Development and Validation of a Daily Monitoring Stroke Scale: A Three-Month Follow up Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Study Protocol

ABSTRACT

Introduction: Stroke is the one of the common health problems world-wide causing significant morbidity and mortality. Various scales are framed and validated for use in stroke trials and clinical use. Most widely used scale for stroke assessment is NIHSS scale but this scale is infrequently used in routine clinical practice. This is because of various limitations like poor representation of posterior circulation deficit and predominant motor and language representation and poor representation of fine motor & cognition deficits in this scale.
Objective: Therefore, the purpose of the present study is to formulate a daily monitoring scale which can objectively assess and prognosticate stroke patients. Present study aims to incorporate daily examined parameters in one instrument to develop a routinely useful tool for neurologist and physician which can be simple, fast, reliable, and reproducible.
Method: We will include GCS score, brainstem reflexes, gaze, speech, distal and proximal motor power, inattention, ataxia, sensory deficits and gait examination parameters in proposed scale. After initial pilot study (15 patients), we will include developmental cohort (400 patients) and validation cohort (60 patients) to formulate and validate this study. Outcome measures will be 30 -

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day mortality and morbidity assessed at day 30 and 90 with modified Rankin score and Barthel index. Total patients included will be 460 patients with follow up for 3 months

Results: It is expected to develop simple, reliable, and reproducible scale for monitoring of acute stroke patients.

Keywords: Stroke Scale; NIHSS; GCS; FOUR score; CNS; SSS.

1. INTRODUCTION

One of the leading causes of death throughout the world is stroke and because of the aging population, stroke incidence and prevalence will increase substantially in the future. According to an estimate by World Health Organization (WHO) approximately 80% of strokes will occur in people living in low- and middle-income countries by year 2030 and it will account for 7.9% of all mortality in these countries. The global incidence of stroke is 2/1000 population/annum and about 4/1000 in people aged 45-84 years. Stroke is the common vascular disease in many parts of Asia, and as more than half of the world's population live in this region, stroke has strong impact on health of people and economy of the countries in this region. It is second leading causes of disability and death in India too [1].

Various scales have been developed, validated, and used for assessment of stroke burden, morbidity, and mortality risk but there is no single tool to measure outcome that can predict or describe dimensions of recovery or disability after acute stroke. For mortality risk assessment and prognostication, commonly used acute assessment scales are Canada Stroke Scale and NIHSS. Glasgow Coma Scale (GCS) which was designed for head injury patients, is also used for daily monitoring of stroke patients but it lacks many vital parameters. FOUR score developed for assessment of consciousness in medical illness has been found to be better than GCS because this score also assesses brainstem and respiration in addition to motor and eye response of GCS. Various other Scales like Scandevian Stroke Scale, European Stroke scale, are extensively validated and used for research and clinical use [2-3].

But there is no single scale which can be used for routine clinical use for day-to-day monitoring enabling clinician to quantify the progress or worsening of acute stroke patients. So, most of the clinicians depend mainly on thorough neurological examination [4]. The daily monitored parameters in stroke units can be clubbed together to develop a daily assessment scale for stroke patients. This perspective present project aims to develop and validate short simple and fast assessment scale which will incorporate common parameters which are assessed daily on bedside round and to evaluate if this scale can help in prognostication of stroke outcome and mortality.

2. MATERIALS AND METHODS

Study Design: Longitudinal observational study.

Study duration: Will be from 01/01/2021 to 31/12/2023. The study will be carried out over a period of three years with each patient follow up visit at 1st month and on 3rd month.

Setup: The present study will be carried out in Department of Medicine, AVBR Hospital, Wardha. It is a multispecialty teaching hospital in Vidarbha region of central India with capacity of 1200 beds out of which 240 beds are allotted to Department of Medicine. On an average 10-15 patients of stroke get admitted from different villages of Wardha district per week. Acute stroke patients will be managed according to guidelines given by the American Heart Association/American Stroke Association.

Sample Size: - Sample size with desired error of margin:

$$n = \frac{Z^2\alpha/2 \ \times \ P \times (1 - P)}{d^2}$$

Where

$Z^2\alpha/2$ = The level of significance at 5% i.e. 95% confidence interval= 1.96 P = Effect size = 5% (0.05)
d = Desired error of margin= 2% (0.02)
So, in present study
n = {1.96[2] × 0.05 × (1-0.05)} ÷ 0.02[2] = 456.19
So, in present study we will include 460 patients during this study period.

Sampling Technique: Acute stroke patients admitted consecutively to ICU/ Medicine ward

who will fulfil inclusion criteria and giving consent for their data collection will be included in the study.

2.1 Inclusion Criteria

- Age more than 18 years
- Patients of either Sex
- Acute stroke defined as "Acute episode of focal deficit involving central nervous system caused by vascular pathology" will be included in the present study.
- Stroke due to intracerebral Haemorrhage or Infarct due to embolic or thrombotic episode.

2.2 Exclusion Criteria

- Stroke patients admitted late after 24 hours of onset
- Cortical venous Sinus thrombosis, subarachnoid haemorrhage, traumatic haemorrhage patients
- Age less than 18 years

2.3 Data Collection

For all eligible patients included in the present study, following data will be collected by the principal investigator under the guidance of Supervisor.

1. Demographic data like age, sex; personal history of addiction and family and past medical history.
2. Pre-morbid conditions like Diabetes, Hypertension, Dyslipidemia, thyroid disorder and other
3. All patients will undergo neuroimaging CT head or MRI brain for evidence of acute stroke /ruling out bleeding
4. Patients will be classified as per TOAST classification and will be managed as per guidelines
5. All patients will be assessed clinically, and their score will be calculated by proposed scale daily for 7 days & NIHSS score on day 1, Day 3, Day 7 and at the time of discharge.
6. Patient will be followed up in OPD up to 3months.

3. METHODOLOGY

3.1 Pilot testing

A preliminary scale will be piloted on a small group of patients (eg.15 patients) who will be excluded from the later part of the study for determination of validity of the instrument. Each item in the preliminary pool will be assessed for its relevance and utility. The highest scoring items representing each domain will be selected. The feedback and comments from the expert panel on pilot group will be used to modify ambiguous and unclear items, reject irrelevant items, and add new items that will help in selecting and aggregating items to frame final proposed scale.

We will randomize the patients from our center into two cohorts: the one group of 400 patients will serve as development cohort for establishing the proposed score and, the other group of 60 patients will serve as external validation cohort for validation of the proposed score.

Development Cohort: Our derivation cohort will consist of 400 consecutive patients of acute stroke admitted to our hospital between 01/09/2020 to 31/08/2023, in the medicine ICU. At the time of initial, patients will undergo detailed history taking and examination. We will develop of the daily monitoring stroke score, based on parameters recorded daily on bedside rounds during the hospitalization of these patients. Based on a comprehensive literature review and clinical relevance, we will identify variables and construct a new simplified daily monitoring instrument for use in stroke patients, which are potentially associated with stroke decision making in day-to-day practice and leading to assessment of morbidity and mortality. Daily monitored GCS score, Pupil and Corneal Reflex, Language assessment, Gaze, Motor Power, sensory deficit, Co-ordination and Gait will be the parameters observed for developing the score.

Validation Cohort: Our validation cohort will include 60 consecutive elderly patients admitted to our hospital. Patients in the validation and derivation cohorts will undergo same type of study protocol and investigations. For external validation of proposed scale, it will be compared with routinely measured NIHSS score for its efficacy in determining morbidity and mortality.

3.2 Outcome Measurement

All patients will be prospectively followed up for 3 months and following parameters will be recorded.

- In hospital mortality / 30day mortality.
- Modified Rankin Score (mRS) and Barthel Index (BI)
- mRS score will be classified as 3-7 as unfavourable and 0-2 as favourable

3.3 Statistical Analysis

- Data will be recorded as Mean ±SD for continuous variables and by frequencies and percentage for categorical variables.
- Binary logistic regression analysis will be done to assess odds ratios of NIHSS score and proposed score.
- To define best cut off point for neuro worsening, ROC curve will be depicted for the difference between day 1, 3 and on discharge for proposed scale & NIHSS score. Best cut off point will be selected having maximum specificity and positive likelihood ratio.
- All hypothesis will be constructed two tailed and p value <0.05 will be considered significant.

3.4 Expected Outcome

It is expected to provide health care professionals a simple and valid instrument that will offer easy monitoring, decision making and prognostication in stoke patients for daily assessment.

4. DISCUSSION

Among all the scales mentioned, most widely used scale is NIHSS which was designed as a rapid, reproducible screening tool and is effective in this role, but it is also not used frequently in routine clinical practice because it has poor representation of posterior circulation deficit and has predominant motor and language representation but less sensitive to milder changes in distal finger movement or cognition. Due to this even patient with significant neurological deficit can score better on NIHSS scale. The NIHSS is not a substitute for a comprehensive neurological examination in view of localization of a lesion or impact of subtle deficits. On the other hand, assessment of consciousness in most of these scales is subjective. GCS and FOUR score can be used for objective assessment of level of consciousness, but these scores lack other dimensions of stroke deficit. FOUR score and GCS are better predictors of mortality while

NIHSS predicts poor outcome and morbidity [3-5].

Mansour et al in their study compared three scores in predicting in hospital mortality calculated on day one and on third day of admission and they found that there was no difference between the NIHSS, the GCS and the FOUR score. All three score predicted an unfavorable outcome comparably. The NIHSS score had the highest AUC compared to the AUC of the GCS scale and of the FOUR score in predicting unfavorable outcome. Third day score of all three scale was better for prediction of outcome compared to first day score. The NIHSS was good to predict outcome between days 2 and 9 [6].

The European Stroke Scale was developed to evaluate patients with stroke involving the territory of the middle cerebral artery preferably, so it is not used routinely [7].

The Canadian Neurological Scale (CNS) is simple and fast than the NIHSS which lack many stroke-related deficits. Compared to the NIHSS, the CNS shows is a more practical scale as it needs complete examination, and it is reproducible. The CNS scale requires a more detailed neurological examination which needs to be done by specialist having expertise. This limits its routine use in practice [8].

The Scandinavian Stroke Scale (SSS) includes conscious level, gaze, arm and leg motor power, dysphasia, facial paresis, and gait. This scale has good reliability and it was also validated for retrospective use [9].

The Toronto Stroke Scale was used in a study of steroid therapy in cerebral infarction. It is a 317 point, 11-category assessment. Though no validation studies were initially reported, a high correlation of the Toronto Stroke Scale compared with other scales was subsequently found. The same study found that the Toronto Stroke Scale had only moderate internal consistency. This scale is relatively cumbersome to apply limiting its routine use [4].

Hemispheric Stroke Scale (HSS) was designed for use in multicenter treatment protocols in acute hemispheric stroke. The Hemispheric Stroke Scale is a 100-point neurological assessment designed for a trial of hemodilution for the treatment of acute ischemic stroke. It was designed using empirical methods, choosing

items based on their practicality, variability, and reliability. However, there was no intra-rater reliability, and the scale suffered included several closely related items [10].

Bawiskar et. al. studied clinico-radiological association of serum calcium, ionic calcium and albumin corrected serum calcium in Acute Ischemic Stroke [11]. Few of the related studies were reviewed [12-14]. Benefits of [15] and Yoga [16] in heart failure cases were reported by Khatib et al. [17-20].

So, there is a lack of standardization in the way neurologic function is monitored and recorded across institutions in the inpatient setting. Present study aims to design daily monitoring scale which will address the short comings of established NIHSS scale in routine assessment and prognostication [5-6]. This study will include parameters which are routinely examined in daily ward rounds and we will check its predictive value in terms of morbidity, mortality and its validity a& reliability

5. CONCLUSION

Daily monitoring stroke scale will improve routine monitoring and prognostication in day-to-day practice.

CONSENT AND ETHICAL APPROVAL

Ethics committee approval will be taken from institutional ethics committee. Informed consent will be taken from patient / relatives before enrolling the patients in the study.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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