Original Article

The MERCI Retrieval System for the Management of Acute Ischaemic Stroke – The NNI Singapore Experience

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Abstract

Introduction: Systemic and local intra-arterial thrombolysis in patients with large vessel ischaemic stroke is hampered by poor re-canalisation rates and risk of haemorrhage. The Merci Retrieval System is an endovascular device for removal of acute intracranial thrombus. We present our initial experience using this device in conjunction with existing thrombolytic therapy already in place in our institute. Materials and Methods: Prospective data in all patients presenting with large vessel ischaemic stroke treated using the Merci Retrieval System from July 2007 to March 2009 were analysed. Selection criteria for patients were similar to the multi-Merci trial of 2008. We compared re-canalisation rate, National Institutes of Health Stroke Score (NIHSS) and modified Rankin score (mRS) outcomes to the published trial results. Results: Seventeen patients were reviewed; none suffered immediate post-procedural complications. Fifteen underwent successful thrombus retrieval but in 2 cases the device failed due to technical considerations. Sites of vascular occlusion included: ICA/ICA-'T' junctions 27%, middle cerebral artery 13% and vertebrobasilar artery 60%. Of the 15 patients treated by MERCI with or without adjuvant thrombolytic therapy, complete re-canalisation was achieved in 60%, partial re-canalisation in 20%, partial re-canalisation with persistent distal vessel occlusion in 6% and failure of re-canalisation in 14%. Asymptomatic haemorrhage occurred in 33% and there was 1 death (6%) from symptomatic haemorrhage. Pre-treatment median NIHSS was 17.88 and 9.5 immediately post-treatment. Median mRS at 30 days was 2.6 for patients who achieved complete re-canalisation and 4.5 in failure or partial re-canalisation with or without persistent distal vessel occlusion. Conclusion: Re-canalisation rates using the Merci Retrieval System was comparable to the multi-Merci trial. Haemorrhagic complications and safety were also found to be satisfactory. Importantly, treatment success with eventual good clinical outcome hinges strongly on the ability of the device to achieve complete re-canalisation.

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Key words: Acute ischaemic stroke, Mechanical revascularisation, Thrombectomy, The Merci Retrieval System

Introduction

Mechanical methods for the acute management of severe large vessel ischaemic stroke have become established over the years as a viable option in addition to systemic or local intra-arterial thrombolytic therapy.[1-11] Mechanical methods offer the advantage of getting directly at the target, which in situations of severe ischaemic stroke with large clot burden, are more effective.

Systemic thrombolytic therapy has the inherent problem of systemic dilution of the drug dose given and thus ineffective in dealing with large clot burden.[12] Studies in systemic therapies looking at increasing systemic drug dose have clearly demonstrated that drug dose in excess of those recommended by the NINDS trial[13] brought about an unacceptable increase in haemorrhagic complications, thus negating its effect in achieving higher re-canalisation rates. Local intra-arterial therapy thrombolytic therapy part circumvents the problem of systemic therapy by bypassing systemic dilutional effects. By bringing the thrombolytic agent directly to the clot increases its effectiveness at the target, but also carries with it marked increase in haemorrhagic risk associated with its use. Studies using local intra-arterial therapies have so far demonstrated that increasing drug concentration at the clot is effective

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in increasing re-canalisation rates, but at the expense of unacceptable increased haemorrhagic risk.[14]

Among mechanical thrombectomy devices, the MERCI Retrieval System was FDA approved in 2004 and has the largest number of patients treated to date worldwide. Although there has not been a randomised, placebo-controlled trial, data obtained so far from the Merci studies,[15-17] have been promising in terms of re-canalisation rates and acceptable haemorrhagic complications, even when used in conjunction with systemic (intravenous) and local (intra-arterial) thrombolytic therapies.[15-19]

Since May 2007, our institute has included the MERCI device as part of our therapeutic options for the treatment of acute ischaemic stroke patients, mainly targeting at severe large vessel stroke patients. We present our initial experience using the MERCI device in our institute, and compare the results with published study outcomes.

Materials and Methods

We enrolled all consecutive patients who underwent treatment with the MERCI thrombectomy device at the National Neuroscience Institute (NNI) between May 2007 and April 2009. NNI is a national centre for the treatment of neurological diseases and has full complement and integrated services of neurology, neurosurgery and neuroradiology. Data are reflective of the entire population of Singapore as the Neuroradiology service in NNI serves the entire nation by having a nationwide on-call system provided by 3 neurointerventionalists from the department of Neuroradiology. All patients were recruited using enrollment criteria similar to the Multi-MERCI trial.[16] The main indications included patients with confirmed large vessel stroke (initial NIHSS of at least 8) presenting within the 8-hour window period from stroke onset, and also included patients who failed initial intravenous thrombolytic therapy. All patients were evaluated neurologically by neurologists experienced in the treatment of acute stroke. Pre-procedure assessment was based on clinical history and neurologic assessment to identify patients presenting with a large artery territorial stroke syndrome.

For all patients presenting within the 8-hour time window, eligibility for endovascular treatment was based on dissociation between the clinical and imaging findings.[20-23] Computed tomography (CT) and magnetic resonance imaging (MRI) using our department's stroke protocol (T2 weighted, diffusion weighted, gradient-recalled echo MR images and time-of-flight MR angiography) were performed on an emergent basis. All neuroimaging studies were reviewed by a trained on-call neuroradiologist for positive findings on CT including 'dense vessel sign' or subtle loss of gray-white matter differentiation, and on MRI including diffusion restriction with large vessel occlusion on MR angiography. Diagnostic cerebral angiography was not part of the emergent initial assessment. Decision for MERCI treatment was based on joint decision by the neurologist and the neuro-interventionalist. All eligible patients underwent a full discussion with family members with regard to potential benefits of the procedure and the risks of complications to be expected.

Vascular occlusion sites or territories eligible for treatment included: intracranial distal internal carotid artery (ICA) up to 'T' junction, middle cerebral artery (MCA) including M1 and proximal M2, intracranial vertebral artery (VA) and basilar artery (BA). Patients were excluded if they had initial CT or MRI evidence of haemorrhage or had stroke onset more than 8 hours. Other exclusion criteria were also similar to the Multi-MERCI trial.

MERCI Procedure

All patients were transferred to the angiography suite as soon as a decision was made for the treatment and all cases were done under general anaesthesia. No patient received heparin pre-treatment. An initial full diagnostic cerebral angiogram was performed to confirm the site of vessel occlusion and the status of the collateral circulation. The MERCI Retrieval System (Concentric Medical Inc., Mountain View, CA) was then used according to the manufacturer's recommended protocol. Deviation from the standard recommended protocol included using a 6F Envoy guiding catheter in place of the balloon-guiding catheter (BGC) in cases of proximal aortic arch vessel tortuosity where the latter could not be used for successful cannulation. MERCI devices used included X6 and L5 in the earlier part of the study and L6 were included at the later half of the study when this device became available. The maximum number of devices used per patient was 2. The maximum number of passes allowed for each of these devices was according to the manufacturer's recommendations (3 passes for X6 and 2 passes for L5 and L6). Assessment of the degree of re-canalisation was made during the procedure by the interventionalist. Re-canalisation status was categorised into complete re-canalisation, partial re-canalisation, re-canalisation partial or complete but with persistent distal small branch vessel occlusion and failure to re-canalise. Need for further adjuvant therapy using intra-arterial tPA was allowed for cases of partial re-canalisation of the parent vessel and also for distal embolic occlusion. Procedure-related complications were recorded. Possible complications include vascular dissection or perforation, device fracture or embolisation of a vascular territory not involved in the initial assessment. As in the MERCI trial, all intracranial haemorrhagic complications were noted and only classified as clinically significant if there is a decline of NIHSS of more than 4 points during follow-up in the

immediate 48 hours post-procedure. Groin haemorrhagic complications are defined as significant if patients required blood transfusion or surgical intervention. All patients underwent NIHSS and Modified Rankin Scale (mRS) scoring at admission and also at 30 days.

Results

There were all together 17 patients (15 males, 2 females) whom MERCI intervention was attempted. Median age of all patients was 67 years (61.5 to 76) and the median initial NIHSS was 17.88 (Table 1). Patients either had preliminary diagnostic imaging using CT or MRI. The majority of patients who underwent CT scan had normal findings. Median time to CT scan from stroke onset was 1.65 hours. Of those patients who underwent initial MRI stroke protocol assessment, all patients showed loss of flow signal on MR angiography in the target occluded vessel. Median time from stroke onset to MRI assessment was 2.75 hours.

Initial diagnostic angiography was performed on all patients as part of the MERCI procedure to confirm the site of vascular occlusion. Of the 17 cases, there were 2 cases of failure to administer MERCI due to technical difficulty (1 case had aortic arch tortuosity, 1 case had post systemic tPA distal clot migration into peripheral small branch vessel making it not amenable to MERCI deployment). Fifteen patients had proceeded to MERCI treatment; median time to application of MERCI device was 5.3 hours. One case revealed tandem proximal ICA stenosis. With regard to lesion locations, distal ICA/carotid 'T' lesions occurred in 27%. Isolated MCA occlusions occurred in 13%. Vertebral/basilar artery lesions occurred in 60%.

Of the 15 patients who received MERCI thrombectomy (with or without adjuvant systemic/local thrombolysis), complete re-canalisation was achieved in 60% of patients. Twenty per cent had partial re-canalisation of parent artery with no distal branch occlusion. Six per cent had partial re-canalisation of parent artery with persistent distal branch occlusion and 14% had complete failure to re-canalise (Table 2). The only patient that had a tandem proximal ICA stenosis was treated with balloon angioplasty prior to the deployment of the MERCI device. There were 9 patients (60%) with MERCI device application alone, 3 patients (20%) had adjuvant intra-arterial tPA and 3 patients (20%) had both systemic and intra-arterial tPA treatment on board. The median dose of intra-arterial tPA given was 17.5 mg (range, 5 to 30). Median systemic tPA dose given was 40 mg (30 to 50). Median procedure time was 2.16 hours (1.5 to 3.2).

Table 1. Patient Characteristics (n = 17)

	Median (IQR)	No. (%)
Age	67 (61.5-76)	
Male		13 (87%)
Pre-stroke mRS score	4.5	
Baseline NIHSS	17.88	
Site of vascular occlusion		
~ ICA/ICA-T		4 (27%)
~ Middle cerebral artery		2 (13%)
~ Vertebrobasilar artery		9 (60%)
Time from onset to CT scan	1.65 h (0.9-2.0 h)	
Time from onset to MRI scan	2.75 h (1.48-3.65 h)	
Time from onset to angiography (MERCI)	5.3 h (4.0-6.0 h)	

IQR: interquartile range; ICA: internal carotid artery

Table 2. Procedure and Results

	Median (IQR)	No. (%)
No. of patients attempted MERCI		17 (100%)
Technical failure to deploy MERCI		2 (13%)
No. of patients with MERCI deployed		15 (87%)
Duration of procedure	2.16 h (1.5-3.2 h)	
Technique		
~ MERCI alone		9 (60%)
~ MERCI + IA thrombolysis		3 (20%)
~ Systemic thrombolysis + MERCI + local thrombolysis		3 (20%)
No of passes		39
Re-canalisation outcome (of the 15 patients with MERCI deployed)		
~ Complete re-canalisation		9 (60%)
~ Partial re-canalisation of parent artery with no distal branch occlusion		3 (20%)
~ Partial with distal branch occlusion		1 (6%)
~ Failure		2 (14%)
Haemorrhagic complications		
~ Asymptomatic haemorrhage		5 (33%)
~ Symptomatic haemorrhage		1 (6%)

IA: intra-arterial; IQR: interquartile range; IV: intravenous

Asymptomatic intracranial haemorrhage was demonstrated on follow-up imaging in 5 patients (33%). There was only 1 patient (6%) with complete re-canalisation that developed symptomatic haematoma in the brainstem with significant mass effect post-thrombectomy; he subsequently died of the haemorrhage. No non-cerebral haemorrhagic complications occurred in the series.

The average length of hospital stay was 15.69 days. Of all the patients who underwent MERCI thrombectomy, median NIHSS pre-treatment was 17.88 and immediate post-MERCI NIHSS was 9.5 (Table 3). Average mRS

scoring for all patients at 30 days was 4.4. There were altogether 4 deaths. Of all the patients who completely re-canalised, average mRS at 30 days was 2.6 with a mortality rate of 22%. Of those patients who failed re-canalisation or had partial re-canalisation with or without persistent distal occlusion, average mRS was 4.5 at 30 days with a mortality rate of 33%.

Discussion

Large vessel stroke carries high morbidity and mortality. To date, rapid re-canalisation is the key to improving patient outcome.[24] Systemic intravenous tPA therapy (FDA approved in 1996) has proven itself to be useful in improving patient outcome at 3 months but has limited time window of 3 hours for treatment to be safe and effective. It is not effective in situations of large vessel stroke with large clot burden due to systemic dilution of the drug dose given, and thrombolysis has inherent systemic haemorrhagic side effects. Efforts at extending time window for treatment or increasing drug dosage beyond that recommended by the NINDS trial of 0.9 mg/kg body weight has been fraught with problems of unacceptable increase in haemorrhagic risk.[25-27] Intra-arterial thrombolytic therapy (PROACT I, PROACT II trials) opens the therapeutic time window up to 6 hours.[14] It has been proven to be effective in improving re-canalisation rates through targeted delivery of the drug, but with the increase in drug efficacy, it also suffers from unacceptable increase in haemorrhagic rates. Combination therapy using both systemic (intra-venous) and local (intra-arterial) thrombolytic therapy have so far demonstrated satisfactory re-canalisation rates with acceptable safety but the exact dosage combination has yet to be ascertained.[28,29] Mechanical options are appealing as they achieve results quickly and at the same time eliminate the systemic thrombolytic side-effects. The MERCI retrieval device has so far been the only FDA approved device for use in acute ischaemic stroke with formal trials [15-18] demonstrating its

Table 3. Clinical Outcome

	NIHSS before treatment	NIHSS after treatment	Median mRS at 30 days	Death
All patients	17.88	9.5	4.4	4/15 (26%)
Complete re-canalisation			2.6	2/9 (22%)
Partial re-canalisation with or without distal occlusion			4	1/4 (25%)
Failure			5	1/2 (50%)

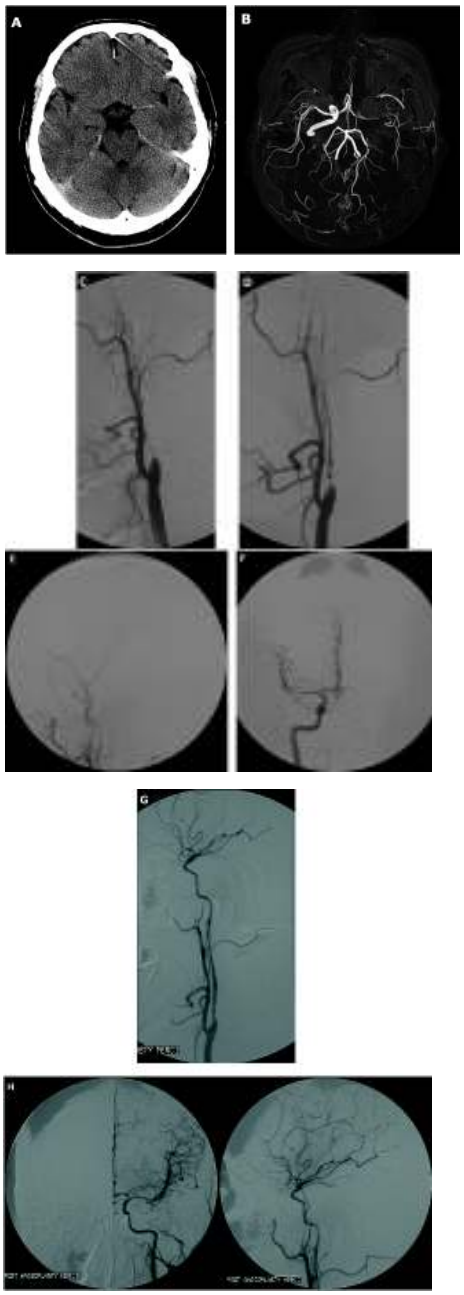

Fig. 1A-H. A 47-year-old presented with acute left MCA large vessel stroke syndrome with clinical-imaging dissociation.

A. Emergent CT scan showed evidence of dense left MCA sign with no evidence of gray-white matter changes.
B. No DWI changes were noted but MR angiogram demonstrated no flow in the left ICA/MCA territory.
C. Diagnostic angiogram was performed at 5.2 hours from stroke onset. Left common carotid artery (LCCA) injection confirmed total occlusion of the left internal carotid artery.
D. Selective injection into proximal left internal carotid artery (LICA) revealed a tight stenosis at the left ICA bulb with only a trickle of contrast into the distal LICA.
E. Multiple filling defects were noted in the distal LICA and proximal M1 of the left middle cerebral artery (LMCA) consistent with clots.
F. Contra-lateral RICA angiogram revealed no flow into the left anterior circulation.
G. Gentle balloon angioplasty was performed at the proximal LICA stenosis allowing the application of MERCI device.
H. Successful retrieval of clots resulting in complete re-canalisation of the entire LICA/MCA.

efficacy with acceptable safety. To date, the MERCI trials have the largest numbers of ischaemic stroke patients treated worldwide, reaching the 10,000 case mark as of March 2009.

Our national centre results and experience of using the MERCI device in this prospective study matched those of the MultiMERCI trial results. With regard to patient demographics, median patient age was 67 years (61.5 to 76), very close to MultiMERCI trial cohort of 68 years (52 to 84). The median NIHSS pre-treatment was 17.88, just two points lower than in the MultiMERCI trial. Median time from stroke onset to groin puncture was slower at 5.3 hours compared to MultiMERCI trial of 4.3 hours (3.2 to 5.3). However, we do note large variations in the time taken to groin puncture as several logistic factors were in play from patient transportation to the availability of anaesthetic support, but improvement in timing was observed as the study progressed. We generally did not find any significant delay resulting from initial neurologic assessment or performing of the initial diagnostic imaging by CT or MRI. With gradual accumulation of experience over time, we noticed an improvement in co-ordination between communications between the stroke neurologist and the stroke interventionalists thereby improving the confidence level in selecting patients with large vessel stroke suitable for the procedure. Patients were identified based on time criteria and findings of clinical-imaging dissociation. In comparison with the Multi-MERCI trial for vascular occlusion sites, our series had a larger percentage of posterior circulation strokes (60% of our cases were occluded vertebral/basilar artery vs. 8% in Multi-MERCI). One patient had tandem proximal severe ICA stenosis necessitating balloon angioplasty before deployment of the MERCI device (Fig. 1), a deviation from patient selection criteria in the Multi-MERCI trial. This patient, however, went on to development infarct in the involved vascular territory.[30] Of the 15 patients who had successful deployment of the MERCI device, the total number of passes made was 39, with an average of 2 passes per patient. Overall, successful complete re-canalisation (Fig. 2) was achieved in 60% (including patients receiving adjuvant intra-arterial tPA administration), partial re-canalisation in 20%, re-canalisation partial or complete but with persistent distal branch vessel occlusion in 6% and failure to re-canalisation in 14%. Two cases of complete re-canalisation were achieved with adjuvant intra-arterial tPA after MERCI device only managed a partial re-canalisation. Of the 5 cases that failed initial intravenous tPA, only 1 case managed complete re-canalisation using MERCI. Overall, the rate of complete re-canalisation with successful reperfusion is comparable with that of the Multi-MERCI trial. It seems that pre-treatment with systemic intravenous tPA has no bearing on the re-canalisation ability of MERCI device. Intra-arterial therapy on the other hand has been demonstrated as a useful adjunct in improving re-canalisation rates.[15-17,19,31-33]

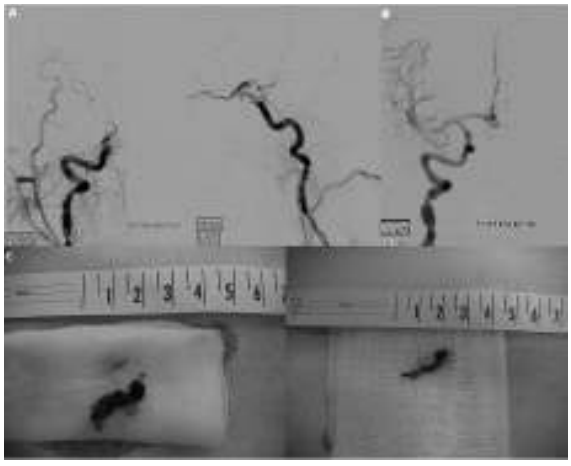

Fig. 2A-C. A 54-year-old man presented with acute right middle cerebral artery (MCA) stroke syndrome.

A. Initial diagnostic right internal carotid artery (RICA) angiogram revealed evidence of multiple clots at the distal RICA with very limited flow of contrast distally.
B. Post-MERCI device application resulted in successful complete re-canalisation of the RICA with good flow seen into the right anterior circulation.
C. Thromboembolus removed from the RICA using the MERCI retrieval device.

With regard to clinical outcome, there was an overall improvement of clinical outcome of all patients treated. Median NIHSS of treated patients improved to 9.5 at 30 days, demonstrating that MERCI intervention has an overall positive effect on the final clinical outcome. This confirmed the hypothesis that rapid re-canalisation achieved under the situation of severe large vessel ischaemic stroke has an important bearing on the final clinical outcome of patients. The final clinical outcome of all patients at 30 days was 4.4 (mRS) with a mortality rate of 26%. Stratifying the outcome by re-canalisation status, those patients with complete re-canalisation had mRS of 2.6 and a mortality rate of 22% compared to those cases that failed or had partial re-canalisation with or without persistent distal vessel occlusion, mRS of 4.5 with a mortality rate of 33%. These results confirmed the beneficial effect of rapid re-canalisation but also demonstrated that re-canalisation must be complete in order for the optimum clinical benefit. The overall outcome for those patients who failed re-canalisation or had persistent distal occlusion remained dismal.

The safety of the MERCI device has been demonstrated in our study. There were no cases of device-related complications such as device fracture or malfunction. There were also no cases of device-related vessel injury like vessel dissection or perforation. No cases of embolic stroke outside the involved vascular territory were observed. Of those patients with follow-up imaging, there were 5 cases

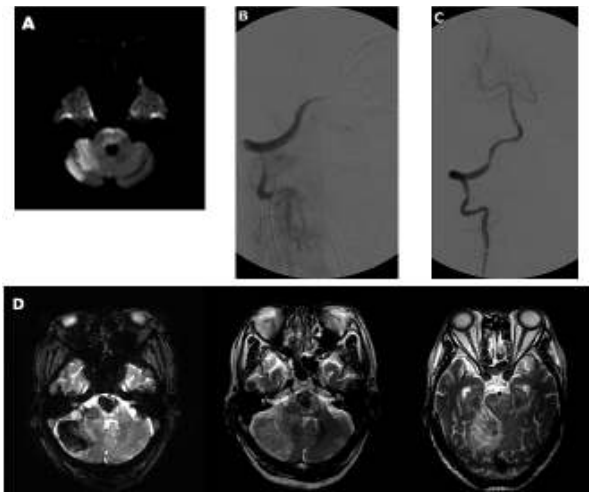

Fig. 3A-D. A 77-year-old man with prior history of atrial fibrillation presented with acute posterior circulation stroke syndrome.

A. Emergent MRI at 2.5 hours from stroke symptom onset revealed evidence of acute infarct in the right cerebellar hemisphere and brainstem.
B. Diagnostic angiogram performed at 6 hours revealed occlusion at the distal right vertebral artery with no flow seen into the entire posterior circulation territory.
C. Successful re-canalisation was achieved after a total of 3 passes using L6 (2 passes) and L5 (1 pass) MERCI devices.
D. Follow-up MRI examination at 15.5 hours revealed extensive haemorrhagic conversion in the infarct territory with significant mass effect in the posterior fossa resulting in patient demise.

(33%) of asymptomatic haemorrhage within the involved vascular infarct territory. There was only 1 case (6%) of severe reperfusion haemorrhage resulting in haematoma with significant mass effect and death (Fig. 3).

The major limitation of our study was the small patient cohort. This limits satisfactory statistical analysis of the data. Nevertheless, the data obtained was comparable to the full MERCI trial that similarly produced positive experience with the MERCI device.

Conclusion

The MERCI mechanical thrombectomy device is safe and improves patient outcome, but only in cases that achieve complete re-canalisation. Early treatment and patient selection using clinical-imaging disssociation findings enable it to be a promising therapeutic option and complements our existing systemic and local thrombolytic therapy strategies. Presently, mechanical method using MERCI does not seem to replace systemic or local thrombolytic therapy. In our institute, mechanical thrombectomy using MERCI is now considered for all potential patients presenting with large vessel stroke syndrome within the therapeutic time window of 8 hours. Intravenous thrombolytic therapy, however, is still the primary front-line tool for the early treatment of patients presenting early within the first 3 hours of stroke onset. In cases of failure of systemic thrombolytic therapy, mechanical rescue using MERCI will be called for. Intra-arterial therapy now plays more of an adjunctive treatment strategy to both systemic and mechanical thrombectomy methods, but a small subgroup of patients presenting with primary small branch vessel occlusion deemed not suitable for the MERCI device, intra-arterial therapy is still considered as an important tool within the 6-hour therapeutic time window.

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