Decision Rules for the Use of Radiography in Acute Ankle Injuries

Refinement and Prospective Validation

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Objective.—To validate and refine previously derived clinical decision rules that aid the efficient use of radiography in acute ankle injuries.

Design.—Survey prospectively administered in two stages: validation and refinement of the original rules (first stage) and validation of the refined rules (second stage).

Setting.—Emergency departments of two university hospitals.

Patients.—Convenience sample of adults with acute ankle injuries: 1032 of 1130 eligible patients in the first stage and 435 of 530 eligible patients in the second stage.

Main Outcome Measures.—Attending emergency physicians assessed each patient for standardized clinical variables and classified the need for radiography according to the original (first stage) and the refined (second stage) decision rules. The decision rules were assessed for their ability to correctly identify the criterion standard of fractures on ankle and foot radiographic series. The original decision rules were refined by univariate and recursive partitioning analyses.

Main Results.—In the first stage, the original decision rules found to have sensitivities of 1.0 (95% confidence interval [CI], 0.97 to 1.0) for detecting 121 malleolar zone fractures, and 0.98 (95% CI, 0.88 to 1.0) for detecting 49 midfoot zone fractures. For interpretation of the rules in 116 patients, \( \kappa \) values were 0.56 for the ankle series rule and 0.69 for the foot series rule. Recursive partitioning of 20 predictor variables yielded refined decision rules for ankle and foot radiographic series. In the second stage, the refined rules proved to have sensitivities of 1.0 (95% CI, 0.93 to 1.0) for 50 malleolar zone fractures, and 1.0 (95% CI, 0.83 to 1.0) for 19 midfoot zone fractures. The potential reduction in radiography is estimated to be 34% for the ankle series and 30% for the foot series. The probability of fracture, if the corresponding decision rule were "negative," is estimated to be 0% (95% CI, 0% to 0.8%) in the ankle series, and 0% (95% CI, 0% to 0.4%) in the foot series.

Conclusion.—Refinement and validation have shown the Ottawa ankle rules to be 100% sensitive for fractures, to be reliable, and to have the potential to allow physicians to safely reduce the number of radiographs ordered in patients with ankle injuries by one third. Field trials will assess the feasibility of implementing these rules into clinical practice.

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There are no widely accepted guidelines for the use of radiography in ankle injuries equivalent to those successfully introduced for skull radiography. Acute ankle injuries are one of the most common presenting complaints seen in emergency departments, and patients with this problem are almost always referred for radiography to exclude a treatable fracture. Because such fractures are typically present in less than 15% of cases, the yield of emergency department ankle and foot radiographic series is relatively low. The ankle radiographic series, along with the cervical spine series, is one of the two most commonly ordered musculoskeletal radiology examinations in emergency departments. We estimate, based on the experience in Ontario, that more than 5 million ankle radiographic series are ordered annually in Canada and the United States. Discriminating guidelines for the use of ankle radiography may reduce waiting times for patients and may allow the money spent for some of these radiographs with normal findings to be used elsewhere in the health care system.

We have previously derived clinical decision rules for the use of radiography in acute ankle injuries in a study involving 750 adult patients, 100 of whom were examined independently by two physicians. Thirty-two clinical variables were systematically assessed for their reliability by the \( \kappa \) coefficient and for association with significant fractures seen on ankle and foot radiographic series. Two decision rules were derived by multivariate recursive partitioning techniques and would have identified 100% of the 70 malleolar and 32 midfoot frac-
tures seen in the study patients. The first rule stated that an ankle radiographic series was only necessary if the patient had pain near the malleoli and one or more of these findings: (1) age 55 years or greater, (2) inability to bear weight immediately after the injury and for four steps in the emergency department, or (3) bone tenderness at the posterior edge or tip of either malleolus. The second rule stated that a foot radiographic series was only necessary if the patient had pain in the midfoot and bone tenderness at the navicular bone, the cuboid, or the base of the fifth metatarsal.

The objective of the current study was to prospectively validate and, if possible, refine these original decision rules. Prediction rules and guidelines frequently do not perform as well on a new set of patients as on the original set from which they were derived.13 Our goal was to demonstrate that the decision rules had a sensitivity of 1.0 for identifying significant fractures of the malleolus and midfoot, with the highest possible specificity.

METHODS

Patient Population

This study was conducted in two stages in the emergency departments of two teaching institutions affiliated with the University of Ottawa (Ontario): Ottawa Civic Hospital and Ottawa General Hospital. During the first stage (February to August 1991), the original decision rules16 for the use of radiography in acute ankle injuries were prospectively validated and then refined. During the second stage (September 1991 to January 1992), the refined decision rules were prospectively validated in a new set of patients.

In both stages, we included adult patients who presented to the emergency departments with pain or tenderness secondary to blunt ankle trauma due to any mechanism of injury. "Ankle" was broadly defined to include the area usually involved in common twisting injuries and was subdivided into the malleolar and the midfoot zones. These zones correspond to the areas that generally require assessment by a standard ankle radiographic series (malleolar zone) or foot radiographic series (midfoot zone). We defined the zones to include the following structures and their overlying soft tissues: (1) malleolar zone: distal 6 cm of tibia and fibula and talus; and (2) midfoot zone: navicular bone, cuboid, cuneiforms, anterior process of calcaneus, and base of the fifth metatarsal. Not included were the body and tuberosities of the calcaneus.18 We excluded patients who were under 18 years of age, were pregnant, had isolated injuries of the skin, were referred from outside the hospital with radiographs, whose ankle injury occurred more than 10 days previously, or who had returned for reassessment of the same injury. This study was approved, without the need for informed consent, by the institutional research ethics committee.

Data Collection

Patients were assessed for 15 clinical variables in the first stage and six in the second stage. Variables clearly shown not to be useful in the original study16 (mechanism of injury, "cracking" sound, ecchymosis, range of motion, drawer sign, soft-tissue tenderness, and proximal fibular tenderness) were not included. Eligible patients were entered into the study when one of 21 designated staff emergency physicians was on duty. These assessor physicians were certified in emergency medicine by either the Royal College of Physicians and Surgeons or the College of Family Physicians of Canada and had participated in the original derivation of the decision rules. The physicians evaluated each patient for the clinical variables, interpreted the decision rules, and recorded their findings on a data collection sheet. All patients were then referred for radiography: a standard ankle series if they had any pain or tenderness in the malleolar zone, and a standard foot series if they had any pain or tenderness in the midfoot zone. To determine the interobserver reliability of the physical findings, the patients were examined, where feasible, by a second emergency physician who was blinded to the results of the first assessment.

The criterion standard that the decision rules were designed to identify were clinically significant fractures seen in the ankle or foot radiographic series. These radiographic series were interpreted by qualified radiologists who were blinded to the content of the data collection sheets. We defined clinically significant fractures as bone fragments greater than 3 mm in breadth. This definition was agreed on by members of the emergency and orthopedics departments and reflects clinical management in that malleolar or midfoot avulsion fractures of 3 mm or less are not treated with plaster immobilization in our institutions.

Statistical Analysis and Model Refinement

The classification performance of the decision rules for identifying clinically significant fractures was assessed by calculating sensitivity and specificity with 95% confidence intervals (CIs).19 Given the binary predictive nature of the decision rules, no attempt was made to construct receiver operating character-

istic curves.20 The accuracy and reliability of the physicians' interpretation of the rules was measured, respectively, by the percentage agreement with the actual rule (as interpreted by the investigators) and the κ coefficient of interobserver agreement.18

Data collected in the first stage were further analyzed in order to refine the decision rules toward the objective of a sensitivity of 1.0 for fractures with the maximum possible specificity. As in the original study, four combined variables were created by grouping inability to bear weight both immediately and in the emergency department, as well as by grouping several areas of bone tenderness. The 20 individual and combined clinical variables were assessed for association with significant fractures in the ankle and foot radiographic series, separately, by the χ² test with 1 df. The reliability of assessing each variable was measured by the κ coefficient. Those variables found to be both reliable (highest κ values) and strongly associated with a fracture (highest χ² values), were analyzed by a χ² recursive partitioning technique to confirm the best combination of predictor variables for the ankle and foot radiographic series, respectively.22,23 These statistical models formed the basis of the refined decision rules.

Model Validation

In the second stage, the classification performance of the refined decision rules was assessed by the calculation of sensitivity and specificity. The accuracy and reliability of the physicians' interpretation of the decision rules was determined in the same fashion as in the first stage. Likelihood ratios and the probabilities of fractures, based on the refined decision rules, were calculated for the two stages combined.24,25

RESULTS

Patient Characteristics

During the first stage (validation and refinement of original rules), 1062 patients were studied (Table 1). Patients were young, on average, but the age range extended to 90 years; men and women were equally represented, and the majority had suffered a twisting mechanism of injury. The 121 patients with clinically significant malleolar zone fractures (12%) represented a variety of injuries, including two fractures of the talus. The large majority of the 49 clinically significant midfoot zone fractures (5%) were at the base of the fifth metatarsal. All patients underwent radiography: 877 with malleolar zone pain had an ankle radiographic series, and 405 with midfoot pain had a foot series. The 116 patients examined inde-
Prospective Validation of the Original Decision Rules for Identifying Ankle and Foot Radiographic Series Fractures Among 1032 Ankle Injury Patients in the First (Refinement) Stage of the Study

<table>
<thead>
<tr>
<th>Decision rule positive</th>
<th>Ankle Series Fracture Yes</th>
<th>No</th>
<th>Foot Series Fracture Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>121</td>
<td>557</td>
<td>46</td>
<td>294</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>354</td>
<td>1</td>
<td>689</td>
</tr>
</tbody>
</table>

Sensitivity (95% confidence interval) 1.0 (0.97-1.0) 0.96 (0.88-1.0)
Specificity (95% confidence interval) 0.39 (0.36-0.42) 0.70 (0.67-0.73)

Refinement of the Foot Series Decision Rule

The associations of eight relevant variables with clinically significant midfoot zone fractures are given in Table 4; four had P values <0.05. The variables that four variables demonstrated substantial interobserver agreement. Recursive partitioning identified a subset of patients free of foot series fracture based on these variables: (1) bone tenderness at the base of the fifth metatarsal, (2) bone tenderness at the navicular, and (3) inability to bear weight immediately and in the emergency department. The corresponding refined decision rule (Fig 2) differs from the original by not including cuboid tenderness and adding the same weight-bearing criterion used in the ankle series decision rule. This rule achieves a sensitivity of 1.0 and a specificity of 0.79 for fractures on retrospective review of the first-stage patients.

Validation of Refined Decision Rules

When applied prospectively to the 453 patients in the second stage of the study (Table 5), the refined rules correctly identified all 50 ankle series fractures (sensitivity, 1.0; 95% CI, 0.93 to 1.0) and all 19 foot series fractures (sensitivity, 1.0; 95% CI, 0.83 to 1.0). The physicians correctly classified patients according to the ankle and foot series decision rules (as interpreted by the investigators) in 99% and 100% of cases respectively and would have missed no fractures due to misinterpretation of the rules.

Application of the decision rules during this stage would have led to relative reductions in the proportion of patients referred for ankle series radiography by 34% (from 85% with malleolar zone pain to 56%) and for foot series radiography by 30% (from 35% with midfoot pain to 24%). Based on the combined 1455 patients seen in the two stages, the likelihood ratio negative for a fracture is estimated to be 0 (95% CI, 0 to 0.06) for the ankle series rule, and 0 (95% CI, 0 to 0.06) for the foot series rule. Therefore, based on the prevalence of fracture in this series of patients, if the corresponding decision rule were “negative,” the physicians would have missed no fractures due to misinterpretation of the rules.

Refinement of the Foot Series Decision Rule

The associations of eight relevant variables with clinically significant midfoot zone fractures are given in Table 4; four had P values <0.05. The variables that four variables demonstrated substantial interobserver agreement. Recursive partitioning identified a subset of patients free of foot series fracture based on these variables: (1) bone tenderness at the base of the fifth metatarsal, (2) bone tenderness at the navicular, and (3) inability to bear weight immediately and in the emergency department. The corresponding refined decision rule (Fig 2) differs from the original by not including cuboid tenderness and adding the same weight-bearing criterion used in the ankle series decision rule. This rule achieves a sensitivity of 1.0 and a specificity of 0.79 for fractures on retrospective review of the first-stage patients.
probability of fracture in the ankle series would be 0% (95% CI, 0% to 0.8%), and the probability of fracture in the foot series would be 0% (95% CI, 0% to 0.4%).

COMMENT

The Ottawa ankle rules offer physicians an opportunity to use clinical judgment to screen patients with acute ankle injuries for the need for radiography. The rapid application of a few simple clinical variables indicates which patients are at negligible risk for a fracture and therefore need not undergo radiography. Based on the findings of several thousand cases, both physicians and patients can be reassured that the probability of a fracture among such low-risk patients is extremely small. The money saved by forgoing hundreds of thousands of ankle and foot radiographs may be better used elsewhere in the health care system.

There has been considerable interest, recently, in the area of clinical prediction or decision rules, which attempt to reduce the uncertainty of medical decision making by standardizing the collection and interpretation of clinical data.27-39 Methodologic standards for the development and validation of decision rules have also been proposed.31-32 We believe that the process for deriving, refining, and validating the Ottawa ankle rules approaches these standards. The outcome identified by the rules—significant fracture on either the ankle or foot radiographic series—was explicitly defined and assessed without knowledge of the predictor variables. These predictor variables were assessed in a standardized fashion and were shown to be reliable or reproducible. The study patients were selected without bias and represented a spectrum of such characteristics as age, mechanism of injury, clinical findings, severity of injury, and type of fracture. The statistical techniques used, including χ², χ², and recursive partitioning analyses, were identified. The rules may be considered sensible for clinical use: they possess a clear and relevant purpose, are concise, and are easy to use in a busy emergency department. The classification performance of the rules and their potential impact on practice has been demonstrated and confirmed prospectively in a new population of patients. Previous studies to develop guidelines for ankle injury radiography,5-10,37-39 have one or more methodologic weaknesses,31,32,38 or fail to give specific rules for ankle injuries in adults.4,39

The major limitation of the Ottawa ankle rules is that they have not yet been demonstrated to have an impact on actual clinical practice. The true test of their usefulness will be whether or not their application reduces the use of radiography in acute ankle injuries.40 Such a reduction depends on the acceptance of the decision rules by physicians and patients.41 The expedient ordering of radiographs for most patients is fostered by the nature of emergency department practice.41 Patients, suffering pain and anxiety, have brief encounters with busy physicians whom they have not seen before and who will not be following their care. Physicians frequently believe that patients expect radiography and are concerned about the medicolegal consequences of missing a fracture.44-45 Although experienced emergency physicians have been shown to have the clinical ability to identify patients at low risk for fracture, they tend not to use these skills.4 We are currently conducting field trials to assess the impact of implementing the decision rules into

Table 3.—Univariate Correlation and χ² Values of Predictor Variables for Significant Fracture in 877 Ankle Radiographic Series

<table>
<thead>
<tr>
<th>Variable</th>
<th>Significant Fracture, % (n=121)</th>
<th>Other Cases, % (n=756)</th>
<th>χ²*</th>
<th>P</th>
<th>ω</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, ≥55 y</td>
<td>22</td>
<td>10</td>
<td>12.9</td>
<td>&lt;.001</td>
<td>...</td>
</tr>
<tr>
<td>Gross deformity</td>
<td>27</td>
<td>6</td>
<td>53.7</td>
<td>&lt;.0001</td>
<td>0.54</td>
</tr>
<tr>
<td>Moderate to marked swelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral malleolus</td>
<td>85</td>
<td>51</td>
<td>48.4</td>
<td>&lt;.0001</td>
<td>0.69</td>
</tr>
<tr>
<td>Medial malleolus</td>
<td>47</td>
<td>10</td>
<td>106.4</td>
<td>&lt;.0001</td>
<td>0.51</td>
</tr>
<tr>
<td>Bone tenderness proximal fibula</td>
<td>11</td>
<td>2</td>
<td>22.5</td>
<td>&lt;.0001</td>
<td>0.42</td>
</tr>
<tr>
<td>Bone tenderness lateral malleolus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior edge</td>
<td>76</td>
<td>35</td>
<td>72.9</td>
<td>&lt;.0001</td>
<td>0.79</td>
</tr>
<tr>
<td>Inferior tip</td>
<td>71</td>
<td>55</td>
<td>9.9</td>
<td>&lt;.01</td>
<td>0.58</td>
</tr>
<tr>
<td>Posterior edge or inferior tip</td>
<td>86</td>
<td>59</td>
<td>31.1</td>
<td>&lt;.0001</td>
<td>0.55</td>
</tr>
<tr>
<td>Bone tenderness medial malleolus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior edge</td>
<td>47</td>
<td>13</td>
<td>79.7</td>
<td>&lt;.0001</td>
<td>0.65</td>
</tr>
<tr>
<td>Inferior tip</td>
<td>56</td>
<td>23</td>
<td>53.1</td>
<td>&lt;.0001</td>
<td>0.59</td>
</tr>
<tr>
<td>Anterior edge</td>
<td>41</td>
<td>13</td>
<td>57.1</td>
<td>&lt;.0001</td>
<td>0.51</td>
</tr>
<tr>
<td>Posterior edge or inferior tip</td>
<td>61</td>
<td>26</td>
<td>58.6</td>
<td>&lt;.0001</td>
<td>0.64</td>
</tr>
<tr>
<td>Inability to bear weight immediately</td>
<td>68</td>
<td>28</td>
<td>72.4</td>
<td>&lt;.0001</td>
<td>0.71</td>
</tr>
<tr>
<td>Four steps in emergency department</td>
<td>85</td>
<td>36</td>
<td>103.6</td>
<td>&lt;.0001</td>
<td>0.79</td>
</tr>
<tr>
<td>Both immediately and in emergency</td>
<td>67</td>
<td>19</td>
<td>122.8</td>
<td>&lt;.0001</td>
<td>0.71</td>
</tr>
</tbody>
</table>

*Pearson χ² value for 1 df.
a variety of hospitals of different sizes and staffing patterns.

The use of these decision rules must remain secondary to the judgment and common sense of physicians. Clearly, there is no need for guidelines in the presence of deformity and a clinically obvious fracture. Physicians should be cautious in patients with multiple painful injuries, altered sensorium, intoxication, paraplegia, or bone disease. The Ottawa ankle rules have not been developed or tested in patients under the age of 18 years.

Whereas the estimated sensitivity of the rules for fracture is 1.0, the 95% CIs (and common sense) suggest that a fracture may occasionally be missed. Nevertheless, we believe that to escape detection by the rules, such a fracture would be relatively small and that the likelihood of morbidity for the patient would also be very small. While the 2235 patients in the original and the current study had 341 clinically significant fractures among them, we have only limited experience with the relatively uncommon fractures of the talus (two cases) and of the midfoot other than the base of the fifth metatarsal (12 cases). Radiography may occasionally demonstrate tibiofibular diastasis without fracture; however, such injuries are rare and were never demonstrated among our patients. We believe that performing a careful and well-documented physical examination and arranging for follow-up will protect both the patient and the physician from the sequelae of missing a fracture. Good clinical practice dictates that follow-up be routinely recommended for patients whose pain and ability to ambulate have not improved after several days.44

We were pleased that the reliability and accuracy of the variables from the original rules44 were confirmed and that the refinement process involved relatively minor changes, which made the rules simpler and easier to remember. The age and cuboid criteria proved to be redundant in that all clinically significant fractures could be identified without them. Addition of the weight-bearing criterion makes the foot rule consistent with the ankle rule. Inability to bear weight appears to be one of the most reliable variables, judged by the χ² values.45 Combining inability to bear weight both immediately and in the emergency department is a more specific predictor of fracture, likely because many patients with soft-tissue injuries are able to walk immediately but not when seen later in the hospital. We define weight bearing in the emergency department as the ability to transfer weight twice onto each leg (a total of four steps), regardless of limping. We assess ability to bear weight only after determining bone tenderness and never attempt to coerce the patient. Most patients are willing to attempt to walk and are frequently surprised by their success. We believe that the likelihood of causing a fracture to displace by this assessment is extremely remote. Unstable fractures are usually grossly apparent with obvious bone tenderness. Patients without these findings are highly unlikely to have more than a small stable fracture.

What are the potential implications of this study for clinical practice? Compliance with the Ottawa ankle rules would lead to a 30% decrease in the use of radiography in patients with acute ankle injuries. One attendant benefit would be decreased waiting times for patients discharged without radiography and possibly for patients who could be sent directly to the radiology department by triage nurses trained to use the rules. The other benefit would be cost savings to the health care system. Low-cost, high-volume items such as plain radiographs may contribute more to rising health care costs than high-technology, low-volume procedures such as computed tomographic scans and coronary catheterization.46 The total professional and technical cost of performing 5 million ankle radiographs annually in North America can be estimated at $500 million.

This study has prospectively validated and refined decision rules for the use of radiography in acute ankle injuries. These rules have been shown to be highly sensitive for identifying fractures and have the potential to reduce the use of radiography by 30%. Implementation studies will assess the actual impact of the Ottawa ankle rules on clinical practice.

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References


Table 4.—Univariate Correlation and χ² Values of Predictor Variables for Significant Fracture in 405 Foot Radiographic Series

<table>
<thead>
<tr>
<th>Variable</th>
<th>Significant Fracture, % (n=49)</th>
<th>Other Cases, % (n=356)</th>
<th>χ²*</th>
<th>P††</th>
<th>κ (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, ≥55 y</td>
<td>33 13 12.9 &lt;.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone tenderness midfoot</td>
<td>92 31 67.9 &lt;.0001</td>
<td>0.57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navicular</td>
<td>13 26 4.0 &lt;.05</td>
<td>0.39</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cuboid</td>
<td>47 61 3.2 0.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fifth metatarsal or navicular</td>
<td>96 51 35.4 &lt;.0001</td>
<td>0.66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inability to bear weight immediately after injury</td>
<td>19 26 1.1 0.71</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four steps in emergency department</td>
<td>45 42 0.2 0.79</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both immediately and in emergency department</td>
<td>17 20 0.3 0.71</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Pearson χ² value for 1 df
†Ellipses indicate not significant.

Table 5.—Classification Performance of the Refined Decision Rules for Identifying Ankle and Foot Radiographic Series Fractures Among 453 Ankle Injury Patients in the Second (Validation) Stage of the Study

<table>
<thead>
<tr>
<th>Ankle Series Fracture</th>
<th>Foot Series Fracture</th>
</tr>
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<tbody>
<tr>
<td>Decision rule positive</td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td>50</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>Sensitivity (95% confidence interval)</td>
<td>1.0 (0.93-1.0)</td>
</tr>
<tr>
<td>Specificity (95% confidence interval)</td>
<td>0.49 (0.44-0.54)</td>
</tr>
</tbody>
</table>


