

# Multicentre trial to introduce the Ottawa ankle rules for use of radiography in acute ankle injuries

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## Abstract

**Objective**—To assess the feasibility and impact of introducing the Ottawa ankle rules to a large number of physicians in a wide variety of hospital and community settings over a prolonged period of time.

**Design**—Multicentre before and after controlled clinical trial.

**Setting**—Emergency departments of eight teaching and community hospitals in Canadian communities (population 10 000 to 3 000 000).

**Subjects**—All 12 777 adults (6288 control, 6489 intervention) seen with acute ankle injuries during two 12 month periods before and after the intervention.

**Intervention**—More than 200 physicians of varying experience were taught to order radiography according to the Ottawa ankle rules.

**Main outcome measures**—Referral for ankle and foot radiography.

**Results**—There were significant reductions in use of ankle radiography at all eight hospitals and within a priori subgroups: for all hospitals combined 82.8% control *v* 60.9% intervention ( $P < 0.001$ ); for community hospitals 86.7% *v* 61.7%; ( $P < 0.001$ ); for teaching hospitals 77.9% *v* 59.9%; ( $P < 0.001$ ); for emergency physicians 82.1% *v* 61.6%; ( $P < 0.001$ ); for family physicians 84.3% *v* 60.1%; ( $P < 0.001$ ); and for housestaff 82.3% *v* 60.1%; ( $P < 0.001$ ). Compared with patients without fracture who had radiography during the intervention period those who had no radiography spent less time in the emergency department (54.0 *v* 86.9 minutes;  $P < 0.001$ ) and had lower medical charges (\$70.20 *v* \$161.60;  $P < 0.001$ ). There was no difference in the rate of fractures diagnosed after discharge from the emergency department (0.5 *v* 0.4%).

**Conclusions**—Introduction of the Ottawa ankle rules 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 methodological approach used to develop and implement these rules may be applied to other clinical problems.

## Introduction

Ankle and foot injuries are a common complaint among patients seen in emergency departments. Though only a few of these cases have suffered a fracture,<sup>1-6</sup> nearly all typically undergo plain radiography of the ankle or foot, or both.<sup>7-12</sup> To deal with this clinical problem decision rules for the use of radiography in acute ankle injuries have been recently developed<sup>13,14</sup> and validated<sup>15</sup> and have been found to be highly sensitive in identifying fractures. These Ottawa ankle rules are based on the assessment of ability to bear weight and areas of bone tenderness and allow physicians to determine quickly which patients are at negligible risk of fracture (figure).

We know of few clinical decision rules that have been studied to determine their impact on patient care in "usual clinical practice."<sup>16,17</sup> A recent study at a single hospital showed that implementation of the Ottawa ankle rules led to a significant reduction in the use of ankle radiography.<sup>18</sup> This clinical trial was designed to assess whether the rules could be shown to reduce the use of radiography without affecting quality of care when used by many physicians of varying experience in a variety of different hospital settings.

## Subjects and methods

### SUBJECTS

All adult patients with ankle injury seen in the emergency departments of the study hospitals during control (before) and intervention (after) periods of 12 months each were included in this controlled clinical trial. The eight hospitals were chosen because they were able to identify eligible cases retrospectively and because they represented various community population sizes (10 000 to 3 000 000), hospital types (community, teaching), annual volumes of patients in emergency departments (20 000 to 68 000), and staffing patterns (emergency physician, family physician, house officers). Patients with acute ankle trauma from any mechanism of injury were eligible. "Ankle" was explicitly defined anatomically.<sup>15,19</sup> The institutional research ethics committees approved the study.

### INTERVENTION

We introduced the Ottawa ankle rules<sup>15</sup> to the study hospitals before the intervention period by means of a single one hour lecture given by the principal investigator (IS) as well as handouts, pocket cards, and two posters mounted in each department. Physicians were asked to complete a data form and to distribute information sheets to patients. The decision to order radiography for individual patients was solely at the discretion of the treating physician.

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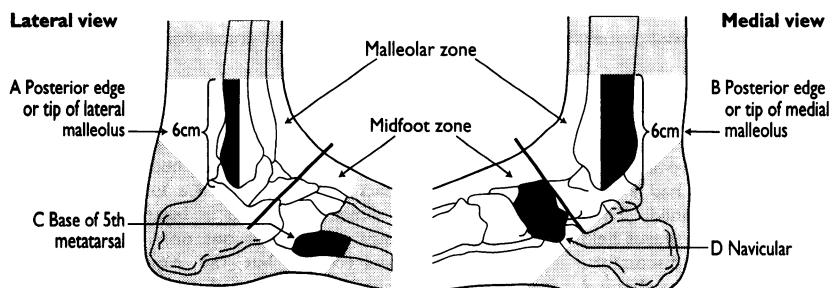
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An ankle x ray series is required only if there is any pain in malleolar zone and any of these findings:

- Bone tenderness at A
- Bone tenderness at B
- Inability to bear weight both immediately and in emergency department

A foot x ray series is required only if there is any pain in midfoot zone and any of these findings

- Bone tenderness at C
- Bone tenderness at D
- Inability to bear weight both immediately and in emergency department

Ottawa ankle rules for use of radiography in acute ankle injuries (adapted from Stiell et al<sup>15</sup>)

OUTCOME MEASURES

For both study periods review of patients' eligibility was made from patients' records independently for each case by three members of the research team, and differences were resolved by consensus. Patients' records were identified (retrospectively for the control period and prospectively for the intervention period) in a consistent fashion by a combination of computerised retrieval from *International Classification of Diseases* (ninth revision) diagnostic codes and a search of daily census logs. The primary outcome measure, the proportion of patients referred for radiography of the ankle, was determined from radiology reports. Clinically important features were defined as fractures greater than three millimetres in breadth.

During the intervention period only, all patients without fracture were followed up by telephone call at 10 days if they had had neither ankle nor foot radiography or if they were seen during the first seven days of each month and did have radiography. Patients

TABLE 1—Characteristics of all patients with ankle injury seen at study hospitals during 12 month control and intervention study periods. Figures are numbers (percentages) of patients unless stated otherwise

Characteristic	Control (n=6288)	Intervention (n=6489)
Median (range) age (years)	32 (18-101)	32 (18-100)
No (%) of men	3398 (54.0)	3384 (52.1)
Important fractures	1030 (16.4)	1082 (16.7)
Malleolar region*	768 (12.2)	796 (12.3)
Lateral malleolus	413	460
Medial malleolus	81	72
Posterior malleolus	35	26
Bimalleolar	127	115
Trimalleolar	79	98
Talus	49	31
Midfoot*	271 (4.3)	294 (4.5)
Base 5th metatarsal	220	254
Navicular	29	22
Anterior process calcaneus	26	12
Cuboid	12	7
Cuneiforms	1	3
Avulsion fractures*	256 (4.1)	255 (3.9)
Treatment:		
Cast	1170 (18.6)	1239 (19.1)
Admitted	254 (4.0)	237 (3.7)
Hospital:		
Brockville General	415 (6.6)	476 (7.3)
Great War Memorial (Perth)	235 (3.7)	235 (3.6)
Hotel Dieu (Kingston)	906 (14.4)	871 (13.4)
Kingston General	940 (14.9)	908 (14)
Peel Memorial (Brampton)	1177 (18.7)	1274 (19.6)
Queensway-Carleton (Nepean)	1447 (23)	1531 (23.6)
Smiths Falls Community	263 (4.2)	247 (3.8)
Sunnybrook Health Science Center (Toronto)	905 (14.4)	947 (14.6)
Hospital type:		
Community	3537 (56.3)	3763 (58.0)
Teaching	2751 (43.8)	2726 (42.0)
Treating physician:		
Emergency physician	3179 (50.6)	3626 (55.9)
Family physician	2173 (34.6)	2031 (31.3)
Housestaff	936 (14.0)	832 (12.8)

\*Patients may have fractures in more than one site.

TABLE 2—Referral for ankle radiographic series of all patients with ankle injury seen during the 12 months control and intervention study periods. Figures are numbers (percentages) of patients

Detail	Control (n=6288)	Intervention (n=6489)	% Relative reduction† (95% confidence interval)
All hospitals combined	5207 (82.8)	3955 (60.9)	26.4 (24.7 to 28.0)
Individual hospitals:			
Brockville General*	317 (76.4)	261 (54.8)	28.2 (20.9 to 34.9)
Great War Memorial (Perth)*	175 (74.5)	130 (55.3)	25.7 (14.8 to 35.2)
Hotel Dieu (Kingston)†	666 (73.5)	508 (58.3)	20.7 (15.0 to 25.9)
Kingston General†	695 (73.9)	516 (56.8)	23.1 (17.7 to 28.2)
Peel Memorial (Brampton)*	1081 (91.8)	832 (65.3)	28.9 (25.7 to 31.9)
Queensway-Carleton (Nepean)*	1269 (87.7)	950 (62.1)	29.2 (26.1 to 32.2)
Smiths Falls Community*	223 (84.8)	149 (60.3)	28.9 (20.3 to 36.5)
Sunnybrook Health Service Center (Toronto)†	781 (86.3)	609 (64.3)	25.5 (21.3 to 29.4)
Hospital type:			
Community	3065 (86.7)	2322 (61.7)	28.8 (26.7 to 30.8)
Teaching	2142 (77.9)	1633 (59.9)	23.1 (20.2 to 25.8)
Treating physician:			
Emergency physician	2605 (81.9)	2235 (61.6)	24.8 (22.5 to 27.0)
Family physician	1831 (84.3)	1220 (60.1)	28.7 (25.8 to 31.5)
Housestaff	771 (82.4)	500 (60.1)	27.0 (22.3 to 31.5)

\*Community hospital. †Teaching hospital. ‡All differences significant, P<0.001.

who had not improved according to explicit criteria regarding pain, ambulation, and ability to work were asked to return for assessment. Patients who had fractures diagnosed after discharge were questioned after six months about possible effects. For patients followed up by telephone calls the total charges for all emergency department and follow up physician visits and radiographic series were estimated in 1993 US dollars.

STATISTICAL ANALYSIS

All patients who met the inclusion-exclusion criteria during the control and intervention periods were included in the analysis regardless of whether physicians completed a data collection form or were compliant with the decision rules. For each hospital separately the uncorrected  $\chi^2$  analysis was used to test the primary hypothesis that there was no difference in the proportion of patients referred for a standard ankle radiographic series between the control and intervention study groups. We calculated 95% confidence intervals of the relative differences in referral rates for radiography between groups.<sup>20</sup> Overall point and confidence interval estimates for the relative reductions were also derived. A similar analysis was used to test the secondary hypothesis that there was no difference in the referral for radiographic series of the foot.

We used  $\chi^2$  analysis to compare the primary outcome between the control and intervention study periods within the a priori subgroups of hospital type (community, teaching) and physician type (emergency, family, housestaff). Comparisons of characteristics of patients and other outcomes were tested with  $\chi^2$ , Student's *t* test, or Mann-Whitney test as appropriate.

An absolute change of 10% for the referral rate for ankle radiography from the estimated baseline rate of 80% was considered to be clinically important. We assumed a statistical power of 80% and a two tailed 5% type I error so a sample size of 293 patients was estimated for each hospital during each study period.

Results

SUBJECTS

The 12777 eligible patients seen at the eight hospitals during the control (1 May 1991 to 30 April 1992) and intervention (1 January to 31 December 1993) periods were similar for all characteristics (table I).

REDUCTION IN RADIOGRAPHY

The overall proportion of patients referred for ankle radiography was 82.8% (5207/6288) during the control period and 60.9% (3955/6489) during the intervention period (P<0.001), with an observed relative reduction between periods of 26.4% (table II). The proportion referred for ankle radiography was significantly less at all eight hospitals for both hospital subgroups and for each physician subgroup.

Three hospitals had significant reductions and five had no significant change in referral for foot radiography. During the intervention period more patients did not have radiography (21.7% v 8.4%) and fewer patients had both ankle and foot series (9.2% v 21.8%). Furthermore, patients without fracture spent less time in the emergency department if they had no radiography compared with those who had radiography (54.0 (SD 42.0) v 86.9 (46.9) minutes; P<0.001).

COMPLIANCE BY PHYSICIANS

During the intervention period physicians completed the study data sheet for 77.1% (5003) of the 6489 patients in the study. The physicians accurately interpreted the rules (97.1% for ankle and 97.6% for foot)

TABLE III—Characteristics of six cases (of 1090 important fractures) in which rules were interpreted as negative and important fractures were diagnosed before discharge from emergency department

Case No	Age (years)	Sex	Hospital	Physician	Fracture	Comments
1	27	Male	Community	Family	Talus	Gross swelling and deformity. Comminuted
2	31	Male	Teaching	Emergency	Posterior malleolus	Hyper-plantarflexion mechanism of injury
3	70	Female	Teaching	Emergency	Lateral malleolus	Gross swelling. Rule misinterpreted—did not palpate distal 6 cm
4	26	Male	Teaching	Emergency	Lateral malleolus	Gross swelling
5	68	Male	Community	Emergency	Lateral malleolus	Gross swelling. Communication barrier
6	34	Male	Community	Emergency	Medial malleolus	Gross swelling

and satisfactorily complied with the rules (95.3% for ankle and 95.0% for foot). Radiography was performed but judged to have been unnecessary according to the rules in 4.9% of cases but in only 0.5% of cases because the patient insisted on radiography. Physicians indicated that they were uncomfortable with implementing the rules in 3.8% of cases.

Six (0.6%) of the 1090 important malleolar and midfoot fractures during the intervention period were diagnosed before discharge from the emergency department in cases in which the rules were interpreted to be negative (table III). Physicians had ordered radiography based on other clinical findings, primarily gross swelling.

FOLLOW UP OF SUBJECTS

Of 2171 patients in the radiography and no radiography groups, 93.6% (2032) were successfully reached by telephone, and there were no important differences in outcomes (table IV). The mean total charges for those who had no radiography in the emergency department were less than for those who had radiography (\$70.20 (SD 52.1) v \$161.60 (71.2);  $P < 0.001$ ).

Ten (0.5%) of the 2033 patients in the follow up group had a fracture diagnosed after discharge from the emergency department despite no repeat injury (table V). Three (0.4%) of 732 had undergone radiography in the emergency department. Seven (0.5%) of 1301 had received no radiography, but in only one of these had the rules been correctly applied. All 10 patients were contacted after six months and all had healed without delay or long term effects. No litigation was initiated. No data about missed fractures were available for the control period.

TABLE IV—Follow up of 2033 patients with ankle injury but without fracture discharged with and without radiography during the intervention period. Figures are numbers (percentages) of patients unless stated otherwise

Characteristic	Radiography (n=732)	No radiography (n=1301)
Satisfied with physician's care in emergency department	705 (96.3)	1214 (93.3)
Satisfied with no radiograph	NA	1116 (85.8)
Subsequent physician visit	179 (24.5)	228 (17.5)
Subsequent ankle radiograph	27 (3.7)	86 (6.6)
Fracture diagnosed after discharge	3 (0.4)	7 (0.5)
Median days off work (range)	3 (0-101)	2 (0-42)

NA=Not applicable.

TABLE V—Characteristics of 10 cases (of 2033 in follow up group) in which fracture was diagnosed after discharge from emergency department

Case No	Age (years)	Sex	Hospital	Physician	Radiography in emergency department	Fracture	Healed	Comments
1	52	Male	Community	Family	Yes	Posterior malleolus	Yes	Initial radiograph negative
2	18	Male	Teaching	Emergency	Yes	Medial malleolus	Yes	Initial radiograph negative; bone scan positive
3	47	Female	Teaching	Emergency	Yes	Posterior malleolus	Yes	Radiograph misinterpreted
4	43	Female	Community	Family	No	Lateral malleolus	Yes	Rule misinterpreted—distal 6 cm not palpated
5	48	Male	Teaching	House officer	No	Lateral malleolus	Yes	Rule correctly interpreted; gross swelling; initial visit after 1 week
6	32	Male	Teaching	Emergency	No	Lateral malleolus	Yes	Rule not used; no study form; diabetic neuropathy
7	26	Male	Community	Family	No	Medial malleolus	Yes	Rule misinterpreted; medial malleolus tenderness
8	65	Male	Teaching	House officer	No	Lateral malleolus	Yes	Rule misinterpreted; medial malleolus tenderness
9	44	Male	Community	Family	No	Medial malleolus	Yes	Rule misinterpreted; medial malleolus tenderness
10	34	Male	Community	Family	No	Base of fifth metatarsal	Yes	Rule not used; no study form

Discussion

We have shown that introduction of the Ottawa ankle rules led to significant reductions in the ordering of ankle radiographic series over a sustained period of time in a variety of community and hospital settings. These reductions were achieved by many physicians with differing experience in emergency medicine and who had not been involved in the development of the rules. Concomitant reductions in the use of the less common radiographic series of the foot were achieved in three hospitals. Physicians accurately interpreted the rules after brief teaching sessions and indicated low levels of discomfort with their application.<sup>21</sup> Patients who did not undergo radiography were satisfied with their care and were no more likely to have a fracture missed in the emergency department than those who did undergo radiography.

The major benefits of introducing the Ottawa ankle rules are time savings for patients and cost savings for the health care system. Our data suggest the potential for large savings: the average medical charges for patients who had no radiography were estimated to be \$90 less than for those patients without fracture who did undergo radiography. Ankle and foot radiographs are typical "little ticket" items,<sup>22,23</sup> the many minor but high volume procedures which may collectively contribute as much to health care costs as "big ticket" items such as magnetic resonance imaging scans or coronary bypass surgery. In these eight hospitals alone more than 6000 patients with ankle injury were seen each year, so even a 25% reduction in radiography would translate into considerable savings.

This study represents the final phase of a multiphase project to develop and test the Ottawa ankle rules. To our knowledge very few other decision rules have been shown to alter clinical practice.<sup>17</sup> The success of the rules may be attributed to the rigour with which they were derived and tested<sup>16</sup> as well as to their clinical sensibility<sup>24</sup>—that is, their ease of use and their high sensitivity. The rules are easy to remember and present a simple "radiograph or no radiograph" decision which may be easier for busy clinicians to incorporate into their practice than a probability of fracture. Future studies should deal with the acceptability of the rules to physicians in other countries<sup>25,26</sup> and methods of disseminating information about their use.<sup>27-31</sup>

We have developed rules with a sensitivity approaching 100%. Patients and physicians alike can be reassured that if the Ottawa ankle rules are properly

## Key messages

- Use of radiography has traditionally been inefficient for the many patients with ankle injury seen in emergency departments
- The Ottawa ankle rules can be successfully applied by physicians of varying experience in many different settings to reduce incidence of ankle radiography
- With proper application of the rules the risk of patient dissatisfaction or missed fractures is negligible
- Widespread use of the Ottawa ankle rules would lead to large savings in health care costs
- The multiphase methodological approach used to develop, validate, and implement these decision rules may be applied to other clinical problems

applied and interpreted the chances of missing a clinically important fracture are remote. Fractures were diagnosed after discharge equally often in those who did and did not have radiography. In the former group, fractures were not diagnosed because either the physician misinterpreted the radiographs or the radiographs did not show a fracture on the first visit. In the group who did not have radiography, fractures were missed because the rules were not used or were misinterpreted and in one case because of gross swelling (table V). None of these patients suffered delayed healing or added morbidity.<sup>32</sup> The most common errors in interpretation of the rules were disregarding the presence of medial malleolar tenderness or failing to palpate the entire distal 6 cm of the posterior edge of the fibula. The latter is especially important because some fractures exit posteriorly 5 or 6 cm proximal to the tip of the fibula.

The rules may be unreliable in cases when clinical assessment is difficult—for example, with altered mentation, intoxication, other painful injuries, diminished sensation in the lower extremities, or a language barrier. In this study physicians thought that the rules were unreliable in a few patients in whom gross swelling made palpation of the posterior edge of the malleolus impossible (table IV). Whether or not radiography is ordered patients must always be advised to seek follow up if their pain or ability to bear weight has not improved in five to seven days.

Our data indicate that patients with ankle injury are satisfied with care that does not include radiography. Integral to this satisfaction is adequate communication from the physician and use of printed instructions. If the physician has carefully applied the rules, documented the clinical findings, used good judgment, and provided advice on follow up the risk of patient dissatisfaction<sup>33-35</sup> or litigation is extremely low even in the unlikely event of a missed fracture.

This study showed that the Ottawa ankle rules can be successfully applied by many different physicians in many settings to achieve considerable reductions in ankle radiography, waiting times, and health care costs without an increase in patient dissatisfaction or the rate of missed fractures. The multiphase methodological approach used to develop, validate, and implement these decision rules may be applied to other clinical problems.

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