

A Study to Develop Clinical Decision Rules for the Use of Radiography in Acute Ankle Injuries

From the Departments of Emergency Medicine, Ottawa Civic Hospital* and Ottawa General Hospital;† and the Department of Epidemiology and Community Medicine, University of Ottawa,‡ Ottawa, Ontario, Canada.

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Ian G Stiehl, MD, FRCPC*
Gary H Greenberg, MD, FRCPC†
R Douglas McKnight, MD, FRCPC*
Rama C Nair, MStat, PhD‡
I McDowell, PhD‡
James R Worthington, MD, FRCPC*

Study objective: To develop decision rules that will predict fractures in patients with ankle injuries, thereby assisting clinicians in being more selective in their use of radiography.

Design: Prospective survey of emergency department patients over a five-month period.

Setting: Two university hospital EDs.

Participants: One hundred fifty-five adults in a pilot stage and 750 in the main study; all presented with acute blunt ankle injuries.

Interventions: Thirty-two standardized clinical variables were assessed and recorded on data sheets by staff emergency physicians before radiography.

Measurements: Variables were assessed for reliability by the kappa coefficient and for association with significant fracture on both ankle and foot radiographic series by univariate analysis. The data then were analyzed by logistic regression and recursive partitioning techniques to develop decision rules for predicting fractures in each radiographic series.

Main results: All 70 significant malleolar fractures found in the 689 ankle radiographic series performed were identified among people who had pain near the malleoli and were age 55 years or more, had localized bone tenderness of the posterior edge or tip of either malleolus, or were unable to bear weight both immediately after the injury and in the ED. This rule was 100% sensitive and 40.1% specific for detecting malleolar fractures and would allow a reduction of 36.0% of ankle radiographic series ordered. Similarly, all 32 significant midfoot fractures on the 230 foot radiographic series performed were found among patients with pain in the midfoot and bone tenderness at the base of the fifth metatarsal, the cuboid, or the navicular.

Conclusion: Highly sensitive decision rules have been developed and will now be validated; these may permit clinicians to confidently reduce the number of radiographs ordered in patients with ankle injuries.

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INTRODUCTION

Radiographic assessment of acute ankle injuries is performed primarily to exclude the presence of a clinically significant fracture that may alter patient management. The incidence of significant fracture is less than 15% among patients commonly presenting to emergency departments with an acute ankle injury.¹⁻⁶ Despite this low proportion of fractures, the vast majority of such patients are routinely referred for a radiographic examination.^{4,7} An ankle radiographic series is typically the second most commonly performed musculoskeletal examination in the ED, after a cervical-spine series.⁸

This conservative approach to patient management by emergency physicians leads to many unnecessary radiologic studies. This results in increased radiation exposure and waiting times for the patient as well as additional costs to the health care system.⁹⁻¹¹ Based on the experience of the province of Ontario, we estimate that some 6 million ankle radiographs are performed annually in Canada and the United States. The annual cost in Ontario for a high-volume procedure such as ankle radiography exceeds that of a low-volume but high-technology procedure such as coronary catheterization (Ontario Ministry of Health, March 1991). Even a modest reduction in the proportion of ankle injury patients having a radiograph would lead to large savings in health care dollars.

There are no widely accepted guidelines for the use of radiography in ankle injuries equal to those successfully introduced for skull radiography.^{12,13} The few studies that have addressed this issue provide contradictory results and have a number of methodological shortcomings in terms of reliability, validity, sensibility, and effectiveness.¹⁴ Lacking recognized guidelines, emergency physicians tend to follow the expedient route of ordering a radiography for most ankle injury patients.¹⁵ This conservative practice is fostered by the nature of emergency medicine: high case volumes with brief physician-patient contact and very little follow-up.¹⁶ Patients appear to expect a radiograph, and physicians fear lawsuits should they miss a fracture.¹⁷

Emergency medicine needs sensible guidelines for the use of radiography in extremity trauma. Emergency physicians and patients are unlikely to be satisfied with a recommendation that correctly classifies most patients yet misses a few fractures.¹⁸ Therefore, our objective in this study was to develop decision rules that were 100% sensitive for detecting clinically significant fractures on each of the ankle and foot radiographic series often ordered for ankle injury patients. Subsequent studies will validate the decision rules and then assess their effectiveness in altering clinical practice.

MATERIALS AND METHODS

Patient Population The study was conducted in the EDs of the Ottawa Civic and Ottawa General Hospitals, tertiary care institutions with a combined annual volume of 120,000 patients. All patients presenting with acute blunt injuries of the ankle (eg, twisting injuries, falls from a height, direct blows, and motor vehicle accidents) were eligible. "Ankle" was broadly defined to include the area generally involved in common twisting injuries and was subdivided into two zones corresponding to the areas that generally require assessment by a standard ankle radiographic series (the malleolar area) or a standard foot radiographic series (the midfoot). We defined the zones to include the following anatomic structures and their overlying soft tissues: 1) the malleolar area, distal 6 cm of tibia, distal 6 cm of fibula, and talus; and 2) the midfoot, navicular, cuboid, cuneiforms, anterior process of the calcaneus, and base of the fifth metatarsal. The body and the tuberosities of the calcaneus were not included in this definition.^{19,20}

Patients were not eligible for the study if they were less than 18 years old, were pregnant, had isolated injuries of the skin (superficial lacerations, abrasions, or burns), had been referred from outside the hospital with radiographs, had suffered their injury more than ten days earlier, or were returning for reassessment of the same ankle injury. This study was approved by our institutional research ethics committee.

Data Collection Data collection forms were designed and then evaluated and refined during a one-month pilot period that involved 155 patients before the actual study. The clinical variables were chosen for the study by the investigators based on their clinical experience and on previous studies. All eligible patients were entered into the main study when one of the 21 designated assessor physicians was on duty. The assessor physicians were all full-time, certified staff emergency physicians who had been instructed by the investigators on a standardized method for collecting the clinical data. Information on 32 clinical variables, including ten specific points of bone tenderness and the ability to bear weight for at least four steps, was recorded on the study data form by the assessing physician. The assessor physician also estimated the probability that the patient had a significant fracture and then ordered a standard ankle radiographic series if the patient had any pain or tenderness in the malleolar zone and a standard foot radiographic series if there was any pain or tenderness in the midfoot zone. To determine the interobserver reliability of the physical findings, 100 of the patients were examined by a second emergency physician who was blinded to the results of the first assessment.

Definition of Outcomes The ankle and foot radiographic series were interpreted by a qualified radiologist who was blinded to the contents of the data collection sheets. He classified the results as follows: ►

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1) no fracture or insignificant fracture (defined as avulsions of 3 mm or less across) or 2) clinically significant fracture (defined as all other fractures). This definition of fracture was agreed on by members of the orthopedic departments and reflects clinical management in that avulsion fractures of 3 mm or less are not usually treated with plaster immobilization in our institutions. To be conservative and consistent with the 3 mm definition, we classified fractures of the base of the fifth metatarsal larger than 3 mm as significant, even though these are rarely treated with a cast.

Data Analysis The clinical variables were assessed separately for association with significant fractures in the ankle and the foot radiographic series by univariate techniques, including the χ^2 test for nominal data and the unpaired *t* test for continuous data. The reliability of each variable was measured by calculating the kappa (κ) coefficient of interobserver agreement.^{21,22} Those variables found to be both reliable ($\kappa > 0.6$) and strongly associated with a significant fracture ($P < .05$) were analyzed by multivariate techniques. Both forward stepwise logistic regression and χ^2 recursive partitioning methods were used to develop models of the best combination of predictor variables for ankle and foot radiographic series separately.²³⁻²⁶ The primary

objective of the model building was to develop a rule that was 100% sensitive for detecting significant fractures while achieving the maximum possible specificity.

RESULTS

Seven hundred fifty ankle injury patients were seen from July through December 1990 and were found to have 70 (9.3%) significant malleolar fractures and 32 (4.3%) significant midfoot fractures (Table 1). The mean number of radiographic series per patient was 1.2, and the yield of the radiographs for significant fracture was 10.2% of the 689 ankle series and 13.9% of the 230 foot series ordered (Table 2).

We found that these experienced physician assessors fared poorly in estimating the probability of significant fracture. The physicians would have missed 29% of fractures on the ankle series if the cutoff point for ordering a radiograph had been their own predicted probability of 50% for a fracture. Only with the threshold reduced to less than 10% probability of fracture would they have performed reasonably well, although even then they would have missed two of the fractures.

The univariate and multivariate analyses were performed for the two major outcomes—significant malleolar fracture on ankle series and significant midfoot fracture on foot series—to derive a rule for each radiographic series.

Derivation of Ankle Radiographic Series Rule Seventeen variables were significantly associated with malleolar fractures on the ankle radiographic series (Table 3). Two continuous variables based on the history, age, and time from injury were dichotomized at various cutoff points and assessed for significance by χ^2 analysis. The cutoff points yielding the significant associations with the lowest *P* values were included in the multivariate analysis, as were two other variables based on history, ability to bear weight immediately, and ability to continue current activity.

Variables based on physical examination were used for multivariate analysis if significantly associated with ankle radiographic series fracture and if their interobserver agreement was high ($\kappa > 0.6$). Although statistically significant, the following variables did not show sufficient interobserver agreement to be included in the model: ecchymosis, range ▶

Table 1.
Characteristics of the 750 patients in the study

Characteristic	No.	%
Mean Age (years \pm SD)	35.1 \pm 14.9	
Range	18-92	
Male	389	51.9
Mechanism		
Twisting	627	83.9
Direct blow	52	7.0
Fall from a height	35	4.7
Motor vehicle accident	15	2.0
Other	18	2.4
Clinically Significant Fractures	102	13.6
Malleolar region	70	9.3
Lateral malleolus	41	58.6
Medial malleolus	7	10.0
Posterior malleolus	2	2.9
Bimalleolar	12	7.1
Trimalleolar	8	11.4
Talus	0	
Midfoot	32	4.3
Base of fifth metatarsal	28	87.5
Navicular	2	6.3
Anterior process calcaneus	2	6.3
Cuboid	0	
Cuneiforms	0	
Clinically Insignificant Fractures*	43	5.7
Lateral malleolus	18	41.9
Talus	13	30.2
Cuboid	7	16.3
Navicular	5	11.6
Anterior process calcaneus	5	11.6
Medial malleolus	1	2.3

* Patients may have had fractures in more than one location.

Table 2.
Use of radiography in the 750 study patients

Radiography Factors	No. of Patients	%
Patients Referred for Radiography		
Ankle series only	520	69.3
Foot series only	61	8.1
Ankle and foot series	169	22.5
Total Radiographic Series Performed	919	
Yield of Radiographs for Significant Fracture		
Both series combined (919)	102	11.1
Ankle series (689)	70	10.2
Foot series (230)	32	13.9

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of motion, anterior drawer sign, swelling of either medial malleolus or anterior aspect ankle, and bone tenderness of proximal fibula, inferior tip lateral malleolus, anterior edge medial malleolus, or posterior edge medial malleolus.

Several combination of variables were found to have acceptable reliability and be highly associated with fractures and were therefore entered for further analysis: inability to bear weight both immediately and in the ED, swelling of lateral malleolus within the first six hours, bone tenderness of either inferior tip or posterior edge of lateral malleolus, and bone tenderness of either inferior tip or posterior edge of medial malleolus.

Logistic regression analysis yielded a model that correctly classified 92% of patients yet would have missed 68% of the fractures on the ankle radiographic series. The sensitivity could have been improved to 100% only by reducing the

Table 3.
Univariate correlates of significant fracture on ankle radiographic series

Variable	% Significant Fracture (70)	% Other Cases (619)
History		
Mean age (yr ± SD)	43.1 ± 18.4	34.1 ± 14.1*
Female	61	46
Mean time from injury (hr ± SD)	9.1 ± 13.3	20.7 ± 33.7*
"Cracking" sound heard	29	24
Twisting mechanism	19	15
Ankle fracture previous 12 months	2	1
Unable to bear weight immediately	62	21†
Able to continue current activity	3	25‡
General Findings		
Ecchymosis	32	22
Range of motion moderately limited	73	37‡
Anterior drawer sign	14	2*
Unable to bear weight in ED (four steps)	80	30†
Moderate to Marked Swelling		
Medial malleolus	40	10*
Lateral malleolus	84	42*
Anterior talofibular ligament	56	44
Anterior aspect of ankle	29	11
Soft-Tissue Tenderness		
Anterior talofibular ligament	69	80
Calcaneofibular ligament	19	17
Deltoid ligament	25	20
Anterior aspect ankle	31	26
Bone Tenderness		
Proximal fibula	7	2‡
Lateral malleolus		
Anterior edge	90	50*
Inferior tip	62	39‡
Posterior edge	69	26‡
Medial malleolus		
Anterior edge	32	7*
Inferior tip	38	13*
Posterior edge	34	5*

* $P < .001$ by t -test.

† $P < .0001$.

‡ $P < .001$.

§ $P < .05$ by continuity-adjusted χ^2 .

threshold for ordering a radiograph to a 1.5% predicted probability of fracture. Such a model would have a potential savings of only 26% of the radiography and was thought to be unnecessarily complex.

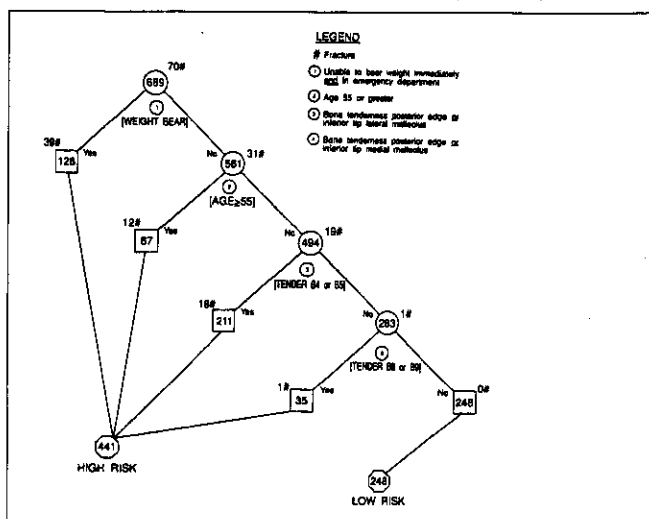
χ^2 recursive partitioning techniques yielded the final model, a rule that was 100% sensitive with 40% specificity (Figure 1). This model represents one of many possible solutions to the problem of achieving 100% sensitivity but was chosen because it provided the highest specificity with the fewest variables. The final variables in this model were 1) age of 55 years or more, 2) inability to bear weight both immediately and for four steps in the ED, 3) bone tenderness at posterior edge (distal 6 cm) or inferior tip of the lateral malleolus, and 4) bone tenderness at posterior edge or inferior tip of the medial malleolus (Figure 2).

The κ value for a combination of the physical examination variables in the rule (bone tenderness and ability to bear weight in the ED) was calculated to be 0.72 (95% confidence intervals, 0.57 to 0.88), suggesting substantial agreement. We have assumed that the interobserver agreement of historical items such as age and ability to bear weight immediately would be high.

Derivation of Foot Radiographic Series Rule

A similar process determined the best predictor variables for midfoot fracture on a foot radiographic series (Table 4). Neither age nor ability to bear weight was significantly associated with fractures, the majority of which were at the base of the fifth metatarsal. The only variable that had high interobserver agreement ($\kappa > 0.6$) and was significantly associated with fracture was bone tenderness at the base of the fifth metatarsal. To achieve a 100% sensitive rule, the acceptable limit for reliability of variables was reduced to a κ value of 0.5. Recursive partitioning then arrived at a model that included bone tenderness at any one of three areas in the

Figure 1.
 χ^2 recursive partitioning of 689 cases for ankle radiographic series fracture.



midfoot: the base of the fifth metatarsal, the cuboid, or the navicular (Figure 3).

The classification performance of the two decision rules is shown (Table 5) and demonstrates that none of the 102 significant fractures would have been missed. Furthermore, the rules would have permitted saving 36.0% of the ankle series and 21.3% of the foot series for an overall savings of 32.3% of the radiographic series ordered. Application of the rules would reduce the number of patients having both an ankle and a foot series from 22.5% to 7.5%.

DISCUSSION

These clinical decision rules have been derived from what was, to our knowledge, the largest prospective study of ankle injury patients. This was the first study to evaluate the interobserver reliability of clinical variables and the first to offer guidelines that would be 100% sensitive and therefore have 100% negative predictive value (ie, no patient negative for the rule would have a fracture). These decision rules have the potential to permit clinicians to confidently forego one third of the ankle and foot radiographic series currently being ordered for acute ankle injury patients. This could reduce costs substantially without increasing the likelihood of missing clinically significant fractures.

We believe that our methodology adhered to the principles and standards for clinical prediction rules as espoused by Wasson et al and Feinstein.^{27,28} First, we assessed the reliability or consistency of our clinical criteria by measuring the interobserver agreement and considering only those variables with sufficiently high κ values. No previous study has assessed the interobserver agreement of findings in ankle injury patients.

Second, we carefully controlled our study to optimize the validity of our findings. The demographic and clinical diversity of our patients suggests that the rules will be generalizable to most adults, regardless of age or mechanism of

injury. The predictor variables were standardized and collected in a consistent, prospective fashion by a selected group of experienced physicians after a pilot stage. The outcomes were clearly defined at the outset and independently assessed. In addition, the mathematical techniques were described, and the classification rates of the decision rules were given. Methodological problems in previous studies have diminished the validity of their findings: small sample size of fewer than 250 patients with ankle injuries,^{1,2,29-35} retrospective assessment,^{5,32} lack of well-standardized collection techniques,^{1,29-32,36} lack of clearly defined outcome,^{1,2,6,7,30,31,34} and inadequate mathematical techniques or absence of classification rates.^{1,3,5,29-32}

Third, we attempted to develop guidelines that are sensible for clinicians. This required a very high sensitivity to fractures (ie, no false-negatives), easy applicability at the bedside, and simplicity. No other guidelines for ankle injuries have offered 100% sensitivity (100% negative predictive value) for significant fractures. One guideline suggested variables that did not make clinical sense, such as the posterior tibial pulse, the Achilles tendon, and the color of the ankle.⁶ Some guidelines require the computation of scores and referral to tables of probabilities or use of handheld computers.^{6,35} Others require the measurement of swelling with a tape or callipers.^{3,34} We believed that busy emergency physicians were unlikely to embrace any protocol that went beyond a "bare hands" approach.

Finally, our study remains incomplete on two counts: prospective validation and demonstration of effectiveness. No clinical decision rule can be considered valid until it has been prospectively assessed because many guidelines do not perform as well when tested on a new group of patients.³⁷ We have started a validation study of our guidelines and will report the results when completed. Others may choose to do the same in different settings. No other ankle guidelines have been validated prospectively with the exception of

Figure 2. Clinical decision rule for ankle radiographic series in ankle injury series.

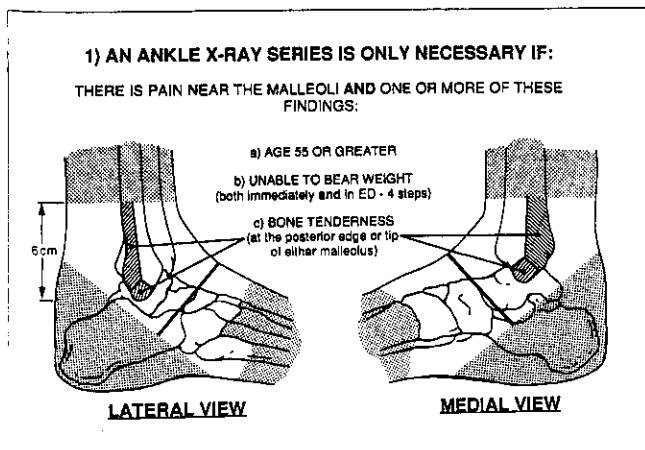
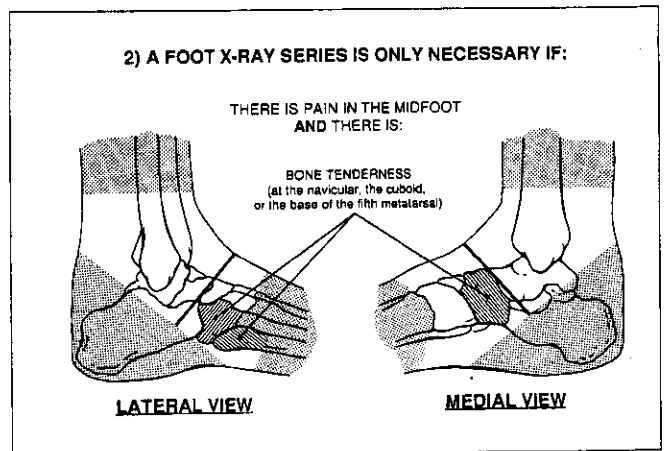


Figure 3. Clinical decision rule for foot radiographic series in ankle injury patients.



two studies on the general use of radiography in extremity injuries.^{7,35}

Furthermore, one cannot be satisfied that a clinical decision is effective until an impact on patient care has been demonstrated. This has been attempted in only one extremity injury study.⁷ Should our rules stand up to prospective validation, we propose to then study their ability to actually change physician radiograph-ordering behavior.

We believe that the final variables in our clinical decision rules will be easy for physicians to remember and apply. The age guideline for ordering an ankle radiographic series is very clear and biologically plausible. Thirty-four percent of the malleolar fractures in the ankle series were seen in people aged 55 years or more, a group that made up only 13% of the total patient population. The increased frequency of malleolar fractures above age 55 is probably due to osteoporosis. On the other hand, there was no age association for fractures of the midfoot.

Judging ability to bear weight for four steps in the ED was shown to be very reliable in our study but is still subject to interpretation and to the reluctance to ask patients to attempt to walk. Many patients were in wheelchairs but were able to bear weight for the requested four steps with little difficulty and with minimal coaxing by the physicians. All such patients had indicated that they had already borne weight on the way to the ED or that they thought they were capable of doing so. We also found that many patients with sprains had walked initially but had increased difficulty the next day, often associated with increased swelling. Therefore, ability to bear weight was a more specific predictor of ankle radiographic series fracture when one took into account the patient's difficulty both initially and at the time of assessment. There was no association between ability to bear weight and midfoot fractures.

As expected, localized bone tenderness was found to be a good predictor of fracture but less reliable than age or ability to bear weight. Soft-tissue tenderness and swelling frequently make bone tenderness difficult to assess; this is probably the major reason that most patients with ankle injuries are referred for radiography. We believe that reliance on tender-

ness of the posterior edge (distal 6 cm) and inferior tip of the lateral malleolus will help to avoid confusion with the tenderness of the anterior talofibular ligament that is so often injured in ankle sprains. Bone tenderness of the medial malleolus is relatively uncommon but, if present, indicates that the patient is at high risk for a fracture.

Soft-tissue swelling is highly correlated with fractures, a finding frequently reported by radiologists.^{10,32} We found, however, that swelling was also influenced by time from injury and had less interobserver agreement than bone tenderness. Therefore, we believe that our decision rules will be more reliable without the inclusion of swelling.

Clinicians may be concerned that our ankle series rule was derived from a patient set that did not include any significant fractures of the talus. Clearly, such fractures are relatively uncommon (none in 905 ankle injury patients in the pilot stage or main study). Several talar fractures have been seen by the authors since the completion of the study and would have been detected by the rule. Our validation study will further assess this issue.

Physician judgment and common sense should always take precedence over clinical guidelines, which are not meant to be inflexible or dogmatic. For example, patients with gross deformity clearly need a radiograph without the need for invoking a decision rule. Caution must be used in interpreting physical findings of patients with altered mental status due to head trauma or drug intoxication.

We could have devised an ankle series decision rule with much greater potential savings of radiographs. For example, dropping the inferior tip of the lateral malleolus would have improved the potential savings to 49.8% and improved the specificity to 55.7%. This, however, would have also missed three small fractures and reduced the sensitivity to 95.7%, which we believe would be unacceptable to physicians in the current context of North American medical practice. However, it may be that society will come to accept the small price of occasional missed fractures (which would probably have led to very little morbidity for the patients) to improve the efficiency and cost-effectiveness of the medical system. ▶

Table 4.
Univariate correlates of significant midfoot fracture on footradiography

Variable	% Significant Fracture (32)	% Other Cases (198)
Mean age (years ±SD)	36.7 ±14.5	40.1 ±16.9
Unable to bear weight immediately	29	18
Ecchymosis	55	27*
Bone tenderness		
Base of fifth metatarsal	94	34†
Cuboid	47	58
Navicular	3	10
Any one of above	100	75*
Unable to bear weight in ED	38	33

* $P < .01$.
† $P < .0001$, by continuity adjusted χ^2 .

Table 5.
Classification performance of clinical decision rules for ankle and foot radiographic series

Predicted Fracture	Ankle Series Actual Fracture		Foot Series Actual Fracture	
	Yes	No	Yes	No
Yes	70	371	32	149
No	0	248	0	49
Total	689		230	
Sensitivity	100%		100%	
Specificity	40.1%		24.7%	
Negative predictive value	100%		100%	
Positive predictive value	15.9%		17.7%	
Potential radiographic savings	36.0%		21.3%	

CONCLUSION

This study has successfully achieved our goal of developing 100% sensitive decision rules for the use of radiography in patients with acute ankle injuries. Our data indicate that patients with pain near the malleoli require an ankle radiographic series only if they have one or more these criteria: age of 55 years or more, inability to bear weight both immediately and in the ED, or bone tenderness at the posterior edge or inferior tip of either malleolus. Similarly, ankle injury patients with pain in the midfoot require a foot radiographic series only if they have bone tenderness at the base of the fifth metatarsal, the cuboid, or the navicular.

These clinical decision rules have the potential to reduce the use of radiography by one third in adult ankle injury patients. The rules, however, must now be validated prospectively, ideally in several different settings. ■

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Address for correspondence: Ian G Stiell, MD, FRCPC, Department of Emergency Medicine, Ottawa Civic Hospital, 1053 Carling Avenue, Ottawa, Ontario, Canada K1Y 4E9.