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ORIGINAL ARTICLE

Safety of intravenous thrombolysis in stroke mimics - a 15-year experience

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The authors have declared that no competing interests exist

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Summary

Introduction: The necessity of timely administration of intravenous thrombolysis (IVT) in the treatment of acute ischemic stroke may result in its administration in conditions that mimic stroke with their clinical presentation ("stroke mimics").

Aim: To assess the safety of IVT administration in stroke mimics.

Material and methods: A retrospective study of 764 patients treated with IVT was conducted at the Department of Emergency Neurology of the University Clinical Centre of Serbia in the period between 2006 and 2021.

Results: Out of 764 stroke patients treated with IVT, the diagnosis of stroke mimics was established in 22 patients (2.9%). The average age of patients with stroke mimics was 49.1 ± 16.3 (min 26, max 86), and 55% of patients were female. The most frequent vascular risk factor in this group of patients was arterial hypertension (41%), followed by smoking (14%) and hypercholesterolemia (14%). In comparison with the control group of thrombolysed patients with stroke (matched according to sex and age), a trend towards a milder initial clinical deficit measured by NIHSS score was determined (5 vs. 9; p=0.058) in the stroke mimics group. Furthermore, a higher probability of favorable functional outcome (mRS 0-2) was registered (91 % vs. 55%, p=0.007). There were no statistically significant differences between the two groups regarding the death outcome (p=1.000). Symptomatic intracerebral hemorrhage was not registered in any patient in the stroke mimics group.

Conclusion: The use of intravenous thrombolysis in acute conditions presenting with the clinical picture of acute ischemic stroke is safe for the patients.

Key-words: acute ischemic stroke, stroke mimics, intravenous thrombolytic therapy (IVT)

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INTRODUCTION

Acute ischemic stroke (AIS) is a sudden, focal, non-convulsive neurological deficit resulting from vascular damage and it represents a significant medical challenge with a noticeable increase in incidence within the general population, especially in low-income countries (1). The decision regarding the type of treatment during its hyperacute phase is determined by clinical presentation, neuroimaging diagnostic findings and the time that passed from symptom onset to patient's arrival at the hospital (2). The only therapeutic approach proven to be efficient in AIS treatment consists of timely recanalization of occluded blood vessels by intravenous thrombolysis and/or mechanical thrombectomy. Intravenous thrombolytic therapy (IVT) refers to the intravenous administration of recombinant tissue plasminogen activator (rt-PA) within a time limit of 4.5 hours from symptom onset (3,4). Furthermore, additional absolute contraindications such as already established ischemia on computed tomography (CT) scan, previous intracranial hemorrhage, current severe uncontrolled hypertension, recent intracranial/spinal surgery or head trauma restrict the use of IVT (4, 5). Nevertheless, the most important factor limiting IVT administration is time, since patients have to reach the hospital within a narrow time frame. Moreover, the benefit of IVT declines as time passes from symptom onset (4,5).

Rapid clinical assessment and brain imaging are essential when a patient presents with symptoms of an acute stroke. In many countries and hospitals only non-contrast CT scan is available in the emergency setting and is typically conducted as the initial neuroimaging procedure in patients suspected of having AIS (6). More sophisticated neuroimaging procedures such as CT perfusion scan and diffusion-weighted MRI (DWI-MRI) sequences, which are more useful imaging modalities for providing valuable support in addition to clinical suspicion in differentiating stroke from stroke mimics, are not widely available in emergency settings. Various conditions and diseases, which lack the pathoanatomical substrate of AIS can mimic its clinical presentation, potentially complicating treatment decisions (7). Considering the urgency of decision making, neurologists who must make fast yet patient-safe decisions, can find themselves in this challenging situation.

The aim of this study was to evaluate the safety of IVT administration in patients presenting with acute conditions with the same or similar clinical presentation to AIS, i.e. those diagnosed with stroke mimics.

MATERIAL AND METHODS

A retrospective analysis was conducted on data from a total of 764 patients treated with IVT at the Emergency Neurology Department of the Neurology Clinic, University Clinical Center of Serbia, between 2006 and 2021. Retrospective and completely anonymous data were used, therefore signed informed consent was not requested.

Patients' demographic characteristics were analyzed, as well as vascular risk factors: hypertension, diabetes mellitus (DM), atrial fibrillation (AF), hypercholesterolemia, smoking, previous coronary disease (myocardial infarction, peripheral arterial disease, etc.), and previous stroke. The use of prestroke medication was also evaluated, including previous antiplatelet/anticoagulant, antihypertensive and statin therapy. Data were obtained through patient history, heteroanamnesis, and review of medical records.

In all patients, evaluation of clinical deficit's severity was assessed by using the National Institutes of Health Stroke Scale score (NIHSS), which was performed upon admission (8). Afterwards, all patients had their blood pressure measured, an electrocardiogram performed, underwent a non-contrast CT scan, and had a comprehensive laboratory tests analysis. Based on clinical and neurological findings, patients with suspected AIS that met all the necessary criteria, according to the recommendations from current European and North American guidelines for the management of acute stroke, were then treated with recanalization therapy (4,9,10). The initial clinical diagnosis of AIS was then confirmed by a follow-up CT/MR neuroimaging performed 12-72 hours upon admission, depending on the administered therapy, and in case of exacerbation even earlier. Symptomatic intracerebral hemorrhage (sICH) was defined according to the ECASS 2 criteria (4). The diagnosis of stroke mimics was made according to the criteria established by Hand et al. (11). Stroke mimics were identified within the patients whose clinical presentations were not confirmed with a vascular etiology, but rather, additional examinations revealed the presence of an alternative diagnosis (12). Patients' follow-up assessment was conducted 3 months after hospitalization, by using the modified Rankin Scale (mRS). Favorable outcome was defined as a mRS score 0-2, while a fatal outcome was defined as a mRS 6 (4).

Furthermore, patients identified as stroke mimics were matched with a control group of patients diagnosed with AIS (gender and age matching) for additional analysis.

The data were analyzed by using descriptive statistical methods which included measures of central tendency (mean, median, percentiles), measures of variability (standard deviation), and structural indicators expressed as percentages. To compare the groups, Pearson's chi-square test or Fisher's exact test was used for categorical data, while Student's t-test or Mann-Whitney U test was used for numerical data. The data were analyzed using the SPSS 22.0 statistical software (IBM Corp. IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp; 2017). Statistical hypothesis testing was performed at a significance level (alpha level) of 0.05.

RESULTS

Out of 764 patients treated with IVT, the diagnosis of stroke mimics was made in 22 patients (2.9%). The average age of patients diagnosed with stroke mimics was 49.1 ± 16.3 (min 26, max 86) years, 55% being female. The most common vascular risk factor in this group was hypertension (41% of cases), followed by smoking (14%) and hypercholesterolemia (14%). The most frequently used chronic therapy in this subgroup of patients was antihypertensive therapy (36.4%). Details are presented in **Table 1**.

Table 1. Vascular risk factors and therapy for primary prevention in patients diagnosed with stroke mimics

Feature	Stroke mimics (n=22)
Hypertension, n (%)	9 (40.9%)
Diabetes mellitus, n (%)	0 (0%)
Atrial fibrillation, n (%)	1 (4.5%)
Hypercholesterolemia, n (%)	3 (13.6%)
Prior coronary disease, n (%)	0 (0%)
Prior stroke, n (%)	1 (4.5%)
Current smoking, n (%)	3 (13.6%)
Prior antihypertensive therapy, n (%)	8 (36.4%)
Prior antithrombotic therapy, n (%)	2 (9.1%)
Prior statin therapy, n (%)	2 (9.1%)

Abbreviations: n= number;

There was a trend towards less severe clinical presentation measured by NIHSS score in the stroke mimics group compared to the group of patients with AIS, but without reaching a statistical significance (5 [IQR 5-10] vs. 9 [IQR 6-19], p=0.058). There was no difference between two groups regarding systolic blood pressure (p=0.07), diastolic blood pressure (p=0.104), or glucose levels (6.0 vs. 6.7; p=0.131). On the other hand, patients with stroke mimics were more likely to have excellent functional outcome (91% vs. 41%; p<0.001), as well as favorable outcome (91% vs. 55%; p=0.007) after three months. Furthermore, it was shown that none of the patients diagnosed with stroke mimics experienced symptomatic intracerebral hemorrhage whereas its prevalence in the AIS group was 0.1% (p<0.001). Additionally, there were no fatal outcomes among the thrombolysed patients in the stroke mimics group, compared to one fatality in the AIS group, which did not constitute a statistically significant difference (p=1.000). Details are presented in **Table 2** and **Figure 1**.

Table 2. Baseline findings and outcome of IVT use in patients with stroke mimics vs. acute ischemic stroke patients

Feature	Stroke mimics (n=22)	AIS (n=22)	p -value
Systolic blood pressure, mmHg, mean ± sd	133.2 ± 19.7	144.2 ± 19.5	0.070
Diastolic blood pressure, mmHg mean ± sd	82.0 ± 12.7	87.7 ± 10.2	0.104
NIHSS, median [IQR]	5.0 (5-10.0)	9.0 (6-19)	0.058
Baseline glucose, mmol/l, mean ± sd	6.0 ± 1.4	6.7 ± 1.8	0.131
sICH, n (%)	0 (0%)	1 (4.5%)	1.000
Death outcome, n (%)	0 (0%)	1 (4.5%)	1.000
Excellent functional outcome (mRS 0–1), n (%)	20 (90.9%)	9 (40.9%)	<0.001
Good functional outcome (mRS 0–2), n (%)	20 (90.9%)	12 (54.5%)	0.007

Abbreviations: AIS = Acute ischemic stroke; SD= Standard deviation; NIHSS = National Institutes of Health Stroke Scale; IQR= Interquartile range; sICH = Symptomatic intracranial hemorrhage; n= number; mRS = Modified Rankin Scale

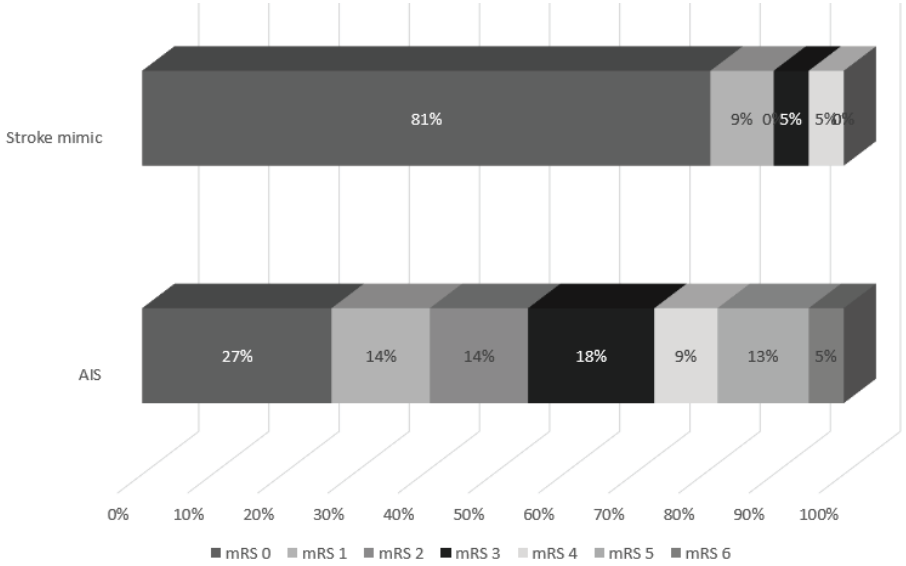

Figure 1. Three-month functional outcome of IVT treated patients with stroke mimics vs. patients with acute ischemic stroke (presented by mRS score)

Abbreviations: AIS = acute ischemic stroke; mRS= modified Rankin Scale

DISCUSSION

Although significant progress has been made in the treatment of AIS, it remains one of the leading causes of disability and death worldwide (13). Furthermore, due to the rising average age of the population and the prevalence of various comorbidities among elderly, it is anticipated that the general population will face an increased burden from AIS in the years ahead, with the assumption that one in four individuals will experience AIS (14). It has been demonstrated that the benefit of IVT rapidly declines over time from symptom onset (15). It has been estimated that every minute without appropriate treatment results in the loss of approximately 1.8 million neurons, emphasizing the importance of minimizing the time period from the onset of symptoms to IVT administration (16).

The proportion of stroke mimics in the group of patients treated with intravenous thrombolytic therapy in our study was 2.9%. Previously published studies reported the frequency of IVT treated stroke mimics ranging from 1.4% to 15.5% (17-26). One potential explanation for such a low proportion in our study is the fact that it was conducted in one of the largest health care centers in the country, where doctors have extensive experience in IVT administration decision-making process. Their clinical experience in treating patients with AIS is valuable for the outcome of the treatment itself. It has been reported that the proportion of patients with stroke mimics is higher in hospitals where the decision to administer IVT is made based on telephone consultations between emergency medicine doctors, who are the first one to examine the patient, and on-call neurologists (24). Although it is known that MRI is more sensitive in detecting potential stroke mimics (24), it is still not routinely performed in most health care centers, and the diagnosis of AIS remains, above all, a clinical diagnosis combined with a non-contrast CT scan (12), as was the case in this study.

Our study showed that none of the patients with stroke mimics developed symptomatic intracerebral hemorrhage while its incidence in the group of AIS patients was 4.5% (p=1.000). Regarding mortality outcomes, there were no deaths in the stroke mimics group, as opposed to one death in the AIS group, which was not a statistically significant difference (p=1.000). These results are consistent with those of a large multicenter international study, which also demonstrated the safety of IVT use in stroke mimics, with a low incidence of complications (12). That study reported the incidence of sICH in the stroke mimics group of 1% (95% CI 1.5-2.2) vs. 7.9% (95% CI 7.2-8.7) in AIS group, while the mortality rate in the stroke mimics group was 2.1% (95% CI 0.3-7.3) vs. 14.4% (95% CI 13.4-15.3) in the group of patients with acute ischemic stroke (12). The cited study also showed a statistically significant difference between the two groups in terms of excellent functional outcome (mRS 0-1) and good functional outcome (mRS 0-2), in both cases, p<0.0001 (12), which is consistent with our results (mRS 0-1 p=0.001, mRS 0-2 p=0.007). Although, ideally, IVT should not be administered to patients without a pathological substrate for acute ischemic stroke, the aforementioned results highlight that the safety of patients with stroke mimics is not compromised by the use of IVT. Moreover, numerous studies have shown that the benefit of early IVT administration is correlated with better outcomes in the treatment of patients with AIS (27, 28, 29). Therefore, in uncertain situations, it is entirely reasonable to administer IVT until an additional/more sophisticated diagnostic method can exclude the diagnosis of AIS (12).

The main limitation of this study lies in the fact that it was conducted at a single health care center, specifically a tertiary healthcare facility with extensive experience, resulting in a relatively small number of patients diagnosed with stroke mimics through retrospective evaluation. Taking this into account, it is assumed that the results could potentially be less favorable in smaller centers. Certainly, one of the plans for future analysis would be to include a larger number of national centers in order to obtain a more comprehensive picture of the frequency of stroke mimics among IVT treated patients.

CONCLUSION

Although the use of intravenous thrombolysis is often still accompanied by some apprehension, our study has demonstrated that IVT administration in acute conditions presenting with a clinical picture of acute ischemic stroke is safe for the patient. While it remains crucial to adhere to clinical guidelines when administering IVT, as well as to continually improve diagnostic approaches for patients with AIS, the results are encouraging. These findings may potentially serve as a rationale for neurologists to confidently initiate IVT in a timely manner, as the risk of complications from administered therapy is minimal, even in cases of stroke mimics.

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Conflicts of interest:

DRJ received speaker honoraria from Medtronic and Boehringer Ingelheim.
VP received speaker honoraria from Medtronic and Boehringer Ingelheim. Other authors declare no conflict of interest related to the presented study.

Ethical approval

In this paper, only retrospective data were used and obtained from medical records, thus Ethical approval was not obtained. Corresponding author and co-authors undertake that this research's processed data are presented in a way that does not allow the individual subject's identification. All data are related exclusively to the topic of research, without possibility of connecting the data with the identity of persons.

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BEZBEDNOST PRIMENE INTRAVENSKE TROMBOLITIČKE TERAPIJE KOD STANJA KOJA IMITIRAJU MOŽDANI UDAR ("STROKE MIMICS") - PETNAESTOGODIŠNJE ISKUSTVO

Uroš Miladinović [1], Rea Mikulan [1], Dejana R. Jovanović [1,2], Višnja Pađen [1,2]

Sažetak

Uvod: Neophodnost donošenja brze odluke o primeni intravenske trombolize (IVT) u lečenju akutnog ishemijskog moždanog udara (AIMU) može imati za posledicu njeno ordiniranje i kod stanja koja svojom kliničkom slikom mogu da imitiraju AIMU.

Cilj: Ispitivanje bezbednosti primene IVT kod drugih akutnih stanja koji se prezentuju istom ili sličnom kliničkom slikom kao AIMU, tj. "stroke mimics".

Materijal i metode: Sprovedena je retrospektivna analiza podataka ukupno 764 pacijenta lečenih trombolitičkom terapijom na Odeljenju urgentne neurologije, Klinike za neurologiju Univerzitetskog kliničkog Centra Srbije u periodu od 2006. do 2021. godine.

Rezultati: Od ukupno 764 pacijenta sa AIMU lečenih primenom IVT, dijagnoza "stroke mimics" je postavljena kod 22 pacijenta (2.9%). Prosečna starost grupe pacijenata sa dijagnozom "stroke mimics" je iznosila 49,1 ± 16,3 (min 26, max 86), od čega je 55% pacijenata bilo ženskog pola. Najučestaliji vaskularni faktor rizika prisutan u ovoj grupi pacijenata bila je arterijska hipertenzija (41%), potom pušenje (14%) i hiperholesterolemija (14%). Poređenjem ovih pacijenata sa kontrolnom grupom tromboliziranih pacijenata sa AIMU (uparenih prema polu i starosti) utvrđeno je postojanje trenda ka blažem inicijalnom kliničkom deficitu merenom NIHSS skorom (5 vs. 9; p=0.058), uz veću verovatnoću nastanka povoljnog funkcionalnog ishoda (mRS 0-2) (91% *vs*. 55%; p=0.007) u "stroke mimics" grupi. Ni kod jednog pacijenta sa "stroke mimcs" nije utvrđena pojava simptomatske intracerebralne hemoragije. Između dve grupe nije utvrđeno postojanje statistički značajne razlike kada je u pitanju pojava smrtnog ishoda (p=1.000).

Zaključak: Upotreba IVT kod akutnih stanja koja se prezentuju kliničkom slikom AIMU je bezbedna po pacijenta.

Ključne reči: akutni ishemijski moždani udar (AIMU), "stroke mimics", intravenska trombolitička terapija (IVT)

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