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Effectiveness and safety of ICA stenting in conjunction with mechanical thrombectomy (antegrade approach) in acute ischaemic stroke patients due to tandem occlusion

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ABSTRACT

Aim of study. We investigated the effectiveness and safety of an antegrade approach consisting of emergency ICA stenting in conjunction with mechanical thrombectomy (MT) in a one-stage procedure as a treatment for Tandem Occlusion (TO).

Clinical rationale for study. We here describe our experience in the treatment of TO with an antegrade approach with long-term results. We also discuss the advantages and drawbacks of this treatment modality with special attention to possible haemorrhagic complications that can be encountered in patients with ischaemic stroke who receive antiplatelet treatment. We believe that our study adds to the limited number of reports on this topic.

Materials and methods. We selected 34 patients diagnosed with acute ischaemic stroke due to ICA and ipsilateral intracranial occlusion treated with ICA stenting in conjunction with MT.

We analysed the short- and long-term results as well as investigating complications with special regard to haemorrhagic transformation associated with the need for antiplatelet treatment after stent implantation in patients after acute ischaemic stroke treatment.

Results. A favourable angiographic outcome was defined as mTICI 2b–3. This was achieved in 33/34 patients (97%). On average, NIHSS at 24 hours after the procedure was 8.5 ± 7, which indicates a significant clinical improvement. Four cases of symptomatic ICH were observed (11.8%). One re-occlusion in stent was noted. At three-month follow-up, mRS scores were 0 in 11 (34.3%), 1 in 5 (16%), 2 in 1 (3%), 3 in 3 (9.3%), 4 in 3 (9.3%), and 5 in 2 (6%) patients. Seven patients did not survive (22%). Overall, a favourable outcome (mRS 0–2) was achieved in 17/34 patients (50%). The final mortality rate was 26.5% (9/34 patients).

Conclusions and clinical implications. We conclude that an antegrade approach is a feasible and effective method for treating acute TO stroke, giving the patient the chance to regain his or her full independence in everyday life, with low overall complication and final mortality rates.

Key words: ischaemic stroke, tandem occlusion, emergency carotid stenting, mechanical thrombectomy

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Introduction

A tandem occlusion (TO) is defined as the simultaneous high-grade stenosis or occlusion of the internal carotid artery in its extracranial segment plus the occlusion of the ipsilateral intracranial vessel. It is estimated that TO accounts for about 20% of all acute strokes [1]. TO and its treatment appear to be underrepresented in the literature [2]. Conservative treatment of tandem occlusions with intravenous thrombolysis (IVT) alone is associated with poor clinical

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outcomes. Therefore several operative strategies have been developed [3].

A two-stage treatment comprising mechanical thrombectomy (MT) and stenting of the extracranial carotid artery lesion in different sessions is reported to cause fewer haemorrhagic complications compared to carotid artery stenting in conjunction with intracranial MT in a one-stage treatment [4]. One-stage treatment poses questions regarding the approach, i.e. antegrade with primary recanalisation of the ICA with subsequent MT, or retrograde where the MT is followed by the ICA recanalisation [5]. Finally, there is the retriever wire supported carotid artery revascularisation (REWISED CARE) technique, which treats both vessels simultaneously [6]. Nonetheless, there is currently no standard approach to the treatment of acute tandem occlusion stroke.

The aim of this study was to assess the efficacy and safety of ICA stenting followed by mechanical thrombectomy as an approach for urgent treatment of tandem occlusions.

Clinical rationale for study

In this manuscript, we describe our experience in the treatment of TO with an antegrade approach, including our long-term results. We discuss the advantages and drawbacks of this treatment modality, paying special attention to the possible haemorrhagic complications that can be encountered in patients with ischaemic stroke who receive antiplatelet treatment. We believe that this study is a valuable addition to the limited number of reports on this topic.

Materials and methods

Materials

This was a prospective, single-centre study of the data of 34 patients (10 female, 24 male) diagnosed between January 2016 and May 2019 with acute ischaemic stroke due to TO. All patients were diagnosed by non-contrast computer tomography and CT-angio. This disclosed extracranial ICA occlusion of atherosclerotic aetiology and a concomitant MCA occlusion. Baseline demographics, medical history and comorbidities were collected from the patients. Neurological status was assessed at baseline using the National Institute of Health Stroke Scale (NIHSS). This study was approved by our institutional review board (IRB) – approval number KE-0254/285/2019.

Statistical analysis of obtained data using Statistica 13.5 (StatSoft Polska, Poland) was performed. Student's t--test was used to analyse data with normal distribution, and a Mann–Whitney U test was applied to data without normal distribution. Logistic regression analyses were carried out to determine the predictors of 90-day mortality.

Inclusion criteria

The inclusion criteria were tandem occlusion and lack of intracerebral haemorrhage (ICH) confirmed in imaging examination. Assessment of ICH was performed according to the guidelines for the management of spontaneous intracerebral haemorrhage issued by the American Heart Association/American Stroke Association [7]. Patients presenting within 4.5 hours from symptoms onset were eligible for intravenous therapy, in accordance with the guidelines of the Polish Neurological Society for the Management of Patients with Ischaemic Stroke [8]. These patients were additionally treated with intravenous tissue plasminogen activator (iv-tPA) (0.9 mg/kg) before undergoing mechanical thrombectomy. Mechanical thrombectomy was performed within a six-hour therapeutic window. Control cranial computed tomography was performed 4–6 hours and again 24 hours after treatment, and in case of ICH further scans were acquired every 48 hours. Symptomatic ICH was defined as any parenchymal haematoma or intracranial haemorrhage associated with worsening of the National Institutes of Health Stroke Scale (NIHSS) score by 4 or more points.

Exclusion criteria

Patients with any contraindications for either thrombolytic or thrombectomic therapy, according to the guidelines of the Polish Neurological Society for the Management of Patients with Ischaemic Stroke [8], or time from symptoms of more than four and half hours in the case of thrombolytic, and more than six hours in the case of thrombectomic, therapy, were classified as ineligible. Patients with a National Institutes of Health Stroke Scale score <6 at baseline, or with evidence of intracranial haemorrhage on admission, or with a modified Rankin Scale Score >2 prior to stroke onset and with dissection of ICA were also excluded from the study.

Methods

All ICA occlusions were treated by balloon angioplasty followed by stenting, and all distal occlusions with mechanical thrombectomy (MT). Data concerning additional IV tissue plasminogen treatment, arrival and treatment times, duration of procedure, as well as technical aspects, was collected.

Endovascular procedure

All interventions were performed under general anaesthesia. Firstly, an 8F guide catheter was advanced distally to the common carotid artery (CCA). Then, a protection device (FilterWire, Boston Scientific, Natick, MA, USA) was placed in the petrous segment of the ICA. The occlusion was passed with a 0.014-inch microwire, and then a micro-catheter was advanced past the occlusion. Angiography assessing ICA and occlusion status was performed. Open-cell stent (Acculink, Abbott Vascular, Temecula, CA, USA) was deployed along the stenosis and post-dilated with a balloon.

Mechanical thrombectomy with an aspiration device (Penumbra System; Penumbra, Alameda, CA, USA) was performed once the adequate patency of ICA had been obtained. During the procedure 2,500 units of heparin was administered.

The reperfusion was assessed by an interventional neuroradiologist after the procedure, based on the modified Treatment in Cerebral Infarction (mTICI) Scale. Successful recanalisation was defined as a persistent mTICI 2b–3 score.

Antiplatelet treatment

Following the endovascular procedure, all patients received antiplatelet treatment: aspirin (75 mg daily for at least six months) after admission to the Stroke Unit (up to 30 minutes after the procedure). Where there was no evidence of ICH in control CT 4–6 hours after the treatment, clopidogrel was administered (75 mg daily for at least three months). Where ICH occurred, this secondary antiplatelet drug was omitted.

Secondary stroke prevention

All patients with atrial fibrillation on admission received additional VKA therapy or NOAC according to the Guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischaemic Attack [9].

Follow-up

A follow-up evaluation was conducted within three months of the procedure. This included clinical and neurological examinations (NIHSS was assessed 12 hours, 24 hours, and seven days after mechanical thrombectomy as well as at discharge from the hospital). The Modified Rankin Scale (mRS) score at 90 days was evaluated by a trained physician and was based either on a clinical investigation or a structured telephone interview. All patients underwent imaging examinations during hospitalisation: two control head CTs (4–6 hours and 24 hours after the intervention) and at least two Transcranial Doppler (TCD) ultrasound examinations (24 hours after procedure and at discharge). In cases of clinical deterioration, additional imaging examinations were performed.

Safety outcomes included periprocedural complications, adverse events occurring during the follow-up period, and overall mortality at three months.

Results

During the study period, 34 patients underwent MT due to TO. The demographic details of the study population are set out in Table 1.

In total, 10 female and 24 male patients were included. Mean age was 70.6 years. Mean baseline NIHSS was 16.4 ± 5.4. Most common risk factors were: hypertension (97%) and hyperlipidemia (47%). Smoking was reported by 35% of patients. Baseline medications included: antihypertensive drugs (97%), statins (35%), antiplatelet drugs (21%), and NOAC (15%). Intracranial occlusion sites were the right and left carotid artery in 59% and 41% respectively. Horizontal segment of the MCA (M1) was occluded in 76.5% and Sylvian (M2) segment in 23.5% of the analysed patients. Mean Onset-to-Reperfusion time was 223 ± 60 min (Tab. 2). Twenty-three patients (67.6%) with a mean Onset-to-Needle time of 115 mins were eligible for IVT.

Table 1. Demographic aspects of study population

Patients (n)	34 10 female (29%), 24 male (71%)
Mean age (years) (min – max)	70.6 (49 to 81)
Mean NIHSS (min – max)	16.4 (7 to 23)
Mean blood pressure	152/85
Blood glucose (min – max)	136 (93 to 262)
Risk factors:	
Hypertension	33 (97%)
Atrial fibrillation	9 (26%)
Hyperlipidemia	16 (47%)
Diabetes mellitus	12 (35%)
Smoking	12 (35%)
Cardiovascular disease	10 (29%)
History of stroke/TIA:	
< 3 months	5 (15%)
Medication:	
Antihypertensive drug	33 (97%)
Statins	12 (35%)
Antiplatelet therapy	7 (21%)
NOAC	5 (15%)
Occluded vessel	
ICA	
Left	14 (41%)
Right	20 (59%)
MCA segment	
M1	26 (76.5%)
M2	8 (23.5%)

Table 2. Mean time elapsed from symptom onset

Time	Minutes (min – max)
Onset — arrival	86 (20 to 240)
Onset — needle	115 (50 to 270)
Onset — reperfusion	223 (110 to 340)
Groin — reperfusion	55 (30 to 120)

A favourable angiographic outcome, defined as mTICI 2b–3, was achieved in 33 out of 34 patients (97%). No emboli to previously unaffected territories occurred. On average, NIHSS at 24 hours after the procedure was 8.5 ± 7, which indicates a significant clinical improvement. Mean hospitalisation time was 16 days (from 6 to 41 days). In one case (3%), haematoma at the site of the arterial puncture occurred, but

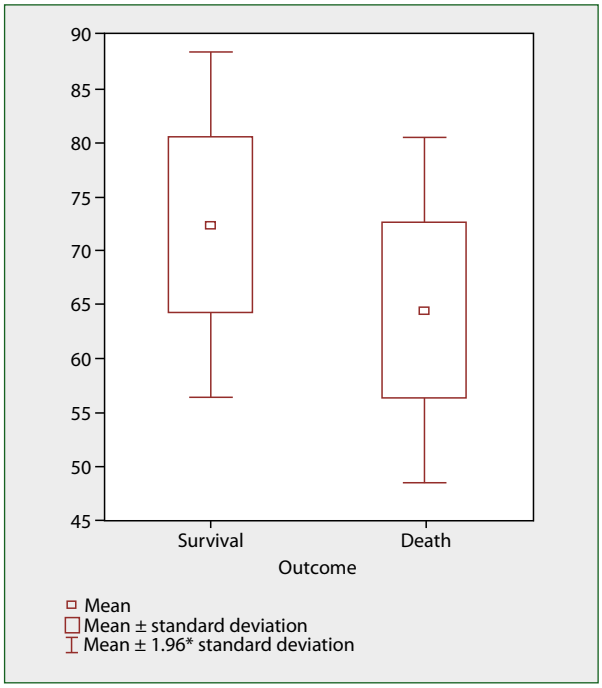

Figure 1. Statistically significant age differences between groups of patients who survived and who died

Figure 2. Statistically significant O–A differences between groups of patients who survived and who died

it did not require surgical intervention. During this period, four cases of symptomatic ICH were observed (11.8%). Two of these patients died during hospitalisation. Thirty-two patients were thus further followed-up. Carotid revascularisation was monitored using Transcranial Doppler (TCD) ultrasound examination. Re-occlusion was observed in one patient. Regarding follow-up at three months, mRS scores were 0 in 11 (34.3%), 1 in 5 (16%), 2 in 1 (3%), 3 in 3 (9.3%), 4 in 3 (9.3%), and 5 in 2 (6%) patients. Seven patients did not survive (22%). Overall a favourable outcome (mRS 0–2) was achieved in 17 of the original 34 patients (50%). The final mortality rate was 26.5% (9/34). No secondary acute ischaemic incidence was observed.

All four patients with haemorrhagic transformation of the stroke had hypertension and two (50%) admitted smoking before their stroke. Other comorbidities included hyperlipidemia (50%) and diabetes mellitus (50%). As far as baseline medication was concerned, all of them reported the use of antihypertensive drugs and half of them the use of statins. Nevertheless, statistical analysis did not show any significant correlation between risk factors and haemorrhagic transformation of the stroke.

Interestingly, a statistically significant negative correlation between the patient's age and mortality was observed ($p < 0.05$) (Fig. 1). The second independent factor ($p < 0.05$) significantly affecting final mortality was Onset-to-Arrival time (Fig. 2, Tab. 3). Figure 3A–B presents the linear regression of statistically significant factors.

Comparing the two groups (favourable vs unfavourable 90-days mRs) showed a statistically significant (p value = 0.018) correlation between baseline NOAC use and long-term outcome. None of the patients with a favourable 90-days mRs score reported NOAC use before admission, while 5/17 (29%) patients with unfavourable mRs score did. Baseline NIHSS and time from onset to arrival were important factors determining a favourable outcome (Tab. 4).

Discussion

Mechanical thrombectomy (MT) has become an established treatment modality for patients with intracranial lesions of anterior circulation. However, the optimal approach to the proximal lesion of the Internal Carotid Artery in Tandem Occlusions remains a matter of debate.

In this study, we demonstrated the safety, technical aspects and clinical outcome of ICA stenting in conjunction with MT as a treatment for patients with TO in a comprehensive manner by prospectively enrolling 34 patients.

Our main conclusion was that it seems to be an effective and safe approach, even in patients treated with Intravenous Thrombolysis prior to the procedure. Our findings accord with those of a meta-analysis including nearly 600 patients [10]. Our favourable outcome at 90 days, defined as mRs < 2, in 50% of patients is comparable with the results of other studies [2].

The need for dual antiplatelet agents in the acute phase of a stroke due to stent implantation raises questions concerning haemorrhagic complications after tandem occlusion endovascular treatment. The results of the most recent meta-analysis comparing two groups of patients treated due to TO (the first received no antiplatelet and the second received at least one antiplatelet agent during the procedure) show that although the rate of favourable outcome was comparable in

Table 3. Comparison of all factors taken into consideration in analysing death and survival of patients; test used — T-student, b — Mann-Whitney U test, *statistically significant difference

	Outcome			
	Survived	Died	p	Used test
	27; 100%	7; 100%		
Age, years (ME ± SD)	72.2 ± 8.1	64.3 ± 8.1	0.027*	a
Gender (male n, %)	18; 67%	6; 85.71%	0.345	b
NIHSS	15.4 ± 5.6	19.9 ± 2.6	0.052	a
Hypertension (n, %)	26; 96%	7; 100%	0.662	b
Atrial fibrillation (n, %)	7; 26%	2; 29%	0.911	b
TIA/stroke (n, %)	5; 19%	0; 0%	0.238	b
Smoking (n, %)	11; 41%	1; 14%	0.208	b
Dyslipidemia	13; 48%	3; 43%	0.825	b
Diabetes mellitus (n, %)	9; 33%	3; 43%	0.662	b
Antiplatelet drugs (n, %)	5; 19%	3; 43%	0.192	b
NOAC (n, %)	3; 11%	2; 29%	0.267	b
Statins (n, %)	12; 44%	2; 29%	0.469	b
Hypotensive drugs (n, %)	26; 96%	7; 100%	0.469	b
O-A min (ME ± SD)	78.2 ± 51.8	125 ± 34.5	0.01*	b
O-N min (ME ± SD)	111.2 ± 54.7	138.3 ± 20.2	0.411	a
O-G min (ME ± SD)	159.8 ± 58.4	198.7 ± 41.4	0.11	a
O-R min (ME ± SD)	214.6 ± 60.6	255 ± 48	0.115	a
Time of procedure min (ME ± SD)	73.3 ± 38.8	60 ± 23.8	0.415	b

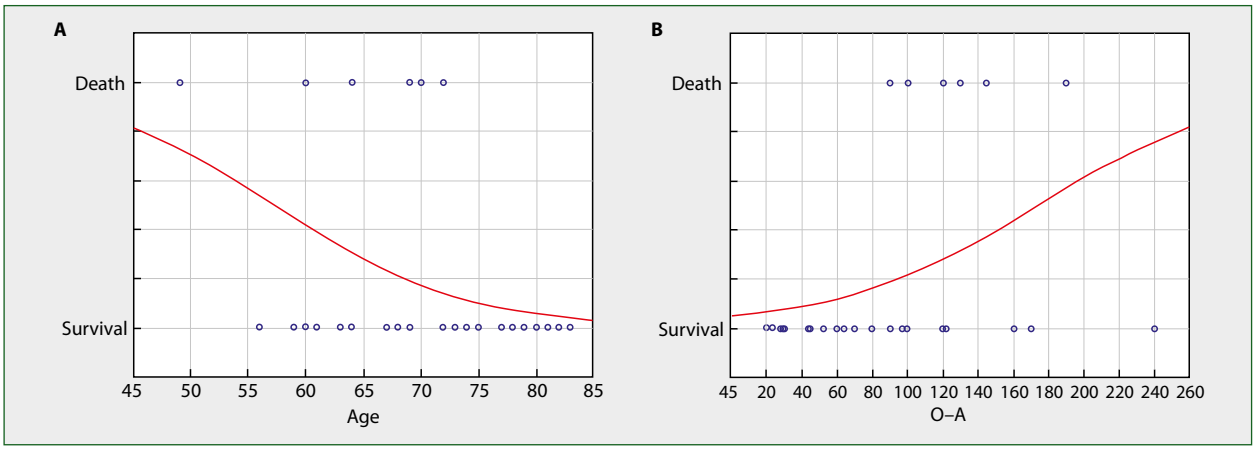

Figure 3. A–B: Logistic regressions of factors determining survival at 90 days. **A.** Logistic regression of age and survival of patients. **B.** Logistic regression of O–A of patients

both groups, both a higher successful reperfusion rate and a lower 90-day mortality rate were observed in the second group [11]. And this was without increasing the risk of any intracerebral haemorrhage. Symptomatic ICH was observed in 9.8% of patients without any antiplatelet, and in 7.3% of patients with ≥ 1 antiplatelet drug.

Antiplatelet treatment after carotid stenting depends on the particular centre's experience. The most common combinations include aspirin, clopidogrel and antiGP2b3. Some authors have reported lowering of the intraoperative thromboembolic complication rate after intraoperative administration of eptyfibatyd during emergent endovascular

Table 4. Comparison of all factors taken into consideration in analysing favourable and unfavourable outcomes in mRS after 90 days; test used a — T-student, b — Mann-Whitney U test, *statistically significant difference

	Outcome			
	Positive	Negative	p	Used test
	17; 100%	17; 100%		
Age years (ME ± SD)	69.4 ± 7.7	71.8 ± 9.4	0.409	a
Gender (male n, %)	11; 65%	13; 76%	0.47	b
NIHSS	13.5 ± 5	19.2 ± 4.2	< 0.001*	a
Hypertension (n, %)	17; 100%	16; 94%	0.35	b
Atrial fibrillation (n, %)	3; 18%	6; 35%	0.26	b
TIA/stroke (n, %)	2; 12%	3; 18%	0.653	b
Smoking (n, %)	6; 35%	6; 35%	1	b
Dyslipidemia (n, %)	6; 35%	10; 59%	0.182	b
Diabetes mellitus (n, %)	4; 24%	8; 47%	0.163	b
Antiplatelet drugs (n, %)	4; 24%	4; 24%	1	b
NOAC (n, %)	0; 0%	5; 29%	0.018*	b
Statins (n, %)	5; 29%	9; 53%	0.18	b
Hypotensive drugs (n, %)	17; 100%	16; 94%	0.35	b
O-A min (ME ± SD)	63.8 ± 53.1	110.9 ± 40.1	0.007*	b
O-N min (ME ± SD)	100.2 ± 60.2	133.5 ± 33	0.131	a
O-G min (ME ± SD)	149.7 ± 58.6	185.4 ± 51	0.071	a
O-R min (ME ± SD)	204.7 ± 55.8	240.6 ± 59.9	0.085	a
Time of procedure min (ME ± SD)	76.8 ± 41.2	64.4 ± 30.7	0.425	b

neurointerventions [12]. They also observed no increase of haemorrhagic complications. Nonetheless, no standard treatment protocol has been developed to date. In our hospital, all patients were treated with dual antiplatelet therapy consisting of aspirin and clopidogrel, a treatment regime of which we have more than 20 years of experience.

In our study, symptomatic ICH was observed in four patients (11.8%). All of them received IVT, which in conjunction with antiplatelet therapy is a known factor elevating the risk of intracranial haemorrhage [13–14]. Diabetes mellitus, which was described as an impactful factor of haemorrhagic transformation by the authors of the TITAN Review Collaboration Study, was noted in 2/4 patients [15]. Of these, two had an mRs score of 4 and the other two patients had died at 90-day follow-up, resulting in mortality of 50%.

The rate of haemorrhagic complications after endovascular treatment of Tandem Occlusion seems comparable with the rate of haemorrhagic complications after isolated intracranial MT, as presented by the authors of major studies [16]. Nevertheless, several authors have described the benefits of a conservative approach consisting of internal carotid angioplasty or its delayed treatment and mechanical thrombectomy.

The most comparable study, with a nearly identical number of cases comparing two groups of patients (with and without acute stenting of cervical lesion), reports similar rates of favourable outcomes in both groups [17]. The authors attributed the favourable outcome to the following factors: preinterventional ASPECT score and successful recanalisation of the intracranial occlusion. No positive impact of ICA stenting in regard to 90-days mRs score was observed in a multi-centre study on nearly 400 patients [18].

However, the authors of both of the abovementioned studies noted a significantly higher rate of successful recanalisation of the intracranial vessel after treating the carotid lesion either by PTA or by PTA and stenting during the acute phase of the stroke. One should bear in mind that successful recanalisation is crucial for clinical success.

As far as the technical aspects of the procedure are concerned, there are several options to treat tandem occlusion. Some authors claim the retrograde approach treating intracranial occlusion firstly to be superior due to the shorter Onset-to--Reperfusion time compared to an antegrade approach [19]. Lockau et al. reported significantly shorter times in a 'thrombectomy-first' group compared to a 'stent-first' group [20]. In our series, the median Groin-to-Reperfusion time of 55.4 ± 23.7 minutes was comparable with the results achieved in the 'thrombectomy-first' group (58.6 ± 26.1).

Navigation through an occluded vessel is an old technique. Modern guiding wires and microcatheters enable passage in most cases [21]. However, there is always a risk of a thrombus

dislodgement, especially while advancing thrombectomy systems.

On the other hand, several cases of spontaneous reperfusion of the intracranial occlusion has been described in patients with tandem occlusions after stenting of the proximal ICA. This may indicate the benefits of an antegrade approach [22].

Another issue that has prompted ongoing debate is the optimal anaesthetic approach during endovascular therapy. General anaesthesia may be associated with less pain and movement during the procedure, which facilitates the endovascular manoeuvres. Additional intubation lowers the risk of aspiration [23]. Conscious sedation, on the other hand, may be associated with less time from onset to reperfusion and a lower ventilation-associated-complications risk. Many systematic reviews and observational studies have reported worse outcomes from general anaesthesia compared to conscious sedation during endovascular therapy for acute ischaemic stroke [24–26].

However, one should bear in mind that patients with more serious stroke and worse outcome prognosis are much more likely to be treated under general anaesthesia. A recent meta-analysis of randomised clinical trials indicated that general anaesthesia during MT results in significantly higher rates of functional independence than does conscious sedation [27]. In our centre, the choice of anaesthetic approach strongly depends on the clinical condition of the patient. Our patients with tandem occlusions typically presented with severe neurological deficits (mean baseline NIHSS 16.4 ± 5.4), and were therefore treated under general anesthesia.

The increased use of novel oral anticoagulants (NOACs) to control atrial fibrillation and its effectiveness in preventing ischaemic stroke and lowering the risk of haemorrhages is another interesting matter. In our study, the use of NOAC was a statistically significant factor among patients with an unfavourable outcome. Shpak et al. compared over 130,000 patients divided into two groups (one on NOACs and one on warfarin) and concluded that there was a significantly higher frequency of ischaemic strokes in the NOAC group [28]. The frequency was higher regardless of the NOAC used, but the highest incidence was observed with dabigatran and apixaban. Embolic events might be explained by poor treatment adherence and subtherapeutic dosages of drugs [29].

Our case series demonstrates the endovascular treatment of Tandem Occlusion consisting of ICA stenting in conjunction with mechanical thrombectomy. The strengths of this report include its prospective character, the comprehensive manner of data collection, and the analysis of short- and long-term outcomes. We are, however, aware of several limitations. Firstly, a small sample size limits the generalisability of the findings. Secondly, our statistical analysis might be imprecise because the study included relatively few patients.

Clinical implications

In conclusion, the described antegrade approach is a feasible and effective method for the treatment of patients with acute ischaemic stroke due to Tandem Occlusion. It gives them the chance to regain full independence in everyday life, and overall complication and final mortality rates are low. Additionally, dual antiplatelet therapy after the procedure does not significantly increase the risk of haemorrhagic transformation of the stroke.

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