

# Safety and efficiency of the Ottawa ankle rule in a Swiss population with ankle sprains

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## Abstract

**Objectives:** we examined the accuracy of the Ottawa Ankle Rule (OAR) to rule out ankle and mid-foot fractures in patients presenting with acute ankle sprain and differences of accuracy between surgeons and non-surgeons.

**Design:** prospective cohort study.

**Setting:** Swiss urban secondary care centre.

**Participants:** between September 2001 and October 2002 359 patients presented with a case of ankle sprain. Of these, 251 patients both met recruitment criteria and provided data for this study. A group of surgeons and non-surgeons assessed the OAR and all patients underwent blinded radiographic assessment.

**Main outcome measures:** sensitivity, specificity of the OAR.

**Results:** of the 251 patients with ankle sprains 33 had an ankle fracture (13%) and none had a mid-foot fracture. All cases with a fracture had a

positive OAR result (sensitivity 100% 95% CI; 89–100) and of 218 patients without a fracture, the OAR was negative in 45 cases (specificity 21%; 16–27). In the subgroup of patients assessed by surgeons, sensitivity was 100% (77–100) and specificity was 32% (20–46). In the non-surgical group, sensitivity was also 100% (82–100) but specificity was lower (17% (11–23).

**Conclusions:** this validation study of the OAR in a Swiss setting produced similar results than those published previously in various other settings. We found differences in the performance of the rule between surgical and non-surgical staff indicating that the OAR has its interpretation component which is more difficult to judge properly by well-instructed non-surgical assessors.

**Key words:** ankle injuries; Ottawa ankle rule; sensitivity; specificity; decision support technique

## Introduction

Clinical decision aids aim to guide diagnosis or treatment by integrating a small set of easily accessible clinical information. The prototype example for such a decision aid is the Ottawa Ankle Rule (OAR) [1] to reduce the number of unnecessary x-rays in patients presenting with acute ankle sprain. The OAR states that ankle series radiographs are only indicated if there is any pain in the ankle region, and if there is either bone tenderness along the distal 6 cm of the posterior edge or the tip of either malleolus or inability to bear weight (4 steps) immediately after the injury and in the Emergency Department (ED).

The OAR is calibrated towards high sensitivity at optimal specificity. High sensitivity minimises false negative results (fracture is present although the OAR is negative). On the other hand specificity correlates with the usefulness of the rule in helping avoid unnecessary x-rays and associated costs. A systematic review assessing the diagnostic value of the OAR revealed substantial heterogeneity of specificity ranging from 11 to 67

percent that could not be explained from reported study characteristics [2]. This indicates that it is fairly unclear what we can expect from an implementation of the OAR in terms of cost savings in practice. More understanding of the circumstances which affected specificity in the reviewed studies could increase our understanding of the optimal use of the OAR in practice.

Therefore, in this validation study of the OAR we had two aims: a) to validate the OAR in a Swiss population and, b) to study variability of the rule's efficiency in practice using a set of co-registered details about the examination itself, the assessor of the rule and the patients. Since interpretation of the bony tenderness item appears to be the most challenging task when applying the rule, we hypothesised that medical staff that completed a surgical training would perform better than surgically inexperienced assessors even if both groups were trained to perform the rule as suggested by the developers [1, 3].

## Methods

This study took place at the emergency department of a district hospital in Zurich Switzerland between September 2001 and October 2002. Eligible were patients aged 18 years and older with a history of isolated ankle trauma within 10 days of presentation. We excluded patients studied by radiography before our assessment; patients with pre-existing musculoskeletal disease, coagulopathy, or patients with previous history of surgery or recent (<3 months) injury of the affected ankle, isolated skin injuries only, pregnancy, patients with altered mental status at the time of consultation, revisits for the same injury, patients with major trauma, patients with gross deformity of the ankle, patients with polyneuropathy and patients with multisystem trauma. The study was approved by the human ethics review board, and patients provided written informed consent.

### Index test

All assessors of the OAR received a presentation about the use and interpretation of the rule and received a printed card with a description. We also placed posters with a description of the rule in the emergency department as suggested by the developers [1, 4].

In addition we secured data of a set of patients' characteristics and contextual information regarding the injury mechanism and circumstances while testing of which we thought *a priori* that they could influence the accuracy of the Ottawa ankle rule. This set contained information about the time of examination (6 pm to 11 pm versus any other time). This interval was chosen because this is the busiest time at this ED. We recorded surgical experience of the examiner (board certified surgeons; versus others (physicians in training to become General Practitioners, and medical students working at the ED), patients' age (continuous variable), male gender, academic profession (yes/no), injury mechanism (pronation, supination), menopausal status, and the body mass index (BMI). We also registered the result of each item of the OAR (bone tenderness along the distal 6 cm of the posterior edge or the tip of either malleolus or inability to bear weight (4 steps) immediately after the injury and in the ED) separately along with the results of the rule.

### Reference test

All patients underwent a series of ankle x-rays (anterior/posterior and lateral) and a series of mid-foot x-rays (anterior/posterior and oblique) after the OAR assessment. All radiographs were interpreted by a trained radiologist who was blinded to the results of the OAR and the emergency physician's interpretation. A clinically significant fracture was any avulsed fracture fragment greater than 3 mm on the radiograph. If the avulsed fracture fragment was smaller than 3 mm, the radiograph was interpreted as a clinically insignificant fracture and was regarded as no fracture in data analysis. The radiologist's interpretation was regarded as the reference against which we assessed the accuracy of the OAR.

### Statistical Analysis

We cross tabulated the OAR result against the result of the x-ray (ankle fracture present/absent) and calculated sensitivity and specificity along with 95% confidence intervals using the exact method. For each patient we determined whether he or she was classified as "false positive" (ie, OAR was positive but the patient had no fracture). We calculated the frequency with which bony tenderness was assessed as positive among surgeons and non-surgeons if the patient was classified as "false positive".

### Modelling

We first assessed the association of each of the contextual items stated above with the classification "false positive" separately using logistic regression analysis. This analysis allowed examination of the influence of each of the independent variables (ie, the set of items listed above) on the dependent variable (ie, false-positive). In a second step we performed multivariate analysis where we entered surgical experience along with various patients' characteristics showing strong association in the univariate analysis as independent variables. Analyses were performed with the Stata<sup>®</sup> 9.2 statistical software package (4905 Lakeway Drive, College Station, USA).

## Results

During the study 6600 patients were referred to the ED out of which 359 presented with a case of ankle sprain (5.4%). Of these, 108 patients had to be excluded from the study because they met exclusion criteria, refused to participate or did not undergo OAR examination (see figure 1). None of the patients had a mid-foot fracture. A description of the study population is given in the table 1.

Of the 251 patients with ankle sprains 33 had an ankle fracture (13%). All cases with a fracture had a positive OAR result (sensitivity 100% 95% CI; 89–100) and of 218 patients without a fracture, the OAR was negative in 45 cases (specificity 21%; 16–27). Figure 2 shows the results of the present study together with sixteen studies [1,4–16] that assessed the ankle rule published in a recent systematic review [2].

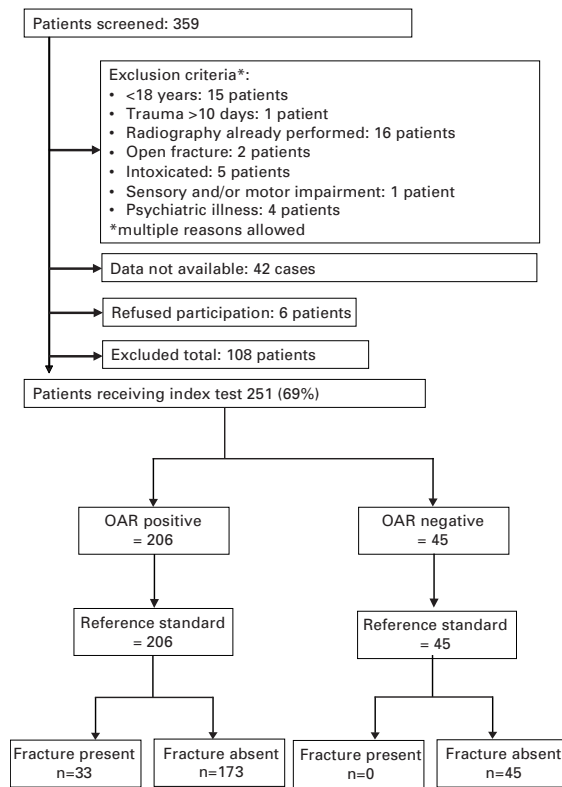
Compared to trained surgeons, general physicians and house officers with only minor surgical training had a higher number of positive OAR results (75% vs. 85%;  $p = 0.06$ ) and had higher numbers of false positive results (OR 2.14 (95% CI; 1.10 to 4.18);  $p = 0.03$ ). A higher BMI was also associated with an increased number of false positives (OR 1.09 (95% CI; 0.99 to 1.21);  $p = 0.08$ ) (table 2). None of the additionally collected

**Table 1**

Showing population means (SD) or numbers (percentage) were appropriate.

Patients' characteristics	Fracture present (n = 33)	Fracture absent (n = 218)
Age	51 (SD 21)	38 (SD 17)
Male	13 (39%)	123 (56%)
BMI	25 (SD 4)	24 (SD 4)
Academic	1 (3%)	37 (17%)
Supination trauma	26 (79%)	195 (89%)
OAR positive	33 (100%)	173 (79%)

**Figure 1**  
Patient flowchart.



factors were strongly associated with the number of false positives. In the subgroup of patients assessed by surgeons, sensitivity was 100 percent (77–100) and specificity was 32 percent (20–46). In the non-surgical group, these figures were 100 percent (82–100) and 17 percent (11–23) indicating that non-surgical staff would order almost twice as many unnecessary radiographs than surgeons (reduction by 32% vs. 17% respectively) however without missing any fractures. (For results see table 3)

**Table 2**

Shows the results of a multivariate model assessing the association between surgical experience and false positive results when correcting for various patients' characteristics.

Patients' characteristics	Odds Ratio (95% CI)	p-value
Non-surgeons	2.14 (1.10 to 4.18)	0.025
BMI	1.09 (0.99 to 1.21)	0.078
Male gender	1.26 (0.622 to 2.57)	0.516
Patients' age	0.99 (0.97 to 1.01)	0.554
Academic	1.09 (0.47 to 2.52)	0.839
Supination trauma	0.67 (0.17 to 2.59)	0.560

**Table 3**

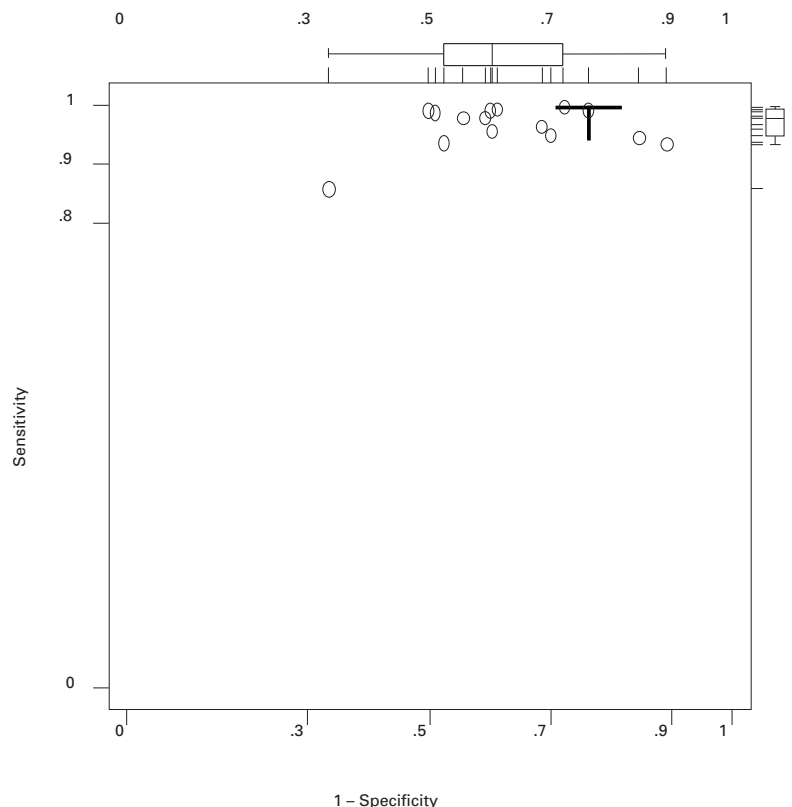
Shows results of the 2x2 tables along with sensitivity and specificity for the complete cohort and the two subgroups of surgeons and non-surgeons.

Group	TP*	FP*	FN*	TN*	Sensitivity [%]	Specificity [%]
All	33	173	0	45	100 (89–100)	21 (16–27)
Surgeons+	14	37	0	17	100 (77–100)	32 (20–46)
Non-surgeons+	18	136	0	27	100 (82–100)	17 (11–23)

\* TP, FP, FN and TN correspond to true positives, false positives, false negatives, true negatives.  
+ Two classifications (surgeon vs. non-surgeon) were missing

**Figure 2**

Receiver operating characteristics plot showing the results of 15 studies (circles) that assessed the ankle rule in a recent systematic review [2] with the results (and confidence intervals) of the current study (T). The box plots on the axes indicate that the results of the current study lie well within the range of the previous reports.



## Discussion

This study has two main findings: we successfully validated the OAR in a Swiss population and we showed that even if properly trained in respect to application of the OAR, assessments of non-surgeons were more likely to be falsely positive than those of surgeons.

Reports of clinical decision rules are becoming increasingly common throughout the medical literature and particularly within journals of emergency medicine. Investigators conducting a validation study have an obligation to ensure that they fully understand how the decision rule is to be applied. If necessary, the investigator should discuss the accurate application of the decision rule with the original researcher and should be prepared to accurately present the decision rule to the study physicians. This must involve a brief but adequate training session (eg, 15 minutes during a rounds presentation) and training tools such as posters, pocket cards, and audiovisual aids [3]. An important aspect of validation that is often overlooked is the consistency with which clinicians interpret the rule. In the case of the OAR the developers were careful to determine the inter-observer agreement between pairs of physicians. Stiell and co-workers were aware about the risk of inter-rater variability and provided careful instructions regarding the rule's correct application and interpretation. Most of the validation studies had adopted this advice but a systematic review summarising them showed that these measures cannot fully standardise the procedure. [2] It appears plausible that the subtlety of palpation technique might impact on the false-positive rates, that is, the percentages of patients who apparently indicated pain (or were unable to walk 4 steps) but had no fracture. We speculate that surgeons assessing the rule were more confident about the results of their examination than non-surgeons which resulted in a lower number of positive OAR results.

Our study has two limitations. Although we carefully planned the study and informed all the medical staff of our hospital we failed to register the result of the OAR in 42 cases. This may have caused selection bias in our population. However, our fracture prevalence of thirteen percent was fairly similar to the median prevalence of twelve percent of ankle fractures found in a systematic review of the OAR [2] which indicates that selection did not necessarily occur based on the severity of trauma. Secondly, although we conducted an *a priori* definition of factors that could potentially explain variability of specificity, only one was significantly associated. This limited the extent to which we could explore the heterogeneity we observed in the systematic review. Arguably, access to the individual patient data of the thirty-two studies included in the review published in 2003 could give more insight into reasons for the variability of specificity across studies than was possible within this study. However, unresolved methodological aspects, resources, time

and cooperation required for such studies limit the feasibility of this approach [17]. Moreover, potentially relevant information such as details concerning the examination, the examiner, or the patient might not have been registered systematically [18].

There is compelling evidence from over thirty studies that the OAR is a useful tool to triage patients to undergo radiography after ankle sprain. Application of the rule does lead to substantial reductions of unnecessary x-rays and costs. A cost effectiveness analysis showed that in the United States, the savings varied between US\$ 614'226 and US\$ 3'145'910 per 100'000 patients, depending on the charge rate for radiography despite the cost of missed fractures including litigation costs [19]. Our study also showed that the rule's performance can be further increased if people trained in surgery apply the rule. Nevertheless we think that one aspect we observed in this study deserves further examination. We speculate that physicians are hesitant to rely on the results of their physical examination. While (trauma) surgeons who are supposed to be better trained to assess the condition of a bone, outperformed non-surgeons in our study, overall both groups performed only moderately but well within the ranges of previously published reports. In times of increased legal pressure and the growing obligation to document and prove clinical findings for social and health insurance purposes it is likely that the performance of the OAR measured in a study can not be reached in clinical practice. The set-up of our study and many other earlier validation studies defined that all patients should undergo radiography irrespective of the OAR result. Thus, assessment of the rule is inconsistent within the study and the discussion about the OAR's capacity to reduce the number of unnecessary x-rays remains somewhat theoretical. Perhaps only registration of x-ray ordering before and after implementation of the OAR in a clinical setting could point at the net benefit of this rule.

In conclusion, this validation study of the OAR in a Swiss setting produced similar results as those published previously in various other settings. We observed differences in the performance of the rule between surgical and non-surgical staff indicating that even this simple rule has its interpretation component which is more difficult to judge properly by well-instructed non-surgical assessors.

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