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THE PROSPECTIVE STUDY ON CLINICAL PARAMETER AND OUTCOME OF EARLY *INTRAVENOUS THROMBOLYSIS BY RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR* IN DEDICATED *STROKE EMERGENCY INTENSIVE CARE UNIT*

Medicine

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KEYWORDS

AIMS & OBJECTIVES:

1. Immediate triage of stroke patients.
2. Call code stroke in of emergency for every stroke patient.
3. To review the timeline and outcome of the thrombolysed patient with respect to time line in form of NIHSS score and MRS score at discharge.
4. To identify DOOR TO NEEDLE and DOOR TO CT time with implementation of code stroke and without its implementation.
5. To evaluate baseline clinical parameters in the patients with acute stroke EMERGENCY INTENSIVE CARE UNIT.

MATERIAL AND METHODS:

1. Study area: Study was conducted on the patient admitted in Jehangir hospital, situated at 32, Sassoon road, pune 411001. Hospital is the oldest tertiary care health center in pune with good amount of stroke cases yearly. Hence study is conducted in Jehangir hospital.

2. Study population: The patients who had a history of sudden onset of signs and symptoms of stroke presented in stroke intensive care unit. Both males and females were included in study. The study population mainly includes urban patients residing in Pune. All the patients included in the study were adult with age > 18 years.

3. Sample size: 52 patients in code stroke implementation group & 48 patients in non-implementation group.

Considering the reported mean & SD of NIHSS score of the reference studies **(Factors associated with long term prognosis after ischemic stroke treated with fibrinolysis agent & thrombolysis on ischemic stroke patients with decrease level of consciousness within 4.5 h)** the sample size of 45 pairs have been estimated to give power of 80% for the study at 5% level of significance to detect the difference in mean of more than 15%. The formula used for sample size estimation is given below.

$\mathbf{N = 2\,(z_\alpha + z_\beta)^2 / (\delta/\sigma)^2}$

Where,

N = Sample size (per group)

$\mathbf{z_\alpha}$ = (1.96) for 95% confidence (i.e. $\alpha = 0.05$)

$\mathbf{z_\beta}$ = Cut-off value for Power (1 - β)

σ = Common Standard Deviation (SD) of both the groups

δ = Mean difference to be detected

δ/σ = Effect size in SD units

4. Data collection technique and tools: We implemented the "SC" protocol was initiated in August 2015, the study time period was divided into the "pre-SC era" (April 2015 to July 2015) in which protocol was not implemented and the "SC era" (August 2015 to April 2017) in which stroke was implemented.

Irrespective of SC activation, patients who arrived at the ED within 4.5 hours of stroke onset were identified. Demographic data (age and gender), medical history and vascular risk factors including hypertension, diabetes mellitus, atrial fibrillation, ischemic heart disease, valvular heart disease, and smoking were recorded. Initial stroke severity was assessed by the NIHSS. Acute ischemic stroke patients who received IV r-tPA were extracted from the registry and specially encoded in another database. The important time points, which includes stroke symptoms onset (onset time), presentation to the ED (door time), neuroimaging (CT time), and bolus IV r-tPA administration (needle time), were all specifically recorded by the nursing practitioner. Stroke characteristics and outcomes were recorded. Follow-up brain imaging by CT or magnetic resonance image was routinely performed 24 to 36 h after IV r-tPA administration to ascertain whether ICH had occurred; symptomatic ICH was defined as a neurological deterioration (NIHSS > 2 points) occurring within 36 hours and with no radiological findings that might have been responsible for this deterioration other than hemorrhage. Outcomes were assessed by the Modified Rankin Scale (MRS) score at discharge. Good outcome, when MRS score <3. We also analyzed for in hospital mortality.

We used informed consent form, consent form for IV r-tPA administration, NIHSS evaluation sheet, checklist for inclusion and exclusion criteria for IV r-tPA thrombolysis and patient information sheet to collect the data.

5. Data analysis:

The data on categorical variables is shown as n (% of cases) and the data on continuous variables is presented as Mean and Standard deviation (SD) if it is normally distributed else median (min – max) is used across two study groups. The inter-group comparison of categorical variables is done using Chi-square test / Fisher's exact probability test. The statistical significance of inter-group difference of mean of continuous variables is tested using unpaired OR independent sample 't' test for normally distributed variables and Mann-Whitney U test is used for comparing non-normally distributed variables across two study groups. The underlying normality assumption was tested before subjecting the study variables to 't' test. The entire data is entered and cleaned in MS Excel before it's statistical analysis. All the results are shown in tabular as well as graphical format to visualize the statistically significant difference more clearly.

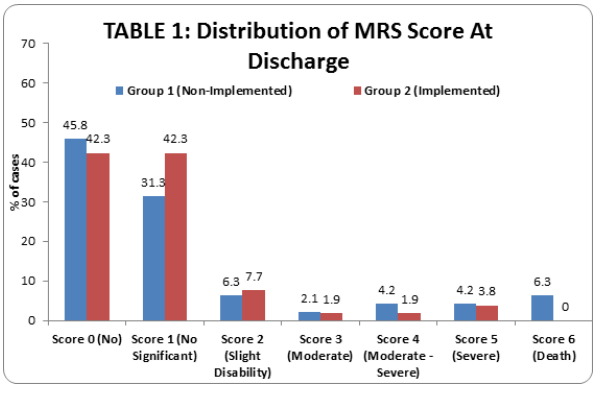
The p-values less than 0.05 are considered to be statistically significant. All the hypotheses are formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 16.0, Inc. IBM Corporation) for MS Windows.

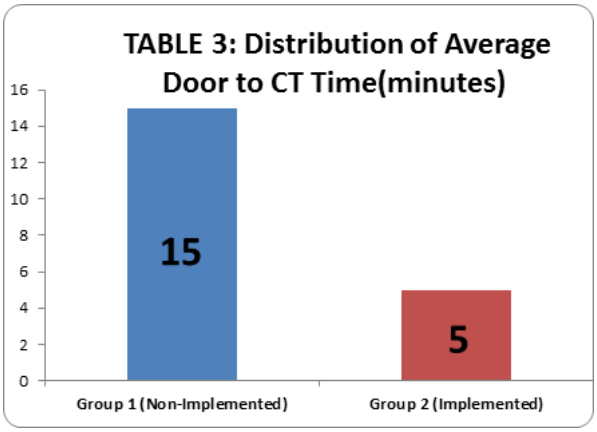
RESULTS:

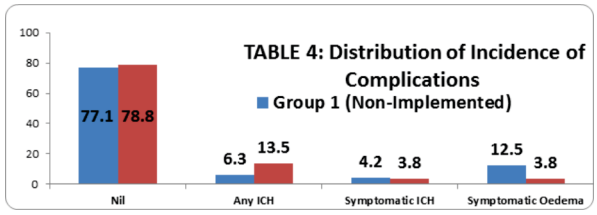
- In present study, we noticed that there was no significant

difference in age distribution between two groups. We also noticed that incidence of stroke increases significantly with age in both men and women.

- In present study, we noticed that majority of the patients were male in both the group. Stroke was more prevalent in male.
- 60 % of the patients had hypertension, 39% of the patients had diabetes, 21 % cases had history of past ischemic heart disease, 23 % of the patients were smokers, 13% of the patients had valvular heart disease, 16 % of the patients had AF and 11 % of total patient had CHF.
- The baseline vital parameters didn't show any significant difference in blood pressure, respiratory rate, heart rate and blood sugar level on the time of admission between two groups.
- Out of total patients, 15% of the patients had regional wall motion abnormality (RWMA), 1% of the patients had intraventricular clot, 9% of the patients had valvular abnormality and 7% patients had AF in 2D ECHO findings. Both the groups didn't defer in 2d echo finding.
- Out of total patients, 39% of the patients had been thrombolysed with CT SCAN findings showing no evidence of hemorrhage, 2% of the patients had malignant infraction, 31% of the patients had early signs of infraction, 21% of the patients had hyper dense MCA sign AND 7% of the patients had basilar dot sign.
- Out of total patients, 2% of the patients had involvement of anterior circulation, 76% of the patients had involvement of middle circulation and 22% of the patients had involvement of posterior circulation. Middle cerebral circulation was most commonly involved in acute ischemic stroke.
- In present study, there was a significant difference in DTNT in implementation and non-implementation group. For non-Implementation group mean DTNT was 37.5 min (28.2), median DTNT 28.0 min (10.0 – 120.0) and for implementation group mean DTNT was 21.2 min (11.9), median DTNT was 17.5 min (5.0 – 60.0).
- In present study, there was a significant difference in DTCT in implementation and non-implementation group. For non-Implementation group mean DTCT was 18.4 (15.9) min, median DTCT is 15.0 min (4.0 – 84.0) and for implementation group mean DTCT was 5.5min (4.1), median DTNT is 5.0 min (1.0 – 25.0).
- In present study, favorable outcome at discharge (MRS = 0, 1) increased from 37(77.08%) patients of non-implementation group to 44 (84.61%) patients of implementation group.
- There was no in hospital mortality of the thrombolysed patients with stroke in stroke code implementation group. Hence, reduction in in-hospital mortality.
- Mean NIHSS at discharge in our study for code stroke implementation group was 2.0 (3.76).
- In present study, there was reduction in symptomatic intracranial hemorrhage respectively from 4.2% to 3.8% in non-implementation group to implementation group.
- Our target in present study was to reduce door to CT scan time <25 minutes which has been achieved in 100% patients of code stroke implementation group.
- In present study, target was to keep door to needle time <60 min which has been achieved in 100% patients of code stroke implementation group.
- Results are tabulated in table 1to 4.







Conclusion:

Implementing strategies suggested by AHA/ASA to reduce door to needle time in a private tertiary care hospital, effectively reduced door to needle time for thrombolysis in acute ischemic stroke. It also improved the outcome of the patients by reducing NIHSS score and MRS score at discharge and also improved functional outcome at discharge.

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