# Sensitivity, Specificity, Predictive Values and Accuracy of Clinical Diagnosis of Acute Stroke

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#### Introduction:

Stroke is defined as rapidly developing clinical signs of focal (at times global) disturbance of

### Abstract

### Background:

Stroke is a leading cause of death and disability globally and particularly in low and middle-income countries, and the burden is increasing. To prevent complications and permanent defects in stroke, early diagnosis is the key that can easily obtained by a CT scan of brain. However, quick access to CT scanning is not available in every country and hospital specially in Bangladesh, various clinical findings especially neurological signs and symptoms and risk factors differentiation are helpful in differentiating the types of stroke.

#### **Objective:**

This study aimed to see the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis in the detection of stroke subtype.

#### **Methods:**

This hospital based cross-sectional comparative study was conducted in Department of Medicine, Rangpur medical college hospital, Rangpur, Bangladesh from January 2010 to December 2011 on three hundred (300) suspected acute stroke patients selected by purposive sampling technique. The clinical diagnosis of type of stroke was made on the basis of mode of presentation, risk factors and signs and confirmed by CT scan of brain within 1 week of attack. Then the clinical diagnosis was compared with the results of CT scan. Statistical analyses related with this study were performed by using of SPSS-19 package program. **Results:** 

Among the 300 patients, 73(24.3%) patients were clinically diagnosed as hemorrhagic stroke and 227(75.6%) patients were as infarctive stroke. Out of 73 clinically diagnosed haemorrhagic stroke patients, CT scan revealed that 61 (83.6%) patients had intracerebral hemorrhage, 5 (6.8%) had infarct. And out of 133 diagnosed ischemic stroke patients, CT scan revealed that 203 (89.4%) patients had infarction, 6 (2.6%) had intracerebral hemorrhage. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of hemorrhagic stroke were 91.0%, 94.8%, 83.6%, 97.4% and 94.0% respectively. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of infarctive stroke were 97.6%, 73.9%, 89.4%, 92.2% and 90.3% respectively. **Conclusion:** 

CT scan of brain remains the gold standard for differential diagnosis, but the availability of CT scan is not always feasible, and it is virtually impossible to submit all stroke patients to CT scan. Adequate knowledge on risk factors, clinical features and initial investigations may contribute to such a differentiation of cerebral infarction from intracerebral hemorrhage with high accuracy where rapid access to Computed Tomography (CT) is lacking.

**Keywords:** Stroke; clinical diagnosis; sensitivity; specificity; positive predictive value; negative predictive value; accuracy

cerebral function lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin.<sup>1</sup> Ischemic and hemorrhagic stroke are the two types of brain stroke. Ischemic stroke comprises 80 of CVAs is due to occlusion and blockage of brain vessels. Hemorrhagic stroke, accounts for 20%, is due to blood vessel rupture.<sup>1,2</sup> Stroke is a leading cause of death and disability globally particularly in low and middle-income countries, and this burden is increasing. According to the latest Global Burden of Disease (GBD) estimates of stroke burden in 195 countries, there were 11.9 million incident (95% UL 11.1 - 12.8), 104.2 million prevalent (98.6-110.2), 6.2 million fatal (6.0-6.3) cases of stroke and 132.1 million stroke-related DALYs (126.5 - 137.4).Although stroke incidence. prevalence, mortality and DALY rates declined from 1990 to 2017, the absolute number of people who developed a new stroke, died, survived or remained disabled from stroke has almost doubled. The bulk of stroke burden (80% all incident strokes, 77% all stroke survivors, 87% of all deaths from stroke and 89 of all stroke-related DALYs) in 2017 was in low- to middle-income countries.<sup>3</sup> In the United States, more than 795,000 people have a stroke every year, of them about 610,000 are first or new strokes.<sup>4</sup> During the year of 2020, 1 in 6 deaths from cardiovascular disease was due to stroke<sup>5</sup>, every 40 seconds, someone had a stroke and every 3.5 minutes, someone died of stroke.<sup>4</sup> In Bangladesh during 2016 the number of stroke patient and death due to stroke were 161,709 and 126,369 respectively.<sup>6</sup> To prevent complications and permanent defects in stroke, early distinguishing the type of stroke (Ischemic or haemorrhagic) and exclusion of stroke mimics. is the key. In most developed countries, diagnosis is easily obtained by CT scan of brain, which allows the accurate distinction of hemorrhagic and ischemic types.<sup>6</sup> However, quick access to CT scanning is not available in every country and hospital, specially in Bangladesh, which may lead to loss of golden time for treatment. Simple clinical findings are helpful in differentiating the type of stroke, but the need for CT scan is an undeniable fact. According to this issue, many studies described various clinical findings especially neurological signs and symptoms and risk factors differentiation, and some of them presented formulas to distinguish stroke types based on clinical evaluations.7-11

Knowledge on the relative role of risk factors in hemorrhagic versus ischemic strokes is still

inconsistent. In a study based on 39 484 patients, factors favoring ischemic strokes as opposed to hemorrhagic strokes were diabetes, atrial fibrillation. previous mvocardial infarction. previous stroke, and intermittent arterial claudication. High alcohol intake and smoking favored hemorrhagic strokes as opposed to ischemic strokes, whereas age, sex, and hypertension favored neither type of stroke.<sup>12</sup> In a previous study on 469 patients with acute stroke, factors favoring ischemic stroke as opposed to hemorrhagic were diabetes, atrial fibrillation, history of previous stroke and increasing age. And hypertension and family history of hypertension favored hemorrhagic stroke as opposed to ischemic stroke.<sup>13</sup>

In Perth study<sup>14</sup> (n=536), hypertension and diabetes favored ischemic stroke and high alcohol intake favored hemorrhagic stroke, whereas smoking did not favor either of the stroke subtypes. Another population-based observational study<sup>15</sup> (n=1254) showed increasing age, previous stroke, and diabetes favored ischemic stroke, whereas ischemic heart disease, atrial fibrillation, hypertension, alcohol intake, and smoking did not favor either of the stroke subtypes. In the hospital-based Copenhagen Stroke Study<sup>16</sup> (n=1000) diabetes and ischemic heart disease favored ischemic stroke. whereas age, hypertension, alcohol consumption, atrial fibrillation, and smoking were not predictors of stroke type. In the hospital-based Lausanne Stroke (n=3901) registry<sup>17</sup> smoking, hypercholesterolemia, migraine, previous transient ischemic attack, atrial fibrillation, and heart disease favored ischemic stroke, whereas hypertension was the only significant factor related to hemorrhagic stroke vs ischemic stroke. However, recent studies showed that the gradient of the relationship between hypertension and hemorrhagic stroke is steeper than that for ischemic stroke.18,19

A previous study showed eight variables associated with ICH: acute onset of deficit, headache, vomiting, neck stiffness, decreased level of consciousness, neurological deterioration within 3 hours from admission, fibrinogen >500 mg dL-1, WBC >12000 mL-1.<sup>8</sup>

Mortality and morbidity can be minimized be early detection of stroke type and prompt initiation of specific treatment like antiplatelet drug, thrombolysis, anticoagulation, carotid endarterectomy etc in ischemic stroke. Although CT of brain remains the gold standard for differential diagnosis, availability of this important diagnostic tool is not always feasible, and it is virtually impossible to submit all stroke patients to CT scan, a weighted clinical score or adequate knowledge of risk factors, clinical features and initial investigations may contribute to such a differentiation of cerebral infarction from intracerebral hemorrhage 7,8,20-21 in order to aid clinicians to decide about starting antiplatelet therapy in settings where rapid access to Computed Tomography (CT) is lacking.<sup>8</sup>

An analysis of, 40000 randomized patients from the Chinese Acute Stroke Trial (CAST) and the International Stroke Trial (IST) had demonstrated that early use of aspirin within 48 hours of onset of stroke among the 9000 patients (22%) randomized without a prior CT scan appeared to be of net benefit with no unusual excess of hemorrhagic stroke. Moreover, even among the 800 subjects (2%) whose presenting event was subsequently discovered to have been a hemorrhagic stroke, there was no evidence of detrimental effect of aspirin (OR 0.86 for further stroke or death, 63 aspirin versus 67 control). Both the CAST and IST trials revealed that the incidence of hemorrhagic stroke or hemorrhagic transformation was low during the first day from the event, whereas that of recurrent ischemic stroke was relatively high, early aspirin use is justifiable when ischemic stroke is suspected and rapid CT scanning is lacking.<sup>22</sup> A follow-up study of 738 European stroke patients<sup>23</sup> showed that the 2-year excess risk of fatal and nonfatal vascular events caused by omitting CT scan and giving aspirin to all patients was rather small (0.6%), whilst the corresponding risk caused by not giving aspirin to a patient with cerebral infraction was much higher (4.1%). Our study aimed to see the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of stroke subtype.

### Methods:

This hospital based cross-sectional comparative study was conducted in Department of Medicine, Rangpur medical college hospital, Rangpur, Bangladesh from January 2010 to December 2011. Three hundred (300) suspected acute stroke patients were selected by purposive sampling technique diagnosed by history, clinical findings and confirmed by CT scan of brain within 1 week of attack. Patients with no definitive CT scan results or those suspected to have transient ischemic attacks and stroke associated with hematological conditions like leukemia. polycythaemia were excluded from the study. For each patient, demographic data (age and sex), type of stroke, risk factors, clinical and initial laboratory variables were recorded. Emphasis was given on risk factors especially hypertension, diabetes mellitus, ischemic heart disease, valvular Heart Disease, atrial fibrillation, peripheral vascular disease, smoking, alcohol, obesity, advanced age (>80 years), previous stroke and family history of stroke, hypertension, diabetes mellitus and coronary artery disease. Every patient and/or responsible attendant were asked for informed consent about the procedure and the study goal. Ethical clearance is taken from ethical committee of RpMC. The clinical diagnosis of type of stroke was made on the basis of mode of presentation, risk factors and signs. Those patients who presented with sudden onset of coma, rapid deterioration of neurological state, severe headache, vomiting, convulsion and neck stiffness along with hypertension were considered to be suffering from hemorrhagic stroke. On the other hand, those who presented with sudden onset of lateralizing signs or gradual deterioration of consciousness, deficit after awakening especially in the presence of diabetes mellitus, atrial fibrillation, rheumatic heart disease, recent myocardial infarction and carotid bruit were considered to be suffering from ischemic stroke. All patients were investigated with routine investigations such as TC, DC, ESR, Hb%, total platelet count, urine examination, RBS (on admission blood sugar level), FBS and 2HABF, fasting lipid profile, serum electrolytes, serum creatinine, ECG. CT scan of brain was done to confirm the diagnosis. Then the clinical diagnosis was compared with the results of CT scan and precision of clinical diagnosis was ascertained. Statistical analyses related with this study were performed by using of SPSS 19 package program. Test of performance were done to detect the sensitivity, specificity, positive predictive value, negative predictive value and accuracy.

#### **Results:**

Table-I showed the mean  $(\pm SD)$  age of the patients with hemorrhagic and ischemic stroke was respectively 60.67±9.34 and 67.06±11.56 years and the difference of mean age between two groups were not statistically significant (p>0.05).Male were predominant in both groups.

Table-I: Demographic status of the patient (n=300)

Demographic status	Haemorrhagic (n=73, 24.3%)	Infarctive (n=227, 75.6%)			
Age of the patients in years					
(Mean±SD)	60.67±9.34	67.06±11.56			
Sex of the patients [Frequency (%)]					
Male	42 (57.5)	112 (49.3)			
Female	31 (42.5)	115 (50.7)			

Among the 300 patients 73(24.3%) patients were clinically diagnosed as hemorrhagic stroke and 227(75.6%) patients were as infarctive stroke. Out of 73 clinically diagnosed haemorrhagic stroke patients CT scan revealed that 61 (83.6%)patients had intracerebral hemorrhage, 5 (6.8%) had infarct, 6 (8.2%)had subarachnoid hemorrhage and 1 (1.4%)had space occupying lesions in the brain. And out of 133 diagnosed ischemic stroke patients, CT scan revealed that 203 (89.4%) patients had infarction, 6 (2.6%) had intracerebral hemorrhage and 18 (7.9%) had space occupying lesions in the brain (Table-II).

## Table-II: Clinical types of strokes and diagnosis by CT Scan

		Clinical diagnosis of Stroke type		Total
		Haemorrhagic	Infarctive	
CT Scan Diagn osis	Haemorrhagic	61(83.6%)	6(2.6%)	67(22.3%)
	Infarctive	5(6.8%)	203(89.4%)	208(69.3%)
	SAH	6(8.2%)	0(0.0%)	6(2.0%)
	SOL	1(1.4%)	18(7.9%)	19(6.3%)
Total		73(100%)	227(100%)	300(100%)

Table-III showed that the sensitivity, specificity, positive predictive value, negative predictive value

and accuracy of clinical diagnosis of hemorrhagic stroke were 91.0%, 94.8%, 83.6%, 97.4% and 94.0% respectively.

# Table-III: Performance of clinical diagnosis indiagnosing hemorrhagic stroke

		CT Scan		
		Haemorrhagic	Other than Haemorrhagic	<b>Total</b>
Clinical diagnosis	Haemorrhagic	61	12	73
	Other than haemorrhagic	6	221	227
Total		67	233	300
Sensitivity		=(61/67)*100		91.0%
Specificity	/	=(221/233	3)*100	94.8%
Positive Predicitive Velue		=(61/73)*100		83.6%
Negative Predicitive Velue		=(221/227)*100		97.4%
Accuracy		={(61+221)/300}*100		94.0%

And the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of infarctive stroke were 97.6%, 73.9%, 89.4%, 92.2% and 90.3% respectively.(Table-IV)

# Table-IV: Performance of clinical diagnosis in diagnosing Infarctive stroke

		CT Scan		
		Infarctive	Other than Infarctive	_ Total
Clinical diagnosis	Infarctive	203	24	227
	Other than Infarctive	5	68	73
Total		208	92	300
Sensitivity		=(203/208)*100		97.6%
Specificity		=(68/92	=(68/92)*100	
Positive Predicitive Velue		=(203/227)*100		89.4%
Negative Predicitive Velue		=(68/73)*100		93.2%
Accuracy		={(203+6	={(203+68)/300}*100	

#### **Discussion:**

As the distinction between hemorrhagic and ischemic stroke has critical implications for

management, previous studies reported on clinical features and risk factors or different clinical scores had been proposed to be used in areas with limited health care facilities where CT scan of brain is not readily available.

Among the 300 patients 73(24.3%) patients were clinically diagnosed as hemorrhagic stroke and 227(75.6%) patients were as infarctive stroke. The mean (±SD) age of the patients with hemorrhagic and ischemic stroke stroke was  $60.67\pm9.34$  years and  $67.06\pm11.56$  years respectively. Among the patients with hemorrhagic stroke 42 (57.5%) were male and 31 (42.5%) were female. Among the patients with ischemic stroke 112 (49.3%) were male and 115 (50.7%) were female.

In a previous study among 469 acute stroke patients 81% (380) were ischemic stroke and 19% (89) were hemorrhagic stroke. Overall male were more than female 308 (65.7%) vs 161(34.4%). The mean age for the ischemic stroke group was 64.1  $\pm$  10.9 years, which was significantly higher than that of the hemorrhagic group (59.8  $\pm$  9.60years) (P<0.05).<sup>13</sup>

Baloch et al on 110 stroke patients, cerebral infarction was suspected in 89 (80.9%) and cerebral hemorrhage in 21 (19.1%) patients and 60 (54.5%) were males and 50 (45.5%) were females, ranged from 22-84 years with mean ( $\pm$ SD) age of 53( $\pm$ 5) years.<sup>24</sup>

Islam SS et observed in a study on 200 patients, 67(33.5%) patients were clinically diagnosed as hemorrhagic stroke and 133(66.5%) patients were diagnosed as ischemic stroke, the mean ( $\pm$ SD) age of the patients with hemorrhagic stroke and ischemic stroke was 57.61( $\pm$ 8.3) years and 56.3( $\pm$ 9.7) years respectively. Among the patients with hemorrhagic stroke 35(52.2%) were male and 32(47.8%) were female. Among the patients with ischemic stroke 63(47.4%) were male and 70(52.6%) were female.<sup>25</sup>

Out of 73 clinically diagnosed hemorrhagic stroke patients, CT scan revealed that 61 (83.6%) patients had intracerebral hemorrhage, 5 (6.8%) had infarct, 6 (8.2%) had subarachnoid hemorrhage and 1 (1.4%) had space occupying lesions in the brain. Out of 227 clinically diagnosed ischemic stroke patients CT scan revealed that 203 (89.4%) patients had infarction, 6 (2.6%) had intracerebral hemorrhage and 18 (7.9%) had space occupying lesions in the brain.

Islam ss, et al observed that out of their 67 clinically diagnosed hemorrhagic stroke patients

CT scan revealed that 56 patients had intracerebral hemorrhage, 5 had infarct, 4 had subarachnoid hemorrhage and 2 had space occupying lesions in the brain. And out of 133 clinically diagnosed ischemic stroke patients CT scan revealed that 119 patients had infarction, 6 had intracerebral hemorrhage and 8 had space occupying lesions in the brain.<sup>25</sup>

But khan et al found differed with our findings, they clinically suspected, 43% patients to have cerebral infarction, 25% intracerebral bleed and 32% indeterminate and CT scan brain showed cerebral infarction, intracerebral hemorrhages, Space Occupying Lesion and hemorrhagic infarct 60%, 27%, 9%, 4% respectively.<sup>10</sup>

In our study, the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of hemorrhagic stroke were 91.0%, 94.8%, 83.6%, 97.4% and 94.0% respectively. And the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of infarctive stroke were 97.6%, 73.9%, 89.4%, 92.2% and 90.3% respectively.

Sensitivity, specificity, positive and negative predictive value of Allen<sup>20</sup>, Siriraj<sup>21</sup>, Besson<sup>7</sup> and Efstathiou SP et al<sup>8</sup> in terms of 'certainly' estimated haemorrhagic and ischaemic strokes as well as in regard to uncertain cases were 61-97%, 94-99%, 74-97% and 90-99% respectively.

Hung LY observed the diagnostic sensitivities of the Siriraj stroke score for intracranial hemorrhage and infarction were 85% and 90% respectively, with an overall predictive accuracy of 88.5%.<sup>26</sup>

In another study, the sensitivity, specificity, positive predictive value, negative predictive value and accuracy of clinical diagnosis of hemorrhagic stroke were 90.32%, 92.03%, 83.58%, 92.02% and 91.5% respectively. In case of ischemic stroke the sensitivity, specificity, positive predictive value, negative predictive value and accuracy were 95.96%, 81.58%, 89.47%, 92.53% and 90.5% respectively.<sup>25</sup>

In the validation study of the Siriraj stroke score the diagnostic sensitivities of the score for cerebral haemorrhage and cerebral infarction were 89.3% and 93.2% respectively, with an overall predictive accuracy of 90.3%.<sup>27,28</sup> To improve the clinical diagnosis of stroke in the emergency department, Nor, et al <sup>29</sup> formulated the ROSIER scale (Recognition of Stroke in the Emergency

Department) was consistent with our study. Rapid assessment and triage by paramedics had achieved a consistent diagnostic accuracy of between 80% and 95%.<sup>29</sup>

#### **Conclusion:**

The diagnosis of strokes can be done clinically with high accuracy, but a CT scan of brain remains the gold standard for differential diagnosis. As the availability of this important diagnostic tool is not always feasible and it is not virtually possible to submit all stroke patients to CT scan, adequate knowledge on risk factors, clinical features and initial investigations may contribute to such a differentiation of cerebral infarction from intracerebral hemorrhage with high accuracy in order to aid clinicians to decide the initiation of antiplatelet therapy in settings where rapid access to Computed Tomography (CT) is lacking.

#### Limitation :

We could not conduct the study at multiple centres and our sample size was small. Though two large trials advocated the initiation of Anti-platelet therapy in suspected ischemic stroke where CT scan is not available or feasible, our research did not cover this matter.

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