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Development of a radiographic rule in trauma to clinically predict mandibular fractures

Admaja K. Nair[1,*], Valsa Thomas[2], Tinky Bose C[3], Sunu Ramachandran[4]

[1]Senior Lecturer, Mar Baselios Dental College, Kothamangalam, [2]Professor, [4]Assistant Professor, Govt. Dental College, Thiruvananthapuram, [3]Professor, Dept. of Oral Medicine & Radiology, Govt. Dental College, Calicut

***Corresponding Author:**
Email: admajaknair@gmail.com

Abstract
Objective: To develop a clinical decision rule with high diagnostic accuracy to detect mandibular fractures in the oral medicine emergency clinic of a tertiary referral centre.
Methodology: A cross sectional study was conducted among 250 trauma patients suspected of mandibular fracture in the oral medicine emergency clinic. Clinical symptoms and signs were recorded in a predesigned proforma. Clinical diagnosis was compared with the gold standard of radiographic diagnosis. Forward step wise logistic regression and recursive partitioning were performed with statistically significant variables, to identify relevant predictors for tool development. It was further refined to develop a maximally sensitive clinical decision rule.
Results: Among the total 250 patients, most common age group for mandibular trauma was 21- 30 years with male to female ratio of 3.4:1. Most common cause of facial trauma was road traffic accidents (RTA). 122 of 250 suspected patients had radiographic evidence of fracture. Condylar fractures were most common. Based on forward step wise logistic regression and recursive partitioning step defect, deranged occlusion, sublingual hematoma and crepitus were identified significant of mandible fracure.The rule RRT Mn# (Radiographic Rule in Trauma- Mandibular Fracture) was developed after recoding each case based on the criteria 'presence of any of the 4 significant variables' which improved the diagnostic accuracy to 96.4%.
Conclusion: RRT Mn# is a simple decision rule with high diagnostic precision that can guide in the clinical diagnosis of fracture mandible.

Keywords: Clinical decision rule, Mandible fracture, Diagnostic accuracy, Facial trauma.

Introduction
The face is one of the most commonly injured areas in human body. Facial injury is a common presentation especially in up to 5 to 16% of major trauma patients.[1,2] Fractures of the mandible have been reported to account for about 30% to 55% of all maxillofacial fractures.[3,4,5] In India it constituted 60.4% of all maxillofacial injuries.[6] The common causes of mandibular fractures may be road traffic accidents, interpersonal violence, accidental falls, sport injuries, industrial trauma.

Clinical prediction rules are commonly used in medical practice to improve decision making by matching a treatment to a specific subgroup of patients. These implements avail to deal with ambiguity of medical decision making and help to improve efficiency and cost-effectiveness.[7]

Only 30-40% of patients presenting with mandibular trauma have mandibular fractures.[8] There is often the lack of guidance as to who should undergo radiography so that most patients are ordered radiographs in fear of omitting a fracture. This leads to increased radiation exposure and unwanted treatment postponement.

Several retrospective studies undertaken to determine the reliability of panoramic radiograph in the evaluation of fractures in the mandible show that about 86-92% of mandibular fractures are detected by the same.[9,10,11]

There is currently little information as to which combination of clinical symptoms or signs may be safely used to prognosticate or omit the presence of a mandibular fracture. The Manchester Mandibular Fracture Decision Rule was put forward in 200,[7] but any such similar studies have not yet been reported in our settings. This study aims to develop a clinical decision rule with high diagnostic accuracy for diagnosing mandibular fracture so that there will be a marked reduction in a number of diagnostic radiographs taken in emergency clinic, thereby incrementing clinical efficacy.

Methodology
This Cross-sectional study was conducted in the emergency clinic, Department of Oral Medicine and Radiology, Government Dental College, Thiruvananthapuram, Kerala from June 2011- August 2012 (15 months). The study proposal was approved by the institutional ethical committee. Any incident case trauma patient, with a suspicion of mandibular fracture was included. Pregnant female patients and patients with severe trauma who are unable to co-operate were excluded.

Sample size: For multivariate analysis, the sample size is the number of variables (including the baseline ones considering for analysis) multiplied by 10. For this study 250 is taken as the sample size based on this criteria.[12]

Steps in Developing the new screening Tool[13, 14]: All steps in the development of a new tool, from item generation to item selection and item reduction were carried out.

Item generation

Item generation was done using qualitative methods. A list of signs and symptoms which are potential predictors of the outcome of interest, the radiographic diagnosis of mandibular fracture was compiled. This was done based on utilizing the expertise of specialists, eliciting symptoms and signs from positively screened patients and using literature reviews.

Item selection and item reduction

After the list was generated, it was circulated among specialists, to get their opinion on content relevance and content coverage. Less relevant factors were omitted. Finally, a questionnaire, containing 17 clinical variables was developed.

Pre-testing

The next step was to pre-test the instrument. Pre-testing was carried out on 20 patients with suspected mandibular fracture. This was done to confirm, how far the items were relevant to the conditions under study. The instrument was further refined after this.

Pilot study

A pilot study was conducted to assess the feasibility of the study in the department. Following piloting, a refined instrument was developed. All patients satisfying the inclusion criteria were included in the study. Since blinding was ensured, observer bias was eliminated in all steps of the study. To assess the interobserver reliability of the clinical findings; the patients were examined by a second physician who was blinded to the results of the first assessment. Good interobserver agreement (kappa > 0.6) was seen between findings. The radiographic evaluation consisted primarily of standardized panoramic view and mandibular occlusal views in relevant cases. A radiologist, who was blinded to the clinical probability of fracture, interpreted the films. All mandibular fractures including dentoalveolar fractures were considered positive for fracture. Planmeca Proline XC with Dimax 3 digital panoramic machine with networking facility was used for taking panoramic radiographs.

Data management& Statistical Analysis

Data entry was done using SPSS for Windows. Clinically relevant variables were categorized and verified for analysis. The outcome measurement was treated as binary (1=yes, 2=no). The descriptive statistics of relevant variables were carried out.

Developing Final Tool: Item Reduction Multivariate analysis

Crosstabs were done for 17 relevant variables from the different domains, against the gold standard and only those variables significant ($p<0 \cdot 05$) in Chi-Square tests, were chosen for multivariate analysis. The clinical parameters strongly associated with output factors (Chi-square test p value <.05) (Table 1) were further analyzed by multivariate techniques. Both forward stepwise binary logistic regression (Table 2) and chi-square recursive partitioning (classification tree) were used to select the clinically relevant items, to be included in the final rule that maximizes the diagnostic accuracy of a mandibular fracture. Recursive partitioning analysis using tree was also done to develop the combination of best predictor variables (Table 3). The sensitivity, specificity and predictive value of the developed model were assessed. The combination of variables, which yielded maximum sensitivity, specificity, and diagnostic accuracy were selected for obtaining the final rule, RRT-Mn # (Table 4).

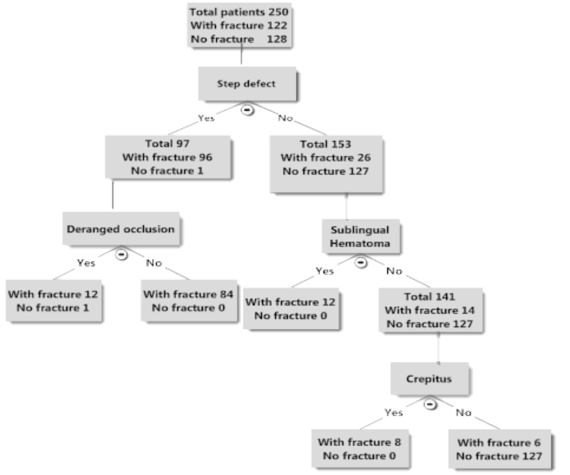
Table 1: Characteristics of study sample

Base line variables	
Age	
Mean+SD	34.13+14.15
Median	32
Gender	
Male	193(77.2)
Female	57(22.8)
Type of injury	
RTA	155(62.0)
Assault	44(17.6)
Fall	40(16.0)
Others	11(4.4)
Distribution of mandibular fracture by radiographic diagnosis	
Fractures Present	122(48.8)
Fractures Absent	128(51.2)
Bivariate analysis of the clinical variables	
Variables	p value
Pain at rest	.256
Swelling	.083
Laceration	.191
Ear Bleed	.451
Trismus	.452
Tenderness	.200
Lateral Movement Limitation	.557
Pain on Opening	.012*
Intra Oral Bleed	.000
Mastication Difficulty	.005*
Broken Teeth	.001*
Loss of Teeth	.030*
Deviation on Opening	.000*
Deranged Occlusion	.000*
Sub Lingual Hematoma	.000*
Crepitus	.000*
Step Defect	.000*
Data are numbers of individuals (%)	
*(p<0.05); statistically significant	

Table 2: **Summary statistics for the rule**

Logistic Regression & recursive partitioning output:	
Sensitivity	95.1(116/122)
Specificity	99.2(127/128)
Diagnostic performance of decision rule RRT-Mn# :	
Sensitivity	0.992(0.958-1.000)
Specificity	0.938(0.905-0.945)
Diagnostic Accuracy	0.964(0.931-0.972)
Positive predictive value (PPV)	0.938(0.906-0.945)
Negative predictive value (NPV)	0.992(0.958-1.000)
Diagnostic Odds	1815.000(219.281-39795.322)
Error Odds	8.067(2.392-135.310)
Youden's J	0.929 (0.864-0.944)
Relative Risk	113.496 (21.482-2176.593)
Kappa	0.928 (0.862-0.943)
The reliability coefficient was 0.928 by kappa statistics	

Table 3: Classification tree by recursive partitioning



10 clinical variables, suggesting fracture was found to be significant in bivariate analysis ($p<0.05$). Four variables came significant in the final step (step 4) of regression. The same variables as in regression came significant by recursive partitioning. Based on regression output and chi-square recursive partitioning, the individual variables to be included in the rule were finalized as:

- Step defect
- Deranged occlusion
- Sublingual hematoma
- Crepitus

The sensitivity and specificity of regression output were calculated. Logistic regression analysis and recursive partitioning yielded a model that correctly classified 95.1% of patients with fracture and 99.2% of patients without fracture.

Development of a maximally sensitive rule:
The rule was further modified by recoding each case based on "presence of any of the four significant variables" to obtain maximum sensitivity. The validity of the new rule was assessed against a gold standard of radiographic diagnosis (Table 2).

Results

Most of the patients were in the 21-30 year age group followed by the 31- 40-year group. The male to female ratio was found to be 3.4:1. RTA was the most common cause of injury followed by assault and fall. A wide range of clinical signs and symptoms were exhibited by patients with mandibular trauma. Almost all the patients exhibited tenderness at the site of trauma (98%) followed by mastication difficulty and pain on opening. The gold standard for diagnosing fracture was panoramic views and mandibular topographic occlusal views.

Among the total 250 patients, 122(48.8%) had radiographic evidence of fracture mandible. Fracture condyle was found to be the most common among isolated fracture mandible. Multiple fractures were seen in 16.4% patients.

The proposed rule ***RRT-Mn # (Radiographic Rule in Trauma – Mandibular Fracture)*** has 4 clinical predictors - step defect, deranged occlusion, sublingual hematoma and crepitus- to predict or rule out the mandibular fracture. Logistic regression analysis and recursive partitioning yielded a model that correctly classified 95.1% of patients with fracture and 99.2% of patients without fracture. 6 patients with fracture were missed by the model. The decision rule should be maximally sensitive to avoid missing cases with fracture, and at the same time retaining high diagnostic accuracy. The sensitivity was improved to the maximum (99.2%) on further recoding each case based on *"presence of any of the four significant variables"*. Both the specificity (93.8%) and diagnostic accuracy (96.4%) of the rule was considered substantial.

The rule, if applied to our data set, would have eliminated the need for 120 radiographs among 128 patients without fracture. The rule failed to identify a single case with fracture- a case of undisplaced hairline mandibular fracture- in which the only significant clinical finding was "mastication difficulty". If this variable was added to the rule, we could have attained 100% sensitivity, but at the cost of very low specificity (13.3%) and diagnostic accuracy (55.6%), which is unacceptable for the rule. 8 cases were identified to have fracture by the rule when there was no radiographic evidence of the same. This false positive rate may be due to the presence of any of the four clinical signs due to other coexistent facio maxillary fractures. Anyway, this does not significantly increase the radiography rate.

Table 4: Final clinical decision rule RRT-Mn #

<table>
<tr><th colspan="5">RRT-Mn#</th></tr>
<tr><th colspan="5">Radiographic Rule in Trauma- Mandibular Fracture</th></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td rowspan="5">Site of fracture:</td></tr>
<tr><td>1</td><td>Step Defect</td><td></td><td></td></tr>
<tr><td>2</td><td>Deranged Occlusion</td><td></td><td></td></tr>
<tr><td>3</td><td>Crepitus</td><td></td><td></td></tr>
<tr><td>4</td><td>Sublingual Hematoma</td><td></td><td></td></tr>
<tr><td colspan="4">If yes to any of the above, then</td><td rowspan="2">Request for radiograph</td></tr>
<tr><td colspan="4">*the rule may not be applicable for undisplaced hairline fractures</td></tr>
<tr><td colspan="4">Radiographic diagnosis:</td><td></td></tr>
</table>

Discussion

Extensive sequences of studies have been conducted in different parts of the world to assess the epidemiological characteristics of mandibular fractures. While soft tissue injuries constitute more than half of total facial trauma, mandibular fractures are seen in only up to 40% cases.[7,15] There is often the lack of guidance as to who should undergo radiography, leading to over investigation in this group.

In this study, the initial process of development and validation of a tool for detection of mandibular fractures clinically was attempted. This is the first study in our setting to look at the diagnostic accuracy of clinical variables in predicting mandibular fractures so that a simple rule that may be used in a day-to-day management of patients with mandibular injuries in the trauma clinic. The reliability of clinical criteria was ensured by assessing the inter-observer agreement. The predictor variables were standardized and collected in a systematic manner and outcome was clearly defined.

The rule ***RRT-Mn#*** has 4 clinical predictors - step defect, deranged occlusion, sublingual hematoma and crepitus- to predict mandibular fracture. When using the criteria 'presence of all the 4 variables, sensitivity of the rule will be 95.1% so that 6 positive cases were missed. Our main purpose was to develop a rule with high diagnostic accuracy, which can be achieved only with high sensitivity and specificity. The addition of more variables to the rule will reduce the specificity drastically. The diagnostic accuracy was improved (96.4%) on further recoding each case based on *"presence of any of the four significant variables"*. Both the sensitivity (99.2%) and specificity (93.8%) was considered substantial.

8 cases were identified to have fracture by the rule when there was no radiographic evidence of the same. This false positive rate may be due to the presence of any of the four clinical signs due to other coexistent faciomaxillary fractures. Anyway, this does not significantly increase the radiography rate.

Radiographer abnormality detection schemes (RADS) is used in many hospitals with the introduction of 'red dot' schemes to assist emergency department (ED) doctors in the correct interpretation of radiographic images.[16] In our setting, where the resident trainees are the first to evaluate trauma patients clinically, a decision rule like RRT-Mn# can be used effectively to improve the timely and cost-effective diagnosis, outcome and management of emergency patients.

The merits of the study include the development of a simple, short, easy to assess 4 -step rule, for diagnosing mandibular fractures which reduce the number of unnecessary radiographs in trauma patients.

The major limitations include the inability to diagnose undisplaced hairline fractures. Case to case detailed examination and further investigations in such cases are needed, if symptoms persist or worsen. Validation of rule is required in a separate and large prospective study sample. Interobserver and intra observer agreement were not assessed in the study sample.

Conclusion

The proposed rule RRT-Mn # (Radiographic Rule in Trauma – Mandibular Fracture) has 4 clinical predictors - step defect, deranged occlusion, sublingual hematoma and crepitus- to predict or rule out the mandibular fracture. It is simple and easy to assess clinically. The rule was able to identify 93.8% of non fracture cases correctly (acceptable specificity) when applied to the study sample. This would have caused a considerable reduction in the number of radiographic procedure in trauma cases.

The rule is not applicable in cases of undisplaced hairline fracture of a mandible, which might present without any of the characteristic features included in the rule. The inclusion of more variables decreased the diagnostic accuracy, which is not desirable. Also, the rule has to be validated in a larger population for better refining with respect to diagnostic gain, rule reliability and applicability in various settings.

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