ACCURACY OF OTTAWA ANKLE RULES IN PREDICTING THE NEED FOR RADIOGRAPHY IN ANKLE AND MIDFOOT INJURIES IN RWANDA

A dissertation submitted in partial fulfilment of the requirements for the award of the Degree of Master of Medicine in Orthopaedic Surgery of the University of Rwanda

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Kigali, September 6th, 2019
Declaration

The researcher:
I hereby declare that this declaration is my own work and it has not been submitted by me to any other University for the award of a degree.

Signature .................................. Date: 21/05/2019

Dr Emmanuel MURWANASHYAKA

The supervisors:
I hereby declare that this dissertation: “Accuracy of Ottawa ankle rules in predicting the need for radiography in ankle and midfoot injuries in Rwanda” was submitted by Dr Emmanuel MURWANASHYAKA with our approval.

Signature .................................. Date: 21/05/2019

Prof Alex M. BUTERA

Signature .................................. Date: 21/05/2019

Dr Jean Claude BYIRINGIRO
Dedication

To my wife Carine UMUNYANA and our son Aiken Danilo MURWANASHYAKA,

my parents,

my brothers
Acknowledgements

I would like to express my sincere gratitude and appreciation to my supervisors namely Prof. Alex M. Butera and Dr. Jean Claude Byiringiro for their invaluable assistance, guidance and constructive criticism offered to me during the preparation of this dissertation.

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Finally, I wish to thank my wife who, without any medical knowledge has given me the support I needed to complete this study. Without her love, support, understanding and words of encouragement none of this would have been possible, and for this I will be forever grateful.

To you all, a big thank you

Emmanuel MURWANASHYAKA, MD
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List of abbreviations

A/E: Accident & Emergency

USA: United States of America

AP: Antero-Posterior

BAR: Bernese Ankle Rules

UK: United Kingdom

RTA: Road Traffic Accident

MVA: Motor Vehicle Accident

CT: Computed Tomography

MRI: Magnetic Resonance Imaging

OAR: Ottawa Ankle Rules

SPSS: Statistical Package for the Social Sciences

RMH: Rwanda Military Hospital

CHUK: Centre Hospitalier Universitaire de Kigali

KFH, K: King Faisal Hospital, Kigali

GCS: Glasgow Coma Scale

CMHS: College of Medicine and Health Sciences

IRB: Institution Review Board
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Operational definitions

- **Accuracy of the test:** the accuracy of a test is its ability to differentiate the patient and healthy cases correctly.
- **Efficacy:** is a mandatory, minimal qualification of a test to allow its further assessment
- **Validation of the test:** is the process of gathering evidence to provide “a sound scientific basis” for interpreting the scores as proposed by the test developer and/or the test user.
- **Clinical Prediction rule:** is a type of medical research study in which researchers try to identify the best combination of medical signs, symptoms, and other findings in predicting the probability of a specific disease or outcome
- **Ottawa Ankle Rules:** are a set of guidelines for clinicians to help decide if a patient with foot or ankle injury should be offered X-rays to diagnose a possible ankle or midfoot fracture.
- **Ankle fracture:** in our study, ankle fracture was predicted when there are inability to bear weight for 4 steps both immediately and at the time of evaluation, bone tenderness at the posterior edge (6 cm) or inferior tip of the lateral malleolus, or bone tenderness at the posterior edge or inferior tip of the medial malleolus;
- **The midfoot fracture:** in our study the midfoot fracture was predicted when the patient was unable to bear weight for 4 steps both immediately and at the time of evaluation and had bone tenderness at the base of the fifth metatarsal, cuboid, or navicular.
Abstract

Background

Acute injuries of the ankle are among the most common injuries of the musculoskeletal system. They often undergo unnecessary radiographic examination to exclude the presence of a fracture, while only few of them have actual fractures. Prediction rules have been developed in order to reduce the need for radiography in patients with acute ankle trauma. The aim of this study was to determine the accuracy and efficacy of Ottawa Ankle Rules in predicting the need for radiography to rule out ankle and midfoot fractures in acute settings in Rwanda.

Methods

This was a prospective multicenter cross-sectional study for 6 months duration, from May 2018 to October 2018 for adult patients presenting with acute ankle injuries at the Accident & Emergency Departments of three referral hospitals in Kigali (University Teaching Hospital of Kigali, Rwanda Military Hospital and King Faisal Hospital, Kigali). Demographic data such as age, sex, and consulted hospital; clinical parameters such as mechanism of injury, time from injury to presentation at emergency, Ottawa ankle rules and imaging findings were collected. Accuracy measures such as sensitivity, specificity, positive and negative predictive values were measured.

Results

A total of 196 patients from 3 referral hospitals in Kigali (CHUK: 102, RMH: 58, and KFH-K: 36) were enrolled in the study. The majority of the patients presented to Accident and Emergency Departments within 24 hours (67.9%) after injury. Orthopedic residents examined most of the patients (40.3%) compared to others. There were more male (104, 53%) than female (92, 47%) patients with ankle or midfoot injuries, giving a male to female ratio of 2:1.7. There were 143 (73%) patients with fractures and 53(27%) patients without fractures who are considered to have ankle sprains. Only 3 (1.53%) cases have been missed by the test (Ottawa ankle rules). The lateral malleolar fracture was the most commonly seen ankle fracture (29.6%) and was commonly seen in patients who presented with inability to bear weight and lateral malleolar tenderness. The sensitivity and specificity of the OAR were 97.9% and 35.8%
respectively. There was a high false positive of 64.2 % and are related to the high sensitivity of the test. The Positive predictive value was 80.45% whereas negative predictive value was 86.3%.

Conclusion

In this study, the OARs showed high sensitivity and low specificity, and our results are comparable to those published previously in other settings. The implementation of the OARs in Rwandan hospitals can help to decrease the number of unnecessary radiographs if used correctly in patients with acute ankle injuries.

Key words: Ottawa ankle rules, radiography, accuracy, validation
CHAPTER 1. INTRODUCTION

Acute injuries of the ankle are among the most common injuries of the musculoskeletal system. They account for 25% of all injuries of the musculoskeletal system and for 36% of all lower extremity injuries\(^1\). In the USA, five to ten million ankle injuries occur each year. It is estimated that about one ankle sprain occurs per 10,000 people each day in Western countries\(^2\). In the United States and the UK, about 23,000 and 5000 injuries of the ankle, occur respectively each day.\(^3\) Kannus et al. found, a relative increase of 319% of ankle fractures in elderly Finnish population from 1970 to 2000\(^4\). In a Nigerian study, 46.3% of all fractures due to road traffic accident had ankle fractures, while 88.6% of ankle fractures were due to road carnage in a Ghanaian experience\(^5,6\).

The prevalence and severity of ankle injuries have been increasing since the 1950s, and this has been attributed to the increase in recreational activity\(^7\). In their systematic review, Fong et al. found that among 70 sports, the ankle ranked the most commonly injured body region with a prevalence of 34.3%, and the ankle sprain was the most common injury in 33 (76.7%) of 43 sports which provided information about the ankle injury.\(^8\) At least one-third of individuals who sustain an ankle sprain will experience residual symptoms, these symptoms, often termed “chronic ankle instability”, can significantly alter an individual’s health and function by causing him or her to become less active over their life span.\(^9\)

Currently, almost all patients with foot and ankle injuries undergo radiographic examination to exclude presence of a fracture; however, fewer than 15% of these patients actually have fractures\(^10\). The main reasons are mostly patients’ expectations and doctors’ fear of missing the fracture. This defensive approach may lead to unnecessary radiographic examinations, resulting in increased radiation exposure and health care expenditure, as well as longer waiting times in the emergency department\(^11,12\). An estimated $500 million is spent annually in Canada and the United States on ankle radiographs alone\(^13\).

Prediction rules have been developed in order to reduce the need for radiography in patients with acute ankle trauma. These rules aim to reduce the amount of radiographs without the risk of missing clinically significant fractures.\(^14,15\). To reduce unnecessary radiography for acute ankle injuries, Stiell
Ian G. et al, developed the clinical decision rules known as “Ottawa Ankle Rules”, used in assessing and predicting the possibility of fractures of the ankle and foot. The rules state that ankle radiographs are needed only if there is pain on palpation on the posterior edge of either malleolus or inability to walk four steps. Researches have been done in many countries for the validation of Ottawa Ankle Rules; and showed high sensitivity and modest specificity for the detection of ankle fractures. Where implemented, it has been shown to reduce the unnecessary x-rays and its costs; and long stay at emergency.

The purpose of this study is to determine the accuracy and efficacy of Ottawa Ankle Rules in predicting the need for radiography to rule out ankle and midfoot fractures in acute settings in Rwanda. Our study will help in the validation of Ottawa ankle rules in acute settings in Rwanda, and we believe that the results from this study may serve as a basis to recommend practice change in Rwandan hospitals by adopting and implementing the Ottawa ankle rules in order to reduce the unnecessary x-rays as well as their costs; and decrease the long stay in the Emergency Department.

1.1 PROBLEM STATEMENT

Ankle injuries are among the most common injuries presenting at the Accident and Emergency Department in our referral hospitals with an estimation of 5 to 8 cases of ankle injuries per week. The routine is to ask radiographs for every ankle or midfoot injury regardless of suspicion of the fracture or not. This means that patients are unnecessarily delayed in the Accident and Emergency Departments contributing to the overcrowding, undergo unnecessary irradiations and pay unnecessary extra money, contributing to the increase of avoidable health expenditure. Despite being validated in many countries, to our knowledge, no single study has been done for the validation of the Ottawa Ankle Rules in Rwanda. The aim of this study, therefore, is to determine the accuracy of Ottawa Ankle rules in Rwanda for possible future implementation of the rules in our emergency departments.
1.2 RESEARCH QUESTION

What is the accuracy of Ottawa Ankle Rules in the diagnosis of ankle fractures in acute settings in Rwanda?

1.3 OBJECTIVES

1.3.1 General
To assess the validity of the Ottawa Ankle Rules in Rwandan Settings.

1.3.2 Specific
1. To describe the characteristics of the acute ankle injuries presenting at the major referral hospitals in Kigali:
   - Demographic data of ankle injuries
   - Types of ankle injuries
   - Mechanism of injury of ankle injuries

2. To assess the accuracy of Ottawa Ankle Rules to rule out ankle and midfoot fractures in Kigali.
ANKLE INJURIES

Types:
- Fractures
- Fracture-Dislocation
- Sprains

Xray:
Negative: Absence of fracture
Positive: Presence of fracture

Demographic Data:
- Age
- Referring health facility
- Sex
- Place of residency

Mechanism of injury:
- RTA: MVA, Motorcycle accident, Motto-pedestrian, bicycle-pedestrian
- Fall
- Sport injury

Ottawa ankle rules:
- Sensitivity
- Specificity
- Positive predictive value
- Negative predictive value

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<tr>
<th>Xray(-)</th>
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<tr>
<td>Ottawa Ankle Rules(-)</td>
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<td>Ottawa Ankle Rules(+)</td>
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Duration: Time from injury to patient presentation at A/E:
- <24hrs
- 24-48hrs
- >48hrs

Demographic Data:
- Age
- Referring health facility
- Sex
- Place of residency

Mechanism of injury:
- RTA: MVA, Motorcycle accident, Motto-pedestrian, bicycle-pedestrian
- Fall
- Sport injury

Ottawa ankle rules:
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CHAPTER 2. LITERATURE REVIEW

2.1 Anatomy of the ankle and midfoot

The ankle joint is a hinge-type synovial joint located between the distal ends of the tibia and the fibula and the superior part of the talus. The joint is considered saddle-shaped, with a larger circumference of the talar dome more laterally than medially. The dome itself is wider anteriorly than posteriorly, and as the ankle dorsiflexes, the fibula rotates externally through the tibiofibular syndesmosis, to accommodate this widened anterior surface of the talar dome.

Stability of the ankle joint is conferred by three groups of ligaments. The syndesmosis limits motion between the tibia and fibula during activities of daily living, maintaining stability between the bone ends. The medial aspect of the ankle joint is supported by the deltoid ligaments which resist eversion motion and valgus stresses within the joint. The lateral collateral ligaments reduce inversion of the joint, limiting varus stresses and reduce rotation.

There are two longitudinal arches in the foot. These are the medial and lateral longitudinal arches. Calcaneus, cuboid; fourth and fifth metatarsals as well as the calcaneocuboid, cuboido-metatarsal, and intermetatarsal joints make the lateral arc of the foot whereas the medial longitudinal arch consists of the calcaneum, talus, navicular, medial, intermediate and lateral cuneiforms and the first three metatarsals. The most important primary stabilizer of the medial arch is the plantar fascia, followed by the long and short plantar ligaments and then the spring ligament.

The midfoot is made of the navicular, cuboid and the three cuneiform bones; and is between the hindfoot and forefoot. The osseous stability of the midfoot is provided by the ‘Roman arch’ arrangement of the metatarsals, and second metatarsal base recession.

2.2 Epidemiology of ankle injuries

Acute ankle injuries are one of the most common musculoskeletal complaints in the emergency room. Ankle sprains are the most common sports injury, accounting for 10% to 15% of sport-related injuries, and are responsible for 7% to 10% of all emergency room visits. In the United States of America, more than 23,000 ankle sprains are estimated to occur per day which equates to
approximately one sprain per 10,000 people daily\(^2\). A recent study by Shah et al. found an incidence rate of 3.29 ankle sprains per 1000 person years in United States emergency departments\(^9\). In Lagos, Owoeye found that ankle/foot was recorded as the most injured part of the body with 27(19.3\%) presentations in sports injuries\(^32\). It has been shown that the incidence of ankle fractures has increased dramatically since the early 1960s and that the incidence of these fractures increased to 174 fractures per 100,000 persons in 2000; and by the year 2030, these fractures will be increased threefold\(^4\). Ankle fractures usually affect young men and older women\(^33\), the highest incidence of ankle fractures occurs in elderly women\(^27\). In Brazil, Sakaki MH et al. found age range of 21-30 years as the most common to have ankle injuries\(^34\). Williams and Haines found ankle (51\%) and foot (26\%) injuries as the most common injured body parts in high heeled footwear patients and the majority of them were women less than 55 years of age\(^35\).

2.3 Biomechanics of ankle joint

The key movement of the ankle joint complex are plantar- and dorsiflexion, occurring in the sagittal plane; abduction-/adduction occurring in the transverse plane and inversion-eversion, occurring in the frontal plane. Combinations of these motions across both the subtalar and tibiotalar joints create three-dimensional motions called supination and pronation\(^28\). Range of motion in the sagittal plane is between 65 and 75\(^\circ\) moving from 10 to 20\(^\circ\) of dorsiflexion through to 40-55\(^\circ\) of plantarflexion.; the total range of motion in the frontal plane is approximately 35\(^\circ\)(23\(^\circ\)inversion-12\(^\circ\)eversion)\(^36\). The ankle joint complex bears a force of approximately five times body weight during stance in normal walking, and up to thirteen times body weight during activities such as running\(^37\). Experimental studies have indicated that approximately 83\% of load is transmitted through the tibiotalar joint, with the remaining 17\% transmitted through the fibula\(^38\).

The most common mechanism of ankle sprain injuries is by inversion, plantar flexion, and internal rotation. The relative shortness of the medial malleolus and the natural tendency for the ankle to go into inversion rather than eversion usually results in lateral ankle sprains\(^39,40\) Whereas in ankle fractures, the most common injury mechanism is supination-external rotation\(^27\). In view of its impacts on patients daily activities and outcome, ankle injuries need early and appropriate treatment\(^3,41,42\).
2.4 Imaging for the ankle injuries

Imaging of the foot and ankle is commonly undertaken and there are different modalities available for assessment of a variety of abnormalities. Radiography remains the mainstay of imaging but there are several more advanced techniques which can be usefully applied\textsuperscript{43}.

Plain radiography is an initial imaging modality of many musculoskeletal conditions of ankle and foot; typically two views of a body part are taken, conventionally in the anteroposterior (AP) and lateral planes. A modified AP image with the foot and ankle in 15-20\textdegree of internal rotation, the mortise view, provides unobstructed assessment of the talar dome, as a standard AP image can obscure pathology here\textsuperscript{43}.

CT scan is indicated in the preoperative planning of fractures, in particular of complex intra-articular fractures, cross-sectional imaging with CT offers a detailed evaluation of fracture complexity and greater detection of loose bodies than plain radiographs. MRIs can demonstrate additional injuries in children with Salter-Harris fractures, and may also be used to evaluate occult injuries of the talar dome and soft tissue injuries\textsuperscript{44}.

2.5 Ottawa ankle rules

2.5.1 Historical background of the Ottawa Ankle Rules

Stiell Ian G et al. first introduced the Ottawa Ankle Rules in 1992 as a guideline with which to reduce costs of ankle radiographs. He recommended radiography for patients who (1) were 55 years of age or older, (2) were unable to bear weight for 4 steps both immediately and at the time of evaluation, (3) experienced bone tenderness at the posterior edge (6 cm) or inferior tip of the lateral malleolus, or (4) had bone tenderness at the posterior edge or inferior tip of the medial malleolus. Radiography of the midfoot was recommended for patients with bone tenderness at the base of the fifth metatarsal, cuboid, or navicular\textsuperscript{16}. As illustrated in figure 1
Stiell IG et al. conducted a two phase study to develop and test decision rules for the use of radiography in acute ankle injuries. In the 1st phase Ottawa ankle rules (OAR) were developed by assessing 750 adult ankle injury patients prospectively for 32 clinical findings. Two physicians examined 100 ankle injury patients to determine the reliability of the findings by kappa analysis\textsuperscript{16,46}. In the second phase, rules were refined and prospectively validated in another 1485 patients. They demonstrated sensitivity of OAR to be 100% for detecting both malleolar and mid foot fractures without missing any fracture and its ability to reduce the number occasions needing radiography by 30\%\textsuperscript{17}.

### 2.5.2 Sensitivity and specificity of Ottawa ankle rules

Many studies have found high sensitivity and modest specificity of Ottawa ankle rules. A recent systematic review by Bachmann et al. involving 27 studies that evaluated accuracy of Ottawa ankle rules\textsuperscript{45}.
rules reported a sensitivity of almost 100%. This meta-analysis suggested a reduction of 30-40% in the number of radiographs if this rule was to be implemented. A study in France for the validation of the Ottawa ankle rules and its ability to predict fractures showed a sensitivity of 0.98, a specificity of 0.45, and a negative predictive value of 0.99 in detecting ankle fractures. Ioannis Spanos et al. in Greece found a sensitivity of 94.12% and a relative low specificity of 37.65% with possible reduction in the radiographs by 28.6%. In India, Meena S et al. found also an estimate sensitivity to be 100% and specificity to be 78.7%. The positive predictive value was 71.7% and concluded that the implementation of the Ottawa Ankle Rules appears to have the potential to reduce the number of radiographs by about 51%.

A study in Netherlands by Pijnenburg et al. for the comparison of the Ottawa Ankle Rules and local diagnostic decision rules, found a sensitivity of 98% for the Ottawa Ankle Rules to identify clinically significant fractures; the local rules scored 88% for the Leiden rules and 59% for the Utrecht rules. The potential savings in radiographs for the 3 decision rules were 24%, 54%, and 82%, respectively.

Ozkan K et al. compared Ottawa ankle rules and Bernese ankle rules, found sensitivity and specificity of Ottawa Ankle rules were 100% and 77% respectively; and sensitivity and specificity of Bernese Ankle Rules were 94% and 95% respectively. He concluded that Ottawa ankle rules are suggested to be used due to its 100% sensitivity.

Sensitivity of Ottawa Ankle Rules has been shown to be high not only in adult patients but also in pediatric patients. Libetta C. et al. found the sensitivity of the Ottawa ankle rules was 98.3% and the specificity 46.9% and there was no increase in the number of missed fractures. A Karpas found the sensitivity of the Ottawa ankle rules of 97% with a specificity of 25% when applied by trained nurses in Pediatric Emergency department and also found Ottawa ankle rules would have reduced the radiography rate by 21%. In their survey for the use of the Ottawa ankle rules in children by Pediatric emergency physician, Shawn K. Dowling and Ian Wishart found that 87.5% (126 of 144) reported applying the Ottawa ankle rules in children to determine the need for radiographs in acute ankle or midfoot injuries and concluded that the majority of Canadian pediatric emergency physicians indicate that they use the Ottawa ankle rules when assessing children with acute ankle and midfoot injuries.
However, there are other studies that could not validate the Ottawa ankle rules. In his study for the validation of Ottawa ankle rules in Asia, Singapore, S-Y Tay et al. found the sensitivity and specificity of the Ottawa ankle rules for predicting the presence of fracture were calculated to be 0.9 and 0.34, respectively and concluded that the Ottawa ankle rules were not applicable to their population because of inadequate sensitivity. Lucchesi GM et al. was not able to validate with 100% sensitivity the Ottawa rules predicting ankle and midfoot fractures and found 94.6% sensitive and 15.5% specific in predicting ankle fractures and 93.1% sensitive and 11.5% specific in predicting midfoot fractures. However, the Ottawa rules were more sensitive than clinical suspicion alone.

2.6 Bernese ankle rules

2.6.1 Historical background of Bernese ankle rules

In view of low specificity resulted from the use of the Ottawa ankle rule, in 2003, Eggli et al. developed rules that can reduce the false positive: Bernese ankle rule (BAR). The rule consists of three items: indirect fibular stress, direct medial malleolar stress, and compression stress of the midfoot and hind foot. In this study, all fractures were detected correctly by the application of the rule, resulting in a sensitivity of 100% and a remarkably high specificity of 91%. Based on these results, a possible reduction of 84% of ankle and midfoot radiographs could be achieved.

The rules are positive and indicate the need for radiography if one of these steps caused pain. (1) Indirect fibular stress: the malleolar fork is compressed approximately 10 cm proximally to the fibular tip. (2) Direct medial malleolar stress: the thumb is pressed flat on the medial malleolus. (3) Compression stress of the midfoot and the hindfoot: one hand fixes the calcaneus in a neutral and the other hand applies a sagittal pressure on the forefoot, so that the midfoot and hindfoot are compressed

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Fig 2. Bernese ankle rules


2.6.2 Sensitivity and specificity

In his randomized controlled trial on diagnostic performance of the Bernese versus Ottawa ankle rules, R.J. Derksen et al. found high specificity of Bernese ankle rules compared to Ottawa ankle rules with sensitivity and specificity of 0.69 and 0.45, respectively when used by Emergency residents; and sensitivity and specificity of 0.86 and 0.40, respectively when used by triage nurses whereas for the OAR, the sensitivity and specificity were 0.97 and 0.29, respectively when obtained by the Emergency residents; and sensitivity and specificity of 0.86 and 0.25, respectively when used by triage nurses.

Ozkan Kose et al also found Bernese ankle rules to have high specificity in his study comparing Ottawa Ankle Rules and Bernese Ankle Rules in Acute Ankle and midfoot injuries with sensitivity and specificity of Bernese ankle rules of 94% and 95% respectively and sensitivity and specificity of OAR of 100% and 77% respectively.
CHAPTER 3. METHODS

3.1 STUDY DESIGN

This was a prospective multicenter cross-sectional study for 6 months duration, from May 2018 to October 2018 for adult patients presenting with acute ankle injuries at Accident & Emergency Departments of the three referral hospitals (University Teaching Hospital of Kigali, Rwanda Military Hospital and King Faisal Hospital) in Kigali, Rwanda.

3.2 STUDY SITES

The study was conducted at three referral hospitals in Kigali, Rwanda named: The University Teaching Hospital of Kigali (CHUK), Rwanda Military hospital (RMH), and King Faisal Hospital Kigali (KFH-K). All the three hospitals are located within Kigali, Rwanda and provide emergency trauma services for cases referred from the whole country and region. The CHUK is located in the center of Kigali city (District of Nyarugenge); it has a capacity of 560 beds with 25% allocated to the department of surgery. RMH is a military and tertiary referral hospital providing care to military personnel and civilians. RMH currently treats 95% civilian and 5% military patients. It is located in Kigali City (Kanombe, Kicukiro District) and its bed capacity is 265 beds. KFH-K is public-private quaternary referral hospital located in Kacyiru, Gasabo District, Kigali City. It has the bed capacity of 162 beds. KFH-K treats mostly patients with private insurances and those referred from other two referral hospitals.

3.3 STUDY POPULATION

Patients with acute and closed ankle or midfoot injuries presenting at Accident & Emergency Departments of 3 referral hospitals in Kigali, Rwanda, during the period of the study and who met the inclusion criteria.

3.4 SELECTION OF STUDY POPULATION

INCLUSION CRITERIA
- Acute ankle injuries < 7 days
• Age: >18 years old
• Closed ankle injury

EXCLUSION CRITERIA
• Pregnant women
• Altered mental status (GCS <15)
• Patient with major distracting injuries
• Patients whose ankle or midfoot x-ray already done

3.5 SAMPLE SIZE

Sample size was calculated using a target Ottawa ankle rules sensitivity of 90%, prevalence of 20% of ankle fractures in previous studies, precision of 10%, power set at 80% and P < 0.05.

Thus, the total sample sizes based on sensitivity was:  

\[ n_{Se} = \frac{Z^2\widehat{Se}(1 - \widehat{Se})}{d^2 \times \text{Prev}} \]

\[ N_{Se} = \frac{(1.96)(1.96)(0.9)(1-0.9)}{(0.1)(0.1)+0.2} = \frac{3.8416+0.9+0.1}{0.01+0.2} = \frac{4.7416}{0.002} \approx 172.872 \approx 173 \]

\( Z_{\frac{\alpha}{2}} \) was inserted by 1.96

\( \widehat{Se} \): Pre-determined value of sensitivity

\( \text{Prev} \): Pre-determined prevalence

\( d \): the precision of estimate (i.e. the maximum marginal error) is pre-determined by clinical judgment of investigators.

This was equal to approximately 173 patients. After estimation of patients received at emergencies of the hospitals of our study, we found that the sample size can be reached in the period of 6 months (May 2018 to October 2018).
3.6 DATA COLLECTION

Data were collected using a data collection sheet containing the demographic data such as age, sex, the referring health facility or home, province of residency; clinical parameters such as mechanism of injury, time from injury to presentation at emergency, Ottawa ankle rules findings and imaging findings such as presence of fracture or absence of fracture following plain radiography of the ankle and midfoot in anteroposterior and lateral views, we assume the above views to be enough to identify fractures.

3.7 STUDY PROCEDURES

In our study, we enrolled patients with acute ankle injury presenting to our Accident & Emergency within 7 days of injury. Needed data were collected using a data collection sheet found at Accident & Emergencies of our research sites, which included demographic data and clinical data such as mechanism of injury, time from injury to presentation at accident and emergency, findings of Ottawa ankle rules and results of radiography. The Ottawa ankle rules were considered positive for the prediction of the ankle fracture when the patient was unable to bear weight for 4 steps both immediately and at the time of evaluation, experienced bone tenderness at the posterior edge (6 cm) or inferior tip of the lateral malleolus, or had bone tenderness at the posterior edge or inferior tip of the medial malleolus; and positive for the prediction of midfoot fracture when the patient had bone tenderness at the base of the fifth metatarsal, cuboid, or navicular. Every patient underwent an x-ray (AP and Lateral views) of the ankle or midfoot regardless of whether the Ottawa ankle rules predicted the fracture or not to exclude the fractures and therefore to calculate the accuracy of the Ottawa ankle rules.

Data collectors were residents (in General surgery, Orthopedics and Emergency & Critical care) and general practitioners working at Emergencies of our research sites. One training session was done in order to teach them how to use the Ottawa Ankle Rules and 2 practical sessions were done showing collectors how to use OAR on real patient. We regularly did a weekly followed up of data collection process in order to limit inter-observer variability.
3.8 DATA ANALYSIS

Data analysis was done using SPSS, the accuracy of Ottawa ankle rules was determined by calculating its sensitivity, specificity, positive predictive and negative predictive values.

Sensitivity is the ability of a test to correctly classify an individual as 'diseased whereas specificity is the ability of a test to correctly classify an individual as disease-free and are calculated as follow:

\[
\text{Sensitivity} = \frac{a}{a + c} \\
\text{Specificity} = \frac{d}{b + d}
\]

<table>
<thead>
<tr>
<th>Disease present</th>
<th>Disease absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test positive</td>
<td>a (TP)</td>
</tr>
<tr>
<td>Test negative</td>
<td>b (FP)</td>
</tr>
<tr>
<td></td>
<td>c (FN)</td>
</tr>
<tr>
<td></td>
<td>d (TN)</td>
</tr>
</tbody>
</table>

Note: Retrieved from Understanding and using sensitivity, specificity and predictive values. Indian J Ophthal mol. 56(1):45-50 by Rajul Parikh et al.

For our study, positive test was a positive Ottawa ankle rules, negative test was a negative Ottawa ankle rules and disease was present in case of the presence of ankle or midfoot fracture; and disease was negative in case of the absence of ankle or midfoot fracture in the plain radiography

Positive predictive value is the percentage of patients with a positive test who actually have the disease and is calculated as \(PPV: = \frac{a}{a+b}\)

Negative predictive value is the percentage of patients with a negative test who do not have the disease and is calculated as \(NPV: = \frac{d}{c+d}\)

Accuracy: The accuracy of a test is its ability to differentiate the patient and healthy cases correctly. To estimate the accuracy of a test, we should calculate the proportion of true positive and true negative in all evaluated cases.
Mathematically, this can be stated as\(^59\):

\[
\text{Accuracy} = \frac{TP + TN}{TP + TN + FP + FN}
\]

### 3.9 ETHICAL CONSIDERATIONS

The participation in this study was voluntary and the participants were free to accept or refuse to participate in the study after full explanation about the study. Confidentiality was ensured and patients’ identity was kept anonymous by encoding the study data. Participants’ identification codes were kept locked and only available to the principal investigator. Patients in this study were not subject to any harmful intervention. The risk to participants was minimal as it was not beyond the usual risk patients are exposed to during routine care.

Only patients who accepted to sign an informed consent were enrolled in our study. The ethical Approvals were obtained from the IRB (Notice N\(^0\) 058/CMHSIRB/2018) of the University of Rwanda and from ethical committees of the specific hospitals (i.e CHUK, RMH and KFH, K).
CHAPTER 4. RESULTS

Our study was conducted in 3 referral hospitals in Kigali (CHUK: 102 patients, RMH: 58 patients and KFH, Kigali: 36 patients), the majority of the patients have been seen at CHUK (102=52.04%), the largest referral hospital in Rwanda. Generally, the majority (67.9%) of the patients presented to Accident and Emergency Departments within 24 hours (24-48 hours: 14.8%, 48-72 hours: 8.2%, >72 hours: 9.2%) after injury. Orthopedic residents examined the majority of patients (40.3%) compared to others.

Figure 2: Gender characteristics

The above figure shows that male patients were likely to present to our emergency with ankle or midfoot injuries, accounting for 53%, with a male to female ratio of 2:1.7

Table 1: Age characteristics

<table>
<thead>
<tr>
<th>N</th>
<th>Median</th>
<th>Mean</th>
<th>Range</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>196</td>
<td>33.5</td>
<td>35.71</td>
<td>69</td>
<td>18</td>
<td>87</td>
<td>12.98551</td>
</tr>
</tbody>
</table>

The mean age was 35.71 years (Standard deviation of 12.98551) and range of 69 with minimum and maximum age of 18 years and 87 years respectively.
Table 2: The mechanism of injury

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor vehicle accident</td>
<td>25</td>
<td>12.8</td>
</tr>
<tr>
<td>Motorcycle accident</td>
<td>30</td>
<td>15.3</td>
</tr>
<tr>
<td>Motorcycle-Pedestrian</td>
<td>4</td>
<td>2.0</td>
</tr>
<tr>
<td>Bicycle-Pedestrian</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Bicycle-Motor vehicle accident</td>
<td>4</td>
<td>2.0</td>
</tr>
<tr>
<td>Pedestrian-car/truck/bus</td>
<td>8</td>
<td>4.1</td>
</tr>
<tr>
<td>Fall from height</td>
<td>27</td>
<td>13.8</td>
</tr>
<tr>
<td>Sports injury</td>
<td>24</td>
<td>12.2</td>
</tr>
<tr>
<td>Ankle twisting during casual walk</td>
<td>70</td>
<td>35.7</td>
</tr>
<tr>
<td>Physical assault</td>
<td>1</td>
<td>.5</td>
</tr>
<tr>
<td>Total</td>
<td>196</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Ankle twisting during casual walk was the most common mechanism of injury in all age groups with 70 (35.7%) patients. Road traffic accident is the second most common mechanism of injury with motor vehicle and motocycle accidents accounting for 25 and 30 patients respectively.
Table 3: Ottawa ankle rules: Ankle

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to bear weight for 4 steps both immediately and at the time of evaluation</td>
<td>11</td>
<td>5.6</td>
</tr>
<tr>
<td>Experiences bone tenderness at the posterior edge (6 cm) or inferior tip of the lateral malleolus</td>
<td>15</td>
<td>7.7</td>
</tr>
<tr>
<td>Bone tenderness at the posterior edge or inferior tip of the medial malleolus</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Unable to bear weight and tenderness of lateral malleolus</td>
<td>46</td>
<td>23.5</td>
</tr>
<tr>
<td>Unable to bear weight and tenderness of medial malleolus</td>
<td>11</td>
<td>5.6</td>
</tr>
<tr>
<td>Unable to bear weight and tenderness of medial &amp; lateral malleoli</td>
<td>78</td>
<td>39.8</td>
</tr>
<tr>
<td>None</td>
<td>32</td>
<td>16.3</td>
</tr>
<tr>
<td>Total</td>
<td>196</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The majority of the patients (39.8%) presented to our Emergencies with inability to bear weight both immediately and at the evaluation; and medial & lateral malleoli tenderness followed by inability to bear weight and lateral malleolar tenderness. This may be explained by the fact that the majority of the patients presented in acute phase of the injury, within 24 hours.

Table 4: Ottawa ankle rules: Midfoot

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone tenderness at the base of the fifth metatarsal</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Unable to bear weight and tenderness of the base of fifth metatarsal</td>
<td>6</td>
<td>3.1</td>
</tr>
<tr>
<td>Unable to bear weight and tenderness at the navicular</td>
<td>1</td>
<td>.5</td>
</tr>
<tr>
<td>None</td>
<td>184</td>
<td>93.9</td>
</tr>
<tr>
<td>Tenderness of 5th metatarsal and cuboid</td>
<td>2</td>
<td>1.0</td>
</tr>
</tbody>
</table>
Midfoot injuries were less commonly seen with only 11 (6.1%) cases having midfoot injuries. Among patients with midfoot injuries, the majority presented with inability to bear weight and tenderness of the 5th metatarsal (3.1%).

Table 5: Association between Ottawa ankle rules and x-ray results: Midfoot

<table>
<thead>
<tr>
<th>Ottawa ankle rule: Midfoot</th>
<th>Midfoot x-ray results</th>
<th>Base of fifth metatarsal fracture</th>
<th>navicular fracture</th>
<th>cuboid fracture</th>
<th>no fracture</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone tenderness at the base of the fifth metatarsal</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Unable to bear weight and tenderness of the base of fifth metatarsal</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Unable to bear weight and tenderness at the navicular</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>182</td>
<td>184</td>
<td></td>
</tr>
<tr>
<td>Tenderness of 5th metatarsal and cuboid</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Tenderness of base of 5th metatarsal, cuboid and navicular</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>2</td>
<td>1</td>
<td>185</td>
<td>196</td>
<td></td>
</tr>
</tbody>
</table>

The base of the 5th metatarsal was the most commonly injured among the patients with midfoot injuries with 8 cases (4.1%) and commonly presented with inability to bear weight and tenderness of the base of the 5th metatarsal.
The lateral malleolar fracture (29.6%) was the most commonly seen ankle fracture and was commonly seen in patients (36 patients) presenting with inability to bear weight and lateral malleolar tenderness. Inability to bear weight and tenderness of medial & lateral malleoli were the most frequently presenting features of the Ottawa ankle rules in all types of ankle fractures with 78 patients, (50%) of them having bimalleolar fracture.
Table 7: Sensitivity, specificity, positive predictive and negative predictive values

<table>
<thead>
<tr>
<th>Ottawa Ankle Rules</th>
<th>Xray results</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>174</td>
</tr>
<tr>
<td>Positive</td>
<td>140</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td></td>
<td>97.9% Sensitivity</td>
<td>64.2% False positive</td>
<td>80.45% PPV</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>2.1% False negative</td>
<td>35.8% Specificity</td>
<td>86.3% NPV</td>
</tr>
<tr>
<td>Total</td>
<td>143</td>
<td>53</td>
<td></td>
</tr>
</tbody>
</table>

The above table shows the following:

- There were 143 (73%) fractures and 53 (27%) patients without fractures who are considered to have ankle sprains. Only 3 (1.53%) cases have been missed by the test (Ottawa ankle rules).
- There was a high sensitivity of 97.9% and low specificity of 35.8% of Ottawa ankle rules.
- There was a high rate of false positives accounting for 64.2% of cases and may be explained by the high sensitivity of the test.
- The positive predictive value of the OAR was 80.45%, whereas the negative predictive value was 86.3%.
- According to the formula highlighted in chapter 3, the accuracy of the ottawa ankle rules in our study was estimated at 81.12%.
- The positive likelihood ratio was 1.52 and negative likelihood ratio was 1.73.
Figure 3: ROC curve

ROC curve is the plot that displays the full picture of trade-off between the sensitivity and (1-specificity) across a series of cutoff points. The curve is useful in finding optimal cut-off point to least misclassify diseased or non-diseased subjects, evaluating the discriminatory ability of a test to properly pick diseased and non-diseased subjects; comparing the efficacy of two or more tests for assessing the same disease; and comparing two or more observers measuring the same test (inter-observer variability)60.

Our curve is below the diagonal line, hence poor correlation of sensitivity and specificity of the test.
CHAPTER 5. DISCUSSION

The majority of patients in our cohort were male, accounting for 53% of the study population, with a male to female ratio of 2:1.7. These findings are comparable to those found in the literature; male predominance has also been found in ankle sprains by Tummala et al., who found 57.6% of males, however Doherty C. et al. in their systematic review found an equal distribution in the prevalence of ankle sprains between males and females and Shah et al. found that the majority of ankle sprains occur in females with 56.36% of cases. In ankle fractures, Shibuya N. et al. found also the male predominance with 157,977 of males out of 280,933 foot and ankle fractures or dislocations, and Oluwadiya KS et al. found 64.2% of males with ankle fractures/fracture-dislocation. However Elsoe R. et al. found that 53.0% of female patients had ankle fractures in a population-based epidemiology of 9767 ankle fractures.

The median age was 33.5 years (Std deviation of 12.9) and the age range was 69 years with minimum and maximum age of 18 years and 87 years respectively. The majority of the patients (54.6), were 18-35 years old. These figures are also consistent with those seen in the literature. Vosseller et al. found almost the same figures as ours, with the peak incidence of high ankle sprains occurring in the age group between 18 and 34 years. However, in the Ghanaian experience for management of complex ankle fracture, Kuubiire et al. found the mean age of the patients of 36 ± 9 years which is quite the same as ours with a range of 11-65 years; and the majority of the patients (62.9%) were within the 31-50 year age bracket.

In our study, ankle twisting was the most common mechanism of injury in all age groups (35.7%) followed by Road Traffic Accidents. Similar findings were reported by Dwivedi R. and Ale S.B. Tharao M.K. et al., found also the same with twisting of the ankle as the most common mechanism of injury accounting for 58.3% followed by Road Traffic Accidents which accounted for 16.6%. However, Meena S.et al. reported different findings where fall (41.4%) frequently occurred as mechanism of injury followed by ankle twisting in 37.1%, and Road Traffic Accidents in 21.4% of patients; home or workplace falls were the most commonly found injury place among those who fell. Oluwadiya K.S. found motor vehicle crashes as the most common mechanism of injury. Luciano AP and Lara LCR., in their study for the epidemiology of foot and ankle injuries in recreational sports
found soccer as the main cause of injuries among the analyzed individuals\textsuperscript{69}. In his systematic review, Fong et al. found aerobal (80\%) as the most common sport causing ankle injury among 70 sports\textsuperscript{8}.

In our study, there were 143 (73\%) fractures, the lateral malleolar fracture (29.6\%) was the most commonly seen ankle fracture and was commonly seen in patients (36 patients) presenting with inability to bear weight and lateral malleolar tenderness. We found a higher percentage of fractures compared to other studies, this is due to the fact that the majority of ankle sprains are treated at the district levels and only fractures are referred for surgical management in referral hospitals where our study were conducted. Meena S et al found 70.83\% of fractures in the malleolar zone and 14 29.16\% in the midfoot zone\textsuperscript{22}. Dwivedi R and Ale SB found lateral malleolar fracture as the most common fracture\textsuperscript{67}.

In this study we found high sensitivity of 97.9\% and low specificity of 35.8\% of Ottawa ankle rules. Ottawa ankle rules have shown high sensitivity and low specificity in many different systematic reviews analyzing its accuracy. In his systematic review analyzing 21 primary studies, Jonckheer P, found sensitivity and specificity of the OAR range from 92–100\% and from 16–51\%, respectively\textsuperscript{70}. In their systematic review including 66 studies, Beckenkamp PR, et al. found a high sensitivity and a poor specificity of 99.4\%, (97.9\% to 99.8\%) and 35.3\%, (28.8\% to 42.3\%) respectively. They also found specificity was higher for Midfoot than for Ankle Rules\textsuperscript{71}. In a systematic review by Bachmann LM et al., they found high sensitivities of the OAR ranging from 99.6\% in studies on application of the rules within 48 hours of injury to 96.4\% in studies of combined assessment, while the specificities ranged from 47.9\% in studies with a prevalence of fracture below the 25th centile of all studies to 26.3\% in studies of combined assessment; and the pooled negative likelihood ratios for the ankle and mid-foot were 0.08 (95\% CI 0.03 to 0.18) and 0.08 (0.03 to 0.20) respectively\textsuperscript{45}. Ottawa ankle rules have also shown high sensitivity in Non-Physician Providers where MacLellan et al. found a sensitivity of 100\% and the specificity of 19\%\textsuperscript{72}.

In view of its high sensitivity, OAR has been validated in many countries\textsuperscript{11,19,23,24,47,73,74}, however it has not been validated in some countries, S-Y Tay et al in Asia, Singapore, found a sensitivity of 90\% and a specificity of 34\%, and he concluded that the OAR cannot be used to screen for the need for x-ray studies in Asian patients who have sustained twisting ankle injuries because of a high false-negative rate\textsuperscript{53}. Perry S et al. in UK found a sensitivity of 93.6\%, and specificity of 46\%. The positive
predictive value was 17.98% and negative predictive value 98.39%. He concluded that decision rules should be used with care and not replace clinical judgment and experience.\textsuperscript{75}

In our study, we would have reduced by 9.7\% (19 cases) the unnecessary x-rays; this is different from other studies; Stiell IG et al. found a reduction of 28\% in the proportion of patients referred for ankle radiographs\textsuperscript{76}. Daş et al. in Turkey found 38.02\% reduction in radiography when OAR is implemented in Emergency Department and used by General Practioners\textsuperscript{77}. In his systematic review, Jonckheer P. found an estimate on the reduction of radiographs ranging from 13\% to more than 40\%\textsuperscript{70}. Tharao MK et al., found a 46\% reduction in ankle radiography\textsuperscript{68}.

In the ROC curve, the curve is under the diagonal line which implies a poor correlation of sensitivity and specificity of the test. RES Pires et al. also found a poor correlation of sensitivity and specificity; and concluded that the Ottawa ankle rules items showed no statistical significance\textsuperscript{78}.

\textbf{5.1 Study Limitations}

The current study had some limitations. There were a limited number of patients in the study due to the fact that not all patients with ankle fractures were referred for management from the district hospital because ankle sprains are managed at the district level and excluded patients whose x-rays have already done. Even if the collectors have been trained how to use OARs and regular follow up done, some collectors appeared not to use properly the OARs due to the busy and overcrowded Emergencies.
6.1 Conclusion
In this study, ankle injuries were commonly found in male than female, frequently due to ankle twisting during casual walk and the majority presented with inability to bear weight both immediately after injury & at Emergency and tenderness of both malleoli; and bimalleolar fractures.

OARs have high sensitivity and low specificity which are similar findings to those published previously in various other settings. When the OARs are positive, there is high probability of ankle or midfoot fracture however we need to consider the possibility of a false positive due to high sensitivity of the test. It can decrease the number of unnecessary radiographs if used correctly in patients with ankle sprains and early diagnosis of ankle fractures to avoid delays in the management.

6.2. Recommendations

✓ We recommend implementation of the OARs in the Emergency Departments of our referral hospitals which will help to reduce unnecessary x-rays and waiting time.
✓ The rules should also be introduced as part of the management protocol in patients presenting with ankle injuries in the district hospitals in order to avoid unnecessary transfers.
✓ We recommend giving enough explanations to the patients and make sure instructions given are understood before applying OARs in order to reduce high false positive rate.
REFERENCES


doi:10.1136/bjsm.37.3.194.


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APPENDICES
APPENDIX 1. Informed consent

PART I: INFORMATION SHEET

RESEARCH: “ACCURACY OF OTTAWA ANKLE RULES IN PREDICTING THE NEED FOR RADIOGRAPHY IN ANKLE AND MIDFOOT INJURIES IN RWANDA”

Principal investigator: Dr. Murwanashyaka Emmanuel, Senior resident in Orthopedic Surgery

I am carrying out the above mentioned research in three referral hospitals (CHUK, KFH, RMH) in Rwanda.

I warmly welcome in my research, further explanation is going to be given and feel free to ask any question right now or later, for what you don’t understand.

• Purpose of the research

Ankle injuries are among the common injuries seen at emergency; the routine is to ask an x-ray for every patient with ankle injuries although few of them have fractures. The purpose of this study is to measure the accuracy of Ottawa ankle rules to diagnose ankle and midfoot fractures in acute settings in Rwanda so as to reduce the unnecessary x-rays and its costs; and long stay at emergency.

• Type of Research Intervention

After arriving at emergency, a doctor will ask you to give some important information containing in our questionnaire, examining you using the Ottawa ankle rules and an x-ray will be asked to rule out fracture. The results of the x-rays will also be documented in order to measure the accuracy of the Ottawa ankle rules. In this research, no follow up will be needed.

• Participant selection

We are inviting all adult (18 years or more) patients with closed ankle or midfoot injuries that occurred within 7 days and able to communicate.

• Voluntary Participation

Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive will continue and nothing will change.
•Risks

Patients in this study will not be subject to any harmful intervention and the risk is there although minimal because every patient will be exposed to x-ray radiation in order not to miss a fracture and therefore measure the accuracy of the Ottawa ankle rules.

•Reimbursements

In this study, no reimbursements of any kind will be provided, participation is voluntary.

•Confidentiality

The information that we collect from this research project will be kept confidential. Your identification code will be kept locked and only available to the principal investigator. Your names will not appeared instead will be replaced by codes.

•Right to Refuse or Withdraw

The patient is free to refuse to participate in this study and refusal to participate will not affect your treatment. You have also the right to withdraw from the study at any time you want.

•Sharing the Results

The results of this study will be published and policy makers informed for possible validation of the Ottawa ankle rules in Rwanda.

PART II: CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I (or witness) have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant/Witness………………………………………………

Signature of Participant/Witness …………………………………………..

Date ……/…../….. (Day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Filling a Questionnaire
2. Physical examination using Ottawa ankle rules

3. X-ray of the ankle or midfoot

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent………………………………………..

Signature of Researcher /person taking the consent……………………………..

Date……./……./……. (Day/month/year)

Researcher contact:

Dr MURWANASHYAKA Emmanuel Tel: + 250 783577831

If you have questions about your rights in the study, contact

CMHS / UR Directorate of Research, Technology Transfer and Consultancy

Tel: + (250) 788563312

Chairperson – IRB CMHS / University of Rwanda

Prof Kato J. NJUNWA, Tel 0788490522
**APPENDIX 2. AMASEZERANO YO KWEMERA KUJYA MU BUSHAKASHATSI**

**UBUSHAKASHATSI: “ACCURACY OF OTTAWA ANKLE RULES IN PREDICTING THE NEED FOR RADIOGRAPHY IN ANKLE AND MIDFOOT INJURIES IN RWANDA”**.

**UMUSHAKASHATSI: Dr MURWANASHYAKA Emmanuel, umunyeshuli w’inzobere mu igisate cy’amagufwa.**

Ndabashimira cyane kandi mbahaye ikaze kubwo kwinjira muri ubu bushakashatsi. Uraza guhabwa ibisobanuro kuburyo burambuy ekandi naweu shobora kubaza ikibazo kubyo udasobanukiwe.

**Icyo ubushakashatsi bugamije**

Ububushakashatsi bugamije kureba ubushobozi bwa Ottawa ankle rules mu kumenya niba umurwayi afite imvune yo mubujana ndetse no ku kirenge murwego rwo kugabanya guca mu cyuma, amafaranga bitwara ndetse no kugabanya igihe umuntu amara ahobakirira indembe n’inkomere.

**Uko buzakorwa**

Mukimara kugera munzu y’indembe n’inkomere muzakirwa n’umuganga uzabakira akabasaba gutanga amwe mumakuru azifashishwa muri ubu bushakashatsi maze ahite agusuzuma akoresheje Ottawa ankle rules hanyuma agusabire guca mucyuma kugirango turebeko udafite imvune. Ibisubizo byo mucyuma nabyo bizakenerwa mubushakashatsi bwacu.

**Guhitamo abajya mu bushakashatsi**

Uja mubushakashatsi agomba kuba afite nibura imyaka 18, afite imvune yo mubujana cg ikirenge itarengeje iminsi irindwi kandi abashakuganira na muganga bitagoranye.

**Uburenganzira bwo kwinjira mu bushakashatsi**

Kwinjira mubushakashatsi ni ubushakebwawe. Mugihe utifuza kubwinjiramo ntacyo bihungabanya mukuvurwa kwawe.

**Ibibazo waterwa nubu bushakashatsi**

Ubu bushakahatsi ntabibazo Bihari byagutera usibye guca mucyuma kugirango turebeko ntamvune ufite.

**Ighembo cyo kujya mu bushakashatsi**

Muri ubu bushakashatsi ntagihembo icyo aricyo cyose gitangwa, kwinjira muri ububushakashatsi ni ubushakebwawe.
Ibanga ry’amakuru uzatanga

Amakuru uzatanga cyangwa ayerekanye n’uburwayi bwawe azagirwa ibanga, amazina yawe ntazigera agaragara azaba ari mumibare yihariye.

Gushaka kuva mu bushakashatsi

Mugihe udashaka kwinjira muri ubu bushakashatsi ni uburenganzira bwawe kubyanga ndetse nigihe wifuza kubuvamo nabyo ni uburenganzira bwawe.

Gutangaza ibizava mu bushakashatsi

Ibizava muri ubu bushakashatsi bizamenyeshwa abashinzwe gufata ibyemezo kugirango igipimo cy a Ottawa ankle rules kijye gikoreshwa mu Rwanda.

KURUHANDE RW’UMURWAYI


Amazina y’umurwayi/umuhagarariye……………………………..

Umukono w’umurwayi/umuhagarariye…………………………….. Italiki……/…./….

KURUHANDE RWA MUGANGA

Maze gusobanurira umurwayi ibyerekanye nubu bushakashatsi,ndemeza ko yasobanukiwe nibiye gukorwa bikurikira:

1. Kuzuza igipapuro cyabugenewe cy’ikusanyamakuru y’ubushakashakatsi

2. Gusuzumwa hakoreshjwe Ottawa ankle rules

3. Guca mucyuma

Ndemeza ko umurwayi namusobanuriye bihagije kandi yagize umwanya wo kubaza ibibazo ndetse ahabwa n’ibisubizo k’uburyo burambuye. Ndahamya ko ntagahato yashyizweho kuko kwinjira muri ubu bushakashatsi ari ubushake.

Amazina ya muganga……………………………..

Umukono wa muganga…………………………….. Italiki……/…./…..
Ukeneye ibindi bisobanuro wahamagara:
Dr MURWANASHYAKA Emmanuel
E-mail: emm02500@yahoo.fr
Phone number: + 250 783577831

Ufite ikibazo k’uburenganzira bwawe muri ubu bushakashatsi, wabaza:
esearchcenter@ur.ac.rw, CMHS / University of Rwanda
Directorate of Research, Technology Transfer and Consultancy
PO Box 3286 Kigali
Tel: + (250) 788563312

Chairperson - IRB, CMHS / University of Rwanda
Prof Kato J. NJUNWA Tel 0788490522
APPENDIX 3. DATA COLLECTION FORM

Patient code: -/-/-/-/- (encoded alphabet)

Collector: Orthopedic resident □  General Practitioner □  Emergency & critical care resident □  General Surgery resident □  Others: ..........................

DEMOGRAPHIC DATA

1. Patient initials:

2. Age:

3. Sex: Male □  Female □

4. PROVINCE OF ORIGIN: Kigali city □  North □  South □  East □  West □

5. Referred from: ..........................

MECHANISM OF INJURY

-RTA:

   Motor Vehicle Accident □
   Motorcycle Accident □
   Motorcycle-Pedestrian □
   Bicycle-Pedestrian □
   Bicycle-motor vehicle accident □
   Pedestrian – car/bus/truck □

-Fall □

-Sport injury □

- Ankle twisting □

- Physical assault □
- Others:………

Duration: Time from injury to patient presentation at A/E:

- <24hrs
- 24-48hrs
- 48-72hrs
- >72hrs

OTTAWA ANKLE RULES

Ankle:
- Unable to bear weight for 4 steps both immediately and at the time of evaluation
- Experiences bone tenderness at the posterior edge (6 cm) or inferior tip of the lateral malleolus
- Bone tenderness at the posterior edge or inferior tip of the medial malleolus.

Midfoot:
- Bone tenderness at the base of the fifth metatarsal
- Bone tenderness at the cuboid
- Bone tenderness at the navicular

X-RAY RESULTS

Ankle: Fracture
- YES
- No
- Lateral malleolar
- Medial malleolar
- Bimalleolar
- Pilon fracture
- Other ……..

Midfoot: Fracture
- YES
- No
- Base of the 5th metatarsal
- Navicular
- Other…..
Testing sensitivity and specificity

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