

# Prospective Validation of a Decision Rule for the Use of Radiography in Acute Knee Injuries

Ian G. Stiell, MD, MSc, FRCPC; Gary H. Greenberg, MD, FRCPC; George A. Wells, PhD; Ian McDowell, PhD; A. Adam Cwinn, MD, FRCPC; Norman A. Smith, MD, FRCPC; Teresa F. Cacciotti, RN; Marco L. A. Sivilotti, MD, MSc, FRCPC

**Objective.**—To validate a previously derived decision rule for the use of radiography in patients with acute knee injury.

**Design.**—Prospectively administered survey.

**Setting.**—Emergency departments of two university hospitals serving adults.

**Patients.**—Convenience sample of 1096 of 1251 eligible adults with acute knee injuries; 124 patients were examined by two physicians.

**Main Outcome Measures.**—Attending emergency physicians assessed each patient for standardized clinical variables and determined the need for radiography according to the decision rule. Patients who did not have radiography underwent a structured telephone interview at day 14 to determine the possibility of a fracture. The rule was assessed for ability to correctly identify the criterion standard, fracture of the knee. An attempt was made to refine the rule by means of univariate and recursive partitioning analyses.

**Results.**—The decision rule had a sensitivity of 1.0 (95% confidence interval [CI], 0.94 to 1.0) for identifying 63 clinically important fractures. Physicians correctly interpreted the rule in 96% of cases, and the  $\kappa$  value for interpretation was 0.77 (95% CI, 0.65 to 0.89). The potential relative reduction in use of radiography was estimated to be 28%. The probability of fracture, if the decision rule were "negative," is estimated to be 0% (95% CI, 0% to 0.4%). Attempts to refine the rule led to a model with improved specificity but with an unacceptable loss of sensitivity.

**Conclusion.**—Prospective validation has shown this decision rule to be 100% sensitive for identifying fractures of the knee, to be reliable and acceptable, and to have the potential to allow physicians to reduce the use of radiography in patients with acute knee injury.

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From the Division of Emergency Medicine (Drs Stiell, Greenberg, Cwinn, Smith, and Sivilotti), the Departments of Epidemiology and Community Medicine (Drs Stiell, Wells, and McDowell) and Medicine (Drs Stiell and Wells), and the Clinical Epidemiology Unit (Drs Stiell and Wells and Ms Cacciotti), University of Ottawa (Ontario) Faculty of Medicine. Dr Stiell is an MRC scientist with the Medical Research Council of Canada Research Personnel Program.

Reprint requests to Clinical Epidemiology Unit, Loeb Medical Research Institute, Ottawa Civic Hospital, 1053 Carling Ave, Ottawa, Ontario, Canada K1Y 4E9 (Dr Stiell).

AN ESTIMATED 1.3 million patients are seen annually in US emergency departments with the problem of acute knee trauma.<sup>1,2</sup> Although only 6% of these patients have suffered a fracture, the vast majority undergo plain radiography of the knee.<sup>2-6</sup> More than 92% of these radiographic results are negative for fracture and exemplify "little ticket" items, the many low-cost but high-vol-

ume tests that may contribute as much to health care costs as high-cost but low-volume procedures.<sup>7,8</sup> There are no widely accepted guidelines or decision rules, such as those recently developed for ankle radiography,<sup>9-12</sup> that would allow physicians to decrease the use of unnecessary knee radiography and thereby diminish costs for health care systems. Standard emergency medicine textbooks imply that radiographs should be routinely performed but have little data on which to base recommendations.<sup>13-17</sup>

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To address this clinical problem, we recently developed a decision rule that would allow physicians to be more selective in their use of knee radiography without missing clinically important fractures.<sup>18</sup> In our previous study,<sup>18</sup> 1047 adult patients with knee injuries were systematically assessed for 23 standardized clinical findings. A total of 127 patients were examined independently by two physicians to determine interobserver agreement. Those variables found to be most reliable and most highly correlated with a fracture were then analyzed using a recursive partitioning multivariate technique. The resulting decision rule would have identified 100% of the 68 fracture cases and is composed of five clinical findings related to age, tenderness, and function (Table 1).

The objective of the current study was to validate prospectively the decision rule in a new set of patients to determine its classification accuracy, reliability, acceptability to physicians, and potential for reducing use of radiography. Clinical prediction rules frequently do not perform as well when tested in patients other than those for whom the rule was derived.<sup>19,20</sup> We also wished to explore the potential for refining the rule by improving simplicity and specificity while maintaining a sensitivity of 1.0 for identifying clinically important fractures of the knee.

## METHODS

### Study Population

The study was conducted in the emergency departments of two teaching hospitals serving adults affiliated with the University of Ottawa (Ontario) Faculty of Medicine: Ottawa Civic Hospital and Ottawa General Hospital. All adult patients who presented with acute knee injuries were eligible and "knee" was broadly defined to include the patella, the head and neck of the fibula, the proximal 8 cm of the tibia, and the distal 8 cm of the femur. We excluded patients who were younger than 18 years, were pregnant, had isolated injuries of the skin, were referred from outside the hospital with radiographs, whose knee injury occurred more than 7 days previously, had returned for reassessment of the same injury, had an altered level of consciousness, were paraplegic, or had multiple injuries. The study was approved, without the need for consent, by the institutional research ethics committee.

### Standardized Patient Assessment

Patients were assessed for 14 clinical variables that were either components of the decision rule or were felt to be potentially valuable in refining the rule. Patients were assessed by one of 31 attending staff physicians who were all certified in emergency medicine by either the American Board of Emergency Medicine, the Royal College of Physicians and Surgeons of Canada, or the College of Family Physicians of Canada. The physicians were trained to assess the clinical variables and interpret the decision rule in a 1-hour lecture. A standardized description of examination techniques was appended to the data collection sheet that the physicians completed before radiography. Radiography was ordered according to the usual clinical practice of the individual physicians. The physicians were asked to rate their theoretical comfort in implementing the decision rule for that patient, using a five-point scale from "very comfortable"

to "very uncomfortable." Whenever feasible, a second data collection form was completed by another attending physician (usually not one of the authors) who was blinded to the results of the first assessment.

### Outcome Measure

The criterion standard that the decision rule was developed to identify was a clinically important fracture of the knee demonstrated on a standard knee radiographic series. The radiographs were interpreted by qualified radiologists who were blinded to the contents of the data collection sheet. Our definition of clinically important fracture was developed by a consensus of orthopedic surgeons and emergency physicians at the University of Ottawa.<sup>18</sup> Clinically unimportant fractures are small avulsion fragments that generally require no specific treatment with a cast or surgery. We defined a clinically important fracture as any bone fragment at least 5 mm in breadth or any avulsion fracture, regardless of size, if associated with complete disruption of tendons (patellar or quadriceps) or ligaments (medial collateral, lateral collateral, anterior cruciate, or posterior cruciate). Such a diagnosis of complete ligamentous disruption was confirmed during follow-up assessment by qualified orthopedic surgeons. We have successfully used an analogous definition of clinically important fracture in the application of the Ottawa ankle rules.<sup>9,10,12</sup>

A structured telephone interview at 14 days after initial examination was used to assess the possibility of fracture in those patients discharged without radiography. We believed that the study could not demand radiography for all patients because the referral rate for radiography at the study institutions before this study was only 70% of patients with a knee injury. Patients were asked to return for reassessment if they failed to satisfy all of these explicit criteria: (1) pain is better, (2) ability to walk is better, (3) does not require assistance to walk (crutches, cast, or splint), and (4) has returned to normal occupational activities. The assessment of these criteria was made by research assistants unaware of the patient's status for the decision rule. These criteria had been successfully applied in previous ankle and knee radiography studies.<sup>10,12,18</sup>

### Statistical Analysis

The classification performance of the decision rule for identifying patients with a clinically important fracture was assessed by calculating sensitivity and specificity with 95% confidence intervals (CIs).<sup>21</sup> Because of the binary pre-

Table 1.—Decision Rule for Radiography in Acute Knee Injuries

A knee x-ray examination is only required for acute knee injury patients with one or more of these findings related to age, tenderness, or function:

- Aged 55 years or older
- or
- Tenderness at head of fibula
- or
- Isolated tenderness of patella\*
- or
- Inability to flex to 90°
- or
- Inability to bear weight both immediately and in the emergency department (four steps)†

\*No bone tenderness of knee other than patella.

†Unable to transfer weight twice onto each lower limb regardless of limping.

dictive nature of the decision rule, no attempt was made to construct a receiver operating characteristic curve.<sup>22</sup> The physicians' accuracy in interpreting the decision rule was measured by the percentage agreement with the actual rule as judged by the investigators. The reliability of the physicians' interpretation was assessed by the  $\kappa$  coefficient of interobserver agreement.<sup>23</sup> The potential relative reduction in radiography referral was estimated by comparing the theoretical referral rate in this study with the baseline referral rate documented at area hospitals.<sup>8</sup> Finally, likelihood ratios and the probability of a fracture, given a "negative" decision rule, were calculated from the combined data of the derivation and validation sets.<sup>24-28</sup>

The data collected were further analyzed to assess the potential for refining the decision rule to achieve a sensitivity of 1.0 with the highest possible specificity and with the fewest number of variables. Two combined variables were created by grouping the individual variables "patellar tenderness" and "direct blow," as well as "inability to bear weight immediately and in the emergency department." The 16 individual and combined variables were assessed for interobserver agreement by calculating the  $\kappa$  coefficient with 95% CIs.<sup>23,27,28</sup> Furthermore, the association of the variables with clinically important fracture was assessed by the  $\chi^2$  test with 1 *df*. Those variables found to be both reliable (highest  $\kappa$  values) and strongly associated with a fracture (highest  $\chi^2$  values) were analyzed by a  $\chi^2$  recursive partitioning technique to confirm the best combination of predictor variables.<sup>29-32</sup>

## RESULTS

### Patient Characteristics

During the study period, January 1994 to March 1995, a total of 1108 (89%) of 1251 eligible patients were enrolled in the study; 12 of these patients were excluded from further analysis because

Table 2.—Characteristics of Knee Injury Patients Entered Into the Study

Characteristic	Patients (n=1096)
Age, y	
Mean (SD)	37 (16)
Range	18-92
Male, No. (%)	600 (55)
Hospital, No. (%)	
Ottawa Civic	582 (53)
Ottawa General	514 (47)
Mechanism of injury, No. (%)	
Twisting	573 (52)
Direct blow (fall or object)	440 (40)
Other indirect	83 (8)
Activity at time of injury, No. (%)	
Work	159 (15)
Sports	396 (36)
Other	541 (49)
Isolated knee injury, No. (%)	942 (86)
Clinically important fracture, No. (%)*	
Patella	28 (3)
Proximal tibia	22 (2)
Head of fibula	8 (1)
Distal femur	9 (1)
Tibial spine	5 (0.5)
Tibial tuberosity	1 (0.1)
Clinically unimportant fracture, No. (%)	5 (0.5)
Radiography performed, No. (%)	
Knee	739 (67)
Patella	60 (5)
Follow-up in cases without radiography (n=357), fracture	0
Immediate management, No. (%)	
Referred to orthopedics	74 (7)
Admitted	24 (2)
Mean time in emergency department for nonfracture cases, min (SD)	
Radiography	123 (49)
No radiography	83 (41)

\*Patients may have fracture in more than one location.

they did not undergo radiography and could not be reached in follow-up. Of the remaining 1096 patients, 63 (6%) were determined to have clinically important fractures and another five (0.5%) were found to have clinically unimportant fractures (Table 2). Of the 357 patients who did not have radiography and were successfully reached in follow-up, none required reassessment. The 143 eligible patients not enrolled in the study were similar in clinical and demographic characteristics to the overall study group except for a higher prevalence of clinically important fractures (13%); this reflects the fact that physicians sometimes missed filling a data form on the more severely injured patients. The subset of 124 patients examined independently by two physicians were also similar to the overall group but had a higher mean age (40 years).

### Prospective Validation

The prospective classification performance of the decision rule is shown in Table 3. All 63 clinically important fractures were identified by the decision rule (sensitivity, 1.0; 95% CI, 0.94 to 1.0). Furthermore, 511 nonfracture patients did not require radiography according to the rule (specificity, 0.49; 95%

Table 3.—Classification Performance of the Decision Rule for Identifying Clinically Important Knee Fractures Among the Study Patients\*

Decision rule	Fracture	
	Yes	No
Positive	63	522
Negative	0	511
Sensitivity (95% CI)	1.0 (0.94-1.0)	
Specificity (95% CI)	0.49 (0.46-0.52)	
Negative predictive value (95% CI)	1.0 (0.99-1.0)	
Positive predictive value (95% CI)	0.11 (0.08-0.13)	

\*CI indicates confidence interval.

CI, 0.46 to 0.52). The physicians correctly interpreted the rule (as determined by the investigators) in 96% of cases and would not have missed any fractures due to misinterpretation. Physician interobserver agreement for interpretation was excellent, with a  $\kappa$  value of 0.77 (95% CI, 0.65 to 0.89). The physicians indicated that they would have been uncomfortable or very uncomfortable in implementing the rule in fewer than 5% of cases. Three of the five clinically unimportant fractures would not have been identified by the rule; none of these cases were treated with a cast.

Application of this decision rule to the study patients would have led a relative reduction in the use of knee radiography of 28% from baseline levels (from 74% to 53%).<sup>8</sup> Among nonfracture patients in this study, those who did not undergo radiography spent an average of 39 minutes less in the emergency department than those who did undergo radiography (84 minutes vs 123 minutes). Based on the combined 2143 patients in the derivation and validation sets, the likelihood ratio negative for a fracture is estimated to be 0 (95% CI, 0 to 0.07). Consequently, given the prevalence of fracture in these patients, if the decision rule were negative, the probability of a clinically important knee fracture would be 0% (95% CI, 0% to 0.4%).

### Attempted Refinement of Decision Rule

Table 4 lists the proportion of patients with and without clinically important knee fractures who were positive for 16 clinical predictor variables. All associations demonstrated statistical significance at a *P* value less than .01. The  $\chi^2$  values corresponding to a distribution with 1 *df*, the basis for the recursive partitioning splits, are also given. Interobserver agreement was substantial ( $\kappa \geq 0.6$ ) for 12 variables; agreement for classifying patients as age of 55 years or older was not measured but was assumed to be good.

A series of  $\chi^2$  recursive partitioning analyses yielded a model that was more

specific than the original decision rule. This refined model was identical to the original rule except that "inability to flex to 90°" was replaced by "inability to flex to 60°." Application of this refined model to the current study population would have yielded a sensitivity of 1.0, a specificity of 0.56, and a potential relative reduction in radiography of 36%. Application of the refined model to the 1047 derivation set patients (1992 to 1993), however, revealed that five clinically important fractures would have been missed. The investigators felt that this loss in sensitivity was unacceptable and that the refined model should not be adopted.

### COMMENT

This study demonstrates the validity of a previously derived decision rule for the use of radiography when applied prospectively to a new population of patients with an acute knee injury. In particular, the rule has proven to be highly sensitive for identifying clinically important fractures and to be reliable in the hands of different clinicians. Busy emergency physicians were able to interpret the rule accurately and were comfortable with its use. Physicians can be confident that if radiography is ordered according to the decision rule the likelihood of missing a clinically important fracture is remote. Application of this rule could lead to a large reduction in the use of radiography and decreased waiting times for patients. Ultimately, widespread use of the decision rule could lead to large financial savings for health care systems.

Clinical decision rules (prediction rules) reduce the uncertainty in patient care for both diagnostic and therapeutic decision making. Methodological standards for the development and testing of clinical decision rules have been well established, and this study satisfies most of the recommended criteria.<sup>19,28</sup> The few previous studies to develop guidelines for knee radiography have been relatively small, have had one or more methodological shortcomings, or have not been validated.<sup>24-27</sup> In this study, the outcome measure, fracture, was clearly defined, was biological in nature, and was assessed without knowledge of the predictors. The predictor variables were well standardized, assessed without knowledge of the outcome, and were shown to have good interobserver agreement. The study subjects were selected without bias and represented a wide spectrum of clinical and demographic characteristics. The mathematical techniques, including  $\kappa$  analyses as well as univariate and multivariate recursive partitioning techniques, were described.

Table 4.—Univariate Correlation and  $\kappa$  Values of Clinical Findings for Clinically Important Fracture in 1096 Knee Injury Patients

Clinical Finding	Clinically Important Fracture, %		$\chi^2$ *	P	$\kappa$ (n=124)
	Yes (n=63)	No (n=1033)			
Age $\geq 55$ y	48	13	58.4	<.001	...
Mechanism					
Twisting	33	53	9.6	<.01	0.76
Direct blow	64	39	15.2	<.001	0.84
Effusion					
Visible	62	28	31.7	<.001	0.58
Tense	40	10	54.4	<.001	0.50
Flexion					
<90°	64	22	54.7	<.001	0.74
<60°	46	10	74.3	<.001	0.83
Lack of extension $\geq 15^\circ$	39	14	27.3	<.001	0.67
Tenderness					
Patella	52	23	27.0	<.001	0.69
Isolated patella	27	13	10.6	<.001	0.60
Patella and direct blow†	46	16	35.3	<.001	0.72
Head of fibula	32	8	40.0	<.001	0.84
Patellar/quadriceps tendon tear	9	1	20.3	<.001	-0.01
Inability to bear weight					
Immediately	44	79	39.1	<.001	0.81
In emergency department (four steps)	28	76	67.5	<.001	0.68
Immediately and in emergency department†	53	15	59.5	<.001	0.81

\*The  $\chi^2$  value for 1 df.

†Variable created by combination.

The current medicolegal climate of North American medical practice does not foster the most efficient use of diagnostic tests:

Physicians can, however, be assured that they are unlikely to miss a clinically important knee fracture if they apply the radiography decision rule accurately. Patients aged 55 years or older are at significantly increased risk for fracture, possibly due to osteoporosis. Specific areas of bone tenderness, either at the patella or the head of the fibula, are high risk features. The specificity of the patellar finding is increased by ordering radiography for patients whose bone tenderness is isolated to the patella only. Patients are also at higher risk for fracture if function is compromised, that is, if they are unable to flex their knee to 90° or to bear weight both immediately and in the emergency department. Patients are judged to be able to bear weight if they can transfer weight twice onto each lower limb, regardless of the presence of limping. This clinical finding has proven to be reliable with good  $\kappa$  scores for this decision rule and for the Ottawa ankle rules.<sup>9,18</sup>

Physicians should not expect the decision rule to be dependable in certain situations. The rule has not been tested in patients younger than 18 years and should not be applied to the pediatric population. The decision rule should not be used in circumstances in which clinical assessment is unreliable: alcohol or other drug intoxication, head injury, multiple painful injuries, paraplegia, or diminished limb sensation. Patients should be given written instructions that include the advice to seek further medical care if pain or ability to walk have not improved in 5 to 7 days.

Physicians should also realize that the vast majority of patients with a knee injury have suffered soft-tissue injuries, which may include serious ligament, tendon, or meniscal tears. In most cases, plain radiography does little to aid the diagnosis of soft-tissue injury.<sup>13,45</sup> Uncommonly, avulsion fractures of the tibial spine and the lateral tibial condyle (Segond fracture) are associated with ligamentous disruptions.<sup>46-48</sup> Furthermore, sophisticated diagnostic measures, such as magnetic resonance imaging or arthroscopy, are rarely available for the emergency department assessment of acute knee injuries. Consequently, physicians must rely on the accuracy of their clinical examination to identify patients at high risk for delayed functional recovery due to major soft-tissue injury of the knee. We are currently developing and validating a decision rule to help with the diagnosis of these patients in the emergency department.

undergo knee radiography at the study institutions. Allowing the physicians to enroll only those patients for whom they felt radiography was indicated would have introduced selection bias and would have denied us a clear and reproducible patient definition. We are confident that the use of a structured telephone interview eliminated the possibility of missed fractures. This follow-up technique has been successfully applied in three previous studies.<sup>10,12,13</sup>

Readers may dispute our decision to discard the apparently more efficient decision model developed during the refinement stage of this study. The refined model, by altering one variable (inability to flex to 60° rather than to 90°) would have improved specificity and the potential relative reduction in radiography. This would have been associated, however, with a reduction in sensitivity (0.92) in the original derivation population. We are convinced that North American emergency physicians are unwilling to miss clinically important fractures and, hence, would not adopt a decision rule with less than near perfect sensitivity. Emergency physicians have been shown to be conservative in ordering radiography, likely due to the nature of emergency department practice.<sup>39,40</sup> These physicians deal briefly with large numbers of patients whom they have not previously met and for whom follow-up is uncertain. Physicians must deal with the "chagrin" of patient expectations and the fear of lawsuits.<sup>41-44</sup>

The decision rule may be considered clinically sensible in that it has a clear purpose, is easy to remember, can be rapidly applied, and gives a simple yes/no direction. The classification performance regarding sensitivity and specificity was clearly documented. Finally, the greatest strength of this study is the prospective validation of the rule in a new set of patients. Many rules either perform less well when tested prospectively or have never been subjected to validation and consequently have had little impact on clinical practice.<sup>20</sup>

The testing of this decision rule for knee radiography remains incomplete in one important aspect: an implementation trial to demonstrate a true reduction in the use of radiography. The true value of a decision rule lies in the ability to alter actual clinical practice.<sup>19,28</sup> The impact of a decision rule may be lessened by patient demands or physician compliance.<sup>39</sup> We have previously demonstrated that properly developed and derived decision rules for ankle radiography led to significant reductions in radiography when used by many physicians in many different settings.<sup>10,12</sup> This decision rule for knee radiography must now undergo the rigorous assessment of an implementation clinical trial, ideally in multiple locations.

Readers may be concerned that not all patients underwent radiography. Requiring radiography for all patients, however, would have been unethical in that only 70% of eligible patients routinely

Use of plain radiography in emergency departments is an important economic issue for health care. Approximately 13.5 million patients undergo extremity radiography annually in US emergency departments.<sup>1</sup> Based on the experience in Ontario, we estimate that more than \$1 billion are spent annually in the United States and Canada on outpatient knee radiography.<sup>49</sup> Current use of radiography for patients with a knee injury is inefficient, with more than 92% of radiographic results being negative for fracture.<sup>3,4</sup> Physicians have lacked evidence-based guidelines that would allow them to be more selective in their

use of knee radiography without jeopardizing patient care. Implementation of validated decision rules would lead to large savings of health care dollars.<sup>50</sup>

The clinical decision rule validated in this study has been shown to be accurate, reliable, and acceptable to physicians, and to have the potential to reduce radiography for patients with a knee injury by 28%. This reduction could lead to important health care savings.

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