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ORIGINAL ARTICLE

Short-term Outcome in Ischemic Stroke Patients after Thrombolytic Therapy.

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ABSTRACT

***Objective*:** Recombinant tissue plasminogen activator (rt-PA, alteplase), as the primary thrombolytic agent, has been proved effective and beneficial in patients with acute ischemic stroke (AIS). This study aimed to predict the three months outcome of AIS patients who received thrombolytic therapy regarding mortality, symptomatic intracerebral hemorrhage (sICH) and functional outcome in comparison to non thrombolyzed patients.

***Patients and methods*:** This study included 80 patients with AIS who attended Zagazig University Hospital (ZUH) during the period from Feb 2016 to Feb 2018. Patients were divided into two groups; Group I included 40 AIS patients who received rt-PA within 4.5 hours from symptom onset. Group II included 40 AIS patients (as a control group) who received regular treatment, rather than rt-PA within the first 24 hours from symptom onset, they were selected to match group I as regard baseline data. Stroke severity was assessed by National Institute of Health Stroke Scale (NIHSS). Modified Rankin Scale (mRS) was used to measure 3 months functional outcome.

***Result*:** After 3 months follow–up, death rate was slightly higher among group I (7.5%) compared to group II (5%). 7.5 % of group I patients had sICH compared to 5% of group II patients, this difference was not statistically significant. More patients in group I had favorable outcome (mRS=0-2) than group II (65% vs. 60%, OR1.38, 95% CI 0.50-3.6, P 0.51).

***Conclusion*:** After 3 months follow up, rt-PA was more frequently associated with favorable outcome; however, it increased the risk of sICH and death compared to controls.

Keywords: Recombinant tissue plasminogen activator, AIS patients, alteplase.

INTRODUCTION

Acute ischemic stroke is among the most common causes of disability and death. About 16 % of the patients have fatal outcome and 20 % have serious long-term disability and left dependent on care-givers for their daily activity **[1,2].**

Recombinant tissue plasminogen activator (rt-PA), as the primary thrombolytic agent, has been proved effective and beneficial in patients with AIS and recommended by many guidelines worldwide **[3].** Alteplase was associated with reduced progression in lesion visibility 24 to 48 hours post treatment using brain CT or MRI **[4]**, however, large number of patients eligible for thrombolysis are currently not receiving rt-PA. The challenge on deciding IV rt-PA in any given patient involve weighing its risks and benefits **[5].** This study aimed to evaluate the three months outcome of AIS patients who received thrombolytic therapy regarding mortality, sICH and functional outcome in relation to non thrombolyzed patients.

PATIENTS AND METHODS

This retrospective study was concerned with all the data of the 43 acute ischemic stroke (AIS) patients treated with IV rtPA in the neurology intensive care unit (ICU) in Zagazig University Hospital (ZUH). All the data of AIS patients who attended ZUH and received thrombolytic therapy from February 2016 to February 2018 was analyzed retrospectively. The clinical, radiological and

laboratory data was obtained from the **www.sits.eu** and the **registry of ICU and Stroke Unit of ZUH.** The patients who received rtPA were diagnosed according to world health organization (WHO**)** criteria **[6].** The inclusion and exclusion criteria were used according to the AHA/ASA guidelines and IV treatment was within 4.5 of the onset of symptoms **[1].** One patient with missing data; without well documented on-site evaluation of examination and brain imaging and 2 patients with missing 3-months function outcome evaluation were excluded.

Clinical, radiological and laboratory data of AIS patients who received regular treatment within the first 24 hours, during the period from February 2016 to February 2018, were also obtained from the registry of ICU and Stroke Unit. 40 patients were included as a control group. They were selected to match the case group as regard age, sex and various risk factors of stroke. They were eligible for thrombolytic therapy according to the AHA/ASA inclusion and exclusion criteria **[1]**; however, they have received regular treatment because of attendance for imaging after 4.5 hours.

Clinical assessment included detailed medical history with special attention to past medical history to establish the presence of any risk factor; hypertension (HTN), diabetes mellitus (DM), dyslipidemia, smoking, obesity (identified by body mass index ≥ 30) **[7]**, previous transient ischaemic attacks, previous ischaemic stroke, atrial Fibrillation (AF) and other cardiovascular diseases. Complete general and neurological examination were reviewed including Glasgow Coma Scale (GCS) **[8]**, National Institute of Health Stroke Scale (NIHSS) **[9]** and stroke subtypes classified according to **TOAST** criteria **[10].**

Complete blood count, liver and kidney function test, random plasma glucose level, coagulation profile and lipid profile were reviewed.

All patients presented with cerebral stroke were subjected to Computed Tomography (CT) brain within the first 24 hours after stroke onset to exclude patients with stroke mimic or primary intracranial hemorrhage. The CT brain was evaluated for the presence of any of signs of early infarction **[11],** hyperdense middle cerebral artery (MCA) sign **[12]** and estimating the size of infarction according to the rules **[13]**. The size was classified as; small, medium and large **[14].** Magnetic Resonance Imaging (MRI) of the brain was done in suspected brain stem lesions, early ischemic stroke and when follow up CT brain is free. Cardiac evaluation including ECG and echocardiography were available.

The case and control groups were followed up for 3 months to assess mortality, sICH and short term functional outcome using the modified Rankin Scale (mRS). Scores on the mRS range from 0 (no symptoms at all) to 6 (death); a score of 2 or less indicates favorable outcome, 3-5 indicates unfavorable outcome (the patient is bedridden and incontinent and requires constant nursing care and attention) **[9].**

Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis: All data were collected and statistically analyzed using IBM SPSS 23.0 for windows (SPSS Inc., Chicago, IL, USA) and NCSS 11 for windows (NCSS, LCC, Kaysville, UT, USA) Continuous variables were expressed as the mean ± SD & median (range), and the categorical variables were expressed as a number (percentage). All tests were two sided. P-value < 0.05 was considered statistically significant (S), P-value < 0.001 was considered highly statistically significant (HS), and p-value > 0.05 was considered statistically insignificant (NS).

RESULTS

Baseline characteristics of both studied groups shown in table 1 shows no statistically significant differences between group I and group II as regards; age, sex, risk factors, clinical data, GCS, baseline NIHSS, subtypes of stroke and radiological findings.

Table 2 shows statistically non-significant increase of sICH among rt-PA group (group I) compared to control group (group II) (7.5% vs 5.0%, OR 1.524, 95% CI 0.252-9.21, p>0.05).

Table 3 shows that 65% of the alteplase patients had favorable outcome compared to 60% of the controls (OR 1.38). The death rate was higher in the alteplase group compared to controls (7.5% vs 5%, OR 1.52). However, these differences were statistically non-significant (P>0.05).

Table (1): Baseline characteristics of both studied groups.

Demographic and Clinical data:	Group I N=40	Group II N=40	Test	P value
Demographic data:				
Male sex (%)	55	55	X^2= 0.00	1.0

Demographic and Clinical data:	Group I N=40	Group II N=40	Test	P value
Age (Mean ±SD)	63.8 ± 11.8	64.9 ± 11.4	t = 0.424	0.672
Risk factors:				
Hypertension, n (%)	25 (62.5)	26 (65.0)	X^2 = 0.05	0.816
Diabetes Mellitus, n (%)	13 (32.5)	12 (30)	X^2 = 0.06	0.809
Hyperlipidemia, n (%)	14 (35.0)	13 (32.5)	X^2 = 0.05	0.813
Atrial fibrillation, n (%)	7 (17.5)	9 (22.5)	X^2 = 0.312	0.567
Current Smoking, n (%)	11(27.5)	9 (22.5)	X^2= 0.267	0.606
Previous stroke / TIA, n (%)	7 (17.5)	8 (20.0)	X^2= 0.082	0.775
Body mass index (Mean ±SD)	28.12 ± 3.8	28.15 ± 4.1	t = 0.03	0.978
Clinical data ;				
Laterality (Right), n (%)	19 (47.5)	19 (47.5)	X^2 = 0.000	1.0
Cranial nerve, n (%)	24 (60)	27 (67.5)	X^2 = 0.487	0.485
Incoordination, n (%)	8 (20)	7 (17.5)	X^2 = 0.082	0.775
Sensory affection, n (%)	23 (57.5)	20 (50)	X^2 = 0.453	0.501
Motor defecit, n (%)	29 (72.5)	30 (75.0)	X^2 = 0.07	0.799
Anti-hyperlipidemic drugs, n (%)	8 (20.0)	8 (20.0)	X^2 = 0.00	1.0
Previous antiplatelet, n (%)	7 (17.5)	6 (15.0)	X^2 = 0.09	0.762
Systolic B P (Mean ±SD)	146.8 ± 18.3	149.8 ± 20.1	t = 0.699	0.784
Diastolic B P (Mean ±SD)	91.3 ±13.4	90.8 ± 10.7	t = 0.184	0.854
Blood glucose (Mean ±SD)	131.9± 44.3	120.4 ± 28.4	t = 1.38	0.171
Admission GCS, range, (Mean ±SD)	11 – 15 (14.5 ± 0.93)	10 – 15 (14.6 ± 1.17)	t = 0.63	0.528
Admission NIHSS, range, (Mean ±SD)	3 – 21 (11.95 ± 5)	4 – 26 (11.88 ± 6.4)	t = 0.06	0.952
TOAST Stroke subtype n (%)				
large artery	16 (40.0)	15 (37.5)	X^2 =0.61	0.894
Cardioembolic	7 (17.5)	5 (12.5)		
small vessel	12 (30.0)	14(35.0)		
Others	5 (12.5)	6 (15.0)		
CT findings ;				
Size n (%)	6 (15)	7 (17.5)	X^2 =0.214	0.899
	21(52.5)	19 (47.5)		
	13(32.5)	14(35)		
Laterality (Right) n (%)	21(52.5)	21(52.5)	X^2 =0.00	1.0
Hyperdense MCA sign n (%)	9 (22.5)	9 (22.5)	X^2 =0.00	1.0

BP=blood pressure, GCS= Glasgow Coma Scale, NIHSS= National Institute of Health Stroke Scale, MCA= midle cerebral artery, P>0.05 =non-significant, x^2= Chi square, t=t test.

Table (2): Hemorrhagic transformation among both studied groups

ICH	Group I No	%	Group II No	%	X^2 Value	OR (95%CI)	P Value
Positive	3	7.5	2	5	0.213	1.524	0.644
Negative	37	92.5	38	95.0		(0.252-9.21)	

**P>0.05 nonsignificant, OR (95%CI): Odds ratio with 95% confidence interval, x^2= Chi square*

Table (3): Outcome at 3 months among both studied groups.

Outcome 3 months	Group I		Group II		X^2	OR (95%CI)	P value
	No.	%	No.	%			
Favorable (mRs ≤ 2)	26	65.0	24	60.0	0.64*	1.38 (0.53-3.6)	0.51
Unfavorable (mRs3-5)	11	27.5	14	35.0		0.71 (0.28-1.8)	0.52
Death (mRS= 6)	3	7.5	2	5.0		1.52 (0.25-9.2)	0.52

**P>0.05 nonsignificant, OR (95%CI): Odds ratio with 95% confidence interval, x^2= Chi square, mRS: modified Rankin Scale.*

DISCUSSION

Recombinant tissue plasminogen activator (rt-PA), as the primary thrombolytic agent, has been proved effective and beneficial in patients with AIS and recommended by many guidelines worldwide **[3].** Alteplase was associated with reduced progression in lesion visibility 24 to 48 hours post treatment using brain CT or MRI **[4]**, However, big number of patients eligible for thrombolysis are currently not receiving rt-PA. The challenge on deciding IV rt-PA in any given patient involve weighing its risks and benefits **[5].**

This study aimed to predict the three months outcome of 40 AIS patients who received thrombolytic therapy regarding; mortality, sICH and functional outcome in relation to non thrombolyzed 40 matched patients. There was no statistically significant difference between the patients who received rt-PA and those who received regular treatment as regard age, sex, regard risk factors; HTN, DM, hyperlipidemia, AF, current cigarette smoking, previous stroke and/or TIA and mean body mass index, clinical data, severity of stroke (NIHSS), level of consciousness (GCS), subtype of stroke (TOAST) or radiological findings (table 1).

The current study revealed that after 90 days a total of five patients died in both groups. The death rate was slightly higher among group (I) on alteplase (7.5 %) in comparison to group (II) (5%) (OR 1.52, 95%CI 0.25-9.2, P=0.5). Two patients in group (I) and one patient in group (II) died within the first seven days.

Our results agreed with results of **Hacke et al. [9]** as regard death rates. They reported that mortality did not differ significantly between alteplase and placebo groups. With the first week the death rates were 2.9 % in their alteplase group and 3.2 % in the placebo group. After 90 day follow up the death rates were 6.7 % and 7.7 % respectively. This agreement is due to nearly similar mean age of the patients included in their study (64.9 years) and our patients (63.8 years), the mean NIHSS of the patients (10.7 vs. 10.4) and the same time window of 4.5 hours. The analysis of SITS-MOST study **[15]** revealed a death rate of 15.5% among AIS patients who treated with intravenous thrombolysis (IVT) within 3 hours of stroke onset. A meta-analysis found that 8.9 % of patients allocated rt-PA and 6.4 % allocated control died within seven days. Data for total deaths by the end of follow up showed that 19.1 % allocated rt-PA and 18.5 % allocated control died. Their higher percentages may be due to heterogenicity of the analyzed studies and variability of the follow up periods **[16]**.

The IST-3 collaborative group [17] reported higher percentages of deaths among alteplase and control groups (27% in both groups), however their follow up period extended to six months. They found that more deaths occurred within seven days in the rt-PA group (11%) than in the control group (7%) but between seven days and six months there were fewer deaths in the rt-PA group than the control group. A more recent study **[18]** reported 9.26% death rate among IVT patients after 3 months follow up, however, with the exclusion of large vessel occlusion.

Chao et al. [19] reported 12.8 % mortality rate within three months among Chinese AIS patients who received standard dose of alteplase and suggested that reduction of the dose from 0.9 to 0.72 mg/Kg may reduce the mortality down to 6.9 %. It has been found that, in-hospital mortality (up to 10 days) was significantly higher in patients treated with IVT (8.7 %) in comparison to the controls (2.9 %). The mortality rate was not significantly different between the IVT patients and control (16.3 % vs. 11.8 %) at a three months follow up. The variation in mortality rates may be due to the difference in mean ages, initial NIHSS, the extended window in some studies as well as the extended time of follow up **[20]**.

Symptomatic intracerebral hemorrhage (sICH) is one of the major causes of an increase of > 4 points of NIHSS score from the baseline after thrombolysis **[3].**

This study found that hemorrhagic transformation occurred in 7.5 % of the patients in the alteplase group and in 5% of the patients who received regular treatment; however, this difference was not statistically significant.

Lower percentage of sICH (2.4 % for alteplase patients vs 0.2 % for placebo patients) have been reported **[9].** The rate of sICH in the current study is very close to the adjusted proportion of sICH in SITS-MOST. After 3 months follow-up, SITS-MOST sICH rate was 8.5% among AIS patients who treated with alteplase within three hours of stroke onset **[15].** We are also, in agreement with the results of **IST-3 [17]** which reported sICH in 7 % of the patients with thrombolysis and only 1 % among placebo group. Also, **Whiteley et al. [21]** found that 6.8 % of the patients treated with rt-PA had sICH by day seven.

In their meta-analysis **Emberson and his colleagues [22],** found that alteplase increased the likelihood of sICH. Type two parenchymal

hemorrhage within seven days occurred in 6.8 % of patients assigned alteplase versus 1.3 % of patients' assigned control. Fatal type two ICH within seven days occurred in 2.7 % in alteplase group versus 0.4 % assigned control. The average absolute increase in the early risk of fatal ICH of about 2 % remained by 90 days but no longer statistically significant. In two recent studies, after three months follow up from IVT, the rate of sICH varied between 3.4% and 14.2% **[18,23].**

Despite an increase in the rates of early sICH and deaths, treatment with intravenous rt-PA may improve clinical outcome at the end of follow-up. Our results demonstrated a statistically significant increase of favorable outcome after 3 months in comparison with the day seven of therapy in both alteplase and control groups. However, the comparison between the 2 studied groups revealed that more patients had a favorable outcome (mRS=0-2) in the rt-PA group than the control group (65% vs 60%, OR 1.38, 95% CI 0.50-3.6, P 0.51) by the end of 90 days. According to **wardlaw et al. [16]**, this deference is equivalent to 50 more patients per 1000 alive and with favorable outcome 3months after alteplase.

The first randomized study, **The National Institute of Neurological Disorders and Stroke (NINDS) in 1995 [24]** demonstrated that intravenous rt-PA was safe and effective in treating AIS within 3 hours of onset. The number of patients with favorable outcome three months after stroke was higher in the rt-PA group than in control group (39% vs 26% , OR 1.7, 95% CI 1.2-2.6). The favorable outcome in the NINDS trial was defined as mRS=0-1 which may explain its low percentages in both groups. **Hacke et al. [9]** also defined favorable outcome as ascore of 0-1 on mRS and reported that 52.4% of the patients in the altaplase group had favorable outcome as compared with 45.2% in those in placebo group, representing an absolute improvement of 7.2% (OR 1.34, 95% CI 1.02 -1.76).

Independency as defined by mRS of 0-2 at 3 months, in the SITS-MOST study, was 50.4% in AIS patients treated with intravenous alteplase within 3 hours of stroke onset **[15].** The Taiwan Thrombolytic Therapy for Acute Ischemic Stroke (TTT-AIS) study group **[19]** reported 48.7% of the patients who received standard dose had mRS of 0-2 at 3 months follow-up**.**

The IST-3 collaborative group [17] found that 37% of the patients in the rt-PA group versus 35% in the control group were alive and independent (OR 1.13, 95% CI 0.95-1.35, P=0.18) as measured by a commonly used variant of mRS 0-2, however the follow-up period extended to 6 months and 53% of the patients where older than 80 years of age. In a systematic review and meta-analysis results for 7012 patients, rt-PA significantly increased the odds of being alive and independent (mRS=0-2) at final follow up as 46.3% of rt-PA patients versus 42.1% of the control group had favorable outcome (OR 1.17, 95% CI 1.06-1.29, P > 0.001). However, in some patients IVT window was extended up to 6 hours after stroke onset and the follow up periods were variable **[16].**

In a recent study, at 3 months, high percentage of the patients (76.54%) had a favorable clinical outcome (mRS=0-2) and 23.46% of them had unfavorable outcome (mRS=3-6) after intravenous thrombolysis in ischemic stroke patients without large vessel occlusion **[18].**

Among the Egyptian patients, at 3 months from onset, 52% of the alteplase patients versus 48% of the control patients had favorable outcome with no statistical difference between both groups **[25].**

The limitations of our study were that it was performed in a single center; Zagazig University Hospital, in which a low number of AIS patients had received rt-PA. Besides the small number, all patients were less than 80 years old except for one patient who was above 80 years.

In spite of these limitations we can conclude that; after 3 months follow up, alteplase was more frequently associated with favorable outcome, however, it increased the risk of sICH and death compared to controls.

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