

A pilot study evaluation of three needlefree IV connectors and their ability to maintain catheter patency over an 11-day period

BACKGROUND

This pilot study involved sheep as test subjects for three different needlefree connectors attached to the hub of a central venous catheter. A needlefree connector is a device intended for use as an accessory to an intravascular catheter to allow delivery of a wide range of fluids to a patient's vascular system without the use of needles.

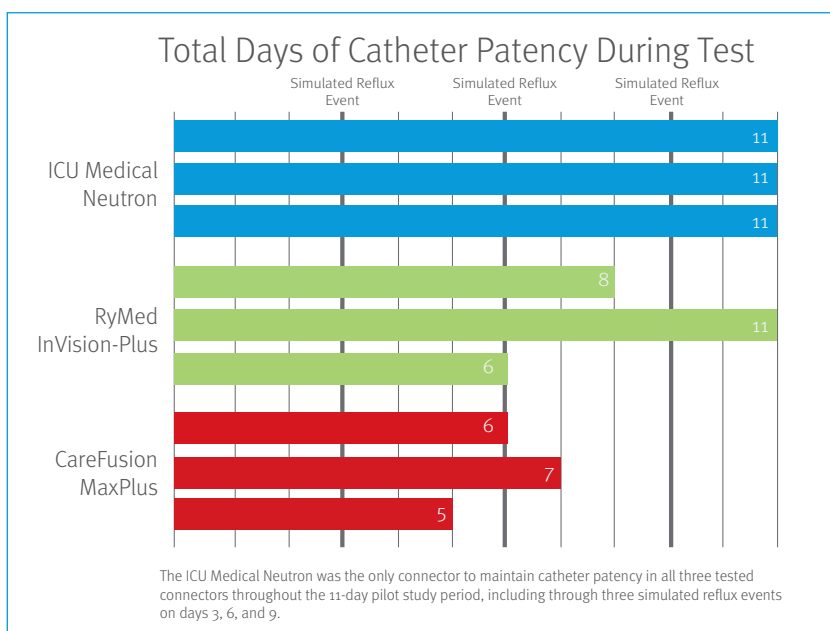
Use of an intravascular catheter is not without possible complications, and among the more serious complications is intraluminal thrombotic occlusion, which results from clot formation in the lumen or tip of the catheter due to the presence of blood. Occlusions can result in a loss or delay of infusion therapy or, ultimately, the need to remove and replace the catheter. This study compares a newly developed needlefree catheter patency device that prevents all types of fluid reflux (Neutron™, ICU Medical) to a positive displacement needlefree connector (MaxPlus®, CareFusion, Inc.) and a neutral displacement needlefree connector (InVision-Plus®, RyMed, Inc).

Each connector type has distinct characteristics that should affect the way it behaves when used to access a catheter in the vascular space. Among these characteristics is the movement or “displacement” of fluid when accessing or de-accessing the connector. “Positive displacement” refers to the movement of fluid from a reservoir in the connector into the lumen of the catheter upon disconnection of an administration set or syringe. “Negative displacement” refers to movement of blood into the tip of the catheter upon disconnection of an administration set or syringe. A “neutral displacement” device is neutral in that fluid displacement at the catheter tip is minimized both during connection and disconnection of a luer device. The Neutron differs from a neutral displacement device in that there is a secondary feature that maintains the fluid in a neutral position within the catheter at all times, preventing all types of reflux. So while neutral displacement can prevent reflux during connection and disconnection of a luer, only the Neutron technology can prevent reflux during other fluid and pressure differential events, such as patient coughing or sneezing.

PURPOSE

The purpose of this pilot study is to determine whether the unique design features of the Neutron Catheter Patency Device from ICU Medical will provide prolonged catheter patency when compared to both the positive displacement MaxPlus and the neutral displacement InVision-Plus devices.

The Neutron is a next generation IV connector that incorporates complete anti-reflux technology. This means that in addition to being designed to prevent fluid reflux in the catheter during both connection and disconnection of a luer, the Neutron is the only device with FDA 510k clearance to claim the ability to prevent fluid reflux during an IV bag run-dry, infusion pump stop, and patient vascular pressure changes caused by coughing or sneezing—all of which have been associated with loss of catheter patency due to intraluminal thrombotic occlusion.



Each of the above described events occurs when the pressure in the patient's vasculature exceeds the pressure of the external administration set infusion. For example, when an IV bag is allowed to run dry, the positive head height pressure, or pump pressure, of the infusion is diminished to less than that of the patient's vascular pressure, which in turn will start to push blood back out through the catheter in the same manner that blood would exit the catheter if the hub were left open. Or alternatively, when a patient coughs or sneezes, their intravascular pressure provides a momentary burst of high pressure that can also overcome the external head height infusion or pump pressure, causing blood again to push out through the catheter lumen.

METHODS

Three connectors for each of the three types of needlefree IV connectors were attached to a 4 French single lumen catheter (PFM Medical, Inc.), inserted percutaneously into the left jugular vein of nine sheep and flushed twice per day measuring injection pressures. All connectors and catheter hubs were disinfected before accessing, and dressings and connectors were changed every 72 hours. Each animal was tested for 11 days or until the catheter was considered occluded, whichever came first. On days 3, 6, and 9, an IV bag run-dry procedure was performed in order to simulate a reflux event where the infusion pressure is overcome by the vascular pressure. The catheter was considered to be occluded if the maximum flush pressure was greater than or equal to 760 mm Hg for two consecutive days.

RESULTS

All of the Neutron devices tested remained occlusion free for the entire 11-day pilot study period. None of the MaxPlus devices maintained catheter patency past seven days, with one device failing at five days and the other at six days. Only one of the InVision-Plus devices maintained patency through the entire 11-day pilot study period, with one device failing at six days and the other at eight days.

CONCLUSION

A fully powered study is needed and planned for the Neutron device, but based upon this preliminary pilot study, the ICU Medical Neutron Catheter Patency Device provides superior catheter patency performance when compared to a positive displacement (MaxPlus) and a neutral displacement (InVision-Plus) device.