

Managing Contrast Injections During Diagnostic and Interventional Coronary Procedures

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BACKGROUND

In 2004, slightly more than 3.9 million patient procedures were performed in US cardiac catheterization laboratories. Approximately 3.6 million of these procedures were contrast enhanced and out of those 63% employed a power injector to achieve the desired opacification¹. Traditionally, power injectors are used in diagnostic studies that require high flow, high volume, fixed rate injections delivered with relatively high pressures. Typical applications of this sort are ventriculograms, aortograms and run-off studies. Interventional procedures and studies that require low, variable flow rate injections are preferably performed with manual syringes and manifold sets. Specifically coronary diagnostic studies and interventions were virtually exempted from power injector application. Reasons cited for the reluctance to use power injectors for these types of procedures are:

- Current processes are well established and existing tools perform adequately
- Lack of variable flow control to allow for deliberate and minute flow adjustments during injections with traditional injectors
- Concern regarding pressures introduced into relatively small and delicate vasculature with powered injection
- Expected loss of "pressure" feedback which is presumed to be detectable with manual syringe
- Skepticism regarding the air handling safety of available devices
- Impact of powered injections on catheter behavior within vasculature (catheter whipping due to sudden high flows)
- Inconvenience of setup and usage
- Anticipated long learning curves for new users

The design of cardiac angiographic catheters has not experienced any major updates over the past 10 to 15 years. In essence, the design still comprises a catheter hub for connection, a catheter body of various sizes, lengths and stiffness, and a tip with a single end-hole to eject fluids. New materials and shapes have been introduced that increase the flow performance and allow for easier vessel engagement, however, contrast and other fluids still exit in one focused stream. When used with

power injectors that generate abrupt high flows, this flow pattern can cause a catheter to "kick back" and disengage from vessels. The smaller the catheter, the more pronounced this effect will present itself.

OBJECTIVES

In recent years, tremendous advancements have been made in injector technology to specifically address the drawbacks of earlier concepts. Just recently, a next generation fluid management injection system was introduced with the potential to alleviate earlier concerns. We evaluated this new injection system in our cath lab with several specific questions in mind:

- How does operation of the system fit into the daily routine of our cath lab? (Note: We utilized the device for all scheduled patients and procedures, both diagnostic and interventional, and did not randomize or pre-select patients.)
- How easy is it to set up, operate, and prepare the system between patients?
- Can the device either generate equal quality images with less contrast or improve the diagnostic quality of images with the same amount of contrast?
- Does the system perform equally well with various contrast media?
- Does use of the system have any impact on fluoroscopy time and total procedure time per patient?

In conjunction with the injector we assessed the performance of a new 4FR angiographic catheter with certain design characteristics that seem to make it particularly well-suited for powered contrast injection. Main evaluation criteria for the catheter were:

- How does handling of the new 4FR catheter compare to the 6FR catheters traditionally used in our lab, specifically, torquability, pushability, tracking over wire and wire advancement?
- Does the ejection profile of the new catheter provide adequate filling and opacification of the coronary vessels?
- Can equal diagnostic quality be achieved with less contrast?



Figure 1: MEDRAD Avanta Fluid Management Injection System (pedestal mounted version)

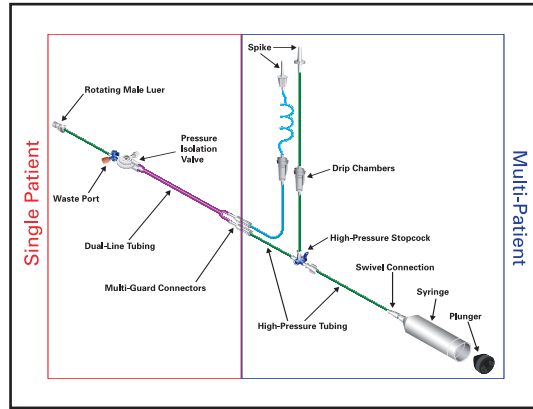


Figure 2: Disposable Sets



Figure 3: Hand-Controller for fixed and variable contrast flow and saline flush

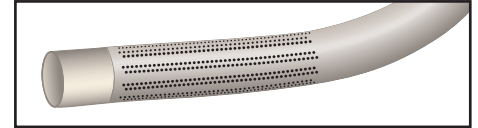


Figure 4: Stylized drawing of the Vanguard Dx tip to illustrate side-hole pattern (not to scale)

MATERIAL

Injector

The MEDRAD Avanta™ Fluid Management Injection System (MEDRAD, INC., Pittsburgh, PA) (Figure 1) is a next generation device designed to allow controlled flow automated injections of the coronaries. The injection protocols are programmed with a color touch screen and operated with a single hand-controller. Contrast is delivered with a piston-driven, 150ml syringe that automatically fills from an attached bulk source of contrast. Saline for flushing is delivered with a peristaltic pump that also draws from a bulk source.

The disposable sets consist of multi-patient and single-patient components (Figure 2). The multi-patient set contains syringe and preassembled tubing and can be used for up to five patients. The hand-controller (Figure 3) is also rated for up to five patients when sheathed. All injections, as well as saline flushing are controlled with this component. The single-patient disposable set consists of separate high-pressure contrast and saline tubing, a pressure isolation valve (to attach pressure transducers) and a waste port.

Catheter

The Vanguard Dx™ Angiographic Catheter (MEDRAD, INC., Pittsburgh, PA) (Figure 4) encompasses a new tip design that creates a distinct ejection profile. A soft restrictor tip drives most of the contrast or saline flow out of a multitude of 50-micron side-holes. These holes are symmetrically arranged around the distal end of the catheter. Because of this hole pattern, the catheter creates a cloud of contrast and not a focused stream thus eliminating the recoil commonly experienced with traditional end-hole catheters.

At the time of the evaluation only three types of the 4FR Vanguard Dx catheter were available to us. These included an angled Pigtail (155°), a Judkins Left 4 and a Judkins Right 4.

METHODS

Prior to the start of the evaluation, a MEDRAD clinical representative provided an extensive in-service for the cath lab personnel participating in the evaluation. The eval-

uation team was comprised of two interventional cardiologists and a select group of cath lab personnel to limit variability and to provide a controlled learning environment. The in-service included demonstration of initial injector setup, subsequent setups between patients, hand-controller operation, device programming, and recall of established protocols. Each participant was given an opportunity to demonstrate competency in injector operation with the operation of the injection system. On the morning of the evaluation the physicians received additional training with particular focus on operation of the hand-controller.

The MEDRAD Avanta Injection System was evaluated over a two-day period in 15 patient procedures. The case mix included ten diagnostic and five interventional coronary procedures. On day one of the evaluation, seven procedures were performed (six diagnostic and one interventional) utilizing our standard 6FR catheters. On day two, four diagnostic and four interventional coronary procedures were performed. In half of these eight patients the 4FR Vanguard Dx catheters were applied for the diagnostic portion of the procedure. All interventions were performed with 6FR guiding catheters.

Procedural data from these 15 procedures were compared to recent historical information based on a similar patient population in terms of age, gender, size, diagnoses and procedure types.

RESULTS

Procedure Flow and Ease of Use

Integrating the injector into our cath lab routines did not pose any challenges. We elected to mount the system at the foot end of the table opposite of the operator and the sheathed display control screen separately on the operator side. This arrangement allowed the injector to move with the table and provided convenient access to the control screen for protocol selection and adjustments.

Preparation of the system for the first patient is relatively simple. The cath lab personnel were able to complete required steps in less than five minutes with little guidance from the company representative. The available on-screen tutor added to the convenience. For subsequent patients, only the single patient set has to be exchanged resulting in overall improvement in room turnover times for successive cases.

The design of the injector, tubing, and hand-controller eliminate the need for a manifold set and hand syringe. Manual switching of stopcocks for syringe filling, injecting, or opening to the pressure port is no longer required. These activities are automated by the injector system. The two physicians who were involved in the evaluation commented that once they became comfortable using the hand-controller, they recognized an appreciable difference in the ease of injections. The variable flow injection mode provides the required flexibility to apply the injector throughout a complete procedure including the diagnostic and interventional portion.

Operations, such as programming, storing, and recalling protocols, are very intuitive. The screen layout is clear, and pertinent information, such as set protocol parameters and actually achieved flows, volumes, and pressures, are visible at all times. In addition, the cumulatively injected contrast volume is constantly displayed per patient. This information had to be estimated previously but is considered an important factor in determining the potential need to switch out contrast type or further limit injection volume.



Figure 5: LCA opacification utilizing the MEDRAD Avanta Injection System with the Vanguard Dx Angiographic Catheter in 4FR size



Figure 6: LCA hand injection with a 6FR angiographic catheter

Image Quality and Contrast Usage

We were able to generate quality images (Figure 5 and 6) by using the MEDRAD Avanta injector and later the Vanguard Dx catheter. Opacification was achieved more rapidly and consistently compared to hand injection. Utilizing the electro-mechanical hand-controller enabled the physician to very precisely manage contrast flow rates and volumes while at the same time reducing hand strain.

One of the objectives was to determine if use of the injection system would save contrast while maintaining image quality. We have established that image quality was maintained or even improved. In addition, we were able to achieve significant contrast savings, especially during diagnostic procedures, with an average reduction of 21%. During interventions we experienced a slight increase of contrast usage of 2%. As we gained more experience with each patient the average contrast usage decreased. Therefore, we expect that we will be able to reduce the average contrast volume even more with future use of the injector.

We typically use two contrast types in our cath lab, Iohexol (Omnipaque® 350) and Iodixanol (Visipaque® 320) (GE Healthcare, UK). Both types are usually warmed prior to use to reduce viscosity. We were able to achieve desired flow rates with either contrast even though Visipaque is the most viscous contrast currently available (26.6 cp at 20°C and 11.8 cp at 37°C)².

Fluoro Time and Procedure Time

We were able to significantly reduce the fluoro time in both diagnostic as well as interventional cases. Overall fluoro times were reduced by 57% with the most dramatic change in interventions (65%). We ascribe this remarkable change to the significant shortening of each individual fluoro shot and lower need for repetitions.

The average procedure time during the evaluation period increased by approximately six minutes. Several factors contributed to this added time. First, it took about four or five cases to become comfortable and confident in the use of the injector. Second, we deliberately concentrated on every phase and step of the injector setup and operation. We stopped to discuss the significance of individual steps and particular features to thoroughly learn and understand the system. And lastly, contrary to standard practice, more individuals were present in the cath lab during procedures for observation and learning.

Catheter Performance

A variety of studies demonstrated advantages of smaller catheters in terms of ambulation time, patient comfort, complication rates, and the opportunity to save wound closure cost^{3,4}. However, smaller catheters are expected to be softer and more bendable than 6FR catheters. This softness is assumed to negatively affect pushability and torquability and thus complicate vessel engagement.

Our limited experience with the Vanguard Dx showed that this catheter is relatively stiff compared to other 4FR catheters. This stiffness allows for good pushability and lets the catheter track easily over a 0.035 guidewire. It posed no problem to place the pigtail in the ventricle and the catheter remained very stable even with high flow injections. The JL catheter engaged the left ostium easily.

The unique tip design prevented any catheter kickback and kept the catheter seated in the vessel. Engaging the right coronary artery posed a higher technical challenge. Because we only had a JR4 available to us, we could not adjust for anatomical variability; in patients with longer torsos, engaging the RC presented difficulties. The propensity to over-torque due to the relative stiffness added to the challenge, and, therefore, we opted to use our traditional 6FR catheter in this subset of patients.

Based on our feedback and that of other clinicians, the company made a change in catheter material composition to reduce the stiffness and over-torquing tendency. In a subsequent evaluation of the catheter with the new material we believe that the torque response is now adequate to consistently enable placement in the right coronary. In addition, there are now 15 different catheter shapes available that allow a selection appropriate to the patient anatomy.

The two physicians involved in the evaluation stated that the smaller diameter catheter did not sacrifice angiographic diagnostic quality when used with the Avanta injector. The cloudlike ejection of contrast enhances mixing with blood and produces adequate vessel filling and opacification. The combination of the 4FR Vanguard Dx catheter and MEDRAD Avanta injector generated images of a quality equal to that previously achieved with manual injection through 6FR catheters (see Figure 5 and 6). These results were achieved, however, with significantly less contrast.

We also evaluated the 4FR Vanguard Dx catheter with hand injection. Like other 4FR catheters it has a higher pressure drop compared to a 6FR catheter and, therefore, it requires a more vigorous injection with the hand syringe. One physician was able to create sufficient flows to produce diagnostic images. The other operator had difficulties in generating enough power to adequately opacify the target vessel. We conclude that success with hand injection may in part depend on patient size - or, more appropriately, on the target vessel size - and on the operator.

DISCUSSION

Our evaluation of the MEDRAD Avanta Fluid Management Injection System and the Vanguard Dx Angiographic Catheter was not a controlled study and involved a limited number of patients. We cannot, therefore, report any statistically significant results. However, the short evaluation period provided us with sufficient experience to provide qualitative statements:

- The MEDRAD Avanta injector was easily integrated into the routine of our cath lab
- Operation of the device is intuitive and can be learned in a short time
- The system improves the quality of images while reducing contrast volume
- Use of the injector can significantly reduce fluoroscopy time and shorten turnover time between patients
- The 4FR Vanguard Dx catheter seems ideally suited for automated contrast injection. When hand injection is performed some operators may be unable to generate sufficient flows
- In combination with the MEDRAD Avanta Injection System the catheter generates quality images and contributes to contrast reduction
- The catheter tip remains very stable even with forceful

injections. The elimination of catheter recoil can streamline the imaging process (no more re-positioning due to catheter whip) and contribute to reduced vessel irritation (e.g. PVC with a traditional Pigtail catheter that shifts position during injection)

We intend to continue our evaluation of the injector and catheter. We will further investigate the impact on overall procedure time and fluoroscopy time. Lowering these two parameters can have important health benefits for the patient and can increase overall patient comfort. In addition, the reduced fluoro time may positively affect staff radiation exposure. The potential to save significant amounts of contrast warrants further examination as well. With the aging population and increasing prevalence of comorbidities, such as diabetes and renal insufficiency, any opportunity to reduce contrast should be seriously considered.

The 4FR Vanguard Dx catheter offers several theoretical benefits that we could not thoroughly investigate in the short evaluation period. In particular, there should be an appreciable reduction in patient ambulation time if compared with traditional 6FR catheters in purely diagnostic procedures. Equal reductions can be readily achieved with wound closure devices, however, these devices add cost and do not necessarily lower access site complications⁵.

In future use, our focus will not only include the clinical significance of both products but also their economic impact. We plan to assess if reduced individual procedure time allows us to increase patient throughput. Another question deserves attention: do the reduction in contrast and the potential to eliminate wound closure devices offset any higher cost that may be associated with the use of the injector and catheter? Lastly, the ease of use of the injector may potentially free staff to focus on other patient or process-related issues and thus achieve economic benefits.

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