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AQURE PASSPORT Intracranial Catheter for Mechanical Thrombectomy in Acute Ischemic Stroke Patients

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Abstract

Objective—We report the first experience with a new intracranial catheter as an adjunct to mechanical thrombectomy in acute ischemic stroke patients.

Methods—We prospectively determined technical success, intended procedure (device delivery at target lesion) completion without a need for a different catheter, technical ease, and intended procedure completion without the occurrence of ≥3 unsuccessful attempts in acute ischemic stroke patients with intracranial occlusion. The initial site of occlusion and recanalization was graded based on Qureshi grading scheme. Grade 0 was used to define complete recanalization.

Results—A total of four procedures were performed in four patients with a mean age of 63.5 years (range 50–81 years). The occlusion was in the proximal middle cerebral artery in two patients, and posterior cerebral artery and basilar artery in one patient each. The procedures were technically successful and met the definition of technical ease in all patients. The distal-most segment where AQURE PASSPORT intracranial catheter was placed was in the supraclinoid internal carotid artery, proximal posterior cerebral artery, proximal middle cerebral artery, and proximal basilar artery in the four patients. Stent retrievers were used in three patients and primary angioplasty was performed in two patients. Complete recanalization was achieved in all four patients. The primary operator rated the performance of guide catheter as superior in all cases.

Conclusion—The present study demonstrates the feasibility of performing mechanical thrombectomy for intracranial arterial occlusion with a new intracranial catheter having superior performance.

Keywords

Intracranial catheter; thrombectomy; acute ischemic stroke; stent retriever; intracranial occlusion

Introduction

Numerous intracranial catheters such as 5MAX™ ACE (Penumbra, Alameda, CA), the Arc™ and Arc™ mini (Medtronic, Irvine, CA), SOFIA and SOFIA PLUS (Soft torqueable catheter Optimized For Intracranial Access, MicroVention Terumo, Tustin, California) have been used in endovascular acute ischemic stroke treatment either as primary catheter for suction or adjunct to thrombectomy with stent retriever for concomitant aspiration [1–8]. The interest in such catheters has increased based on recent American Heart Association/American Stroke Association guidelines in 2015 and 2018 that strongly recommend endovascular treatment in the selected group of patients [9,10]. We report the initial experience with the use of a new intracranial catheter as an adjunct to mechanical thrombectomy.

Methods

Patients

All patients were treated at Liaocheng Neuro Hospital, Liaocheng, Shandong, China. Acute ischemic stroke patients with neurological deficits secondary to large arterial occlusions were treated. Informed consent for

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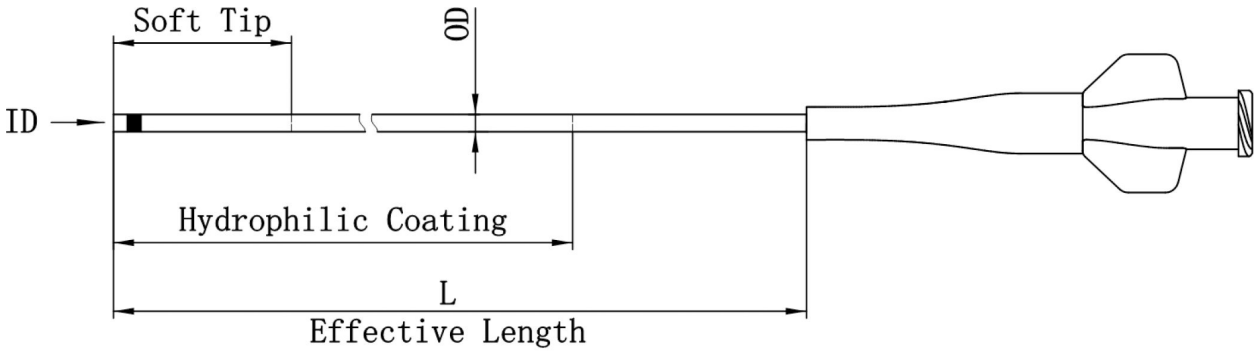

Specifications	OD	ID	L
5F-115	5Fr	0.055″	115cm
5F-125	5Fr	0.055″	125cm
6F-105	6Fr	0.068″	105cm
6F-115	6Fr	0.068″	115cm
6F-125	6Fr	0.068″	125cm

Figure 1. The characteristics of AQURE PASSPORT intracranial catheter.

the procedure was acquired by the patient and/or their family.

Procedure

All procedures were performed under general anesthesia. Arterial access was acquired by placing an 8 F introducer sheath in the femoral artery. The guide catheter/sheath was placed in the appropriate internal/common carotid artery or subclavian/vertebral artery. In general, AQURE PASSPORT 5 F intracranial catheter (AQURE Medical Inc., Shoreview, MN, USA) was introduced in the appropriate internal carotid or vertebral artery using 0.035-inch guidewire in the extracranial segment followed by microcatheter and microwire combination to advance in the intradural and intracranial segments. The appropriate microcatheter, Prowler Select Plus (Codman and Shurtleff, MA, USA), Rebar 18 (Medtronic, Minnesota, USA), or Headway 21 (Microvention, California, USA), was advanced to the target lesion and used for delivering stent retriever. The retriever was retracted under aspiration from AQURE PASSPORT 5 F intracranial catheter. Other devices such as angioplasty balloon catheters or stents were used as deemed appropriate by the primary operator.

AQURE PASSPORT intracranial catheter

The AQURE PASSPORT intracranial catheter is available with two working lengths of approximately 115 cm or 125 cm for 5 F system and three working lengths of approximately 105 cm, 115 cm, or 125 cm for 6 F system with conical fittings with a 6% Luer taper at one end. The details of the catheter are presented in Figure 1. It has a band-like radiopaque platinum marker at its distal tip, which allows for proper visualization under fluoroscopic guidance. The AQURE PASSPORT catheter can be navigated over a guide wire with a minimum OD of 0.035″.

Data collected

We collected demographic and clinical data on each of the patients using a standard data collection form. The presence of hypertension, diabetes mellitus, hyperlipidemia, active cigarette smoking, and coronary artery disease was ascertained. The patients presenting symptoms were classified as either minor (National Institutes of Health Stroke Scale score <4), or major (National Institutes of Health Stroke Scale score ≥4) ischemic stroke. Procedural data included target lesion and devices used

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Table 1. The clinical and procedural characteristics of the acute ischemic stroke patients treated with AQURE PASSPORT intracranial catheter

Variables	Patient # 1	Patient # 2	Patient # 3	Patient # 4
Age (yrs.) gender	57 man	81 woman	66 man	50 woman
Cardiovascular risk factors	None	Hypertension, coronary artery disease	Active cigarette smoking, coronary artery disease	None
Presenting symptom	Major ischemic stroke (NIHSSS	Minor ischemic stroke (NIHSSS <4)	Major ischemic stroke (NIHSSS	Major ischemic stroke (NIHSSS
Procedure	Thrombectomy	Thrombectomy	Thrombectomy	Thrombectomy
Vessel catheterized	Basilar artery	Left middle cerebral artery	Right posterior cerebral artery	Left MCA
Site of occlusion	Mid basilar artery	Proximal left middle cerebral artery (M1 segment)	Proximal posterior cerebral artery	M2 segment left middle cerebral artery
Occlusion grade	4 B	3 B	1	2
Distal-most portion reached by AQURE PASSPORT catheter	Proximal basilar artery	Supraclinoid internal carotid artery	Proximal posterior cerebral artery	Proximal middle cerebral artery
Stent retriever type	Solitaire™ revascularization device 4 × 30 mm	Solitaire™ revascularization device6 × 30 mm	Solitaire™ revascularization device 4 × 20 mm	
Angioplasty balloon catheter	Gateway balloon catheter 2.5 mm × 9 mm			Gateway balloon catheter 2.5 mm × 9 mm
Stent type and size	Neuroform EX 3.5 × 15 mm stent			
Final results	Complete recanalization	Complete recanalization	Complete recanalization	Complete recanalization

Abbreviations used: NIHSSS, National Institutes of Health Stroke Scale score.

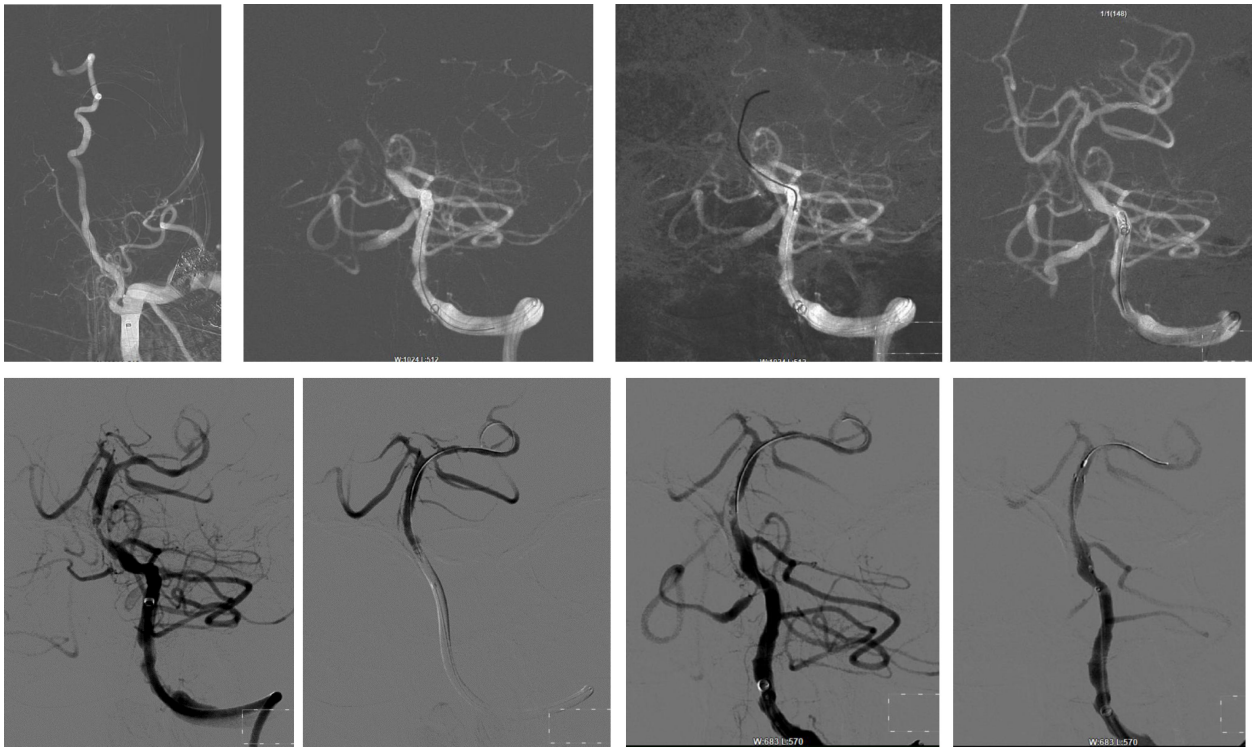

Figure 2. Various components of the thrombectomy of the middle portion of basilar artery occlusion using AQURE PASSPORT 5 F placed in the proximal portion of the basilar artery in patient 1 are demonstrated. Note the stent retriever placed in the basilar artery and subsequent stent deployment.

(included stent retrievers and angioplasty balloons or stents used). All angiographic images were electronically archived and sent for central review. The initial site of occlusion and recanalization was graded based on Qureshi grading scheme [11]. Grade 0 was used to define complete recanalization.

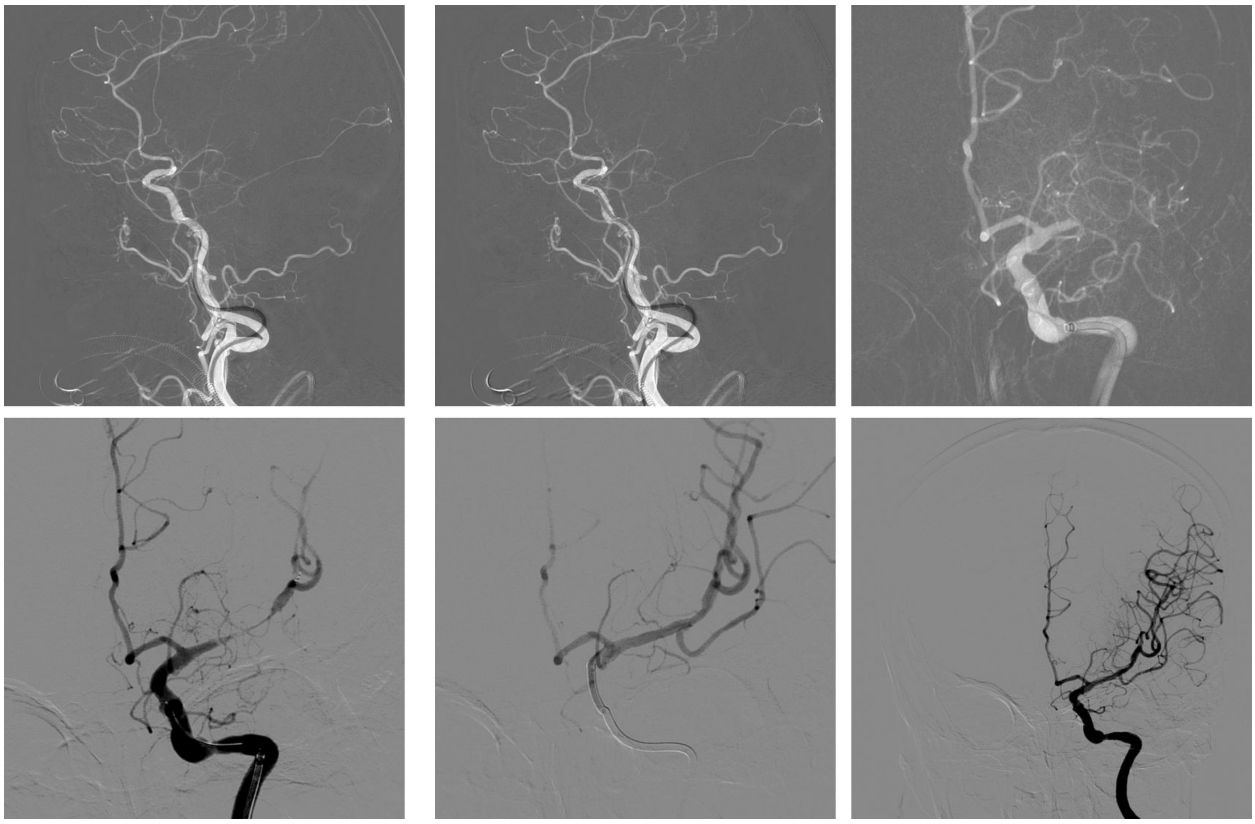

Figure 3. Various components of the thrombectomy of proximal left middle cerebral artery occlusion using AQURE PASSPORT 5 F placed in supraclinoid segment of the internal carotid artery in patient 2 are demonstrated. Note the stent retriever placed in a middle cerebral artery.

Outcomes

The following outcomes were assessed using a previously used questionnaire [12]: technical success, intended procedure completion without the need for a different catheter; technical ease, intended procedure completion without occurrence of three or more unsuccessful attempts; dissection, disruption of the arterial vessel wall on imaging studies manifesting as stenosis, intimal flap, false lumen, mural thrombus, or pseudoaneurysm; spasm, concentric narrowing of arterial lumen which resolves spontaneously or with treatment with vasodilators; and distal embolization, appearance of an occlusion on a downstream vessel which was confirmed to be patent earlier in the procedure. Technical failures were to be further classified as inability to catheterize target proximal artery with AQURE PASSPORT intracranial catheter, inability to access target lesion, or inability to deliver stent retriever, an angioplasty balloon catheter or stent device, through the lumen of the catheter. The primary operator also was asked to provide an opinion regarding the comparison of performance with another catheter used in such procedures and rated into one of three categories: inferior, equivalent, or superior.

Results

A total of four procedures were performed in four patients; two men and two women, with a mean age of 63.5 years (range 50–81 years). All four patients had presented with acute ischemic stroke (see Table 1). The occlusion was in the proximal middle cerebral artery in two patients, and posterior cerebral artery and basilar artery in one patient each. The representative angiographic images from the procedure for each procedure are presented in Figure 2–5. The procedure was technically successful and met the definition of technical ease in all patients. The distal-most segment where AQURE PASSPORT catheter was placed was in the supraclinoid internal carotid artery, proximal posterior cerebral artery, proximal middle cerebral artery, and proximal basilar artery in the four patients. Stent retrievers were used in three patients and primary angioplasty was performed in two patients. Complete recanalization was achieved in

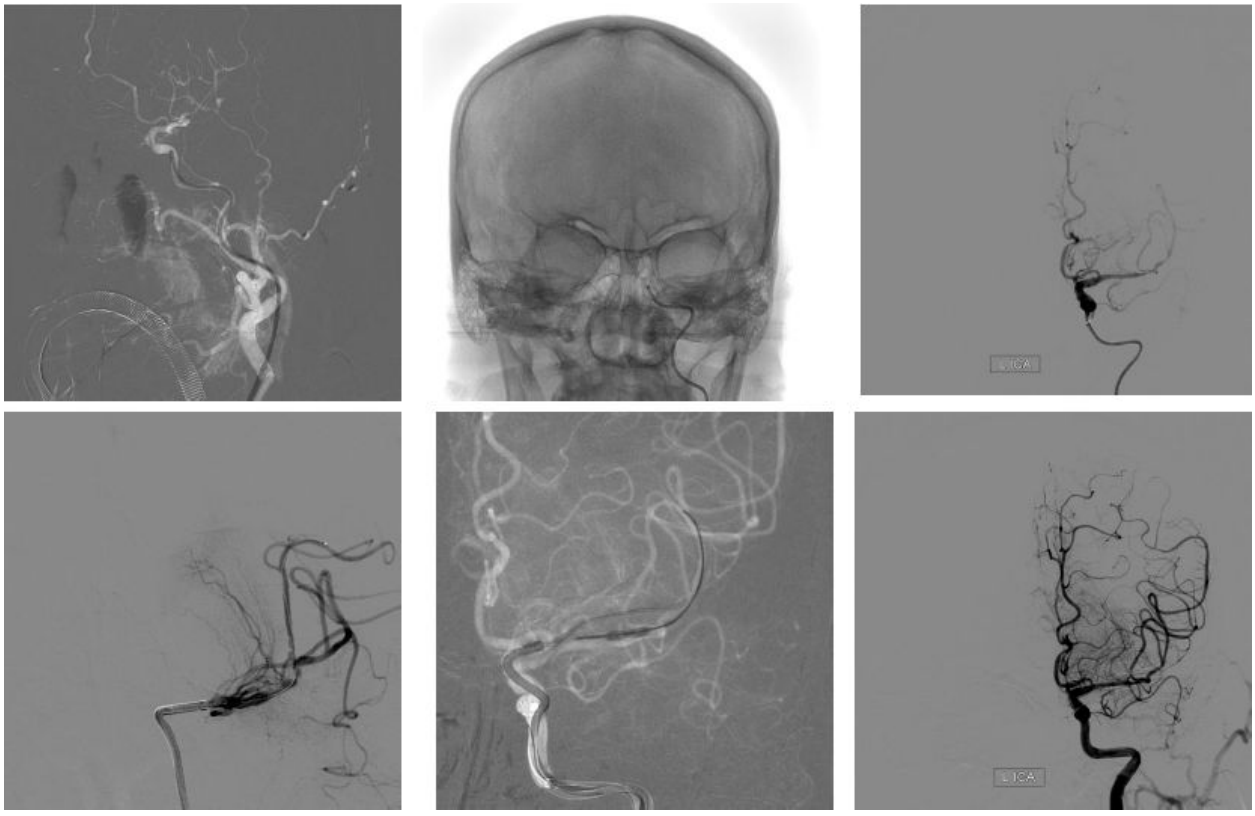

Figure 4. Various components of the thrombectomy of the M2 segment of the left middle cerebral artery occlusion using AQURE PASSPORT 5 F placed in a proximal middle cerebral artery in patient 3 are demonstrated. Note the primary angioplasty performed in the M1 segment of the left middle cerebral artery.

all four patients. None of the patients suffered arterial dissection, thrombosis, or distal embolization during the procedure. The primary operator rated the performance of guide catheter as superior in all cases.

Illustrative procedure

A 57-year-old man (patient # 1) presented with acute onset loss of consciousness 6 hours after symptom onset. An 8 F introducer sheath was placed in the right femoral artery using a modified Seldingers technique. A 6 F Flexor Check Flow 70 cm sheath (COOK MEDICAL, Bloomington, IN, USA) was placed in the left subclavian artery. The AQURE PASSPORT intermediate catheter was introduced through the introducer sheath over an ASAHI Chikai 0.014 inch 300 cm (ASAHI INTECC, Seto-Shi, Japan) 0.014″ × 200/300 cm microwire into the intracranial left vertebral artery. Initial angiographic images demonstrated complete occlusion of the basilar artery after the origin of anterior inferior cerebellar arteries. The Rebar 18 microcatheter was advanced over a Traxcess14 0.014-inch 200 cm microwire (Microvention Terumo, California, USA) through the intermediate catheterand used to traverse the occlusion. A Solitaire™ revascularization device 6 × 30 mm, a stent retriever (Medtronic, Minnesota, USA), was advanced through the microcatheter and deployed at the site of occlusion. The retriever was retracted under concurrent suction from the intermediate catheter, and thrombus was identified within the struts of retriever. A second attempt was made with Solitaire retriever. Complete recanalization was observed at the site of occlusion but a high-grade stenosis of middle segment basilar artery was identified. A Gateway balloon catheter 2.5 mm × 9 mm (Stryker, Michigan, USA) was advanced through the AQURE PASSPORT intermediate catheter, and the intermediate catheter was advanced into the proximal basilar artery. The Gateway balloon catheter was advanced over the Traxcess microwire across the stenosis and inflated once to 8 atmospheres. Subsequently, the Rebar 18 microcatheter was advanced past the site of stenosis in a proximal left posterior cerebral artery. A Neuroform EX 3.5 × 15 mm stent (Stryker, Michigan, USA) was advanced through the microcatheter and deployed across the stenotic segment. A resid-

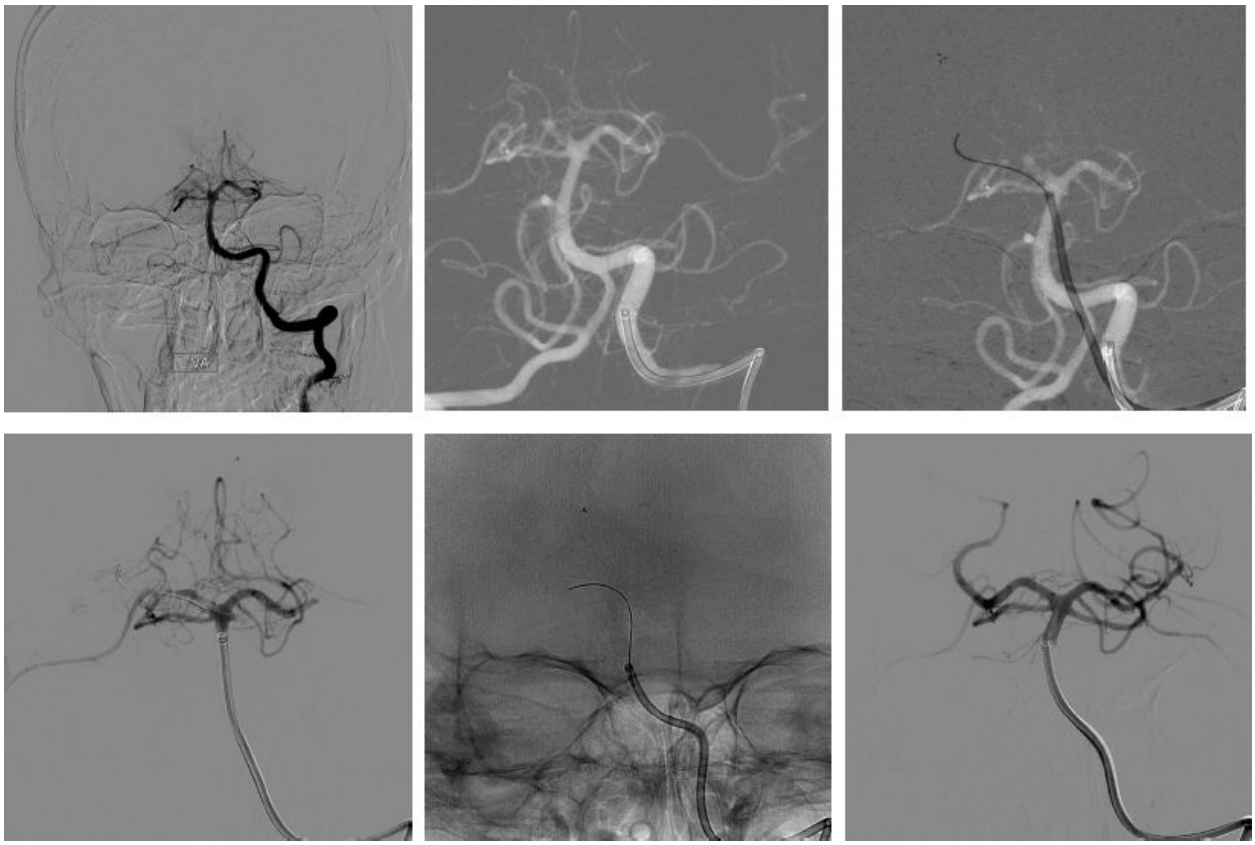

Figure 5. Various components of the thrombectomy of the proximal segment of right posterior cerebral artery occlusion using AQURE PASSPORT 5 F placed in the proximal posterior cerebral artery in patient 4 are demonstrated. Note the stent retriever placed in a posterior cerebral artery.

ual stenosis of <50% was observed with good flow in both posterior cerebral and superior cerebellar arteries. After an observation period of 20 min, no stent thrombosis was observed and the procedure was completed.

Discussion

We report the feasibility of using AQURE PASSPORT intracranial catheter for performing mechanical thrombectomy. The catheter was the intracranial platform for delivering stent retrievers, angioplasty balloon catheters, and intracranial stents. In addition, the catheter served as a platform for aspiration. In the initial experience, AQURE PASSPORT intracranial catheter was used as a multipurpose platform, but the value in the future may be more focused on primary aspiration.

In recent studies, the therapeutic value of contact aspiration as a primary modality has been highlighted in the treatment of acute ischemic stroke [13–15]. In the Contact Aspiration versus Stent Retriever for Successful Revascularization (ASTER) study [16], patients with a large vessel occlusion in the anterior circulation within 6 hours of symptom onset undergoing mechanical thrombectomy were randomized to contact aspiration (n = 192) or stent retriever (n = 189). There was no significant difference in the proportion who had a modified Rankin score of 0–2 at 90 days (45.3% in the contact aspiration group vs. 50.0% in the stent retriever group). In the COMPASS trial [15], patients presenting with acute ischemic stroke secondary to anterior circulation large-vessel occlusion within 6 hours of onset and an Alberta Stroke Program Early CT Score ≥6 were randomized to contact aspiration (n = 134) or stent retriever (n = 136). There was no significant difference in the proportion who had a modified Rankin score of 0–2 at 90 days (52% in the contact aspiration group vs. 50% in the stent retriever group). In another trial, patients with large-vessel intracranial occlusion presenting with a National Institutes of Health Stroke Scale score of ≥8 within 8 hours of onset were randomized to 3-D stent retriever with aspiration (n = 98) and or con-

tact aspiration alone (n = 100). There was no significant difference in the proportion who had a modified Rankin score of 0–2 at 90 days (45.8% in the contact aspiration group vs. 45.3% in the stent retriever group). A meta-analysis of nine studies [17], reported a higher rate of modified Rankin score of 0–2 at 90 days (odds ratio, 0.77; 95% confidence interval, 0.66–0.97) and shorter procedural time with contact aspiration compared with stent retrievers. The COMPASS trial [15], also demonstrated that using aspiration as first pass group can result in cost saving between $4541 and $5074 in the cost of devices used.

The design of the AQURE PASSPORT intracranial catheter makes it a useful device for performance of intracranial therapeutic procedures and the catheter is available in lengths and configurations that may be best suited for particular applications.

Acknowledgments

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