CME

A 20-year perspective on the Ottawa Ankle Rules: Are we still on solid footing?

Lawrence Herman, DMSc, MPA, PA-C, DFAAPA

ABSTRACT

The Ottawa Ankle Rules, finalized in 1995, are a clinical decision directive for the use of radiographs in patients with traumatic ankle and foot injuries. The researchers who developed the rules defined clinically insignificant ankle fractures as distal fibular or malleolar chip fractures of 3 mm or less. They concluded that at least one-third of all ankle and foot radiographs could be eliminated by using their rules, which have since been adopted as the standard of care in EDs. This article explores whether, after more than 20 years in use, the Ottawa Ankle Rules are still valid, and whether they should continue to be used or be replaced by a superior protocol.

Keywords: Ottawa Ankle Rules, ankle sprains, ankle fractures, foot fractures, ankle trauma, radiographs

Learning objectives

- Discuss the prevalence, cost, and impact on efficiencies of patients presenting with ankle injuries to the emergency department.
- Describe the historical development and validation of the Ottawa Ankle Rules, a landmark guideline developed to reduce unnecessary radiographs.
- Assess other potential guidelines concluding if the Ottawa Ankle Rules should continue to be utilized or be supplanted by a superior protocol.

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In 2008, studies estimated that 675,000 to 4 million ankle sprains were reported and treated in EDs in the United States.[1-3] The range of these data is broad and challenging to quantify and fully interpret, in part, because ankle and midfoot injuries frequently overlap and are blurred by reporting. Some data include only primary, isolated ankle injuries; others include ankle injuries even with other distracting trauma. In a study involving more than 3.1 million ankle sprains, males compared with females overall did not demonstrate a higher rate of ankle sprains.[4] However, males between the ages of 15 and 24 years had a substantially higher incidence rate of sprains than females of the same age range.[4] Subsequent studies have looked at average costs or costs of specific segments of the population only. Ankle sprains are estimated to represent 10% of ED visits, and are one of the most common musculoskeletal injuries seen in EDs in the United States, with direct medical costs of $2 billion.[5-7]

Until the development of the Ottawa Ankle Rules (OARs), first published in 1992, and eventually validated and widely implemented beginning in 1995, an estimated up to 98% of patients presenting emergently with an ankle sprain had imaging.[8] The vast majority (85%) of these radiographs were negative for fracture.[9-12] These avoidable radiographs resulted in increased use of resources, ultimately slowing throughput in the ED, lengthening wait times, increasing unnecessary radiation for patients, and increasing global healthcare costs. Stiell and colleagues found that patients who did not have imaging spent less time in the ED (54 versus 86.9 minutes; $P < .001$).[12] Subsequent studies have necessarily focused on revalidating the OARs as a primary outcome, and not assessing throughput times because it would be unethical to ignore the OARs as the current *de facto* standard of care for comparison. And in recent times,

Lawrence Herman is president of Palantir Healthcare, LLC, in Boiling Springs, S.C., an adjunct faculty member in the Doctoral of Medical Science program, part of the School of PA Medicine at the University of Lynchburg in Lynchburg, Va., and a speaker for NOVO Nordisk in the area of obesity treatment. The author has disclosed no other potential conflicts of interest, financial or otherwise.

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Key points

- The OARs are a clinical decision directive for the use of radiographs in patients with traumatic ankle and foot injuries.
- At least one-third of all ankle and foot radiographs could be eliminated by using the OARs in EDs.
- Other protocols and technologies may approach or equal the OARs, but none supplants them for simplicity, reproducibility, and reliability.

although some ED protocols allow clinicians to order radiographs in triage to, in part, speed flow through the department, this may obviate the purpose of the OARs, which were specifically developed to reduce unnecessary radiographs, ultimately reducing the associated global cost.

A BRIEF DESCRIPTION OF THE OARS

The decision to use or defer radiographic imaging in a patient presenting with foot and ankle injuries is guided by the OARs, the existing standard of care.[13] Briefly, these guidelines advise that ankle radiographs are required only if the patient has pain in the malleolar zone and any of the following three findings:

- Bone tenderness at the posterior edge or tip of the lateral malleolus (the lower 6 cm of the fibula)
- Bone tenderness at the posterior edge or tip of the medial malleolus (the lower 6 cm of the tibia)
- Inability to bear weight (as defined by at least four steps) immediately after the injury and in the ED. The inability to bear weight is a binary event and means precisely what is described. In the simplest of terms, if the patient can, or cannot, take four steps in the ED, regardless of limp or pain, the patient either has, or has not, met this specific requirement.

The OARs state that a foot radiographic series is required only if the patient has any pain in the midfoot zone and any of the following three findings:

- Bone tenderness at the base of the fifth metatarsal
- Bone tenderness at the navicular bone
- Inability to bear weight (as defined by at least four steps) immediately after the injury and in the ED.

Furthermore, clinical judgment should prevail over the rules if the patient:

- is intoxicated or uncooperative
- has other distracting painful injuries
- has diminished sensation in their legs
- has gross swelling that prevents palpation of the malleolar bone tenderness.

DEVELOPMENT AND VALIDATION

Table 1 summarizes the evaluation, validity, and effect of each of Stiell and colleagues' multiphase, methodologic studies over time as he validated his protocol in an escalating manner. Beginning by confirming inter- and intra-rater reliability, the rules were piloted by a small cohort of experienced emergency medicine physicians in two large university teaching hospitals. They then proceeded to determine if this guideline could be duplicated, transferred, and scaled by evaluating the implementation of the OARs to many physicians of varying experience and specialties in a variety of university and community hospital EDs. Collectively, 17,509 patients were enrolled in these four prospective studies.

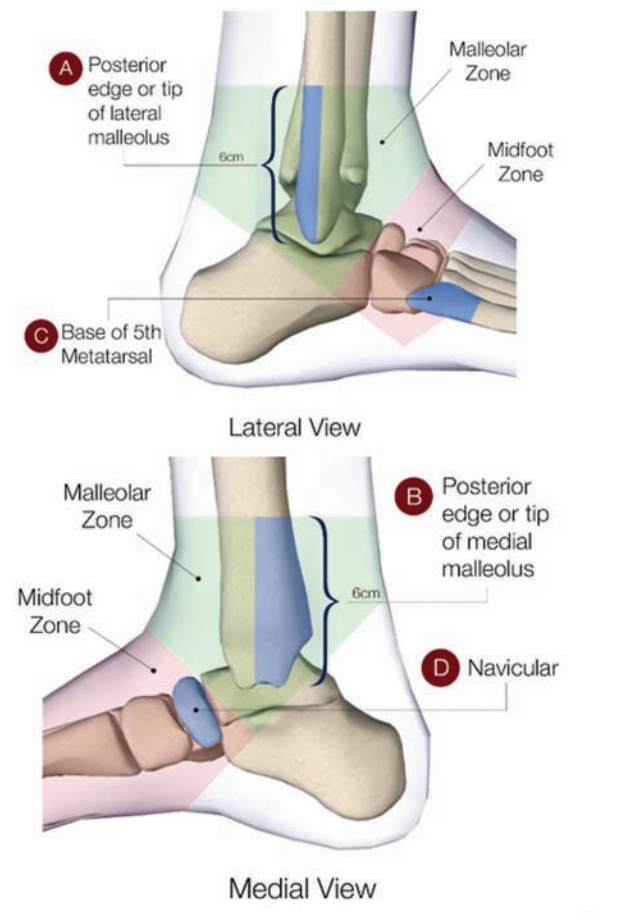

FIGURE 1. The Ottawa Ankle Rules

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META-ANALYSES OF THE OARS

Bachmann and colleagues, Jonckheer and colleagues, Barelds and colleagues, and others have performed comprehensive, systematic reviews confirming the validation of the OARs.[14-16] This research entailed assessing studies beginning immediately after implementation of the OARs in 1995 and until shortly before each review was published. Each supported the continued validation of the OARs. Some argued that the application of the OARs would be more extensive save for defensive medicine and the fear of lawsuits, patient expectations, and patient satisfaction surveys, all of which continue

Table 1. Studies evaluating the validity and effect of implementation of the OARs

Study description	Study setting and patients (N)	Statistical analysis results	Results	Conclusion
Pilot study evaluating acute ankle trauma, examining 32 clinical variables, followed by main stage study[9]	• Two university hospital EDs; staff emergency medicine physicians • Pilot stage: 155 adults; main stage, 750	Variables assessed for reliability and for association with significant fracture on ankle and foot radiographic series. Data analyzed by logistic regression, recursive partitioning techniques to develop decision rules.	All 70 significant malleolar fractures found in the 689 ankle radiographs performed identified among people using the specified criteria. The rule was 100% sensitive and 40.1% specific for detecting malleolar fractures. Similarly, all 32 significant midfoot fractures on the 230 foot radiographs performed were found using the specified criteria.	Highly sensitive decision rules have been developed and will now be validated.
Convenience study of patients with acute ankle injuries. Stage 1: validation of original rules. Stage 2: validation of refined rules[10]	• Two university hospital EDs; staff emergency medicine physicians • Stage 1: 1,032 of 1,130 eligible patients • Stage 2: 453 of 530 eligible patients	Variables assessed in both stages for reliability and for association with significant fracture on ankle and foot radiographic series. Data analyzed by logistic regression, recursive partitioning techniques to develop decision rules.	Refinement and validation have shown the OARs to be 100% sensitive for fractures and to be reliable.	Field trials will assess the feasibility of implementing these rules in clinical practice.
Assessment of the effect on clinical practice of implementing the OARs[11]	• EDs of a university (intervention) and community (control) hospital; staff emergency physicians • All 2,342 adults seen with acute ankle injuries over a 5-month period before and after the intervention	Relative reduction in ankle radiography by 28% at the intervention hospital but an increase by 2% at the control hospital ($P < .001$). Foot radiography was reduced by 14% at the intervention hospital but increased 13% at the control hospital ($P < .05$)	Implementation of the OARs led to a statistically significant decrease in use of ankle radiography, waiting times, and costs without patient dissatisfaction or missed fractures.	Future studies should address generalizability of these decision rules in a variety of hospital settings.
Assessment of the feasibility of introducing the OARs to a large number of physicians over a wide variety of hospitals over an extended period of time[12]	• 8 teaching and community hospitals in Canadian cities (pop. 10,000 to 3 million); emergency physicians, family physicians, and housestaff • All 12,777 adults (6,288 controls and 6,489 interventions) seen during two 12-month periods before and after intervention	Statistically significant reduction in the use of ankle radiography at all 8 hospitals: combined 82.8% control vs. 60.9% intervention ($P < .001$); for emergency physicians 82.1% vs. 61.6% ($P < .001$); and for housestaff 82.3% vs. 60.1% ($P < .001$).	Introduction of the OARs proved to be feasible in a large variety of hospital and community settings. Use of the rules over a prolonged period of time by many physicians of varying experience led to a decrease in ankle radiography, waiting times, and costs without an increased rate of missed fractures.	The multiphase methodologic approach used to develop and implement these rules may be applied to other clinical problems.

to drive the use of radiographs, conspiring against the purpose of the OARs.[1]

Bachman pooled data from 27 studies involving 15,581 patients to determine the clinical usefulness of the OARs; the review largely correlates with the original data compiled by Stiell and colleagues (**Table 2**).[14]

ALTERNATIVE PROTOCOLS

Researchers have proposed alternative decision-making protocols using different physical examinations or readily available devices such as tuning forks.[14] The Bernese ankle rules arguably have the most significant promise, claiming 100% sensitivity and a specificity of 91%, which

Table 2. Pooled indices of the clinical usefulness of the OARs for ankle, midfoot, and combined fractures

All figures are percentages

	Ankle	Midfoot	Combined ankle and midfoot
Sensitivity (95% CI)	98 (96.3, 99.3)	99 (97.3, 100)	96.4 (93.8, 98.6)
Specificity (interquartile range)	39.8 (27.9, 47.7)	37.8 (24.7, 70.1)	26.3 (19.4, 34.3)
Negative likelihood ratio (95% CI)	0.08 (0.03, 0.18)	0.08 (0.03, 0.2)	0.17 (0.1, 0.3)

would lead to a further reduction in unnecessary radiographs.[17] The physical examination is arguably more complicated, raising the specter of a possible decline in inter- and intra-rater reliability, scalability, and transferability. These proposed alternative protocols primarily are pilot studies and have yet to be validated to the extent that the OARs have been. These and other alternative approaches remain only possibilities.

Others have proposed the use of bedside ultrasound as a two-step imaging algorithm. The Sonographic Ottawa Foot and Ankle Rules (SOFAR) study is typical, recommending the use of ultrasound when the OAR examination yields a positive result, and proceeding to a radiograph only when ultrasound is positive or equivocal.[18] The SOFAR protocol has the potential of adding a step, further slowing throughput and increasing cost, while reducing the need for some radiographs. Ultrasound also is highly operator-dependent, and during this study, clinically significant fractures were missed and only found after radiograph.[18] A subsequent ultrasound was able to identify the fracture, but only if the sonographer knew the fracture location. Unlike radiography and CT scans, ultrasound is not helpful in planning repair. The choice of a two-step process may be fundamentally flawed.

Of particular note, in a study of 21 patients with traumatic injuries highly suspicious for ankle fracture based on OARs and negative radiographs, subsequent CT scans revealed a clinically significant fracture in 5 patients (23.8%), demonstrating the compelling positive predictive value of the OARs.[19]

MISSED CLINICALLY SIGNIFICANT FRACTURES

Sporadic case reports exist of clinically significant ankle and foot fractures that were missed, but it remains unclear whether the OARs were appropriately applied in these cases or if the studies strictly adhered to the definition of clinically significant fractures. One commonly reported miss in the literature involved a 31-year-old man who was parachuting, and deployed his smaller backup parachute after his main parachute failed.[20] Using the smaller backup parachute usually results in landing at a higher velocity; although the case report did not specify that the patient landed at a higher velocity, it was likely. Furthermore, rather than landing on the ground and then intentionally falling, as parachutists are trained to do to reduce injuries, the patient landed awkwardly on an aircraft wing. The case report states that the patient was weight-bearing immediately after the accident and again in the ED. Despite the unique mechanism of injury, the study author concluded that a radiograph was not warranted based on the OARs. Subsequently, the patient was diagnosed with a fracture of the dome of the talus. The case report does not indicate the length of delay in treatment and if the delay changed the treatment or prognosis. A single case report may skew subsequent literature. This case abstract has been downloaded 2,362 times since publication, with 4,248 downloads of the full article and 1,056 downloads of the PDF file associated with it.

In the single most robust meta-analysis that included other diagnostic examinations, including enhanced or modified physical examinations, patient histories, and supplemental tools such as tuning forks or point-of-care ultrasound, or ancillary rubrics requiring a calculation to assess the need for imaging, the authors could only conclude that those studies "had potential."[14] However, they were either more complicated to raise significant issues of widespread implementation, inter- and intra-rater reliability, or that they provided any added value has not yet been confirmed.

A single prospective, multicenter trial published in 1994 in New Zealand by Kelly and colleagues involved a much smaller cohort of 350 adults presenting with ankle trauma and argued against using the OARs.[21] The authors of this study reported a total of five missed fractures, including an unstable fracture of the ankle, and fractures of the talus, calcaneus, cuboid, and navicular bones. This small study resulted in an unacceptable sensitivity of 93% and specificity of 11%. The study appears to be the single prospective study that contradicts Stiell and colleagues' protocol. However, the study had several flaws. The researchers enrolled 350 patients, 2% of the number of patients enrolled by Stiell and colleagues. The protocol used a convenience sample. Enrollment of patients depended on staff remembering about the study.[21] Minor injuries with minimal signs and symptoms were excluded at the discretion of the treating physicians.[21] All grades of the staff, from first-year residents to experienced senior clinicians, were involved in the assessment of ankle injuries. The authors did not describe the training, if any, received by those involved in assessing patients for the study. Collectively, these differences are

substantially different enough when compared with the original OAR studies to call into suspicion the results.

Stiell and colleagues replied in 1995 with a letter to the editor detailing these and other points of contention.[22] Kelly responded to that letter by stating that the physicians were trained appropriately in the application of the OARs, including the fact that there were clear diagrams on the study data collection instrument.[22] However, Kelly pointed out that the data for the study were collected primarily by junior medical staff (first- and second-year residents) in 1993 and was well underway before the publication of Stiell and colleagues' refinement and validation studies published in 1994 and 1995. Despite the refinements made by Stiell and colleagues, Kelly and colleagues continued with their research and failed to point out these differences in their publication. Kelly proposed that these differences may be why their study differed in its conclusions.[22] This study was not a head-to-head comparison.

APPLICABILITY BEYOND EMERGENCY PHYSICIANS

The OARs are useful not only for emergency medicine trained physicians. Stiell and colleagues validated their use with physicians who were not trained in emergency medicine, including family practitioners and housestaff.[9-12] Speculatively, they would have included physician assistants (PAs) in their study had they been practicing in Canada at the time. After implementation in North America, the OARs have been validated across the world in studies performed first in France, Denmark, Switzerland, Taiwan, Iran, and elsewhere, and confirmed in subsequent studies.[23-27] Although it may be logical to use this same protocol in other settings, specifically urgent care and primary care, the OARs have only been tested and validated in EDs. However, they have been validated in studies using nonphysicians, most notably ED triage nurses.[28,29] Expanding OAR use broadly in ED triage is reasonable if trained nurses are used. Recently, additional studies examined applicability of the OARs in children, as well as applicability for specific subtypes of ankle fractures, although these applications are outside the scope of this article.

Despite infrequent outlier case reports of missed clinically significant fractures, and a single questionable small contradictory study, the remaining controlled trials, systematic reviews, and meta-analyses all concluded that:

- The original OARs are valid, with a sensitivity approaching 100% for detecting clinically significant fractures of the ankle and foot.
- Using the OARs can reduce unnecessary foot and ankle radiographs by up to 40%, shorten throughput in the ED, and reduced unnecessary costs.
- OARs are the standard of care and can—and should—continue to be used preferentially over other guideline-directed decision-making by EDs.
- OAR implementation likely should be expanded to include ED nurses and other settings such as family practice.

CONCLUSION

The OARs remain the *de facto* standard of care for clinical decision-making and for using or deferring radiographic imaging in patients with traumatic ankle and foot injuries. Other protocols and technologies may approach or equal the OARs, but none supplants them for simplicity, reproducibility, and reliability. Research supports the broad adoption beyond North America and to other practice settings such as urgent care and family practice. Research also supports the full adoption and implementation by other healthcare providers, including ED triage nurses. After more than 20 years, the OARs remain on solid footing. **JAAPA**

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