DOI:10.4274/tnd.2023.70292
Turk J Neurol 2023;29:249-255

Original Article / Özgün Araştırma

Acute Stroke Management in Türkiye: Intravenous Tissue Plasminogen Activator and Thrombectomy NöroTek: Türkiye Neurology Single Day Study

Türkiye'de Akut İnme Yönetimi: IV tPA ve Trombektomi NöroTek: Türkiye Nöroloji Tek Gün Çalışması

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Received/Geliş Tarihi: 12.09.2023 **Accepted/Kabul Tarihi:** 05.10.2023

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Abstract

Objective: To reveal the profile and practice in patients with acute stroke who received intravenous tissue plasminogen activator (IV tPA) and/or neurointerventional therapy in Türkiye.

Materials and Methods: On World Stroke Awareness Day, May 10, 2018, 1,790 patients hospitalized in 87 neurology units spread over 30 health regions were evaluated retrospectively and prospectively.

Results: Intravenous tPA was administered to 12% of 859 cases of acute ischemic stroke in 45 units participating in the study. In the same period, 8.3% of the cases received neurointerventional treatment. The rate of good prognosis [modified Rankin score (mRS) 0–2] at discharge was 46% in 83 patients who received only IV tPA [age: 67 ± 12 years; National Institutes of Health Stroke Scale (NIHSS): 12 ± 6; hospital stay, 24 ± 29 days]; 35% in 51 patients who underwent thrombectomy (MT) alone (age: 64 ± 13 years; NIHSS: 14.1 ± 6.5; length of hospital stay, 33 ± 31 days), 19% in those who received combined treatment (age: 66 ± 14 years; NIHSS: 15.6 ± 5.4; length of hospital stay, 26 ± 35 days), and 56% of 695 patients who did not receive treatment for revascularization (age: 70 ± 13 years; NIHSS: 7.6 ± 7.2; length of hospital stay, 21 ± 28 days). The symptom-to-door time was 87 ± 53 minutes in the IV treatment group and 200 ± 26 minutes in the neurointerventional group. The average door-to-needle time was 66 ± 49 minutes in the IV tPA group. In the neurothrombectomy group, the door-to-groin time was 103 ± 90 minutes, and the TICI 2b-3 rate was 70.3%. In 103 patients who received IV tPA, the discharge mRS 0–2 was 41%, while the rate of mRS 0–1 was 28%. In 71 patients who underwent neurothrombectomy, the mRS 0–2 was 31% and mRS 0–1 was 18%. The door-to-groin time was approximately 30 minutes longer if IV tPA was received (125 ± 107 and 95 ± 83 minutes, respectively). Symptomatic bleeding rates were 4.8% in IV recipients, 17.6% among those who received only MT, and 15% in combined therapy. Globally, the hemorrhage rate was 6.8% in patients receiving IV tPA and 16.9% in MT.

Conclusion: IV thrombolytic and neurointerventional treatment applications in acute ischemic stroke in Türkiye can provide the anticipated results. Heterogeneity has begun to be reduced in our country with the dissemination of the system indicated by the "Directive on Health Services to be Provided to Patients with Acute Stroke."

Keywords: Acute stroke, thrombolytic therapy, thrombectomy, prognosis, treatment window, metric

Öz

Amaç: Türkiye'de intravenöz doku plazminojen aktivatörü (IV tPA) ve/veya nöro-girişimsel tedavi uygulanan akut inme hastalarının profili ve uygulamaya dair pratiklerin ortaya konulması.

Gereç ve Yöntem: 10 Mayıs 2018 Dünya İnme Farkındalık Günü'nde 30 sağlık bölgesine yayılmış olan 87 nöroloji biriminde yatmakta olan 1.790 hasta retrospektif ve prospektif olarak değerlendirilmiştir.

Bulgular: Çalışmaya katılan 45 birimde 859 akut iskemik inme olgusundan %12'sine IV tPA uygulanmıştır. Aynı dönemde %8,3 olgu nörogirişimsel tedavi almıştır. Taburculuk esnasında iyi prognoz [modifiye Rankin skoru (mRS) 0–2] oranı sadece IV tPA uygulanan 83 olguda [yaş: 67 ± 12 yıl; Ulusal Sağlık İnme Ölçeği (NIHSS): 12 ± 6, hastanede yatış süresi 24 ± 29 gün] %46; sadece trombektomi (MT) uygulanan 51 olguda (yaş: 64 ± 13 yıl; NIHSS: 14,1 ± 6,5; hastanede yatış süresi 33 ± 31 gün) %35, kombine tedavi alanlarda (yaş: 66 ± 14 yıl, NIHSS: 15,6 ± 5,4, yatış süresi 26 ± 35 gün) %19 ve revaskülarizasyona yönelik tedavi uygulanmayan 695 olguda (yaş: 70 ± 13 yıl, NIHSS 7,6 ± 7,2; ortalama yatış süresi: 21 ± 28 gün) %56'dır. Semptom kapı zamanı IV tedavi alanlarda 87 ± 53 dakika iken nörogirişimsel grupta 200 ± 26 dakikadır. IV tPA grubunda ortalama kapı iğne zamanı 66 ± 49 dakikadır. Nörotrombektomi grubunda kapı-kasık zamanı 103 ± 90 dakika ve TICI 2b-3 oranı %70,3'dür. IV tPA uygulaması yapılan 103 olguda taburculuk mRS 0–2 %41 iken mRS 0–1 oranı %28 olarak belirlenmiştir. Toplam nörotrombektomi uygulanan 71 olguda mRS 0-2 %31 ve mRS 0-1 %18 olarak kaydedilmiştir. Kapı-kasık girişi zaman IV tPA almış ise yaklaşık yarım saat daha uzundur (sırasıyla; 125 ± 107 dakika ve 95 ± 83 dakika). Semptomatik kanama oranları ise sadece IV alanlarda %4,8; sadece MT yapılanlarda %17,6; kombine tedavide %15 olup IV alan hastalarda global olarak %6,8 ve MT'de %16,9'dur.

Sonuç: Türkiye'de akut iskemik inmede IV trombolitik ve nörogirişimsel tedavi uygulamaları beklenen sonuçları sağlayabilmektedir. Ülkemizde "Akut İnmeli Hastalara Verilecek Sağlık Hizmetleri Hakkında Yönerge"nin işaret ettiği sistemin yaygınlaştırılması ile heterojenite azaltılma yoluna girmiştir.

Anahtar Kelimeler: Akut inme, trombolitik tedavi, trombektomi, prognoz, tedavi penceresi, metrik

Introduction

In Türkiye, intravenous (IV) tissue plasminogen activator (tPA) was licensed in May 2006, approximately 10 years after licensing in the European Union region (1). In the period that followed, many individual hospital-based series (2,3,4), one multi-center study (5), one meta-analysis (6), and the Turkish Neurological Society practice guidelines were published in Türkiye on the use of IV tPA (7,8). This retrospective data revealed that IV tPA treatment can be applied as a standard in Türkiye. The mechanical (stent and/or aspiration-mediated) thrombectomy (MT) method, which had been used successfully in the treatment of acute stroke in Türkiye for a long time and was issued in the "Directive on Health Services to be Provided to Patients with Acute Stroke" published on July 18, 2019 (referred to herein as "Stroke Directive") (9), was increasingly used and became widespread (10). However, the data demonstrating the effectiveness of MT in acute stroke in Türkiye is more limited (11). "NöroTek," the first application of the "point prevalence" or "flash-mob" research (FMR) study technique in neurology in Türkiye, was performed prior to the coronavirus disease-2019 (COVID-19) outbreak and provided an important perspective on both IV tPA and MT (12,13). NöroTek's findings on acute treatment are shared in this article, with the aim that they might serve as a resource for comparing current practice results and evaluating temporal development.

Materials and Methods

The NöroTek study was based on data obtained from patients who had been hospitalized in the neurology units of hospitals participating in World Stroke Day on May 10, 2018. All patients hospitalized on the morning of May 10, 2018, were evaluated prospectively and retrospectively. The form used to collect the data was a single sheet, the front side of which was completed on May 10, and the back side on the day that the patient was discharged (13). The NöroTek study was evaluated and approved by the Non-invasive Ethics Committee of the Hacettepe University Faculty of Medicine within the scope of "clinical study for consortium" (date: 27.03.2018; number, 18/331). Data-sharing consent, permissions obtained from hospital/unit managers, and the originals of the completed forms were kept in the participating centers. Details regarding the financing, logistics, data collection, and processing of the study were previously published (13). To summarize, in addition to all units that voluntarily participated in the study, invitations were sent to hospitals determined to represent 30 health service regions in Türkiye and representation was provided (Supplementary 1) (14). Within the scope of the first day of the NöroTek study, descriptive demographic characteristics, vascular risk factors, previous hospitalization(s), symptom onset, hospital arrival and hospitalization times, and the preference of the first imaging method [computed tomography (CT) and magnetic resonance imaging] and its time were included in the form. Whether IV tPA and/or MT was/was not performed, and the reason(s) for excluding either/both, were noted.

Discharge time, discharge destination (to home, rehabilitation center, or other hospital), modified Rankin Score (mRS) score (15), and mortality data were noted.

Where and when IV tPA was administered (emergency department, stroke unit, neurology intensive care unit, other units), 24-hour National Institutes of Health Stroke Scale (NIHSS) score (16) and 24-hour brain CT result were noted; if CT images showed bleeding on the brain or if new symptoms occurred, this information was also noted. Fiorelli classification was used to categorize hemorrhagic complications in cranial CT images (17). Imaging findings before MT, the branch of the specialist performing the procedure, femoral puncture time, post-procedure thrombolysis in cerebral infarction (TICI) score (18), second-day brain CT findings and NIHSS score, and, if any, bleeding complications, were noted.

Statistical Analysis

All values were expressed as mean ± standard deviation, mean (95% confidence interval), percentage (95% confidence interval), and median (interquartile range) outcomes. The normality of the data distribution was examined via histogram inspection or via Kolmogorov–Smirnov or Shapiro–Wilk tests. Accordingly, differences between groups were evaluated using a Student's t-test, Mann–Whitney U test, chi-square test, Fisher's exact test,

or analysis of variance. The statistical significance level was set at $P < 0.05$. All calculations were performed using SPSS version 22.0 software.

Results

A total of 1,790 patients (2.2/100,000), 859 of whom had had an acute ischemic stroke, were included in this study from 87 centers located in 30 health regions (13). Of the centers participating in the study, 16 (6.4%) met the definition of "stroke-ready hospital," (SRH); the terms "hospital" or "SRH" are used for these hospitals in this article (19). There is no definition in the stroke guideline for this group (9). Among the included centers, 26 (31%) met the definition of "primary stroke center" and are described as "stroke unit" in the Stroke Directive (9,20). Forty-five (62.5%) centers met the "stroke center" definition of the Stroke Directive, as well as the "comprehensive stroke center" criteria (9,20).

IV tPA was administered to 103 patients in 45 centers. While 24.3% of the applications were performed in stroke units and 75.7% in stroke centers, tPA was not given in SRHs. MT was performed in 71 patients in 27 stroke centers. Approximately 50% of all hospitals and 60% of stroke centers had at least one patient who underwent a MT and was hospitalized in neurology units on the study day. Successful recanalization (TICI 2b-3) was achieved in 70.3% of the patients who underwent MT.

While the door-to-needle time was 66 ± 49 minutes in the patient group that received only IV tPA, it was 67 ± 49 minutes in the patient group that received post-IV tPA MT bridging, and no statistical difference was detected between the groups. The average interval between admission to the emergency department and femoral artery puncture, that is, "door-to-groin time," was 103 ± 90 minutes.

Symptom-to-door time was 87 ± 53 minutes in patients who received IV tPA, which was not different in patients who received only IV tPA (88 ± 51 minutes) and, subsequently, MT (86 ± 64 minutes). As expected, symptom onset time was significantly longer (200 ± 26 minutes) in patients treated with MT only.

Door-to-groin time was 125 ± 107 minutes in patients who received IV tPA before the procedure (data was available for 16 patients) and was longer (95 ± 83 minutes) than in those who did not receive tPA (data was available for 45 patients). The completion time of the interventional treatment starting from the groin access was recorded in 62% of the patients and was 76 ± 35 minutes. This period was not different between those who received IV tPA and those who did not [71 ± 29 minutes if IV tPA (+) and 78±37 minutes if IV tPA (-)].

The rate of patients with a very good functional prognosis (mRS ≤1), according to the mRS scores given at the third month or at discharge, was 28% among those who received IV tPA (IV tPA only, 33%; combined treatment, 7%), while the rate of those with a good functional prognosis (mRS ≤2) was 46% (IV tPA only, 41%; combined treatment, 19%) (Table 1). A significant decrease in NIHSS score was observed in all groups at the end of the first 24 hours. It was noted that in the MT group, the NIHSS score 24 hours after the procedure was not sufficiently collected.

After solo IV tPA administration, the cerebral hemorrhagic transformation rate was 14.4%, and symptomatic Fiorelli parenchymal hemorrhage type-2 was detected in 4 patients (4.8%). Hemorrhagic transformation detected in post-treatment imaging was 45% (15% symptomatic) in patients treated with bridging therapy, while this was 33% (17.6% symptomatic) in patients treated with MT only. The rates of any bleeding and symptomatic bleeding were 20.4% and 6.8% in all patients who received IV tPA, while these were 36.7% and 16.9% in all patients who received MT.

Although the duration of hospital stay was quite heterogeneous, it was longer in patients who received recanalization treatments [IV tPA only (24 ± 29 days); MT only (33 ± 31 days), and IV tPA + MT (26 ± 35 days), there was no statistical difference between the groups] than for those who did not receive recanalization treatments (21 ± 28 days).

Finally, data concerning the reasons for not applying IV treatment, the branch of the specialist performing the MT procedure, the discharge destination, and the hospital unit where IV tPA was administered were completed.

Discussion

The NöroTek study falls into the "nationwide point prevalence" category and was conducted for the first time in the field of neurology in Türkiye. Worldwide, there are few examples of this method involving neurological diseases. For example, delirium has been successfully studied using this method, but there is no example of the method in major neurological disease groups including stroke (21). With its simple form, FMR stands out as a method primarily used in infectious disease surveillance and intensive care practices (22,23,24,25). When using this approach, at a certain point in time, a single question is typically answered

Table 1. Functional results according to treatment groups

Treatment		n	Age	Pre-treatment NIHSS score	24-hour NIHSS score	mRS 0-1	mRS 0-2
IV tPA	MT		Mean ± SD				
+	-	83	67 ± 12	11.9 ± 6	8.4 ± 6.7	33%	46%
+	+	20	66 ± 14	15.6 ± 5.4	13.9 ± 7.9	7%	19%
-	+	51	64 ± 13	14.1 ± 6.5	-	22%	35%
-	-	695	70 ± 13	7.6 ± 7.2	-	40%	56%
Total IV tPA		103	67 ± 12	12.5 ± 6.2	9.3 ± 7.2	28%	41%
Total MT		71	65 ± 13	14.5 ± 6.3	-	18%	31%

IV tPA: Intravenous tissue plasminogen activator, mRS: Modified Rankin score, MT: Mechanical thrombectomy, NIHSS: National Institutes of Health Stroke Scale, SD: Standard derivation

[e.g., "What supplement is the patient taking?" on the "nutrition day" (26) or "Was the patient mobilized today?" (27) in intensive care units]. The FMR method was introduced to organize social action using social media environments and was later transferred to scientific environments (28). We developed this method by identifying the patients and answering critical questions both retrospectively and prospectively. The evidence clearly indicates that a NöroTek FMR-type study can be applied in the field of neurology in Türkiye.

The NöroTek study produced clear daily life data on thrombolytic/TM applications in acute stroke cases in Türkiye. Previously, a prospective data bank study (n = 1.133) conducted with the participation of 38 stroke centers in 18 cities called the "Turkey National Intravenous Thrombolysis Registry Study" and a meta-analysis of case reports/series were published in peer-reviewed journals from Türkiye (5). IV tPA data from the NöroTek study were compared with the results of these studies. The Türkiye National Intravenous Thrombolysis Registry Study data were removed from the original meta-analysis (6) and the analysis of the remaining 21 studies was conducted by us for this purpose. The total number of patients in this partial meta-analysis was 1.216 and their data had not been previously published.

The patients' mean age in the NöroTek study was older than in both the meta-analysis and the Turkish National Intravenous Thrombolysis Registry Study [mean ages: 67 years in the NöroTek study, 63.8 years in the meta-analysis (P = 0.001), and 64 years in the Turkish National Intravenous Thrombolysis Registry Study (P = 0.024)] (5,6). In the NöroTek study, symptom-to-needle time and door-to-needle time were at a similar level to the results of the meta-analysis and the Turkish National Intravenous Thrombolysis Registry Study (5,6). This current survival data may indicate that logistics in hospitals are suitable for IV tPA administration. However, these require improvement, especially when compared to the standards in European countries.

In the NöroTek study, the neurological deficit weight quantified by the NIHSS score in patients using IV tPA was significantly lower (12.5 ± 6, 2, P = 0.001 and P = 0.007, respectively) (5,6). Keeping this point in mind, the NöroTek study indicates that the benefits and harms to be expected from IV tPA are currently compatible with both the Turkish National Intravenous Thrombolysis Registry Study, meta-analysis results, and global data. In other words, IV tPA in acute stroke cases is applied in accordance with general quality metrics in Türkiye and good results are being obtained. The rate of patients discharged with an mRS score of 0–2 was 41% in the NöroTek study, which was lower than in the Turkish National Intravenous Thrombolysis Registry Study (65%, P = 0.001), and similar to the meta-analysis (46%, P = 0.382) (5,6). This observed difference may be related to the higher participation of advanced and experienced stroke centers in the Turkish National Intravenous Thrombolysis Registry Study; the inclusion of severely ill or unresponsive patients undergoing MT in the NöroTek study may also have been a contributing factor.

The symptomatic bleeding rate in the NöroTek study was 4.8%, which was numerically lower than both the Turkish National Intravenous Thrombolysis Registry Study (4.9%, P = 0.847) and meta-analysis (6.2%; P = 0.722), but was within range of the average results in similar studies in the literature (5,6).

Five years have passed since the completion of the NöroTek study (12,13). A significant part of this time ensued under the influence of the COVID-19 pandemic. For the past year, we have been experiencing the implementation process of the Stroke Directive in parallel with its normalization in Türkiye. Currently, the dataset produced by the NöroTek study, which reflects the most scientifically valid overview among existing studies conducted just before the outbreak of the COVID-19 pandemic (and remains up-to-date), serves as both an important source and a critically important reference point for comparisons to determine future progress.

Conclusion

In conclusion, the NöroTek study reflects strong current survival data, indicating that performing IV tPA and MT in cases of acute ischemic stroke in Türkiye can provide the anticipated results. That is, IV tPA is being administered safely in Türkiye and positive results can be obtained. The observed heterogeneity can be reduced by the introduction of the Directive on Health Services to be Provided to Patients with Acute Stroke and the dissemination of its systematic application. Academia and practitioners must develop methods to publicize IV tPA in acute ischemic stroke cases and to continuously improve quality metrics. The NöroTek study represents an important step taken in this context.

Ethics

Ethics Committee Approval: Non-invasive Ethics Committee of the Hacettepe University Faculty of Medicine (27.03.2018; number, 18/331).

Informed Consent: The authors have stated that they obtained signed consent for data sharing from the patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: All authors, Concept: M.A.T., E.M.A., A.Ö.Ö., Design: M.A.T., E.M.A., A.Ö.Ö., Data Collection or Processing: All authors, Analysis or Interpretation: M.A.T., E.M.A., A.Ö.Ö., Literature Search: M.A.T., Writing: M.A.T.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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Supplementary 1 Link: http://glns.co/22j3m