CT Contrast Media Power Injectors Can Rupture Conventional IV Sets

ABSTRACT

PA-PSRS has received reports of intravenous (IV) tubing rupturing during contrast media injections into patients during computed tomography scans. Many of these occurrences result in contrast or blood and fluids contacting patients or staff. Similar events have also been reported to the U.S. Food and Drug Administration (FDA). Contact with contrast media or blood and fluid could result in harm to patients or staff. In addition, rupture of a set would cause delay or cancellation of the contrast study. Often, conventional IV tubing, which can easily rupture, is used to introduce the contrast media through a power injector, spraying contrast medium or blood and fluid onto patients or staff. FDA has developed guidelines to prevent harm to patients and staff during contrast injections, which include checking the labeling of each vascular access device for its maximum pressure and flow rates, knowing the pressure limit setting for the power injector and how to adjust it, and ensuring that the pressure limit set for the power injector does not exceed the maximum labeled pressure for the tubing or other vascular access device. (Pa Patient Saf Advis 2008 Sep;5[3]:136-7.)

Contrast media are sometimes used during computed tomography (CT) and magnetic resonance imaging scans to enhance the contrast between blood vessels and their surroundings, such as in angiograms. Typically, a contrast medium is introduced into a patient’s blood vessel via a power injector. Contrast power injectors are typically flow-rate controlled with user-adjustable pressure-limiting capability. The flow rate is dependent on solution viscosity, solution volume, pressure, and the cross-sectional area of the tubing. Often, the contrast is introduced through conventional intravenous (IV) sets (i.e., sets used with infusion pumps to deliver medication therapy), which may rupture if the injector pressures exceed the pressure tolerance of the IV set. A ruptured IV set can expose a patient or staff member to the contrast solution or blood and fluid, potentially resulting in harm. For example, contrast solution or blood sprayed into the eyes of a patient or staff member could result in burning of the eyes or cross-contamination, respectively. Between July 2004 and March 2008, 29 reports were submitted to PA-PSRS related to IV tubing rupturing during contrast media injection into patients. Below are descriptions of a few of the reports submitted through PA-PSRS.

The patient underwent a CT scan with IV contrast. The patient IV tubing split during power injection of contrast; contrast went all over the patient. The patient was given [brand name omitted] IV contrast during a CT scan when the IV tubing ruptured. Members of the staff were sprayed with blood and fluid.

A Breakdown of the Problem

To prepare the patient for a contrast study, the clinician connects the power injector to the proximal end of the tubing. The distal end of the tubing is connected to a vascular access port, typically at a peripheral intravenous access site (e.g., the hand) on the patient. The contrast medium is then delivered to the patient. For CT scans, typical power injector peak pressures can be between 300 to 325 psi, but could exceed those pressures because of problems related to the patency of the access or some other obstruction. Those pressures can exceed the maximum pressure tolerances of conventional IV sets, which can typically tolerate 10 or 15 psi for IV or epidural delivery, respectively. Therefore, the higher pressures of power injectors can readily cause conventional IV tubing to rupture. Even when the conventional IV tubing has not been visibly damaged by the high pressures of the injector, the seals of the IV tubing connectors may become compromised, potentially causing leaks or air entrained into the IV sets.

Conventional IV sets are often used for contrast media injection as a matter of convenience. For example, some patients may already have an IV set connected to an access port (e.g., for medication IV therapy) before undergoing a contrast study. Using this existing set is convenient for clinicians because they do not have to create a new access site or disconnect the set from a catheter and connect a high-pressure set specifically designed for use with power injectors. However, using the existing set creates opportunities for the set to rupture or leak. The consequences of such occurrences could result in harm to patients or staff.

The U.S. Food and Drug Administration (FDA) has identified some consequences of ruptured IV sets, including IV set fragmentation, sometimes with embolization or migration requiring surgical intervention; extravasation of contrast media; loss of venous access requiring set replacement; and contamination of the CT room and personnel with blood and contrast media. Another consequence is compromised patient therapy, brought about by reuse of a conventional set for IV therapy after contrast injection, in which the set may have sustained a leak due to the high pressure of the injector. Additionally, when IV tubing ruptures during injection, as demonstrated in the PA-PSRS reports above, contrast is sprayed or
spilled from the IV set, resulting in delay or cancellation of the contrast study.

**FDA Reports of Ruptured IV Tubing**

A search of FDA’s Manufacturer and User Device Experience (MAUDE) database, using the keyword search terms “power” and “injector” and “ruptured,” revealed 158 reports between 1996 and 2008 describing similar events of conventional IV tubing rupturing during contrast media power injection, some resulting in patient blood loss. Many of the manufacturer narratives from the reports concluded that conventional IV sets were used instead of the recommended high-pressure sets appropriate for use with power injectors.

**FDA Prevention Guidelines**

FDA has developed the following guidelines to prevent or minimize harm to patients or staff and, as a secondary benefit, to prevent damage from ruptured IV tubing or other venous access devices when used with power injectors:

- When possible, avoid the use of conventional IV tubing with contrast media power injectors.
- Check the labeling of each vascular access device for its maximum pressure and flow rates. If none are provided, assume that the device is not intended for use with power injectors and do not use it.
- Know the pressure limit setting for your power injector and how to adjust it.
- Ensure that the pressure limit set for the power injector does not exceed the maximum labeled pressure for the vascular access device, but is not too low so as to compromise the quality of the study.

**Notes**
