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This supplement and the ensuing post test are designed to be completed within 30 minutes. The goal of this supplement is to provide an overview of safety features on contrast power injectors and to provide a real-world example of how they are used in the CT suite to help technologists identify and prevent instances of extravasation or air embolism.

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Evaluating CT Contrast Injectors

Kathleen Dallessio

Each year millions of Americans undergo contrast-enhanced computed tomography (CT) scanning. A significant number of these procedures employ power injectors for contrast media administration.

Recently, the ECRI Institute (Plymouth Meeting, PA), evaluated the safety and utility of the CT contrast injectors currently marketed in the United States. They rated basic and optional system configurations.

"Injectors are used in almost 50% of CT studies and are an important technology affecting many patients each year," said Jason Lauenders, MSc, Senior Medical Physicist at ECRI. "We have had reports of a few CT injector-related incidents and manufacturers are developing new technologies to help combat these issues, so we thought it was a good time to see what precautions were built into these systems."

In this study, the ECRI Institute tested the 3 main CT contrast injectors currently available in the United States: ACIST EmpowerCTA by ACIST Medical Systems Inc., A Bracco Group Company (Eden Prairie, MN); the Covidien Optivantage DH by Covidien Imaging Solutions (Hazelwood, MO); and the MEDRAD Stellant D by MEDRAD Inc., a Unit of Bayer Medical Care (Warrendale, PA).

System evaluations and findings

To evaluate these systems, ECRI testers visited each manufacturer and asked them to demonstrate the safety features incorporated in each system.

"We spent about a day with each of them going through all the safety precautions and we tried to defeat them," said Lauenders.

Inspectors tested basic safety features including visual and audible alerts and warnings, as well as additional safety features including extravasation detection, forced air purging and system integration.

Based on the study findings, each system was given 2 separate ratings—one for a basic configuration and one for a system with all of the optional features engaged. ECRI used a 1- to 5-star rating system where 1 star was the lowest and a 5-star rating was the highest.

They found that all the systems worked well and that they were mainly differentiated by the selection of safety features. For the basic system, the EmpowerCTA was given a 4-star rating, while the Optivantage DH and Stellant D each received 3 stars. When the optional features were engaged, the EmpowerCTA and Stellant D were both given 5 stars and the Optivantage DH received 4 stars.

"In a CT environment, patient throughput is absolutely critical for most facilities, so you only have about 10 to 15 minutes per patient," said Lauenders. "People expect these systems to be used safely time and time again. Most of the problems that we see occur when people think that the safety precautions are built into the injector and it turns out that they are not, or that a safety device has not been activated or has been accidentally deactivated in the injector."

Kathleen Dallessio is a technology writer for *Applied Radiology*.

The three main safety areas that ECRI studied were extravasation detection, air embolism prevention, and system integration.

Extravasation detection

The most significant safety concern with the rapid injection of contrast media is the risk of extravasation, the leakage of contrast medium from the vein to the surrounding tissue. Each of the systems tested has some feature designed to lower the risk of an undetected extravasation. The Optivantage DH requires the user to conduct a test for patency using saline at the maximum injection rate before contrast can be injected. The other two systems, EmpowerCTA and Stellant D, have optional automated extravasation detection devices. This feature employs a single-use adhesive patch that is placed on the patient at the injection site. The system can detect potential extravasations and automatically stop the injection. ECRI concluded that the safety benefits of this approach outweigh the financial costs and extra time involved. They recommended that healthcare facilities consider using automated detection systems.

The detection tools have a long history of clinical use. ACIST pioneered the technology when it released the Extravasation Detection Accessory (EDA) in 1997. MEDRAD has commercially marketed its Extravasation Detector System (XDS) since 2007.

Air embolism prevention

All of the systems require the user to purge air from the tubing during set up, but none of the systems have an automated air-detection system.

"In the case of CT injectors, air detection is not part of any of the injectors on the market, so that is still a concern," said Launders. "I think part of the reason for that is that the time required to set up a CT procedure is so short. So the extra steps and the extra

cost, provide negative incentive when coupled with the fact that there is no real perceived need for air detection."

CT injectors introduce contrast into the venous system, and so air embolism is less of a concern in these procedures. ACIST has a standard tilt lockout feature on the Empower CTA which can help minimize the likelihood of air embolism.

"However, we have investigated a few cases where there were poor outcomes due to some pre-existing medical conditions with some patients," Launders said. "We think it has been underrated as a potential problem and the addition of air detection would be a way of ameliorating that potential threat."

System integration

Documentation of contrast use emerged as a significant area for improvement in the ECRI study. Improved integration and record keeping would allow facilities to use the acquired data to optimize and individualize contrast dosing. The Injector Reporting Information System (IRiSCT), from ACIST, is a standard feature on the EmpowerCTA, and the Certegra informatics platform, from MEDRAD, is an optional feature on the Stellant D.

"Up to now, contrast has been delivered in a one-size-fits-all approach," said Launders. "But research has shown that when you start optimizing the contrast injector protocol, the image quality can be improved. So you could, for example, start lowering the X-ray dose as a side effect."

Conclusion

Contrast injectors contribute to high-quality images and with the industry looking to further mature these offerings through better integration to CT systems, to radiology reporting systems, and ultimately to the patient record, contrast injectors are becoming an integral component of CT systems.

Erratum

In the original version of this article, *Applied Radiology* did not obtain proper permission to use ECRI Institute's product ratings.

In addition, the citation should have read: Safety features on CT Contrast Injectors: Enhancing Patient Protection [Evaluation]. *Health Devices*. 2010 May;39(5):150-65.

ECRI Institute has a strict no-commercialization policy and is not in any way related to or funded by Bracco, ACIST Medical Systems, or the ACIST EmpowerCTA. *Applied Radiology* regrets the error.

Ensuring Patient Safety with CT Contrast Power Injectors

Contrast media is routinely used in computed tomography (CT) studies to visualize the vasculature, and in a growing number of these cases, power injectors are employed to automatically deliver the contrast dose. While this technology has been shown to be extremely safe in clinical practice, there are safety concerns that the clinician and technologist must consider. The two

most important issues are extravasation, the leakage of contrast media into the tissue surrounding the vein, and the potential for the injection of air into the venous system.

Using a power injector

When using a power injector, the person setting it up, typically a radiology technologist or

nurse, loads a single-use syringe with the proper volume and concentration of contrast medium into the injector and attaches the single-use tubing. A cannula is then inserted into the patient's vein. The tubing is purged of air and connected to the cannula. The injector is synchronized with the CT scanner, timing the injection to begin a few seconds prior to the start of the scan. Injection rates vary depending on the study, but 100 mL of contrast delivered at a rate of 4 mL/sec is typical.

"Extravasation is probably the most significant safety concern," said Rendon C. Nelson, MD, FACR, Reed and Martha Rice Professor of Radiology, Duke University, Durham, NC.

According to the American College of Radiology (ACR), the incidence of extravasation related to power injectors ranges from approximately 0.1% to 0.9% of all procedures.¹

Typical symptoms include swelling, tightness, stinging, or burning pain at the site, although some patients will experience little or no symptoms. When examined, the area may appear edematous, erythematous, or tender.¹ For the patient, the consequences can range from mild to severe.

"It can be a painful ordeal for the patient when a large volume extravasation occurs," said Donna Parker, RT(R)(CT), Chief Technologist, Department of Radiology at Duke. "If it is just a small amount, such as 10 or 20 mL, it should dissipate within the tissue over a period of time without a lasting effect. However, if the entire 100 to 150 mL bolus goes into the soft tissue, plastic surgery would most likely be contacted to evaluate the patient. "Even without significant sequelae, management of a severe extravasation requires vigilant supportive care from nurses and most likely a consult from plastic surgery.

"[Our procedure is to] watch them for a period of time, requiring supportive care from nurses," said Dr. Nelson. "If it is a more severe extravasation, we have a consult from plastic surgery. Either way, the patient spends more time in the hospital or clinic and isn't able to leave right away."

In the most severe cases, patients can develop compartment syndrome. "Sometimes the extravasation doesn't occur in the skin, but occurs deep around the muscle, in which case the patient can develop a compartment syndrome which can compromise blood supply to the hand and the forearm," said Nelson. "This is pretty uncommon but it can occur." In a study by Wang, et al. 475 extravasations occurred among the 69,657 patients studied, for a rate of 0.7%, with only one case of compartment syndrome found among the 442 adults with extravasation.²

Table 1. Understanding Extravasation Risk Factors

Patients at increased risk

- Patients who cannot communicate adequately including the elderly, infants, children and those with altered consciousness
- Severely ill or debilitated patients
- Patients with abnormal circulation in the limb to be injected including those with atherosclerotic peripheral vascular disease, diabetic vascular disease, Raynaud's disease, venous thrombosis or insufficiency, prior radiation therapy, or extensive surgery in the limb to be injected

Injection sites that contribute to increased risk

- The hand, wrist, foot, or ankle should be avoided if possible
- In-dwelling peripheral IV lines that have been in place for >24 hours
- Multiple punctures into the same vein

American College of Radiology. Manual on Contrast Media v7. Chapter 3. Extravasation of Contrast Media. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual/Extravasation.aspx. Accessed August 18, 2010.

"We really don't know for sure why extravasations occur," Nelson noted. "There are several theories and probably they are all plausible."

According to the ACR certain patients may be at increased risk for extravasation (Table 1).¹

Preventing extravasation

Good clinical practice, combined with extravasation detection technology integrated in the injector system, can help eliminate, or at least lessen the severity, of extravasations. Duke uses the ACIST EmpowerCTA by ACIST Medical Systems Inc., A Bracco Group Company (Eden Prairie, MN). The system comes with an optional automated extravasation detection device known as the Extravasation Detection Accessory (EDA). The system uses an adhesive patch with an embedded sensor.

"The extravasation device is a wonderful tool for us," said Parker, "because it can detect extravasation and turn off the machine so that the contrast doesn't go in, or if it does go in, it is a very small amount. The patch goes on the patient around the catheter site. If any extravasation happens on the surface around that patch, the sensors detect it and turn off the injector. The technologist or nurse then verifies if there is an extravasation or not."

With the detection technology, noted Nelson, "extravasation is detected early and [typically] involves relatively small volumes, although sometimes it is not detected until later. Overall, it does tend to help prevent the more severe or large-volume extravasations."

Preventing air embolism

A second safety concern with the power injection of CT contrast is the risk of the injection of air into the venous system which can lead to the development of an air embolism.

"It is a big concern but it is very rare," noted Nelson. "We see little bubbles here and there from time to time, but I have never seen a major power injection of air. The system must do something right because we just never see that."

To address this concern, the EmpowerCTA injector includes automatic air purging in the filling sequence and requires that the power head be tilted all the way down—thereby sending any air bubbles to the back of the syringe—before the system can be armed. In addition, once the patient tubing is connected, the user is reminded to purge the tubing and must visually confirm that all air is purged.

"Once again, you are relying on your staff to determine that the contrast has been purged through to the end of the tubing. They must check and re-check,

before making the actual connection between the tubing and the IV catheter," said Parker.

Conclusion

The most important safety feature, however, is always the personnel conducting the study.

"You can't always rely on machines," Parker said. "The technologist or nurse should advise the patient to communicate, if there is pain at the injection site during the injection. You have to stay alert and remain in contact with the patient throughout the injection and scan. You can never be too conscientious or safe."

References

1. American College of Radiology. Manual on Contrast Media v7. Chapter 3. Extravasation of Contrast Media. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual/Extravasation.aspx. Accessed August 18, 2010.
2. Wang CL, Cohan RH, Ellis JH, et al. Frequency, management, and outcome of extravasation of nonionic iodinated contrast. *Radiology*. 2007;243:80-87.

Quiz

Post your quiz answers to appliedradiology.com/contrast to receive your CE certificate for this activity. Opt-in to receive a digital version of the next 3 supplements in this series and you will be automatically entered into 4 quarterly raffles for an Apple iPad®!



1. Which injection site is most routinely associated with an increased risk of extravasation?
 - A. Hand
 - B. Arm
 - C. Leg
 - D. None of the above
2. Standard power injector tubing may be re-used how many times?
 - A. 0
 - B. 1
 - C. 2
 - D. 3
3. Extravasations are more likely when injections are made through in-dwelling peripheral IV lines that have been in place for >__ hours.
 - A. 5
 - B. 24
 - C. 48
 - D. 18
4. Extravasation during rapid contrast media injection is defined as leakage of contrast medium from the vein to the surrounding tissue.
 - A. True
 - B. False
5. As noted by the American College of Radiology, extravasations occur in
 - A. 10% to 15% of all CT procedures
 - B. 1% to 9% of all CT procedures
 - C. 0.1% to 0.9% of all CT procedures
 - D. A statistically insignificant number of procedures
6. Which symptoms are most indicative of an extravasation?
 - A. Shortness of breath and nausea
 - B. Memory loss, inability to speak
 - C. Swelling, tightness, stinging or burning pain at the injection site
 - D. Excessive bleeding at the injection site
7. When a patient is experiencing an extravasation how would the injection site appear on examination?
 - A. Edematous
 - B. Erythematous
 - C. Tender
 - D. All of the above
8. Severe cases of extravasation may require a consult from which specialty?
 - A. Cardiology
 - B. Endocrinology
 - C. Plastic surgery
 - D. Internal medicine
9. Which group of patients present the highest risk of extravasation?
 - A. Patients with altered consciousness
 - B. Severely ill patients
 - C. Those with abnormal circulation in the limb to be injected
 - D. All of the above
10. Which of these methods is most likely to lessen the severity/likelihood of extravasation?
 - A. Extravasation detection technology
 - B. Good clinical practice
 - C. Both good clinical practice and extravasation detection technology
 - D. None of the above

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