

Predictors of mortality and 30 day disability in patient admitted with acute incident stroke

¹Dr. Urvashi Jain, Senior Resident, Dept. of Medicine, Sakra World Hospital, Bangaluru.

²Dr. Asmita Meshram, Senior Resident, Dept. of Medicine, Dharamlok Hospital, Katni.

³Dr. Nitin Tiple, Associate Professor, Dept. of pathology, GMC, Chandrapur.

⁴Kalantri SP, Resident, Dept. of Medicine, Dharamlok Hospital, Katni

Corresponding Author: Dr. Asmita Meshram, Senior resident, Dept. of Medicine, Dharamlok hospital, Katni.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Stroke is the third leading cause of death, worldwide. About 1 of 10 patients with an acute ischemic stroke and 1 of 3 with acute hemorrhagic stroke die within 30 days of the stroke. Physicians can effectively use their resources more meaningfully and can help caregivers cope with stroke if they are able to identify predictors of mortality or disability soon after a stroke. Hence the study was undertaken.

Material And Methods: We enrolled patients of acute incident stroke admitted to the intensive care unit of a rural not-for-profit teaching hospital in Vidarbha. All patients underwent neurological evaluation, laboratory tests, and neuroimaging and were offered the standard of care in a resource limited setting. We administered NIHSS and GCS to assess severity of stroke, ICH score to assess predictors of 30-day mortality and assessment of disability.

Results: We enrolled 415 patients with acute incident stroke, confirmed by computed tomography. The median [IQR] GCS of survivors were observed. NIHSS was a significant predictor of 30-day mortality: each point increment in the NIHSS scale was associated with 25% increase in the risk of mortality [OR 1.25 [95% confidence intervals 1.14-1.39].

The final model was 73.3% sensitive and 92% specific for predicting 30-day mortality; the positive predictive value was 71.7%, and the negative value, 92.6%.

Conclusions: We found that GCS was an independent predictor of 30-day mortality or disability in patients with hemorrhagic stroke. NIHSS and GCS were independent predictors of 30-day mortality or disability in patients with ischemic stroke.

Introduction

Stroke is the third most common cause of disability and second most common cause of death worldwide. Clinicians are often asked to predict outcome after stroke by the patient, family, and other healthcare workers. A wide variety of factors influence stroke prognosis, including age, stroke severity, stroke mechanism, infarct location, comorbid conditions, clinical findings, and related complications. In addition, interventions such as thrombolysis, stroke unit care, and rehabilitation can play a major role in the outcome of ischemic stroke. Knowledge of the important factors that affect prognosis is necessary for the clinician to make a reasonable prediction for individual patients, to provide a rational approach to patient management, and to help patient and family understand the course of the disease. Globally, the incidence of stroke due to ischemia is 68 percent, while the incidence of hemorrhagic stroke intracerebral.

Globally, the incidence of stroke due to ischemia is 68 percent, while the incidence of hemorrhagic stroke [intracerebral hemorrhage and subarachnoid hemorrhage combined] is 32 percent, reflecting a higher incidence of hemorrhagic stroke in low- and middle-income countries.[1]

Hemorrhagic stroke

Given high mortality in ICH, it is important for the physicians to distinguish potential survivors from non-survivors. To do so, physicians often use stroke severity rating scales such as Glasgow coma scale and National Institutes of Health Stroke Scale [NIHSS] to categorize patients into low, intermediate and high risk of dying.[2 & 3]

NIHSS a measure of stroke severity- has become a standard stroke impairment scale for use in both clinical trials and clinical care. The baseline NIHSS score is predictive of long-term outcome after acute stroke. An NIHSS score of ≤ 6 predicted a good recovery while a score ≥ 16 was associated with a high probability of death or severe disability.[2]

The ICH score, developed by Hemphill and colleagues, is the most commonly used simple six-point clinical grading scale in predicting the 30-day mortality as well as the short-term and long-term functional outcome of ICH.[4 & 5].

Prediction of mortality in stroke is no longer based on clinical subjectivity, but more on evidence-based, proven prediction models. Prognostic models have been found to be more accurate than merely relying on clinical judgment.[6] To be useful, the risk score for predicting should be clinically credible, accurate [well calibrated with good discriminative ability], have generality [be externally validated], and, ideally, be shown to be clinically effective that is, provide useful additional information to clinicians that improves therapeutic

decision making and thus patient outcome. The models must be evaluated on a new series of patients, ideally in a different location, to know whether work, as well as they, did in the original cohort[7].

We designed this study to assess the accuracy of the NIHSS, GCS and ICH score to predict 30-day mortality, and disability among the stroke patients admitted to a not-for-profit public hospital in central India.

Subjects and methods

Ethics statement: The study protocol was approved by the Institutional Review Board [A-322/2013]. The ethics committee waived the need for obtaining the informed consent because it concurred with our argument that we were collecting data from hospitalized patients with acute incident stroke that was a part of the standard care in the hospital and no intervention was being carried out.

Setting: We conducted this study in a medical intensive care unit of a 760-bed teaching hospital in Maharashtra, with 100000 outpatient visits to the internal Medical services and about 10500 patient admissions to medicine wards per year. The hospital, located in a small town in Maharashtra state, serves the predominantly rural population. According to the data from the electronic hospital information system, of the 10564 patients admitted to the medicine wards in 2013, a total of 864 patients [533 with ischemic stroke, 331 with hemorrhagic stroke] were assigned a discharge diagnosis of stroke [International Classification of Diseases, tenth revision diagnosis code I 61 to I 69]

Participants: Between December 2013 and December 2014, we identified all cases of strokes and enrolled in patients who had an incident stroke, proven by computed tomography scan within 24 hours of arrival.

Inclusion Criteria

We enrolled all the patients with stroke admitted to the ICU. Stroke was defined as “rapidly developing clinical

signs of focal [or global] disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin”, according to the World Health Organization criteria.[8]

Exclusion Criteria

Patients are presenting 24 hours after the onset of stroke, those who have had a past stroke, those who died before complete data could be collected, and those who had an alternate diagnosis on computed tomography [CT] brain scan, patients with traumatic intracranial hemorrhage and patients with subarachnoid hemorrhage.

Sample Size: We used *stpower cox* command in Stata to calculate the sample size. We estimated that with 410 stroke patients [102 deaths [25% 30-day mortality]], the study would have 80% power to detect a hazard ratio of 1.5, with a type 1 error of 0.05.

Data Collection

A standardized data sheet was used to record the variable. We defined each variable and standardized them to enhance their generalization and application to practice. For example, because many patients either didn't know or couldn't recall their exact date of birth, we verified the age of all participants by several sources such as *Aadhar* card, driving license, school leaving certificate or voter card.

Risk factors were defined as follows: hypertension [reported systolic blood pressure ≥ 160 mmHg, reported diastolic blood pressure ≥ 95 mmHg, patient's self-report of hypertension, or use of antihypertensive drugs], diabetes mellitus [fasting blood glucose level ≥ 120 mg/dL, patient's self-report of diabetes, or use of antidiabetic drugs], smoking habit [current smoker, yes or no], and cardiac disease [history of myocardial infarction, coronary artery disease, congestive heart failure, arrhythmia, or valvular heart disease]. Each variable was coded as 1, if present and 0, if absent.

Other data abstracted from the case records included estimated time from stroke to the admission, estimated time from hospitalization to computed tomography of the head. Temperature, pulse, systolic blood pressure, and diastolic blood pressure were recorded at the time of admission. Hemoglobin and white cell counts were estimated by an electronic cell counter [Beckman Coulter, Inc. Fullerton, CA, USA] in the hematology division of the central laboratory. Blood glucose was measured using the glucose oxidase-peroxidase method. Non-fasting Serum cholesterol was measured by a CHOD-PAP method, triglycerides by a GPO-PAP method, and HDL by the phosphotungstic method—all on a discrete analyzer. LDL and very low-density lipoprotein [VLDL] values were calculated by using the Friedewald formula.

Neurological Scales

We administered [1] Glasgow Coma Scale [2, 9, 10] and [2] National Institutes of Health Stroke Scale [NIHSS] [2&11] to all patients. The GCS and the NIHSS scored at the time of admission was used because this is the point at which initial acute intervention was considered. Briefly the GCS elicits information on best ocular, verbal and motor response; the score ranges between 3 and 15. The NIHSS was used as a clinical stroke assessment tool to evaluate and document and predict both short and long term outcome of stroke patients. The NIHSS uses 11 neurological clinical signs and is represented by a score from 0 to 42. The details of GCS and NIHSS are given in the appendix.

Computed Tomography Scan

All enrolled patients underwent a computed tomography head scan as soon as they were admitted to the hospital. A radiologist specifically looked at three variables on the CT scan in patients with intracerebral haemorrhage: Intracerebral haemorrhage volume, extension into the

subarachnoid system and the site of the intracerebral haemorrhage: supratentorial or infratentorial. ICH hematoma volume was measured on the initial head CT scan with the use of the ABC/2 method, in which A is the greatest diameter on the largest haemorrhage slice, B is the diameter perpendicular to A, and C is the approximate number of axial slices with haemorrhage multiplied by the slice thickness.[12] The presence or absence of IVH was noted on initial head CT.

Infarcts on CT scan were classified into OCSP subtypes: TACI, PACI, LACI, and POCI.[13]

We also classified all ischemic strokes into a small vessel, large vessel, undetermined and embolic infarcts based on the clinical profile and the CT findings.[14 & 15]

ICH Score

The ICH Score was determined by creating a sum score of points assigned for individual components: GCS [3–4 = 2, 5–12 = 1, 13–15 = 0], hematoma volume [≥ 30 mL = 1, < 30 mL = 0], presence of IVH [yes = 1, no = 0], infratentorial origin [yes = 1, no = 0], and patient age ≥ 80 [yes = 1, no = 0].[28] Patient ICH Scores ranged from 0 to 5; no patient in this cohort achieved an ICH Score of 6. Each brain location that contained hemorrhage on CT was recorded [putamen, globus pallidus, thalamus, internal capsule, deep periventricular white matter, ventricles only]. The origin of each hemorrhage was categorized as supratentorial and infratentorial. [16]

Outcome

The outcome was assessed as mortality and disability at 30 days after stroke. The follow-up started on the index date and ended on the date of the first instance of one of the following: death in the hospital or home or day 30 after the patient developed stroke. Patients were followed for up to 30 days after admission and clinical status [alive/dead and scores on the mRS[17] [a commonly used stroke ordinal outcome scale with scores ranging from 0

[no symptoms at all] to 6 [dead]]] was assessed at 30 days post-ICH either in person or via telephone by a resident trained in the administration of the modified Rankin score.[18]

The scale runs from 0-6, running from perfect health without symptoms to death.

0 - No symptoms.

1 - No significant disability. Able to carry out all usual activities, despite some symptoms.

2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.

3 - Moderate disability. Requires some help, but able to walk unassisted.

4 - Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted.

5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent.

6 - Dead.

All patients received the usual standard of care in the hospital, and their management was left to the individual physicians. All patients were treated according to the American Heart Association Guidelines for the Management of stroke. Patients received standard therapy that included ventilatory support, blood-pressure reduction, osmotherapy, fever control, seizure prophylaxis, and supportive care in intensive care unit. No patient received emergency hematoma evacuation or ventricular drainage. No patient received thrombolytic therapy for ischemic stroke.

Statistical Analysis

We entered data in a spreadsheet [Microsoft Excel] and analyzed data with Stata software [Version 13, Stata Corporation, Texas, USA]. Age > 65 [median value 65], Sex, ICH volume [> 30 and < 30 ml], site of Intracerebral hemorrhage [supratentorial vs. infratentorial], and

intraventricular extension was coded as binary variables [coded as 0= absent and 1= present]. GCS was ordered into three categories: >4, between 5 and 13 and >13. NIHSS score was categorized into three categories >16 largestrokes, 6-16 medium size stroke and <6 small sized strokes. Ischemic strokes were categorized into lacunar, small vessel, embolic and large vessel infarct. The vascular territory was classified as TACI [total anterior circulation infarct], PACI [partial anterior circulation infarct, POCI [posterior circulation infarct] and LACI lacunar circulation infarct]. [13-15]

Descriptive Statistics

Categorical variables were reported as numbers and percentages and were compared using the χ^2 test or Fisher exact test. Continuous variables were reported as the mean [standard deviation] or median [interquartile range] as appropriate and these variables were compared using the *t* test or the Mann-Whitney test. All analyses were conducted using Stata version 13 [Stata Corporation]. All tests were 2-sided, and a *p* value of less than 0.05 was considered statistically significant.

Cox Proportional-Hazards Regression Model

We explicitly considered the time to event for each individual in the study and analyzed the data with "survival analysis" methods. We explicitly considered the time to event for each individual in the study, and analyzed the data with 'survival analysis' methods. The Kaplan–Meier product-limit estimator was used to estimate survival and for the time-to-event plot. Time to death was investigated with follow-up for all patients starting at hospital admission and ending on day 30. Patients were censored if they die as the primary end point in this analysis was 30-day mortality. To identify those predictors with the most significant independent influence on prognosis, we used the log-rank test for simple comparisons. Crude hazard ratios were computed to assess

the strength of association between risk factors [covariates] and outcome [30-day mortality].

We used the Cox proportional-hazards regression model for analyses of multiple predictor variables. This model measures the hazard ratio the relative effect of a predictive factor on an outcome by assuming that this relation is constant over time. The assumption of proportional hazards was validated graphically by the log–log time plot. Only five variables with a significant unadjusted association with death were included in our final regression model. Since we had 90 outcome events, this approach accords with accepted statistical practice. A backward stepwise technique was used in the selection of covariates. For a variable to enter in the model, the *p*-value had to be <0.1, and for it to exit, the *p* value had to be >0.1. No interactions were entered into the final model because they did not improve the fit of the model. Both the crude and the adjusted hazard ratio estimates were computed along with 95% confidence intervals [CI].

Multivariate Logistic Regression

The following steps were used for multivariate logistic regression model development: We did a univariate analysis to "screen" out potentially significant variables for consideration in the multivariate model. Baseline variables that were considered clinically relevant or that showed a univariate relationship with outcome was entered into multivariate logistic regression models. We chose the variables for inclusion carefully to ensure parsimony of final models. The full preliminary model included all the variables selected using the criteria described above. From this full model, variables that did not contribute significantly were dropped one at a time until all those remaining contributed significantly. At each step, the variable with the smallest contribution to the model [largest *p* value] was dropped. The impact of the elimination of each variable on the model was evaluated

using the likelihood ratio test. The backward, stepwise process was continued until the best fitting; most parsimonious final model was identified.

Results

Study Population: Between 1 December 2013, and 31 December 2014, a total of 878 stroke patients, aged 18 years and older, consisting of 612 men and 266 women [mean [SD] age 58[13] years] were admitted to the hospital. We excluded 255 patients [153 patients with the sequel of stroke, 26 patients with subdural haemorrhage, and 45 patients with subarachnoid haemorrhage]. A total of 623 patients, aged 18 and older, consisting of men and women [mean [SD] age 60 [14] years] were admitted to the hospital with acute incident stroke. We could not enroll 208 patients [all variables could not be assessed in 83 patients, CT scan of the head could not be obtained in 40 patients, 17 patients died before the

physical examination could be performed, and 68 could not be enrolled because the study investigator was on leave.] [Figure 1]

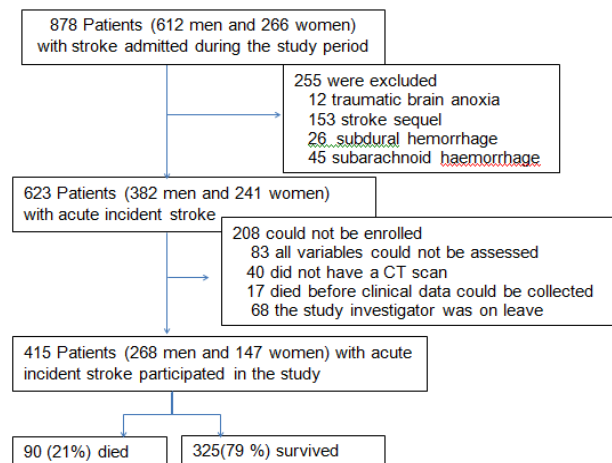


Figure 1: Flow Chart of the study

Table 1: Univariate analysis of baseline characteristics of 415 patients of stroke

| | Alive [n=325] | Dead [n=90] | Total [n=415] | p Value |
|--------------------------|---------------|-------------|---------------|---------|
| Characteristic | | | | |
| Mean [SD] age [in years] | 62.35[12.5] | 63.6[13.1] | 62.63[12.6] | 0.47 |
| Median | 65 | 65 | 65 | |
| Interquartile range | 55.5-70.5 | 56.5-70 | 55.5-70 | |
| Age Categories | | | | |
| <40 | 7 [2.15] | 4 [4.44] | 11[2.65] | |
| 40-59 | 100[30.7] | 24[26.67] | 124[29.88] | |
| 60-79 | 201[61.8] | 53[52.22] | 254[61.2] | |
| >80 | 17[5.2] | 9 [10.67] | 26[6.27] | |
| Male Sex, no. [%] | 208[64] | 60[66.7] | 268[64.6] | 0.64 |

| | | | | |
|---|-------------|------------|------------|-------|
| Time from onset of stroke to admission, hr | | | | 0.01 |
| Median | 24 | 8 | 24 | |
| Interquartile range | 5-25 | 4-24 | 4.5-24 | |
| Time from admission to CT scan, Median [hrs] | 24[5-24] | 8 [4-24] | 25[4-14] | 0.01 |
| Interquartile range | | | | |
| Blood Pressure on arrival [mmHg] | | | | |
| Systolic | 152[26.13] | 160.7[37] | 153.95[29] | 0.012 |
| Diastolic | 90.1[13.05] | 92.2[18.5] | 90.5[14.4] | 0.18 |
| Prior Risk factors | | | | 0.39 |
| Hypertension | 146[44.92] | | | 0.09 |
| Diabetes mellitus | 11[11.7] | | | 0.07 |
| Prior MI | 11[11.7] | | | 0.24 |
| Other comorbidity | 5[5.68] | | | 0.90 |
| Ever smokers | 23[24.47] | | | 0.54 |
| AF | 9[9.57] | | | |
| GCS Score | | | | 0.001 |
| Median | 13 | 4 | 12 | |
| Interquartile range | 10.5-15 | 3.5-7 | 7-14 | |
| NIHSS score | | | | 0.001 |
| Median | 14 | 31 | 16 | |
| Interquartile range | 10.5-20.5 | 28-32.5 | 11.5-28 | |
| Location of infarct | | | | 0.001 |
| LACI | 86[89.6] | 10[10.4] | 96 | |
| PACI | 126[92] | 11[8] | 137 | |
| POCI | 10[67] | 5[33] | 15 | |
| TACI | 27[64] | 15[36] | 42 | |

| | | | | |
|-----------|------------|-----------|-----------|--------|
| ICH Score | | | | <0.001 |
| 0 | 19 [25.33] | 0 | 19[15.32] | |
| 1 | 30[40] | 2[4.08] | 32[25.81] | |
| 2 | 9[12] | 8[16.33] | 17[13.71] | |
| 3 | 10[13.33] | 5[10.2] | 15[12.10] | |
| 4 | 5[6.67] | 14[28.57] | 19[15.32] | |
| 5 | 2[2.66] | 20[40.82] | 22[17.7] | |
| 6 | 0 | 0 | 0 | |

The final data set comprises records of 415 patients with acute incident stroke, confirmed by computed tomography [mean 62.61[SD] age [12.67] years]; [268 [64.6%] men and 147 [35.4%] women]. Twenty-six of the 415 patients [6.2%] were aged > 80 years. Overall 30-day mortality was 21.7% [95% confidence interval, 17.7% to 26.6 %]. No patient was lost to follow-up.

Among 415 patients [26 aged 80 or older] with stroke, the hazard ratio for 30-day mortality for age >= 65 years was 1.20 [95% CI, 0.78-1.84; *p* 0.39]. Those who died were about 1.5 years older than those who survived [mean age 62.3 vs. 63.6 years; *p* =0.39]. Of the 415 participants, 268 were men. The 30-day mortality did not differ between men and women [60 of 268 vs. 30 of 147; *p*=0.60].

Risk Factors for Stroke

As shown in Table 1, the admission characteristics were well balanced between the two groups [alive vs dead]. A similar number of the patient had prior hypertension: [45%] survivors vs. [50%] non-survivors; *p*= 0.39]. Patients who survived were twice as likely to be diabetic compared to those didn't [65 of 325, [20%] vs. 11 of 90 [12.22%]]; however the difference was not statistically significant [*p*= 0.09]. The number of patients with a history of acute coronary syndrome was two times more in non-survivors as compared to survivors [21 [6.46%] vs. 11[12.22%], *p*= 0.09]. Only 35 patients [26[8%] in

survivors and 9[10%] in non-survivors groups] had documented atrial fibrillation [AF] in the past. AF was also not an independent predictor of mortality [*p*=0.54]. Survivors were as likely to have other comorbidities compared to non-survivors [7% vs. 6%; *p*=0.24]. Survivors were as likely to have had smoked compared to non-smokers [81 of 325 [24.9%] vs. 23 of 90 [25.5%]; *p*= 0.90].

Severity of Stroke

NIHSS

The median NIHSS was substantially higher among patients who died compared with those who were alive at 30 days [31, IQR 28.5-32] versus 14[IQR, 12 to 21]. The relation between each score on the NIHSS and 30-day. We categorized NIHSS score into three 3 groups, using cut points of < 6, 7 to 16, and 17 to 42. By doing so, we were able to identify on admission patients with stroke at low [8%], medium [about 43%], and high [49%] 30-day mortality risk as shown in Table 2. Although patients with an NIHSS score of >16 constitute 48.9 % of the cohort with acute stroke [ischemic and haemorrhagic], these patients account for close to 88% of all deaths. [Table 2] There was a graded near linear relationship between increases in the NIHSS and 30-day mortality in patients with haemorrhagic stroke. No patient with an NIHSS score <6 died; the 30-day mortality rate was 2.2 % [2 of 90] for patients with a score of 7 to 16 and was 97.8 % [88

of 90] for patients with a score of > 16. As a continuous variable, NIHSS was a significant predictor of 30-day mortality: each point increment in the NIHSS scale was associated with 20 percent increase in the risk of mortality [odds ratio 1.20 [95% confidence intervals 1.12- 1.28]. In addition, the NIHSS also provided excellent discrimination of 30-day mortality with a c-statistic 0.89 [95% confidence interval [CI], 0.85–0.95]

Glasgow Coma Scale Score

We divided the GCS into three subgroups [GCS scores of 3 to 4, 5 to 12, and 13 to 15] to assess the influence of GCS score on the outcome. There was a graded near linear relationship between decreases in the GCS and 30-day mortality. Of note, only 9 of 55 patients with a presenting GCS score of 3 or 4 survived to 30 days and only 3 of 90 patients with a presenting GCS score of 13 to 15 died,

Table 2: Severity of Stroke

| Variable | Total [n=415] | Alive [n=325] | Dead [n=90] | p value |
|-------------------------|---------------|---------------|-------------|---------|
| GCS | | | | |
| 3-4 | 55[13.2] | 9 [2.8] | 46[51.1] | <0.001 |
| 5-12 | 178[42.8] | 137[42.1] | 41[45.6] | <0.001 |
| 13-15 | 182[43.8] | 179[55] | 3[3.3] | <0.001 |
| NIH stroke scale | | | | |
| <6 | 32[7.71] | 32[9.85] | 0 | <0.001 |
| 7-16 | 180[43.3] | 178[54.7] | 2[2.2] | <0.001 |
| >16 | 203[48.9] | 115[35.5] | 88[97.8] | <0.001 |

whereas 41 of 90 patients with a GCS score of 5 to 12 died within 30 days.[Table 2]

As a continuous variable, GCS was a significant predictor of 30-day survival for ischemic stroke [odds ratio 0.61[95% confidence intervals 0.54- 0.70] as well as hemorrhagic stroke [odds ratio 0.49[95% confidence intervals 0.39- 0.63].

Indicating that each point increment in GCS was associated with a decline in mortality rate. In addition, the GCS also provided excellent discrimination of 30-day mortality with a c-statistic 0.94, [95% confidence interval [CI], 0.90–0.97].[Figure 3]

There was a significant correlation between GCS score and NIHSS score [Pearson’s test; correlation coefficient: p=0.001].[Figure 6]

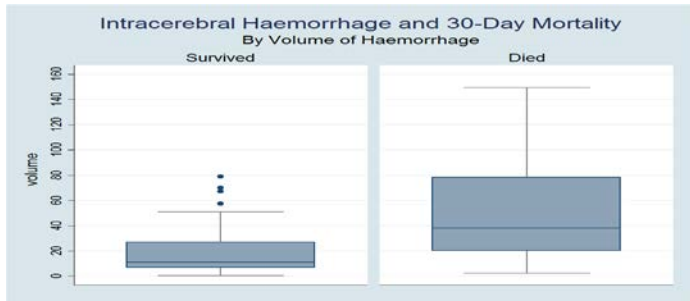


Figure 2: ICH Volume in Patients with Intracerebral Haemorrhage

The horizontal line in each box indicates the median value.

Computed Tomography Findings

Of the 290 patients with infarct 42 [14.5%] had total anterior circulation infarct, 137 [47.2%] had partial anterior circulation infarct, 15[5.17%] had posterior-

Table 3 .Distribution of Key Computed Tomography Findings

| Characteristic | Dead [n=90] | Alive [n=325] | Total N=415 | p Value |
|-------------------------------|-------------|---------------|-------------|---------|
| ICH Volume [ml]Median | 38 | 11 | 18.6 | 0.001 |
| Interquartile range | [20-78.4] | [6.7-26.8] | [17.8-38.8] | |
| < 30 ml | 17[34.7] | 61[82.4] | 78[63.4] | |
| > 30 ml | 32[65.3] | 13[17.6] | 45[36.6] | |
| Intraventricular extension No | 7[14.3] | 45[60.0] | 52[41.9] | 0.001 |
| Yes | 42[85.7] | 30[40.0] | 72[58.0] | |
| Midline shift Yes | 36[11.1] | 50[55.6] | 76[18.3] | 0.001 |
| No | 289[88.9] | 40[44.4] | 339[81.7] | |
| Infratentorial Yes | 71[21.8] | 46[51.1] | 117[28.2] | 0.001 |
| No | 254[78.1] | 44 [48.9] | 298 [71.8] | |

Table 4: Predictors for 30-day mortality in Stroke

| Characteristic | Crude Odds Ratio | 95% CI | p-value |
|---|------------------|------------|---------|
| ICH volume > 30 ml Yes, vs. No | 8.33 | 3.64-19.04 | 0.001 |
| Intraventricular extension Yes, vs. No | 9.20 | 3.65-23.15 | 0.001 |

anterior circulation infarct and 96 [33.1%] had lacunar infarct.

We categorized ischemic strokes into small vessel, lacunar, large vessel and embolic based on the clinical picture and CT findings. Of the 290 patients with ischemic stroke, patients with lacunar stroke tended to have a higher probability of survival [158 survivors and ten non-survivors]; compared to patients with large vessel stroke [73 survivors and 27 non-survivors] and those with embolic stroke [18 survivors and four non-survivors]. [p=<0.001].

| | | | |
|-------------------------------|------|------------|-------|
| Midline shift Yes, vs. No | 6.42 | 3.73-11.03 | 0.001 |
| Infratentorial Yes, vs. No | 3.80 | 2.33-6.52 | 0.001 |

Table 5: GCS AND NIHSS in Acute Stroke: Univariate Logistic Regression Analysis

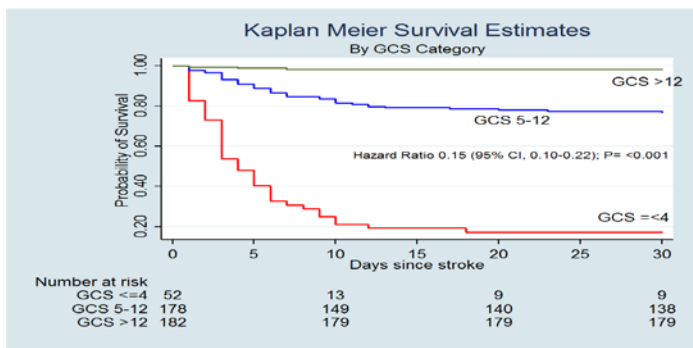


Figure 3: Kaplan-Meier Analysis of 30-Day Survival by GCS Score

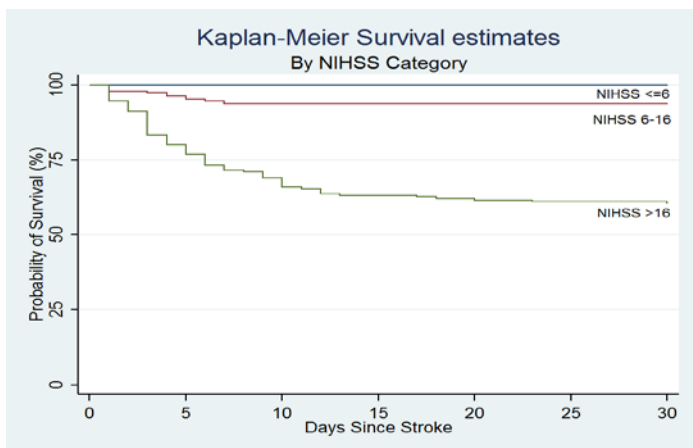


Figure 4: Kaplan-Meier Analysis of 30-Day Survival by NIHSS Category

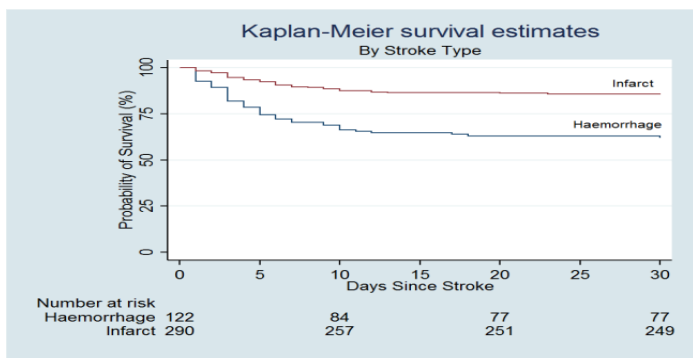


Figure 52: 30-Day Mortality by Stroke Type: Infarct Vs. Haemorrhage

| Characteristic | Odds ratio | 95% Confidence Interval | p Value |
|----------------------------|------------|-------------------------|---------|
| Haemorrhagic Stroke | | | |
| GCS | 2.01 | 1.58-2.55 | 0.001 |
| NIHSS | 1.06 | 0.96-1.17 | 0.20 |
| Ischemic Stroke | | | |
| GCS | 1.30 | 1.08-1.58 | 0.001 |
| NIHSS | 1.14 | 1.04-1.25 | 0.001 |
| All Strokes | | | |
| GCS | 1.56 | 1.37-1.78 | 0.001 |
| NIHSS | 1.08 | 1.02-1.15 | 0.001 |

Table 6: Predictors for 30-day mortality in acute stroke:

Final multivariate logistic regression analysis

| Variable | Adjusted Odds ratio | 95% CI | p-value |
|----------------------------------|---------------------|-------------|---------|
| Age>65 years | 1.18 | 0.24 - 4.02 | 0.79 |
| GCS | 0.54 | 0.41 - 0.71 | 0.001 |
| ICH volume > 30 ml Yes vs. No | 1.00 | 0.98 - 1.03 | 0.57 |

| | | | |
|--|------|--------------|------|
| Intraventricular extension Yes vs. No | 3.00 | 0.67 - 13.82 | 0.14 |
| NIHSS | 1.05 | 0.95- 1.16 | 0.27 |
| Infratentorial Yes, vs. No | 0.80 | 0.20-3.16 | 0.75 |

Outcome

The 30-day mortality was 21 % [95% CI, 17% to 25%]; in the haemorrhagic stroke group, 39% [95% CI, 30% to 48%] and that in ischemic stroke, 14% [95% CI, 10% to 18%].

In the univariate logistic regression analysis, lower Glasgow coma scale score, NIHSS score, ICH volume, serum glucose level and presence of intraventricular extension were significant independent predictors of 30-day mortality.

Admission GCS was an independent predictor of 30-day outcome [OR, 0.62; 95%CI, 0.54 to 0.71; p= 0.001]. Similarly, each point increment in the admission NIHSS score [OR, 1.08; 95%CI, 1.02 to 1.14; p= 0.006] was associated with 8% increase in 30-day mortality. For the group of all ICH patients, GCS score [OR 0.53; 95% CI, 0.41 to 0.68, p= 0.001], NIHSS score [OR, 1.08; 95%CI, 1.02 to 1.14; p= 0.006] were strong predictors of outcome, with GCS score being most strongly associated with outcome. Age >65 was not a statistically significant predictor of outcome in the entire cohort [OR, 1.19; 95% CI 0.75 to 1.92; p= 0.45] and also in both haemorrhagic stroke [OR, 1.35; 95% CI 0.65 to 2.80; p= 0.41] as well as ischemic stroke [OR, 1.89; 95% CI 0.90 to 3.94; p= 0.089]. Neither sex [OR, 0.73; 95% CI, 0.97 to 1.50; p= 0.40], admission systolic blood pressure [OR, 0.99; 95%CI, 0.35 to 1.01; p= 0.96], admission diastolic blood

pressure [OR, 0.99; 95%CI, 0.95 to 1.03; p= 0.71] could predict the outcome accurately.

Admission haemoglobin [p=<0.16], platelet count [p=0.12] and creatinine [p= 0.26] were not associated with 30-day mortality in patients. Neither age >65 years [OR 1.28; 95% CI, 0.38 to 4.25, p=0.68]; infratentorial location of the hematoma [OR, 1.48, 95% CI, 0.37 to 5.78; p= 0.57]; intraventricular extension of the hematoma [OR, 3.06, 95% CI, 0.69 to 13.4; p= 0.13] and ICH Volume [OR 1.00; 95% CI, 0.97 to 1.02; p= 0.84] were independently associated with the mortality.

The ICH Score

We evaluated the accuracy of the ICH Score in our study. The total ICH Score is the sum of the points of the five variables. The ICH Score was an accurate predictor of outcome assessed as 30-day mortality. The range of ICH Scores was 0 to 5, and ICH Scores from the cohort were distributed among the various categories. Each increase in the ICH Score was associated with a progressive increase in 30-day mortality [p<0.005 for trend]. Thirty-day mortality rates for patients with ICH Scores of 0, 1, 2, 3, 4 and 5 were 0%, 4.1%, 16.3%, 10.2%, 28.6% and 40.8% respectively. No patient in the study had an ICH Score of 6 because no patient with an infratentorial ICH had a hematoma volume >30 cm³. In the multivariate logistic regression, several independent predictor of 30-day mortality lost their statistical association with mortality: age > 65 years [OR = 1.28, 95% confidence interval [CI]0.38-4.25, p= 0.68]; volume of the intracranial haemorrhage > 30 ml [OR 1.48, 95 % CI,0.97-1.025; p= 0.84]; infratentorial location of haemorrhage [OR 1.48, 95% CI,0.37-5.78 ; p =0.57] and intraventricular extension of hemorrhage [OR = 3.066, 95% CI, 0.98-1.02, p = 0.138]. The admission Glasgow Scale was protective: OR, 0.53 [95% CI, 0.41-0.68; p= 0.001]. [Table 6] The final model was 85.7% sensitive and 85.5% specific for

predicting 30-day mortality; the positive predictive value of the model was 79.2% and the negative predictive value was 90.3%. [C statistic=0.94; Homer Lemeshow Goodness of Fit= 0.63 indicating a good fit of the model. [Figure7]

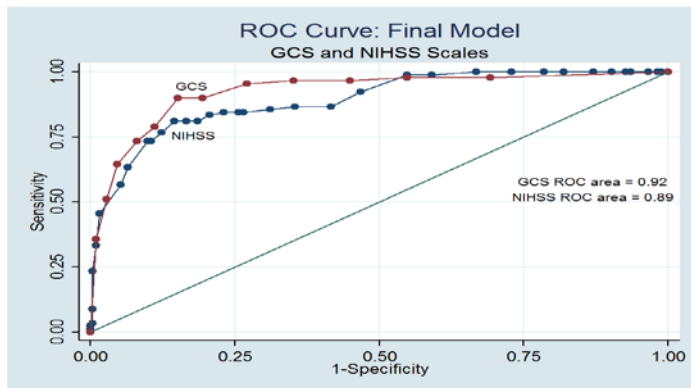


Figure 6: Receiver Operating Characteristic Curve Of The Final Model.

Discussion

Our study shows that the Glasgow Coma Scale [GCS] is the strongest predictor of 30-day mortality or disability in first-ever hemorrhagic stroke. Our study also shows that GCS and NIHSS are equally powerful predictors of 30-day mortality or disability in first-ever ischemic strokes.

Stroke Mortality and Disability

The 30-day mortality in our study was 21.7% [95% CI, 17.7% to 26.6%]. The mortality due to hemorrhagic stroke [49 of 124; 39.2 % [95% CI 31.1 – 47.9] 49 of 125] was three times than ischemic stroke [41 of 290], 14.1 % [95% CI 10.6-18.6]. The 30 day- case fatality after first ischemic stroke ranges between 16 and 23 % and that for hemorrhagic stroke is up to 40%. [19] The 30-day mortality from ICH ranges from 35 to 52 percent of ICH. [20] One-half of these deaths occur within the first two day. Many patients after stroke are disabled and some fail to function independently after the stroke. A systematic review estimated that between 12 and 39 percent of patients achieve independent function. [21] Our study also shows that of the 325 [78%] survivors, only a third had no disability or slight disability [modified Rankin score ≤ 2].

Two-fifths of the survivors had a moderate disability requiring some help, and a sixth of survivors were either moderately disabled or were severely disabled – bound to their beds, incontinent or requiring substantial support from the family for activities of daily living. Previous studies have looked at independent predictors of mortality. [4,22-25] Old age, low Glasgow coma scale score, ICH volume, intraventricular and subarachnoid spread, midline shift, narrow pulse pressure, high pulse pressure, infratentorial location, and high blood glucose have been such predictors. The prognosis after ICH depends upon the location of hemorrhage [supra versus infratentorial location], size of the hematoma, level of consciousness, patient age, and overall medical health and condition.

Neurologic Severity of Stroke

The severity of stroke on the neurologic exam is probably the most important factor affecting short- and long-term outcome and NIHSS is a good predictor of stroke outcome demonstrated by many studies. [2 & 26]. In our study, the 30-day mortality rates were 0% [0 of 32], 1% [2 of 180] and 43.34 % [88 of 203] for NIHSS scores <6 , 7-16 and >16 respectively. Studies showed that at three months, the proportion of patients with excellent outcomes for NIHSS scores of 7 to 10 and 11 to 15 was approximately 46 and 23 percent, respectively. An NIHSS score of ≤ 6 predicted a good recovery], while a score ≥ 16 was associated with a high probability of death or severe disability. Our study showed that disability which means higher rankin scores were more in patients with higher ICH scores and lower GCS score. NIHSS does not evaluate recovery of social activity leisure activity and employment. The outcome varies according to the time elapsed from stroke onset as in case of stuttering strokes. NIHSS score associated with specific outcome shiftsto changes over time as the deficit progresses or recovers. [27]

Age

In our study, non-survivors tended to be a year older than those who survived [mean age 63.6 [13.1] vs. 62.35 [12.5] years; $p= 0.09$]. We used 65 years [median age of our study population] to test if patients aged ≥ 65 years were more likely to die in the first month. Although, in the univariate analysis, this cut point was associated with a hazard ratio of 1.19 [95% CI, 0.74-1.92; $p>0.01$], in the final multivariate logistic regression model, age was no longer a predictor [OR 1.18, [95% CI 0.24-4.02, $p = 0.79$]]. Also patients with older age and higher ICH volume are most likely to die.

Advancing age negatively impacts stroke morbidity, mortality, and long-term outcome in both minor and major strokes. Older adults [over 65 years] have increased the chance of dying in two months after stroke and being significantly disabled if they survive.[28 & 29] Several studies have looked at age as a predictor of mortality in patients with stroke.[4, 30-31]

NIH Stroke Scale [NIHSS]

There was a linear relationship between increases in NIHSS and 30-day mortality. No patient with an NIHSS score <6 died; the 30-day mortality rate was 2.2 % [2 of 180] for patients with a score of 7 to 16 and was 43.3% [88 of 203] for patients with a score of >16 . NIHSS was a significant predictor of 30-day mortality for ischemic stroke. As a continuous variable, NIHSS was one of the independent predictors of 30-day mortality [adjusted odds ratio, 1.05 [0.95-1.16; $p=0.27$] suggesting that each point increment in NIHSS was associated with 5% higher risk of mortality. Although it didn't emerge as a statistically significant predictor, we retained the NIHSS score in the final model because there was a significant correlation between GCS and NIHSS. In addition, NIHSS also provided excellent discrimination of 30-day mortality a C statistic of 0.89 [95% CI, 0.81 to 0.93]. Furthermore, NIHSS performed well in both supratentorial [adjusted

odds ratio 1.25, 95 % CI, 1.17-1.33] as well as infratentorial lesions [adjusted odds ratio 1.22, 95% CI, 1.14-1.31].

Glasgow Coma Scale Score [GCS]

GCS was the strongest predictor of 30-day mortality and disability in hemorrhagic stroke both in the final multivariate logistic regression model. Our data show a linear relationship between the decrease in the GCS and 30-day mortality. GCS was the strongest predictor of 30-day survival [odds ratio 0.62; 95% confidence intervals 0.54-0.71] indicating that each point increment in GCS was associated with a 40% decline in mortality rate. Only 9 of 55 patients with a presenting GCS score of 3 or 4 survived to 30 days, and only 3 of 182 patients with a presenting GCS score of 13 to 15 died, whereas 41 of 178 patients with a GCS score of 5 to 12 died within 30 days. The GCS score, originally used in a patient with traumatic brain injury is now widely used to assess all patients with acute neurological disorder. GCS score is now a standard neurological assessment tool that is reproducible and reliable.[22]The scale is simple, takes less than a minute to administer and has proven reproducibility. Several studies have used GCS to predict short term outcomes in patients with ICH.[3, 4, 15, 17, 30,32]

Neuroimaging

Findings on neuroimaging including stroke size and location are an important adjunct to the neurologic exam when gauging prognosis. Early after stroke, the neurologic exam alone can suggest a falsely grim or favorable prognosis. For example, a patient may have a small stroke on neuroimaging and present with stupor or coma caused by a seizure or metabolic derangement that is reversible. Conversely, a patient presenting with mild stroke and a low NIHSS score on an examination may have large vessel occlusion and a large perfusion deficit on

neuroimaging, suggesting the possibility of stroke progression and worse outcome.

Infarct location

We categorized ischemic strokes into lacunar, large vessel and embolic based on the clinical picture and CT findings. Of the 290 patients with ischemic stroke, patients with lacunar stroke tended to have a higher probability of survival [158 survivors and ten non-survivors]; compared to patients with large vessel stroke [73 survivors and 27 non-survivors] and those with embolic stroke [18 survivors and four non-survivors] [$p<0.001$]. In univariate analysis, compared to lacunar stroke [reference], embolic strokes generated an OR of 3.5 [95% CI 0.99-12.3]; $p=0.05$; while large vessel strokes generated a OR of 5.48; 95% CI [2.7-12.7; $p=0.001$]. Our findings thus concur with those from previous studies.[33&34]

ICH Score

We validated ICH score, and our study shows that this the ICH score tool is easy to use at the bedside, requiring information only from the initial patient evaluation and CT scan to calculate the score and is a valid clinical prediction scale that accurately predicts 30-day mortality in patients with ICH. The 30-day mortality rates for patients with ICH Scores of 0, 1, 2, 3, 4 and 5 were 0%, 4.1%, 16.3%, 10.2%, 28.6% and 40.8% respectively. No patient in the study had an ICH Score of 6 because no patient with an infratentorial ICH had a hematoma volume $>30\text{cm}^3$. The ICH score was similarly effective in identifying those patients who achieve functional independence at 30 days among the ICH survivor.

In 2001, Hemphill and colleagues[4] introduced the original ICH score [oICH], which is one of the first simple and easily assessable clinical grading scales for ICH. They used multivariate logistic regression models to identify Independent predictors of 30-day mortality and developed

a risk stratification scale [the ICH Score]. In this score, factors independently associated with 30-day mortality were Glasgow Coma Scale score [$p<0.001$], age >80 years [$p<0.001$], the infratentorial origin of ICH [$p<0.03$], ICH volume [$p<0.047$], and presence of intraventricular hemorrhage [$p<0.05$]. The ICH Score was the sum of individual points assigned as follows: GCS score 3 to 4 [2 points], 5 to 12 [1], 13 to 15 [0]; age >80 years yes [1], no [0]; infratentorial origin yes [1], no [0]; ICH volume $\geq 30\text{cm}^3$ [1], $<30\text{cm}^3$ [0]; and intraventricular hemorrhage yes [1], no [0]. Thirty-day mortality showed a linear relationship with ICH Score: All 26 patients with an ICH Score of 0 survived, and all six patients with an ICH Score of 5 died. Thirty-day mortality rates for patients with ICH Scores of 1, 2, 3, and 4 were 13%, 26%, 72%, and 97%, respectively. The authors argued this score provide a standard assessment tool that can be easily and rapidly calculated at the time of ICH presentation by physicians who lack training in neurology. Finally, the score could also help doctors tell patient's relatives the shape of the things to expect- more objectively

This study demonstrates that the ICH Score is a valid clinical grading scale for stratifying likelihood of favorable after acute ICH, out to 12 months. All patients within their dataset with an ICH score of 0 survived, and 2 of 22 patients with a score of 5 [a highest score assigned] died.

ICH volume

In our study, ICH volume [$\geq 30\text{ml}$] was a significant predictor of mortality: Non-survivors tended to have significantly larger hematomas compared to survivors [38 ml [IQR, 20-78.4] vs. 11 ml [IQR 6.7-26.8; $p<0.001$]; [OR, 8.33 [95 % CI, 3.64-19.04; $p=0.001$]]. An ICH volume $\geq 30\text{ml}$ had a hazard ratio of 7.05 [95% CI, 3.1-15.8]. In the final multivariate logistic regression model, as a continuous variable, the ICH volume had an odds ratio of 1.00 [95% CI, 0.98 to 1.03] indicating that ICH volume was

not an independent predictor of mortality when adjusted to GCS and NIHSS.

In original ICH study, ICH volume was not an independent predictor for the outcome because patients with larger hematomas who died also tended to be older, had lower GCS score, or IVH- factors strongly associated with mortality.[4]

Intraventricular Extension of Haemorrhage

We found that only 14 % of non- survivors had ICH that had found its way into ventricles. Patients with the extension of hematoma into ventricles were nine times more likely to die compared to those without. [Odds ratio 9.20 [95% CI, 3.36-22.6; $p=0.001$]. But when we adjusted intraventricular extension with GCS and NIHSS, we found that it failed to stand as an independent predictor of mortality [OR 3; 95% CI, 0.67 to 13.83; $p = 0.14$]. [Table 9] Our finding concurs with the original ICH score in which the intraventricular extension of the hematoma was not a robust predictor of mortality [odds ratio [2.97 [0.99–8.92]. IVH was strongly correlated with GCS, ICH volume, and ICH location; thus, once controlled for these factors, IVH no longer remained significant. Juvela and colleagues found IVE as an independent predictor of mortality.[30]

Midline Shift

Compared to survivors, non-survivors were significantly more likely to have midline shift on computed tomography [50 vs. 76 %; $p=0.001$]. Midline shift was also an independent predictor of mortality in the univariate analysis [OR, 6.42, 95% CI, 3.73 to 11.03, $p=0.001$] but lost its predictive power in the multivariate model when it was adjusted with other significant predictors [adjusted OR, 1.9 [95% CI, 0.92 to 4.27]; $p= 0.080$].

In previous study [411 ICH patients, 84% supratentorial hematomas and 24% with midline shift], midline shift was a significant predictor of mortality: ≥ 6 mm lateral shift of

midline structures was associated with mortality [OR, 13.5; 95% CI, 5.6 to 32.5].

Infratentorial Origin of ICH

Although the infratentorial location of the hematoma present in 12% of those who died- was a significant predictor of 30-day mortality in haemorrhagic stroke [OR 3.8, 95% CI 2.3-6.2] ; it lost its statistical significance in the final multivariate logistic regression model [OR, 0.80; 95% CI, 2.2-3.2]. According to the study by Juvela[30], cerebellar hemorrhage was associated with reduced mortality [OR, 0.16; 95% CI, 0.04 to 0.60; $p = 0.08$]. [Table 9]

In the original ICH score study [4] infratentorial origin of ICH was a strong predictor of 30-day mortality [OR, 4.24; 95% CI, 1.15 to 15.65; $p = 0.03$].

Conclusion

We found that GCS was an independent predictor of 30-day mortality or disability in patients with haemorrhagic stroke. NIHSS and GCS were independent predictors of 30-day mortality or disability in patients with ischemic stroke.

Predictors of Mortality

Factors independently associated with mortality were: age > 80 years [odds ratio, 13.61; 95% CI- 2.55 to 72.58], ICH volume > 30 ml [odds ratio, 7.58; 95% CI-2.97-19.30], intraventricular extension [odds ratio, 3.57; 95% CI-1.50 to 8.47] , infratentorial origin of ICH [odds ratio, 4.11; 95% CI-1.10-15.28], midline shift [odds ratio, 6.42, 95% CI- 3.73-11.03]. The admission Glasgow Coma Scale was protective: OR, 0.53 [95% CI, 0.41-0.68; $p= 0.001$]. NIHSS was a significant predictor of 30-day mortality: each point increment in the NIHSS scale was associated with 25 percent increase in the risk of mortality [odds ratio 1.25 [95% confidence intervals 1.14-1.39]

The final model was 73.3% sensitive and 92% specific for predicting 30-day mortality; the positive predictive value

of the model was 71.7%, and the negative predictive value was 92.6%.

Predictors of Disability

A clear gradient was seen between GCS score, NIHSS score and ICH volume and disability as measured by modified Rankin scale. Compared to patients assigned modified Rankin scale of 1, patients assigned modified Rankin scale score of 5 were more likely to have larger ICH hematomas [10 ml[4-11] vs. 16ml [8-48]] , low GCS[15 [14-15] vs.8[6-11]] and high NIHSS score [8 [6-10] vs.25 [20-29]].

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How to citation this article: Urvashi J, Meshram A, Tiple N, Kalantri SP, "Predictors of mortality and 30 day disability in patient admitted with acute incident stroke", *IJMACR*- November - December - 2020, Vol – 3, Issue - 6, P. No. 08 – 26.

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