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A Prospective observational study on comparison of pharmacological management of acute ischemic stroke

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Abstract

Background:

Acute ischemic stroke (AIS) is a leading cause of disability and death worldwide. Timely and effective pharmacological intervention is essential to improve outcomes. This study aimed to evaluate and compare real-world pharmacological management strategies in patients with AIS.

Methods:

A prospective observational study was conducted at a tertiary care hospital involving 70 patients diagnosed with AIS. Data were collected on demographics, risk factors, stroke type, treatment modalities, neurological status (NIHSS), functional outcomes (mRS), and side effects.

Results:

Dual antiplatelet therapy (n=58), intravenous thrombolysis (n=24), and endovascular therapy (n=10) were commonly employed. NIHSS and mRS scores significantly improved in patients receiving thrombolytic or interventional treatment. Most strokes were of undetermined etiology (n=29). Common risk factors included hypertension (n=61) and diabetes (n=45). Gastritis and gum bleeding were frequent but manageable side effects.

Conclusion:

Early pharmacological intervention, particularly thrombolysis and DAPT, was associated with better short-term neurological and functional outcomes. Further multicenter studies are warranted.

Keywords: AIS, observational study, Dual antiplatelet therapy, thrombolysis and DAPT

Introduction

Acute ischemic stroke (AIS), a critical public health issue and one of the highest contributors to the incidence of mortalities and long-term disabilities across the world, is basically defined as a sudden stoppage of blood flow to the brain due to thrombotic or embolic occlusion in one of the arteries, which consequently leads to the necrosis or infarction of brain tissues. Rapid diagnosis and the initiation of therapeutics reduce the area of brain damage and can also better improve functional recovery. The burden of stroke is particularly great in low and middle-income countries because limitations on rapid access to care and standardized protocols for treatment are even more severe there.[1,2]

Pharmacological treatment of AIS has undergone various changes over the past few decades, with the introduction of thromlytic agents and their standardization to certain treatment windows. IV thrombolysis with rtPA still remains the key treatment for acute settings, especially when administered within 4.5 hours of the onset of the symptoms. EVT has also gained traction over the years as an active arm in selected patients with large vessel occlusion. Supplementary adjunctive therapy including antiplatelet agents, statins, and anticoagulants are routinely applied to reduce the occurrences of such events and to manage contributory risk factors.[3,4]

Despite such treatment options being available, practice worldwide remains variable concerning the choice and combinations of drugs used in an acute setting. The time of presentation, stroke severity, comorbidities, and institutional protocols all enter into the decision. However, there is a dearth of documentation available regarding the real-world effectiveness and safety profile of varying pharmacological regimens due to restricted settings outside clinical trial situations concerning different regions, particularly those settings where resources are limited. The great number of stroke cases in the country and a variety of healthcare infrastructures produces different challenges in stroke management. These challenges arise in early diagnosis, access to thrombolytic therapy, and the need for consistent follow-up to eventually raise the percentages of good outcomes. Observational trials reflecting routine clinical practices are helpful for understanding existing patterns for treatment and identifying gaps in care. They will also help to assess the feasibility and impact of different therapies in real-time scenarios.[5,6]

The prospective observational study comparing the pharmacotherapy treatment in patients suffering from acute ischemic stroke in a tertiary care hospital. Scoring clinical outcomes on NIHSS in mRS, observing side effects of treatments, will generate efficacy, safety, and trend inputs in stroke management. All these informations are anticipated to guide clinicians on the refinement of therapeutic strategies in stroke care delivery.[7,8]

Aim

This observational study aims to investigate the current practices of pharmacological management for AIS in a tertiary hospital setting.

Objectives:

1. To evaluate the utilization rates of different pharmacological interventions, including rt-PA, endovascular thrombectomy, antiplatelet agents, anticoagulants, and other relevant medications, in patients diagnosed with AIS.
2. To analyze the factors influencing treatment decisions, such as patient characteristics, stroke severity, time of presentation, and contraindications for specific therapies.
3. To assess the safety and efficacy of these pharmacological interventions in terms of treatment-related complications and patient outcomes, including mortality, functional disability, and discharge disposition.

Methodology

Ethical Approval: The study is conducted after the approval of institutional ethics committee

Study Site: This study was done in inpatient, neurology department at Lalitha Super Specialty Hospital, Old Guntur, Andhra Pradesh -522001.

Study Duration: The study was carried out for a period of 6 months i.e., from (October 2023-April 2024).

Sample Size: 70 samples

Study Design: Prospective, Observational, Comparative study

Study Criteria

Inclusion criteria:

a) Age from 18 to 80 years.
b) Patients diagnosed with ischemic stroke.
c) On set less than 1 week from symptom on set.

Exclusion criteria:

d) Less than 18 years and above 80 years.
e) On set greater than 1 week from symptom onset.
f) Patients diagnosed with hemorrhagic stroke.

Study Method

The study was a prospective observational cohort conducted at Lalitha Super Specialty Hospital, Old Guntur, from October 2023 to March 2024, focusing on patients with acute ischemic stroke. Participants who met the inclusion criteria were enrolled, and informed consent was obtained after explaining the study procedures. Data was collected through selective questionnaires via direct and indirect interaction with the patients. The information gathered was analyzed to evaluate the therapeutic outcomes of various treatments. The study aimed to identify the most effective treatment options that provided better outcomes for patients with acute ischemic stroke.

Statistical Analysis

All raw data was collected and entered into an Excel sheet. Statistical analysis was performed using SPSS software, with a paired t-test applied to determine the p-value. Descriptive summary statistics and graphical summaries were presented to provide a clear overview of the study's findings.

Results

1. PATIENT CHARACTERISTICS

Patient Characteristics		NUMBER OF SUBJECTS
Age	25-40	6
	41-55	28
	56-70	21
	71-80	15
Gender	Male	58
	Female	12
Risk factors	Hypertension	61
	Diabetes	45
	Dyslipidaemia	20
	Smoking	17
	Alcohol	16
	IHD/AF	3
	CKD	2
	Hypothyroidism	3

The study enrolled 70 patients, predominantly male (n=58), with the highest age group representation between 41–55 years (n=28). The most common risk factor was hypertension (87.1%, n=61), followed by diabetes mellitus (64.3%, n=45), while ischemic heart disease/atrial fibrillation and hypothyroidism were less frequently observed (each n=3).

2. TYPE OF STROKE OCCURRED TO THE SUBJECTS AND THEIR TYPE OF THERAPY

TYPES OF STROKES	SAPT	DAPT
1ST Stroke	9	38
Recurrent stroke	4	19

Among the patients, the majority experienced a first-time ischemic stroke, with dual antiplatelet therapy (DAPT) being the predominant choice (n=38) compared to single antiplatelet therapy (SAPT) (n=9). Recurrent strokes were also more frequently managed with DAPT (n=19) than SAPT (n=4), suggesting a clinical preference for dual therapy in both primary and recurrent cases.

3. TYPES OF THERAPY GIVEN TO THE STUDY SUBJECTS

TREATMENT	NUMBER OF SUBJECTS
IVT (Intravenous thrombolytic therapy)	24
EVT (Endovascular thrombolytic therapy)	10
SAPT	12
DAPT	58
STATINS	60
ANTI COAGULANTS	17

DAPT was the most commonly prescribed therapy (n=58), followed by statins (n=60) and IV thrombolytic therapy (IVT) (n=24). Endovascular therapy (EVT) was administered in 10 patients. Anticoagulants were used in a minority (n=17), and SAPT was comparatively less frequent (n=12).

4. THROMBOLYTIC THERAPY WITH SAPT&DAPT

TREATMENT	NUMBER OF SUBJECTS
IVT with SAPT	4
IVT with DAPT	20

Of the 24 patients receiving IVT, most were also treated with DAPT (n=20), indicating a synergistic approach to improve outcomes. Only 4 patients received IVT in combination with SAPT.

5. IVT Vs WINDOW PERIOD

WINDOW PERIOD	ALTEPLASE	TENECTEPLASE	AGRIBLOCK
within 1 hour	1	2	2
within 2 hours	1	5	1
within 3 hours	2	4	3
within 4 hours	0	3	0

Thrombolytic agents were administered within a range of 1 to 4 hours from symptom onset. Tenecteplase was more commonly used than alteplase or Agriblock across all time windows. Alteplase use was limited to within the first 3 hours, while Agriblock was used mostly within 1 to 3 hours.

6. DRUGS Vs WINDOW PERIOD

WINDOW PERIOD	A	B	C	D
4 HOURS	3	1	0	0
4 HOURS 21 MIN	0	0	2	1
5 HOURS	0	3	0	0
6 HOURS	0	0	1	3
6 HOURS 30MIN	0	2	1	0
7 HOURS	1	2	0	0
8 HOURS	3	3	2	3
8 HOURS 21MIN	0	2	0	0
10 HOURS 30MIN	0	2	1	0
24 HOURS	1	0	3	0
31 HOURS	0	2	0	0

Different drug regimens were used depending on the window period from stroke onset. Regimen A was more frequently used within the 4-hour window. Regimens B, C, and D were administered across various extended time periods, including up to 31 hours post-onset, reflecting tailored pharmacological choices based on the timing of presentation.

A - ecosprin -150 mg, clopidogrel-75 mg, cerecetum-15 ml

B - ecosprin-150 mg, clopidogrel-75 mg, cerecetum-15 ml, atorvastatin-80 mg

C - ecosprin-150 mg, clopidogrel-75 mg, cerecetum-15 ml, leviteracetam-250 mg

D - ecosprin-150 mg, clopidogrel-75 mg, cerecetum-1 ml, leviteracetam-250mg, atorvastatin-80mg.

7. NIHSS WISE DISTRIBUTION AT THE TIME OF ADMISSION

NIHSS	NUMBER OF SUBJECTS
NO STROKE (0)	0
MINOR STROKE (1-4)	9
MODERATE STROKE (5-15)	60
MODERATE TO SEVERE STROKE (16-20)	1
SEVERE STROKE (21-42)	0

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Most patients had moderate stroke severity at admission, with 60 patients scoring between 5 and 15 on the NIHSS scale. Nine patients had minor stroke severity (NIHSS 1–4), and one patient had moderate-to-severe stroke (NIHSS 16–20). No patients were classified as having severe stroke or no stroke symptoms.

8. DISTRIBUTION OF NIHSS FOR VARIOUS TREATMENT OPTIONS

TREATMENT	NIHSS DURING ADMISSION	NIHSS DURING DISCHARGE
ALTEPLASE	8	1
TENECTEPLASE	7	2
AGRIBLOCK	7	3
EVT	6	1
DRUGS	6	4

All treatment modalities were associated with reduced NIHSS scores at discharge. Alteplase showed a reduction from 8 to 1, Tenecteplase from 7 to 2, Agriblock from 7 to 3, and EVT from 6 to 1. Patients managed with drugs alone had a reduction from 6 to 4, suggesting clinical improvement across all treatments.

9. MRS SCORE WISE DISTRIBUTION

MRS SCALE SCORE	FREQUENCY
MRS 1	0
MRS 2	26
MRS 3	22
MRS 4	15
MRS 5	7
MRS 6	0

The majority of patients had moderate disability at discharge. The most common mRS scores were 2 (26 patients) and 3 (22 patients). Fifteen patients had a score of 4, and seven patients had a score of 5. No patients had a score of 1 or 6.

10. DISTRIBUTION OF MRS FOR VARIOUS TREATMENT OPTIONS

TREATMENT	MRS DURING ADMISSION	MRS DURING DISCHARGE
ALTEPLASE	3	0
TENECTEPLASE	3	1
AGRIBLOCK	2	1
EVT	3	1
OTHER DRUGS	3	2

Functional outcomes improved across treatment groups. Patients receiving alteplase improved from an mRS of 3 at admission to 0 at discharge. Those treated with Tenecteplase and EVT improved from mRS 3 to 1. Other therapies resulted in smaller improvements, such as mRS 3 to 2.

11. TOAST CLASSIFICATION OF STUDY SUBJECTS

TOAST CLASSIFICATION	FREQUENCY
1 (large-artery atherosclerosis)	6
2 (cardio embolism)	11
3 (small-vessel occlusion)	15
4 (stroke of other determined etiology)	9
5 (stroke of undetermined etiology)	29

The most common stroke subtype was of undetermined etiology (29 cases). Small-vessel occlusion was observed in 15 patients, cardioembolism in 11, other determined etiology in 9, and large-artery atherosclerosis in 6.

12. SIDE EFFECTS

Side Effect	Frequency
Gum bleed	28
Gastritis	33
Diarrhoea	17
Loss of appetite	6
Nausea	12
Insomnia	4
None	16

The most frequently reported side effects were gastritis (33 cases) and gum bleeding (28 cases). Other side effects included diarrhea (17), nausea (12), loss of appetite (6), and insomnia (4). Sixteen patients did not report any side effects.

Discussion

The study observed a higher incidence of ischemic stroke in males, with the most affected age group being between 41 and 55 years. These findings are consistent with previous literature, where male sex and middle to older age are established risk factors for stroke. Hypertension and diabetes emerged as the most common comorbidities, highlighting their critical role in stroke pathogenesis and the need for better primary prevention strategies.

Dual antiplatelet therapy (DAPT) was the most frequently administered treatment, particularly in patients with both first-time and recurrent strokes. This aligns with current stroke guidelines that recommend short-term DAPT for secondary prevention in selected patients. Intravenous thrombolysis (IVT) and endovascular therapy (EVT) were administered based on clinical eligibility and time of presentation. The study noted higher utilization of Tenecteplase compared to Alteplase, likely due to its bolus administration convenience and emerging evidence of non-inferiority. Agriblock was used within earlier therapeutic windows, although its role in stroke management warrants further investigation.

The therapeutic window played a critical role in the choice of thrombolytic agent. Most patients receiving Tenecteplase and Alteplase were treated within 3 hours of symptom onset, which is in concordance with established recommendations for optimal benefit. The variation in drug regimens (A through D) based on time intervals demonstrates tailored approaches, possibly reflecting efforts to balance efficacy and safety depending on the delay in presentation.

Improvements in NIHSS scores across all treatment modalities indicate neurological

recovery, with thrombolytic therapies (Alteplase, Tenecteplase, EVT) showing the most marked reductions in NIHSS scores from admission to discharge. This reinforces their efficacy in acute stroke management. Furthermore, Modified Rankin Scale (mRS) outcomes suggest that most patients achieved moderate functional independence by discharge. Notably, patients treated with thrombolysis or EVT achieved better mRS outcomes compared to those managed conservatively, emphasizing the importance of timely and appropriate intervention.

According to the TOAST classification, a substantial number of patients were categorized under stroke of undetermined etiology. This could reflect limitations in diagnostic work-up, delayed presentation, or multifactorial causation. Small-vessel occlusion and cardioembolic strokes also comprised a significant portion of the cohort, underscoring the need for individualized evaluation and long-term secondary prevention strategies.

The most commonly reported side effects were gastritis and gum bleeding, which are known complications of antiplatelet therapy. The absence of major adverse events such as intracranial hemorrhage indicates a relatively safe pharmacological profile in the cohort studied. Notably, 16 patients did not experience any side effects, suggesting that stroke therapy can be well tolerated with appropriate monitoring.

Conclusion

In this prospective observational study, various pharmacological and interventional strategies were compared in the management of acute ischemic stroke. Dual antiplatelet therapy (DAPT), intravenous thrombolysis (IVT), and endovascular therapy (EVT) emerged as the most frequently employed treatments. Patients treated with IVT or EVT showed greater neurological improvement, as evidenced by reductions in NIHSS and mRS scores from admission to discharge. Timely administration of thrombolytics, particularly within the first 3 hours, significantly influenced outcomes. Hypertension and diabetes were the most common comorbidities, highlighting the importance of preventive care. The side-effect profile was manageable, with gastritis and gum bleeding being the most reported. These findings support the effectiveness and safety of early pharmacological interventions in acute stroke management. Larger, multicenter studies with extended follow-up are recommended to confirm these outcomes and guide future treatment protocols in varied clinical settings.

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