Reliability of Hallux Rigidus Radiographic Grading System

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Abstract

Introduction. The purpose of this study was to determine the inter- and intra-observer reliability of a clinical radiographic scale for hallux rigidus.

Methods. A total of 80 patients were retrospectively selected from the patient population of two foot and ankle orthopaedic surgeons. Each corresponding series of radiographic images (weight-bearing anteroposterior, weight-bearing lateral, and oblique of the foot) was randomized and evaluated. Re-randomization was performed and the corresponding radiograph images re-numbered. Four orthopaedic foot and ankle surgeons graded each patient, and each rater reclassified the re-randomized radiographic images three weeks later.

Results. Sixty-one out of 80 patients (76%) were included in this study. For intra-observer reliability, most of the raters showed "excellent" agreement except one rater had a "substantial" agreement. For inter-observer reliability, only 14 out of 61 cases (23%) showed total agreement between the eight readings from the four surgeons, and 11 out of the 14 cases (79%) were grade 3 hallux rigidus. One of the raters had a tendency to grade at a higher grade resulting in poorer agreement. If this rater was excluded, the results demonstrated a "substantial" agreement by using this classification.

Conclusion. The hallux rigidus radiographic grading system should be used with caution. Although there is an "excellent" level of intra-observer agreement, there is only "moderate" to "substantial" level of inter-observer reliability.

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Introduction

Osteoarthrosis of the first metatarsophalangeal (MTP) joint of the foot may cause significant pain, disability, and difficulty wearing footwear. The term, hallux rigidus, is used to describe a condition commonly associated with degenerative arthritis of the first MTP joint with osteophyte formation, which results in a painful joint with reduction in the range of motion, especially dorsiflexion.[1-3] Hallux rigidus is a progressive condition, and may present in early or late stages with varying degrees of stiffness and osteophytic thickening of the joint. Chronic MTP joint inflammation leads to capsular distention and eventually to a loss of capsular and collateral ligament integrity.

Throughout the literature discussing foot and ankle disabilities, there have been multiple classification methods for hallux rigidus that have involved clinical findings,[4] radiographic findings,[5-9] or a combination of both.[10-14] The role of these classification systems is to help a physician to choose an appropriate method of treatment as well as to provide a reasonably precise estimation of the outcome of that treatment.[3,5,8,10,14-16] Some researchers have used these classification systems to compare the results of different studies and treatment procedures.[6,7,9,11-13,17-26]

For these classification systems to be useful, the classification system must produce the same desired results time after time in the hands of any physician or researcher who attempts to use it. Reliable

testing is critical to the orthopaedic literature, including hand conditions,[27-29] radiograph measurements,[30-33] Legg-Calve-Perthes disease grading,[34-35] joint arthroplasty loosening,[36] and fracture classifications.[37-48] Beeson et al.[26] performed an exhaustive literature review on hallux rigidus classification systems, and found a total of 18 different classification systems without any studies to determine the reliability of the systems. Clinical radiographic grading system is the fundamental assessment tool to classify the severity of hallux rigidus among all the different classification systems.[5-14] Giannini et al.[5] and Coughlin et al.[10] presented a reasonable summary of the various radiographic grading systems. To our knowledge, there has not been a study that specifically addressed the reliability of radiographic grading for hallux rigidus. The purpose of this study was to determine the inter- and intra-observer reliability of a clinical radiographic scale for hallux rigidus.

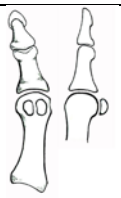
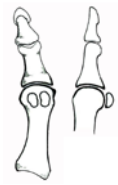
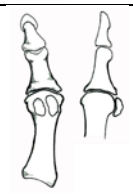
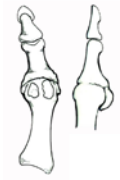
Methods

Participants. A total of 80 patients were selected retrospectively from the patient population of two orthopaedic surgeons, who specialized in foot and ankle surgery, in a mid-western city. The study sample was selected based on three radiographs (weight bearing anterior-posterior (AP), oblique, and lateral) of the patients who were diagnosed with hallux rigidus. Poor quality or inadequate radiographs, or evidence of prior surgery were exclusions in this study. Patients with inter-metatarsal angles of greater than 15 degrees (normal is 9 degrees) or hallux valgus angles greater than 20 degree (normal is 15 degrees) also were excluded.

Instruments and Procedures. This study was approved by the Human Subjects Committees as minimal risk and with a waiver of consent and waiver of HIPAA authorization. Three different hard copy radiograph images that had been used for clinical decision-making for each selected patient were obtained. Radiograph images included views of the hallux from the weight-bearing AP, weight-bearing lateral, and oblique radiographs. These radiographs were de-identified of any patient information, and were enhanced and converted to black and white using Kodak EasyShare software (Version 8.2, Kodak, Rockester, NY). Each corresponding series of radiographic images (weight-bearing AP, weight-bearing lateral, and oblique) was randomized, given a number, and recorded on a CD-ROM disk of images.

The inter- and intra-observer reliability for classifying the hallux rigidus involved adjustment of the proportion of agreement among observers with a correction for the proportion of expected agreement by chance. To evaluate inter-observer variability, four attending orthopaedic surgeons whom were trained in foot and ankle surgery were asked to classify the group of radiographic images independently according to the Giannini-modified Coughlin and Shurnas' classification systems (Table 1). Each attending orthopaedic surgeon was given a packet which contained descriptions and diagrams of Giannini's modification of Coughlin and Shurnas' grading system,[5] a score sheet, a CD-ROM disk of radiographic images, and a return mail envelope. To evaluate intra-observer reliability, two rounds of scoring were conducted for each rater with re-randomization of the radiographic images three weeks later and re-numbering between each round.

Table 1. Grading System for Hallux Rigidus[5] (JBJS License Number: 2002840476064).

Grade		**Radiographic Findings**
Grade 0		Normal
Grade 1		Dorsal osteophyte is main finding, minimal joint space narrowing, minimal periarticular sclerosis, minimal flattening of the metatarsal heads with a lateral spur
Grade 2		Dorsal, lateral, and possibly medial osteophytes with a flattened appearance of the metatarsal head, no more than ¼ of dorsal joint space involved on the lateral radiograph, and mild to moderate joint space narrowing and sclerosis, sesamoids usually not involved
Grade 3		Substantial joint space narrowing, periarticular cystic changes, more than ¼ of dorsal joint space involved, sesamoids are enlarged, cystic, and/or irregular

Statistics. The inter- and intra-observer reliability for classifying the hallux rigidus was calculated with the use of weighted Kappa coefficients by using the SPSS software (Version 16.0; SPSS Inc., Chicago, IL). According to guidelines described by Landis and Koch,[49] a value of $\leq$ 0.2 indicates "poor" or "slight" agreement, 0.21 to 0.40 is "fair" agreement, 0.41 to 0.6 is "moderate" agreement, 0.61 to 0.8 is "substantial" agreement, and > 0.80 is "excellent" agreement. In addition, the percentage of patients where all four examiners agreed on the grade was determined.

Results

Of the 80 patients diagnosed with hallux rigidus from the two foot and ankle surgeons' patient populations, 61 patients (76%) met the required criteria and were included in this study. For intra-observer reliability, most of the attending surgeons showed "excellent" agreement by using the Giannini-modified Coughlin and Shurnas' classification systems to grade the hallux rigidus of the foot (mean weighted Kappa coefficient: 0.82 ± 0.07; range: 0.72 - 0.88; Table 2). These results implied that each rater agreed well with themselves when reading the same radiographs at different time points. Only one of the raters had a "substantial" agreement (weighted Kappa coefficient of 0.72).

Table 2. Intra- and inter-observer reliability.

		Rater 1	**Rater 2**		**Rater 3**		**Rater 4**	
		Reading 2	**Reading 1**	**Reading 2**	**Reading 1**	**Reading 2**	**Reading 1**	**Reading 2**
Rater 1	Reading 1	High*	High	Substantial	Substantial	High	Moderate	Moderate
	Reading 2		Substantial	Substantial	Substantial	High	Moderate	Moderate
Rater 2	Reading 1			High*	Substantial	Substantial	Moderate	Moderate
	Reading 2				Substantial	Substantial	Moderate	Moderate
Rater 3	Reading 1					High*	Moderate	Moderate
	Reading 2						Moderate	Moderate
Rater 4	Reading 1							Substantial*

*Represents intra-observer reliability

For inter-observer reliability, only 14 out of the 61 cases (23%) showed total agreement between the eight readings from the four surgeons, and 11 out of the 14 cases (79%) were grade 3 hallux rigidus. Figures 1 and 2 illustrate "excellent" agreement cases for Grade 2 and Grade 3 hallux rigidus, respectively. Most of the cases showed "excellent" agreement within one grade difference (53 out of 61, 87%) and the mean weighted Kappa was 0.64 ± 0.13 (range: 0.44 -0.83). Figure 3 shows an example of poor agreement. One of the raters had a tendency to grade the hallux rigidus radiographs at a higher grade than the other three raters, resulting in poorer agreement. If this rater was excluded, the results show a "substantial" agreement by using this classification to grade the hallux rigidus of the foot (mean weighted Kappa coefficient: 0.76 ± 0.06; range: 0.68 - 0.83).

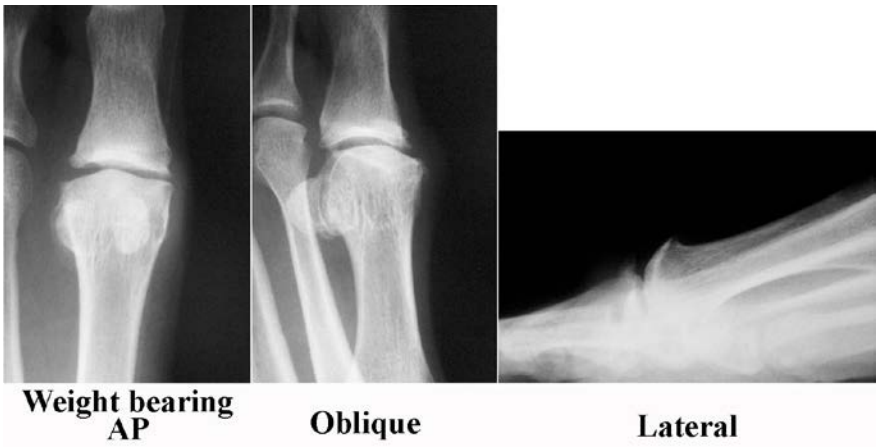


Figure 1. Radiographs demonstrating good agreement case for Grade 2 hallux rigidus.

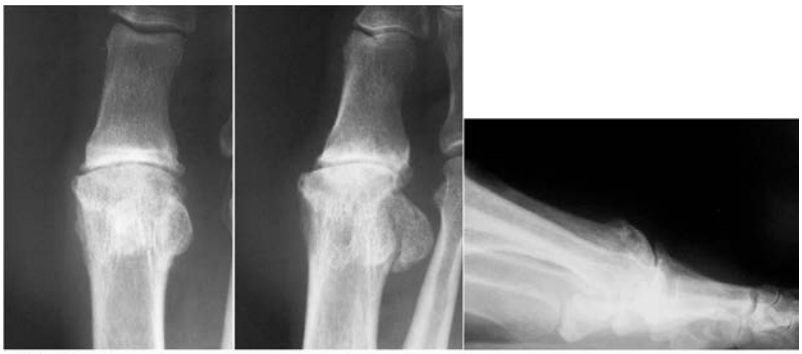


Figure 2. Radiographs demonstrating good agreement case for Grade 3 hallux rigidus.

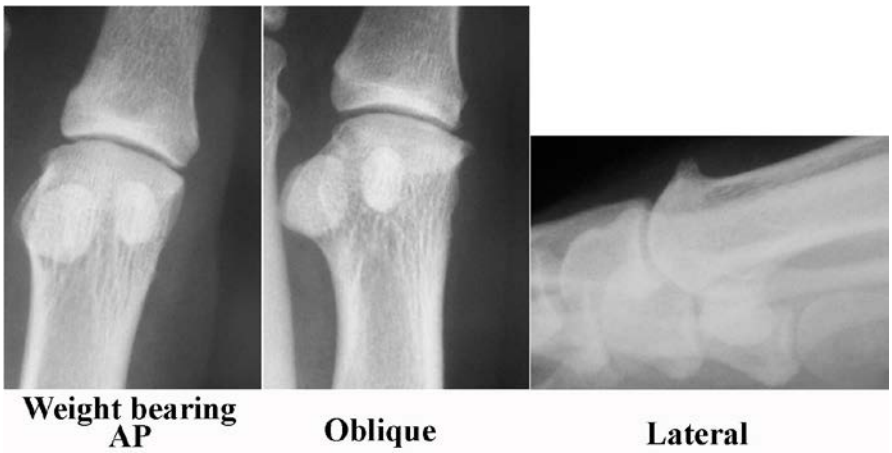


Figure 3. Radiographs demonstrating poor agreement case for hallux rigidus.

Discussion

Hallux rigidus is a common form of osteoarthrosis in the foot.[50] Radiographic examination, including weight-bearing AP and lateral radiographs, usually finds asymmetric joint narrowing and a flattened metatarsal head. The lateral radiographs usually are the most revealing. With advancement of the disease, more of the joint surface is involved. Subchondral cysts, sclerosis, and bony proliferation at the joint margins occur and the joint narrowing progresses.[19,31,51] With the use of the radiographic grading system, orthopaedic surgeons should be able to provide optimum care to patients who have these common acquired disorders of the foot. The Giannini-modified Coughlin and Shurnas' classification system, like all other classification systems, is intended to aid clinical decision-making for treatment as well as to provide a reasonably precise estimation of the treatment outcome for hallux rigidus. There are many other hallux rigidus classification systems which are very similar to each other. This study used the Giannini-modified Coughlin and Shurnas' classification system because it is widely referred in studies. However, this classification system relies on radiographic findings, regardless of subjective and clinical findings. To be useful, a classification should have at least moderate rater consistency. The results of this study indicated that this particular grading system should be used with caution, as only 75%

reach "excellent" agreement for intra-observer reliability, and "moderate" to "substantial" agreement for the inter-observer reliability. The practical utility of having a system with only high intra-observer reliability is questionable, and it likely would not provide any help with communications between physicians or researchers regarding the population in their studies.

A major point of concern with a radiograph-only system for hallux rigidus was that radiographs are only a part of the evaluation of a patient with hallux rigidus. Coughlin et al.[10] addressed this concern and included a fourth category for patients with pain in the midrange of motion (a clinical finding) and grade 3 radiographic changes. An ideal study with this subject would have both a radiographic and a clinical exam component which would reproduce the clinician's experience treating this disorder more closely. The logistics of such a study likely would be difficult.

To achieve optimal results, surgical treatment should be individualized with use of different surgical techniques depending upon the degree of arthritis and other clinical considerations. Non-operative treatment, including modifications of shoe wear, use of a shoe insert, and use of anti-inflammatory medication, should be discussed in detail with the patient in accordance to the degree of symptoms.[10,52] If non-operative measures fail, operative intervention, such as arthrodesis, arthroplasty, cheilectomy, proximal phalanx osteotomy, dorsal closing wedge osteotomy, waterman green, Youngswick, Reverdin green, distal oblique sliding osteotomy, sagittal Z osteotomy, and Drago may be indicated.[53] Cheilectomy, which essentially consists of a debridement arthroplasty of the joint, may be appropriate.[54,55] Once more extensive involvement has occurred, arthrodesis is preferred for younger patients whereas resection arthroplasty may be more appropriate for elderly patients who have a less active lifestyle.[56] Taranow et al[57] recently presented a different classification system and surgical algorithm for treatment of the varied manifestations of hallux rigidus. This classification includes radiographic findings, motion restriction, and location of pain to guide appropriate surgical choices better. They also recommended procedures to preserve motion, when present, and address the significance of mid-motion and sesamoid pain.

In this study, there were several limitations. First, this was a pilot study that addresses an area where further research is needed. The sample size was relatively small and patients were only drawn from practices of two local foot and ankle surgeons. As such, only four raters were included in the study and bias of an outlier potentially could affect the inter-observer reliability substantially. Furthermore, each rater only evaluated the hallux rigidus radiographs on two occasions.

This study was limited due to the presence of fewer "normal" radiographs rather than "abnormal" radiographs. This also was a retrospective study evaluating a single radiographic classification system. Further research should include a larger sample size, multiple foot and ankle surgeons, and patients should be followed prospectively to assess the validity of the classification system treatment outcome and establish guidelines that would allow orthopedists to allocate their treatment more efficiently.

Conclusion

This study was the first to evaluate the reliability of any hallux rigidus radiographic grading system. Overall, this hallux rigidus radiographic grading system should be used with caution as the results showed that even

though there is an “excellent” level of intra-observer agreement, but there is only “moderate” to “substantial” level of inter-observer reliability. As is common in many orthopaedic grading systems, the overall reliability of this grading system was not “excellent”, thus they may cause confusion with communication in the literature regarding the treatment of hallux rigidus. Further studies are encouraged and needed to support the conclusion of this study.

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A Survey Assessing Kansas Physician Assistants' Attitudes/Beliefs and Current Practices Regarding Implementation of Fall Prevention Strategies in Older Adults

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Abstract

Background. Falls are the leading cause of injury death, nursing home placement, and hospital trauma admissions in older adults. Although guidelines to reduce falls have been available for over a decade, routine implementation by healthcare providers is less than optimal. The purpose of this study was to evaluate the attitudes/beliefs and current practices of Kansas physician assistants (PAs) regarding fall assessment/prevention strategies in older adults and barriers to implementing strategies into daily practice.

Methods. A 67-item survey was mailed to all 760 Kansas PAs in 2009; 152 responded. Logistic regressions were performed on current fall prevention practices (exercise, home safety, medications, and vision) to determine attitudes, beliefs, and barriers associated with implementation.

Results. Most PAs believe falls are preventable (87%) and implementation of various prevention strategies are their professional responsibility (88% - 96%); yet, less than 50% routinely implement them. Barriers included lack of time (27%), lack of staff (26%), and feeling ill-prepared (18%). Multiple logistic regressions revealed correlations among implementing the medication review strategy and lack of time as well as practicing the exercise strategy and lack of time and awareness of local exercise programs.

Conclusions. PAs are aware of the importance of fall prevention, believe falls are preventable, and believe it is their professional responsibility to implement fall prevention strategies with their older adult patients. However, most do not implement strategies in their practice due to a variety of internal and logistical barriers. Fall prevention materials/tools that are practical, simple, inexpensive, and require little implementation time may overcome barriers.

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Introduction

Falls are the leading cause of injury death, traumatic brain injury, nursing home placement, and hospital trauma admissions in older adults (aged 65 years and older).[1,2] Of those that fall, 20% to 30% suffer moderate to severe injuries with impaired mobility and independence.[2] In 2011, approximately 2.4 million older adults were treated in emergency departments (EDs) for nonfatal fall-related injuries.[3] These injuries can include fractures, head traumas, joint dislocations, and soft tissue injuries. In 2013, the direct cost of unintentional falls in older adults (adjusted for inflation) was $34 billion. The average hospitalization cost for a fall injury is over $35,000.[3]

The Centers for Disease Control and Prevention (CDC), the National Council on Aging (NCOA), and the American Geriatrics Society (AGS) have identified key areas to reduce falls in older adults including: 1) increasing physical activity and balance/strength training, 2) evaluating and resolving home safety issues, 3) reviewing and resolving medication issues, and 4) screening and referral of vision problems.[1,4,5] Exercise programs and home safety interventions as well as multifactorial interventions targeting multiple fall risk strategies have demonstrated a reduction in the number of falls.[6]

Although guidelines have been available for over a decade, routine implementation by healthcare providers is less than optimal.[7,8] Barriers previously identified by physicians were divided into three distinct categories: 1) physician factors (e.g., awareness, competing risks, training), 2) logistic factors (e.g., transportation, time, reimbursement) and 3) physicians' perception of patient factors (e.g., reporting, attitudes towards medications, positive feedback).[8] It is essential to identify barriers to implementing evidence-based practices and determine the most effective method for incorporating those strategies in patient encounters to reduce fall risk.

Barriers and reasons for underutilization have not been well studied among Physician Assistants (PAs). PAs provide a significant amount of primary and emergency care across the nation. This is particularly true among rural and underserved communities similar to those found across much of Kansas where the percentage of older adults is on the rise. Therefore, understanding Kansas PAs' perceptions and practices regarding fall prevention is an important step in developing approaches to increase implementation nationwide. The purpose of this study was to evaluate the attitudes/beliefs and practices of PAs in Kansas regarding fall assessment and prevention in older adults and barriers to integrating currently recommended, evidence-based fall prevention strategies into daily practice to increase implementation.

Methods

Mailing addresses for all 760 certified Kansas PAs were obtained from the Kansas Board of Healing Arts. A 67-item survey was created to ascertain respondent characteristics, attitudes/beliefs, current practices, and barriers to implementing fall prevention strategies. Survey content was drafted based upon fall prevention consensus guidelines[1,4,5] and previously published data regarding barriers to implementation.[8] Eleven questions ascertained respondent characteristics. Thirty-five questions assessed attitudes/beliefs using a 4-point Likert scale ranging from "strongly agree" to "strongly disagree"; and eight questions assessed current practices as: "never", "sometimes", "frequently", and "always". Six commonly cited barriers were listed and respondents were asked to "check all that apply". Additionally, several open-ended questions were included and learner preferences were asked. Approval was obtained from all appropriate institutional review boards.

Statistical Analysis. Descriptive characteristics are reported as percentages and means, as appropriate. Binary logistic regressions were performed on current fall prevention practices (exercise, home safety, medications, and vision) as the criterion (dependent) variables. Variables found to be uncorrelated via multicollinearity diagnostics (VIF < 10) were entered into the logistic regression model.[9] Statistical significance was set at $p < 0.05$. Statistical analyses were performed using SPSS for Windows, Version 20.0.[10]

Results

The response rate was 20% (152/760). Demographics including education, primary practice setting, and population of primary practice setting are shown in Table 1. Fifty-one (51%) percent of responding PAs reported that the majority (50% or more) of their patients were 65 years or older.

Table 1. Demographics of responding Kansas PAs (n = 152).

	Mean	**SD**
Age	41.7	12.7
Years in Practice	11.3	9.5
	#	**Percent**
Female	100	66%
Education		
Bachelor	69	45%
Masters	73	48%
Doctorate	2	1%
Primary Practice		
Family Medicine	60	40%
Emergency Medicine	17	11%
Orthopedics	19	13%
Cardiology	13	9%
Internal Medicine	12	8%
Other[a]	27	18%
Population of Primary Practice Setting		
<10,000	37	24%
10,000-49,999, not near a metro area	13	9%
10,000-49,999, near a metro area	15	10%
50,000-99,999	12	8%
100,000-299,999	21	14%
>300,000	47	31%

Note: Percentages may not match total sample due to missing data; percentages may not total 100% due to rounding.

[a]Dermatology (2); geriatrics (1); obstetrics/gynecology (2); occupational (2); pediatrics (1); surgery (4); infectious disease (1); VA general medicine (1); ENT (1); oncology (1); pulmonary/critical care (2); trauma (2); urology (1); urgent care (1); residential rehabilitation (1); pain management (1); hematology (1).

Attitudes/Beliefs. Respondents agreed (agree or strongly agree) falls are a significant public health problem (99%) and most falls are preventable (87%). They believe falls are under-reported by older adults out of fear of losing independence (80%), fall prevention programs should be funded by the state (64%), and screening for fall risk should be as routine as screening for other medical problems such as cancer, high

cholesterol, and diabetes (93%). Table 2 shows attitudes/beliefs regarding the four fall prevention strategies: exercise, home safety, medications, and vision. The majority agreed these strategies are effective (95% - 99%). Respondents agreed they have a professional responsibility to implement them (88% - 96%) and are willing to implement them (85% - 93%). However, respondents' beliefs that patients would be compliant with their suggestions regarding these strategies were somewhat lower for exercise (47%), home safety (69%), and vision (84%) as compared to medications (90%). Twenty percent (20%) agreed (agree or strongly agree) with the statement, "I assume the pharmacy will notify me if I order a drug that potentially increases fall risk", and 82% agreed or strongly agreed with the statement, "I would appreciate being notified by the pharmacy if I order a drug that is known to potentially increase fall risk". In response to "As a learner, I prefer information from…", 97% marked agree or strongly agree when asked about continuing medical education programs, 88% for professional journals, 63% for internet resources, and 69% for consultations with specialists.

Current Implementation of Strategies. Despite the favorable attitude/beliefs and willingness to implement regarding these four fall prevention strategies, there was a significance gap in actual implementation rates (Table 2). Only 19% of respondents indicated they had received training/education regarding fall prevention in older adults. When asked if there was a balance/strength training exercise program for older adults in their area, 40% marked yes, 13% marked no, and 41% marked unsure.

Table 2. Kansas PAs' attitudes/beliefs and current practices regarding four key fall prevention strategies (n=152).

	Exercise	**Home Safety**	**Medications**	**Vision**
Believe the strategy reduces falls[a]	99%	99%	97%	95%
Believe PAs have a professional responsibility to implement the strategy[a]	95%	91%	96%	88%
Believe most patients would be compliant with suggestions regarding the strategy[a]	47%	69%	90%	84%
Willing to implement the strategy[a]	93%	90%	90%	85%
Currently implement the strategy[b]	48%[c]	23%	45%[d]	24%

[a]Percentage includes those responding as "agree" or "strongly agree".
[b]Percentage includes those responding as "frequently" or "always".
[c]Average of values obtained in response to "ask about exercise habits" (52%) and "recommend strength/balance programs" (44%).
[d]Average of values obtained in response to "review medications with a focus on fall prevention" (44%) and "decrease or eliminate medications that potentially increase fall risk" (45%).

Perceived Barriers. When asked why fall prevention strategies were not implemented routinely in patient encounters, "lack of time" (27%), "lack of support staff" (26%), and feeling "ill-prepared to conduct fall screening" (18%) were marked as barriers. No respondents marked "not important" and only 1% marked "not my responsibility" or feeling "ill-prepared to conduct fall focused medication reviews" as barriers. Other potential barriers were identified within the questions asking about difficulties providing

fall-related preventive care to various populations. Respondents either agreed or strongly agreed that it was difficult to provide fall-related preventive care to patients rarely visiting the practice (86%), who seem healthy (63%), have a low socioeconomic status (47%), or have a different cultural background (41%).

Logistic Regression. Multiple logistic regression analyses examined factors associated with implementation of the four main fall prevention strategies. The predictor variables chosen for analysis varied depending upon the strategy evaluated (Table 3). Only time was identified as a barrier and independently was associated with implementation of the medication review strategy. When time was not identified as a barrier, respondents were 3.7 times more likely to review medications with a focus on falls. Both time and a balance and strength exercise program in the area were associated positively with implementation of the exercise strategy. When time was not identified as a barrier, respondents were three times more likely to implement the exercise strategy. In addition, when respondents reported there was a balance and strength exercise program in the area, they were four times more likely to implement the exercise strategy.

Table 3. Analysis of predictor variables associated with Kansas PA current practices regarding implementation of four key fall prevention strategies.

Predictor Variable	**Exercise n=137**	**Home Safety n=139**	**Medications n=141**	**Vision n=140**
Years in Practice (Reference Group = 0 - 4 years)	p = .788	p = .526	p = .379	p = .733
5 - 8 years	1.195 (.42 - 3.42) p = .740	2.103 (.64 - 6.89) p = .219	1.687 (.60 - 4.75) p = .322	1.295 (.38 - 4.37) p = .677
9 - 16 years	1.676 (.62 - 4.54) p = .309	2.308 (.70 - 7.67) p = .172	1.711 (.65 - 4.54) p = .281	1.060 (.32 - 3.54) p = .924
More than 17 years	1.255 (.44 - 3.59) p = .671	1.600 (.48 - 5.36) p = .446	2.477 (.89 - 6.91) p = .083	1.810 (.57 - 5.71) p = .311
Patient will be compliant	1.246 (.59 - 2.62) p = .561	2.615 (.94-7.28) p = .066	1.354 (.41 - 4.47) p = .619	2.490 (.64 - 9.70) p = .188
Prior fall prevention training	1.042 (.39 - 2.80) p = .934	1.990 (.74 - 5.36) p = .173	1.460 (.60 - 3.58) p = .409	2.424 (.91 - 6.43) p = .075
Balance and strength program in the area	4.064 (1.91 - 8.63) p < .001[a]	NA	NA	NA
Barrier: Not enough time	3.095 (1.25 - 7.65) p = .014[a]	3.120 (.96 - 10.09) p = .057	3.7 (1.50 - 9.11) p = .004[a]	2.580 (.81 - 8.20) p = .109
Barrier: Not prepared to conduct fall screenings	1.148 (.43 - 3.08) p = .784	NA	NA	NA

Note: Odds ratio (95% confidence interval) provided; NA = not applicable due to that predictor not being included in the logistic regression model.

[a]Indicates that the predictor variable was significant.

Discussion

Although the majority of respondents expressed positive attitudes expected to be linked with a high level of implementation, most reported they never or only sometimes provide fall-related preventive care to their older adult patients in compliance with the four targeted strategies. This is similar to what has been observed in the literature.[7,8] As expected, a large number of respondents reported working in rural communities and largely with older adults, indicating the survey likely captured the target respondent population. The top three practice settings reported in this survey were family medicine, orthopedics, and emergency medicine; three common settings where older adults may present following a traumatic fall. Fall prevention programs have been advocated in outpatient clinic settings and also in ED settings.[11]

Many fall prevention strategies rely on improving patients' understanding of fall prevention and lifestyle modification. Therefore, PAs routinely treating older adults should become knowledgeable of not only what they can do to reduce fall risk in their patients, but also identify which members of the healthcare team (e.g., pharmacist, physical/occupation therapists, optometrists) and specific community resources are available to support that goal. The lowest implementation rates reported were for home safety evaluation/referral (23%) and vision (24%). During patient encounters, evidence-based practices need to be translated from research ideas to bedside practices. To incorporate these evidence-based practices in patient encounters, strategies to address implementation barriers must be developed at the practitioner level.[12]

A belief that patients will not be compliant might explain a low implementation rate; however, this does not seem to be the case with regards to medication, home safety, and vision, where most respondents believed patients would be compliant, 90%, 69%, and 84%, respectively. Notably, fewer respondents believed patients would be complaint with exercise recommendations (47%). Beliefs that a particular intervention is ineffective, unimportant, or not one's responsibility were also common barriers that did not appear to be problematic among the PAs in this survey. The majority of respondents reported they believed it was their professional responsibility to implement fall prevention guidelines.

Several barriers to implementation were identified and should be targeted including feeling ill-prepared to conduct fall screening, lack of time, and support staff. Feeling ill-prepared is an internal barrier that could be overcome through broader offering of targeted, fall-related educational programs and continuing medical education (CME). CME should be available to ensure PAs are trained appropriately to provide this type of preventive care. Issues with practice logistics and resources (lack of time and staffing) are more difficult to resolve in a global manner.

One-third of the respondents reported working in rural settings with populations less than 10,000 (24% of respondents) or 10,000 to 49,000 and not near a metro area (9%). Fall prevention programs tailored to metro areas or large practice settings within hospitals or full-service clinics likely will not be feasible in rural communities or small clinics with limited resources. Therefore, practical fall prevention programs with materials and tools that are evidence-based, inexpensive or free, quick and easy to implement with the patient and caregivers in communities with limited resources, would be ideal.[13] For example, such tools might include home safety checklists that can be completed by the patient or caregiver rather than a physical or occupation therapist who may not be available in that county.

Instructional materials for in-home individual balance/strength programs should be available to distribute to the patient if transportation is an issue or a local program is unaffordable or unavailable. Comprehensive patient/caregiver materials that are interesting, informative, and easy to understand could reduce the one-on-one educational time the PA would have to spend with the patient. Fall risk assessment toolkits are available online (e.g., The Falling LinKS Toolkit).[14] Lists of community-specific resources (e.g., local fall prevention programs, balance/strength classes, and community organizations that provide home safety evaluation and modification for free or low cost) should be developed and made available.

Development and implementation approaches for these tools and materials as well as provider fall prevention education also should take into account other expressed barriers including how to overcome difficulties in providing preventive care to individuals who rarely visit the practice (e.g., interventions that require less follow-up by the PA), of a low socioeconomic status (e.g., low cost or free), and with different cultural backgrounds (e.g., multi-language materials with diverse photos). Interestingly, many PAs reported it is difficult to provide preventive care to patients who seem healthy. As the goal of prevention is to maintain health and independence, this should be re-emphasized with patients to increase awareness and openness to the preventive measures and with the PAs who need to feel comfortable initiating preventive care.

Limitations. The response rate was low. Therefore, non-respondent bias in the results may misrepresent a certain segment of the population who could not or chose not to respond to the survey. However, compared to state data regarding PA practice settings from the American Academy of Physician Assistants (AAPA) Annual Survey,[14] our survey yielded a slightly higher than expected percentage of PAs working in family medicine and internal medicine, indicating a sample of the desired population was achieved. AAPA data demonstrated that 43.5% of Kansas PAs practiced in primary care (defined as family medicine, internal medicine, general pediatrics, and OB/GYN) and 35% specifically in family medicine. In our sample, 48% practiced in primary care (family medicine and internal medicine) and 40% specifically in family medicine.[14] There also may have been a social desirability bias or reluctance on the part of the participants to give a negative response to current practices and their attitudes/beliefs.

Conclusions

PAs in Kansas are aware of the importance of fall prevention, believe falls are preventable, and believe it is their professional responsibility to implement fall prevention strategies with their older adult patients. However, most do not implement strategies in their practice due to a variety of logistic and resource factors (lack of time, lack of staff) and internal barriers (feeling ill-prepared). Strategies to bridge the gap between willingness to implement and actual implementation are required. Increased educational opportunities may help PAs feel better prepared to provide targeted fall prevention care to older adults. Access to fall prevention materials, tools, and resources that are practical, simple, inexpensive, and require little implementation time, may overcome some of these barriers and promote the transference of research findings into clinical care.

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A Qualitative Assessment of Kansas Tracking and Reporting of Controlled Substances (K-TRACS)

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Abstract

Introduction. This study assessed the Kansas Tracking and Reporting of Controlled Substances system (K-TRACS), the online controlled prescription medication monitoring website in Kansas. The specific aims were to determine if and when pharmacists and physicians in Kansas were using K-TRACS and to identify any perceived benefits or barriers to using K-TRACS.
Methods. A non-randomized, convenience sample of Kansas pharmacists and family physicians were interviewed face to face using a guided semi-structured questionnaire. NVivo 10 (QSR International Pty Ltd.) was used to analyze data.
Results. Ten physicians and sixteen pharmacists were interviewed. All pharmacists and 70% of physicians were using K-TRACS. Usage was prompted by encounters with new patients or unease with the patient interaction. The perceived benefits included increased communication with the patient and all providers, increased provider comfort with treating chronic pain, and altered prescriber habits. Barriers to the use of K-TRACS were identified as login, password, and operating system problems.
Conclusions. Among study participants, K-TRACS is used regularly, is perceived to be a benefit to providers, patients and communities, and has become a useful new tool in the treatment of chronic pain. K-TRACS is perceived to facilitate increased communication between providers and with patients.
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Introduction

Prescription drug monitoring programs (PDMPs) have been identified as an important tool for licensed healthcare providers, state governments, and licensing boards in monitoring controlled prescription medication use and misuse.[1] PDMPs were first utilized in 1939 when California launched a program using carbon copies of prescriptions and the US postal system to relay information about filled prescriptions. As of July 2014, forty-nine states and one territory have enacted laws to establish PDMPs, and forty-eight states have operational online systems. PDMPs have decreased diversion of controlled substances[1,2] and doctor shopping for controlled prescription medications,[3,4,5] to alter prescriber habits,[4,6] enhanced communication between patients and physicians,[7] and slowed the increase in rates of opioid treatment admissions.[8]

The Kansas Tracking and Reporting of Controlled Substances (K-TRACS) system is the PDMP for the state of Kansas. It was written into law in 2008 and is an

independent (i.e., not integrated into any one electronic medical record system) online, web-based, proactive data bank under the oversight of the Kansas State Board of Pharmacy.[9] It contains data on all controlled prescription medications dispensed in or mailed into the state of Kansas from July 2010 to the present and can be accessed by registered licensed healthcare providers. Moreover, at the time of our study, data from thirteen other states' PDMPs can be accessed through K-TRACS, albeit not from states adjoining Kansas.

Prescription data include the name and address of the patient, names of the prescriber and dispenser, medication name, quantity dispensed, dosage, and date dispensed.[9] In the state of Kansas, individuals or businesses that dispense medications are mandated by law to report all controlled prescription medications dispensed; however, healthcare providers who prescribe controlled prescription medications are legally not obligated to access the system.[9] Even though dispensers are required to report to KTRACS on a daily basis, the system, at the time our data was collected, was only updated weekly. Data on all scheduled II-IV controlled prescription medications, as well as information on three additional medications deemed "drugs of concern," are collected.[9] These "drugs of concern" include promethazine with codeine, any compound, mixture or preparation that includes prescription ephedrine or pseudoephedrine, and medications containing the combination of butalbital, caffeine, and acetaminophen.[9]

Since PDMPs are governed by state law, each state's PDMP is unique and varied in its implementation, rules, and participation. Evidence-based "best practices" for their design, implementation, and use have not been determined and are likely to differ by location.[1,10] Various states have reported the impact their unique PDMP has had on their health care system,[11,12] but the impact of K-TRACS in the state of Kansas since its implementation in July 2010 has not been studied. The goal of this project was to perform a qualitative assessment of the impact of K-TRACS by interviewing practicing pharmacists and physicians and identify any perceived benefits of the system in the areas of patient and community safety, practice impact, and chronic pain management, as well as any barriers to use or operating system problems.

Methods

Pharmacists and family physicians practicing in various communities across Kansas including rural and metropolitan areas were identified for participation in the study. Inclusion criteria for recruitment were: (1) being licensed and actively practicing in Kansas and (2) consenting to participate in a face to face recorded interview in their community setting. Pharmacists and family physicians from the same community or geographic area were selected to be interviewed. Practice settings included independent and chain retail pharmacies as well as solo, group, and residency family medicine practices. Study participants were interviewed face to face using a guided semi-structured questionnaire. Implied consent was obtained through the interviewee's verbal responses to the questionnaire. Interviews were performed from December 2012 through March 2013 and conducted primarily by the primary investigator and two family medicine resident physicians. Each interview was conducted in the participant's practice community and averaged 45 minutes in length. All interviews were audiotaped, transcribed, and analyzed.

Three reviewers independently analyzed the transcripts for thematic codes related to the benefits and barriers of K-TRACS according to qualitative research analysis

standards.[13] Discrepancies in codes were discussed among the group to reach consensus. Inter-rater reliability surpassed 90%. General demographic data in addition to the frequency and type of technology (laptop/computer, mobile device or email) used to access health information were collected for all participants. Questions regarding K-TRACS' utilization and the benefits of and barriers to using K-TRACS were asked of all participants. Multiple thematic codes were identified, defined, and applied to all transcripts by the three reviewers. Study approval was obtained through the University's Institutional Review Board.

Results

Participant characteristics. Ten physicians and sixteen pharmacists in sixteen different communities were interviewed (Figure 1). Sixty percent of the physician respondents and 69% of the pharmacist respondents were male, 90% of the physician respondents and all of the pharmacist respondents were non-Hispanic white (Table 1). All of the physician respondents were under the age of 61 years with the majority (60%) of those interviewed between the ages of 31-40 years. There was greater variation in the pharmacist respondents' age with 31% in the 51-60 year old age group, and 25% in both the 31-40 and 41-50 age groups. When asked what technology was used regularly to access general healthcare information, all responders reported using the internet accessed from a laptop or PC. All of the physician respondents and 63% of the pharmacist respondents used the internet via a cell phone. Ninety percent of the physician respondents noted accessing information from email as well as mobile device applications, while only 69% of the pharmacist respondents accessed information via email and 81% through a mobile device application.

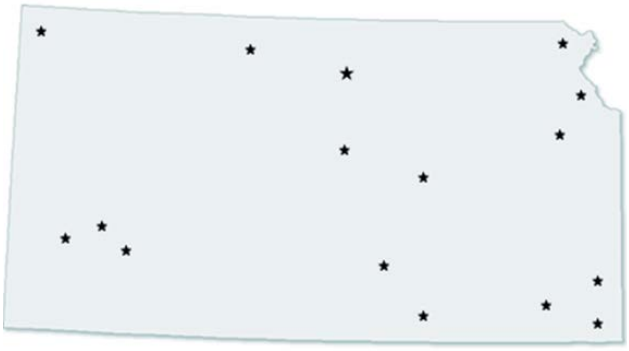

Figure 1. Location of K-TRACS interviews across Kansas.*

* Physicians and phramacists and cities are not identified on the map to protect confidentiality since several respondents come from rural areas where they easily can be identified.

Table 1. Participant characteristics (N=26).

	Physician N=10 N (%)	Pharmacist N=16 N (%)
Gender		
Male	6 (60)	11 (69)
Female	4 (40)	5 (31)
Age (years)		
21-30	1 (10)	2 (13)
31-40	6 (60)	4 (25)
41-50	1 (10)	4 (25)
51-60	2 (20)	5 (31)
61-70	0 (0)	1 (6)
Race/ethnicity		
Non-Hispanic White	9 (90)	16 (100)
Hispanic	1 (10)	0 (0)
Technology used to access health information		
Email	9 (90)	11 (69)
Internet from laptop or PC	10 (100)	16 (100)
Internet via cell phone	10 (100)	10 (63)
Mobile device applications	9 (90)	13 (81)

Utilization of K-TRACS

All of the pharmacist respondents and 70% of the physician respondents reported using K-TRACS for one to three years, which demonstrated use from the time K-TRACS was implemented in 2010. Use ranged from occasional to frequent and included both personal and staff accession of K-TRACS information. Pharmacist respondents reported accessing K-TRACS more frequently than physician respondents, who tended to delegate the task to a designated agent. K-TRACS use occurred in a variety of settings including pharmacies, clinics, emergency departments, hospitals and hospices. One physician respondent reported that "K-TRACS has been a godsend to our program" adding that the nurses were "on there [K-TRACS] pulling reports up all the time."

Several scenarios prompted respondents to access a patient's K-TRACS record including a new or unknown patient, a new or unknown prescriber or multiple prescribers, an unusual quantity or dosage of a controlled prescription medication or one not usually prescribed in the area, and repeated requests for early refills. Additionally, pharmacist respondents mentioned that patients requesting to pay for the medication with cash, particularly one that had pharmacy insurance coverage, prompted them to check K-TRACS. Respondents commented that a patient's behavior, (e.g., "antsy" or "impatient"), or their own feelings of discomfort about the patient, (e.g., "something just doesn't feel right here"), at the time of the service might prompt a K-TRACS inquiry. Respondents indicated a report might be requested if the provider was perceived to be over-prescribing, over-dispensing, or practicing outside the standards of chronic pain management care for the community.

Benefits

Study respondents identified many perceived benefits of K-TRACS which are identified in Table 2. Overall, K-TRACS was perceived to have been a benefit to community safety by 77% of responders with a perceived decrease in the amount of doctor and pharmacy shopping by patients. One responder noted, "I think that it has stopped a lot of this multi-pharmacy, multiple doctor, poly-pharmacy, poly-doctor…it's very easy to see what they've been doing. And it does make a difference."

Improved patient safety was perceived by 81% of responders as a benefit of K-TRACS. "You know, if we see that something's not adding up then we'll go to K-TRACS or call the physician's office." Responders reported that K-TRACS helped them to set what was perceived to be healthy and safer boundaries with patients on chronic controlled prescription medications and boundaries within the practice setting.

Respondents reported instances when K-TRACS facilitated an increase in communication between the patient and the provider and between the prescriber and the pharmacist. As one pharmacist respondent said, "We run a K-TRACS and the prescriber that prescribed this particular prescription didn't realize that there had already been one or two other prescribers. So we call them and tell them, they're like, 'thanks for calling'." This increase in communication offered an opportunity to improve patient safety and education as well as alter some prescriber's habits. In one community, the pharmacist respondent "had some concerns because he thought there was some over-prescribing. And, he voiced some concerns about that. I think the K-TRACS allowed him to document that. You know, 'this is what you are doing'. And so it was very helpful…he [the physician] was thanking me for [my partner] doing that to help him."

Respondents reported that K-TRACS provided a surprising increase in their comfort level in treating patients needing

chronic pain management and an improvement in their confidence that they were delivering quality care to these patients. As one pharmacist respondent said, "It helps me feel more confident when I'm filling a prescription that I'm taking care of the patient the way that they should be…it makes me feel a little more confident in my practice. That we're actually doing the right thing for people."

Table 2: Benefits and barriers of K-TRACS as identified by physician and pharmacist respondents.

Benefits	**Barriers**
Supports community safety: Prevents doctor shopping	Technology: Password, login, and system problems
Increases patient safety: Prevents medication abuse and poly-pharmacy	Time management: Report running is time consuming
Promotes communication among physicians, pharmacists, patients and helps to establish prescribing boundaries	Workflow: interrupts clinic/ pharmacy workflow to use K-TRACS
Increases comfort level in chronic pain management and confidence in quality of care	Cost: Revenue loss from using K-TRACS

Barriers

Several themes emerged in the barriers identified by K-TRACS users. These included technological issues, time management, workflow disruption, and costs, all of which ultimately impact patient care. These themes are detailed in Table 2. Overall, 96% of responders cited technological barriers including forgotten passwords, trouble logging on to the system, and trouble re-setting passwords. Lack of time to run a report was noted by 46% of the responders, (e.g., "the truth is we don't have that kind of manpower or time, and reimbursements aren't right to allow that to happen"), and an interruption to workflow was a problem for 29%. Revenues lost from the time spent utilizing K-TRACS was noted by 38% of responders.

Operating system problems were described as barriers among those using K-TRACS. Responders identified several problems within the K-TRACS computer program. Frequently reported issues included an inconsistent reporting of compounded controlled prescription medications by the system, an inability to correct data within K-TRACS after submission and lack of real-time data since the website is updated only weekly. These programming issues have led to inaccurate K-TRACS reports and have impacted patient care negatively in some situations. Additionally, none of the data from states that border Kansas can be viewed even though data from thirteen other states' PDMPs can be viewed on K-TRACS. This was reported as a problem, as was the inability to integrate K-TRACS into some practice settings' EMRs. Multiple doctors with the same name, lack of a practice identifier, and confusing report displays (e.g., "when you print it, it prints it in a really jumbled way") were described by study participants as program problems.

Discussion

Among the study respondents, K-TRACS is used in many clinical situations even though it is not required to be used by physicians. All of the pharmacist respondents and over two-thirds of the

physician respondents reported the use of K-TRACS directly or by staff in their practice. Although use does not occur with every patient encounter involving controlled prescription medications, respondents are using it to bring objective data to subjective, often emotionally charged patient care situations. Additionally, they are using it to familiarize themselves with a new patient, provider, or prescription.

K-TRACS is perceived to be performing in ways reported of other PDMPs, specifically in decreasing the amount of doctor shopping[3-5] and positively altering prescriber habits by promoting the appropriate prescribing and dispensing of controlled prescription medications.[4, 6] Respondents perceived improvement in community safety which might translate into a decrease in diversion of controlled prescription medications, another reported attribute of a PDMP.[1,2]

Overall, respondents reported several benefits and barriers to the use of K-TRACS. Among the benefits of using K-TRACS, respondents pointed to increased patient safety and a decrease in pharmacy and doctor shopping, which has been shown to be a risk factor for drug-related overdose death.[5,14] Additionally, increased communication was a key finding. Physicians reported that using K-TRACS facilitated communication with their patients.[15] Moreover, pharmacists reported better communication with patients as well as with prescribers, which is a novel finding for a PDMP. Such communication has been shown to improve patient outcomes and ensure quality of care for patients with chronic disease, which could help pharmacists and physicians improve their delivery of chronic pain management.[15,16] Among our respondents, the objective data of the K-TRACS report seemed to help physicians and pharmacists more readily discuss any concerns they might have had with both the patient as well as with each other. These discussions have validated prescription decisions, identified the need for abuse and addiction treatment, and in some instances, decreased prescription abuse and overprescribing. These discussions additionally could help to implement the Institute of Medicine's report on "Preventing Medications Errors" action agenda to support the consumer-provider partnership, considered a key step in improving the safety of the medication-use process.[17] The report suggests that the "most powerful strategy for improving safety may be motivating providers and organizations to support the full engagement of patients and surrogates in improving the safety of medication use".

Primary care providers often lack confidence or feel frustration in treating patients with chronic pain.[18,19] Our study respondents reported that K-TRACS helped them feel more confident and comfortable in chronic pain treatment. This is a novel finding of any PDMP to date. With K-TRACS, physicians can work in tandem with pharmacists to manage complex pain patients. Such collaboration can alleviate some of the perceived burden of chronic pain management. In a state where specialists in pain management are, as one respondent suggested, "rare as a unicorn," this benefit has the potential to decrease the number of family physicians who no longer provide chronic pain management and to improve access to care for Kansas patients who suffer with chronic pain.

The most frequently cited barrier centered on accessing K-TRACS in terms of forgotten passwords and frustrations of logging into the system. Several important problems in the system were identified by the interviewees and emerged as significant barriers to patient care. Improved reporting of compounded controlled prescription medications, availability of real-time data,

the ability to correct previously reported information and greater access to other states' PDMP data, could provide additional benefits from the system.

Limitations. This study provides qualitative data from the personal experiences of a small number of selected pharmacists and family physicians with a single state's PDMP. It may not be reflective of the experiences of all pharmacists or physicians in Kansas with K-TRACS and may not translate to other states' PDMPs. Further studies involving quantitative methods across larger study groups are needed to determine if these findings are representative of the majority of Kansas physicians and pharmacists and compare that to other states' PDMPs.

Conclusion

K-TRACS is being utilized by pharmacists and family physicians. K-TRACS has been a benefit to respondents' practices, patients, and communities, despite several operating system barriers. It has become an important new tool in their treatment of chronic pain and has facilitated an increase in communication between the physician, pharmacist, and patient. These are benefits yet to be reported of a PDMP. Efforts to decrease program barriers, increase usage, and ensure sustainability and funding of the system could extend the scope of these identified benefits to more providers across the state.

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Keywords: prescription drugs, controlled substances**,** drug monitoring, Kansas

When Anemia, Atypical Plasma Cells, and a Lytic Bone Lesion are not Myeloma: An unusual presentation of osteomyelitis

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Introduction

Osteomyelitis is an infection of bone that leads to tissue destruction and can be caused by a wide variety of organisms including bacterial, fungal, and viral organisms.[1] Osteomyelitis can present with a history of local inflammation, erythema, or swelling. It also can present as low grade fever, malaise, and fatigue, along with non-specific chronic pain at the site of infection. With its myriad of different presentations, osteomyelitis can be hard to diagnose. We describe an unusual case of osteomyelitis thought to be a lytic bone lesion of multiple myeloma.

Case Report

A 64-year-old male was referred for anemia. He had been anemic for six months and received four IV iron infusions. Past workup showed a high level of ferritin (1450 ng/mL). Esophago-gastroduodenoscopy and colonoscopy were negative. Erythrocyte sedimentation rate and C-reactive protein were elevated. Bone marrow biopsy revealed atypical plasma cells accounted for less than 5% of cellularity.

Myeloma workup included a skeletal survey, showing three lucencies in the calvarium, superiorly near the midline, with the largest measuring 6 mm in diameter. Another lucency was present in the proximal right humeral diaphysis. Analysis revealed a beta 2 microglobulin of 3.3 mg/L (normal range 1.21-2.70 mg/L), elevated free kappa (146.16 mg/L), and lambda (65.26 mg/L) light chains with free kappa/lambda ratio of 2.24. A CT of the skull without contrast confirmed a 3 mm lytic lesion within the left frontal skull region thought to be consistent with a myeloma lesion.

During the patient's follow-up visit, he complained of pain in the left forehead. He complained that this area was increasingly painful and tender. With anemia, atypical plasma cells on bone marrow biopsy, a lytic lesion in left frontal skull region, beta 2 microglobulin of 3.3 mg/L, and elevated kappa and lambda free light chains, multiple myeloma was diagnosed.

Biopsy of the growing skull lesion was not done due to the concern that with treatment of multiple myeloma, wound healing of a scalp incision might be impeded. Thus, treatment with bortezomib and dexamethasone was started. The patient tolerated bortezomib well, but the presumptive plasmacytoma on the forehead increased in size to that of an orange and was tender and fluctuant on exam. A CT scan showed an increased size of the bony lytic lesion involving the frontal skull region with adjacent extracranial fluid collection. A craniectomy revealed the presence of a mass and subgaleal abscess.

The resected left frontal mass showed acute and chronically inflamed granulation tissue reaction and marked chronic inflammation consistent with osteomyelitis and non-diagnostic for plasmacytoma. Gram stain showed numerous white blood cells with no micro-organisms and an anaerobic

culture positive for a small amount of Fusobacterium species.

Follow-up post-operative CT scanning showed no new lytic lesions. Treatment for multiple myeloma was discontinued. Repeat films of the humerus showed no evidence of abnormalities.

Discussion

Musculoskeletal infections like osteomyelitis are very common and can be life threatening. It is a diverse disease in its pathophysiology, clinical presentation, and management.[2] Osteomyelitis is an ancient disease and is one of the most difficult infectious diseases to treat. Progressive destruction of the bone and the formation of sequestra are characteristics of this disease.

Osteomyelitis can be due to contiguous spread from adjacent soft tissues and joints, hematogenous seeding, or direct inoculation of microorganisms into the bone as a result of trauma or surgery.[2] A multidisciplinary team is required to treat these patients optimally.[3] Osteomyelitis of the skull usually results from the contiguous spread from an infected sinus or from penetrating trauma (i.e., post-operative).[4]

Our case illustrated an atypical presentation of osteomyelitis with an unusual organism which led to the misdiagnosis of multiple myeloma and resultant cytotoxic treatment. The linchpin was the lytic bone lesions, which were the cornerstone of the diagnosis. There was some uncertainty with both kappa and lambda elevation and the less than 5% plasmacytosis on bone marrow exam, so a biopsy of the calvarial lytic lesion was planned, but not done due to clinical worsening. In this case, a biopsy for tissue confirmation to solidify the diagnosis of multiple myeloma would have resulted in the correct diagnosis and earlier institution of antimicrobial therapy.

Thus, this case appeared to be something that it was not. There were lytic bone lesions, anemia (which in retrospect was due to an inflammatory anemia), elevated beta-2-microglobulin, and elevated serum free light chains (knowing what we now know, this was from the infection), all of which pointed to multiple myeloma.[5] The patient met formal diagnostic criteria for multiple myeloma based on the presence of lytic bone lesions and anemia. In this case, these findings trumped the bone marrow plasma cell percentage, which can be less than 10%, especially in a case where the disease burden appeared to be low based on a paucity of lytic lesions and a minimally elevated beta-2-microglobulin.

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Keywords: osteomyelitis, myeloma, osteolysis

Diagnosis and Treatment of Superior Sagittal Sinus Thrombosis

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Introduction

Cerebral venous sinus thrombosis (CVST), although a common diagnosis, is missed frequently by both general practitioners and neurologists.[1] The most common presenting complaints are headache with focal neurological symptoms such as weakness, numbness, and aphasia.[2] CVST has a female predominance of 3:1.[3] A risk factor usually is able to be determined, most common of which is oral contraceptive use.[4,5] Other prothrombotic risk factors include antithrombin III deficiency, dehydration, factor V Leiden mutation, increased factor VIII, infection, protein C and S deficiency, pregnancy, prothrombin mutation, malignancy, and trauma.[2,6] The superior sagittal sinus is the most common site of cerebral venous thrombosis, followed by the other sinus systems.[7-10] Treatment of CVST includes anticoagulation or thrombolytics with symptomatic support, although treatment with heparin has been controversial with some physicians hesitant to administer it due to the risk of hemorrhagic infarction.[2,11] We report the diagnosis and treatment of superior sagittal sinus thrombosis.

Case Report

A 44-year-old, gravida 2, para 2, right-handed, Caucasian female presented to the emergency department with acute symptoms of right leg, right arm, and right hand numbness and paresthesia. Additionally, she had difficulty moving her right leg which made it hard to walk. When she could no longer stand due to right leg weakness, she was taken to the emergency department. The MRI performed at this hospital showed diffusion restriction in the right parietal cortex. Additionally, there was a well demarcated fluid signal abnormality in the right dorsal medulla and the caudal aspect of the inferior cerebral peduncle. Rostral to this, there were bilateral circinate areas of fluid signal abnormality. Suspecting an acute stroke, she was transferred to our facility.

The patient reported a history of progressive dysmotility of the right hand extending over the course of five years. Fine motor skills had degenerated to the point that the patient began to write with her non-dominant left hand. While doing this, she noted tremor-like associated movements of the right hand. Medications included atorvastatin, escitalopram, omeprazole, and trazodone. She had taken oral contraceptives in the past, but stopped approximately five years prior.

Physical exam showed reduced facial sensation in the ophthalmic, maxillary, and mandibular branches of the trigeminal nerve on the right. The patient had a modest right hemiparesis and dysmotility and a moderate ataxia in the right arm and leg. Stereognosis was reduced on the right. The patient could

not stand due to right leg weakness. Pupils were round and reactive to light bilaterally with extra ocular eye movements intact and no photophobia. She did not have nuchal rigidity. Palatal arch elevated symmetrically. Reflexes were normal and symmetric bilaterally.

An ultrasound carotid duplex study showed minimal atherosclerotic disease involving both carotid systems, but no evidence for a hemodynamically significant stenosis of the common or internal carotid arteries. An echocardiogram bubble study showed normal left ventricular systolic function and wall motion with ejection fraction estimated at 55 to 60% and no evidence of right-to-left shunting. MRI of the cervical spine showed no evidence for spinal stenosis or nerve root encroachment, but there were several sub-centimeter nodules associated with the thyroid gland. Magnetic resonance arteriogram (MRA) of the brain without contrast showed no evidence of an aneurysm of the circle of Willis and there was no hemodynamically significant stenosis identified. MRI of the brain with and without contrast showed a new para-Rolandic central and parietal high convexity cortical signal abnormality in addition to the signal abnormality seen on the right parietal cortex on previous imaging. Abnormal signal in the right inferior cerebellar peduncle and left dorsal medulla also were seen, as well as a sulcal tendril of abnormal signal flowing down from a high convexity cortical or meningeal level, indicating a possible subarachnoid bleed (Figure 1). She was admitted for further workup of the etiology of her symptoms.

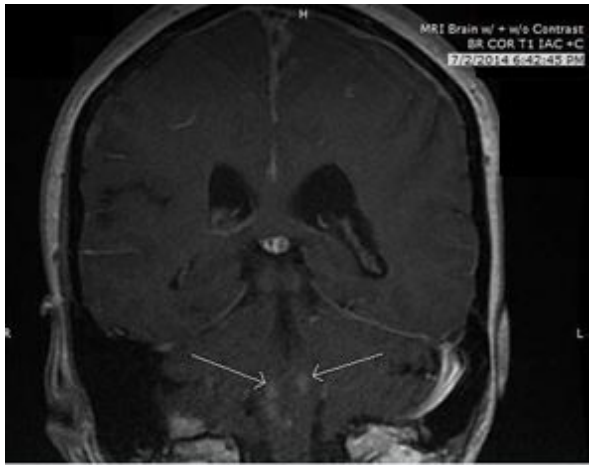

Figure 1. Coronal T1W MRI demonstrates small foci of abnormal hyperintense signal demonstrated within the dorsal medulla (arrows).

On day two post-admission, she experienced new-onset numbness on the left side of her face and the palm of her left hand that was accompanied by ataxia of her left arm and uncontrollable head bobbing. This episode lasted for approximately one minute and was not apparent on physical exam. The patient reported being able to walk with minimal assistance but dragging of her right foot was observed. These symptoms raised concerns of a new neurologic process of unclear etiology, and an extensive workup for demyelinating disease, infectious disease, or thrombotic disease was undertaken.

On day six, cerebral spinal fluid analysis showed 18 white cells (92% lymphocytes) and 253 red cells. Cerebrospinal fluid protein was 45 mg/dL and glucose 65 mg/dL (serum 113 mg/dL). No oligoclonal bands were detected. Cryptococcal antigen and VDRL titers were negative. Further infectious workup of Lyme disease, West Nile virus, and HIV were negative. Dexamethasone 2mg PO TID, divalproex sodium 500 mg PO BID, topiramate 25 mg PO daily, and minocycline 100 mg PO q12hr were started for the suspicion of a demyelinating process possibly contributing

to her symptoms. Thyroid ultrasound revealed multiple hypo-echoic lesions in each lobe which were interpreted as benign with a recommendation to repeat in six months. Thyroid stimulating hormone with reflex free T4 level was normal. Computed tomography (CT) of the chest and abdomen revealed a 4 mm right lower lobe pulmonary nodule with a recommendation to reimage in six months to assess stability. No abnormally enlarged lymph nodes in the chest, abdomen, or pelvis were found.

Repeat MRI revealed a new abnormal high T1 signal intensity demonstrated throughout the superior sagittal sinus as well as some central low signal within the superior sagittal sinus on the gradient acquisition, suggestive of superior sagittal sinus thrombosis (Figure 2). FLAIR acquisition also demonstrated some nonspecific foci of high T2 signal demonstrated within the posterior aspect of the medulla. This appeared unchanged from previous imaging. Dexamethasone, divalproex sodium, topiramate, and minocycline were discontinued and anticoagulation started with heparin drip 18 unit/kg/hr and warfarin 5 mg PO daily with a partial thromboplastin time (PTT) goal of at least 75 and an INR goal of 2-3.

Seven days post-admission, the patient reported the abnormal movements of her right arm had improved. She was walking without assistance. She also denied symptoms of right leg or right arm weakness, but reported mild dizziness and another brief episode of left palm numbness that lasted approximately one minute. A coagulopathy workup was initiated in an attempt to determine the source of the thrombosis. Blood and urine homocysteine levels were normal. The patient was heterozygous for methylenetetrahydrofolate reductase (MTHFR) gene mutation and negative for prothrombin G20210A mutation. Coagulation studies indicated an elevated Factor VIII of 227 (normal 50-150). Antithrombin, protein C and S, B6, folate and B12 levels were within normal ranges.

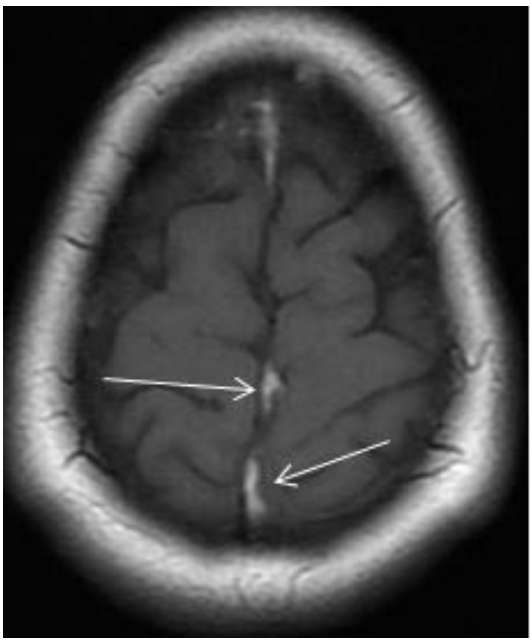

Figure 2. Axial T1W MRI demonstrates thrombosis throughout the superior sagittal sinus (arrows).

Eleven days after admission, the patient denied right leg or right arm numbness with no ataxia of her right limb. She was able to walk normally without assistance and denied dizziness or weakness. Routine CT scan of the brain revealed no intracranial hemorrhage as a result of heparin and warfarin treatment. At that time, her PTT was 91.7 and INR 1.7. Her warfarin dose was increased to 7.5 mg PO daily and heparin drip adjusted to 22.5 mL/hour. Urinalysis was negative for white cells, red cells, leukocyte esterase, glucose, or protein. Blood cultures were negative for bacterial or fungal growth.

On the sixteenth and final day of hospitalization, the patient had no symptoms of weakness, numbness, paresthesia, dizziness, or difficulty walking. On discharge, her INR was 2.1 and PTT 99.3.

Heparin was discontinued and the patient continued on 7.5 mg warfarin PO daily, with a follow up appointment scheduled in the outpatient clinic and repeat MRI to assess treatment.

Discussion

Although a common diagnosis, cerebral venous sinus thrombosis (CVST) is missed frequently by both neurologists and general practicitioners.[1] The most common symptom is headache (70%), followed by focal neurologic signs such as aphasia, numbness, and weakness (29%).[2] A study that included 625 patients from 89 centers in Europe with CVST found the mean age of patients was 39.1 years with a 3:1 female predominance.[3] In most diagnoses of CVST, there is usually a prothrombotic risk factor that is likely the etiology that predisposes to CVST, most commonly oral contraceptive use. Some studies calculate a >10-fold increase in the risk of thrombotic events in women taking oral contraceptives.[4,5] Other prothrombotic risk factors include antithrombin III deficiency, dehydration, factor V Leiden mutation, increased factor VIII, infection, protein C and S deficiency, pregnancy, prothrombin mutation, malignancy, and trauma.[2,6]

Hyperhomocysteinemia has been suggested as a risk factor for deep vein thrombosis and stroke, but has not been shown to cause increased risk for CVST.[7] The heterozygous mutation of the MTHFR gene is not an independent risk factor for CVST; however, this patient's combined risk factors of elevated factor VIII, previous exposure to oral contraceptives, and prior pregnancies may be compounded further by heterozygosity of the MTHFR gene.[12] The superior sagittal sinus is the most common site of cerebral venous thrombosis. Other sinus systems can be affected, including the sigmoid and transverse sinuses.[7-10]

Imaging of the brain is necessary to diagnose CVST.[13] Non-contrast computed tomography (CT) usually is performed in the emergency department when a central neurologic process is suspected. The most common findings in CVST using this method are hyperdense foci or generalized swelling.[14] However, a normal CT scan or MRI does not exclude the diagnosis of CVST. In a study where 52 patients had evidence of CVST, 9 of the 30 patients who had a CT as the first imaging study had normal findings. Of these nine, the MRIs of four of the patients were also normal. Using an MR venogram (MRV) study, evidence of CVST was revealed in two of the four patients. The authors of this study concluded that MRV is the investigation of choice for confirming CVST.[1]

Treatment for CVST includes initial anticoagulation with heparin or thrombolytics, with symptomatic therapy.[11] The use of heparin has come into question because of its association with hemorrhagic infarction in up to 40% of CVST cases.[2] For this reason, physicians hesitate to administer heparin. Unfortunately, there are few controlled trials on the safety and efficacy of anticoagulation treatment for CVST. A meta-analysis of two small trials of 80 patients which compared the safety and efficacy of anticoagulation with placebo showed that the use of anticoagulation had an absolute risk reduction in death or dependency of 13% (confidence interval -30 to +3%) with a relative risk reduction of 54%.[15] Intracranial hemorrhage has not been shown to be a contraindication to anticoagulation when related to CVST.[11] It is unclear if low molecular weight heparin (LMWH) is a better choice than dose-adjusted intravenous heparin, or vice versa. LMWH given subcutaneously increases the mobility of patients and reduces the need for laboratory monitoring and dose adjustments. However, intravenous heparin can be discontinued and an activated partial

thromboplastin time normalized within one to two hours if complications occur.

Thrombolytic therapy for the treatment of CVST is an option.[16] Thrombolytic therapy with tissue plasminogen activator (tPA) after failed anticoagulation was an effective treatment in patients with severe or worsening CVST. Those who had thrombolytic treatment after worsening of symptoms survived with mild residual neurologic damage or symptom-free recovery. The same study also found that patients who had only mild symptoms or no worsening of clinical course benefited from anticoagulation therapy alone.

Other studies of thrombolytic therapy for the treatment of CVST have seen similar results, with rapid and complete recanalization achieved with full recovery. However, there were two extra-cerebral bleeding events and two patients whose pre-treatment intracranial hemorrhage worsened.[17,18] There may be a higher risk of bleeding complications with thrombolytic treatment compared to anticoagulation therapy, particularly in patients with intracranial hemorrhage before treatment.[19]

Oral anticoagulation for three months with a target international normalized ratio (INR) of 2.0-3.0 has been recommended if CVST is believed to be secondary to a reversible risk factor such as oral contraceptive use, infection, or dehydration. If idiopathic, oral anticoagulation is recommended for 6-12 months.[20] Oral anticoagulation for 6-12 months is recommended for patients with a mild hereditary thrombophilia such as prothrombin G202A mutation, heterozygous factor V Leiden mutation, or protein C or S deficiency. More severe cases of hereditary coagulopathies with frequent recurrences such as antithrombin deficiency or homozygous factor V Leiden mutation may require oral anticoagulation indefinitely. The clinician's judgment in the severity of the hereditary thrombophilia, if present, may decide the length of treatment. Our patient had identifiable risk factors for CVST which may warrant long-term treatment with oral anticoagulation and scrupulous monitoring for potentially fatal side effects of treatment.

The etiology of the patient's new neurologic symptoms on day 2 post-admission remained unclear. The small foci of the abnormal hyper-intense signal demonstrated within the dorsal medulla were present even when the symptoms resolved. Workup did not reveal a cause for these lesions and the patient had become asymptomatic. As such, follow-up to the neurology clinic as an outpatient was recommended to monitor the lesions for any changes.

While common, CVST is a frequently missed diagnosis. Its symptoms can present similarly to an acute stroke and should be suspected in patient populations where acute strokes are uncommon. The superior sagittal sinus is the most common site of dural sinus thrombosis, and the gold standard for diagnosis is MRV. Treatment is controversial but intravenous heparin administration with bridging to oral anticoagulation is used most commonly. More studies are needed to determine the safest and most efficacious treatment for CVST.

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Keywords: superior sagittal sinus, venous thrombosis

Diabetic Myonecrosis of Bilateral Thighs in Newly Diagnosed Type 2 Diabetes Mellitus

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Introduction

Diabetes mellitus (DM) and its complications remain a global challenge to health care systems. Diabetic myonecrosis is a rare and under-diagnosed complication of DM that was first reported in 1965.[1] Diabetic myonecrosis affects patients with poorly controlled and longstanding type 1 diabetes mellitus (DM) and associated microvascular complications.[2] Recently, diabetic myonecrosis also has been reported in type 2 diabetes mellitus patients.[3] Elevation of muscle enzymes such as creatine phosphokinase (CPK) is present in half of all cases of diabetic myonecrosis. It can be misdiagnosed as cellulitis, inflammatory myopathy, deep vein thrombosis or fasciitis.[4] The diagnosis is based on the constellation of clinical, laboratory, imaging, and pathological findings. It is usually self-limited and responds well to conservative management if diagnosed early.[5] The short-term prognosis is usually good with slow recovery. Failure to recognize this condition can result in significant morbidity. Physicians should consider diabetic myonecrosis in the differential diagnosis of acute focal myalgia in a diabetic patient. We report two cases of diabetic myonecrosis in patients with type 2 diabetes mellitus.

Case Report

Our first case was a thirty-six-year old male with history of type 2 diabetes mellitus who had been diagnosed within the past six months and treated with oral hypoglycemic agents. He presented with bilateral thigh pain of two-month duration. The pain had worsened with progressive swelling of both thighs. The swelling was acute in onset and located diffusely over the thighs which severely impaired him from performing activities of daily living. The patient denied any history of trauma, intramuscular injections, infections, or drug abuse. He had similar history of pain and swelling in the right thigh five months prior, which resolved spontaneously. Medical records revealed that the patient was noncompliant and his diabetes was poorly controlled.

On examination, his vital signs were stable. He had a body mass index (BMI) of 29.3 kg/m^2. The physical examination revealed bilateral pitting pedal edema and diffuse swelling of the anterior, medial, and postero-lateral regions of the thigh along with induration and tenderness, but no inflammation, fluctuation, or crepitus. Peripheral pulses were palpable in the lower extremities. There was no focal weakness or sensory loss. Deep tendon reflexes were normal in all four limbs. The laboratory

studies included normal complete blood count with differential, serum creatinine, alanine aminotransferase (ALT), aspartate aminotransferase (AST), lactate dehydrogenase (LDH) and thyroid stimulating hormone (TSH). His abnormal labs included a creatine phosphokinase (CPK) of 2531 IU/L (normal range 32-162), erythrocyte sedimentation rate (ESR) of 140 mm/h, C-reactive protein (CRP) of 25.6 mg/l, and hemoglobin A1c of 13.5%. Autoimmune serologies were normal or negative including anti-nuclear antigen (ANA), extractable nuclear antibodies, double stranded DNA, Jo-1, and serum complements. Radiographic studies of both the thighs and knees were unremarkable.

A Doppler ultrasonography of bilateral lower extremities did not reveal a deep venous thrombosis (DVT) or a collection of fluid in the muscle planes, but there was subcutaneous edema. Magnetic resonance imaging (MRI) of the bilateral thighs demonstrated high signal intensity on T2-weighted images showing diffuse myoedema and focal myonecrosis bilaterally and subcutaneous edema of the anteromedial compartment in the right thigh and the posterior medial compartment of the left thigh (Figures 1 and 2). A diagnosis of diabetic myonecrosis was made based on clinical presentation, negative immunological markers, ultrasound, and characteristic MRI findings. Management with bed rest, limb elevation, insulin therapy and analgesics was initiated. His pain and swelling improved significantly without the need for further evaluation, such as muscle biopsy. At the time of discharge, the patient was able to ambulate with assistance.

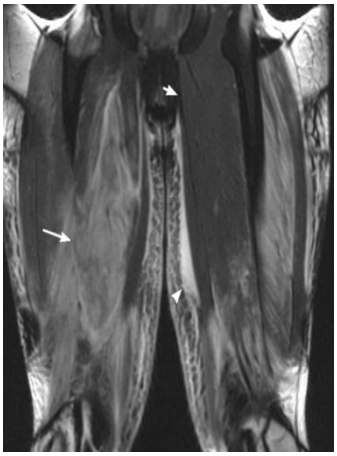

Figure 1. Coronal T2 fat saturation image shows diffuse increased muscle signal and edema bilaterally (long arrow), with areas of normal muscle signal (short arrow). There is also diffuse subcutaneous stranding and edema, as well as perifascicular fluid (arrowhead).

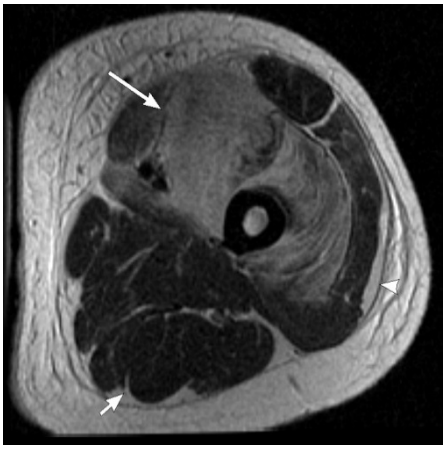

Figure 2. Axial T2 image in the same patient shows diffuse increased T2 signal consistent with muscle edema in the anterior compartment of the left thigh (long arrow) with normal muscle signal in the posterior compartment (short arrow). There is a small amount of perifascicular fluid (arrowhead).

The second case was a 48-year-old morbidly obese female with uncontrolled diabetes mellitus type 2 with complications of end-organ damage. The patient was admitted to the hospital with complaints of acute onset right thigh pain and swelling. She was afebrile on physical examination. There was a well-defined erythematous area of induration on the right posterior lateral thigh. Her right leg had a mottled

appearance with evidence of pitting edema. Pain was elicited on palpation of the right lower extremity. Muscle strength was intact. She had limited range of motion on flexion/extension of the knee and difficulty with weight-bearing activities on the right lower extremity due to pain. She had decrease sensation in her lower extremities distally secondary to known diabetic neuropathy. Peripheral pulses were intact.

Venous Doppler of the right lower extremity showed scarring associated with her previous DVT and a popliteal cyst. MRI imaging of the right thigh showed multiple areas of abnormal signal and contrast enhancement involving the muscles of the right thigh consistent with muscle infarcts (Figures 3 and 4). A punch biopsy of the area of erythema and induration revealed subcutaneous fat necrosis and trace dermal fibrin deposition. There was no evidence of infection on skin biopsy staining and culture. Abnormal laboratory studies included an elevated CPK of 7,491 IU/L, CRP 3.81 mg/dl, ESR 22 mm/h, and hemoglobin A1c of 7.7%. All other studies, such as thyroid function and autoimmune serologies to exclude an inflammatory myopathy, were negative.

The decision was made to wait for a muscle biopsy to reduce the potential for limb threatening complications due to need for a wide surgical debridement. The diagnosis of diabetic myonecrosis was established based on history, clinical examination, laboratory, and imaging studies.

The patient's symptoms and findings improved following pain control, bed rest, and better glycemic control. She presented to the outpatient internal medicine clinic eight weeks post-discharge with complete resolution of her thigh pain and swelling.

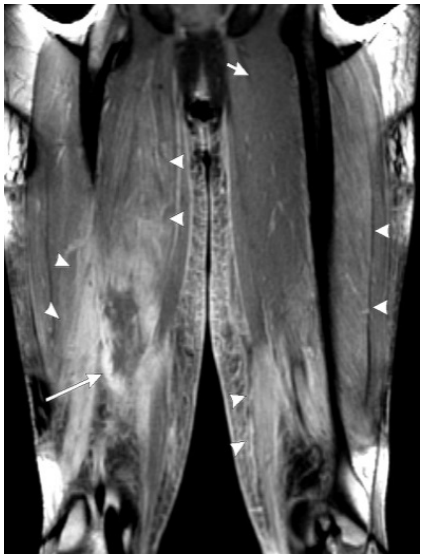

Figure 3. Coronal T1 fat saturation post contrast image shows diffuse scattered muscle enhancement (arrowheads), with areas of normal muscle (short arrow). There is a focal area of non enhancing muscle with peripheral rim like enhancement in the right thigh consistent with muscle infarction (long arrow).

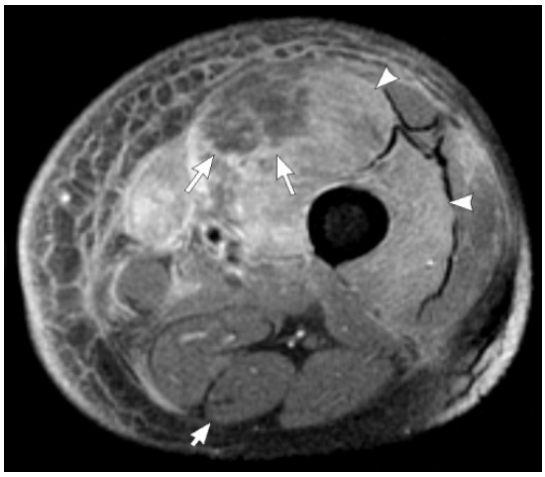

Figure 4. Axial T1 fat saturation post contrast image in the same patient shows diffuse increased signal consistent with enhancement in the anterior compartment of the thigh (arrowheads) compared to the normal muscle in the posterior compartment (short arrow). There is a focal area of non-enhancing muscle with peripheral enhancement in the anterior compartment consistent with infarction (long arrows).

Discussion

Diabetic myonecrosis is an uncommon complication of a long-standing and poorly controlled DM.[2] The majority of patients have diabetic end-organ damage such as retinopathy, neuropathy, and nephropathy.[3] Since it was first described in 1965, less than one hundred cases have been reported.[1] In most of these cases, diagnosis was delayed because of failure to recognize this condition.[4] Diabetes myonecrosis is more prevalent in women (61.5%) with mean age at presentation of 42.6 years, and mean duration of diabetes of 14.3 years.[5] Typically, it involves the thigh, but it can extend to the calf as well (19.2%).[5] Among the thigh muscles, it has a predilection for the quadriceps (62%, especially vastus medialis), hip adductors (13%), hamstrings (8%), and hip flexors (2%).[6] Rarely, can it involve the upper extremities and paraspinal muscles.[7-9]

The pathogenesis of this disease is unclear. Several hypotheses have been suggested. Muscle infarction could be caused by atherosclerosis and diabetic microangiopathy leading to ischemia of the muscle resulting in an intense inflammatory response, edema, hyperemia, and reperfusion. This generates oxygen-free radicals and increased pressure in the fascial compartment leading to muscle infarction.[10] Another hypothesis points to an alteration in the coagulation-fibrinolysis system as the cause of diabetic muscle infarction, as described by Palmer and Greco.[11] Gargiulo et al.[12] implicated a role for antiphospholipid antibodies in the progression of diabetes complications. Myonecrosis may occur in other disease states that predispose to peripheral vascular occlusion such as vasculitis, thromboembolism, trauma, compartment syndrome, and calciphylaxis.[13,14]

Patients with diabetic myonecrosis usually complain of abrupt onset of severe leg pain in the medial aspect of the anterior thigh. The pain is diffuse and may radiate to surrounding structures such as the low back, knees, and calves. The pain usually worsens over days to weeks. Examination early in the course reveals diffuse tenderness and swelling, which after several weeks may develop into a firm, discrete, and fusiform mass-like appearance. Pulses usually are palpable in the extremities and there are no signs of gangrene. Strength and sensation are unaffected, but movement may be limited due to pain.[14]

CPK levels may be elevated over three to four-fold and may become normal when the patients are tested after improvement of the acute event. Aldolase, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and lactate dehydrogenase (LDH) levels may be elevated. The white blood cell count (WBC) typically is normal and erythrocyte sedimentation rate (ESR) may be quite elevated (50-150 mm/h).[15]

The most effective diagnostic modality in diabetic myonecrosis is MRI. The typical features of MRI in diabetic myonecrosis are high intensity signal on T2 weighted-images with marked muscle edema extending to the perifascicular and subcutaneous tissues.[1,13,16] Muscle biopsy is the gold standard diagnostic procedure. However, based on literature review and clinical experience, the muscle biopsy could be reserved for cases in which the clinical presentation is atypical or the diagnosis is uncertain, as well as when appropriate treatment fails to elicit improvement.[17] Additionally, muscle biopsy or surgical excision either could prolong the disease or acutely exacerbate the condition.[18] Usually MRI, clinical examination, patient history, and a reasonable exclusion of other etiologies suffice in securing the diagnosis. Other diagnostic tools that may be considered include Duplex venous ultrasound,

computed tomography scan (CT), bone scintigraphy, venogram, angiography, and electromyography (EMG).[15,19] Deep vein thrombosis ranks highest on the differential diagnosis of diabetic myonecrosis of the extremities, so Duplex venous ultrasound commonly is used to exclude deep vein thrombosis.

Other differential diagnoses of myonecrosis include cellulitis, compartment syndrome, superficial thrombophlebitis, necrotizing fasciitis, abscess, hematoma, pyomyositis, osteomyelitis, tumors (benign and malignant including sarcomas), dermatomyositis, proliferative or focal myositis, parasitic myositis, ruptured Baker's cyst, diabetic amyotrophy, muscle strain, exertional muscle rupture, bursitis, vasculitis, lymphedema, amyloidosis, sarcoidosis, myositis ossificans, drug related myositis (statin group) and bone fracture.[2,3,14,18,20,21,22] In the cases presented here, the differential diagnoses were excluded by the history, clinical examination, laboratory, and imaging investigations.

Treatment of diabetic myonecrosis includes adequate bed rest, short-term immobilization, analgesics (nonsteroidal anti-inflammatory medications, narcotics, or both), and most importantly optimal glycemic control. Some authors propose the use of antiplatelet therapy to treat the underlying microvasculopathy, although this has not been established as a standard of care.[22,23] Exercise or physical therapy exacerbates pain and extends infarction, thus is discouraged in the acute setting.[18,21] The long-term prognosis, especially when diagnosis and management are delayed, can be poor and recurrence rate could be as high as 50% with 8-9% involving the originally affected muscles and 39% involving other muscles. However, the short-term prognosis is good with supportive care and following tight glycemic control. Overall, patients with diabetic myonecrosis could have a poor prognosis, and most patients die within five years of diagnosis due to end-organ microvascular complications.[10,14,15]

Conclusion

Diabetic myonecrosis should be considered in diabetic patients who develop a painful and swollen muscle. It is a manifestation of poor glycemic control, and a marker of underlying progressive microvascular disease. Patients with diabetic myonecrosis should undergo evaluation for potential complications of diabetes, including retinopathy, nephropathy, neuropathy and atherosclerosis. Diabetic myonecrosis is another reminder that aggressive diabetic control is essential to prevent end-organ damage, morbidity and mortality.

These two cases are unique as they describe patients with type 2 diabetes mellitus who suffered from involvement of bilateral thighs.

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Keywords: diabetes mellitus, diabetic complications, necrosis, muscles

Posterior Tibial Polyethylene Fracture in Cruciate-Retaining Total Knee Arthroplasty

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Introduction

One of the common prostheses for primary total knee arthroplasty (TKA) is a cruciate-retaining (CR) design. The tibial polyethylene inserts commonly used in TKA are made of ultra-high molecular weight polyethylene (UHMWPE). The CR TKA design retains the posterior cruciate ligament (PCL), which is believed to provide increased stability, promote femoral roll back, improve proprioception, and enhance stair-climbing ability.[1,2] Delamination, adhesive wear, and abrasive wear of the polyethylene component are common mechanisms of failure, but fracture of the component at the posterior side in a CR TKA is rare. The cause of this type of failure is often multifactorial. This case report presents a case of posteromedial polyethylene fracture in a CR TKA.

Case Report

A 56-year-old female (height: 5 feet 7 inches, weight: 185 lbs., BMI 29 kg/m^2) presented with left knee pain for which she had undergone a total knee replacement three and one-half years prior with a diagnosis of primary osteoarthritis. Since the surgery, her knee never felt stable, particularly when walking up and down stairs. She also complained of pain and swelling to the knee, which had been worsening in severity. She previously had undergone physical therapy without any significant relief of the symptoms. She denied any fever or chills, night sweats, or recent weight loss. The patient's past medical history was unremarkable for any trauma to the knee after surgery.

On physical examination, the patient's left knee was mildly tender to palpation medially and laterally. It had range of motion of 0 to 120 degrees of flexion with neutral alignment. The joint opened up 1 mm with valgus stress medially and 2 mm with varus stress laterally in extension. In flexion, the anterior drawer test showed gross laxity with anterior tibia translation. The posterior drawer test also showed significant laxity. Neurovascular function was intact. Her Knee Society score was "poor" (score: 54) according to the Knee Society clinical rating system[3] and her functional outcome score was "fair" (score: 60).

Three radiographs of the left knee were taken (anteroposterior, lateral, and sunrise). The results showed a CR knee without any sign of prostheses loosening. Anterior translation of the tibia was noticed (Figure 1). Laboratory blood tests were negative for infection. Therefore, she was diagnosed with flexion instability status post left TKA, and the plan was for the patient to undergo revision knee arthroplasty. The medical record of the patient's initial surgery obtained from an outside hospital showed a size 2 Stryker Triathlon CR femoral component (Stryker, Mahwah, NJ), and a size 2 Triathlon tibial baseplate with a 9 mm thickness of X3 CR tibial polyethylene insert.

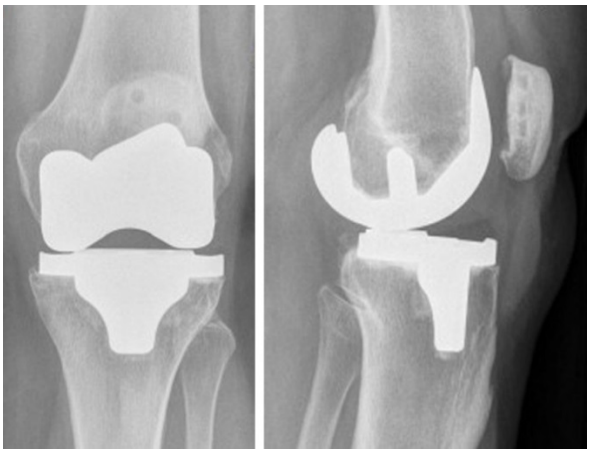

Figure 1. Anteroposterior and lateral radiographs of left knee show evidence of instability with anterior subluxation of tibia.

During the surgery, after the medial parapatellar arthrotomy and synovectomy were performed, a loose fragment of polyethylene was noted in the lateral gutter. This measured 5 mm X 15 mm (Figure 2). Subsequently, the polyethylene insert was removed. A fracture was seen at the posteromedial aspect of the polyethylene insert with severe wear posterolaterally (Figure 2). The femoral component was revised to a size 3 Stryker Triathlon total stabilizing femoral component with 12 mm x 50 mm cemented stem and 5 mm posterior augments both medially and laterally (Figure 3). A 9 mm thickness polyethylene tibial insert also was used to restore the joint line. The tibial component was retained. Intraoperative exam showed excellent range of motion and stability in both flexion and extension.

At the six-week follow-up, the patient reported excellent satisfaction with the TKA revision. Her pain was minimal, and she was able to ambulate unlimited distances without any assistive device. Physical examination of the left knew showed the range of motion of 0 to 130 degrees of flexion with neutral alignment.

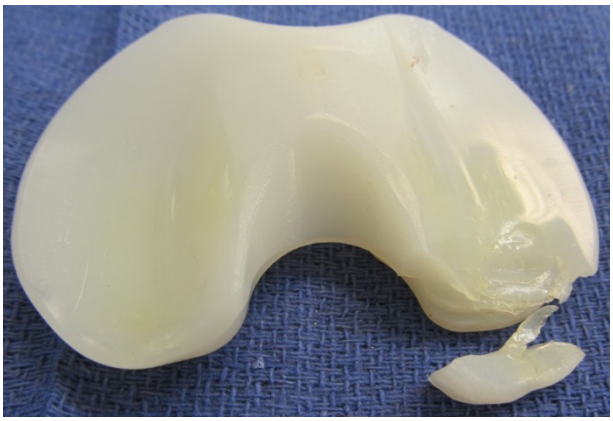

Figure 2. Polyethylene insert with significant posterior wear and posteromedial fracture.

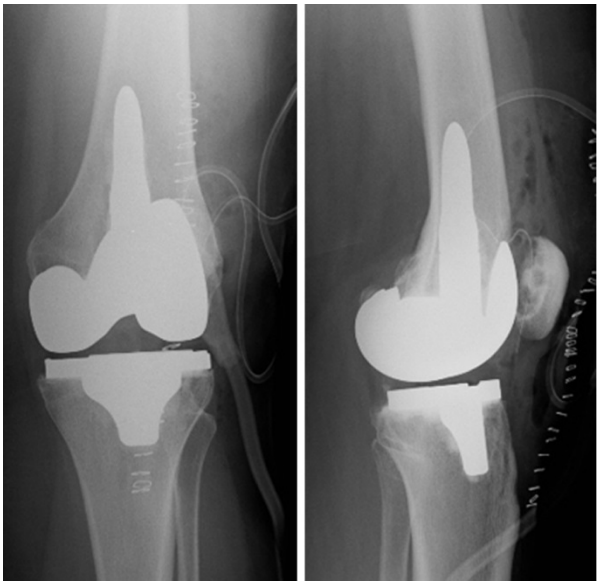

Figure 3. Immediate post-op anteroposterior and lateral radiographs following the revision of the left TKA.

In extension, the joint space opened up 1 mm medially and 1 mm laterally with valgus and varus stresses. Flexion and mid flexion demonstrated stable anterior and posterior drawer tests with firm endpoints. Her Knee Society score improved significantly to "excellent" according to the Knee Society clinical rating system[3] (score: 95) and functional outcome score also improved to "excellent" (score: 90). Her six-week post-operative radiographs are shown in Figure 4.

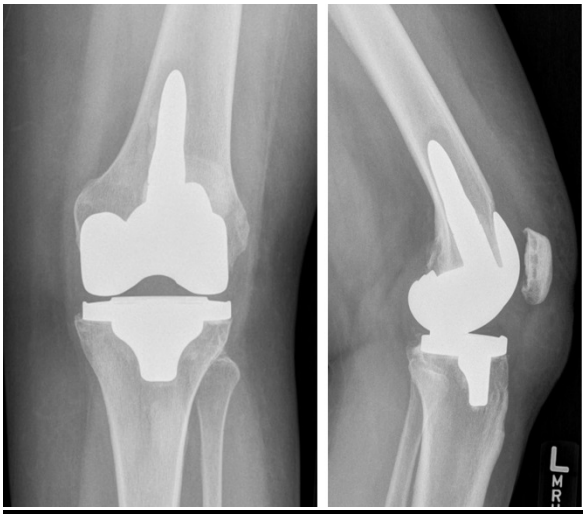

Figure 4. Six-week post-operative anteroposterior and lateral radiographs.

Discussion

In this case, the primary causes of accelerated posterior wear and fracture of the polyethylene tibial insert was suspected to be the improper balance of the soft tissues. To have an excellent outcome with CR TKA, the surgeon must appreciate the importance of proper PCL tensioning. A loose or lax PCL may defeat the purpose of the design as the knee may have instability with anterior and posterior displacement when the PCL is too loose.[4] Along with a flat design and little inbuilt constrain of CR polyethylene insert, anteroposterior instability can allow the femoral component to slide and rotate excessively on the tibia surface. This may increase the shear force and accelerate the polyethylene wear, leading to down sloping of the polyethylene surface. It further accentuates the tibiofemoral subluxation, surface degradation, and subsequent component failure. Alternatively, excessive tensioning of the PCL may lead to excessive femoral rollback. This may lead to increased translation of the articulation posteriorly, thus producing high stress and even increased wear on the posterior polyethylene insert.

Swany and Scott[5] presented three cases of catastrophic posterior wear of tibial polyethylene in CR TKA. In their discussion, the authors contributed the effect of excessive tensioning of PCL as the primary cause of the failures. This could be related to a variety of technical problems such as malrotating or placing a tibial tray too far anteriorly and under resecting the posterior femoral condyles, causing flexion gap tightness. In knees with severe valgus or varus deformities, the medial or lateral release to maintain a balanced gap may require placing a thicker polyethylene insert, thus causing tightness of PCL.

Apart from the technical problems described above, the catastrophic failure observed in this case might come from the inherent properties of the polyethylene. The X3 tibial polyethylene used in this case is a highly cross-linked UHMWPE. The gamma irradiation process, which was used to induce cross-linking, causes restriction of chain mobility in the amorphous region of the polymer and results in limited plasticity within the polyethylene. Decreased in plasticity improves wear resistance. Mechanical properties such as toughness, ductility and resistance to crack propagation, however, are reduced as the consequence.[6] The highly cross-linked UHMWPE is more brittle in fatigue compared to conventional UHMWPE.[7,8] The reduced fatigue strength of highly cross-linked UHMWPE could lead to mechanical failure in conditions that are associated with cyclic local tensile and sheer stresses as seen in total knee arthroplasty.

Another possible cause of the fracture of the polyethylene tibial insert could be influenced by the extent of oxidative embrittlement of the polyethylene resulting from gamma sterilization and subsequent shelf aging. Shelf aging of post-irradiated polyethylene decreases the principal strains of the polyethylene insert by 5% to 10%.[9] Aged polyethylene inserts also showed delamination after fewer than five million cycles.[10] Such decreases in abrasive wear

resistance due to oxidation when subjected to high contact stresses, particularly from an unstable TKA, can exceed the yield stress of the UHMWPE, leading to permanent deformation and subsequent catastrophic failure of the implant. The majority of polyethylene has a standard shelf-life of five years. Therefore, it is advisable to observe expiration dates strictly to reduce the risk of implant failure.

There are many factors to be considered regarding fracture of tibial polyethylene in total knee arthroplasty. Catastrophic failure due to extreme wear and heavy oxidation are quite uncommon with today's improved manufacturing and processing techniques. Nevertheless, such wear and fracture can occur when the knee has flexion instability as highlighted in our case. Accurate bony cuts, restoration of the mechanical axis of weight bearing, and accurate soft tissue balancing, therefore, remain the most important basic fundamentals for the achievement of a successful TKA.

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Keywords: total knee arthroplasty, posterior cruciate ligament, tibia, polyethylene

CLINICAL INQUIRY

Efficacy of Local Corticosteroid Injection for Carpal Tunnel Syndrome

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Clinical Question

In patients with carpal tunnel syndrome (CTS), do local corticosteroid injections provide symptomatic relief beyond one month?

Evidence-Based Answer

Local steroid injections provide symptomatic relief for greater than one month in patients with CTS (Strength of Recommendation (SOR) A) and up to 12 months (SOR B). Local steroid injection also decreases the need for surgery at one year for patients with non-severe CTS (SOR B).

Methodology

A search was conducted on relevant studies published since a 2007 Cochrane review[1] of local steroid injection for CTS. PubMed and the Cochrane Database were searched from January 2007 to November 2014. Search terms included steroid injection, corticosteroid injection, injection, carpal tunnel, and carpal tunnel syndrome. Thirty-eight relevant studies were found, and of these, eight relevant studies have been published since the Cochrane review and were included in this review. Participants included adults ages 18 and older diagnosed with CTS. CTS may have been defined using clinical or electrodiagnostic criteria. Patients with all severities of CTS were included.

Evidence Summary

Carpal tunnel syndrome is a condition frequently managed by primary care providers, and is the most common compressive neuropathy of the upper extremity.[2] Non-surgical management is the initial treatment strategy for most patients with mild to moderate CTS. Conservative treatment also may be used as a bridge for patients who wish to avoid or delay surgery. Multiple non-surgical options exist, including splinting, oral corticosteroids, and physical therapy. Conservative treatment options generally provide relief from two to 12 weeks.[3] Local corticosteroid injection is a simple, quick office procedure that may provide longer benefit. While a 2007 Cochrane review of local corticosteroid injection for CTS only found evidence for

symptomatic benefit up to one month after injection,[1] more recent evidence suggests benefit lasting from three months to one year. In addition, corticosteroid injection may delay the need for surgery.

Corticosteroid injection leads to symptomatic improvement in CTS for greater than one month. In a double-blinded, randomized trial, adults with carpal tunnel syndrome of moderate severity were treated with a single injection of either 80 mg of methylprednisolone, 40 mg methylprednisolone, or placebo.[1] Primary end points included change in CTS symptom score (range 1 through 5, 5 being most severe) at ten weeks and one year, and rate of surgery at one year. Patients who received 80 mg or 40 mg of methylprednisolone noted greater improvement in symptoms compared to those who received placebo (difference in change from baseline, -0.64 [95% CI, -1.06 to -0.21; $p = 0.003$] and -0.88 [95% CI, -1.30 to -0.46; $p < 0.001$], respectively). However, there was no difference at one year in symptom score.

In a single-blinded, randomized trial, 46 adults with CTS of moderate severity were treated with either a single ultrasound-guided or palpation-guided injection of 40 mg methylprednisolone.[2] Primary end points included change in CTS symptom and function scores (range 1 through 5, 5 being most severe) at 6 and 12 weeks. Patients experienced relief of symptoms and return of function at six weeks of follow up, with no difference between groups. At 12 weeks, the ultrasound-guided group had a greater reduction in symptoms, but there was no difference in function compared to palpation-guided group (mean symptom score 1.30 +/- 0.45 vs 1.67 +/- 0.73, $p < 0.001$; mean function score 1.36 +/- 0.49 vs 1.86 +/- 1.09, $p = 0.298$). It is theorized that an ultrasound-guided approach leads to more accurate placement of injection, and therefore possibly greater efficacy.

A randomized, placebo-controlled trial of 57 patients with CTS randomized 90 wrists to triamcinolone acetonide injection (40 mg), 1% procaine HCl injection, or normal saline injection.[3] A previous study found that local anesthetic injection alone can lead to improvement in carpal tunnel syndrome, leading the investigators to compare local anesthetic, local steroid, and saline injections.[4] Outcomes included both symptomatic scores and electrophysiologic measurements. At two and six months of follow-up after a single injection, treatment with triamcinolone injection showed significant improvement in electrophysiologic and symptomatic scores compared to placebo ($p < 0.05$). While no difference was found between the triamcinolone and procaine groups, there was a trend toward greater improvement from baseline in symptomatic and electrophysiologic scores for the steroid group versus procaine group. Lack of significance could be due to small sample size.

Corticosteroid injection leads to symptomatic improvement in CTS for up to 12 months. In a trial of 163 wrists with CTS, wrists were randomized to either surgical decompression or paramethasone acetonide 20 mg injection and followed for 24 months.[5] In the steroid group, an additional injection was allowed if symptoms had not resolved completely, and 84% of participants in the injection group received a second injection. At three months follow-up, symptoms were improved significantly in the injection group compared to the surgery group. At 6, 12 and 24 months, there was no difference in percentage of patients achieving at least a 50% improvement in symptom and functional scores. However, at 24 months, surgery was more effective than injection in those achieving 70% improvement in functional scores (60.0% vs 44.6% respectively; $p = 0.049$).

A trial of 69 patients with CTS in a general practice setting randomized participants to either triamcinolone acetonide 10 mg or normal saline injection and observed symptomatic and functional scores for 12 months.[6] Up to two steroid injections were allowed. Steroid injection

was significantly more effective than placebo for improvement of symptoms and function at 3, 6, and 12 months, with greater than 30% of patients reporting symptomatic improvement at 12 months.

In a prospective cohort study, 120 patients with CTS underwent up to three injections with 40 mg methylprednisolone and were followed for one year.[7] Forty-six patients (38%, 95% CI 30-47%) had significant improvement at one year.

In a retrospective cohort study by Visser et al.[8], 273 with patients with CTS were treated with up to two local injections of 40mg methylprednisolone. Symptomatic improvement was seen in 63% of patients at 6 months, 48% at 12 months, and 34% for more than 18 months.

Patients with moderate CTS who have a corticosteroid injection are less likely to undergo surgical decompression at one year. In the trial by Atroshi et al.[4] noted above, patients injected with 80 mg of methylprednisolone were less likely to have surgery at one year compared to placebo (odds ratio, 0.24 [CI, 0.06 to 0.95]; p = 0.042), and when time to surgery was analyzed, both the 80 mg and 40 mg methylprednisolone groups had a lower likelihood of surgery (hazard ratio, 0.46 [CI, 0.27 to 0.77; p = 0.003] and 0.57 [CI, 0.35 to 0.94; p = 0.026], respectively). In the retrospective cohort study noted above by Visser et al.[10], the median time until surgery was 15 months for mild, 5 months for moderate and 4.5 months for severe CTS ($p = 0.02$). Finally, a survivorship analysis of 824 patients receiving a single injection of 20mg methylprednisolone for CTS found that the rate of surgery was 14.5% after one year and 33.2% after five years.[9]

Recommendations from Others

The American Academy of Orthopaedic Surgeons (AAOS) recommends conservative treatment for patients with mild to moderate carpal tunnel syndrome before considering surgery, and considers local steroid injection to be effective treatment.[10] The American College of Occupational and Environmental Medicine gave a level A recommendation for carpal tunnel injections for subacute or chronic CTS.[11] Specific recommendations concerning length of treatment and number of injections are lacking, however in general, most wait 12 weeks before repeating intra-articular steroid injections.

Conclusion

Current evidence shows benefit from local steroid injection for greater than one month in patients with CTS. Benefit can last beyond 12 months and limit the need for surgery. Interestingly, studies that allowed for repeat injection tended to show greater efficacy in the long-term. Time to second injection in the above studies ranged from 1 week to 6 months, with most patients requiring injection before 6 months[7]. Further study is needed to compare frequency and timing of steroid injections for carpal tunnel syndrome.

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Keywords: carpal tunnel syndrome, glucocorticoids

Appendix
(Adapted from American Family Physician[*])

Strength of recommendation	***Basis for recommendation***
A	Consistent, good-quality patient-oriented evidence[**]
B	Inconsistent or limited-quality patient-oriented evidence[**]
C	Consensus, disease-oriented evidence[**] (usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention, or screening)

[*]http://www.aafp.org/dam/AAFP/documents/journals/afp/sortdef07.pdf

[**]Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, and quality of life.

Disease-oriented evidence measures intermediate, physiologic, or surrogate end points that may or may not reflect improvements in patient outcomes (e.g., blood pressure, blood chemistry, physiologic function, pathologic findings).