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Validation of the Ottawa ankle rules: Strategies for increasing specificity

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ABSTRACT

Introduction: The majority of patients with ankle injuries undergo radiological examinations of the foot, ankle or both. The objective of this study was in the first place to validate the Ottawa Ankle Rules (OARs) for the population of our centre. Secondly, an attempt was made to identify parameters that contribute to improve the specificity of the method, with a view to reduce the need for patients to be exposed to radiation as well as optimizing the expenses of the Emergency Ward (EW).

Materials and methods: This was a prospective study conducted during a 9-month period. The study population included 148 patients, in 54 (36%) of the patients a fracture was present on the exams performed. Patients were submitted to a sequential protocol in the EW with a form completion, evaluation of OARs, application of the Visual Analog Pain Scale (VAS) and radiographic exams.

Results: We found a sensitivity of OARs in ankle injuries of 100%, specificity of 26% and in midfoot injuries of 100% and 62% respectively. All patients with fractures had a VAS of 5 or more points in any of the tested sites. With the VAS criterium, we found a significant increase of global specificity (38% vs 15%), as well as when applied only to the ankle (26% to 47%) or to midfoot trauma (62% to 67%). In both, there would have been a 100% reduction of CT scans.

Patients with a fracture or with fractures who required surgical treatment had a mean VAS significantly higher than patients with no fracture or fractures submitted to conservative treatment respectively. Although there was a lower percentage of fractures in the group of injuries in Work Accidents (31% vs 37% Sports Activity and 38% Leisure Activity), there was a statistically significant increase in the sum of average VAS in Accidents at Work vs Leisure Activities and vs Sports Activities.

Conclusion: We seek to confirm the usefulness of OARs for our population and we investigated strategies to further reduce the need for unnecessary radiographs. The introduction of parameters for grading pain and adapting to the context of the accident seem promising.

Introduction

Ankle injuries are one of the most frequent causes of emergency room visits [1–4]. The most common injuries are sprains, dislocations and fractures, the latter present in only 15% of patients in most centers. [5–7] The majority of patients observed undergo radiological examinations of the foot, ankle or both, even if there is evidence that these tests could be partially avoided if the Ottawa Ankle Rules (OARs) were evaluated.

Stiell et al. [8–10] developed the OARs, having established clinical criteria that assess the ability to carry out load and pain under palpation of pre-defined anatomical areas in order to rationalize the use of radiographs.

Since then, several groups have carried out identical studies for local validation that generally confirmed the conclusions of the original study. [3, 11–15] The most recent systematic reviews [16,17] demonstrate that OARs, although presenting good levels of average sensitivity (99.4%), nevertheless have relatively low average specificity values (35.3%), not allowing the exclusion of imaging tests of a large number of patients.

The objective of this work was in the first place to validate the Ottawa Ankle Rules (OARs) for the population of our centre. Secondly, an attempt was made to identify parameters that contribute

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to improve the specificity of the method, with a view to reduce the need for patients to be exposed to radiation as well as optimizing the expenses of the Emergency Ward (EW).

Materials and methods

Study design

This was a prospective, mono-center study, with the objective of validating the OARs for the population of the center and studying strategies to increase their specificity. The study included five doctors who work in the orthopedics service of the EW of Hospital São José in Lisbon, Portugal. This is a multipurpose emergency service in a tertiary hospital.

The study took place over a period of 9 months from June 2018 to February 2019 and was submitted and approved by the ethics committee.

Population under study

The target population were patients with ankle trauma who were admitted to the EW and were observed by Physicians who participated in the study. Our EW is part of a central, state-of-the-art hospital and has a 24-hour operating schedule, 7 days a week. The population that normally uses this center is characterized by being mostly city-dwelling. Physicians in the orthopedic specialty of this EW observe an average of 11,000 patients per year.

Inclusion criteria were minimum age of 18, trauma for less than 48 hours and ability to communicate with the interviewers. The exclusion criteria were patients who did not wish to participate in the study, patients with evident ankle deformities, patients with skin lesions, patients previously observed in healthcare, pregnant women and patients with cognitive or state of consciousness changes.

Intervention

Patients were submitted to a sequential protocol in the EW:

- **Form Completion:** the patients eligible by the inclusion criteria answered a form with questions about demographic data, previous illnesses, context of the accident, therapy and type of load after trauma.
- **Evaluation of OARs:** the classically defined parameters [8] were then registered and the diagnosis of presumed fracture was attributed: (1) “inability to perform 4 steps either immediately or in the EW”, or (2) “pain in the posterior extremity of the malleoli ”, (3) “navicular pain”, (4) “pain at the base of the fifth metatarsal”.
- **Application of the Visual Analog Pain Scale** [18] **(VAS):** the patients classified the pain on palpation in the areas covered by the OARs according to VAS of 0-10 points and these values were recorded.
- **Radiographs:** all patients were submitted, with their consent, to 4 radiographs: ankle and foot in 2 planes each.
- **Examination Analysis:** the diagnosis of presence or absence and type of fracture present were made and registered. Subsequently, a second Physician reviewed the tests performed and the radiographic images.
- **Data Collection:** all data collected for each patient was recorded in *Microsoft Excel®* computer format.

Data processing

The data were analyzed using the Statistical Package for the Social Sciences 22.0 for *MAC® (SPSS Inc, Chicago, IL, USA).* A power analysis was performed to ensure that the study sample size was adequate. Shapiro-Wilk test was used as a normality test.

A descriptive statistical analysis of the results was performed including frequency, percentage, mean and standard deviation. The Chi-square test was used for analysis of non-parametric data, independent samples *t* test and Mann-Whitney *U* test were used for the analysis of parametric data. A 95% confidence interval (CI) was used, a *p*-value of <0.05 was considered statistically significant.

Table 1
Patient Characteristics.

			(%)
Average Age		46.1	
Sex			
	Female	97	66%
	Male	51	34%
Comorbidities			
	None	71	48%
	Orthopedic	18	12%
	Cardiovascular	12	8%
	Metabolic	12	8%
	Autoimmune	5	3%
	Psychiatric	4	3%
	Infectious	4	3%
	Respiratory	2	1%
	Several	40	27%
Total		148	

Results

Flow of participants

During the 9-month period in which the study was conducted, 169 patients with ankle trauma were observed. 21 patients did not meet the inclusion criteria and were therefore excluded. 6 of these patients had open fractures, 4 had evident deformities with joint dislocation, 4 had alterations in the state of consciousness, 3 did not want to participate in the study, 2 had more than 48 hours of trauma and 2 patients were pregnant.

Demographics of participants

Age and Gender: the average age was 46.1 with a standard deviation (SD) of 18.7 years. The minimum age was 18 years and the maximum age was 88 years. 97 (66%) were female and 51 (44%) were male.

Comorbidities: 71 (48%) patients had no comorbidities and 40 (27%) had multiple comorbidities (Table 1).

Injury Context: 97 (65%) of the patients suffered trauma in the context of Leisure Activity, 32 (22%) of the patients suffered trauma in the context of Work Accidents and 19 (13%) of the patients suffered trauma in the context of Sports Activity.

Post Trauma Therapy: 122 (82%) had not undergone any type of therapy since the trauma, 17 (12%) underwent cryotherapy, 7 (5%) underwent oral therapy, and 2 (1%) underwent topical therapy.

Type of Load: 43 (29%) of the patients did not tolerate load on the injured limb, 83 (56%) tolerated partial load and 22 (15%) tolerated full load.

Application of the Ottawa rules

All patients ($n = 148$) underwent OARs verification (Table 2). It was found that 14 (9%) had negative criteria and had no fracture. Of the 134 (91%) who presented positive OARs criteria, 54 (36%) had a fracture in the radiological exams performed (Table 5): sensitivity of the OARs of 100%, specificity of 15%, a Positive Predictive

Table 2
Application of OARs in general.

Radiograph	Fracture	No Fracture	Total
OAR+	54	80	129
OAR-	0	14	14
Total	54	94	148

Table 3
Application of OARs to the Ankle.

Radiograph	Fracture	No Fracture	Total
OAR+	49	73	122
OAR-	0	26	26
Total	49	99	148

Table 4
Application of OARs to the Midfoot.

Radiograph	Fracture	No Fracture	Total
OAR+	5	55	60
OAR-	0	88	88
Total	5	143	148

Table 5
OAR Performance.

Parameters	General	Ankle	Midfoot
Sensitivity	100%	100%	100%
Specificity	15%	26%	62%
Positive Predictive Value	42%	40%	8%
Negative Predictive Value	100%	100%	100%

* 95% confidence level and 7.98 confidence interval

Value (PPV) of 42% and a Negative Predictive Value (NPV) of 100% (Confidence Level (CL) 95% and Confidence Interval (CI) 7,98).

The investigation of OARs only in ankle injuries, revealed that 26 (18%) had negative criteria and had no fracture. Of the 129 (82%) who had positive criteria, in 49 (33%) there was a fracture present in the radiological exams performed (Table 3): sensitivity of OARs of 100%, specificity of 26%, a PPV of 40% and a NPV of 100% (CL 95% and CI 7.98).

The investigation of OARs only in midfoot injuries, revealed that 88 (60%) had negative criteria and had no fracture. Of the 55 (37%) that presented positive criteria, in 5 (3%) there was a fracture present in the radiological exams performed (Table 4): sensitivity of OARs of 100%, specificity of 62%, a PPV of 8% and a NPV of 100% (CL 95% and CI 7.98).

Characterization of the group without a fracture

We recorded that 94 (64%) of the patients had no fracture on the radiological exams performed. The average age of these patients was 41.4 (SD 17.9) and 65 (69%) were female. In terms of comorbidities, 48 patients had no other diseases and 22 had several.

In this group with no fracture, 14 (15%) of these patients had negative OARs and in 6 cases (6%) it was necessary to perform a computed tomography (CT) exam due to doubts in the interpretation of the radiographs.

In terms of ability to perform load on the affected limb, 21 (22%) of the patients did not tolerate load, 18 (19%) tolerated full load and 55 (59%) tolerated partial load.

We found that 77 (82%) patients had not undergone therapy since the trauma, 13 (14%) underwent cryotherapy, 4 (4%) underwent oral therapy and 0 (0%) underwent topical therapy.

The average value of the sum of the VAS was 7.5 (SD 6.9) with a minimum value of 0 and a maximum of 30. The minimum assigned per tested point was 0 and the maximum 10.

All patients were treated conservatively.

Characterization of the group with fracture

In the total population, 54 (36%) of the patients had a fracture on the exams performed. The mean age of these patients was 54.2 (SD 17.2), older than the group of patients without fractures ($p = 0.00002$). Of these, 32 (59%) were female, which does not appear to be statistically different from patients without fractures ($p = 0.22295$). In terms of comorbidities, 23 patients had no other diseases and 18 had several.

In this group, 100% had positive OARs and 5 patients (10%) underwent a computed tomography (CT) exam to better characterize the fracture.

Analyzing the ability to perform load on the affected limb, we found that 22 (41%) of the patients did not tolerate load, 4 (7%) tolerated full load and 28 (52%) tolerated partial load. Compared with patients without fractures, they tended to tolerate less partial and total load ($p = 0.02412$)

In terms of previous therapy, 45 (83%) of patients had no therapy since the trauma, 4 (7%) underwent cryotherapy, 3 (6%) underwent oral therapy and 2 (4%) underwent topical therapy which does not appear to be statistically different from patients without a fracture ($p = 0.51348$).

The analysis of radiographic exams revealed that, 26 (48%) patients had fractures of the external malleolus, 18 (33%) had bimalleolar fractures, 5 (10%) trimalleolar fractures and 5 (10%) fractures of the base of the fifth metatarsal. The average value of the sum of the VAS was 10.7 (SD 6.1) with a minimum value of 5 and a maximum of 35. The minimum assigned per tested point was 5 and the maximum 10.

We recorded that 24 (44%) patients were treated surgically and 30 (56%) patients were treated conservatively (Table 12).

Characterization of the trauma in leisure activity group

The investigation of type of activity revealed that, 97 (65%) suffered trauma in the context of Leisure Activity. Their average age was 50 years (SD 18.8) and 69 (71%) were female (Table 6).

Table 6
Lesion Characteristics.

		n	(%)
Context			
	Leisure Activity	97	65%
	Work Accident	32	22%
	Sports Activity	19	13%
Load			
	Partial	83	56%
	Does not Tolerate	43	29%
	Total	22	15%
Therapy since Trauma			
	None	122	82%
	Cryotherapy	17	12%
	Oral	7	5%
	Topical	2	1%
Type of Fracture			
	External Malleolus	26	48%
	Bimalleolar	18	34%
	Trimalleolar	5	10%
	Base of the 5th Metatarsus	5	10%
Treatment			
	Conservative	124	84%
	Surgical	24	16%

In this group, 60 (62%) of these patients had no fracture and 51 (53%) had positive OARs but had no fracture, that is, a PPV of 42% (CL 95% and CI 7.98).

The average value of the sum of the VAS of these patients with pain was 9.1 (SD 5) points.

The treatment was in 82 (84%) patients conservative and 15 (16%) were treated surgically.

Characterization of the trauma in accident at work group

The results of Accidents at Work revealed that, 32 (22%) of the patients suffered trauma in this context. The average age was 39.4 (SD 16.5) years and 18 (56%) were female.

The radiological exams performed showed that, 22 (69%) of these patients had no fracture and 17 (53%) had positive OARs but had no fracture, that is, a PPV of 37% (CL 95% and CI 7.98).

The average value of the sum of the VAS of these patients with pain was 13.5 (SD 9.9) points.

The options of treatment were in 27 (84%) patients conservative and surgical in 5 (16%).

Characterization of the trauma in sports activity group

The results of Trauma in Sports revealed that, 19 (13%) of the patients were injured in this context. The average age was 37.2 (SD 15.4) years and 10 (53%) were female.

On the exams performed, 12 (63%) of these patients had no fracture and 12 (63%) had positive OARs but had no fracture, that is, a PPV of 37% (CL 95% and CI 7.98).

The average value of the sum of the VAS of these patients with pain was 7.1 (SD 4.3) points.

The treatment was in 15 (79%) patients conservative and in 4 (21%) surgical.

Discussion

Proportion of radiographs performed

This study confirmed that OARs are an effective method for detecting fractures in our population: sensitivity and NPV of 100%, although with a low specificity of 15%. Our data are similar to those published in the literature [1,2,16,19]

We noticed that, the application of OARs, permitted to decrease only 9% of the radiographs performed, 60% of the radiographs with positive criteria did not reveal a fracture. In addition to this data, the fact that CTs were performed for diagnostic clarification in 8% of cases with positive criteria but without fracture is paradigmatic of the importance of increasing specificity to the test.

Other data that seemed interesting was the importance of the criterion: "inability to perform during 4 steps, either immediately or in the EW". In our population, this criterion presented a limited degree of interest. In the group of patients with fracture, 32 (59%) of these patients tolerated load and the PPV and VPN recorded for this criterion were just 51% and 40% for fracture detection respectively. In 2 patients was only this criterion recorded, and in none of them was a fracture present.

VAS scoring system

The VAS sum seems to be important in the initial assessment of patients in the EW. We found that all patients with fractures had a VAS of 5 or more points in any of the tested sites. This introduction of the VAS criterion increased the sensitivity to 100% and specificity to 38% (CL 95% and CI 7.98), which was statistically different from the specificity and sensitivity of the results applying only the OARs 15% and 100% respectively ($p = 0.004793$). With the introduction of the VAS criterion there wouldn't be needed to do any CT scan (Tables 8, 9 and 10).

The VAS sum criterion was particularly useful because it increased the specificity when applied to the ankle trauma, with a reduction from 73 to 53 patients with negative criteria and an increase in specificity from 26% to 47% ($p = 0.034859$) (Table 11).

Regarding the application of the VAS sum criterion for the midfoot trauma, there was a reduction from 55 to 47 patients with negative criteria and an increase in specificity from 62% to 67%. ($p = 0.05$)

The fracture patients had a mean VAS sum significantly higher than that of the patients without fracture 10.7 (SD 6.1) vs 7.5 (SD

Table 7
Patients with Fracture Vs No Fracture.

		Fracture	No Fracture	*p*
Average Age		54.2 (17.2)	41.4 (17.9)	0.00002
Sex				
	Male	22 (41%)	29 (31%)	
	Female	32 (59%)	65 (69%)	0.22295
Comorbidities				
	None	23	48	0,32069
	Orthopedic	6	12	0,76684
	Cardiovascular	3	9	0,36932
	Metabolic	3	9	0,36932
	Autoimmune	1	4	0,43594
	Psychiatric	1	3	0,62852
	Infectious	1	3	0,62852
	Respiratory	0	2	NA
	Several	18	22	0,32069
Load				
	Partial	28 (52%)	55 (59%)	
	Does not Tolerate	22 (41%)	21 (22%)	
	Total	4 (7%)	18 (19%)	0.02412
Context				
	Leisure	37 (68%)	60 (64%)	
	Work Accident	10 (19%)	22 (23%)	
	Sport Activity	7 (13%)	12 (13%)	0.78085
Previous Therapy				
	None	45 (83%)	77 (82%)	
	Cryotherapy	4 (7%)	13 (14%)	
	Oral	3 (6%)	4 (4%)	
	Topical	2 (4%)	0 (0%)	0.51348
Total		54	94	

Table 8
Application of VAS criterium* in General.

Radiograph	Fracture	No Fracture	Total
VAS criterium+	54	58	112
VAS criterium-	0	36	36
Total	54	94	148

* VAS criterium: pain > 4 on VAS

Table 9
Application of VAS criterium* in Ankle trauma.

Radiograph	Fracture	No Fracture	Total
VAS criterium+	49	53	102
VAS criterium-	0	46	46
Total	49	99	148

* VAS criterium: pain > 4 on VAS

Table 10
Application of VAS criterium* in Midfoot trauma.

Radiograph	Fracture	No Fracture	Total
VAS criterium+	5	47	52
VAS criterium-	0	96	96
Total	5	143	148

* VAS criterium: pain > 4 on VAS

Table 11
Performance of VAS criterium*.

Parameters	General	Ankle	Midfoot
Sensitivity	100%	100%	100%
Specificity	38%	47%	67%
Positive Predictive Value	48%	48%	10%
Negative Predictive Value	100%	100%	100%

*VAS criterium: pain > 4 on VAS
* 95% confidence level and 7.98 confidence interval

Table 12
Average Sum of VAS by Characteristic.

	VAS (SD)	*p*
No Fracture n=94	7.5 (6.9)	
		0.004
With Fracture n=54	10.7 (6.1)	
Conservative Treatment n=30	9.3 (3.6)	
		0.0492
Surgical Treatment n=24	12.4 (6.7)	
Leisure Activity* n=87	9.1 (5)	
		0.036
Work Accident* n=26	13.5 (9.9)	
		0.006
Sport Activity* n=19	7.1 (4.3)	
Midfoot Fracture n=5	8.8 (1.1)	
		0.0498
Ankle Fracture n=49	10.6 (5.1)	
Total n=148	8.8 (6.8)	

* with pain

6.9) ($p = 0.004$). Patients with ankle fractures had a mean VAS sum significantly higher than that of patients with midfoot fractures 10.6 (SD 5.1) vs 8.8 (SD 1.1) ($p = 0.0498$). We also emphasize that patients with more severe fractures and who required surgical treatment had a mean VAS of 12.4 (SD 6.7), which was significantly higher than that of fractures submitted to conservative treatment 9.3 (SD 3.6) ($p = 0.0492$).

Accident context and clinical features

It was interesting to analyze the severity of the lesions found in each context in order to understand the empirical clinical characteristics underlying them. We found that although there was a lower percentage of fractures in the group of injuries in Work Accidents (31% vs 37% Sports Activity and 38% Leisure Activity), there was a statistically significant increase in the sum of average VAS in Accidents at Work vs Leisure Activities 13.5 (SD 9.9) vs 9.1 (SD 5) ($p = 0.036$) as well as vs Sports Activities 13.5 (SD 9.9) vs 7.1 (SD 4.3) ($p = 0.006$). The difference in the sum of the average VAS between Leisure Activities and Sports Activities was not statistically significant 9.1 (SD 5) vs 7.1 (SD 4.3) ($p = 0.085$) although it is interesting to note that athletes presented with lower VAS values.

Limitations

The main limitations of this study are related to the low number of patients ($n = 148$) and the low number of midfoot fractures ($n = 5$). Despite this, the information collected allowed us to reach interesting conclusions and add value to this work. The number of midfoot fractures is the most sensitive subject. Still, all these fractures were detected with the OARs and we found a significant increase of specificity with the application of our update. Nevertheless, further prospective studies are needed.

Conclusions

Excessive use of radiographs in the context of ankle trauma has consequences in terms of economics, productivity and above all for patient's health [13-20]. In this prospective study, we confirmed the utility of OARs in our population and we found strategies to further reduce the need for unnecessary radiographs. The introduction of parameters as de VAS criterium for grading pain and the study of accident's context seem promising. We found no difference in fracture detection with patient's gender, previous therapy, comorbidities or "inability to perform during 4 steps, either immediately or in the EW". Patients with fractures were older, had a VAS of 5 or more points in any of the tested sites and didn't tolerate partial or total load when compared with patients without fractures. Patients victims of Work Accidents had a statistically significant increase in the sum of average VAS vs Sports Activities and Leisure Activities although they had the lowest percentage of fractures. Interestingly athletes were those with lower VAS values.

With the method of VAS criterium, we found a significant increase of global specificity (38% vs 15%), as well as when applied only to the ankle (26% to 47%) or to midfoot trauma (62% to 67%). In both, there would have been a 100% reduction of CT scans.

This work reinforces the utility of OARs in our daily practice. The addition of VAS criterium and trauma circumstances may constitute an even safer way to detect foot and ankle fractures without radiation. We believe that with larger groups it would be possible to increase the specificity even more with a higher VAS criterium for younger patients, victims of Work Accidents.

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Declaration of Competing Interest

None.

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