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Abstract

Keywords

► intracranial

aneurysms

 neurological outcome

aneurysmal rupture

mortality predictors

spontaneous SAHsubarachnoid

hemorrhage

Objective Spontaneous subarachnoid hemorrhage (SAH) is a neurological condition that causes significant morbidity and mortality. It is known to have regional differences in its incidence. Indian studies have shown conflicting results about the incidence of aneurysms as the cause of SAH, varying from 35% to 80%. The data available on the epidemiology of spontaneous SAH in the South Indian population are very few. Our study aims to describe the clinical profile of patients presenting with spontaneous SAH to the emergency department in a tertiary center in South India and describe the factors influencing the clinical outcome.

Materials and Methods The study included 75 patients diagnosed with spontaneous SAH in our emergency department. Demographic data, medical history, details about the first medical contact, clinical features at admission, complications during the hospital stay, and interventions underwent were recorded. The study participants were followed-up at 6 weeks after discharge from hospital to assess the neurological outcome based on modified Rankin Scale (mRS) score, using a 9-point questionnaire. **Results** Of the 75 patients with spontaneous SAH, the majority were females, and in the age group of 50 to 69 years. The median time to first medical contact was observed to be 2 hours; and SAH was diagnosed at the first medical contact only in 37% of the patients. Hypertension was the most common comorbid condition associated with SAH (53%). Almost 80% of the patients who underwent angiographic studies had aneurysmal SAH (aSAH). Hydrocephalus was the most common complication seen in 37% of the patients, followed by hyponatremia (28%) and vasospasm (25%). At the time of follow-up after 6 weeks, we found that 36% of the patients were having a neurologically favorable outcome with an mRS score of 0 to 2, 8% of patients were

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having moderate to severe disability (mRS 3 to 5) and were living a dependent life. The mortality rate (mRS 6) was observed to be around 50% (6% lost to follow-up). **Conclusion** We observed a relatively higher incidence of aneurysmal rupture among the patients with spontaneous SAH in our region. The misdiagnosis rate at first medical contact was higher. The mortality rate was observed to be around 50% at 6 weeks. Loss of consciousness at ictus, aneurysmal rupture, WFNS grades IV–V, hydrocephalus, vasospasm, hypernatremia, and delayed cerebral ischemia were found to be the mortality predictors in SAH.

Introduction

Subarachnoid hemorrhage (SAH) remains a significant cause of morbidity and mortality among the patients who present to the emergency department. It may either be traumatic or nontraumatic. Out of the nontraumatic causes of SAH, 85% of cases are due to rupture of aneurysms. Studies have shown that regional differences exist in the incidence of SAH and are high in certain countries such as Finland and Japan.¹ Indian studies have shown conflicting results about the incidence of aneurysms as the cause of SAH, varying from 35% to 80%, with lesser incidence of aneurysms having been reported in South India previously.²⁻⁴ Aneurysmal SAH (aSAH) is often associated with poor outcomes with a mortality rate as high as 50%.⁵ The data available on the epidemiology of spontaneous SAH in the South Indian population are very few. We conducted this study to describe the epidemiology of spontaneous SAH in our area and describe the clinical picture and factors influencing the outcomes in SAH.

Materials and Methods

Study Participants

This prospective observational study was conducted in the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry from February 2020 to January 2022, after obtaining approvals of the Institute Research Council and Institute Human Ethics Committee (JIP/IEC/ 2019/416 dated February 4, 2020). All patients who presented to the emergency department and were diagnosed with SAH by noncontrast computed tomography brain were included in the study. Patients with a history of significant traumatic head injury in the past two weeks (any demonstrable abnormality in the CT brain which required admission for more than 24 hours), those who had undergone previous intracranial surgeries, those who were known cases of intracranial vascular malformations or tumors, those with pre-existing significant neurological pathology unrelated to the present illness, and those who were less than 13 years of age were excluded from the study.

Study Variables

A detailed clinical history and the details about the first medical contact were obtained. A general medical and neurological examination was performed in all. The clinical severity of the patients was graded using the World Federation of Neurological Societies (WFNS) grading as either good grade (WFNS grades I–III) or poor grade (WFNS grades IV–V). The routine investigations performed for the patients such as complete blood count, renal function tests, blood sugar, and coagulation studies were collected. Details obtained from the specialized neuroimaging studies done such as CT scan, CT angiography, MR angiography, and 4-vessel digital subtraction angiography were also noted with the assistance of the radiologist. The interventions done in the patients were recorded. The patients who got admitted were observed until discharge. Complications such as rebleeding, hydrocephalus, hyponatremia, and vasospasm were recorded. The neurological outcome was assessed using the modified Rankin Scale (mRS) at the time of discharge and 6 weeks after discharge during follow-up through a telephonic call, and a 9-point questionnaire was used to assess the mRS. A favorable neurological outcome was defined by an mRS score of 0 to 2 and an unfavorable neurological outcome was defined by an mRS score of 3 to 6.

Statistical Analysis

All independent continuous variables are expressed as median with range and all independent categorical variables and outcome variables are expressed in frequencies and percentages. The association between the independent continuous variables and the outcome variables (neurological outcome and mortality) were assessed using the Mann-Whitney *U* test. The association between the independent categorical variables and the outcome variables were assessed using the chi-square test or Fisher's exact test. All statistical analyses were carried out at a 5% level of significance. The data were analyzed using the SPSS software version 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp).

Results

We studied 75 patients with spontaneous SAH during a period of 2 years from February 2020 to January 2022, out of which 20 patients died in the hospital; 50 patients were followed up at 6 weeks after discharge from the hospital. Their neurological outcome and mortality at 6 weeks were recorded; 5 were lost to follow-up.

Characteristic	Frequency (%) (<i>n</i> = 75)	Characteristic	Frequency (%) (<i>n</i> = 75)
Gender		First symptom at ictus	-
Male	32 (43)	Headache	40 (53)
Female	43 (57)	Loss of consciousness	25 (33)
Age (years)	55 (18–85) ^a	Light-headedness	4 (5)
Risk factors/comorbid conditions		Vomiting	3 (4)
Hypertension	40 (53)	Decreased sensorium	2 (2)
Smoking	18 (24)	Weakness	1 (1)
Diabetes mellitus	18 (24)	WFNS grading	
Alcoholism	8 (11)	Grade I	32 (43)
Others		Grade II	8 (11)
Previous history of SAH	4 (5)	Grade III	6 (8)
Systemic rheumatic disease	1 (1)	Grade IV	21 (28)
Symptoms		Grade V	8 (11)
Headache	60 (80)	Admission status (based on WFNS grading)	
Neck stiffness	60 (80)	Good grade (WFNS I-III)	46 (61)
Loss of consciousness	48 (64)	Type of SAH	•
Decreased sensorium	48 (64)	Aneurysmal	46 (61)
Vomiting	48 (64)	Non-aneurysmal	12 (16)
Thunderclap headache	37 (49)	Not determined	17 (23)
Neck pain	24 (32)		
Previous similar symptoms (sentinel headaches)	22 (29)	1	
Dyspnoea	10 (13)]	
Seizures	9 (12)]	

Abbreviations: SAH, subarachnoid hemorrhage; WFNS, World Federation of Neurosurgical Societies. ^aMedian (range).

In all, 57% of our study participants were females, and 43% were males. The median age of the study population was 55 years with a range of 18 to 85 years. Also, 91% were from the districts of Tamil Nadu and 9% were from Pondicherry. Only 7% of patients had the study center as their first medical contact, while the remaining had presented to peripheral centers initially from where they were referred. The median time to first medical contact was 2 hours (range: 0.2–149 hours). The median time taken for the presentation to our emergency department from the time of ictus was 21 hours (**~Table 1**).

Headache was found to be the predominant symptom and neck stiffness was the predominant sign (80% each). The majority (61%) of our patients were in good clinical grade (WFNS I-III) at the time of admission (**-Table 1**).

Only 58 of the 75 patients included in our study underwent angiographic studies (CT angiogram/DSA/MR angiogram) to delineate the cause of SAH. Forty-six out of 58 patients (79.3%) were detected with either a single or multiple intracranial aneurysms in angiography and hence the rupture of the intracranial aneurysm was the most common cause of spontaneous SAH in the study population. Twelve patients had an angiogram negative for intracranial aneurysms and were found to have nonaneurysmal causes of SAH. Also, 23% of our study participants did not undergo angiographic studies and hence the cause of SAH among them remained undetermined.

Hydrocephalus was observed to be the most common complication, found in 37% of the patients. Hyponatremia was the second common complication, found in 28% of the patients, followed by vasospasm found in 25% of patients (**►Table 2**). Other complications included acute kidney injury, ventilator-associated pneumonia, shunt meningitis, sepsis, and multiorgan failure. Also, 27% of the patients were managed conservatively, 27% of the patients were surgically managed, 37% of the patients were referred to another center, and 9% of the patients were discharged against medical advice.

Further, 72% had a neurologically unfavorable outcome (mRS 3–6) at the time of discharge, whereas 57.3% had an unfavorable outcome at 6 weeks of follow-up. The mortality rate at 6 weeks was observed to be around 50% (27% died in hospital; 23% died at 6 weeks after discharge) (**►Table 3**).

Table 2 Complications in patients with SAH (n = 75)

Complications	Frequency (%) (<i>n</i> = 75)
Hydrocephalus	28 (37)
Hyponatremia	21 (28)
Vasospasm	19 (25)
Delayed cerebral ischemia	12 (16)
Seizures	11 (15)
Hypernatremia	9 (12)
Rebleeding	7 (9)
Cardiovascular compromise/ pulmonary edema	4 (5)
Others	14 (19)

Table 3 Outcome in patients with SAH (n = 75)

Characteristic	Frequency (%) (<i>n</i> = 75)
Neurological status at the time of	discharge
mRS 0-2	21 (28)
mRS 3–5	34 (45)
mRS 6	20 (27)
Neurological status at 6-week follo	ow-up
mRS 0-2	27 (36)
mRS 3–5	6 (8)
mRS 6	37 (50)
Mortality	
In-hospital mortality	20 (27)
Mortality at 6 weeks follow-up	17 (23)
Overall mortality	37 (50)

Abbreviation: mRS, modified Rankin Scale.

Discussion

We observed that SAH was more common among females compared to males, with females contributing about 57% of our study population and a male to female ratio of 1:1.3. The female preponderance of SAH in our region is contrary to the previous studies performed in parts of South India, in which males were contributing to the majority of the study population, but our observation is similar to that of the study conducted in North Indian and West African population.^{2–4,6} The median age of our study population was 55 years. Approximately half of the study population were in their fifth and sixth decades of life. These results are comparable with previous studies.^{3,5–7}

Thirty-nine percent of patients were misdiagnosed at their first point of medical contact, with an alternate primary diagnosis made, and were treated for the same. Hypertension and primary headache (migraine or tension headache) were the most common alternate diagnoses made at first medical contact (**~Table 4**). In our study, misdiagnosing SAH at first medical contact was found to be at a higher rate compared to

Table 4 Clinical profile of patients with SAH (n = 75)

Characteristic	Frequency (%) (<i>n</i> = 75)
Type of first medical contact	
Government district hospital	29 (39)
Private clinic	16 (21)
Primary health center	13 (17)
Private hospital	11 (15)
Our center	5 (7)
Others	1 (1)
At first medical contact, CT brain	
Done	31 (41)
Not done	44 (59)
Diagnosis arrived at first medical o	contact
SAH	28 (37)
No clear diagnosis	18 (24)
Hypertension	10 (13)
Primary headache	6 (8)
Cerebrovascular accident	5 (7)
Head injury	2 (3)
Hyperglycemia	1 (1)
Alcohol withdrawal seizures	1 (1)
Others	4 (5)

that reported in western literature.⁸ The gap in knowledge about the clinical and radiological profile of patients with spontaneous SAH prevalent in the region might explain the differences.

Fifty-nine percent of patients had not undergone computed tomography of the brain at their first medical contact, either due to low suspicion for the diagnosis of SAH or due to nonavailability of the facility at the center. Of the remaining who underwent CT (n = 31), 90% had been diagnosed with SAH, while in the remaining 10%, SAH was not the primary diagnosis made at first medical contact. About 24% of patients were referred to our center with no definite diagnosis made at first medical contact, because of the nonavailability of adequate facilities (**– Table 4**).

In our study, hypertension was observed in around half of patients with spontaneous SAH. Our findings are comparable to that of the previous studies on SAH conducted in the Asian as well as Western populations, in which hypertension was found to be the most common risk factor.^{2,3,7,9,10} Diabetes mellitus was observed to be prevalent in around one-fourth of our study population. This is contrary to the previous observations.⁵ A Korean study had even suggested that diabetes may be a protective factor for the development of SAH.¹¹ The majority of our study population was from Tamil Nadu and a small fraction was from Puducherry. The prevalence of diabetes in India has increased from 5.5% in 1990 to 7.7% in 2016, and Tamil Nadu has been reported to have had the highest prevalence of diabetes among the Indian states in

2016.¹² The incidence rate of diabetes in Puducherry has been reported to be 21.5 per 1000 person years.¹³ The higher prevalence and incidence of diabetes in our community might be the reason for our finding. Alcoholism was observed in around 24% of patients. Smoking is known to be a significant risk factor for the development of SAH, which has been emphasized in various studies previously.^{1,5,7,10,14} However, unexpectedly smoking was observed in a comparatively lesser proportion of our study participants (11%). This could be explained by the overall female preponderance in the study population and that the smoking rate among the female population is less in the region. Four of our patients (5.3%) had a previous history of SAH and presented with rebleeding from the culprit aneurysm. Chaturbedi et al have also reported a previous history of SAH in 4.4% of their study population, a finding similar to our study⁷ (\succ Table 1).

Headache was the most common symptom reported by 80% of our study population. Thunderclap headache was reported to be experienced by around half of our study participants. Sentinel headaches which are warning headaches were reported by around 30% of our patients. A systematic review of nine studies done in 2003 reported the incidence of sentinel headaches to be 10% to 43% among the patients with aSAH.¹⁵ Loss of consciousness at ictus was reported as a symptom by around 64% of our patients. In the study done in New York, loss of consciousness was reported in 40.4% of SAH patients at the time of ictus.¹⁶ In our study, 12% of patients had seizures at presentation. This is in concordance with the previous studies, in which onset seizures are reported to occur in 4 to 26% of SAH patients.¹⁷ Neck stiffness (neck rigidity) was the most common sign noted in our study (80%). Our results are similar to that of the study conducted in Kashmir, in which meningeal irritation was the most common sign seen in around 68.5% of all SAHs⁴ (►**Table 1**).

Sixty-one of our patients were in good clinical grade (WFNS I-III) and almost 43% patients had a GCS score of 15 and a WFNS grade of 1 at admission. This finding is comparable with the Kashmir study, in which almost 64% of patients with SAH were in good clinical grade (WFNS I-III) at admission.⁴ In the Kerala study, only 4% of the patients were in WFNS grade 5.² The variation in the neurological status of patients among different populations might be due to the regional differences in the accessibility to hospitals, local protocols in referral, mortality before reaching the hospital, as well as due to the different sample sizes (**-Table 1**).

Of the 58 patients who underwent angiographic studies, 79.3% were aneurysmal SAHs and 20.6% were nonaneurysmal SAHs. The results of our study are contrary to that of the previous study conducted in South India, in which only 35.4% of SAH patients who underwent four-vessel angiogram were detected with aneurysms.² However, studies conducted in the Northern states of India showed a higher incidence of aneurysmal SAH, which is comparable to the results of our study.^{3,4} Western literature also says the ruptured intracranial aneurysm to be the cause of around 75 to 85% of all spontaneous SAHs¹⁸ (**-Table 1**).

Hydrocephalus was the most common complication found in 37% of patients in our study. Twenty-seven percent

of our patients required extraventricular drainage, while the remaining 10% were managed conservatively. Our results are comparable to that of a study conducted in the Netherlands, in which 36% of 138 consecutive patients with SAH had acute hydrocephalus.¹⁹ Hyponatremia was the second common complication observed in 28% of our patients. In another study done among the SAH patients in Kerala, hyponatremia was observed in 37% of patients and it was also observed that hyponatremia was more common in patients with anterior communicating artery aneurysms.²⁰

We detected either angiographic vasospasm or transcranial doppler (TCD) vasospasm in 25% of our patients. Sixteen percent of patients developed delayed cerebral ischemia, which was defined by a neurological deterioration of the patient and cerebral infarction in the CT brain. In the Kashmir study, vasospasm was observed in 40.2% of patients with SAH.⁴ Rebleeding was reported in only 9% of our patients, which is lesser compared to the previous studies. In the Kashmir study, rebleeding occurred in 25.35% of SAH patients.⁴

However, since 37% of our patients were referred to a nearby center for interventional radiological procedures, mostly within 24 hours after presentation to our center, we could not capture the complications that could have occurred after referral. Hence the complications might be under-reported in our study (**-Table 3**).

All our patients received medical management for spontaneous SAH initially in the emergency department including anti-edema measures, anti-epileptics, and calciumchannel blocker (nimodipine) to prevent vasospasm. Twenty-seven percent of our patients were conservatively managed with the above-mentioned measures, which included patients who died in the hospital before any surgical intervention (12%), and the patients who were diagnosed with nonaneurysmal SAH.

Twenty-six percent of our patients underwent neurosurgical clipping for the intracranial aneurysm identified. Out of 46 patients who were diagnosed with aneurysmal SAH, 41.3% (n=19) underwent neurosurgical clipping in our center, 2.1% (n=1) was conservatively managed, 10.8% (n=5) died in hospital before surgical intervention, 34.7% (n=16) were referred, and 10.8% (n=5) discharged against medical advice.

A significant number of our patients (37%) were referred to another center nearby because our center lacked the facility for interventional radiological procedures (endovascular coiling for intracranial aneurysms). The practice of endovascular coiling for intracranial aneurysms is at low rates in South India and it has not been reported in previous studies for comparison. This emphasizes the need for expertise in interventional radiology for endovascular coiling procedures, given the higher incidence of aneurysmal SAH in our population. Currently, to promote endovascular treatment procedure, our center has a dedicated interventional radiologist and our DSA (digital subtraction angiography) laboratory is under installation, which will become operational soon.

The mortality rate in subarachnoid hemorrhage has been reported to be around 32 to 67%, based on the review of

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Risk factors Gender (female) Diabetes Hypertension Smoking	Mortality N (%)					
ors female) ision		<i>p</i> -Value	RR [95% CI]	Unfavorable outcome N (%)	p-Value	RR [95% CI]
female) Ision						
	20 (50%)	0.580	0.76 [0.29–1.98]	23 (57.5%)	0.436	0.67 [0.25–1.81]
	9 (50%)	0.778	0.85 [0.29–2.50]	13 (72.2%)	0.275	1.90 [0.59-6.13]
Smoking Alcoholism	20 (55.6%)	0.642	1.25 [0.48–3.20]	24 (66.7%)	0.354	1.57 [0.59–4.16]
Alcoholism	5 (71.4%)	0.434	2.42 [0.43-13.42]	6 (85.7%)	0.236	4.21 [0.47-37.13]
	10 (62.5%)	0.379	1.66 [0.53–5.23]	12 (75%)	0.204	2.22 [0.63–7.79]
Symptomatology						
Loss of consciousness	31 (68.9%)	< 0.001	7.01 [2.30–21.35]	33 (73.3%)	0.006	4.12 [1.46–11.64]
Decreased sensorium	30 (65.2%)	0.004	4.55 [1.56-13.26]	32 (69.6%)	0.053	2.70 [0.97–7.48]
Headache	25 (45.5%)	0.018	0.20 [0.05-0.82]	30 (54.5%)	0.023	0.18 [0.03-0.89]
Thunderclap headache	15 (42.9%)	0.094	0.44 [0.17–1.15]	18 (51.4%)	0.086	0.42 [0.15–1.13]
Neck stiffness	32 (58.2%)	0.087	2.78 [0.83–9.23]	37 (67.3%)	0.054	3.08 [0.95-10.0]
Sentinel headaches	12 (60%)	0.449	1.50 [0.52-4.29]	14 (70%)	0.351	1.69 [0.55–5.12]
Seizures	4 (44.4%)	0.726	0.67 [0.16–2.77]	4 (44.4%)	0.292	0.45 [0.11–1.85]
WFNS grade at admission						
Poor clinical grade at admission	22 (75.9%)	0.001	5.44 [1.88-15.75]	22 (75.9%)	0.037	5.57[1.46-21.14]
Type of SAH						
Aneurysmal SAH	25 (56.8%)	0.014	6.57 [1.28–33.61]	29 (65.9%)	0.011	5.80 [1.36-24.67]
Complications						
Rebleeding	5 (71.4%)	0.434	2.42 [0.43–13.42]	5 (71.4%)	0.699	1.64 [0.29–9.14]
Hyponatremia	7 (36.8%)	0.101	0.40 [0.13–1.21]	11 (57.9%)	0.711	0.81 [0.27–2.38]
Hydrocephalus	19 (70.4%)	0.020	3.29 [1.18–9.18]	21 (77.8%)	0.026	3.34 [1.12–9.90]
Vasospasm	15 (78.9%)	0.008	4.94 [1.43–16.98]	18 (94.7%)	< 0.001	18.72 [2.32–150.92]
Seizures	5 (45.5%)	0.592	0.70 [0.19–2.56]	5 (45.5%)	0.315	0.46 [0.12–1.69]
Hypernatremia	8 (88.9%)	0.030	8.82 [1.04–74.93]	8 (88.9%)	0.139	5.94 [0.69–50.50]
DCI	9 (81.8%)	0.036	4.98 [0.99–25.05]	11 (100%)	0.005	1.84 [1.45–2.33]
Time taken from ictus to ED presentation	ion					
\leq 12 hours	16 (69.6%)	0.022	3.36 [1.16–9.74]	17 (73.9%)	0.133	2.28 [0.76–6.83]
\leq 24 hours	24 (61.5%)	0.030	2.90 [1.09–7.73]	28 (71.8%)	0.046	2.71 [1.00-7.31]

population-based studies.²¹ We observed 50% mortality rate in our study population, which is comparable to the previous studies done in other parts of the world and this high mortality rate might probably be explained by the poor clinical grade (almost 40% of patients) at the time of presentation to our center.²² Almost 8% of those who survived at 6 weeks were dependent (**~Table 3**). In the Kashmir study, 15% of all SAHs had a good recovery, 20% had a moderate disability, 16% had a severe disability, 12.5% were in a vegetative state, and 37% of all SAHs died.⁴

In our study, patients with loss of consciousness as a symptom, poor clinical grade at admission with WFNS grades IV–V, rupture of the intracranial aneurysm as the cause for SAH, and those who were complicated by hydrocephalus, vasospasm, or delayed cerebral ischemia were found to be at a significantly higher risk for an unfavourable neurological outcome. (**-Table 5**) This finding is comparable to that of the previous studies on functional outcomes in SAH.^{3,14,23–25}

Patients with spontaneous SAH who had a loss of consciousness and/or a decreased sensorium as a symptom, poor clinical grade at admission with WFNS grades IV–V, rupture of the intracranial aneurysm as the cause for SAH, and those who were complicated by hydrocephalus, vasospasm, hypernatremia, or delayed cerebral ischemia were found to be associated with significantly higher mortality in our study. Similar mortality predictors in SAH have been reported in a previous study.²⁶ Patients who presented to our center within 24 hours from the time of ictus were also found to be associated with significantly higher mortality, which might signify the highest mortality rates during the initial hours after ictus in patients with SAH, which is not well documented in the previous literature.

Conclusion

We observed a relatively higher incidence of aneurysmal rupture among patients with spontaneous SAH in our region, compared to the previous studies conducted in South India. Headache was the predominant symptom in around 80% of patients with about 50% reporting thunderclap headache and around 30% had experienced sentinel headaches. Around 50% mortality was observed among the spontaneous SAH patients. Functional outcome at 6 weeks was good in around 36% of patients. Loss of consciousness at ictus, aneurysmal rupture, WFNS grades IV-V, hydrocephalus, vasospasm, hypernatremia, and delayed cerebral ischemia were found to be the mortality predictors in spontaneous SAH. The rate of misdiagnosis at the first medical contact was found to be higher compared with that reported in Western studies.⁸ This signifies the need for training physicians at primary health centers and peripheral hospitals for early and appropriate identification of SAH, which might improve the patient outcomes.

Limitations

Five patients were lost to follow-up. This study also was done during the period of lockdown due to the COVID-19 pan-

demic, which could have altered the findings of the study. We had a follow-up period of only 6 weeks though mRS disability scale is recommended at 90 days postdischarge to assess the neurological outcome.

Author's Contributions

Anuusha Subathra Sadasivam contributed to investigation, project administration, writing original draft, and analysis. Balamurugan Nathan contributed to conceptualization, writing, review, and editing, and supervision of the study. Sathia Prabhu Anbazhagan contributed to conceptualization, and writing, review, and editing.

Institutional Review Board Approval

The study was approved by the Institute Research Council and Institute Human Ethics Committee (Project No. JIP/IEC/2019/416 dated February 4, 2020).

Conflict of Interest None declared.

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