

White Paper: Issues Related to Detection of Hemodialysis Venous Needle Dislodgement

Hemodialysis

Hemodialysis is the most common method used to treat advanced and permanent kidney failure¹. According to the National Kidney Foundation, there are 468,000 Americans on dialysis,² and the European Renal Care Providers Association reports that 350,000 people in the EU are on dialysis,³ and the numbers continue to grow each year.

“The prevalence of dialysis therapy for kidney failure is increasing faster than population growth in most parts of the world” - American Society of Nephrology⁴

Frequent dialysis treatments are necessary, and may be done in a clinic setting by healthcare professionals, or patients who receive specialized training learn how to dialyze themselves at home. Hemodialysis uses a machine as an artificial kidney to filter impurities from the blood. Two needles are inserted in the patient using a special access site. The arterial needle is connected to tubing that pulls the patient’s blood into the dialysis machine. After the blood is cleansed, it is pumped back to the patient through a different set of tubing, and enters the patient’s bloodstream through the venous needle. Dialysis is normally a safe procedure, but complications may occur.

Venous Needle Dislodgement (VND)

When the venous needle pulls out of the access site, it is referred to as venous needle dislodgement, or VND. Instead of the cleansed blood returning back to the patient’s bloodstream, it is pumped into the chair, bed, or floor. This can lead to a rapidly declining blood volume, and may cause morbidity and mortality if not discovered quickly⁵. VND may range from minimal blood loss, if it is discovered as soon as the needle dislodges, to a fatal hemorrhage if not recognized in the first minutes. Time is of the essence because a patient will lose blood rapidly. Up to 40% of the total blood volume may be lost in a matter of minutes⁶. The challenge is that VND is very unpredictable. It can occur at anytime, to anyone. Even under ideal conditions⁷.

VND is an underreported, life-threatening complication of hemodialysis.⁸

¹ National Institute of Diabetes and Digestive and Kidney Diseases (NIH) <http://www.niddk.nih.gov/health-information/health-topics/kidney-disease/hemodialysis/Pages/facts.aspx>

² National Kidney Foundation www.kidney.org

³ European Renal Care Providers Association www.ercpa.eu

⁴ The Rapidly Growing Global Burden of End-Stage Renal Disease – An Analysis of the Change in Maintenance Dialysis Prevalence between 1990 and 2010. ASN Kidney Week 2013 (Abstract 4163)

⁵ Axley, B., Speranza-Reid, J., & Williams, H. (2012). Venous Needle Dislodgement in Patients on Hemodialysis. *Nephrology Nursing Journal*, 39(6), 435-445

⁶ Hurst J. It Can Happen Without Warning: Venous needle dislodgement. *Renal Business Today*, 4(9), 18- 22

⁷ Hurst J. It Can Happen Without Warning: Venous needle dislodgement. *Renal Business Today*, 4(9), 18- 22

⁸ Michael B. Venous Needle Dislodgement. *Kidney News*. Aug. 2014 (6#8)

Global Estimates of The Incidence of VND⁹

*2,100 venous needles dislodge each day
21 patients are seriously injured each day
21 patients die each week*

Venous Pressure Monitoring Required, But Not Optimal In Detecting VND

Hemodialysis machines in the United States and Europe must meet medical safety standards. The American National Standard for Hemodialysis Systems¹⁰ insists on requirements which will “at a minimum, help ensure the effective, safe performance of hemodialysis systems, devices, and related materials.” According to this standard, the dialysis machines must be equipped with venous pressure monitoring. These internal alarm systems are designed to alert the caregiver/user to a malfunction; such as a drop in pressure from needle dislodgement. If a drop in arterial pressure is sensed, an alarm will sound, and the machine will be turned off. The venous pressure alarm, however, may be delayed, or not triggered at all.

“The risk of complications from venous needle dislodgement is magnified by dislodgements that do not trigger a venous pressure alarm to alert patient care staff, or the patient.”¹¹

The standards acknowledge that venous pressure monitoring is not optimal for detecting venous needle dislodgement. It says:

“Blood line separation or needle pullout is uncommon but does occur, and can cause potentially lethal situations enabling significant blood loss from venous needle disconnection. No system in current use will reliably detect such a separation or needle pullout.”¹²

European Standards are similar, stating that the dialysis machine:

“Shall include a protective system to protect the patient from extracorporeal blood loss to the environment that can cause a safety hazard. An acceptable method for complying with this requirement is, for example, a protective system utilizing measurement of the venous pressure-.”¹³

Venous Pressure Monitoring and VND

Currently, there is no venous pressure monitoring system that reliably responds to detection of blood loss from VND. Without a reliable means of detecting blood loss from the venous needle access, patients will

⁹ Sandroni S, Shockerman T, Hayes-Light K. Catastrophic Hemorrhage from Venous Needle Dislodgment during Hemodialysis, *Journal of the American Society of Nephrology*. November 2008 (9), Abstract issue. / RPA Renal Physicians Association, Health and Safety Survey to improve patients safety in end stage renal disease (2007) / Ahlmén J, Gydell KH, Hadimeri H, Hernandez I, Rogland B, Strömbom U. A new safety device for hemodialysis. *Hemodialysis International* 2008; 12 (2): 264-267.

¹⁰ AANSU/AAMI RD5-2003

¹¹ Sandroni et al., 2008

¹² AANSU/AAMI RD5-2003 Section A. 4.2.4.1, General

¹³ European Standard for Medical Electrical Equipment EN 60601-2-16

continue to be at risk for the potentially fatal complication.

It is agreed that the best method for detecting VND is visual observation of the access site¹⁴. However, in practical application, this is often not possible. For example, patients are frequently chilly during treatments, and cover themselves with blankets. Lighting may dimmed during nocturnal treatments, making it difficult to see the access. Restless, or confused patients may require the addition of dressing material and/or rolled-gauze material to secure the needles and bloodlines, thus covering the access. In instances where the access cannot be clearly seen, a VND can occur without being detected. Under these conditions, patient safety is a concern.

ECRI Institute, a nonprofit safety-centered organization, released a Medical Device Safety Report (MDSR): Undetected Venous Line Needle Dislodgement during Hemodialysis¹⁵

“The ECRI believes that the venous pressure monitor is not a reliable means of detecting needle dislodgements and agrees with manufacturers that visually monitoring the status of the blood lines appears to be the only sure way to spot these problems.” - ECRI Institute

ECRI also noted:

“In the specific case of venous line needle dislodgments, venous pressure alarms cannot be relied on to detect a problem”

The overall unreliability of venous pressure monitoring systems is well documented. In addition, a study of venous pressure monitoring using different types of access, further identified that only 29% of instances of VND in fistulas were detected, which is the preferred type of access.¹⁶

Reported instances of venous needles dislodging are noted when searching the FDA’s Manufacturer and User Facility Device (MAUDE) database¹⁷. Numerous instances noted failure of the venous pressure system to alarm.

“Approximately 3-3.5 hours into a scheduled hemodialysis treatment, it was noted the patient had blood under her chair. The patient was unresponsive, diaphoretic and agonal breathing. Blood pressure was 87/57 and heart rate was 42. It was determined the venous line had disconnected from the venous needle connection. Estimated blood loss was 900 ml – MAUDE 8/8/2015

¹⁴ Axley, B., Speranza-Reid, J., & Williams, H. (2012). Venous Needle Dislodgement in Patients on Hemodialysis. *Nephrology Nursing Journal*, 39(6), 435-445

¹⁵ Undetected Venous Line Needle Dislodgment during Hemodialysis, *Health Devices* Nov 1998;27 (11):404-6

¹⁶ Ribitsch W, Schilcher G, Hafner-Giessauf H, Krisper P, Horina J, Rosenkranz A, Schneditz D. Prevalence of Detectable Venous Pressure Drops Expected with Venous Needle Dislodgement. *Seminars in Dialysis*. Sept-Oct 2014; 27 (507-11)

¹⁷ MAUDE Database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=5094767

VND Monitoring More Important in Nocturnal and Home Dialysis

In nocturnal home hemodialysis, the patient is both the giver and receiver of the treatment, and most likely asleep through most of it. According to the FDA guidelines¹⁸, “safety becomes a primary concern”, and:

“Any device malfunction, access problems, or break in the seal of the hemodialysis circuit (e.g., dislodged access needle, blood leaks) would be life threatening, even with lower blood flows used in nocturnal home dialysis.”

The FDA guidelines also identify the risk of inadvertent disconnections:

“Most current systems rely on the venous needle return pressure to monitor for vascular disconnect, since the disconnection should result in a noticeable drop in venous pressure. However, inherent resistance in the blood tubing and small gauge needles can cause backpressure in the system to prevent the venous return pressure alarm from triggering. This situation could result in significant blood loss and eventual exsanguination of a patient.”

“Vascular access disconnections remain one of the most serious risks of performing extracorporeal therapies.”

These guidelines recommend alarms to detect fluid (blood or dialysate) leaks, and moisture detector at the site of the access, which was previously the only alternative detection method.

Note: The Redsense alarm is the only cleared blood loss detection device for use in hemodialysis, and may be used with all treatment regimens, including: acute, chronic, nocturnal, and all home hemodialysis methods.

Cost of VND

The cost of VND depends upon the severity of blood loss. From as little as a few hundred dollars for the administration of additional fluids and blood products to replace minor blood loss, to hundreds of thousands of dollars for intensive care treatment and lost revenue for the dialysis facility from missed dialysis treatments while the patient is hospitalized¹⁹. Patients who survive a serious VND may suffer catastrophic brain damage from hemorrhagic shock²⁰, and require lifelong care. In the event of a fatal VND, the cost can soar. If the family files a successful wrongful death lawsuit, the dialysis provider may be liable for millions of dollars paid in damages to the family²¹.

Are Users Informed of The Risks?

According to standards, manufacturers (of dialysis machines) are required to inform users about risk. To

¹⁸ FDA Medical Devices Advisory Committee. June 8, 2005

¹⁹ Hurst, J. A costly complication: Venous needle dislodgement. *Renal Business Today*, 2010 5(9), 18-22.

²⁰ Gutierrez G, Reines HD, Gutierrez M: Clinical Review: Hemorrhagic Shock. *Critical Care*, 2004 8(5): 373-381.

²¹ Fields, R. (2010). *When needles dislodge, dialysis can turn deadly*. Retrieved from <http://www.propublica.org/article/w hen-needles-dislodge-dialysis-can- turn-deadly>

what extent dialysis professionals are aware of the risk is not known.

In 2008, the European Dialysis and Transplant Nurses Association and European Renal Care Association (EDTNA/ERCA) identified the need for increased awareness of venous needle dislodgement, and they developed twelve (12) clinical practice recommendations to help reduce the risk of VND and detect blood leakage as early as possible²². The EDTNA/ERCA continued their VND educational endeavors, and in 2010, worked in collaboration with Redsense Medical to develop a clinical Assessment Tool poster illustrating EDTNA/ERCA practice guidelines to prevent VND²³.

A survey conducted by the American Nephrology Nurses' Association (ANNA) of its members indicated that of the 1173 dialysis nurses answering the survey, 76.6% said they had seen a VND in the past five (5) years, with 8.2% of those having seen five (5) or more events in that timeframe. 71.2% of the nurses indicated that potential benefit of a VND risk assessment. In 2012, utilizing EDTNA/ERCA materials, a special ANNA VND workgroup project developed a VND risk assessment and practice recommendations for the prevention of VND, as well as patient educational materials that are applicable to the United States. The ANNA recommendations, and also a number of researchers have recommended VND protection using a FDA-cleared device for blood loss in the environment for high-risk patients, and for patients doing home hemodialysis²⁴.

Note: The Redsense Blood Loss Detection System is the only cleared blood loss detection device for use in hemodialysis, and is approved for use in all areas of hemodialysis.

²² Van Waeleghem JP, Chamne M, Lindley, M, Pancirova, J, *Venous needle dislodgement How to minimize the risks*, Journal of renal Care 2008, Page 163-167.

²³ EDTNA/ERCA Venous Needle Dislodgement (VND) How To Minimize The Risks. 2010.
<http://www.edtnaerca.org/pages/erb/venousneedle.php>

²⁴ Ahlmen, J., Gydell-Leight, K., Hadimeri, H., Hernandez, H., Rogland, B., & Strombom, U. (2008). A new safety device for hemodialysis. *Hemodialysis International*, 12, 264-267., Cowperthwaite, J., Rivers, A., Sundström, M., & Hegbrant, J. (2011, February 11). Assessment of a device to detect venous needle dislodgement (VND). Abstract presented at the Meeting of the Annual Dialysis Conference, Phoenix, AZ., Fields, R. (2010). When needles dislodge, dialysis can turn deadly. Retrieved from <http://www.propublica.org/article/w hen-needles-dislodge-dialysis-can- turn-deadly.>, Hurst, J. (2009). It can happen without warning: Venous needle dislodgement. *Renal Business Today*, 4(9), 18- 22., Sandroni, S., Sherockman, T., & Hayes- Light, K. (2008). Catastrophic hemorrhage from venous needle dislodgement during hemodialysis: Continued risk of avoidable death and progress toward a solution.