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ORIGINAL ARTICLE

Efficacy and safety of intravenous thrombolytic therapy in acute ischemic stroke: Predictors of good prognosis and outcomes of the elderly population

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ABSTRACT

Objectives: This study aims to evaluate the efficacy, safety, and complications of intravenous thrombolytic therapy (IVTT), identify the prognostic factors in treated patients, and assess outcomes in patients aged over 80 years.

Patients and methods: Between June 2014 and March 2020, 155 patients with acute ischemic stroke were enrolled in this retrospective observational study and assigned to the IVTT group (44 males, 37 females; median age: 69 years; IQR, 58–79 years) and the non-IVTT group (30 males, 44 females; median age: 74 years; IQR, 65–82 years). The modified Rankin scale score at the third month for all patients and hemorrhagic transformation rates in the IVTT group were recorded. Outcomes were compared between patients aged over and under 80 years within the IVTT group.

Results: Good outcomes at the third month were significantly higher in the IVTT group than in the non-IVTT group (37% *vs.* 17.6%, $p = 0.007$), with symptomatic intracerebral hemorrhage occurring in 6.2% of patients within the first 36 h after IVTT; baseline National Institutes of Health Stroke Scale (NIHSS) score and age were independent predictors of favorable outcomes.

Conclusion: In our study, IVTT reduced the disability at the third month and can be safely performed in carefully selected patients. In older patients or those with high NIHSS scores, alternative therapies may also be considered.

Keywords: Hemorrhagic transformation, ischemic stroke, thrombolytic therapy, treatment outcome.

The benefits of intravenous thrombolytic therapy (IVTT) in the acute phase of ischemic stroke have been well demonstrated in large-scale studies to date.[1,2] Although some studies indicate that IVTT is safe in patients over 80 years old, its safety in this age group remains controversial.[3,4] Additionally, identifying the patient groups that may benefit less from IVTT could help guide decisions toward alternative options, such as direct thrombectomy, bridging therapy, or intra-arterial thrombolysis. Therefore, understanding the predictors of favorable outcomes is crucial. Another important consideration is the timing of IVTT administration. While some studies have determined that IVTT is safe when given within 3 to 4.5 h, there are also studies that show that the rate of symptomatic intracranial hemorrhage and mortality rates in the third month increase.[5-8] In this context, this study aims to investigate the efficacy, safety, and complications of IVTT, the prognostic factors for patients treated with IVTT, and the outcomes of patients over 80 years old who undergo this therapy.

PATIENTS AND METHODS

Study population

This retrospective observational study was conducted at Süleyman Demirel University Faculty of Medicine, Department of Neurology between June 2014 and March 2020. A total of 155 patients

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with acute ischemic stroke were included in the study and divided into two groups according to IVTT status. Baseline demographic characteristics were as follows: the IVTT group included 81 patients (44 males, 37 females; median age: 69 years, IQR: 58–79 years), and the non-IVTT group included 74 patients (30 males, 44 females; median age: 74 years, IQR: 65–82 years). Patients younger than 18 years of age, those with mild ischemic stroke presenting with non-disabling symptoms, and those who underwent endovascular treatment were excluded from the study. Written informed consent was obtained from each patient. The study protocol was approved by the Süleyman Demirel University Faculty of Medicine Clinical Research Ethics Committee (Date: 16.01.2020, No: 006). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Data were obtained from patient files and corporate databases. The third-month outcomes of the IVTT and non-IVTT groups were compared by calculating the modified Rankin scale (mRS) score. In addition, the results of patients over 80 and those under 80 years of age were compared in the IVTT group. Demographic data, cerebrovascular disease risk factors, smoking habits, and the use of antiaggregant therapy before stroke were recorded for both groups. In addition, the time from the onset of symptoms to treatment (symptom-needle time) in the IVTT group was also calculated. Arterial system involvement was categorized into anterior circulation, posterior circulation, and both circulations based on the brain imaging of the patients at admission to the hospital. The methods used for patient selection in the IVTT and non-IVTT groups are shown in Figures 1 and 2.

Patient outcomes

For both groups, the hemorrhagic transformation was clinically divided into two groups, symptomatic and asymptomatic, according to the European Cooperative Acute Stroke Study (ECASS) III, and radiologically into five groups, namely, hemorrhagic infarct type 1, hemorrhagic infarct type 2, parenchymal hemorrhage type 1, parenchymal hemorrhage type 2, and extraischemic hematoma according to the ECASS II.[2,9] The ECASS III definition was used for symptomatic intracranial hemorrhage. Symptomatic intracranial hemorrhage is defined as any extravascular hemorrhage in the brain or head within 36 h after therapy that results in an increase in the National Institutes of Health Stroke Scale (NIHSS) score of 4 points or leads to clinical deterioration or death. Clinical deterioration or death should be the main cause of neurological deterioration.[2]

Those with an mRS score of 0–1 were considered good results; those with a score of 0–2 were considered favorable outcomes; those with a score of 3 were considered moderately dependent; those with scores of 4 and 5 were considered poor outcomes; and those with a score of 6 represented mortality. Both groups were compared in terms of good results, favorable outcomes, and mortality.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive analyses were presented as medians and interquartile ranges for the non-normally distributed variables and means ± standard deviations (SD) for normally distributed variables. The variables, such as the initial NIHSS score and age, were investigated using visual methods, including histograms and probability plots, as well as analytical methods such as Kolmogorov-Smirnov and Shapiro-Wilk tests to determine whether they were normally distributed. None of the variables in our study were distributed normally. Therefore, the variables were compared between the two groups via a non-parametric Mann-Whitney U test, and categorical variables were evaluated using Pearson's chi-square and Fisher exact test. For the multivariate analysis, the possible factors identified with univariate analyses were further entered into the logistic regression analysis to determine independent predictors of favorable outcomes in the third month. Variables showing at least a marginal association ($p \leq 0.1$) with the outcome of interest in the univariate

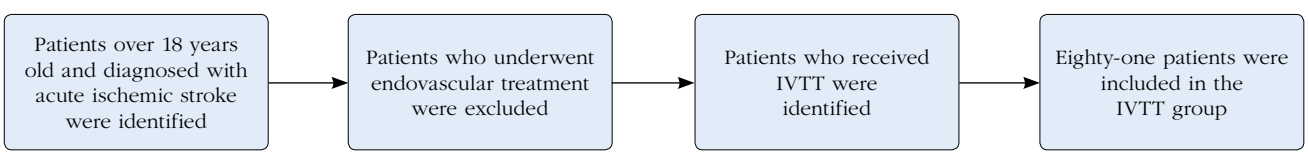

Figure 1. Patient selection for the IVTT group.
IVTT, intravenous thrombolytic therapy.

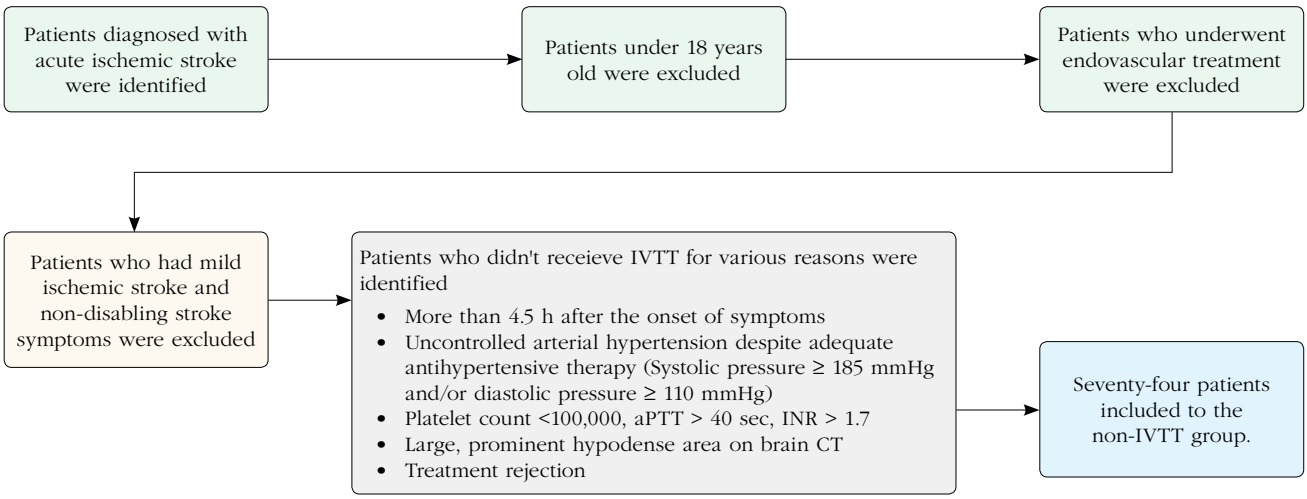

Figure 2. Patient selection for the non-IVTT group.

IVTT, intravenous thrombolytic therapy; aPTT, activated partial thromboplastin time; INR, international normalized ratio.

TABLE 1
Demographic data, initial NIHSS scores, vascular system involvement, and cerebrovascular risk factors in the IVTT and non-IVTT groups

	IVTT group				Non-IVTT group				
	n	%	Median	IQR	n	%	Median	IQR	*p*
Age (year)			69	58–79			74	65–82	0.06
Initial NIHSS score			8	6–11			10	6–14	0.065
Age <80 years	66	81.5			51	68.9			0.069
Age ≥80 years	15	18.5			23	31.1			
Sex									
Male	44	54.3			30	40.5			0.086
Female	37	45.7			44	59.5			
Anterior circulation stroke	68	84			63	85.1			
Posterior circulation stroke	7	8.6			7	9.5			
Both anterior and posterior circulation stroke	6	7.4			4	5.4			0.871
Hypertension	42	51.8			55	74.3			0.004*
Diabetes mellitus	37	45.6			29	39.2			0.414
Hyperlipidemia	28	34.5			23	31.1			0.644
Atrial fibrillation	30	37			35	47.3			0.196
Coronary artery disease	27	33.3			27	36.5			0.681
Heart failure	12	14.8			26	35.1			0.003*
Prior CVD	12	14.8			18	24.3			0.134
Prior TIA	2	2.5			2	2.7			0.655
Antiaggregant use before stroke	34	42			31	41.9			0.992
Smoking status	19	23.5			9	12.2			0.068

NIHSS, National Institutes of Health Stroke Scale; IVTT, intravenous thrombolytic therapy; IQR, interquartile range; CVD, cerebrovascular disease; TIA, transient ischemic attack; *, statistically significant.

analysis were included as covariates in the multivariate logistic regression. Hosmer-Lemeshow goodness-of-fit statistics were used to assess model fit. A 5% type 1 error level was used to infer statistical significance.

RESULTS

There was no statistically significant difference between the two groups in terms of age, sex, vascular system involvement, initial NIHSS score

or the number of patients over the age of 80. Considering cerebrovascular risk factors, the rates of hypertension and heart failure were significantly higher in the non-IVTT group, as shown in Table 1.

When both groups were compared in terms of good results at the third month, there were 30 (37%) patients in the IVTT group and 13 (17.6%) in the non-IVTT group. The difference was statistically significant (p = 0.007). The number of patients with favorable outcomes at the third month was 17 (23%) in the non-IVTT group, and 38 (46.9%) in the IVTT group, as shown in Table 2.

There was no statistically significant difference between the initial NIHSS scores of patients aged 80 years and younger and those over 80 years of age in the IVTT group. However, the third-month mortality rate was higher in patients over 80 years of age, and third-month good results were higher in patients 80 years of age and younger. These results were statistically significant. In addition, there were no statistically significant differences between the groups in terms of the SICH rate (Table 2).

The radiological and clinical classification of hemorrhagic transformation within the first 36 h in patients who received IVTT is presented in Figure 3. While five (6.2%) patients had SICH, 16 (19.8%) patients had aSICH.

There was no significant difference between the initial NIHSS scores of our patients who received IVTT in the first 3 h (early IVTT) and between 3 and 4.5 h (late IVTT). The mean symptom-needle time was 158.48 ± 52.67 min in the IVTT group. In the early IVTT and late IVTT subgroups, this time was 127.5 ± 31.92 min and 220.44 ± 21.88 min, respectively. In addition, no statistically significant difference was observed in terms of symptomatic intracerebral hemorrhage (SICH) rates or third-month mortality rates between early and late IVTT groups, as shown in Table 3.

According to the univariate logistic regression analysis, the initial NIHSS score and age were significantly associated with favorable outcomes at the third month in the IVTT group. Multiple logistic regression analysis revealed that these two factors were independent predictors of favorable outcomes, as shown in Table 4.

DISCUSSION

In our study, IVTT increased the rates of good outcomes and favorable outcomes in the third month in acute ischemic stroke patients. These results are consistent with previous similar studies.[1,10-12] Symptomatic intracerebral hemorrhage, the most critical complication of IVTT, was observed in 6.2% of our patients who received this therapy. These results are similar to those of studies in the literature.[2,13,14] Given the radiological classification

TABLE 2
Comparisons of the third-month outcomes between the IVTT and non-IVTT groups, and results for patients under and over 80 years old in the IVTT group

	IVTT group		Non-IVTT group		
Outcomes	n	%	n	%	p
Good results (mRS 0–1)	30	37	13	17.6	0.007*
Favorable outcome (mRS 0–2)	38	46.9	17	23	0.002*
Moderately dependent (mRS 3)	6	7.4	5	6.8	0.875
Bad results (mRS 4–5)	11	13.6	12	16.2	
Death (mRS 6)	4	4.9	11	14.9	0.069

	IVTT group								
	Age < 80				Age ≥ 80				
	n	%	Median	IQR	n	%	Median	IQR	p
Initial NIHSS score			8	6-10			10	6-12	0.1
Good results at third month	29	43.9			1	6.7			0.007*
Favorable outcome at third month	36	54.5			2	13.3			0.004*
Third month mortality	16	24.2			10	66.7			0.004*
Symptomatic intracerebral hemorrhage	3	4.5			2	13.5			0.229
Total intracerebral hemorrhage	12	18.2			9	60			0.001*

IVTT: Intravenous thrombolytic therapy; IQR: Interquartile range; NIHSS, National Institutes of Health Stroke Scale; * Statistically significant.

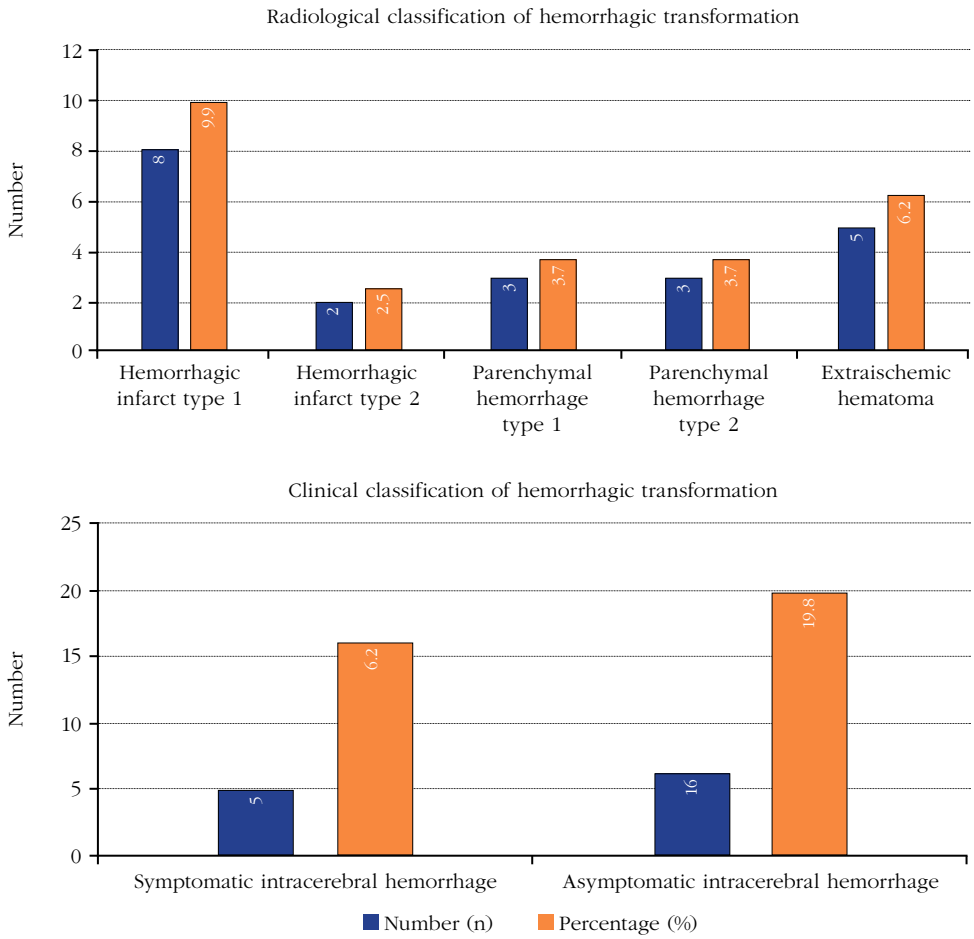

Figure 3. Radiological and clinical classification of hemorrhagic transformation in the IVTT group.

IVTT, intravenous thrombolytic therapy.

TABLE 3
Data of patients who received treatment in the first 3 h and between 3 and 4.5 h in the IVTT group

	First 3 h				3-4.5 h					
	n	%	Median	IQR	n	%	Median	IQR	Mean±SD	*p*
Initial NIHSS score			8	6-11			8	6-12		0.516
Third month mortality	14	25.9			12	44.4				0.092
SICH rates	2	3.7			3	11.1				0.192
The mean symptom-needle time (min)										
IVTT group									158.48±52.67	
First 3 h									127.5±31.92	
3-4.5 h									220.44±21.88	

IVTT, intravenous thrombolytic therapy; IQR, interquartile range; SD, standard deviation; NIHSS, National Institutes of Health Stroke Scale; SICH, symptomatic intracerebral hemorrhage.

of hemorrhagic transformation, there are studies in the literature close to the rate of parenchymal hemorrhage in our study, but there are also studies with higher parenchymal hemorrhage rates.[15-18] This might be related to our patients' initial NIHSS scores. As the initial NIHSS score decreases, the rate of parenchymal hemorrhage after IVTT also decreases.[19]

TABLE 4
Factors affecting favorable outcomes at the third month and multiple logistic regression analysis

Risk factor	OR	95% CI	*p*
Age	0.934	0.886-0.985	0.012*
Sex	1.250	0.428-3.650	0.683
Initial NIHSS score	0.828	0.705-0.971	0.021*
Symptom-needle time	1.003	0.993-1.014	0.573
Hypertension	0.359	0.119-1.078	0.068
Diabetes mellitus	0.489	0.166-1.443	0.196
Hyperlipidemia	0.615	0.204-1.853	0.388
Atrial fibrillation	0.750	0.246-2.288	0.613
Coronary artery disease	0.543	0.179-1.653	0.282
Heart failure	3.030	0.330-27.837	0.327
Multiple logistic regression analysis in the IVTT group			
Age	0.933	0.879-0.990	0.022*
NIHSS score at onset	0.809	0.673-0.971	0.023*
Hypertension	1.385	0.387-4.961	0.617

OR, odds ratio; CI, confidence interval; NIHSS, National Institutes of Health Stroke Scale; IVTT, intravenous thrombolytic therapy.

The fact that our patients over the age of 80 who received IVTT had higher mortality rates and lower rates of good outcomes than our patients who received IVTT under the age of 80 indicates that IVTT is more effective in patients aged 80 years and younger than in those over 80 years of age. In the literature, consistent results were reported in studies involving people over 80 years old.[20,21] However, the absence of an increase in the rate of SICH in patients over the age of 80 years in our study indicates that IVTT can be safely administered in this age group.

In our study, no significant difference was observed between the SICH rates of those who received IVTT in the first 3 h and those who received treatment between 3 and 4.5 h. There are studies in the literature compatible with this result.[5,6,8] There was no significant difference between the two groups in terms of mortality rates in the third month. Although some studies support this result,[5,6] other studies have shown that those who receive IVTT between 3 and 4.5 h have higher mortality in the third month than those who receive IVTT in the first 3 h.[7,8] Importantly, IVTT is administered in the first 3 h. However, if the treatment has to be administered between 3 and 4.5 h, our study contributes to the literature that SICH rates may not increase and suggests that IVTT can be given safely in clinical practice during this period.

Our study revealed that age and initial NIHSS score were independent prognostic factors for favorable outcomes. The predictive value of the initial NIHSS score has also been reported in previous studies; lower baseline NIHSS scores are associated with more favorable outcomes.[22-24] Age, another prognostic factor in our study, was also shown to be a good predictor in several studies. As age increases, the percentage of patients who achieve favorable outcomes decreases.[25-27]

Our study has several limitations. Given that this was a retrospective analysis, selection bias cannot be excluded. In addition, the small sample size and baseline differences between the groups may have influenced the results.

In conclusion, in our study, the findings suggest that IVTT clearly reduced the disability rates of patients in the third month, and the SICH rates were consistent with those reported in the literature. In addition, our study found that the rate of SICH was not increased in patients over the age of 80 years who received IVTT and that there was no increase in the mortality rate in those who received IVTT within 3 to 4.5 h after the onset of symptoms. These results reveal that IVTT can be administered safely. In parallel with the increase in clinical experience regarding the use of IVTT, we believe that better clinical outcomes will be achieved when the eligible patient selection is made.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: B.G.: Performed the calculations and wrote the manuscript with input from all authors; V.A.Y.: Designed the study, was in charge of overall direction and planning; B.G., V.A.Y.: Analysed the data.

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