CLINICAL OUTCOMES OF INTRAVENOUS THROMBOLYSIS WITH ALTEPLASE IN PATIENTS WITH ACUTE ISCHEMIC STROKE: AN EXPERIENCE AT MUKHTAR A SHEIKH HOSPITAL, MULTAN

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ABSTRACT

Objective: To evaluate the safety and efficacy of intravenous (IV) alteplase in patients with acute ischemic stroke (AIS) and to assess the clinical and functional outcomes, time intervals and any complications associated with the treatment.

Methods: This observational retrospective study was conducted at Mukhtar A. Sheikh Hospital, Pakistan from January 2025 to December 2025. Patients aged ≥ 18 years old with AIS were included. Only patients who were treated with IV alteplase in a specific time window were included. Data was collected and analyzed using SPSS. The stroke severity was measured as NIHSS scores. Continuous outcomes were expressed as medians. Frequencies were used to express categorical variables. Mann Whitney U test and chi square test were used to determine the incidence of favorable functional outcomes among different categories.

Results: The study included 48 participants. The median age was 62 years (50 – 68.25). The baseline NIHSS score was 13 (10-17.75). The symptom onset to arrival time was 150 (120-180) mins. The NIHSS score significantly improved over time ($p<0.0001$). The functional outcome at 3 months was favourable for 37 (77.1%). The functional outcomes were significantly associated with age ($p=0.032$).

Conclusion: The IV administration of alteplase was associated with increased early neurological improvement and good safety outcomes.

Keywords: Acute Ischemic Stroke, Thrombolysis, Tissue Plasminogen Activator, Stroke.

INTRODUCTION

Acute ischemic stroke (AIS) is one of the most common causes of death and disability globally (1). The effects of AIS place a tremendous burden on both healthcare and society at large due to the socio-economic consequences incurred for patients in low and middle income countries (2).

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Restoration of blood flow to the brain as quickly as possible is the primary focus when treating patients suffering an AIS (3). As continued loss of oxygen to neurons happens when blood flow is reduced, the importance of rapidly restoring normal cerebral blood flow cannot be overstated. Administration of reperfusion therapy within an appropriate time frame has been established to be helpful, in improving the chance of functional disability at long term follow-up, as well as reducing the likelihood of developing a significant disability, such as paralysis, from AIS (4).

IV thrombolytic therapy, using alteplase (recombinant tissue plasminogen activator-tPA), is

the only approved and recommended treatment option for eligible patients who present with an AIS (5). There have been a number of randomized controlled trials, as well as a large number of registry and observational studies that have investigated the use of alteplase on the functional outcome of patients (including patients at high-risk for developing a hemorrhagic complication) when administered early in the course of an AIS (6,7). Therefore, careful selection of patients, following established therapeutic protocols and keeping treatment delays to a minimum will assist each physician in both maximizing the potential benefits and minimizing the potential risks of thrombolytic therapy.

The use of IV alteplase is known to be effective and safe from data obtained in clinical studies. However, the effectiveness of alteplase when used in practice varies from patient to patient based upon their characteristics, healthcare delivery systems, and speed of receiving treatment (8). In developing countries, patients often face barriers related to obtaining timely treatment, such as a delay in coming to the hospital, the inability to recognize stroke symptoms prior to arriving at an emergency room, and inadequate resources available to treat patients (9,10). Therefore, it is critical to aggregate and publish data from hospitals to aid researchers in obtaining a clear understanding of any practical issues with thrombolysis as well as its effectiveness in different health care delivery systems.

In Pakistan, insufficient data exists regarding the outcome of IV thrombolysis for patients with AIS, as most current literature consists of singular hospitals documenting their clinical experience with this treatment as well as associated complications and recovery rates. Assessing regional experiences with IV thrombolysis is essential to understand how quickly patients receive treatment, whether they experience early neurological improvement, how safe this treatment is, and what types of patients will benefit from treatment. This information will allow researchers to identify deficits in stroke care and develop methods to enhance the delivery of services. This research focuses on how safe and effective IV alteplase is for patients that develop AIS in the Mukhtar A. Sheikh Hospital located in Multan, Pakistan. The goal was to analyse clinical data to see how well patients did after receiving thrombolysis; looking for early neurological improvements, recovering functionally, and if there were any complications associated with the treatment. We also wanted to find out how long it took each patient from onset of symptoms until they received the treatment and see if there were any factors predicting their response to treatment (e.g., age, co-morbidities). Therefore, our study provides insight into the outcome of thrombolytic therapy in a resource-limited region.

MATERIAL/SUBJECTS/PATIENTS AND METHODS

Study Design and Setting

This retrospective observational study was carried out in Mukhtar A. Sheikh Hospital, Pakistan, over a period of twelve monthson patients aged 18 years and older with diagnosed ischemic stroke. The purpose of this study was to determine the clinical outcome of patients who were treated with alteplase used as the preferred first-line treatment for AIS through IV administration. The ethical approval was taken from the Ethical Approval Committee of Mukhtar A. Sheikh Hospital. Patient confidentiality was maintained by removing all patient identification information from the collected data before it was analyzed. Since this study was a retrospective observational study that used clinical data collected routinely, the requirement for informed consent was waived. This study was reported in accordance with the STROBE guidelines.

Study Population

Patients aged 18 years and older who were diagnosed with AIS and received alteplase as a treatment were included. The diagnosis for all patients who were treated byalteplasewas confirmed by neuroimaging. The patients who have been treated with IV alteplase within the appropriate therapeutic window of time (<4.5 hours) and have had available baseline clinical data were included. Patients were excluded from the evaluation that was missing baseline data and/or patients who did not receive thrombolytic treatment.IValteplase was given to consecutive adult patients who met inclusion criteria during the study period (48 total patients). As this study was observational in design, no formal sample size calculation was undertaken.

Data Collection

Data from clinic and demographic records were collected from the hospital's medical records system as well as the thrombolysis treatment log. The data that was collected included the following: age, sex, body weight, clinical characteristics related to their AIS. Stroke Severity was determined using the National Institute of Health Stroke Scale (NIHSS) at baseline (before treatment), two hours and twenty-four hours after the administration of alteplase. Time-related information regarding symptom onset, hospital arrival and time of onset to needle placement was also collected when available.

Thrombolysis Protocol

According to the standard guidelines for stroke management, IV alteplase was given at a 0.9 mg/kg body weight dosage. The treatment consisted of an initial bolus of 10% of the full dosage, and then an infusion of the rest of the dose over a period of 60 minutes. All patients had a baseline cranial neuroimaging completed prior to receiving alteplase treatment to ensure no intracranial bleeding was

present. Patients were closely observed for change in neurological status and possible adverse events after treatment.

Outcome Measures

Efficacy Outcomes

The principal efficacy outcome was neurological improvement as measured by the NIHSS assessment at two and 24 hours following alteplase treatment. A secondary outcome was evaluated via NIHSS used as surrogate outcome, at 30 days and three months including all available follow-up data. NIHSS 0 - 2 was classified as a favorable outcome, whileNIHSS ≥ 3 were deemed unfavorable outcomes. As modified Rankin Scale (mRS) was not measured, this surrogate NIHSS outcome was used to define functional outcome.

Safety Outcomes

The safety outcomes of this study included the incidence of intracranial hemorrhage (ICH), seizure activity, angioedema, and hospital death after administering IV alteplase. Symptomatic ICH was defined as any ICH detected on follow-up neuroimaging and associated with clinical worsening as noted in the medical records. Asymptomatic ICH was defined as any ICH seen on neuroimaging with no associated neurologic deterioration as documented in the medical record. The retrospective design of the study prevented the ability to apply the ECASS or NINDS criteria for classification of events in a uniform manner; therefore, event classification was made by each physician based upon the documentation in the medical and radiologic records.

Statistical Analysis

SPSS version 23.0 was used to conduct the statistical analysis of the data. Continuous variables were reported as either mean ± standard deviation (SD) or median with interquartile range (IQR) as appropriate. Categorical variables were reported as frequency and percentages (%).The change in NIHSS scores over time (baseline, at 2 hrs, and at 24 hrs.) was performed with the Friedman Test. When an analysis showed statistical significance, post hoc multiple pairwise comparisons were made with the Wilcoxon Signed-Rank Test and proper adjustment for multiplicity.

All functional outcome measures were categorized into favorable and unfavorable groups and the relationship between baseline demographic characteristics to the likelihood of achieving favorable outcomes was assessed using the Mann-Whitney U Statistics for Continuous Variables and Chi-square for Categorical Variables.

Additionally, exploratory analyses were undertaken to identify factors associated with therapy response and functional outcomes including age, baseline NIHSS score and time to thrombolysis. Because of the limited number of patients included in our analyses, the exploratory nature of these analyses should be emphasized. Analyses on missing data were performed using an available case approach; imputation of the missing data was not performed. A result was considered statistically significant when, $p < 0.05$.

RESULTS

Study Population and Baseline Characteristics

The total number of participants with AIS included in the study was 48. The median age of the participants was 62 years (50 – 68.25), and 31 (64.6%) patients were male. The median blood glucose at the time of presentation was 155 (115-217.75). The median symptom onset to arrival time was 150 (120-180) minutes, while door to imaging time was 20 (15-20) minutes and lastly the door to needle time was 40 (35-55) minutes (Table 1) (Figure 1). Diabetes as a risk factor was present in 22 (45.8%), HTN in 35 (72.9%), ischemic heart disease in 19 (39.6%), and current smoking in 8 (16.7%) of the participants (Table 2).

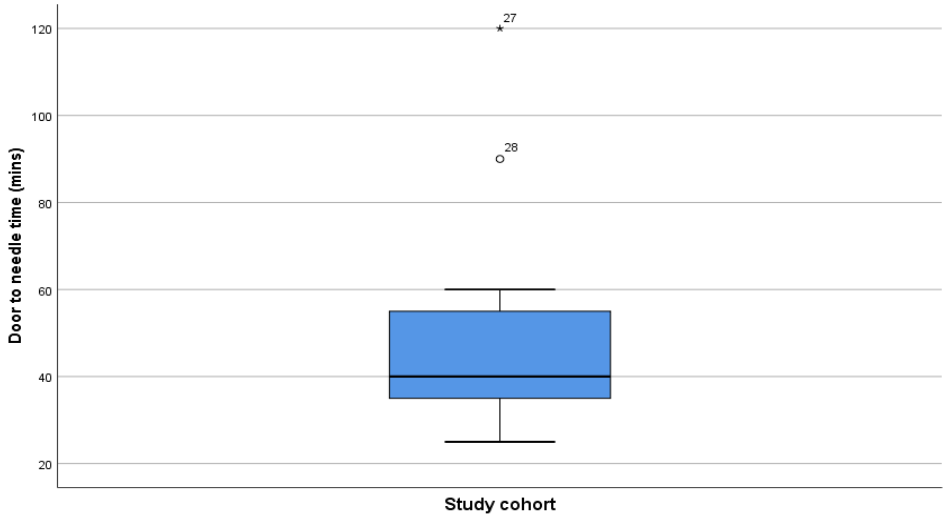
Table 1: Baseline characteristics of the included participants.

Variable	Median	Interquartile Range (IQR)
Age (yrs)	62	50 – 68.25
Random Blood glucose (mg/dL)	155	155-217.75
Onset to arrival time (mins)	150	120-180
Door to imaging time (mins)	20	15-20
Door to needle time (mins)	40	35-55

Table 2: Incidence of risk factors among the participants.

Risk Factors	n (%)
Diabetes	22 (45.8%)
Hypertension	35 (72.9%)
Ischemic heart disease	19 (39.6%)
Current smoking	8 (16.7%)

Figure 1: Box plot showing the median door to needle time in minutes.



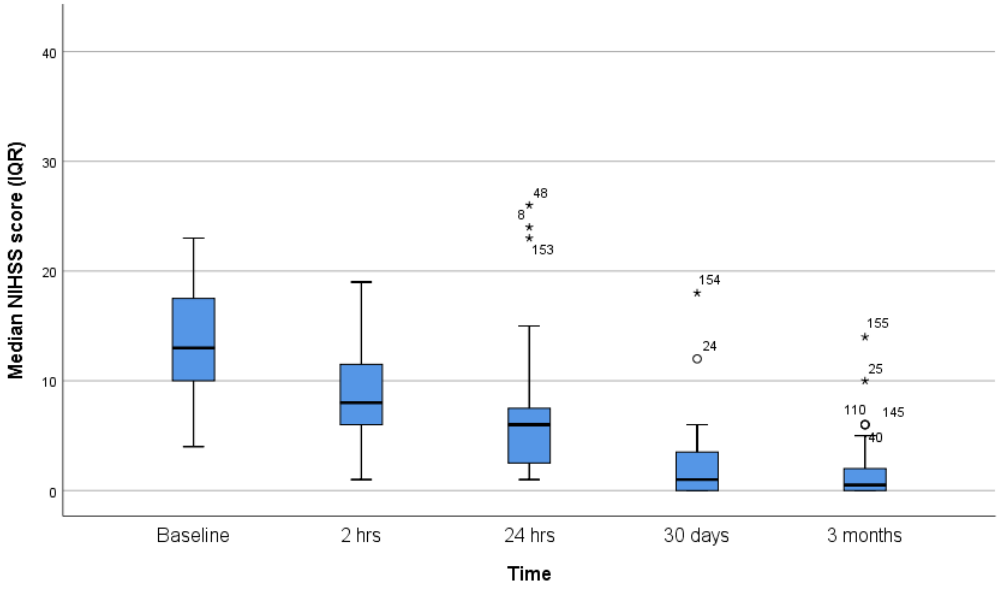
Neurological Outcomes Following Thrombolysis

The median NIHSS score showed a progressive improvement in the scores following IV alteplase treatment. The median NIHSS score was 13 (10-17.75) at baseline and decreased to 8 (6-11.75) and 6 (2.25-7.75) at the 2 hour and 24 hour marks after thrombolysis (Table 3), respectively. This improvement over time was statistically significant (p <0.0001) (Figure 2).Post-hoc pairwise comparisons showed that the differences between the baseline and the 2-hour; as well as the baseline and the 24-hour timepoints, were statistically significant (p <0.0001), while the difference between the 2-hour and the 24-hour timepoints was also significant (p <0.0001). Early neurological improvement, which was defined as a 4-point or greater decrease in the NIHSS score at 24 hours after administration of alteplase, occurred among 39 (81.3%) of patients treated.

Table 3: NIHSS scores of included participants at baseline, 2 hours and 24 hours.

NIHSS scores	Median (IQR)
NIHSS at baseline	13 (10-17.75)
NIHSS at 2 hours	8 (6-11.75)
NIHSS at 24 hours	6 (2.25-7.75)

Figure 2: Box plots showing NIHSS scores at baseline, 2 hrs, 24 hrs, 30 days and 3 months.



Functional and Safety Outcomes

Functional outcome results were assessed on the basis of the NIHSSas a surrogate via follow-up assessments at 3 months. The functional outcome at 3 months was favorable for 37 (77.1%) of patients, while 11 (22.9%) patients had a functional outcome that was not favorable.

Treatment related adverse events were rarely found. Among the patients treated, intracranial hemorrhage was present in 6 (12.5%). Among these 3 (6.25%) were symptomatic, with 1 having hemorrhagic conversion and 2 remained static. Seizures and angioedema both occurred in 1 (2.1%) patient, each. The in-hospital death occurred in 5 (10.4%) patients (Table 4). Age differed significantly between patients with favorable and unfavorable functional outcomes at 3 months, with patients achieving favorable outcomes being younger than those with unfavorable outcomes (p= 0.032). While, gender (p=0.52), diabetes (p=0.98) and HTN (p=0.45) were not found related to functional outcomes.

Table 4: Incidence of treatment related adverse events (safety outcomes) in included participants.

Treatment related adverse events	n (%)
Intracranial haemorrhage	6 (12.5%)
Seizures	1 (2.1%)
Angioedema	1 (2.1%)
In-hospital death	5 (10.4%)

DISCUSSION

The findings of the current study demonstrated that treatment with alteplase administered IV produced an early neurological benefit in patients suffering from AIS based on the results of the NIHSS scale over time. In addition to finding that many patients experienced an early improvement in their neurological status, we also found thatmore than half of the patients had favorable functional outcomes at 3 months. Our study has shown that the safety profile of IV thrombolysis with alteplase is similar to what has been shown previously.

Based on previous studies that have been conducted with larger clinical trial and registry databases, the results of this study support that alteplase is effective in providing rapid recovery of neurological function when used in AIS patients treated in a standard clinical environment (11,12), even though this study represents patients with limited resources. Time from symptom onset to initiation of treatment has been recognized as a critical factor in determining the efficacy of thrombolytic therapy. In this study, time periods between treatment initiation and reperfusion were generally consistent with those reported from studies of thrombolytic therapy in everyday clinical practice.

Safety outcomes of thrombolysis in this study are similar to findings from the literature. The rates of ICH, seizure activity, and death while hospitalized were similar to the known risk of IV alteplase. These data reinforce the concept that if alteplase is used according to the established guidelines, alteplase can be considered safe with an overall positive balance of risk versus benefit. No unforeseen adverse events occurred.

The efficacy of IV alteplase for treating AIS during the therapeutic window has been validated by many large RCTs from throughout the world with the assessment of improvement in neurological status and enhancement of functional outcomes for patients treated within the therapeutic time frame (13). They have reported high percentages of patients attaining full independence at 3-months post thrombolysis (14,15). Results from our investigation have revealed significant evidence for the improvement of neurological status after the initial treatment intervention. It is important to note that even though there are several differences between controlled trial environments versus the real-world application of a treatment regimen with limited financial resources, there remain a large percentage of patients who achieve an acceptable level of functional outcomes (NIHSS) within three months following treatment intervention. These conclusions are similar to those of the large trials performed using IV thrombolytic therapy(16).

Existing literature regarding the experience of IV thrombolysis within South Asian lower- and middle-income countries shows a varied range of results. Most studies describe the lower proportion of patients with some degree of functional recovery following thrombolysis compared to those from developed parts of the world(17,18). Though the majority of available data provide no clear statements regarding the quality of life or other long-term outcomes related to thrombolysis, they do indicate that neurological recovery can be realized at every region with acceptable safety profiles associated with thrombolysis. Although the findings from our study demonstrate relatively favorable functional outcomes as compared to previous studies in the region, thissuggests that reasonable functional recovery can be achieved, even in situations with limited resources. Poor hospital presentation times, limited availability of a structured stroke rehabilitation program, and inadequate follow-up are all cited as substantial impediments to the achievement of good functional recovery following thrombolysis in the region(19). These findings highlight that healthcare factors that

are experienced within a given context influence the outcome of thrombolysis beyond just the initial treatment period.

The known risk profile of IV alteplase has been established through international clinical trials and through extensive observational data from large-scale registry studies, which have documented mortality and intracranial hemorrhage rates (20,21). In general, the safety outcomes are also very similar in our patient group relative to these published reports; thus we support the external validity of using alteplase in this population. Despite some differences in patient demographics, health service availability and resources, we have not observed any excess or unexpected adverse events. Thus, we would suggest that thrombolysis can be safely delivered in similar settings when based on guideline-based protocol.

Numerous studies throughout the world have shown that age is a major factor affecting recovery after receiving thrombolysis (22,23). Our findings also support age as one of those important factors. We found no significant relationship between functional outcome and either sex, diabetes, or hypertension, which differs from results reported by many larger studies that have shown these variables to be associated with the outcome of thrombolysis (24,25). This difference likely relates to the smaller sample size used in our study, as well as differences between our study population and others' study populations.

The findings from this research study support both the efficacy and safety of IV alteplase in a tertiary care setting under conditions of limited resources. Since these results have been derived from real-world data, they can assist in the development of local stroke services, as well as reinforcing the need to have structured stroke pathways in place. There is still a need for larger, more prospective, multicenter studies to continue to examine what determines whether or not a patient will have a good outcome, and these studies would increase the generalizability of our findings.

There are limitations to this study; being an observational study from a single site with a small sample size limits the number of patients available for analysis, thus impacting generalizability. Because we used retrospective methods to collect data, it is possible there was an information bias related to the quality of the data collected. Due to absence of any control group, we cannot make any causal relationship regarding the effects of treatment on the outcome. Predictors should only be interpreted as potential hypotheses and not definitive conclusions. As mRS was not measured, functional outcomes were reported using a surrogate marker, NIHSS, which is a major limitation of this study. Even with all of these limitations, this study has provided important information about the outcomes of thrombolysis as they occur in everyday practice for actual patients.

CONCLUSION

In this observational study, IV administration of alteplase was associated with increased early neurological improvement while also exhibiting a reasonably good safety profile in AIS patients. A large proportion of patients also exhibited favorable long-term functional outcomes. This evidence supports the safe administration of IV alteplase in the setting of a tertiary-care hospital with limited resources as well as reinforces the need for timely administration of thrombolytic agents in patients being treated for an acute stroke. Furthermore, the observed association between early neurological improvement and long-term functional recovery underscores the need for comprehensive stroke care pathways that integrate evidence-based clinical practices, enhanced rehabilitation strategies, and effective secondary prevention measures alongside optimization of acute stroke management. Additional studies evaluating multi-center and prospected cohorts on larger numbers of patients will be needed to provide a greater understanding of factors predicting sustainable recovery after an initial period of function.

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