Sensitivity of a clinical examination to predict need for radiography in children with ankle injuries: a prospective study

Kathy Boutis, Luba Komar, Diego Jaramillo, Paul Babyn, Benjamin Alman, Brian Snyder, Kenneth D Mandl, Suzanne Schuh

Summary

Background Radiographs are ordered routinely for children with ankle trauma. We assessed the predictive value of a clinical examination to identify a predefined group of low-risk injuries, management of which would not be affected by absence of a radiograph. We aimed to show that no more than 1% of children with low-risk examinations (signs restricted to the distal fibula) would have high-risk fractures (all fractures except avulsion, buckle, and non-displaced Salter-Harris I and II fractures of the distal fibula), and to compare the potential reduction in radiography in children with low-risk examinations with that obtained by application of the Ottawa ankle rules (OAR).

Methods Standard clinical examinations and subsequent radiographs were prospectively and independently evaluated in two tertiary-care paediatric emergency departments in North America. Eligible participants were healthy children aged 3–16 years with acute ankle injuries. Sample size, negative and positive predictive values, sensitivity, and specificity were calculated. McNemar’s test was used to compare differences in the potential reduction in radiographs between the low-risk examination and the OAR.

Findings 607 children were enrolled. 581 (95.7%) received follow-up. None of the 381 children with low-risk examinations had a high-risk fracture (negative predictive value 100% [95% CI 99–100]; sensitivity 100% [93–100]). Radiographs could be omitted in 62.8% of children with low-risk examinations, compared with only 12.0% reduction obtained by application of the OAR (p<0.0001).

Interpretation A low-risk clinical examination in children with ankle injuries identifies 100% of high-risk diagnoses and may result in greater reduction of radiographic referrals than the OAR.

Lancet 2001; 358: 2118–21

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Participants This study took place at two urban, university-affiliated paediatric emergency departments—the Hospital for Sick Children in Toronto, Canada, and the Children’s Hospital in Boston, USA. Eligible children were aged between 3 and 16 years and had a history of isolated ankle trauma within 72 h of presentation. We excluded children younger than 3 years of age because their ability to cooperate is limited, and those older than 16 years because many show adult injury patterns. We also

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excluded children studied by radiography before our assessment) patients with pre-existing musculoskeletal disease, coagulopathy, or developmental delay; patients with previous history of surgery or recent (≤3 months) injury of the affected ankle; and children with multisystem trauma. The study was approved by the human ethics review boards of both institutions, and parents or patients provided written informed consent. A list of patients who were missed or whose parents declined participation was kept to assess whether our cohort was biased.

**Design**

Before the study, the emergency-department staff, paediatricians, and fellows of both hospitals were instructed by the participating orthopaedic surgeons in the physical examination of the ankle and its documentation. Eligible children were assessed by the paediatric emergency-department fellow or attending physician. A relevant history included information on various sociodemographic factors, the mechanism of injury, the time to presentation to the emergency department, and ability to bear weight. Physical examination of the ankle included identification of the site of greatest pain or tenderness and the presence of swelling or ecchymosis. A standard study sheet including the clinical data and a detailed diagram of the ankle joint was prepared by the principal investigator in collaboration with the orthopaedic associates, and completed for each child before the radiographic examination. Ankle radiographs were read by two staff radiologists with expertise in paediatric musculoskeletal imaging (one in each institution) who were unaware of the details of the initial presentation. In each study patient, at least three views of the ankle (anteroposterior, lateral, and mortise) were radiographed, and films were analysed for the presence or absence of physyal closure, soft-tissue swelling, effusions, and fractures. At the Hospital for Sick Children, the participating children were asked to return to the orthopaedic outpatient clinic within a week for confirmation of the initial diagnosis. At the Children’s Hospital in Boston, only the children whose injuries were thought by the emergency-department attending physician to warrant orthopaedic reassessment were followed up in the orthopaedic clinic; the remaining children were advised to see their paediatrician. Two investigators subsequently telephoned all enrolled children at least a month after the initial presentation to assess whether our cohort was biased.

The low-risk clinical examination was defined as isolated pain, tenderness, or both, with or without oedema or ecchymosis of the distal fibula below the level of the joint line of the ankle and/or adjacent lateral (ie, anterior and posterior talofibular and calcaneofibular) ligaments (figure).

The low-risk clinical examination was defined as high risk. Final diagnosis was based on the masked interpretation of the initial radiograph and the follow-up information. Low-risk diagnoses were sprains or contusions, lateral talar avulsion fractures, and fractures of the distal fibula including non-displaced Salter-Harris I and II, metaphyseal buckle, and epiphyseal avulsion fractures. These are stable injuries, which carry an excellent prognosis, and management decisions are generally based on maximising the patient’s comfort and compliance. All other fractures were classified as high risk, because they may destabilise the ankle, and they require closer orthopaedic and radiographic follow-up. The primary outcome measure was the proportion of patients who had a low-risk clinical examination in the emergency department before radiographic examination but were subsequently found to have a high-risk injury. We also assessed the potential for a reduction in radiographs by comparing the low-risk clinical findings with those obtained by applying the OAR.

**Statistical analysis**

The sample size was chosen to give an SE of 1% for the estimated proportion of patients with a low-risk examination and a high-risk diagnosis, with the assumption of a true value of 1%. This calculation necessitated enrolment of 381 children in the low-risk examination category. Patients’ clinical characteristics were compared with respect to low-risk and high-risk diagnoses. Student’s t test and the Mann-Whitney U test were used to compare continuous variables. Odds ratios were used to estimate the relative risk of low-risk versus high-risk diagnoses for various sociodemographic and clinical factors. We calculated point estimates of predictive values, sensitivity, and specificity of the low-risk examination and the OAR to discriminate between low-risk and high-risk diagnoses. McNemar’s test was used to assess the potential difference in the reduction of radiographs obtained by application of the OAR compared with the low-risk examination alone. A κ statistic was calculated to assess the interobserver reliability of the participating clinicians.

**Results**

Between January, 1998, and September, 2000, 1017 children with acute ankle injury were seen in the two emergency departments. Of these, 201 were excluded: 97 were too young or too old; 36 had had a diagnosis made in another institution; 27 had had the injury for longer than 72 h; nine had congenital bone abnormalities; nine had multiple bone fractures or multisystem trauma; eight had recent ankle injuries, previous surgery of the affected ankle, or both features; eight were thought to be at risk of pathological fracture; three had haemophilia; three had developmental delay; and one family refused to participate. 209 eligible patients were missed. A total of 607 children were enrolled (422 in Boston and 185 in Toronto). 381 had low-risk clinical examinations and 226
had high-risk findings (table 1). Significant associations included an inversion mechanism and the inability to bear weight. There was no significant difference between the two centres in terms of demographics or the proportions of children enrolled with low-risk examination or high-risk diagnoses. There was no significant difference in the proportion of patients with high-risk diagnoses between those enrolled and those missed (7·4 vs 6·7%; p=0·32). 74 (12%) patients had fracture visible on the radiograph, and 533 (88%) had normal radiographs.

None of the 381 children with low-risk examinations had subsequent high-risk final diagnoses (negative predictive value of low-risk examination for low-risk final diagnosis 100% [95% CI 99·2–100]; sensitivity 100% [93·3–100]; table 2), whereas 45 of the 226 children with high-risk clinical findings had a high-risk diagnosis (positive predictive value of high-risk examination for high-risk final diagnosis 19·5% [14·9–25·7]).

Of the 381 children with low-risk clinical examinations, 87 (23%) were diagnosed clinically as having Salter-Harris type I fracture of the distal fibula, 274 (72%) had ligament sprain, and only 20 (5%) had radiographically visible fractures. Visible fractures on radiographs in the low-risk group included nine non-displaced distal fibular Salter-Harris II fractures, ten avulsions of the distal fibula, and one avulsion fracture of the lateral talus. By contrast, of the 226 children with high-risk clinical findings, 54 (24%) had visible fractures, 45 of which were classified as high risk. These fractures included one avulsion fracture of the medial malleolus, two fractures of the base of the fifth metatarsal, and the following distal tibial physeal fractures: six Salter-Harris I, five Salter-Harris II, two Salter-Harris III, two Salter-Harris IV, seven Tillaux, four triplane, and 16 fractures of the ankle involving both the tibia and fibula.

537 patients (89%) would have undergone radiography under the OAR. Of these patients, 463 (86%) had normal radiographs and 74 (14%) had visible fractures. Of the 70 patients who would not have undergone radiography under the OAR, none had visible fractures (sensitivity 100% [95% CI 93·3–100]; negative predictive value 100% [95·9–100]; positive predictive value 81% [6·2–11·1]).

<table>
<thead>
<tr>
<th>Demography</th>
<th>Low-risk diagnosis (n=562)</th>
<th>High-risk diagnosis (n=45)</th>
<th>p</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>276 (49%)</td>
<td>26 (58%)</td>
<td>0·33</td>
<td>1·3 (0·7 to 2·4)</td>
</tr>
<tr>
<td>Female</td>
<td>286 (51%)</td>
<td>19 (42%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (median [range], years)</td>
<td>13 (3–16)</td>
<td>12 (3–16)</td>
<td>0·55</td>
<td>--</td>
</tr>
</tbody>
</table>

**Table 1:** Clinical characteristics of patients with low-risk and high-risk diagnoses

**Table 2:** Comparison of low-risk and high-risk clinical examination with low-risk and high-risk final diagnosis

<table>
<thead>
<tr>
<th>Examination</th>
<th>No radiograph under OAR</th>
<th>Radiograph under OAR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>381</td>
<td>0</td>
<td>381</td>
</tr>
<tr>
<td>High risk</td>
<td>181</td>
<td>45</td>
<td>226</td>
</tr>
<tr>
<td>Total</td>
<td>562</td>
<td>45</td>
<td>607</td>
</tr>
</tbody>
</table>

**Table 3:** Comparison of low-risk and high-risk examinations with OAR

345 (64%) of the 537 children who would have had radiographs taken under the OAR had low-risk clinical examinations with no high-risk fractures observed on radiography (table 3). Of the 562 patients with low-risk diagnoses, 381 were correctly identified by a low-risk examination (specificity 67·8% [63·8–71·6]). By contrast, only 70 low-risk diagnoses were identified by the OAR (specificity 13·0% [10·3–16·1]). The low-risk clinical examination could therefore reduce the number of radiographs taken by 62·8% (381 of 607), whereas application of the OAR yielded a significantly (p<0·0001) lower reduction of 12·0% (70 of 607).

Of the 607 enrolled children, 255 (42%) were seen in the orthopaedic outpatient clinic and 571 (94%) were contacted by telephone. Only 20 children (4%) received neither follow-up approach. On orthopaedic follow-up, no patient with a low-risk examination was found to have a high-risk diagnosis. Two patients who despite a high-risk examination in the emergency department had a radiograph initially interpreted by both the non-study staff radiologist and the emergency-department staff as normal, were later found to have a Tillaux fracture on orthopaedic follow-up and by the study radiologists. The telephone follow-up showed that, although no children with low-risk injuries complained of symptoms while walking, eight children diagnosed with Salter-Harris type I fracture of the distal fibula or sprain still had symptoms on exercise after 4 months. A year later, seven of these children were free of symptoms; one child was lost to follow-up.

**Discussion**

In our study, no children with acute ankle injury and isolated clinical findings restricted to the distal fibula below the level of the joint line of the ankle or adjacent lateral ligaments had a subsequent high-risk diagnosis. Therefore, most (63%) of the radiographs currently undertaken could be avoided on the basis of low-risk examination alone, by contrast with only 12% reduction in imaging based on application of the Ottawa algorithm. This finding could substantially reduce costs and improve flow of patients in the emergency department, without increasing the likelihood of missing clinically significant high-risk fractures. The low-risk and high-risk findings were easily distinguished by the clinicians, as assessed by a high degree of agreement between observers. The clinical data were collected in a consistent, prospective manner by appropriately trained physicians. We used a definition of low-risk clinical examination that is simple and easy to use in a busy emergency department (figure).

Three previous studies have assessed the applicability of the OAR in children. Chande found a potential 25% reduction in radiographs by application of the OAR, which were shown to be 100% sensitive to the detection of fractures. Notable limitations of this study include its small sample size and lack of follow-up. In a similar study, Libetta and co-workers found a potential reduction in ankle radiographs of 7%, and a large study by Plint and colleagues showed that 16% of children with ankle injuries might avoid radiographs by application of the
Ottawa algorithm. However, all studies classified patients with Salter-Harris I fractures of the distal fibula in the fracture group, thereby defining them as injuries that require a radiograph. The radiographic diagnosis of a Salter-Harris I fracture is presumptive, based on soft-tissue swelling overlying the physeal injury. The findings on the radiograph do not add to those detectable on physical examination. This fracture is believed to be the most common ankle fracture in children, representing about 60% of those in this study. Strict application of the OAR in children may therefore result in a substantial number of unnecessary radiographs. By contrast, more than half our study population who would have had radiographs under the OAR had low-risk diagnoses and therefore may not benefit the intervention. Our study therefore shows that a radiograph do not add to those detectable on physical examination. This fracture is believed to be the most common ankle fracture in children, representing about 60% of those in this study. Strict application of the OAR in children may therefore result in a substantial number of unnecessary radiographs. By contrast, more than half our study population who would have had radiographs under the OAR had low-risk diagnoses and therefore may not benefit the intervention. Our study therefore shows that a low-risk examination was 100% predictive of a low-risk diagnosis, and may result in greater reduction of radiographic examination when making management decisions. In addition, we encourage follow-up of patients within a week to identify those who need repeated radiography or other imaging modalities because of persistent symptoms. The results of our study may not be generalisable to medical staff less well trained in the clinical assessment of children’s ankles. Therefore, low-risk and high-risk clinical findings must be carefully reviewed and the approach appropriately applied. In conclusion, a low-risk examination was 100% predictive of a low-risk diagnosis and may result in greater reduction of radiographic referrals than the OAR.

Contributors
Kathy Boutis contributed towards the design of the study, coordination of coauthors’ involvement, and recruitment and follow-up of the patients in Toronto and Boston. Luba Komar was involved in recruitment and follow-up of most of the patients in Toronto. Paul Babyn and Diego Jaramillo are the paediatric radiologists who were involved in the masked interpretation of the radiographs at Toronto and Boston. Benjamin Alman and Brian Snyder were involved in the design of the study and follow-up in orthopaedic clinics; they were instrumental in the design of the study. The report was written by Kathy Boutis and Suzanne Schuh and reviewed by the other authors.

References