Research Article

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Single Center Experience with Catheter Based Treatment in Acute Ischemic Stroke

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ABSTRACT

Objectives: *We present our initial experience of endovascular treatment (EVT) in patients with acute ischemic stroke (AIS).*

Background: *Several randomized trials have indicated a benefit from endovascular therapy in selected ischemic stroke patients.*

Methods: *During last 3 years we performed EVT of 18 consecutive AIS patients National Institutes of Health Stroke Scale 13.6 ±4.8 at presentation. The following EVT methods were applied: (A) mechanical thrombaspiration with Penumbra system (PS) alone in 4 patients; (B) combination of PS thrombaspiration plus balloon angioplasty (PTA) in 4 patients; (C) combination of wire recanalization, PTA and supraselective fibrinolysis with low dose t-PA in 4 patients, and (D) supraselective intra-arterial fibrinolysis alone in 5 patients. Stenting of the extracranial ICA and consecutive distal balloon PTA or PS thrombectomy in MCA was performed in other 2 patients. The target occluded arteries were: middle cerebral artery (MCA), extracranial internal carotid, pericalosal artery, basilar artery, vertebral artery and 2 patients with ACA/MCA occlusion.*

Results: *The mean symptom onset-to-reperfusion time was 252 ±116 min. Post-interventional TICI 2b-3 flow was achieved in 72.2%. %. In patients treated with different methods, the results were respectively: A–75%, B-25%, C-80%, D-100%. A poor recanalization (TICI≤2) had 4 patients (22.2%). We observed mortality in only one patient (5.6%), malignant MCA infarct in 2 patients, and two patients developed nonfatal intracerebral hemorrhage. Modified Rankin Scale score 0-2 (at 90 days) was observed in 9 patients (50%).*

Conclusions: *Our initial experience with EVT of AIS is encouraging, with a relatively moderate to high rate of successful angiographic recanalization and good clinical results.*

Keywords
Acute ischemic stroke, Endovascular stroke treatment, Intra-arterial thrombolysis, Mechanical thrombectomy, Neurointerventional stroke treatment.

Introduction
Ischemic stroke is one of the most important causes of death and functional impairment worldwide, with a very high human price and a strong impact on healthcare systems and society.

For almost two decades systemic intravenous thrombolysis with t-PA was the only approved method and the gold standard in the treatment of patients with acute ischemic stroke (AIS) up to 4.5 hours of symptoms onset [1-3]. Well-recognized limitations of this therapy, however, include the narrow therapeutic time window and contraindications such as recent surgery, coagulation abnormalities, and a history of intracranial hemorrhage. Moreover, intravenous tissue plasminogen activator (t-PA) is not so effective at opening proximal occlusions of the major intracranial arteries, accounting for more than one third of cases of AIS, and early recanalization after intravenous t-PA is seen in only about one third of cases.

For these reasons, intraarterial (IA) treatment has been introduced into clinical practice [4-6]. IA therapy can be broadly divided into chemical dissolution of clots with locally delivered thrombolytic agents and clot retrieval or thrombectomy with mechanical devices [7,8].

Few paradigm-changing randomized trials MR CLEAN [9], ESCAPE [10], REVASCAT [11], SWIFT PRIME [12], EXTEND-IA [13], and meta-analysis [14-16] have showed better results and outcome benefit for appropriately selected stroke patients after EVT, compared to standard intravenous thrombolysis. At present the best results for EVT come from trials using stent retriever devices like Solitaire [9-15,17] and thromboaspiration devices like Penumbra system (PS) [4,18-20], which are the most effective and investigated.

The goal of the current paper was to present our initial experience with several catheter based EVT techniques in AIS patients during the last 3 years, in the first centre for endovascular AIS treatment in Bulgaria, and to discuss the probable best options for our interventional practice in the context of the new technical achievements.

Methods

Between 2013 and 2016 we performed EVT in 18 ischemic stroke patients. The group included 7 women and 11 men at mean age of 63.3 ±14 years (range 29-86 years), with AIS up to 6 hours after onset of symptoms.

Patients' history, demographic information, vascular risk factors, neurological deficit graded by National Institutes of Health Stroke Scale (NIHSS), and neuroradiological findings from non-contrast computed tomography (CT) of the head or CT angiography (Philips Ingenuity Core128TM), or MRI, (magnetic resonance imaging), MR angiography (Philips Ingenia 3 Tesla) are presented in Table 1. We excluded intracerebral hemorrhage or another etiology of the stroke in all patients with imaging before proceeding to interventional treatment. Stroke subtypes were defined in accordance to TOAST classification [21]. The site of arterial occlusion, onset-to-needle time (ONT), time from groin to recanalization (GRT), symptom onset-to-reperfusion time, clinical complications, and applied medical devices and agents were also reviewed.

On admission we performed standard laboratory examinations, ECG, cardiology and angiology evaluation, extra- and transcranial ultrasound assessment for all patients (Philips HD 15, Philips HD7 XE, Philips CX50). The protocol included intra-procedural digital subtraction angiography (PhilipsAllura Xper) of cerebral vessels with assessment of the angiographic Thrombolysis in Cerebral Infarction (TICI) score after the procedure. Clinical outcome was defined according to the modified Rankin Scale (mRS) on admission, at 90 days and 12 months after the interventional procedure. General anesthesia or short conscious sedation was used in according to the discretion of the physician and some current studies [22].

Criteria for EVT were: age between 18 and 85 years; signed informed consent; AIS with clear defined onset up to 6 hours for anterior circulation (internal carotid artery - ICA, middle cerebral artery - MCA, anterior cerebral artery - ACA) and up to 8 hours for the posterior vertebrobasilar circulation; NIHSS from 4 to 24 points;, AV4 segment, acute basilar artery occlusion; patients with contraindications for systemic IV thrombolysis in the therapeutic window; neuroimaging excluding intracranial hemorrhage. Contraindications to EVT include: AIS outside the pre-specified time window, AIS with intracranial hemorrhage, aneurismal SAH, arterio-venous malformation (AVM), brain abscess, and tumor with hemorrhagic presentation. The EVT was performed by 2 experienced interventional cardiologists trained for interventional treatment of stroke.

Femoral access was used in all cases with 6 Fr short femoral sheath. After a diagnostic angiogram of the four cerebral vessels, a 6 Fr guiding catheter (JR 4.0 Launcher, Medtronic) or 90 cm guiding sheath was positioned supraselectively in the proximal part of the occluded target vessel.

The four following EVT methods were applied: (A) mechanical thrombaspiration with Penumbra system; (B) combination of PS thrombaspiration plus balloon percutaneous trans-catheter angioplasty (PTA) and low dose t-PA; (C) combination of wire recanalization, balloon PTA and supraselective fibrinolysis with low dose t-PA, and (D) only supraselective IA fibrinolysis with t-PA.

Statistical analyses were performed using SPSS statistical software for Windows version 20.0. The distribution of continuous variables was tested using the Kolmogorov-Smirnov test. Normally distributed data were presented as mean ± standard deviation (SD), whereas non-normally distributed data – as median and interquartile range (IQR) (the difference between the 25th and 75th percentile). Categorical variables were presented in percentage terms.

All patients fulfilling the criteria were informed about the benefits and risks of the procedure. All patients or their relatives signed informed consent form, approved in advance by the local ethics committee, for EVT of AIS, for thrombolysis, as well as for personal data analysis. The study protocol is in accordance with the Declaration of Helsinki.

Results

In 6 patients AIS was associated with large artery atherothrombosis, in 8 with cardioembolic origin, in 2 with embolization during cardiologic interventional procedure, and in 2 with unknown cause. Eleven of 18 patients (61%) had arterial hypertension (AH) as a main risk factor, 6 atrial fibrillation (AF), and 5 patients had diabetes mellitus (DM) type 2. Five patients had a history of previous myocardial infarction and percutaneous coronary intervention. Two of the patients had recent cardiac surgery (coronary artery bypass grafting - CABG and CABG combined with valve replacement). The initial mean NIHSS of the patients before EVT was 13.6 ± 4.8 (range 4 to 24). Three of the patients (16.7%) had mild stroke (NIHSS <9 points), 11 patients (61.1%) had moderately severe stroke (NIHSS 9-15 pts.) and 4 patients (22.2%) suffered severe stroke (NIHSS >16 pts) (Table 1).

Parameter		Distribution
Age (years) – mean ± SD		63.3 ± 14
Males, n (%)		11 (61.1%)
Arterial hypertension		11 (61.1%)
Atrial fibrillation		6 (33.3%)
Diabetes mellitus		5 (27.8%)
Coronary artery disease		5 (27.8%)
Recent cardiac surgery		2 (11.1%)
NIHSS baseline – mean ± SD		13.6 ±4.8
Severity of AIS	Mild (NIHSS <9)	3 (16.7%)
	Moderate (NIHSS 9-15)	11 (61.1%)
	Severe (NIHSS >16)	4 (22.2%)

Table 1: Demographic characteristics and clinical presentation. NIHSS - National Institutes of Health Stroke Scale.

Conscious sedation was used in 14 patients (77.8%) and general anesthesia in only 4 patients (22.2%). The target occluded arteries were as follows (Table 2): middle cerebral artery (MCA, M1 segment) in 10 patients, extracranial internal carotid artery (ICA) in 2 patients, pericallosal artery 1, 2 basilar artery (BA) occlusions, 1 vertebral artery (VA) and 2 patients with ACA/MCA occlusion, one of which with T-occlusion.

Parameter	Distribution
CT imaging at baseline	15 (83.3%)
MRI imaging at baseline	9 (50%)
Occlusion site	
MCA	10 (55.6%)
ICA (2 high-grade stenosis and 1 T-occlusion)	3 (16.7%)
Basilar artery	2 (11.1%)
Vertebral artery	1 (5.6%)
Anterior cerebral artery	1 (5.6%)
Pericallosal artery	1 (5.6%)
Onset-to-needle time (min) – mean ± SD	187 ± 112
Groin puncture-to-recanalization time (min) - mean ± SD	68,6 ± 14.3
Onset-to-TICI 2b/3 recanalization time (min) - mean ± SD	255 + 113
Intravenous thrombolysis	7 (38.9%)
Penumbra system (PS) mechanical thromboaspiration (A-method)	4 (22.2%)
PS, balloon PTA and low-dose supraselective intra-arterial thrombolysis (B-method)	4 (22.2%)
Wire manipulation, balloon PTA and low-dose supraselective intra-arterial thrombolysis (C-method)	5 (27.8%)
Supraselective intra-arterial thrombolysis (D-method)	5 (27.8%)
ICA stenting	2 (11.1%)
TICI 2b-3 flow	4+9 (72.3%)
Reocclusions after EVT and Device related complications	0 (0%)
Symptomatic ICH	2 (11.1%)
Asymptomatic ICH	1 (5.6%)
Minor systemic bleeding	3 (16.7%)
NIHSS final - mean ± SD	8.7 ± 7.2
mRS 0-2 at 90 days	9 (50%)
Mortality at 3 months	1 (5.6%)

Table 2: Interventional treatment characteristics and outcome of patients (number and %).
MCA: Middle Cerebral Artery; ICA: Internal Carotid Artery; ACA: Anterior Cerebral Artery; BA: Basilar Artery; VBS: Vertebrobasilar System; TICI: Thrombolysis in Cerebral Infarction; ICH: Intracerebral Hemorrhage; mRS: modified Rankin Scale.

MRI neuroimaging in the emergency settings (including DWI, T2, FLAIR, MRI-TOF angiography) was performed in 9 of 18 patients (50%), CT in 15 (83.3%), and both methods were used in 6 (33.3%). A larger than baseline ischemic lesion on CT/MRI was observed in 8/18 patients (44.4%). The postprocedural control CTA and neurosonology examinations after EVT (including transcranial color coded duplex sonography) showed that the recanalized arteries were patent in 14 out of 18 patients (77.8%) after 24 hours. No additional endovascular interventions were not done during the in-hospital stay.

The mean symptoms onset-to-needle time (ONT) was 187 ± 112 (range 20 to 380 min). Six of the patients arrived at the clinic between the 5th and the 6th hour of the time window, and one had an in-hospital wake-up stroke after cardiac surgical procedure. The groin puncture-to-reperfusion time (GRT) was 68.6 ± 14.1 min. The median symptoms onset-to-angiographic reperfusion time (ORT) in our series was 255 + 113 min.

Dramatic clinical improvement, within 24 hours after the EVT procedure (NIHSS reduction > 10 pts.), was observed in 2 patients (11.1%), moderate clinical improvement (with NIHSS 5-7 points reduction) in 5 patients (27.8%), minimal change (deficit reduction of 2-4 pts.) in 4 patients (22.2%), no change (0-1 pts.) in 3 patients, and worsening had 4 patients (3 of whom with unsuccessful proximal MCA recanalization and 1 after BAO and multi-level brain stem stroke). Ten of our patients (55.6%) needed intensive care treatment after the EVT procedure. On discharge, the median cohort NIHSS was reduced to 8.5 ±7.

Penumbra thrombaspiration system (PS) was used overall in 8 patients (44.4%): PS 5Max aspiration catheter alone (A-method) was used to achieve successful mechanical thromboaspiration (MTA) in 4 patients (with distal ICA occlusion in 1 patients, M1 occlusions in 2 patients, and tandem ICA stenosis plus acute MCA occlusion in 1 patient). A combination of PS plus balloon PTA (B-method) was used in other 4 patients because of evidence of severe underlying atherosclerotic plaque in 3 of them.

A total of 14 patients (77.8%) received IA supraselective t-PA: IA fibrinolysis alone was carried out in 5 patients (D-method);

a combination of wire recanalization, balloon PTA and low dose supraselective fibrinolysis was performed in 5 other patients (C-method); and a combination of PS plus PTA plus IA thrombolysis – 4 other patients (EVT B-method). Only one patient (5.6%) received 60 mg IV t-PA as a bridging therapy before EVT. The total average supraselective IA dose of t-PA used for overall treatment in our cohort was 30.7 ± 15 mg. After the EVT, an intravenous tPA infusion was additionally given in 7 patients (38.9%) for one extra hour. Their cumulative total intra-arterial (IA) plus IV dose was 41 ± 24.7 mg.

Excellent angiographic result (TICI 3 flow) after applied EVT was achieved in 9 patients (50%), a partial recanalization (TICI 2b) in 4 (22.2%). Summarizing, TICI2b-3 results were achieved in 72.2% of the treated patients: with PS thromboaspiration A-method had 3 patients (3 out of 4; 75%); with B-method – 1 patient (1/4, 25%); with C-method 4 patients (4/5, 80%); and with D-method in the IA fibrinolysis group 5 patients (5/5; 100%). Poor or no recanalization (<TICI 2a) had 4 patients from different subgroups. Re-occlusion after successful EVT was not observed in our series.

Minimal systemic bleeding (oral and urinary tract bleeding) after EVT was observed in 3 patients (16.7%) that did neither impact the infusion with t-PA nor necessitate other therapeutic interventions. Ten of the patients were pretreated with antiplatelet drugs before EVT, two with subcutaneous anticoagulants, and one female patient was taking vitamin K antagonist (acenocoumarol) with suboptimal dosing. An intracranial asymptomatic localized mild reperfusion hemorrhage was observed at 24-hours in one patient. That happened after PS aspiration of the acute ICA thrombus, and following stenting of a high-grade ICA stenosis, performed in the acute phase. The patient's intracranial M2 segment of MCA remained occluded. In this patient the thromboaspiration procedure was efficient on the ICA level and not complete at the MCA level. Therefore we are considering it as incomplete recanalization with final MCA flow TICI 0.

Symptomatic intracranial bleeding was found in 2 patients (11.1%) after EVT with PS: one 89-year old man after unsuccessful MCA recanalization and one 56-year old woman after TICI 3 complete recanalization of the ICA/MCA/ACA T-occlusion. There was no association between type of EVT or applied t-PA dose and hemorrhagic complications.

Mean mRS, assessing clinical and functional outcome at 90 days, was 2.2 ± 1.4. Nine of 18 patients (50%) treated with EVT demonstrated favorable clinical outcome with mRS 0-2 at 90 days. Three-month mortality was 5.6%. Two patients were sent for decompressive craniecotomy due to malignant MCA infarct with no recanalization after EVT. One of these patients had a large proximal MCA occlusion with no recanalization despite EVT (a combination method of wire recanalization, balloon PTA and supraselective fibrinolysis with low dose t-PA supraselective fibrinolysis). Penumbra system was not available for him at that time. He developed malignant MCA infarction, underwent decompressive craniecotomy, and finally died from a pulmonary embolism in another hospital. In the second patient, a 51-year old woman, we did not achieve MCA recanalization after PS thrombaspiration plus balloon PTA. She had early clinical improvement after craniecotomy and despite severe left-sided motor deficit, mRS 4 at 90 days, and her live was saved (Table 2).

Discussion

Considering the positive results of several large randomized clinical trials with EVT for AIS [9-15] and the positive experience of other countries' real life EVT practice [4,5,23,24], we decided to join the efforts of interventional cardiologists and neurologist in order to develop the first center for EVT of AIS in Bulgaria. This article describes our initial results from a low volume acute stroke center with a mean number of 100 patients per year. For above mentioned 3 year period we have treated a total of 322 patients with stroke, from which 18 with EVT (5,59% was the proportion of mechanical reperfusion), and only with IV thrombolysis 16 patients (4,96% the proportion of standard IV reperfusion). The selection process biased in favour of the interventional instead of conservative treatment, according to the presence of proximal large vessel occlusion on CTA or MRA, NIHSS deficit between 4 and 24 points, and the therapeutic time window within 6 hours of symptom onset (based also to our institutional protocol, [25]). CT or MRI perfusion or other techniques for assessment of the penumbra were not used. We accepted patients mainly from Sofia city and from three other hospitals which could send us patients within 1 hour.

In the present study we were able to prove in an initial small group of 18 AIS patients, that catheter based EVT with mechanical thromboaspiration, or balloon PTA, wire recanalization and supraselective fibrinolysis with low dose t-PA were acceptably safe and could provide relatively good angiographic revascularization rates (72.3%) and early clinical outcomes (50%). In 22.2% of patients there was no reperfusion and recanalization. Long-term outcome at 1 year later was subsequently better with mRS 0-2 in 12 patients (66.6%) without additional mortality.

To underline different technical methods, which are important for recanalization successes to our understanding, we divided the patients into relative subgroups for the description of the results. Despite the different methods and medications used for EVT in the different arteries occlusions, our results were similar to some early studies [6,26,27]. Unfortunately, stent retrievers for mechanical recanalization were not routinely used because at that time there was no reimbursement for that type of treatment in our country.

Our group is an example of a combined application of some older (IA-TL) and newer (PS) technical methods of EVT used in heterogeneous AIS cohort of patients. Most of our subjects were middle-aged men with anterior circulation occlusions (M1 segment occlusions) and moderately severe stroke (61% with NIHSS 9-15) treated in the first 6 hours after onset of their symptoms. Unlike the big pivotal EVT trials, we had also treated two patients with acute basilar artery occlusion.

Considering the non-randomized design and small number of cases in our group, we could only mention the fact that the desired recanalization (TICI 2b-3) was observed in some patients treated with PS thrombaspiration, and also with different combination of wire manipulation, balloon PTA and supraselective IA-TL. Important other influencing factors were the type and vessel location of the clot, the time to recanalization, and the EVT experience. Most of our patients with successful recanalization had better clinical outcome. However, we observed fewer patients without recanalization and good functional outcome, as well as patients with excellent recanalization and poor mRS afterwards (Figures1-3).

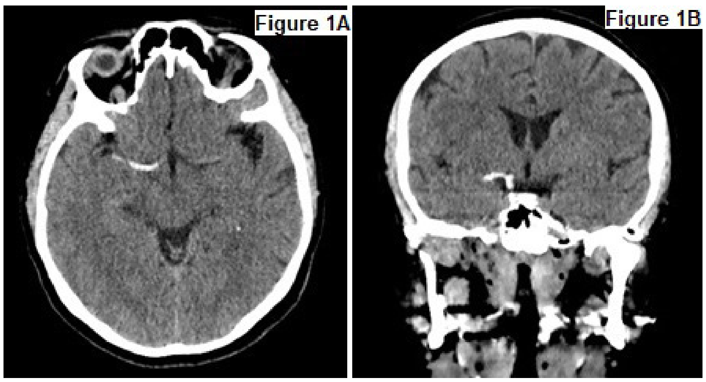

Figure 1: Contrast CT of a 57 y/o patient with AIS due to acute T-occlusion of ICA four and a half hours after the onset of symptoms (A, axial plane and B, coronal plane); she had left-sided hemiplegia and baseline NIHSS 13.

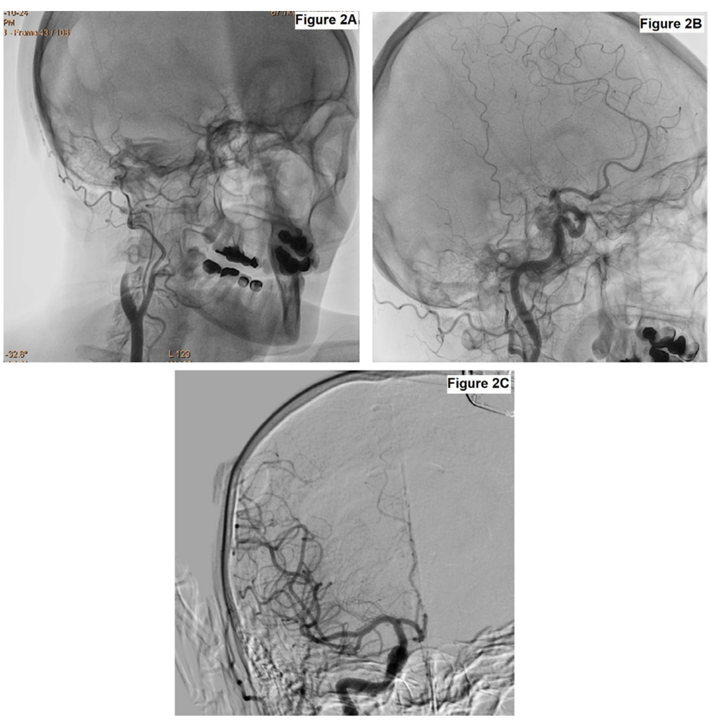

Figure 2: On carotid angiography, there is no contrast filling after the bulb of right ICA. Intracranial segments of MCA and ACA arteries are not seen initially (Figure 2A); during mechanical thromboaspiration with Penumbra system of ICA, first, the ACA was recanalized (Figure 2B), and after that the TICI 3 angiographic revascularization of MCA was achieved 5:30 h after onset of symptoms (Figure 2C).

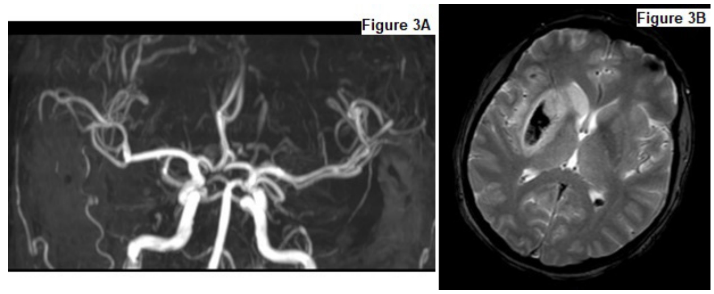

Figure 3: The control MRI TOF-angiography showed a patent MCA vessel (Figure 3A), and a reperfusion hemorrhagic transformation in the ischemic right basal ganglia area was seen on T2W-FFE MRI (Figure 3B). The patient was discharged on day 7 with NIHSS 10 and mRS 4.

It has been shown that mechanical thrombectomy has a number of advantages over systemic thrombolysis [11,13]. It extends the therapeutic window beyond the 4.5-hour for thrombolysis, and up to 8 hours from the time of symptom onset for mechanical thrombectomy. Mechanical thrombectomy is more efficient than systemic thrombolytic agents in removing clots with mature fibrin and cross-linked thrombi, resulting in higher rate of revascularization. Finally, mechanical thrombectomy could be used in patients with contraindications against systemic thrombolysis.

Time for AIS matters even more strongly for the brain than for the heart, in acute myocardial infarction [28]. Functional outcome and prognosis depend on the time that has passed between symptom onset and restoration of flow with a significant negative correlation – the shorter the time, the better the outcome. In our series we managed to reach the time periods that were reported from large randomized trials and registries [9-15], and that could explain some of our positive results. The time management in our angio-suit was relatively good. Both for the pre-hospital and in-hospital time parameters, we have to improve our organization and collaboration. There is definitely room for intra-procedural time optimization.

Limitations of our study were its retrospective and non-randomized design, the small number of patients, and the heterogeneity of the group and of the treatment methods. The best options for our future interventional practice in the context of the new technical achievements would be to combine stent retrievers (Solitaire, Trevo, etc.) where needed with PS [7,8,10,17,29,]. However, in the years described, we had no available new generation of stent retrievers as suggested from the Consensus statement by ESO-Karolinska Stroke Update 2015 for the first-choice treatment of large arteries occlusions in AIS [30]. Therefore, our report should be accepted more like sharing an early experience in a single center, rather than as a clinical study.

Conclusions

Our initial experience with EVT for AIS patients in the first Bulgarian center for EVT of stroke was encouraging and should be further developed in accordance with new guidelines [17,22]. The EVT combining mechanical thromboaspiration, balloon PTA, wire recanalization, and supraselective fibrinolysis with low dose t-PA could be still safely implemented in carefully selected patients to provide relatively good angiographic and clinical results.

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