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ABSTRACT

BACKGROUND AND PURPOSE: Mechanical thrombectomy is a fundamental intervention for acute ischemic stroke treatment. While conventional techniques are effective, cyclic aspiration (CyA) shows potential for better recanalization rates. We aim to investigate factors affecting CyA and compare them with static aspiration (StA).

MATERIALS AND METHODS: StA setup consisted of an aspiration pump connected to pressure transducer. CyA was tested with 5 subsequent iterations: single solenoid valve with air plus saline (i1) or saline alone (i2) as aspiration medium; 2 solenoid valves with air plus saline (i3) as aspiration medium; complete air removal and saline feeding (i4); and pressurized saline feeding (i5). To assess the efficacy of clot ingestion, the pressure transducer was replaced with a distal aspiration catheter. Moderately stiff clot analogs (15 mm) were used to investigate the ingestion quantified as clot relative weight loss. Additionally, the aspiration flow rate was assessed for each setup.

RESULTS: With CyA i1, the amplitude of the achieved negative pressure waves declined with increasing frequencies but progressively increased with each subsequent iteration, achieving a maximum amplitude of 81 kPa for i5 at 1 Hz. Relative clot weight loss was significantly higher with i5 at 5 Hz than with StA (100% versus 37.8%; $P = .05$). Aspiration flow rate was lower with CyA than with StA (i5 at 5 Hz: 199.8 mL/min versus StA: 311 mL/min; $P < .01$).

CONCLUSIONS: CyA with the appropriate setup may represent an encouraging innovation in mechanical thrombectomy, offering a promising pathway for improving efficacy in clot ingestion and recanalization. The observed benefits warrant confirmation in a clinical setting.

ABBREVIATIONS: CyA = cyclic aspiration; DAC = distal aspiration catheter; FPR = first-pass reperfusion; MT = mechanical thrombectomy; StA = static aspiration

First-pass reperfusion (FPR) is the preferred angiographic outcome in the treatment of acute ischemic stroke due to its well-documented correlation with reduced mortality and disability rates at 90 days.[1] The latest reported FPR rates ranging from 35%–50% remain far from optimal and might be improved because final recanalization rates can be as high as 85%–95%.

In routine clinical practice, the most common aspiration methods used during mechanical thrombectomy, either alone or in combination with a stent retriever, involve syringes or aspiration pumps that generate continuous negative pressure, inducing static aspiration (StA). While these techniques have shown to be effective in removing clots,[2] they are not without limitations, notably due to the risk of clot loss or fragmentation and distal embolization during retrieval.[3] This highlights the compelling need for further improvement of the tools and techniques used during mechanical thrombectomy (MT).

Cyclic aspiration (CyA) has been presented as an evolution of aspiration in MT.[4] It relies on inducing material fatigue within the clot by applying high-frequency repetitive pressure cycles. The phenomenon is well-recognized in the field of structural engineering, where materials experiencing repeated low-intensity impacts might eventually fail and fracture.[5] In the context of MT, the clot undergoes an analogous fatigue-like behavior but in a controlled, deliberate process. CyA aims to induce accumulated damage and changes in the physical properties of the clot,

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SUMMARY

PREVIOUS LITERATURE: Previous studies have explored different approaches to CyA pointing out its superior efficacy and safety compared with conventional static aspiration techniques.

KEY FINDINGS: This exploratory in vitro study investigates various configurations of CyA, revealing the influence of factors like aspiration medium, solenoid actuation, pulse frequency, and catheter dimensions on efficacy. Optimal setups involved pressurized saline inflow and dual-solenoid systems, enhancing cyclic metrics compared with static aspiration techniques.

KNOWLEDGE ADVANCEMENT: Optimized CyA emerges as a potential important step forward in mechanical thrombectomy, suggesting improved recanalization rates and clinical outcomes in acute ischemic stroke. While further validation through clinical trials is needed, preclinical findings suggest CyA could reshape endovascular stroke treatment paradigms.

potentially creating microfractures and, ultimately, leading to rapid progressive thrombus ingestion and removal.

At its core, CyA involves the generation of an oscillating pressure wave characterized by its absolute minimal and maximal pressure values and frequency. The optimal combination of these variables will determine the dynamics of the waves and the efficacy in retrieving the clot. In theory, higher pressure amplitude per cycle and frequencies[6] should accelerate material fatigue improving efficiency in recanalization.

Modifying the CyA system setups may induce changes in the characteristics of the generated pressure waveform and, therefore, in its performance. We aim to investigate the impact of different system setups on the generated waveforms and MT efficacy to optimize recanalization outcomes.

MATERIALS AND METHODS

StA Setup

StA experiments were performed by using a commercially available aspiration pump (Penumbra) with its corresponding aspiration tubing connected to the pressure transducer (Omega Engineering) (Fig 1, STATIC).

CyA Setup

This section outlines the iterative development of a CyA setup featuring distinct experimental subgroups. Each subgroup represents a deliberate exploration of a single CyA parameter or configuration, offering insights into its potential implications for MT efficacy. The features considered being most appropriate are progressively implemented in the CyA setup.

Initial Prototype. The initial CyA configuration involved an aspiration pump (Penumbra), connected to a solenoid valve (U.S. Solid) controlled by a microcontroller (Arduino Uno). In this setup, air plus saline served as the aspiration medium (Fig 1, i1). This configuration formed the foundation upon which subsequent iterations were built to explore the parameters influencing CyA and their impact on thrombectomy outcomes.

Compressible versus Incompressible Medium. In real-case scenarios, although the distal aspiration catheter (DAC) is typically flushed with saline to prevent air presence, air bubbles can still be present in the aspiration tubing unless specifically flushed. The whole aspiration medium, including the DAC and tubing, transmits the pressure waves generated at the solenoid valve, and the presence of air can dampen these waves.

The next step involved the comparison of a compressible transmission medium (system including saline plus air bubbles) with a noncompressible medium in which air bubbles were excluded from the segment of the system going from the solenoid valve to the pressure transducer. A saline flush was connected to this portion of the system to ensure air bubbles do not progress to the referred portion of the system at any time (Fig 1, i2). Configuration without air bubbles was geared toward evaluating the performance implications of using a noncompressible medium and its impact on the transmitted pressure waveforms at the tip of the catheter.

Solenoid Valve Synergy. A second identical solenoid valve was added to the system where air plus saline served as an aspiration medium. It was set to operate at the inverse synchronic frequency of the first valve: valve 1: open/closed – valve 2: closed/open. The measure was taken to ensure that the whole aspiration pressure is directed to the catheter when valve 1 is open while allowing the saline inflow to passively neutralize the negative pressure in the catheter when valve 2 is open (Fig 1, i3).

Enhancing Aspiration Dynamics. Building on the 2-solenoid concept, in this setup we aimed to assess the impact of an incompressible medium to enhance aspiration parameters further. All air bubbles were flushed out from the system before aspiration was applied (Fig 1, i4).

The Impact of Pressurized Saline. In the final configuration, the saline inflow through solenoid valve 2 was pressurized at different pressures by using an adjustable roller pump (Stockert Instruments) (Fig 1, i5 and Fig 2). The purpose of the measure was to actively infuse saline when valve 2 is open to achieve a faster decrease of the negative pressure at the tip of the catheter. The infusing pressure could be modified to modulate the amplitude of the resulting pressure waveform.

Pressure and Flow Measurements

In the laboratory, we performed repeated experiments with StA and different setups of CyA to characterize the impact on pressure dynamics and clot aspiration efficacy. The absolute pressure values achieved and aspirated flow rates were recorded. Each experiment was repeated 5 times, and the mean values and standard deviations were reported.

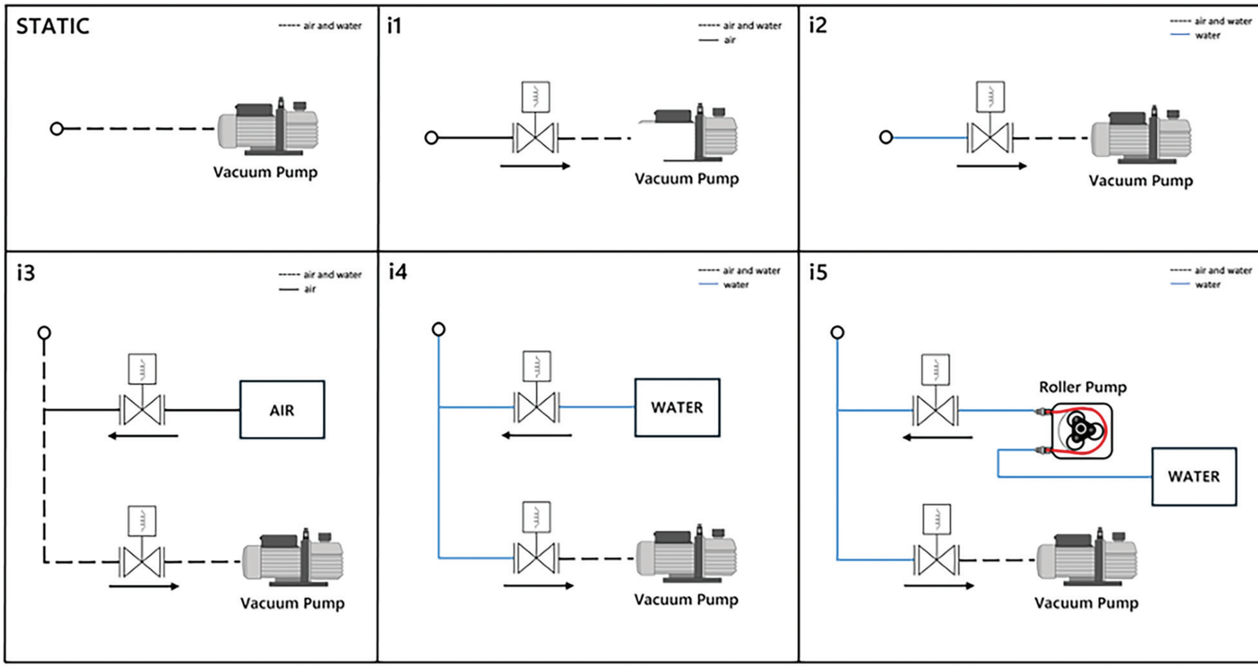

FIG 1. Graphic visualization of different aspiration setups. *i1*, CyA setup with a single solenoid valve exposed to air medium. *i2*, CyA setup with a single solenoid valve exposed to saline flush. *i3*, CyA setup with 2 solenoid valves exposed to air medium. *i4*, CyA setup with 2 solenoid valves exposed to saline flush. *i5*, CyA setup with two solenoid valves exposed to pressurized saline flush. *STATIC*, static aspiration setup composed of aspiration pump and pressure transducer.

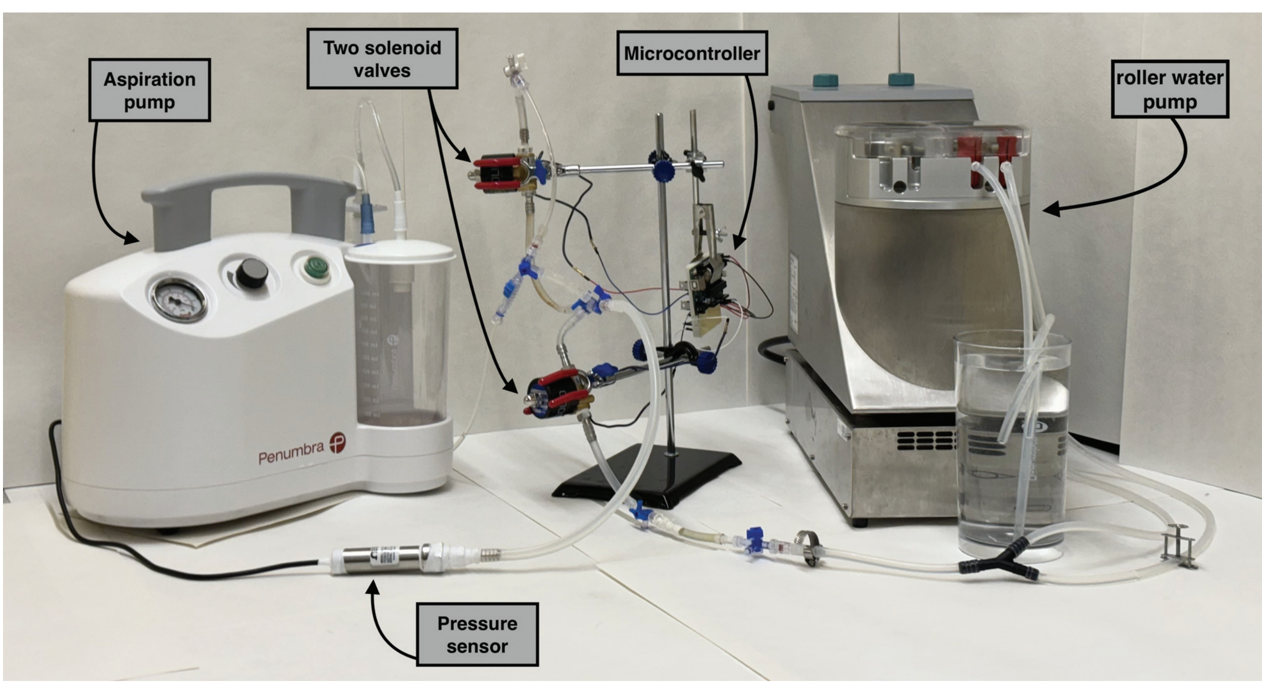

FIG 2. Visualization of the final CyA setup.

A pressure transducer was used to monitor the pressure changes at the proximal part of the catheter. The system provides a graphical interface that displays real-time pressure data, allowing for detailed monitoring throughout the experiment.

To measure the aspiration flow rate, the pressure transducer was replaced with a DAC (React 71, Medtronic) submerged in a water container. The volume per minute of water aspirated through the catheter was collected in the pump's canister and measured with a graduated cylinder.

Collapsibility Experiments

To assess the impact of the different aspiration modalities on vessel collapse, the DAC was inserted in a collapsible tube attached to a pressurized flow system simulating a cerebral artery. The collapsibility of the tube was visually observed under the different aspiration modalities.

Clot Ingestion Measurements

To determine the degree of clot ingestion under StA and predefined CyA setups, a 2.5 × 15 mm previously described synthetic clot[7] was placed in a 3-mm transparent tube simulating an artery submerged in a water container. The DAC (React 71) was advanced through the tube to the level of the clot, and aspiration was initiated and maintained for 60 seconds. To assess the degree of ingestion accurately, the clot was weighed before and after the experiment. Each experiment was repeated 5 times for each aspiration method, and the mean values and standard deviations were reported.

Impact of Aspiration Catheter Size

Pressure and flow rate under an identical CyA setup were measured at the tip of different DACs to evaluate the impact of the length and diameter of the used DAC. To assess the impact of DAC length on the effectiveness of CyA, the pressure was determined at the tip of a 0.068-inch inner diameter, 132 cm catheter length (ACE 68, Penumbra). The experiment was repeated after cutting the last 17 cm of the DAC (total length of 115 cm).

Additionally, to evaluate the influence of the DAC inner diameter on CyA parameters, 2 catheters of different diameters, 0.068 inch (ACE 68) and 0.062 inch (RED 62, Penumbra), were used. To achieve a consistent setup, the last 6 cm of the RED 62 DAC (originally 138 cm in length), were cut off to match the 132 cm length of the ACE 68. This allowed for a direct comparison of the impact of inner diameter on CyA parameters.

Statistical Analysis

All analyses were performed by using the SPSS Statistics software version 23.0 (IBM).

The Shapiro-Wilk test was used to assess the normality of the data. The Kruskal-Wallis test coupled with pair-wise comparisons adjusted by the Bonferroni post hoc method, was chosen as a statistical approach to compare aspiration setups in terms of the degree of clot ingestion, and ANOVA and Tukey post hoc tests were used to compare aspiration flow rates and pressure variables. The statistical significance was defined as $P < .05$.

RESULTS

Pressure Waveforms/Pressure Amplitudes

The obtained results reveal distinctive pressure amplitudes across various iterations of the setup, showing the trend of increased amplitude with subsequent setups ($P < .001$) and decreasing amplitude as the frequency increases ($P = .013$) (Fig 3*A* and *B*).

StA achieved an absolute negative pressure of 88.94 kPa with no variations (pressure amplitude: 0 kPa).

In the first CyA iteration (i1: 1 solenoid with air plus saline as an aspiration medium), the maximum negative pressure was achieved at 1 Hz (0.16 kPa) and the pressure amplitudes declined with increasing frequencies: 0.13 kPa at 1 Hz, 0.1 kPa at 2.5 Hz, and 0.06 kPa at 5 Hz.

For CyA iteration 2 (i2: only saline as the aspiration medium), maximum negative pressure was achieved at 1 Hz (0.55 kPa) and the pressure amplitudes declined with increasing frequencies: 0.37 kPa at 1 Hz, 0.16 kPa at 2.5 Hz, and 0.19 kPa at 5 Hz.

For CyA iteration 3 (i3: 2 solenoids with air plus saline as aspiration medium), maximum negative pressure was achieved at 1 Hz (74.33 kPa) and the pressure amplitudes declined with increasing frequencies: 73.09 kPa at 1 Hz, 48.23 kPa at 2.5 Hz, and 0.49 kPa at 5 Hz.

For CyA iteration 4 (i4: 2 solenoids with only saline as an aspiration medium), the maximum negative pressure was achieved at 1 Hz (81 kPa) and the pressure amplitudes declined with increasing frequencies: 80.81 kPa at 1 Hz, 72.13 kPa at 2.5 Hz, and 36.68 kPa at 5 Hz.

For CyA iteration 5 (i5: pressurized saline infusion), the maximum negative pressure was achieved at 1 Hz (81.02 kPa) and the pressure amplitudes declined with increasing frequencies: 79.52 kPA at 1 Hz, 72.07 kPA at 2.5 Hz, and 58.71 kPa at 5 Hz. A comprehensive data table providing detailed results for each iteration is available (Table).

Comparing the Degree of Clot Ingestion: StA versus Different CyA Setups

We performed a total of 40 experiments: 5 experiments for StA and 5 experiments each for the following configurations: i1 at 5 Hz, i2 at 5 Hz, i3 at 1 Hz and 5 Hz, i4 at 1 Hz and 5 Hz, and i5 at 5 Hz. The relative clot weight loss was the lowest for StA (37.8%) and highest for i5 at 5 Hz (100%; $P = .05$) (Fig 4*B*).

StA versus CyA: Flow Rate

Additionally, we conducted a total of 40 experiments to assess the aspirated flow rate through a DAC, by using the same setups as described in the preceding experiment. The mean aspiration flow rate was significantly higher for StA compared with CyA i5 at 5 Hz (311 mL/min versus 199.8 mL/min; $P < .0001$) (Fig 4*A*).

When the DAC was inserted in the collapsible tube simulating the cerebral artery, StA induced immediate collapse, while CyA did not (Online Supplemental Data).

Aspiration Catheter Size

When comparing catheters with equal lengths (132 cm) but different diameters (0.062 inch versus 0.068 inch), larger diameter resulted in a higher transmitted pressure amplitude (37 kPa versus 55 kPa; $P < .001$). Conversely, for catheters with the same diameter (0.068 inch) but varying lengths (132 cm versus 115 cm), the longer catheter exhibited a minimal nonsignificant reduction in the transmitted pressure amplitude as compared with the shorter one (55 kPa versus 57 kPa; $P = .5$) (Fig 3*C*).

DISCUSSION

To our knowledge, this is the first in vitro experimental study that reports a comprehensive stepwise evaluation of various configurations of CyA, revealing the pivotal factors that influence and optimize its efficacy. The most efficient configuration found was composed of 2 inversely synchronized solenoid valves, operating at a high frequency (5 Hz), where one is connected to a continuous aspiration source and the other to a pressurized saline supply. This setup yielded the optimized combination of high

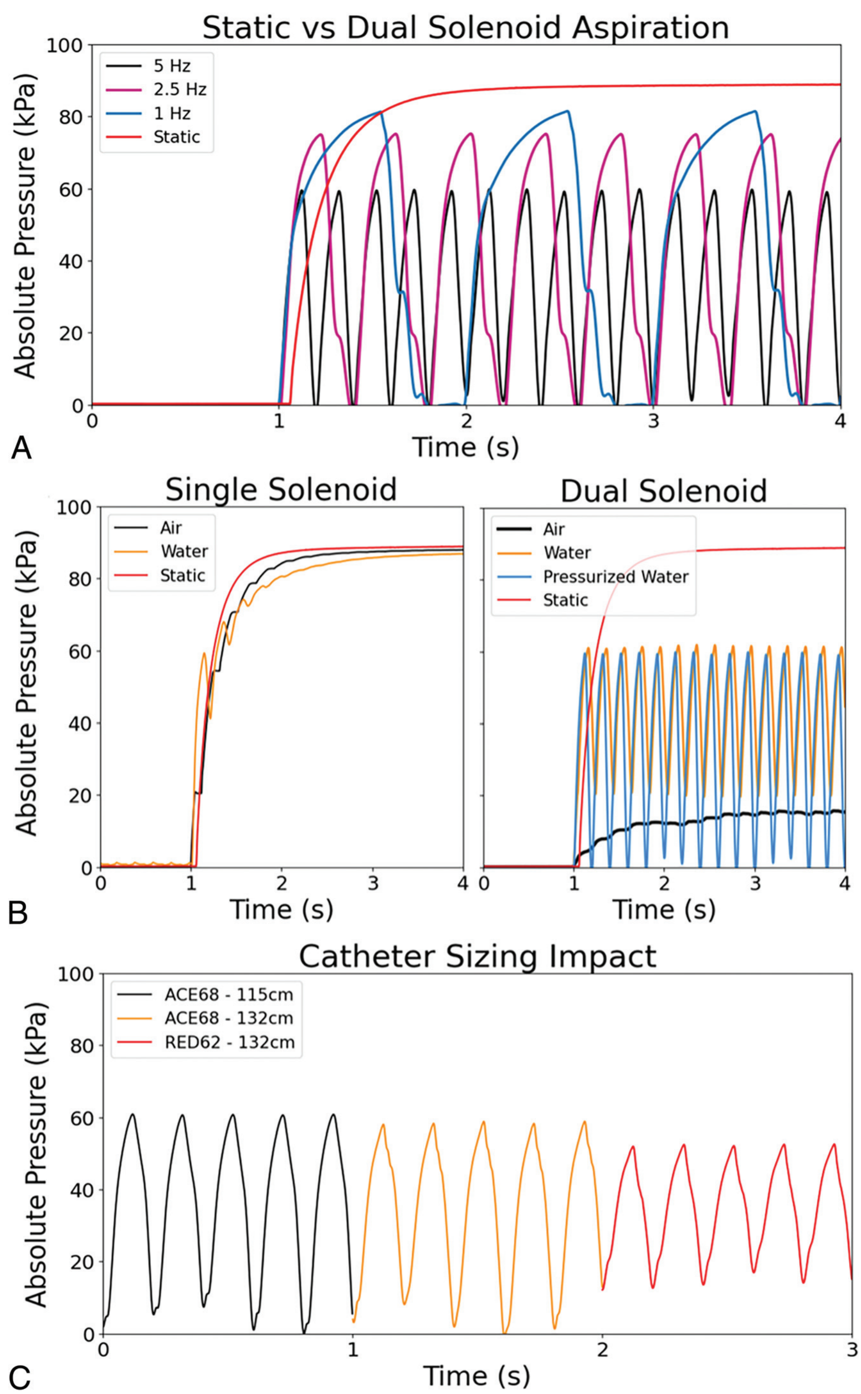

FIG 3. Waveform analysis of dynamic pressure in varied aspiration scenarios. *A*, Visualization of pressure curves comparing StA with different frequencies for i5. *B*, Visualization of pressure curves comparing single and double solenoid valves with variations in the aspiration medium for each iteration at 5 Hz. *C*, Pressure waveforms for DAC 0.068 inch 115 cm, 0.068 inch 132 cm, and 0.062 inch 132 cm measured with i5 at 5Hz.

negative pressure amplitude at a high frequency, the theoretic ideal scenario to maximize CyA efficacy in clot removal.

Experimental explorations of the physical properties of materials have shown that higher stress ranges induced varying cycling pressure amplitudes, translated to a lower number of stress cycles needed to induce fracture, meaning less time is required for material failure. In contrast, lower stress ranges need a longer time to achieve comparable outcomes. Ultimately, cyclic pressure amplitudes below a certain threshold will not induce fractures or material fatigue despite unlimited exposure.[8]

In our study, static aspiration was able to generate the highest absolute negative pressure value (88.94 kPa), which was, however, only able to ingest the experimental clots in approximately 37% of their weight. The absence of repeated pressure waveform fluctuations prevents material fatigue induction on the clot, which, most of the time, after initial partial ingestion, remains stuck at the tip of the DAC. At this stage, a rescue switch to cyclic aspiration led to rapid and complete clot removal (Online Supplemental Data).

A previous study also demonstrated that the chances of achieving complete clot ingestion were notably enhanced by the incorporation of CyA, pointing to its significant potential in improving the rate of complete clot removal.[9]

The initial setup of CyA (i1 at 1 Hz) generated an oscillating pressure wave with an amplitude that minimized over time. The recorded pressure amplitude was low due to the absence of a mechanism to release the accumulated vacuum pressure. The solenoid actuator delayed the time required for the system to reach plateau, where the maximum pressure equals that of the static aspiration. A progressive increase of the frequency under this setup (i1 2.5 Hz and 5 Hz) only led to a reduction of the observed pressure amplitude because the rapid oscillation shortened the time in which the pressure variation could be transmitted to the DAC. Moreover, the presence of air bubbles in the system, being a compressible medium acting like a spring, could also impair the fast and efficient transmission of pressure changes. As a result, despite achieving higher absolute pressure values, this setup showed similar efficiency in terms of clot ingestion compared with StA.

To ensure efficient pressure transmission, air bubbles were removed from the segment of the system distal to the solenoid valve by adding a flushing saline bag (i2). As a result, the observed pressure amplitude increased; however, the absolute negative pressures decreased because the aspiration force is now divided into 2

Summary of aspiration parameters for predefined aspiration setups

	Frequency [Hz]	Mean Amplitude [kPa] ± SD
Static aspiration	N/A[a]	0
Cyclic i1	1	0.13 ± 0.03
	2.5	0.1 ± 0.07
	5	0.06 ± 0.01
Cyclic i2	1	0.37 ± 0.17
	2.5	0.16 ± 0.1
	5	0.19 ± 0.11
Cyclic i3	1	73.09 ± 1.3
	2.5	48.23 ± 2
	5	0.49 ± 0.04
Cyclic i4	1	80.81 ± 0.2
	2.5	72.13 ± 2.68
	5	36.68 ± 2.2
Cyclic i5	1	79.52 ± 1.11
	2.5	72.07 ± 5.01
	5	58.71 ± 1.1

Note:—N/A indicates not applicable, SD, standard deviation.

pathways, the DAC on one side and the saline bag tubing on the other. Our results are in line with a previous study, where the choice of aspiration medium was an important factor, with saline providing higher initial pressure amplitudes compared with air.[10]

Because the pressure waves of i1 and i2 did not lead to a significant increase in pressure amplitude and were similar to the StA waveshape, we created i3 composed of 2 solenoid valves, where the second solenoid was exposed to atmosphere. This iteration resulted in more profound oscillations compared with setups with 1 solenoid valve. However, exposing the system to the air entrance has 2 primary drawbacks. First, the vacuum pump struggled to efficiently expel airflow from the system, leading to a gradual decline in absolute pressure over time. Second, incomplete removal of air raises concerns regarding the risk of air embolism, thus posing safety considerations.

Following single solenoid valve setups and to prevent the aspiration pressure splitting that occurred in i2, we added a saline supply to the second solenoid valve inversely synchronized with the first valve (i4). This modification enabled passive saline inflow that released the vacuum pressure in each cycle, which resulted in an increase in the absolute pressure values and oscillating amplitude. This iteration was particularly effective to improve low-frequency setups (1 and 2.5 Hz), as valve 2 (saline) was open for enough time for the saline to bring the vacuum pressure down to neutral. Nonetheless, there was margin for improvement for 5 Hz, as passive saline inflow was not sufficient to compensate for the vacuum.

To address the limited performance of the i4 for high-frequency cyclical aspiration, the final step (i5) involved adding a roller pump into the setup to pressurize the saline medium and actively reduce the negative pressure at the tip of the DAC in the intervals when valve 1 (vacuum) is closed. This resulted in a significant shift in aspiration dynamics and a substantial increase in pressure amplitude, which translated into a significantly superior efficacy in clot ingestion (Online Supplemental Data). Nonetheless, it is crucial to carefully adjust the feeding pressure because an excessive pressure reduction leading to a temporary positive pressure at the tip of the DAC may induce arterial flow reversal, clot migration, or distal embolization (Online Supplemental Data). To avoid this effect and account for the pressure in the phantom model, the maximal pressure at the catheter tip should, at most, only achieve marginally positive values.

Our additional experiments demonstrated that CyA was associated with significantly lower total aspirated fluid volumes compared with StA. In CyA, the vacuum pressure is rapidly cycling on and off, creating fluctuations in pressure within the system. These pressure fluctuations may prevent the constant intake of fluid, resulting in lower aspiration volumes. Marked reduction in the aspirated fluid volume potentially accounts for the absence of vessel collapse as the circulating pumped volume into the arterial segment remains higher than the aspirated volume. In contrast, StA, which continuously applies suction aspirating higher fluid volumes increased the risk of vessel collapse.

To maximize the benefits of CyA, optimizing specific DAC parameters becomes imperative. Our study sheds light on the significance of catheter diameter and its length in influencing CyA parameters. We found that a larger catheter inner diameter results in a higher amplitude under consistent saline flow parameters. According to the Hagen-Poiseuille equation, the viscous resistance to flow is directly proportional to catheter length and inversely proportional to catheter radius at the fourth power. Thus, the larger diameter facilitates a less restrictive flow of fluid, resulting in a higher pressure amplitude during aspiration. The lack of significant differences observed between catheters of varying lengths but with the same diameter may be explained by considering the resilience of the system to variations in length. This resilience can be attributed to the relatively smaller effect of length changes compared with the more pronounced impact of diameter changes on the volumetric flow rate, as elucidated by the Hagen-Poiseuille equation. Consequently, our findings underscore the importance of individually adjusting CyA parameters for each specific catheter, which is consistent with prior research.[11] A setup not optimized for a given catheter (length, diameter, and compliance) might decrease efficiency or even generate partial positive pressures leading to adverse events such as clot migration or embolization as described above.

Moving from the laboratory to clinical settings, the application of CyA has yielded promising results.[4] Among patients with large vessel occlusion strokes, high rates of FPR with complete or near-complete reperfusion have been reported. Importantly, the initially observed FPR rates seem to surpass those achieved with conventional thrombectomy devices, suggesting the potential advantages of CyA in clinical practice. Patients undergoing cyclical aspiration have also exhibited substantial early neurologic improvement, reduced mortality, and favorable functional outcomes, underlining the clinical benefits of CyA. The safety and efficacy of cyclic aspiration still need to be confirmed in large controlled clinical trials. However, the preliminary evidence underscores the potential of novel systems to further improve outcomes of endovascular treatment and reduce the complexity and cost associated with treating large vessel occlusion strokes.[12]

Limitations

While our study describes valuable insights into the effectiveness of CyA and its influencing factors, it is important to acknowledge several limitations.

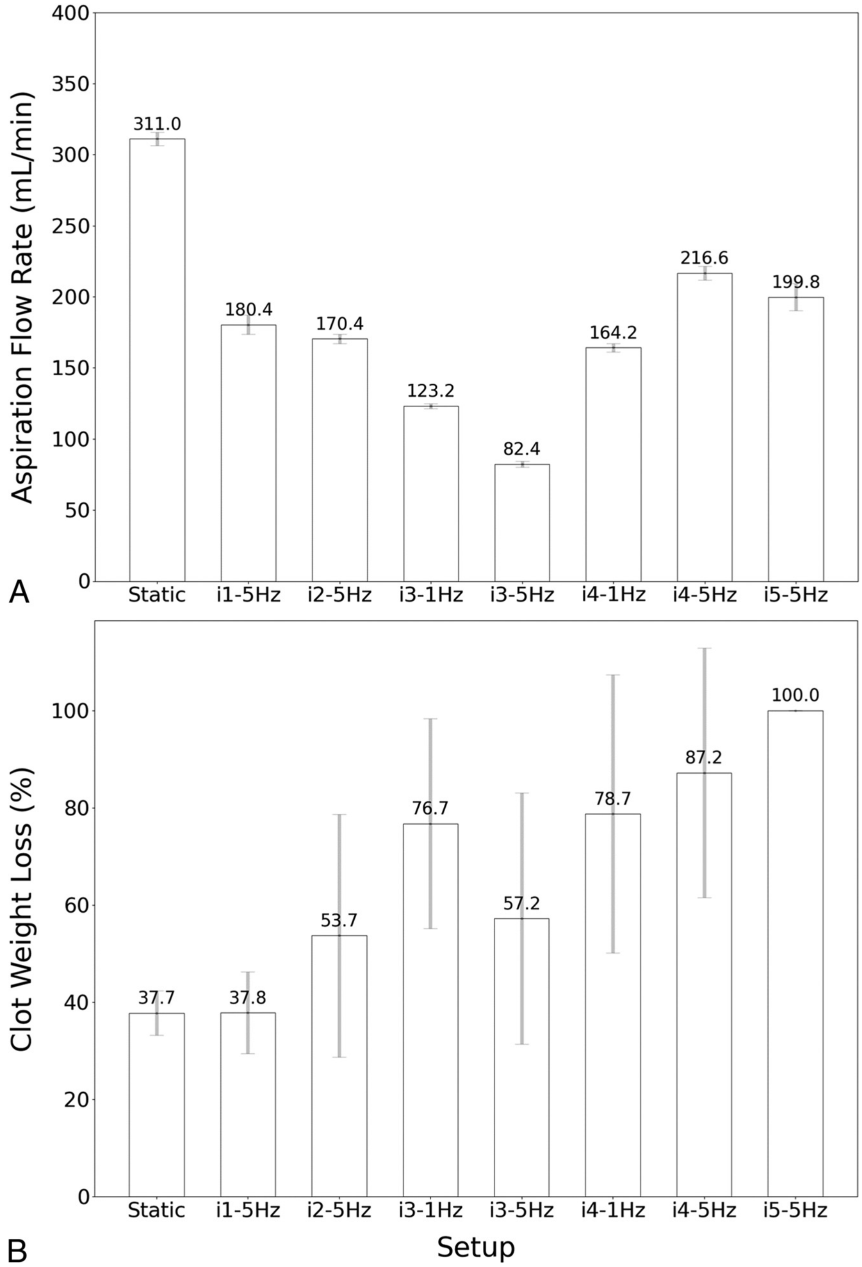

FIG 4. Summary of the results of aspiration flow rate (*A*) and relative weight loss (*B*) for predefined aspiration setups.

Our experiments were conducted in a simplified in vitro setup. While this approach allows for controlled testing, it cannot fully replicate the complexities of in vivo conditions. Real-world clinical scenarios involve diverse patient characteristics, variations in clot length, diameter, and composition, arterial pressure, and dynamic vessel responses that may affect thrombectomy outcomes differently.

We utilized medium stiff clot analogs in our experiments, which may not perfectly mimic the full range of physical properties of human clots. The mechanical and compositional differences between clot analogs and human clots could influence the outcomes observed in our study.

The number of experiments conducted for each setup configuration was relatively limited. While our results are informative, a larger sample size and additional repetitions could enhance the statistical robustness and general applicability of our findings.

Despite these limitations, our study provides a foundation for understanding the potential benefits and challenges associated with CyA in MT. Further research, including clinical trials and in vivo studies, is essential to validate our findings and determine the clinical utility of CyA in improving patient outcomes.

CONCLUSIONS

CyA emerges as a significant evolution for MT, holding the potential to enhance recanalization rates and clinical outcomes in patients with acute ischemic stroke. While further research and randomized controlled trials are warranted to validate its safety and efficacy, the evolving body of evidence suggests that CyA techniques have the potential to improve the landscape of endovascular stroke treatment. This study serves as a valuable resource for clinicians and researchers seeking a comprehensive understanding of cyclic aspiration in MT.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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