Diagn Interv Radiol 2020; 26:565–569

INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

# Side-hole catheters have higher thrombus aspiration efficiency than regular end-hole catheters in an *in vitro* model

Jamal Moosavi
Parham Sadeghipour
Omid Shafe
Amir Abdi

**PURPOSE**
We aimed to evaluate and compare thrombus aspiration efficiency between side-hole and end-hole thrombus-aspirating catheters.

**METHODS**
Using an *in vitro* model of acute thrombus occlusion, we performed thrombus aspiration with two catheter designs. Two end-hole and two side-hole catheters, 8 F and 10 F in diameter, were examined. Thrombus aspiration was performed with each catheter 30 times, and the amount of thrombotic material aspirated in each attempt was determined. The mean weight of the thrombotic material and the mean weight of the non-fluid thrombotic material extracted in all 30 attempts by each catheter were also determined.

**RESULTS**
The 10 F side-hole catheter aspirated more thrombotic material than did the 10 F end-hole catheter (44.76 g vs. 28.35 g). The 8 F side-hole catheter had higher thrombus aspiration capacity than did the 8 F end-hole catheter in terms of the mean weight of the aspirated thrombus at each aspiration attempt (1.41 g vs. 0.58 g; $P < 0.001$) and the mean volume of the aspirated thrombotic material at each aspiration attempt (1.79 mL vs. 1.01 mL; $P < 0.001$). The mean weight of the non-fluid thrombotic material aspirated with the side-hole catheters was higher than that aspirated by the end-hole catheters with the same diameter size (31.06 g vs. 22.41 g for the 10 F catheters; $P < 0.001$; and 4.54 g vs. 2.99 g for the 8 F catheters; $P < 0.001$).

**CONCLUSION**
Side-hole catheters are more effective in aspirating acute thrombi. The added benefit of the side-hole design is more remarkable in smaller-sized catheters. Animal models are needed to examine their aspiration capacity in a real elastic vascular conduit and in the presence of wall-adherent thrombi.

With recent advances in interventional techniques and devices, it is now possible to treat many venous and arterial thrombotic occlusions via endovascular approaches (1–3). These include pharmacomechanical thrombectomy, which is applied in many cases with vascular thrombotic occlusions. Although the periprocedural results are good in selected cases, the efficacy of these approaches is not uniform in different vascular beds and clinical scenarios (4–6). In addition, mechanical thrombectomy devices are not always available. Manual aspiration devices are rapid and effective to overcome thrombi or at least reduce the bulk of thrombi, thereby making *in situ* thrombolysis more effective (7–9). Unlike the evolution of mechanical thrombectomy devices and catheters, the design of thrombus-aspirating catheters has not been modified or changed considerably. The structure of the latter includes an end hole that connects to a vacuum or aspirating system from the proximal end (Fig. 1). With the insertion of the catheter tip into the thrombus and activation of the vacuum or aspirating system, the catheter aspirates the thrombus (10–12). A few modifications have been applied to this aspiration system; for instance, the inner diameter of the catheter has been increased to augment clot-extraction efficacy. There have also been studies on the effects of the suction forces of different vacuum systems and syringes (13–15). However, the overall structure and design of thrombus-aspirating catheters have not been modified or changed considerably.

Cardiovascular Intervention Research Center (J.M., P.S., O.S. ✉ *omid-shafe@hotmail.com*), Rajaie Cardiovascular, Medical, and Research Center, Iran University of Medical Sciences, Tehran, Iran; Islamic Azad University of Medical Sciences (A.A.), Tehran, Iran.

Received 20 October 2019; revision requested 09 November 2019; last revision received 04 January 2020; accepted 20 January 2020.

Published online 8 September 2020.

DOI 10.5152/dir.2020.19529

You may cite this article as: Moosavi J, Sadeghipour P, Shafe O, Abdi A. Side-hole catheters have higher thrombus aspiration efficiency than regular end-hole catheters in an *in vitro* model. Diagn Interv Radiol 2020; 26:565–569

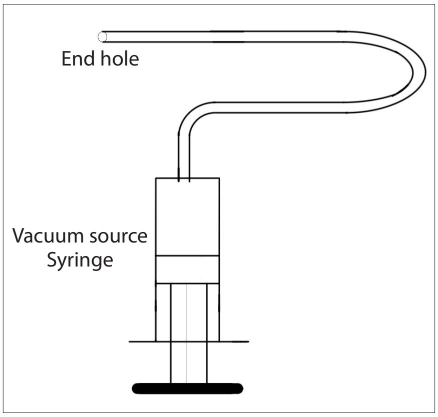


**Figure 1.** The end-hole catheter system. An end-hole catheter is connected to a vacuum source. In this example, syringe is the vacuum source.

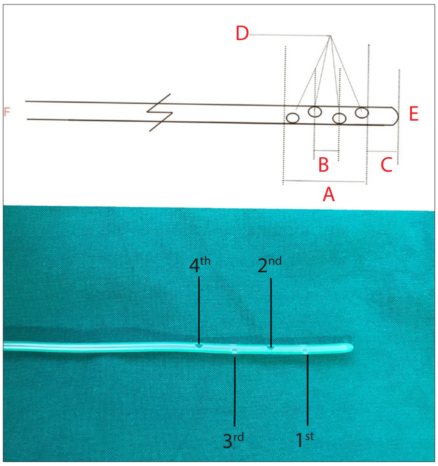


**Figure 2.** A side-hole catheter containing 4 holes. The holes are located 1 cm apart from one another (distance B), and the first one is located at 1 cm distance from the tip (distance C). The length covered by the holes (therapeutic length [distance A]) is 4 cm in this example and in our experiment. D, points to the holes.

In the present study, we examined the thrombus aspiration efficacy of side-hole (SH) manual aspiration catheters in an *in vitro* model. Our aim was to evaluate the thrombus aspiration efficacy of a new design of SH catheters and compare it with that of end-hole (EH) aspiration catheters.

**Main points**

- Side-hole catheters have higher efficiency in aspirating thrombus.
- The added thrombus aspiration capacity of side-hole design is more prominent in 8 F versus 10 F catheters.
- 10 F catheters, whether side-hole or end-hole type, have higher capacity in removing thrombus than 8 F catheters.

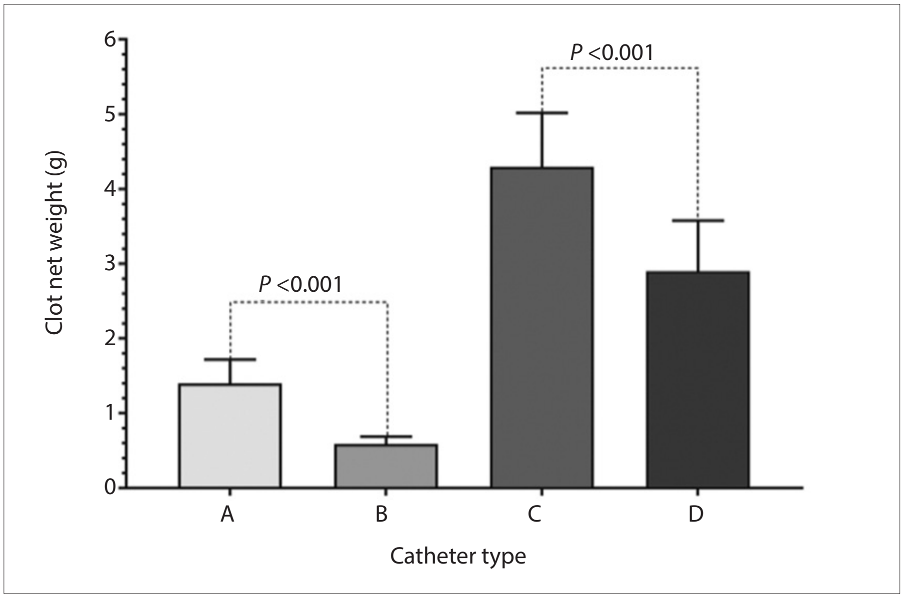


**Figure 3.** A comparative overview of the mean weight of the thrombotic material aspirated with each catheter. *P* values are according to Bonferroni post-hoc test. Catheter type A, 8 F side-hole; B, 8 F end-hole; C, 10 F side-hole; D, 10 F, end-hole.

# Methods

## Catheters and aspirating system

The design of the present study was approved by the research committee of our center. To compare thrombus aspiration capacity between SH and EH catheters, we used two 8 F and two 10 F catheters, one SH and one EH for each size. The catheters were made of plastic. Although the shape of holes were oval on SH catheters and circular for EH catheters, the size of the holes were the same in both SH and EH catheters in terms of the area and was 4.56 $mm^2$ for 8 F and 6.2 $mm^2$ for 10 F catheters (r= 1.2 mm and 1.4 mm for circular end holes of 8 F and 10 F catheters and r1= 0.85 mm and r2= 1.7 mm for oval side holes of 8 F and r1= 1 mm and r2= 2 mm for oval side holes of 10 F catheters). The wall thickness of catheters was equal for both 8 F and 10 F catheters and was 0.27 mm. Also the inner diameter was 1.2 mm for 8 F catheters (SH or EH) and 1.4 mm for 10 F catheters .

The SH catheters were designed to have 4 side holes at the distal end and no hole at the tip. The last side hole on the SH catheters was located 1 cm before the catheter tip, and the holes were 1 cm apart from one another. Therefore, the therapeutic length of the SH catheters (i.e., the length covered with holes) was 4 cm (Table 1, Figs. 1, 2).

The total length of each catheter, irrespective of its SH or EH design, was 60 cm; and they all had a thrombus-penetration length of 40 cm.

The aspirating system was a 50 mL syringe, which was connected to the end of the catheters.

## Vascular thrombotic occlusion model

To have a model of vascular thrombotic occlusion, we applied the method introduced by Kwon et al. (16). Briefly, we used tubes, 20 mm in diameter and 100 cm in length, filled with fresh bovine blood clots as a model for acute thrombotic occlusion.

## Procedure

First, clot fragmentation was performed to facilitate the passage of the catheter and increase its thrombus aspiration capacity. In our center, clot fragmentation is a routine procedure in cases with pulmonary thromboembolism and deep vein thrombosis (DVT) with a high clot burden. This can be done by inflating a high pressure balloon prior to aspiration of thrombus and rotating a pigtail catheter over a 0.035-inch j-tip wire within the thrombotic material. Next, the catheter was inserted into the clot in the tube while connected to the aspirating syringe. After the catheter was penetrated 40 cm into the clot, negative pressure was applied with the syringe. The negative pressure was maintained for 30 seconds with the catheter in place. The catheter was thereafter withdrawn while the negative pressure was maintained. After each aspi-

**Table 1.** Catheter characteristics

| | Catheter label | | | |
|---|---|---|---|---|
| | A | B | C | D |
| Size | 8 F | 8 F | 10 F | 10 F |
| Design | Side hole | End hole | Side hole | End hole |
| Number of holes | 4 | 1 | 4 | 1 |
| Therapeutic length (mm) | 40 | - | 40 | - |

**Table 2.** The total amount of thrombotic material at the end of 30 aspiration runs for each catheter

| | Catheter label | | | |
|---|---|---|---|---|
| | A | B | C | D |
| Volume (mL) | 18 | 9 | 50 | 35 |
| Net weight (g) | 14.2 | 5.96 | 44.76 | 28.35 |
| Non-fluid thrombotic material weight (g) | 4.54 | 2.99 | 31.06 | 22.41 |
| Density of extracted thrombotic material (g/mL) | 0.78 | 0.66 | 0.89 | 0.815 |

**Table 3.** Mean values of thrombotic material collected in 30 runs of aspiration

| Catheter | Volume of thrombotic material (mean±SD) | Net weight of thrombotic material (mean±SD) | Non-fluid weight of thrombus (mean±SD) |
|---|---|---|---|
| A | 1.79±0.27 | 1.41±0.31 | 0.44±0.07 |
| B | 1.01±0.19 | 0.58±0.10 | 0.32±0.07 |
| *P* for A vs. B* | <0.001 | <0.001 | <0.001 |
| C | 5.06±0.41 | 4.32±0.72 | 3.35±0.44 |
| D | 3.59±0.47 | 2.92±0.68 | 2.08±0.43 |
| *P* for C vs. D* | <0.001 | <0.001 | <0.001 |

SD, standard deviation.
*According to Bonferroni post-hoc test.

ration procedure, the aspirated thrombotic material was removed and placed in a dish for weight and volume measurement. In order to compensate the space of the vacuumed material from the tube, we injected saline into the tube in the same volume as that of the extracted thrombotic material with a view to simulating the blood return that occurs during thrombus aspiration in acute DVT or acute limb ischemia in a real patient. The thrombus aspiration procedure was performed 30 times for each catheter consecutively. Thus, the total number of suctions was 120. All aspirated thrombotic material of each catheter was gathered after the 30 attempts for further assessment (Fig. 3).

### Measurements

The aspirated thrombotic material of each aspiration was examined for volume and total weight. At the end of 30 attempts, the total amount thrombotic material aspirated with each catheter was gathered to determine the amount of the non-fluid thrombus. Each sample was centrifuged so as to separate the fluid phase from the non-fluid phase, and the mean weight of the non-fluid thrombotic material was measured.

### Statistical analysis

The fitness of the interval variables to a normal distribution was assessed via the one-sample Kolmogorov–Smirnov test. The data are described as the mean ± the standard deviation (SD). The one-way analysis of variance (ANOVA), followed by the Bonferroni post-hoc test, was applied for the comparisons between the catheter types. The statistical analyses were conducted using GraphPad Prism, version 6.05, for Windows (GraphPad Software).

## Results

The 10 F SH catheter had the highest mean weight and mean volume of the aspirated thrombotic material at each attempt. The 8 F SH catheter aspirated more thrombotic material than did the 8 F EH catheter. Additionally, the total amount of the non-fluid thrombotic material aspirated by the SH catheters was higher than that aspirated by the EH catheters of the same size. This was consistent for the density of the total thrombotic material aspirated (Table 2).

Furthermore, the 8 F SH catheter aspirated more thrombotic material than did the 10 F EH catheter; and the 10 F SH catheter aspirated more thrombotic material than did the 10 F EH catheter when the net weights of the thrombotic material and the non-fluid thrombotic material were expressed as the mean and the standard deviation derived from the data of each single aspiration (Fig. 4, Table 3).

Moreover, the SH-to-EH aspirated thrombotic material net weight ratio was higher for the 8 F catheters than for the 10 F catheters in each aspiration run (2.38±0.21 for 8 F SH /8 F EH and 1.57±0.14 for 10 F SH/ 10 F EH; $P < 0.001$).

## Discussion

Thrombotic acute occlusions of the vascular system, arterial or venous, need prompt treatment. The therapeutic options include medical, endovascular, and surgical. In recent years, new endovascular devices and techniques have been introduced to remove clots from both arterial and venous vascular systems (17–20). These approaches include catheter-directed thrombolysis along with mechanical thrombectomy such as manual aspiration (21). Albeit effective in many cases, they have some limitations in terms of effectiveness and safety, including the risk of major bleeding, incomplete clot removal, vessel-wall trauma, distal embolization, hemolysis, and higher costs (22–24). Manual aspiration is usually available and is an affordable technique to treat thrombotic occlusions, but it also has limited efficacy in extracting the clot (25). Moreover, only a few modifications have been applied to the design of manual aspiration devices since their introduction. Kwon et al. (16) studied 32 different methods of thrombus aspiration and found no significant improvement in thrombus aspiration capacity by upsizing catheters from 8 F to 10 F. Nonetheless, the aspiration capacity was increased when they increased the length at which the EH catheter traversed through the thrombus.

SH catheters are available for other indications in vascular and nonvascular systems, but they have not been used for thrombus aspiration. Our results showed that the SH catheters aspirated considerably more thrombotic material than did the EH catheters. This can reduce the need for further endovascular techniques such as catheter-directed thrombolysis and mechanical thrombectomy devices. Further, given that SH catheters exert their suction and aspiration forces circumferentially, the aspiration capacity of the thrombotic material appears to be higher in cases with vessel-wall adherent thrombi (26, 27).

Another finding in the current study was the added thrombus aspiration capacity of the SH design when we upsized it from a 8 F diameter to a 10 F diameter. The 10 F catheter had more capacity in removing thrombi; however, the SH-to-EH thrombus removal ratio in the 10 F catheters was lower than that in the 8 F catheters.

The larger, 10 F EH catheter had higher capacity in aspirating thrombi than did the 8 F EH catheter. This result is different from the finding in the study by Kwon et al. (16), who showed that upsizing the catheter did not have a significant effect on the thrombus aspiration capacity of an EH catheter.

The thrombus structure is rather soft; nevertheless, it is quite difficult to insert the catheter through it, unless it is fragmented. Clot fragmentation can also enhance the efficacy of aspiration (28, 29). This is because smaller-sized fragmented clots are more prone to be aspirated. In addition, fragmented clots are mixed with fluid—including blood, plasma, and thrombotic debris—which can facilitate the thrombus aspiration through the holes (30). It is, therefore, essential to fragment the thrombus cast before suction irrespective of the type of the aspiration catheter. Fragmentation and maceration is done routinely before manual aspiration thrombectomy in venous thromboembolism (VTE) cases in our center, as described in the methods section.

This study has some limitations. First, we were not able to fully simulate an actual venous conduit; the elasticity of the venous system is different from that of the tubes we used. Additionally, the normal venous flow could not be simulated in the tubes. What is deserving of note here is that we injected saline into the tube in the same volume as that of the aspirated thrombotic material in order to create verisimilitude with a real DVT intervention, during which the extraction of the thrombotic material is followed by a small amount of fresh blood refilling the thrombus-aspirated space. Second, it was impossible to have a biological surface *in vitro* in tubes similar to that of endothelial cells precluded the creation of exact wall-adherent thrombi. Since wall-adherent thrombi need circumferential aspiration rather than centric aspiration, the capacity of the thrombus aspiration of SH catheters may be higher in this setting. A thorough evaluation of this subject requires further studies on animal models. Third, there are different SH patterns that can be considered for catheters with the SH design. The effects of these different patterns should be evaluated in detail in future studies. Fourth, this study evaluated the thrombus aspiration efficacy of SH and EH catheters in acute thrombus and the results may not extrapolate in cases with subacute or older thrombus. Finally, since the SH catheters have 4 cm length at the tip covered with side holes, their tube length is 4 cm shorter than EH catheters. Theoretically, according to Poiseuille's law the length of a tube affects the maximum flow of the tube, i.e., catheter, when it comes to fluid materials. However, this formula describes the dynamic of fluid materials and clot is not fluid. Also, after calculating the flow within each catheter type by considering the length difference the results has shown that the difference is too small to have a significant effect on the results.

In conclusion, the SH catheters had higher thrombus aspiration capacity than did the regular EH catheters in this study. Using higher profile catheters increased the thrombus aspiration capacity significantly. However, the added thrombus aspiration capacity of the SH design with a smaller diameter was higher than that with a larger diameter. An animal model is needed for a more meticulous assessment of the thrombus aspiration capacity of SH catheters in a biologically active vascular system.

## Conflict of interest disclosure

The authors declared no conflicts of interest.

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