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14. ABSTRACT
PURPOSE: The primary purpose of this study is to compare the effectiveness of two management strategies for patients with a recent onset of low back pain. One is based on usual care and the other is based on early access to physical therapy following a pragmatic treatment-based classification approach. The secondary purposes are to compare the subsequent healthcare utilization associated with two management strategies as well as to evaluate the importance of psychosocial factors on outcomes within both groups of treatment.
DESIGN: A randomized trial comparing the effectiveness of two primary care management strategies for managing patients with a recent onset of low back pain (LBP). One strategy will be usual care (UC) based on a stepped care approach. The other strategy will involve early access to physical therapy (PT). The primary difference between the strategies is the management in the first 4 weeks.
SCOPE: Active duty Soldiers with low back pain ï 1 year follow-up period
MAJOR FINDINGS: No research findings to report at this time as we are still in the recruitment/enrollment process.

15. SUBJECT TERMS
Low back pain, military readiness, primary care, physical therapy

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INTRODUCTION:
Low back pain is the most significant contributor to lost workdays related to injury in the entire U.S. Armed Forces. The detrimental impact on combat readiness of low back pain cannot be understated, as back problems are the number one cause of evacuation from Iraq and Afghanistan, making it one of the largest causes of attrition in Soldiers in combat.

This randomized clinical trial seeks additional evidence to determine if early physical therapy access using a treatment based classification (TBC) algorithm will result in greater improvements in function and quality of life and decreased healthcare utilization over 1 year as compared to a stepped ñusual careò strategy in 220 active duty Soldiers presenting with low back pain.

BODY:

SOW Tasks:

Initial Tasks (months 1-7): Coordinate IRB approval, investigator participation and subject recruitment in conjunction with ongoing standard of care for patients at MAMC healthcare clinics.

Task #	Task Title	Status
a.	Submit study protocol to MAMC IRB (months 0-2)	Submitted successfully June 2011
b.	Educate participating clinicians in the 2 treatment algorithms (months 2-4)	PTA research assistant has been hired. She has completed training. Have held 2 meetings with staff at the medical clinic where enrollment will occur (once in December 2011 and in January 2012)
c.	Receive approval for study by MAMC IRB (month 6)	Completed August 2011
d.	Receive approval for study by CIRO (months 6-11)	Completed November 2011
e.	Establish administrative support for enrolling subjects (months 5-8)	Had a face to face meeting with Dr. Fritz and Dr. Cleland at a conference in November 2011 and also in February 2012. We walked through the entire methods. Subject folders have been created for data collection.
f.	Trial registered with clinicaltrials.gov (months 8-9) http://clinicaltrials.gov/ct2/show/NCT01556581	Trial registered in March 2012

Aim 1: Compare the effectiveness of two primary care management strategies for patients with a recent onset of combat-related LBP.

Task 1a (months 11-22): Enrollment into study (220 subjects). Active duty Soldiers with low back pain are randomized into one of two primary care management strategies (usual care stepped approach or early referral to physical therapy for treatment-based classification approach). Subjects are consented, baseline measures taken, randomization to treatment group occurs, and then allocated intervention is given.

Task #	Task Title	Status
1a	Recruitment and enrollment of subjects began in March 2012	We finished up enrollment at the Madigan site. A total of 80 subjects have been enrolled now, out of a total of 271 potentials screened. We also added 2 other sites to increase our ability to reach the recruitment goal.
	Other notes:	Met with Dr. Julie Fritz twice during this year, once while simultaneously attending a conference, and also a site-visit to UoU.

Task 1b (months 12-34): Track outcomes at 4 weeks, 12 weeks, and 1 year after initial enrollment.

Method of tracking outcomes: Follow-up re-assessments will be performed 4 weeks, 12 weeks and 1-year after the baseline examination. Follow-up assessments will be performed by a Research Assistant blinded to the patientôs treatment group assignment. Subjects will be called 2 weeks prior to their projected follow-up date and scheduled a follow-up appointment. Subjects will arrive at their appointment and fill out the appropriate outcome measures. The data from the outcomes will be placed in a patient folder with only their subject ID for identification. Data will then be entered into a protected spreadsheet as described in the protocol.

Task #	Task Title	Status
1b	Follow-up of Subjects began	We have had 53 subjects complete the entire 1-year period of the study.

Aim 2: Compare the subsequent healthcare utilization associated with two management strategies for patients with a recent onset combat-related LBP.

The tasks (2) for Aim 2 cannot be started or completed until all the data collection from AIM 1/ Task 1 is completed.

Aim 3: Compare and contrast any differences in psychosocial factors between success and failures within both groups of treatment.

The tasks (3) for Aim 3 cannot be started or completed until all the data collection from AIM 1/ Task 1 is completed.

Challenges:
The task of recruitment of eligible subjects had become a challenge. Fort Lewis continues to be a prime location for access to active duty Soldiers. Our plan was detailed and the approach researched in detail, but there were 3 unanticipated events that have occurred affecting recruitment.

1. We were unable to anticipate combat deployment schedules for the Soldiers as that information is classified and was not available at the time we formulated and submitted our grant proposal. At the start of the recruitment phase, two (2) of the three (3) Brigade Combat Teams (BCT) on Fort Lewis were deployed.

This still allowed for recruitment to stay relatively on target as evidenced by our ability to screen 117 Soldiers, and recruit 26 subjects. Shortly following that, right at the beginning of the new fiscal year, all 3 BCT units were deployed and our eligible recruitment pool had significantly decreased. Two of those units began to return early 2013 and were finally processed back in and off of leave ready for regular garrison life by the beginning of May 2013. The other unit was in the same situation by the end of September 2013.

2. The sick call (walk-in) procedures that have been used for many years had recently changed between protocol derivation and implementation. Historically, patients have been able to come in for walk-in appointments in the morning. Traditionally, this is where we have been able to capture a high number of low back pain patients. Earlier this year, the Madigan Healthcare System rolled out an online and telephone appointment booking service, which gives Soldiers the option to call or schedule a same day appointment online. As we evaluated the use of this system we saw that more patients with LBP were opting to schedule an appointment later in the day rather than come in for the walk-in clinic in the morning. Even accounting for this, the overall numbers of patients seeking care for low back pain was unusually small.

3. The government sequestration had 2nd and 3rd order affects that impacted this study. The hospital leadership had put a lot of pressure on miniminizing research and shifting priorities and resourcs to clinical care. The hospital had initially allotted the use of an additional civilian physical therapist for part-time help with this study. She was used often when MAJ Rhon had to travel for TDY or other mission-related travel. We lost the ability to use her. MAJ Rhon has some unanticipated travel for military required schooling and some unanticipated health issues. Usually these sorts of situations are covered by support from the hospital clinic, but in these cases we had no one to recruit/enroll during these periods of time. Future studies should consider funds to hire a full-time physical therapist at each site to counter the staffõs FTE requirements for patient care.

4. Finally, MAJ Rhon has now completed a PCS move to San Antonio, and so recruitment can no longer occur at the Fort Lewis Site.

Plan: Systems went into place during active recruitment at Fort Lewis to help mitigate the issues stated above. These helped the research team reach an enrollment point of 80 subjects. Since then, we have added 2 other sites to the project with a target of enrolling 30-50 subjects at each of those additional sites.

Career Development/Mentorship-Related Activities:

- MAJ Rhon is now an active peer reviewer for the Journal of Orthopaedic and Sports Physical Therapy and Manual Therapy.
- MAJ Rhon and Dr. Fritz have been working 2 additional projects related to LBP, adding to the value of the mentoring relationship. He has had abstracts from that project accepted at 2 conferences and is working on a manuscript to summarize those findings (see appendix A).
- MAJ Rhon was able to use what he learned from mentoring and this current experience to lead the efforts as the PI for submission of a protocol for a randomized clinical trial, through another PRORP, CDMRP award mechanism, for a different and unrelated research question.

  Peer Reviewed Orthopaedic Research Program Clinical Trial Award
  Funding Opportunity Number: W81XWH-13-PRORP-CTA
- MAJ Rhon has had 3 manuscripts published in this last year, the most recent being a different pragmatic trial published in one of the leading medical journals, the Annals of Internal Medicine (Appendices B-D).
- MAJ Rhon applied for and was awarded another grant to study musculokeletal and thoracic spine injury prediction models in active duty service members, for $1.2 million (Appendix E).

  Injury Prevention, Physiological and Environmental Health Award (IPPEHA)
  Funding Opportunity Number: W81XWH-13-MOMJPC5-IPPEHA
- MAJ Rhon prepared, submitted, and had 2 new studies approved by the IRB

- Association between back education, disability, sleep, and healthcare utilization in patients with low back pain attending a self-management class. IRB#396449
    - Expedited specialty care for Soldiers returning from combat: cost effectiveness, patient satisfaction and the role of subjective pain reports. IRB#395946
- MAJ Rhon helped develop and initiate a clinical trial that garnered the interest of the Defense Health Agency (DHA). They sought him and the PI out from the DHA and offered to fund the study to ensure it is completed, as it is answering a question very relevant to policy decisions that DHA is being asked to make.
    - A physical therapy program versus surgery for femoracetabular impingement: A randomized clinical trial
    - ClinicalTrials registry: http://clinicaltrials.gov/show/NCT01993615
- MAJ Rhon had an abtract accepted and presented at the 3rd Interntional Congress for Soldier Physical Performance in August of 2014 (Appendix F)

KEY RESEARCH ACCOMPLISHMENTS:

Research:
- IRB Approval by CIRO and MRMC
- Trial registered with ClinicalTrials.gov
- Enrollment of subjects at the Fort Lewis completed
- Trials approved by IRB at 2 additional sites (Fort Carson, CO and Fort Bliss, TX)

REPORTABLE OUTCOMES:

No presentations have yet been generated from data collected in this study as we are still in the data collection phase. Because the purpose of this initiative is dual in nature as a career development award, to both execute a relevant research trial and to focus on development of an independent clinician-scientist researcher, we have reported progress for both sections of this grant.

CONCLUSION: There are no significant outcomes to report as the trial is still early in the recruitment and enrollment phase. Obstacles to recruitment were identified and consisted of both access routes and decrease in the number of Soldiers due to deployment, in addition to site changes and relocation of the primary investigator. However, modifications have occurred and plans put into place to maximize success with enrollment at new sites.

REFERENCES: None

APPENDICES:
A: Abstract ï Identification of Potential Adverse Events Following Spinal Manipulation
B: Clinical reasoning and advanced practice privileges enable physical therapist point-of-care decisions in the military health care system: 3 clinical cases. Phys Ther. 2013 Sep;93(9):1234-43. doi: 10.2522/ptj.20120148. Epub 2013 Feb 7. PMID: 23392183
C: Manual physical therapy and perturbation exercises in knee osteoarthritis. J Man Manip Ther. 2013 Nov; 21(4):220-8. doi: 10.1179/2042618613Y.0000000039. PMID: 24421635
D: One-year outcome of subacromial corticosteroid injection compared with manual physical therapy for the management of the unilateral shoulder impingement syndrome: a pragmatic randomized trial. Ann Intern Med. 2014 Aug 5;161(3):161-9. doi: 10.7326/M13-2199. PMID: 25089860
E: Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after Discharge from Physical Rehabilitation- Quad chart
F: Abstract presentation for 3rd ICSPP Conference ï Comparison of Performance between Rangers, Combat, Combat Service, and Combat Service Support Soldiers

Research Report

IDENTIFICATION OF POTENTIAL ADVERSE EVENTS FOLLOWING SPINAL MANIPULATION

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BACKGROUND: The safety of spinal manipulation is often debated despite reports that adverse events occur infrequently (less than 1 in 3 million). While they can be challenging to identify, those serious enough to require medical attention may be easier. The purpose was to identify potential serious adverse events following the use of spinal manipulation.
METHODS: Patients at Madigan Army Medical Center with an initial spine or shoulder condition from 1 January to 31 December 2009 were followed for a 12-month period. Encounters that included spinal manipulation current procedural codes (CPT) performed by physiotherapists (PT), chiropractors (DC), or osteopathic physicians (DO) were captured using the MHS Management Analysis and Reporting Tool. Potential adverse events from an apriori established list of ICD9 codes were identified. Any visits including these codes occurring within 7 days of a spinal manipulation event, were further abstracted.
RESULTS: From 6706 initial encounters with potential manipulation procedure codes, 1084 encounters were identified as a potentially adverse event within 45 days, representing 337 unique subjects. There were 133 potential adverse events within 30 days, 43 within 7 days, and only 9 occurring within 24 hours. After qualitative analysis of each potential case, none of the potential adverse events could be attributed to spinal manipulation.
CONCLUSION: There was no evidence of serious harm found after the use of spinal manipulation. However, the number of spinal manipulation encounters were low to expect an adverse events consistent with published reports. This study presents a standardized manner with which to identify serious adverse events in retrospective epidemiological studies.

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Clinical Reasoning and Advanced Practice Privileges Enable Physical Therapist Point-of-Care Decisions in the Military Health Care System: 3 Clinical Cases

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Clinical Reasoning and Advanced Practice Privileges Enable Physical Therapist Point-of-Care Decisions in the Military Health Care System: 3 Clinical Cases

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[Rhon DI, Deyle GD, Gill NW. Clinical reasoning and advanced practice privileges enable physical therapist point-of-care decisions in the military health care system: 3 clinical cases. *Phys Ther.* 2013;93:1234–1243.]

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Background and Purpose. Physical therapists frequently make important point-of-care decisions for musculoskeletal injuries and conditions. In the Military Health System (MHS), these decisions may occur while therapists are deployed in support of combat troops, as well as in a more traditional hospital setting. Proficiency with the musculoskeletal examination, including a fundamental understanding of the diagnostic role of musculoskeletal imaging, is an important competency for physical therapists. The purpose of this article is to present 3 cases managed by physical therapists in unique MHS settings, highlighting relevant challenges and clinical decision making.

Case Description. Three cases are presented involving conditions where the physical therapist was significantly involved in the diagnosis and clinical management plan. The physical therapist's clinical privileges, including the ability to order appropriate musculoskeletal imaging procedures, were helpful in making clinical decisions that facilitate timely management. The cases involve patients with an ankle sprain and Maisonneuve fracture, a radial head fracture, and a pelvic neoplasm referred through medical channels as knee pain.

Outcomes. Clinical pathways from point of care are discussed, as well as the reasoning that led to decisions affecting definitive care for each of these patients. In each case, emergent treatment and important combat evacuation decisions were based on a combination of examination and management decisions.

Discussion. Physical therapists can provide important contributions to the primary management of patients with musculoskeletal conditions in a variety of settings within the MHS. In the cases described, advanced clinical privileges contributed to the success in this role.

Physical therapists often are positioned to make point-of-care management decisions within their area of specialty training, most often musculoskeletal conditions.[1–7] In the Military Health System (MHS), these management decisions can occur while the physical therapist is deployed in a combat support role,[4,7,8] in addition to the more traditional hospital settings.[9,10] Physical therapists in the MHS are often the first credentialed providers to examine and diagnose patients with musculoskeletal conditions.[6] Formal clinical privileges to order basic laboratory and diagnostic imaging studies and refer patients to the appropriate specialty clinic may facilitate timely and cost-effective management of musculoskeletal injuries and conditions.[5,10–12]

Strong patient interview and physical examination skills also can facilitate timely and accurate decisions regarding necessary additional screening. Physical therapists should carefully formulate or select each interview question or diagnostic test that may provide valuable information to help rule in or rule out a clinical hypothesis.[13] Most clinical decision tools used for screening and diagnosis have not been studied in combat settings. Keeping this perspective, a blend of current best evidence and clinical experience is helpful to identify and appropriately channel patients with injuries and conditions requiring treatment outside a physical therapist's scope of practice. Examples of pathology a physical therapist may encounter include tumors, infections, aortic abdominal aneurysms, fractures, dislocations, and a variety of other systemic diseases. Additionally, conditions such as cauda equina syndrome, stress fractures of the femoral neck, or compartment syndrome[14] may require emergent surgical intervention.[14,15] Injuries that disrupt joint surfaces or produce instability, such as Lisfranc or ankle syndesmosis injuries, have a better prognosis with timely recognition and early appropriate management.[16–18] Although very uncommon, neoplasms also can masquerade as musculoskeletal pathology, as the skeletal system is a common site of metastasis for various primary cancers.[19–23]

The purpose of this article is to present 3 cases where physical therapists in the MHS played roles in the diagnosis and clinical management and provide insight into their decision-making and clinical reasoning processes. Each case illustrates a focus on clinical decisions, including ordering diagnostic musculoskeletal images and implementing appropriate subsequent care.

Therapist and Environment Characteristics

The physical therapist providing care for the first 2 patients had a master's degree in physical therapy, 4 years of outpatient orthopedic experience in direct access settings, and formal credentials for advanced clinical privileges, including ordering musculoskeletal imaging and basic laboratory studies. These cases occurred during a 12-month combat deployment while serving in a forward operating base in Iraq, where the physical therapist served as the musculoskeletal asset attached to a mechanized infantry brigade and saw 309 unique patients (1,362 total visits) during that time frame.[7] The last case was seen in a large military medical treatment facility by a physical therapist with a master's degree in physical therapy, 20 years of general and orthopedic physical therapy experience, and similar clinical privileges. In each of these cases, the physical therapist played a helpful role in guiding the diagnostic process and ultimate management of these patients.[7]

In the forward operating base, the front-lines environment was austere, with limited medical resources, and the only imaging medium available was a small mobile radiography system. A computed tomography scanner was available in the Combat Support Hospital a short flight away, where the closest surgeon was located.[24] The medical personnel in the forward operating base included 2 physicians (internal medicine and family medicine specialties), a physical therapist, 2 physician's assistants, a dentist, a nurse, and a mental health provider. Although there were trauma, mass casualty, and evacuation protocols that were practiced by the medical team, none existed for the standard management of musculoskeletal injuries and conditions. Additionally, leaving the confines of the forward operating base for a convoy to the Combat Support Hospital was a dangerous and potentially life-threatening course of action and had to be weighed accordingly in the management decisions. Two of these cases were chosen from a file of cases brought back from a combat deployment,[7] based on their musculoskeletal imaging application.

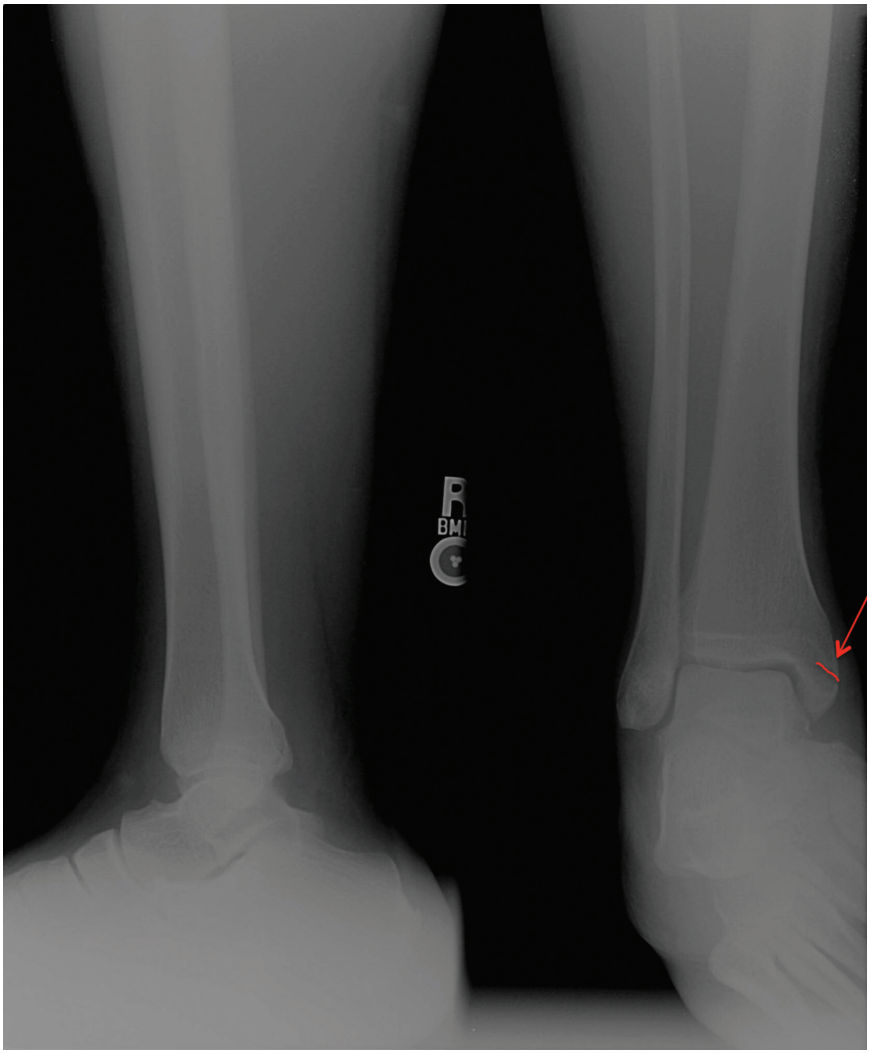

Figure 1.
Initial radiographs (lateral and anterior-posterior oblique/mortise views) taken of the ankle. Note the exposed area on the radiograph was below the proximal fibula. The hairline fracture can be seen on the medial malleolus in this image, but it is not easy to detect.

Case Descriptions

Case 1 (Maisonneuve Fracture)

Patient history and systems review. A 38-year-old Hispanic male physician's assistant reported that he was on a combat foot patrol in Iraq when he "stepped wrong" and twisted his right ankle. He reported immediate pain that increased with weight bearing, but he was able to continue the patrol. After 30 minutes, due to increasing pain, he was placed in a vehicle and returned to the forward operating base for further evaluation by medical staff. He denied any low back, hip, or knee pain, and all of his vital signs were normal. He was not currently on other medications. He was able to take 4 steps with some weight distributed on his right lower extremity, although he winced from pain. Upon removal of his boots, there was obvious ankle effusion on the right compared with the left. The attending physician in the trauma room cleared the foot and ankle for lacerations, wounds, or other irregularities and verified neurovascular integrity. A radiographic study of the ankle (Fig. 1) was ordered in the trauma triage room and read verbatim as a "possible avulsion of medial malleolus but otherwise unremarkable." It was unknown whether the Ottawa Clinical Decision Rule[25] was used before ordering the radiograph. He was provided crutches, a compression wrap, and instructions to ice and elevate the ankle. Two days later, after the swelling had slightly subsided, he came in to see the physical therapist for additional care.

Clinical impression 1. The otherwise healthy patient was using crutches, tolerating partial but not full weight bearing. Moderate joint effusion and ecchymosis over the lateral ankle were still present. The physical therapist's plan was to rule out a fracture, and if a fracture existed, to determine whether surgical stabilization was required (which would require an evacuation out of the country). The physical therapist's differential diagnosis included medial collateral (deltoid) or lateral collateral ligament ankle sprain, rearfoot or midfoot sprain (Lisfranc or Charcot), and high ankle (syndesmosis) sprain (Table). Unique considerations for prognosis included the need to ambulate on rocky terrain while wearing body armor (~8 kg). The decision to consult with an orthopedic surgeon would not be trivial, as it required an escorted caravan of vehicles on a hostile route. This patient case demonstrates some unique considerations of managing a patient with a musculoskeletal injury in a combat environment, including an assessment of resources and implications of clinical decisions on further care and prognosis.

Examination. The physical therapist used the Ottawa Ankle Rule[25] to screen the patient for a fracture, even though a radiograph had already been taken. The rules indi-

Table.
Clinical Reasoning Summary for All Cases

Case	Differential Diagnosis	Differentiation Point[a]	Management Plan	Outcome
Maisonneuve fracture	1. Lateral collateral ligament ankle sprain 2. Syndesmosis (high ankle) sprain 3. Proximal fibula fracture	Mechanism of injury. Sharp pain on medial malleolus and proximal fibula with palpation. Inability to fully bear weight in single-limb stance due to pain.	Discussion with orthopedic surgeon in remote location. Surgical intervention usually required for this condition. Patient was evacuated out of theater for surgical consideration.	After 2 weeks of immobilization, and based on minimal pain and minimal widening with proper stress views of the ankle, the decision was made to manage the fracture nonsurgically. The patient returned to the combat theater 4 months later.
Radial head fracture	1. Elbow contusion 2. Radial collateral ligament sprain 3. Radial head dislocation 4. Olecranon fracture	Mechanism of injury, joint effusion, fracture-quality pain, and inability to fully extend the elbow. Fat pad sign seen on radiograph.	Discussed with orthopedic surgeon the nature of the fracture (articular surface). Based on age and work demands, recommendation was made to evacuate patient out of theater for surgical fixation.	Based on status and function of patient on further evaluation, decision was made to manage the fracture nonsurgically. Patient was able to return to theater because the physical therapist was able to manage him there. By 14 weeks, patient was able to do 10 push-ups pain-free.
Hip neoplasm	1. Tumor: malignant or benign 2. Infection 3. Pelvic inflammatory disease 4. Fracture: hip or pelvis	Gait indicating impaired hip function with no mechanism of injury. Red flags: 1. Night pain 2. Early satiation 3. Bowel changes 4. Bladder changes 5. Menstrual irregularity Palpable fullness in the right anterior pelvic region	Screening radiographs ordered by physical therapist at initial visit revealed aggressive malignant process.	Same-day evaluation by orthopedic oncologist initiated plan for differential diagnosis and definitive care.

[a] Differentiation point marks critical aspects from the examination leading to the decision to order diagnostic imaging. The results could have a significant impact on determining the intervention plan.

cate that radiographs are necessary only if there is any pain in the malleolar zone along with the presence of at least 1 of these 3 factors: (1) bone tenderness along the distal 6 cm of the posterior edge of the tibia or tip of the medial malleolus, (2) bone tenderness along the distal 6 cm of the posterior edge of the fibula or lateral malleolus, or (3) inability to bear weight both immediately after the injury and for at least 4 steps in the emergency department. The sensitivity for ruling out a fracture without the need of a radiograph if these factors are not present is 100%[25]; however, these rules have not been validated in a combat setting. The patient was putting partial bodyweight on his foot, but it caused significant pain and discomfort. Tenderness was elicited with palpation of the lateral malleolus. Gentle ligamentous stress tests (talar tilt and anterior drawer) were inconclusive due to pain. Additionally, their value as conclusive diagnostic tests for ligament disruption is questionable due to poor reliability.[26,27]

In order to provide a thorough evaluation, the entire fibula was carefully palpated for a possible fracture and compressed against the tibia as a provocative assessment of the syndesmosis, suggestive of a positive test for syndesmotic injury (kappa=0.50),[28] although it should not be relied on alone for the diagnosis.[29] This intervention reproduced the patient's pain.[17] Palpation to the proximal fibula produced sharp pain, even without a provocative squeeze. Joint mobility assessment of the forefoot and mid-foot joints did not reproduce any pain. The Achilles tendon was intact, and resisted straight plantar flexion was not painful. A mild forced external rotation force[17] to the leg and foot reproduced pain in the medial and lateral ankle, in addition to the proximal lateral leg. The medial malleolous also was tender. The physical therapist evaluated the radiographs taken 2 days prior, but the proximal fibula was not visualized in that particular image (Fig. 1). The differential at this point included a syndesmosis sprain versus a proximal fibula fracture, with the potential for a concurrent medial ankle sprain or fracture. He placed the patient non–weight bearing on crutches with an immobilizer boot and ordered repeat radiographs

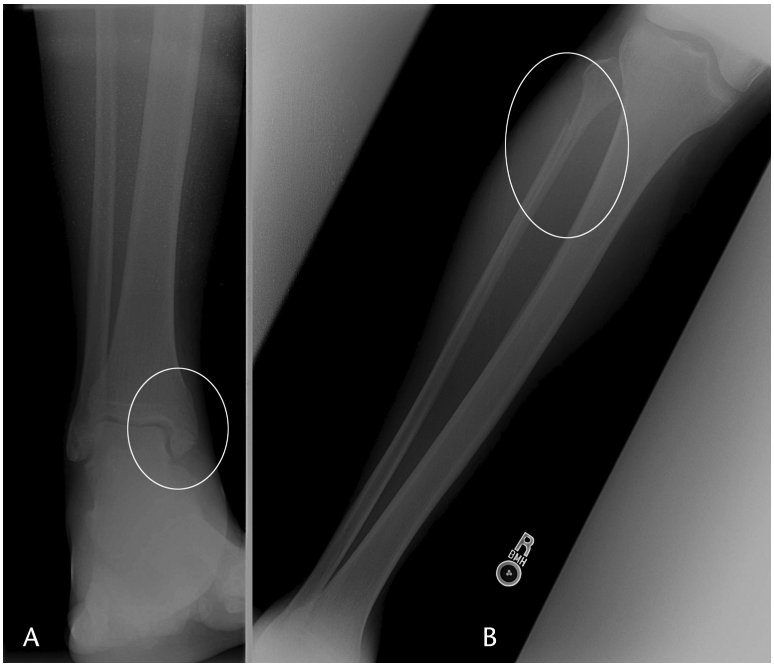

Figure 2.
The combination of a proximal fibular fracture (often indicating injury to the syndesmosis) and medial malleolus fracture can predispose the talocrural joint to significant instability and often requires surgical fixation. (A) The fracture of the medial malleolus was more evident on anterior-posterior view than in the oblique (mortise) view in Figure 1. (B) Exposure of the entire leg revealed a fracture of the proximal diaphysis of the fibula.

to include the proximal leg and knee region.

Clinical impression 2. The physical therapist evaluated the new images and visualized a spiral fracture of the proximal fibula in addition to a fracture of the medial malleolus (Fig. 2). These findings were consistent with the clinical examination and the diagnosis of a Maisonneuve fracture.[30,31]

Outcome. The injury had been assessed as thoroughly as permitted in that clinical setting. The decision was made to medically evacuate the patient to the United States for further evaluation by an orthopedic surgeon at a large Army hospital. The decision, based on the rocky terrain and instability of the ankle from the Maisonneuve fracture, was in the best interest of the patient. An injury of this nature without proper treatment could result in greater disability. The diagnosis may have been missed without the additional radiographic images of the knee and proximal fibula. After several weeks of rest and proper immobilization during the transition back to the United States, the injury showed early callus formation and minimal widening of the mortise with proper stress imaging (radiographs and fluoroscopy). The surgeon decided to treat the well-positioned fracture conservatively with a short leg cast in a non–weight-bearing status for 6 additional weeks.

Discussion. Maisonneuve fractures are easy to misdiagnose.[30,31] A comprehensive clinical examination that assesses areas above and below the area of symptoms can make misdiagnosis less likely. Examination of ankle injuries should include assessment of adjacent joints,[32] in this case, careful palpation of the fibula[31,33] and the bones of the foot,[34] in addition to the malleoli. The areas above and below the area of primary symptoms should be assessed for less obvious injury and potentially related or referred pain. Maisonneuve fractures occur as a result of an external rotation injury to the ankle (often causing medial malleolus pathology) whose force is transmitted up through the interosseous membrane, ultimately resulting in a fracture of the proximal fibula. The proximal fibular fracture, in isolation, can in many cases be managed nonsurgically.[35] However, some medial malleolar fractures and deltoid ligament sprains may result in significant ankle instability, requiring surgical fixation.[35,36] Because of these possible complications and the austere medical setting, the physical therapist decided to have the patient medically evacuated. Once back in the United States, the orthopedic surgeon decided that due to optimal initial management and good joint stability, the best option was to continue treating the fracture conservatively with immobilization. Had the fracture been missed originally, the patient may have displaced his fracture, creating greater instability and a need for surgery, leading to a longer period of disability. In this case, optimal early management by the physical therapist may have contributed to the surgeon's decision to forgo surgery and return the soldier to the combat theater later that year.

Case 2 (Radial Head Fracture)

Patient history and systems review. A 21-year-old Caucasian male soldier was seen by the physical therapist with a complaint of right elbow pain after a fall sustained while playing basketball several hours earlier. The pain was primarily in the posterior-lateral elbow, and the patient was unable to fully extend his elbow because of the pain. The patient denied any symptoms in the neck, shoulder, or hand, other medical issues, or prior history of elbow injury. The soldier was 3 months into his 1-year deployment in Iraq, hoping to remain in theater with his unit. After initial triage in the trauma room to rule out other injuries, the patient was sent to the physical therapist for a thorough evaluation of the elbow.

Clinical impression 1. The soldier presented with his arm in a sling, and he was fully alert and oriented to the situation. He denied hitting his head or any symptoms in the wrist, shoulder, or neck but reported his lateral elbow pain as 9/10 on the numeric pain rating scale. Despite the swelling, he was willing to take his arm out of the sling, but guarded his elbow against full elbow extension.

Examination. Gentle palpation produced intense pain on the posterior lateral aspect of the elbow. There was visible elbow effusion, and pain limited full elbow extension. There was neurovascular integrity of the distal forearm and hand. Shoulder range of motion was full and pain-free. The physical therapist decided to order a set of anterior-posterior and lateral view radiographs of the elbow in order to rule out a fracture. The inability to fully extend the elbow (elbow extension test) has been associated with a 50% likelihood of fracture.[37] Alternately, full extension of the elbow can rule out a fracture with a sensitivity of 98.4% (negative likelihood ratio of 0.03).[37] The patient was instructed to continue wearing the sling, monitor his neurovascular status, use ice, elevate the upper extremity, and report back the next day. The physical therapist reasoned that even if a fracture were present (Table), it would be better to wait at least 24 to 48 hours to allow the effusion to diminish before casting or splinting the elbow.

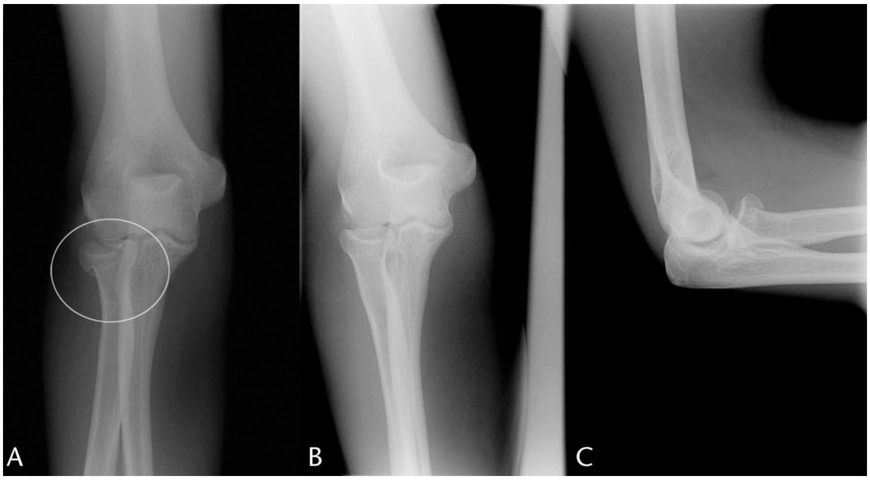

Figure 3.
Mason grade II fracture: (A) anterior-posterior view with forearm in supination, (B) anterior-posterior view with forearm in pronation, (C) lateral view. Note the value in this case of obtaining pronation and supination views of the forearm. The views in images B and C appear unremarkable at first glance, and the fracture is difficult to visualize. The view in supination (A) reveals the extent of the fracture coursing across articular surface of the radial head.

Clinical impression 2. In the absence of a radiologist or orthopedist, the physical therapist initially evaluated the radiographs. A radial head fracture, later categorized as a Mason grade II, was identified spanning through the articular surface and coursing the length of the radial head (Fig. 3).[38–40] The Mason classification system for radial head fractures is: (1) type I—nondisplaced fracture of the radial head; (2) type II—marginal radial head fracture with minimal displacement, depression, or angulation; and (3) type III—comminuted radial head fracture.[40] Although the reliability of the classification system has been called into question,[39] it has been shown to be one of the more reproducible classification systems (intrarater kappa=0.58, interrater kappa=0.43–0.56).[41] The patient returned after 72 hours, reporting decreased pain of 0/10 at rest and 3/10 when moving the elbow. The effusion had decreased substantially, and the therapist placed the patient in a plaster-fabricated long-arm cast in elbow flexion and full forearm supination.

Outcome. Due to the nature of the fracture involving the articular surface, the physical therapist presented the case to an orthopedic surgeon at a larger Combat Support Hospital using e-mail to send him the radiographic images. In this particular case, the surgeon felt that surgical evaluation was appropriate; therefore, the patient was evacuated to a hospital outside the combat theater. Ultimately, because the fracture was minimally displaced and the patient was already showing promising signs of recovery, the fracture was managed nonsurgically in a long-arm cast. The patient requested to return to the combat theater, despite medical evacuation orders stating, "Patient will need conservative treatment unavailable in theater due to his job." Subsequently, the soldier's case manager contacted the physical therapist on the base in Iraq to determine whether the patient could receive conservative care there. The

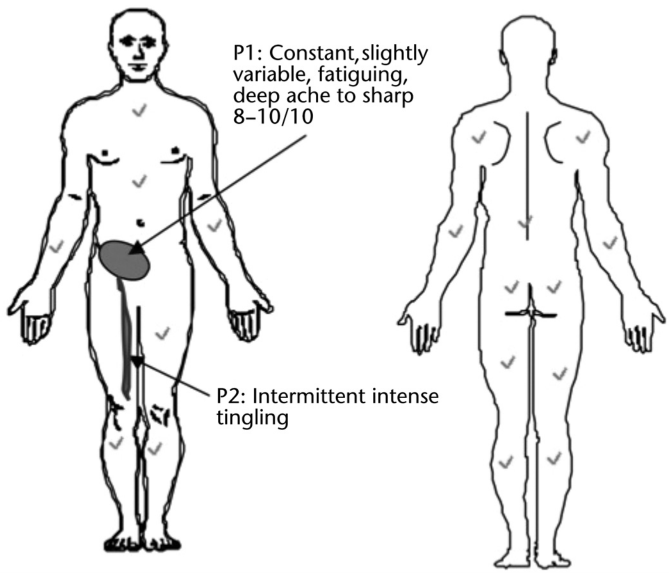

Figure 4.
Body chart or map of patient-reported symptoms. P1 represents the worst or most severe area of symptom reported by the patient. Cleared areas were determined by touching the area and asking the patient whether she was experiencing any symptoms in this location. Check marks indicate symptom-free areas.

physical therapist confirmed that the soldier's fracture could be managed there, and the soldier was able to return to Iraq.

Discussion. The articular surface involvement of the radial head fracture required evaluation by an orthopedic surgeon. Management of this type of fracture can be conservative[42] or surgical, depending on age or functional demands of the patient.[43] The outcome often can be favorable without surgery.[44] Evidence for surgical versus nonsurgical care for a Mason type II radial head fracture remains inconclusive. A recent systematic review showed there was insufficient evidence from which to draw firm conclusions.[43] After the surgeon decided on nonsurgical treatment, the physical therapist was able to help manage the patient in the combat theater. At 6 weeks, radiographs revealed incomplete healing, so the physical therapist transitioned to partial immobilization by fabricating a splint that could be removed for active-assisted range-of-motion exercises in the physical therapy clinic. By 14 weeks, there was adequate union, and the patient was able to complete 10 push-ups without pain. Ultimately, the soldier was able to finish his entire deployment in Iraq.

Case 3 (Tumor Case)

Patient history and systems review. A 21-year-old African American female college student with right knee, thigh, and hip region symptoms was referred to a physical therapist at a large MHS academic medical center. Although the patient had received prior medical attention for a variety of signs and symptoms associated with her condition, the physical therapist's diagnostic hypothesis shifted the focus to examining structures of the hip and pelvic region, including radiographic studies, which revealed an aggressive malignant neoplasm.

The patient attended college and worked nights in a convenience store. She denied regular physical or athletic activity, a specific mechanism of injury, or a change in her work-related duties. She had been seen in the medical center adolescent clinic on 3 occasions during the previous month for right hip and knee pain. The prescribed naproxen did not provide appreciable symptom relief. A contrast bowel study performed due to her recent history of difficult bowel movements was unremarkable. No imaging of the pelvis, hip, or thigh had been obtained. The referral diagnosis from the physician in the adolescent clinic was patellar tendinitis. Her primary complaint was a constant, slightly variable ache to sharp pain (10/10 at worst) with intermittent intense tingling that extended from the anterior pelvic region distally to the anterior knee (Fig. 4). The symptoms were severe enough to keep her from getting more than 1 hour of sleep per night. Her pain was most intense when squatting, lifting her leg to get out of the car or shower, moving her leg for braking while driving, and while standing to operate the cash register at work. During health screening, she indicated that she was experiencing a decreased capacity for food, urgency and frequency of urination, difficulty initiating bowel movements, and menstrual irregularity. She also indicated general health changes of fatigue and malaise.

Clinical impression 1. The patient/client history indicated that injury or overuse influencing the musculoskeletal system was not likely. The onset, progression, behavior, and severity of symptoms were atypical for a musculoskeletal condition. Additionally, the "red flags" of early satiation,[45] consistent difficulty with bowel movements, urinary urgency,[46] changes in menstrual regularity,[46] and general health changes suggested the possibility of pathology outside the musculoskeletal system and possibly within the genitourinary or lower gastrointestinal system (Table). The physical therapist planned a careful examination of the pelvic region, hip, thigh, and knee.

Examination. Her pain at rest in a standing position was 8/10. The patient's gait was antalgic, and she walked on her forefoot on the painful side with a flexed hip and knee. Active attempts to straighten the hip and knee in a standing position increased the pain to 10/10. During supine examination, the knee could reach full passive extension when the hip was slightly flexed without increasing her knee pain. Knee flexion was equal to the contralateral side and did not increase her pain if the hip was held stable. No ligamentous instability was noted at the knee. There were no typical signs of infrapatellar tendinitis such as swelling or crepitus, but there was vague palpation tenderness over the anterior aspect of the infrapatellar tendon. By disrobing the patient to her undergarments and carefully palpating the pelvic region,[47,48] fullness in the right anterior lateral pelvic region was appreciated, with pain over the superior pubic ramus and anterior ipsilateral hip. Hip passive range of motion was limited by pain in all directions. Resisted strength tests of the foot and ankle were 5/5, but those of the hip and thigh were weak and painful.

Clinical impression 2. Due to the atypical history, including several red flags, and the abnormal examination findings in the pelvic and hip region, the physical therapist decided additional screening was indicated. She selected an initial screening strategy of plain film radiographs to be followed as necessary by the appropriate screening laboratory studies such as an erythrocyte sedimentation rate[49] and complete blood cell count[50] and advanced imaging. The thigh and knee seemed to be minimally involved. The physical therapist ordered an anterior-posterior and lateral view radiographic study of the pelvis, which also would reveal hip structures.

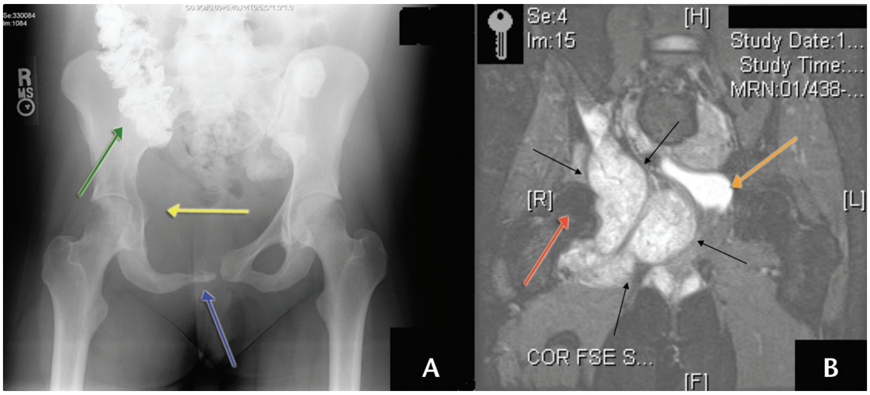

Figure 5.
Imaging of the pelvic neoplasm. (A) An anterior-posterior view radiograph of the pelvis reveals an aggressive destructive lesion involving the right superior pubic ramus (blue arrow) and acetabulum. A Codman's reactive triangle of bone is present along the medial surface of the right ilium (yellow arrow). Residual contrast material from previous bowel study is apparent (green arrow). (B) Coronal magnetic resonance image of the pelvis revealing large soft tissue tumor (black arrows), displaced bladder (orange arrow), and femoral head (red arrow).

Outcome. A highly aggressive, destructive lesion was identified on the radiographic images involving the right superior pubic ramus and right acetabulum (Fig. 5A). The musculoskeletal radiologist's report stated that a Codman's triangle (a triangular periosteal bone formation)[51] was present along the medial surface of the right ilium with aggressive periosteal reaction. This finding has been reported in other tumors of the pelvis.[52] The radiologist's initial differential diagnosis included telangietatic osteosarcoma[53] and infection. The radiologist contacted the physical therapist recommending a magnetic resonance imaging (MRI) scan and a bone scan. The physical therapist immediately notified the orthopedic oncologist on call, who contacted the patient. The subsequent MRI study revealed a lytic bone lesion that had completely destroyed the right superior pubic ramus (Fig. 5B). A large necrotic soft mass displacing the bladder and rectum likely accounted for the bowel and bladder changes and early satiation the patient had experienced. Ultimately, upon receiving definitive cancer treatment, the diagnosis was a malignant peripheral nerve sheath tumor,[54] a class of sarcoma.

Discussion. This patient presentation was identified as atypical by a physical therapist who routinely examines patients with musculoskeletal problems. Accurately completing the body chart or symptom map helped focus the examination to the hip and pelvic region (Fig. 4). The patient interview helped identify red flags and changes associated with 2 major body systems. Tenderness at the knee was most likely referred pain from the involved somatic structures in the pelvic region, a well-documented phenomenon.[55–59] The intense tingling may have been caused by the peripheral nerve sheath pathology. The physical therapist facilitated the diagnosis with a thorough examination of the patient, including an appropriate imaging screening strategy. The physical therapist's credentials to order the appropriate musculoskeletal imaging helped facilitate a more timely diagnosis.

Outcomes

The 3 cases in this report describe select patient management processes in these various clinical settings within the MHS. Point-of-care clinical decision pathways and relevant clinical reasoning affected definitive care for each of these patients (Table). Urgent intervention and important medical evacuation decisions in these cases were possible, in part, because of the physical therapists' full scope of relevant clinical privileges. The value of an appropriately tailored examination, combined with the skills and credentials to perform simple screening tests such as musculoskeletal imaging when indicated, was illustrated.

Discussion

Physical therapists in the MHS often serve the role of musculoskeletal specialists, many times being the first credentialed provider to evaluate and diagnose these patients.[6] These cases illustrate examples of decision-making and clinical reasoning processes by physical therapists in the MHS and augment similar reported cases in this setting.[3,15,60–64] The year that the physical therapist served in Iraq was the first year that physical therapists were organically and routinely placed within Brigade Combat Teams to provide advanced musculoskeletal care closer to the point of injury (cases 1 and 2). There was little precedence for physical therapists working at this level in the combat theater; however, preliminary data suggest that other members of the medical team highly value the their musculoskeletal expertise.[11] Future research should evaluate outcomes for military units with and without physical therapists as part of their teams. These cases exemplify the potential advantages of early involvement by physical therapists with appropriate clinical privileges, and they add to the body of literature describing progressive clinical practice patterns of physical therapists.

All authors provided concept/idea/project design and writing. Dr Rhon and Dr Deyle provided the patient cases. Dr Deyle and Dr Gill provided consultation (including review of manuscript before submission).

The views expressed are those of the authors and do not reflect the official policy of the Department of the Army, the Department of Defense, or the US Government.

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Manual physical therapy and perturbation exercises in knee osteoarthritis

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Objectives: Knee osteoarthritis (OA) causes disability among the elderly and is often associated with impaired balance and proprioception. Perturbation exercises may help improve these impairments. Although manual physical therapy is generally a well-tolerated treatment for knee OA, perturbation exercises have not been evaluated when used with a manual physical therapy approach. The purpose of this study was to observe tolerance to perturbation exercises and the effect of a manual physical therapy approach with perturbation exercises on patients with knee OA.

Methods: This was a prospective observational cohort study of 15 patients with knee OA. The Western Ontario and McMaster Universities Arthritis Index (WOMAC), global rating of change (GROC), and 72-hour post-treatment tolerance were primary outcome measures. Patients received perturbation balance exercises along with a manual physical therapy approach, twice weekly for 4 weeks. Follow-up evaluation was done at 1, 3, and 6 months after beginning the program.

Results: Mean total WOMAC score significantly improved (P=0.001) after the 4-week program (total WOMAC: initial, 105; 4 weeks, 56; 3 months, 54; 6 months, 57). Mean improvements were similar to previously published trials of manual physical therapy without perturbation exercises. The GROC score showed a minimal clinically important difference (MCID)$\geq +3$ in 13 patients (87%) at 4 weeks, 12 patients (80%) at 3 months, and 9 patients (60%) at 6 months. No patients reported exacerbation of symptoms within 72 hours following each treatment session.

Discussion: A manual physical therapy approach that also included perturbation exercises was well tolerated and resulted in improved outcome scores in patients with knee OA.

Keywords: Knee osteoarthritis, Manual therapy, Perturbation exercises, Physical therapy

Introduction

Exercise interventions are important in the evidence-based treatment of knee osteoarthritis (OA).[1–9] The goals of exercise for knee OA are typically to improve movement, function, and cardiovascular fitness, while reducing pain and body mass index.[4,5] Impairments of balance, joint proprioception, and kinesthesia are also related to knee OA and may persist even after knee replacement surgery.[10,11] These impairments may result in falls and increased cost of management.[12] Joint laxity and proprioceptive inaccuracy are predictors of poor functional outcomes.[13] However, the measurement of proprioceptive deficits has been poorly defined in the literature.[14]

There is limited evidence supporting the efficacy of proprioceptive exercise for patients with knee OA.[15–19] There may be no additional benefit of perturbation and agility training exercises when added to an impairment-based exercise program.[19] Some even advocate that other approaches, such as task-specific exercises, may have more value than some impairment-based exercise approaches.[18] Although a case report on perturbation exercises for a patient with knee OA suggested a positive outcome,[20] perturbation exercises may be poorly tolerated.[16,21,22] This may be related to the increased joint compression forces that closed-chain exercises are thought to place on the knee joints.[22] Other studies suggest that repetitive loading can adversely affect the viability of cartilage in the knee. [21,23] Consideration of the irritability of knee OA symptoms with closed-chain exercises has led to several studies looking at methods of exercise that limit weight through the joints, specifically to improve tolerance.[16,17,24,25] For example, Lin *et al.*[17] argued that while closed-chain exercises activate more muscle spindle and joint proprioceptors, they can also lead to an increase in pain, swelling, and inflammation if not properly controlled. Based on this rationale, they sought to provide perturbation exercises to patients

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with knee OA while seated by way of a computer-facilitated proprioception device. In another study, Jan *et al.*[26] stated that while perturbation training may be valuable, it can increase pain and inflammation when performed in the standing position. They also sought to evaluate perturbation exercise prescription in a seated position. While perturbation exercises may increase joint load in the knee, we were unable to find any studies that compared joint compression forces from perturbation exercise to other forms of exercise. However, consideration of patient tolerance to prescribed exercise appears to be a valid concern, and this may be why some clinicians avoid perturbation exercises in this population.

Another treatment strategy for knee OA is the manual physical therapy approach, which has demonstrated substantial benefits that can last out to 1 year.[27–30] This approach is based on clinical reasoning and includes highly specific passive manual techniques and therapeutic exercises that support and reinforce those techniques (Appendix 1).[31] In the context of this approach, the integration of perturbation exercises as a multimodal treatment may lead to improved perturbation training tolerance. Manual therapy has been reported to act, in part, by inhibiting and modulating pain,[32,33] or altering the acute inflammation in response to exercise.[34] This may lead to an increase in exercise tolerance that would otherwise be lacking or diminished without the combination of manual therapy.

This investigation is the first step in a line of research to ultimately evaluate the effect of perturbation exercises on knee OA. It aims to include effects on patient-centered outcome measures, functional tests, and eventually tests of balance and proprioception with the overarching goal of reducing fall risks. The purpose of this study was to evaluate tolerance to and outcomes associated with the addition of proprioceptive exercises to an already established manual physical therapy approach. If this therapy is appropriate for addressing proprioception impairments, and delivery in conjunction with a manual physical therapy approach can be well tolerated,[35] then this combined intervention could be a focus for future studies.

Materials and Methods

Subjects

This study was a repeated-measures, prospective, observational cohort study. Patients were recruited from a convenience sample of consecutive patients evaluated for knee OA at the Physical Therapy Clinic, Brooke Army Medical Center, San Antonio, Texas from January to May 2008. Patients were treated by licensed physical therapists who were training in an APTA-credentialed manual physical therapy fellowship program. All patients were screened and provided informed consent. Inclusion and exclusion criteria are presented in Table 1. The study was approved by the Brooke Army Medical Center Institutional Review Board.

Instrumentation

The Western Ontario and McMaster Universities arthritis index (WOMAC), a self-administered health status instrument, is valid, reliable, and responsive to change in this population. It has satisfactory test-retest reliability for function, and acceptable overall inter-rater reliability.[38–40] The WOMAC has three clinical subscales (pain, stiffness, and physical function), and lower scores are associated with less pain and stiffness, and better function. The minimal

Table 1 Inclusion and exclusion criteria for enrollment in the study

Inclusion criteria
1. Meeting ≥1 of the three classification criteria for knee osteoarthritis (OA) as previously described (sensitivity, 89%; specificity, 88%) *[36,37]
a. Knee pain for most days of the prior month and
i. Crepitus with active motion (and)
ii. Morning stiffness in knee ≤30 minutes (and)
iii. Age≥38 years
b. Knee pain for most days of the prior month and
i. Crepitus with active motion (and)
ii. Morning stiffness in knee >30 minutes (and)
iii. Bony enlargement
c. Knee pain for most days of the prior month and
i. No crepitus (and)
ii. Bony enlargement
2. Eligible for care in a military medical treatment facility
3. Minimum age 38 years
4. Read, write, and speak sufficient English to complete the outcome tools
Exclusion criteria
1. Only periarticular pain or pain referred from another region; no joint pain
2. Injections to the knee within the last 30 days
3. History of knee joint replacement surgery on involved limb
4. Evidence of other systemic rheumatic condition (rheumatic arthropathies such as lupus, rheumatoid arthritis, psoriasis, or gout)
5. Balance deficits from other non-musculoskeletal conditions (such as neurologic impairments, diabetic neuropathy, cerebellar disorders, or Parkinson disease)

* Altman (1991)[37] and Altman *et al.* (1986)[36].

clinically important difference (MCID) for the WOMAC is a change of 12%.[41]

The global rating of change (GROC) is a common, feasible, and useful method for assessing outcome measures and overall changes in quality of life from an established baseline point. It is responsive to change, and has been used in clinical trials for knee OA.[19,42,43] The GROC has a 15-point scale, with a score of 0 indicating no change, -1 to -7 indicating worsening of symptoms, and $+1$ to $+7$ indicating improvement of symptoms. A change of $\geq +3$ points indicates the MCID related to a patient's perception of quality of life.[42]

Tolerance to treatment was assessed by asking patients a series of questions related to their signs and symptoms on the subsequent visit. They were asked if their symptoms had gotten significantly worse at five different time points since their last treatment: (i) immediately after treatment, (ii) several hours after treatment, (iii) that evening before going to bed, (iv) the following morning, and (v) from the following morning until the follow-up which was typically 72 hours later. They were told immediately after each treatment to try and remember how they felt, as they would be asked these questions on their next follow-up.

The functional squat test is a provocative test and measure of function, with excellent intra-rater reliability,[44] that uses pain and range of motion (ROM) to report its score. In the functional squat test, pain was measured with the 11-point numeric pain rating scale (NPRS) and ROM was measured with a gravity inclinometer (Baseline, Fabrication Enterprises Inc, White Plains, NY).[44] Patients stood with their feet shoulder-width apart and pointed forward. The top edge of the gravity inclinometer was placed just below the tibial tuberosity and set to 0°. The patients bent their knees and lowered their buttocks straight down toward the heels, without bending forward or letting the heels come off the ground. The knee ROM measurement was taken at the greatest angle at which the patient maintained this posture or stopped because of pain. A 2-point change in the NPRS represented a clinically meaningful change.[45,46] No MCID was available for ROM changes in the functional squat test in this population.

The step-up test is valid and reliable for measuring balance in patients post stroke[47] and has been used to measure balance impairments in patients with knee OA.[47,48] The step-up test may correlate with functional reach (r=0.68), gait velocity (r=0.83), and stride length (r=0.82) in stroke patients.[47] There is a significant difference in step-up test ability between patients with knee OA and healthy controls.[48] The step-up test was performed as previously described, with only one trial allowed for each subject after two practice steps.[48] Patients stood on the symptomatic leg (or the most symptomatic leg when there was bilateral involvement) and maintained balance while placing the opposite foot from the ground onto a 15-cm step and back onto the ground. A full repetition was defined as the full step-up and step-down movement, with the foot placed fully onto the step and fully back onto the ground. The number of repetitions performed within 15 seconds was recorded. If loss of balance occurred, the test was terminated and the assigned score was the number of steps recorded. This did not occur with any of the patients in this study. No MCID has been established for the step-up test.

Evaluation

The primary dependent variables were 72-hour tolerance to treatment, the WOMAC, and the GROC. The WOMAC was measured at 0 weeks (initial), and then along with the GROC at 4 weeks, 3 months, and 6 months. The secondary dependent variables were the step-up and functional squat tests measured at 4 weeks, in order to assess functional tasks immediately upon completion of treatment. Another investigator who did not treat the subject verified that the WOMAC was complete and placed it in a locked file. The treating therapist was blinded to all outcome variables throughout the treatment of the study. The initial evaluation included a detailed history, review of systems, and physical examination. The history included questions about the duration, severity, location, and distribution of symptoms. The physical examination included functional tests, palpation of bony landmarks, ROM measurement, muscle length tests, and manual assessment of the joints and soft tissues including the knees, hips, lumbar spine, feet, and ankles.

Intervention

Patients were treated in the physical therapy clinic twice weekly for 4 weeks (total, 8 sessions). The manual physical therapy approach included joint and soft tissue mobilization (Appendix 1 and online supplementary material 1) with stretching, range of motion, and strengthening exercises that reinforced the manual techniques.[35] These were also prescribed for the home exercise program. Exercises were chosen that addressed common functional limitations and impairments, and were customized to each subject based on impairments identified during the physical examination, as previously described (Appendix 1).[27,28,49]

In addition to the manual physical therapy approach, perturbation exercises, modified from a case study (Fig. 2),[20] were performed at each clinical visit (Appendix 2 and online supplementary material 2). Patients were also given the standard home exercise program used in prior manual therapy trials for knee OA,[27,28,35] and tailored to impairments found in each patient.[35] The progression of the

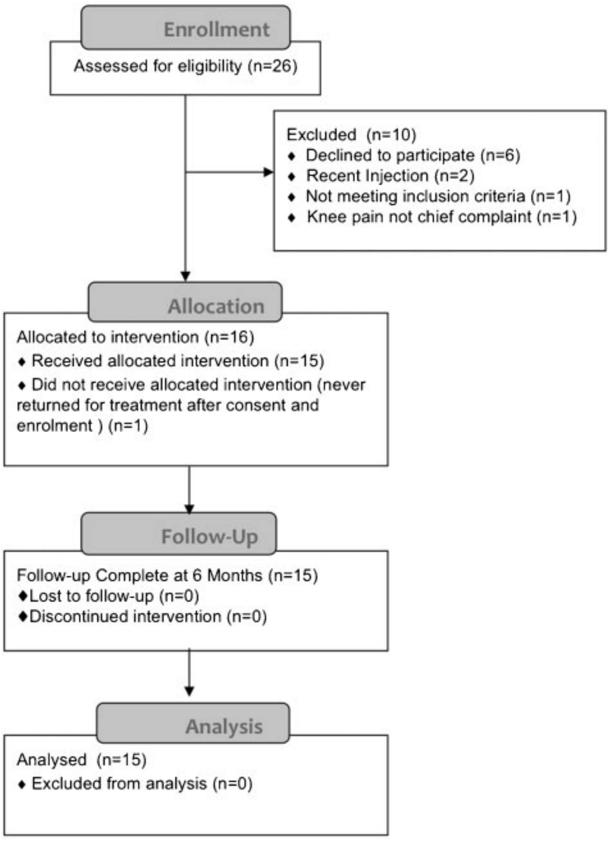

Figure 1 **Study flowchart.**

Figure 2 **Perturbation challenge exercises.**

perturbation exercises was guided by clinical reasoning, and varied depending on each patient's presentation, with careful assessment of the severity and persistence of symptoms in response to a very low initial intensity of perturbation exercises. The first few sessions typically included more emphasis on applying manual treatment and teaching reinforcing exercises. The final sessions included more emphasis on the perturbation exercises (Appendix 2 and online supplementary material 2).

Data analysis

Data were analyzed with statistical software (SPSS for Windows 16.0, SPSS Inc., Chicago, IL). Descriptive statistics were calculated on demographic and outcome data. Inferential statistics were calculated for the dependent variables (WOMAC, GROC, functional squat test, and step-up test). The 72-hour response to treatment was calculated descriptively. The independent variable was time. Analysis of variance (ANOVA) was performed for the WOMAC total score at initial time, 4 weeks, 3 months, and 6 months. Separate ANOVA tests were also performed for the WOMAC subscales of pain, stiffness, and function. The Greenhouse–Geisser correction factor was applied when assumptions of sphericity were not accomplished. Post hoc analyses were performed using the least significant difference test for comparisons between different times. The GROC was assessed at 4 weeks, 3 months, and 6 months, and reported as frequency counts of scores achieving no change (≤2 points), clinically important change (≥3 points), and dramatic change (≥6 points). Paired *t* tests were performed for the functional squat test (NPRS and ROM) and step-up test (initial to 4 weeks). Statistical significance was defined by $P \leq 0.05$.

Results

During the 3-month period, 26 patients were referred for knee OA. All 16 patients enrolled in the study (Fig. 1) had radiographic signs of knee OA, and 10 had bilateral knee symptoms (Table 2). Visible bony enlargement of the knee joint was noted on clinical observation in 10 patients. Mean total WOMAC score improved significantly, with 46% improvement from initial to 6 months (Table 3). The total WOMAC score was significantly improved at the end of the 4-week treatment ($P=0.001$), and this improvement remained for 6 months ($P=0.009$). For all three WOMAC subscales, significant differences from baseline were found at all time points except at the 6 month follow-up for stiffness (Table 3).

The GROC score showed marked improvement with 87% of the patients reporting a clinically important improvement (GROC≥+3) at the 1-month follow-up, 80% at the 3-month follow-up, and 60% at the 6-month follow-up point. Nearly half (47%) reporting dramatic change (GROC≥+6) at all time points (Table 3). The two functional tests were only assessed immediately after the treatment regimen and compared to baseline. The functional squat test had significant improvement in both mean NPRS and ROM from initial to 4 weeks (Table 3). The mean step-up test improved significantly from initial to 4 weeks, with a mean improvement of 4–5 steps during the 15 second test (Table 3). All 15 patients who received treatment were compliant with all follow-up appointments during the study.

Table 2 Clinical and demographic features of patients*

	Men	Women	Total
Number of patients	7	8	15
Age (years)	52	57	55
Active duty soldier (*n*)	3	1	4
Duration of symptoms (months)	98	31	60
Height (m)	1.75	1.69	1.72
Body weight (kg)	99	218	218
Body mass index (kg/m^2)	32	35	34
Body surface area (m^2)	2.18	2.15	2.16
Most symptomatic knee			
Left	4	4	8
Right	3	4	7
Bilateral involvement	5	5	10
Crepitus present	5	8	13
Morning stiffness			
None	3	0	3
<30 minutes	3	2	5
≥30 minutes	1	6	7
Imaging findings			
Radiographic signs	7	8	15
MRI done	4	1	5
Meniscus abnormal (MRI)	4	1	5
Compartment involvement			
Lateral	3	6	9
Medial	7	6	13
Patellofemoral	4	7	11
Co-morbidities†			
1	7	8	15
≥2	6	4	10
Diabetes mellitus	1	1	2

* *N*=15 patients. Data reported as mean or number.
† Co-morbidities included additional body regions with marked pain (low back, hip, ankle, neck, or shoulder).

Discussion

In the present series of patients with knee OA, a manual physical therapy approach incorporating perturbation exercises resulted in significant improvement in all outcome scores and functional tests. The mean 46% improvement in total WOMAC score from initial to 6 months is well above the MCID of 12% and is consistent with previous trials using the same manual therapy approach without perturbation exercises.[27,28] Improvements in the GROC score, step-up test, and functional squat test also were significant. These results suggest that the addition of carefully applied perturbation exercises within the context of a manual therapy approach may be well tolerated and a reasonable treatment delivery strategy. These results lay groundwork for future research to directly compare a manual therapy approach with and without perturbation exercises, a manual therapy approach with perturbation exercises to a functional exercise approach with perturbation exercises, and to investigate other outcome measures that appropriately measure balance, proprioception, stumble response, and ultimately falls.

By 6 months five patients had received knee joint injections of either corticosteroid or viscosupplementation and two of those same patients received arthroscopic surgery. Arthroscopic surgery was done during the study in two patients (one patient with a more symptomatic knee, and one with a less symptomatic knee initially). Pain medication was used by 12 patients initially (10 patients daily; 2 patients as needed), including non-steroidal anti-inflammatory drugs and/or acetaminophen. At each of the follow-up points fewer patients were taking medications than at baseline (4 weeks and 3 months, 7; 6 months, 10). There were no adverse events or reports of acute flare-ups during treatment or within 72 hours after each treatment in any subject.

The risk of falls in patients with knee OA[12,50–52] has been attributed, in part, to decreased balance, agility, muscle function, proprioception, and the ability to respond to perturbations.[10,14,53–57] Therefore, it may be important to design interventions to address these impairments, with careful attention to the type and dose of exercise to address balance and proprioception.[14,58,59] Manual physical therapy as an effective treatment approach for knee OA has been well established.[27–30] It has been shown to improve pain and function for at least 1 year, in multiple settings, and in patients with or without concurrent meniscus tears.[27–30] Perturbation and agility training

Table 3 Outcome measures for patients*

Outcome measures	Initial	4 weeks†	P≤‡	3 months	P≤‡	6 months	P≤‡
Functional squat							
Numeric pain rating scale (NPRS)	5±2	3±2	0.000				
ROM	29±9	35±10	0.001				
Step-up test	9±3	14±4	0.02				
WOMAC							
Stiffness	10 (6.8–12.9)	6 (3.1–8.5)	0.002	5 (2.4–8.4)	0.001	7 (3.3–10.1)	0.083
Pain	22 (16.8–26.2)	10 (4.7–15.0)	0.000	11 (4.3–16.9)	0.004	12 (5.6– 17.4)	0.006
Function	74 (52.5–94.5)	40 (21.7–59.0)	0.001	38 (16.7–58.6)	0.003	39 (17.0–60.8)	0.009
Total (MCID=12)	105 (77.0–132.7)	56 (30.3–81.7)	0.001	54 (23.7–83.6)	0.003	57 (26.3–87.9)	0.009
GROC							
MCID≥+3		13 (87%)		12 (80%)		9 (60%)	
MCID+6 or +7		7 (47%)		7 (47%)		7 (47%)	

* Reported as mean±SD; mean (95% confidence interval); or number (%). Abbreviations: GROC, global rating of change; MCID, minimal clinically important difference; ROM, range of motion in degrees; WOMAC, Western Ontario and McMaster Universities osteoarthritis index.
† Functional tests performed only initially and at 4 weeks.
‡ Comparison against initial value.

may improve proprioceptive deficits, but it is unknown whether addressing balance and proprioceptive deficits will actually decrease the risk of falls. While more research is needed to determine this, our study is the first in this line of research demonstrating that an intensive perturbation training program may be undertaken, within the context of a manual physical therapy approach, without apparent irritation or increase in pain or disturbance of functional outcomes.

Substantial improvement in the pain and function subscales of the WOMAC, along with no report of increased joint irritation in the 72 hours following each treatment, suggest that the exercises were well tolerated and not associated with adverse effects. As increased joint inflammation and effusion may decrease proprioception, it is important that all aspects of a knee OA treatment program be well tolerated.[53] The observations from the present study suggest that perturbation exercises in the weight bearing position can be safely added to a manual physical therapy approach, using clinical reasoning to adjust individually for dose and progression, in patients with knee OA.

There is no solid consensus on the exact mechanisms resulting from manual physical therapy that result in therapeutic benefits. However, it is likely that it works through both biomechanical and neurophysiological mechanisms.[60] The clinical trials that demonstrated the effectiveness of manual therapy for improving pain and function in patients with knee OA did not speculate on specific potential mechanisms other than suggesting that the effects of manual therapy may be derived from treating the spectrum of tissues in and around the knee and other related body regions.[27,28] The knee has proprioceptive mechanoreceptors that may be damaged from the degenerating joint process common in OA.[61,62] Dysfunction within these neural structures may mediate weakness and instability in joints affected by OA and negatively affect proprioception.[63] Manual physical therapy has also been reported to inhibit and modulate pain,[32,33] induce a controlled inflammatory response that initiates healing and influences processing of pain,[64–66] and alter acute inflammation in response to exercise.[34] These could all contribute to decreased pain from muscle contraction, improving tolerance for exercise. Joint mobilizations also may modulate proprioceptive input to joint structures, prime the joint and surrounding muscles for optimal response to strengthening programs, and improve muscle control and reaction times.[67,68] These are all possible mechanisms contributing to the improvements seen with the patients in this cohort. However, we do not know if perturbation training is tolerated better when prescribed in conjunction with manual therapy, or the additional effect of this multimodal treatment on balance and functional measures of proprioception. This may be an important area to consider in future research related to perturbation training.

Limitations of the present study include a cohort study design with no comparison group, therefore no cause-and-effect relationship can be assessed. In addition, five patients received viscosupplementation or corticosteroid injections to the knee, and two of those also had arthroscopic surgery during the 6-month follow-up period. While this may confound the results, only three of these additional procedures (injections) occurred during the initial 1-month period of treatment, and two of these patients had no improvement in their WOMAC scores at the 4-week follow-up. Both of the arthroscopic surgeries occurred at the 3-month mark. All of the patients responded that they felt no significant change in symptoms after their injection or arthroscopic surgery procedure. Also, four of the five patients stated that these procedures had already been considered as part of their treatment management plan before they were referred to physical therapy. However, they did not make this known until the end of the study when asked about the reasons for pursuing surgery when they seemed to be improving with the physical therapy program. While we may not fully understand what drives these patient behaviors, this is not isolated to our study alone. In a recent randomized trial comparing physical therapy to surgery, 30% of subjects randomized to receive physical therapy crossed over to the surgery group, despite mean improvement in the physical therapy group being equal to that of the surgery group.[30] Therefore, these decisions may not have been made due to a lack of improvement with the manual therapy and exercise program. This may be a separate focus for future research. In addition, it is unknown whether the present intervention improved impairments in proprioception and balance, which were assessed only indirectly with the step-up test.

In summary, a manual physical therapy approach including perturbation exercises in a symptomatic knee OA cohort was well tolerated. It was also associated with improved pain, function, and balance as previously noted with manual physical therapy alone. This is an important first step in describing a combined intervention, which can be studied within the context of future clinical trials to determine efficacy related to pain, function, balance, and falls compared to other physical therapy or medical approaches.

Conflict of Interest

None of the authors have any disclosures to make regarding any actual or perceived conflict of interest related to this research report.

Disclaimer

The views expressed are those of the authors and do not reflect the official policy of the Department of the Army, the Department of Defense, or the United States Government.

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Appendix 1: Manual physical therapy program

The manual physical therapy program included a passive manual examination, followed by tailored manual treatment techniques, and then reinforced with supporting exercises.[31] To begin, a passive manual examination was performed on each knee. Joints were progressively stressed to demonstrate impaired movement or to reproduce symptoms comparable to the patient's primary pain complaint. Maitland grading system[69] was used to clear the joints in single and combined motion planes; grade IV– indicates the point in the range of movement where resistance to motion begins, and grade IV++ indicates the end-range resistance of the joint. A joint was considered cleared if movement was normal, no pain could be identified throughout the ROM, and if the joint could be taken to a grade IV++ (end-range resistance of joint) without reproducing the subject's symptoms. If the tibiofemoral joint for example, could be cleared in one plane (isolated plane of flexion or extension), then the therapist attempted to clear the joint in a combined plane. This was performed by adding a combined movement such as a varus force with tibial adduction or a valgus force with tibial abduction to the end-range of flexion or extension. This detailed movement and symptom examination helped identify impairments in any aspect of the knee and ensure thorough assessment before declaring a joint clear.

Any joint movements that were not cleared were documented and formed the basis for choosing the mobilization techniques and dosage that each subject would receive for an intervention. Over the course of several treatment sessions a joint that was not initially cleared could become cleared when impaired movements or symptoms were no longer reproduced with a grade IV++ (end-range) mobilization. Remaining treatment session would then focus on the residual impairments to movement and the symptoms of the patient. If symptoms that were reproduced in the first or second treatment session improved after several treatments, the treating physical therapist progressed the manual intervention to combinations of accessory and physiological movements as described earlier.

Reinforcement exercises were given based on the impairments identified. When patients presented with restriction of knee extension or flexion, terminal knee extension or flexion ROM exercises were taught to reinforce the knee mobilizations. Hip flexor, quadriceps, hamstring, and calf muscle length tightness were common impairments in these patients, and these were addressed with manual stretching techniques and self-stretching exercises. The patellofemoral and proximal tibiofibular joints were also manually assessed for stiffness and symptom reproduction. Mobilizations to these joints were targeted to impairments found on examination, and included a progression of medial, lateral, superior, inferior, or rotatory glides of the patella and anterior-to-posterior and posterior-to-anterior glides of the proximal tibiofibular joint.

Manual physical therapy – video demonstration found in online supplementary material 1:

A1. Knee extension mobilizations, grade IV in single plane. Combined movements into varus/abduction or valgus/adduction were added as a progression. This was performed for joint motion evaluation and treatment.
A2. Knee extension mobilizations, grade III in single plane. Combined movements into varus/abduction or valgus/adduction were added as a progression. This was performed for joint motion evaluation and treatment.
A3. Knee flexion mobilizations, grade IV in single plane. Combined movements into varus/abduction or valgus/adduction were added as a progression. This was performed for joint motion evaluation and treatment.
A4. Knee flexion mobilizations, grade III in single plane. Combined movements into varus/abduction or valgus/adduction were added as a progression. This was performed for joint motion evaluation and treatment.
A5. Knee flexion mobilizations, grade III with popliteal wedge modification.
A6. Patellar mobilizations: medial-lateral glide, medial-lateral rotation, and inferior glide with distraction.

Appendix 2: Perturbation exercise progression

Patients removed their shoes and stood without any equipment. They received unpredictable perturbation exercises in medial, lateral, anterior, and posterior directions. The patients placed their arms out in front, parallel to the ground over the therapist's shoulders, without touching the therapist; this would enable them to support themselves when they lost balance. The therapist was positioned to stabilize the subject when the subject began to lose balance. If the initial movement was tolerated, the patient progressed to single-limb stance. The subject progressed to standing on the 2-inch foam, the wooden rocker board, and the foam that was placed on top of the rocker board. The stance was progressed from double- to single-limb stance. Assessment of symptoms was ongoing to minimize flare-ups during the perturbation training. Careful questioning at each session helped to determine if the previous session was well tolerated or if latent pain occurred despite the careful assessment during treatment.

Perturbation exercise – video demonstration found in online supplementary material 2:

Demonstration of balance challenge and perturbation exercise progression.

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Annals of Internal Medicine | Original Research

One-Year Outcome of Subacromial Corticosteroid Injection Compared With Manual Physical Therapy for the Management of the Unilateral Shoulder Impingement Syndrome

A Pragmatic Randomized Trial

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Background: Corticosteroid injections (CSIs) and physical therapy are used to treat patients with the shoulder impingement syndrome (SIS) but have never been directly compared.

Objective: To compare the effectiveness of 2 common nonsurgical treatments for SIS.

Design: Randomized, single-blind, comparative-effectiveness, parallel-group trial. (ClinicalTrials.gov: NCT01190891)

Setting: Military hospital–based outpatient clinic in the United States.

Patients: 104 patients aged 18 to 65 years with unilateral SIS between June 2010 and March 2012.

Intervention: Random assignment into 2 groups: 40-mg triamcinolone acetonide subacromial CSI versus 6 sessions of manual physical therapy.

Measurements: The primary outcome was change in Shoulder Pain and Disability Index scores at 1 year. Secondary outcomes included the Global Rating of Change scores, the Numeric Pain Rating Scale scores, and 1-year health care use.

Results: Both groups demonstrated approximately 50% improvement in Shoulder Pain and Disability Index scores maintained through 1 year; however, the mean difference between groups was not significant (1.5% [95% CI, −6.3% to 9.4%]). Both groups showed improvements in Global Rating of Change scale and pain rating scores, but between-group differences in scores for the Global Rating of Change scale (0 [CI, −2 to 1]) and pain rating (0.4 [CI, −0.5 to 1.2]) were not significant. During the 1-year follow-up, patients receiving CSI had more SIS-related visits to their primary care provider (60% vs. 37%) and required additional steroid injections (38% vs. 20%), and 19% needed physical therapy. Transient pain from the CSI was the only adverse event reported.

Limitation: The study occurred at 1 center with patients referred to physical therapy.

Conclusion: Both groups experienced significant improvement. The manual physical therapy group used less 1-year SIS-related health care resources than the CSI group.

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The shoulder impingement syndrome (SIS) is a generic term used for patients with shoulder pain that encompasses the rotator cuff syndrome, tendinosis of the rotator cuff muscles, and bursitis in the shoulder area (1). It has a cumulative incidence between 5 and 30 per 1000 person-years (2, 3).

Conservative treatment options include corticosteroid injections (CSIs) and physical therapy. Subacromial CSI is one of the most common procedures used by orthopedists, rheumatologists, and general practitioners (4, 5). However, evidence to support long-term efficacy is conflicting (6–10). Clinical practice guidelines cannot recommend for or against CSI for rotator cuff pathology without evidence of tears (11). Four recent systematic reviews have differing conclusions on the efficacy of CSI for SIS (6, 8, 9, 12), but the consensus suggests that any benefit may only be short-term.

Although manual physical therapy (MPT) may be effective for SIS management (13–21), 2 recent systematic reviews found no clear evidence to suggest additional benefits of MPT to other interventions (22, 23), indicating the need for further research. Data are also lacking about the patterns and timing of CSI and MPT use for patients with SIS. Studies suggest that a CSI is often considered initially (4, 5), whereas a referral to physical therapy may occur only 24% of the time (24). Other studies introduced CSI only after 6 weeks of physical therapy was unsuccessful (5). Some investigations evaluated the effect of providing CSI before, or in conjunction with, MPT or shoulder exercises (14, 25, 26), but CSI and MPT have not been directly compared. The objective of this study was to compare the 1-year effectiveness of CSI and MPT for SIS management.

Methods

Design Overview

This pragmatic, randomized, controlled trial compared 2 treatments for patients with SIS: subacromial CSI and MPT. The primary end point was 1-year improvement on the Shoulder Pain and Disability Index (SPADI). Sec-

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Context

The shoulder impingement syndrome includes conditions, such as rotator cuff tendinosis and shoulder bursitis. Conservative management may include corticosteroid injections (CSIs) or manual physical therapy (MPT).

Contribution

In this randomized, controlled trial, groups of patients with the shoulder impingement syndrome receiving CSI or MPT showed similar symptom improvements that did not differ significantly. Compared with the MPT group, the CSI group used more health care resources during the 1-year follow-up.

Caution

The trial recruited only patients referred to MPT.

Implication

Manual physical therapy and CSI produced similar clinical outcomes in patients with the shoulder impingement syndrome.

—The Editors

ondary outcomes included changes in Global Rating of Change (GRC) scale and Numeric Pain Rating Scale (NPRS) scores and shoulder-related health care use. We followed the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement at the time of protocol development (27), and our reporting followed the CONSORT (Consolidated Standards of Reporting Trials) extension for pragmatic clinical trials (28). The study was approved by the Madigan Army Medical Center Institutional Review Board, the trial was registered (ClinicalTrials.gov: NCT01190891), and the protocol was published with open access (29).

Setting and Participants

Consecutive patients aged 18 to 65 years with a primary symptom of unilateral shoulder pain referred from family practice and orthopedic clinics to the physical therapy department at Madigan Army Medical Center were screened for eligibility during their initial visit in the physical therapy clinic. Exclusion criteria included a history of shoulder dislocation, fracture, or adhesive capsulitis; history of CSI or physical therapy for the shoulder pain in the past 3 months; baseline SPADI score less than 20%; reproduction of shoulder symptoms with cervical spine examination; history of systemic or neurologic disease affecting the shoulder; positive rotator cuff lag sign or history of full-thickness rotator cuff tear; pending litigation; or inability to attend physical therapy for 3 consecutive weeks. Patients at this medical center included a mix of active-duty and retired military service members and their families. Copayments were not required for care.

Randomization and Interventions

The randomization schedule was computer-generated, with assignments placed in opaque, sequentially numbered envelopes by an off-site investigator not involved with patient care or follow-up. Treatment allocation was revealed after collection of baseline outcomes. Patients and treating clinicians were not blind to the intervention. The research assistant who collected outcome assessments at each time point was blind to group assignment. Two physical therapists provided the MPT, and 1 physician administered all of the injections. Patients were allowed to continue any current medications prescribed by their primary care providers (PCPs).

MPT Group

At the first session, the physical therapists performed a standardized clinical examination to identify relevant impairments (weakness, mobility, or pain). The MPT intervention consisted of a combination of joint and soft-tissue mobilizations; manual stretches; contract–relax techniques; and reinforcing exercises directed to the shoulder girdle or thoracic or cervical spine. Specific details of the treatment are published (29). Patients did not receive identical treatments, but the MPT techniques were matched to individual impairments identified on examination. Patients were treated twice weekly over a 3-week period, a typical episode of care for SIS, by the same physical therapy in most cases. Home exercises were prescribed to reinforce clinic interventions (29). The physical therapists were fellowship-trained in MPT from an American Physical Therapy Association–credentialed program.

CSI Group

A credentialed family practice physician with sports medicine fellowship training injected 40 mg of triamcinolone acetonide to the subacromial space of the symptomatic shoulder (29). Each participant received a handout explaining the effects of the steroid injection and how to manage potential side effects. As many as 3 total injections could be administered by the study physician (>1 month apart) during the 1-year period. Patients received printed instructions to perform a gentle gravity-assisted distraction and oscillatory pendulum exercise.

Patients were discouraged, but not prohibited, from seeking additional care for at least the first month (study-related treatment period). At the 1-, 3-, and 6-month follow-up periods, patients were also given written instructions and a number to call if they believed that they were not improving and needed additional care. A study coordinator, who was not involved with data collection or treatment, fielded these calls. She advised patients in the MPT group to return to their PCP for additional care and facilitated contact with the physician providing the injection for patients in the CSI group. Each case was managed individually, and another CSI was administered if the patient and physician mutually agreed that it was appropriate. Patients in either group could return to their PCP if they felt the need, and the PCP would manage the patient as they thought best, potentially including a CSI or referral to physical therapy. These patients would not see the same physical therapist or physician who administered the initial study intervention.

Outcomes and Follow-up

Outcome measurements were administered at baseline, 1 month, 3 months, 6 months, and 1 year. The SPADI is a 100-point, 13-item, self-administered questionnaire that is divided into 2 subscales: a 5-item pain subscale and an 8-item disability subscale. It is valid, is responsive to change, and accurately discriminates between improving and worsening status (30, 31). The minimal clinically important difference for the SPADI is a change between 8 and 13 points (6% to 10%) (32).

The GRC is an instrument that measures overall perceived changes in the participant's quality of life (33). It provides a valid measurement of change in patients' perceived status (34). A GRC score of 3 rating points or greater is clinically meaningful (35).

An 11-point NPRS ranging from 0 (no pain) to 10 (worst imaginable pain) was used to assess pain intensity (36). This scale has been demonstrated to be a reliable, generalizable, and internally consistent measure of clinical and experimental pain intensity (37, 38). The suggested minimal clinically important difference for the NPRS is a change of 2 points (39).

A research assistant blinded to treatment allocation collected health care use information from electronic health records at the 1-year follow-up using an established process (40, 41). This included additional use after completion of the study interventions. We identified shoulder-related visits to physical therapists, PCPs, rheumatologists, and orthopedists, as well as frequency and types of procedures, including additional steroid injections, magnetic resonance imaging, and radiography, similar to other studies (42). A second clinician manually verified the electronic health record information to ensure that the care was related to the same shoulder condition.

Statistical Analysis

The sample size estimated to achieve 80% power to detect a 12-point difference (or a 9.2% change) in the SPADI, based on a reported minimal clinically important difference range of 8 to 13 points (32), with an SD of 10 points, a 2-tailed test, and an α level of 0.05 was 43 participants per group. To allow for a conservative withdrawal rate of approximately 20%, we recruited 104 participants.

The primary analyses of effectiveness included all available data from patients who received their assigned treatment (that is, the CSI or at least 1 session of MPT). We used a linear mixed-effects model, which is flexible in accommodating data assumed to be missing at random (43) (MIXED in SPSS, version 20 [SPSS, Chicago, Illinois]) with data from 5 time points (0, 1, 3, 6, and 12 months) for the SPADI (primary outcome) and NPRS and 4 time points for GRC. The intervention (MPT or CSI) was the fixed effect with random effects for the repeated measures over time within a patient; the primary treatment comparison was the difference between groups from baseline to 1 year. For the sensitivity analysis to explore the effect of missing data, they were imputed for the 3 outcome variables at all follow-ups (20 imputations using MULTIPLE IMPUTATION-FULLY CONDITIONAL SPECIFICATION) (44). Descriptive statistics were provided for demographic and health characteristics that may influence prognosis between groups.

Health care use for 1 year after enrollment was compared between groups using frequency counts and risk ratios with 95% CIs (CROSSTABS-RISK).

Role of the Funding Source

The study was partially funded by Cardon Rehabilitation Products through the American Academy of Orthopaedic Manual Physical Therapists. The funding source had no role in the design or analysis.

Results

Over a 22-month period (June 2010 to March 2012), 242 consecutive patients were screened for eligibility (**Figure 1**), and 138 patients were excluded. The most common reasons for exclusion were the patient not wanting an injection (24%), nonimpingement classification of shoulder pain (18%), and unavailability for treatment if randomly assigned to the MPT group (10%). The remaining 104 patients met the inclusion criteria, provided informed consent, and were randomly assigned. Six patients in the MPT group were randomly assigned but never received any treatment and were not included in the analysis. Comorbid conditions, mean body mass index, and reported fear avoidance beliefs were the same in both groups (**Table 1**). Twice as many patients disclosed that they smoked tobacco in the MPT group than in the CSI group. All other baseline variables were similar in each group.

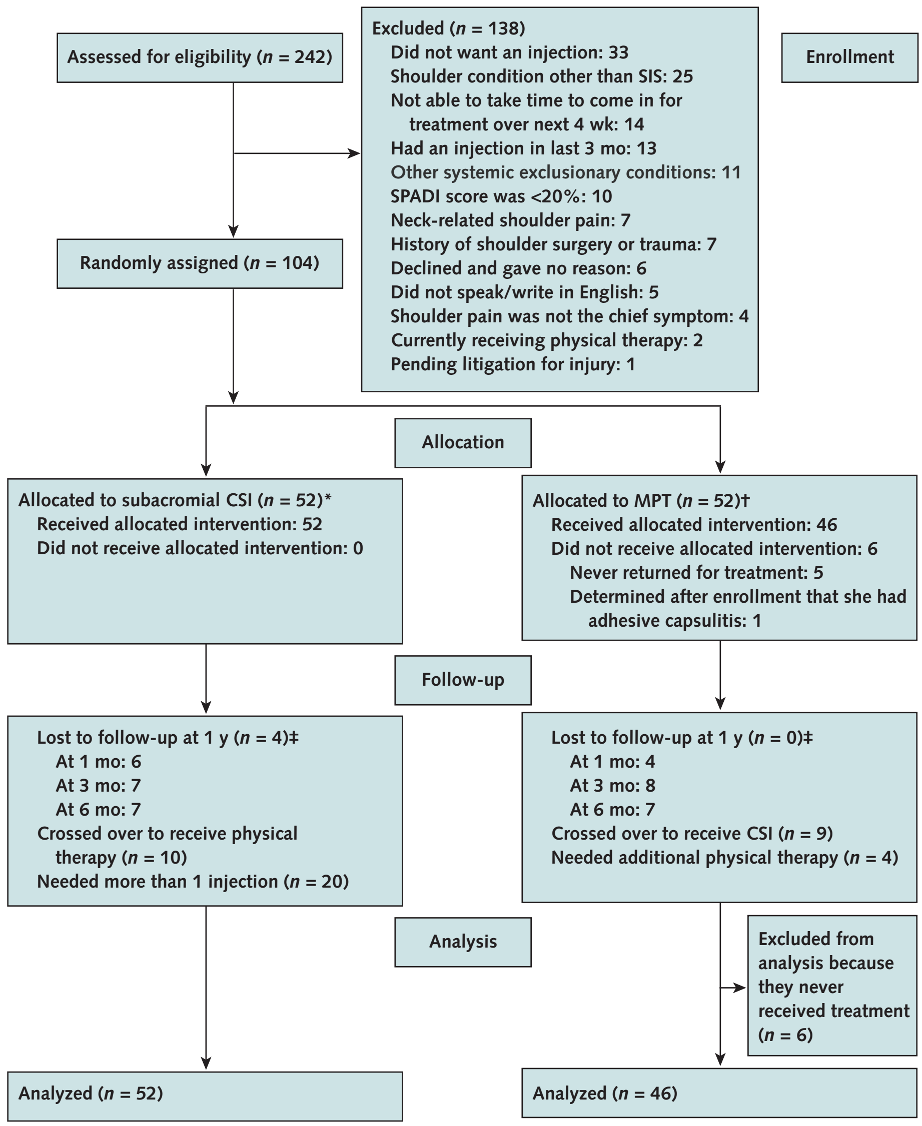
Treatment Implementation

All patients in the CSI group received at least 1 injection as required by the study protocol; 20 patients (38%) had more than 1 injection. All but 6 patients in the MPT group received the 6 physical therapy treatments according to the protocol; overall, the MPT group received a median of 5.5 PT treatments (minimum, 1; maximum, 6).

1-Year Outcomes

Most patients (96%) returned for follow-up visits at 1 year. Although an improvement greater than 50% was seen in the SPADI from baseline to 1 year in each group (**Figure 2**), neither treatment was superior (between-group difference at 1 year, 1.5% [95% CI, −6.3% to 9.4%]). Self-perceived improvement on the GRC was 3 points [CI, 2 to 4]), and self-reported pain (NPRS) improved at 1 year (mean change, 0.8 for CSI and 1.7 for MPT), but neither

Figure 1. **Study flow diagram.**



CSI = corticosteroid injection; MPT = manual physical therapy; SIS = shoulder impingement syndrome; SPADI = Shoulder Pain and Disability Index.
* 1 clinician performed the subacromial CSI.
† 2 clinicians performed MPT.
‡ Loss to follow-up was reported independently for each time point. It is possible that a patient missed 1 time point but then was followed up at a different time point. The primary outcome was measured at 1-y follow-up.

group was superior (between-group difference in change from baseline to 1 year: GRC, 0 [CI, −2 to 1]; NPRS, 0.4 [CI, −0.5 to 1.2]). The differences at each time point are shown in **Table 2**. We performed a sensitivity analysis with imputation for missing data (43) and the results remained unchanged. Other than transient pain from the CSI, there were no other adverse events reported by patients in either group.

Health Care Use

Shoulder-related health care use is detailed in **Figure 3**. Patients in the MPT group made fewer visits to their PCP for shoulder pain—37% of patients in the MPT group versus 60% in the CSI group had at least 1 additional visit (risk ratio, 0.64 [CI, 0.43 to 0.95]). The MPT group also had fewer additional CSIs than the CSI group; 20% compared with 38% had at least 1 additional injection (risk ratio, 0.77 [CI, 0.59 to 0.99]). Out of the patients who had additional injections, 4 in the CSI group had 4 total injections each (including some from providers outside of this study), and 1 from both the MPT and CSI group had 3 total injections each. In addition, 10 patients (19%) in the CSI group and 4 patients (9%) in the MPT group received physical therapy after the planned study intervention period.

DISCUSSION

Regardless of treatment, patients in our study had significant improvement from baseline to 1 month (>50% mean change), and that improvement was sustained for 1 year. Most studies that assessed CSI for shoulder disorders have only reported short-term results (4 to 12 weeks) (26, 45–49). We found only 1 trial that followed patients to 12 months, reporting no difference between CSI and acupuncture plus home exercises (50). One observational study without a control followed patients receiving CSI for 1 year and reported a satisfaction rate of 88% (51). Gaojoux-Viala and colleagues (7) conducted a meta-analysis on the safety and efficacy of steroid injections for the shoulder. In the short term (8 weeks), effect sizes reached 1.3, but after 12 weeks, the effects were no longer significant, and no study collected outcomes at 1 year.

The long-term effectiveness of CSI has been questioned, as well as the potentially deleterious effects of repetitive CSIs (7–9, 12). For example, physical therapy, CSI, "wait and see," and placebo injection have been compared in patients with lateral epicondylalgia (52, 53). Although CSI was effective in the short term, those patients had worse outcomes than the "wait and see" or placebo groups at 1 year. We did not see these results in the current study, and the question about side effects and safety of CSI still remains. Furthermore, symptom improvement may not necessarily reflect decreased progression of the disease. Ramirez and colleagues (54) found a 17% incidence of full-thickness rotator cuff tears after CSI (66% had a previous partial-thickness tear), even though patients reported a decrease in pain. Future work is needed to understand the effect of both interventions on disease progression.

The long-term improvements with MPT are consistent with previous reports (13, 14). However, the CSI group also had similar improvements. We found 1 study with a 1-year follow-up that compared CSI with 10 sessions of acupuncture, both combined with a home exercise protocol (50). Both groups showed improvement, but there were no between-group differences. However, this study used a different outcome measure, limiting direct comparisons with our results. Another study compared CSI with a community-based physiotherapy program and also showed improvement in both groups at 6 months but no between-group differences (55).

The CSI group used more health care throughout the 1-year follow-up than the MPT group. More than one third of the CSI group (38%) received more than one injection, whereas 20% of the MPT group also had a CSI after their original treatment. Although the MPT group was not offered maintenance MPT after the planned intervention, 4 patients sought additional physical therapy. Ten patients in the CSI group also sought physical therapy. This additional care received by the CSI group throughout the 1-year follow-up may have led to their reporting improved pain and function.

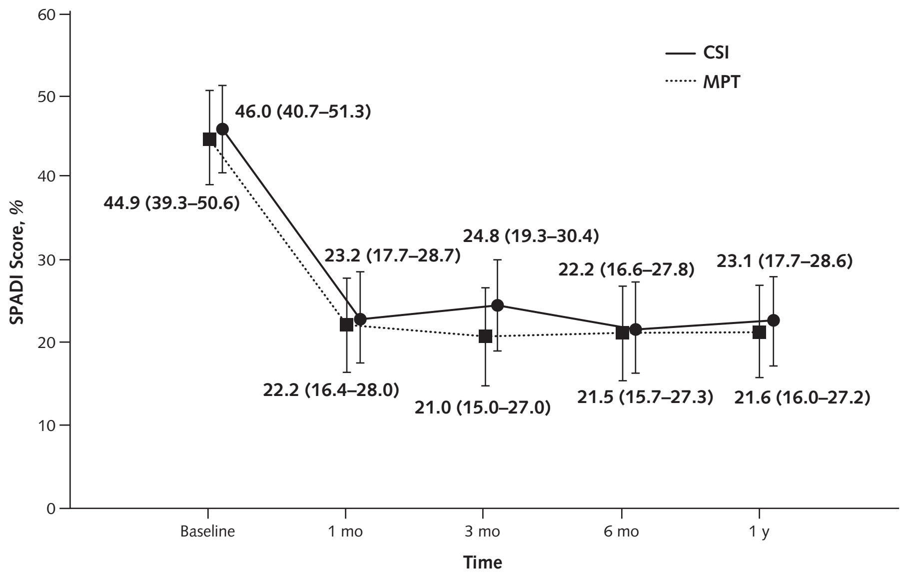
Other factors can affect the prognosis of shoulder conditions, including psychosocial risk (56–58). Fear avoidance beliefs were originally described by Lethem and colleagues (59) as a model for how patients develop chronic pain by implementing coping strategies that avoid activity or exercise. The Fear Avoidance Beliefs Questionnaire is a standard measure taken in our physical therapy clinic, and both groups had similar scores. Shoulder pain severity has also been associated with sleep quality (60, 61) and obesity (62). Both groups reported similar effects of pain on sleep quality. Although overall the patients in this study were overweight (mean body mass index >25.0 kg/m^2) (63), body mass index did not differ between groups. Tobacco use may be associated with a greater prevalence of shoulder pain (62), and the MPT group reported more tobacco use than the CSI group. The CSI group had more than twice

Table 1. **Characteristics of Patients With the Shoulder Impingement Syndrome***

Characteristic	Patients Receiving CSI (n = 52)	Patients Receiving MPT (n = 46)
Mean age (SD), *y*	42 (12)	40 (12)
Male sex	38 (73)	29 (63)
Mean BMI (SD), *kg/m²*	28.65 (4.72)	28.34 (4.24)
Mean duration of symptoms (SD), *mo*	6.5 (13.9)	4.9 (4.4)
Comorbid conditions	16 (31)	22 (48)
Mental health conditions	6 (12)	11 (24)
Hypertension	10 (19)	10 (22)
Type 2 diabetes mellitus	1 (2)	2 (4)
Other cardiovascular (e.g., angina and history of MI)	3 (6)	3 (7)
Obesity	–	1 (2)
Beneficiary category		
Active-duty service member	28 (54)	24 (52)
National Guard or reservist	2 (4)	6 (13)
Family member/dependent	8 (15)	10 (22)
Retired service member	14 (27)	6 (13)
Currently smoking tobacco	6 (12)	11 (24)
Right-hand dominance	45 (87)	39 (85)
Shoulder pain on same side as hand dominance	27 (52)	26 (57)
Percentage of work/daily activities that require overhead movement		
75%–100%	1 (2)	2 (4)
50%	7 (13)	8 (17)
1%–25%	31 (60)	24 (52)
0%	11 (21)	10 (22)
How shoulder pain affects sleep		
Not at all	3 (6)	4 (9)
Some, but still able to sleep	40 (77)	38 (83)
Cannot sleep due to pain	8 (15)	4 (9)
Mean baseline FABQ score (SD)		
Work subscale	12 (10)	12 (10)
Physical activity subscale	15 (4)	15 (5)

BMI = body mass index; CSI = corticosteroid injection; FABQ = Fear Avoidance Beliefs Questionnaire; MI = myocardial infarction; MPT = manual physical therapy.
* Values are numbers (percentages) unless otherwise indicated.

Figure 2. **Comparative effectiveness measured by changes in SPADI scores over time.**



Mean effect estimates (95% CIs) from observed data. Overlapping error bars indicate that no significant difference was found between groups at any time point. CSI = corticosteroid injection; MPT = manual physical therapy; SPADI = Shoulder Pain and Disability Index.

the number of retired military personnel than did the MPT group. However, after 20 years of military service, retirement can occur as early as age 38 years. As a result, a patient on active duty may actually be older than a retired one. However, we do not believe that this was a considerable issue because the mean age between both groups was almost identical.

Although CSI is relatively safe, adverse effects of transient pain (10.7%) and changes in skin pigmentation (4%) are most commonly reported (7), and progression to full-

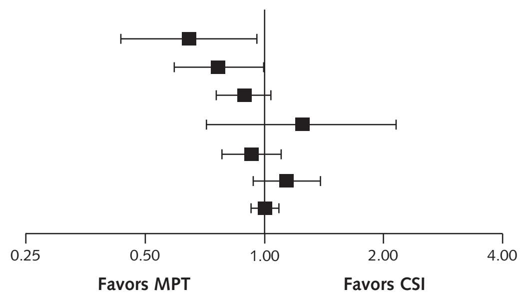
Table 2. **Outcome Measures at All Time Points***

Outcome Variable	Mean Measure (95% CI)			*P* Value Mean Difference
	CSI	MPT	Difference	
SPADI score (0 to 100), %				
Baseline	46.0 (40.7 to 51.3)	44.9 (39.3 to 50.6)	1.0 (6.7 to 8.8)	0.79
1 mo	23.2 (17.7 to 28.7)†‡	22.2 (16.4 to 28.0)†‡	1.0 (7.0 to 9.0)	0.81
3 mo	24.8 (19.3 to 30.4)†‡	21.0 (15.0 to 27.0)†‡	3.8 (−4.3 to 12.0)	0.36
6 mo	22.2 (16.6 to 27.8)†‡	21.5 (15.7 to 27.3)†‡	0.7 (7.3 to 8.7)	0.86
1 y	23.1 (17.7 to 28.6)†‡	21.6 (16.0 to 27.2)†‡	1.5 (−6.3 to 9.4)	0.70
GRC score (−7 to +7)				
1 mo	3 (2 to 5)‡	3 (2 to 5)‡	0 (−2 to 2)	0.99
3 mo	3 (2 to 4)‡	4 (3 to 5)‡	1 (−2 to 1)	0.32
6 mo	3 (2 to 4)‡	3 (1 to 4)‡	1 (−1 to 2)	0.32
1 y	3 (2 to 4)‡	3 (2 to 4)‡	0 (−2 to 1)	0.53
NPRS score (0 to 10)				
Baseline	3.3 (2.7 to 3.9)	3.8 (3.2 to 4.5)	0.5 (1.4 to 0.4)	0.26
1 mo	1.7 (1.1 to 2.4)†	1.6 (1.0 to 2.3)†	0.1 (−0.8 to 1.0)	0.80
3 mo	2.6 (2.0 to 3.2)†	1.8 (1.1 to 2.5)†	0.8 (−0.1 to 1.8)	0.077
6 mo	2.2 (1.6 to 2.8)†	1.7 (1.1 to 2.4)†	0.5 (−0.4 to 1.4)	0.29
1 y	2.5 (1.9 to 3.1)†	2.1 (1.5 to 2.8)†	0.4 (−0.5 to 1.2)	0.42

CSI = corticosteroid injection; GRC = Global Rating of Change; MPT = manual physical therapy; NPRS = Numeric Pain Rating Scale; SPADI = Shoulder Pain and Disability Index.
* Report based on observed data. The numbers of patients at each follow-up visit were as follows: 1 mo = 88; 3 mo = 83; 6 mo = 84; 1 y = 94.
† Significant improvement from baseline ($P < 0.05$).
‡ Meets established minimally clinically important improvement from baseline (≥12 points for SPADI; ≥3 points for GRC).

Figure 3. **Relative risk for using additional health care resources.**

	Participants, *n (%)*		Risk Ratio (95% CI)
	CSI	MPT	
All patients	52	46	
PCP visits after initial care	31 (60)	17 (37)	0.64 (0.43–0.95)*
Needed any additional CSI	20 (38)	9 (20)	0.76 (0.59–0.99)*
Additional PT visits	10 (19)	4 (9)	0.86 (0.75–1.04)
Orthopedic surgeon visits	8 (15)	10 (22)	1.24 (0.71–2.15)
Plain radiography	10 (19)	6 (13)	0.93 (0.78–1.11)
MRI	7 (13)	11 (24)	1.14 (0.94–1.38)
Surgery	2 (4)	2 (4)	1.01 (0.93–1.09)



CSI = corticosteroid injection; MPT = manual physical therapy; MRI = magnetic resonance imaging; PCP = primary care provider; PT = physical therapy.
* Significantly favors MPT.

thickness rotator cuff tear after CSI is possible (54). We could not find any reports of adverse effects of MPT in this patient population. Considering that aversion to an injection was the main reason that patients chose not to participate in the study, MPT may serve as an effective low-risk alternative.

Our study has limitations. Patients and clinicians were not blinded to the intervention. It also was limited to patients who were referred to physical therapy, so our sample may not be representative of all patients who present to primary care for SIS management. Some patients referred to physical therapy had already tried other interventions without success (average symptom duration, 5 to 6 months). Others may have elected physical therapy specifically because they did not want an injection, which was the primary reason that persons declined participation (24%).

Another limitation is the lack of standardized diagnostic criteria for SIS. We used criteria from previous studies (13, 15) in an attempt to identify a homogeneous subset of patients with similar impairments and functional limitations. Use of imaging criteria in isolation, especially magnetic resonance imaging, is potentially problematic because greater than 50% of the asymptomatic population can have abnormal findings (64–68). We also included only participants with a negative lag sign, decreasing the likelihood of enrolling someone with a full-thickness rotator cuff tear (negative likelihood ratio, 0.02) (69, 70). Although CSI or MPT may benefit patients with full-thickness rotator cuff tears (54, 71), we chose to include a more homogeneous group of patients and opted to exclude patients with those findings. A recent Cochrane review suggested that screening for larger rotator cuff tears is important because it may change the plan of care (72). We do not believe that this was a problem because all but 2 patients in the CSI group had a reduction in pain symptoms by at least 50% immediately after receiving an injection. Pain reduction after CSI has been used to confirm SIS diagnosis (73–75).

It is possible that patients received care outside the military health system; however, the PCP managing each of these patients was within the military health system and coordinated all care. It is unlikely that ongoing care for an established condition would transition outside the military health system. In these cases, patients would have likely paid the cost of care. We also asked each patient about additional care at each follow-up visit.

Future work should compare MPT and CSI in persons with new symptoms of shoulder impingement based on their initial presentation at the primary care level. Additional research is needed to better understand the optimal timing and long-term costs associated with each treatment pathway.

Manual physical therapy and CSI produced similar outcomes in the treatment of patients with SIS. However, patients receiving CSI had more shoulder-related health care use through 1 year. A better understanding of how to effectively integrate these 2 management strategies or the optimal timing of use may help better establish standardized best practice guidelines.

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Reproducible Research Statement: *Study protocol:* Published and available (29). *Statistical code:* Available from Dr. Rhon (daniel.i.rhon.mil@mail.mil). *Data set:* Available after execution of a Cooperative Research and Development Agreement and Data Use Agreement with the appropriate Department of Defense regulatory agencies. Contact Dr. Rhon (daniel.i.rhon.mil@mail.mil) if interested.

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Administrative, technical, or logistic support: D.I. Rhon, R.B. Boyles.
Collection and assembly of data: D.I. Rhon, R.B. Boyles.

Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after Discharge from Physical Rehabilitation

Development of predictive models based on physical and performance measures for musculoskeletal injuries.

PI: MAJ Daniel Rhon, PT, DPT, DSc **Org:** Madigan Army Medical Center

DMRDP

Problem, Hypothesis and Military Relevance

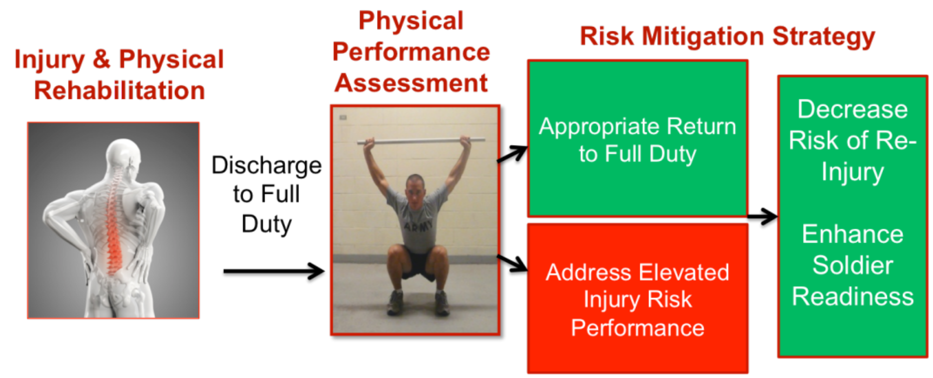
Problem: Musculoskeletal injuries are the largest cause of disability in the military, and adversely affect military readiness.

Hypothesis: Performance on a battery of functional screening tests will predict the risk of sustaining an injury during the following year.

Rationale: Prior injury is a well-known risk factor for future injury, and all service members (SM) discharged back to full duty after an injury are already at high risk for re-injury. There is no physical performance threshold that provides guidance as to when a SM is ready to return to full duty, and at decreased risk for re-injury.

Military Relevance: Predictive models for re-injury are highly needed in the military, where 40% and 23% of all medical evacuations out of combat theater are for lower extremity and spine (lumbar/thoracic) injuries respectively.

Injury Prevention, Physiological and Environmental Health Award (IPPEHA)
Funding Opportunity Number: W81XWH-13-MOMJPC5-IPPEHA



Proposed Solution

Objective: Determine if physical performance can predict risk for re-injury after returning back to full duty

Aims:

1. Compare physical performance between injured and non-injured at 1-year post discharge from Physical Rehabilitation.
2. Develop predictive models from collected variables to derive a multi-factorial 1-year risk prediction algorithm.
3. Develop an optimal physical a performance standard that should be met prior to discharge from physical rehabilitation that is associated with decreased future 1-year injury.

Anticipated Outcomes: At the completion of this study, we will have developed a risk prediction algorithm for service members returned to full duty after an injury, and an optimal performance measure threshold that should be met in order to decrease future risk of injury

Timeline and Cost

Activities FY	14	15	16	17
IRB Approval, hiring and training of support personnel				
Subject enrollment and data collection and 1-year follow-up.				
Healthcare utilization pull from DoD database & medical records				
Data analysis, interpretation, prediction model derivation, and reporting of results				
Estimated Budget ($K)	$432K	$382K	$249K	$75K

Comparison of Performance between Rangers, Combat, Combat Service, and Combat Service Support Soldiers

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Purpose: Emerging evidence indicates that performance on fitness and movement tests can identify athletes at risk for injury. The purpose of this study was to establish normative data and compare performance between Soldiers based on military unit type: Rangers, Combat, Combat Service, and Combat Service Support. It was hypothesized that Soldiers in Rangers and Combat units would outperform Soldiers in Combat Service or Combat Service Support units.

Methods: Service members actively participating in military and fitness training were recruited as part of a larger trial. Participants (n = 1,466) were active duty Soldiers (1.8 ± 0.1m, 82.4 ± 12.4kg, 26.7 ± 3.4kg/m^2, 24.7 ± 5.0 years) at Joint Base Lewis-McChord, WA. The sample included 207 Rangers, 624 Combat, 298 Combat Service, and 301 Combat Service Support Soldiers. Participants completed the following tests: closed chain ankle dorsiflexion (DF), Functional Movement Screen (FMS), Y-Balance Test Lower Quarter (YBT-LQ), Y-Balance Test Upper Quarter (YBT-UQ), triple hop, and Army Physical Fitness Test (APFT; push-ups, sit-ups, and 2-mile run). Analysis of Variance (ANOVA, $p < 0.05$) was performed to compare the results based on military unit type (Rangers, Combat, Combat Service, and Combat Service Support). Data were collected electronically using handheld devices and were synchronized with a server computer. Data were collected in a single session lasting approximately 90 minutes.

Results: Normative data for Soldier performance included 36.2 ± 7.8° DF, 14.4 ± 2.7 FMS score, 96.9 ± 8.9% limb length for YBT-LQ, 88.3 ± 9.7% limb length for YBT-UQ, 449.8 ± 88.0 cm for triple hop, 67.0 ± 14.8 push-ups, 71.4 ± 12.2 sit-ups, and 868.8 ± 121.2 seconds for 2-mile run. Rangers performed better than all other unit types on all performance and fitness measures ($p<0.05$). Combat Soldiers performed better than Combat Service and Service Support Soldiers on FMS, YBT-LQ, and APFT ($p<0.05$). Performance was equivalent between Combat Service and Service Support Soldiers performance on DF, FMS, YBT-LQ, and APFT ($p<0.05$).

Conclusions: As hypothesized, Soldiers in Ranger units performed better than those in other units. The impact of musculoskeletal injury on unit readiness, retention, and disability is well documented and plagues the military in a garrison and deployed environment. A better understanding of unit-specific normative data for tests associated with physical performance and injury risk provides a foundation for future injury prediction and prevention strategies.