Review of hemodynamics in direct aspiration thrombectomy for the treatment of acute ischemic stroke

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ABSTRACT

Introduction: Acute ischemic stroke (AIS) is a common and lethal cerebral vascular disease. Early thrombus removal is crucial to the patient treatment and recovery. Clinical studies suggested that Direct Aspiration Thrombectomy (DAT) is a promising minimally invasive treatment option for AIS patients. It is necessary to summarize the hemodynamic studies about the DAT for further improvement of the technology. **Methods:** This paper reviewed the current in vitro and computer modelling studies of the hemodynamic response in the DAT, commenting on the merits and the deficiencies in the related research works reported in the literature. **Results:** Review of literature reveals that majority of current studies were focused on the comparison of the responses produced by using various suction systems on catheters of different calibers. For future technical improvement to facilitate clinical treatment, we suggest that further research to concentrate on more in-depth hemodynamic analysis of the DAT procedure, including replacement of the constant suction pressure with pulsatile suction pressure, comparison of contact aspiration and non-contact aspiration, and optimization of catheter tip design. **Conclusions:** This review summarized the concurrent technical development about the hemodynamic studies of the DAT technique and suggested directions for future improvement, which is helpful for the improvement of the AIS treatment planning and design optimization of next generation of interventional catheters.

Keywords: Acute ischemic stroke, direct aspiration thrombectomy, mechanical thrombectomy, thrombus.

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INTRODUCTION

Acute ischemic stroke (AIS) is a common but lethal cerebral vascular disease. It occurs suddenly, develops rapidly, exhibits severe symptoms, and causes high incidences of disability and mortality. The pathogenesis is the acute closure of a segment of the cerebral artery caused by thrombosis or arteriosclerosis plaques falling off the walls of the diseased blood vessels, which in turn causes a series of irreversible physiological pathological reactions such as depolarization of tissue, inflammatory response, apoptosis etc. in distal ischemic brain tissue.[1] Early removal of the thrombus and restoration of the blood flow in the blocked vessels are essential in the treatment of AIS.[1] Based on a series of clinical randomized controlled trial studies,[2–4] professional bodies such as the American Stroke Association have recommended the catheter-based mechanical thrombectomy (MT) as the primary treatment option for the AIS patients.[5–8]

Mechanical thrombectomy for AIS treatment has experienced rapid development in the past decade, with a number of interventional devices designed for usage in the operation.[9] Among the various types of design implementations, direct aspiration thrombectomy

(DAT) represents the latest development in the area.[10,11] Different from other implementation examples which mostly rely on mechanical structures to trap or hook the thrombus for clot removal, DAT exerts a sucking force onto the thrombus surface and extracts the clot through aspiration, which is much simpler and cheaper to conduct. A number of review papers have been published over the past years, to summarize the various types of MT devices invented including the DAT and explain their design features,[2,4,9,10,12–19] to outline the scenario of MT therapy[14,16,20,21] and the common complications associated to MT therapy,[10,22] and to compare the efficacy of different MT devices demonstrated in clinical trials to aid device selection.[2–4,9,10,12–17,20–27] These reviews effectively depicted the concurrent development of the MT technique including the DAT, and served as valuable guidance for further advancement of the MT as well as the DAT technique.

Accompanying the aspiration operation, blood flow during DAT intervention demonstrates a complex flow pattern, which is governed by sophisticated hemodynamic interactions among the blood, the thrombus body, the vessel wall, and the catheter tip. Obviously such hemodynamic responses are directly attributed to the geometry of the catheter tip and the operational protocol, and these in turn strongly influence the outcome of the treatment. Hemodynamic studies on DAT form the foundation for the optimization of device designs to enable safer surgical intervention and better therapeutic outcomes, thus attract the attention of both scientific researchers and industrial manufacturers. So far there is no systematic review on the hemodynamic studies on DAT in the open literature. To fill the gap we searched the literatures, summarized the hemodynamic studies in DAT, commented on the problems in the current studies, and suggested directions for future efforts.

METHODS

Figure 1 illustrates the flow chart of the literature review process in this study. We searched the mainstream technical databases of Web of Science and PubMed using the keywords "aspiration thrombectomy", "hemodynamics" and "haemodynamics" and setting the time range as from January 1, 2004 to January 1, 2024, and retrieved a total of 135 research papers related to thrombus aspiration, among which 57 papers described the useful technical information about hemodynamic studies in the aspiration thrombectomy and were included in the current analysis. These literatures are the main source of information and target of analysis in the current study. The following parts analyze the technical information collected and commented on the concurrent development in the DAT field.

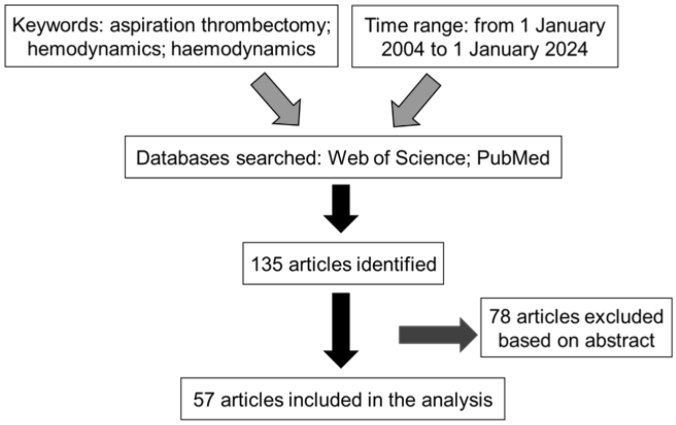

Figure 1: Flow chart of the literature review process

RESULTS AND DISCUSSION

Current status of the aspiration thrombectomy

For the MT implementation, usually the femoral artery is punctured for catheter insertion. A mechanical thrombus removal device is fixed to the distal end of the intervention catheter. The doctor manipulates the catheter and sends the thrombus removal device to the diseased vessel segment for thrombus removal. A number of thrombus removal devices have been designed for the purpose. Among them the famous ones include the first-generation corkscrew-shaped Merci device, the second-generation separator and aspiration-based Penumbra device, and the third-generation self-expandable stent based Stentriever device.[9] These thrombectomy devices rely on grabbing, smashing, and clamping the thrombus for removal, which can cause damage to the vessels and induce bleeding, and lead to clot fragmentation with many micro-clots forming and escaping from the removal device to the downstream vessels, thus blocking more distal vessels.[10] In addition, these devices sometimes develop mechanical failure, and are unable to work on the stiff clot pieces. In recent years, the latest generation of the DAT technique has been developed to address the above problems.[10,11] In the DAT technique, a flexible large caliber catheter is inserted directly to the proximal side of the blood clot, and a negative pressure is applied in the catheter to suck and remove the thrombus. Since the DAT is entirely based on the suction rather than mechanical lodging and embedding, it causes much less mechanical damage to the blood vessels and significantly reduced thrombus fragmentation. In addition, the DAT technique does not involve those complex mechanical structures as used in the earlier generations of device, thus avoiding the possibility of mechanical failures. Clinical studies have shown that DAT can achieve the same revascularization rate[26,28] and the same rate of first pass effect[20,29] (which designates a near complete revascularization obtained after a single device pass with no rescue therapy, and thus leads to improved clinical outcome and decreased mortality) as the stent retrieval devices (which is most widely used in the clinical treatment of AIS presently),[26,28] with increased safety,[26] shorter operation time,[30] while save approximately $20,000 per patient in the treatment cost.[28] Overall, DAT has promising clinical prospect.

The DAT technique does not use the stent and other expensive consumables as happened in the previous generations of the MT system, only the suction catheter needs to be dispensed to the proximal end of the thrombus, and then a negative pressure is applied to suck and remove the thrombus. This has the advantages of saving the expense and operation time, while it also raises a new issue of controllability: the only thing requiring control during the DAT procedure is the suction pressure. How to set the suction pressure to achieve a balance between efficiency and safety becomes an important issue. For efficiency, the magnitude of the suction pressure should be set as high as possible, so as to quickly loosen and remove the thrombus trapped in the vessel and suck the clot fragments and prevent them from escaping to downstream vessels. However, for safety reasons, the magnitude of the suction pressure should be maintained to as low as possible, to protect the fragile cerebral arteries. Lower magnitude of the suction pressure helps to avoid the formation of high-speed jet and thus the high shear stress near the vessel wall, which is the main cause of mechanical damage to the vessel wall. This happens in the situation of uneven thrombus surface (which is true in most of situations) or the tilting catheter tip. In extreme situations of careless manipulation, the catheter tip may be tilted too much, so that the suction is directed towards the vessel wall instead of the thrombus, thus causing direct damage of the vessel wall and bleeding. Therefore, setting the suction pressure level should take into account the property parameters and the response parameters including the surface tension of the thrombus, the friction between the thrombus and the vessel wall, the magnitude and the pattern of changes of the wall shear stress, the specific location of the clotted vessel, etc.

In order to achieve the optimal treatment outcome under the constraints of these complex and often contradictory factors, it is necessary to observe in detail the flow phenomenon and quantify the dynamic changes of blood flow in the DAT procedure, and understand in-depth the underlying mechanism of the dynamic interactions involved. Due to the small caliber and the complex geometry of the cerebrovascular vessels, this aim is not possible to achieve through clinical observations or animal experiments, and has become a bottleneck in the development of the DAT technique.

Current status of the DAT studies

To improve the DAT technique researchers have carried out a lot of theoretical and experimental studies. These mainly focused on the comparison of the responses produced by using various clinical suction systems on catheters of different calibers, and collecting results data in large numbers of case studies to find out the most effective aspiration parameters. To evaluate the effectiveness of different DAT systems, Froehler et al.[31] measured the suction pressure generated by three suction devices of different brands, and the suction force and flow generated by these devices when they acted on catheters of different inner diameters. Nikoubashman et al.[32] derived an equation for the minimum catheter diameter based on the force balance relation in the DAT system, and validated the results against the data measured in pigs. Alawieh et al.[33] studied the suction force and the therapeutic effect of two suction pumps used clinically, and proved that high suction pressure is beneficial for the improvement of the efficiency in the operation. Yaeger et al.[34] used polyvinyl alcohol gel to produce artificial thrombi, and conducted in vitro experiments to compare the suction force generated by applying several commercial DAT pumps on commonly used large diameter catheters. Results showed that the larger the inner diameter of the catheter, the greater the suction force produced. Other researchers further used the suction flow as the evaluation index. Simon et al.[35] tested the suction pressure, suction force, and suction flow generated by applying different DAT pumps and syringes on a series of catheters of different calibers. Results show that under the same suction pressure, the larger the inner diameter of the catheter, the greater the suction flow produced. Hu et al.[36] conducted similar measurements. Kallmes et al.[37] pointed out that in a considerable number of DAT operations, the thrombus was adsorbed to the catheter tip and then taken out of the body with the catheter withdrawal, rather than being sucked into the catheter and discharge directly and immediately, thus comparing the suction flow generated in different pump and catheter combinations was not of great practical significance.

These studies have provided a wealth of knowledge about DAT and promoted the development of the technique, but they were mostly limited to the inspection of the suction process, focusing on the measurement of those clinically observable variables including the suction pressure, the suction force, the recanalization rate, the duration of DAT operation, the number of thrombus fragment escaped etc., and the evaluation of the effectiveness of the DAT based on the comparison of these variables in different case studies. They have not worked on in-depth analysis of the physical mechanism of DAT, such as how physical properties like viscosity, surface tension etc. of the thrombus influence the local velocity, pressure, shear stress distributions, thus changing the interactions between the blood, the thrombus, the vessel wall, and the catheter. In addition, in evaluating the performance of different commercial DAT systems, these studies over-emphasized the importance of the bigger magnitude in the suction pressure which facilitated the clots removal, while neglected that the high suction pressure potentially causes mechanical damage to the vessel wall.

New research directions for the technical improvement of DAT

To facilitate technology transfer of DAT and its full-scale usage in clinical practice, it is imperative for the next stage of DAT study to focus more on the hemodynamic analysis and study the fundamental fluid mechanics in the thrombus aspiration process. By referring to the forefront development of DAT, there are three potential topics deserving to be explored for the technical improvement of DAT: 1. Replace the constant suction pressure with the pulsatile suction pressure: using a low amplitude pulsatile suction pressure to replace the high amplitude constant suction pressure currently in use, which helps to reduce the mechanical damage to the vessel wall while maintaining the efficiency of thrombus removal; 2. Choose between the non-contact suction and the contact suction: unlike the current mainstream operation which presses the catheter tip tightly onto the proximal surface of the blood clot, deliberately maintaining a small gap between the catheter tip and the surface of the thrombus helps to avoid squeezing the thrombus and causing the thrombus fragmentation, and possibly this works more effectively; 3. Optimize the geometry design of the catheter tip: evaluating different geometry designs of the catheter tip and analyzing the specific flow field changes in each case, identifying the optimal ones which improve the efficiency of thrombus removal and reduce the damage to blood vessels at the same time.

Using pulsatile or constant suction pressure

Simon et al.[38] connected the Penumbra 5 Max catheter to the Penumbra suction pump to study the thrombus removal in vitro on a mock cerebral flow test rig, and compared the pumping efficiency under constant and periodic pulsatile suction pressure. They found that the aspiration speed and the removal rate under periodic pulsatile pressure mode were better than those for the constant pressure mode. Arslanian et al.[39] conducted similar in vitro test, and found that using the periodic pulsatile suction helps to achieve better first-pass success rate and reduce the occurrence of thrombus fragmentation compared to using the constant suction. Although these were preliminary studies and did not advise which specific profile for the pulsatile pressure change was conducive to clinical adoption, nevertheless they confirmed the feasibility of using pulsatile suction in the DAT.

Good et al.[40] neglected the blood flow, and used finite element analysis to calculate the shape change of the thrombus under both constant and pulsatile suction. Also they fabricated mock thrombus models with neoprene rubber, and used the high-speed camera to record the shape change of the mock thrombus model under both constant and pulsatile suction. The results were compared for verification. They found that compared to constant suction operation, using pulsatile suction could more effectively remove blood clots, and much lower pressure magnitude was needed in the pulsatile mode to achieve the same clot removal efficiency compared to the constant suction mode. The study further supports the feasibility of pulsatile suction in DAT. The study neglected the blood flow and thus the dynamic interaction between the blood flow and the thrombus, which has much influence on the validity of the study. More studies are needed to investigate the pulsatile versus constant pressure suction with further improved accuracy.

Comparison of non-contact suction and contact suction

Pearce et al.[41,42] first suggested that non-contact suction helps to avoid squeezing the thrombus and minimize the thrombus fragmentation, and helps to achieve greater suction force. Continuing with this idea, Romero's team conducted numerical simulation studies of non-contact thrombus aspiration.[43,44] Romero's studies used the lumped-parameter model to describe the friction in blood flow, the compressibility and inertia of the blood. They used a group of small balls to model the thrombus, and the mechanical properties of the thrombus were represented with the spring-damper combination. The studies used an assumed fixed proportional relationship between the blood flow and the thrombus volume to model the interaction between the blood and the thrombus, which might not be reliable and needs to be re-examined. Neidlin et al.[45] used a 3D computational fluid dynamics model to study the non-contact thrombus aspiration process in the blocked left middle cerebral artery, and compared the flow changes when the catheter tip was positioned at different distances (about five times and ten times the inner diameter of the catheter) away from the proximal surface of the thrombus. It is noted that the catheter tip was too far away from the thrombus to effectively reveal the thrombus aspiration process in this study. Chitsaz et al.[46] used 3D computational fluid dynamics to analyze the thrombus aspiration with two types of catheters under non-contact suction, and suggested that non-contact suction could achieve thrombus removal. The study modelled the blood vessel as a very simple regular short tube, which was a significant simplification of the vessel geometry. Besides, the length of the tube used was too short so that the pressure boundary condition imposed at the outlet became less physical.

Using in vitro experimental study combined with 3D computational fluid dynamics simulation, Lally et al.[47] compared the contact and non-contact suction in a straight glass tube which served as the simplified cerebral artery model, and concluded that non-contact suction could not achieve thrombus removal. The study did not give sufficient technical details about the experimental conditions and calculation process. To further investigate the effectiveness of non-contact suction, Shi et al.[48] studied the relationship between the suction distance (defined as the distance between the catheter tip and the proximal surface of the thrombus) and the suction force using 3D computational fluid dynamics simulation. Both contact suction and non-contact suction were analyzed in the study. It was found that the suction force increased exponentially as the suction distance was reduced, and the suction force generated when the suction distance was reduced to 0.1 mm was slightly greater than the theoretical suction force value calculated when the catheter tip was in full contact with the thrombus. The result supported the feasibility of non-contact suction. The study also used a simple straight tube to represent the artery vessel, and the thrombus was modelled as a rigid body fixed to the vessel wall.

Overall, these studies suggested the possibility of using non-contact suction for thrombus removal. However, they used greatly simplified models for analysis, and have not given a systematic comparison between the contact and non-contact suction with respect to the advantages and disadvantages in each. There is a significant need for more studies in this area.

Optimization of the catheter tip geometry

Pearce et al.[41,42,49] designed a non-contact suction catheter which has spiral cuts in the inner cylindrical surface of the catheter tip, and they named this Gwen Pearce (GP) device. The idea was that the spiral grooves in the inner cylindrical surface of the catheter tip facilitated the formation of strong vortex flow near the catheter tip during the suction process, and this local vortex flow would make the thrombus removal easier. Besides, the non-contact suction operation could reduce the formation of thrombus fragments. Pearce et al.[42,49,50] measured the flow characteristics and the suction force generated with the GP device in the in vitro cerebral flow test rig, tested its efficiency and efficacy, evaluated the influence of the thrombus removal process to the vascular tissue, and compared the results of the GP device with those of using the mainstream stent retriever and the current commercial DAT devices. They concluded that the performance of the GP device was superior to the mainstream thrombus removal devices.

Pearce et al. in their works set a good example for the optimization of the DAT catheter design. It is possible that more sophisticated geometry designs in the catheter tip could induce more significant performance improvement in the DAT system, and this could be effectively examined using a combination of computer simulation and in vitro experimental study, which could have much impact to the future design of new generation of neurosurgical equipment.

Other directions for further research

Besides the above potential research directions suggested, there are other important aspects about DAT which need to be explored. For example, navigating the catheter through the tortuous arteries to arrive at the thrombus location has always been a challenging task, especially in the DAT when larger caliber catheters are used.[9,19,20,51] The histology and the mechanical behavior of the clots have significant influence on the thrombectomy procedure and success rate.[52–57] These studies need joint efforts from biomedical engineers and clinical researchers.

CONCLUSIONS

DAT as a promising minimal invasive treatment option for the AIS therapy has attracted much attention among researchers. Plenty of clinical, in vitro, and computer modelling studies have been conducted to analyze the hemodynamic response in the DAT for the advancement of the technique. Most of these were focused on the measurement of clinically observable variables (suction pressure, suction flow, recanalization rate etc.) for the evaluation of the effectiveness of the DAT. Further research can be planned to study more of the physical mechanism about the DAT, for example to consider the technical possibilities of issues of replacing the constant suction pressure with pulsatile suction pressure, comparison of contact aspiration and non-contact aspiration, and optimization of catheter tip design.

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AUTHORS' CONTRIBUTIONS

YS designed the study, performed the literature search and selection, extracted and analyzed the data, and wrote and revised the manuscript. HY analyzed the data and revised the manuscript. JD and PB revised the manuscript. All authors granted the final approval for submission.

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