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Diagnostic Utility of Head CT Rule in Predicting Intracranial Injuries in Minor Traumatic Brain Injury: A Prospective Analysis from a Tertiary Emergency Care Centre in India

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ABSTRACT

Background: Minor head injuries with Glasgow Coma Scale (GCS) score of 13-15 account for approximately 84% of all traumatic brain injuries. While the vast majority of these patients have favourable outcomes, identifying those requiring neurosurgical intervention from those who can be safely managed conservatively remains clinically challenging. The Canadian CT Head Rule (CCHR) is a well-established and validated clinical decision instrument for selective computed tomography imaging in minor head injury, yet its diagnostic utility in Indian populations requires systematic evaluation.
Objectives: The primary objectives of this study were to estimate the diagnostic accuracy of CCHR in predicting intracranial injuries on CT scan and to assess the association between Glasgow Coma Scale score and structural abnormalities in minor head injury patients.
Methods: A prospective, cross-sectional, hospital-based study was conducted over an 18-month period at the Emergency Department. Adults aged 16 years and above presenting with minor head injury (GCS 13-15, injury sustained within 24 hours) were enrolled consecutively. All patients underwent systematic CCHR assessment following stabilisation according to Advanced Trauma Life Support protocols, followed by non-contrast head CT imaging. Statistical analysis included calculation of sensitivity, specificity, predictive values, likelihood ratios, and chi-square tests with $p<0.05$ as the threshold for statistical significance.
Results: Among 203 study participants with mean age 49.5±20.6 years and male predominance of 70%, positive CT findings were documented in 116 patients (57.1%). Neurosurgical intervention was required in 10 patients (8.6% of those with positive CT). CCHR demonstrated sensitivity of 68.1% (95% CI 61.2%-75.0%) and specificity of 42.5% for predicting positive CT findings. Retrograde amnesia ($p<0.01$), ear/nose/throat bleed ($p<0.01$), and hemotympanum ($p=0.008$) showed statistically significant correlation with positive CT. Notably, neurological features, including post-traumatic seizures and pupillary abnormalities, demonstrated 100% sensitivity for identifying positive CT findings.
Conclusion: In this Indian cohort, CCHR demonstrated moderate sensitivity and specificity for CT prediction, findings comparable to international validation studies. The Canadian CT

Head Rule provides a practical, clinically useful tool for systematic risk stratification of minor head injury patients in emergency settings, facilitating judicious use of imaging resources while maintaining diagnostic accuracy. Implementation in Indian emergency departments can optimise resource allocation, reduce patient costs, minimise unnecessary radiation exposure, and provide evidence-based standardisation of minor head injury evaluation, particularly in resource-constrained healthcare systems.

Keywords: Minor head injury, Canadian CT Head Rule, Traumatic brain injury, Clinical decision rule

INTRODUCTION

Head injury remains among the most common presenting complaints in emergency medicine, representing a significant proportion of trauma admissions[1]. While the vast majority of head injuries are classified as minor in severity, the optimal evaluation and management protocol for this large heterogeneous patient population remains a subject of ongoing clinical debate and research[1]. Intracranial hematoma, ranging from epidural to subdural and subarachnoid haemorrhage, represents a leading cause of death and disability in patients presenting with head injury[2]. Early diagnosis through computed tomography imaging followed by timely neurosurgical intervention, when indicated, has proven critical in improving patient outcomes and minimizing long-term morbidity and mortality[1].

Classification and Epidemiology of Minor Head Injury

Minor head injury is clinically defined as any patient presenting with a history of loss of consciousness, post-traumatic amnesia, or acute alteration in mental status, with a Glasgow Coma Scale score of 13-15[3]. Epidemiological data consistently demonstrate that eighty-four percent of all head trauma cases present as minor head injuries[4]. Although the clinical course in the majority of minor head injury patients is benign, permitting safe discharge following appropriate observation periods, a small but clinically significant proportion of patients experience clinical deterioration and subsequently require neurosurgical intervention for management of intracranial hematoma, with reported incidence ranging from 0.5% to 2% depending on study population and methodology[5].

The advent of computed tomography imaging in 1974 revolutionized the diagnostic approach to head trauma management. However, historically there has been widespread lack of evidence-based clinical guidelines. Previous attempts at guideline development were characterized by weak methodology and inconclusive findings, creating an urgent clinical need for valid, reliable, and evidence-based decision tools that would allow physicians to be more selective in CT utilization without compromising patient safety or quality of care. Clinical decision rules, also termed prediction rules or clinical scoring systems, represent a structured approach to reduce medical decision-making uncertainty by standardizing collection and interpretation of relevant clinical data. These decision-making tools are derived from original perspective research, incorporate multiple variables derived from patient history, physical examination findings, and simple investigations, and have been demonstrated to facilitate more evidence-based clinical practice patterns.

Burden of Traumatic Brain Injury in India

Traumatic brain injury represents a major public health problem both globally and specifically within the Indian healthcare context[6]. In India, the rising burden of traumatic brain injury has been directly attributable to rapid economic growth coupled with increased population density, accelerating motorization trends, and

advancing industrialization[6]. Economic growth has paralleled marked increases in TBI incidence, with each successive year witnessing incremental increases in the absolute number of TBI cases presenting to Indian emergency departments and trauma centres[6]. An epidemiological study conducted in Bangalore reported TBI incidence of 150 per 100,000 population, with mortality rate of 20 per 100,000 and case fatality rate of 10%[6]. Within India, road traffic accidents account for approximately 60% of all TBI cases, with falls contributing 25% and assaults accounting for approximately 10% of traumatic brain injuries[6]. The population injury rate per lakh (100,000) has increased approximately two-fold between 1970 and 2011, with road traffic accidents consistently accounting for the major share of the overall TBI burden. The total annual costs of road traffic injuries alone have been estimated at approximately 55,000 crores annually in the Indian economy[6]. In contrast, in the United States, a TBI is estimated to occur every 15 seconds, generating 1.7 million new head injury victims annually, responsible for 50,000 deaths, leaving 80,000 individuals with permanent disabilities, and incurring total healthcare costs exceeding 77 billion USD annually[7].

Clinical Decision Rules and Selective CT Imaging

Multiple clinical decision rules and prediction instruments have been developed and validated for the purpose of minimizing unnecessary head CT imaging while maintaining sensitivity for identifying clinically significant intracranial injuries[8]. The Canadian CT Head Rule, published in 2001, was systematically developed and validated as a clinical tool to predict which minor head injury patients will demonstrate intracranial injury on CT imaging, thereby enabling selective CT utilization and reduction in the number of unnecessary CT scans performed in this patient population[1]. Comparative studies have consistently demonstrated that CCHR exhibits superior specificity compared to competing decision rules, particularly the New Orleans Criteria (NOC), for identifying injuries requiring neurosurgical intervention[9,10]. Other established decision instruments include the New Orleans Criteria, NEXUS-II criteria, NICE guidelines, and Scandinavian Neurotrauma Committee guidelines, each with varying levels of sensitivity and specificity in different patient populations and healthcare settings[11,12,13,14,15].

Radiation Concerns and Health Economics

While CT imaging is exquisitely sensitive for detection of intracranial blood and effectively guides emergency department management decisions, widespread utilization of head CT raises significant concerns regarding cumulative radiation exposure[16]. The U.S. Food and Drug Administration estimated that one fatal malignancy develops in every 10,000 patients receiving a head CT scan[16]. Extrapolating this risk, if all 2.5 million emergency department encounters for minor TBI in 2010 had received head CT imaging, an estimated 250 fatal cancers would have resulted from radiation exposure alone. In the Indian healthcare context, documented evidence indicates that demand and supply of imaging services have escalated substantially over the past two decades[17-20]. Paradoxically, irrational ordering of imaging modalities has become increasingly prevalent in most regions of the country, despite burgeoning economic constraints and healthcare costs[20]. Implementation of evidence-based clinical guidelines for head injury risk stratification and selective imaging has potential to substantially ease the financial and healthcare burden on both patients and healthcare institutions, particularly in resource-constrained settings[20].

Literature Gaps and Study Rationale

A comprehensive literature search conducted using Medline and PubMed

databases with keywords including "Head Injury in India," "Canadian CT Head Rule," and "Minor Head Injury" revealed that very few contemporary studies have specifically evaluated CCHR efficacy in developing countries, particularly within India[6,17]. While CCHR has been systematically validated in Western populations, its diagnostic accuracy, applicability, and clinical utility in Indian populations with distinctly different epidemiological profiles, injury mechanisms, and diverse healthcare settings have remained understudied[8,9,17]. This important gap in the literature necessitated the conduct of the present study to evaluate CCHR efficacy specifically in an Indian adult population, thereby sealing this critical lacuna in the emergency medicine literature and providing evidence for clinical practice guidelines within Indian healthcare settings[17].

Study Objectives

The primary objective of this study was to estimate the diagnostic efficacy and accuracy of the Canadian CT Head Rule in predicting the need for CT imaging in patients presenting to the emergency department with minor head injury. The secondary objectives included assessing the association between Glasgow Coma Scale score and structural abnormalities on CT imaging in minor head injury patients, and identifying specific clinical and radiological predictors of positive CT findings in this population.

MATERIALS & METHODS

Study Setting and Design

This prospective, cross-sectional, hospital-based observational study was conducted in the Department of Emergency Medicine, Krishna Institute of Medical Sciences, Karad, India. The study setting was a tertiary level teaching hospital with 24-hour emergency services and on-site neurosurgery facilities. The total study period spanned 18 months from August 2023, commenced after institutional ethical approval with number KVV/IEC/08/2023 with protocol number 667/2022-2023.

Study Population and Inclusion Criteria

The study population consisted of consecutive adult patients aged 16 years or above who presented to the emergency department with minor head injury (Glasgow Coma Scale score of 13-15) sustained within 24 hours preceding emergency department presentation.

Exclusion Criteria

Patients were excluded from the study if they met any of the following criteria of active use of anticoagulant medications or pre-existing bleeding disorder; unwillingness or inability to undergo head CT scan; presence of acute neurological deficit unrelated to the index head injury; or head injury sustained more than 24 hours prior to emergency department evaluation.

Sample Size Calculation

The required sample size was calculated using standard statistical methodology based on anticipated diagnostic performance characteristics of the CCHR from prior[1] validation studies. Assumptions for sample size calculation included an anticipated sensitivity of CCHR as 100%, an anticipated specificity of 36.3%, confidence interval of 99%, and a prevalence of minor head injury with positive CT findings of 11.5%. Using the standard formula for diagnostic test validation studies, the calculated required sample size was 203 patients.

The sample size calculation formula employed was:

$N = [Z^2_{1-\alpha/2} \times Sp(1-Sp)] / [d^2 \times (1-P)]$

Where N represents the required sample size, $Z_{1-\alpha/2}$ is the standard normal deviate corresponding to the specified alpha level and confidence interval (1.96 for 95% confidence, 2.576 for 99% confidence), Sp represents the anticipated or expected specificity of the diagnostic test, P represents the anticipated prevalence of positive findings in the study population,

and d represents the desired precision or acceptable margin of error. Applying the parameters of this study: $Z_{1-\alpha/2} = 2.576$ (for 99% confidence interval), Sp = 0.363, P = 0.115, and d = 0.05 (5% precision), the calculated sample size was 203 patients. This sample size was deemed adequate to achieve the primary study objective of evaluating CCHR diagnostic accuracy with acceptable statistical power and precision.

Ethics Approval and Informed Consent

Ethical approval for the study was obtained from the Research and Ethics Committee of Krishna Institute of Medical Sciences, Karad (KVV/IEC/08/2023 with protocol number 667/2022-2023) prior to patient enrolment. Written informed consent was obtained from all study participants or their legal next of kin in the local language (Marathi/Hindi) prior to enrolment in the study. Participants were fully informed of the study nature, its objectives, procedures, and their right to withdraw at any time without affecting their clinical care or treatment decisions.

Study Tools and Data Collection

The study employed three primary data collection instruments. The first was the Canadian CT Head Rule, a standardised clinical decision instrument incorporating high risk and medium risk criteria for predicting the need for CT imaging in minor head injury. The second was a non-contrast head CT, the standard imaging modality employed for detecting traumatic intracranial pathology. The third was a semi-structured data collection proforma designed to systematically capture demographic variables (age, gender, occupation), injury characteristics (mechanism, time, witness status), CCHR components, Glasgow Coma Scale components, and imaging and surgical findings.

Methodology and Study Protocol

The study protocol followed a clearly defined sequence of clinical assessment and management steps. Upon arrival to the emergency department, all trauma patients underwent triage and priority level assignment. Simultaneously, primary and secondary surveys were performed according to Advanced Trauma Life Support protocols with concurrent implementation of life saving procedures as clinically indicated. After achieving clinical stabilization, the Canadian CT Head Rule was systematically and prospectively applied to all patients presenting with minor head injury. The presence or absence of high risk and medium risk CCHR criteria was systematically documented. Based on CCHR risk stratification, patients were classified into high-risk (requiring neurosurgical intervention), medium-risk (clinically important brain injury), or low-risk (can be safely observed and discharged) categories. Non-contrast head CT imaging was performed based on CCHR recommendations and clinical judgment. Patients demonstrating positive CT findings including calvaria fractures or intracranial haemorrhage (epidural, subdural, subarachnoid, or intraparenchymal) were admitted for hospital observation and continued clinical monitoring. Patients requiring neurosurgical intervention (including procedures such as external ventricular drainage, decompressive craniectomy, hematoma evacuation, or depressed fracture elevation) were identified and followed. Patients without positive CT findings were discharged following appropriate observation and clinical clearance.

CCHR Components and Assessment

The Canadian CT Head Rule encompasses multiple clinical components systematically documented in all study participants. These components included the presence of dangerous mechanism of injury, episodes of vomiting (categorized as 0, 1, or ≥2 episodes), history of retrograde amnesia exceeding 30 minutes, documented ear/nose/throat bleed suggesting temporal bone or basilar skull involvement,

hemotympanum on otoscopic examination, raccoon eyes indicating orbital ecchymosis, cerebrospinal fluid leakage from ear (otorrhea) or nose (rhinorrhea), Battle's sign indicating mastoid ecchymosis, presence of visible depressed or palpable skull fracture, and neurological clinical features including post-traumatic seizures, altered level of consciousness, or focal neurological deficits.

Glasgow Coma Scale Assessment

The Glasgow Coma Scale, a widely accepted objective measurement of neurological status following head injury, was systematically assessed in all study participants. The GCS comprises three components: eye opening response (scored 1-4), verbal response (scored 1-5), and motor response (scored 1-6). Total GCS scores range from 3 to 15, with scores of 13-15 defining the minor head injury category. Serial GCS measurements were obtained in the emergency department to identify any deterioration in neurological status during the observation period.

STATISTICAL ANALYSIS

Data were entered and analyzed using Microsoft Excel and SPSS (Statistical Package for Social Sciences) version 25.0. Categorical variables including demographics, CCHR components, and imaging findings, were expressed as frequency distributions and percentages. Quantitative variables, including age were expressed as mean and standard deviation. Statistical tests employed included the chi-square test with appropriate contingency table analysis to assess associations between categorical variables. To evaluate the diagnostic accuracy of CCHR, the following metrics were calculated, sensitivity (true positive rate among patients with positive CT findings), specificity (true negative rate among patients without CT findings), positive predictive value (probability of positive CT findings given positive CCHR criteria), negative predictive value (probability of negative CT findings given negative CCHR criteria), positive likelihood ratio (sensitivity divided by 1-specificity), negative likelihood ratio ((1-sensitivity) divided by specificity), and overall diagnostic accuracy (proportion of correct predictions among all study participants). For all statistical tests and comparisons, a two-tailed alpha level of 0.05 was established as the threshold for statistical significance. Confidence intervals at 95% level were calculated for key diagnostic performance metrics.

RESULT

Demographic Characteristics

The study enrolled 203 consecutive adult patients with minor head injury during the 18-month study period. The mean age of study participants was 49.5 ± 20.6 years, with age range spanning from 16 to 85 years. Age distribution analysis demonstrated the following: 45 patients (22.2%) were aged 16-30 years, 78 patients (38.4%) were aged 31-50 years, 56 patients (27.6%) were aged 51-65 years, and 24 patients (11.8%) were aged over 65 years. Gender distribution demonstrated male predominance with 142 patients (70%) being male and 61 patients (30%) being female as shown in Table 1.

Table 1: Demographic Characteristics of Study Population

Variable	Category	Number	Percentage
Age (years)	16-30	45	22.2
	31-50	78	38.4
	51-65	56	27.6
	>65	24	11.8
	Mean ± SD	49.5 ± 20.6	—
Gender	Male	142	70.0
	Female	61	30.0
Total		203	100.0

Mechanism of Injury

Analysis of injury mechanisms demonstrated that road traffic accidents were the predominant cause of minor head injury, occurring in 112 patients (55.2% of study population). Falls from height were documented in 52 patients (25.6%), assaults or interpersonal violence accounted for 25 cases (12.3%), and falls on the same level occurred in 14 patients (6.9%). The predominance of road traffic accidents reflects the epidemiological pattern of head injury in the Indian healthcare setting, where motor vehicle collisions represent a major public health problem as shown in Table 2.

Table 2: Mechanism of Injury Distribution

Mechanism	Number	Percentage
Road Traffic Accident	112	55.2
Fall from height	52	25.6
Assault	25	12.3
Fall on same level	14	6.9
Total	203	100.0

Glasgow Coma Scale Distribution

Analysis of Glasgow Coma Scale scores at emergency department presentation demonstrated that the majority of study participants (145 patients, 71.4%) presented with a GCS score of 15, indicating intact consciousness with no documented loss of consciousness or post-traumatic amnesia. Forty patients (19.7%) presented with GCS score of 14, indicating mild alteration in consciousness. Eighteen patients (8.9%) presented with GCS score of 13, representing the lower end of the minor head injury spectrum. No patients with GCS scores below 13 were included in the study cohort, consistent with the defined inclusion criteria as shown in Table 3.

Table 3: Glasgow Coma Scale Distribution

GCS Score	Number	Percentage
15	145	71.4
14	40	19.7
13	18	8.9
Total	203	100.0

CCHR Components Distribution

Systematic assessment of Canadian CT Head Rule components revealed varying prevalence of individual criteria across the study population. Neurological clinical features were the most commonly observed CCHR component, documented in 80 patients (39.4%), encompassing post-traumatic seizures, altered consciousness, and focal neurological deficits. Ear/nose/throat bleed suggestive of basilar skull involvement or temporal bone fracture was present in 59 patients (29.1%). Dangerous mechanism of injury was documented in 58 patients (28.6%). Raccoon eyes indicating periorbital ecchymosis were observed in 30 patients (14.8%). Vomiting with two or more episodes was reported in 30 patients (14.8%). History of retrograde amnesia exceeding 30 minutes was documented in 22 patients (10.8%). Hemotympanum on otoscopic examination was identified in 9 patients (4.4%). Depressed or palpable skull fracture was identified in 3 patients (1.5%). Cerebrospinal fluid leakage from ear or nose was documented in 2 patients (1.0%). Battle's sign was observed in only 1 patient (0.5%). (Table 4)

Table 4: Prevalence of CCHR Components in Study Sample

CCHR Component	Number	Percentage
Neurological clinical features	80	39.4
ENT bleed	59	29.1
Dangerous mechanism of injury	58	28.6
Raccoon eyes	30	14.8
Vomiting ≥2 episodes	30	14.8

Retrograde amnesia	22	10.8
Hemotympanum	9	4.4
Depressed skull fracture	3	1.5
CSF leakage	2	1.0
Battle's sign	1	0.5

Computed Tomography Findings

Among the total study population of 203 patients, 116 patients (57.1%) demonstrated positive CT findings consistent with traumatic intracranial or skull pathology, while 87 patients (42.9%) demonstrated negative CT findings without evidence of acute traumatic pathology. Among the 116 patients with positive CT findings, calvaria (skull) fractures were the most prevalent finding, occurring in 98 patients (84.5% of positive CT scans). Epidural hematoma (blood between dura and skull) was documented in 8 patients (6.9%). Acute subdural hematoma (blood beneath the dura mater) was identified in 5 patients (4.3%). Subarachnoid haemorrhage (blood within the subarachnoid space) was documented in 3 patients (2.6%). Cerebral contusion (brain parenchymal injury) was identified in 2 patients (1.7%). (Table 5)

Table 5: Computed Tomography Findings

CT Finding	**Number**	**Percentage**
Positive CT findings	116	57.1
Negative CT findings	87	42.9
Total	203	100.0
Among 116 positive CT findings		
Specific Finding	**Number**	**Percentage**
Calvaria fractures	98	84.5
Epidural hematoma	8	6.9
Subdural hematoma	5	4.3
Subarachnoid haemorrhage	3	2.6
Cerebral contusion	2	1.7

Neurosurgical Interventions

Among the 116 patients with positive CT findings, neurosurgical intervention was required in 10 patients (8.6%). Hematoma evacuation, representing the most common operative procedure, was performed in 6 patients (75% of those requiring intervention). Surgical elevation of depressed cranial bone fractures was performed in 3 patients (37.5% of those requiring intervention). Placement of external ventricular drainage (EVD) for management of haemorrhagic complications or intracranial hypertension was performed in 1 patient (12.5% of those requiring intervention). The remaining 106 patients (91.4%) with positive CT findings were managed conservatively with observation and serial clinical examination without requirement for operative intervention. (Table 6)

Table 6: Neurosurgical Intervention Requirements in Patients with Positive CT

Intervention	**Number**	**Percentage of Positive CT (n=116)**
Hematoma evacuation	6	75.0
Depressed fracture elevation	3	37.5
External ventricular drainage	1	12.5
No intervention	106	91.4

CCHR Diagnostic Accuracy Metrics

The primary analysis examined the diagnostic accuracy of the Canadian CT Head Rule in predicting positive CT findings. CCHR demonstrated a sensitivity of 68.1% (95% confidence interval 61.2%-

75.0%) for identifying patients with positive CT findings. Specificity was 42.5%, indicating the proportion of patients without CT findings correctly identified by the rule. Positive predictive value was 61.2%, representing the probability that a patient meeting high-risk CCHR criteria actually has positive CT findings. Negative predictive value was 50.0%, representing the probability that a patient not meeting CCHR criteria actually has negative CT findings. The false negative rate (proportion of positive CT cases missed by CCHR criteria) was 31.9%. The false positive rate (proportion of negative CT cases incorrectly flagged by CCHR criteria) was 57.5%. The positive likelihood ratio was 1.18, indicating modest increase in probability of positive CT with positive CCHR criteria. The negative likelihood ratio was 0.75, indicating modest decrease in probability of positive CT with negative CCHR criteria. Overall diagnostic accuracy (proportion of correct predictions) was 57.1%. (Table 7) and the ROC curve for CCHR diagnostic performance (Figure 1) demonstrates an Area under the curve (AUC) of 0.60 (95% CI: 0.53-0.67), indicating fair discriminatory ability for predicting positive CT findings.

Table 7: Diagnostic Accuracy of CCHR for Positive CT Findings

Diagnostic Parameter	Value
Sensitivity	68.1%
Specificity	42.5%
Positive Predictive Value (PPV)	61.2%
Negative Predictive Value (NPV)	50.0%
False Negative Rate	31.9%
False Positive Rate	57.5%
Positive Likelihood Ratio	1.18
Negative Likelihood Ratio	0.75
Diagnostic Accuracy	57.1%
95% Confidence Interval for Sensitivity	61.2%-75.0%

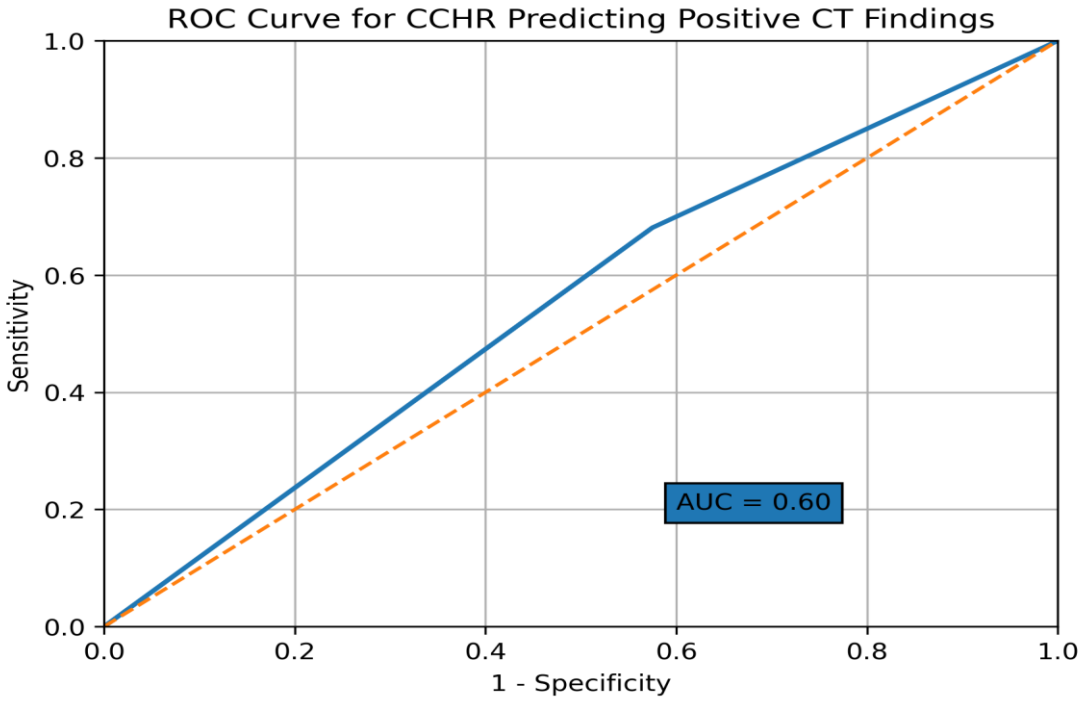

Figure 1: ROC curve analysis of Canadian CT Head Rule (CCHR) for predicting positive CT findings in minor head injury patients (n=203). The operating point shows sensitivity=68.1% at 1-specificity=57.5% (specificity=42.5%). Area under the curve (AUC)=0.60 (95% CI: 0.53-0.67). Diagonal line represents chance performance (AUC=0.50).

Statistical Association of Clinical Variables with CT Findings

Chi-square analysis was performed to identify clinical variables demonstrating statistically significant association with positive CT findings. Retrograde amnesia exceeding 30 minutes was present in 18 of 22 patients with this finding (81.8%) who had positive CT findings, while only 4 of 22 (18.2%) with retrograde amnesia had negative CT findings, representing a highly significant association ($p<0.01$). Ear/nose/throat bleed was documented in 44 of 59 patients (74.6%) with this finding who demonstrated positive CT, compared to 15 of 59 (25.4%) with negative CT, also representing highly significant association ($p<0.01$). Hemotympanum was present in 8 of 9 patients (88.9%) with positive CT and 1 of 9 (11.1%) with negative CT ($p=0.008$). Neurological clinical features were identified in 72 of 80 patients (90.0%) with positive CT and 8 of 80 (10.0%) with negative CT ($p<0.01$). Lower Glasgow Coma Scale score (GCS 13) was associated with higher likelihood of positive CT findings, with 13 of 18 patients with GCS 13 (72.2%) having positive CT compared to 5 of 18 (27.8%) with negative CT ($p=0.032$). (Table 8)

Table 8: Statistical Analysis of CT Findings with CCHR Components

Variable	Positive CT	Negative CT	p-value	Significance
Retrograde amnesia	18/22 (81.8%)	4/22 (18.2%)	<0.01	Highly significant
ENT bleed	44/59 (74.6%)	15/59 (25.4%)	<0.01	Highly significant
Hemotympanum	8/9 (88.9%)	1/9 (11.1%)	0.008	Significant
Neurological features	72/80 (90.0%)	8/80 (10.0%)	<0.01	Highly significant
GCS 13 vs 14-15	13/18 (72.2%)	5/18 (27.8%)	0.032	Significant

Neurological Features and Predictive Values

Among patients presenting with neurological clinical features (encompassing post-traumatic seizures, pupillary abnormalities, altered consciousness, and focal neurological deficits), specific findings demonstrated remarkably high predictive value for positive CT findings. Post-traumatic seizures, documented in 6 patients, were associated with positive CT findings in all 6 patients (100% sensitivity). Pupillary abnormalities, including fixed and dilated pupils or other abnormalities, documented in 4 patients, were similarly associated with positive CT findings in all 4 patients (100% sensitivity). Depressed or palpable skull fracture, present in 3 patients, demonstrated positive CT findings in all 3 patients (100% correlation). Battle's sign, present in 1 patient, was associated with positive CT findings in that single patient (100% correlation).

DISCUSSION

Study Overview and Key Findings

This prospective hospital based observational study systematically evaluated the diagnostic accuracy and clinical utility of the Canadian CT Head Rule in 203 consecutive adult patients presenting with minor head injury to the emergency department of Krishna Institute of Medical Sciences, a tertiary-level teaching hospital. The fundamental findings of this investigation demonstrated that CCHR achieved a sensitivity of 68.1% and specificity of 42.5% in predicting positive CT findings in this Indian cohort, values that demonstrate reasonable concordance with previously published international validation studies[8,9,18] while simultaneously highlighting important considerations specific to the Indian patient population and healthcare context.

Comparison with International Literature

The diagnostic performance characteristics observed in this study warrant comparison with published findings from validation studies conducted in diverse geographic regions and healthcare settings. The original derivation study by Stiell and colleagues in 2001, conducted across emergency departments in ten large Canadian hospitals,

reported sensitivity of 100% and specificity of 76.3% for predicting need for neurosurgical intervention[2,14]. However, subsequent validation studies have yielded more variable findings. A prospective multicentre cohort study[9] conducted in the Netherlands between 2002 and 2004 by Smits and colleagues, evaluating 3,181 consecutive adult patients with minor head injury, demonstrated 100% sensitivity for neurosurgical intervention identification, with 52% specificity for clinically important brain injury. Validation in the Chinese population by Yang and colleagues (2016) involving 625 patients demonstrated 100% sensitivity but lower specificity of 43.36%. An Iranian study by Sadegh and colleagues (2013-2014) involving 500 patients with medium and high-risk minor head injury confirmed CCHR utility in that population, documenting coverage of 7 of 8 CCHR criteria. A study from the United States by Sharp and colleagues (2014-2015) involving 44,947 head injury patients reported a 5.3% absolute reduction in CT utilization postintervention with implementation of CCHR, coupled with modest improvement in diagnostic yield of positive CT scans. The findings from a prior Indian study by Arab and colleagues (2010-2011) involving 368 patients reported CCHR sensitivity of 66.7% and specificity of 63.31%, with study conclusion that CCHR represents a useful clinical tool for minor head injury diagnosis and reduction of unnecessary CT scanning. The current study's findings (68.1% sensitivity, 42.5% specificity) demonstrate strong concordance with the prior Indian study by Arab and colleagues (66.7% sensitivity and 63.31% specificity), suggesting regional consistency in CCHR performance when applied to Indian populations[20].

Explanation of Moderate Specificity

The moderate specificity observed in this Indian cohort merits careful clinical consideration and discussion[6]. Several factors may contribute to the less-than-optimal specificity in the current study cohort[6,10]. First, the consecutive enrolment methodology may have resulted in case selection bias, potentially enriching the study sample with relatively higher-risk patients compared to purely population-based epidemiological studies, thereby increasing the baseline prevalence of positive CT findings[13]. Second, the epidemiological profile of head injury in India differs significantly from the original CCHR derivation population, with road traffic accidents predominating (55.2% in this cohort) compared to the more diverse injury mechanisms in the original Canadian cohort[6]. Road traffic accidents may carry inherently higher intracranial injury risk compared to other injury mechanisms. Third, clinical uncertainty in resource-variable healthcare settings may predispose to increased reliance on CT imaging as a diagnostic and reassurance tool, thereby potentially increasing the proportion of positive findings in the imaged population[10]. Fourth, patients with polytrauma or injuries affecting multiple body regions may have elevated baseline rates of intracranial injury despite meeting criteria for minor head injury based on GCS assessment[13].

Clinical Significance of Individual CCHR Components

The prospective assessment of individual Canadian CT Head Rule components in this study identified specific findings demonstrating particularly high clinical predictive value for positive CT findings[1]. Neurological clinical features, encompassing post-traumatic seizures, pupillary abnormalities, altered consciousness, and focal neurological deficits, were present in 80 patients (39.4% of cohort) and demonstrated remarkable predictive value, 90% of patients with neurological features had positive CT findings ($p<0.01$)[8,12]. Furthermore, specific neurological manifestations demonstrated near-perfect discrimination: post-traumatic seizures were 100% sensitive for positive CT findings (6/6 patients with seizures had positive CT), as were pupillary

abnormalities (4/4 patients with pupillary changes had positive CT)[8,12,16]. These findings strongly suggest that neurological features warrant mandatory CT imaging regardless of other CCHR criteria, as such features constitute robust markers of intracranial pathology.

Retrograde amnesia exceeding 30 minutes demonstrated a highly significant association with positive CT findings, present in 81.8% of patients with this finding who had positive CT ($p<0.01$). Ear/nose/throat bleed, potentially indicating temporal bone involvement or basilar skull fracture, was documented in 74.6% of patients with this finding who demonstrated positive CT ($p<0.01$). Hemotympanum on otoscopic examination, indicating middle ear involvement, demonstrated strong association with positive CT findings, present in 88.9% of patients with this finding and positive CT ($p=0.008$). These findings suggest that specific physical examination abnormalities carry high diagnostic significance and warrant consideration in clinical decision-making beyond rigid application of a single decision rule[1].

Glasgow Coma Scale and Injury Severity

The relationship between Glasgow Coma Scale score and likelihood of positive CT findings was clearly evident in this study cohort. Patients presenting with GCS score of 13 (the lower end of minor head injury spectrum) demonstrated substantially higher rates of positive CT findings (72.2%) compared to patients with GCS scores of 14-15 (27.8%), with this difference reaching statistical significance ($p=0.032$)[9,17]. This finding is consistent with prior literature demonstrating that lower GCS scores within the minor head injury range (13-15) are associated with increased risk of intracranial injury and worse outcomes[13]. The Glasgow Coma Scale thus remains a fundamental component of initial head injury assessment and risk stratification, validating its incorporation into clinical decision-making algorithms and emphasizing the importance of serial GCS measurements in the emergency department setting[13].

Neurosurgical Intervention Requirements

The rate of neurosurgical intervention requiring operative management in this study (8.6% of patients with positive CT findings, 10 total patients) aligns well with literature estimates typically ranging from 1-2% of all minor head injury patients[14,21]. The predominance of calvaria fractures (84.5% of positive CT findings) among imaging findings reflects the high frequency of relatively uncomplicated fractures that, while radiographically evident, do not require operative management[18]. This distinction proves clinically important for resource allocation and patient counselling, as the majority of positive CT findings represent fractures or isolated blood collections managed conservatively rather than requiring urgent neurosurgical intervention[18]. The 8.6% rate of surgery requirement suggests that CCHR's goal of selective imaging appears reasonable, as the majority of minor head injury patients can be managed conservatively based on clinical assessment and selective imaging[20].

Clinical Utility in Resource-Constrained Settings

Several factors strongly support implementation of the Canadian CT Head Rule in Indian emergency departments and resource-constrained healthcare settings[6]. First, selective imaging based on CCHR criteria provides significant opportunities for resource optimization, as CT scan costs typically range from 2,000-5,000 rupees per examination in Indian hospitals, representing meaningful financial burden for individual patients and contributing substantially to institutional imaging costs[20]. Implementation of CCHR criteria enables reduction in unnecessary imaging while maintaining diagnostic yield for clinically important injuries[10]. Second, minimization of unnecessary head CT scans yields important health benefits through reduction of cumulative radiation exposure,

particularly crucial in younger populations where long-term cancer risks must be weighed against immediate diagnostic benefits[16]. Third, CCHR represents a scalable decision tool that requires only bedside clinical examination skills and simple physical assessment manoeuvres, making it applicable across varied healthcare settings ranging from tertiary care centres to peripheral hospitals without requiring advanced technological infrastructure. Fourth, this study and prior Indian research provide region-specific validation evidence, increasing clinician confidence and acceptance of CCHR applicability to Indian populations with similar epidemiological profiles[6]. Fifth, implementation of standardized, evidence-based clinical decision rules facilitates more consistent and equitable clinical practice patterns, reducing unexplained variation in imaging utilization and promoting more rational healthcare resource allocation.

Study Limitations

Several important limitations require discussion. First, the single centre study design conducted at one tertiary-level teaching institution limits generalizability to all Indian healthcare settings, particularly non-teaching hospitals or smaller peripheral healthcare facilities that may have different patient demographics, available imaging capabilities, and institutional practices. Second, the exclusion of patients below 16 years of age limits applicability to paediatric populations, who may have distinctly different injury mechanisms, injury patterns, and clinical course compared to adults. Third, systematic exclusion of patients on anticoagulant medications or with pre-existing bleeding disorders represents a significant limitation, as these comprise an increasingly prevalent population with substantially higher intracranial injury risk that merits specific investigation. Fourth, the institutional setting as a teaching hospital with on-site neurosurgery facilities may establish different clinical thresholds for CT imaging compared to community hospitals without immediate neurosurgical availability, potentially affecting the generalizability of findings. Fifth, while the 203-patient cohort achieved adequate statistical power for the primary study objective, this sample size limits robust performance of detailed subgroup analyses. Sixth, the study does not comprehensively document long-term follow-up outcomes for all discharged patients, limiting assessment of potential missed injuries or delayed clinical deterioration.

Strengths of the Study

This investigation possessed several important methodological strengths. The prospective study design, as opposed to retrospective methodology, minimizes recall bias and allows systematic, contemporaneous data collection. The consecutive enrolment of all eligible patients presenting during the study period substantially reduces selection bias compared to convenience sampling methods. The systematic and comprehensive assessment of all CCHR components in every study participant ensures data completeness and minimizes missing data. The rigorous statistical methodology incorporating calculation of not only sensitivity and specificity but also predictive values, likelihood ratios, and confidence intervals provides comprehensive assessment of diagnostic test performance. The clinical relevance of the study addresses a specific gap in medical literature regarding CCHR efficacy in Indian populations, providing actionable evidence for emergency medicine practice in the Indian context.

Clinical Practice Recommendations

Based on the findings of this investigation and integration with broader medical literature, the following evidence-based recommendations are offered for clinical practice. First, systematic implementation of the Canadian CT Head Rule is recommended in emergency departments caring for adult patients with minor head

injury, as CCHR provides a structured, evidence-based approach to standardize imaging decisions and reduce unjustified variation in CT utilization practices. Second, regardless of CCHR risk categorization, patients presenting with specific neurological features, particularly post-traumatic seizures, pupillary abnormalities, or significant alteration in consciousness, should undergo CT imaging, as these features demonstrated near-perfect discrimination for intracranial pathology in this study. Third, patients meeting CCHR medium-risk criteria should undergo CT imaging, as this study demonstrated moderate sensitivity (68.1%) for identifying positive CT findings, suggesting that the majority of clinically significant injuries are identified by CCHR criteria. Fourth, clinical decision-making should not rely exclusively on rigid application of CCHR but rather should integrate additional contextual factors including mechanism of injury severity, patient age, premorbid medical conditions, anticoagulation status, and institutional resources when making imaging decisions in borderline cases. Fifth, even in patients categorized as CCHR "low-risk," serial clinical neurological examinations should be performed during observation periods, as emergent deterioration in neurological status warrants urgent CT imaging regardless of initial risk classification. Sixth, prospective multi-institutional validation studies spanning diverse healthcare settings (teaching hospitals, non-teaching community hospitals, peripheral health centres) across different geographic regions of India are warranted to establish population-specific validation of CCHR and facilitate guideline development specific to emergency medicine practice in India.

CONCLUSION

This prospective hospital-based study conducted over an 18-month period evaluated the diagnostic accuracy and clinical utility of the Canadian CT Head Rule in predicting intracranial injuries among 203 consecutive adults presenting with minor head injury to the emergency department. The investigation demonstrated that CCHR achieved sensitivity of 68.1% and specificity of 42.5% for predicting positive CT findings in this Indian cohort, findings that demonstrate reasonable concordance with international validation studies while simultaneously highlighting important considerations specific to the Indian healthcare and epidemiological context.

The Canadian CT Head Rule provides a clinically practical and systematic tool for risk stratification of minor head injury patients, facilitating reduction of unnecessary CT imaging while maintaining adequate diagnostic sensitivity for identifying clinically important intracranial injuries requiring intervention or close observation. Specific CCHR components, particularly neurological features, retrograde amnesia, ear/nose/throat bleed, and hemotympanum, demonstrated strong statistical associations with positive CT findings and should guide clinical decision-making and imaging decisions. Lower Glasgow Coma Scale scores within the minor head injury spectrum were associated with increased intracranial injury risk and more frequent positive CT findings, validating GCS assessment as a fundamental component of head injury evaluation and risk stratification.

Implementation of the Canadian CT Head Rule in Indian emergency departments offers substantial clinical and healthcare system benefits. These benefits include optimization of precious and costly imaging resources in the context of resource-constrained healthcare systems, reduction of patient out-of-pocket costs for imaging services, minimization of unnecessary radiation exposure particularly crucial in younger populations, and provision of a standardized, evidence-based approach to minor head injury evaluation that reduces unexplained variation in clinical practice patterns. Such implementation would represent an important advance toward more

rational and equitable healthcare resource allocation in the Indian healthcare setting.

However, clinical judgment and individualised patient assessment remain paramount and cannot be replaced by rigid adherence to any single decision rule. Clinical contextual factors including severity and mechanism of injury, patient age, premorbid medical conditions, anticoagulation status, and institutional resources should be integrated with CCHR assessment in decision-making, particularly in borderline or equivocal clinical scenarios. Future prospective, multi-institutional studies across diverse Indian healthcare settings, spanning tertiary teaching centres, non-teaching community hospitals, and peripheral health facilities, are strongly warranted to establish population-specific validation of CCHR and facilitate development of region-specific clinical practice guidelines for emergency medicine in India. The findings of this study affirm that the Canadian CT Head Rule can serve as a valuable and reliable clinical tool for selective CT imaging in minor head injury, achieving the critical balance between maintaining diagnostic sensitivity for identifying patients requiring neurosurgical intervention while simultaneously minimizing unnecessary investigations and healthcare costs, particularly important in optimising emergency trauma care within resource-limited and economically constrained Indian healthcare systems.

Declaration by Authors

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