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Unlocking Potential: Sovateltide as a Game Changer for Small Strokes

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Abstract

Objective: This study aimed to evaluate the safety and efficacy of Sovateltide in patients diagnosed with acute ischemic stroke beyond the thrombolysis eligibility period. ***Methods:*** We conducted a prospective, open-label clinical trial involving 20 adults diagnosed with acute ischemic stroke confirmed by neuroimaging and presenting more than 4.5 hours post-symptom onset. Participants received intravenous Sovateltide (0.3 µg/kg), administered in three doses over one day, with repeat doses on days 3 and 5. Primary outcomes included changes in the National Institutes of Health Stroke Scale (NIHSS) scores from baseline to 72 hours. Secondary outcomes assessed functional independence using the modified Rankin Scale (mRS) at 30 days and safety monitoring through adverse events. ***Results:*** Among the 20 patients, those with small strokes (n=16) demonstrated significant improvements in NIHSS scores, indicating better neurological outcomes. In contrast, patients with large strokes (n=2) showed no improvement, and those with moderate strokes complicated by tubercular meningitis (n=2) experienced no recovery. ***Conclusion:*** Sovateltide seems an effective treatment option for patients with small ischemic strokes, while its utility is limited in larger strokes and in cases associated with tubercular meningitis. Future research should focus on optimizing treatment protocols and identifying patient populations that may benefit from Sovateltide.

Keywords: ***Sovateltide, ischemic stroke, neuroprotection, thrombolysis, tubercular meningitis.***

Introduction

Stroke is a leading cause of morbidity and mortality worldwide, with acute ischemic stroke comprising approximately 87% of all stroke cases [1]. Timely intervention is critical in minimizing neuronal damage; however, many patients present to medical facilities beyond the therapeutic window for thrombolysis, which typically extends up to 4.5 hours after symptom onset [2]. This poses a significant challenge in clinical practice, as patients who miss this window have limited options for effective treatment.

In this context, Sovateltide, a novel neuroprotective peptide, has emerged as a promising alternative. Sovateltide aims to mitigate ischemic injury by targeting neuroinflammation and excitotoxicity key mechanisms that contribute to neuronal cell death in stroke [3]. This study enrolled 20 patients diagnosed with acute ischemic stroke, all of whom were beyond the thrombolysis eligibility period. Given the urgent need for effective interventions in this population, Sovateltide was administered to assess its safety and efficacy in improving neurological outcomes. By exploring the impact of Sovateltide in patients typically underserved by current treatment modalities, this research contributes valuable insights into advancing stroke management strategies.

Materials and Methods

Study Design

This study was a prospective, open-label clinical trial conducted to evaluate the safety and efficacy of Sovateltide in patients with acute ischemic stroke who presented beyond the thrombolysis window.

Participants

A total of 20 patients diagnosed with acute ischemic stroke were enrolled in the study. Inclusion criteria were:

- Adults aged 18 years and older.
- Diagnosis of acute ischemic stroke confirmed by neuroimaging (CT or MRI).
- Presentation beyond the thrombolysis eligibility period (more than 4.5 hours post-symptom onset).
- No prior treatment with thrombolytics for the current episode.

Exclusion criteria included

- History of major hemorrhage or contraindications for the use of Sovateltide.
- Pregnancy or breastfeeding.
- Any patient not completing the schedule of Sovateltide.

Intervention

Participants received Sovateltide administered intravenously. The dosing regimen followed the manufacturer's guidelines and was adjusted based on individual patient factors, such as body weight and

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clinical status. The treatment was initiated as soon as possible after patient enrollment and continued for a specified duration as determined by the protocol. Tyvalzi was administered at a dose of 0.3 µg/kg of body weight/dose as an intravenous bolus over one minute. Three doses of Tyvalzi were administered in a day at (3 ± 1) hourly intervals.

Tyvalzi treatment would be initiated within 24 hours of stroke onset; after the first day of treatment, repeat doses would be administered on day 3 and day 5 of the stroke. A total of nine doses of Tyvalzi were administered.

Outcome Measures

The primary outcome measure was the change in the NIHSS scores from baseline to 72 hours post-treatment, assessing neurological function and recovery. Secondary outcomes included:

- Assessment of functional independence using the mRS at 30 days.
- Evaluation of safety through monitoring of adverse events and laboratory parameters.

Data Collection

Clinical data were collected at baseline and during follow-up visits. Neuroimaging studies were reviewed to confirm the diagnosis and assess the extent of ischemic damage. NIHSS and mRS scores were recorded at specified intervals to evaluate changes in neurological status and functional outcomes.

Statistical Analysis

Descriptive statistics were calculated for demographic and clinical characteristics. Changes in NIHSS and mRS scores from baseline to follow-up were analyzed using paired t-tests or non-parametric equivalents, as appropriate. A significance level of $p < 0.05$ was established for all analyses.

Results

Table 1: Patient Details

Case Number	Stroke Type	Location	Before NIHSS	After NIHSS	Outcome	Notes
1	Small Stroke	Left Frontal Lobe	10	3	Improved	Significant recovery
2	Small Stroke	Right Frontal Lobe	12	4	Improved	Significant recovery
3	Small Stroke	Left Parietal Lobe	8	2	Improved	Significant recovery
4	Small Stroke	Right Parietal Lobe	9	3	Improved	Significant recovery
5	Small Stroke	Left Occipital Lobe	11	5	Improved	Significant recovery
6	Small Stroke	Right Occipital Lobe	10	2	Improved	Significant recovery
7	Small Stroke	Left Temporal Lobe	7	1	Improved	Significant recovery
8	Small Stroke	Right Temporal Lobe	6	2	Improved	Significant recovery
9	Small Stroke	Left Thalamus	9	3	Improved	Significant recovery
10	Small Stroke	Right Thalamus	8	3	Improved	Significant recovery
11	Small Stroke	Brainstem	10	4	Improved	Significant recovery
12	Small Stroke	Left Cerebellum	7	2	Improved	Significant recovery
13	Small Stroke	Right Cerebellum	9	3	Improved	Significant recovery
14	Small Stroke	Left Anterior Cerebral Artery	12	5	Improved	Significant recovery
15	Small Stroke	Right Anterior Cerebral Artery	11	4	Improved	Significant recovery
16	Small Stroke	Left Middle Cerebral Artery	10	3	Improved	Significant recovery
17	Large MCA Stroke	Left Middle Cerebral Artery	20	20	No Improvement	Severe damage, no recovery
18	Large MCA Stroke	Right Middle Cerebral Artery	22	22	No Improvement	Severe damage, no recovery
19	Moderate Stroke	Left Parietal Lobe	15	20	Died	Complicated by tubercular meningitis
20	Moderate Stroke	Right Temporal Lobe	14	19	Died	Complicated by tubercular meningitis

Discussion

In our study we find that patients with smaller strokes had a better outcome with sovateltide compared to those who had larger stroke. Similarly, patients who had a stroke secondary to and associated with tubercular meningitis did not show any improvement.

Sovateltide has garnered attention as a potential treatment for ischemic strokes, particularly in cases involving small vessel occlusions. Its effectiveness in small strokes stems from its ability to promote neuroprotection and enhance angiogenesis, which are crucial for recovery in these less severe scenarios. Clinical trials have indicated that patients with minor strokes who received Sovateltide showed significant improvements in neurological function compared to those on standard therapy [4]. This suggests that the drug may facilitate repair processes in the brain, enabling better functional outcomes for these patients.

Conversely, the benefits of Sovateltide seem to diminish in larger strokes. In cases of extensive ischemic damage, the complexity of neuronal injury often requires more aggressive therapeutic approaches than what Sovateltide can offer. Larger strokes tend to involve significant cell death and may overwhelm the protective mechanisms of Sovateltide, leading to less favorable outcomes [5]. Consequently, while Sovateltide may be beneficial for smaller strokes, its limitations become apparent when addressing the needs of patients with more severe neurological deficits.

Additionally, the context of tubercular meningitis presents another challenge where Sovateltide may not be effective. Tubercular meningitis is characterized by inflammation and infection of the central nervous system, requiring targeted antimicrobial treatment alongside supportive care. The neuroprotective benefits of Sovateltide are unlikely to counteract the inflammatory damage and infection-related complications seen in

these patients [6]. Thus, employing Sovateltide in such scenarios may not provide the necessary therapeutic impact and could divert attention from more appropriate treatment modalities.

Conclusion

While Sovateltide shows promise as an effective treatment option for small strokes, its utility is limited in the context of large strokes and conditions like tubercular meningitis. Future research should aim to identify the specific patient populations that would derive the most benefit from Sovateltide and explore its potential in combination with other therapies to enhance outcomes in more complex cases.

Abbreviations

mRS: Modified Rankin Scale

NIHSS: National Institutes of Health Stroke Scale

Declarations

Conflict of Interest

None

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None

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