

Aspiration Thrombectomy In Acute Large Vessel Occlusive Stroke

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Abstract

Background: A direct aspiration technique recently approved to be not inferior to stent retrieval as a mechanical thrombectomy for acute ischemic stroke patients with a large vessel occlusion. Few reports use distal access catheters for aspiration.

Objectives: Our study aims to evaluate distal access catheters as a first pass approach of thrombus aspiration for safety and efficacy.

Patients and methods: Forty patients with acute stroke due to large vessel occlusion have been divided into aspiration thrombectomy group in which thrombectomy is done by aspiration and control group which receive medical treatment only. Prospective functional outcomes and complications are compared between both groups.

Results: Successful revascularization was achieved in 10 /20 (50%) of patients with aspiration thrombectomy as stand-alone and in 18 /20 (90%) of patients when adding stent retrieval as a rescue maneuver. Functional independence at 90 days was achieved on 9/20 (45%) patients with aspiration versus 2/20 (10%) patients of control group; P = 0.015, While Mortality with aspiration is less than control group 4/20 (20%) versus 9/20 (45%) respectively P = 0.088. Spontaneous intracerebral hemorrhage has occurred in 3/20 (15%) patients with aspiration versus 4/20 (20%) patients in the control group. One patient had carotid dissection as a complication of thrombectomy.

Conclusion: Our study demonstrates that aspiration thrombectomy by distal access catheters is easily manipulating, safe, and have fewer complications. Aspiration reveals a significant difference regarding functional independence at three months and despite less mortality with aspiration, there is an insignificant difference between both groups.

Keywords: Aspiration; Stroke; Distal access catheter.

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Introduction

Early recanalization as a subsequent of large vessel occlusion has been associated with improved outcomes in acute stroke. In 2015 five RCTs were published thrombectomy via recent generation stent retrievers compare to the Merci device in earlier RCT and approved higher outcomes in the endovascular group with effective revascularization (58%–88%) and high rates of functional independence at 90 days (53%–71%) using stent retriever vs (19%–40%) using tPA alone, along with the low incidence of complications (Berkhemer et al.,2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al.,2015; Saver et al., 2015).

The main implications for management acute ischemic stroke are approval of efficacy after extending the time window from 6 to 24 and 6 to 12 by *DAWN* and *DEFUSE 3* trials respectively. The *DAWN* trial enrolled patients with stroke onset 6–24 h and mechanical thrombectomy (MT) was initiated within this time. Eligibility for MT is the mismatch between clinical and DWI on imaging, and established a 73% risk reduction in disability (48.6% in MT group vs. 13.6% in the control group). *DEFUSE 3* trials revealed clinical benefit after MT in patients presenting after 6 hours from ictus. Eligibility for MT is the mismatch between perfusion and diffusion imaging the results approve a higher percentage of functionally independency than standard medical treatment alone (45% vs 17%)

(Nogueira et al.,2018; Albers et al.,2018). Thrombectomy by a flexible aspiration catheter is an alternative method of recanalization occluded vessels. When the tractable and large aspiration catheters were introduced the revascularization rate and functional outcomes of aspiration thrombectomy became comparable to stent-based thrombectomy (Turk et al.,2014).

A direct aspiration first pass technique (ADAPT) is fast and safe procedure for recanalization of vessel occlusion. This method implicates navigating a distal access catheter to the proximal part of the occlusion followed by the direct application of suction via the distal access catheters by syringe or pump (Jovin et al., 2015).

Direct aspiration (DA) has been a progressively standard option for mechanical thrombectomy, especially with the latest advancement in catheter technology with subsequent improve - ment in suction force, flexibility (Jovin et al., 2015).

Even though stent retrievers (SR) remain the first-line device for thrombectomy, the AHA/ASA also recommend usage of other thrombectomy methods particularly in selected cases (Powers et al.,2018).

Currently, aspiration thrombectomy and stent-based thrombectomy are the basic treatment options for endo -vascular therapy in selected patients with acute ischemic stroke. The combined use of SR and aspiration as a first-line and rescue treatment has also been shown to be effective for vessel recanalization (Kim et al.,2015).

Recently, AHA/ASA recommend aspiration thrombectomy

as non-inferior to stent retriever for patients who meet all the following criteria: groin puncture within < 6 hours from symptom onset; age ≥ 18 years; internal carotid artery (ICA) or M1 occlusion; ASPECTS ≥ 6 ; NIHSS score of ≥ 6 ; and pre stroke mRS score of 0 to 1 (Powers WJ et al.,2019).

Patients and methods

This study has been permitted by the Ethics Committee of the Faculty of Medicine, Qena, Egypt. Written Consent from patients or their relatives to participate in this study.

This study is a Prospective cohort study that has been done between July 2018 and January 2020. Forty patients presented by ischemic stroke secondary to occlusion in the anterior circulation (occlusions in the distal (ICA) and/or middle cerebral artery M1 or M2) were included in the study and divided into two groups:

Thrombectomy group: twenty patients received thrombectomy plus standard medical treatment and *Control group*: twenty patients received Standard medical care alone. We compared the mean score of the National Institutes of Health Stroke Scale (NIHSS) and functional independence by modified Rankin scale (mRS) which ranges from 0 to 6 after 90 days between both groups. Patients subjected to Non-contrast CT brain. DWI was ordered for clinical diffusion mismatch if symptoms onset > 6 hours in the thrombectomy group.

The procedure of Aspiration Thrombectomy

The procedure was performed with the patient under either conscious sedation or general anesthesia. The femoral puncture was done by introducing femoral sheath 8- French With seldinger technique in the mid portion of the femoral artery, The following step start by advancing 8- French guiding catheter to the proximal part

of the occluded vessel. 5-French distal access catheter (Navien catheter; Covidien) a flexible, single-lumen, straight tip configuration With radiopaque platinum marker at its distal tip, which permits proper visualization under fluoroscopy, The usual length of the navien catheter is 125 cm with a distal inner diameter of 0.058 inches, micro-catheters 2.4-French and micro guide-wire 0.014 advanced coaxially with Navien catheter through the Guiding Catheter as a unit up to the occlusion site to reach smaller vessels while simultaneously permitting continuous saline flushing and preventing air entry into the system.

Once the distal access catheter is situated optimally, the inner micro-catheter and micro guide-wire are then removed. Subsequently, the proximal hub of the distal access catheter directly is connected to a 50 mL syringe. First, we attempt to use the great maximum suction force. Second, we tried to maintain the tip of the distal access catheter parallel to the imaginable pathway of the occluded vessel to prevent direct contact between catheter tip and the endothelium. Then negative pressure was applied via forceful pulling of the plunger of the syringe for 1-2 minutes. After that, the distal access catheter is slightly progress into the thrombus and then gently withdrawn under continuous aspiration. It is essential to accomplish at least three attempts at revascularization using the consigned aspiration technique before switching to (ST) by solitaire as rescue therapy.

Outcome measures

The primary efficacy outcome is the proportion of patients achieving functional independence) at 90 days, as measured by achieving 0–2 on the (mRS) and rate of mortality (Saver et al.,2010).

The secondary efficacy outcomes are assessed by (1) - modified Thrombo -lysis in Cerebral Infarction (mTICI) score where the goal is the proportion of patients who reach successful revascularization as defined by of 2b or 3 at the end of aspiration technique and proportion of patients with successful revascularization at the end of entire procedures. (2) - NIHSS score change between both groups at admission and after 7 days post-procedure or discharge (Zaidat et al.,2013).

Safety outcome has been evaluated according to procedure serious adverse events as distal embolization, emboli -zation in a new vascular territory, arterial perforation, arterial dissection, vasospasm or Symptomatic intra cerebral hemorrhage related to deteriorating of the NIHSS score by 4 within 24 hours. The (mRS) must be assessed at 90 days by face-to-face or phone interviews.

Statistical analysis

Data was analyzed by SPSS version 21.0. Means, medians, SD were used for continuous variables. Frequencies and proportion for categorical variables. The independent t-test or Mann-Whitney test was used to compare the differences of means and the Pearson c2 test or Fisher exact test was used to comparing the frequencies or proportions between both groups. P-value < 0.05 is considered statistically significant in all analyses.

Results

Baseline Characteristics

Among forty patients mean age, 62.3 (SD, 9.74) years; 20/40 (50%) male, according to the site of occlusion of anterior circulation; 21/40 (52.5%) on the left side. According to risk factors; 14/40 (35%) were diabetic, 20/40 (50%) hypertensive, 10/40 (25%) smokers, three (7.5%) with previous stroke,

13/40 (32.5%) with dyslipidemia, six (15%) with valvular heart disease, 10/40 (25%) with atrial fibrillation, seven (17.5%) with ischemic heart disease, risk factors in each group illustrated in (figure 1).Nine patients (22.5%) received IV.tPA. NIHSS at admission; mean 17.15, SD = 4.69 CI (15.68 18.62), ASPECT score; mean = 7.48, SD = 1.26, CI (7.07-7.88) (Table. 1 & Fig.1).

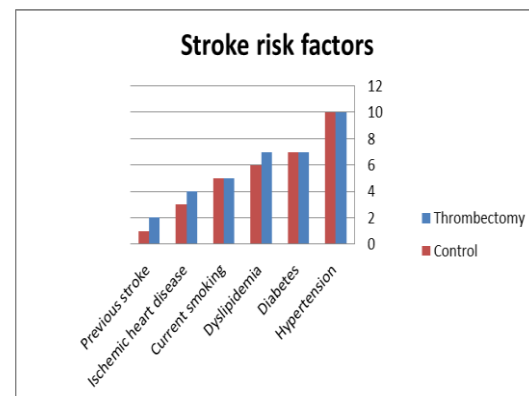


Fig.1. Stroke risk factors

Procedural data

Twenty patients undergo thrombectomy by a direct aspiration as the first-line thrombectomy using 5 French distal access catheter.

Diagnostic angiography reveals that 12/20 (60 %) show occlusion in (MCA-M1) segment, 8/20 (40%) occlusion in the distal part of (ICA). Collateral grade; 4 /20 (20%) grade 1; 11/20 (55%) grade 2; 5/20 (25%) grade 3. Time from onset to puncture; mean = 5.75 hours, SD =1.95. Time from diagnosis to puncture; mean = 67 minutes, SD = 29.7 minutes. Procedural time; mean = 61.2 minutes SD =32.6. General anesthesia was used on 17/20 (85%) and conscious sedation on 3/20 (15%).

Aspiration thrombectomy had been done using distal access catheter (nevan catheter, 5-French) as stand-

alone on 10/20 (50%) patients and had successful revascularization (mTICI) \geq 2b, 6/10 achieved recanalization after 1st attempt, 2/10 after 2nd attempt and 2/10 after 3rd attempt with the average Irvine, CA, USA) after the failure of aspiration thrombectomy. Finally, 18/20 (90%) patients achieved successful revascularization with both procedures with the overall average time from femoral access to final revascularization; mean = 61.2 minutes, SD = 32.6 minutes. 2/20 (10%) patients failed to achieve full revascularization. four patients (20%) have tandem occlusion, angioplasty was done before MT and carotid wall stent deployed after thrombectomy in three patients (15%), one patient (5%) was planned for late stenting.

Outcome

1. Primary efficacy endpoint

Nine patients (45%) in the thrombectomy group achieved functional independence (mRS) of \leq 2 at 90 days, compared to two (10%) patients in the control group; adjusted risk ratio:4.5, 95% CI (1.1-18.27), With statistically significant difference (P = 0.015). Mortality at 90 days (mRS = 6) four patients (20%) in thrombectomy group, and nine patients (45%) in the control group, Fisher's Exact Test; P = (0.088) with no significant difference between both groups (Fig.2).

2. Secondary efficacy outcomes

10 / 20 patients (50%) achieve (mTICI) \geq 2b revascularization after aspiration thrombectomy as stand-alone procedure while 18 / 20 (90%) patients achieve TICI \geq 2b revascularization after aspiration with

time from femoral access to final revascularization; mean 40 minutes, SD = 19.8 minutes. 10/ 20 patients (50%) need a rescue maneuver using stent retrieval (Solitaire, Medtronic, stent retrieval thrombectomy procedure. There was a marked reduction in NIHSS score in the thrombectomy group at discharge where, NIHSS at admission: for thrombectomy group; Mean = 17.55, SD = 4 , (C.I) (15.68-19.42). while, for the control group Mean = 16.75, SD =5.2 , (C.I) (14.31-19.19), student t-test; P-value = (0.59) no significant difference. NIHSS at discharge: for thrombectomy group; Mean = 13.45, SD = 6.7, (C.I) (10.31-16.59). while, for control group Mean = 21.95, SD = 6.1, (C.I) (19.08 -24.82), student t test; P value \leq 0.001 statistically significant difference.

3. Safety outcomes

Assessed by the occurrence of spontaneous intracranial hemorrhage at 24 hours after the procedure. three patients (15%) for the thrombectomy group, four patients (20%) for the control group, Fisher's Exact Test (P = 0.5) with no significant difference between both groups (Table. 2).

Discussion

The earlier clinical trial (THERAPY) failed to approve the efficacy of aspiration for acute stroke, 108 patients were enrolled and received treatment by direct aspiration (DA) (Penumbra System) plus (IV tPA) versus IV tPA alone. The trial was stopped early, after the publication of five Controlled Trial approving the efficacy of MT with SR, and patients managed-

Table .1.Baseline Characteristics

Variables	Thrombectomy (N = 20)	Control (N = 20)
Age, mean (SD),y	63.15 (9.76)	61.45 (9.89)
Men, No./ (%)	9 (45%)	11 (55%)
Laterality, right	11 (55%)	10 (50%)

Hypertension	10 (50%)	10 (50%)
Diabetes	7 (35%)	7 (35%)
Dyslipidemia	7 (35%)	6 (30%)
Current smoking	5 (25%)	5 (25%)
Ischemic heart disease	4 (20%)	3 (15%)
Previous stroke	2 (10%)	1 (5%)
NIHSS ^a, mean (SD)	17.55 (4)	16.75 (5.2)
ASPECTS ^b, median	8 (6-10)	7 (6-9)
Large artery athero - sclerosis	3 (15%)	3 (15%)
Cardio embolic	7 (35%)	8 (40%)
Cryptogenic	10 (50%)	9 (45%)
I.V. tPA	6 (30%)	3 (15%)

^a (NIHSS) range from 0 to 42, with higher scores indicating more severe neurologic deficit.

^b (ASPECTS) ranges from 0 to 10, with higher scores indicating a smaller infarct core.

Table 2. Primary and Secondary Efficacy Outcomes

Efficacy & Safety Outcomes	Thrombectomy (n=20)	Control (n=20)
NIHSS discharge; mean (95% CI)	13.45 (10.31-16.59)	21.95 (19.08 -24.82)
Functional independence at 3 months ≤ 2	9 (45%)	2 (10%)
Mortality	4 (20%)	9 (45%)
Spontaneous (I.C.H)	3 (15%)	4 (20%)

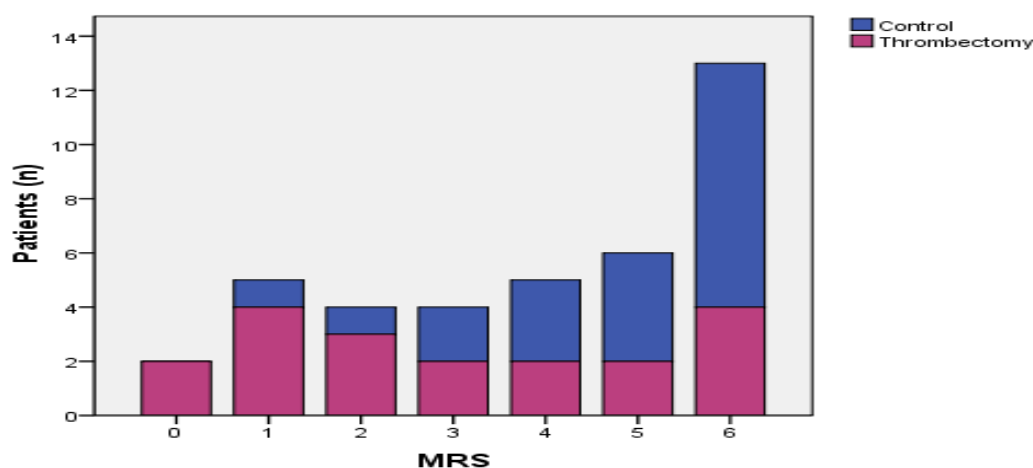


Fig.2. (mRS) score at 90 days. (0) No symptoms, (1) No significant disability (2) Slight disability (3) Moderate disability (4) Moderately severe disability (5) Severe disability (constant nursing care bedridden, incontinent) (6) Dead.

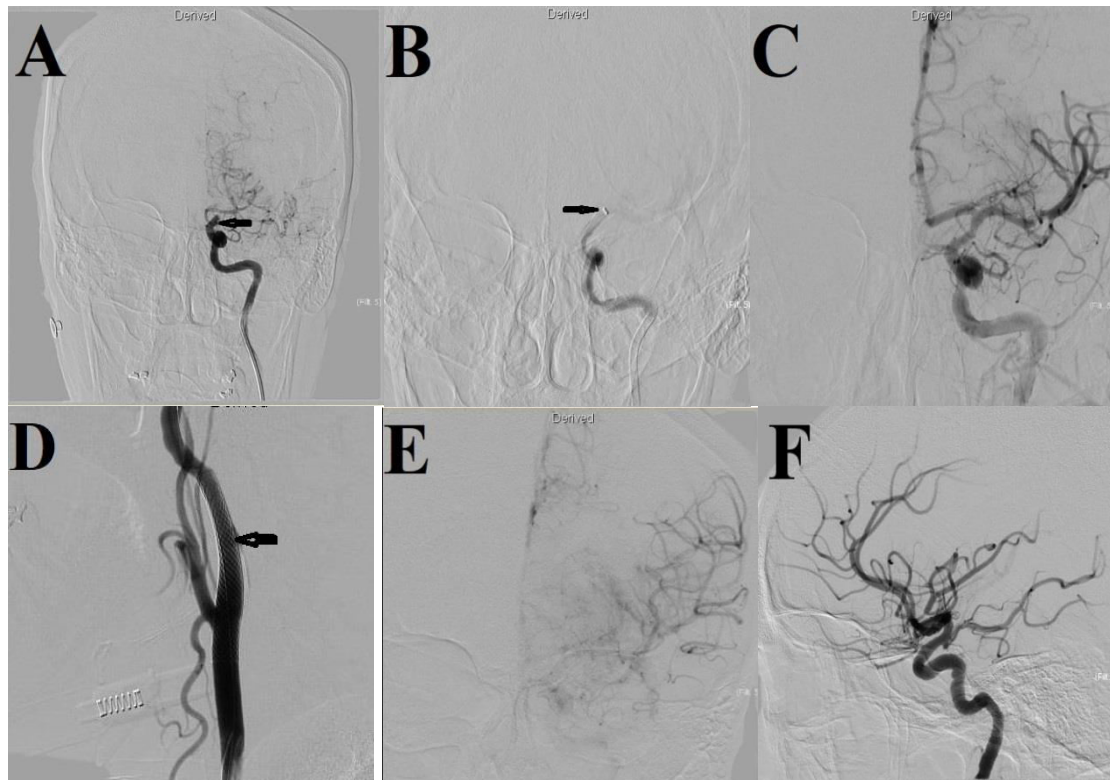


Fig.3. (A) (DSA) of (ICA) shows an occlusion M1 segment of the left (MCA) (arrow); (B) distal tip of the navien catheter was engaged in the thrombus (arrow) then the thrombus is entrapped in the catheter; (C) DSA of left (ICA) show recanalization of left MCA; (D) DSA show carotid wall stent in placed in the left common carotid artery (tandem occlusion) (arrow); (E&F) DSA shows complete perfusion of the left ICA territory.

by DA and IV tPA did not have superior outcomes (mRS 0–2) in comparison with IV tPA alone (38% vs 30%, $p=0.44$). while there is clear evidence that MT with SR is superior to best medical treatment (Mocco et al.,2016). Our analysis confirms the benefit of aspiration thrombectomy, based on data from 20 patients; the (Navien) distal access catheter (Fig.3) appears to have efficacy and safety for endovascular management of stroke, with better navigability and tractability into the distal anatomy. However, the major difficulty in accessing the intracranial occlusion in patients with arterial tortuosity. A similar result was noticed with other large-bore catheters

and it is a major limitation of the ADAPT in comparison to the stent retriever (ST) thrombectomy (Turk et al.,2014). ST was used in 10/20 (50%) patients of our study, distal access catheter could lead to increase reperfusion rate and decrease procedure duration. The percentage of patients who achieved functional independence at 90-days was significantly higher in the aspiration group (45%, vs. 10% in the control group; $P = 0.015$), our results revealed to be similar to other studies using SR for thrombectomy; ESCAPE (53.0% thrombectomy group vs. 29.3% in the control group; $P<0.001$); REVASCAT (43.7% vs. 28.2%; adjusted odds ratio,

2.1; 95% CI, 1.1 to 4.0); SWIFT PRIME (60% vs. 35%, $P < 0.001$).

No significant difference between both groups in mortality (20% vs. 45% in the control, $P = 0.088$) compared to REVASCAT (18.4% in intervention and 15.5% in control $P = 0.60$); EXTEND-IA (9% vs 20% in control).

The majority of studies comparing aspiration versus stent retriever first-line technique demonstrated similar successful revascularization rates (TICI 2b or more) both after the first-line technique and at the end of the procedure. Successful reperfusion ranged from (42–83%) after first-line aspiration, and (78–92%) after the whole procedure. Nevertheless, several studies have advocated that the percentage of patients who required rescue therapies was higher amongst patients who received first-line aspiration. A comparable result in the ASTER trial found 32.8% of patients in aspiration arm received rescue treatment compared to 23.8% in the SR arm (OR 1.57; $P = 0.05$) (Boisseau et al., 2020). Our analysis also demonstrated that procedural duration with aspiration only mean was 40 minutes, final revascularization time after the whole procedure 61.2 minutes. Conferring to the ASTER and COMPASS trials procedural time with aspiration 38 minutes, 25 minutes respectively, DA diminish mean procedural time to 7–10 min in comparison with SR. Even though this time gain, DA was not associated with improvement in patient outcomes. The probable benefits include reduction of procedural duration and treatment cost if no additional device is needed.

We had not found a significant influence with the use of general anesthesia versus conscious sedation on clinical outcome in large vessel

occlusions. Promising results favor (ADAPT). Efficacy of ADAPT has been endeavored by the newly completed Assessment of Aspiration versus ST as a First Approach (COMPASS) trial. This trial establishes no difference in functional outcomes between both groups, reperfusion rates were (92% in aspiration, 89% ST), and convey non-inferior functional outcome at 90 days matched with the ST as the first-line technique. This clinical outcome was attained with considerably lower maneuver costs for the aspiration first pass technique. The study supports the usage of the aspiration first pass technique for thrombectomy, and the results might affect recent stroke treatment recommendations (Turk et al., 2019). In the current study, we reported great effectiveness of the aspiration thrombectomy with an overall final mTICI 2b,3 rates of 90% with a mean procedural time of 61.2 minutes. These results when compared to the best device Solitaire ST since a TICI 2b,3 was observed in 71.1% of patients (Campbell et al., 2016). Similar results were reported with SOFIA Plus distal access catheter, a multicenter study enrolled 85 patients, the SOFIA Plus attained a final mTICI 2b,3 rates of 96.5%, with mean procedural time of 21 minutes, the favorable outcome was 49%, and the mortality was 20%. Another meta-analysis enrolled patients treated by ACE catheters found a 90-day good outcome of 51% and a mortality rate of 13% (Möhlenbruch et al., 2017).

Contact aspiration did not achieve superiority in revascularization rates compared with ST in the anterior circulation convening to (ASTER) trial finding (Lapergue et al., 2017).

In a meta-analysis including 1113 patients using ACE distal access catheter with possible addition of

rescue devices stated a high revascularization rate (89% mTICI 2b/3) (Gory et al.,2018). Shallwani reported that the mean time from groin entry till revascularization was 28 min from first attempt and reported that distal access catheter (Sofia PLUS) be safely used to reach full reperfusion with direct suction or in combination with ST as long as constant aspiration close to the site of thrombus. Achieving an overall reperfusion rates of 87% (TICI 2b/2c/3) using direct aspiration and/or aspiration in combination with SR. with mortality (7%), (6%) of patients had tandem occlusions. In all of these cases, the Sofia PLUS was successfully navigated through the ICA and thrombectomy was performed (Shallwani et al.,2018).

Conclusion

In our initial experience, the Navien distal access catheter appears to be safe for direct aspiration thrombectomy. Enhancement of its navigability into the intracranial vessels, need further technological change to permit fast clot aspiration without the further use of a ST. Our initial experience with this catheter has been promising. Upcoming studies, in the form of multi-center or randomized clinical trials, are necessary for further assessment regarding comparison in safety and efficacy. Contact aspiration has been a progressively standard option for MT, particularly with the latest developments in catheter technology and subsequent increase in suction force, flexibility, and less traumatic tips.

Limitations

There were several limitations to our study. Although data have been collected prospectively, the number of

patients was small, and finding contributed to only one center. The angiography was self-assessed and, consequently, the results may be biased to better mTICI scores. Direct aspiration has been a progressively prevalent decision for mechanical thrombectomy, especially with recent developments in catheter technology as increased suction force, flexibility, tractability, and fewer traumatic tip.

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