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ORIGINAL ARTICLE **ÖZGÜN ARAŞTIRMA**

RISK FACTORS FOR THE DEVELOPMENT OF EMBOLISM TO A NEW TERRITORY AFTER ENDOVASCULAR STROKE TREATMENT

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ABSTRACT

INTRODUCTION: The development of embolism to a new site (ENT) is an important complication in the endovascular treatment (EVT) of acute stroke and is associated with a poor outcome. The aim of our study was to investigate risk factors for the development of ENT.
METHODS: Prospectively recorded files of patients who underwent EVT for acute stroke between 2015 and 2023 were reviewed. ENT development, demographic data, vascular risk factors, clinical findings, IV thrombolysis treatment at admission, EVT procedure modalities such as duration of the procedure, mechanical thrombectomy techniques including the use of stent retriever, balloon guiding catheter, and prognoses were evaluated for all patients.
RESULTS: This study included 235 patients: 23 (9.8%) and 212 patients (90.2%) in the ENT group and non-ENT group, respectively. When comparing the case characteristic data of the two groups, the door-to-groin puncture (p=0.045) and groin puncture-to-recanalisation (p<0.001) times were longer, and the number of device passes (p<0.001) and symptomatic intracranial cerebral haemorrhage (sICH; p=0.049) increased in the ENT group. The number of device passes (OR=1.555; 95% CI 1.193–2.027; p=0.001) and and door-to-groin puncture time (OR=1.012; 95% CI 1.000–1.025; p=0.034) were identified as independent risk factors for the development of ENT.
DISCUSSION AND CONCLUSION: ENT development after EVT of acute stroke is not uncommon and results in prolongation of procedure times. The number of device passes and longer door-to-groin puncture time are risk factors associated with ENT.
Keywords: Embolism to a new site, endovascular treatment, mechanical thrombectomy.

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ENDOVASKÜLER İNME TEDAVİSİ SONRASI YENİ BİR BÖLGEYE EMBOLİ GELİŞİMİ İÇİN RİSK FAKTÖRLERİ

ÖZ

GİRİŞ ve AMAÇ: Yeni bir bölgede emboli (YBE), akut inmenin endovasküler tedavisinin (EVT) önemli bir komplikasyondur ve kötü sonlanım ile ilişkilidir. Çalışmamızın amacı, YBE gelişimi için risk faktörlerini araştırmaktı.
YÖNTEM ve GEREÇLER: 2015 ile 2023 yılları arasında akut inme nedeniyle EVT uygulanan hastaların prospektif olarak kaydedilmiş dosyaları incelendi. Tüm hastaların YBE gelişimi, demografik verileri, vasküler risk faktörleri, klinik bulguları, başvuruda IV tromboliz tedavisi, işlem süresi gibi EVT işlem modaliteleri, stent retriever, balon kılavuz kateter kullanımını içeren mekanik trombektomi teknikleri ve prognozları değerlendirildi.
BULGULAR: Bu çalışmaya YBE gelişen grupta 23 (%9,8) ve YBE gelişmeyen grupta 212 hasta (%90,2) olmak üzere 235 hasta dahil edildi. İki gruptaki vakaların karakteristik verileri karşılaştırıldığında, YBE gurubunda kapı-femoral ponksiyon (p=0,045), femoral ponksiyon-rekanalizasyon (p<0,001) süreleri daha uzun, cihaz geçiş sayısı (p<0,001) ve semptomatik intraserebral kanama (sİSK; p=0.049) daha fazlaydı. Cihaz geçiş sayısı (OR=1.534; 95% CI 1.185–0.001; p=0.001) ve femoral ponksiyon zamanı (OR=1.012; 95% CI 1.000–1.025; p=0.034) YBE gelişimi için bağımsız risk faktörleri olarak tanımlandı.
TARTIŞMA ve SONUÇ: Akut inmede EVT sonrası YBE gelişimi nadir değildir ve işlem sürelerinin uzamasına neden olur. Cihaz geçiş sayısı ve uzamış femoral ponksiyon zamanı, YBE ile ilişkili risk faktörleridir.

Anahtar Sözcükler: Yeni bir bölgeye emboli, endovasküler tedavi, mekanik trombektomi.

INTRODUCTION

Endovascular therapy (EVT) is an effective and safe treatment strategy for acute large vessel occlusions (1,2). However, EVT may cause complications, such as distal embolisation, during the periprocedural period. Distal embolisation of a fragmented target thrombus is divided into two groups: embolism to the new site (ENT) and embolisation to the distal site (EDT) (3). In cases of ENT, emboli typically escape after being pulled below the first target occlusion vessel and enter a new arterial site that has not previously experienced ischemia. A common example is a new anterior cerebral artery (ACA) embolic occlusion (ipsilateral/contralateral/bilateral) occurring after EVT has been performed for a target middle cerebral artery (MCA) occlusion (4). Other examples would be contralateral MCA, ipsilateral/contralateral/bilateral posterior cerebral artery, posterior communicating artery embolism or combinations (5).

ENT is a parameter used to assess the outcomes in various studies. PRISMA meta-analysis was used to evaluate the efficacy and safety of direct aspiration versus stent retrievers (SR) for recanalisation in acute cerebral infarction. The analysis revealed that the prevalence of ENT was 4.6% and 8.3% in the direct aspiration group and SR group, respectively (6). Among randomised controlled trial (RCT) studies, the MR CLEAN study reported the highest ENT rate of 8.6% (2), whereas in non - RCT studies, Gascou et al. reported a higher rate of 12.5% (7). Periprocedural ENT is not a rare condition as evidenced by the reported rates in various studies. Moreover, it has been associated with increased mortality and disability rates, which tend to be proportional to the size of the infarct it causes (4,8,9). This finding highlights the importance of closely monitoring and managing the risks of distal embolisation during EVT to minimise its impact on patient outcomes.

Previous studies have identified various features, such as thrombus structure, mechanical thrombectomy (MT) techniques (including SR), the number of device passes and the specific target occlusion site, as risk factors for the development of EVT-related complications (4,10,11). Additionally, IV thrombolytic treatment remains a controversial risk factor, with certain studies suggesting it may increase the risk of distal embolisation (12), whereas others argue it could offer protection (9,10). Due to these potential risks, interventional and stroke specialists must be aware of the factors that can lead to ENT and make an early diagnosis. ENT can be easily diagnosed using angiographic images, and prompt treatments, such as rescue MT, can help prevent the occurrence of new infarcts (13).

Accordingly, our study aimed to determine the prevalence of ENT and identify the risk factors that may lead to its development in a high-volume tertiary stroke centre.

METHODS

Study Population: The study population for this research consisted of 573 patients who underwent EVT at Eskisehir Osmangazi University Medical Faculty Hospital between 2015 and 2022. Data on this population collected prospectively were examined retrospectively. Inclusion and exclusion criteria were determined before the study. As a result, the study included 235 participants, and 338 were excluded based on the specified criteria.

The inclusion criteria for the study population were as follows:

- Patients with MCA, internal carotid artery (ICA) or tandem occlusion confirmed by digital subtraction angiography (DSA)
- Patients admitted within an 8-hour time window from symptom onset (or when the patient was last seen normal)
- Patients presenting with a neurological deficit of acute stroke with a National Institutes of Health Stroke Scale (NIHSS) score of ≥ 4

The exclusion criteria were applied to the study population and included the following:

- Presence of cerebral vascular occlusion or agenesis in a previous diagnostic imaging
- Acute stroke due to ACA and posterior system occlusion
- Insufficient imaging material or missing data scanned in the study
- Minor stroke with an NIHSS score ranging from 1 to 4
- Age being younger than 18 years or older than 80 years

The cohort was divided into two groups based on their outcomes after undergoing MT treatment: patients who developed ENT and those otherwise. To obtain the necessary images for the study, cerebral angiography was performed before and after the intervention using the Philips Allura Xper FD10 Cardiovascular X-ray System manufactured by Philips Healthcare in Best, the Netherlands.

Data Collection and Definitions: The data collection method of the study included the prospective collection of various parameters from the study participants. These parameters included patient demographics, vascular risk factors, previous antiplatelet and anticoagulation therapy, time elapsed since symptom onset (or since the patient was last seen normal), admission blood glucose levels, systolic and diastolic blood pressure levels, arterial occlusion site and localisation and IV thrombolysis administration. Additionally, stroke severity was assessed using the NIHSS scores, with scores of 1–4, 5–15, 16–20 and 21–42 indicating a minor, moderate, moderate to severe and severe stroke, respectively.

The Alberta stroke program early CT scores (ASPECTS) and hyperdense artery findings were recorded by evaluating non-contrast computed tomography (CT) scans (14). Collateral assessments were performed in CT angiography using the TAN (15) and modified TAN (mTAN) scoring systems (16). The TAN system involves categorisation based on the degree of collateral supply to the occluded artery MCA territory, whereas the mTAN system differentiates between poor (< 50%) and good collateral status (≥ 50%).

The patients received a score based on the bovine arch, aortic arch and ICA dolichoarteriopathy (B.A.D. score) (17). Data on EVT procedure modalities, such as procedure times (door-to-groin puncture, symptom–groin, groin puncture–revascularisation, symptom-reperfusion times), use of balloon guide catheter (BCG) or SR, type of device used, number of device passes and distal embolisation, were also collected. The MT first technique was divided into three subgroups during the procedure: aspiration component, SR and a combination of both devices.

Furthermore, stroke aetiologies were recorded based on the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification. The TOAST classification categorises stroke aetiologies into different groups, including large-vessel atherosclerosis, cardioembolic source, small-vessel disease, other 'determined' causes and undetermined causes (15).

Definition of Outcomes

Post-Procedure Symptomatic Intracranial Cerebral Haemorrhage: The occurrence of symptomatic intracranial cerebral haemorrhage (sICH) after the procedure was recorded. sICH is defined as any intracranial bleeding that leads to clinical symptoms and is associated with an increase of at least 4 points on the NIHSS within 24 hours or results in death. This definition is based on the criteria outlined in the European Cooperative Acute Stroke Study criteria (16).

Development of Embolism to the New Site or Embolisation to the Distal Site: Instances of embolisation occurring after the procedure were monitored and recorded. It is categorised into two groups: ENT, the detection of a new vessel occlusion outside the affected area on DSA, and EDT, the detection of an embolism at a distal location from the target occlusion site on DSA.

Reperfusion Results: Reperfusion results were reported using the modified thrombolysis in cerebral infarction (mTICI) score (17). Successful reperfusion was defined as an mTICI score of ≥ 2b.

Clinical Outcome: The clinical outcome of the patients was measured at 3 months using the modified Rankin Scale (mRS) score. It classifies patients into the following categories: 0–2, 3–5 and 6, indicating good functional outcome, moderate to severe disability and death, respectively.

Endovascular Treatment: Femoral access was utilised to reach the thrombus. A femoral 6–8F introducer sheath was exchanged with a guide sheath using a 0.35 Roadrunner wire. For passing distal to the target occluded segment, a 0.014-inch microguide wire, a 0.021-inch microcatheter with a distal access catheter (or BCG) or both were employed. MT was performed after resolving the lesion. The procedures were routinely conducted on the patient under sedation. During the procedure, 5000 units of heparin and 150 cc of contrast material were administered.

The decision to repeat or stop manoeuvres and the choice of MT technique, whether utilising the direct aspiration first-pass technique (ADAPT), SR only or combined techniques, such as Solumbra, were at the discretion of the operator. The occurrence of ENT during the procedure could lead to a change in the MT technique and a potential rescue MT. In such cases, the operator could use the same or different devices for the rescue procedure.

Ethics: Before conducting this study, written permission was obtained from the Eskişehir Osmangazi University Ethics Committee (Date: 17.01.2023, No:16). The study was conducted in strict accordance with the principles outlined in the Helsinki Declaration and adhered to the highest standards of research and publication ethics.

Statistical Analyses: The data were analysed using SPSS Version 26, Chicago/USA. Descriptive statistics are presented as n (%) for categorical variables and as mean ± standard deviation and median (minimum–maximum) for continuous variables. The Mann–Whitney U test was utilised to compare nonparametric continuous variables, whereas chi-square, Fisher's exact test and Fisher–Freeman–Halton's exact tests were employed to compare categorical variables. $P<0.05$ was considered statistically significant. To identify the risk factors, backward stepwise regression was performed on all variables that were significant for $p<0.10$. In the last step of the stepwise regression analysis, the door-to-groin puncture time, B.A.D. scores, number of device passes were added to the model (model: $p<0.001$).

RESULTS

This study included 235 patients: 23 (9.8%) and 212 patients (90.2%) in the ENT group and non-ENT group, respectively. The mean age in the ENT group was 61.5±13 years, and 12 patients were female. In the non-ENT group, the mean age was 61.6±12 years, and 96 patients were female. Although HT (43.9%) is the most common vascular risk factor in the ENT group, atrial fibrillation (52.2%) is prominent in the non-ENT group. When comparing the case characteristic data of the two groups, the door-to-groin puncture ($p=0.045$) and groin puncture-to-recanalisation ($p<0.001$) times were longer, and the number of device passes ($p<0.001$) and sICH ($p=0.049$) increased in the ENT group (Table 1).

The logistic regression analysis results show that the number of device passes (OR=1.534; 95% CI 1.185–0.001; p=0.001) and door-to-groin puncture time (OR=1.012; 95% CI 1.000–1.025 p=0.034) were identified as independent risk factors for the development of ENT (Table 2).

Figure shows an illustrative case of ENT and recanalization.

DISCUSSION AND CONCLUSION

ENT is a potential adverse event in MT, typically resulting from thrombus fragmentation and loss of control during withdrawal (3). The prevalence of ENT has been reported in the literature at rates ranging from 1% to 12.5%. (2,7,10,18-23). In our study, we found the prevalence of ENT to be 9.8%. The ENT group exhibited longer durations for door-to-groin puncture, groin puncture-to-recanalisation and onset-to-reperfusion procedures. Additionally, the

Table 1. Case characteristics and comparison of cases with and without ENT.

	No ENT (n=212)			ENT (n=23)			
Variables	**n**	**%**	**Median (min–max)**	**n**	**%**	**Median (min–max)**	***p***
Age (years)			63 (27–80)			64 (28–80)	0.907
Sex (female/male)	96/116	45.3/54.7		12/11	52.2/47.8		0.529
Vascular risk factors							
HT	93	43.9		8	34.8		0.403
DM	44	20.8		4	17.4		1
HL	29	13.7		5	21.7		0.345
CAD	58	27.4		6	26.1		0.896
Atrial fibrillation	72	34		12	52.2		0.083
Stroke history	23	10.8		5	21.7		0.166
Medication							
Antiplatelet	67	31.6		6	26.1		0.587
Anticoagulant	40	18.9		0	4.3		0.090
Admission serum glucose, mg/dl			123 (55–432)			120 (82–278)	0.370
Admission SBP, mmHg			143 (100–240)			147 (110–190)	0.817
Admission DBP, mmHg			83.50 (55–150)			89 (55–154)	0.134
Admission NIHSS, points			16 (6–25)			15 (6–22)	0.406
Moderate stroke, 5–15	93	43.9		12	52.2		
Moderate to severe stroke, 16–20	95	44.8		9	39.1		
Severe stroke, 21–42	24	11.3		2	8.7		
ASPECTS			9 (6–10)			9 (6–10)	0.121
TAN collateral score			2 (0–3)			2 (0–3)	0.814
mTAN collateral score, good	115	54.2		15	52.2		0.850
Site of occlusion, right/left	106/106	50/50		15/8	65.2/34.8		0.165
Occlusion location							0.324
M1	114	53.8		11	47.8		
M2	22	10.4		2	8.7		
ICA	34	16.5		3	13		
Tandem	41	19.3		7	30.4		
Hyperdense artery sign	155	73.1		16	69.6		0.717
B.A.D. score			1 (0–3)			2 (0–3)	0.074
Arcus type							0.725
Type I	45	21.2		6	21.7		
Type II	136	64.2		15	64.3		
Type III	31	14.6		2	14		
Pretreatment with IV thrombolysis	100	47.2		14	60.9		0.212
Procedure duration, min							
Onset-to-door			68.5 (7–315)			60 (15–279)	0.359
Door-to-groin puncture			88 (12–216)			116 (50–174)	0.045
Onset-to-groin puncture			170 (20–357)			170 (85–359)	0.922
Groin puncture-to-recanalisation			39 (10–155)			65 (30–129)	< 0.001
Onset-to-reperfusion			226 (71–425)			245 (168–470)	0.064
Successful recanalisation							
mTICI 2b-3	201	94.8		22	95.7		1
mTICI 2C-3	152	71.7		13	56.5		0.131
MT first technique							0.084
Isolated ADAPT	19	9		1	4.3		
Isolated SR	88	41.5		5	21.7		
Combined technique	105	49.5		17	74		
Balloon-guide catheter	139	65.6		12	52.2		0.203
SR thrombectomy	187	88.2		23	100		0.145
First pass recanilisation	93	43.9	39.1	9			0.663
Number of device passes			2 (1–8)			3 (1–7)	< 0.001
3-month mRS, grades			1 (0–6)			2 (0–6)	0.085
0–2, good functional outcome	139	65.6		12	52.2		0.203
3-month mortality	33	15.6		3	13		1
sICH	17	8		5	21.7		0.049
Emboli to distal territory	128	60.4		17	73.9		0.205
Stroke aetiologic Classification							0.463
Large-vessel atherosclerosis	46	21.7		4	17.4		
Cardioembolic source	123	58		15	65.2		
Other 'determined' causes	8	3.8		2	8.7		
Undetermined	35	16.5		2	8.7		

Table 2. Risk factors for the development of ENT.

Variables	OR	95% Cl		*p*
		Lower	Upper	
B.A.D. score	1.579	0.955	2,612	0,075
Door-to-groin puncture times	1.012	1.000	1.025	0.034
Number of device passes	1.534	1.185	1.986	0.001

Model: p<0.001.

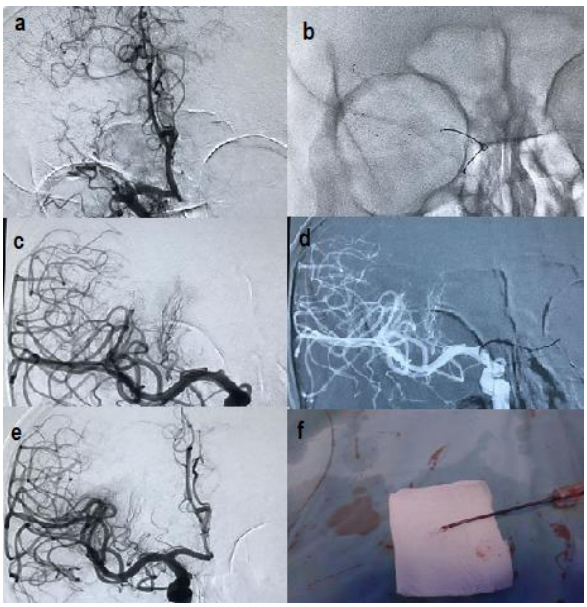

Figure: (a) Right MCA M1 segment occlusion. (b) Application of MT procedure with SR. (c) Right ACA occlusion after MT. (d) MT application via SR by passing distal ACA occlusion. (e) Successful recanalization. (f) Thrombus in the stent retriever.

number of device passes and the rate of sICH were also higher in the ENT group. Furthermore, our logistic regression analysis revealed that the number of device passes and door-to-groin puncture times contributed as risk factors for ENT development.

According to a consensus published in 2020, ENT is defined as the embolism to a new territory area that was not previously affected (3). The angiographic imaging utilized in our study has been identified in the literature to detect over 90% of cases with ENT involvement (8). After the procedure, invisible emboli can be detected by non-contrast CT or magnetic resonance imaging (MRI) techniques, including diffusion-weighted images (DWI), and are called infarct in new territory (INT) (9,12,13,17). As expected, INT can be detected with higher sensitivity, especially in MRI (8). However, MRI or CT-based studies have a disadvantage as they cannot differentiate between embolisms secondary to diagnostic DSA (24) and peri-MT embolism complications. Furthermore, detecting complications after the procedure may lead to a delay in the treatment management strategy, particularly in cases of salvage thrombectomy. The prevalence of ENT in our study is consistent with the literature and highlights the importance of evaluating angiographic images.

Although not detected in our study, the association of ENT with poor prognosis underscores the importance of identifying the risk factors. In the study of Chalumeau et al. in which they evaluated 690 angiography images for ACA embolism, similar to our study, the number of passages was determined as an independent risk factor and showed that intracranial cerebral hemorrhagic complications were higher in the group with ENT (4). The number of device passes is related to the difficulty of the procedure and thrombus fragmentation (28). We believe this phenomenon elucidates the role of the number of device transitions as a risk factor in our study's patients. Another significant factor, the door-groin time, and its impact on ENT development may stem from an increased thrombus burden due to reduced cerebral blood flow. The prolonged procedure times observed in patients who developed ENT further substantiate the arduous nature of the treatment process in these individuals. In the literature, frequently debated thrombectomy techniques, such as ADAPT, SR and BGC usage, as well as factors like IV thrombolysis and occlusion site were not found to be statistically significant.

Despite our comprehensive analysis, certain limitations should be acknowledged. The sample size in the ENT group was relatively small, which may have affected the statistical power and accuracy of our findings. Other limitations include the following: performing ENT scanning with angiographic images only, not including posterior system acute stroke cases and not evaluating the thrombus structure. Additionally, as a single-centre study, the generalisability of our results to broader populations should be interpreted with caution.

In conclusion, our study sheds light on the risk factors contributing to the development of ENT after endovascular stroke treatment. The identification of independent risk factors, including the number of device passes and door-

to-groin puncture time, emphasises the importance of optimising procedural techniques and patient management strategies to minimise the occurrence of ENT. Further multi-centre studies with larger cohorts are warranted to validate our findings and establish more robust risk stratification models for this significant complication.

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Ethics

Ethics Committee Approval: The study was approved by Non-Invasive Clinical Research Ethics Committee of Eskişehir Osmangazi University (Date: 17.01.2023, No: 16).

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

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