RESULTS OF MECHANICAL THROMBECTOMY IN ACUTED ISCHEMIC STROKE PATIENTS DUE TO LARGE VESSEL OCCLUSIONSAT BACH MAI HOSPITAL: SHARING EXPERIENCES FROM 227 CASES

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Evaluation of the results of mechanical thrombectomy (MT) with acute ischemic stroke (AIS) due to large vessel occlusions (LVO) at Bach Mai hospital. 227 patients with acute ischemic stroke due to large vessel occlusion were treated at Bach Mai Radiology Center from January 2018 to June 2019. Patients were divided into sub-groups depending on the treatment method. Successful recanalization rate (TICI 2b-3), good clinical recovery (mRS ≤2) after 3 months and other clinical and imaging features were analyzed and compared. The mean age was 65 ± 13 with 55% males. The NIHSS, ASPECTS and pc-ASPECTS baseline were 14.3, 7.7 and 7.6 with the distribution of occlusion sites as 23.8% ICA, 41.9% M1, 13.2% M2, 11.5% Tandem and 9.7% BA. The ratio of good revascularization (TICI 2b-3) was 84.6% after first-choice devices of 93 stent retriever (41%), 90 aspiration (40%) and 44 Solumbra (19%) – no significant difference seen (p > 0.05). 3 months after treatment, patients with good clinical recovery (mRS ≤ 2) accounted for 65.2% while intracranial symptomatic hemorrhage rate was only 3.5%. Thrombectomy for AIS patients due to LVO is very effective with high rate of good revascularization and clinical recovery. Using different mechanical devices at first pass (stent, aspiration or solumbra) do not correlated to any significantly different results.

Keywords: Acute ischemic stroke (AIS), Large vessel occlusion (LVO), Mechanical thrombectomy (MT).

I. INTRODUCTION

Ischemic stroke is the leading cause of brain death and disability in the world, especially large vessel occlusions at the internal carotid artery, the middle cerebral artery and the basilar artery. Although intravenous recombinant tissue plasminogen activator (rt-PA) have been approved since 1995 by the FDA and the window of treatment was extended to 4.5 hours in 2005 (thanks to ECASS III trial), the rate of recanalization in patients with LVO using this method is still low (<15%).[1,2] In contrast, endovascular treatment (EVT) plays more and more important role in the treatment of this AIS group thanks to the thrombus contact and direct force of its structure. After the failure in 2013 with the 1st generation of mechanical devices, five large randomized controlled trials using 2nd generation were published in 2016 that demonstrated the positive results and cleared the role of endovascular treatment in AIS due to LVO.[3–6] Additionally, there are many controversies about which device is better in recanalization between main methods of stent retriever, aspiration and combined technique. In Vietnam, from 5 years ago, the number of

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patients treated annually has increased rapidly along with many others stroke centers of the country but there was no study conducted with a large number of patients. Therefore, our study aims not only to prove the effectiveness of thrombectomy at Bach Mai hospital but also make the comparison between sub-groups of treatment with different devices.

II. METHODS

Study design

Prorspective study with no blind and randomization. Criteria for selecting patients for mechanical thrombectomy in our study are based on the American Heart Association (AHA/ASA) 2018 guidelines:

(1) age ≥18 years;

(2) NIHSS ≥ 6;

(3) ASPECTS ≥ 6;

(4) large vessel occlusion sites: internal carotid artery (ICA), middle cerebral arterie (MCA) segments M1, M2 and basilar artery (BA);

(5) Patients who come to the hospital after the 6-hour window need to satisfy the criteria for cerebral perfusion imaging according to the DEFUSE 3 study: infarct core < 70ml and penumbra/ infarct core volume ratio ≥ 1.8 times ;[7]

(6) the patient's family was fully aware and accepted the risk and signed a commitment to treat the disease.

In addition to the general treatment results, we performed a subgroup analysis based on the initial choice of mechanical devices.

Diagnosis and thrombectomy procedure

Usually, clinicians receive and assess the neurological deficits of patients based on the NIHSS scale (0 - 42 points), collect others informations (age, gender, onset time) and necessary tests (Glucose, INR). Imaging examination was then performed urgently, with priority given to multislice computed tomography (MSCT) including assessment of parenchymal lesions (ASPECTS and pc-ASPECTS scores), occlusion site and the collateral circulation evaluation (multiphase CTA). Patients who come to the hospital later than 6 hours from onset have to undergo cerebral perfusion scan, process the results on the neuro-perfusion software of Siemens. Based on the penumbra/ core volume ratio, we decide the indication for the mechanical thrombectomy according to the criteria of DEFUSE 3.[7] Cases of suspected posterior circulation occlusion will be prioritized to conduct magnetic resonance imaging (MRI) to accurately assess the lesions in the brainstem. Patients admitted to the hospital within the first 4.5 hours with no contraindication to intravenous (IV) rt-PA, will be administered immediately in the imaging room after excluding hemorrhagic stroke in order to optimize therapy before switching directly to interventional room.

Thrombectomy was performed in digital substracted angiography (DSA) room by 2 neuro-intnerventionalists who are certified to perform the neuro procedures. Patients underwent local or general anesthesia depending on their consciousness. Normally, an 8F sheath was inserted at the superficial femoral arterial site. Then an 8F guiding catheter was placed at occluded artery to confirmed the thrombus position after an angiopraphy. A microcatheter (size 18-24) with co-axial 0.014" microwire was advanced to the occlusion site to help the insertion of an aspiration catheter or stent-retriver. The chosen device (aspiration or stent) was decided based on individual preference of the neuro-interventionist, no randomization. The procedure is completed when TICI 2b-3 recanalization rate was achieved or stopped if no more benefit was gained for the patient (high risk of bleeding in late window, vessel wall damage with pro-longed thrombectomy…). The information related to the

procedure was recorded, including: time from hospital admission to femoral artery puncture, time of recanalization, number of thrombectomy passes, symptomatic intracranial hemorrhage (sICH) grade etc..

Imaging and clinical follow-up

Successful revascularization after intervention was defined as grade 2b-3 on the TICI scale. Clinical outcome was assessed based on the mRS score at the time of discharge and after 3 months (90 days) by direct contact with the patients. Favorable outcomes are defined as mRS ≤ 2.

Data collection and analysis

Clinical and imaging information is stored in the original medical record and the PACS system. Descriptive analysis of data on the number of patients, sex ratio, median NIHSS, ASPECTS… with standard deviation. In univariate analysis in treatment groups, the distribution of age, sex, clinical and imaging information between groups was performed using the "chi-square" algorithm or the ANNOVA test. These statistical analyzes used SPSS 23 software. The difference was statistically significant when $p < 0.05$.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/ or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the researchs ethics committees of Bach Mai Hospital and Hanoi Medical University.

III. RESULTS

There were 227 patients treated by mechanical thrombectomy due to acute LVO at Bach Mai Hospital from January 2018 to June 2019. The mean age was 65 ± 13 with 55% male, 80.2% of patients aged from 55 to 80. The co-morbidities included hypertension (59.5%), diabetes (58.6%) and atrial fibrillation (24.7%). At the time of admission, the mean NIHSS score was 14.3, parenchymal lesions had a mean ASPECTS of 7.7 (in 205 patients with the anterior circulatory occlusion) and pc-ASPECTS of 7.6 (in 22 patients with the posterior circulatory occlusion).

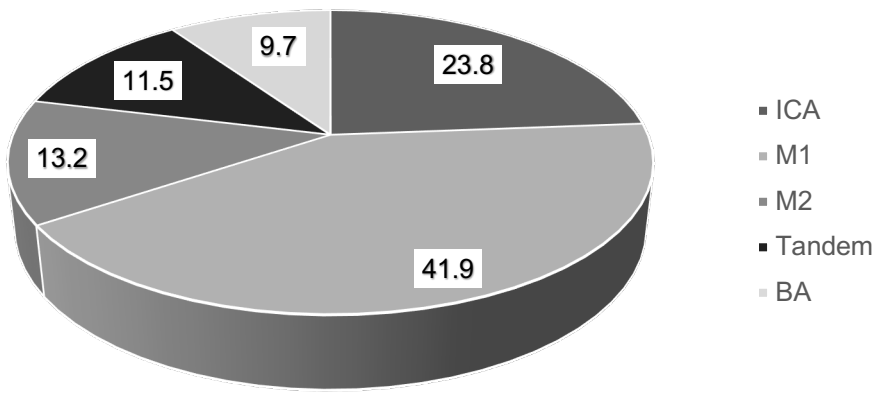

Figure 1. Occlusion site

We recorded 41.9% occlusion of middle cerebral artery segment M1, 23.8% occlusion of internal carotid artery and 9.7% occlusion of basilar artery. There were 11.5% cases of intracranial thrombosis combined with occlusion of the extracranial carotid artery (Tandem lesion).

Table 1. Interventional treatment results

The interventional procedure parameters		N = 227	
		n	Percentage (%)
Anesthesia method	Endotracheal anesthesia	183	80,6%
	Local anesthesia	44	19,4%
Intervention time (minutes)		40 ± 27 (9-150)	
Good recanalization rate after intervention (TICI 2b-3)		192	84,6%
Decrease in NIHSS after 24h		3,59 ± 4,0	
Symptomatic Intracerebral Hemorrhage (sICH)		8	3,5%
Good clinical recovery rate at 3 months (mRS 0-2)		148	65,2%

80.6% of patients received endotracheal anesthesia during the procedure. The average intervention time was 40±27 minutes, the fastest was 9 minutes. After intervention, the rate of good recanalization reached 84.6%, sICH seen in 8 cases (3.5%). The good clinical recovery rate after 3 months was 65.2%.

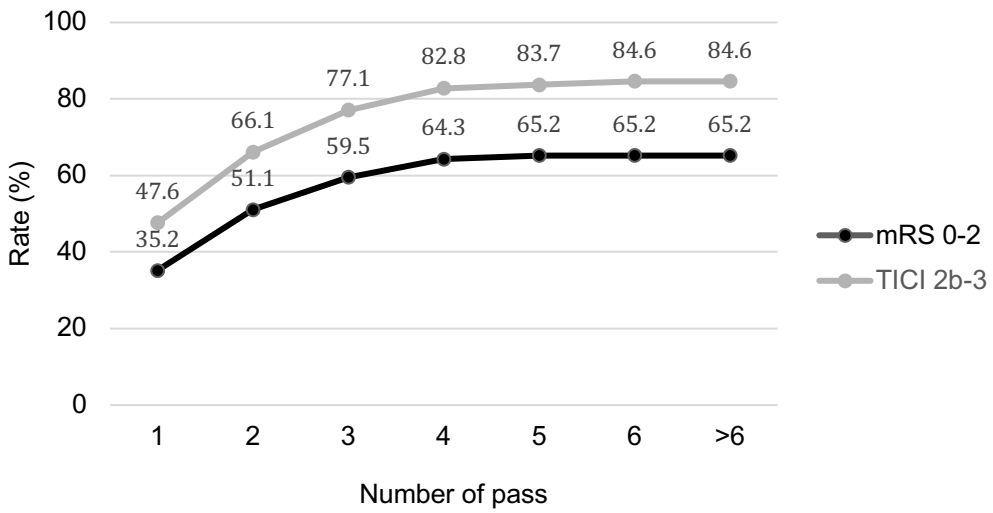

Figure 2. Rate of good recanalization and clinical recovery by number of thrombectomy pass

With the 1st pass of treatment, there were 47.6% good recanalization and 35.2% good clinical recovery after 3 months. Up to 4th pass, the accumulative rate was 82.8% and 64.3%, respectively.

Table 2. Comparison of characteristics of mechanical thrombectomy methods

Characteristics/Groups (N = 227)	Stent retriever (n = 93)	Aspiration (n = 90)	Combined device (n = 44)	p
Occlusion site				
ICA (54)	12 (12.9%)	29 (32.2%)	13 (29.5%)	0.01
MCA M1 (95)	39 (41.9%)	37 (41.1%)	19 (43.2%)	
MCA M2 (30)	21 (22.6%)	6 (6.7%)	3 (6.8%)	
Tandem (26)	13 (14%)	9 (10%)	4 (9.1%)	
BA (22)	8 (8.6%)	9 (10%)	5 (11.4%)	
NIHSS on admission	13.7 ± 4.7	14.6 ± 4.7	14.5 ± 5.3	0.43
Time of intervention	41 ± 26	35 ± 23	46 ± 34	< 0.001
Passes of thrombectomy	1.61 ± 0.92	2.11 ± 1.41	1.93 ± 1.40	0.02
Good first recanalization rate	57 (61.3%)	39 (43.3%)	25 (56.8%)	0.04
Rate of need for relief intervention	7 (7.52)%	30 (33.33%)	-	< 0.001
Good recanalization (TICI 2b-3)	77 (82.8%)	79 (87.8%)	36 (81.8%)	0.55
Good clinical recovery (mRS 0-2)	62 (66.7%)	69 (65.6%)	27 (61.4%)	0.82

There was no significant difference between the sub-groups of treatment in the good recanalization (p = 0.55) and good clinical outcome at 90 days (p = 0.82) when different initial devices were selected. It was noted that the time to remove thrombus when using the devices of aspiration was the shortest while the number of times using mechanical devices in the stent group was the least, the difference was significant with p = 0.00 and 0.02.

IV. DISCUSSION

In our study, 227 patients were recruited and underwent mechanical thrombectomy. The ratio of male (55.1%) was higher than that of SWIFT (42%) and IMS III (50%) but lower than the results of Dao Viet Phuong (63%).[8–10] Middle age and elderly patients still accounted for the majority (80.2%) with a mean age of 65 ± 13, similar to the results of MR CLEAN study (65.4 ± 14) or ESCAPE study (71 ± 11.5).[4,11] The number of young stroke patients (defined as < 45 years old) only accounted for 5.7%, but this group needed consideration because of the increasing trend in recent years. When evaluating comorbidities, hypertension (59.5%) and diabetes (58.6%) were recorded at a highest rate in our study. Hypertension was associated with stroke while hyperglycemia affects the results of treatment and risk of hemorrhagic transformation according to studies by Leonardi and Kissela.[12]

The main results are comparable with others large internationals trials of mechanical thrombectomy included location of occlusion, passes of thrombectomy, recanalization rate, post-intervention hemorrhagic transformation rate and clinical recovery rate at 90 days. At the time of admission, we recorded an average NIHSS score of 14.3, while an ASPECTS score of 7.7. This result was lower than that of the MR CLEAN or ESCAPE studies (median ASPECTS was 9) but comparable to SWIFT

PRIME (median was 7). This was explained by the fact that MR CLEAN selects patients with good clinical status (NIHSS score ≥2) while ESCAPE favors patients with good collateral score (4-5 points). The most common location of occlusion, similar to domestic and international results, was the middle cerebral artery M1 segment (accounting for 41.9%). In our study, there were 32 patients admitted to the hospital at the window later than 6 hours. This resulted in a mean time from onset to recanalization of 342 minutes, comparable to REVASCAT (355 minutes) and significantly higher than others studies (within 250 minutes) [6]multicenter, randomized trial seeking to establish whether subjects meeting following main inclusion criteria: age 18-80, baseline National Institutes of Health Stroke Scale ≥6, evidence of intracranial internal carotid artery or proximal (M1 segment. However, the clinical recovery rate of 65.2% was a remarkable result, only lower than EXTEND IA (71%) and equivalent to SWIFT PRIME (60%) [13]. This was partly due to the good recanalization rate (TICI 2b-3) at the first pass of thrombectomy reaching 47.6% and the overall rate after intervention is 84.6%. This rate was higher than that of the REVASCAT or ESCAPE studies (66% and 72%). Area for improvement was that the number of patients requiring endotracheal anesthesia still accounts for over 80%, leading to a longer interventional time (40±27 minutes) and the immediate clinical evaluation post-intervention was limited. At comprehensive stroke centers, patients were prioritized for local anesthesia in fully staffed conditions to optimize revascularization time.

An important factor to be considered is the number of passing in the thrombectomy interventions. The results in our study (Figure 2) showed that within 4 passes of thrombectomy, the accumulative rate increased rapidly both of good revascularization (47.6% - 82.8%) and good clinical recovery after 3 months (35.2% - 64.3%). However, from the 5th pass, the effect was almost nonexistent with the flat histogram. This was also proven in domestic and international studies of the author Mai Duy Ton or Gudin, the good recanalization rate when the passing of thrombectomy was less than or equal to 2 times, reaching 74.4% and 75% respectively [10]. Therefore, improve the effectiveness of each thrombectomy and reduce the number of mechanical pass in order to shorten the procedural time is a big target in the intervention of AIS. Thus, the neurointerventionalists recently tend to choose the combined method with two devices (stent-retriever + aspiration catheter) from the beginning to optimize this theory. To evaluate the rate of sICH after treatment, we only recorded 8 cases, accounting for 3.5%. This was a low rate with the same results of SWIFT PRIME (2%) and ESCAPE (2.6%) studies when compared to the MR CLEAN study (7.7%) or TREVO 2 study (7%) [11,14] intraarterial treatment is highly effective for emergency revascularization. However, proof of a beneficial effect on functional outcome is lacking.\nMETHODS: We randomly assigned eligible patients to either intraarterial treatment plus usual care or usual care alone. Eligible patients had a proximal arterial occlusion in the anterior cerebral circulation that was confirmed on vessel imaging and that could be treated intraarterially within 6 hours after symptom onset. The primary outcome was the modified Rankin scale score at 90 days; this categorical scale measures functional outcome, with scores ranging from 0 (no symptoms).

There are two basic types of devices selected for mechanical thrombectomy, the stent-retriever pulling the thrombus from the distal end (Solitaire, Trevo...) or the direct catheters of aspiration from the proximal part (Sofia, Jet7,

ACE, React…). In fact, the recommendations of the AHA/ASA support the choice of stents for the initial passing of thrombectomy, although each method has its own mechanism of action and advantages.[15] In our study, the stent-retriever group (93 cases) had the same rate as the aspiration group (90 cases). In table 2, when comparing the results in 3 treatment groups with different initial devices of choice, there was no significant difference ($p > 0.05$) in the effectiveness of recanalization (81.8% - 87.8%) and good clinical recovery results (61.4% - 66.7%). This good recanalization rate was similar to the study of Machi (89% recanalization with Solitaire FR) or Turk (78% recanalization with the aspiration).[16,17] Specific analysis showed that the new generation of aspiration catheter (wide lumen, better access) with strong negative pressure at proximal part leading to the shortest intervention time (35 ± 23 minutes, $p = 0.00$) meanwhile stent-retriever, acting from the distal end, increased the thrombus contact area resulting in the least number of passing (1.61 ± 0.92, $p = 0.02$) during procedure. Additionally, the rate of using the remaining method for rescue (when the initial device did not achieve good recanalization results) in the catheter of aspiration group was up to 33.33%, much higher than in the stent group (only 7.52%), the difference was statistically significant ($p < 0.001$). This was similar to ASTER (2017) results that also noted the catheter of aspiration group required more rescue treatment than the stent group, 33% and 24%, respectively.[18] The bigger rescue rate in our study could be explained due to site distribution in the aspiration group, mostly ICA (32.2%) but least M2 occlussion (6.7%). Although the effectiveness was similar to other groups, the technique of combining both stents and catheters of aspiration at the beginning of our study was still limited when evaluating the results due to the small number of patients (44 cases). This was partly due to the lower cost of treatment with one device as first choice whereas in developed countries when the insurance covers all cost of entire procedure, the preference was to combine two devices from the beginning to shorten the procedure time with minimum number of thrombectomy passes.

Even thought the total number of patients were large, there were some limitations noted in our study. First, this was a single-center study, dividing patients between sub-groups of treatment without randomization which may affect the reliability of the results. Second, it is not a blind study. This means the imaging results and treatment options (chosen devices), although conducted by doctors who are experienced in neurological diagnosis and intervention, depend on the subjectivity of each individual. In the future, with the number of AIS patients being diagnosed and intervened constantly increasing at many centers across the country, we hope to be able to conduct a multicenter study with a comprehensive design.

V. CONCLUSION

Endovascular mechanical thrombectomy in patients with acute ischemic stroke due to large vessel occlusion is a safe method with a high rate effectiveness of recanalization as well as a good clinical recovery after the treatment. The choice of the initial device (the stent retriever, the catheter of aspiration the thrombus, or a combination of both) did not affect post-treatment outcomes but based on neuro-interventionalist's preference without randomization. It was noted that the use of aspiration catheter had faster interventional time while stent retriever had fewer pass of mechanical thrombectomy.

Compliance with ethical standards

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Disclosure statement

All the authors have no conflict of interest relevant to this article.

Informed consents

These forms were obtained from the patients included in the study.

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