Rescue intracranial stenting in acute ischemic stroke: a preliminary Vietnamese study

C.-C. TRAN¹, M.-T. LE¹, B.-W. BAXTER², G. NGUYEN-LUU¹, M.-T. NGO¹, N.-H. NGUYEN-DAO¹, L. DUONG-HOANG¹, M. MAI-VAN¹, M.-D. NGUYEN³

Tran Chi Cuong and Le Minh Thang contributed equally to this article as co-first authors

Abstract. – **OBJECTIVE:** In cases of acute ischemic stroke (AIS) caused by intracranial large vessel occlusion, rescue intracranial stenting (RIS) has recently emerged as a treatment option for achieving recanalization when mechanical thrombectomy (MT) fails. However, few studies to date have reported on the beneficial outcomes of RIS. Our goal was to analyze whether RIS use can improve prognosis in patients 3 months post-treatment.

PATIENTS AND METHODS: A retrospective analysis was performed on a prospective cohort of patients with AIS treated with RIS at Can Tho S.I.S General Hospital. The study inclusion criteria were evidence of intracranial large vessel occlusion, absence of intracranial hemorrhage (ICH), and severe stenosis or reocclusion after MT. Patients with tandem occlusions, failure to follow up after discharge, or severe or fatal illness concomitant with AIS were excluded from the study. The primary outcome was the "nonpoor" prognosis status rate at 3 months after RIS and post-procedural symptomatic ICH (sICH).

RESULTS: The post-treatment outcomes of 85 eligible patients who received RIS between August 2019 and May 2021 were assessed. Of the 85 included patients, 82 (96.5%) achieved successful recanalization, and 4 (4.7%) experienced sICH. At 3-months post-treatment, 47 (55.3%) patients had "non-poor" outcomes, whereas 35 (41.2%) had good outcomes. The use of dual antiplatelet therapy was associated with new infarcts (relative risk [RR]: 0.1; 95% confidence interval [CI]: 0.01-0.7) and sICH occurrence (RR: 0.1; 95% CI: 0.01-0.9).

CONCLUSIONS: Our study suggests that despite the occurrence of post-procedural sICH in a small proportion of cases, RIS could serve as a useful alternative or additional treatment in the event of MT failure.

Key Words:

Stroke, Stents, Cerebrovascular circulation, Stroke rehabilitation, Magnetic resonance imaging.

Abbreviations

AF, atrial fibrillation; AIS, acute ischemic stroke; CI, confidence interval; CKD, chronic kidney disease; CT, computed tomography DAPT, dual antiplatelet therapy; DSA, digital subtraction angiography; ICH, intracranial hemorrhage; LICA, left internal carotid artery; MRA, magnetic resonance angiography; mRS, modified Rankin Score; MT, mechanical thrombectomy; mTICI, modified treatment in cerebral infarction; NNH; number needed to harm; NNT, number needed to treat; RICA, right internal carotid artery; RIS, rescue intracranial stenting; RR, relative risk; rTPA, recombinant tissue plasminogen activator; sICH, symptomatic intracranial hemorrhage; SWI, susceptibility-weighted imaging.

Introduction

Each year, large intracranial arterial stenosis lesions account for more than 30% of all ischemic stroke cases among Asian populations compared with only 10% of cases among Caucasian populations¹. The human brain typically contains approximately 130 billion neurons. Without appropriate treatment, large vessel ischemic stroke can result in neuronal loss in 1 hour equivalent to the expected loss over 3.6 years of normal aging². From December 2010 to December 2014, five randomized controlled trials using mechanical thrombectomy (MT) were performed (MR CLE-AN, ESCAPE, REVASCAT, SWIFT PRIME, and EXTEND IA). The success rates reported in these trials led to MT becoming the recommended first-line treatment for acute ischemic stroke (AIS). However, the HERMES meta-analysis showed that MT results in recanalization failure in 28.9% of patients older than 80 years3. Recent studies^{4,5} have suggested that rescue intracranial stenting (RIS) may represent an alternative treatment for achieving permanent recanalization in

¹Digital Subtraction Angiography Unit, Can Tho S.I.S General Hospital, Can Tho, Vietnam

²Department of Radiology, Erlanger Hospital, Chattanooga, TN, United States

³Department of Radiology, Pham Ngoc Thach University of Medicine, Ho Chi Minh City, Vietnam

the event of MT failure. Permanent recanalization is among the most important factors impacting patients' outcomes after AIS. Our study assessed both "non-poor" outcomes at 3-months post-treatment in patients receiving RIS and evaluated the occurrence of symptomatic intracranial hemorrhage (sICH) due to the procedure.

Patients and Methods

Patients

Informed consent was obtained from all patients' representatives after detailed explanations were provided regarding the procedures. The study protocol was approved by the Ethics Council in biomedical research at Can Tho S.I.S General Hospital; 8120/QD-S.I.S, dated May 18, 2020). All procedures involving human participants were performed in accordance with the ethical standards of the institutional and national research committees and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

We retrospectively evaluated a prospective database to obtain information for 85 consecutive patients diagnosed with AIS who were treated with rescue stenting at Can Tho S.I.S. General Hospital between August 2019 and May 2021. The inclusion criteria were: 1) evidence of intracranial large vessel occlusion [based on the Warfarin-Aspirin Symptomatic Intracranial Disease method for the measurement of intracranial stenosis: mild

(<50%), moderate (50-69%), severe (70-99%), and occlusion (100%)]; 2) absence of ICH; 3) severe stenosis or reocclusion after MT. The exclusion criteria were: 1) tandem lesion (defined as severe stenosis or occlusion of the extracranial segment inclosing with the ipsilateral intracranial segment); 2) failure to follow up after discharge; 3) any severe or fatal comorbidity before AIS (defined as severe pneumonia, respiratory distress, septic shock, multiple organ failure or Acquired Immune Deficiency Syndrome with a CD4 count below 250 cells/mm³. Figure 1 shows the patients' selection process.

Procedures

Either sedation anesthesia or general anesthesia were applied before the intervention. After identifying a large artery occlusion due to thrombus using either susceptibility-weighted imaging (SWI) or digital subtraction angiography (DSA), the most common MT procedure applied was aspiration or aspiration combined with stent retriever⁶. The recanalization outcome was evaluated using the modified treatment in cerebral infarction (mTICI) score. If angiography revealed either severe stenosis or reocclusion (mTICI < 2b) despite multiple passes, we performed stenting following the application of a dual antiplatelet therapy (DAPT) loading dose (300 mg clopidogrel and 162 mg aspirin) via nasogastric tube, as described by Chang et al7 (100-500 mg aspirin and 300 mg clopidogrel)8. During the procedure, patients received an intravenous bolus dose of

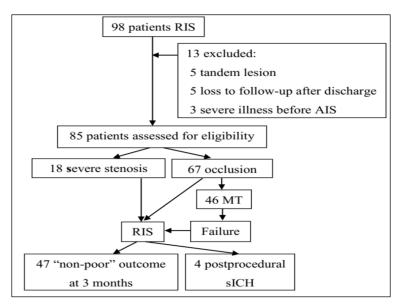


Figure 1. Flow-chart of patient selection in the study, showing reasons for patient exclusion.

3,000-5,000 units of heparin to maintain a target activated clotting time of 250-300 seconds. Similar to the angioplasty protocol used in the WEA-VE trial, we used a balloon size with a nominal diameter of 80% of the true luminal diameter or 60% of the diameter of lesions near visible perforators. If residual stenosis remained \geq 50% within 5 minutes after deploying the stent, we dilated the balloon within the stent. Successful stent deployment across the lesion was defined as 0% to 20% residual stenosis post-stenting, and successful recanalization was defined as mTICI 2b- 310 . The total procedure time was defined as the interval from groin puncture to completion.

After procedure completion, the patient was transferred to the intensive care unit and monitored continuously for clinical signs, with systolic blood pressure maintained from 120 to 140 mmHg. After 24 hours, a head computed tomography (CT) scan was performed to determine whether the patients experienced any of the following complications: cerebral swelling, new post-procedural infarcts, or sICH. sICH was defined as post-procedural ICH with mRS \geq 5 and no other evident causes for increased mRS. If CT did not show any hemorrhage, the patient was initiated on oral 75 mg clopidogrel and 81 mg aspirin, taken daily for 3 months. After 3 months, the patient transitioned to an ongoing daily dose of 75 mg clopidogrel coupled with intensive management of vascular risk factors. If CT indicated evidence of hemorrhage, antiplatelet treatment was suspended, and a daily dose of 75 mg clopidogrel alone was prescribed based on the characteristics of hemorrhage.

Outcomes

At 3 months, the primary outcome was "non-poor" clinical outcomes assessed using the mRS. Poor clinical outcomes were defined as mRS 4-6, and "non-poor" outcomes were defined as the total of good (mRS 0 to ≤ 2) and fair (mRS 3) clinical outcomes. These scores were evaluated through telephone interviews.

We described a typical case from our study. A 64-year-old male presented to the local hospital with onset of left hemiplegia. No improvement was observed after alteplase (0.9 mg/kg) administration. The patient presented with conscious disturbance and a National Institute of Health Stroke Scale (NIHSS) score of 22. The patient was transferred to Can Tho S.I.S General Hospital 5 hours after onset and was administered 300 mg of clopidogrel and 162 mg of aspirin. Detailed

procedures for this patient were presented in Figure 2. The mRS improved from 4 immediately post-intervention to 0 after 3 months.

Statistical Analysis

Statistical analyses were performed using Stata 16 (StataCorp LLC, TX, USA). Categorical variables were compared using Fisher's exact test. A multivariate binary logistic regression model was used to assess the effects of various risk factors on mRS. The *p*-values < 0.05 were considered significant with appropriate 95% confidence intervals (CIs). The number needed to treat (NNT) was defined as the estimated number of patients required to receive a new treatment to achieve a reduction of one adverse event compared with standard or no treatment. The number needed to harm (NNH) was defined as the estimated number of patients required to receive a new treatment to achieve an increase of one adverse event compared with standard or no treatment.

Results

Between August 2019 and May 2021, 85 patients with AIS underwent RIS at S.I.S. Can Tho. Patients ranged in age from 28 to 101 years, and the mean \pm standard deviation age was 63.1 \pm 13.8 years. Among included patients, 27.1% were 70 years or older, and 70.6% were men. Onset-to-door times greater than 6 hours were recorded for 50.6% of patients, which was associated with an increase in the probability of poor patient outcomes at 3-months post-treatment (relative risk [RR]: 1.7, 95% CI: 1.1-2.8, p = 0.04, Table I). Common patient histories included hypertension (100%), smoking (47.1%), diabetes (45.9%), and myocardial infarction (35.3%); however, a history of hypertension, diabetes, or myocardial infarction was not significantly associated with an increased risk of poor patient outcomes (p = 0.9, p = 0.1, and p = 0.8 respectively, Table I).Posterior circulation lesions were significantly less common than anterior circulation lesions (27.1% and 72.9%, respectively) but were associated with an increased risk of poor patient outcomes (RR: 1.8, 95%) CI: 1.1-2.7, p = 0.01, Table I). Self-expanding stents were used in 28.2% of RIS procedures, which did not lead to significantly different post-procedural outcomes from the use of other stent types (p = 0.5, Table I). Fewer patients were treated with only RIS (45.9%) than those treated with many procedures (combination MT with RIS; 54.1%), but the number of procedures did not significantly affect the risk of

Table I. Association of pre-procedural and post-procedural characteristics with poor functional modified Rankin Score outcomes at 3-months post-treatment.

Baseline Variables	Poor outcome	RR (95% CI)	<i>p</i> -value	NNH
Age ≥ 70 years	16 (18.8%)	1.9 (1.3-3)	0.002	
Women	15 (17.6%)	1.6 (0.9-2.5)	0.06	
Smoking	23 (27.1%)	1.7 (1.1-2.8)	0.03	
Hypertension	38 (44.7%)	0.9 (0.1-6.4)	0.9	
AF	1 (1.2%)	2.3 (1.8-2.9)	< 0.0001	
CKD	5 (5.9%)	2.3 (1.8-2.9)	< 0.0001	
Diabetes	21 (24.7%)	1.5 (0.9-2.3)	0.1	
Myocardial infarction	14 (16.5%)	1.1 (0.7-1.7)	0.8	
rTPA	3 (3.5%)	0.8 (0.3-2.1)	0.7	
DAPT	38 (44.7%)	0.9 (0.1-6.4)	0.9	
Onset over 6 hours	24 (28.2%)	1.7 (1.1-2.8)	0.04	
Dysphagia	13 (15.3%)	1.8 (1.1-2.7)	0.01	
DWI-ASPECTS < 8 points	15 (24.2%)	2.3 (1.1-4.6)	0.02	
pc-ASPECTS < 6 points	8 (34.8%)	2.1 (1.2-3.7)	0.01	
Posterior circulation lesion	15 (17.6%)	1.8 (1.1-2.7)	0.01	
Anesthesia (sedation)	1 (1.2%)	2.3 (1.8-2.9)	< 0.0001	2
Self-expanding stent	24 (28.2%)	1.2 (0.7-1.9)	0.5	
Number of procedures: Only RIS	17 (20%)	0.9 (0.6-1.5)	0.8	
Total procedure time > 60 minutes	32 (37.6%)	2.2 (1.1-4.6)	0.03	
Complication	13 (15.3%)	1.7 (1.1-2.7)	0.02	
Post-procedural new infarcts	2 (2.4%)	1.5 (0.7-3.5)	0.3	
sICH	4 (4.7%)	2.4 (1.8-3.1)	< 0.0001	
Decompressive craniectomy	3 (3.5%)	2.3 (1.8-3.1)	< 0.0001	2
Lack of rehabilitation	7 (8.2%)	1.7 (1.1-2.8)	0.03	2 3

AF, atrial fibrillation; ASPECTS, Alberta Stroke Program Early Computed Tomography Score; CI, confidence interval; CKD, chronic kidney disease; DAPT, dual antiplatelet therapy; DWI, diffusion-weighted imaging; NNH, number needed to harm; pc, posterior circulation; RR, relative risk; rTPA, recombinant tissue plasminogen activator; sICH, symptomatic intracranial hemorrhage.

poor outcomes at 3 months.

Complications were experienced by 15.3% of patients experienced after RIS treatment, including 3.5% of patients with new infarcts after treatment, ICH, and metabolic acidosis due to renal failure. ICH was the most common complication, accounting for 10.6% of post-procedural complications, whereas metabolic acidosis due to renal failure was the least common complication (1.2%). All patients had a pre-procedural mRS of 5. At discharge, 20% of patients were classified as "non-poor," which increased to 55.3% after 3 months (Figure 3). In addition, 13 patients died between discharge and 3 months.

Additionally, 3.5% decompressive craniectomy for diffuse cerebral swelling (2.4%) and hemorrhagic transformation (1.1%) were performed. For every 3 patients who remained unrehabilitated or every 2 patients who required procedural sedation or operations by neurosurgeons, one additional case would experience a poor outcome after RIS (NNH = 3, 2, and 2, respectively, Table I).

Occlusive lesions were significantly more common (p < 0.0001, Table II) than stenosis lesions (83.5% and 16.5%, respectively). One false-nega-

tive case with a posterior circulation lesion was diagnosed with stenosis on the MRI (Figure 4). To evaluate the diagnostic accuracy of 3 Tesla MRI for occlusive lesions, we determined the sensitivity (Se, 98.5%), specificity (Sp, 72.2%), positive predictive value (PPV, 92.9%), negative predictive value (NPV, 92.9%), positive likelihood ratio (LR+, 3.5), and negative likelihood ratio (LR-, 0.02). Self-expanding stents were associated with twice as many poor outcomes as balloon-expanding stents, but the use of self-expanding stents was not significantly associated with an increase in the RR of poor outcomes relative to "non-poor" outcomes (Table III).

Discussion

In our study, hypertension at admission was recorded in all patients with AIS, which served as a compensatory mechanism for maintaining cerebral perfusion in cases of large vessel lesions and severe stroke resulting in the loss of cerebral blood flow^{11,12}. Smoking is one of the most common risk factors for cardiovascular disease because it

can contribute to the initiation and progression of atherosclerosis, including thrombus occlusion, due to increased vasomotor dysfunction, modification of lipids, alteration of antithrombotic factors, and genetic predispositions¹³. Smoking was identified as a factor associated with a significant increase in the risk of poor outcomes after RIS in our study (RR: 1.7, 95% CI: 1.1-2.8, p = 0.03, Table I). A loading DAPT dose was administered before all procedures in our study. Although DAPT was not associated with poor outcomes (p = 0.9, Table I), DAPT use was significantly associated significantly with a decreased risk of new infarcts (p = 0.03, Table III) and sICH (p = 0.04, Table III). For every 2 patients who had been administered DAPT in AIS, one fewer case with new infarcts or sICH (NNT = 2, Table IV) would be expected. The anterior circulation was involved in post-procedural sICH in 4.8% (3/62) of ca-

Table II. Relationship between occlusion diagnoses made using 3 Tesla magnetic resonance imaging (MRI) and those made using angiography.

	3 Tesla		
Angiography	Occlusion	Stenosis	<i>p</i> -value
Occlusion Stenosis Total	66 (77.6%) 5 (5.9%) 71 (83.5%)	1 (1.2%) 13 (15.3%) 14 (16.5%)	<0.0001

Clots detected using SWI (48.2%) were significantly associated with the performance of MT (p = 0.02, Table III). The diagnostic accuracy of clot detection using SWI resulted in a Se of 60.9%, an Sp of 66.7%, a PPV of 68.3%, an NPV of 59.1%, an LR+ of 1.8, and an LR- of 0.6.

ses, similar to the proportion reported by Meyer et al¹⁴ (4.8%), but smaller than the proportions reported by Pérez-García et al⁵ (10%) or Baek et

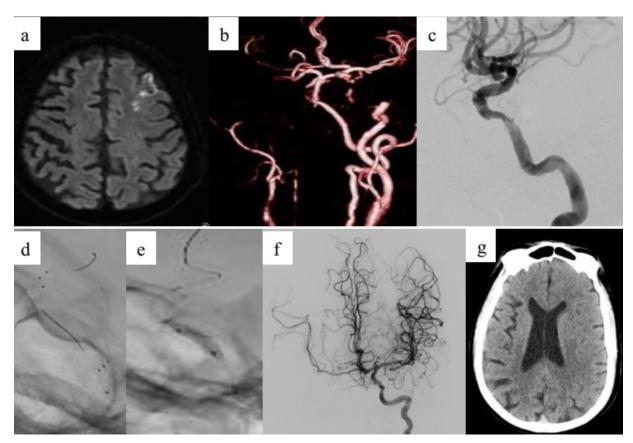


Figure 2. Sample case: **a)** Diffusion-Weighted Imaging Alberta Stroke Program Early Computed Tomography Score (DWI-A-SPECTS) 9; **b)** magnetic resonance angiography (MRA) showing the chronic occlusive origin in the right internal carotid artery (RICA) and stenosis in the left internal carotid artery (LICA); **c)** digital subtraction angiography showing severe stenosis and dissection of the cavernous portion of the LICA; **d)** after the stent deployment (Acclino 4.0 × 25; Acandis, Pforzheim, Germany); **e)** post-dilation was performed with a balloon (Sapphire II NC 3.0 × 10; OrbusNeich, Hong Kong, China); **f)** successful recanalization (modified treatment in cerebral infarction [mTICI] 3); **g)** a postoperative CT scan did not show any indication of intracranial hemorrhage.

Table III. Associations of stent design and dual antiplatelet therapy (DAPT) use with the occurrence of complications.

Baseline -	New infarcts			sICH				
Characteristics	n (%)	RR (95% CI)	<i>p</i> -value	NNT	n (%)	RR (95% CI)	<i>p</i> -value	NNT
Self-expanding stent DAPT	3 (3.5) 3 (3.5)	0.3 (0.02- 5.3) 0.1 (0.01- 0.7)	0.4 0.03	2	2 (2.4) 4 (4.7)	2 (0.3-13.7) 0.1 (0.01-0.9)	0.5 0.04	2

CI, confidence interval; NNT, number needed to treat; RR, relative risk; sICH, symptomatic intracranial hemorrhage.

al¹⁵ (11.8%). The posterior circulation was involved in 4.3% (1/23) of post-procedural sICH. Only 8 patients were also treated with rTPA, none of whom experienced ICH, indicating the safety of RIS combined with DAPT in the setting of rTPA.

Dysphagia was among the most common symptoms of posterior circulation lesions, especially those in the brainstem. Lesions in the posterior circulation are associated with higher rates of in-hospital pneumonia, malnutrition, dehydration, and prolonged hospital stay due to the need for prolonged antibiotic treatments and longer periods without motion in long-term care^{16,17}. Patients were only hospitalized for recanalization if they presented with severe symptoms of posterior ischemic lesions (altered consciousness, dysphagia, weakness, and ataxia), since initial symptoms (headache, nausea, and dizziness) of posterior lesions present early but are often milder and less obvious than the symptoms of lesions in the anterior circulation¹⁸. Late recanalization and the expansion of the infarct core volume due to a lack of response to mild symptoms may explain the association between posterior lesions and poor outcomes compared with anterior lesions (RR: 1.8, 95% CI: 1.1-2.7, p = 0.01, Table I).

Due to the high sensitivity for clot detection using SWI (Se = 60.9%, LR+ = 1.8, Table IV), the total time required to differentiate between intracranial stenosis and thrombus lesions at admission and prepare for the surgical intervention was shortened, reducing the number of cases with total procedure times longer than 60 minutes, which is usually associated with poor functional outcomes (RR: 2.2, 95% CI: 1.1-4.6, p = 0.03, Table I). Our study showed that a posterior circulation Alberta Stroke Program Early Computed Tomography Score (pc-ASPECTS) < 6 was always associated with a poor outcome (RR: 2.1, 95% CI: 1.2-3.7, p = 0.01, Se = 100%, Table I) and this score had a

Table IV. Effect of clot detection during susceptibility-weighted imaging (SWI) and the decision to perform mechanical thrombectomy (MT).

	SW		
Procedure	Clot	None	<i>p</i> -value
MT None Total	28 (32.9%) 13 (15.3%) 41 (48.2%)	18 (21.2%) 26 (30.6%) 44 (51.8%)	0.02



Figure 3. Modified Rankin Score distribution among patients before and after rescuing intracranial stenting.

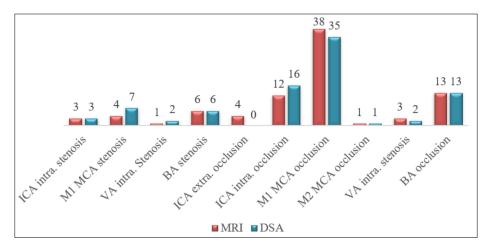


Figure 4. Relationship between occlusion diagnosis on 3 Tesla magnetic resonance imaging (MRI, red) and digital subtraction angiography (DSA, blue). ICA, internal carotid artery; M1 MCA, M1 segment of the middle cerebral artery; M2 MCA, M2 segment of the middle cerebral artery; VA, vertebral artery; BA, basilar artery; intra., intracranial; extra., extracranial.

greater impact on prognosis than the time to intervention¹⁹. The use of 3 Tesla MRI allowed us to diagnose occlusive lesions four times as often as angiography with a high positive likelihood ratio (Se = 98.5%, LR+ = 3.5, Table II).

Compared to the patients treated with RIS in the study by Stracke et al20, we observed a larger proportion of good outcomes at 3 months (41.2%) vs. 44.8%) and a lower mortality rate (18.8% vs. 18.5%). The mortality rate associated with lesions in the anterior circulation was 11.2% (7/62), emphasizing the role of RIS in reducing the mortality rate in AIS, as Karamchandani et al²¹ reported mortality rates of 26% for groups treated with and without MT. The stent design was also an important factor in RIS because balloon-expanding stents are more rigid with a greater radial outward force than self-expanding ones, which could either restrict the approach to the target intracranial artery or cause occlusions or ruptures in perforators adjacent to the target artery due to the "snowplowing" effect, in which atherosclerotic plaque or thrombi are displaced into perforator vessels²². However, our study showed that balloon- and self-expanding stents were associated with similar rates of new infarcts and sICH (p = 0.4 and p =0.5, respectively, Table III). Although 44 patients had initial reperfusion (mTICI < 2b) with MT, RIS increased this number to 62 cases. The total successful recanalization rate was 96.5%, the success rate for the anterior circulation was 96.7%, and the success rate for the posterior circulation was 95.7%, whereas Stracke et al²⁰ reported anterior circulation and posterior circulation success rates of 77.9% and 97.1%, respectively). Among cases with failed recanalization after RIS, 33.3% (1/3) of those in the anterior circulation had good outcomes.

In addition to treatment, the failure to undergo rehabilitation after the procedure could delay recovery despite successful recanalization (Table I). Stroke rehabilitation limits the high risks of deep venous thrombosis and pulmonary embolisms that can occur due to limb immobility and reduced activity levels, and long-term dependence on nasogastric tubes can lead to communication disorders²³. Therefore, the primary goal of rehabilitation is to return to independence and improve quality of life.

Strengths and Limitations

This was the largest study of RIS performed in Southeast Asia and one of the few studies to include a large sample of Asian participants, who experience large intracranial arterial lesions at higher rates than other populations. Our study was conducted in a relatively homogeneous population in Vietnam, excluding variations due to ethnic differences. Moreover, in our hospital, 3 Tesla MRI 3 is used during first-line diagnostic testing, and many interventional devices were readily available, allowing for rapid decision-making and shorter times to recanalization. However, a number of limitations may have influenced these results. Since this study was conducted as a retrospective study at a single center, the results could be influenced by selection bias and may not be generalizable to other countries in Asia.

Conclusions

We found that RIS in patients with AIS due to large vessel occlusion was a crucial treatment resulting in notable improvements in post-procedural mRS, particularly 3-months after treatment. Our study provided data to support the performance of a randomized controlled trial evaluating RIS for AIS treatment.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Ethics Approval

The study protocol was approved by the Ethics council of Can Tho Stroke International Services General Hospital (8120/QD-S.I.S., dated on May 18, 2020). All procedures involving human participants were performed in accordance with the ethical standards of the institutional and national research committees and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all patients' representatives after detailed explanations were provided regarding the procedures.

Availability of Data and Materials

The datasets generated and/or analyzed during the current study are not publicly available due to privacy concerns but are available from the corresponding author on reasonable request.

Authors' Contributions

C.-C. Tran and M.-T. Le gave a substantial contribution in acquisition, analysis, and data interpretation. M.-T. Le and M.-D. Nguyen prepared, drafted, and revised manuscript critically for important intellectual content. Each author gave the final approval of the version to be published and agreed to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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ORCID ID

Nguyen Minh Duc: 0000-0001-5411-1492.

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