Drainage Performance of a Novel Catheter Designed to Reduce Drainage Catheter Failure

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Abstract

Objective Efficient flow of fluids through drainage/infusion catheters is affected by surrounding tissue, organ compression, and scar tissue development, limiting or completely obstructing flow through drainage holes. In this work, we introduce a novel three-dimensional (3D) drainage catheter with protected side holes to reduce flow blockages. We then compare its drainage performance to standard straight and pigtail catheters using computer-generated catheter designs and flow analysis software.

Methods Drainage performance was computed as flow rate through the catheter for a given pressure differential. Each catheter contained drainage holes on the distal (insertion) end and a single outlet (hub) hole open to atmosphere. Computational fluid dynamics using ANSYS AIM 18.2 was used to simulate flow through the catheter and examine drainage performance based on variations to the following parameters: (1) side hole shape, (2) cross-sectional area of the catheters, (3) number of side holes, and (4) cross-sectional area of the side holes.

Results Drainage through the newly introduced catheter in all simulations was nearly identical to standard pigtail and straight catheters. While working to optimize the 3D catheter design, we found that the changes in side hole shape and side hole cross-sectional area had little effect on the total flow rate through the catheters but had a large impact on flow rate through the side hole nearest to the hub (proximal hole). Additionally, the majority of flow in all catheters occurred at the most proximal 1 to 3 side holes closest to hub, with relatively little flow occurring at side holes more distally located (closest to insertion end). The 3D catheter demonstrated no changes in flow characteristics when the coiled segment was occluded, giving it an advantage over other catheter types when the catheter is compressed by surrounding tissue or other external obstruction.

Conclusions The majority of fluid flow in catheters with a diameter of 4.67 mm (14 Fr) or smaller occurred at the most proximal 1 to 3 side holes. A novel 3D coiled catheter design can protect these proximal holes from external blockage while maintaining drainage performance compared with standard straight and pigtail catheters.

Keywords
- catheter occlusion
- innovation and design
- suction catheter

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Introduction

There has been a significant increase in the use of drainage catheters over the last decade for all purpose drainage.[1,2] However, there has been relatively little work on reducing catheter complications, which remain frequent.[3] For instance, a study using the Medicare database, demonstrated that while annual percutaneous cholecystostomy procedures increased by over 500% (1994–2009),[4] these catheters are still plagued by high complication rates (up to 60%) related to catheter occlusion or dislodgment.[4-7] Several clinical studies have failed to identify predictors of catheter dysfunction.[5]

Computational fluid dynamics (CFD) uses numerical analysis (commonly based on the Navier–Stokes equations) to predict fluid flow subject to various conditions.[8] With improvements in computing power and availability of more user-friendly software, there has been an increase in the use of such modeling techniques in medicine.[8-10] Simulations and flow rate analysis may help to guide optimal catheter design.[11] For instance, in one simulation study, characteristics of the stopcock or the Luer lock connections attached to a drainage catheter were a major cause of catheter-related reduction of flow.[11,12] Through high-fidelity simulations, common catheter-related parameters, such as drainage hole placement and catheter shape, can be adjusted and changes in catheter function examined in highly controlled environments.

To overcome these limitations, we designed a novel three-dimensional (3D) coiled catheter (hereby referred to as the 3D catheter) with protected side holes to reduce flow blockages (►**Fig. 1**). The design allows for typical catheter insertion over a guide wire and introducer, and once the introducer is removed, the catheter takes on a 3D looped configuration that protects certain drainage holes from external blockage. The objective of this study is to examine the effects of catheter configuration and side hole shape, number, and cross-sectional area on catheter function and compare our new 3D catheter design using simulated catheter flow data.

Methods

Catheter Shapes

Drainage flow was simulated in three computer generated drainage catheters: a straight, pigtail, and novel 3D catheter (►**Fig. 1**). During drainage, fluid enters the catheter through drainage holes and exits via an outlet hole by the hub open to atmosphere. The drainage holes were placed on the sides, referred to as side holes, and at the distal end (insertion end) of the catheters. All catheter specifications, such as side hole size, catheter diameter, and number of side holes, were designed according to representative data from the latest commercially available products (►**Table 1**).[12] The distance between each side hole was 10 mm. The number of side holes varied depending on the catheter type. Side holes were present on two sides of the straight catheter (and straight portion of the 3D catheter), and the inner curvature of pigtail catheter (and coiled portion of the 3D catheter). Catheter tips were tapered and contained an end hole. The catheter geometries are shown in ►**Fig. 1**.

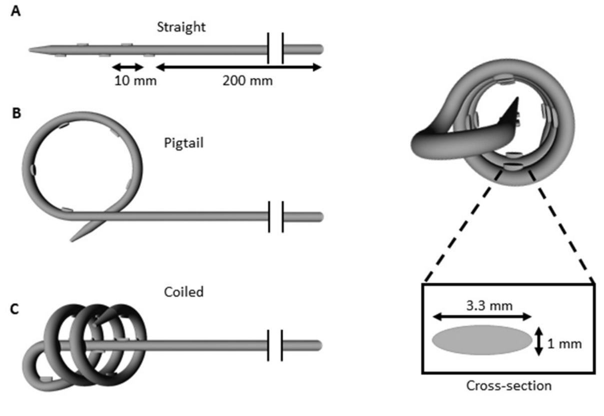

Fig. 1 Three catheter designs were tested: (**A**) straight, (**B**) pigtail, and (**C**) coiled. A cross-section of the side hole is also shown.

Simulation Setup

Flow was simulated using the finite volume method in ANSYS AIM 18.2 (ANSYS, Inc.), which subdivides the domain into discrete tetrahedral volumes. Walls of the catheter were rigid. The fluid was treated as Newtonian, and flow was assumed to be laminar. The simulated fluid had properties of water with density 998.2 kg/m^3 and viscosity 0.0089 Pa-s. While fluids in the body have a range of densities and viscosities, we chose these values because many bodily fluids have similar properties to water. For example, one study tested bile viscosity, a commonly drained fluid, in 138 patients and found that the viscosity in the majority of patients ranged from 0.007 Pa-s to 0.01 Pa-s.[13] Similarly, another study tested bile density and found values very close to water at approximately 1,000 kg/m^3.[14]

Computational Study Design

For the baseline case, all side holes and the end hole were exposed to a constant pressure of 10 mm Hg, and zero pressure was applied to the hub, resulting in a pressure differential of 10 mm Hg to drive flow. The 10 mm Hg pressure differential was based on reasonable physiological values. For example, intracranial pressures often range from 7 to 15 mm Hg, and pressure in the gall bladder has mean values around 10 mm Hg.[15,16]

Table 1 Baseline parameters of catheters

Parameter	Baseline value
Number of side holes[a]	5 (straight and pigtail), 15 (coiled)
Side hole separation	10 mm
Side hole dimensions[b]	3.3 mm × 1 mm
Distance from first side hole to outlet	200 mm
Inner diameter of catheter[c]	2.67 mm
Tapered end inner diameter	0.097 mm
Taper length	6.46 mm

[a] The number of side holes was varied from 0 to 5 for straight and pigtail catheters, and from 0 to 15 for the coiled catheter.

[b] Side hole cross-sectional area was varied from 1.09 to 5.59 mm^2 while keeping the elliptical aspect ratio constant. Side hole shape was varied from elliptical to circular while keeping the cross-sectional area constant (2.59 mm^2).

[c] The inner diameter of the catheters was varied from 1.67 to 4.67 mm.

Catheter parameters and baseline flow rates are listed in ►**Fig. 1** and ►**Table 1**. Simulations were performed after changing catheter features, including side hole number, size and shape, and catheter diameter. Elliptical versus circular side holes were also compared with a constant cross-sectional area of 10.37 mm^2. Initial studies found no change in catheter performance based on side hole shape, and thus, all other simulations in this work used elliptical side holes according to industry standards. The number of side holes in all three catheter types was varied by removing side holes sequentially from the distal (insertion end) end. The side hole number ranged from 0 to 5 in the straight and pigtail catheters and 0 to 15 in the 3D catheter. The cross-sectional area of the side holes was varied by proportionally altering the lengths and widths of the elliptical side holes while maintaining a constant catheter diameter. The side hole cross-sectional areas ranged from 4.37 to 22.37 mm^2. The inner diameter of the catheter was varied, ranging from 1.67 to 4.67 mm, while maintaining a constant cross-sectional area of the side holes. Flow rates through the drainage holes and hub were recorded. An analytical solution for a pipe with varying inner diameters was also plotted for comparison. The analytical solution was obtained by assuming an initial flow rate and pressure differential based on results from the straight catheter with diameter 1.67 mm. Flow versus pressure differential for each subsequent change in diameter was then assumed to follow Poiseuille's law.

Temporal and spatial convergence tests were performed for each simulation. Temporal convergence ensures that simulations reach steady state, where the solution no longer changes with respect to time. Spatial convergence tests provide a grid-independent solution which we can achieve by refining the number of discrete volumes in the mesh until the discretization error approaches zero. The number of volumes required to attain spatial convergence in each simulation depended on the catheter type, side hole parameters, catheter diameter, and catheter length and ranged from 191,180 to 772,797. To achieve steady state solutions, flow was simulated until the relative momentum and continuity residuals were below a threshold value of 10^{-7}.

Results

The three types of catheters studied had several different baseline catheter-specific characteristics (►**Table 1**). No differences in flow were seen for elliptical versus circular side hole configurations when holding the cross-sectional area constant, and thus, elliptical side holes were used for the remaining studies. CFD outputs with pressure profiles and velocity streamlines in each catheter are shown in ►**Fig. 2**. The pressure profiles demonstrate higher pressures toward the side holes (where flow is applied) and low pressure at the hub. Based on velocity streamlines, the highest side hole velocity occurs through the most proximal (closest to hub) side hole and quickly decreases toward the distal (insertion) end. The Reynolds (Re) and Dean (De) numbers were calculated for each catheter type immediately proximal to each side hole (►**Tables 2** and **3**). Results show similar Re but significantly higher De in the pigtail catheter compared with the 3D catheter.

All three types of catheters showed exponentially increasing flow rates with larger catheter diameters, as expected (►**Fig. 3A**, **B**). However, increment in side hole area led to modest changes in overall catheter flow (►**Fig. 4A**). Flow through the proximal hole grew significantly when these parameters were increased indicating their important roles in overall catheter drainage performance (►**Fig. 4B**). In all three catheter types, additional side holes beyond the first three did not add significant flow through the catheter (►**Fig. 5A**, **B**). When the catheters only included the most proximal side hole, 53 to 55% of total flow was still observed. By adding the second side hole, 78 to 80% of total flow was recovered, and over 90% by adding the third most proximal hole (►**Fig. 6A**, **B**).

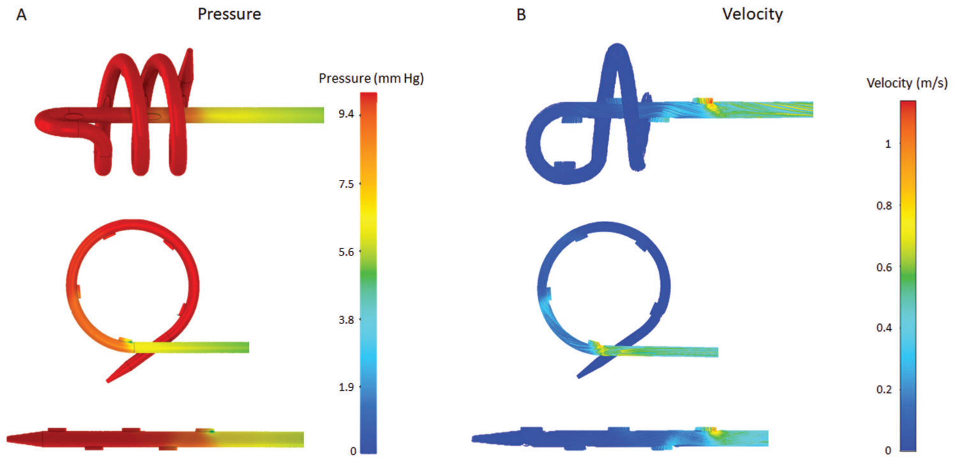

Fig. 2 (**A**) Pressure profile and (**B**) velocity streamlines for the three catheter designs. In each case, the greatest pressure differential and greatest velocity were observed at the drainage hole closest to the outlet. The velocity streamlines in the 3D catheter are cut off in the coils because the velocity beyond that location is zero.

Table 2 Reynolds (Re) number at the drainage holes closest to the outlet for the three catheter designs

Hole number	Re: straight	Re: pigtail	Re: coiled
1	1,806.47[a]	1,795.49	1,835.51
2	819.78	779.93	837.96
3	366.61	311.20	366.39
4	155.79	114.23	147.17
5	54.63	33.79	39.97

[a] Re approximately < 2,300 indicates laminar flow.

Table 3 Dean (De) number at the drainage holes in curved segments for the three catheter designs

Hole number	De: straight	De: pigtail	De: coiled
1	N/A[a]	390.66[b]	N/A
2	N/A	239.99	N/A
3	N/A	95.76	N/A
4	N/A	35.15	N/A
5	N/A	10.40	16.64

Abbreviation: N/A, not available.
[a] De characterizes flow in curved channels; only holes 1 to 5 in the pigtail catheter and hole 5 in the coiled catheter were located in curved channel segments.
[b] De approximately < 400 indicates laminar flow.

Discussion

In this study, we examined drainage flow dynamics in different catheter types by varying several catheter design parameters. We found that increasing catheter diameter led to an increase in overall catheter flow, but such flows were less than expected by Poiseuille's law likely due to distortion of the flow field near the drainage holes. The most important finding of this study is the majority of fluid flow in these catheters takes place at the most proximal 1 to 3 side holes with little to no flow occurring with the addition of more side holes.

Drainage efficiency could be influenced by turbulent flow in the catheters. Based on Re alone, flow was found to be laminar in all three catheter types (Re approximately < 2,300). Interestingly, the De in the pigtail catheter was significantly higher than the 3D catheter but still laminar (De approximately < 400). This result is unique and is explained by the fact that the proximal holes of such pigtail catheters (where most flow occurs) are placed within the curvature part of the catheter. In the novel 3D catheter, the majority of flow occurs in the most proximal holes (positioned along a protected and noncurved portion of the catheter). Almost no flow is taking place after the elbow, where the catheter begins to form loops, which leads to a desirable low De. Since the straight catheter has no curvature, De = 0. While the De in the pigtail catheter was significantly higher, we note that flow rates through the catheter were largely unaffected.

A key observation in this study is that increasing the number of side holes beyond the first three holes contributes very little additional flow. This is an important finding, as some commercially available catheters today market an increased number of side holes as a reason for superior catheter performance. In fact, a major limitation in further advancing the field of catheter design forward is the lack of rigorous studies and reporting of catheter related complications and failure. For example, in a large scale systematic review of the literature evaluating 53 papers and nearly 1,900 patients receiving percutaneous cholecystostomies, the authors found no controlled studies in this patient population with all reports having an evidence grade of C.[17] This is despite an overall increase in the number of catheters placed in a wide range of different clinical scenarios.

There has been an increase in the use of pigtail-shaped catheters,[12,18] mainly because their shape has the potential to decrease catheter drift and dislodgment compared with straight catheters. Furthermore, the drainage holes on these catheters are typically placed on the inner curvature of the catheter, with a potential benefit being protection from external blockage. Despite this shape, clinical reports demonstrate that pigtail catheters continue to have high dislodgment and

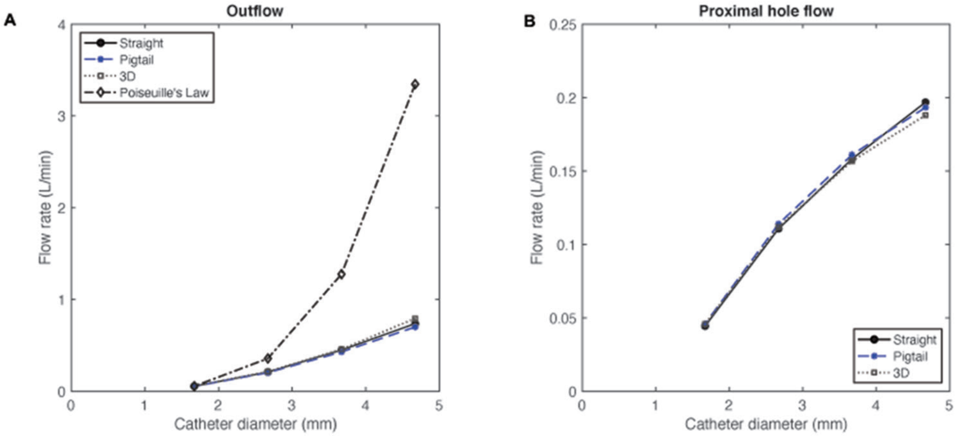

Fig. 3 Changes in flow rate (**A**) overall and (**B**) within the hole closest to the outlet with increasing catheter diameter. An analytical solution using Poiseuille's law is shown in panel A for comparison.

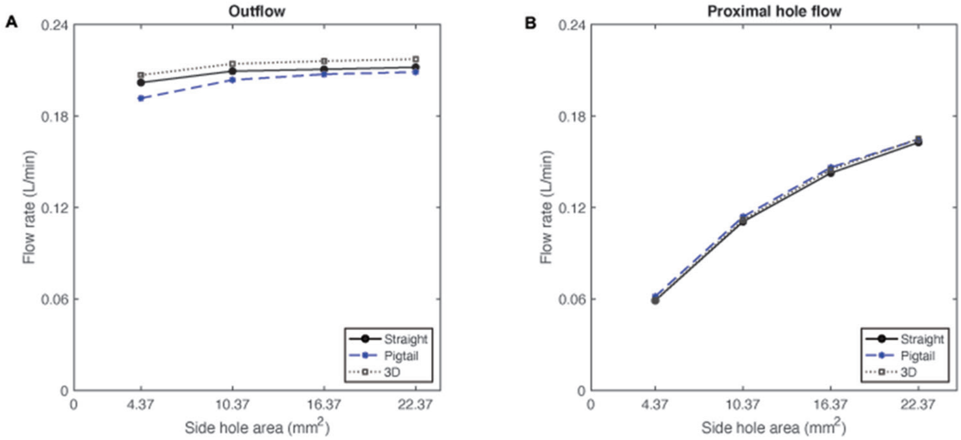

Fig. 4 Changes in flow rate (**A**) overall and (**B**) within the hole closest to the outlet with increasing side hole cross-sectional area.

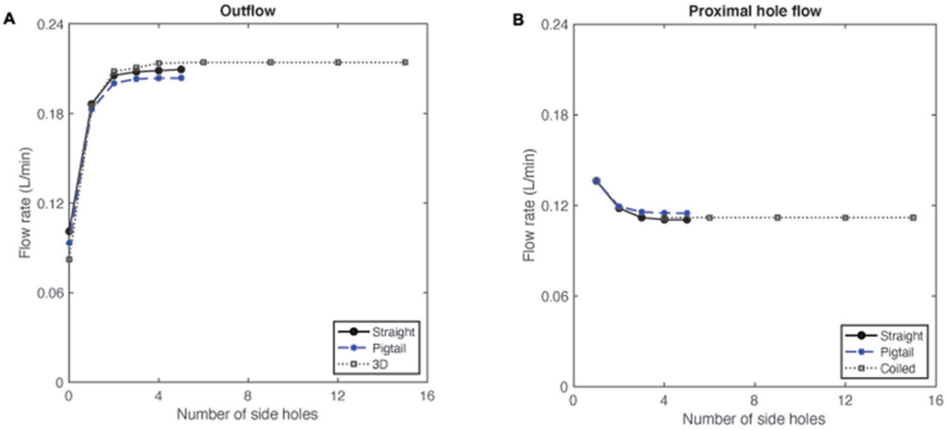

Fig 5 Changes in flow rate (**A**) overall and (**B**) within the hole closest to the outlet with increasing number of side holes.

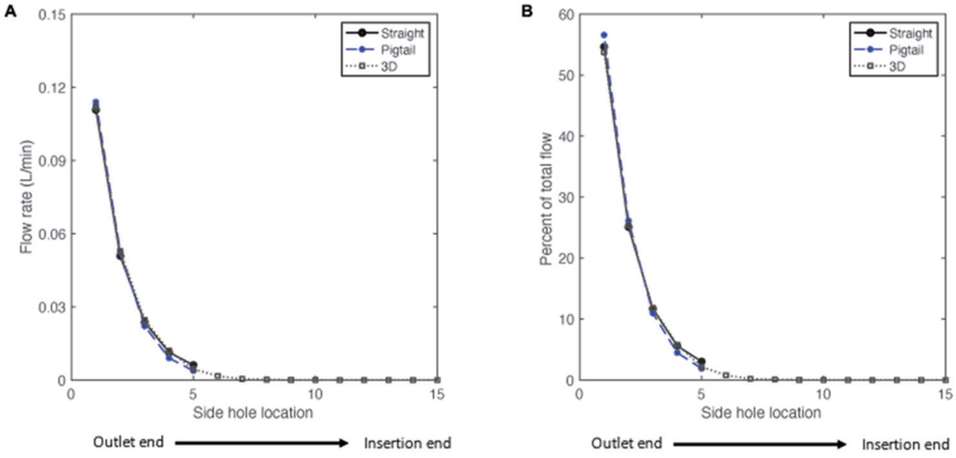

Fig 6 (**A**) Flow rate at each side hole starting at the outlet end. (**B**) Percentage of overall catheter flow at each side hole. Over 90% of the overall flow occurred within the three side holes closest to the outlet.

obstruction rates which require reintervention and increased costs.[19] In one study examining percutaneous cholecystostomy, unplanned readmissions related to the catheter were seen in 71% of patients at a mean follow-up of 834 days.[20] Of those readmitted, tube dislodgment accounted for 40% of readmissions, and tube obstruction accounted for 29% of readmissions.[20] Combined, these two major tube-related complications accounted for over two-thirds of all readmissions. A study of abdominal and pelvic abscess drainage found that 85% of tubes required an exchange prior to eventual removal.[5] In another retrospective long-term follow-up single-institutional study, 46% of patients experienced catheter-related dysfunction with most requiring reintervention.[3] Similar patterns of catheter obstruction were seen for peritoneal dialysis (PD) catheters.[21] In one study that examined 6-month outcomes of PD catheters, catheter obstruction/dysfunction was a major complication after insertion occurring in up to 30% of cases.[21] Revision rates were similarly high with up to 42% of patients requiring some type of revision.[21] A catheter that is more resilient to external obstruction and dislodgment is likely to further improve outcomes in this fast-growing procedure.

In this study, we report on a unique catheter design that is focused on protecting the proximal holes (where most fluid exchange takes place) from external obstruction. Similar to a pigtail catheter, the novel 3D catheter is straightened during insertion using a hard introducer. Once the introducer is removed, the catheter takes on its 3D shape in the desired location. The final 3D shape is locked using a suture on the outside of the patient. Our data suggest that fluid drainage properties of this catheter are similar to those of commercially available straight and pigtail catheters. As catheter use continues to grow for the treatment of many conditions and indications, further evidence-based studies are warranted to improve our understanding of this basic, yet largely used medical tool.

There remain several important questions related to catheter function that must be studied in clinical practice. For example, the size and location of fluid collections that are best drained by the 3D catheter will need to be determined. It will be important to determine the catheter deployment restrictions in a fixed space (i.e., gallbladder) as opposed to a less limited space, such as the abdomen. Other important endpoints to be tested in the clinical setting are related to cavity collapse after drainage is completed, and if this unique shape will influence this outcome. Further modifications to the catheter might be required to include less loops to decrease the overall profile of the catheter, yet still protecting the proximal holes, in certain indications. This will also be true for the spacing between the loops, to allow for fluid flow, yet restrict certain sizes of debris from flowing through the loops and obstructing the drainage holes. Finally, while the planned catheter will be made of the same material as current catheters, it will be important to study catheter erosion rate into surrounding tissue and if that will be different than current commercially available catheters.

Limitations

There are several important limitations to this study. The properties of the fluid used were similar to that of water, but other biological fluids with different properties are often drained. Furthermore, simulation-based studies are limited by the lack of in vivo based factors (scar tissue formation, changes in sitting/standing positions, activity levels, temperature, etc.). However, they are useful in creating controlled testing environments and iterating over many parameters to gain important insights into the impact of a variety of factors on flow.

Conclusion

The majority of flow in drainage catheters occurred at the first proximal three side holes closest to the hub, with relatively little flow occurring at distal side holes (near the insertion tip). A novel 3D coiled catheter design was introduced and shown to have similar flow efficiency to standard catheters, with the added advantage of coils that protect the side holes from external blockage. Future catheter design research is warranted to help reduce high rates of catheter failure.

Conflicts of Interest

A.R. reports other fees from Lacuna Medical, outside the submitted work; and all other coauthors are advisors to Lacuna medical. While they do not have any direct pay, they did receive options (shares) in the company.

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