Results of Endovascular Mechanical Thrombectomy for Acute Ischemic Stroke in Siriraj Hospital

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Objective: *Endovascular mechanical thrombectomy has become a treatment option for acute ischemic stroke patients who have contraindications for intravenous recombinant tissue plasminogen activator (rt-PA) or who missed the 4.5-hours therapeutic window at Siriraj hospital. The purpose of the present study was to evaluate the initial result of the treatment at Siriraj Hospital.*
Material and Method: *A retrospective review of all patients with acute ischemic stroke who underwent treatment by endovascular mechanical thrombectomy at Siriraj Hospital from November 2009 to August 2012 was performed.*
Results: *There were 41 patients who had at least 30 day-period follow up. The mean age was 61.4±14.5 years. The initial mean NIHSS was 19.4±5.52. Successful recanalization rate was documented in 92.7% of patients. Good clinical outcome (modified Rankin Scale scores equal or lesser than 2) at mean 16-month follow-up time was found in 34.15%.*
Conclusion: *Endovascular mechanical thrombectomy is the option of treatment for large vessel acute ischemic stroke can help rescuing those patients who have contraindications for intravenous rt-PA or who miss the golden time window.*

Keywords: *Acute ischemic stroke, Mechanical thrombectomy, Treatment of acute ischemic stroke*

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In Thailand, stroke is a major health burden and the first leading cause of death and long term disability in both men and women[1]. The Thai Epidemiologic Stroke Study reported the prevalence of stroke in individuals aged 45-80 years to be 1,880/100,000[2].

The proven treatment benefit for acute ischemic stroke patients is the intravenous recombinant tissue plasminogen activator (IV rt-PA)[3,4]. However, there are some limitations and contraindications for the use of this treatment. The IV rt-PA should be started within 4.5-hour window.

Recanalization is a strong predictor of good outcome in cerebral ischemia secondary to large vessel occlusion[5]. Endovascular mechanical thrombectomy can yield rapid flow reperfusion rates. It allows a broader treatment window for patients who miss the 4.5-hour therapeutic window and who are ineligible or non-responsive to IV rt-PA. It has become a treatment option for those patients[5].

To our knowledge, the endovascular mechanical thrombectomy is a novel treatment option for acute ischemic stroke in Thailand, especially in tertiary care hospitals. The primary goal of our paper is to report the result of mechanical thrombectomy for acute ischemic stroke in Siriraj Hospital, and the secondary objective is to identify the factors which may be associated with good treatment outcome.

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Material and Method

Patient population

The present study was approved by the Siriraj Review Board of Faculty of Medicine Siriraj Hospital, Mahidol University (591/2553 EC1). Data were collected retrospectively from the patients who underwent endovascular mechanical thrombectomy for acute ischemic stroke in Siriraj hospital from November 2009 to August 2012. The inclusion criteria were as the follow: (1) age not under 18 years, (2) signs

and symptoms of acute ischemic stroke with NIHSS score not lesser than 8 according to the Thai version of National Institutes of Health Stroke Scale (NIHSS) score[6], (3) a cranial CT scan excluding hemorrhage,(4) duration of stroke symptom between 0 and 4.5 hours with a contraindication for IV rt-PA, or duration of stroke onset during 4.5- 8 hours for anterior circulation, or 4.5 - 24 hours for posterior circulation,(5) presence of more than 1/3 perfusion mismatch on perfusion CT, if uncertain stroke onset.

Patients were excluded if any of the followings were presented: (1) informed consent was not obtained, (2) current pregnancy, (3) capillary blood glucose below 50 mg/dL, (4) known hemorrhagic diathesis, or known coagulation factor deficiency, or oral anticoagulation treatment with international normalized ratio (INR) more than 3.0, (5) platelet count less than 30,000/ mm3, (6) NIHSS score more than 30, (7) rapid improvement of neurological status, (8) history of severe allergy to contrast media, (9) seizure at onset, (10) sustained systolic blood pressure more than 180 mm Hg or diastolic blood pressure more than 110 mm Hg despite treatment, (11) CT scan revealing brain tumor, or significant mass effect with midline shift or greater than one-third of the MCA region with hypodensity, (12) life expectancy less than 6 months.

Mechanical thrombectomy procedure and devices

The procedure was performed under general anesthesia, using biplane digital subtraction angiographic machine (DSA). Devices were selected by operator preference. Via a transfemoral approach, the affected vessel (internal carotid or vertebral artery) was selected by a 6F guiding catheter, the occluded artery was then probed with a microcatheter under roadmap fluoroscopic guidance. Once the microcatheter was navigated distal to the clot, the thrombectomy device (Solitaire AB stent, Merci device, CATCH) was advanced via the microcatheter, then it was deployed within the clot. After 3-5 minutes waiting, the thrombectomy device and microcattheter were gently withdrawn together through the guiding catheter where a manual aspiration was applied. A control angiography was done to assess recanalization. The goal of the procedure was to achieve a complete recanalization. If there was no or suboptimal revascularization at the first pass, repeated clot retrieval maneuver would be individually considered by each interventional neuroradiologist.

Data collection and measurement

Time to femoral puncture was defined as the time from stroke onset to the time when femoral puncture was performed.

Time to recanalization was defined as the time from stroke onset to the time when the affected vessel was opened successfully.

Site of arterial occlusion was recorded as cervical internal carotid artery (ICA), terminal ICA, M1 or M2 segment of the middle cerebral artery for either right or left ICA for the anterior circulation; and vertebrobasilar junction or basilar artery for the posterior circulation.

Successful recanalization was defined as achieving Thrombolysis In Myocardial Infarction (TIMI) grade 2 or better assessed immediately after the treatment.

The NIHSS and modified Rankin Scale (mRS) scores were recorded at baseline, 24 hours, 30 days, and 3 months.

Cranial CT scan was performed at the period between 12-24 hours after procedure, or at any time that there was a decline in patient neurological status. Symptomatic intracranial hemorrhage was defined as a decline of 4 or more points in the NIHSS score within 24 hours with any hemorrhage identified on CT scan.

Primary outcome was a rate of vascular recanalization. Secondary outcomes were clinical outcome measured by the mRS at 30 days, and the combined events of death and second stroke within 30 days. Good clinical outcome was defined as a mRS equal or lesser than 2.

Clinically significant procedural complications were defined as a procedure complication with decline in NIHSS of equal or more than 4, or death, or groin complication requiring surgery.

Statistical analysis

Data are presented as mean and range for continuous variables, and as frequency for categorical variables. Analysis was carried out using unpaired t-test, Chi-square, and Fisher's exact tests. Each clinical and demographic variable was tested as a predictor of good clinical outcome. These variables included age, gender, baseline NIHSS score, time to femoral puncture, site of vascular occlusion, side of affected cerebral hemisphere (in case of having lateralization), recanalization rate, and time to recanalization. All analyses were performed using SPSS for Windows, version 16.0.

Results

From November 2009 to August 2012, there were 41 patients with acute ischemic stroke patients who met the criteria and were treated by mechanical thrombectomy at the interventional radiology unit, Siriraj hospital. Twenty of the patients (51.2%) were females. The mean age was 61.4±14.5 years with the median age at 63 years. The mean NIHSS was 19.4±5.52 with median NIHSS at 20. All of the patients had major arterial occlusion. Sites of occlusion were cervical internal carotid artery 22%, internal carotid artery bifurcation 19.5%, M1 segment of middle cerebral artery 36.6%, M2 segment of middle cerebral artery 4.9%, vertebrobasilar junction 9.8%, and basilar artery 7.3%. Patient characteristics were listed in Table 1.

In case of known stroke onset, the mean time to femoral puncture was 305 minutes (5.08 hours), ranged from 120-960 minutes, (2-16 hours) the mean time to vascular recanalization was 417 minutes (6.95 hours), ranged from 220-1,200 minutes (3.7-20 hours).

The using thrombectomy devices were 37 Solitaire, 3 Catch and 1 Merci, respectively.

Successful recanalization rate was documented in 92.7% (38/41), and as high as 97.3% (36/37) by Solitaire (Fig. 1-2).

Good clinical outcome at mean 16-month-follow-up time was found to be 34.15% (14/41), and 31.7% in patients younger than 80 years old versus 2.4% in the octogenarians (p = 0.645); 19.5% male versus 14.6% female (p = 0.44), 22.5% treated within 4.5-hour window versus 12.5% treated after 4.5-hour window (p = 0.273), 34.1% with good recanalization group versus 0% without recanalization group (p = 0.539%), 12.2% of the left affected hemisphere versus 17.1% of the right affected hemisphere (p = 0.726), and 29.3% of the anterior circulation occlusion site versus 4.9% of the posterior circulation occlusion site.

There was no a significant difference in baseline NIHSS score and time to vascular recanalization between patients with good and poor outcomes.

Concerning 5 octogenarian patients who were included in the present study, there was one patient getting mRS lesser than 2 on follow-up.

It was also noted that 58.5% of patients with good recanalization had poor outcome (Fig. 3). The comparison between the patients with good and poor outcome were summarized in Table 2.

Symptomatic intracerebral hemorrhage (according to ECASS III criteria[4]) was found in 12.2% of the patients (5/41). One of those 5 patients (2.43%) had intraprocedural massive subarachnoid hemorrhage. This occurred in a 71-year-old female presented with an acute right M1 segment occlusion. During the mechanical thrombectomy procedure, the guidewire perforated the supraclinoid internal carotid artery leading to massive subarachnoid hemorrhage with subsequently expired.

Two cases had early recurrent stroke (within 30 days), resulting to the clinical outcome of mRS at 4 and 6 respectively. One patient, although initially received successful mechanical thrombectomy had contralateral intracerebral haemorrhage, leading to final outcome of mRS 5.

The mortality rate at 30-day period was 29.3% of the patients (12/41), and at the mean 16-month follow-up time, was 34.15% (14/41).

Discussion

The only pharmacological treatment for acute ischemic stroke approved by U.S. Food and Drug Administration (FDA) is recombinant tissue plasminogen activator (rt-PA). It was approved in 1996 to be used in the first 3 hours of symptom onset[3]. Even in a developed country, only 15% of the patients arrived in the emergency department within the 3-hour time window[7]. In contrast, in Thailand at the same time window, stroke fast track program was activated 10.3% of the patients. However, only 2.1% of patients were eligible for the treatment[8]. Then, the 3-hour time window was further expanded to 4.5 hours in a subgroup of patients after the European Cooperative Acute Stroke Study (ECASS) III trial[4]. Even after the publication of ECASS III and subsequent guideline modification with extension of time window to 4.5 hours, only approximately 10% of patients with ischemic stroke receiving IV rt-PA[9].

The IV rt-PA recanalization rate for proximal arterial occlusions ranges from only 8% for cervical internal carotid artery (ICA) occlusion to 29% for proximal middle cerebral artery (MCA) occlusion and basilar artery (BA) occlusions[10]. Endovascular techniques allow for selective treatment via either thrombolytic delivery or mechanical clot extraction in patients who have failed, or are not eligible for IV rt-PA. Intra-arterial rt-PA administration decreases the undesired effects of systemic infusion and allows for direct delivery to the region of maximal clot burden. Because of the risk of hemorrhage into infarcted tissue, treatment with intra-arterial thrombolytic drug is recommended to be limited to a 6-hour window[11].

Compared with intra-arterial thrombolysis, endovascular mechanical thrombectomy has more advantages, including higher rates of recanalization ranging from 57% to 88%[12-15] , and a wider treatment window up to 8 hours for anterior circulation stroke[12]. Data from literatures have supported endovascular treatment for acute ischemic stroke after 4.5 hours or failure treatment after IV rt-PA therapy[16]. Thus, in carefully selected patients, recanalization of major occluded vessels is feasible with a chance of better clinical outcome.

Although age and NIHSS cannot be modified, the recanalization can be modified. Final recanalization status represents a strong predictor of clinical outcomes in patients undergoing endovascular mechanical thrombectomy[17]. According to the results of the present study, which is a preliminary report, good recanalization rate was 92.7%, good clinical outcome was found at 34.15%, however, 58.5% of patients with good recanalization had poor outcome. All causes 30-day mortality rate was 29.3 %. Even though a high rate of recanalization could be achieved, the percentage of good outcome was quite low. Nevertheless, the result was agreed with the other reports from literatures[13,14]. Thus it is suggested that good recanalization does not always mean good clinical outcome.

Concerning the symptomatic intracerebral hemorrhage which occurred in 12.2% (5/41) in the presented study, one patient had intra-procedural technical complication whereas the other four patients had hemorrhagic transformation later, after successful procedures. In this circumstance, it may suggest of too long time lapses between stroke onset and vessel recanalization. Recurrent stroke within 30 days which

Table 1. Patient characteristics

Mean age	61.4+14.5 years
Mean NIHSS	19.4+5.52
No of patients (%)	
Medical history	
Diabetes mellitus	10 (24.4%)
Valvular heart diseases	9 (22%)
Myocardial diseases	10 (24.4)
Hypertension	17 (41.5%)
Atrial fibrillation	10 (24.4%)
Dyslipidemia	3 (7.3%)
Previous ischemic stroke	4 (10%)
Transient ischemic attack	2 (4.9%)
Chronic kidney diseases	3 (7.3%)
Cancer	6 (14.6%)
Hepatitis	1 (2.4%)
Site of occlusion	
Cervical internal carotid artery	9 (22%)
Internal carotid artery bifurcation	8 (19.5%)
M1 segment of middle cerebral artery	15 (36.6%)
M2 segment of middle cerebral artery	2 (4.9%)
Vertebrobasilar junction	4 (9.8%)
Basilar artery	3 (7.3%)
Side of the affected hemisphere (anterior circulation)	
Right	17 (41.46%)
Left	17 (41.46%)

Table 2. Comparison between patients with good and poor outcomes

Factors	Number of patients (%)			$\chi 2$	*p*-value
	Good outcome	Poor outcome	Total		
Age					
<80 years	13 (31.7)	23 (56.1)	36 (87.8)	0.507	0.645
>80 years	1 (2.4)	4 (9.8)	5 (12.2)		
Sex					
Male	8 (19.5)	12 (29.3)	20 (48.8)	0.595	0.44
Female	6 (14.6)	15 (36.6)	21 (51.2)		
Time to femoral puncture					
<270 min (4.5 hr)	9 (22.5)	12 (30)	21 (52.5)	1.200	0.273
>270 min (4.5 hr)	5 (12.5)	14 (35)	19 (47.5)		
Side of the affected hemisphere					
Left	5 (12.2)	12 (29.3)	17 (41.5)	0.640	0.726
Right	7 (17.1)	10 (24.4)	17 (41.5)		
TIMI score					
Good recanalization	14 (34.1)	24 (58.5)	38 (92.7)	1.678	0.539
Poor recanalization	0 (0)	3 (7.3)	3 (7.3)		
Site of occlusion					
Anterior circulation	12 (29.3)	21 (51.2)	33 (80.5)	0.687	0.698
Posterior circulation	2 (4.9)	5 (12.2)	7 (17.1)		
Both anterior and posterior circulations	0 (0)	1 (2.4)	1 (2.4)		

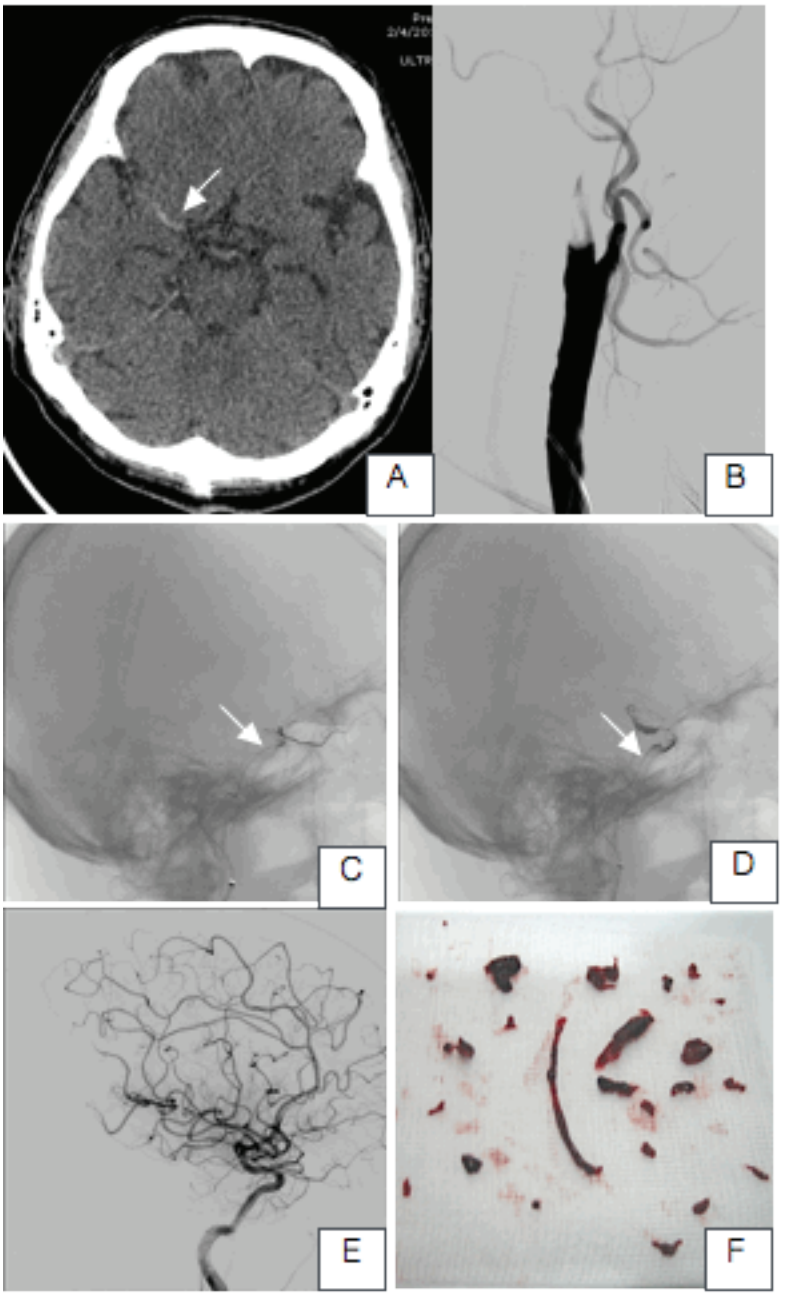

Fig. 1 A 76-year-old man with right hemiparesis and aphasia about 6 hours. (A) noncontrast CT scan showing hyperdense thrombus at right MCA white arrow. (B) lateral view of right common carotid angiogram showing complete clot filling at the proximal ICA which extended up to the carotid bifurcation and right middle cerebral artery. (C-E) during mechanical thrombectomy procedure with successfully re-opening of the vessel (white arrow in (C) and (D) pointing at the micro-catheter during clot retrieval). (F) demonstrating the removal long clot in a piecemeal fashion. The patient had good recovery with grade 4 right-sided weakness on 1-month period follow up.

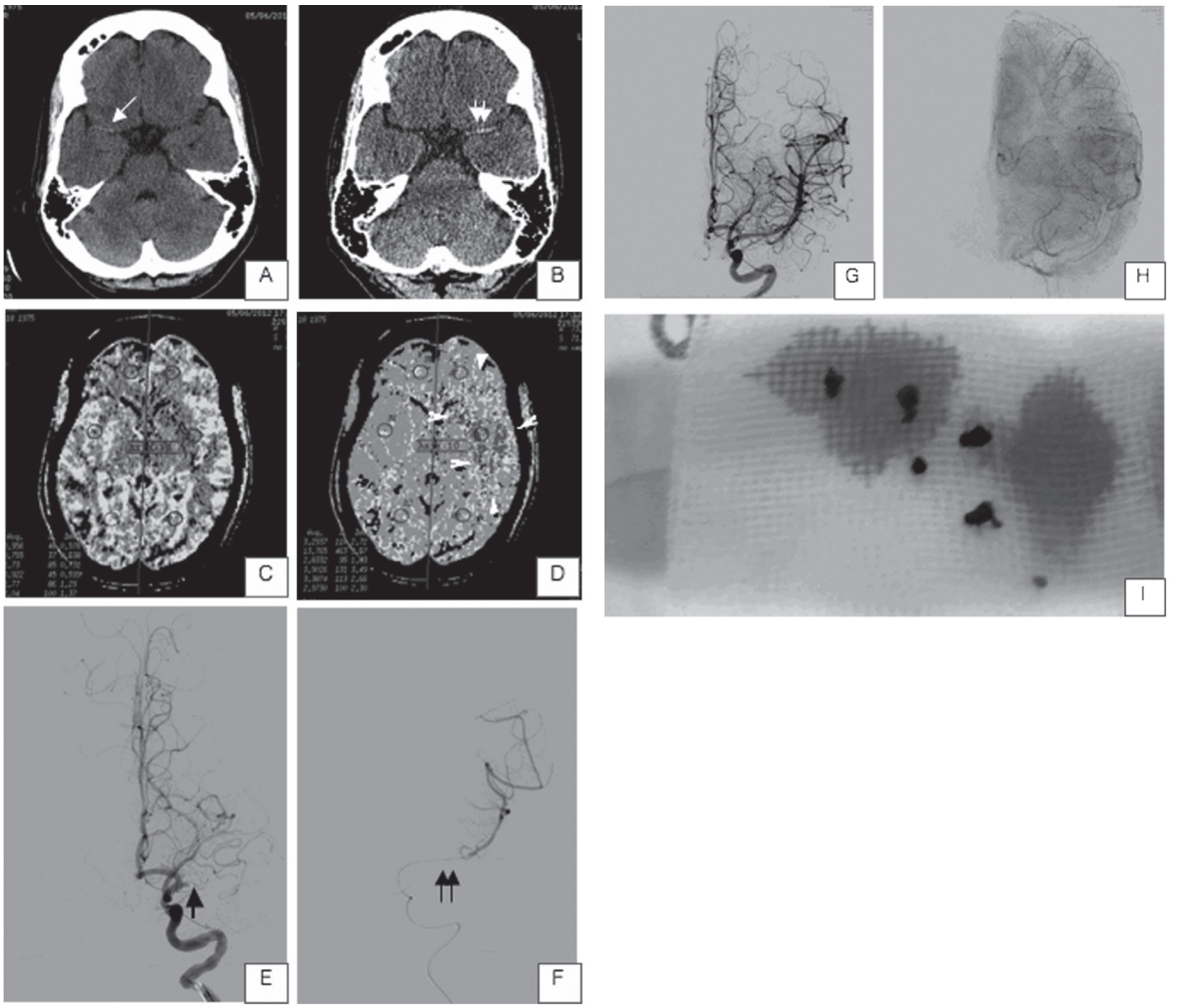

Fig. 2 A 36-yr-old female with Noonan syndrome; hypertrophic obstructive cardiomyopathy and atrial fibrillation, presented with alteration of consciousness and left sided weakness (grade 0) for 2 hrs. (A) noncontrast CT scan showing thrombus at right MCA white arrow. After 7 hrs post IV rt-PA with developed alteration of consciousness again, with right sided weakness, motor power: Rt. grade II, Lt. grade IV. (B) repeated noncontrast CT scan revealing a new thrombus at left MCA double white arrows. (C) and (D) perfusion CT scan revealing a large missed match area corresponding to territory of left MCA arrow heads. (E) left ICA angiogram demonstrating complete occlusion at left M1 segment of MCA black arrow. (F) test injection after probing a microcatheter beyond the thrombus double black arrows. (G) and (H) post mechanical thrombectomy revealing complete recanalization with TICI 3 by using stent retriever device. (I) several pieces of retrieved clot. Recanalization was achieved after 5 hours of onset, the patient had complete recovery on discharge.

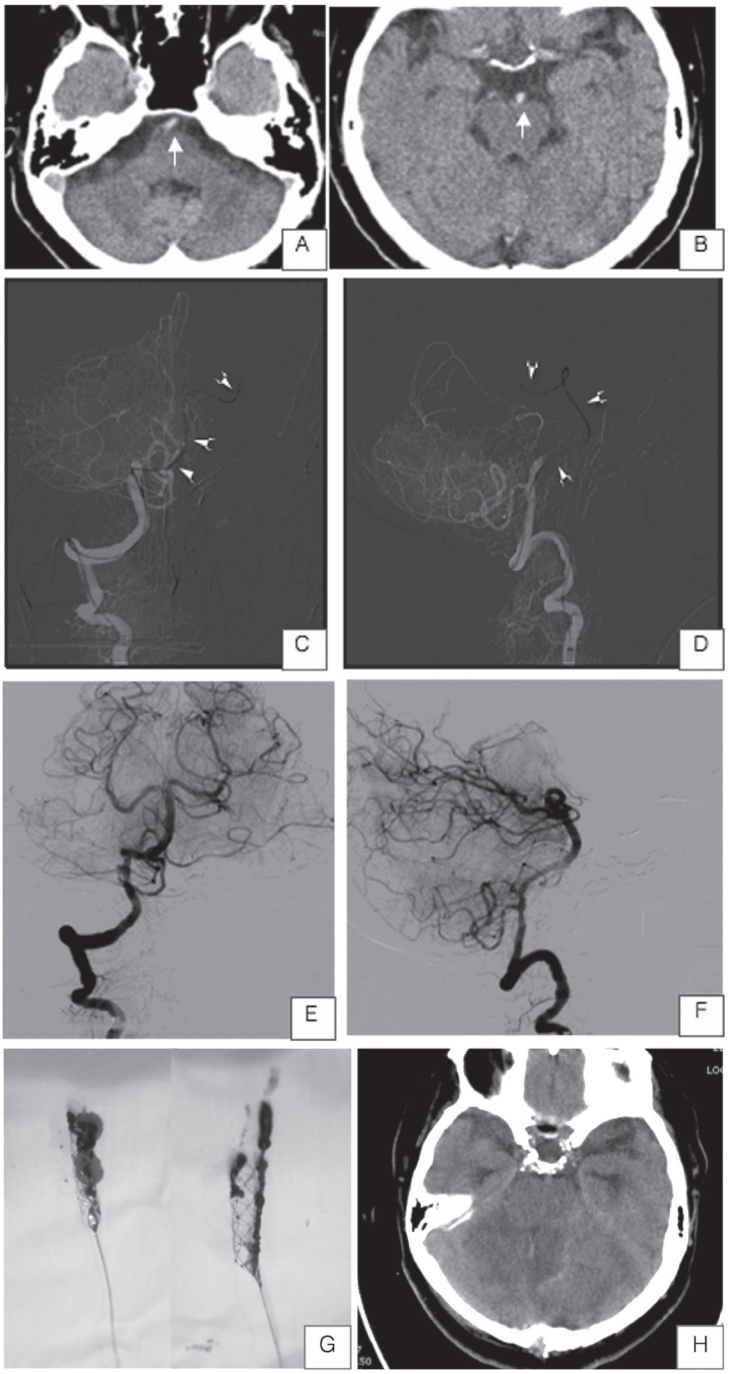

Fig. 3 A 81-year-old female had acute loss of consciousness 2 hr before arrival, with history of hypertension, tripple vessels disease, atrial fibrillation, E1V1M1 NIHSS 21 (A) and (B) non contrast CT revealing hyperdense clot in the basilar artery white arrow. (C) frontal and (D) lateral view of roadmap fluoroscope of right vertebral artery injection during navigating a microcatheter white arrow heads through the occluded basilar artery into the left posterior cerebral artery. (E) and (F) post thrombectomy revealing complete reopening of the basilar artery. (G) retrieved clots within the stent device. (H) cranial CT at 24 hour-period follow up revealing progression of cerebellar infarction, even successful mechanical thrombectomy. The patient had undergone decompression craniotomy and finally died later.

were recognized in 2 patients with atrial fibrillation was correlated with delayed administration of anticoagulant therapy.

The data from pool analysis of MERCI and multi-MERCI concluded that final recanalization, younger age, and low baseline NIHSS were significantly associated with good outcome and mortality at 90 days[12,17]. However, no predictive factors for good outcome was identified in the present paper. Comparing between patients with good and poor outcomes, there was no significant difference between age, gender, baseline NIHSS, time to femoral puncture, time to vascular recanalization, side of the hemisphere, and site of the vascular occlusion. The authors suggest that the volume of penumbra area and the amount of collateral circulations are the important roles that influence the results of stroke treatment. The more collateral circulation is, the higher success rate of brain rescue will achieve. Time is not the only important factor that indicates good outcome. In the authors' opinion, if the large penumbra area is preserved, the patient could have a good outcome even the stroke onset is beyond the timeframe. Thus proper patient selection is very crucial. Currently, there are several new imaging modalities to assess the collateral circulation and penumbra, which can guide for better patient selection. However, it must be considered that any sophisticated imaging study should not delay mechanical thrombectomy procedure.

Although data from either interventional or medical studies excluded patients whose age was more than 80 years, our study had 5 octogenarians. The authors found that the results of endovascular mechanical thrombectomy in octogenarians were not significantly different from those in the younger age group. Although the sample size was small, endovascular mechanical thrombectomy might be also an optional treatment for stroke in octogenarians.

One limitation of the current study is the small sample size which is a major factor that makes it difficult to interpret result statistically.

Conclusion

In acute ischemic stroke patients who have contraindications for intravenous rt-PA or missed the so called "golden time" 4.5-hour window, endovascular mechanical thrombectomy is an option of treatment that can help at least a third of patients to live independently. The decreased time lapse prior to recanalization may increase rates of good patient outcome and decrease rates of hemorrhagic event. However, more experiences, improvement of technical skills and precise patient selection will improve the results of the treatment. In addition, further investigation is necessary for the use of mechanical thrombectomy in Thailand as an adjunct to standard IV rt-PA therapy.

What is already known on this topic?

Mechanical thrombectomy is a useful technique for restoring blood in patients with large vessel acute ischemic stroke, particularly in those who are ineligible for intravenous thrombolytic therapy. The degree of recanalization is associated with a favorable outcome at 90 days.

What this study adds?

This study is the first report of result of mechanical thrombectomy in Thailand. Our result of success rate of recanalization was quite high. All patients with good outcome had good recanalization, whereas one-third of patients with good recanalization had good outcome.

No identified factors which may associate with good or poor outcome in the selected patients according to the criteria of indications and contraindications for mechanical thrombectomy.

The results of mechanical thrombectomy in octogenarian group were also good, showing no significantly difference from those in the younger age group.

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Potential conflict of interest

None.

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ผลการรักษาโรคหลอดเลือดสมองอุดตันเฉียบพลันด้วยวิธีการลากลิ่มเลือดออกในโรงพยาบาลศิริราช

อัญชลี ชูโรจน์, ทวีศักดิ์ เอื้อบุญญาวัฒน์, อติเทพ มงคลรัตน์นันต์, ฑิตพงษ์ ส่งแสง, เอกวุฒิ จันแก้ว, ภัทรวิทย์ วิทยาสุข, บุญฤกษ์ แสงเพชรงาม, ยงชัย นิลนานนท์

วัตถุประสงค์: *การรักษาโรคหลอดเลือดสมองอุดตันเฉียบพลันด้วยวิธีการลากลิ่มเลือดออก ได้ใช้เป็นวิธีหนึ่งของการรักษาผู้ป่วยในโรงพยาบาลศิริราชสำหรับผู้ป่วยที่มีข้อห้ามของการให้ยา rt-PA ทางหลอดเลือดดำ หรือผู้ป่วยที่มีระยะเวลาของโรคเกิน 4.5 ชั่วโมง ซึ่งเป็นช่วงเวลาที่เลยจากกำหนดของการให้ยานั้นแล้ว จุดประสงค์ของการศึกษาคือเพื่อประเมินผลลัพธ์ผู้ป่วยที่ได้รับการรักษาด้วยวิธีนี้*

วัสดุและวิธีการ: *เป็นการศึกษาย้อนหลังจากบันทึกประวัติและข้อมูลของผู้ป่วยที่มารับการรักษาโรคหลอดเลือดสมองอุดตันเฉียบพลันด้วยวิธีการลากลิ่มเลือดออก ที่โรงพยาบาลศิริราช ระหว่างเดือนพฤศจิกายน พ.ศ. 2552 ถึง เดือนกรกฎาคม พ.ศ. 2555*

ผลการศึกษา: *มีผู้ป่วยโรคหลอดเลือดสมองอุดตันเฉียบพลันทั้งหมด 41 รายที่ได้รับการรักษาด้วยวิธีการลากลิ่มเลือดออก และสามารถได้รับการตรวจติดตามการรักษาได้อย่างน้อยภายใน 30 วันหลังการรักษา มีอายุเฉลี่ย 61.4±14.5 ปี ค่าเฉลี่ย NIHSS เริ่มแรกอยู่ที่ 19.4±5.52 ความสำเร็จของการเปิดหลอดเลือดคิดเป็นร้อยละ 92.7 ของจำนวนผู้ป่วย ผลลัพธ์ผู้ป่วยที่ดีคิดเป็นร้อยละ 34.15 ของจำนวนผู้ป่วย โดยที่ค่าเฉลี่ยของการตรวจติดตามอยู่ที่ 16 เดือน*

สรุป: *หัตถการการรักษาผ่านทางหลอดเลือดแดงเพื่อการลากลิ่มเลือดออกนี้จัดได้ว่า เป็นวิธีการรักษาที่มีประสิทธิภาพ ที่สามารถช่วยให้ผู้ป่วยโรคหลอดเลือดสมองอุดตันเฉียบพลันที่พ้นระยะ หรือมีข้อห้ามของการรักษาด้วยการให้ยา rt-PA ทางหลอดเลือดดำตามมาตรฐานสากลของการรักษาโรคนี้ ได้รอดจากความตายหรือความพิการที่อาจจะเกิดจากการที่สมองขาดเลือดได้*