Hiding in Plain Sight: The Impact and Safety Risks Associated with Accidental Dislodgement

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The Problem: Accidental Dislodgement of Vascular Access Devices

Scope of the problem

Most hospital stays require intravenous (IV) access for infusion or delivery of medications. Current estimates report that IV access is established and maintained in 70%-90% of acute care patients in the United States.[1] Administration of infusion therapy in acute and home care settings carries a risk of complications such as catheter failure, infection, and accidental dislodgement of the catheter or attached tubing. These complications can jeopardize patient safety and increase the risk of morbidity and mortality.[2,3] Accidental dislodgement—a major contributor to catheter failure and ensuing treatment delays—is prevalent among adult and pediatric populations, yet it is often underrecognized as a serious medical concern by clinical staff because it happens practically every day. Pulling, jerking, entanglement of tubing, or intentional removal by a very young or confused patient are the most common causes of accidental catheter migration or complete removal. More than 5 million catheters are dislodged annually underscoring the need for viable solutions to address this ongoing issue.[4-9]

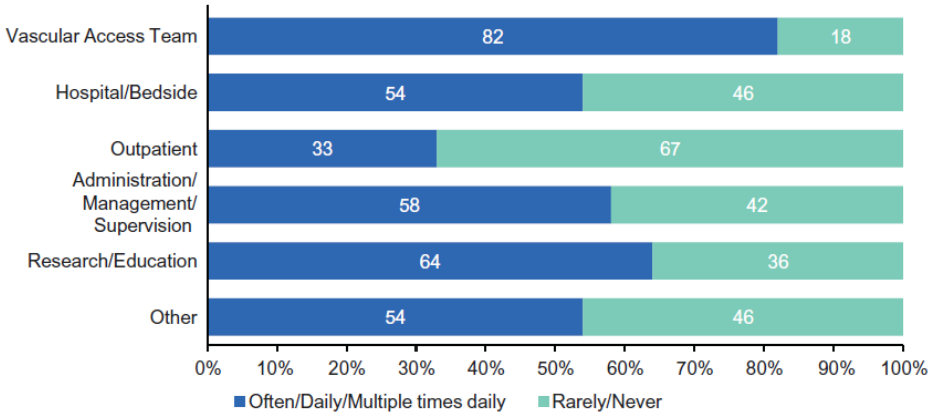
Various IV catheters are used for the infusion of fluids and medications. All types of peripheral and central IV catheters, tubing and the components used to safely administer treatment are prone to accidental dislodgement. The risk for dislodgement varies depending on the type of catheter and the location of the insertion. Notably, larger catheters, central positioning, and larger vein access points pose a greater risk of life-threatening air emboli or hemorrhage. In an ECRI Polyurethane Medical Device Material Safety Report published in 2021, peripheral arterial catheters, peripherally inserted central catheters (PICC), and central venous catheters (CVC) were cited as having the highest rates of complete dislodgement.[10-18]

Consequences of dislodgement

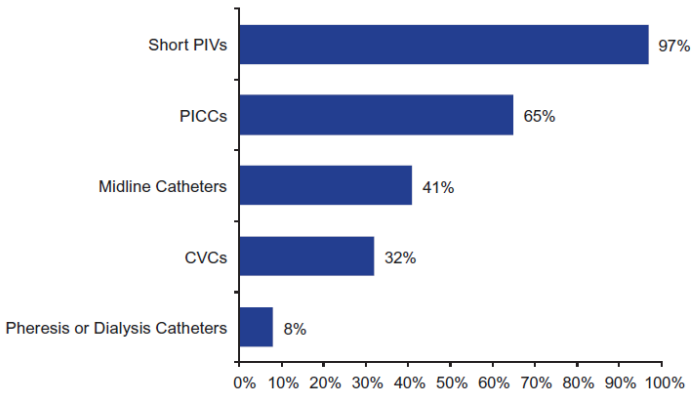
Accidental dislodgement and subsequent catheter failure can result in loss of venous access, treatment delays, and the need to replace the IV catheter.[7] Additionally, delays in treatment and medication waste can lead to prolonged hospitalization and increased healthcare costs.[19-21] IV administration tubing can remain connected to the patient for up to 7 days when not used for blood, parenteral nutrition, or lipid administration, so limiting the frequency of IV tubing changes is desirable. In the US, costs associated with tubing disconnection, catheter failure, and restarts are estimated at more than $7 billion; therefore, accidental dislodgement represents not only a patient safety issue but also a significant economic burden.[22,23] Improving clinician awareness and providing evidence-based strategies to safeguard against accidental dislodgement contributes to patient safety for all ages, provides the necessary delivery of treatment, and reduces the incidence of other complications like infection, trauma, and vein depletion associated with unnecessary catheter reinsertion.

Real-World Perspectives

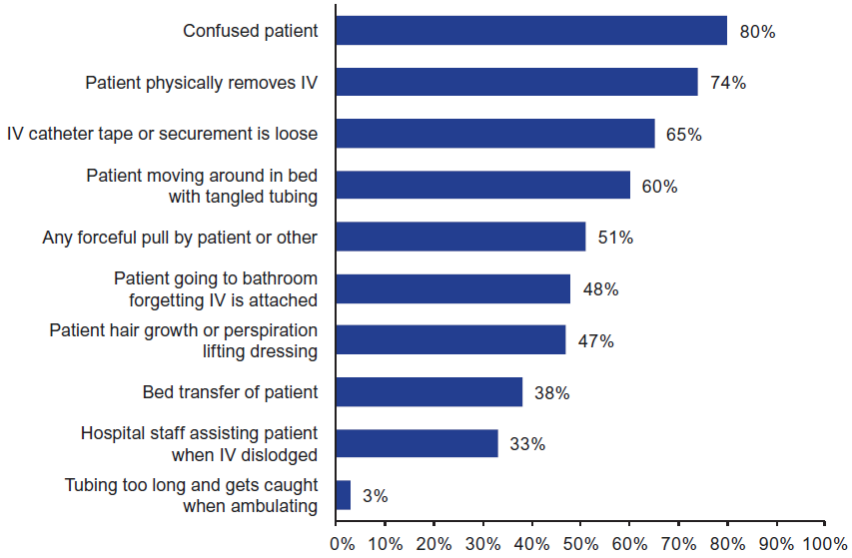
A research survey conducted by Moureau examined clinician perceptions and experiences related to accidental dislodgement of IV devices.[7] Sixty-eight percent of the 1,561 respondents reported observing accidental dislodgement daily, often multiple times in one day (Figure 1A). Consistent with findings from other studies, 96.5% of respondents reported that these occurrences happened primarily with peripheral IV catheters (Figure 1B). Furthermore, respondents indicated that patient confusion (80%), physical removal of the catheter by the patient (74%), and loose IV catheter or securement tape (65%) were the top three factors contributing to accidental dislodgement of IV devices. Unsurprisingly, most of the clinician participants agreed that accidental dislodgement represents a serious safety concern and that it was inadequately addressed by their care facility. These findings highlight the need for effective and easy-to-integrate solutions to mitigate the risk of accidental dislodgement.



A. How often do you see accidental dislodgement of any IV catheter?



B. Which types of catheters have you seen accidentally dislodge? (multiple answers allowed)



C. What are the most common contributors of accidental dislodgement? (multiple choices allowed)

Figure 1. Clinicians' perceptions and experience related to accidental dislodgement of IV devices.

The Solution: Orchid Safety Release Valve (Orchid SRV™ or SRV)

What it is

The Orchid Safety Release Valve (Orchid SRV™ or SRV) is a tension-activated accessory for single patient use. It is designed to allow flow to an IV catheter while aiding in reduction of accidental or unwanted IV dislodgement. In the US, the Orchid SRV is approved by the Food and Drug Administration (FDA) to reduce the occurrence of mechanical complications with intravenous catheters in patients two (2) weeks of age and older. [36] (21 CFR 880.5220).

How it works

Mechanical catheter dislodgement occurs when a pull force between 1 to 8 lbs is applied.[24,25] Although catheter and securement tape are useful for increasing the stability of the IV device and reducing vein irritation while it is inserted, securement alone cannot withstand the force applied during pulling, jerking, and other forceful movements.[26-33]

The device is placed between the existing IV extension set and the general IV tubing connection intended for use in the delivery of fluid to and from an IV catheter (Figure 2). The safety release device is installed within the tubing of IV or intra-arterial administration sets for continuous or intermittent infusions. When activated by tension on the IV tubing, the valve separates, and closes the flow path in both directions. [36]

Orchid SRV is constructed of two bonded pieces that enable the separation of the device into two parts when the predetermined disconnect tension force reaches or exceeds 3.25 pounds of force (lbf).[24]

Activation of the separation mechanism creates an automatic sterile seal for the fluid pathway. The seal is designed to stop the infusion and preserve the IV catheter for continued use. Once separated, the two parts of the SRV remain attached to the tubing end and the needleless connector catheter end. When the seal is activated and infusion flow ceases, an occlusion alarm alerts the clinician to check and replace the SRV device. Then the clinician reconnects a new SRV onto IV tubing and catheter access by simply removing the separated halves and replacing them with the new, prepackaged, sterile valve using an aseptic technique. This feature is particularly useful when clinical staff need to disconnect the IV tubing to allow patients to go to the bathroom or change their clothes without the concern over introducing microbes into the IV line.

Figure 2. The Orchid SRV™ is placed between the existing IV extension set and general IV tubing connection intended for use in the delivery of fluid to and from an IV catheter.

The Proof: More than 90% of catheter dislodgements from pull force tension can be avoided

Performance

Stress testing in simulated clinical conditions was conducted to evaluate the performance of the Orchid SRV.[25] Investigators measured exerted forces applied to the device in x, y, and z directions, in conjunction with securement, and at various pull speeds. Data from 371 Orchid SRV devices were collected. The data demonstrated that pulling the IV setup at slower speeds resulted in higher separation forces. The faster the pulling speed, the more easily the device separated and prevented IV dislodgement. Orchid SRV prevented IV dislodgements by 91.9% across all testing scenarios and experimental groups.

The Orchid SRV is contraindicated for applications that require power injection systems or high-pressure infusion systems.[36] The SRV is designed to be used in conjunction with virtually all standard commercially available IV dressings, transparent film dressings, and tape.

Cost and value

Accidental dislodgement is associated with significant healthcare costs. Available estimates suggest that the average cost to replace a dislodged IV catheter in the US is $50. The cost of replacing the catheter alone is extrapolated to be $2500 per day, or up to $912,500 annually for a typical 200-bed facility.[21,34-35] Therefore, preventing even a fraction of accidental dislodgements would result in significant healthcare savings.

The Conclusion

Accidental dislodgement is a serious, yet largely preventable complication associated with IV catheters. Catheter failure, treatment delays, injury, and the need for IV device replacements can result in extended

hospital stays and significantly raise healthcare costs. Clinicians agree that the dislodgement of IV devices is a significant medical event that occurs daily but is not adequately addressed in healthcare facilities. Orchid SRV is a cost-effective, easy-to-use device that separates into two aseptically sealed compartments when activated by pull forces ≥ 3 lbs. It is compatible with existing IV sets and standard securement products. Performance testing leading to the approval of SRV demonstrates that it can prevent approximately 90% of accidental dislodgements. This novel device represents an effective solution for addressing the clinical challenge of accidental IV device dislodgements in acute and at-home settings.

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