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ABSTRACT

BACKGROUND AND PURPOSE: Sonolysis is a new therapeutic procedure for arterial recanalization. The aim of this study was to confirm the safety and efficacy of endovascular sonolysis by using the EkoSonic Endovascular System in subjects with acute ischemic stroke.

MATERIALS AND METHODS: Patients with acute ischemic stroke with occlusion of the middle cerebral artery or basilar artery were enrolled consecutively in this prospective study. The control group (44 MCA and 12 BA occlusions) was selected from historical controls. EkoSonic Endovascular System was started within 8 hours after stroke onset. The NIHSS score at hospital admission, after 24 hours, and at 7 days; arterial recanalization; early neurologic improvement; symptomatic intracerebral hemorrhage; and favorable 3-month clinical outcome defined as a modified Rankin Scale score of 0–2 were evaluated by statistical means.

RESULTS: Fourteen patients (10 men; mean age, 65.1 ± 11.2 years; median NIHSS score, 16.5) underwent EkoSonic endovascular sonolysis. Arterial recanalization after endovascular treatment was achieved in 6 of 7 (85.7%) patients with MCA occlusion (4 complete recanalizations) and in all 7 (100%) patients with BA occlusion (6 complete recanalizations). No (0%) symptomatic intracerebral hemorrhage or periprocedural complications occurred. Seven (50%) patients were independent at 3 months (median mRS score, 2). Early neurologic improvement and favorable clinical outcome were significantly more frequent in patients with MCA occlusion undergoing EkoSonic endovascular sonolysis than in controls (100% and 71.4% versus 4.6% and 13.6% of patients; $P = .0001$ and $P = .003$, respectively). Three-month mortality was significantly lower in patients with BA occlusion undergoing EkoSonic endovascular sonolysis than in controls (0% versus 66.7% patients, $P = .013$).

CONCLUSIONS: In this small study, EkoSonic endovascular sonolysis allowed safe and potentially effective revascularization in patients experiencing acute ischemic stroke.

ABBREVIATIONS: BA = basilar artery; cPTAS = combined percutaneous transluminal angioplasty and stenting; mRS = modified Rankin Scale; IAT = intra-arterial thrombolysis; TICI = Thrombolysis in Cerebral Ischemia

Acute occlusion of cervical or intracranial arteries is the most common cause of ischemic stroke. Detection of arterial occlusion during the first 6 hours after the onset of ischemic stroke is possible in ≤70% of patients.[1-4] Clinical studies have shown that the prognosis of patients with occlusion of the intracranial arteries in the acute phase of ischemic stroke is worse compared with patients without occlusion of a major intracranial artery.[5] One of the most important prognostic factors in patients with occlusion of the intracranial arteries is the time to recanalization.[6-9]

Data from a meta-analysis of 53 clinical trials (2066 patients) suggest that early recanalization is present in only 24.1% of patients without specific treatment (spontaneous recanalization), 46.2% of patients treated with intravenous thrombolysis, 63.2% of patients treated with intra-arterial thrombolysis, 67.5% of patients treated with combined IV thrombolysis–IAT, and in ≤83.6% of patients treated by mechanical methods.[5]

The options for acceleration of recanalization of intracranial

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artery occlusion are the following: IV thrombolysis, IAT, or combined thrombolysis; mechanical recanalization by using several mechanical devices for thrombectomy and/or stent placement; and remote or local sonolysis.[10-24] Endovascular sonolysis can be used to accelerate and achieve recanalization of intracranial arterial occlusion.[22-24]

The aim of the present study was to confirm the safety and efficacy of endovascular sonolysis by using the EkoSonic Endovascular System (EKOS, Bothell, Washington) in patients with acute ischemic stroke with occlusion of the middle cerebral artery or basilar artery within 8 hours after stroke onset.

MATERIALS AND METHODS

Patients

Consecutive patients who fulfilled the following inclusion criteria between August 2009 and September 2011 were recruited into this prospective case control study: acute ischemic stroke due to occlusion of the MCA or BA detected by using CTA; presenting with an NIHSS score of 4–25 on hospital admission; contraindicated for IV thrombolysis or with persistent artery occlusion 60 minutes after IV thrombolysis commencement; 18–80 years of age; and start of therapy within 8 hours of symptom onset. Patients with a modified Rankin Scale score of >1 before stroke onset, intracranial hemorrhage, or brain tumor detected by using CT were excluded from the study. The control group was selected from consecutive historical controls fulfilling the same inclusion and exclusion criteria, hospitalized between July 2006 and January 2008 (ie, before the era of mechanical recanalization at the stroke center in which the study was performed).

Diagnostics

On hospital admission, physical examination, blood samples, electrocardiography, chest radiography, and standard neurologic evaluation by a certified neurologist using the NIHSS were undertaken. These tests were followed by CT of the brain and CTA of the cervical and brain arteries. Duplex sonography of the cervical portion of the carotid and vertebral arteries and transcranial color-coded duplex sonography were performed before and 60 minutes after IV thrombolysis commencement.

Neurologic and physical examinations were repeated after 24 hours, at 7 days, and at 90 days. Early neurologic improvement was defined as an NIHSS score of zero or 1 at 24 hours after treatment or a decrease of ≥4 points in the NIHSS score 24 hours after treatment. The mRS was used for the evaluation of clinical outcome 90 days after ischemic stroke onset with a favorable clinical outcome defined as mRS 0–2. Intracranial bleeding detected in the control brain CT 24 hours after therapy onset was recorded. Intracranial bleeding with worsening of neurologic symptoms (≥4 points in the NIHSS) was classified as "symptomatic intracerebral hemorrhage."[25]

Treatment

Patients were treated at a comprehensive stroke center with 24/7 accessibility to IV thrombolysis and endovascular interventions, and they underwent standard treatment.[26] All patients who fulfilled the Safe Implementation of Thrombolysis in Stroke-Monitoring Study criteria for IV thrombolysis were treated by using rtPA (0.9 mg/kg) within 4.5 hours after ischemic stroke onset.[26,27]

Anticoagulation therapy (oral, subcutaneous, or intravenous) and oral administration of acetylsalicylic acid or other antiplatelet agents were used as standard treatment for patients 24 hours after ischemic stroke onset according to guidelines set by the European Stroke Organization.[26]

Table 1: Thrombolysis in Cerebral Ischemia criteria[28]

TICI Flow Grade	Characteristics
Grade 0	No perfusion
Grade I	Perfusion past the initial occlusion, but no distal branch filling
Grade IIa	Partial perfusion with incomplete distal filling of <50% of the expected territory
Grade IIb	Partial perfusion with incomplete distal filling of 50%–99% of the expected territory
Grade IIc	Near-complete perfusion, but with delay in contrast runoff
Grade III	Full perfusion with normal filling of distal branches in a normal hemodynamic fashion

Endovascular Treatment

For vessel occlusion, verification was confirmed in all patients by using 4-vessel diagnostic DSA (Innova 4100; GE Healthcare, Milwaukee, Wisconsin). After intra-arterial administration of heparin (total dose, 50 IU/kg) and placement of the EkoSonic Endovascular catheter within the occluded segment of the artery, the insonation with pulsed high-frequency (2.05–2.35 MHz) and low-power (400 mW/cm^2) sonographic waves and local administration of rtPA directly into the thrombus were started simultaneously. Patients without contraindication to thrombolysis treatment received rtPA (15 mg/h). The maximum calculated total dosage was ≤20 mg of rtPA, and the endovascular sonolysis was ≤60 minutes.

In the case of partial recanalization or early reocclusion after endovascular sonolysis, patients had additional treatment with angioplasty and stent implantation (Enterprise; Cordis Neurovascular, Miami Lakes, Florida or Wingspan; Boston Scientific, Natick, Massachusetts). In all patients with stent implantation, 500 mg of acetylsalicylic acid was administered intravenously at the end of the endovascular procedure. Subsequently, within the next 2 hours, 150 mg of oral clopidogrel followed by 6-week dual oral antiplatelet therapy (100 mg acetylsalicylic acid daily and 75 mg clopidogrel daily) was used in all patients with cPTAS, as an instituted therapy regimen. Repeated diagnostic angiography of the treated region was undertaken to assess the recanalization grade according to Thrombolysis in Cerebral Ischemia criteria (Table 1).[28]

Evaluation of Recanalization

The efficacy of recanalization was evaluated at the end of the endovascular procedure by using TICI criteria. Final recanalization status, TICI IIa or IIb, was considered "partial recanalization" and final status, TICI IIc or III, was "complete recanalization." An experienced independent radiologist (A.K.), blinded to the study protocol, evaluated all findings before definitive assessment of the diagnosis.

Table 2: Demographic data of the study group

	EKOS MCA	Control MCA	*P*	EKOS BA	Control BA	*P*
No. of subjects	7	44	–	7	12	–
Age (mean) (yr)	69.1 ± 11.4	68.7 ± 11.2	<.05	61.0 ± 9.4	68.9 ± 12.9	<.05
Males (No.) (%)	5 (71.4%)	22 (50.0%)	<.05	5 (71.4%)	9 (75.0%)	<.05
Arterial hypertension (No.) (%)	7 (100%)	33 (75.0%)	<.05	4 (57.1%)	9 (75.0%)	<.05
Diabetes mellitus (No.) (%)	2 (28.6%)	8 (18.2%)	<.05	1 (14.3%)	3 (25.0%)	<.05
Hyperlipidemia (No.) (%)	2 (28.6%)	9 (20.5%)	<.05	2 (28.6%)	5 (41.7%)	<.05
Atrial fibrillation (No.) (%)	2 (28.6%)	19 (43.2%)	<.05	2 (28.6%)	4 (33.3%)	<.05
Smoking (No.) (%)	2 (28.6%)	8 (18.2%)	<.05	1 (14.3%)	2 (25.0%)	<.05
Heavy alcohol consumption (No.) (%)	0 (0%)	1 (2.3%)	<.05	0 (0%)	0 (0%)	<.05
ICA/VA stenosis >50% (No.) (%)	1/0 (14.3/0%)	7/0 (15.9/0%)	<.05	0/3 (0/42.3%)	0/4 (0/33.3%)	<.05
Left hemisphere (No.) (%)	3 (42.9%)	25 (56.8%)	<.05	–	–	–
Use of acetylsalicylic acid (No.) (%)	2 (28.6%)	15 (34.1%)	<.05	2 (28.6%)	4 (33.3%)	<.05
Stroke in medical history (No.) (%)	1 (14.3%)	7 (15.9%)	<.05	1 (14.3%)	3 (25.0%)	<.05
Myocardial infarction in history (No.) (%)	1 (14.3%)	8 (18.2%)	<.05	1 (14.3%)	2 (16.7%)	<.05
IV thrombolysis (No.) (%)	3 (42.9%)	26 (59.1%)	<.05	2 (28.6%)	6 (50.0%)	<.05
IAT (No.) (%)	6 (85.7%)	0 (0%)	–	7 (100%)	0 (0%)	–
cPTAS (No.) (%)	3 (42.9%)	0 (0%)	–	5 (71.4%)	0 (0%)	–

Note:—VA indicates vertebral artery; EKOS, EkoSonic Endovascular System.

Table 3: Recanalization at the end of use of the EkoSonic Endovascular System in patients with MCA and BA occlusion and procedural data

	MCA	BA	All
Complete MCA recanalization (TICI IIc-III)	4 (57.1%)	6 (85.7%)	10 (71.4%)
Partial MCA recanalization (TICI IIa-IIb)	2 (28.6%)	1 (14.3%)	3 (21.4%)
No recanalization (TICI 0-I)	1 (14.3%)	0 (0%)	1 (7.1%)
Time from onset to admission (mean) (min)	139.3 ± 76.6	171.4 ± 76.4	155.4 ± 78.1
Time from onset to EKOS start (mean) (min)	163.6 ± 75.5	210.7 ± 78.6	187.1 ± 80.6
Length of procedure (mean) (min)	67.1 ± 11.4	57.9 ± 9.4	62.5 ± 28.0

Note:—EKOS indicates EkoSonic Endovascular System.

Statistical Analyses

Kolmogorov-Smirnov and Shapiro-Wilk methods were used for testing the fit of the parameters calculated to a normal distribution. Data with a normal distribution are reported as the mean ± SD. All parameters that did not fit a normal distribution are presented as median and interquartile ranges; the Mann-Whitney *U* test and Fischer exact test were used for comparisons of groups. Statistical analyses were performed by using the Statistical Package for the Social Sciences software, Version 14.0 (SPSS, Chicago, Illinois). $P < .05$ was considered significant.

Approval of the Study Protocol by the Ethics Committee

The entire study was conducted in accordance with the Helsinki Declaration of 1975 (as revised in 2004 and 2008). The ethics committee of the stroke center in which the study was performed approved the study. All patients signed informed consent forms for treatment. Independent witnesses verified the signatures if there were technical problems.

RESULTS

Fourteen patients (10 men; range, 47–80 years of age; mean, 65.1 ± 11.2 years) with acute ischemic stroke due to MCA or BA occlusion were enrolled in this prospective study. Five patients fulfilling the criteria for IV thrombolysis started receiving rtPA within 4.5 hours after ischemic stroke onset. The control group comprised 44 patients with acute ischemic stroke with MCA occlusion and 12 patients with BA occlusion (demographic data are shown in Table 2). Median NIHSS scores on hospital admission did not differ significantly between treatment and control groups (MCA: 15 versus 15.5; BA: 27 versus 24; $P > .05$). General anesthesia was used in 6 patients treated with the EkoSonic Endovascular System; conscious sedation was administered in 8 patients.

Time of onset to treatment (IV thrombolysis, endovascular treatment) commencement, length of the endovascular procedure, and recanalization at the end of the endovascular intervention are presented in Table 3. The mean time of onset to endovascular treatment start was 187.1 ± 80.6 minutes, and the mean length of the procedure was 62.5 ± 28.0 minutes. Complete recanalization of the MCA and BA after endovascular treatment (combined with percutaneous transluminal angioplasty with stent placement when indicated) was achieved in 4 (57.1%; 95% confidence interval [CI], 18.4%–90.1%) and 6 (85.7%; 95% CI, 42.1%–99.6%) patients, respectively. Furthermore, partial recanalization was achieved in 2 (28.6%; 95% CI, 3.7%–71.0%) patients with MCA occlusion and in 1 (14.3%; 95% CI, 0.4%–57.9%) patient with BA occlusion.

The NIHSS scores at day 7 and 90-day mRS scores were significantly better in patients with acute ischemic stroke after endovascular sonolysis (cPTAS when indicated) than in controls (Table 4). Early neurologic improvement and favorable clinical outcome at day 90 were achieved in 7 (100%; 95% CI, 65.2%–100%) and 5 (71.4%; 95% CI, 29.0%–96.3%) patients with MCA occlusion treated by using the EkoSonic Endovascular System compared with 2 (4.5%; 95% CI, 0.6%–15.5%) and 6 (13.6%; 95% CI, 5.2%–27.4%) patients in the control group ($P = .0001$ and $P = .003$). Symptomatic intracerebral hemorrhage did not occur in any patient treated by using the EkoSonic Endovascular System compared with 3.6% of patients in the control group (Table 4). No periprocedural complication occurred in patients who underwent endovascular treatment.

Seven-day and 3-month mortality were significantly lower in patients with BA occlusion treated by using endovascular sonolysis than in the control group ($P < .05$) (Table 4). No significant

Table 4: Clinical results in the particular subgroups

	EKOS MCA	Control MCA	*P*	EKOS BA	Control BA	*P*
Baseline NIHSS (median) (IQR)	15 (10–18)	15.5 (12–20)	<.05	27 (14.5–33)	24 (12–32)	<.05
NIHSS 24 hr (median) (IQR)	4 (2–6)	16 (12–20)	.0001	10 (7–25)	24 (14–28)	<.05
NIHSS day 7 (median) (IQR)	2 (1.5–4)	15.5 (7–20)	.0001	6 (4.5–19)	33 (8–33)	.049
Presence of ENI after 24 hours (No.) (%)	7 (100%)	2 (4.6%)	.0001	4 (57.1%)	2 (16.7%)	<.05
90-day mRS (median) (IQR)	1 (1–3.5)	5 (3–5)	.037	3 (2–4.5)	6 (4.5–6)	.034
mRS 0–3 at day 90 (No.) (%)	5 (71.4%)	8 (18.2%)	.008	4 (57.1%)	2 (16.7%)	<.05
mRS 0–2 at day 90 (No.) (%)	5 (71.4%)	6 (13.6%)	.003	2 (28.6%)	2 (16.7%)	<.05
SICH (No.) (%)	0 (0%)	1 (2.3%)	<.05	0 (0%)	1 (8.3%)	<.05
Malignant infarction (No.) (%)	0 (0%)	3 (6.8%)	<.05	0 (0%)	0 (0%)	<.05
7-day mortality (No.) (%)	0 (%)	3 (6.8%)	<.05	0 (%)	6 (50.0%)	.044
3-month mortality (No.) (%)	2 (28.6%)	10 (22.7%)	<.05	0 (0%)	8 (66.7%)	.013

Note:—ENI indicates early neurologic improvement; EKOS, EkoSonic Endovascular System; SICH, symptomatic intracerebral hemorrhage; IQR, interquartile range.

difference in mortality rates was detected in patients with MCA occlusion.

DISCUSSION

The results of the present study indicated the safety of endovascular sonolysis by using the EkoSonic Endovascular System without symptomatic intracerebral hemorrhage or periprocedural complications. No occurrence of symptomatic intracerebral hemorrhage is even more remarkable when comparing it with the results of the Interventional Management of Stroke (IMS) II trial, in which symptomatic intracerebral hemorrhage occurred mainly (in all except 1) in patients with NIHSS scores of ≥20, though in the present study, the number of patients with NIHSS scores of ≥20 was 6 (42.9%)[23] and all patients received heparin, 5 (35.7%) received IV thrombolysis, 13 (92.9%) received intra-arterial thrombolysis, and 8 (57.1%) patients were treated with dual antiplatelet therapy. This result may be biased by a small number of patients.

In the study, 3-month mortality was observed in 14.3% of patients. The efficacy of endovascular sonolysis (cPTAS when indicated) was suggested. Complete or partial MCA recanalization after endovascular treatment was achieved in 92.9% of patients.

In the past decade, the number of methods used for the acceleration of arterial recanalization has increased greatly. In addition to pharmacologic methods, especially IV thrombolysis and intra-arterial thrombolysis, mechanical neurointerventional methods (eg, Merci retriever [Concentric Medical, Mountain View, California]; Penumbra System [Penumbra, Alameda, California]; Solitaire stent [ev3, Irvine, California]; Trevo Pro [Concentric Medical]; Catch device [Balt, Montmorency, France]; Phenox clot retriever [phenox, Bochum, Germany]; BONnet Intracranial Flow Restoration Device [phenox]; or pREset Thrombectomy Retriever [phenox]; EkoSonic Endovascular System [EKOS, Bothell, Washington]; or, direct stent placement) have been introduced into clinical practice.[10-19] One of these, the EkoSonic Endovascular System, is the first tool system approved by the FDA that allows local endovascular application of high-frequency (2 MHz) and low-power (400 W/cm^2) sonography in clinical practice with or without simultaneous catheter-directed thrombolysis by application of thrombolytic drugs.[22-24]

Several in vitro, in vivo, and clinical studies have shown the potential effect of sonography (sonolysis) to accelerate clot lysis. The first clinical studies with endovascular sonolysis were used for the recanalization of coronary arteries. In the Analysis of Coronary Sonography Thrombolysis Endpoints in Acute Myocardial Infarction study, low-frequency (45 kHz) sonography was used with high intensity (18 W/cm^2) in the treatment of acute occlusion of the coronary arteries.[29] Complete recanalization was achieved in 87% of patients. No side effects were observed during therapy, and 80% of patients showed clinical improvement. Other studies showed the effect of endovascular sonolysis by the EkoSonic Endovascular System in patients with deep venous thrombosis of the lower extremities and in patients with pulmonary embolism.[30-35] Complete recanalization was achieved in 85.2%–96.0% of patients with arterial thrombosis[34,35] and in 83.0% patients with venous thrombosis.[31]

Mahon et al[22] published the first experience with endovascular sonolysis by using the EkoSonic Endovascular System in patients with acute ischemic stroke. It was a combination of intra-arterial thrombolysis using rtPA with endovascular sonography in 10 patients with MCA occlusion and in 4 patients with BA occlusion. Partial or complete recanalization was detected in 57% of patients, and there were no adverse effects during therapy. Three patients died within the first 24 hours. The mean mRS score in survivors with MCA occlusion was 2, and in survivors with vertebrobasilar occlusion, it was 3.

The system was tested subsequently in the IMS II trial with promising results.[23] Complete recanalization was achieved within 60 minutes and 120 minutes in 12 (41%) and 20 (68.9%) patients, respectively. Symptomatic intracerebral hemorrhage occurred in 9.9% of subjects in IMS-II, including 3.8% of patients treated with intravenous rtPA alone. Direct perforation of vessels, primary subarachnoid hemorrhage, or intracranial dissection was not documented in the subjects treated. The results of the present study showed an even higher prevalence of recanalization without symptomatic intracerebral hemorrhage.

The complex effect of sonography on the acceleration of thrombus lysis is incompletely understood, but it is assumed that the sonographic waves accelerate enzymatic fibrinolysis primarily by nonthermal mechanisms. Mechanisms that have been postulated include the following: increasing the transport of fibrinolytic agents into the thrombus by mechanical disruption of its structure[36]; direct activation of fibrinolytic enzymes (either mechanical dissociation of the complex molecules, in which fibrinolytic enzymes are inactivated by binding to their inhibitors, or irrita-

tion of the endothelium with increased production of fibrinolytic enzymes[37,38]); and transient peripheral (capillary) vasodilation caused probably by increased production of nitric oxide in the endothelium.[39,40] Radiation force and acoustic cavitation are mechanical effects of sonography that have also been postulated to be a potential mechanism.[41]

Several clinical studies have tested the feasibility and safety of other mechanical devices, especially of the Merci Retrieval System, Penumbra System, Solitaire stents, and direct placement of stents. The reported prevalence of recanalization in those studies ranged from 46% for the Merci retriever system,[10] 84% for the Penumbra system,[11,12] 90% for the Solitaire stent,[13] and up to 100% for direct stent placement.[18,19] Periprocedural complications varied between 3.4% and 9.0%. Symptomatic intracerebral hemorrhage occurred in 10%–11%, and the mortality rate was 32.8%–35.0%. Favorable clinical outcome (defined as mRS, 0–2) ranged from 36% up to 74%.[10-19] The present study showed that the prevalence of recanalization and favorable outcome in patients treated by endovascular sonolysis in combination with local or systemic thrombolysis (and cPTAS if indicated) was comparable with (or even superior to) other endovascular methods, especially in patients with MCA occlusion. Moreover, it seemed to be safer.

Previous studies primarily involved patients with occlusion in the anterior circulation. Nevertheless, the likelihood of achieving a favorable outcome in patients with a BA occlusion is worse than in those with an MCA occlusion. More than 90% of patients with a BA occlusion and any type of treatment die or have a permanent disability.[42,43] Studies have shown that patients treated by antithrombotic drugs have a chance of favorable outcome of 7%, but patients treated by IV thrombolysis (or by a combination of IV thrombolysis with intra-arterial treatment) have a chance of favorable outcome of 41%. In patients treated intra-arterially, partial or complete recanalization (defined as a Thrombolysis in Myocardial Infarction score of 2–3) of the BA at the end of an intra-arterial procedure was found in 72% of patients and symptomatic intracerebral hemorrhage was reported in 14% of patients.[44] Jung et al[45] reported similar results in patients with BA occlusion treated by intra-arterial thrombolysis (prourokinase) and/or mechanical interventions. Complete or partial recanalization was achieved in 69.8% of patients, with favorable 3-month clinical outcome (defined as an mRS score of 0–3) achieved in 44% patients and an occurrence of symptomatic intracerebral hemorrhage of 0.9%. Those results are in agreement with those of the present study, in which recanalization was achieved in 100% of patients, with a favorable 3-month clinical outcome (defined as an mRS score of 0–3, especially for the BA group) achieved in 57.1% of patients and an occurrence of symptomatic intracerebral hemorrhage of 0%.

Several limitations of the present study should be mentioned. It was a case control study in which the main goal was to assess the safety and prevalence of recanalization with endovascular sonolysis by using the EkoSonic Endovascular System. Although the criteria for symptomatic intracerebral hemorrhage evaluation are well-defined, the evaluation of the recanalization of brain arteries remains subjective (even though in the present study, a radiologist blinded to the study protocol evaluated vascular status). Finally, the open-label design of the present study with only blinded evaluation of recanalization in the TICI scale cannot prevent bias in the clinical evaluation of dependency (mRS) after 3 months. Furthermore, a low reliability of the TICI scale for stroke trials should be also taken into account,[46,47] and even though it was independently reviewed, the interobserver correlation of the TICI scale was not evaluated in the present study due to a small number of patients.

CONCLUSIONS

Endovascular treatment by using the EkoSonic Endovascular System in combination with thrombolysis and cerebral percutaneous transluminal angioplasty and stent placement seems to be a potentially effective therapeutic method for patients with acute ischemic stroke with MCA or BA occlusion after IV thrombolysis failure or with a contraindication to IV thrombolysis. Nevertheless, the efficacy of this endovascular treatment must be confirmed by large prospective randomized trials.

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