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ORIGINAL ARTICLE

Comparison of Vacuum Pressure Syringe Aspiration Technique with Penumbra Aspiration Thrombectomy System: an In Vitro Study

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ABSTRACT

Objective: *In aspiration thrombectomy, a 60-mL syringe has a higher aspiration force than a 20 inHg aspiration pump. The recommended pressure of a new pump (Penumbra Pump MAX) is 28.5 inHg. We evaluated and compared the negative pressure flow rates during aspiration from locked syringes to the Penumbra Pump MAX. We also sought to determine how an increase in syringe volume affects the duration and volume of aspiration phases.*

Methods: *A Penumbra Pump MAX, a 60-mL VacLok negative pressure syringe, and a 100-mL syringe were used as negative pressure generators and were connected to catheters. The pump was allowed to reach its peak negative pressure at 28.5 inHg before aspiration. The 100-mL syringe was pulled to 60, 70, 80, and 90 mL and locked. The mean flow rates (mL/s) and standard deviations were calculated.*

Results: *The 60-mL syringe created higher flow rates than the Penumbra Pump MAX at 28.0 inHg (5.51 vs. 5.01 mL/s). Every 10 mL increase in syringe volume extended the plateau phase by 2 s without altering the flow rate, acceleration phase, or deceleration phase.*

Conclusion: *The aspiration power of the two negative pressure generators was comparable. Increasing syringe volume directly increases the effective aspiration time.*

Key Words: *Hydrodynamics; Stroke; Suction; Syringes; Thrombectomy*

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Ethics Approval: This study included no human or animal subjects; ethics approval was not required.

Declaration: We certify that this work was poster presented at the XXI Symposium Neuroradiologicum during 19-23 March 2018 at Taipei, Taiwan, and no work resembling the enclosed article has been published or is being submitted for publication elsewhere.

中文摘要

真空壓力注射器抽吸技術與Penumbra抽吸血栓切除術的比較：體外研究

C Kobkitsuksakul、T Jaroenngarmsamer

目的：在抽吸血栓切除術中，60 mL注射器的抽吸力比20 inHg抽吸泵更高。新一代Penumbra Pump MAX的建議壓力為28.5 inHg。本研究旨在評估和比較 Penumbra Pump MAX 和不同容量的鎖緊式注射器在抽吸時的負壓流速，並檢視注射器容積增加時如何影響不同抽吸時相的持續時間和容積。

方法：將Penumbra Pump MAX、60-mL VacLok負壓注射器和100-mL注射器用作負壓發生器並將其連接到導管上。抽吸前使泵達到其最大負壓的28.5 inHg。將100-mL注射器拉至並鎖定於60mL、70mL、80mL和90 mL，計算其平均流速（mL / s）和標準差。

結果：60-mL注射器在負壓為28.0 inHg時產生的流速（5.51 mL / s）高於Penumbra Pump MAX（5.01 mL / s）。注射器容積每增加10 mL時流速平穩期可延長2秒而不改變整體流速、加速時段或減速時段。

結論：兩種負壓發生器的抽吸力相若，增加注射器容積可增加有效抽吸時間。

INTRODUCTION

In the treatment of acute ischaemic stroke, syringes or an aspiration pump are used as negative pressure generators. They are used exclusively in aspiration thrombectomy, in which the distal end of a large-bore catheter directly aspirates a clot at large vessel occlusion sites.[1,2] They are used adjunctively in stent-retrieval thrombectomy (Solumbra technique), which combines stent retrieval with suction thrombectomy.[3] In both methods, the choice of a negative pressure generator is up to the interventionists, who take into consideration the pros and cons of both devices, including aspiration power and, for syringes, the size (20-60 mL).

A recent study showed that the aspiration power of a 60-mL locked syringe (a syringe pulled and locked at 60 mL in a closed system to create negative pressure) was higher than the pressure of an aspiration pump (20.0 inHg, recommended by the manufacturer). Even though the pump could reach its highest negative pressure at 26.5 inHg, the syringe force was still superior to the pump.[4] A new device, the Penumbra Pump MAX (Penumbra, Inc., Alameda [CA], US) has a recommended pressure of 28.5 inHg, raising the question as to whether the 60-mL syringe still has a higher aspiration force than a 28.5-inHg aspiration pump.

A study by Simon and Grey[5] indicated that the dynamic pressure and average flow rate of the Penumbra System pump were lower than all syringe sizes (3-60 mL). The larger the syringe, the higher the static and dynamic pressure attained. However, the pump had higher static pressure than all syringe sizes.[5] This contradiction of higher static pressure and lower dynamic pressure of the pump compared with syringes led us to focus mainly on the dynamic rather than the static characteristics of aspiration. Moreover, a newer pump, the Penumbra Pump MAX, with a higher adjusted pressure (28.5 inHg vs. the studied pump 26.5 inHg) has been developed, suggesting that a new comparison would be relevant.

The primary objective of this study was to evaluate and compare the flow rates during aspiration created by negative pressure from locked syringes to the Penumbra Pump MAX, while the secondary objective was to determine how a larger 100-mL syringe affects time and volume of phases of the aspiration.

METHODS

A Penumbra Pump MAX, a 60-mL VacLok negative pressure syringe (Merit Medical System Inc., South Jordan [UT], US), and a 100-mL syringe (Wilburn Medical, Kernersville [NC], US) locked by an external device were used as negative pressure generators. The Penumbra Pump MAX, together with a MAX Canister and high-flow aspiration tubing, were connected to a Penumbra ACE68 reperfusion catheter as per the standard method. The pump was allowed 30 s to reach its peak

negative gauge pressure of 28.5 inHg before aspiration for 120 s. The aspiration characteristics were defined as the acceleration phase at the beginning of aspiration; followed by the plateau phase, where the aspiration rate was constant; and ended with the deceleration phase. Syringes were connected to a two-way valve before connection to the ACE catheter. Since the largest volume of a lockable syringe commercially available is 60 mL, the 100-mL syringe was pulled to initial volumes of 60, 70, 80, and 90 mL and locked using two steel Vernier callipers. Negative pressure was created before the valve was opened until the flow rate reached the deceleration phase and aspiration stopped. The experiment was set to mimic free-flow aspiration using water as a medium. The weight of water aspirated at the distal tip of the catheter was recorded every 2 s by a two-digit digital analytical balance device, and the mean flow rate (mL/s) was calculated at the plateau phase for the syringes and at 2 s to 120 s for the pump. The first 2 s were the acceleration phase of all equipment and were excluded from the calculation. Each experiment was repeated 10 times (n = 10), and the mean flow rates (mL/s) and standard deviations of the samples were calculated.

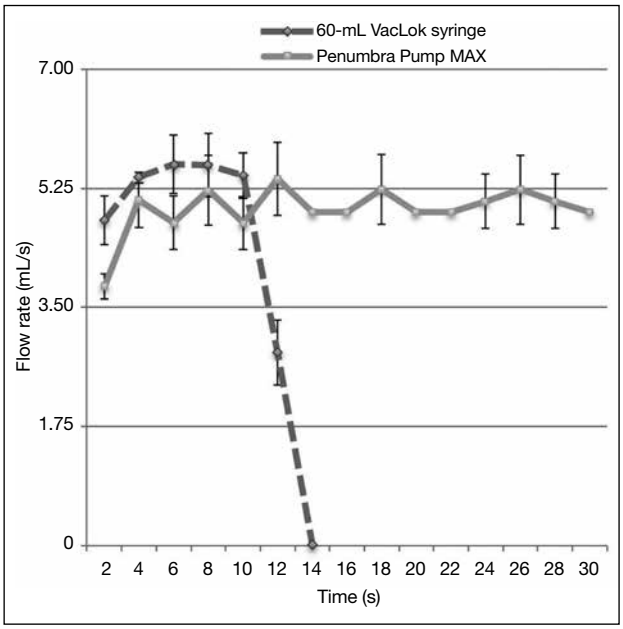

Figure 1. Flow rates of a 60-mL VacLok syringe and the Penumbra Pump MAX.

RESULTS

The Penumbra Pump MAX created a constant flow rate without a plateau phase, while the 60-mL VacLok syringe created higher flow rates than the Penumbra Pump MAX (5.51 mL/s vs. 5.01 mL/s, $p < 0.001$) [Figure 1].

The hydrodynamic character of all syringes began with an acceleration phase for 2 s, followed by a plateau phase, and ended with a deceleration phase before fluid filled the syringes. The 60-mL VacLok syringe and the 60-mL initial volume of the 100-mL syringe had the same 8-s plateau phase even though the latter created a slightly higher average flow rate (5.51 mL/s vs. 5.73 mL/s, $p<0.001$) [Figure 2].

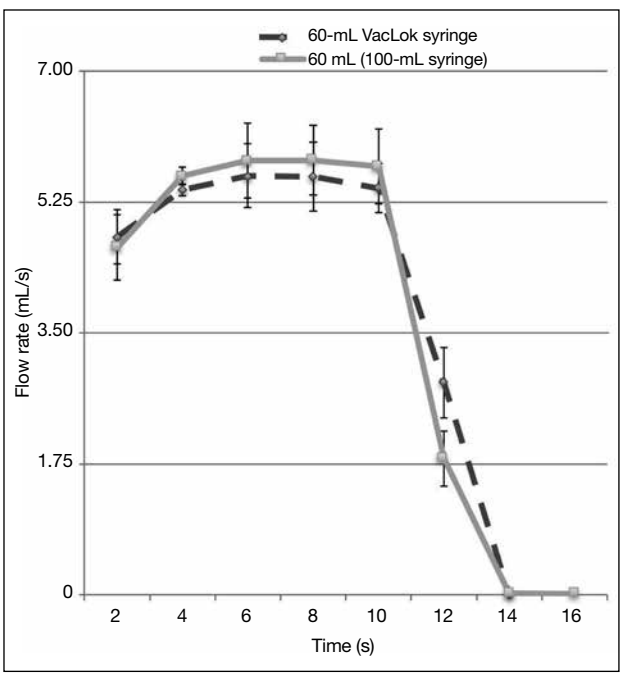

Figure 2. Fow rates of the 60-mL VacLok syringe and an initial volume of 60 mL in a 100-mL syringe.

For the plateau phase of the 100-mL syringe, the larger the initial volume, the longer the achieved plateau phase was, that is, 10 s (70 mL), 12 s (80 mL), 14 s (90 mL) [Figure 3]. Flow rates of all initial volumes were comparable with one another.

DISCUSSION

Even though the 60-mL VacLok syringe generated a higher flow rate than the Penumbra Pump MAX, the syringe had a flow rate comparable with that of the pump, which was tested by the company at 5.51 mL/s versus 5.47 mL/s (unpublished data, 2017). This may be due to lower maximal negative pressure reached by the pump in this experiment at 28 inHg, an acceptable range for standard treatment, compared with the 28.5 inHg reached by the company. This means the Penumbra Pump MAX must always reach 28.5 inHg to achieve equal aspiration power as a 60-mL VacLok syringe. The

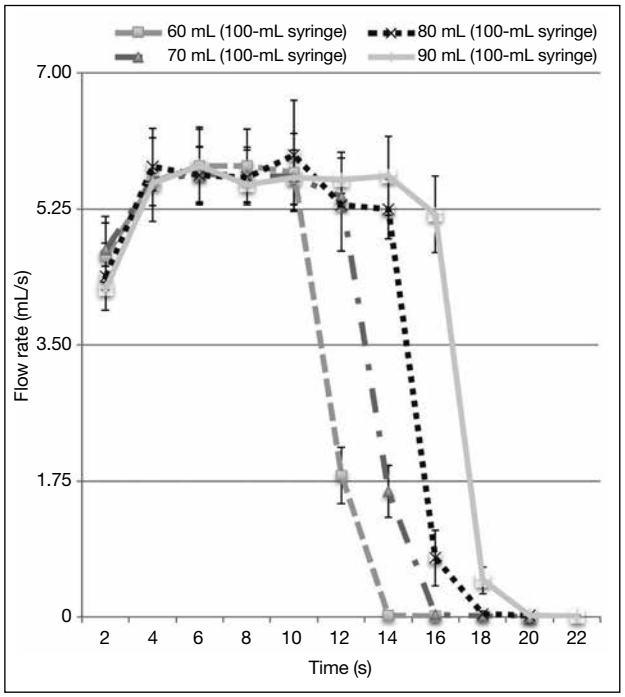

Figure 3. Flow rates for initial volumes of 60 mL, 70 mL, 80 mL, and 90 mL in a 100-mL syringe.

flow rates of this study were higher than previous results due to a larger bore of ACE68 catheter (1.73 mm) versus 5MAX catheter (1.37 mm).[5]

In practice, phases will be volume-dependent instead of time-dependent (Table). Whenever the catheter fully engages the clot, no flow enters the catheter and the negative pressure will remain constant at that volume-specific phase. The aspiration capability will be extended, especially in blood with high viscosity. In the partial flow condition, a 60-mL syringe could reach >60 s of its plateau phase in a blood-like fluid as shown in a previous study.[4] However, in the worst-case scenario of dislodgement of a partial clot, the flow may enter a near free-flow stage, and the syringe may not reach the stated time, <30 s in water aspiration. In contrast, an aspiration pump is able to aspirate in a free-flow condition for >120 s, outperforming the short plateau phase of the 60-mL VacLok syringe and with no doubt the routinely used 20-mL and 50-mL syringes. With a limited plateau phase, syringes cannot be used in the new CAPTIVE technique,[6] which requires long aspiration times before, during, and after stent retriever deployment.

For the experiment using a larger syringe to observe the changes in hydrodynamic characteristics of water aspiration, the plateau phases in the 60-mL VacLok syringe and 60 mL initial volume of the 100-mL syringe were equal, but the mean flow rates slightly differed ($p < 0.001$), probably due to the different materials and designs of both syringes.

The increase in syringe volume extended the duration of the plateau phase without altering the duration of the acceleration phase and deceleration phase and the flow rate. Since the volume of fluid aspirated determined phases, aspiration should be terminated before the deceleration phase, which is 5 mL before the full capacity (60, 70, 80, or 90 mL) of the 100-mL syringe in water aspiration. The increase in syringe volume was equal to the increase in the plateau phase volume. However, a large, lockable syringe is currently not manufactured, and the use is also limited to interventionists who have enough strength to pull the syringe under a vacuum.

For every 10-mL increase in syringe volume, the plateau phase time was extended by 2 s in water aspiration (Table). Because of this linear correlation, we postulated that for every 10-mL decrease in syringe volume, the plateau phase time would be reduced by 2 s until the plateau phase vanished in a ≤20-mL syringe. This hypothesis is consistent with the low percentage (59%) of recanalisation by a 20-mL syringe manual aspiration thrombectomy.[7]

Table. Comparison of volume aspirated by syringes and the Penumbra pump MAX.

Negative pressure generator	End of phase I (acceleration phase)		End of phase II (plateau phase)		Length of phase II (s)
	Volume aspirated, mL	Time required, s	Volume aspirated, mL	Time required, s	
60-mL VacLok syringe	9.57	2	53.64	10	8
60 mL (100-mL syringe)	9.29	2	55.16	10	8
70 mL (100-mL syringe)	9.47	2	65.64	12	10
80 mL (100-mL syringe)	8.76	2	76.06	14	12
90 mL (100-mL syringe)	8.46	2	86.67	16	14
Penumbra pump MAX	7.61	2	298.80	120	-

Interventionists can now consider the advantages and disadvantages of the 60-mL VacLok syringe and the 28.5 inHg Penumbra Pump MAX regardless of the comparable flow rates. Syringes are cost-effective,[4] quick and straightforward to assemble, and easy to use[8]; however, they do require strength to create negative pressure and have a short plateau phase, demanding multiple disassembly and reassembly cycles in multiple aspirations. The aspiration pump has a high capacity with an extended constant flow rate without the need for reassembly, but it requires preparation time for the assembly of the apparatus and for the negative pressure to reach 28.5 inHg before aspiration can be initiated.

Since this study was an in vitro experiment based on water aspiration in a free-flow model, it reflects the real treatment of mechanical thrombectomy in a limited way, as blood has higher viscosity, which may result in lower aspiration rates and a less precipitous acceleration phase. The free-flow model of this study also could not reflect full-clot engagement in the real thrombectomy, which would increase the effective aspiration time. However, partial clot engagement or clot dislodging could be encountered in real-life treatment, creating a free flow similar to this model. Despite the above limitations, the aspiration rate created by both syringes and the pump was shown to have the same characteristic acceleration and plateau phases. Future research should consider using alternative blood-like fluid, or in vivo experiments should be conducted, focusing on finding the syringe aspiration termination volume. Syringes should be designed to indicate the termination volume and to have high capacity while being labour-saving in the meantime.

In conclusion, interventionists can consider the advantages and disadvantages of the two negative pressure generators regardless of the comparable aspiration power in the treatment of acute ischaemic stroke. Moreover, the increase in syringe volume directly increases the time of effective aspiration without altering the aspiration force.

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