Even the Simplest Devices May Malfunction: Split Septum Design Revisited

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Abstract

Split septum medical devices are used in tubing for intravenous (IV) fluid administration—an extremely common clinical task. These tubing caps contain a needleless, valveless system that allows fluid to flow directly through the lumen of the catheter but prevents backflow of fluid or blood when the tubing extension is not connected. We experienced complete failure of a needle-free connector extension set with a Luer-access split septum device in multiple patients due to the split septum remaining fused and essentially unsplit despite being connected on both ends. This led to an adverse event in a patient due to repeated unnecessary IV insertion attempts. This case shows how even the simplest of devices can malfunction and highlights the need for vigilance in clinical practice.

Split septum medical devices are used in tubing for intravenous (IV) fluid administration—an extremely common clinical task. Typically, the angiocatheter is inserted into a vein and connected to a short tubing extension that is capped by split septum ends. The split septum cap then can be conveniently connected to the longer IV tubing, which is connected to the infusion and exchanged as needed.

These tubing caps contain a needleless, valveless system that allows fluid to flow directly through the lumen of the catheter while also preventing backflow of fluid or blood when the tubing extension is not connected. This is achieved through a simple design of a prepierced rubber diaphragm. When the blunt cannula of the tubing is connected, it pierces the diaphragm open, allowing fluid to flow. Conversely, when the tubing is disconnected, the diaphragm acts as a physical barrier to flow and to the entry of bacteria.

In contrast, mechanical valve devices consist of centerpieces that open on the external connection surface. When the Luer end pushes the centerpiece downward, internal components move to allow the flow of fluid within the device. This is commonly achieved through an elastic spring-like mechanism that keeps the centerpiece in the closed position when disconnected. Split septum designs, on the other hand, lack these internal moving parts.[1] Because of their 64% to 70% lower catheter-related blood stream infection (CRBSI) rates, in 2011, the Centers for Disease Control and Prevention released a Category II recommendation favoring split septum valve devices over mechanical valve devices.[2–5] These needleless designs have gained favor in clinical practice since they reduce needle stick injuries and decrease the rate of CRBSI.[6]

Over the years, several engineering features have been favored when designing needle-free connectors (NFCs). These include a direct fluid pathway with minimal tortuosity, Luer access with minimal or no blood reflux, closed-system feature, and lack of a clamping sequence.[7] Implementing these features minimizes biofilm development in the internal luminal surface of the device and decreases the risk of red blood cell hemolysis, in turn minimizing the risk of CRBSI, fibrin clot formation, and occlusion.[7,8]

Typically, clinical practices purchase a single type of NFC model for routine use. Usually, the NFC is already attached to the short tubing extension. A given healthcare facility is likely to stock one pediatric model and a separate adult model. In our opinion, the parameter with the greatest influence on the average clinician's decision regarding whether to use the NFC is the gauge diameter of the connector in the context of the clinical need for the IV. For example, if a large-bore IV is inserted for the purpose of massive resuscitation, and the available NFC was of a smaller gauge than the IV and

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tubing, then the clinician will likely discard it from the connector.

A common NFC is the BD Q-Syte (BD, Franklin Lakes, NJ). Its intraluminal fluid pathway is not laminar and promotes turbulent fluid dynamic.[7] It follows a negative displacement of fluid,[7] meaning that once the NFC is connected to the tubing on both ends, fluid moves toward the patient and, when it is disconnected, blood refluxes into the catheter.

Hull et al.[8] studied the differences in blood reflux experienced among negative, positive, and neutral displacement NFC designs. They found a reflux volume of 9.73 to 50.34 µL for negative displacement, 3.60 to 10.80 µL for neutral displacement, and 0.02 to 1.73 µL for pressure-activated antireflux NFC. Although less reflux volume was noted on the pressure-activated antireflux NFCs, the authors concluded the importance of choosing a NFC based on performance of individual connector design rather than the displacement of fluid.[8]

The current prevention guidelines continue to recommend the use of neutral-valve NFCs, as they have demonstrated prevention in occlusions and infections.[9–12] Despite the impressive engineering considerations, our clinical experience highlights the susceptibility of malfunction in designs.

Over the course of a year, we experienced complete failure of the BD Q-Syte 15-cm extension set with a Luer-access split septum device in five patients because the split septum remained fused and essentially unsplit despite being connected on both ends. This led to an adverse event in one of the patients. The Luer tip was inserted to the Luer-access split septum device and all clamps were unlocked; however, flushing of the line failed. IV access was attempted multiple times before it was noticed that blood was returning from the angiocatheter. Troubleshooting revealed that the NFC was impervious.

When the Luer tip was disconnected from the split septum, patency of the tubing was confirmed. In a patient with more limited IV access, this could have resulted in greater harm by potentially wasting the valuable peripheral access sites and ultimately necessitating a central-line insertion procedure and escalating the risk.

Of note, this medical device was subject to a Class 1 recall by the Food and Drug Administration in 2010 due to a manufacturing defect of the opposite etiology, whereby the septum would not seal and therefore could allow air entry resulting in an air embolism.[13] The problem we have encountered is that, occasionally, the split septum does not split. Thankfully, our patient only suffered pain from numerous sticks.

We continue to use this NFC in our clinical practice. Since the incident described here, we confirm proper functioning of the device by observing IV fluid flow out of the Luer tip and visually confirm patency of the system before connecting the tubing extension to the angiocatheter.

Occasionally, we encounter repetition of such problems with the device septum. If the clinicians themselves did not prepare the flushed tubing, it may be advisable for them to test the tubing by opening the valve prior to connecting. Based on our anecdotal experience, we estimate the incidence of this product malfunction to be about five per 1,000 cases.

In our opinion, in some clinical situations, it is certainly reasonable to refrain from using a connector extension and thereby avoid the need for a split septum device, or another NFC altogether, by connecting the IV tubing directly to the angiocatheter. For example, in a minor outpatient same-day procedure (e.g., a cataract surgery with light sedation, minimal anticipated blood loss, no expected need for IV tubing exchange, and a plan for the whole tubing and angiocatheter to be removed shortly after the procedure), skipping the use of the connector seems reasonable. This case highlights how even the simplest of devices can malfunction and, most importantly, the need for vigilance in clinical practice.

References

1. Hadaway L. Needleless connectors for IV catheters. *Am J Nurs*. 2012;112(11):32–44.

2. Rupp ME, Sholtz LA, Jourdan DR, et al. Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. *Clin Infect Dis*. 2007;44(11):1408–14.

3. Salgado CD, Chinnes L, Paczesny TH, Cantey JR. Increased rate of catheter-related bloodstream infection associated with use of a needleless mechanical valve device at a long-term acute care hospital. *Infect Control Hosp Epidemiol*. 2007;28(6):684–8.

4. Maragakis LL, Bradley KL, Song X, et al. Increased catheter-related bloodstream infection rates after the introduction of a new mechanical valve intravenous access port. *Infect Control Hosp Epidemiol*. 2006;27(1):67–70.

5. Field K, McFarlane C, Cheng AC, et al. Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit. *Infect Control Hosp Epidemiol*. 2007;28(5):610–3.

6. Casimero C, Ruddock T, Hegarty C, et al. Minimising blood stream infection: developing new materials for intravascular catheters. *Medicines (Basel)*. 2020;7(9):49.

7. Jarvis WR, Murphy C, Hall KK, et al. Health care–associated bloodstream infections associated with negative- or positive-pressure or displacement mechanical valve needleless connectors. *Clin Infect Dis*. 2009;49(12):1821–7.

8. Hull GJ, Moureau NL, Sengupta S. Quantitative assessment of reflux in commercially available needle-free IV connectors. *J Vasc Access*. 2018;19(1):12–22.

9. Guembe, Pérez-Granda MJ. What does really affect the colonization of needleless connectors? *Enferm Infecc Microbiol Clin*. 2020;38(3):97–8.

10. O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the prevention of intravascular catheter-related infections. *Clin Infect Dis*. 2011;52(9):e162–93.

11. Guembe M, Pérez Granda MJ, Cruces R, Alcalá L, Bouza E. The NeutraClear needleless connector is equally effective against catheter colonization compared to MicroClave. *J Vasc Access*. 2017;18(5):415–8.

12. Tabak YP, Jarvis WR, Sun X, et al. Meta-analysis on central line-associated bloodstream infections associated with a needleless intravenous connector with a new engineering design. *Am J Infect Control*. 2014;42(12):1278–84.

13. Food and Drug Administration. Class 1 device recall: BD QSyte Extension Set, Luer access extension. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=86456. Accessed Jan. 14, 2021.