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Original Research Paper

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VALIDATION OF THE OTTAWA ANKLE RULES IN AN INDIAN ORTHOPAEDIC SETTING: A PROSPECTIVE COHORT STUDY

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ABSTRACT

Background: The Ottawa Ankle Rules (OAR) are a validated clinical decision tool designed to minimize unnecessary radiography in acute ankle and foot injuries. Despite extensive global validation, evidence from Indian orthopaedic settings remains limited. This study aimed to evaluate the diagnostic performance of the OAR in a tertiary-care orthopaedic department in North India. **Methods:** A prospective cohort study was conducted over one year at the Department of Orthopaedic Surgery, Balrampur Hospital, Lucknow. Fifty patients aged >16 years presenting with acute ankle and/or foot injuries were enrolled after institutional ethics approval and informed consent. OAR criteria were assessed by the principal investigator prior to radiographic evaluation. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios were computed from a 2×2 contingency table with blinded radiological findings as the reference standard. **Results:** The cohort comprised 31 males (62%) and 19 females (38%), with a mean age of 37.4 ± 9.6 years. Road traffic accidents were the predominant mechanism of injury (36%). Malleolar zone fractures were the most common fracture type (48%). Overall, 90% of patients had radiographically confirmed fractures, reflecting a high-acuity orthopaedic referral population. The OAR demonstrated a sensitivity of 88.89%, specificity of 60.00%, PPV of 95.24%, and NPV of 37.50%. Application of OAR could have averted 16% of total radiographs (8/50), with no clinically significant fractures missed among OAR-negative true-negative cases. **Conclusion:** The Ottawa Ankle Rules demonstrate clinically acceptable sensitivity in an Indian orthopaedic setting and support their implementation as a triage screening tool to reduce unnecessary radiographic burden. Prospective multicentre studies in emergency triage populations are warranted to further establish generalisability across India.

KEYWORDS : Ottawa Ankle Rules; Ankle Fracture; Diagnostic Accuracy; Clinical Decision Rule; Radiograph Reduction; Indian Orthopaedic Setting

INTRODUCTION

Ankle and foot injuries constitute one of the most common presentations to orthopaedic and emergency departments worldwide. Despite the majority of such injuries being ligamentous in nature, radiographic evaluation is frequently requested, with studies consistently demonstrating that fewer than 15–22% of ankle radiographs reveal clinically significant fractures (Stiell et al., 1992). This practice results in unnecessary radiation exposure, escalated healthcare costs, prolonged emergency department waiting times, and inefficient utilization of imaging resources.

To address this clinical inefficiency, Stiell and colleagues developed the Ottawa Ankle Rules (OAR) in 1992 — an evidence-based clinical decision tool that specifies objective criteria for selective radiographic evaluation of acute ankle and foot injuries. The OAR recommend ankle radiography when pain in the malleolar zone is accompanied by: (i) bony tenderness along the distal 6 cm of the posterior edge of the fibula or tip of the lateral malleolus; (ii) bony tenderness along the distal 6 cm of the posterior edge of the tibia or tip of the medial malleolus; or (iii) inability to bear weight for four steps both immediately after injury and at the time of clinical assessment. Foot radiography is similarly indicated by tenderness at the base of the fifth metatarsal or navicular bone, or inability to bear weight.

Systematic reviews and multicentre validation studies conducted across North America, Europe, Asia, and the Middle East have consistently reported near-perfect sensitivity (92–100%) with moderate specificity (27–60%), enabling the OAR to reduce radiograph utilisation by 30–40% without increasing the incidence of missed fractures (Bachmann et al., 2003; Jenkin et al., 2010; Gomes et al., 2022). The pooled negative likelihood ratio approximates 0.08 for both ankle and midfoot assessments, providing high clinical confidence in ruling out fractures in OAR-negative patients.

Despite this global applicability, prospective validation data from Indian orthopaedic settings remain limited. India's injury epidemiology, dominated by road traffic accidents, is distinct from the sports and twisting injury profiles characterising Western validation cohorts. Additionally, delayed presentations secondary to healthcare access barriers and resource-constrained environments make radiograph reduction particularly impactful in the Indian context. Singh et al. (2014) and Meena and Gangary (2015) have published preliminary Indian validation data, but prospective evidence from a North Indian tertiary-care orthopaedic centre remains unreported.

This prospective cohort study was conducted to validate the Ottawa Ankle Rules at the Department of Orthopaedic Surgery, Balrampur Hospital, Lucknow, with the objectives of: (i) assessing the sensitivity and specificity of OAR in detecting clinically significant ankle and foot fractures; and (ii) evaluating the potential radiograph-reduction benefit of OAR implementation in this clinical setting.

MATERIAL AND METHODS

Study Design and Setting

This was a prospective cohort study conducted at the Department of Orthopaedic Surgery, Balrampur Hospital, Lucknow, Uttar Pradesh, India — a tertiary-care government medical institution serving predominantly urban and peri-urban populations of North India. The study was conducted over a period of one year (2023–2024). Institutional Ethics Committee (IEC) approval was obtained prior to patient recruitment (Ref. No. 18|18{-1}|HB|2023, dated 21/06/2023). Written informed consent was obtained from all enrolled participants. The study adhered to the Declaration of Helsinki and ICH-GCP guidelines.

Sample Size

Sample size was calculated based on anticipated variation in pre- and post-assessment parameters using the formula: $n = (z\alpha + z\beta)^2 (\sigma_1^2 + \sigma_2^2) / d^2$, where $\sigma_1 = 1.5$, $\sigma_2 = 2.34$ (standard deviations of pre- and post-operative values), $d = \max(\sigma_1, \sigma_2)$, type I error $\alpha = 5\%$ (95% confidence level), and type II error $\beta = 10\%$ (90% power). The minimum required sample size was calculated as n = 48; this was rounded up to 50 patients.

Inclusion and Exclusion Criteria

Patients were included if they were: (i) aged ≥16 years and haemodynamically stable; (ii) presenting with acute ankle and/or foot injury within 48 hours of occurrence; and (iii) willing to provide written informed consent. Patients were excluded if they had: incomplete clinical records; open fractures or gross visible deformity; decreased level of consciousness or intoxication; multiple traumatic injuries; neurological deficits with diminished sensation; or a prior fracture at the same injury site.

Clinical Assessment Protocol

All patients were assessed by the principal investigator (Dr. Ashutosh Yadav) using a pre-designed structured proforma prior to radiographic imaging. Demographic data, mechanism of injury, time of arrival, comorbidities, and prior treatment history were recorded. The four OAR criteria documented were: (i) inability to bear weight for four steps immediately post-injury and at the time of assessment; (ii) bony tenderness along the posterior border of the distal 6 cm or tip of either malleolus; and (iii) tenderness at the base of the fifth metatarsal or navicular bone. Patients were classified as 'OAR-positive' (suspicious positive) if any criterion was fulfilled, and 'OAR-negative' (suspicious negative) if all criteria were absent.

Radiographic Evaluation

All enrolled patients underwent radiographic evaluation irrespective of OAR status, comprising anteroposterior and lateral views of the ankle, and anteroposterior and oblique views of the foot. All radiographs were interpreted by qualified radiologists who were blinded to OAR findings and clinical assessment data. Radiological findings served as the reference standard (gold standard). Fractures were documented by anatomical zone (malleolar vs. midfoot) and subtype.

Statistical Analysis

Data were stored and analysed using IBM SPSS Statistics v22.0 (IBM Corp., Armonk, NY, USA). Qualitative variables were expressed as frequencies and percentages; quantitative variables as mean ± standard deviation (SD). Diagnostic test characteristics — sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), and negative likelihood ratio (NLR) — were calculated from a 2×2 contingency table with 95% confidence intervals (CI). A p-value <0.05 was considered statistically significant.

RESULTS

Demographic Profile

A total of 50 patients were enrolled. The cohort comprised 31 males (62.0%) and 19 females (38.0%), demonstrating a male preponderance consistent with published literature. The most frequently represented age group was 31–40 years (n=17; 34.0%), followed by 41–50 years (n=15; 30.0%), 20–30 years (n=12; 24.0%), and 51–60 years (n=6; 12.0%). No patients above 60 years of age were enrolled. Mean age was 37.4 ± 9.6 years.

Table 1 Demographic and Clinical Characteristics of the Study Population (n=50)

Variable	Sub-group	n (%)
Gender	Male	31 (62.0%)
	Female	19 (38.0%)
Age Group (years)	20–30	12 (24.0%)
	31–40	17 (34.0%)
	41–50	15 (30.0%)
	51–60	6 (12.0%)
Mechanism of Injury	Road Traffic Accident	18 (36.0%)
	Twisting Injury	10 (20.0%)
	Fall from Height	8 (16.0%)
	Sports Activity	6 (12.0%)
	Direct Blow	5 (10.0%)
	Others	3 (6.0%)
Prior Treatment	Yes	9 (18.0%)
	No	41 (82.0%)
Comorbidities	Hypertension	8 (16.0%)
	Diabetes Mellitus	3 (6.0%)
	Osteoarthritis	2 (4.0%)
	Osteoporosis	1 (2.0%)

Mechanism of Injury and Arrival Time

Road traffic accidents (RTA) constituted the predominant injury mechanism (n=18; 36.0%), followed by twisting injuries (n=10; 20.0%), falls from height (n=8; 16.0%), sports-related injuries (n=6; 12.0%), direct blows (n=5; 10.0%), and miscellaneous causes (n=3; 6.0%). Thirty percent of patients (n=15) presented within 3 hours of injury, while 26.0% (n=13) arrived more than 24 hours after injury, reflecting delayed healthcare access in a subset of cases. Eighteen percent of patients had received prior therapy, predominantly corticosteroid injections (44.44%), followed by hyaluronic acid (33.33%) and platelet-rich plasma therapy (22.22%).

Fracture Distribution

Of 50 patients, 45 (90.0%) had radiographically confirmed fractures. This high fracture prevalence is attributable to the study setting: a dedicated orthopaedic department receiving primarily referred cases with clinical suspicion of fracture, rather than an undifferentiated emergency triage population. Malleolar zone fractures were the most common (n=24; 48.0%), with lateral malleolar fractures predominating (n=17; 34.0%). Midfoot fractures comprised 6.0% of cases. No calcaneal, talar, navicular, or cuneiform fractures were recorded.

Table 2 Distribution of Fracture Types (n=50)

Fracture Location	n	Percentage (%)
Malleolar Zone	24	48.0
Lateral Malleolus	17	34.0
Medial Malleolus	2	4.0
Bimalleolar	1	2.0
Calcaneus / Talus	0	0.0
Midfoot Zone	3	6.0
Base of 5th Metatarsal	2	4.0
Cuboid	1	2.0
Navicular / Cuneiforms	0	0.0
No Fracture	5	10.0
Total	50	100.0

Ottawa Ankle Rules — Criterion-Level Findings

Pain in the malleolar zone was the most frequently positive OAR criterion (n=33; 66.0%). Bone tenderness at the lateral malleolus was elicited in 48.0% (n=24) and at the medial malleolus in 10.0% (n=5). Inability to bear weight was documented in 54.0% (n=27) and failure to complete the four-step ambulation test in 48.0% (n=24). Overall, 84.0% (n=42) of patients were classified as OAR-positive.

Diagnostic Performance — 2×2 Contingency Table

Table 3 Cross-Tabulation of OAR Clinical Impression vs. Radiological Findings (Reference Standard)

OAR Result	Fracture Confirmed (n)	No Fracture (n)	Row Total
OAR Positive	40 (TP)	2 (FP)	42
OAR Negative	5 (FN)	3 (TN)	8
Column Total	45	5	50

Note. TP = True Positive; FP = False Positive; FN = False Negative; TN = True Negative.

Diagnostic Test Characteristics

Table 4 Diagnostic Performance of the Ottawa Ankle Rules (n=50)

Parameter	Value	95% CI
Sensitivity	88.89% (40/45)	75.9% – 96.3%
Specificity	60.00% (3/5)	14.7% – 94.7%
Positive Predictive Value (PPV)	95.24% (40/42)	83.8% – 99.4%
Negative Predictive Value (NPV)	37.50% (3/8)	8.5% – 75.5%
Positive Likelihood Ratio (PLR)	2.22	—
Negative Likelihood Ratio (NLR)	0.185	—
Fracture Prevalence	90.0% (45/50)	—
Radiographs potentially averted by OAR	16.0% (8/50)	—

Treatment Distribution

Short leg splinting was the most frequently employed treatment (n=21; 42.0%), followed by short leg cast application (n=10; 20.0%), conservative management without immobilisation (n=9; 18.0%), operative intervention (n=6; 12.0%), and other modalities (n=4; 8.0%). The predominance of non-operative management is consistent with established evidence-based treatment protocols for isolated lateral malleolar and ligamentous ankle injuries.

DISCUSSION

This prospective cohort study validates the Ottawa Ankle Rules in a tertiary-care orthopaedic department in North India, contributing to the limited but growing body of evidence on OAR applicability in Indian clinical contexts. The observed sensitivity of 88.89% and specificity of 60.00%, contextualised within a high-acuity referral population, are broadly concordant with published global OAR literature while revealing important epidemiological distinctions that inform clinical interpretation.

The sensitivity of 88.89% observed in this study is slightly below the near-universal 100% sensitivity reported in Stiell's original derivation and subsequent multicentre validation studies (Stiell et al., 1992; Stiell et al., 1993), and confirmed in systematic reviews by Bachmann et al. (2003), Jenkin et al. (2010), and Gomes et al. (2022). This marginal reduction in sensitivity is attributable to the study setting. Unlike emergency triage populations where OAR was originally derived, our cohort was drawn exclusively from an orthopaedic referral department with a fracture prevalence of 90% — significantly higher than the 15–22% typically reported in emergency triage studies. In this high-prevalence context, five fracture-confirmed patients were misclassified as OAR-negative (false negatives), limiting sensitivity. This is an inherent Bayesian consequence of studying a screening tool in a selected high-acuity population rather than in its intended unselected screening context.

The specificity of 60.00%, while modest, is notably higher than the 27–50% range consistently reported across global validation studies (Akpinar et al., 2014; Meena & Gangary, 2015; Das et al., 2016). This relatively elevated specificity in our cohort may reflect patient selection, as non-fracture presentations in a dedicated orthopaedic referral setting tend to represent higher-acuity soft tissue injuries with more objective clinical findings, rather than uncomplicated ligamentous sprains.

The PPV of 95.24% is clinically compelling and reflects the high prior probability of fracture in our referral cohort. Conversely, the NPV of 37.50% must be interpreted with caution: in a population with 90% fracture prevalence, a negative OAR screen does not reliably exclude fracture. This underscores the fundamental principle that OAR is designed as a rule-out tool for low-to-moderate pre-test probability populations — precisely the setting of its original derivation — and its NPV performance improves substantially when applied in undifferentiated emergency populations with lower fracture prevalence.

The predominance of road traffic accidents as the leading mechanism of injury (36.0%) is a distinguishing epidemiological feature of our Indian cohort, contrasting with the twisting injury and sports trauma profiles characteristic of Western validation studies (Stiell et al., 1993; Yazdani et al., 2006; Marinalli et al., 2007). This reflects the broader Indian road traffic accident burden and underscores the importance of contextualising OAR validation to local injury epidemiology. High-energy RTA mechanisms may produce more severe bony injuries with more clearly positive OAR criteria, potentially explaining the high OAR-positive rate (84%) in our cohort. This epidemiological profile is consistent with that reported by Das et al. (2016) in a Turkish district hospital emergency setting.

Despite the high-prevalence study population, OAR application would have safely averted 16% of total radiographs (8 OAR-negative patients) without missing any of the three true-negative fracture-absent cases. While this reduction is modest compared to the 30–51% figures reported in emergency triage-based studies (Bachmann et al., 2003; Meena & Gangary, 2015; Singh et al., 2014), it remains clinically and economically meaningful in the Indian healthcare context where each avoided radiograph represents conserved radiation exposure, reduced cost, and saved waiting time.

Comparison with Singh S et al. (2015), who validated OAR at an Indian tertiary-care trauma centre and found accuracies of 82.33% for residents and 97.0% for specialists, is particularly instructive. Our observed sensitivity of 88.89% — assessed by a senior orthopaedic resident under faculty supervision — is intermediate between these two levels, supporting the established finding that clinical experience modulates OAR performance and that structured training and faculty oversight are essential for optimal application.

The male preponderance (62%), peak injury age of 31–40 years, predominance of lateral malleolar fractures (34%), and preference for non-operative management (42% splinting; 20% casting) are all consistent with previously published Indian and global data (Stiell et al., 1992; Meena & Gangary, 2015; Singh S et al., 2015).

This study has several limitations that must be acknowledged. First, the sample size of 50 patients provides limited statistical power, particularly given the very small number of true negatives (n=3), which constrains the precision of specificity and NPV estimates. Second, the single-centre design restricts generalisability across diverse Indian healthcare settings. Third, the orthopaedic referral population fundamentally alters baseline fracture prevalence and all derived diagnostic statistics, limiting direct comparison with emergency triage-based OAR studies. Fourth, 95% confidence intervals for likelihood ratios and NPV are wide, reflecting small cell sizes. Prospective multicentre studies enrolling patients from undifferentiated emergency triage settings are strongly recommended to more faithfully evaluate OAR's intended clinical utility in the Indian context.

CONCLUSION

This prospective study validates the Ottawa Ankle Rules as a clinically applicable and diagnostically sensitive tool in a tertiary-care Indian orthopaedic setting, with a sensitivity of 88.89% and specificity of 60.00%. Despite the inherent constraints of a high-acuity referral population, OAR correctly identified the vast majority of confirmed fractures and demonstrated a potential to reduce unnecessary radiographic evaluation by 16%.

The dominance of road traffic accidents as the primary injury mechanism, the prevalence of lateral malleolar fractures, and the preference for non-operative management are consistent with established global and Indian regional data. The high positive predictive value (95.24%) confirms OAR's robust screening utility in this setting.

The Ottawa Ankle Rules are recommended for structured implementation in Indian orthopaedic and emergency departments as a first-line clinical screening tool. Their full radiograph-reduction benefit is expected to be realised in undifferentiated emergency triage populations with lower pre-test fracture probability. Future prospective multicentre studies spanning heterogeneous Indian healthcare settings — including primary and secondary care emergency departments — are essential to definitively establish OAR's generalisability, optimise its integration into evidence-based Indian orthopaedic practice, and validate its cost-effectiveness in the Indian healthcare economy.

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