Role of clinical predictors in determining the need for mechanical ventilation in patients with acute stroke and their outcome- A Prospective observational study

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ABSTRACT

Background: Stroke is the third leading cause of death in developed countries and the leading cause of long term disability. As the mortality during initial few days depends upon the compression of vital organs in brain stem due to raised intracranial tension and possible herniation, treatment for impending or early herniation requires intubation and mechanical ventilation and up to 10% of patients with acute stroke need mechanical ventilation due to different reasons. **Aims and Objective:** The aim of the study was to find the role of clinical predictors in determining the need for mechanical ventilation in patients with acute stroke and their outcome. **Materials and Methods:** This prospective observational cohort study was conducted from September 2017 to march 2019 of patients with acute stroke admitted either through OPD or Emergency/ Triage of Max super specialty hospital, Saket, New Delhi. Patients with acute Stroke defined as the presence of sudden onset of focal neurological deficit and admitted within 24 h of onset of symptoms with Age ≥18 years were included in the study. Patients already on ventilator support at the time of admission were excluded. **Results:** A total of 165 patients met the inclusion and exclusion criteria and were enrolled for the study. Out of 165 patients included in the study 43 (26.06 %) were put on the mechanical ventilation due to various reasons. Multivariate analysis of statistically significant and most clinically important variables showed the overall predictor accuracy of requirement of mechanical ventilation of 81.2% if the patients had loss of consciousness at the time of onset (OR = 0.076) and Glasgow Coma Scale (GCS) motor score of ≤ 5 (OR = 0.000). About 58.62% (17/29) patients who were put on ventilator support were found to have favorable outcome Modified Rankin Scale (MRS score ≤ 2) at discharge compared to 6.90% (2/29) before ventilation. **Conclusion:** We concluded that loss of consciousness at onset, GCS motor score ≤ 5 (OR = 0.000) were associated with overall predictor accuracy of 81.2% in determining the need for mechanical ventilation. We found overall in-hospital mortality rate of 9.1% whereas mortality rate in patients on mechanical ventilation was 32.55%.

Key words: Herniation; Ventilation; NIHSS; Predictors; GCS; Mechanical; Mortality

INTRODUCTION

Stroke is the third leading cause of death in developed countries and the leading cause of long term disability.[1] As the mortality in stroke during initial few days depends upon the compression of vital organs in brain stem due to raised intracranial tension and possible herniation, treatment for impending or early herniation requires intubation and mechanical ventilation and up to 10% of patients with acute stroke need mechanical ventilation due to different reasons.[2] The identification of such patients early on is also very important because delay in mechanical ventilation almost always leads to death within the

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next 24 to 48 hours.[3] The present study has the objective of identifying clinical factors which may help in predicting the requirement of support of mechanical ventilation in patients with acute stroke and evaluating the outcome of patients who require ventilator support.

MATERIALS AND METHODS

Study design
This prospective observational cohort study was conducted from September 2017 to march 2019 of patients with acute stroke admitted either through OPD or Emergency/ Triage of Max super specialty hospital, Saket, New Delhi.

Inclusion criteria
Patients with acute Stroke defined as the presence of sudden onset of focal neurological deficit and admitted within 24 h of onset of symptoms with Age ≥18 years were included in the study.

Exclusion criteria
Patients already on ventilator support at the time of admission were excluded.

One of the primary aims of the study was to find out the prediction accuracy of the predictors such as presence of loss of consciousness at the onset, progression of symptoms since onset, and GCS motor score ≤ to 5 at onset for ventilation requirement. According to study done by Gupta P et al [4], the prediction accuracy of these parameters was 88%. Considering an error of 5% on either side with 95% confidence level, our sample size came out to be 165. So we covered 165 cases in the study. The sample size was calculated by applying the following equation:

$$n = \frac{(Z^2\_(1\text{-}\alpha/2) * P * (1\text{-}p))}{d^2}$$

METHODS OF MEASUREMENT OF OUTCOME OF INTEREST

The predictor accuracy was measured for the following parameters:
a. Loss of consciousness at the onset
b. GCS motor score ≤ 5 at onset for ventilation requirement

Besides the above important parameters the other factors like age, headache, vomiting and comorbidities which may predict the requirement of mechanical ventilation were also considered for the analysis.

The need for the ventilation was defined by the following factors as per the standard guidelines for mechanical ventilation.

a. GCS
b. Respiratory rate
c. Arterial blood gas analysis (Spo$_2$,Pao$_2$ and Pco$_2$)

The outcome of the patients of acute stoke was analyzed for the mortality during the hospital stay and disability if any at the time of discharge by the modified Rankin Scale.

Data collection methods
For the purpose of the study the data was collected with regard to age, sex, headache, vomiting, loss of consciousness, seizures at the onset of symptoms, progression of symptoms since the onset - deterioration in sensorium or any neurological deficit, blood pressure, respiratory pattern, fever, Glasgow coma scale, ICH score, NIHSS score and other risk factors like diabetes mellitus, hypertension, etc. as mentioned in the Tables 1 and 2. All patients were followed up during their hospital course for their outcome till discharge.

Ethical consideration
This research was carried out in accordance with the Basic Principles defined ICMR 'ethical guidelines for biomedical research on human participants (2006)', CDSCO' guidance on good clinical practice for clinical research India. The study was conducted only after the approval by the Scientific and Ethics committees of the hospital participating in the study.

Statistical analysis
The predictive utility of parameters such as presence of loss of consciousness at the onset and GCS motor score ≤ to 5 at onset, was evaluated by running a logistic regression separately for cases requiring mechanical ventilation and for cases not surviving or surviving. Statistical significance of each predictor was assessed at 5% level and the odds ratio and their confidence intervals were obtained. These odds ratios would quantify the predictive utility of various parameters. SPSS 16 software was used for statistical analysis.

We have modified the binary logistic regression output by reversing the reference categories in the explanatory variables to come out from the confusion created by odds ratio 0. It was not exactly zero but very close to zero and when it was rounded by the software, it simply gave output for odds ratio as zero. Now we have reversed the reference category, to ease the interpretation of odds ratio and the modified output is given in Table 3 and Table 4. More over from Table 4, we have removed variables "Headache" and "SPO2" because of highly non-significant nature.

Table 1: Base Line parameters at the time of admission

	Mechanical Ventilation		P-value
	No (n = 122)	Yes (n = 43)	
Age (yrs)			
20-40	14 (11.48%)	7 (16.28%)	0.816
41-60	31 (25.41%)	12 (27.91%)	
61-80	53 (43.44%)	17 (39.53%)	
81-100	24 (19.67%)	7 (16.28%)	
Sex			
Male	83 (68.03%)	24 (55.81%)	0.147
Female	39 (31.97%)	19 (44.19%)	
LOC			
Present	28 (22.95%)	35 (81.40%)	**<0.05**
Absent	94 (77.05%)	8 (18.60%)	
Progression of symptoms			
Rapid	113 (92.62%)	40 (93.02%)	0.075
Slow	9 (7.38%)	3 (6.98%)	
Headache			
Present	23 (18.85%)	18 (41.86%)	**<0.05**
Absent	99 (81.15%)	25 (58.14%)	
Vomiting			
Present	17 (13.93%)	13 (30.23%)	**<0.05**
Absent	105 (86.07%)	30 (69.77%)	
Smoking			
Present	16 (13.11%)	5 (38.46%)	0.791
Absent	106 (86.89%)	38 (88.37%)	
Hypertension			
Present	101 (82.79%)	36 (83.72%)	0.888
Absent	21 (17.21%)	7 (16.28%)	
Diabetes Mellitus			
Present	53 (43.44%)	14 (32.56%)	0.206
Absent	69 (56.56%)	29 (67.44%)	
Type of Stroke			
Ischemic	104 (85.25%)	30 (69.77%)	**<0.05**
Hemorrhagic	15 (12.30%)	11 (25.58%)	
Venous	3 (2.45%)	2 (4.65%)	
Seizure			
Present	6 (4.92%)	12 (27.91%)	**<0.05**
Absent	116 (95.08%)	31 (72.09%)	
Dyslipidemia			
Present	41 (33.61%)	9 (20.93%)	0.123
Absent	81 (66.39%)	34 (79.07%)	
AF			
Present	24 (19.67%)	9 (20.93%)	0.859
Absent	98 (80.33%)	34 (79.07%)	
CAD			
Present	40 (32.79%)	17 (39.53%)	0.434
Absent	82 (67.13%)	26 (60.47%)	
Outcome			
Survived	121 (99.18%)	29 (67.44%)	**<0.05**
Died	01 (0.82%)	14 (32.56%)	
GCS Motor			
≤ 5	92 (75.41%)	43 (100%)	**<0.05**
>5	30 (24.59%)	0 (0%)	
GCS Motor Score at Intubation			
≤5	92 (75.41%)	43 (100%)	**<0.05**
>5	30 (24.59%)	0 (0%)	
MRS score at presentation			
1	34 (27.87%)	1 (2.33%)	<0.01
2	45 (36.89%)	1 (2.33%)	
3	33 (27.05%)	20 (46.51%)	
4	9 (7.37%)	19 (44.18%)	
5	1 (0.82%)	2 (4.65%)	
RR at Intubation	15.426±2.203	30.605±5.054	**<0.05 (Mann -Whitney)**
PO2 at Intubation	87.648±2.642	67.674±8.677	**<0.05 (Mann Whitney)**
SPO2 at Intubation	95.738±2.442	81.884±6.274	**<0.05 (Mann-Whitney)**

Table 2: Base Line parameters of patients who were on Mechanical Ventilation

	Died (n = 14)	Discharged (n = 29)	P-value
Age (yrs)			
20-40	2 (14.29%)	5 (17.24%)	
41-60	1 (7.14%)	11 (37.93%)	
61-80	8 (57.14%)	9 (31.04%)	
81-100	3 (21.43%)	4 (13.79%)	
Sex			
Male	8 (57.14%)	16 (55.17%)	0.896
Female	6 (42.86%)	13 (44.83%)	
LOC			
Present	13 (92.86%)	22 (75.86%)	0.357
Absent	1 (7.14%)	7 (24.14%)	
Progression of Symptoms:			
Rapid	13 (92.86%)	27 (93.10%)	0.526
Slow	1 (7.14%)	2 (6.90%)	
Headache			
Present	6 (42.86%)	12 (41.38%)	0.948
Absent	8 (57.14%)	17 (58.62%)	
Vomiting			
Present	7 (50.00%)	6 (20.69%)	0.076
Absent	7 (50.00%)	23 (79.31%)	
Smoking			
Present	0 (0.00%)	5 (17.24%)	0.262
Absent	14 (100%)	24 (82.76%)	
Hypertension			
Present	11 (78.57%)	25 (86.21%)	0.285
Absent	3 (21.43%)	4 (13.79%)	
Diabetes Mellitus			
Present	8 (57.14%)	6 (20.69%)	**0.018**
Absent	6 (42.86%)	23 (79.31%)	
Type of Stroke			
Ischemic	13 (92.86%)	17 (58.62%)	0.071
Hemorrhagic	1 (7.14%)	10 (34.48%)	
Venous	0 (0.00%)	2 (6.90%)	
Seizures			
Present	6 (42.86%)	6 (26.09%)	0.128
Absent	8 (57.14%)	23 (79.31%)	
Dyslipidemia			
Present	8 (57.14%)	8 (27.59%)	0.059
Absent	6 (42.86%)	21 (72.41%)	
AF			
Present	5 (35.71%)	4 (13.79%)	0.120
Absent	9 (64.29%)	25 (86.21%)	
CAD			
Present	7 (50.00%)	10 (34.48%)	0.318
Absent	7 (50.00%)	19 (65.52%)	
Hyperhomocystinenia			
Present	3 (21.43%)	8 (27.59%)	0.940
Absent	11 (78.57%)	21 (72.41%)	
MRS score at presentation			
1	0 (0.00%)	1 (3.45%)	0.834
2	0 (0.00%)	1 (3.45%)	
3	6 (42.86%)	14 (48.28%)	
4	7 (50.00%)	12 (41.37%)	
5	1 (7.14%)	1 (3.45%)	
RR at Intubation	31.929±3.240	29.966±5.617	**0.657(Mann-Whitney)**
PO2 at Intubation	61.786±1.739	70.517±9.239	**0.007 (Mann-Whitney)**
SPO2 at Intubation	780357±2.223	83.586±6.861	**0.022 (Mann-Whitney)**

RESULTS

A total of 165 patients met the inclusion and exclusion criteria and were enrolled for the study. About 134 patients had ischemic stroke, 26 patients had hemorrhagic stroke and remaining 5 patients were having venous stroke. Out of 165 patients included in the study 43 (26.06 %) were put on the mechanical ventilation due to various reasons.

Mechanical ventilation rate in case of hemorrhagic stroke was 42.3 % and in case of ischemic stroke it was 23.03%. The clinical parameters which were statistically significant in determining the need for mechanical ventilation included loss of consciousness at the time of presentation (p value <0.05), headache (p value <0.05), vomiting (p value <0.05), seizures at the onset and GCS motor score ≤5 (p value <0.05) as shown in Table 1. At the time of intubation we found significant correlation between certain clinical parameters e.g. increased respiratory rate 30.065 ± 5.054 (p value <0.05) Vs 15.426 ± 2.203, PO2 at intubation 67.674 ± 8.677 Vs 87.648 ± 2.642 (p value <0.05) and SPO_2 81.884 ± 6.274 Vs 95.738 ± 2.442 (p value <0.05) as shown in Table 2. Among the patients requiring the mechanical ventilation 21 (48.83%) were having MRS score of ≥4.

Multivariate analysis of statistically significant and most clinically important variables showed the overall predictor accuracy of requirement of mechanical ventilation of 81.2% if the patients had loss of consciousness at the time of onset (OR = 0.076) and GCS motor score of ≤ 5 (OR= 0.000) as shown in Table 3. Clinical parameters which showed 100% predictor accuracy in determining the need for mechanical ventilation are shown in Table 4.

The LOC is statistically significant as p-value<0.001 while controlling GCS. LOC (GCS motor score ≤ 5) has 13.125 times more risk as compared to LOC (GCS motor score ≥ 5) for getting ventilator support. The variable GCS is statistically non-significant with p-value 0.998

While controlling RR and PO2, LOC (GCS motor score ≤ 5) has 50.274 times more risk (Odds ratio=50.274) as compared to LOC (GCS motor score ≥ 5) for getting ventilator support. The variable RR is also statistically significant with p-value <0.05. A Unit increase in RR will cause 2.273 times risk for getting ventilator support (Odds ratio 2.273). Unit increase in PO2 will cause 0.508 times risk for getting ventilator support (Odds ratio 0.058) Table 4.

Among 43 patients who required the mechanical ventilation, the mortality was 32.55% and majority of the patients (78.57%) were in the age group of 60 years and above and were having increased percentage of diabetes mellitus (p value 0.018). Majority of the patients who were put on mechanical ventilation were having MRS score of ≥3 (p value < 0.01) as shown in Table 1. The average duration of the patients on ventilator was 13.07 days with a standard deviation of 7.86 days.

Out of 32 patients of the ischemic stroke who were put on mechanical ventilation 13 (40.06%) expired while as rest were discharged. Among the patients of ischemic stroke mortality rate was 53.84% (7 patients) in patients having NIHSS score between 6 to13 and mortality was 0% in patients with an NIHSS score of 5 (P value 0.346). Among 11 patients of hemorrhagic stroke who were put on mechanical ventilator 1 (9.09%) patient expired while as rest of the patients were discharged after extubation as shown in Table 5. Among 29 patients who required mechanical ventilation and survived, improvement in the MRS was observed as 6 (20.69 %) patients achieved MRS of 1 at discharge as against 1 (3.45%) patient before ventilation. Similarly 11 (37.93%) patients achieved MRS 2 at discharge as compared to 1 patient (3.45%) before ventilation. In other words taking the MRS score of ≤ 2 as favorable outcome, 58.62% (17/29) patients who were put on ventilator support were found to have favorable outcome at discharge compared to 6.90% (2/29) before ventilation. Out of 29 patients 48.28% patients were having MRS 3 which decreased to 34.48% at the time of discharge thereby showing a trend towards improvement

Table 3: Overall predictor accuracy in all stroke patients

Parameters	B	S.E.	P-value	Odds Ratio	95% confidence interval (odds Ratio)		Predictor Accuracy
					Lower	Upper	
LOC (reference=2)	2.575	0.460	<0.001	13.125	5.328	32.329	81.2%
GCS_Intubation (reference=2)	20.006	6814.57	0.998	28.04	1.67	469.62	
Constant	-22.160	6814.57	0.997				

Table 4: Overall predictor accuracy of significant parameters in all stroke patients

Parameters	B	S.E.	P-value	Odds Ratio	95% confidence interval (odds Ratio)		Predictor Accuracy
					Lower	Upper	
LOC (reference=2)	3.917	2.515	0.119	50.274	0.363	6954.95	99.2%
RR	0.821	0.369	0.026	2.273	1.103	4.680	
PO2	-0.678	0.385	0.078	0.508	0.239	1.080	
Constant	36.813	27.841	0.186				

Table 5: Outcome of patients who were put on mechanical ventilator (ischemic and hemorrhagic stroke patients)

NIHSS Score (n=32)	Died (n=14)	Discharged (n=18)	p-value
≤5	0 (0%)	1 (5.56%)	0.346
6 to 13	8 (57.14%)	13 (72.22%)	
≥14	6 (42. 86%)	4 (22.22)	
ICH Score (n=11)	**Died (n=1)**	**Discharged (n=10)**	
1	0	0 (0.00%)	
2	0	3 (30%)	
3	1 (100%)	5 (50%)	
4	0	2 (210)	

Table 6: MRS score of the survived patients at the time of discharge

MRS score	Mechanical ventilation		P value
	No (n=122)	Yes (n=29)	
0	20 (16.39%)	0	
1	68 (55.74%)	6 (20.69)	
2	24 (19.67%)	11 (37.93%)	<0.05
3	9 (7.38%)	10 (34.48%)	
4	0	2 (6.90%)	
5	1 (0.82%)	0	

in the number of patients with better MRS after ventilator support (Table 2 and Table 6).

DISCUSSION

In this study we found that 15.75 % of patients were having hemorrhagic stroke and 84.25% patients were having ischemic and venous stroke. In other studies done in India up to 80% of strokes have been found to be ischemic in nature. Young stroke (age < 40 years) percentage was 21% in our study while as other studies have recorded young stroke percentage up to 10 to 15%.[5,6] The rate of mechanical ventilation (MV) in our study was 26.06% overall and for ischemic stroke patients it was 23.02 % while as in case of hemorrhagic stroke patients the rate of MV was 42.03%. This was in accordance with the similar study conducted by Gupta P et al.,[4] who reported a MV rate of 30.0 % overall in which they found a rate of mechanical ventilation of 16.0% for ischemic stroke and 55.8% for hemorrhagic stroke patients. In our study we found that presence of loss of consciousness at onset (OR = 0.076) and GCS motor score of ≤ 5 (OR = 0.000) were associated with an overall predictor accuracy of requirement of mechanical ventilator of 81.2%. For patients of the ischemic stroke the above factors showed a predictor accuracy of 84.9% for the requirement of mechanical ventilation. In case of hemorrhagic stroke patients LOC at the onset showed a predictor accuracy of 80.8% for the requirement of

mechanical ventilation. Gupta P et al [4] in their study had found a predictor accuracy of 90 % for requirement of mechanical ventilation if the patients had presence of LOC at the onset, progression of symptoms since onset and GCS motor score of ≤ 5. We have used only the GCS motor score in analysis as the GCS verbal score evaluation in aphasic patients result in patient being assigned a much lower verbal score which would give falsely low total GCS score. Other studies have acknowledged this fact and have reported that the motor component of GCS score accurately predicted outcome with nearly same accuracy as the total GCS score.[7,8]

In our study we found a predictor accuracy of 100% for the requirement of mechanical ventilation if the patients were having increased respiratory rate (p value <0.05), decreased PaO_2 at the time of intubation, decreased SPO_2 at the time of intubation, headache and loss of consciousness at the onset. We recorded an overall in- hospital mortality rate of 9.1% (15 patients out of 165 patient expired) which was in accordance with other studies who had also found an in-hospital mortality rates ranging between ~6%-9% for ischemic stroke patients and 22%-45% for hemorrhagic stroke patients.[9,10] The overall mortality rate in case of patients who required mechanical ventilation was found to be 32.55%. Higher age , low GCS motor score at the time of intubation, higher MRS ≥ 3 at presentation (p value < 0.01), diabetes mellitus (p value < 0.01) were poor predictors of mortality in univariate analysis. Gupta P et al had reported an overall mortality of 52% in patients of acute stroke who required mechanical ventilation. Most of the reported previous studies of intubated patients with stroke have reported a mortality of 49 to 93%. Mayer et al., reported overall mortality at 30 days as 60 % and it was 50% in patients with ischemic stroke and 71 % in patients hemorrhagic stroke.[11-14] We observed in our study that MRS score predicts the requirement for mechanical ventilation in case of ischemic stroke patients as majority of the patients who were put on mechanical ventilation were having MRS score of ≥ 3 (p value < 0.01). In our study we found a mortality rate of 34.14% (14/41) in patients with MRS ≥ 3 who were put on the mechanical ventilator compared to zero % (0/2) mortality in patients with MRS score ≤ 2. Mittal Saumya H et al., in their study have recorded more than 25% mortality (47/170) in patients who presented with MRS score of > 3.[15]

While taking the MRS score ≤ of 2 as favorable outcome, 58.62% (17/29) patients who were put on ventilator support were found to have favorable outcome at discharge compared 41.38% (12/29) who were having MRS score of ≥ 3 at discharge and hence were disabled. In a study conducted by Eva Schielke while observing the functional, cognitive and emotional long–term outcome of patients

with ischemic stroke requiring mechanical ventilation they found that of 33 surviving patients, nine (27%) had a good functional outcome (MRS 0–2).[16]

Limitations of the study

The limitations of our study was that we were having majority of the patients with the middle to upper socioeconomic status with less number of patients belonging to the lower socioeconomic status.

CONCLUSION

We concluded that loss of consciousness at onset, GCS motor score ≤ 5 (OR= 0.000) were associated with overall predictor accuracy of 81.2% in determining the need for mechanical ventilation. We found overall in-hospital mortality rate of 9.1% whereas mortality rate in patients on mechanical ventilation was 32.55%.

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