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ORIGINAL ARTICLE **ÖZGÜN ARAŞTIRMA**

EFFECT OF INTRAVENOUS THROMBOLYTIC TREATMENT ON PROGNOSIS AND INTRACEREBRAL HEMORRHAGE IN STROKE PATIENTS TREATED WITH MECHANICAL THROMBECTOMY

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ABSTRACT

INTRODUCTION: Intravenous thrombolytic therapy (iv tPA) and mechanical thrombectomy (MT) are effective treatments for acute ischemic stroke (AIS). Iv tPA is recommended for all AIS patients within 4.5 hours. However, iv tPA isn't effective in large vessel occlusions (LVO). MT is an effective treatment for LVOs. Current guideline recommend both treatments for AIS patients with LVO in first 4.5 hours. Intraserebral hemorrhage (ICH) is the most important complication of these treatments. This study aims to evaluate the effect of iv tPA on intracerebral hemorrhage (ICH) and clinical prognosis in AIS patients treated with MT.

METHODS: This study was designed as retrospectively. AIS patients treated with MT between 2018-2022 were included in this study. Patiens were divided to two groups as only MT and MT+iv tPA. Rates good clinical outcome and ICH were compared between two groups.

RESULTS: A total of 103 patients were included in this study. Forty-seven (45.6%) patients were male. mean age was 64.3±12.7 years, and mean NIHSS score was 16.2±3 points. Symptomatic ICH occured in six (5.9%) patients. Fifty-four (52.4%) patients had good clinical outcome, and 27 (26.2%) patients died. Iv tPA was adminitered to 51 (49.5%) patients. Rates of symptomatic ICH and good clinical outcome were similar in only MT and iv tPA+MT groups.

DISCUSSION AND CONCLUSION: Administration of iv tPA before MT didn't effect the clinical outcome in AIS patients. In addition, iv tPA before MT didn't icrease the risk of ICH and symptomatic ICH.

Keywords: Mechanical thrombectomy, thrombolytic, intracerebral hemorrhage, prognosis.

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MEKANİK TROMBEKTOMİ YAPILAN İSKEMİK İNME HASTALARINDA İNTRAVENÖZ TROMBOLİTİK TEDAVİNİN PROGNOZ VE İNTRASEREBRAL KANAMA ÜZERİNE ETKİSİ

ÖZ

GİRİŞ ve AMAÇ: İntravenöz trombolitik tedavi (iv tPA) ve mekanik trombektomi (MT) akut iskemik inme hastalarının tedavisinde kullanılan iki yöntemdir. iskemik inme hastalarına ilk 4,5 saatte iv tPA önerilmektedir. MT ise büyük damar oklüzyonlarında etkin bir tedavidir. Mevcut kılavuzlar ilk 4,5 saate gelen büyük damar oklüzyonlarında her iki tedaviyi de önermektedir. Ancak iki tedavinin de en korkulan yan etkisi intraserebral kanamadır. Bu çalışmanın amacı, MT yapılan hastalarda iv tPA verilmesinin intraserebral kanama ve prognoz üzerine etkisini incelemektir.

YÖNTEM ve GEREÇLER: 2018-2022 yılları arasında Nöroloji Kliniği'nde mekanik trombektomi yapılan hastaların dosyaları retrospektif olarak tarandı. Hastaların MT öncesi iv tPA alıp almadığı sorgulandı ve hastalar iv tPA verilenler ve iv tPA verilmeyenler olmak üzere 2 gruba ayrıldı. Grupların 3. ay modifiye Rankin Skalası skorları (mRS) ve intraserebral kanama oranları karşılaştırıldı.

BULGULAR: Toplam 103 hasta çalışmaya dahil edildi. Hastaların 47'si (%45,6) erkekti. Ortalama yaş 64,3±12,7 yıl, ortalama NIHSS skoru ise 16,2±3,3 bulundu. Semptomatik intraserebral kanama 6(%5,9) hastada gelişti. İyi klinik sonuç 54 (%52,4) hastada ve ölüm 27 (%26,2) hastada izlendi. Iv tPA 51 (%49,5) hastaya uygulandı. Her iki grup arasında iyi klinik sonuç ve semptomatik intraserebral kanama oranları arasında anlamlı fark izlenmedi.

TARTIŞMA ve SONUÇ: MT öncesinde iv tPA verilmesinin 3. ay klinik sonuç üzerine etkisinin bulunmadığı izlendi. Ek olarak MT öncesi iv TPA verilmesinin intraserebral kanama ya da semptomatik intraserebral kanama riskini artırmadığı saptandı.

Anahtar Sözcükler: Mekanik trombektomi, trombolitik, intraserebral kanama, prognoz.

INTRODUCTION

Intravenous thrombolytic therapy (IV tPA) and mechanical thrombectomy (MT) are two methods used in the treatment of patients with acute ischemic stroke. In a study published by the National Institute of Neurological Disorders and Stroke working group in 1995, it was shown that IV tPA reduced the disability rate when given to ischemic stroke patients within the first 3 hours (1). The ECASS III study published in 2008 showed that IV tPA was beneficial when given within 3 and 4.5 hours after the onset of symptoms (2). After these studies, the use of IV tPA within the first 4.5 hours in patients with acute ischemic stroke was included in the treatment guidelines. MT is a later-adopted method of treatment. In five randomized controlled studies published in 2015, it was shown that MT is superior to IV tPA in ischemic stroke due to large vessel occlusions (3-7). The American Heart Association and American Stroke Association recommend that patients with ischemic stroke be given IV tPA in the first 4.5 hours if there is no contraindication, and MT should be performed if there is a large vessel occlusion (8). In a recent study in which patients who underwent MT alone and those who underwent MT with IV tPA were compared, the prognoses of the patients were found to be similar (9). In another meta-analysis, it was observed that the prognosis of patients who were given IV tPA with MT was better than that of those who underwent only MT (10). Co-administration of the two treatments in large vessel occlusions may increase the chance of reperfusion. However, the most feared side effect of both treatments is intracerebral hemorrhage (ICH). Hacke et al., in their meta-analysis, found that IV tPA was associated with ICH (11). Ciccone et al. reported in their randomized controlled study that the risk of ICH was similar in patients who were given IV tPA and who underwent MT (12). There is no study on this subject in Turkiye. The objective of this study is to examine the effect of IV tPA administration on ICH and prognosis in patients who underwent MT.

METHODS

The files of patients who underwent mechanical thrombectomy between 2018 and 2022 were reviewed retrospectively. Demographic data, medical history, antiaggregant or anticoagulant use, imaging findings, baseline and 3rd month examination findings, and angiographic findings were obtained from patient files. The patients were divided into two groups: those who

were given IV tPA and those who were not given IV tPA before MT. This study was approved by the Health Sciences University, Kocaeli Derince Training and Research Hospital Clinical Studies Ethics Committee (Number: 2023-4, Date: 12.01.2023) and was performed in accordance with the Helsinki Declaration Ethical Standards.

Patient selection and endovascular treatment: Patients who had internal carotid artery (ICA) (tandem, T, L) or middle cerebral artery (MCA) M1 segment occlusion, no hemorrhage in brain computed tomography (CT), an Alberta Stroke Program Early Computed Tomography (ASPECT) score of >6, a National Institutes of Health Stroke Scale (NIHSS) score of ≥6, a pre-stroke modified Rankin Scale (mRS) score of 0-1, a symptom-gate time of less than 4.5 hours, and who underwent MT were included in the study. The inclusion criteria are shown in Table 1.

Table 1. Inclusion criteria.

Inclusion criteria
>18 years of age
Symptom onset-to-door time of <4.5 hours
Having ICA (tandem, T, L) or MCA M1 occlusion
ASPECT >6
NIHSS >6
Pre-stroke mRS 0 or 1

Acute ischemic stroke patients were evaluated by a neurologist in the emergency department. Non-contrast brain CT and CT angiography (CTA) were performed on the patients. Alteplase at a dose of 0.9 mg/kg was started in the emergency department for patients who had no contraindications for IV tPA, and then they were taken to the angio unit for MT. Patients with contraindications (Table 2) were taken directly to the angio unit without administering IV tPA. MT was performed on a monoplane angio device under conscious sedation. After the femoral sheath was placed, 2500 IU of heparin was administered intra-arterially. No additional heparin was applied during or after the procedure. A 6 French (F) guiding catheter (Destination, Terumo, Tokyo, Japan) was advanced into the common carotid artery or the cervical segment of the ICA. Occlusion was passed with a microcatheter (Headway, Microvention, Tustin, California, USA; Rebar, Medtronic, Minneapolis, USA) and a 0.014-inch microwire. Subsequently, mechanical thrombectomy was performed using either stent-retriever thrombectomy (isolated stent-retriever, ARTS, SAVE, solumbra) or neuro-aspiration (ADAPT) techniques. A stent-retriever of appropriate diameter and length in stent-retriever thrombectomy (Eric, Microvention, Tustin, California, USA; Trevo, Stryker, Kalamazoo, Michigan, USA; Aperio Hybrid, Acandis, Pforzheim, Germany; Thrombite, Zylox-Tonbridge, Hangzhou, China; Solitaire X, Medtronic, Minneapolis, USA) was placed to the occluded segment. In the direct aspiration technique, the distal access catheter (Sofia 6F Microvention, Tustin, California, USA; Navien 5F-6F, Medtronic, Minneapolis, USA) was advanced into the occluded segment, and aspiration was performed. If recanalization could not be achieved after two attempts, the thrombectomy technique was changed. If recanalization could not be achieved after five thrombectomy attempts, the procedure was terminated. Balloon angioplasty was performed at the origin of the ICA in tandem occlusions. In cases of reocclusion at the origin of the ICA despite balloon angioplasty, carotid artery stenting was performed after loading 300 mg of acetylsalicylic acid and 300 mg of clopidogrel. The patients who underwent MT were taken to the intensive care unit following the procedure. In the intensive care unit, blood pressure and neurological examinations were monitored every 30 minutes for the first two hours, and then each hour thereafter. No antiaggregant or anticoagulant treatment was given for 24 hours after MT thrombectomy. A control brain CT was performed in all patients after MT. If there was no hemorrhage in the brain CT, acetylsalicylic acid (300 mg/day) was initiated.

Table 2. IV tPA contraindications.

Over 4.5 hours after the symptom onset
Hemorrhage on brain CT or having an ASPECT score of ≤6
Having had an ischemic stroke in the last 3 months
Severe head trauma in the last 3 months
Having undergone intracranial or intraspinal surgery in the last 3 months
History of intracranial hemorrhage
Subarachnoid hemorrhage
GIS malignancy or GI hemorrhage in the last 3 weeks
Platelet count of < 100000/mm3
INR>1.7 or aPTT>40 sec or PT>15 sec
LMWH use in the last 24 hours
Infective endocarditis
Intra-axial or intraspinal tumor
NOAC (dabigatran, apixaban, rivaroxaban, edoxaban) use in the last 48 hours

Clinical evaluation scales: Non-contrast brain CT was evaluated with ASPECT scoring (13). The collateral level in CTA was evaluated with the modified Tan scale (14). According to this scale, if more than 50% of the MCA perfusion area had a contrast transition, it was defined as good collateral. The level of recanalization after thrombectomy was evaluated according to the modified Treatment In Cerebral Ischemia (mTICI) classification. Accordingly, mTICI 0 was defined as no flow; mTICI 1 was defined as filling of the distal of MCA but no blood in cortical branches; mTICI 2a was defined as the blood flow in less than half of the MCA irrigation area; mTICI 2b was defined as the blood flow in more than half of the MCA irrigation area; mTICI 2c was defined as the blood flow in the entire MCA irrigation area but with slower filling than the normal side filling; and mTICI 3 was defined as complete recanalization (15). mTICI 2b-3 recanalization after MT was defined as successful recanalization. Following a single thrombectomy attempt, mTICI 2c-3 recanalization was considered a first-pass effect (15). Intracerebral hemorrhages in brain CT at hour 24 after thrombectomy were evaluated according to the criteria of the European Cooperative Acute Stroke Study (ECASS III). Accordingly, small petechiae in the infarct area were defined as type 1 hemorrhagic transformation; petechiae that tend to coalesce were defined as type 2 hemorrhagic transformation; hemorrhages that cover less than 30% of the infarct area and have a mild mass effect were defined as type 1 hematoma; and hemorrhages that cover more than 30% of the infarct area and cause a significant mass effect were defined as type 2 hematoma (2). Hemorrhage with an increase of ≥4 points compared to the baseline NIHSS score was defined as symptomatic ICH. The disability status of the patients at third month was evaluated by mRS. An mRS score of ≤2 was defined as a good clinical outcome.

Statistical analysis: Statistical analyses were performed using the SPSS 15 program. Categorical data were presented as frequency and percentage. The distribution of numerical data was evaluated with the Kolmogorov-Smirnov test. Data with a normal distribution were shown as the mean and standard deviation, and data with a non-normal distribution were shown as the median and interquartile range. Numerical data were analyzed using Mann-Whitney U and an independent t-test, and categorical data were analyzed using a chi-square test. A p value of <0.05 was accepted as statistically significant.

RESULTS

A total of 188 patients with acute ischemic stroke underwent endovascular treatment between 2018 and 2022. 103 patients who met the inclusion criteria were included in the study. Forty-seven (45.6%) of the patients were male. The mean age was 64.3±12.7, and the mean NIHSS score was 16.2±3.3. MCA M1 occlusion was observed in 67 (65%) patients, intracranial ICA (T or L) occlusion in 22 (21.4%) patients, and tandem ICA occlusion in 14 (13.6%) patients. The mean symptom onset-to-door time was 109±62 minutes, symptom puncture time was 188±56 minutes, and symptom-recanalization time was 239±60 minutes. The mean symptom-needle time in patients given IV tPA was 147±56 minutes. Successful recanalization (mTICI 2b-3) was observed in 79 (76.7%) patients. Symptomatic ICH developed in 6 (5.9%) patients. At the end of three months, 54 (52.4%) patients had good clinical outcome, while 27 (26.2%) patients died. The general information about the patients is shown in Table 3.

IV tPA was administered to 51 (49.5%) patients. The smoking rate and the mean SBP value were high only in the MT group. While stent-retriever thrombectomy was observed at a higher rate only in the MT group, neuro-aspiration was more common in the MT+IV tPA group (p=0.024). There was no significant difference in clinical outcomes and symptomatic ICH rates between the two groups. The comparison of the two groups is shown in Table 4.

DISCUSSION AND CONCLUSION

In this study, the effect of IV tPA administration on clinical outcomes was examined in patients treated with MT. It was observed that IV tPA administration before MT had no effect on the clinical outcome at third month. Additionally, it was determined that IV TPA administration before MT did not increase the risk of ICH or symptomatic ICH. The rate of good clinical outcome in the literature ranges between 36.7% and 66.3% (17-21). In this study, the good clinical outcome rate was 52.4%, which is consistent with the literature.

Table 3. General information about the patients.

Number	103
Age (years) (SD)	64.3±12.7
Male (%)	47 (45.6)
Hypertension (%)	68 (66)
Atrial fibrillation (%)	44 (42.7)
Diabetes mellitus (%)	27 (26.2)
Smoking (%)	36 (35)
Coronary artery disease (%)	25 (24.3)
Antiaggregant (%)	34 (33.3)
Anticoagulant (%)	14 (13.7)
NIHSS-onset (SD)	16.2±3.3
NIHSS-24th hour(SD)	10±7.8
ASPECT (IQR)	8(7-9)
Occluded vessel	
MCA M1(%)	67 (65)
ICA (T or L) (%)	22 (21.4)
Tandem ICA (%)	14 (13.6)
Symptom-puncture time-min (SD)	188±56
Door-to-puncture time-min (SD)	79±33
Puncture-to-recanalization time-min (SD)	50±26
Symptom onset-to-recanalization time-min (SD)	239±60
Symptom-needle time-min (SD)	147±56
Thrombectomy pass count (IQR)	2(1-3)
mTICI 2b-3 recanalization (%)	79 (76.7)
Intracerebral hemorrhage (%)	36 (%35)
Symptomatic intracerebral hemorrhage (%)	6 (5.9)
mRS at third month (IQR)	2(1-6)
Good clinical outcome (mRS 0-2)	54 (52.4)
Death (%)	27 (26.2)

SD: Standard deviation; IQR: Interquartile range.

The effect of IV tPA administration on prognosis in patients treated with MT has been examined in previous randomized controlled studies. The inclusion criteria for the DIRECT-MT study were the same as for this study. In the DIRECT-MT study, it was found that the mRS scores at third month were similar in patients who received and did not receive IV tPA before MT, while IV tPA was found to be associated with recanalization before thrombectomy (17). Unlike this study, in the SKIP study, IV tPA was administered at a dose of 0.6 mg/kg. In the SKIP study, good clinical outcome rates were found to be similar only in patients who underwent MT and those who underwent IV tPA+MT (18). In the DEVT study, it was also found that IV tPA administration before MT had no effect on clinical prognosis (19). Similar findings were obtained in a recently published meta-analysis (22). In this study, good clinical outcome rates were similar in patients who were administered and not administered IV tPA before MT which is consistent with the literature. In the literature, the rate of ICH was found to be between 26-46.6%, while the rate of symptomatic ICH was found to be between 3.9-9.8%. In this study, the rate of ICH was found to be 35% and the rate of symptomatic ICH to be 5.9%, which is consistent with the literature. ICH and symptomatic ICH are the most important complications of both MT and IV tPA. The risk of symptomatic ICH is known to increase 3–10 times with IV tPA (23,24). It has been reported that symptomatic ICH is an indicator of poor clinical outcome and mortality after MT (25). It can be thought that the co-administration of the two treatments may further increase the risk of symptomatic ICH. However, this is not supported by the literature data. In RCT studies, symptomatic ICH rates were found to be similar in patients who were treated and not treated with IV tPA before MT (7,17). It was observed only in the DEVT study that any ICH was higher in the group given IV tPA (19). In a recent prospective study, Nguyen et al. reported that the administration of IV tPA before MT did not increase the ICH risk (21). Du et al. also found in their meta-analysis that bridging treatment (IV tPA+MT) did not increase the risk of ICH (22).

In this study, it was found that the neuro-aspiration technique was used more frequently in the IV tPA+MT group. Previous studies didn't compare the thrombectmy techniques. Only two studies examined the rates of the use of neuro-aspiration and stent-retriever techniques and found them to be similar (9,18). It was shown that the stent-retriever technique causes more damage to the vessel wall, especially to the endothelium, than neuro-aspiration (26). It is possible that the increased use of neuroaspiration in patients receiving IV tPA results in lower than expected rates of intracranial hemorrhage and symptomatic intracranial hemorrhage in this group. Nevertheless, in two RCTs (ASTER and COMPASS) comparing stent-retriever thrombectomy and neuroaspiration, it was shown that the rates of any ICH and symptomatic ICH were similar in patients who used both techniques (27,28).

This study has limitations. First, this study was retrospective. Second, the sample size of the study is small. Different results can be obtained with larger study groups. Third, all patients were started with a dose of 0.9 mg/kg of IV tPA in one hour, but not all of the patients received the full dose of tPA. Some patients were taken to the angio unit without receiving the full dose. Additionally, the total IV tPA doses received by the patients were not evaluated.

Table 4. Comparison of MT only and IV tPA+MT groups.

	Only MT	IV tPA+MT	p
Number (%)	52 (50.5)	51 (49.5)	
Age (years) (SD)	64.8±11.9	63.7±13.5	0.651
Male (%)	25 (48.1)	22 (43.1)	0.694
Hypertension (%)	37 (71.2)	31 (60.8)	0.303
Atrial fibrillation (%)	24 (46.2)	20 (39.2)	0.552
Diabetes mellitus (%)	15 (28.8)	12 (23.5)	0.655
Smoking (%)	24 (46.2)	12 (23.5)	0.023
Coronary artery disease (%)	17 (32.7)	8 (15.7)	0.065
Antiaggregant (%)	18 (35.3)	26 (31.4)	0.834
NIHSS-onset (SD)	15.9±3.8	16.5±2.6	0.292
NIHSS-24th hour(SD)	9.9±8.6	10.1±7	0.809
ASPECT (IQR)	8 (7-9)	8 (7-9)	0.437
SBP-mmHg (SD)	171±36	157±36	0.025
DBP-mmHg (SD)	92±21	86±12	0.073
Glucose-mg/dl (IQR)	130 (106-177)	126 (108-150)	0.410
Platelet-10^3/mm^3(SD)	244±98	227±73	0.296
Occluded vessel			
MCA M1(%)	34 (65.4)	33 (64.7)	
ICA (T or L) (%)	10 (19.2)	12 (23.5)	0.789
Tandem ICA (%)	8 (15.4)	6 (11.8)	
Symptom-puncture time-min (SD)	188±62	189±49	0.967
Door-to-puncture time-min (SD)	74±32	85±33	0.078
Puncture-to-recanalization time-min (SD)	46±21	54±30	0.325
Symptom onset-to-recanalization time-min (SD)	243±63	243±57	0.445
Thrombectomy pass count (IQR)	2 (1-3)	2 (1-3)	0.445
Stent retriever thrombectomy (%)	44 (84.6)	33 (64.7)	0.024
Neuro-aspiration (%)	8 (15.4)	18 (35.3)	0.024
Intra-arterial tPA (%)	10 (19.2)	10 (19.6)	1.000
First-pass effect (%)	13 (25)	12 (23.5)	1.000
Distal embolism (%)	5 (9.6)	8 (15.7)	0.390
mTICI 2b-3 recanalization (%)	39 (75)	40 (78.4)	0.816
Intracerebral hemorrhage (%)	20 (38.5)	16 (31.4)	0.537
Symptomatic intracerebral hemorrhage (%)	5 (9.8)	1(2)	0.205
mRS–third month (IQR)	2 (1-6)	2 (1-5)	8.840
Good clinical outcome (mRS 0-2)	27 (51.9)	27 (52.9)	1.000
Death (%)	15 (28.8)	12 (23.5)	0.655

SD: Standard deviation; IQR: Interquartile range.

In conclusion, IV tPA administration prior to the procedure has no effect on the clinical outcome in patients treated with MT. Besides, IV tPA administration in patients treated with MT does not increase the risk of ICH following the procedure. Further studies with larger patient groups are needed on this subject.

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Ethics

Ethics Committee Approval: The study was approved by Health Sciences University, Kocaeli Derince Training and Research Hospital Clinical Studies Ethics Committee (Number: 2023-4, Date: 12.01.2023)

Informed Consent: The author declared that it was not considered necessary to get consent from the patients because the study was a retrospective data analysis.

Copyright Transfer Form: Copyright Transfer Form was signed by all authors.

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