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RESEARCH ARTICLE **ÖZGÜN ARAŞTIRMA**

EVALUATION OF MECHANICAL THROMBECTOMY RESULTS IN PATIENTS WHO DEVELOPED ACUTE ISCHEMIC STROKE WHILE USING NEW GENERATION ORAL ANTICOAGULANTS

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ABSTRACT

INTRODUCTION: Direct oral anticoagulants have demonstrated efficacy and safety in cerebrovascular prevention. We aimed to investigate the safety and efficacy of mechanical thrombectomy in patients with major vascular occlusion while receiving DOAC, and to evaluate the clinical characteristics and treatment outcomes of patients.
METHODS: A retrospective study of prospectively collected data based on data from the registry of the Osmangazi University was performed between January 2015 and December 2019. All patients have cardioembolic etiology. We collected the demographics, clinical and brain imaging, and stroke etiology. A good outcome was defined as a modified Rankin Scale (mRS) score ≤0-2 at three months follow-up.
RESULTS: 140 patients were included. Patients were classified and compared into two study groups according to DOAC at admission. There were no differences in basic demographics, clinical characteristics, and vascular risk factors between the two groups, A total of 23 patients adherent with DOAC were admitted, All patients, except 2, were using DOAC regularly. 69.6% of the patients receiving DOAC and 84.3% of the other group were fully recanalized (TICI 2b-3) (p=0.18). No significant difference was observed in intracranial hemorrhage, The Thrombolysis in Cerebral Infarction (TICI) score, and mortality between patients with and without DOAC. The patients with mRS ≤0-2 were 26.1% in the DOAC group and 53.8% in the other group. This difference was statistically significant (p=0.02).
DISCUSSION AND CONCLUSION: Despite similar recanalization rates, 3rd-month mRS scores were worse in patients receiving DOAC. In conclusion, given the complexity of the clinical situation, it would be beneficial to establish standardized protocols for the development of endovascular treatment.
Keywords: Acute stroke, direct oral anticoagulants, mechanical thrombectomy, large vessel occlusion.

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YENİ KUŞAK ORAL ANTİKOAGÜLAN KULLANIRKEN AKUT İSKEMİK İNME GELİŞEN HASTALARDA MEKANİK TROMBEKTOMİ SONUÇLARININ DEĞERLENDİRİLMESİ

ÖZ

GİRİŞ ve AMAÇ: Direkt oral antikoagülanların, serebrovasküler hastalıkları önlemede etkinlik ve güvenirlikleri gösterilmiştir. DOAC alırken majör damar tıkanıklığı olan hastalarda mekanik trombektominin güvenliğini ve etkinliğini araştırmayı ve hastaların klinik özelliklerini ve tedavi sonuçlarını değerlendirmeyi amaçladık.
YÖNTEM ve GEREÇLER: Ocak 2015 ile Aralık 2019 tarihleri arasında Osmangazi Üniversitesi kayıtlarından elde edilen verilere dayalı olarak prospektif toplanan verilerin retrospektif analizi yapıldı. Tüm hastalarda inme etyolojisi kardiyoembolikti. Hastaların demografik bilgileri, klinik ve beyin görüntülemesini ve inme etiyolojisini topladık. İyi klinik sonlanım, üç aylık takipte modifiye Rankin Skalası (mRS) skoru ≤0-2 olarak tanımlandı.
BULGULAR: Çalışmaya140 hasta dahil edildi. Hastalar başvuruda DOAC alma durumuna göre sınıflandırıldı ve gruplar karşılaştırıldı. İki grup arasında temel demografik özellikler, klinik özellikler ve vasküler risk faktörleri açısından fark yoktu, DOAC alan toplam 23 hasta vardı, 2 hasta dışında tüm hastalar düzenli olarak DOAC kullanıyordu. DOAC alan hastaların %69,6'sı ve diğer grubun %84,3'ü tamamen rekanalize edildi (TICI 2b-3) (p=0,18). DOAC olan ve olmayan hastalar arasında intrakraniyal kanama, The Trombolysis in Cerebral Infarction (TICI) skoru ve mortalite açısından anlamlı bir fark gözlenmedi. mRS ≤0-2 olan hastalar DOAK grubunda %26.1, diğer grupta %53,8 idi. Bu fark istatistiksel olarak anlamlıydı (p=0.02).
TARTIŞMA ve SONUÇ: Benzer rekanalizasyon oranlarına rağmen DOAK alan hastalarda 3. ay mRS skorları daha kötüydü. Sonuç olarak, klinik durumun karmaşıklığı göz önüne alındığında, endovasküler tedavinin geliştirilmesi için standart protokoller oluşturmak faydalı olacaktır.

Anahtar Sözcükler: Akut inme, direkt oral antikoagülan, mekanik trombektomi, büyük damar tıkanıklığı.

INTRODUCTION

Cardioembolic stroke accounts for 13-27% of ischemic strokes. Atrial fibrillation is the most common cause among cardioembolic stroke patients, with an annual stroke risk of 4.5% being reported in patients with atrial fibrillation, who do not receive anticoagulant therapy. Vitamin K antagonists and direct oral anticoagulants (DOACs) are among the existing anticoagulant therapies (1).

Recent studies have provided support for the efficacy and safety of the use of dabigatran (direct thrombin inhibitor), rivaroxaban, edoxaban, and apixaban (direct Factor Xa inhibitors) therapies compared to vitamin K antagonists, considering the ease of use and the decreased risk of intracranial hemorrhage (1). There has been an increase in the number of patients with AF receiving DOACs. It was demonstrated that 1-2% of these patients present with ischemic stroke (2).

Mechanical thrombectomy (MT) can be performed in patients with acute ischemic stroke receiving an anticoagulant therapy, but the studies have reported that this procedure might be associated with a high risk of symptomatic intracerebral hemorrhage and poor prognosis (3). The randomized trials reporting positive results and the HERMES (Highly Effective Reperfusion Evaluated in Multiple Endovascular Stroke Trials) study did not provide reliable data regarding the safety and efficacy of MT (4).

The present study aims to investigate the safety and efficacy of mechanical thrombectomy in patients sustaining major vessel occlusion while receiving DOACs, and to evaluate clinical characteristics and treatment outcomes of the patients.

METHODS

Study Population: The registered data of patients, who were diagnosed with acute ischemic stroke due to major vessel occlusion and who underwent mechanical thrombectomy in Eskişehir Osmangazi University Hospital, Neurology Clinic between January 2015 and December 2020, were reviewed retrospectively. The study included only patients aged 18 years and older with an etiological cause of cardioembolic stroke who underwent mechanical thrombectomy. Patients on warfarin therapy and those with a baseline modified Rankin Scale score (mRS) of 2 and higher were excluded.

Data Recorded: Baseline characteristics such as age, gender, baseline mRS, risk factors (diabetes mellitus, hypertension, smoking, dyslipidemia), medical history (previous ischemic coronary artery disease and atrial fibrillation), data on

compliance with the anticoagulant drugs, stroke onset, stroke severity based on the National Institutes of Health Stroke Scale (NIHSS), blood pressure, blood glucose, and International Normalized Ratio (INR) value were recorded.

The etiological classification of ischemic stroke was made according to the Trial of Org 10172 in Acute Stroke Treatment etiologic classification (TOAST) (5).

The DOAC used by patient, the time when the last dose of the drug was taken, and the use of indications were recorded.

All patients underwent head computed tomography (CT) and computed tomography angiography (CTA). The Alberta stroke program early CT score (ASPECT) was recorded. Patients with an occluded M1 segment of the middle cerebral artery (MCA), the intracranial segment of the internal carotid artery (ICA) (T and L occlusion), and those with proximal (ICA-MCA tandem) and vertebrobasilar occlusion were included in the study.

The symptom-to-door time, door-to-imaging time, door-to-groin puncture time, and puncture-to-recanalization time were recorded.

Treatment: Patients presenting within the first 4.5 hours after the symptom onset were administered intravenous thrombolytic (IVT) therapy (tissue plasminogen activator [tPA], Alteplase 0.9 mg/kg) before undergoing mechanical thrombectomy. However, tPA was not administered if patient had received DOAC in the last 24 hours.

Mechanical thrombectomy was performed by neuro interventionalists with an experience of at least five years, as per the current guidelines. Patients with an NIHSS score greater than five and those presenting within 6 hours after the symptom onset underwent mechanical thrombectomy. Patients presenting 6 hours after the symptom onset and those with unknown symptom onset time underwent CT perfusion using the automated RAPID (iSchemaView, Menlo Park, CA) software. Patients exhibiting a mismatch pattern underwent mechanical thrombectomy.

All patients underwent the procedure under neurosedation. Balloon guiding catheter was used as the guiding catheter in some patients. Balloon catheters were 8-9-French large-diameter catheters that blocked anterograde flow when inflated proximally; and allowed better aspiration and increased treatment success both in the isolated and combined techniques. Mechanical thrombectomy was performed using stent retrievers and aspiration catheters. The first pass recanalization rate and the number of passes were evaluated. The recanalization status was evaluated in the final angiography using the Thrombolysis in Cerebral Infarction (TICI) scale. A TICI scale score of 2b-3 was considered as successful recanalization.

The periprocedural complications related to the mechanical thrombectomy included collateral embolism, distal embolism, dissection, and vessel rupture.

The safety of endovascular therapy in patients receiving anticoagulant therapy was evaluated by comparing intracerebral hemorrhage rates. The presence of intracerebral hemorrhage (HI1, HI2, PH1, PH2) in all patients was evaluated by control CT scans at 24 hours. Symptomatic intracerebral hemorrhage was defined as any hemorrhage resulting in at least 4 points deterioration in the NIHSS score or death according to the ECASS-3 (European Cooperative Acute Stroke) study (6).

The modified Rankin Score (mRS) was used to evaluate functional outcomes during discharge and at three months. Patients with an mRS of 0-2 at two months were considered to have achieved good outcomes while those with an mRS of 3-6 at three months in whom recanalization was achieved were classified as futile recanalization (7).

The study was conducted in accordance with the ethical standards of the Declaration of Helsinki and approved by the Clinic Research Ethics Committee of Eskişehir Osmangazi University (Date: 16.06.2020 No: 20).

As this was a non-interventional retrospective study and no personal data of the participants were recorded, informed consent was deemed unnecessary.

Statistical Analysis: SPSS software (version 21.0; SPSS, Chicago, Illinois) was used for the statistical analysis. Fisher's exact test and Kruskal–Wallis test were used for nonparametric variables. Data normality was tested using Shapiro–Wilk test. Multivariate logistic regression analysis was used to identify the possible predictors of ICH, SICH, and good clinical outcome. An alpha of 0.05 was used in all tests for statistical significance.

RESULTS

Three hundred and fifty-one patients who underwent mechanical thrombectomy due to an acute ischemic stroke between January 2015 and December 2020 were evaluated. There were 168 patients (47.8%) with cardioembolic stroke. Twenty-eight patients who present with stroke while on warfarin therapy were excluded from the study (Figure 1).

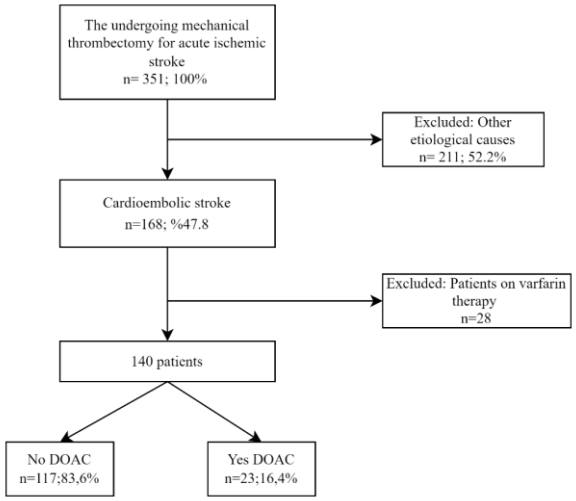

Figure 1. Flow chart of study.

Baseline demographic characteristics of patients receiving or not receiving DOAC are summarized in Table 1. Of our patients, 12 (8.6%) had rheumatic valve disease, 1 (0.7) aortic valve replacement, 16 (11.4%) mild heart failure, 21 (15%) severe heart failure, 11 (7.9%)) atrial thrombus, 4 (2.9) had a history of cardiac catheterization, 1 (0.7%) had a cardiac anomaly (functional single ventricle), and 74 (52.9%) had non-valvular atrial fibrillation. Of 140 study participants, 23 (16.4%) were using DOAC (78.3% were females, the mean age was 71.3±5.4 years). The DOACs used by our patients are given in Table 1. Of these patients, only two (8.7%) had irregular drug use history. There was no significant difference in baseline median NIHSS score between the two groups (p=0.366). Patients presenting with stroke while receiving DOACs were significantly older (p<0.001) and had a higher rate of atrial fibrillation (p<0.001). There was no difference between the two groups regarding other vascular risk factors (Table 2).

tPA was contraindicated; thus, not administered in 47% of patients receiving or not receiving DOAC therapy (20% with delayed presentation 4.5 hours after symptom onset, 4% with stroke with an unknown onset time, 8% with wake-up stroke, 12% with major surgery, 2% with stroke history in the last three months, 32% using DOAC, and 22% with other causes). Sixty-five patients (55.6%) who did not receive DOAC therapy were administered intravenous thrombolytic therapy before undergoing mechanical thrombectomy while only one patient (4.3%) receiving DOAC therapy was administered intravenous thrombolytic therapy. This difference was statistically significant (p<0.001). The rate of successful recanalization (TICI 2b and 3) was 69.6%, and the rate of complete recanalization (TICI 3) was 30.4% in patients receiving DOAC therapy. This rate was statistically comparable to that in patients not treated with DOACs (p=0.075) (Table 4). Good clinical outcomes were achieved at three months in 53.8% of patients not receiving DOAC therapy and 26.1% of patients receiving DOAC therapy. The difference was statistically significant (p=0.021) (Table 3).

Table 1. Previous anticoagulant therapy.

	n	%
Dabigatran 110 mg	2	%8.7
Dabigatran 150 mg	7	%30.4
Rivaroksaban 15	2	%8.7
Rivaroksaban 20	11	%47.8
Apixaban 5 mg	1	%4.3

Intracerebral hemorrhage was observed after mechanical thrombectomy in 26.1% (p=1.00) of patients receiving DOAC therapy, and 21.7% of these patients had symptomatic intracerebral hemorrhage (p=0.04) (Table 3).

The rate of good clinical outcomes in 90 days after mechanical thrombectomy was significantly lower in patients receiving DOAC therapy (p= 0.021, Table 3, Figure 2). Among patients receiving DOAC therapy, the rate of poor clinical outcomes after mechanical thrombectomy was significantly higher in patients with high NIHSS score on presentation (12.3 vs. 18.3, p=0.01) (Table 5).

In univariate logistic regression analysis, age, NIHSS score, and the groin-puncture to recanalization time were the predictors of a good prognosis. DOAC use is not an independent variable in predicting a poor prognosis. However, in univariate analysis, DOAC use was associated with poorer prognosis compared to other causes of cardioembolic stroke (Table 6).

Table 2. Baseline characteristics of the study population.

	No DOAC n (%)	Yes DOAC n (%)	p value
Female gender, n (%)	63 (53.8)	18 (78.3)	0.038
Age (years, mean ± SD)	64.2±13.2	71.3±5.4	**<0.001**
Vascular risk factors			
Hypertension, n (%)	65 (55.6)	17 (73.9)	0.112
Heart Failure, n (%)	35 (32.1)	2 (11.1)	0.093
Diabetes mellitus, n (%)	27 (23.1)	7 (30.4)	0.437
Coronary Artery Disease, n (%)	43 (36.8)	7 (30.4)	0.640
Previous İschaemic Stroke, n (%)	20 (17.2)	5 (21.7)	0.565
Smoking, n (%)	22 (18.8)	1 (4.3)	0.124
Intake of alcohol, n (%)	2 (1.8)	0 (0)	1.000
Atrial fibrilation, n (%)	66 (57.3)	23 (100)	**<0.001**
Obesity, n (%)	14 (12)	5 (22.7)	0.313
Coronary Artery Bypass Grafting, n (%)	11 (9.4)	1 (4.3)	0.690
Admission systolic BP, mm Hg	140 (90-210)	180 (110-200)	**<0.001**
Admission diastolic BP, mm Hg	80 (50-130)	90 (70-150)	**0.003**
Admission glucose, mmol/L	117 (55-165)	156 (62-260)	**0.019**

DOAC: direct oral anticoagulants, BP: Blood pressure.

Table 3. Stroke severity and outcomes of study participants.

	No DOAC	Yes DOAC	p value
NIHSS score on admission, median (IQR)	16 (2-25)	18 (5-30)	0.366*
Topography n(%)			
Left hemisphere	56 (47.9)	8 (34.8)	
Right hemisphere	61 (52.1)	13 (56.5)	**0.004**†
Vertebrobasilar	0 (0)	2 (8.7)	
Site of occlusion			
M1-MCA	87 (74.4)	15 (65.2)	0..13†
Tandem	14 (12)	2 (8.7)	
Intracranial ICA	16 (13.7)	4 (17.4)	
Vertebrobasilar	0 (0)	2 (8.7)	
Hyperdens artery sign	80(72.7)	15(68.2)	0.795†
Internal carotid artery occlusion	30 (25.6)	6(26.1)	1.000†
Isole MCA occlusion	82(70.1)	12 (52.2)	0.143†
ASPECT score, median IQR	9 (6-19)	9 (4-10)	0.773*
Intracerebral hemorrhage, n(%)	33(28.2)	6 (26.1)	1.000†
Symptomatic intracerebral hemorrhage, n (%)	8 (6.8)	5 (21.7)	**0.004**†
New territory embolism, n (%)	4 (3.4)	0 (0)	0.495†
Modified Rankin scale score at 3 months ≤2, n (%)	63 (53.8)	6 (26.1)	**0.021**†
Resistance to thrombectomy, n (%)	78 (%68.4)	16 (%72.7)	0.689
Futile recanalization, n (%)	40 (34.2)	11 (47.8)	0.241†
Mortality at 3 months, n (%)	20 (17.1)	5 (21.7)	0.562†

*Mann–Whitney U-test, †Chi-square test, ‡Student t-test
NIHSS: National Institutes of Health Stroke Scale, TICI: Thrombolysis in Cerebral Infarction, ASPECT: The Alberta stroke program early CT score, DOAC: direct oral anticoagulants, MCA: Middle cerebral artery, ICA: Internal carotid artery

Table 4. Treatments administered during the acute phase.

	No DOAC (n=117)	Yes DOAC (n=23)	p value
Intravenous thrombolysis, n (%)	65 (55.6)	1 (4.3)	**<0.001**†
Intravenous thrombolysis contraindicated, n (%)	29 (24.8)	21 (91.3)	**<0.001**†
Minutes from symptom onset to door, median (IQR)	99 (0-890)	59 (20-556)	0.460*
Minutes from door to neuroimaging, median (IQR)	14 (2-90)	17 (7-100)	0.341*
Minutes from door to groin-puncture recanalization, median (IQR)	90 (3-540)	87 (17-187)	**0.039***
Minutes from groin-puncture to microcatheter, median (IQR)	16 (5-126)	15 (5-105)	0.613*
Minutes from groin-puncture to recanalization, median (IQR)	60 (19-156)	15 (5-105)	0.156*
Balloon guiding catheter, n (%)	82(%70.1)	10 (%43.5)	***0.018**†*
Stent retriver, n (%)	103 (%88)	20 (%87)	1.000†
First-pass thrombectomy, n (%)	39 (%33.3)	7 (%30.4)	0.787†
Succesful recanalization (TICI2b or 3), n (%)	100 (85.5)	16(69.6)	0.075†

*Mann–Whitney U-test, †Chi-square test, ‡Student t-test
TICI: Thrombolysis in Cerebral Infarction

Table 5. Comparison of good and poor clinical outcomes at 3 months after mechanical thrombectomy in patients receiving DOAC.

	Patients with mRS 0-2	Patients with mRS 3-6	p
n (%)	6 (73,9)	17 (26,1)	-
Age (years, mean ± SD)	68,5±3,3	72,9±5,7	0,14‡
Admission NIHSS (median)	12,3±5,0	18,3±4,4	**0.01**‡
Symptomatic intracerebral hemorrhage	5 (16,7)	4 (23,5)	0.608†
TICI 2b-3 complete recanalization	6 (100)	10 (58.8)	0.124†

NIHSS: National Institutes of Health Stroke Scale, TICI: Thrombolysis in Cerebral Infarction

Table 6. Univariate logistic regression analysis for prediction m RS 0-2.

Variable	β	S.E.	p value	OR	%95 CI for OR	
					Lower Limit	Upper Limit
Age	0.044	0.022	0,004	0,901	0.256	1.420
Minutes from groin-puncture to recanalization	0.027	0,009	<0.001	0,934	0.278	1.240
Admission NIHSS	0.131	0.053	0,015	0.863	0.040	0.942
TICI2b-3 complete recanalization	0.067	0.035	0,001	0.119	0.133	0.254
ASPECT score	0.081	0.181	0,200	0.901	0.278	1.142
DOAC use	0.007	0.742	0,013	0,551	0.190	1.170
Glucose	0.010	0.005	0,099	0,974	0.047	1.320

β:Beta coefficient, S.E.:Standard error of mean, OR: Odds Ratio, CI: Confidence interval
NIHSS: National Institutes of Health Stroke Scale, TICI: Thrombolysis in Cerebral Infarction, ASPECT: The Alberta stroke program early CT score, DOAC: direct oral anticoagulants

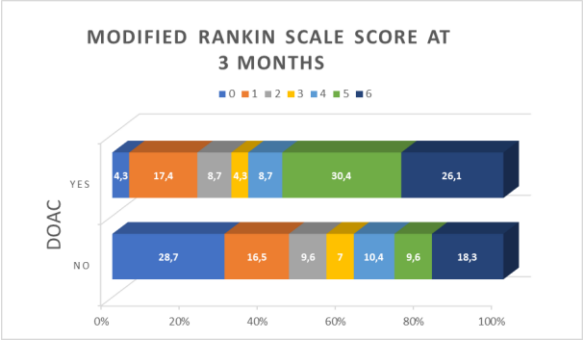

Figure 2. Distribution of modified Rankin Scale (mRS) scores at 90 days.

DISCUSSION AND CONCLUSION

Acute ischemic stroke is not rare in patients receiving DOAC therapy. The randomized trials have reported an annual acute ischemic stroke risk of 0.9-1.34% in patients receiving DOAC therapy (7, 8).

There are limited data regarding the treatment outcomes of mechanical thrombectomy in patients presenting with acute ischemic stroke while receiving anticoagulant therapy. A retrospective study analyzed 15 patients who sustained stroke while receiving DOAC therapy and underwent mechanical thrombectomy. Good clinical outcomes were achieved at three months in 47% of these patients, with a reported mortality rate of 27%, and no symptomatic hemorrhage was observed (9).

The findings of the present study suggest that mechanical thrombectomy is effective and safe in the treatment of acute ischemic stroke in patients receiving DOAC therapy. The high rate of patients with poor clinical outcomes at three months after mechanical thrombectomy can be attributed to a high prevalence of AF and a high rate of symptomatic intracerebral hemorrhage in this population (10).

Current guidelines recommend IV rtPA before endovascular thrombectomy in patients eligible for thrombolytic therapy (11). IV rtPA administration before endovascular intervention; early reperfusion, fragmentation of distal emboli, increased success of microvascular reperfusion has such positive effects. However, there are also negative effects such as increased bleeding risk, thrombus fragmentation, distal embolism, and disruption of the blood-brain barrier. Only two of our patients who received DOAC had no contraindications for IV tPA (12). One of our patients had a posterior system stroke. Even if this patient came in the first 4.5 hours, a direct endovascular procedure was performed because the angiogram unit was ready. Only one could be given thrombolytic therapy.

Previous studies have reported a lower rate of hemorrhage in patients receiving DOAC therapy (9). However, the rate of symptomatic intracranial hemorrhage following mechanical thrombectomy was 21.7% in patients receiving DOAC therapy.

This high rate can be associated with an advanced age of these patients.

Systolic and diastolic blood pressure and glucose levels were significantly higher in the DOAC group than in the DOAC group. However, no relationship was detected in the logistic regression analysis.

The studies have reported the early reperfusion of the ischemic brain tissue as among the strongest predictors of neurological improvement (13). The door-to-recanalization time was longer in patients not receiving DOAC therapy in the present study. Despite this significant difference, the prognosis was worse in patients receiving DOAC therapy.

The use of balloon guiding catheter was lesser in patients receiving DOAC therapy in the present study. Due to the older age of the patient group receiving DOAC, the anatomy of the aortic arch is elongated in these patients, and the possibility of king and loop in the common carotid artery is high. Therefore, the use of less balloon guiding catheters were preferred in these patients.

Age, NIHSS score, and the puncture-to-imaging time predicted a good prognosis at three months in the present study. Although the study demonstrated that DOAC use is not an independent variable in predicting poor prognosis, it was associated with poorer prognosis compared to other causes of cardioembolic stroke.

The present study has some limitations. These limitations include being a single-center study, retrospective study design, and a small number of study patients.

In conclusion, our data suggest that mechanical thrombectomy is feasible in patients with acute ischemic stroke using DOAC. The rate of symptomatic intracerebral hemorrhage was higher in patients receiving DOAC therapy. However, this difference was not significant when adjustment was made for age factor. The study found that the most important factor resulting in poor clinical outcomes is the NIHSS score on presentation. There is a need for prospective, randomized, and controlled studies involving a larger number of patients to evaluate the effect of DOAC use on the outcomes of mechanical thrombectomy and determine the prognostic factors.

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Ethics

Ethics Committee Approval: The study was approved by Clinical Research Ethics Committee of Eskişehir Osmangazi University (Date: 16.06.2020, No: 20)

Informed Consent: The authors declared that informed consent was not obtained from the patients because of the retrospective study design.

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