Endovascular catheter manometry reliability: a benchtop validation study

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OBJECTIVE Catheter manometry is used frequently in neuroendovascular surgery for assessing cerebrovascular pathology. The accuracy of pressure data with different catheter setups requires further validation.

METHODS In a silicone human vascular model with a pulsatile pump, pressure measurements were taken through multiple arrangements of 2 guide catheters and 6 microcatheters. The systolic pressure, diastolic pressure, mean pressure, pulse pressure, and area under the curve of the waveform were recorded through catheters with controls at arterial blood pressure ranges. Linear regression modeling was performed, correlating transduction area and relative pulse pressure. Thresholds for acceptable accuracy were ≥ 90%.

RESULTS Mean pressure demonstrated < 4% variation between all 24 catheter setups and respective controls. A strong linear correlation ($r^2 = 0.843, p < 0.0005$) between microcatheter transduction area and relative pulse pressure with a threshold of 0.50 mm$^2$ was seen (i.e., 0.031-inch inner diameter [ID]). For guide catheters with indwelling microcatheters, there was also a strong linear correlation ($r^2 = 0.840, p < 0.0005$) of transduction area to pulse pressure. The guide catheters with obstructing microcatheters required a transduction area over fourfold higher compared with unobstructed microcatheters (2.21 mm$^2$ vs 0.50 mm$^2$).

CONCLUSIONS Mean pressure measurements are accurate through microcatheters as small as 0.013-inch ID. Pulse pressure and waveform morphology may require a microcatheter ≥ 0.031-inch ID to achieve 90% accuracy, although the 0.027-inch ID microcatheter reached 85% accuracy. A 0.070-inch guide catheter with a microcatheter ≤ 0.042-inch outer diameter (e.g., Marksman 0.027-inch ID or smaller) allows accurate transduction of pulse pressure. Further validation of these benchtop findings is necessary before application in a clinical setting.

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KEYWORDS endovascular technique; endovascular procedures; venous sinus manometry; venous sinus stenosis; venous sinus stent; interventional neurosurgery; vascular disorders
tions of guide catheters and microcatheters that can be created where the transduced pressure can be altered and provide a clinician with discrepant data by which to make clinical decisions.

We aimed to create multiple catheter setups in a laboratory model with varying sizes of guide catheters and microcatheters. The dampening effect of microcatheters during pressure transduction is well known.\textsuperscript{1,2} It is our aim to quantify pressure measurements through varying sizes of endovascular catheters and suggest size thresholds for use in endovascular manometry.

**Methods**

The laboratory setup included a silicone human vascular model (United Biologics) connected to a FlowTek 125 pulsatile pump (United Biologics). The great vessels of the aortic arch were occluded with manual clamps with the exception of the left subclavian artery, which was used to transduce the model’s pressures as a control. We used replicator fluid (Vascular Simulations) through the vascular model that mimics the physical properties of human blood, including viscosity. The replicator fluid was added to the system to create the equivalent of a systolic blood pressure of 110–130 mm Hg. The pump was set to a pulse of 70 beats per minute and a flow of 100%. Recordings were obtained through a TruWave pressure transducer (Edwards Lifesciences) and processed through a physiology monitor (SpaceLabs Healthcare, Ultraview SL). The catheters were positioned in the proximal descending aorta of the vascular model.

The two guide catheters used included a Neuron 070 (Penumbra Inc.) with a 0.070-inch inner diameter (ID) and a 5Max (Penumbra Inc.) with a 0.054-inch ID. Microcatheters with varying IDs from smallest to largest included Marathon (Medtronic), Headway Duo (MicroVention Inc.), Echelon 14 (Medtronic), Headway 21 (MicroVention Inc.), Marksman (Medtronic), and 3Max (Penumbra Inc.) (Table 1). Catheter diameters are reported in inches to maintain consistency with clinical practice. Pressures were transduced through each guide catheter without a microcatheter with concomitant control recordings through the left subclavian artery. Next, pressures were transduced concomitantly through the guide catheter harboring each compatible microcatheter with control readings through the left subclavian artery. All guide catheter/microcatheter combinations were evaluated with the exception that the 3Max was not placed in the 5Max due to incompatibility with catheter sizes. This totaled 13 unique guide catheter recordings (2 guide catheters without microcatheters, 6 Neuron 070 readings with 6 different microcatheters, and 5 5Max with 5 different microcatheters) and 11 unique microcatheter recordings (6 microcatheters within the Neuron 070 and 5 microcatheters within the 5Max) for a total of 24 pressure recordings. Additionally, for each catheter setup, a control pressure was transduced from a port off the left subclavian artery of the vascular model during every new catheter setup (13 total) (Fig. 1). The transducing areas of the catheters are presented in square millimeters and calculated by squaring the inner radius of the catheter times pi (transduction area = \([\text{transducing catheter ID}/2]^2 \times \pi\)) and, if present, subtracting the inner catheter distal outer diameter (OD): (**inner catheter distal

**TABLE 1. Catheter specifications**

<table>
<thead>
<tr>
<th>Category</th>
<th>Catheter</th>
<th>ID (inches)</th>
<th>OD (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide</td>
<td>Neuron 070</td>
<td>0.070</td>
<td></td>
</tr>
<tr>
<td>Guide</td>
<td>5Max</td>
<td>0.054</td>
<td></td>
</tr>
<tr>
<td>Micro</td>
<td>3Max</td>
<td>0.035</td>
<td>0.062</td>
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<tr>
<td>Micro</td>
<td>Marksman</td>
<td>0.027</td>
<td>0.042</td>
</tr>
<tr>
<td>Micro</td>
<td>Headway 21</td>
<td>0.021</td>
<td>0.033</td>
</tr>
<tr>
<td>Micro</td>
<td>Echelon 14</td>
<td>0.017</td>
<td>0.032</td>
</tr>
<tr>
<td>Micro</td>
<td>Headway Duo</td>
<td>0.013</td>
<td>0.027</td>
</tr>
<tr>
<td>Micro</td>
<td>Marathon</td>
<td>0.013</td>
<td>0.036</td>
</tr>
</tbody>
</table>

Guide = guide catheter; Micro = microcatheter.

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FIG. 1. Diagram of the experimental setup including the silicone model of the human aorta with its major branches (light gray). A catheter (dark gray) with indwelling microcatheter (white) with tips in the rostral descending aorta that enter the system through the left iliac artery and are connected to the pressure transducer. The pulsatile pump is connected with inflow into the ascending aorta and outflow from the right iliac artery (black). The control pressures are measured directly from the left subclavian artery.
OD/2\]^2 \times \pi\). The transduction areas of all setups are reported in Table 2.

The pressures were continuously recorded over 1 minute (i.e., 70 pump cycles). The average systolic pressures, diastolic pressures, and mean pressures were recorded at the beginning of each procedure from the control port. The mean pressure was recorded from the Ultraview SL Multiparameter Command Module (SpaceLabs Healthcare), which uses an oscillometric calculation. The pulse pressure was calculated as systolic pressure minus diastolic pressure. The 24 catheter pressures are reported as relative (%) change from the control pressure (Table 2).

The pressure readings from both the guide and microcatheters were compared with the control pressure, from the left subclavian artery, as a baseline. The guide and microcatheter pressure readings can vary in pulse height and pulse profile and can also be shifted temporally from the control pressure. To align the guide and microcatheter pressures temporally, each is separately cross-correlated against the control pressure and then shifted in time accordingly.

In an attempt to quantify both the diminished peak pressure and loss of wave structure of the guide and microcatheter waveforms, the absolute value of the area under the curve (AUC) of the waveform, centered about the mean arterial pressure, is used. This area is integrated across 5 periods and averaged for each waveform. The control pressure is then normalized to 100%, and the guide and microcatheter AUC are reported with respect to the control, as seen in Table 2.

Transducing microcatheters and transducing guide catheters with an obstructing inner catheter were analyzed separately by linear regression. SPSS (version 26 software, IBM Corp.) was used for linear regression analysis, and p < 0.05 was considered significant. The regression analysis was used to solve for the transduction area required from a microcatheter and from an obstructed guide catheter to achieve 90% of the relative pulse pressure, according to the Association for the Advancement of Medical Instrumentation/American National Standards Institute (AAMI/ANSI) standards.

### Results

The mean pressure demonstrated < 4% variation between any of the 24 different catheter setups and their respective controls (Table 2). Dampening of the pulse...
pressure and AUC was substantial for all microcatheters with a ≤ 0.021-inch ID. These microcatheters had a 67%–95% reduction in pulse pressure compared with the control, whereas microcatheters ≥ 0.027 inch had only a 4%–12% reduction in pulse pressure (Fig. 2). There was a strong linear correlation between microcatheter transduction area and relative pulse pressure by linear regression analysis \( (r^2 = 0.843, p < 0.0005) \) (Fig. 3). To achieve a relative pulse pressure of 90% with a microcatheter, the linear regression yields a microcatheter transduction area that must be \( \geq 0.50 \text{ mm}^2 \) (95% CI 0.381–0.763), which converts to a 0.031-inch ID (95% CI 0.027–0.039 inch). Of note, the 0.027-inch ID microcatheter did achieve 88% relative pulse pressure on both setups in which it was used.

Substantial dampening with all setups using the 0.054-inch 5Max guide catheter was seen. Any microcatheter present in the 5Max catheter dampened the waveform by 47%–84% (Table 2). Conversely, transduced pressures through the Neuron 070 only showed significant reduction with the largest microcatheter, the 3Max. The Neuron 070 had a 44% reduction in pulse pressure with the 3Max catheter inside of it compared with only 4%–16% reduction with the 5 other smaller microcatheters (Fig. 2). The relative pulse pressure measured through guide catheters that were partially obstructed with microcatheters correlated well with the transduction area \( (r^2 = 0.840, p < 0.0005) \) (Fig. 4). By linear regression analysis, an obstructed guide catheter must have \( \geq 2.21 \text{ mm}^2 \) of remaining transduction area to achieve 90% relative pulse pressure.

**Discussion**

Catheter manometry is a growing area of interest in neuroendovascular practice and research, with both arterial and venous applications. In particular, venous sinus manometry and stenting of venous sinus stenosis in patients with the clinical diagnosis of idiopathic intracranial hypertension (IIH) is one of the more validated indications for the use of endovascular pressure measurement. In 1995, King et al. published findings in a population of patients with IIH with a venous stenosis pressure gradient that they noted was difficult to visualize on venography. Almost a decade later, Higgins et al. published a small series of venous sinus stenting cases for the treatment of IIH in patients in whom they documented sinus stenosis pressure gradients. Since that time, a significant body of literature has developed supporting the application of this treatment strategy for IIH patients with venous stenosis.

Despite the growing acceptance of venous manometry and sinus stenting, the indications for stenting and the tools used to assess for physiological sinus stenosis remain topics of debate. For example, while many advocate for a measured mean pressure gradient across the stenosis of 8 mm Hg, some have proposed as minimal as 4 mm Hg as a cutoff in select cases or as high as 10 mm Hg. Other authors have noticed elevated pulse pressures in the venous sinus proximal to the stenosis as an indication for venous sinus stenting. Additionally, there is variation on whether the mean pressure or peak pressure is used. Regardless of the pressure gradient cutoff or pulse pressure criteria used, interventionalists should have guidance on which catheter setups to use to produce data reflective of the true physiological pressure on which to base treatment decisions.

Two previous studies sought to determine the optimal endovascular microcatheters for venous pressure measurement. Henkes et al. performed an ex vivo investigation of microcatheters that are no longer commercially available, which varied in ID from 0.012 to 0.021 inch. They made measurements for both venous and arterial pressures. Overall, their findings were similar to ours. The mean pressure measurements across all catheters were relatively accurate within 12% of their reference measure-
ment compared with our findings that showed 23 of 24 setups were within 2% of the control with one exception, which was within 4%. They also found a direct correlation between ID and dampening of pulse pressure.

Avery et al. created a synthetic venous stenosis model to test 5 microcatheters that are used in current clinical practice, including the Echelon 10 (Medtronic), Excelsior SL-10 (Stryker), Excelsior 1018 (Stryker), Prowler Select Plus (Codman Neuro), and Marksman (Medtronic), which ranged in ID from 0.0165 to 0.027 inches. Pressure measurements were made through a monoaxial microcatheter at various positions in relation to the stenotic segment, and the system pressure was kept at a venous hypertension level. A 3F Mikro-Tip Pressure Catheter (Millar) high-fidelity microcatheter (HFM) was used for a control pressure measurement. The Echelon 10, Prowler Select Plus, and Marksman microcatheters were found to meet the standards set by the AAMI/ANSI for accuracy for intracranial pressure (ICP) monitoring devices. These standards include an accuracy of within 2 mm Hg for pressures <

![Graph](image1.png)

**FIG. 3.** Linear regression analysis of transduction area versus relative pulse pressure of 11 unobstructed microcatheters with 95% confidence intervals. $y = 2.04x + -0.117; r^2 = 0.843, p < 0.0005$.

![Graph](image2.png)

**FIG. 4.** Linear regression analysis of transduction area versus relative pulse pressure of 11 guide catheters with obstructing inner catheters with 95% confidence intervals. $y = 0.455x + -0.104; r^2 = 0.840, p < 0.0005$. 
20 mm Hg and ± 10% for pressures ≥ 20 mm Hg. The Excelsior 1018 was accurate in the stenosis model but not in the stenosis-free model, while the SL-10 did not meet the standards in any setup. While the Echelon-10 was the smallest catheter that they used, the authors found it to outperform larger microcatheters of the SL-10 and Excelsior 1018, and thus they postulated that catheter construction may affect the ability to accurately transduce mean pressures.1 They did find that the ID of the catheter directly correlated to waveform damping, although this was not a focus of the study. The lack of reliability to measure mean pressure in some catheters differs from ours, as all mean pressure measurements in our study were kept within a tight range, only deviating ≤ 4% at most by any catheter, thus meeting the AAMI/ANSI standards for all catheter sizes. The consistency of the mean arterial pressure measured across vastly different catheter configurations and that with the controls demonstrates that the measured fluid was continuous with the main system and that the loss in measured pulse pressure is a function of the geometry of the catheter(s), as opposed to an error created by an occlusion of fluid.

While a pressure gradient across the stenosis has been the only consensus physiological criterion for venous sinus stenting, there have been other interesting findings related to wave morphology and pulse pressure noted in the literature.7,13–15 West et al. reported their findings of the venous manometry waveform proximal to symptomatic stenosis as being characteristic of an ICP Lundberg waveform, while the waveform distal to stenosis were more of a central venous pressure morphology.14 They also found that the proximal measurement waveform appears to have the equivalent of an elevated P2 in relation to P1, which is suggestive of poor compartmental compliance when seen in an ICP waveform. We have also noted these findings in our clinical practice. Given the documented coupling of ICP and venous sinus pressure, as well as direct response of a decrease in ICP following venous sinus stenting, it is not surprising that a venous wave morphology proximal to a stenosis would emulate an ICP waveform.16,17 Multiple reports have noted that the proximal waveforms normalized to a central venous pressure waveform following stenting, along with a decrease in pulse pressure, absolute pressure, and pressure gradient across the stent.13–15

Given these potentially meaningful clinical findings in waveform morphology and pulse pressure, it may be important to minimize measurement dampening to provide true pressure measurements to an interventionalist. As noted previously, prior microcatheter reliability studies demonstrated that the dampening effect is directly related to the ID of the catheter.1,2 However, neither study commented on a threshold that the waveform and pulse pressure is no longer reliable. Our AUC analysis demonstrated that dampening remained < 20% when using a microcatheter with a ≥ 0.027-inch ID, with a steep stepoff in the AUC at 0.021-inch ID and below. To extend AAMI/ANSI standards of recorded pressures within 10%, a microcatheter at least 0.031 inch (95% CI 0.027–0.039 inch) in diameter is required to accurately record pulse pressures.

Additionally, our novel exploration of manometry through the intermediate catheter with an indwelling microcatheter showed that the AUC wave was maintained within 20% with a 0.070-inch guide catheter with any ≤ 0.027-inch microcatheter is within it, but not with the 0.035-inch 3Max indwelling catheter (which was the largest microcatheter studied). Also, we found that the AUC decreased by nearly 50% or more in all setups of a 0.054-inch guide catheter with any indwelling microcatheter. Our results demonstrate the reliability of pressure measurements through a 0.070-inch guide catheter containing an indwelling microcatheter with an OD ≤ 0.042 inch. However, the only microcatheter (3Max) evaluated in this study that would give an accurate pulse pressure was also the only microcatheter too large to allow the 0.070-inch guide catheter to concomitantly provide an accurate pulse pressure. A guide catheter harboring a 3Max catheter, which has a distal outer cross-sectional area of 1.22 mm², would require a 0.082-inch ID to maintain a transduction area of 2.21 mm² determined by our linear regression analysis to be necessary for 90% pulse pressure accuracy. This setup may translate clinically into reliable simultaneous manometry proximal and distal across a stenosis by measuring through the microcatheter and guide catheter, respectively.

The transduction area required for accurate pressure measurements through an unobstructed microcatheter versus a guide catheter obstructed with a microcatheter differs greatly. This is best appreciated objectively by the slope of our linear regression in Figs. 3 and 4 (2.04 vs 0.455, respectively). The guide catheters with obstructing microcatheters required a transduction area over fourfold higher compared with unobstructed microcatheters (2.21 mm² vs 0.50 mm²). While these findings are likely multifactorial, it is most likely linked to sources of energy loss from the pressure wave. This energy loss would result in a decrease in amplitude (i.e., pulse pressure), and a dampening of wave morphology. We hypothesize that there are many components of energy loss, including friction of the fluid column on increased surface area, mechanical disruption of fluid wave by the microcatheter crossing the inner lumen of the guide catheter, and pulsatile movement of the indwelling microcatheter. These concepts are theoretical and outside the scope of this study.

There are many limitations to this benchtop analysis of catheter pressure measurements. First, we analyzed only a small sample of commercially available endovascular catheters with limited representative catheters in each catheter size category. Second, we chose to maintain the system at an arterial pressure to create a visible wave morphology in the model system. While this allowed for better waveform analysis, it may limit applicability at venous pressures. An analysis of catheter reliability in the venous pressure range is a meaningful area for future studies, as well as in other pathologic states such as stenoses, aneurysms, or other vascular lesions. Also, due to catheter tapering, the transduction area at the catheter tip may be an oversimplification of the wave transduction fluid space. We did observe a loss of pulse pressure with decreasing transduction area for both the obstructed guide catheter and unobstructed microcatheter. However, a linear regression fit the obstructed catheter analysis very well but did not fit the unobstructed microcatheter data as well due
to clustering at lower transduction areas. To address this observed limitation, we would require more data from microcatheters with an ID between 0.021 and 0.027 inch. Lastly, our statistical analysis did have a wide confidence interval, and recommendations for catheter sizes should be interpreted cautiously from this report until validated with a larger data set and preferably in a clinical setting.

Conclusions
Our benchtop analysis demonstrates that accurate and precise mean pressure measurements may be made through any size catheter that is currently being used in neuroendovascular surgery (as low as 0.013-inch ID). For preservation of 90% of the pulse pressure and waveform morphology, a 0.031-inch ID microcatheter may be required according to our linear regression model. However, a 0.027-inch ID microcatheter preserved at least 88% of the pulse pressure and 85% of the waveform morphology in this study. For preservation of pulse pressure and waveform morphology through a guide catheter with an indwelling microcatheter, a remaining transduction area of 2.21 mm² is required, which is nearly achieved with a 0.070-inch guide catheter and a microcatheter with ≤ 0.042-inch OD (e.g., Marksman 0.027-inch ID or smaller). Further validation of these findings is necessary at venous pressures, with more catheter sizes, and, most importantly, in a clinical setting.

References

Disclosures
The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions
Conception and design: all authors. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: all authors. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Heiferman. Statistical analysis: Le, Klinger.

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