in soapy water, and rinsed again three times in ultrapure water. Implants were separately packaged and autoclaved at

121 ℃ for 20 min for sterilization.

Animal model

Animal care and use statement: Study protocols were approved by the University of Arkansas for Medical Sciences Institutional Animal Care and Use Committee and all appropriate measures were taken to minimize pain and discomfort.

Nine New Zealand white rabbits were anesthetized with 1-2 cc of a xyalzine/ketamine mixture intramuscularly for a dose range of 3-7 mg/kg xylazine and 30-40 mg/kg ketamine. Rabbits were maintained on 0.5%-3% isoflurane administered by nose cone to produce surgical anesthesia and monitored by a veterinary technician. The right forelimb of each rabbit was shaved and prepped using a betadine scrub and rinsed with 70% ethanol. An incision was made on the anterior surface of the right forelimb through the epidermis, musculature, and fascia until the radius was exposed. A 1 cm mid-radial segment was be excised from the right forelimb using a miniature saw blade (Exakt, Oklahoma City, OK). The excised segment was then infected by inoculation of *S. aureus* [10 μL of 10^7 colony forming units (CFUs)/mL; UAMS-1 strain] directly into the intramedullary canal.

Animals were divided into two treatment groups: Wire with 25% vancomycin-loaded coating (n = 5) or non-coated controls (n = 4). During surgical procedures titanium wires in the coated group were coated by direct manual application of coating through the syringe applicator. Coated or control wires were inserted into the medullary canal of the infected segment immediately after inoculation. Approximately 5 mm of wire extended through the proximal end of the segment and was inserted into the medullary canal of the intact proximal bone. The segment was then replaced in the same orientation and the wound was closed with sutures.

Rabbits were euthanized after 7 d. Forelimbs were removed and imaged by X-ray, noting signs of inflammation and swelling. A swab of the soft tissue and bone exposed was taken to determine bacteriological score of surrounding tissue. The segment was removed for retrieval of the wire and placed in 10% neutral buffered formalin for further processing. The wire was rinsed in sterile phosphate buffered saline (PBS) and sonicated in 5 mL of PBS for enumeration of viable CFUs attached as biofilm. The remaining forelimb was also trimmed and fixed in formalin for histological characterization. Fixed tissue was decalcified in ethylenediaminetetraacetic acid and stained with hematoxylin and eosin as well as a modified Gram stain[23]. Images taken at 4 × magnification were scored by three independent blinded reviewers for severity of inflammatory response on a scale of 0-4.

Statistical analysis

Mann-Whitney nonparametric t tests in Sigma Plot were used to determine whether there were statistically significant differences in colony counts in coated wires compared to uncoated control wires. Mann-Whitney tests were also used to determine statistical differences in bacteriological score and histological scores. Using results of previous studies determining log fold reduction of CFUs in response to antimicrobials[24], an a priori power analysis was performed using Sigma Plot. Assuming a standard deviation of 1 unit in log-transformed CFU counts, 4 animals per group are required to have 80% power to detect a difference of 2.5 units between the control and each of the 4 experimental treatment groups at a significance level of 5%. The statistical methods of this study were reviewed by Jessica Amber Jennings of the University of Memphis.

RESULTS

After the 7 d implantation period, animals with uncoated implants were noted to have characteristics indicative of inflammation such as swelling (Figure 1), redness, and increased temperature, compared to those with implants coated with vancomycin-loaded phosphatidylcholine. Pus formation was evident in muscle tissue of several animals with uncoated wires.

Bacteriological scores confirmed that there were statistically significant reductions in bacteria recovered from surrounding tissue (P = 0.01) (Figure 2). CFU counts of *S. aureus* remaining as biofilm on Ti implants revealed that there were statistically fewer colonies retrieved from coated implants, 20 ± 21 CFUs *vs* 6.0 × 10^5 CFUs in the control group (P < 0.001) (Figure 3). Complete clearance of attached *S. aureus* biofilm was achieved in 40% of the coated wires *vs* 0% in the control group.

In histological specimens, evidence of inflammatory cell infiltration was evident in many of the control groups with confirmed bacterial presence, while inflammatory cell presence was minimal in the groups with vancomycin coating (P < 0.001) (Figure 4). Representative histological slides show severe infiltration of inflammatory cells in uncoated groups and evidence of Gram-positive staphylococci in the tissue surrounding the implant and in the cortical bone (Figure 5). Although some evidence of Gram-positive staphylococci was observed in the cortical bone of animals with antibiotic coated implants, the tissue surrounding the implant had minimal evidence of bacteria.

DISCUSSION

Successful function of orthopaedic implants can be threatened by infections, which are not always prevented by systemic antibiotic treatment[25-27]. Implant coatings are among the local drug delivery strategies that aim to prevent or treat colonization of implants with biofilm bacteria[21,28,29]. The naturally-derived material phosphatidylcholine has not been approved by the Food and Drug Administration (FDA) as a carrier of antibiotics,

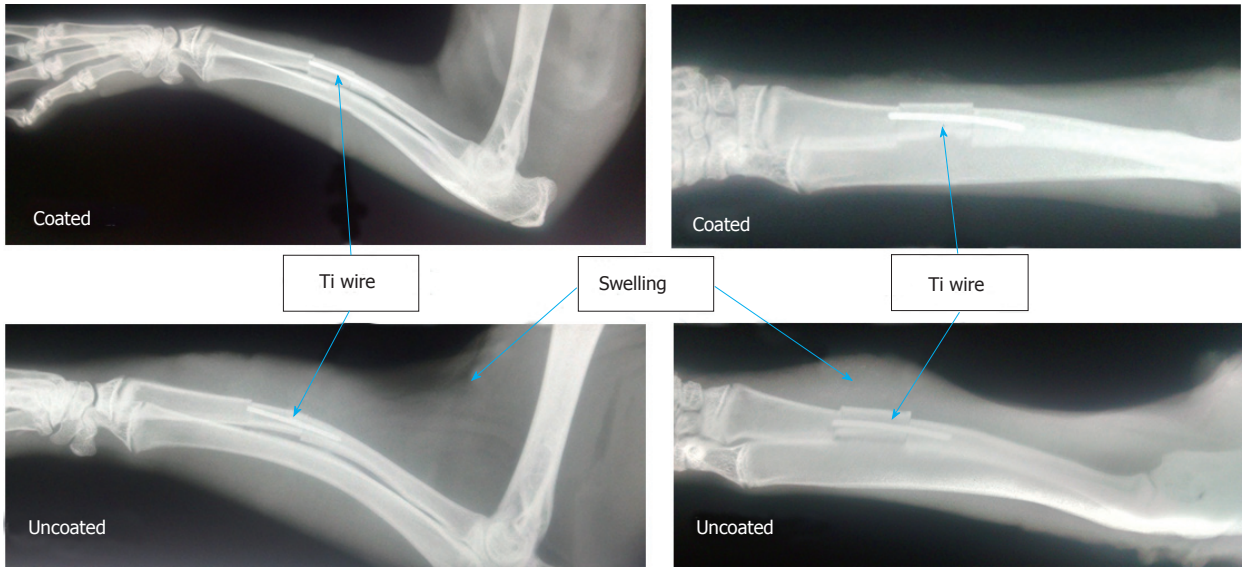

Figure 1 Representative radiographs from implant-associated osteomyelitis model after 7 d in antibiotic-coated group (top) and uncoated control group (bottom). Location of Ti wires and swelling in tissue surrounding implants are noted by arrows.

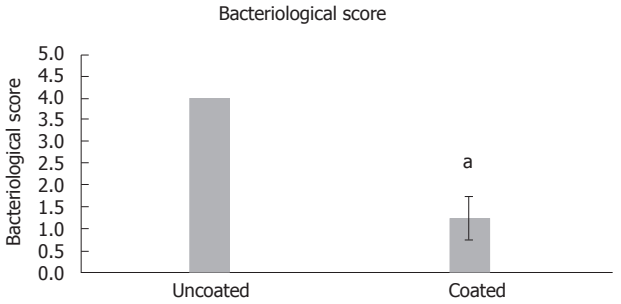

Figure 2 Graphical representation of bacteriological scores from surrounding tissue on a 0-4 point scale. Data is represented as mean ± SD. Statistically significant difference between groups was determined by Mann-Whitney Rank Sum test ($^aP < 0.05$).

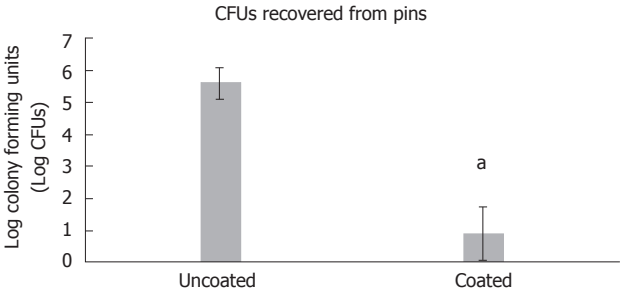

Figure 3 Graphical representation of log colony forming units retrieved from Ti wires. Data is represented as mean ± SD. Statistically significant difference between groups was determined by Mann-Whitney Rank Sum test ($^aP < 0.05$). CFUs: Colony forming units.

but is a component of FDA approved matrices for demineralized bone graft materials[30]. Confirming results of previous preliminary studies[22], this initial study of a novel antibiotic loaded coating further recommends the potential of the coating to prevent implant-associated osteomyelitis.

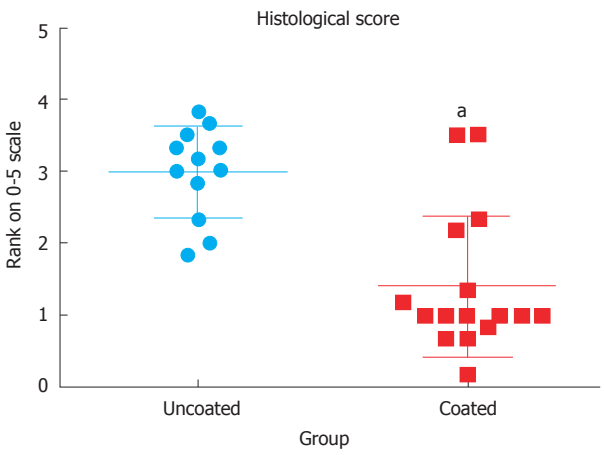

Figure 4 Plot of histological scores for uncoated and coated groups. Statistically significant difference between groups was determined by Mann-Whitney Rank Sum test ($^aP < 0.05$).

This study demonstrates significant reduction in contamination and progression of disease, though some bacteria were recovered from the cortical bone and observed in the Gram stains. Any remaining bacteria could potentially rebound and lead to osteomyelitis. We chose vancomycin as the first antibiotic to evaluate in this coated implant model due to the known susceptibility of this strain of bacteria[24]. We have demonstrated previously that the coating can be loaded with different antibiotics or combinations of antibiotics such as amikacin, although the release profile may vary based on solubility or other chemical properties of the antimicrobial[22]. In the context of preventing biofilm, vancomycin has lower efficacy than antibiotics such as daptomycin[24] though it is commonly used as an adjunctive therapy in local drug delivery devices or even sprinkled into a surgical site after implantation of

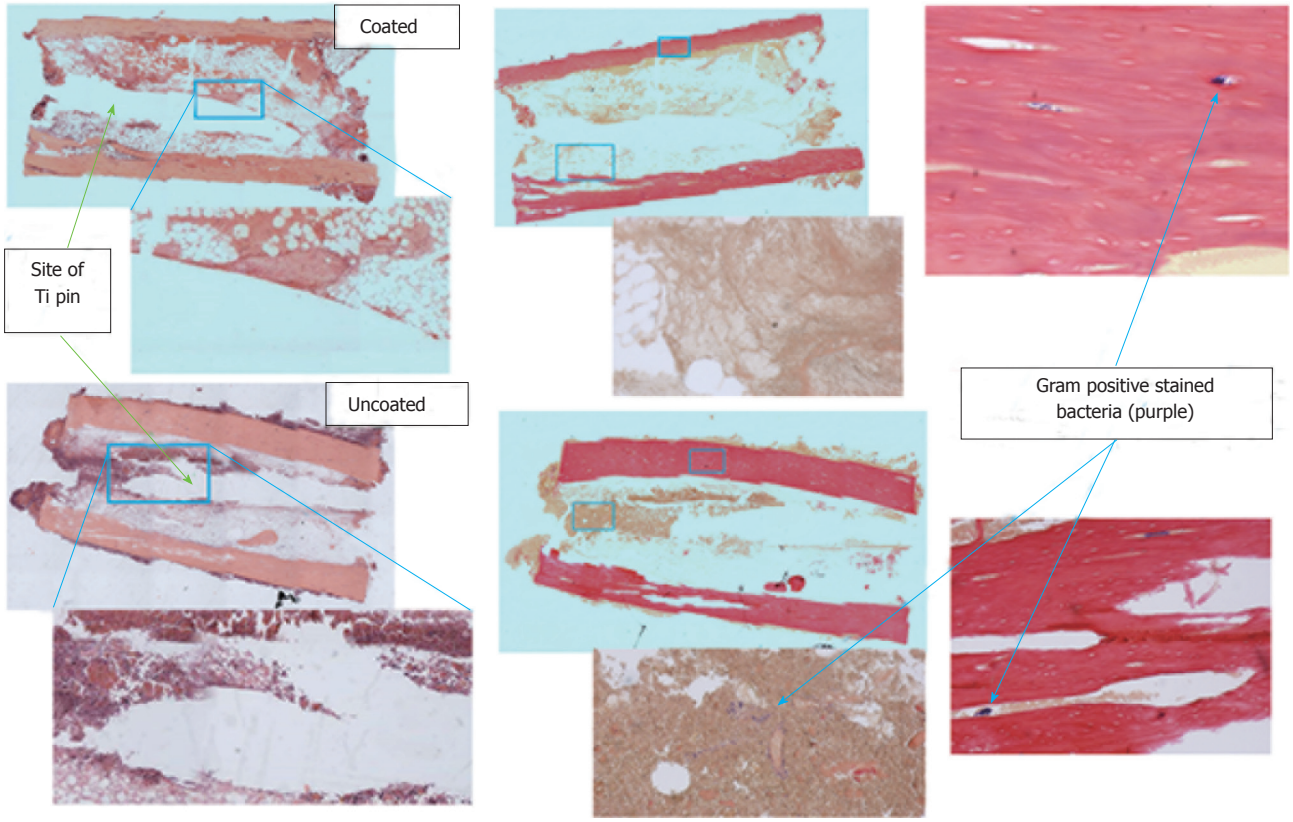

Figure 5 Photomicrographs of sections of decalcified bone stained with hematoxylin and eosin and the modified Gram stain at 4 × and 10 ×. Approximate areas of higher magnification are denoted by blue boxes. Areas where pin was removed and areas of visible staphylococci are marked with arrows.

orthopaedic devices[31-34]. An advantage of this coating is that it may provide clinicians with a choice of antibiotic- or antimicrobial-loaded coating based on patient assessment and risk evaluation. Recently, investigations into biofilm inhibitors such as cis 2-decenoic acid, D-amino acids, and farnesol have offered potential therapeutic options to specifically target biofilm[35-37]. The phosphatidylcholine coating could serve as delivery system for combined therapy with antibiotics and biofilm inhibitors, since additive and synergistic prevention of biofilm and bacterial growth have been demonstrated *in vitro*[38-42].

The results of this study confirm that the results of our previous *in vitro* and soft-tissue *in vivo* studies of this coating are applicable within an orthopaedic implant context. Inflammatory response was typical of normal infiltration of inflammatory cells during the healing process[43] and was reduced compared to when active infection was present. During implantation procedures used in this study, the manual application of coating was sufficient to retain antibiotic for local release. *In vitro* simulations of implant scenarios or alternative orthopaedic models[44-46] may be useful in determining coating retention during intra-cortical implantation procedures such as fixation nails or bone screws. The lipid-based coating can be applied to different surfaces, though differences in adhesion to the surface and elution from different surfaces have not been fully characterized. Future studies will evaluate the properties of the coatings on different surfaces other than metal commonly used in orthopaedic applications, such as polyether ether ketone polymer or hydroxyapatite ceramic biomaterials.

Our results should be interpreted in light of the limitations of this preliminary study. A short duration with a small number of samples in each group was selected for this initial evaluation of only 7 d. For this pilot study, we powered the study to detect large differences in remaining bacteria, but this study should be repeated for robust results. While this model has been used previously and confirmed to lead to osteomyelitic infection without an implant[47,48], previous studies have monitored disease progression and treatment of existing infection after 3 or more weeks post-inoculation. Since the ulnar bone is still intact, the implant does not provide stability to the defect but provides a surface on which biofilm can form, so that animals return to normal activity hours after recovery without the need for fixation devices. Since the focus of this study was prevention of osteomyelitis in an implant-associated infection model, we selected an early time point at which histological and microbiological differences could still be observed[49]. Further studies expanding on these preliminary results should include increased animal numbers and longer durations of implantation, as well as non-contaminated control groups for comparison.

The development of this model has been refined so the strain of *S. aureus* and the amount of CFUs in the inoculum results in significant evidence of infection in more than 75% of rabbits[49]. Although this provides consistent results for evaluation of anti-infection therapy, it may not be representative of the clinical scenario where infection occurs at much lower rates and presumably with fewer contaminating bacteria. The evidence in this study demonstrating that the antibiotic coating does prevent bacterial growth even in this model of high levels of contamination indicates the clinical potential of this coating. Further, while we did observe histology for uncoated and coated groups to note any potential inflammatory responses, there were no non-antibiotic loaded coatings used as controls or defects without contamination to monitor inflammatory response in this preliminary study. Since this material has been used as a component of bone graft substitutes without issues of severe inflammation[30], it is expected that a degradable thin coating on the implant surface would not lead to negative tissue response and may even stimulate bone growth and healing around the implant. Further studies expanding on these preliminary results should include longer durations of implantation as well as non-contaminated control groups for comparison.

In conclusion, vancomycin-loaded phosphatidylcholine coatings effectively reduced bacterial biofilm formation in an orthopaedic implant-associated model of infection. Local release of antibiotic inhibits bacterial growth and inhibits biofilm formation on the implant. These easily-applied coatings can be used at the time of surgery to prevent orthopaedic infection and improve patient outcomes.

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COMMENTS

Background

Infections associated with medical implants can pose severe threats to patient health. Methods to prevent attachment of bacteria and the formation of biofilm on implants could prevent life-threatening musculoskeletal infections. Phosphatidylcholine coatings can be loaded with antibiotics to protect the implant and surrounding tissue from pathogenic microorganisms.

Research frontiers

Phosphatidylcholine is a naturally-derived lipophilic material that forms a thin layer when manually applied to an implant surface. The point-of-care application provides versatility for use on various implant types and with many different types of antimicrobial molecules.

Innovations and breakthroughs

Compared to systemic administration of antibiotics, local delivery provides high concentrations of therapeutic molecules at the site of injury and potential contamination. Phosphatidylcholine provides a short-term degradable drug carrier matrix that can be directly coated on implants. Complete degradability, as well as implant coverage and biocompatibility, are advantages over other common local drug delivery devices such as polymethylmethacrylate beads or calcium sulfate.

Applications

Results suggest that vancomycin-loaded coatings significantly inhibited staphylococcal growth in a model of implant-associated osteomyelitis, providing prophylactic drug release to prevent infection.

Terminology

Phosphatidylcholine is an amphiphilic molecule consisting of a polar head group and fatty acid tails that when purified can be fabricated into a coating material that leaves a waxy residue on the surface of a biomaterial. Biofilm forms when bacteria or other microorganisms attach to a surface, such as a metal implant or damaged tissue, and causes infection that is highly resistant to antibiotics or immune system clearance. *Staphylococcus aureus* is among the common pathogens that cause infections in the musculoskeletal system and can lead to osteomyelitis, which is infection of bone.

Peer-review

Interesting paper. This is a basic science study with a useful clinical application.

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ORIGINAL ARTICLE

Basic Study

Using simulation to train orthopaedic trainees in non-technical skills: A pilot study

Samuel R Heaton, Zoe Little, Kash Akhtar, Manoj Ramachandran, Joshua Lee

Samuel R Heaton, Zoe Little, Kash Akhtar, Manoj Ramachandran, Joshua Lee, Centre for Orthopaedics, Royal London Hospital, Barts Health NHS Trust, London E1 1BB, United Kingdom

Author contributions: Heaton SR and Akhtar K drafted the manuscript; Little Z collated the statistics; Ramachandran M and Lee J designed the course.

Institutional review board statement: All participant questionnaires were obtained with the informed consent from the candidates with express permission for this paper. All responses are anonymised. There was no requirement for ethical approval as this was purely a questionnaire of doctors experiences of a course.

Informed consent statement: All involved persons gave their verbal informed consent prior to study inclusion. All study responses were anonymised.

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Correspondence to: Samuel R Heaton, FRCS, Centre for Orthopaedics, Royal London Hospital, Barts Health NHS Trust, Whitechapel Road, London E1 1BB, United Kingdom. samheaton@hotmail.com
Telephone: +44-20-73777000

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Abstract

AIM: To enhance non-technical skills and to analyse participant's experience of a course tailored for orthopaedic surgeons.

METHODS: A Delphi technique was used to develop a course in human factors specific to orthopaedic residents. Twenty-six residents (six per course) participated in total with seven course facilitators all trained in Crisis Resource Management providing structured feedback. Six scenarios recreated challenging real-life situations using high-fidelity mannequins and simulated patients. Environments included a simulated operating suite, clinic room and ward setting. All were undertaken in a purpose built simulation suite utilising actors, mock operating rooms, mock clinical rooms and a high fidelity adult patient simulator organised through a simulation control room. Participants completed a 5-point Likert scale questionnaire (strongly disagree to strongly agree) before and after the course. This assessed their understanding of non-technical skills, scenario validity, relevance to orthopaedic training and predicted impact of the course on future practice. A course evaluation questionnaire was also completed to assess participants' feedback on the value and quality of the course itself.

RESULTS: Twenty-six orthopaedic residents participated (24 male, 2 female; post-graduation 5-10 years), mean year of residency program 2.6 out of 6 years required in the United Kingdom. Pre-course questionnaires showed

that while the majority of candidates recognised the importance of non-technical (NT) skills in orthopaedic training they demonstrated poor understanding of non-technical skills and their role. This improved significantly after the course (Likert score 3.0-4.2) and the perceived importance of these skills was reported as good or very good in 100%. The course was reported as enjoyable and provided an unthreatening learning environment with the candidates placing particular value on the learning opportunity provided by reflecting on their performance. All agreed that the course achieved its intended aims with realistic simulation scenarios. Participants believed patient care, patient safety and team working would all improve with further human factors training (4.4-4.6). and felt that NT skills learnt through simulation-based training should become an integral component of their training program.

CONCLUSION: Participants demonstrated improved understanding of non-technical performance, recognised its relevance to patient safety and expressed a desire for its integration in training.

Key words: Teaching; Learning; Simulation; Non-technical; Surgery

Core tip: We have developed what we believe to be the first non-technical skills course specifically catering to the unique issues affecting orthopaedic surgeons in everyday practice. Participants demonstrated an improved understanding of the importance of non-technical performance, recognised its relevance to improving patient safety and expressed a desire for it to become an integral part of training. Non-technical skills training may also provide a means of identifying and supporting trainees in difficulty.

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INTRODUCTION

Non-technical (NT) skills are those abilities of a surgeon that may influence performance but do not relate directly to clinical knowledge or surgical technique. These "human factors" can be divided into cognitive skills or social skills and include situational awareness, decision-making, communication, teamwork and leadership[1].

Such interpersonal skills have traditionally been overlooked in training programs, with a premium placed on technical skills such as surgical dexterity, clinical expertise and factual knowledge. While these are essential factors in successful and safe patient interactions, there is increasing evidence that sub-optimal human factors can have negative effects on final patient outcomes. This can lead to adverse events during surgery and also during patient or staff interactions[2]. Communication errors have been shown to be causal factors for up to 43% of surgical errors[3], which suggests that technical skills alone are not sufficient to minimise risk sufficiently.

NT skills have already been noted to be of importance in non-medical fields and within some medical specialities. The National Aeronautics and Space Administration found that 70% of errors in the aviation industry were due to human factors such as failures in communication, leadership and decision-making[4]. This led to the development of Crew Resource Management (CRM) training in order to enable individuals to manage human performance limits and improve safety. CRM training has subsequently been adopted in the manufacturing, military and nuclear industries[5], civil aviation and oil exploration[6]. The anaesthetics community[7,8] has largely driven CRM in medicine with the development of Anaesthetic Crisis Resource Management[9]. This allows a participant to practice team-training skills in a simulated environment and then receive feedback on their performance. This has been well received with the significant majority of people confirming it has benefited their regular practice[10]. Cardiac surgery[11], operating room personnel[12,13], general surgery[14,15], nursing[16], obstetrics[17] and undergraduate medical curricula[18] are all increasingly recognising the importance of NT skills.

The Royal College of Surgeons of Edinburgh has produced a course designed for surgeons called NOTSS: Non-Technical Skills for Surgeons. It rates behaviour in surgeons and evaluates various non-technical skills with feedback given by consultants (attendings) based on structured observations[19]. A scoring system has been developed termed the Oxford Non-Technical Skills scale[20], which solely focuses on team work in an operating theatre. It is therefore somewhat surprising that the only specific orthopaedic communication roles in routine training are limited to the Advanced Trauma Life Support simulated moulages, which are still heavily loaded towards technical skills.

MATERIALS AND METHODS

Participants

Twenty-six orthopaedic residents participated in total. The faculty consisted of three orthopaedic attendings, one senior resident and three full-time course facilitators from the department of medical simulation trained in Crisis Resource Management. Each course was undertaken with six participants and seven staff members.

Course structure

The faculty used a Delphi technique[21] to devise six

Table 1 Examples of scenarios used

Setting	Scenario
Clinic	Discussing a surgical complication with an upset patient
Clinic	Breaking bad news to an anxious patient
Operating room	Managing a large team in crisis during a bone cement implantation reaction
Operating room	Dealing with an intoxicated senior colleague
Ward	Managing team members in a critically ill patient setting
Ward	Making a complex referral to an obstructive colleague

Table 2 Non-technical skills perceptions questionnaire

Please indicate how inclined you are to agree with the following statements
I have a good understanding of non-technical skills
Non-technical skills are important in orthopaedic training
Non-technical skills simulation should be an integral part of orthopaedic training

scenarios occurring in a realistic physical environment supported by a multidisciplinary team. These were based on actual events experienced by faculty members or reported in the General Medical Council archives[22] and were designed to immerse participants in the scenario and represent real-life challenging situations so as to test trainees' NT skills across the range (Table 1).

Each participant agreed to be filmed for feedback purposes and signed a confidentially agreement. They then filled in a pre-course questionnaire about their understanding of NT skills. An introductory presentation was delivered by the course leader describing the aims of the course and the outline for the day's activities.

The scenarios were viewed directly through one-way screens by the other candidates and faculty members and were also concomitantly filmed for feedback purposes. Each scenario was undertaken in a purpose built simulation suite, which included a high fidelity adult patient simulator, actors as simulated patients, a mock operating room (Figure 1), outpatient clinic room or in-patient ward setting. All scenarios were controlled from the simulation control centre (Figures 2 and 3).

Two examples are described in detail below with the instructions for the candidate and the Simulated Patient plus the end point aims.

Clinic scenario 1

Discussing a surgical complication with an upset patient: (1) candidates brief. The patient has had an ankle fracture and a subsequent operation leading to chronic syndesmotic injury with pain. The original operation was poorly performed, leading to the current situation. The patient now needs revision surgery and returns to clinic today to discuss this. The patient has sent a complaint letter to the hospital demanding compensation and for the initial surgeon to be disciplined. The patient is unhappy with the response they have received; (2) patients brief: You have come back for your follow-up, which is to discuss the next part of your treatment. You are not satisfied by the response you have received, you feel entitled to compensation and you want that surgeon who did the operation to be suspended; and (3) end point aim: Empathises with patient, manages the situation and the patient appropriately, explains the hospital's formal complaints procedure and how to proceed. Is aware of the formal complaints procedure. Comes to an acceptable management plan for the clinical problem.

Operating room scenario 2

Dealing with an intoxicated senior colleague: (1) candidates brief: You are in the operating room, the patient has received general anaesthesia and you are preparing to assist your attending in a total knee replacement. This is your first week working with this attending; (2) attending's brief: Display signs of being intoxicated and inability to keep focus on the task. If candidate does not realise the situation then scrub nurse to take them aside and express concern. If candidate asks directly if you are drunk, deny it vehemently and express annoyance at their question; (3) scrub nurse: Wait for candidate to start scrubbing and whilst consultant is fiddling with setup, suggest to the candidate that the consultant is drunk. Tell the candidate in no uncertain terms that they must take action to protect patient safety; and (4) end point aim: To prevent the attending from operating. Arrange for another surgeon or decide to abandon the procedure and wake up the patient. Put patient safety first followed by duty of care to colleague. Plan for discussion with department director and suggest occupational health referral. Keep accurate and appropriate records (Figure 3).

Questionnaires

All questions were answered on a 5 point Likert-type scale (strongly disagree to strongly agree). A questionnaire (Table 2) was designed to determine participants' understanding of NT skills and their perceptions of the relevance and importance of these in orthopaedics, both before and after training.

A course evaluation questionnaire (Table 3) was designed to assess participants' feedback on the value and quality of the course.

A debriefing session was conducted after each scenario, during which the participant reflected on their own performance and received constructive feedback from their peers and the faculty. Following debriefing after the final scenario of the day, the NT skills perception questionnaire was completed again, together with the course evaluation questionnaire.

RESULTS

Twenty-six participants took part, 24 were male and 2 were female (post-graduation 5-10). The mean year of

Figure 1 Mock operating room with viewing room behind one way mirror.

Figure 2 Simulation control centre.

Figure 3 A typical operating room scenario used during the course.

training on the residency program was 2.6 (out of the 6 training years required in the United Kingdom).

Understanding and perception of NT skills

In terms of the understanding Prior to the course, the majority of participants recognised the importance of NT skills in orthopaedic training but only 42% reported a good understanding of them. The course increased the reported understanding of NT skills and further emphasised their importance in orthopaedic training.

Table 3 Course evaluation questionnaire

Please indicate how inclined you are to agree with the following statements
I enjoyed this simulation day
It was useful to reflect on my performance
The course met the initial aims as presented in the introductory lecture
I thought the simulation scenarios were realistic
Simulation provided an unthreatening learning environment
This course will improve my team working
This course will improve my practice in terms of patient care
This course will improve my practice in terms of patient safety

Table 4 Results of the course evaluation questionnaire

Please indicate how inclined you are to agree with the following statements	Agree or strongly agree (%)
I enjoyed this simulation day	100
It was useful to reflect on my performance	100
The course met the initial aims as presented in the introductory lecture	100
I thought the simulation scenarios were realistic	92
Simulation provided an unthreatening learning environment	96
This course will improve my team working	88
This course will improve my practice in terms of patient care	88
This course will improve my practice in terms of patient safety	88

Moreover, all participants valued NT skills and thought that simulation-based training should become an integral component of orthopaedic training (Figure 4).

Course value and quality

All participants enjoyed the course and valued reflecting on their performance. All agreed or strongly agreed that the course achieved its intended aims (Table 4).

The majority found the simulation scenarios realistic and all but one reported that the course provided an unthreatening learning environment. Furthermore, 88% of participants agreed or strongly agreed that the course would improve their clinical practice in terms of team working, patient care and patient safety.

DISCUSSION

We have developed and piloted a new NT skills simulation course specifically for orthopaedic trainees. This simulation-based training was shown to provide a realistic, enjoyable and unthreatening learning environment and was well accepted by trainees. Course participants were able to reflect on their performances in various clinical scenarios and to improve their understanding of NT skills. The majority of those taking part felt that the course would improve team working and patient care. Their perception of the relevance of NT skills to orthopaedic training and their importance in clinical practice became more positive after experiencing the course. Participants demonstrated an improved

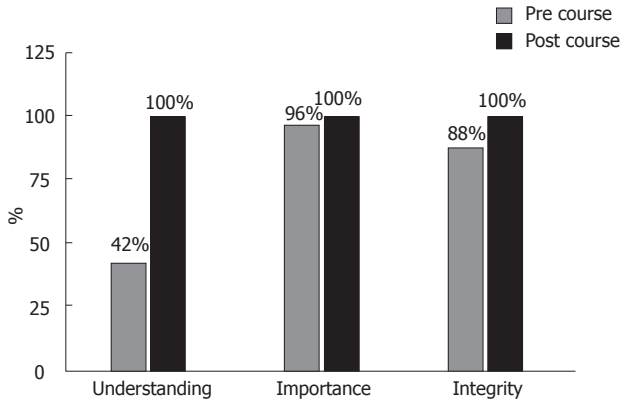

Figure 4 Results of the pre- and post- non-technical skills perceptions questionnaire shown in table 2 (percentage declaring "agree" or "strongly agree").

understanding of the importance of non-technical performance, recognised its relevance to improving patient safety and expressed a desire for it to become a part of their training.

The purpose of this course was to provide teaching and feedback on NT skills specific to orthopaedic surgery with immersion in high fidelity environments simulating the operating room and outpatient clinic settings. The participants were shown the importance of NT skills in routine practice and were able to demonstrate and practice these skills in a safe environment, without posing risk to patients. They were able to critically evaluate their own performances and those of others, as well as receiving guided feedback from the experienced faculty. This allowed identification of areas for consolidation or improvement in order to prepare trainees for more senior clinical roles.

The importance of reflection in clinical training continues to grow and it is invaluable for surgeons of all grades to reflect on their own practice in order to ensure ongoing professional and personal development, as well as improvement in their practice.

It has been proposed that learners can be helped stepwise through this learning cycle by the creation of appropriate experiences and by assessment and feedback to facilitate transformation[23]. A training programme such as outlined in this paper can be one way of achieving this safely.

There is relatively little emphasis on NT skills in the orthopaedic literature, although their importance in obtaining successful clinical outcomes is clear and well recognised in many high-risk fields. We have described a way to use simulation to develop NT skills in orthopaedics in a risk-free environment and this was well received by trainees. Similar NT skills courses exist in other medical specialties, but this is the first we are aware of to focus specifically on the unique issues affecting orthopaedic surgeons. This course is becoming an integral component of our registrar training programme and may also provide a means for identifying and supporting the trainee in difficulty.

There is growing evidence for NT skills to be embedded into the orthopaedic training curriculum and the use of simulation may be a means of achieving this.

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COMMENTS

Background

Non-technical skills include situational awareness, decision-making, communication, teamwork and leadership. Evidence suggests these attributes are the key to reducing errors and avoiding adverse events.

Research frontiers

Training in non-technical skills is widely used in many high-risk industries and some medical specialties. Simulation-based training in the orthopaedic community is based predominantly on technical skills such as dexterity with little emphasis on human factors training.

Innovations and breakthroughs

The authors have developed what they believe to be the first non-technical skills course specifically catering to the unique issues affecting orthopaedic surgeons in everyday practice.

Terminology

Non-technical skills include situational awareness, decision-making, communication, teamwork and leadership.

Peer-review

The paper is very well presented.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Criteria for level 1 and level 2 trauma codes: Are pelvic ring injuries undertriaged?

Brittany E Haws, Scott Wuertzer, Laura Raffield, Leon Lenchik, Anna N Miller

Brittany E Haws, Wake Forest School of Medicine, Medical Center Boulevard, Winston-Salem, NC 27157, United States

Scott Wuertzer, Leon Lenchik, Department of Radiology, Medical Center Boulevard, Winston-Salem, NC 27157, United States

Laura Raffield, Department of Molecular Genetics and Genomics, Medical Center Boulevard, Winston-Salem, NC 27157, United States

Anna N Miller, Department of Orthopaedic Surgery, Medical Center Boulevard, Winston-Salem, NC 27157, United States

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Correspondence to: Brittany E Haws, BS, Medical Student, Wake Forest School of Medicine, Medical Center Boulevard, Winston-Salem, NC 27157, United States. behaws1@gmail.com
Telephone:+1-336-7163950
Fax: +1-336-7167310

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Abstract

AIM: To determine the association of unstable pelvic ring injuries with trauma code status.

METHODS: A retrospective review of all pelvic ring injuries at a single academic center from July 2010 to June 2013 was performed. The trauma registry was used to identify level 1 and level 2 trauma codes for each injury. The computed tomography scans in all patients were classified as stable or unstable using the Abbreviated Injury Scale. Pelvic injury classifications in level 1 and level 2 groups were compared. Patient disposition at discharge in level 1 and level 2 groups were also compared.

RESULTS: There were 108 level 1 and 130 level 2 blunt trauma admissions. In the level 1 group, 67% of pelvic injuries were classified as stable fracture patterns and 33% were classified as unstable. In the level 2 group, 62% of pelvic injuries were classified as stable fracture patterns and 38% were classified as unstable. level 1

trauma code was not associated with odds of having an unstable fracture pattern (OR = 0.83, 95%CI: 0.48-1.41, *P* = 0.485). In the level 1 group with unstable pelvic injuries, 33% were discharged to home, 36% to a rehabilitation facility, and 32% died. In the level 2 group with unstable pelvic injuries, 65% were discharged to home, 31% to a rehabilitation facility, and 4% died. For those with unstable pelvic fractures (*n* = 85), assignment of a level 2 trauma code was associated with reduced odds of death (OR = 0.07, 95%CI: 0.01-0.35, *P* = 0.001) as compared to being discharged to home.

CONCLUSION: Trauma code level assignment is not correlated with severity of pelvic injury. Because an unstable pelvis can lead to hemodynamic instability, these injuries may be undertriaged.

Key words: Pelvic ring; Trauma code; Triage; Unstable pelvis; Abbreviated injury scale

Core tip: The assignment of trauma level is important as it dictates the urgency of response and the size of the responding team. Because of the high morbidity and mortality from pelvic fractures, especially unstable pelvic fractures, it is critical that these injuries be appropriately triaged once discovered or suspected. Our study did not show an association between the severity of the pelvic ring injury and the trauma code level. This lack of an association suggests patients with significant pelvic injuries may be under-triaged. These injuries may benefit from a more severe trauma code status to prevent any undue morbidity or mortality.

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INTRODUCTION

At all accredited trauma centers, patients are triaged into a level 1 or level 2 trauma code based on specific criteria. The composition of the trauma team and the urgency of the trauma response can then be tailored to meet the needs of the patient based on the trauma code level[1]. Patients with the most serious injuries are designated a level 1 trauma, indicating a need for a larger trauma team and faster response time[2]. The determination of trauma code criteria varies between hospitals and is based on elements such as physiologic data, types of injury, and mechanism of injury. Specific field criteria for a level 1 designation have been previously investigated. Criteria that are commonly used include hypotension in the field[3], truncal gunshot wounds[4], field Glasgow coma scale (GCS) < 15[5], and age > 70[6].

Pelvic ring injuries are associated with a high rate of morbidity, with a short-term complication rate ranging from 50%-80%[7], and a high rate of mortality of over 8%[8]. Our primary purpose was to determine if there is any association between trauma code level and the severity of pelvic ring injuries. Specifically, our hypothesis was that unstable pelvic ring injuries would have a higher association with level 1 trauma code status due to the hemodynamic compromise often seen with these severe injuries. Our secondary purpose was to compare post-hospital disposition associated with pelvis fractures for level 1 and 2 trauma codes to determine if the trauma code status correlated with different outcomes for these injuries.

Table 1 Inclusion criteria for designation as a level 1 trauma code at the author's home institution

Level 1 adult trauma code criteria
Cardiac arrest (secondary to trauma)
Airway compromise, poor ventilation, or high potential for same (includes assisted ventilations, field intubation, referring facility intubation compromise, or inability to intubate)
Hypotension or shock (Systolic BP < 90 mmHg adults and age specific hypotension)
GCS ⩽ 8 (Presumably due to trauma)
GSW to neck or torso (chest, back, abdomen, or groin), or extremity proximal to the elbow/knee
Receiving blood transfusion at any time prior to arrival to maintain vital signs (transfer patients, air transport)
Emergency physician discretion
Patients who develop any level 1 criteria during their Emergency Department stay should be upgraded to a level 1 trauma code

GCS: Glasgow coma scale; GSW: Gunshot wound.

MATERIALS AND METHODS

A retrospective review of all pelvic ring injuries at a single academic center from July 2010 to June 2013 was performed. The trauma registry was used to determine the trauma codes for each patient. Criteria from our home institution were used to define code status for each patient (Tables 1 and 2).

A single fellowship-trained orthopedic trauma surgeon retrospectively reviewed the computed tomography (CT) examinations of all patients and classified the injuries as stable or unstable using Abbreviated Injury Scale codes. This system was chosen because it is commonly used, is relatively simple, and has high reliability[9]. For the purpose of this study, an intact posterior arch or an incomplete disruption of the posterior arch was considered stable and a complete disruption of the posterior arch was considered unstable. The pelvic injury classifications from the level 1 and level 2 groups were then compared. Patient disposition at discharge in level

Table 2 Inclusion criteria for designation as a level 2 trauma code at the author's home institution

Level 2 adult trauma code criteria
Heart rate < 50 or > 125 (> 100 if age > 65 yr)
Systolic BP < 110 mmHg (only if age > 65 yr)
Respiratory rate < 10 or > 29
GCS ⩽ 10
Stab to neck or torso (chest, back, abdomen, or groin)
GSW head (without airway compromise)
Amputation proximal to knee or elbow
Two or more proximal long bone fractures
Crush injury to chest or pelvis
Paralysis/suspected spinal cord injury
Neurovascular compromise of an extremity
Age > 65 yr + anticoagulant use + significant trauma
Intubation at outside hospital (transfer patients)
Multisystem trauma on outside imaging (transfer patients)
Emergency physician discretion

GCS: Glasgow coma scale; GSW: Gunshot wound.

1 and level 2 groups were also compared.

Relationships between assignment of level 1 and level 2 trauma codes and pelvic injury stability and patient disposition at discharge were analyzed using logistic regression models in SAS 9.3.

RESULTS

There were 108 level 1 and 130 level 2 blunt trauma admissions. The mean age was 41 years, age range 15-90 years. In the level 1 group, 72/108 (67%) of pelvic injuries were stable and 36/108 (33%) were unstable. In the level 2 group, 81/130 (62%) of pelvic injuries were stable and 49/180 (38%) were unstable.

In the level 1 group with stable pelvic injuries, 27/72 (38%) were discharged to home, 28/72 (39%) to a rehabilitation facility, and 17/72 (24%) died. In the level 2 group with stable pelvic injuries, 63/81 (77%) were discharged to home, 14/81 (17%) to a rehabilitation facility, and 4/81 (5%) died. In the level 1 group with unstable pelvic injuries, 12/36 (33%) were discharged to home, 13/36 (36%) to a rehabilitation facility, and 11/36 (32%) died. In the level 2 group with unstable pelvic injuries, 32/49 (65%) were discharged to home, 15/49 (31%) to a rehabilitation facility, and 2/49 (4%) died (Table 3).

Assignment of a level 1 trauma code was not associated with odds of having an unstable fracture (OR = 0.83, 95%CI: 0.48-1.41, $P = 0.485$) ($n = 238$). There is an association between trauma code level and patient discharge status with higher rates of mortality in level 1 trauma activation (28 deaths in the level 1 group and 6 in the level 2 group). For all participants ($n = 238$), assignment of a level 2 trauma code was associated with reduced odds of death (OR = 0.09, 95%CI: 0.03-0.23, $P < 0.0001$) or being dispatched to a rehabilitation center (OR = 0.29, 95%CI: 0.16-0.53, $P < 0.0001$) as compared to being dispatched to home. For those with stable pelvic fractures ($n = 153$), assignment of a level 2 trauma code was associated with reduced odds of death (OR = 0.10, 95%CI: 0.03-0.33, $P < 0.0001$) or being dispatched to a rehabilitation center (OR = 0.21, 95%CI: 0.10-0.47, $P < 0.0001$) as compared to being dispatched to home. For those with unstable pelvic fractures ($n = 85$), assignment of a level 2 trauma code was associated with reduced odds of death (OR = 0.07, 95%CI: 0.01-0.35, $P = 0.001$) as compared to being dispatched to home, with a trend towards reduced odds of being dispatched to a rehabilitation center as well (OR = 0.43, 95%CI: 0.16-1.17, $P = 0.099$).

Table 3 Numbers of unstable and stable pelvic fractures in level 1 compared to level 2 trauma code patients. Further stratified percentages of the outcomes of these patients (discharged home, discharged to rehabilitation facility, or died)

Trauma level	Stable or unstable	Discharged home	Discharged to rehabilitation facility	Died
Level 1 108 patients	Stable (72/108) 67%	38%	39%	24%
	Unstable (36/108) 33%	33%	36%	32%
Level 2 130 patients	Stable (81/130) 62%	77%	17%	5%
	Unstable (49/130) 38%	65%	31%	4%

DISCUSSION

The criteria used to determine trauma code status is not consistent across institutions. Although there are guidelines set by the American College of Surgeons (ACS), each institution modifies these guidelines for their own environment and patient population. Kouzminova *et al*[10], evaluated a two-tiered trauma activation system based on ACS field trauma center triage criteria. Their approach was effective in identifying patients with potentially serious injuries as all evaluated indicators of severe injury (including intubation, transfer to ICU or OR, and death) were significantly different between the level 1 and level 2 group ($P < 0.0001$)[10]. Another study by Kaplan *et al*[11] compared a three-tiered system with a two-tiered system. This three-tiered system resulted in earlier involvement of the trauma service and decreased time in the emergency department. They also found that the amount of overtriage was decreased as defined by the number of patients who were not admitted to the hospital after Emergency Department evaluation. Eastes *et al*[12] evaluated patient outcomes in a tiered response system. They found that although this system led to a prolonged length of stay in the emergency department for those patients designated as a "partial trauma code", it did not compromise quality of patient care. These three studies all had their own criteria for defining a

level 1 trauma, however, many of these indications were similar, including hemodynamic instability, penetrating trauma, and altered consciousness. The use of other criteria such as breathing difficulty, focal neurological deficit, proximal extremity fracture, and paralysis varied among the three studies[10-12]. Additionally, only one of the above studies included pelvic instability as an indicator for severe trauma[12]. Although each of these studies had their own criteria for level 1 trauma activation, all were found to be effective at categorizing incoming traumas.

At our institution, pelvic ring instability is not included in the criteria for level 1 trauma code designation. Yoshihara *et al*[13] studied patients with unstable pelvic fractures and found an in-hospital mortality rate of 8.3%. Another study reported that patients with complex pelvic injuries have a mortality rate of 31.1%, and patients with pelvic fracture without concomitant soft tissue injury have a mortality rate of 10.8%[14]. Due to the high morbidity and mortality from pelvic fractures, especially unstable pelvic fractures, the main purpose of this study was to determine if there is any association between trauma code level and the severity of pelvic ring injuries. In other words, the relationship of these injuries to adverse outcomes suggests a benefit for including them in level 1 criteria, leading to a larger trauma team and faster response time to manage these complex injuries.

An association between pelvic fractures and an increased injury severity score has been evaluated previously. Cordts Filho Rde *et al*[15] compared injury severity scores between trauma patients with a pelvic fracture and those without a pelvic fracture. They found that pelvic fractures were associated with a worse prognosis, including a 27.9% mortality rate in those with a pelvic fracture compared to a 1.8% mortality rate in those without a pelvic fracture. Our study is the first to evaluate the relationship between trauma code levels and pelvic fractures. Although previous studies have investigated patient disposition to validate the efficacy of their trauma criteria[2,10,12], no study has directly examined how patient disposition compares between level 1 and level 2 trauma activations.

Our study did not show an association between the severity of the pelvic ring injury and the trauma code level. Because of the high morbidity and mortality from pelvic fractures, this lack of an association suggests patients with significant pelvic injuries may be under-triaged. Additionally, for the level 2 group with less severe injuries, patients with unstable pelvic injuries were less likely to be discharged home and more likely to be discharged to a rehabilitation facility compared to patients with stable pelvic injuries. Our data suggest that patients placed into the level 2 group with unstable pelvic injuries may have been under-triaged.

As expected, we found higher rates of mortality in level 1 trauma activations. Many of these patients would have sustained significant injuries (*e.g.,* neurologic) that placed them into the level 1 trauma group, irrespective of their pelvis status. Our study shows the need to continually assess the trauma code criteria. For example, unstable pelvic fractures can rapidly lead to many of the criteria used by institutions for level 1 trauma designation, such as hemodynamic instability, but these criteria may not be present at the initial classification. In other words, because of the potential for morbidity and mortality, an unstable pelvic fracture should be used as a stand-alone criterion for categorizing a patient as a level 1 trauma.

Physical assessment of the pelvis should be performed in an emergency or prehospital setting to determine if a pelvic injury is likely present. This information could then be used to guide the trauma code level assignment. Important aspects of the evaluation include presence of pelvic pain or tenderness, pelvic deformity, and assessment of pelvic stability with gentle lateral compression (any gross motion should be considered a sign of instability). Shlamovitz *et al*[16] studied the probability that these parameters will accurately indicate the presence of a pelvic injury. The determined that the sensitivity and specificity of pelvic pain or tenderness in patients with GCS > 13 were 0.74 (95%CI: 0.64-0.82) and 0.97 (95%CI: 0.96-0.98), respectively for diagnosing any pelvic fractures, and 1.0 (95%CI: 0.85-1.0) and 0.93 (95%CI: 0.92-0.95), respectively for diagnosing mechanically unstable pelvic fractures. The sensitivity and specificity of the presence of pelvic deformity were 0.30 (95%CI: 0.22-0.39) and 0.98 (95%CI: 0.98-0.99), respectively for detection of any pelvic fracture and 0.55 (95%CI: 0.38-0.70) and 0.97 (95%CI: 0.96-0.98), respectively for detection of mechanically unstable pelvic fractures. Instability to pelvic ring compression had a sensitivity and specificity of 0.08 (95%CI: 0.04-0.14) and 0.99 (95%CI: 0.99-1.0), respectively, for detection of any pelvic fracture and 0.26 (95%CI: 0.15-0.43) and 0.999 (95%CI: 0.99-1.0), respectively, for detection of mechanically unstable pelvic fractures. While these findings are not highly sensitive, they are specific for pelvic fractures - particularly unstable fractures. Therefore, if any of these are found upon the prehospital assessment the likelihood of unstable pelvic fracture is high and could potentially be investigated for its utility as part of the criteria for level 1 trauma code assignment.

This study has some limitations, including the inherent flaws of any retrospective study. The use of a database relies on the quality of input, which may include inaccurate data or inaccurate data entry. Pelvic CT classification can be difficult[17-19], however, we purposely chose a commonly used and reproducible scale to decrease errors in classification.

The assignment of trauma level is important as it dictates the urgency of response and the size of the

responding team. Because of the high correlation of internal injuries with unstable pelvic ring injuries, it is critical that these injuries be appropriately triaged, perhaps with a more severe trauma code status to prevent any undue morbidity or mortality.

COMMENTS

Background

At all accredited trauma centers, patients are triaged into a level 1 or level 2 trauma code based on specific criteria. The composition of the trauma team and the urgency of the trauma response are tailored to meet the needs of the patient based on the trauma code level. Patients with the most serious injuries are designated a level 1 trauma, indicating a need for a larger trauma team and faster response time. The determination of trauma code criteria varies between hospitals and is based on elements such as physiologic data, types of injury, and mechanism of injury. Because of the high morbidity and mortality from pelvic fractures, especially unstable pelvic fractures, it is thought that these injuries would likely be associated with a higher trauma code status.

Research frontiers

This study assessed the correlation between the severity of pelvic ring injury and the trauma code level. The authors found that patients with significant pelvic injuries may be under-triaged because of the lack of association with high trauma code status. This conclusion is supported by data analysis of patients with pelvic ring injuries compared to their trauma code level and disposition at discharge.

Innovations and breakthroughs

Data regarding the utility of using the severity of pelvic ring injury as criteria for higher trauma code level has not previously been assessed. This study describes a lack of association between the severity of the pelvic ring injury and the trauma code level. This suggests patients with significant pelvic injuries may be under-triaged potentially increasing the likelihood of morbidity or mortality.

Applications

Patients with suspected or confirmed unstable pelvic ring injury will benefit from higher trauma code status in order to allow for a more urgent response and therefore prevent undue morbidity and mortality. Inclusion of unstable pelvic ring injury in the criteria for level 1 traumas may lead to improved outcomes in this population.

Terminology

Trauma Code response in the Emergency Department is a standardized procedure used at trauma centers that dictates the initial management of trauma patients. This response may vary by timing and team size depending upon the perceived urgency indicated by the trauma code level. Upon arrival, trauma patients are evaluated clinically and with imaging by the general surgery team. After initial assessment, subspecialty services are consulted based upon the injuries found. General trauma surgeons do not typically manage pelvic fractures, so they would consult the orthopaedic surgery team in that circumstance. Assigning trauma code level determines which patients have the most severe injuries and therefore would benefit from the most rapid evaluation in order to allow for earliest intervention and best possible outcome.

Peer-review

The authors provide an interesting retrospective study on the relevance of pelvic injuries for the assignment of a trauma code level.

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ORIGINAL ARTICLE

Retrospective Study

Femoro Patella Vialla patellofemoral arthroplasty: An independent assessment of outcomes at minimum 2-year follow-up

Mansur Halai, Andrew Ker, Iain Anthony, Graeme Holt, Bryn Jones, Mark Blyth

Mansur Halai, Andrew Ker, Iain Anthony, Bryn Jones, Mark Blyth, Department of Trauma and Orthopaedics, Glasgow Royal Infirmary, Glasgow G4 0SF, United Kingdom

Graeme Holt, Department of Trauma and Orthopaedics, University Hospital Crosshouse, Kilmarnock KA2 0BE, United Kingdom

Author contributions: Halai M conducted the study with the help of Ker A; Anthony I and Holt G performed the biostatistical analysis; Jones B and Blyth M conducted the study and supervised the entire project; all authors had read and approved the final version to be published.

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Correspondence to: Mansur Halai, Specialty Registrar, Department of Trauma and Orthopaedics, Glasgow Royal Infirmary, Gatehouse Building, 84 Castle Street, Glasgow G4 0SF, United Kingdom. mansurhalai@gmail.com
Telephone: +44-7790-508019

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Abstract

AIM: To determine outcomes using the Femoro-Patella Vialla (FPV) arthroplasty and if there is an ideal patient for this implant.

METHODS: A total of 41 FPV patellofemoral joint replacements were performed in 31 patients (22 females, 9 males, mean age 65 years). Mean follow-up was 3.2 years (minimum 2 years). Radiographs were reviewed preoperatively and postoperatively. We assessed whether gender, age, previous surgery, patella atla or trochlear dysplasia influenced patient satisfaction or patient functional outcome.

RESULTS: The median Oxford Knee Score was 40 and the median Melbourne Patellofemoral Score was 21 postoperatively. Seventy-six percent of patients were satisfied, 10% unsure and 14% dissatisfied postoperatively. There was no radiological progression of tibiofemoral joint arthritis, using the Ahlback grading,

in any patient. One patient, who was diagnosed with rheumatoid arthritis postoperatively, underwent revision to total knee replacement. There were no intraoperative lateral releases and no implant failures. Gender, age, the presence of trochlear dysplasia, patella alta or bilateral surgery did not influence patient outcome. Previous surgery did not correlate with outcome.

CONCLUSION: In contrast to the current literature, the FPV shows promising early results. However, we cannot identify a subgroup of patients with superior outcomes.

Key words: Patellofemoral; Arthritis; Femoro-Patella Vialla; Outcomes; Arthroplasty

Core tip: We demonstrate good outcomes regarding the Femoro-Patella Vialla implant which recently has had poor outcomes reported. As it is a popular implant, we think this article is important as there is a paucity of literature concerning outcomes from independent centres. In addition, we are the first group to use a patellofemoral score as one of the outcome measures. However, we cannot identify a subgroup of patients with superior outcomes.

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INTRODUCTION

Patellofemoral arthroplasty (PFA) is a bone preserving procedure for the treatment of severe isolated patello-femoral arthritis. Its legacy dates back to Blazina' s first report of PFA in 1979[1]. Early designs, such as the Lubinus device, reported high failure rates[2]. Since then, newer devices have been developed which more accurately mimic normal knee anatomy and patellar alignment. PFA is now a tibiofemoral joint-sparing alternative to traditional total knee arthroplasty in the treatment of patellofemoral arthritis.

The AVON (Stryker Howmedica Osteonics, Allendale, New Jersey) design was developed from the Kinemax plus (Stryker Howmedica Osteonics, New Jersey) which had a low rate of patellofemoral complications. The early results of this prosthesis from the originating centre have been promising[3]. In another prospective review, good results were also experienced in 37 cases at 2 years[4]. However, there have been mixed results in terms of revision rates at short term follow-up for patellofemoral arthroplasty in general, with rates of between 3% and 15% quoted in the literature[5].

Newer devices such as the Femoro-Patella Vialla (FPV, Wright Medical, United Kingdom) have more recently become available. Stated benefits include a broad trochlea with proximal extension, together with a sagittal curve that promotes superior patella tracking. The sulcus angle of the FPV is 140 degrees, which mimics the human trochlear anatomy more accurately, compared to the Avon which has an angle of 125 degrees[6]. The trochlea is also designed to extend distally to the intercondylar notch, ensuring that the patella does not dislocate inferiorly in deep flexion. The patella features a facetted design with a longitudinal ridge which in theory contains the patella more readily in full extension. The footprint of the patella component is oval in shape, increasing patella contact area, in contrast to the AVON which has a medially offset dome.

There have been reports suggesting that the presence of preoperative trochlear dysplasia can be associated with superior outcomes after PFA[7]. Another series have shown that patellofemoral arthritis associated with malalignment, such as patella alta, was the most common clinical presentation prior to PFA[8]. Furthermore, Farr *et al*[9] confirmed that the best outcome after PFA can be expected when the indication is trochlear dysplasia or patellar malalignment. All of these studies were not based on the FPV.

There are three independent outcome studies of the FPV in the literature, of which two of these report high rates of revision of 17%[10,11]. We are not aware of any studies looking at the effects of pre-existing patella alta, trochlear dysplasia or bilateral disease on outcome of the FPV specifically. In addition, none of the published studies have used a validated patellofemoral score as one of their outcome measures. We report early outcomes of the FPV in 41 consecutive knees with a minimum follow up of 2 years.

MATERIALS AND METHODS

Forty-four consecutive FPV PFAs were performed at a single tertiary centre between November 2007 and November 2011. One patient died from unrelated causes and another patient, who had bilateral FPVs implanted, was lost to follow up. The patient lost to follow-up had a normal postoperative recovery and satisfactory radiographs, with no revision surgery documented in their case-notes.

This left 41 FPV procedures in 31 patients producing a 94% follow-up rate. There were 22 females and 9 males. There were 11 patients (22 FPVs) who had bilateral replacements as staged procedures. The mean age of the cohort was 65 years (range 41-81). The mean follow-up was 3.2 years with a minimum of 2-year follow-up for all patients. The causes of the patellofemoral arthritis were as follows: Osteoarthritis (39 cases, 95%) and trauma (2 cases, 5%).

Patients were considered for surgery if they had

Table 1 Previous surgery in 41 knees

Previous surgery	No. of knees (% of total)
Arthroscopy	3 (7)
Tibial tuberosity transfer	2 (5)
Medial patellofemoral ligament reconstruction	2 (5)
No intervention	34 (83)
Total	41 (100)

disabling knee pain, Outerbridge grade 4 patellofemoral arthritis and normal medial and lateral knee compartments on weight-bearing radiographs[12]. The preoperative diagnosis was isolated severe patellofemoral arthritis in all cases. Diagnosis was based on a combination of clinical, radiological and, where available, arthroscopic findings. Previous surgery was documented and summarised in Table 1.

Each patient had a weight-bearing anteroposterior, lateral radiograph and skyline radiograph of their affected knee preoperatively (Figure 1). The presence of a dysplastic trochlea was evaluated on preoperative radiographs, including a true lateral. This was scored independently by two of the authors. Trochlear dysplasia was identified where there was a crossing sign and a sulcus angle greater than 145° as has been previously described[13]. The presence of patella alta was also documented from the lateral preoperative radiographs using the Insall-Salvati ratio[14]. A ratio of greater than 1.2 was taken to be indicative of patella alta.

All operations were performed by, or under direct supervision of, the two senior authors. A medial parapatellar approach was adopted in all cases under pneumatic tourniquet control. All patients had intravenous antibiotics at induction as per local microbiology policy. Palacos R and G cement was used in all cases. No lateral releases were performed. The mean tourniquet time was 49 min. No patients required a blood transfusion postoperatively. The median time for discharge for all patients was at day 3 postoperatively.

Patients were followed in our Outcomes Assessment clinic run by independent nurse practitioners. We performed a retrospective audit of case-notes and radiographs. Patient factors such as preoperative diagnosis and a history of previous surgery or trauma were noted. Functional outcome was assessed at scheduled appointments. These consisted of a preoperative visit and a 3 mo postoperative visit. Thereafter patients were reviewed on a yearly basis. The mean follow-up at the latest appointment was 3.2 years (range 24-58 mo). Patient reported outcome measures included the Oxford Knee Score (OKS) and the validated Melbourne Patellofemoral Score[15,16]. Patient satisfaction with the outcome of the surgery was also documented using a simple 5 point question. The patient was asked in writing, at latest follow-up, to grade their satisfaction postoperatively as: Very satisfied, satisfied, unsure, dissatisfied or very dissatisfied. Radiographs were reviewed postoperatively for the development of tibiofemoral arthritis using the Ahlback grading[17]. Complications were determined at postoperative clinic visits and from the case-notes. The data presented was collected retrospectively and analysed as part of a routine audit of our clinical practice.

Table 2 Effect of different patient characteristics on outcome

Patient factor	Category	*n*	Median OKS (Q1, Q3)	*P* value	Mean Melbourne Score (SD)	*P* value
Sex	Male	12	42 (38, 46)	0.28	21.3 (4.7)	0.31
	Female	29	40 (37, 42)		19.1 (6.4)	
Trochlear dysplasia	Non-dysplastic	10	41 (36, 43)	0.95	20.0 (5.7)	0.67
	Dysplastic	31	41 (38, 43)		19.0 (7.1)	
Patella alta	Yes	21	41 (37, 42)	0.56	19.3 (6.4)	0.65
	No	20	40 (36, 44)		20.2 (5.6)	
Uni- or bi-lateral	Unilateral	19	41 (37, 42)	0.83	19.8 (5.6)	0.97
	Bilateral	22	41 (37, 43)		19.7 (6.4)	
Previous surgery	Yes	10	40 (37, 42)	0.70	22.0 (5.0)	0.28
	No	31	41 (37, 43)		19.0 (6.1)	

OKS: Oxford Knee Score.

Statistical analysis

All data was analysed using SigmaPlot vs11.0 (Systat Software Inc). Parametric data (Melbourne Score) was analysed using *t* test and non-parametric data (OKS) was analysed using Mann-Whitney test. Pearson's correlation was used to determine linear correlation between variables. *P* value less than 0.05 was considered significant for all tests. The statistical methods of this study were conducted by the biostatistician Iain Anthony of the Glasgow Royal Infirmary.

RESULTS

The median postoperative OKS and Melbourne scores were 40 and 21 respectively at latest follow-up. Thirty-eight percent of patients were very satisfied, 38% satisfied, 10% unsure and 14% dissatisfied with their final result. There were no patients who were "very dissatisfied". The results are summarised with respect to different patient characteristics in Table 2. Patient factors (gender, the presence of trochlear dysplasia or patella alta, or if bilateral surgery was performed) did not impact on clinical outcome scores. Previous surgery had no significant effect on clinical outcome. No significant correlation was found between age and OKS or Melbourne score ($P = 0.162$, $r = 0.273$ and $P = 0.278$, $r = -0.173$ respectively).

Two patients had superficial wound infections that were diagnosed and treated with a course of oral antibiotics in the community within 2 wk of discharge. Both patients went on to have favourable outcomes and were satisfied. There were no deep infections to date and there have been no infections that have required operative attention. We report no mechanical failures of the FPV prosthesis and there have been no

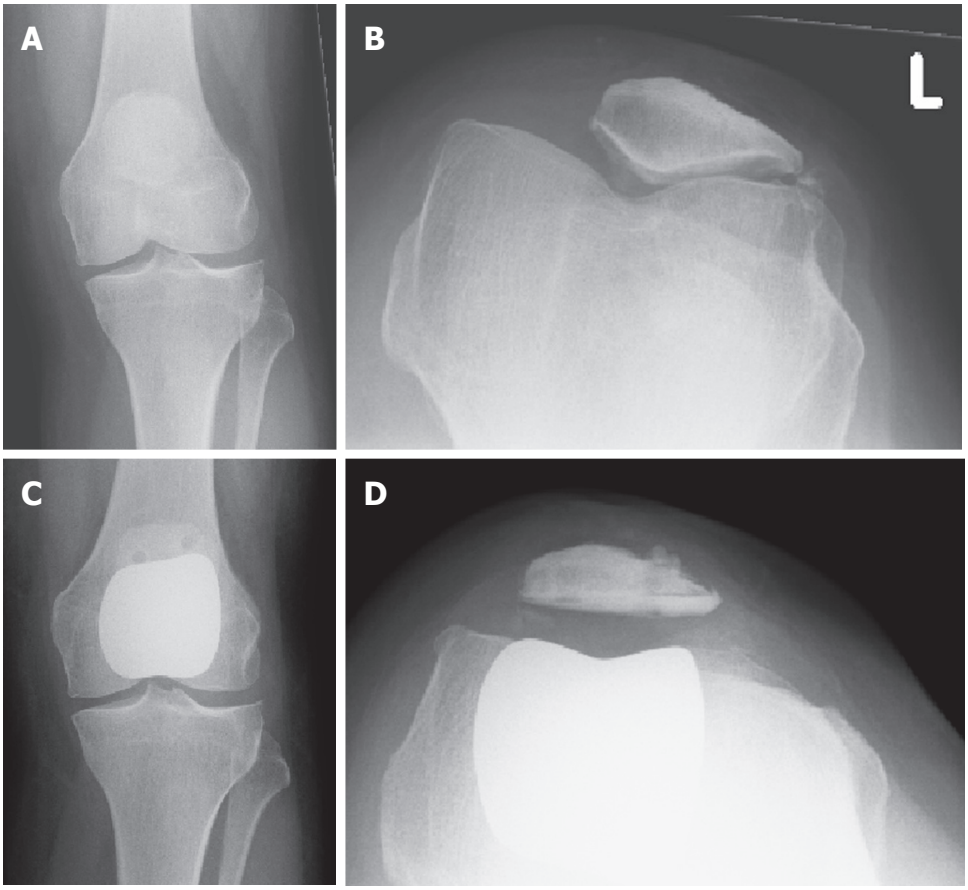

Figure 1 Preoperative and postoperative radiographs using the Femoro-Patella Vialla implant. Preoperative (A) weight-bearing anteroposterior, (B) skyline radiographs in a 60-year-old woman with severe patellofemoral degeneration and subluxation. Postoperative weight-bearing radiographs show satisfactory placement of the prosthesis on the (C) anteroposterior, and (D) skyline views of the same patient at 2 years.

periprosthetic fractures. The complications are included in Table 3.

One patient was diagnosed with seronegative rheumatoid arthritis subsequent to her FPV replacement and was revised to a total knee replacement (TKR) at 6 mo following her index procedure. This represents a 97.6% survival at minimum 2 years of follow-up.

At latest follow-up, there was no progression of arthritis of the tibiofemoral joint using the Ahlback grading in any case. In addition there was no medial or lateral tilt of the patella postoperatively and no lateral releases have been performed postoperatively.

DISCUSSION

Our study shows that good results can be achieved in the short term with the FPV patellofemoral joint replacement. The high Oxford and Melbourne scores observed are reflected in a 78% patient satisfaction rate (satisfied or very satisfied). The procedure compares favourably to TKR with a mean tourniquet time of 49 min, no blood transfusions, a mean length of stay of 3 d and an OKS of 40, at a minimum of 2 years follow-up.

The philosophy behind PFR is theoretically appealing for selected patients with isolated patellofemoral arthritis whom have failed with non-operative therapies. The PFR spares the tibiofemoral joint, with both anterior and posterior cruciate ligaments and menisci, and therefore allows for more natural kinematics, leaving more bone stock for revision surgery[18].

Anatomical patellofemoral abnormalities such as trochlear dysplasia and patella alta are increasingly recognised as the underlying cause of the later development of patellofemoral osteoarthritis. Farr *et al*[9] concluded in their study that better outcomes after PFR were seen in patients with trochlear dysplasia. Williams *et al*[10] has recently explored the relationship between trochlear dysplasia and FPV outcomes. They reported 7 revisions in their cohort of 48 knees at 2 years follow-up. Trochlear dysplasia was associated with a significantly lower rate of revision and a lower incidence of persistent pain in their cohort. In our study, it was interesting that over 80% of patients had a dysplastic trochlea according to Dejour's classification, with over half displaying patella alta. Patellofemoral abnormalities were therefore present in the majority of the patients undergoing surgery in our series, although their presence had neither a positive or negative effect on clinical outcome.

Interestingly, despite the relative paucity of published

Table 3 A comparison of our results with those previously published for patellofemoral arthroplasty and total knee replacement for isolated patellofemoral arthritis

Ref.	Implant	Number knees/patients	Mean age (yr)	Mean follow-up (yr)	OKS	Melbourne Score	Patient satisfaction	Trochlear dysplasia	Complications	Further operations
Dalury[23]	TKR	33/25	70	5.2	NR	NR	100%	NR	NR	0
Ackroyd *et al*[3]	AVON	109/85	68	5.0	39	25	80%	NR	4 superficial infections 2 stiffness	4 (4.2%) conversions to TKR
Starks *et al*[4]	AVON	37/29	66	2.0	39	28	86%	NR	1 patella fracture 1 patella resurfacing	1 (2.7%) patella resurfacing
Al-Hadithy *et al*[22]	FPV	49/41	62	3.0	38	NR	NR	NR	1 scar pain	3 (6%); 2 (4%) to TKR
Williams *et al*[10]	FPV	48/48	63	2.1	NR	NR	NR	Trochlear dysplasia associated with less revision	10 persistent pain 1 infection, 1 fracture, 1 hypertrophic scar	7 (15%); 5 to TKR
The present report	FPV	41/31	65	3.2	40	21	78%	84% of cases had trochlear dysplasia preoperatively No difference in outcomes	2 superficial infections: Treated with oral antibiotics	1 (2%) conversion to TKR. No lateral releases

NR: Not recorded; OKS: Oxford Knee Score; FPV: Femoro-Patella Vialla; TKR: Total knee replacement.

results, the FPV is the second most used prosthesis for PFR in England and Wales, with the 10th annual National Joint Registry report stating that the FPV was used in approximately 20% of all PFRs performed in 2012 (National Joint Registry for England and Wales[19]). Revision rates for PFR are reported in the National Joint Registry to be 6 times higher than that of primary cemented TKR. Persistent pain is the main cause of revision according to the recent registry data. If all FPVs are considered, the registry calculates a 6.4% (range 4.9%-8.2%) Kaplan-Meier estimate of the cumulative percentage probability of first revision (95%CI) at 3 years. Our 3-year data shows a FPV revision rate of 2%.

Baker *et al*[20] examined the National Joint Registry and concluded that persistent unexplained pain was the principal reason for early revision following PFR, and that revisions usually occurred within the first 2 years. They suggested that patient selection was extremely important, and that PFR surgery should be concentrated in specialist centres. Therefore, we are encouraged by our 2% rate of revision at 3 years.

As with all partial knee replacements, ease of revision undoubtedly affects the rate of early failure. Faced with the unhappy patient, surgeons are potentially more likely to offer conversion to a TKR, as this can usually be achieved with straightforward surgery using primary TKR implants. However there is evidence that revision of partial joint replacements for unexplained pain does not give the pain relief experienced by those who are revised when a cause for failure has been identified[21]. Our low early revision rate might be explained by our reluctance to offer revision surgery to patients dissatisfied with the results of their procedure unless an identified cause for the dissatisfaction could be found.

A further apprehension about PFR is the advancement of osteoarthritis in the tibiofemoral articulation. In our series, there was no progression of tibiofemoral osteoarthritis at latest follow-up. Patient selection is critical and our success may be explained by our selection of patients with underlying trochelar dysplasia as a cause of their patellofemoral arthritis in the vast majority of cases. These patients are perhaps less likely to develop failure of the remainder of the knee over time, than patients whose patellofemoral arthritis develops as part of a more generalised degenerative process. Tibiofemoral osteoarthritis is not always easily identified either preoperatively. Magnetic resonance imaging (MRI) has been used to identify occult degenerative changes in the tibiofemoral articulation by the presence of subchondral cysts[7]. We did not routinely use MRI to screen for occult tibiofemoral arthritis in our patients and our good early results question the requirement for this expensive screening investigation.

The main weakness of our study is a lack of preoperative scores. In addition, this is a retrospective series with relatively small numbers and we do not have long-term follow-up yet. Nevertheless, out mean follow-up of 3.2 years is the longest for this implant in the literature. We specifically did not use a validated satisfaction score, such as the Western Ontario and McMaster Universities Osteoarthritis Index or SF12, for simplicity as we decided that the outcome measure process had to be streamlined. The satisfaction grading

that was used in this study is used for all research projects from our institution.

Table 3 shows that our postoperative results are comparable to those previously published for patellofemoral arthroplasty and for TKR for isolated patellofemoral arthritis. There is one published report by Al-Hadithy *et al*[22], and they report similar satisfactory FPV outcomes with OKSs of 38 at 3 years. They reported 2 revisions, which were attributed to poor patient selection. Indeed, the one conversion to TKR in our series was due to a subsequent diagnosis of rheumatoid arthritis and this could also be retrospectively attributed to poor patient selection.

In conclusion, our early results suggest that the FPV patellofemoral joint replacement is a good alternative to TKR in the surgical management of advanced isolated patellofemoral osteoarthritis. However, we are unable to identify a subgroup of patients with superior outcomes, however do not recommend this procedure in patients suffering from rheumatoid arthritis. Further research is required to see if these initial promising results are maintained at longer term follow-up.

COMMENTS

Background

The knee joint has three compartments: Medial, lateral and patellofemoral. Some patients have isolated patellofemoral arthritis and therefore a novel "patellofemoral arthroplasty" is a treatment option to replace this compartment only, sparing the rest of the native knee joint.

Research frontiers

These patellofemoral replacements are new and there is limited outcome evidence on this particular implant: The Femoro Patella Vialla (FPV) arthroplasty.

Innovations and breakthroughs

In contrast to the current literature, the FPV shows promising early results at 2 years in this study. However, the authors cannot identify a subgroup of patients with superior outcomes. The authors do not recommend performing this procedure on patients with a history of inflammatory arthritis.

Applications

These encouraging outcomes are some of the first published outside the designing centre. The authors await longer outcome studies.

Terminology

"Patellofemoral" means the joint of the femur and patella (kneecap).

Peer-review

The authors have submitted a clinical analysis of the efficacy of using FPV patellofemoral joint replacement as a good alternative to total knee replacement in the surgical management of advanced isolated patellofemoral osteoarthritis. The authors have a relatively good selection of patients in the clinical trial (41 replacements in 31 patients) with radiographic observations and lysholm scoring techniques. The paper is well written and will be of interest to readers.

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ORIGINAL ARTICLE

Retrospective Study

Condensing osteitis of the clavicle in children

Antonio Andreacchio, Lorenza Marengo, Federico Canavese

Antonio Andreacchio, Lorenza Marengo, Department of Pediatric Orthopedic Surgery, Regina Margherita Children's Hospital, 10100 Torino, Italy

Federico Canavese, Department of Pediatric Surgery, University Hospital Estaing, 63003 Clermont Ferrand, France

Author contributions: Andreacchio A and Canavese F designed and performed the research and wrote the paper; Marengo L contributed to the analysis and revised the text.

Institutional review board statement: The study was reviewed and approved by the local Institutional Review Board (Comité de Protection des Personnes Sud-Est 6; ref. 2016/CE01).

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

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

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Correspondence to: Federico Canavese, MD, PhD, Professor of Pediatric Orthopedic Surgery, Department of Pediatric Surgery, University Hospital Estaing, 1 place Lucie et Raymond Aubrac, 63003 Clermont Ferrand, France. canavese_federico@yahoo.fr
Telephone: +33-4-73750293
Fax: +33-4-73750291

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Abstract

AIM: To confirm the rarity of this disorder and then to evaluate the effects of antibiotic treatment alone and assess whether this could produce a complete remission of symptoms in children and adolescents.

METHODS: We made a retrospective review of all cases of condensing osteitis of the clavicle in children and adolescents between January 2007 and January 2016. Outpatient and inpatient medical records, with radiographs, magnetic resonance imaging, triphasic bone scan and computed tomography scans were retrospectively reviewed. All the patients underwent biopsy of the affected clavicle and were treated with intra venous (IV) antibiotics followed by oral antibiotics.

RESULTS: Seven cases of condensing osteitis of the clavicle were identified. All the patients presented with swelling of the medial end of the clavicle, and 5 out of 7 reported persisting pain. The patients' mean age at presentation was 11.5 years (range 10.5-13). Biopsy confirmed the diagnosis in all cases. All the patients completed the treatment with IV and oral antibiotics. At last follow-up visit none of the patients complained of residual pain; all had a clinically evident reduction in the swelling of the medial end of the affected clavicle. The mean follow-up was 4 years (range 2-7).

CONCLUSION: Our findings show that condensing osteitis of the clavicle is a rare condition. Biopsy is needed to confirm diagnosis. The condition should be managed with IV and oral antibiotics. Aggressive

surgery should be avoided.

Key words: Condensing osteitis; Clavicle; Children; Benign tumor; Infection

Core tip: Condensing osteitis of the clavicle is a rare benign disorder. It is characterized by pain and swelling at the medial end of the clavicle, with increased radiodensity. Neither the etiology of this rare condition nor its treatment options are completely clarified. Condensing osteitis of the clavicle in children and adolescents should be recognized promptly. Biopsy is needed to confirm diagnosis. Once diagnosis is made, the condition should be treated by parenteral and oral antibiotic therapy, and aggressive surgery should be avoided.

Andreacchio A, Marengo L, Canavese F. Condensing osteitis of the clavicle in children. *World J Orthop* 2016; 7(8): 494-500 Available from: URL: http://www.wjgnet.com/2218-5836/full/v7/i8/494.htm DOI: http://dx.doi.org/10.5312/wjo.v7.i8.494

INTRODUCTION

Brower *et al*[1] first described condensing osteitis of the clavicle in 1974. The condition was originally described as a syndrome causing pain and swelling over the medial end of the clavicle with increased radiographic density (sclerosis).

Since its first description, few cases of this condition have been described in the English-language literature[2-6]. Some authors consider it as an infective disease - a low-grade chronic osteomyelitis - while others suggest it could be a benign neoplastic process[4,7-9]. However, the etiology of this condition and its best treatment options still remain to be determined[2,5,7,10,11].

Although some cases of spontaneous remission have been observed, the disease often requires treatment. Conservative and surgical options have been described. A number of other different treatments have been recommended over the years, including antibiotic treatment, radiotherapy, chemotherapy, injection of corticosteroids or surgical resection of the medial end of the clavicle in refractory cases[4-6]. However, the etiology of this rare condition and its best form of treatment are still unknown[2,4,11-14].

This study set out to confirm the rarity of this pathology and to assess the outcome of patients treated by parenteral [intra venous (IV)] and oral antibiotic therapy. A review of the literature was also made.

MATERIALS AND METHODS

We made a retrospective review of the archive of clinical records identifying all cases of condensing osteitis of the clavicle diagnosed at our children's hospital from January 2007 to January 2016. Informed consent was obtained. Outpatient and inpatient medical records were reviewed, and we collected the following information for each of the patients: Sex, age at time of diagnosis, side involved, symptomatic picture at presentation, blood tests, type and length of antibiotic therapy, complications and outcome (Table 1).

Standard antero-posterior (AP) radiographs of the clavicle, magnetic resonance imaging (MRI), triphasic bone scan (TBS) and computed tomography (CT) scans were also retrospectively reviewed.

All the patients underwent biopsy of the affected clavicle.

Literature review

A search of the Medline database from 1950 to 2016 was made to identify papers related to condensing osteitis of the clavicle in children, adolescents and adults.

As recommended by the Cochrane Handbook of Systematic reviews[15], a variety of search terms ("condensing", "osteitis", "clavicle" and "children") were used, including a combination of index and free-text terms.

Abstracts were screened, and relevant full texts of articles retrieved for further review. Reference sections of papers were also scrutinized to identify additional literature. All levels of evidence were included.

We retrieved 23 studies reporting a total of 51 patients (52 clavicles) with condensing osteitis of the clavicle. A total of 58 patients (59 clavicles), including our cases, were identified (Table 2).

RESULTS

Seven cases of condensing osteitis were identified during study period (Table 1). There were 5 girls and 2 boys. The mean age of the patients at the time of diagnosis was 11.5 years (range 10.5-13 years). The right side was involved in all cases. All the patients presented with swelling of the medial end of the clavicle. Five out of 7 patients complained of pain worsened by finger pressure at the level of the sterno-clavicular joint.

The swelling was investigated in all the patients, with a standard AP radiograph of the affected clavicle, MRI and TBS. Five out of 7 patients also underwent a CT scan of the affected clavicle.

AP radiographs of the right clavicle (7/7 patients) showed expansion of the medial end of the clavicle, with signs of bone resorption and apposition in all cases (Figure 1).

MRI (7/7 patients) showed bone signal alterations of the medial end of the affected clavicle, and edema of the surrounding soft tissues in all cases.

CT scans (5/7 patients) showed expansion of the

Table 1 Patient demographics

Patient	Age (yr)	Side	Gender	Symptoms	Biopsy	Antibiotic 1	Antibiotic 2	Evolution	Complications
1	10.5	Right	Male	Pain and discomfort in the sterno-clavicular joint Swelling	Yes	Teicoplanin Rifampin 8 wk		Remission	-
2	11.2	Right	Male	Pain and discomfort in the sterno-clavicular joint Swelling	Yes	Teicoplanic Amoxicillin/ clavulanic acid 17 d	Rifampin Trimethoprim-sulfamethoxazole 13 d	Remission	-
3	11.2	Right	Male	Pain and discomfort in the sterno-clavicular joint Swelling	Yes	Teicoplanic Amoxicillin/ clavulanic acid 17 d	Rifampin Trimethoprim-sulfamethoxazole 13 d	Remission	-
4	12.1	Right	Female	Pain and discomfort in the sterno-clavicular joint Swelling	Yes	Teicoplanic Amoxicillin/ clavulanic acid 17 d	Rifampin Trimethoprim-sulfamethoxazole 13 d	Remission	-
5	12.4	Right	Male	Pain and discomfort in the sterno-clavicular joint Swelling	Yes	Teicoplanin Rifampin 8 wk		Remission	-
6	11.5	Right	Female	Swelling	Yes	Teicoplanin Amoxicillin/ clavulanic acid 13 d	Azitromycin 5 d Rifampin Amoxicillin/clavulanic acid 10 wk	Remission	Adverse effect with Teicoplanin
7	13	Right	Male	Swelling	Yes	Teicoplanic Amoxicillin/ clavulanic acid 17 d	Rifampin Trimethoprim-sulfamethoxazole 13 d	Recurrence of pain	-

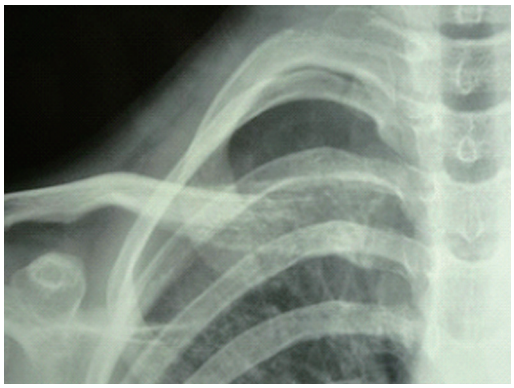

Figure 1 Radiograph of a patient with condensing osteitis showing expansion of the medial end of right clavicle and remodeling of bone.

medial half of the clavicle with no evidence of infection or tumor in all cases (Figure 2).

TBS (7/7 patients) was characterized by a strong hyperfixation of the medial half of the affected clavicle in all cases (Figure 3).

Results of blood tests, including inflammatory markers, were normal in all but 2 cases, in which C-reactive protein level was slightly increased (22.3 mg/dL), reverting to its normal range (< 10 mg/dL) after 4 d of IV antibiotic therapy.

All the patients underwent an incisional biopsy taken from the medial end of the affected clavicle for histology and cultures. Tissues cultures were negative, while histological results reflected a chronic inflammatory process in all the patients. These features were compatible with the diagnosis of condensing osteitis.

Antibiotic treatment

In agreement with Jones' hypothesis of an infectious etiology[6], all the patients received teicoplanin (10 mg/kg every 12 h for a total of 3 doses, followed by 10 mg/kg every 24 h) combined with another type of antibiotic. Two patients received teicoplanin combined with rifampin (300 mg every 12 h) for 56 d. Five patients received teicoplanin combined with amoxicillin/clavulanic acid (1 g every 6 h) for 17 d. The treatment choice was decided by the pediatric infectiologist.

At discharge, all the patients discontinued the IV treatment and started oral rifampin (600 mg every 24 h) and trimethoprim-sulfamethoxazole (80 mg + 200 mg every 12 h) for 13 d.

One patient developed an adverse drug reaction to teicoplanin after 13 d of treatment. The treatment with teicoplanin and amoxicillin was discontinued, and was replaced by azitromycin (300 mg every 12 h) for 5 d and amoxicillin/clavulanic acid (680 mg + 97 mg every 8 h) for 70 d and rifampin (450 mg every 24 h) for 65 d.

All the patients responded well to antibiotic therapy, and showed complete remission of pain and an initial decrease in the swelling.

After 5 mo of therapy one patient experienced a recurrence of pain at the same site. The patient was treated with amoxicillin/clavulanic acid for 14 d with complete remission of symptoms.

Table 2 Review of the literature

Ref.	Number of cases	Symptoms
Brower *et al*[1]	1	Pain
Teates *et al*[12]	2	
Simpson[3,5-7,10]	1	Limited ROM
Duro[3,5-7,10]	2	
Appell *et al*[2]	7	
Weiner[3,5,10]	1	Pain
Franquet[3,5,10]	2	Pain (related to work)
Cone[3,5,10]	1	Pain (worsening)
Kruger *et al*[7]	3	Pain (mild to moderate)
Outwater *et al*[10]	1	Limited ROM
Stewart[3,5,10]	1	Pain (intermittent)
Jones *et al*[6]	3	Pain
Lissens *et al*[8]	2	
Greenspan *et al*[4]	3	
Vierboom *et al*[13]	1	Pain (worsening)
Latifi[3,5-7,10]	1	
Tait[3,5-7,10]	1	
Berthelot *et al*[3]	2	
Hsu *et al*[5]	1	
Rand *et al*[14]	4	Pain (intermittent) Discomfort in the sterno-clavicular joint
Noonan *et al*[9]	1	Pain (chronic)
Sng *et al*[11]	9	Pain Discomfort in the sterno-clavicular joint
Imran[3,5-7,10]	1 (bilateral)	
Present study (2016)	7	Pain Discomfort in the sterno-clavicular joint
Total		58 patients (59 clavicles)

ROM: Range of movement.

Follow-up

The mean length of follow-up was 4 years (range 2-7). At last follow-up visit none of the patients complained of pain. All reported a significant remission of pain and a marked reduction in the swelling on the medial half of the affected clavicle.

DISCUSSION

This study reviewed 7 skeletally immature patients with condensing osteitis of the clavicle. We found that an appropriate IV and oral antibiotic treatment could lead to a significant remission of signs and symptoms in children and adolescents with condensing osteitis of the clavicle (Figure 4).

Since its first description by Brower *et al*[1] in 1974, very few cases of condensing osteitis of the clavicle have been reported in the English-language literature (Table 2).

In 1991 Greenspan *et al*[4] highlighted the rarity of this condition and reported three new proven cases, to be added to the 13 previously reported. The first reported cases all occurred in middle-aged women. It was only in 1983 that Appell *et al*[2] observed this clinical feature at a pediatric age. Noonan *et al*[9] described the first male adult patient in 1998.

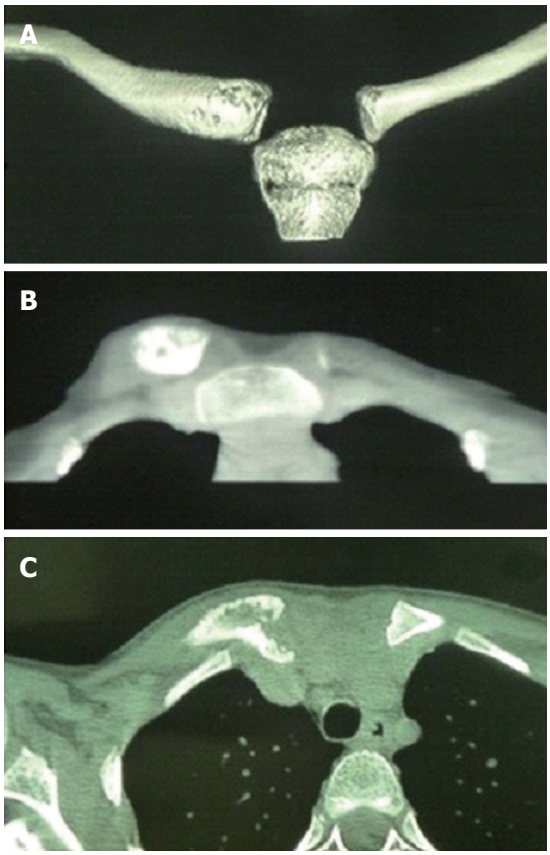

Figure 2 Computed tomography scan with three-dimensional reconstruction (A) of the right clavicle in a patient with condensing osteitis (B, C).

Although many etiopathogenetic hypotheses have been suggested for this disease, its exact cause still remains unknown. Originally, the condition was considered as a response to abnormal and repetitive mechanical stresses, such as might occur with the lifting of heavy loads. In the case of children and adolescents, this hypothesis might be linked to the carrying of a school backpack on a single brace[2].

However, in 1987, Kruger *et al*[7] described 3 women affected by condensing osteitis with no risk factor. One year later, Outwater and Oates[10] reviewed 11 cases with no history of direct trauma. They suggested that osteonecrosis might play an important role in the pathogenesis of this disorder, noting that devitalized bone and marrow fibrosis with remodeling of cancellous bone may be observed in condensing osteitis.

In 1990, Jones *et al*[6] reported three new cases of children with clinical and radiological evidence of condensing osteitis of the clavicle, and concluded that the disorder might be due to low-grade staphylococcal osteomyelitis.

In 1995, Berthelot *et al*[3] pointed out that the disease tended to occur in bone areas overlaid by fibrocartilage, while not affecting the joint areas covered by hyaline cartilage. They therefore suggested that fibrocartilage might play an important role in the

Table 3 Differential diagnosis

Disease	Clinical and/or radiological features
Osteoarthritis	Narrowed joint space with marginal osteophytes, sclerosis restricted to the sub-chondral bone on both sides of the joint
Infection	Bone destruction, synovial abnormality, joint space narrowing, and periosteal reaction
Chronic, sclerosing osteomyelitis	Dense sclerosis similar to condensing osteitis of the clavicle, but periosteal reaction and/or foci of bone destruction
Osteoblastic lesion	Different age at onset, shorter duration of symptoms, epiphyseal location is atypical, periosteal reaction ± bony destruction, progression on serial studies
Metastases	As a solitary bone scan abnormalities in the clavicle epiphysis (unusual)
Osteoid osteoma	Classic central lucent nidus
Sternoclavicular hyperostosis	Usually bilateral, ossification of sterno-clavicular ligaments, bone scan abnormalities at sternum superior ribs, spinal ligamentous ossification and sacro-iliac abnormalities, systemic and specific dermatologic manifestations (palmoplantar pustulosis)
Friedreich's disease	Shorter duration of symptoms, clearer relationship to trauma, bone scan similar, X-rays similar ± subchondral irregularity and focal lucencies, biopsy: Osteonecrosis is typical (but marrow fibrosis or osteonecrosis have been described in several cases of condensing osteitis of the clavicle)
Tietze's syndrome	Involvement of one or more costal cartilages, the clavicle is not involved on radiographs or scan
Chronic recurrent multifocal osteomyelitis	The lesion is initially lytic and with healing, sclerotic and expansile, involves the middle two thirds sparing the medial end, and is typically at presentation. Inflammatory process can be seen at histological examination
Paget's disease	Greater area involved, and the bone scan dramatically more abnormal, localizations in other bones, elevated level of alkaline phosphatase occurs in adults

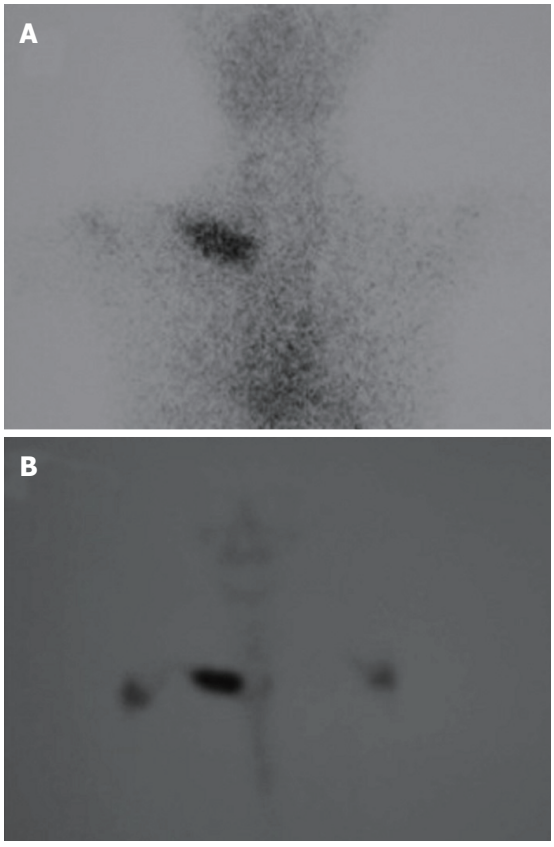

Figure 3 Triphasic bone scan showing strong, localized and isolated hyperfixation of the tracer at the level of the medial end of the right clavicle (A, B).

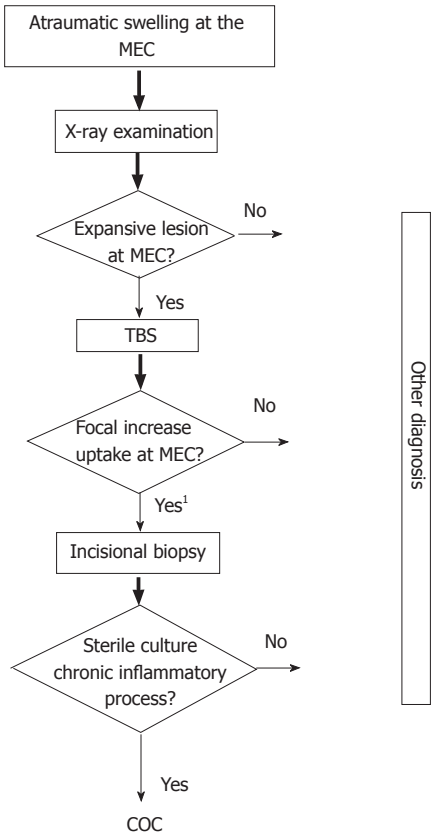

Figure 4 Diagnostic algorithm. [1]If any doubt, fisrt perform MRI or CT scan. MRI: Magnetic resonance imaging; TBS: Triphasic bone scan; MEC: Medial end of calvicle; COC: Condensing osteitis of the clavicle.

pathogenesis of the disease.

In 1978, Teates *et al*[12] pointed out the usefulness of a radionuclide bone scan in the diagnostic process; the radionuclide bone scan is characterized by a significant uptake of the tracer at the level of the affected clavicle. All our patients underwent TBS, and we found a strong, localized and isolated hyperfixation of the tracer at the level of the medial half of the affected clavicle in all cases.

During the 1990s MRI proved a useful non-invasive procedure for the diagnosis of condensing osteitis of the clavicle. MRI can reveal edema and sclerosis of the clavicle, most probably indicative of different stages

in the disease[13,14]. In all our patients MRI showed morphological alterations of the affected clavicle, and edema of the surrounding soft tissues in all cases.

Although Berthelot *et al*[3] reported some cases of spontaneous remission, the condition often requires treatment. Kruger *et al*[7] and Lissens *et al*[8] report that non-steroidal and anti-inflammatory medications have proved effective in relieving the pain. However, resection of the medial end of the clavicle may be required in refractory cases[4,7,8]. On the other hand, Jones *et al*[6] observed complete remission of symptoms in the case of antibiotic therapies.

Over the years, a number of different treatment options have been described, including radiotherapy, chemotherapy, injection of corticosteroids, and surgical resection of the medial end of the clavicle in refractory cases[4,5,7,8]. However, the best treatment option for this condition is still unknown.

In conclusion, the rarity of this pathology is highlighted by the fact that fewer than 60 proven cases have been reported in the scientific literature (Table 2). Nevertheless, the appearance of a non-traumatic swelling of the clavicle, even in the pediatric age group, should evoke this rare disorder, which should be considered in differential diagnosis (Table 3).

The potential consequences of a missed diagnosis are that the patient may undergo unnecessary, extensive and costly clinical and radiological investigations, especially if the lesion is thought to be metastatic. Furthermore, although the etiology remains unclear (seemingly either mechanical or an infectious), the complete remission of symptoms reported in our case series as a consequence of the antibiotic treatment suggests an infectious etiology, as in Jones' hypothesis[6]. Biopsy is, however, necessary to confirm the diagnosis.

We therefore recommend approaching the disease with an appropriate IV and oral antibiotic therapy in order to avoid unnecessary aggressive surgery. Antibiotic treatment should start after the pathology report has confirmed the diagnosis. Resection of the affected medial half of the clavicle should be reserved for refractory cases only.

COMMENTS

Background

Condensing osteitis of the clavicle is a rare benign disorder of unknown origin that should be recognized promptly. It is characterized by pain and swelling at the medial end of the clavicle, with increased radio-density. Biopsy is needed to confirm diagnosis. The condition should be treated by parenteral and oral antibiotic therapy.

Research frontiers

The potential consequences of a missed diagnosis are that the patient may undergo unnecessary, extensive and costly clinical and radiological investigations, especially if the lesion is thought to be metastatic. Biopsy is necessary to confirm the diagnosis.

Innovations and breakthroughs

The disease should be approached with an appropriate intra venous (IV) and oral antibiotic therapy in order to avoid unnecessary aggressive surgery. Antibiotic treatment should start after the pathology report has confirmed the diagnosis. Resection of the affected medial half of the clavicle should be reserved for refractory cases only.

Applications

The study results suggest that IV and oral antibiotic therapy is effective in controlling the disease.

Terminology

Condensing osteitis of the clavicle is a rare benign disorder of unknown origin that should be recognized promptly. It is characterized by pain and swelling at the medial end of the clavicle, with increased radio-density.

Peer-review

The manuscript has been described very well. Although it is a case series, the authors summarized the previous literature and presented well.

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ORIGINAL ARTICLE

Observational Study

Four corner fusion using a multidirectional angular stable locking plate

Tahseen Chaudhry, Michelle Spiteri, Dominic Power, Mark Brewster

Tahseen Chaudhry, Michelle Spiteri, Dominic Power, Mark Brewster, Department of Hand Surgery, Queen Elizabeth Hospital, Birmingham B15 2TH, United Kingdom

Author contributions: Chaudhry T contributed to design and planning, protocol, data collection and processing, literature review, paper write up and revisions; Spiteri M contributed to data collection and processing, literature review; Power D contributed to study design and setup, data collection, paper review; Brewster M contributed to design and planning, protocol, data collection and processing, literature review.

Institutional review board statement: The study met the requirements of our hospital Institutional Review Board for clinical research. None of the authors have any conflict of interest to declare.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: None of the individual authors of this paper have any conflicts of interest.

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Correspondence to: Dr. Tahseen Chaudhry, Department of Hand Surgery, Queen Elizabeth Hospital, Edgbaston, Birmingham B15 2TH,
United Kingdom. tahseen_c@hotmail.com
Telephone: +44-1217-775956
Fax: +44-1213-712000

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Abstract

AIM: To review the results of our experience with the Medartis Aptus plating system for four corner arthrodesis of the wrist, which uses a combination of compression screws and variable angle locking screws.

METHODS: We reviewed the results of 17 procedures in 16 patients that underwent scaphoid excision and four corner fusion using the Medartis Aptus system between May 2010 and June 2014. The primary outcome measure was radiographic and clinical union.

RESULTS: The mean clinical follow up time was 20.6 mo. The mean union time was 6 mo. Two non-unions required revision procedures. The mean disabilities of the arm, shoulder and hand score taken after union was 36. The mean final grip strength was 27 kg. The mean final range of movement was 30° flexion and 31° of extension. All patients had a restored scapholunate angle on postoperative radiographs. There were no incidences of dorsal impingement.

CONCLUSION: Overall our experience with the Aptus plating system shows comparable results to other methods of fixation for four corner fusion, in the short to medium term.

Key words: Wrist surgery; Arthrodesis; Locking plate;

Scaphoidectomy; Partial fusion

Core tip: This paper demonstrates that a multi angle locking plate is a suitable device for four corner fusion. It demonstrates that results are comparable to those of other means of fusion in the short to medium term.

Chaudhry T, Spiteri M, Power D, Brewster M. Four corner fusion using a multidirectional angular stable locking plate. *World J Orthop* 2016; 7(8): 501-506 Available from: URL: http://www.wjgnet.com/2218-5836/full/v7/i8/501.htm DOI: http://dx.doi.org/10.5312/wjo.v7.i8.501

INTRODUCTION

Scaphoidectomy with four corner fusion is a well recognised surgical option for scapholunate advanced collapse (SLAC) and scaphoid non-union advanced collapse (SNAC) when the radio-lunate joint is preserved[1]. Multiple fixation options have been employed including K wires, headless screws, staples and plates[2-4]. Many techniques have been associated with significant complications. Circular "hub-cap" plates in particular have been associated with complications such as non-union and dorsal plate impingement[3,5]. In response to this, newer implants are increasingly being trialled including memory staples and plates with newer designs such as the carpal fusion plate[6,7]. Medartis™ (Basel, Switzerland) have designed the APTUS™ four corner fusion plate with some design variations compared to previous plates aimed at improving union rates and decrease dorsal impingement. Results of this plate have not previously been reported in the literature.

MATERIALS AND METHODS

A retrospective review of cases undergoing treatment with the Medartis APTUS™ Four Corner Fusion plate was performed in our unit. Cases performed at The University Hospital Birmingham and the Royal Orthopaedic Hospital were identified from a review of operating logs between May 2010 and June 2016, and the patients reviewed. Indications for surgery, associated procedures, pre-operative radiographic deformity and lunate type in particular were noted. Time to union, complications and need for further surgery were also assessed. At follow up patients also had their wrist range of movement assessed with flexion and extension measured according to the method described by Kendal *et al*[8] with a goniometer placed dorsally over the wrist and flexion measured on the ulnar border of the wrist. Grip strength was measured using a dynamometer (Jamar dynamometer; Sammons Preston Roylan, Bollingbrook Illinois) with the best grip strength of three trials of each surgically treated wrist compared with that of the opposite wrist (except in the one case of bilateral four corner fusion). A disabilities of the arm, shoulder and hand (DASH) score survey was also performed. All assessments were performed by four consultant hand surgeons within the 2 hospitals.

The study met the requirements of our hospital Institutional Review Board for clinical research. None of the authors have any conflict of interest to declare.

Surgical technique

All surgeries were performed by one of four hand surgeons at the Birmingham Hand Centre (which entails a group of hand surgeons working at both hospitals). All surgeons used the same dorsal approach under tourniquet control following intravenous antibiotics. A regional block was used in all cases except when iliac crest bone graft was taken. In all cases a dorsal 3-4 approach through the extensor retinaculum was used. A dorsal wrist ligament preserving approach was used, extending up along the radial styloid[9]. The radio-lunate articular surfaces were assessed either by arthroscopy or direct vision to ensure the joint was well preserved. The scaphoid was excised and where possible used for bone graft. A radial styloidectomy was performed in 1 case. The interfacing chondral surfaces of the four bones were denuded with a nibbler, curved periosteal elevator and osteotome leaving the very volar aspects untouched to maintain the normal gap between adjacent bones. Where subchondral bone was sclerotic, further holes were created with a K wire to allow maximal bone bleeding.

K wires were inserted into the carpal bones to realign the capitate and lunate and if necessary stabilise the hamate and triquetrum (only required about half the time). This was performed in 2 main ways: (1) an antegrade 1.6 mm K wire from radius to lunate (once the radiolunate angle had been corrected by flexion or extension of the wrist) and then advanced onto the capitate once a neutral capito-lunate angle was achieved and the radio-ulna translation corrected (often the capitate tries to slip off the lunate radially); and (2) a retrograde wire is passed between the second and third metacarpal bases with around 20 degrees of elevation off the hand, through the capitate and onto the lunate, which allows correction of any carpal malalignment present. Both K wire insertion methods are technically difficult due to the angles required and in addition the wire needs to be seated palmar in both bones to allow for the subsequent reamer to cut freely.

During K wire introduction it is important to reduce the capitate into the lunate, which can be especially difficult in type 2 lunates in which there is a tendency for the capitate to slip off the lunate radially.

A custom APTUS™ reamer is then placed in the cross of the 4 bones to allow the plate to be countersunk. It is important to ream the bones to equal depths especially

Table 1 Patient and surgery characteristics, time to union and follow up

Number	Age	Sex	Hand	Classification	Lunate type	VISI/ DISI	Associated surgery	No. of screws	Union (mo)	Complications	Follow up (mo)
1a	64	M	L	SLAC	1		PIN	11	4		30
1b	65	M	R	SLAC	1		PIN	11	6		24
2	52	F	R	SLAC	2	V	PIN	12	3		10
3	40	M	L	SLAC	1	D	Distal radius graft (previous PIN)	12	9		11
4	38	M	L	SNAC	1	D	PIN + styloidectomy	11	16	Screws Penetrating CMC joint	35
5	72	F	L	SNAC	1	D	PIN + Iliac BG	8	3		8
6	55	M	L	SNAC	2	D	PIN + distal radius graft	11	2		18
7	61	M	R	SNAC	2	D	PIN + distal radius graft	11	3		10
8	33	M	L	Lunate fracture	1	V	PIN	12	17[1]	Non-union, revised	23
9	35	M	L	SNAC	2		PIN	11	7	Hypertrophic bone	16
10	50	M	R	SNAC	2		PIN	10	6	Scar sensitivity	25
11	55	M	L	SNAC	1		PIN	10	4		26
12	46	M	L	SNAC	2	D	PIN	12	7		25
13	48	F	L	SNAC	1	D	PIN	12	5		25
14	40	M	R	SNAC	2		PIN	12	8	Skin necrosis over plate + flap coverage	24
15	18	M	R	Scaphoid	2		PIN, plate removal distal radius graft	10	9		16
16	50	M	R	SLAC	1		PIN	12	27[1]	Non-union, revised	27

[1]Indicatates total time to final union including both index procedure and revision surgery. PIN: Posterior interosseous neurectomy; M: Male; F: Female; L: Left; R: Right; SLAC: Scapholunate advanced collapse; SNAC: Scaphoid nonunion advanced collapse; V: VISI; D: DISI; BG: Bone graft; CMC: Carpometacarpal.

on the lunate to allow the plate to be flush of deep to the dorsal lip to avoid dorsal impingement on wrist extension.

In some cases additional dorsal radial or iliac crest graft was taken to pack between the bones and this can be further compressed by reaming on a reverse setting with the bone graft *in situ*.

Once the plate is seated, inner non-locking compression screws are inserted to secure the four bones. Outer multidirectional (30 degree arc of variability) locking screws were then inserted. However if an angle outside the 30 degree arc is required to gain carpal purchase, a non locking screw can be used in these outer holes. The triquetrum was included in all fusions. An image intensifier was used throughout to check implant and carpal positions.

There was a variation in post-operative immobilisation from wool and crepe to 6 wk in a below elbow plaster (Table 1). If a cast was used for less than 6 wk patients began active mobilisation with a removable thermoplastic splint for comfort. From six weeks post-operative date onwards signs of union were assessed at regular intervals clinically by a lack of tenderness at the fusion site and/or with radiographic evidence of bridging trabeculae between the bones (although this was appreciably difficult due to the multiple overlapping cortices seen on plain radiographs (Figure 1A). Dorsal impingement was identified according to the description of Shindle *et al*[3] by the patient complaining of a sharp dorsal pain with maximal passive or active wrist extension.

RESULTS

Seventeen procedures were performed on sixteen patients, 13 men and 3 women. The demographic data of the patients is included in Table 1. The mean age of the patients was 48 years (range 18-72 years). Ten operations were on a left wrist, seven on a right wrist. The indications were SLAC grade 2 in three wrists, grade 3 in two wrists and SNAC in ten wrists. One case was a salvage procedure for a failed fixation of a scaphoid fracture, another was a salvage procedure for a lunate fracture. Typical pre-operative appearances are shown in Figure 1.

The mean follow up time was 20.6 mo (range 8-35). Excluding the two non-unions that required revision procedures, the mean time to union on radiographic and clinical assessment was 6 mo (range 3-16). All fusions ultimately united including the two that required revision surgery. One case united after 16 mo but multiple screws were found to have broken during the follow up period. This patient went on to undergo metalwork removal as one screw penetrated the fifth carpometacarpal joint.

The final range of movement was invariably reduced compared to the contralateral side. The mean final flexion was 30 degrees (20-45) and the mean final extension was 31 degrees (10-60). There were no instances of dorsal impingement from the plate. Post-operative radiographs for a number of patients were taken in full wrist extension, and these demonstrated the ability of the plate to remain deep to the dorsal lip

Table 2 Outcomes at discharge or at latest follow up

Number	JAMAR (kg) (unaffected)	% grip strength difference	Flexion (unaffected)	Extension (unaffected)	DASH	Return to work	Satisfied?
1a	22	NA	30	20	43	Retired	Yes
1b	24	NA	25	40	43	Retired	Yes
2	11 (26)	42%	25 (50)	15 (40)	48	Office	Yes
3	30 (36)	83%	45	45	15	Office	Yes
4	32 (37)	87%	35 (92)	18 (80)	48	Heavy manual	Yes
5	4 (18)	22%	30	10	35	Retired	Yes
6	48 (32)	150%	30	45	20	Office	Yes
7	25 (38)	66%	45	45	13	Retired	Yes
8	22 (55)	40%	30	20	61	No	No
9	36 (48)	75%	20	10	43	No	Yes
10	30 (40)	75%	30	60	20	Office	Yes
11	18 (52)	35%	20	20	35	Office	Yes
12	26 (35)	74%	40	40	15	Yes	Yes
13	25 (30)	83%	20	50	13	Manual	Yes
14	45 (35)	129%	30	40	42	No	No
15	20 (38)	53%	20	35	15	Office	Yes
16	40 (55)	73%	30	15	27	Office	Yes

Data for the unaffected wrist where available are given in brackets. DASH: Disabilities of the arm, shoulder and hand.

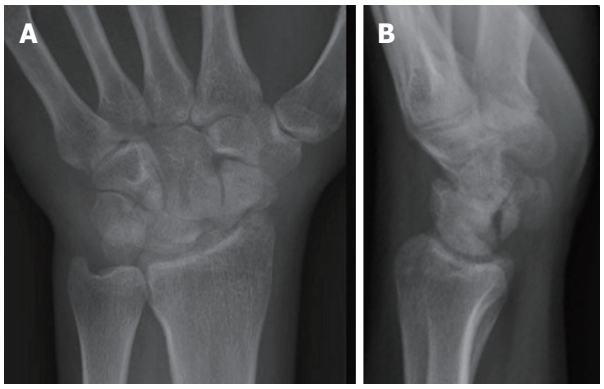

Figure 1 A posterior-anterior (A) and lateral (B) view of a typical Scapholunate advanced collapse wrist prior to undergoing four corner fusion.

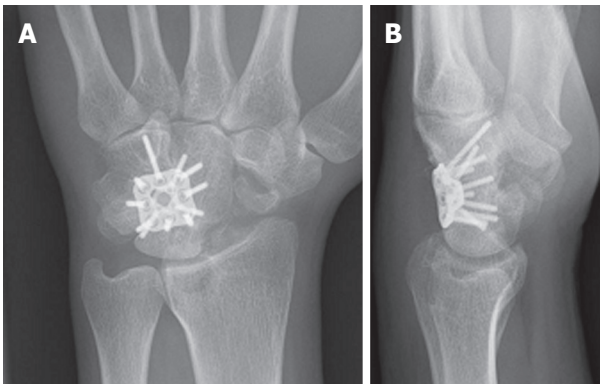

Figure 2 A posterio-anterior (A) and lateral (B) view of the plate in its final position.

of the radius in extension (Figure 1A).

All patients had a restored scapholunate angle on postoperative radiographs (Mean = 60°). The mean capitolunate angle was 3° (range: 15°-3°)

Typical post-operative X-ray and computed tomography appearances are shown in Figures 2 and 3.

The mean final grip strength was 27 kg (range: 4-48) which represented 72% (22%-129%) of the unaffected side. The mean DASH score at the latest follow up was 32 (13-61).

Table 2 shows that all but two patients managed to return to their previous occupation.

Two patients remain unsatisfied at the last follow up for reasons mentioned below. One is awaiting a wrist arthroscopy and the other had skin necrosis around the dorsal wound requiring flap coverage. No additional data are available.

Complications

One patient had broken screws that were impinging on the 5th CMCJ and required removal.

One patient had a very sensitive scar that failed to settle down during the follow up period.

Two patients exhibited radial drift, with the trapezium abutting the radius on post operative radiographs. Neither had any associated clinical symptoms. A further patient had an area of skin necrosis over the dorsal wrist incision site and required debridement and a radial forearm flap to cover the soft tissue defect. He has made a good functional recovery but is significantly affected by the cosmetic appearance of his wrist.

Two patients failed to unite by 15 mo and were therefore revised with the same implant. Both went onto unite successfully. One of these patients has returned to work and is satisfied, and the other has ongoing ulnar sided wrist pain which is awaiting a wrist arthroscopy.

DISCUSSION

In the setting of SNAC and SLAC wrists, scaphoidectomy and four corner fusions with a plate is very attractive.

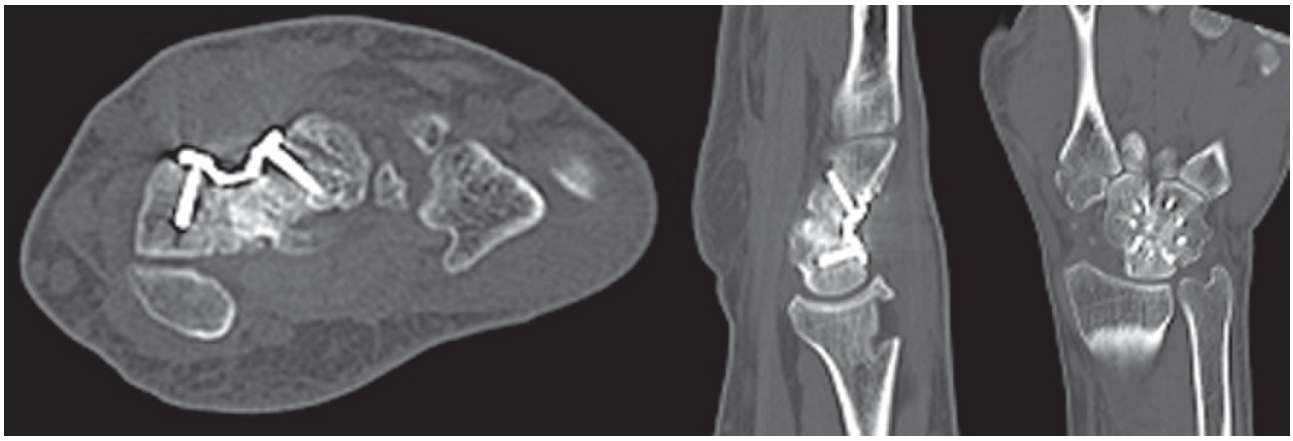

Figure 3 Coronal, Sagittal and axial, postoperative views following plate application and fusion.

Compared to fixation techniques such as K wires, four corner fixation plates have the potential advantages of increased stability, higher fusion rates, shorter periods of immobilisation and improved range of motion[8].

The design of the Medartis APTUS™ plate arose from documented concerns with previous circular dorsal plates[3,5]. Complications included radiographic non-union rates as high as 62.5% dorsal impingements as frequent as 25% and an overall complication rate of up to 56%[3,8]. The Medartis™ plate design is low profile (1.4 mm thick) and has variable screw fixation options. The carpus is reamed to allow the plate to sit sunken within the carpal bones, to minimise plate impingement on the dorsal lip of the radius. There was no evidence of dorsal impingement in our study.

The Medartis™ plate (which comes in 2 sizes, 17 and 15 mm diameter) allows compression with central non-locking screws as well as locking screw fixation. Each locking screw can be inserted within a 30 degree arc (locked with a unique Trilock™ system allowing adjustment of the screw angle up to 3 times), this allows for greater adjustment by the surgeon to get optimal bony purchase with the screws. Locking screws are theoretically stronger than traditional screws as was borne out in Kraisarin's cadaveric study[10]. Locking screws alone may hinder compression at the fusion site and fix the carpus bone in a distracted position[8]. They may also create too rigid a construct to allow interfragmentary motion, a factor which we think occurred in our case when several screws broke. The high fusion rate of implants that allow compression including K wires memory staples and the carpal fusion system plate highlights the need for compression in a four corner fusion[6,7,11].

Hence, by allowing compression prior to locking fixation, the Medartis™ plate appears to promote fusion over previous dorsal plate designs.

All patients in our study reported mild to no pain following surgery, in contrast to Kendall *et al*[8] but in keeping with other studies[12]. In all cases a PIN neurectomy was performed at the time of surgery, except in one case when the PIN neurectomy had previously been performed. Pain tended to be located over the ulnar side of the wrist in flexion and ulnar deviation.

The patients in our study fixed with the Medartis APTUS™ plate appeared to have a relatively long time to fusion. It is known however that time to union is difficult to diagnose on plain radiographs as the circular plate blocks the area of fusion and hence some authors only diagnose a non-union where a secondary procedure is required[3,8]. Whilst we used clinical assessment to diagnose carpal fusion, this has not been validated. As time to union may not be an objective measurement, it may be that the need for a secondary procedure for fusion as reported by Kendall *et al*[8] is more useful.

Our mean follow up is just under two years. A long term follow up study of four corner fusions suggests that most complications occur with a two year initial period after which there is long term satisfaction with the procedure[13].

The main limitation with this study, in that, it involved a relatively small retrospective cohort. Furthermore, the addition of pre-operative range of motion, grip strength and DASH scores would have been a useful adjunct to this data. We believe that our data support performing a PIN neurectomy at the time of surgery as well as using an inset circular plate that allows both compression and locking screw fixation of the carpus. With an improvement of wrist plates specifically designed for four corner fusion, there will hopefully be an improvement in the results of four corner fusion to match the high success and low complication rates of total wrist fusion.

COMMENTS

Background

Scaphoidectomy with four corner fusion is a well recognised surgical option for scapholunate advanced collapse (SLAC). A variety of fixation methods have been tried and the newest implants are plates of various designs.

Research frontiers

Many of the current plates have problems with non-union or impingement.

Innovations and breakthroughs

The Medartis Aptus plate has some design variations compared to previous plates aimed at improving union rates and decrease dorsal impingement. These may be achieved through its multiangle locking configuration as well as its cortical screw holes and low profile design.

Applications

This plate is a useful solution for four corner arthrodesis in patients with SLAC or scaphoid non-union advanced collapse.

Terminology

SLAC wrist: Scapholunate advanced collapse.

Peer-review

It is a well written manuscript overall that worth publishing.

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ORIGINAL ARTICLE

Observational Study

Validation of the functional rating index for the assessment of athletes with neck pain

Soofia Naghdi, Noureddin Nakhostin Ansari, Somaye ShamsSalehi, Ronald J Feise, Ebrahim Entezary

Soofia Naghdi, Noureddin Nakhostin Ansari, Somaye ShamsSalehi, Ebrahim Entezary, Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Sciences, Tehran 11489, Iran

Ronald J Feise, Institute of Evidence-Based Chiropractic, Scottsdale, AZ 85251, United States

Author contributions: Naghdi S, Nakhostin Ansari N, and Feise RJ conceived and designed the study; ShamsSalehi S drafted the research protocol, which was edited and revised by Naghdi S, Nakhostin Ansari N, and Entezary E; ShamsSalehi S collected the data; Nakhostin Ansari N performed all the statistical analyses; Naghdi S, Nakhostin Ansari N and ShamsSalehi S drafted the manuscript, which was further edited and approved by all authors to be published; Nakhostin Ansari N was the chief investigator and guarantor.

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Correspondence to: Noureddin Nakhostin Ansari, Professor, Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical sciences, Enghelab Ave, Pitch-e-shemiran, Tehran 11489, Iran. nakhostin@sina.tums.ac.ir
Telephone: +98-21-77533939
Fax: +98-21-77727009

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Abstract

AIM: To validate the culturally-adapted Persian Functional Rating Index (PFRI) for assessing neck pain (NP) in athletes.

METHODS: In this cross-sectional study, 100 athletes with NP and 50 healthy athletes participated and responded to the PFRI. Fifty athletes with NP completed the PFRI for at least 7 d later to establish test-retest reliability.

RESULTS: The athletes with NP responded to all items, indicating excellent clinical utility. No floor and ceiling effects were found, indicating content validity and responsiveness. The PFRI revealed capability to discriminate between the athletes with NP and healthy athletes. The PFRI demonstrated strong correlation with the Numerical Rating Scale (Spearman's rho = 0.94), and the Persian Neck Disability Index (Pearson r = 0.995), supporting criterion and construct validity. Internal consistency reliability was high (Cronbach's α coefficient: 0.97). The test-retest reliability was excellent ($ICC_{agreement}$ = 0.96). The absolute reliability values of standard error of measurement and smallest detectable change were 3.2 and 8.84, respectively. An exploratory

factor analysis yielded one factor explaining 78.03% of the total variance.

CONCLUSION: The PFRI is a valid and reliable measure of functional status in athletes with NP.

Key words: Athletes; Neck pain; Functional rating index; Reliability; Validity

Core tip: Patient-reported outcomes are widely used to evaluate the functional effectiveness of treatments in clinical investigations. There has been a lack of patient-reported outcome measure for athletes with neck pain (NP). This study assessed the psychometric properties of the culturally-adapted Persian Functional Rating Index in a group of athletes with NP and demonstrated excellent validity and reliability.

Naghdi S, Nakhostin Ansari N, ShamsSalehi S, Feise RJ, Entezary E. Validation of the functional rating index for the assessment of athletes with neck pain. *World J Orthop* 2016; 7(8): 507-512 Available from: URL: http://www.wjgnet.com/2218-5836/full/v7/i8/507.htm DOI: http://dx.doi.org/10.5312/wjo.v7.i8.507

INTRODUCTION

Neck pain (NP) is a common musculoskeletal complaint in athletes. The lifetime incidence of NP has been estimated at 47.6%, with approximately 64% being sports related[1]. An epidemiological study found a relatively higher rate of NP in cycling athletes[2]. The NP in athletes may result from sprains, strains, and soft tissue contusions resulting in various problems such as deficits in mobility, strength, endurance, and postural stability[3-6]. In order to help the athletes with NP return quickly to their sporting function, it is important to accurately assess their symptoms and function using valid and reliable tools.

There are several disease-specific questionnaires developed to assess the functional limitations in people with spinal disorders including neck pain (*e.g.,* neck disability index, neck pain and disability scale). Any outcome tool should be validated among different populations before using in the clinical assessments. The validity of the questionnaires to measure neck related pain and disability is not established among athletes with NP. Currently, there is no validated test developed specifically for assessing NP in athletes.

The Functional Rating Index (FRI) is a patient-reported questionnaire developed to evaluate the patients' perspectives on their pain and functional status in patients with low back pain (LBP) as well as NP[7]. The Persian FRI (PFRI) is validated in the general population with LBP[8] and NP[9], and it was recently validated for athletes with LBP[10]. The present study aims to validate the PFRI in athletes with NP. The psychometric properties of floor or ceiling effects, discriminant validity, concurrent criterion validity, construct validity, internal consistency reliability, test-retest reliability, standard error of measurement (SEM), smallest detectable change (SDC), and factor structure were evaluated.

MATERIALS AND METHODS

The protocol of this cross-sectional study was approved by the review board, School of Rehabilitation, Tehran University of Medical Sciences (TUMS). The study was performed after approval by the TUMS Ethics Committee, and all subjects gave their written informed consent for taking part in the study.

Participants

Adult athletes age ⩾ 18 years with NP, participating in sport activities for at least 2 h, 3 d/wk, and be able to read and write Persian were recruited from Tehran, Iran sport clubs and included in the study. Athletes were excluded if they had osteoporosis, spinal fracture, previous spinal surgery, or rheumatologic diseases. The sample size for this study was based on the recommendation provided in the guideline; thus, 100 athletes with NP were included in the study[11].

Procedure

We followed the procedure used for validation of the FRI in athletes with LBP[10]. Eligible athletes were sampled from the Tehran sport clubs, Iran. The study aim and procedure were first thoroughly described to each eligible athlete. Then, after an informed consent form was read and signed by each athlete, demographic data including age, education, NP duration, and sports activities were recorded. Each eligible athlete was asked to fill out the PFRI, validated Persian Neck Disability Index (NDI)[12], and the Numerical Rating Scale (NRS)[13]. Fifty athletes with NP refilled out the PFRI at least 7 d later to evaluate the test-retest reliability. Fifty healthy athletes with no neck pain filled out the PFRI to assess discriminant validity. The NDI and the NRS were filled out to assess respect construct validity and concurrent criterion validity. High correlation was expected between the PFRI and NDI for construct validity.

Instruments

FRI: The FRI is a reliable and valid instrument that contains 10 items measuring both pain and function from 0 (no pain/full function) to 4 (worst possible pain/unable to perform function). The formula (total score/40) × 100% was used to calculate the disability score ranging from 0% (no disability) to 100% (severe disability)[7,14]. The culturally adapted and validated Persian FRI was used in this study[8-10].

NDI: The instrument used to evaluate the construct validity was the reliable and valid NDI[15]. The NDI

contains 10 items with each item rated from 0 (no activity limitation) to 5 (major activity limitation). The NDI total score is calculated as a percentage, with higher scores meaning greater disability. In this study, the culturally adapted Persian NDI was used[12].

NRS: The NRS was used to assess concurrent criterion validity. With the NRS, the athletes with NP were asked to score their pain intensity between 0 (no pain) and 10 (worst possible pain)[13,16].

Statistical analysis

The floor and ceiling effects were analyzed by calculation of percentage of the lowest (0%) and the highest (100%) scores for the total PFRI. Discriminant validity was assessed by comparing the PFRI total scores of the athletes with NP with scores of the healthy athletes using the independent *t* test. The construct validity was analyzed by examining the correlation between the PFRI and the NDI using Pearson correlation test with levels of 0.6 $\geqslant$ [7]. The Spearman rank order correlation was used to assess concurrent criterion validity by correlating the PFRI total scores to the NRS with at least 0.7 as acceptable. The Cronbach's α was applied to analyze the internal consistency reliability with a level of 0.7 or higher as satisfactory[11]. The intraclass correlation coefficient agreement ($ICC_{agreement}$) (two-way random effects model, absolute agreement, and single measure) was used for the test-retest reliability analysis with a level of at least 0.70 as acceptable. The absolute reliability measures of the standard SEM and the SDC were estimated using the formulas $\sigma\sqrt{1\text{-ICC}}$ and 1.96 × SEM × $\sqrt{2}$, respectively. A principal component analysis (PCA) with varimax rotation (VR) was used to analyze the factor structure of the PFRI. The SPSS software, V17 (SPSS, Inc, Chicago, IL) was used for the statistical analyses.

RESULTS

Overall, this study recruited 150 athletes. One hundred athletes with NP (60 male/40 female; mean age ± SD 30.8 ± 6.7 years; education 15.0 ± 2.2 years; NP duration 3.72 ± 1.74 mo) and 50 healthy athletes (27 male/23 female; mean age 31.5 ± 7.4 years; education 15.0 ± 2.4 years) participated in the study. Of the 100 recruited athletes with NP, 50 athletes completed the PFRI again after at least 7 d (range: 7.0-32.0 d) to establish test-retest reliability.

The sports activities of athletes in this sample of athletes (*n* = 150) included bodybuilding (*n* = 46, 30.7%), aerobics (*n* = 27, 18.0%), swimming (*n* = 16, 10.7%), karate (*n* = 17, 11.3%), taekwondo (*n* = 13, 8.7%), volleyball (*n* = 10, 6.7%), soccer (*n* = 9, 6.0%), yoga (*n* = 6, 4.0%), and badminton (*n* = 6, 4.0%).

Floor and ceiling effects

The athletes with NP responded to all items, and no missing data were detected. No floor or ceiling effect was observed for PFRI scores (range: 10.00-92.50). No athletes with NP scored the highest or lowest possible score on the PFRI. Table 1 shows the clinical data for the athletes with NP.

Table 1 Summary of clinical data in athletes with neck pain (*n* = 100)

Outcome measures	Mean	SD	Range	
			Minimum	Maximum
PFRI	30.85	15.94	10.00	92.500
PNDI	30.22	15.93	8.00	88.00
NRS	Median (IQR) 2 (2-3)			

PFRI: Persian functional rating index; PNDI: Persian neck disability index; NRS: Numerical rating scale; IQR: Interquartile range.

Validity

For discriminant validity, the PFRI scores from the 50 athletes with NP who participated in the test-retest reliability evaluation were compared with those of the healthy athletes. The PFRI scores for athletes with NP (32.2 ± 19.04) were statistically worse than those of healthy athletes (3.7 ± 2.5) (Levenes's test: F = 69.001, $P < 0.001$; $t = 10.5$, df = 50.7, $P < 0.001$).

For the evaluation of the concurrent criterion validity, Spearman's rho displayed an excellent correlation between the PFRI scores and the NRS (correlation coefficient = 0.94, $P < 0.001$; 95%CI: 0.9-0.97).

An excellent correlation was found between the PFRI and the NDI (Pearson correlation coefficient = 0.995, $P < 0.001$; 95%CI: 0.99-1.0) for construct validity.

Relative reliability

Cronbach's α coefficient of internal consistency was 0.96, and values of Cronbach's α if an item was deleted ranged between 0.961 and 0.964. Corrected item-total correlation ranged from 0.812 to 0.896 (Table 2).

$ICC_{agreement}$ was excellent for test-retest measurements ($ICC_{agreement}$ = 0.96, 95%CI: 0.93-0.98, $P < 0.001$) (Table 3).

Absolute reliability

The SEM and the SDC were calculated to be 3.2 (95%CI: -6.25-6.25) and 8.84, respectively (Table 3).

Factor analysis

The Kaiser-Meyer-Olkin was 0.94, which indicates the adequacy of the sample for performing the factor analysis. The Bartlett's test of sphericity produced a high χ^2 of 1107.421, df = 45, $P < 0.001$, which indicates that the factor model was appropriate. The PCA with VR revealed a model with 1 factor, explaining 78.03% of the total variance. Figure 1 shows the scree plot curve for factor analysis of the 10-item PFRI.

DISCUSSION

In this study, the PFRI was evaluated for validity and reliability in Persian-speaking adult athletes with NP, and

Table 2 Cronbach's alpha and item-total statistics for persian functional rating index

FRI items	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
Pain intensity	10.89	34.240	0.877	0.801	0.963
Sleeping	11.45	33.563	0.823	0.724	0.964
Personal care	11.02	33.353	0.852	0.780	0.963
Travel	10.83	31.819	0.852	0.753	0.963
Work	11.04	34.463	0.867	0.804	0.963
Recreation	11.07	33.399	0.846	0.735	0.963
Frequency of pain	10.57	32.591	0.812	0.750	0.964
Lifting	10.97	33.686	0.831	0.723	0.963
Walking	11.58	31.620	0.896	0.865	0.961
Standing	11.64	31.930	0.883	0.854	0.962

FRI: Functional rating index.

Table 3 Results of relative and absolute reliability measures for the Persian Functional Rating Index in athletes with neck pain (n = 50)

Scale	Mean ± SD		d (SD)	$ICC_{agreement}$ (95%CI)	SEM	SDC
	Test	Retest				
PFRI	32.15 ± 19.04	30.70 ± 15.90	1.45 (4.95)	0.96 (0.93-0.98)	3.2	8.84

d: Mean difference of the test and retest scores; ICC: Intraclass correlation coefficient; SEM: Standard error of measurement; SDC: Smallest detectable change; PFRI: Persian Functional Rating Index.

it was shown to have excellent psychometric properties. All athletes with NP completed the PFRI without any problem, indicating the cultural acceptability and clinical utility of the questionnaire. The PFRI, consistent with the previous validation study in athletes with low back pain[10], is a valid and reliable tool for measuring pain and functional status in athletes with NP. To the best of our knowledge, this is the first study validating a self-administered instrument for assessing athletes with NP.

All athletes completed the PFRI without any difficulties and with no missing responses. Responding to all questions on PFRI indicates acceptability and clinical utility. The distribution of the PFRI was satisfactory as demonstrated by the absence of floor or ceiling effects. The lack of floor or ceiling effects indicates the content validity and the responsiveness of the PFRI, in accordance with findings in athletes with LBP[10].

When PFRI scores for athletes with NP were compared to the scores of healthy participants, the athletes with NP had significantly worse scores and function. This finding suggests that the PFRI discriminated athletes with NP from healthy controls. In a study which tested the ability of the PFRI to discriminate athletes with LBP from healthy athletes, a similar finding was found[10]. These data indicate that the discriminant validity of the Persian FRI in athletes with NP or LBP is consistent with those observed in the general population[8,9].

The excellent correlation between the PFRI and the NRS suggests the concurrent validity of the PFRI in

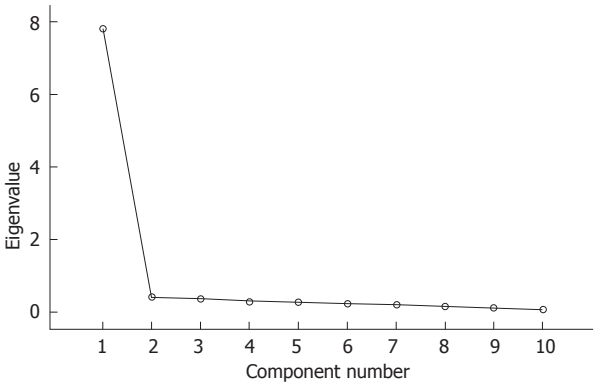

Figure 1 Scree plot of eigenvalues produced 1 factor for persian functional rating Index in athletes with neck pain (n = 100).

athletes with NP. Our finding is in accordance with that in athletes with LBP (rho = 0.72)[10].

Construct validity was assessed by correlating the PFRI with the NDI, and, as hypothesized, excellent association was observed between the two tools. The significant correlation between the PFRI with the Persian NDI suggests that these two questionnaires measure similar construct. A similar result was found for the PFRI in athletes with LBP (r = 0.83)[10].

The PFRI showed excellent internal consistency as reflected in a Cronbach's α value well above the minimum recommended value. Cronbach's alpha when an item was deleted was very close to the overall alpha, which indicates similar contribution of each PFRI item to the construct measured. These results support the homogeneity and interrelatedness of the PFRI items. The internal consistency found in the present study was similar to that observed by Naghdi *et al*[10] when the PFRI was applied in athletes with LBP (Cronbach's α = 0.90).

The test-retest reliability of the PFRI in athletes with NP between two assessment sessions was found to be excellent ($ICC_{agreement}$ = 0.96) in agreement with the result ($ICC_{agreement}$ = 0.97), as similarly reported in athletes with LBP[10]. The high value of $ICC_{agreement}$ found in this study indicated excellent reproducibility of the PFRI and consistency of the scores between two measurements.

The SEM found in this study was small, which indicates the reliability of the PFRI to identify real changes. The SDC is a useful estimate to identify real change score in an individual patient after an intervention. The SDC in the present study was 8.84%, which is clinically acceptable. This indicates only a change score greater than 9.0% can be interpreted as a real change with a 95% confidence using the PFRI. Estimation of SEM and SDC were not reported for the PFRI in athletes with LBP[10].

Factor analysis was applied to determine the possible subscales of the PFRI despite acceptable Cronbach's α and item-total correlation values found in this study. The factor analysis resulted in a 1-factor solution for the PFRI, in accordance with results demonstrated in

athletes with LBP[10]. The factor analysis confirmed that the PFRI assessed predominantly a distinct factor of the underlying construct concerning pain and function. This finding provides further evidence for construct validity of the PFRI. The PFRI can be used independently to identify changes in pain and function of athletes with NP.

There were limitations for the present study. First, the effect size based responsiveness of the PFRI to detect change over time was not evaluated in this study. The evaluation of floor and ceiling effects is one of the methods used for quantifying responsiveness[17,18]. The lack of floor and ceiling effects found in this study implies that the PFRI is able to detect changes following treatment. Second, this study assessed only the Persian FRI. An English FRI must be separately validated for athletes with NP.

In conclusion, the PFRI demonstrated excellent validity and reliability, and therefore, can be used in both clinical and research settings for athletes with NP.

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COMMENTS

Background

Neck pain (NP) is one of the common complaints in athletes. Reliable and valid tests are required to accurately examine the athletes with NP. There are various self-report questionnaires [*e.g.,* Functional Rating Index (FRI)] developed for evaluation of disability in patients with various spinal conditions such as NP. The self-report questionnaires allow the clinicians to evaluate the extent to which spinal disorders affect pain and function perceived by patients. However, the commonly used self-report questionnaires are developed for use in general population with spinal disorders.

Research frontiers

It is necessary to use self-report questionnaires validated specifically for athletes with NP. The current research hotspot is that there is no specific test available for assessing athletes with NP. It is, therefore, necessary to develop either new self-report questionnaires or validate existing instruments for athletes with NP.

Innovations and breakthroughs

FRI is one of the commonly used self-report instrument to evaluate the patients' perspectives on their disability in general population with low back pain (LBP) as well as NP. The FRI first developed in English language is reliable, valid and responsive, and has been adapted and validated into various languages. The Persian FRI (PFRI) is previously validated for athletes with LBP. This report presents a study, for the first time, validating the PFRI in athletes with NP. The results show satisfactory psychometric properties of PFRI for use in athletes with NP.

Applications

The results of the present study demonstrated that the PFRI is reliable and valid in athletes with NP and it may be useful for assessing pain and functional status of Persian speaking athletes with NP. The equivalency of PFRI with the original English version indicates that the FRI is reliable and valid in athletes with NP, and may be used in multinational investigations as an outcome measure.

Terminology

Many athletes may experience NP due to ligament sprains, muscle strains, and contusions. The athletes with NP may complain from deficits in neck mobility, muscle recruitment, strength, endurance, or postural stability. The FRI is a quick, self-report questionnaire used to assess disability in patients with both LBP and NP. The scale contains 10 questions measuring both pain and function in a five-point scale from 0 (no pain/full function) to 4 (worst possible pain/unable to perform function). Total score calculated in percentage range between 0% and 100%, with higher scores indicating higher disability.

Peer-review

This paper is a well designed paper and gives out the result that the other scoring system can be used for evaluation for neck pain of the athletes.

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CASE REPORT

Slacklining and stroke: A rehabilitation case study considering balance and lower limb weakness

Charles P Gabel, Natalie Rando, Markus Melloh

Charles P Gabel, Coolum Physiotherapy Sunshine Coast, Queensland 4573, Australia

Natalie Rando, Physiotherapy Program, Faculty of Health Science and Medicine, Bond University, Gold Coast, Queensland 4226, Australia

Markus Melloh, Centre for Health Sciences, School of Health Professions, Zurich University of Applied, Sciences, 8400 Winterthur, Switzerland

Markus Melloh, Centre for Medical Research, University of Western Australia, Nedlands 6909, Australia

Author contributions: Charles PG performed the rehabilitation exercises with the case study patient in the clinical setting; Markus M provided vital input for the manuscript content, references and editing of the manuscript; Natalie R provided specific vital input regarding neurological rehabilitation, referencing and editing of the manuscrip; all authors contributed to writing the manuscript.

Institutional review board statement: This case study was approved by the Coolum Physiotherapy Clinic through a clinical directors meeting to approve the study as part of a research initiative.

Informed consent statement: The patient has provided her informed consent.

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Correspondence to: Charles P Gabel, MDT, PHD, Private Researcher, Coolum Physiotherapy Sunshine Coast, PO Box 760, Coolum Beach, Queensland 4573, Australia. cp.gabel@bigpond.com
Telephone: +61-7-54461022
Fax: +61-7-54717022

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Abstract

To ascertain the effectiveness of slacklining as a supplementary therapy for elderly stroke patients who are functionally non-progressing. This case study involved an 18-mo prospective observation of the management of an 87-year-old female stroke-patient of the left hemisphere with reduced balance, reduced lower limb muscular activation, hypertonia, and concurrent postural deficits. This entailed the initial acute care phase through to discharge to home and 18-mo final status in her original independent living setting. The introduction of slacklining as an adjunct therapy was made 12 mo post incident. Slacklining involves balance retention on a tightened band where external environmental changes cause a whole-body dynamic response to retain equilibrium. It is a complex neuromechanical task enabling individualized self-developed response strategies to be learned and adapted. This facilitates the innate process of balance retention, lower-limb and core muscle activation, and stable posture through a combination of learned motor skills and neurological system down regulation. Individuals adopt and follow established sequential motor learning stages where the acquired balance skills

are achieved in a challenging composite-chain activity. Slacklining could be considered an adjunct therapy for lower limb stroke rehabilitation where function is compromised due to decreased muscle recruitment, decreased postural control and compromised balance. Initial inpatient rehabilitation involved one-month acute-care, one-month rehabilitation, and one-month transitional care prior to home discharge. A further six months of intensive outpatient rehabilitation was provided with five hourly sessions per week including: supervised and self-managed hydrotherapy, plus one individual and two group falls' prevention sessions. These were supported by daily home exercises. At 12 mo post incident, recovery plateaued, then regressed following three falls. Rehabilitation was subsequently modified with the hydrotherapy retained and the group sessions replaced with an additional individual session supplemented with slacklining. The slacklining followed stages one and two of a standardized five-stage protocol. Self-reported functional progression resumed with improvement by 14 mo which further increased and was sustained 18 mo (Students' t test $P < 0.05$). Slacklining's external stimulations activate global-body responses through innate balance, optimal postural and potentially down-regulated reflex control. Incorporated into stroke rehabilitation programs, slacklining can provide measurable functional gains.

Key words: Stroke; Rehabilitation; Lower limbs; Balance; Slacklining

Core tip: Slacklining may supplement stroke rehabilitation where lower limb function is compromised. This case study considers an 87-year-old female with reduced balance, reduced lower limb activation, and hypertonia. Rehabilitation from acute care to home discharge and subsequent six-month intensive outpatient therapy showed progression then plateaued at nine months. Three falls resulted in regression and rehabilitation was modified by supplementing slacklining. Functional progression improved by 14 mo and was sustained at 18 mo. Slacklining's external stimulations activate global-body responses through innate balance, optimal postural response and potentially down-regulated reflex control that can provide quantifiable functional gains. Further prospective cohort studies are required.

Gabel CP, Rando N, Melloh M. Slacklining and stroke: A rehabilitation case study considering balance and lower limb weakness. *World J Orthop* 2016; 7(8): 513-518 Available from: URL: http://www.wjgnet.com/2218-5836/full/v7/i8/513.htm DOI: http://dx.doi.org/10.5312/wjo.v7.i8.513

INTRODUCTION

Stroke survivors are often required to adapt to a restricted lifestyle with reduced activities of daily living (ADL). They also have increased dependence on continuous external support to survive[1]. Thirty-five per-cent of Australians who experienced a stroke had a resulting disability, with 64% needing assistance with health care, 58% with mobility and 47% with self-care[2]. Furthermore, this neurologic pathology significantly impacts the ADL of individuals through impaired postural control. Following stroke, some patients have delayed and disrupted equilibrium reactions[3], exaggerated postural sway in both sagittal and frontal planes[4], reduced weight-bearing on the paretic limb during functional tasks[5,6] and an increased risk of falling[7,8].

Additionally, impaired dexterity in both the affected and unaffected lower extremities is a major reported problem post-stroke[9]. Activation failure in the affected lower limb can often be explained by weakness, which correlates strongly with reduced functional performance[7]. Furthermore, the presence of co-activation, muscle activation on both sides of the joint, is a common postural coordination strategy reported in those with neurologic deficits, including stroke[10]. Consequently, research is required for post-stroke rehabilitation strategies that focus strongly on improving the affected lower limb's dexterity and postural control. One such novel technique not yet reported in the literature is slacklining as a supplementary therapy[11-14]. It is a complex neuromechanical task that involves balance retention on a tightened band where whole-body dynamics drive the response to external environmental changes[13,15]. This activity innately facilitates recruitment of muscles within the core[11,16] and the lower limb, particularly the quadriceps and gluteals[12]. Some studies have found that slacklining has transferable learning and skill acquisition including improved posture[14,17], static and dynamic balance[18-20], lower limb control[12,21,22], joint specific control[12,23,24], sporting performance[13,25] and probable neuroplastic changes[26,27]. Slacklining also stimulates the balance mechanism and functional control through individualized global body responses and learned movement patterns that are adaptations to external stimuli[15,17,22].

This paper presents a case study where slacklining was supplemented to an existing balance and functional control rehabilitation program.

CASE REPORT

An 87-year-old female who had sustained a non-specific cerebro-vascular accident within the left hemisphere affecting lower limb strength, balance control and hypertonia was monitored over an 18 mo period. Rehabilitation was progressed through five stages: (1) an initial one month of acute inpatient management; (2) one month inpatient rehabilitation at a specialized rehab centre; (3) one month of transitional care in a different inpatient facility to assist home skills for self-care and daily living; (4) home discharge with nine-month

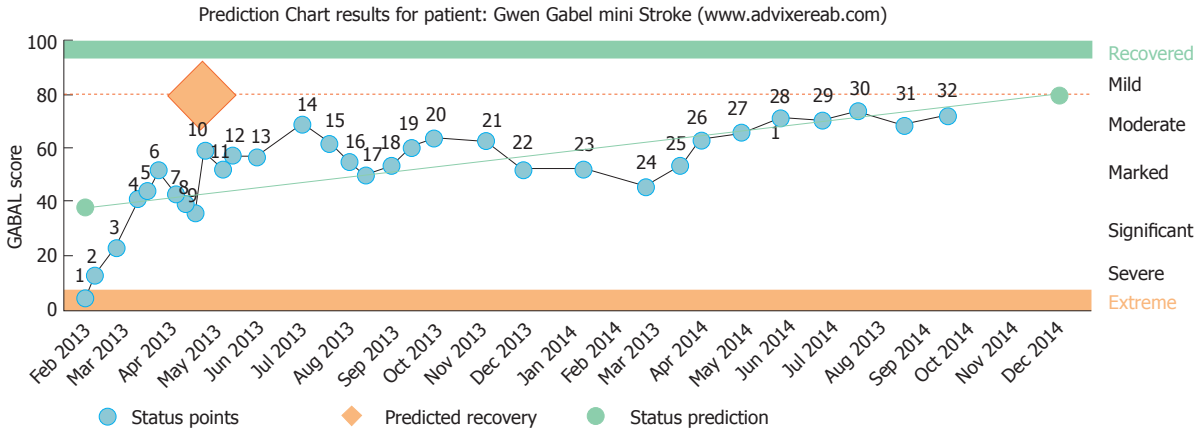

Figure 1 Visual history of recovery stages.

early care community support through nursing and carers; plus five times per week intensive outpatient rehabilitation involving hourly sessions of twice weekly occupational and physical therapy group falls prevention, an individual physical therapy session providing balance training, mobilization and massage with planning of additional home exercise, and two hydrotherapy sessions; and (5) management in the community for a further six months with modification of the outpatient sessions combined with the introduction of slacklining and a phase out of regular home care assistance. Slacklining, as part of the neurological rehabilitation program, was introduced and initially graduated over six weeks following the standardized protocol[12,13]. The sessions were initiated at three minutes and increased to seven and, finally, ten minutes in duration. They involved a step up onto the slackline, located over a grassy surface at a height of approximately 20 cm, with the patient provided balance support, initially from the front with both hands touching or holding the therapists hands and progressing to a hand support such as a wheeled frame or a walking stick (Figure 1). The adjunct or supplementary addition of slacklining to the standard rehabilitation program continued after the case study observation period finished at 18 mo. Sessions were twice weekly with minor progressions in the program difficulty levels based upon the individual's adaptations, capacity and status (Figure 2).

The status and the key points were recorded using computerized decision support software patient-reported outcome measurement[28] (Figure 1). Recovery plateaued at the six-month mark and there was subsequent regression following three falls at home over the subsequent six months despite the specific falls prevention program. At twelve-months the hydrotherapy continued and the group rehabilitation falls prevention program was ceased and replaced by a further individual rehabilitation session that was supplemented with slacklining (Figure 1). The slacklining was provided with the intention of specifically activating the quadriceps[12,22] and improving core muscle recruitment[14,19], postural position and awareness[14,17], and balance[18,21]. The slacklining followed stages one and two of a standardized five-stage, 20-step protocol[13]. This standard protocol was modified through the initial use of hand support that was progressively withdrawn. Initially a bilateral, two hand support position was provided, then progressed to a single hand, then one hand support to a fixed ground object, then a walking stick and finally free-standing and stepping up. At all times immediate close support was available for safety, feedback and confidence. Subsequently, functional status progression resumed with statistically significant improvement over the following six months (Students' *t* test $P < 0.05$) (Figure 2).

DISCUSSION

Slacklining has an innate or automatic muscle recruitment action, particularly for the quadriceps and to a lesser degree the gluteals, calf and core[12,14]. These actions provide a positive focus for stroke patients with local muscle inhibition from the centrally derived deficits[12].

A further consideration is that the action of standing on a slackline requires muscular recruitment in a sequential and learned manner in order for the individual to remain upright and balanced[12,17]. This is a postural benefit for individuals with lower limb functional deficits of a central source that are acquired following stroke[29,30]. An additional benefit is that the Hoffman's reflex (H-reflex)[12,31] can be affected through the pre-synaptic pathway[17] resulting in a learned activity that inhibits the reflex action from down regulation[32,33]. Such inhibition is advantageous as the H-reflex shows heightened sensitivity that may negatively affect the gait of stroke survivors[34,35]. However, it is considered to be a learned and temporary effect as withdrawal of the training stimulus results in reduction the training effect. Consequently, the effectiveness of the slacklining program as a rehabilitation therapy must be maintained through the ongoing practice of the activity[11,13,18].

This is of significance as the stroke patient has phase-related modulation of both the soleus H-reflex,

Figure 2 Right lower limb affected stroke patient participating in Slackline balance training. A: Therapist assist - single stick; B: Patient 1 leg stand with no balance aids - therapist standby assist.

that affects the ankle directly and less so the knee - regardless of joint stiffness[29]; and the quadriceps H-reflex primarily affecting the knee control[31]. Both of these actions are also partially disordered during hip movement due to modulated limb spasticity[34,35]. The anticipated beneficial consequence is that the action of slacklining may provide a positive effect through the action of pre-synaptic inhibition and down-regulation of the H-reflex[27] as well as supplement the quadriceps and soleus activation and control[12] in conjunction with balance, postural control, and an overall learning process[14,18,24]. This can assist the individual to adapt towards normalized balance and actively controlled positions[36]. The anticipation is that this specific action within the training phase will then overflow to normal daily activity[17,18] including the functional movements of walking and postural control. This in theory could subsequently improve the innate response action to perturbations and reduce the incidence of falls and in turn improve individual confidence while reducing health and socioeconomic costs[36].

It is widely accepted that the central nervous system of adult human beings has enormous potential for recovery and adaptability. The actions of slacklining can theoretically cause down-regulation of the muscle inhibitory action and the Hoffman reflex. This suppression of a spinal reflex may transfer the control of muscular activation from primary spinal to more supraspinal centers, which can be beneficial in terms of improved movement control[37,38]. Consequently, slacklining and its potential to influence cortical areas and the central nervous system of stroke patients is an area that needs investigation in this population group[34,35].

Slacklining may be a beneficial rehabilitation method that could be incorporated into the programs of stroke patients. The external stimuli activate global-body responses through innate balance and reflex modulations that provide quantifiable functional gains. In addition, the activity of slacklining provides an innate activation of the lower limb muscles, particularly the quadriceps, calf, gluteals and also the trunk core muscles in normal and lower limb injured individuals; consequently, it would seem likely to have a similar effect in stroke patients. Slacklining is a novel adjunct therapy that is challenging and rewarding where quantifiable exercise specific gains can be achieved and potentially transformed into daily functional status improvements in the areas of ADL, gait and balance. Further prospective studies are required to validate these initial findings and eventually to determine therapy frequency and progression rates.

COMMENTS

Case characteristics

An 87-year-old female stroke patient is discussed within the context of a novel method of rehabilitation through the use of slacklining to facilitate balance and function and to reduce and prevent falls.

Clinical diagnosis

Right lower limb weakness, mildly reduced sensation, reduced balance and general limb control with tonal changes and intermittent upper limb tonal alterations to a mild level.

Differential diagnosis

Stroke affecting the right leg below the knee due to a left cerebral vascular accident (CVA).

Treatment

A progressive graded rehabilitation over 18 mo from inpatients to transitional care and final home and community including a group falls reduction program. Progression to twice weekly physiotherapy outpatients with balance training, limb mobilization and massage and the addition of slacklining.

Term explanation

Stroke is due to a CVA affecting the cortical tissue and slacklining as a novel therapy involves balance retention on a tightened band where external environmental changes cause a whole-body dynamic response to retain equilibrium. As such slacklining is a complex neuromechanical task enabling individualized self-developed response strategies to be learned and adapted to

facilitate balance, strength, control and functional improvement and/or stability.

Experiences and lessons

This study offers a new frontier into the use of neural plasticity accessed through physical rehabilitation exercises to enhance and maintain balance and function. This is the first reported study with the use of this novel method of rehabilitation, "slacklining", in a clinical setting for stroke.

Peer-review

This paper proposes the activity 'Slacklining' as a rehabilitation supplement following stroke in the form of a case report and theoretical explanation. The manuscript is well written, and supported by references appropriately.

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