

Endovascular therapy of acute ischemic stroke by interventional cardiologists: initial national experience

Akut iskemik inmenin girişimsel kardiyologlar tarafından damarıçi yolla tedavisi: İlk ulusal deneyim

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ABSTRACT

Objectives: We report our initial experience with thrombectomy devices in patients with acute ischemic stroke.

Study design: Demographic, clinical, and angiographic findings of 19 consecutive patients (7 females and 12 males; mean age 61.4±12.5 years) with acute ischemic stroke were evaluated retrospectively.

Results: The mean initial National Institutes of Health Stroke Scale (NIHSS) score was 19.5±5.6. Middle cerebral artery was the occluded artery in all of the patients (proximal occlusion in 11, distal in 8 and tandem occlusions in 7 patients). Successful revascularization was achieved in 16 patients (84%). The mean NIHSS score was 8.4±8.2 at 24 hours after the procedure, and 60% of patients showed a modified Rankin scale score of ≤2 at 90 days. New occlusion by migrated emboli was observed in 2 (11%) cases. None of the patients had experienced post-procedural symptomatic intracerebral hemorrhage; 3 patients died during the three-month follow-up. In all patients, thrombectomy was performed with retrievable Solitaire AB stent system.

Conclusion: This single-center experience with mechanical thrombectomy devices demonstrated that high success rates can be achieved by experienced interventional cardiologists in equipped cath labs throughout the country.

ÖZET

Amaç: Akut iskemik inme tanısı alan ve damarıçi yolla tedavi uygulanan hastalar ile ilgili ilk deneyimlerimizi sunmayı amaçladık.

Çalışma planı: Akut iskemik inme nedeniyle hastanemize başvuran ve mekanik trombektomi uygulanan ardışık 19 hastanın (7 kadın, 12 erkek; ort. yaş 61.4±12.5 yıl) demografik, klinik ve anjiyografik bulguları geriye dönük olarak değerlendirildi.

Bulgular: Başvuru sırasında ortalama NIHSS (National Institutes of Health Stroke Scale) skoru 19.5±5.6 idi. Olguların hepsinde orta serebral arter (11'inde proksimal, 8'inde distal) tam tıkalı idi. Yedi olguda hem kraniyum dışı hem de kraniyum içi tıkanma (tandem oklüzyon) tespit edildi. Olguların 16'sında (%84) başarılı revaskülarizasyon sağlandı. İşlemden 24 saat sonra ortalama NIHSS skoru 8.4±8.2 idi. Üçüncü ayın sonunda ise olguların %60'ında modifiye Rankin skoru ≤2 idi. İki olguda (%11) işlem sırasında emboli distale kaydı. Hiçbir olguda semptomatik kafa içi kanama olmadı. Üç aylık takipte üç hasta hayatını kaybetti. Tüm hastalarda trombektomi işlemi Solitaire AB geri çekilebilir stent sistemi kullanılarak yapıldı.

Sonuç: İlk deneyimlerimiz, akut iskemik inmenin damarıçi tedavisinin deneyimli girişimsel kardiyologlar tarafından ülkemizin birçok modern kateter laboratuvarlarında yüksek başarıyla uygulanabileceğini göstermektedir.

Stroke is the third most common cause of death and the leading cause of severe disability worldwide.^[1,2] Current treatment options for acute ischemic stroke include intravenous (IV) fibrinolytic therapy

and endovascular management with intra-arterial (IA) fibrinolytics or mechanical thrombectomy using aspiration devices and retrievable stents. Although IV fibrinolysis is the preferred treatment strategy in

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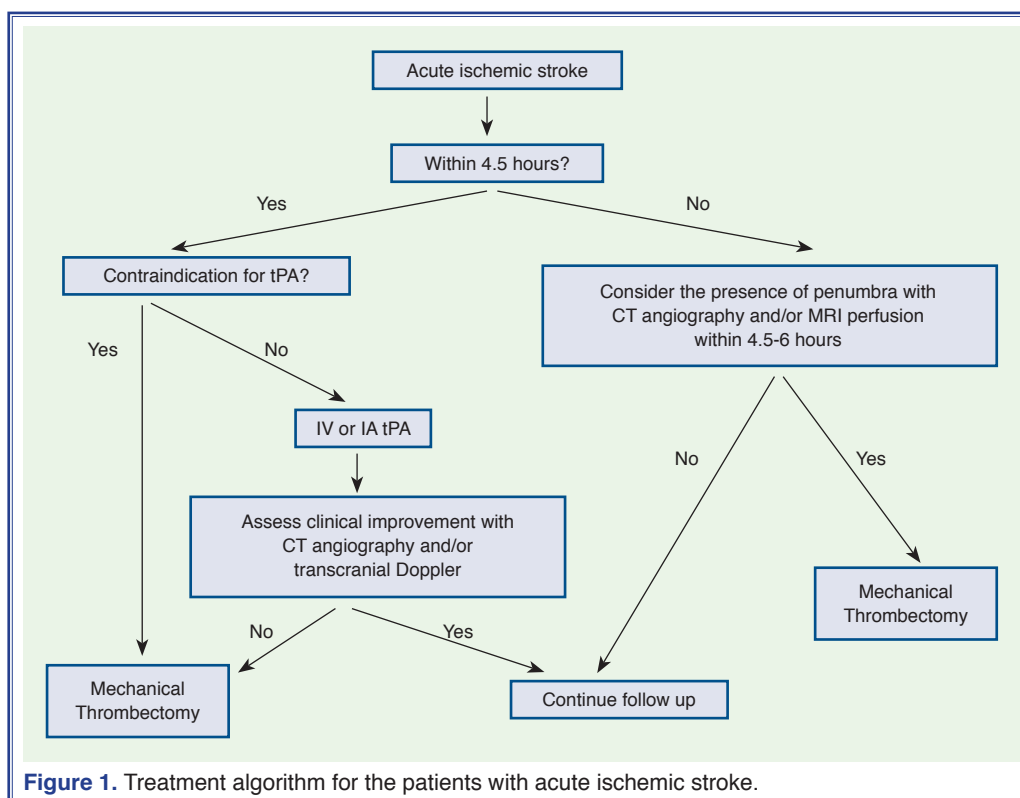
daily practice, the narrow therapeutic time window (<4.5 hours), numerous absolute contraindications, and the relatively low efficiency have restricted its use. Results of the previous studies suggested that the success rate of IV tissue-type plasminogen activator (t-PA) in achieving revascularization ranges from 35%-52%, depending on the degree and location of the culprit arterial occlusion; however, it could be associated with a reocclusion rate of up to 17%.^[3-6] IA administration of thrombolytics provides direct contact to the clot with fewer systemic complications and higher recanalization rates compared to IV use.^[7] It may also facilitate extension of the therapeutic window to 6 hours and appears as an option for patients with contraindications to systemic thrombolysis (i.e., postoperative stroke) or patients in whom IV thrombolysis has failed. Angiographic assessment of the patient provides characterization of the obstructive lesion, imaging of collateral flow anatomy, combined use of fibrinolytics with mechanical thrombectomy devices, and confirmation of recanalization. Delay in treatment, risks of catheter manipulation, and the need for skilled endovascular facilities and personnel have emerged as the disadvantages of IA treatment.^[7]

The improvements in endovascular technology have led to a movement towards acute stroke intervention. Contrary to fibrinolytics, retrievable stent thrombectomy devices have widened the therapeutic window to 8 hours with high recanalization rates (80%-90%).^[8,9] Among thrombectomy devices, the fully retrievable and self-expanding Solitaire stent (ev3 Inc., Irvine, CA, USA), which was initially used in stent-assisted embolization of intra-cranial aneurysms, is a preferable device, with relatively quick performance and satisfactory recanalization rates.^[10]

National statistics have revealed that 14.5% of men and 15.7% of women die each year from stroke in our country.^[11] Furthermore, a large proportion of these patients had more severe disease (modified Rankin scale=3-5) and greater time delays from symptom onset until hospital admission.^[12] These unignorable national facts gave way to the need for more effica-

Abbreviations:

CT	Computed tomography
IA	Intra-arterial
ICH	Intracerebral hemorrhage
IV	Include intravenous
MCA	Middle cerebral artery
NIHSS	National Institutes of Health Stroke Scale
t-PA	Tissue-type plasminogen activator
TICI	Thrombolysis in cerebral infarction



cious and feasible treatment options instead of the currently recommended reperfusion strategies such as IV and IA fibrinolytic therapies. To best of our knowledge, there has been no previous report about the use of mechanical thrombectomy in patients with acute ischemic stroke in our country. Here, we report our initial, single-center experience with the Solitaire AB mechanical thrombectomy device in the treatment of acute ischemic stroke.

PATIENTS AND METHODS

Patient assessment and imaging

A total of 19 consecutive patients admitted to our institution with acute ischemic stroke were evaluated retrospectively. All the patients had a large intracranial

artery occlusion and underwent mechanical thrombectomy using Solitaire AB retrievable stent. Brain computed tomography (CT) scan was performed in order to rule out hemorrhagic stroke on admission. Magnetic resonance imaging (MRI) with diffusion-weighted imaging was performed for the assessment of occluded vessels. After the interventional procedure, brain CT scan was performed routinely in order to rule out intracerebral hemorrhage (ICH). Patients with (1) National Institutes of Health Stroke Scale (NIHSS) score ≥ 8 ; (2) Thrombolysis in cerebral infarction (TICI) score of 0 to 1 in an accessible vessel; (3) no detection of ICH; and (4) hospital admission within 8 hours from symptom onset were included in the present study.

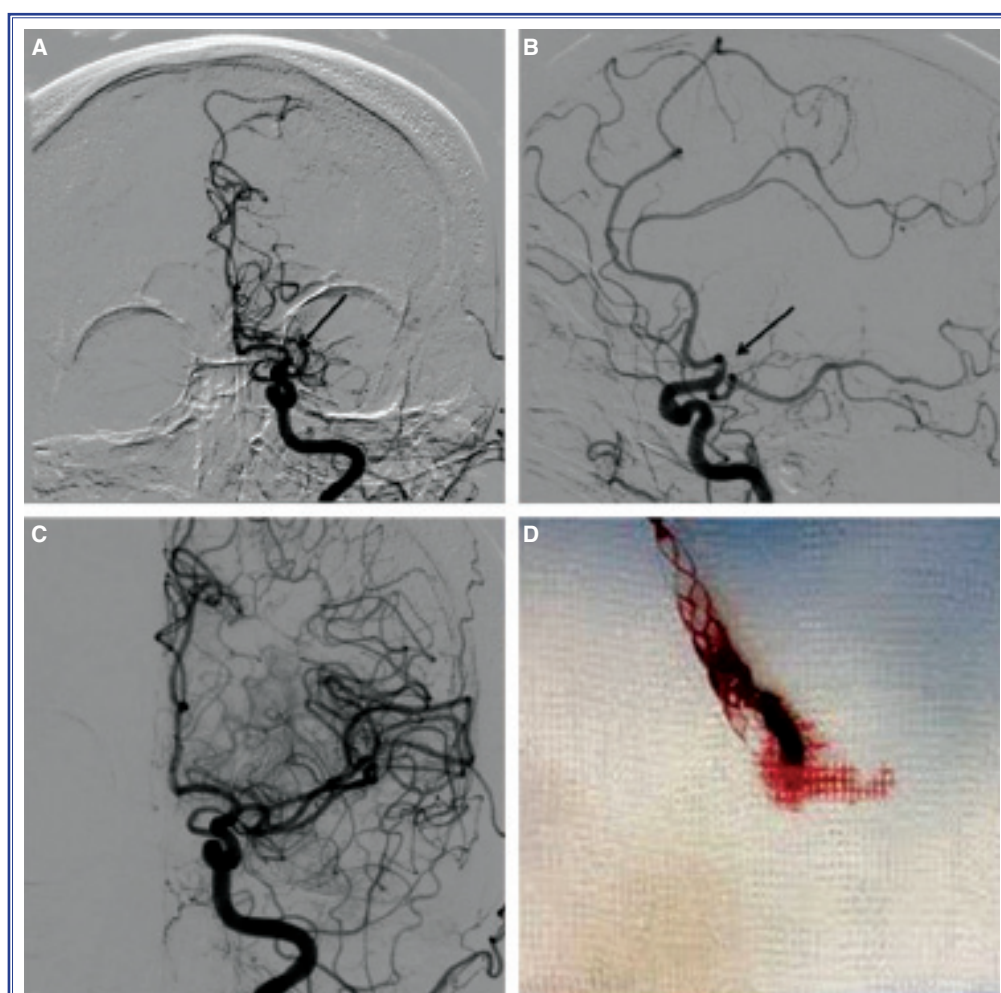


Figure 2. Initial and post-treatment angiogram: (A and B) Initial angiogram (Towne's and lateral views) demonstrating the occlusion of the M1 segment of the left middle cerebral artery (MCA) (black arrow), (C) immediate post-treatment angiogram showing complete revascularization of left MCA, and (D) solitaire stent within the thrombus.

Procedure

Patients admitted to the emergency department with the diagnosis of acute ischemic stroke were treated according to our hospital's stroke protocol (Fig. 1).^[1] Initially, the patient is assessed by the stroke neurologist, and then, if the patient is a candidate for endovascular management, he is transferred to the cath lab. The stroke team, composed of a cardiologist, neurologist, and anesthesiologist, decide and perform the appropriate management of the patient. All procedures were performed under slight sedation and local anesthesia by a team consisting of an interventional cardiologist, a neurologist and an anesthetist. For evaluation of the degree of leptomeningeal collaterals, angiogram of a non-infarct-related artery was performed first. Then, the occlusion status and TICI scale of the occluded vessel were confirmed by taking an angiography after locating the 8F guiding catheter (Launcher, Medtronic Inc, Minneapolis, MN, USA) to the left internal carotid artery. To prevent occurrence of a new thromboembolic event during the procedure, 5.000 IU of unfractionated heparin was administered through the guiding catheter. In patients with tandem occlusions, a proximal protection device (MoMa; Invatec, Roncadelle, Italy) was used. Next, a Rebar-18 microcatheter (ev3 Inc., Irvine, CA, USA) under the guidance of a hi-torque Whisper LS guide-wire (Abbott Laboratories, Abbott Park, IL, USA) was introduced into the target vessel and located at the distal portion of the occlusion site after passing the thrombus segment. A Solitaire AB stent (ev3 Inc, Irvine, CA, USA) was deployed over the whole length of the thrombus. The retrievable stent's radial force is able to immediately create a channel by compressing the thrombus and to partially restore blood flow to the distal territory. The device is left in place for 5 minutes (min) to allow engagement of the thrombus within the stent struts. Partial recanalization was observed immediately after stent deployment. The microcatheter and stent were gently pulled back under continuous aspiration using a 50 cc syringe through the guiding catheter to prevent development of a new embolism by lost clots. Patency of the carotid artery was maintained with a stent after successful recanalization of the distal occlusion in patients with tandem lesions. To assess the patency of the artery, a follow-up angiography was performed immediately after the interventional procedure (Fig. 2). When the subsequent angiogram showed a TICI score <2, the proce-

cedure was repeated until a TICI score of ≥ 2 or 3 was achieved. TICI scoring is summarized in Table 1.^[13] NIHSS score was calculated on admission, after the procedure and at the time of discharge in all patients. The modified Rankin Scale (mRS) was recorded at the third month. A mRS ≤ 2 was defined as a good neurological outcome. The study was approved by the local Ethics Committee.

RESULTS

The clinical and imaging characteristics of 19 consecutive patients are shown in Table 2. The patients were admitted to our center 120-310 min (mean, 210 min) after the onset of symptoms. Most of our patients presented with dense right hemiparesis. In addition, patients had neglect, dysphasia, and difficulty in swallowing. The presence of a thrombus was confirmed by CT angiogram in all patients. The clinical and post-procedural imaging characteristics are shown in Table 3. Reperfusion time was defined as the time from onset of symptoms to complete recanalization of the occluded artery, and it was determined to range from 150-360 min (mean, 234 min). The duration of the revascularization procedure was 45-125 min (mean, 68 min). All patients had a middle cerebral artery (MCA) occlusion. Both internal carotid artery and MCA occlusions were detected in seven patients. Successful

Table 1. Demographic characteristics of the study population (data demonstrated as mean \pm standard deviation)

Characteristic	n	%
Number of patients	19	
Demographic data		
Mean age (years)	63.2 \pm 13.6	
Gender (male) (%)	12	63
Atrial fibrillation (%)	4	21
Hypertension (%)	13	68
Coronary artery disease (%)	8	42
Site of occlusion		
ICA + MCA (Tandem) (%)	7	36
MCA M1 (%)	11	58
MCA M2 (%)	8	42

rTPA: Recombinant tissue plasminogen activator; ICA: Internal carotid artery; MCA: Middle cerebral artery; M1, M2: First and second segment of MCA.

Table 2. The clinical and post-procedural angiographic characteristics of the study population

No	Age/Gender	NIHSS on presentation	NIHSS on discharge	mRS on presentation	mRS at 3 months	Artery site occluded	Recanalization time	A	TICI*
1	60/Male	25	5	5	1	LMCA	180	3	3
2	60/Female	22	3	4	1	LMCA	360	1	3
3	69/Male	25	23	5	-	LMCA+ICA (Tandem)	-	5	0
4	55/Female	8	0	1	0	LMCA	150	1	3
5	88/Female	20	17	4	3	LMCA	150	1	3
6	45/Male	23	7	4	3	RMCA+ICA (Tandem)	360	1	3
7	53/Male	24	3	4	1	LMCA	180	1	3
8	65/Male	20	11	4	3	RMCA+ICA (Tandem)	300	4	2a
9	67/Male	8	2	2	0	RMCA+ICA (Tandem)	180	3	3
10	65/Male	24	23	5	3	RMCA	180	3	3
11	70/Female	14	1	4	1	LMCA	360	1	3
12	67/Female	12	3	1	1	LMCA	240	1	3
13	71/Male	23	18	4	-	LMCA	-	5	1
14	25/Female	20	4	4	2	RMCA	150	5	2a
15	58/Female	24	0	5	0	RMCA+ICA (Tandem)	240	1	3
16	57/Male	24	23	5	-	LMCA+ICA (Tandem)	310	5	1
17	59/Male	14	4	4	0	LMCA	260	2	3
18	64/Male	19	8	4	1	LMCA	280	1	3
19	69/Male	22	5	4	1	LMCA	180	1	3

A: No of devices passes; TICI*: TICI postprocedure; NIHSS: National Institutes of Health Stroke Scale; TICI: Thrombolysis in cerebral infarction; mRS: Modified Rankin Scale; ICA: Internal carotid artery; MCA: Middle cerebral artery.

revascularization (TICI 2b and 3) was achieved in 16 of 19 (84%) patients, and a TICI 3 state was observed in 14 (73%) patients. Balloon angioplasty after thrombectomy was performed in one patient with infective endocarditis who underwent cardiac open surgery for aortic valve replacement. In two patients who had tandem occlusion, the procedure was unsuccessful. NIHSS on admission was 19.5 ± 5.6 . Almost three-fourths of the patients (73.3%) improved by >5 points on the NIHSS at discharge, and 60.0% showed a mRS of ≤ 2 at 90 days. Three patients died during the follow-up due to nosocomial infection. None of the patients had experienced symptomatic post-procedural ICH at the three-month follow-up.

Table 3. Thrombolysis in cerebral infarction (TICI) perfusion grading^[13]

0	No perfusion
1	Perfusion past the initial obstruction, but limited distal branch filling with little or slow distal perfusion.
2a	Perfusion of less than $\frac{1}{2}$ of the vascular distribution of the occluded artery (e.g., filling and perfusion through 1 M2 division).
2b	Perfusion of $\frac{1}{2}$ or greater of the vascular distribution of the occluded artery (e.g., filling and perfusion through 2 or more M2 divisions).
3	Full perfusion with filling of all distal branches.

Table 4. Technical properties of the currently available retrievable stents

Device	Company	Feature	Delivery system diameter (inch)	Sizes (mm)	Vessel diameter range (mm)	
Solitaire FR	Covidien/ev3	Honeycomb-like cell design longitudinal open slit design	0.021	4x15/20	2-4	
				6x20/30	3-5.5	
Solitaire AB	Covidien/ev3	Closed cell design high cell deformation resistance	0.021	3x20/30	2.2-3	
				0.027	4x15/20/30/40	3-4
					5x20/30/40	4-5
					6x20/30	5-6
Trevo Pro	Stryker Neurovascular	Endoluminal orientation of the broader base of stent struts to enhance clot integration, active area with higher radial force, closed distal end	0.021	4.5x20	1.5-4	
Revive SE	Codman	Decreased cell size from proximal to distal retrieval zone to enhance clot engagement, high radial force, closed distal end	0.021	4.5x22	1.5-5.5	
Aperio	Acandis	Hybrid open-closed cell design	0.027	4.5x40	2-4	
Capture	Mindframe	Constant radial force minimizing cell deformation	0.027	3x30	2-3	
				5x30	2.5-4.5	
Capture LP	Mindframe	Low profile delivery system	0.0165	3x30	2-3	
				5x30	2.5-4.5	
pREset	Phenox	Helically shaped slit design, proximal cell connector	0.021	4x20	2-4	
Penumbra Seperator 3D	Penumbra	4 intraluminal chambers	0.025	4.5x26	≥3	
CATCH+	BALT	Longitudinal open slit design	0.025	4.5x26	≥3	

DISCUSSION

Here, we have reported our first experience with mechanical thrombectomy device (Solitaire AB self-expanding retrievable stent) in patients with acute ischemic stroke performed by interventional cardiologists. A high recanalization rate (84%) without an increase in the number of hemorrhagic complications was the major finding of our study. A large proportion of patients almost completely recovered, only four patients exhibited long-term disability, and three patients died during the three-month follow-up.

Aging of the population is a growing reality in our country as in western countries of the world. This

translates into an increasing prevalence of cardiovascular disorders, especially coronary artery disease and stroke. Ischemic strokes account for 80% of all strokes. Current treatments for acute ischemic stroke include IV thrombolytic therapy with t-PA and endovascular therapies, including IA thrombolytic therapy, the use of clot retrieval devices, and surgical embolectomy. In acute ischemic stroke, re-establishment of blood flow as soon as possible through the occluded cerebral artery is essential.^[14] IV infusion of recombinant t-PA (rTPA), which is recommended as a first choice of treatment, has a relatively narrow time period for application, with insufficient rates of recanalization.^[15] While IA thrombolysis extends the time

of application up to 6 hours, the results still appear unsatisfactory.

Although mechanical thrombectomy is recommended in case of failed recanalization after thrombolysis or for patients with contraindications to thrombolytic therapy, results of some studies have demonstrated its efficacy as first-line treatment.^[16-19] Accumulated data with the use of mechanical thrombectomy look very promising for the treatment of stroke caused by large arterial occlusions.^[20,21] A variety of devices have been developed for mechanical thrombectomy, but all of them showed limited results in comparison with Solitaire retrievable stent (Table 4).^[22] Some of the studies showed that these new generation retrievable stents were more rapid, potent and safe to provide recanalization compared to the older devices like Merci and Penumbra.^[10,23] For example, the SWIFT trial (Solitaire FR with the Intention for Thrombectomy), which compared the efficacy and safety of a retrievable stent (Solitaire FR system) with that of the Merci device, randomly assigned 113 stroke patients within 8 hours of stroke onset.^[10] Fifty-eight percent of Solitaire-treated patients had good mental/motor functioning at 90 days, compared with 33% of Merci patients. At present, there is no study comparing new retrievable stents with IV tPA. Recently, Ciccone et al.^[24] compared the efficacy of endovascular treatment with conventional lytic therapy in a randomized study including 362 patients with acute stroke. They concluded that endovascular therapy was not superior to standard treatment with IV t-PA. We suggest that the results of this study cannot be generalized to all the patients treated with mechanical thrombectomy in view of: the small number of patients (18 patients) that underwent mechanical thrombectomy, very limited use of new generation retrievable stents in the study, and use of IA thrombolysis instead of device-based therapy in most of the patients in the endovascular treatment arm. The higher recanalization rates of Solitaire AB retrievable stent could be related with its design and rapid applicability. We examined higher recanalization rates (84%) without an accompanying increase in the number of hemorrhagic complications in stroke patients with Solitaire AB thrombectomy device. We suggest that mechanical thrombectomy could be performed for the treatment of acute ischemic stroke in several modern cath labs providing 24/7 (24 hours per day, 7 days per week) cardiac care throughout the country. Trained

interventional cardiologists in cooperation with neurologists could perform intracranial endovascular procedures and provide important contributions in the management of patients with acute ischemic stroke. Thus, a significant portion of these patients would be treated with mechanical thrombectomy, which is a more effective modality of treatment. We believe that the results of this study can motivate the government and public health administrators to support this new management modality in our country. The main limitations of the present study are the lack of a control group and the small sample size. Despite the small sample size, the use of the Solitaire AB device provided good technical and clinical outcomes.

In conclusion, mechanical thrombectomy by trained interventional cardiologists appears to be a safe, effective and feasible technique with a high recanalization rate and favorable clinical outcomes in patients presenting with acute ischemic stroke.

Conflict-of-interest issues regarding the authorship or article: None declared

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Key words: Embolectomy/instrumentation; fibrinolytic agents/therapeutic use; stents; stroke/therapy; thrombectomy/instrumentation; Turkey.

Anahtar sözcükler: Embolektomi/enstrümantasyon; fibrinolitik ajanlar/terapötik kullanım; stentler; inme/tedavi; trombektomi/enstrümantasyon; Türkiye.