Automated Contrast Injection System Insights into Flow Rate Parameters and Pressure

A Candid Conversation with Dr. Bob Wilson about the ACIST CVi Contrast Management System

Bob Wilson, MD

Clinical Chief, Cardiovascular Division, University of Minnesota, Dr. Bob Wilson has spent decades focusing on the development of medical devices for the diagnosis and treatment of cardiovascular diseases. His research into methods for studying the coronary circulation in humans led to the development of the first coronary Doppler catheter to measure coronary blood flow, one among many contributions to science and biomedical engineering projects. He was Founder and Chairman of the Board of Directors of ACIST Medical Systems, which now markets a range of devices in 44 countries worldwide.

All quotes are taken from the interview with Dr. Wilson.

Can you give us an overview of the ACIST CVi Contrast Management System?

The ACIST CVi System is an automated, variable-rate contrast injection system for angiographic procedures. The operator delivers contrast using a sensitive, interactive handheld controller. Some of the key features of the system are:

- Variable rate injection controlled by a handheld AngioTouch® controller that allows the operator to inject contrast with great precision
- 4 active safety sensors for patient safety
- Peristaltic pump for saline delivery
- Integrated hemodynamic monitoring from the catheter

Dr. Wilson, you mentioned variable rate; could you explain what that means?

Variable rate gives the operator the ability to control not just the amount of contrast that is delivered, but the rate and time it is injected as well.

Could you explain how the ACIST CVi uses pressure?

Pressure is a bit arbitrary when using ACIST CVi — the technology drives to achieve a flow rate, not a pressure limit. In other words, CVi will only use the pressure necessary to achieve the desired flow rate selected, and that pressure is only at the syringe as it starts to push the contrast forward. As the fluid travels down the tubing and through the catheter, that pressure drops significantly, and there is virtually no pressure at the catheter tip.

Why is pressure displayed on the CVi Control Panel?

The pressure displayed on the Control Panel is the limit, or maximum amount of pressure CVi will allow inside the syringe when delivering flow. This is to ensure that the consumable components (tubing, stopcock, Tuohy, catheter, etc.) which are rated at 1200 PSI are protected at their inlet from the injector. If a lower pressure rated consumable component was used, the limit should be reduced to ensure that component is not damaged. This adjustment is made by a trained user.

Figure 1: Flow Rates, Pressures and Pressure Drops with a 5 FR Catheter

FLOW RATE (mL/s)		PRESSURE (psi)				PRESSURE DROP (psi)		
Set	Measured	Exiting Syringe* (A)	Entering Patient Kit (B)	Exiting Patient Kit (C)	Exiting 5Fr Catheter (D)	From A-B BT Kit*	From B-C Patient Kit	From C-D 5Fr Catheter
12	11.3	625	565	540	2.6 (~130mmHg)	60	25	537
10	9.5	511	451	427	2.2 (~110mmHg)	60	23	425
6	6.0	313	253	238	1.5 (~75mmHg)	60	16	236
2	1.9	121	61	32	0.4 (~20mmHg)	60	29	31

* Estimated
Data on file at ACIST Medical Systems

To clarify, the user would set the pressure limit on CVi?

Yes, the operator has the ability to select the pressure limit, although in most situations the users do not change the cardiac software from the default settings. Remember, the pressure limit is the maximum amount of pressure the system will allow inside the syringe when delivering flow.

If the pressure inside the syringe reaches the set pressure limit, say 600 PSI, what is the pressure of the fluid that is exiting the catheter?

Regardless of the pressure that is inside the syringe, the pressure that is exiting the catheter is around 50-120 mmHg over surrounding blood pressure. A flow rate of 12ml/second through a 5 Fr catheter will result in a larger pressure drop from the syringe to the exit of the catheter compared to a flow rate of 2ml/second through that same 5 Fr catheter. We have collected empirical data that shows a 2 mL/s injection through a 5 Fr catheter results in a ~120 PSI pressure drop from syringe to catheter tip. The fluid pressure at the tip of the catheter was ~30mmHg over surrounding blood pressure. A 12 mL/s injection through a 5 Fr catheter results in a pressure drop of ~625 PSI. The fluid pressure at the exit of the catheter during the 12ml/sec injection was on the order of 130 mmHg (Figures 1 & 2).

Does the ACIST CVi Contrast Management System have any injection safety features?

Yes, the ACIST CVi Contrast Management System has safety features for both pressure and flow, in addition to air detection. Since we were just talking about flow, I will use that as an example.

- If the ACIST CVi is unable to achieve the set flow rate for an injection, the operator will see an error message, “Pressure Limit Exceeded”, which will either stop the injection entirely or reduce the flow of contrast to help prevent damage to the catheter. It is up to the operator to determine the cause, whether it is a kinked catheter, a closed stopcock at the catheter attachment, or the PSI limit may be set too low for the desired flow rate.

I thought you said PSI doesn’t really matter? Because the ACIST CVi drives to achieve a flow rate, not pressure.

That is correct, but you still must generate sufficient pressure to overcome the resistance of the tubing and the catheter, that is pressure in the syringe as it starts pushing contrast in the syringe.

- If the pressure inside the syringe exceeds the set pressure limit the system will stop the flow of contrast. For example, if you want to perform a 20 mL/s injection into the aorta using a 5 Fr catheter, but only have the pressure limit set to 200 PSI, the system will probably not be able to deliver that contrast flow rate at a pressure of 200

PSI- the catheter of that size is too small to conduct a flow that fast. The operator will see the error message; “Pressure Limit Exceeded”. One would have to raise the PSI limit to give ACIST CVi the ability to overcome the downstream resistance of the tubing and catheter associated with delivering 20ml/sec. All injection systems do this, but not all systems alert the user.

What is the difference between flow rate, pressure, and velocity for contrast injections?

Flow Rate is the volume of fluid that is delivered in a specified amount of time. The pressure associated with a flow rate is the byproduct of moving the high viscosity contrast through a tube. ACIST CVi delivers the specified flow rate by advancing the syringe plunger at a certain rate. As a result of the resistance to outflow provided by the catheter system attached to the syringe, the syringe pressure rises. This difference in syringe pressure and pressure in the catheter causes contrast to flow through the catheter system. As the contrast travels down the catheter system, the pressure continuously falls until it reaches the end of the catheter, where it is slightly above blood pressure. The same pressure dynamics occur with hand injections and motorized injections, which is how any pump works. The ACIST CVi has safety sensors to limit injection pressures.

The amount of pressure needed for an injection is a function of:

- The length of the patient tubing, the longer the catheter, the more pressure needed
- Diameter of the tubing, the smaller the catheter the more pressure needed. Most catheters are rated for 1200 PSI, but small catheters – like 4 and 5 Fr, cannot deliver very high flow rates because they very quickly dissipate pressure in the catheter.
- Viscosity of the fluid injected — contrast is very viscous- similar to honey, and it is more difficult to inject through a catheter — particularly if the catheter diameter is small.

Why is the Pressure Limit variable? Why isn’t the limit the same for all injections?

The main purpose of the Pressure Limit is to detect something wrong in the system, such as a kinked catheter or a closed stopcock. At slower injection rates, we know that the pressure should be very low in an open system. By setting the pressure limit low for slower injection rates — such as during coronary angiography, the system can be more sensitive and precise.

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Is there is an increased risk of dissection with different catheter sizes?

Catheters can cause dissections and the most common culprit is placement of the catheter tip into the wall of the artery. This is why we always look at the blood pressure at the catheter tip before injecting — for this reason, the CVi was designed with integrated blood pressure monitoring. Any catheter size, if improperly placed can cause a dissection.

Is there an increased risk of thrombus or plaque dislodgement?

With the variable rate controller the operator has sensitive control of the injection, with the ability to deliver a very small amount of contrast at a very low flow rate, or, again, to “ease into” the injection. Mastering the technique of the hand controller allows the operator to use ACIST CVi with confidence regardless of procedure type, or what may be found intra procedure.

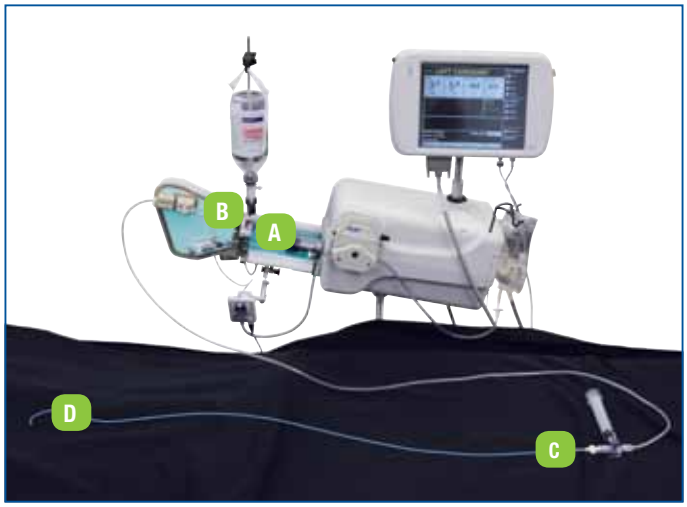

Figure 2: The CVi System showing points where pressure drops occur from the syringe to the catheter tip.

How would you summarize these insights?

The ACIST CVi, far from increasing risk of dissection, offers multiple features to help the physician reduce such risk. The system automatically selects the correct pressure to achieve a given flow rate; hemostatic monitoring at the catheter tip tells the physician if the tip may be too close to the artery wall. The touch-sensitive controller enables even finer adjustment to the flow rate during the procedure.

With very little practice, the ACIST CVi gives physicians high confidence in their ability to address a wide range of procedure types, and to manage whatever arises intra procedure.

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